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Chapter I

The Policies and Regulations of the Related Departments of the State
Decree No. 2 of the State Science and Technology
Commission of the People’s Republic of China

《Regulations for the Administration of Laboratory Animals》 was approved by the State Council on October 31, 1988 and promulgated by Decree No. 2 of the State Science and Technology Commission on November 14, 1988.

Officer: Song Jian

November 14, 1988
Regulations for the Administration of Laboratory Animals

Section I General Provisions

Article 1 These Regulations are formulated for the purpose of strengthening the administration of, and guaranteeing the quality of, laboratory animals so as to meet the needs of scientific research, economic construction, and social development.

Article 2 The term "laboratory animals" that is used in these Regulations refers to animals that are artificially fed and bred, the microorganisms on or in whose bodies are kept under control, whose genetic backgrounds are definite or whose sources are clear, and which are to be used in scientific research, teaching, production, examination and verification, and other scientific experiments.

Article 3 These Regulations shall apply to those units and individuals that are engaged in the research in, and the conservation of, breeds, feeding and breeding, supply, use, administration, and supervision of laboratory animals.

Article 4 The administration of laboratory animals shall be guided by the principle of unified planning, rational division of work, and being beneficial to the promotion of the scientific research in, and the utilization of, laboratory animals.

Article 5 The State Science and Technology Commission shall be in charge of the work throughout China with respect to laboratory animals.

The science and technology commissions of the provinces, autonomous regions, and municipalities directly under the Central Government shall be in charge of the work in their respective regions with respect to laboratory animals.

The various departments under the State Council of the People's Republic of China shall be in charge of the administration of the work in their respective departments with respect to laboratory animals.

Article 6 The State shall institute a system of supervision over the quality of laboratory animals and of the attestation of the up-to-standard quality of laboratory animals. The specific procedures in this respect shall be separately formulated by the State Science and Technology Commission.

Article 7 The national standards in respect of genetics, microbiology, nutriology, and the feeding and breeding environment concerning laboratory animals shall be formulated by the State Bureau of Technology Supervision.

Section II The Administration of the Feeding and Breeding of Laboratory Animals

Article 8 Units that are engaged in the work of feeding and breeding laboratory animals shall, in accordance with the standards in respect of genetics, microbiology, nutriology, and the feeding and breeding environment, exercise regular quality monitoring over laboratory animals. Comprehensive and accurate records shall be kept of the various work processes and of the data derived from the monitoring, in which a statistical report system shall also be established.

Article 9 Feeding and breeding rooms and laboratories for laboratory animals shall be built in different areas and each shall be kept in strict isolation.
There shall be scientific management systems and operating rules for feeding and breeding rooms and laboratories for laboratory animals.

Article 10 With respect to the conservation of breeds and the feeding and breeding of laboratory animals, breeds, and strains of breeds that are domestically or internationally approved shall be adopted, with certificates attesting to their being up to standard.

Article 11 Laboratory animals shall be fed separately in accordance with their different sources, breeds, and strains of breeds as well as different experimental purposes.

Article 12 Laboratory animals shall be categorised into four classes: Class 1 - ordinary animals, Class 2 - clean animals, Class 3 - animals carrying no specific pathogens, and Class 4 - animals carrying no bacteria.

Laboratory animals of different classes shall be administered in accordance with the corresponding standards for controlling microorganisms.

Article 13 Laboratory animals shall be fed with wholesome feed that is up to standard in quality. No feed that has become mouldy and rotten, or deteriorated in quality, or moth-eaten or polluted may be used for feeding laboratory animals. Green vegetables and fruits that are to be fed directly to the laboratory animals shall be washed clean and sterilised and shall be kept fresh.

Article 14 The drinking water for laboratory animals of the first class shall measure up to the hygiene standards of urban drinking water. The drinking water for laboratory animals of the second, third, and fourth classes shall measure up to the hygiene standards of urban drinking water and undergo treatment to kill bacteria.

Article 15 The cushioning materials for laboratory animals shall, based on the needs of different classes of laboratory animals, be treated accordingly so that they shall be clean, dry, absorptive of water, poison-free, pest-free, infection-free, and pollution-free.

Section III The Quarantine of Laboratory Animals and the Control of their Infectious Diseases

Article 16 Laboratory animals that are newly introduced shall be subject to quarantine in isolation. Wild animals that are captured for the purpose of supplementing the sources of breeds or developing new breeds shall be subject to quarantine in isolation in the locations where they are captured and a certificate to that effect that is issued by the animal quarantine department shall be obtained. When a wild animal is carried to the place where laboratory animals are kept, it shall be subject to quarantine once again before it is allowed into a feeding and breeding room for laboratory animals.

Article 17 Laboratory animals that must take preventive inoculations shall, in accordance with the requirements of experiments or with the relevant provisions of the 《Regulations for the Immunisation of Poultry and Livestock》, undergo such inoculations, with the exception of those laboratory animals that are to be used as materials for biological products.

Article 18 When a laboratory animal dies of an illness, the cause shall be investigated and ascertained in good time, and the case shall be properly handled and kept on file. When a laboratory animal contracts an infectious disease, it shall, depending on the respective circumstances, be destroyed or given medical treatment in isolation immediately. Laboratory animals that are likely to be infected shall undergo emergency preventive inoculations. Strict sterilisation measures shall be taken for areas inside and outside the feeding and breeding room.
and the case shall be reported to the higher authority for the administration of laboratory animals and to the local animal quarantine and epidemic prevention unit so that emergency preventive measures can be taken to prevent the spread of the disease.

Section IV The Utilisation of Laboratory Animals

Article 19 In the utilisation of laboratory animals, only the related ones that are up to standard shall be selected in accordance with the different purposes of the respective experiments. The use of up-to-standard laboratory animals shall be taken as one of the basic requirements in the research projects that are submitted for approval and in assessing the results of such projects. If any laboratory animals that come short of the standard are used, the results of the examination and safety assessment that are thus obtained shall be invalid and the products, thus made, shall not be used.

Article 20 With respect to a laboratory animal that is to be utilised, the following comprehensive data shall be required:
1) The exact names of the breed, strain, and subline;
2) Its genetic background or its source;
3) Microorganisms testing condition;
4) A certificate attesting to its being up to standard; and
5) The signature of the person in charge of the feeding and breeding unit.
In default of the previously mentioned data, no laboratory animals may be used.

Article 21 The transport of laboratory animals shall be the responsibility of those persons especially appointed thereof. The means of transport for laboratory animals shall be safe and reliable. No laboratory animals of different breeds, strains, or sublines that are being transported may be mixed together.

Section V Administration of the Import and Export of Laboratory Animals

Article 22 A laboratory animal that is imported from abroad as an element breed shall be accompanied by data that are duly signed by the person in charge of the feeding and breeding unit, concerning the names of the breed and the strain and the information concerning its heredity and the microorganisms that it carries.
In default of the previously mentioned data, no laboratory animals may be imported or used.

Article 23 When importing from abroad laboratory animals as element breeds, units dealing with laboratory animals shall register with the unit that is designated by the State Science and Technology Commission for the conservation of breeds, breeding, and quality control with respect to the said animals.

Article 24 The export of laboratory animals shall be subject to examination and approval by the State Science and Technology Commission. The export procedures shall be handled only after such an approval has been obtained.

With respect to the export of laboratory animals that are developed by use of wild animals that enjoy the priority of State protection, the export procedures shall be handled only after an export licence has been obtained in accordance with the pertinent provisions of the State.

Article 25 The quarantine of import and export laboratory animals shall be handled in accordance
with the provisions of the Regulations of the People's Republic of China Concerning the Quarantine of Import and Export of Animals and Plants.

Section VI Personnel Handling Laboratory Animals

Article 26 Units handling laboratory animals shall, according to the respective needs, be staffed with technical personnel and specially trained personnel for the feeding and breeding thereof. Personnel of various kinds shall all abide by the various rules and regulations concerning the administration of the feeding and breeding of laboratory animals and shall be acquainted with, and have a good mastery of, the operating rules.

Article 27 Competent authorities, at various levels, in various localities in charge of the work with respect to laboratory animals shall gradually institute a qualifying system for personnel of various kinds dealing with laboratory animals.

Article 28 Units dealing with laboratory animals shall regularly organise physical check-ups for the working personnel who are in direct contact with laboratory animals. Those who have contracted infectious diseases, and are no longer suitable for their jobs, shall be transferred in good time.

Article 29 Personnel dealing with laboratory animals shall protect these animals and may not play with or maltreat them.

Section VII Rewards and Penalties

Article 30 Units and individuals that are long engaged in the feeding and breeding and administration of laboratory animals and who have scored remarkable achievements shall be praised or rewarded by the department in charge of the administration of the work with respect to laboratory animals.

Article 31 With respect to those units that violate the provisions of these Regulations, the department in charge of the administration of the work with respect to laboratory animals shall, in accordance with the seriousness of the cases at hand, impose on them such administrative sanctions as issuing a warning, setting a deadline for them to improve their work, or ordering them to close down.

Article 32 The working personnel concerned, who violate the provisions of these Regulations, shall be given administrative sanctions by the units where they belong in accordance with the seriousness of the cases and with the pertinent provisions of the State.

Section VIII Supplementary Provisions

Article 33 The people's governments of the provinces, autonomous regions, and municipalities directly under the Central Government and the departments concerned under the State Council of the People's Republic of China may, in accordance with these Regulations and in line with the actualities, formulate procedures of implementation. The administration of the work with respect to laboratory animals in the armed forces shall be governed with reference to these Regulations.

Article 34 The State Science and Technology Commission shall be responsible for the
interpretation of these Regulations.

Article 35 These Regulations shall go into effect as of the date of promulgation.
The Notice Concerning the Issuance of the 《Measures of the Quality Administration of Laboratory Animals》

Science and Technology Commission and Bureau of Technology Supervision in each province autonomous region, municipality, and planned separate city, The Production and Construction Corps of Xinjiang, Ministries and Commissions and Departments Directly under the State Council, and Chinese Academy of Sciences:

In order to completely implement the 《Ninth Five-Year Plan of the People's Republic of China for Development of Scientific Research Conditions and the Outline of the Long-Term Target for the Year 2010》 and to further strengthen the quality administration of laboratory animals so as to ensure the quality of laboratory animals and animal experiments, the 《Measures of Quality Administration of Laboratory animals》 is formulated now based on the 《Regulations for the Administration of Affairs Concerning Laboratory animals》 and on the extensive collections of public opinions. Now, this document is issued to you and it shall be implemented carefully and completely, in turn combining with the actual conditions of each location and department.

State Science and Technology Commission of the People’s Republic of China
State Bureau of Technology Supervision of the People's Republic of China
December 11, 1997

The Measures of the Quality Administration of Laboratory Animals
Section I  General Rules

Article 1  Based on the ‘Regulations for the Administration of Affairs Concerning Laboratory Animals’ these measures are formulated for the purpose of strengthening the quality administration of laboratory animals, establishing and improving the quality control system of laboratory animals nationally and guaranteeing the quality of laboratory animals and animal experiments so as to meet the needs of scientific research, economic construction, social development, and opening up to the outside world.

Article 2  Unified standards relating to the national standard of quality of laboratory animals shall be implemented nationally. Trade standards or local standards shall be used in turn during the interim in cases where the relevant national standards have not yet been formulated.

Article 3  Unified quality control systems of laboratory animals shall be implemented nationally.

Article 4  These measures shall apply to those fields and units that are engaged in or relate to the research in, and the conservation of breeds, feeding and breeding, supply, use, administration, and supervision of laboratory animals.

Section II  National Resource Centre for Laboratory Animals

Article 5  Maintenance of the breeds and strains of breeds of laboratory animals is of importance for ensuring the quality of laboratory animals and the level of scientific research and, therefore, the National Resource Centre for Laboratory animals is established to scientifically protect and manage the resources of laboratory animals in China so as to achieve an assurance of the quality of breeds.

Primary missions of the National Resource Centre for Laboratory animals include the introductions, collections, and conservations of breeds and the strains of breeds of laboratory animals, research in the new technologies of conservations of breeds of laboratory animals, breeding of new breeds, and new strains of breeds as well as the supplies of standard breeds of laboratory animals for home and overseas customers.

Article 6  As a network system, the National Resource Centre for Laboratory animals comprises various resource centres of specific breeds of laboratory animals. Resource Centres of Laboratory animals shall be established from institutions that have favourable conditions. These institutions shall meet the following basic requirements:
1. Long-term engagement in the conservation of breeds of laboratory animals;
2. Relatively high technical competence with and good fundamental conditions of laboratory animal research;
3. Acceptable facilities and inspection instruments for breeding laboratory animals;
4. Outstanding technological achievements and research findings in the conservation of breeds of laboratory animals;

Article 7  Application, examination, and approval of Resource Centres of Laboratory animals shall be handled as the following procedures.

All of the institutions with the afore-mentioned fundamental conditions, which is recommended by most specialists, can fill out a ‘letter of application for the National Resource Centre of Laboratory Animals’ that, with the relevant documentation, shall be submitted to the State Science and Technology Commission of the People's Republic of China by the Science and Technology
Commission or the industrial competent authorities of various provinces (autonomous regions and municipalities directly under the Central Government).

After receiving the application, the State Science and Technology Commission will organise a specialist group to investigate and evaluate the applicant. Once the evaluation result is submitted to, and approved by, the State Science and Technology Commission, the applicant will become a Resource Centre of Laboratory Animals.

Resource Centre of Laboratory Animals is in the charge of the respective competent authorities and businesses thereof and are subject to the instructions and supervisions of the State Science and Technology Commission.

Article 8 The National Resource Centre of Laboratory Animals is responsible for the unified introductions of laboratory animals from foreign countries and supplies of breeds of laboratory animals for customers. Nevertheless, international communications and technical co-operation shall be subject to the approval of the State Science and Technology Commission. Any other institutions, if necessary, can also directly introduce, from abroad, those breeds and strains of breeds that do not exist in China, but these breeds and strains of breeds shall be used for the animal experiments of these institutions and shall not be supplied as breeds of laboratory animals to customers.

Section III Licence for the Production and Usage of Laboratory animals

Article 9 A licence system shall be implemented for the production and usage of laboratory animals and the institutions engaging in the production and usage of laboratory animals shall be licensed.

A licence for the production of laboratory animals is applied to those institutions that are engaged in the breeding and commercial operations of laboratory animals.

A licence for the usage of laboratory animals is applied to those institutions that are engaged in animal experiments and that produce pharmaceuticals and biological products by making use of laboratory animals.

Article 10 To obtain a production licence, those institutions engaging in breeding and commercial operations of laboratory animals shall have the following fundamental conditions:
1. With definite genetic backgrounds and quality conforming to the national standards, breeds of laboratory animals shall come from the National Resource Centre of Laboratory Animals.
2. The quality of the produced laboratory animals shall conform to the national standards;
3. Possession of a raising and breeding environment and facilities as well as inspection instruments, which ensure the respective quality of laboratory animals;
4. The quality of feedstuffs that are used for laboratory animals shall conform to the national standards;
5. Being in possession of a complete and effective quality control system;
6. Specialised technical personnel, skilled workers, and inspectors who can guarantee regular production and the quality of the laboratory animals and must hold all the relevant certificates;
7. Other conditions as stipulated by the laws and administrative regulations;

Article 11 Those institutions engaged in animal experiments and that produce pharmaceuticals and biological products by making use of laboratory animals must be in possession of the following fundamental conditions to obtain a usage licence.
1. Laboratory animals that are used must have a conformity certificate;
2. Raising and breeding environments and facilities conform to the national standards;
3. The quality of the feedstuffs that are used for laboratory animals shall conform to the national standards;
4. Feeders and experimenters shall have been subject to professional training;
5. Being in possession of a complete and effective management system;
6. Other conditions as stipulated by the laws and administrative regulations;

Article 12 Application, examination, and approval of the production and usage licence for laboratory animals shall be handled as the following procedures.

Each applicant shall submit a letter of application, with an inspection report and relevant documentation that are issued by a nationally authorised inspection institution, to the Science and Technology Commissions of the provinces (autonomous regions and municipalities directly under the Central Government) where the applicant is located. The selection of an inspection institution is at the discretion of the applicant.

The Science and Technology Commissions of the provinces (autonomous regions and municipalities directly under the Central Government) are responsible for handling licence applications and for implementing an evaluation, examination, and approval. After an application is approved, the Science and Technology Commissions of the provinces (autonomous regions and municipalities directly under the Central Government) authorised by the State Science and Technology Commission of the People’s Republic of China shall issue a production licence or a usage licence for laboratory animals to the applicant.

The State Science and Technology Commission of the People’s Republic of China is responsible for preparing a production licence and usage licence for laboratory animals, which are effective throughout China.

Article 13 The institutions that have obtained a licence must undergo an annual reinspection. The effectiveness of the licence will continue when the institutions pass the reinspection. In case any of the conditions do not pass the reinspection, the institutions shall carry out rectification measures within 3 months and be subject to reinspection again. When the institutions still fail to pass the reinspection again, their production or usage qualification shall be cancelled and their licences shall be withdrawn by those competent authorities that issue the licences. However, an application for a licence can be submitted again when the conditions of the institutions fully meet relevant requirements.

Article 14 Science and Technology Commissions of the provinces (autonomous regions and municipalities directly under the Central Government) shall organise and implement an annual reinspection on the institutions engaging in the production and usage of laboratory animals. Moreover, the results of the reinspections shall be submitted to the State Science and Technology Commission of the People’s Republic of China for filing.

Article 15 Those institutions engaging in the production of laboratory animals must perform quality inspections on raised and bred laboratory animals according to the relevant national standards. Furthermore, laboratory animals shall be sold with a conformity certificate that must clearly indicate the number of the production licence for the laboratory animals, along with the exact names of the breed and strain of breed, classification, genetic background or source, state concerning the examination of the microorganisms and parasites it carries as well as the signature of the institution’s leader.
Article 16 In case non-conforming laboratory animals are supplied or sold or unauthentic contents are filled out in a conformity certificate by those institutions engaging in the production of laboratory animals, a punishment with a warning shall be given or licences of these institutions shall be cancelled as appropriate. In case of serious consequences, these institutions shall bear the financial and legal liability.

Article 17 Any institution that does not obtain a production licence for laboratory animals is prohibited from raising, breeding, and dealing in laboratory animals. All laboratory animals, which are used for animal experiments and productions of pharmaceuticals and biological products by the institutions without a usage licence for laboratory animals, shall be considered as non-conforming.

Section IV Inspection Institutions

Article 18 Inspection institutions of laboratory animals shall be classified into the national and provincial levels for management.

Subject to the national standard (GB/T 15481) “General Requirements for the Competence of Testing and Calibration Laboratories”, inspection institutions at various levels must be relatively independent organisations that actually engage in inspection activities and shall not deal in the raising and breeding of laboratory animals. With a reasonable personnel structure as well as the instrumentation and special places that are required by inspections, the institution shall have technicians with professional titles of a middle-level and above accounting for at least 50% of all the technicians.

Inspection institutions shall be subject to the approval of the China National Accreditation Committee for Laboratories and shall observe the relevant regulations.

Article 19 In charge of the relevant departments of State Council or competent authorities of Science and Technology Commission of various provinces (autonomous regions and municipalities directly under the Central Government), National Quality Inspection Institutions of Laboratory animals shall be established at the institutions with a relatively high technical level in respect of heredity, microorganisms, parasites, nutrition, environment, and facility of laboratory animals and their business shall be subject to instructions and supervisions of the State Science and Technology Commission of the People’s Republic of China.

Article 20 Serving as a training institution for the quality inspectors of laboratory animals and a authoritative service institution for the quality inspection of laboratory animals, the National Quality Inspection Institution of Laboratory animals is engaged in research in the methods and technologies of a quality test and inspection of laboratory animals. Its major missions include research in the testing methods and technologies of laboratory animals and relevant conditions, training on quality inspectors of laboratory animals, acceptance of the entrustment of examinations, and annual inspections on the establishment of Provincial Quality Inspection Institution of Laboratory animals, supplies of reports of quality tests, and arbitration inspections with respect to laboratory animals, technical communications, and co-operation with foreign countries.

Article 21 Application, examination, and approval of National Quality Inspection Institution of Laboratory Animals shall be handled as in the following procedures. All institutions with the afore-mentioned fundamental conditions can fill out a 《Letter of Application for the Quality Inspection Institution of Laboratory Animals》 that, with the relevant
documentation, shall be submitted to the State Science and Technology Commission of the People's Republic of China by the Science and Technology Commission or the industrial competent authorities of various provinces (autonomous regions and municipalities directly under the Central Government). After receiving the application, the State Science and Technology Commission of the People's Republic of China will organise experts to perform examinations and evaluations on the applicant. Once the evaluation results are submitted to, and approved by, the State Science and Technology Commission of the People's Republic of China, the applicant will become a National Quality Inspection Institution of Laboratory Animals.

Article 22 The Provincial Quality Inspection Institution of Laboratory animals is mainly engaged in an inspection service concerning the quality of laboratory animals and shall be managed by the competent authorities in accordance with the relationship with administrative subordination.

Article 23 Application, examination, and approval of the Provincial Quality Inspection Institution of Laboratory Animals shall be handled as per the following procedures.
All institutions meeting the afore-mentioned fundamental requirements can fill out a 《Letter of Application for the Quality Inspection Institution of Laboratory Animals》 that, with the relevant documentation, shall be submitted to the Science and Technology Commission of various provinces (autonomous regions and municipalities directly under the Central Government).
Entrusted by the Science and Technology Commission of various provinces (autonomous regions and municipalities directly under the Central Government), the National Quality Inspection Institution of Laboratory animals shall examine (or test) the applicant according to the fundamental conditions of the Quality Inspection Institution of Laboratory animals and examination report thereof shall be prepared. After the evaluation reports are approved by the Science and Technology Commission of various provinces (autonomous regions and municipalities directly under the Central Government) and submitted to the State Science and Technology Commission of the People's Republic of China, the applicant that passes the examinations will become a Provincial Quality Inspection Institution of Laboratory Animals.

Article 24 National Quality Inspection Institution of Laboratory animals shall undergo inspections by an expert group that is to be organised by the State Science and Technology Commission of the People's Republic of China every 2 years. Provincial Quality Inspection Institution of Laboratory animals shall be subject to examinations (or tests) by the National Quality Inspection Institution of Laboratory animals every year. When they fail to pass the examinations, the Quality Inspection Institutions shall carry out improvements within 3 months and undergo reinspection again. In the case of another failure, the qualifications of these Quality Inspection Institutions for quality inspections shall be cancelled.

Section V Supplementary Provisions

Article 25 The State Science and Technology Commission shall be responsible for the interpretation of these measures.
Article 26 The measures shall enter into force on the date of promulgation.
Documents from the State Science and Technology Commission, Ministry of Health, Ministry of Education, Ministry of Agriculture, General Administration of Quality Supervision, Inspection and Quarantine, State Administration of Traditional Chinese Medicine of the People’s Republic of China, Health Department and General Logistics Department of Chinese People's Liberation Army

Notice No. 545 [2001] of State Science and Technology Commission

The notice concerning the issuance of the Administrative Measures for the Licence for Laboratory Animals (trial)

Science & Technology Department (Science and Technology Commission and Bureau), Health Department (Bureau), Department of Education (Provincial Education Commission), Department (Bureau) of Agriculture, Quality Inspection Bureau and Administration of Traditional Chinese Medicine in each province autonomous region, municipality, and planned separate city, each Military Area, Heath Department and Logistics Department and Other Relevant Departments of Armed Forces, The Production and Construction Corps of Xinjiangthe relevant Departments of State Council, and the Chinese Academy of Sciences:

In order to completely implement the 《Regulations for the Administration of Affairs Concerning Laboratory Animals》 (Decree No. 2 of the State Science and Technology Commission of the People's Republic of China in 1988) and the relevant regulations so as to further strengthen the administration of laboratory animals, 《Administrative Measures for the Licence for Laboratory Animals (trial)》 is formulated now based on extensive collections of opinions from the relevant departments and experts. Now, this document is issued to you and it shall be implemented carefully and completely.

Appendix: Administrative Measures for the Licence for Laboratory Animals (trial)
Ministry of Science and Technology
Ministry of Health
Ministry of Education
Ministry of Agriculture
General Administration of Quality Supervision, Inspection, and Quarantine of the PRC
State Administration of Traditional Chinese Medicine
Health Department and General Logistics Department of Chinese People's Liberation Army

December 5, 2001
Administrative Measures for the Licence for Laboratory Animals (trial)

Section I  General Provisions

Article 1 In order to strengthen the management of laboratory animals, to guarantee the needs of scientific effort, and to enhance the level of scientific research, these measures are formulated based on the 《Regulations for the Administration of Affairs Concerning Laboratory Animals》 (Decree No. 2 of the State Science and Technology Commission of the People's Republic of China in 1988) and the relevant regulations.

Article 2 These measures shall apply to those organisations and individuals engaging in affairs concerning laboratory animals within the boundaries of the People's Republic of China.

Article 3 Licences of laboratory animals consists of a production licence and usage licence for laboratory animals.

A production licence for laboratory animals is applied to those organisations and individuals that are engaged in the conservation of breeds, breeding, production, supply, transportation, and commercial operations of laboratory animals. A usage licence for laboratory animals is applied to those organisations and individuals that are engaged in scientific research and experiments by means of laboratory animals and products thereof.

A licence shall be prepared, printed, issued, and managed by the Science and Technology Commissions of the provinces (autonomous regions and municipalities directly under the Central Government).

One licence has an original and copy that have equal legal status.

Article 4 Provinces, autonomous regions, and municipalities directly under the Central Government, which meet the requirements, shall establish a Provincial Quality Inspection Institution of Laboratory Animals that is responsible for inspections of the quality and relevant conditions of laboratory animals of those institutions engaging in the production and usage of laboratory animals.

Certification of Provincial Quality Inspection Institution of Laboratory Animals shall be handled according to the 《Measures of Quality Administration of Laboratory Animals》 (Notice No. 593 [1997] of State Science and Technology Commission) and the relevant regulations of the China National Regulatory Commission for Certification and Accreditation. Furthermore, these Provincial Quality Inspection Institutions of Laboratory Animals shall pass metrological authentication in accordance with the Metrology Law of the People's Republic of China.

The Provinces, autonomous regions, and municipalities directly under the Central Government, which have not yet established a Provincial Quality Inspection Institution of Laboratory Animals, shall entrust other Provincial Quality Inspection Institution of Laboratory animals to carry out inspections for the quality and relevant conditions of laboratory animals. In addition, the Provincial Science & Technology Department (Science and Technology Commissions) of the provinces (autonomous regions and municipalities directly under the Central Government) where the entrusting party and entrusted party are located shall reach an agreement that shall be submitted to the Ministry of Science and Technology for filing.
Section II Application

Article 5 The organisations and individuals applying for a production licence for laboratory animals shall meet the following requirements:

1. With definite genetic backgrounds and quality conforming to the prevailing national standards, breeds of laboratory animals shall come from the National Resource Centre of Laboratory Animals or other resource institutions of laboratory animals that have been approved by the People’s Republic of China;
2. Possession of raising, breeding, and production environments and facilities as well as inspection instruments, which ensure the quality of laboratory animals and relevant products;
3. The feedstuffs, cushioning (bedding?) materials, and drinking water shall conform to the national standards and meet the relevant requirements.
4. Specialised technical personnel, skilled workers, and inspectors who can guarantee regular production and quality of laboratory animals;
5. Being in possession of a complete and effective quality control system;
6. The quality of the produced laboratory animals shall conform to the national standards;
7. Other conditions as stipulated by the laws or regulations.

Article 6 The organisations and individuals applying for a usage licence for laboratory animals shall meet the following requirements:

1. With acceptable quality, the laboratory animals and the relevant products shall come from those institutions holding a valid production licence for laboratory animals;
2. Raising and breeding environments and facilities of laboratory animals shall conform to the national standards;
3. The quality of the feedstuffs used for laboratory animals shall conform to the national standards;
4. Feeders and experimenters shall have been subject to professional training;
5. Being in possession of a complete and effective management system;
6. Other conditions as stipulated by the laws or regulations;

Article 7 The organisations and individuals, which would like to apply for a production or usage licence for laboratory animals, shall submit a letter of application for a production licence for laboratory animals (see appendix 1) or a letter of application for a usage licence for laboratory animals to the Provincial Science & Technology Department (Science and Technology Commissions) of the provinces (autonomous regions and municipalities directly under the Central Government) where the applicants are located. Additionally, inspection reports and relevant documentation that are issued by a Provincial Quality Inspection Institution of Laboratory Animals shall be attached with the letter of application and submitted together.

Section III Examination, Approval, and Issuance of a Licence

Article 8 The Provincial Science & Technology Department (Science and Technology Commissions) of the provinces (autonomous regions and municipalities directly under the Central Government) are responsible for handling the licence applications and for implementing the evaluation, examination, and approval.

After receiving an application for a licence, the Provincial Science & Technology Department (Science and Technology Commissions) of the provinces (autonomous regions and municipalities directly under the Central Government) shall organise a specialist group to perform examinations
and on-site acceptances on the applicant’s application documents and actual conditions and an acceptance report shall be issued by the specialist group. As for those institutions that apply for a production licence, breeds of laboratory animals that are used for production by these institutions shall be confirmed as per the《Disposal Considerations on Current Issues Concerning the Resources of Laboratory animals during the Issuance of a Licence》.

The corresponding evaluation result shall be given by the Provincial Science & Technology Department (Science and Technology Commissions) of the provinces (autonomous regions and municipalities directly under the Central Government) within 3 months after receiving a licence application. Documents concerning the production or usage licence for laboratory animals shall be issued and approved and a licence shall be released by the Provincial Science & Technology Department (Science and Technology Commissions) of the provinces (autonomous regions and municipalities directly under the Central Government).

Article 9 The relevant documents (letter of application, application materials, acceptance report of a specialist group, and approval documents) shall be submitted by the Provincial Science & Technology Department (Science and Technology Commissions) of the provinces (autonomous regions and municipalities directly under the Central Government) to the Ministry of Science and Technology and the relevant departments for filing.

Article 10 Nationally unified format and coding method (see appendices 3 and 4) shall be employed for a licence for laboratory animals.

Section IV Administration and Supervision

Article 11 Institutions that have obtained a production licence for laboratory animals shall implement production and quality control according to the national quality standards relating to laboratory animals. A conformity certificate of laboratory animals (appendix 5), with a recent quality inspection report of laboratory animals conforming to the regulations of the standards attached, shall be provided when selling laboratory animals. The contents of the conformity certificate of laboratory animals shall include the producer’s name, number of their production licence, strain of breed, quality grade, and specification and quantity of laboratory animals, the latest date of a quality inspection, name of the Quality Inspection Institution, signature of the QC responsible officer, the user's name, as well as the purpose of the laboratory animals.
Article 12 With a five-year period of validity, the licence shall be renewed by means of re-examinations after the expiry date. Six months before the expiry date, the institutions that are required to renew the licence shall submit an application to the Provincial Science & Technology Department (Science and Technology Commissions) of the provinces (autonomous regions and municipalities directly under the Central Government) where the institutions are located. The Provincial Science & Technology Department (Science and Technology Commissions) of the provinces (autonomous regions and municipalities directly under the Central Government) shall re-examine the applicants according to the same procedures as that for the first application.

Article 13 When those institutions holding a usage licence for Laboratory Animals are entrusted by other institutions with animal experiments, an agreement shall be signed between both parties. Moreover, a copy of the usage licence shall be used together with the agreement as effective documents for the validity of the conclusion of an experiment.

Article 14 The licence for Laboratory Animals shall not be lent, transferred, and rented to other institutions or individuals for usage. In addition, the institutions that obtained the production licence for Laboratory Animals shall not be commissioned to sell animals and relevant products that are produced by institutions that have no licence.

Article 15 In the case of the requirement for changes in the registration particulars of a licence, institutions shall submit an application to the original license-issuing authority 1 month in advance. When institutions apply for changes in the scope of the application, this shall be handled according to articles 8 to 13 within these administrative measures. Facilities subject to reconstruction and extension shall be handled as new-built facilities or changes in registration particulars as appropriate. In case institutions stop undertaking work within the scope of the licence, the licence for Laboratory Animals shall be withdrawn within 1 month after work has ceased. In the event of the loss of the licence, the respective loss shall be reported and the licence shall be reissued in a timely manner.

Article 16 The administration system of annual inspection is put into practice for licences. Licences shall be cancelled by the Provincial Science & Technology Department (Science and Technology Commissions) of the provinces (autonomous regions and municipalities directly under the Central Government) when institutions fail to pass the annual inspection. Furthermore, cancellations of licences shall be reported to the Ministry of Science and Technology and other relevant departments in order for filling and public announcement shall be made.

Article 17 Institutions that did not obtain a production licence for Laboratory Animals shall not undertake production or business operations in experimental animals. All of the results obtained from animal experiments will not be accepted if the animal experiments are carried out by institutions that did not obtain a usage licence for Laboratory Animals, or if the Laboratory Animals or relevant products come from the institutions that did not obtain a usage licence for Laboratory Animals or the qualities of these Laboratory Animals or relevant products are non-conforming.

Article 18 Licence-issuing authorities have the right to withdraw licences and to publish an announcement after verification if those institutions that have obtained a licence for Laboratory Animals violate the regulations of article 14 to produce or use non-conforming experimental animals. If the circumstances are malicious and serious, administrative and criminal responsibilities shall be claimed in accordance with the regulations and laws.
Article 19 Licence-issuing authorities and working personnel thereof must strictly abide by the 《Regulations for the Administration of Affairs Concerning Laboratory Animals》 and the relevant regulations and regulations in these measures.

Section V Supplementary Provisions

Article 20 The printing, issuance, and administration of a licence with respect to Laboratory Animals in the armed forces shall be governed with reference to these measures by the competent authorities in the army.

Article 21 Based on industry characteristics and local conditions, various departments and local administrative authorities can prepare corresponding detailed rules for implementing administration, which shall be reported to the Ministry of Science and Technology for filing.

Article 22 The Ministry of Science and Technology is responsible for interpreting these measures.

Article 23 These measures shall become effective on 1 January 2002.
Appendix 1

Production License of Laboratory Animals

Letter of Application

Applicant (official seal):__________________________

Legal Representative (Signature):__________________

Date of Application:_____________________________

Contact Person:________________________________

Contact Telephone:______________________________

Institution of Receiving Application:_______________

Date of Receiving Application:_____________________
Explanations for Filling out the Form and Applying

1. “Breed of Product” and “Quality Grade” in this letter of application refer to the breeds and monitoring levels of the applicable Laboratory Animals and relevant products thereof (such as a mouse, rat, shrewmouse, guinea pig, chicken, rabbit, dog, monkey, and feedstuffs, etc.) according to the national standards relating to experimental animals. Trade standards or local standards (such as cat and SPF pig, etc.) shall be used in turn during the interim in those cases that the relevant national standards have not yet been formulated.

2. “Facility Classification” in the letter of application means “Classifications of and Technical Requirements for Facilities” (such as an open system, a barrier system, an isolation system, etc.) as stipulated in the 《National Standards of the People’s Republic of China for Laboratory Animals—Environments and Facilities》.

3. Breeds of Laboratory Animals (such as reptiles, amphibians, fish, etc.) for which unified standards have not yet been formulated shall be governed by the various local competent authorities according to the local regulations.

4. Licences shall be respectively applied for and drawn for the facilities of Laboratory Animals that are set up at different places by the same institution.

5. The licence shall be applied and drawn for newly-built facilities after a trial run and before formal use.

6. The letter of application can be accepted as complete application documents only if submitted together with the following appendices.
   (1) Certificate proving that the resources of breeds of Laboratory Animals conform to the regulations;
   (2) Inspection report concerning environments and facilities and the qualities of the Laboratory Animals as issued by the Provincial Quality Inspection Institution of Experimental Animals;
   (3) Other relevant documentary evidence;

7. With legible writings, the letter of application shall be filled out in pen or with a computer;

8. Additional pages can be added in case there are insufficient spaces for filling the form out.

9. This letter of application is also applicable to the adding of scopes to the application.
1. **Basic information of institution**

Name of institution: ____________________________
Address of institution: ____________________________ Postal code: ____________________________
Contact Telephone: ____________________________ Contact Person: ____________________________
Legal representative: ____________________________ Person in charge for laboratory animal facilities: ____________________________
Location of facilities: ____________________________

2. **Application item**

<table>
<thead>
<tr>
<th>Breed of Product</th>
<th>Quality Grade</th>
<th>Resource of Breeds and Time of Introduction</th>
<th>Classification and Area ($m^2$) of Facility as well as Production Capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
3. Quality Assurance Condition of Product

3.1 Major employees (including primary production management personnel, veterinarians and quality inspectors, etc.)

<table>
<thead>
<tr>
<th>Name</th>
<th>Professional and Technical Titles</th>
<th>Speciality</th>
<th>Academic Records</th>
<th>Principle Duties</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3.2 Major instruments and equipments (or standard materials)

<table>
<thead>
<tr>
<th>Name of Instruments and Equipments (or Standard Materials)</th>
<th>Quantity</th>
<th>Running Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3.3 Important rules and regulations (facility management, equipment maintenance, personnel training and SOP, etc.)
Usage License of Laboratory Animals

Letter of Application

Applicant (official seal): ______________________
Legal Representative (Signature): ______________
Date of Application: __________________________
Contact Person: ______________________________
Contact Telephone: ____________________________

Institution of Receiving Application: __________
Date of Receiving Application: ________________
Explanations for Filling out the form and Applying

1. “Facility Classification” in the letter of application means “Classifications of and Technical Requirements for Facilities” (such as an open system, a barrier system, an isolation system, etc.) as stipulated in the 《National Standards of the People’s Republic of China for Laboratory Animals—Environments and Facilities》.

2. Licences shall be respectively applied for and drawn for the facilities of Laboratory Animals that are set up at different places by the same institution.

3. The licence shall be applied and drawn for newly-built facilities after a trial run and before formal use.

4. The letter of application can be accepted as complete application documents only if submitted together with the following appendices.
   (1) Certificate proving that the resources of breeds of Laboratory Animals conform to the regulations;
   (2) Inspection report concerning environments and facilities and the qualities of the Laboratory Animals as issued by the Provincial Quality Inspection Institution of Experimental Animals;
   (3) Other relevant documentary evidence;

5. With legible writings, the letter of application shall be filled out in pen or with a computer;

6. Additional pages can be added in case there are insufficient spaces for filling the form out.

7. This letter of application is also applicable to the adding of scopes to the application.
1. Basic information of institution

Name of institution: ____________________________
Address of institution: ____________________________ Postal code: ____________________________
Contact Telephone: ____________________________ Contact Person: ____________________________
Legal representative: ____________________________ Person in charge for laboratory animal facilities: ____________________________
Location of facilities: ____________________________

2. Application item

2.1 General laboratory facilities of laboratory animals

<table>
<thead>
<tr>
<th>Facility Classification</th>
<th>Major Subjects of Animal Experiments and Used Breed of Animal</th>
<th>Area of Facility (m²)</th>
</tr>
</thead>
</table>

2.2 Special laboratory facilities of laboratory animals

<table>
<thead>
<tr>
<th>Facility Classification</th>
<th>Major Subjects of Animal Experiments</th>
<th>Area of Facility (m²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Animal experiment for radioactivity;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Animal experiment for infectivity;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Animal experiment for chemical toxicity;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Other animal experiments (detailed description);</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
3. Assurance of Facilities of Laboratory Animals

3.1 Major employees (including primary production management personnel, veterinarians and experimental technical personnel, etc.)

<table>
<thead>
<tr>
<th>Name</th>
<th>Professional and Technical Titles</th>
<th>Speciality</th>
<th>Academic Records</th>
<th>Principle Duties</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3.2 Major instruments and equipments (or standard materials)

<table>
<thead>
<tr>
<th>Name of Instruments and Equipments (or Standard Productive Materials)</th>
<th>Quantity</th>
<th>Running Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3.3 Important rules and regulations (facility management, equipment maintenance, personnel training and SOP, etc.)
Appendix 3

Samples of Original and Copy of License of laboratory Animals

Sample of Original of Production License of Laboratory Animals (A3 size, single-sided, anti-counterfeiting shading)

Production License of Laboratory Animals

License Number:

Name of Institution:

Legal Representative:

Location of Facilities:

Scope of Application:

(Additionally affixed official seal of license-issuing authority)

(Date of Issue)
<table>
<thead>
<tr>
<th><strong>Usage License of Laboratory Animals</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>License Number:</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Name of Institution:</strong></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Legal Representative:</strong></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Location of Facilities:</strong></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Scope of Application:</strong></th>
</tr>
</thead>
</table>

(Additionally affixed official seal of license-issuing authority)

(Date of Issue)
<table>
<thead>
<tr>
<th>Production License of Laboratory Animals (copy)</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Production license of Laboratory Animals is a legal document for doing experiments on Laboratory Animals and making products thereof for the purpose of self-use and commercial operations.</td>
<td></td>
</tr>
<tr>
<td>2. One license has an original and copy which has equal legal status.</td>
<td></td>
</tr>
<tr>
<td>3. License shall not be counterfeited, altered, rented or assigned; no any institution or individual except the license-issuing authority can withhold and cancel the license.</td>
<td></td>
</tr>
<tr>
<td>4. Institutions holding license shall carry out production and operating activities within the scopes of license.</td>
<td></td>
</tr>
<tr>
<td>5. Application for changes in registration shall be submitted to original license-issuing authority when registration particulars of license change. Original and copy of license shall be sent back when business of Laboratory Animals is cancelled.</td>
<td></td>
</tr>
<tr>
<td>6. Institutions holding license shall be subject to annual inspections and license continues to be effective after pass the annual inspections.</td>
<td></td>
</tr>
<tr>
<td>7. License automatically becomes invalid after it is withdrawn by license-issuing authority.</td>
<td></td>
</tr>
</tbody>
</table>
Production License of
Laboratory Animals
(c)copy)

License Number:

Name of Institution:

Legal Representative:

Location of Facilities:

Scope of Application:

(Additionally affixed official seal of license-issuing authority)

(Date of Issue)
Usage License of Laboratory Animals

Notes

1. Production license of Laboratory Animals is a legal document for doing experiments on Laboratory Animals.
2. One license has an original and copy which have equal legal status.
3. License shall not be counterfeited, altered, rented or assigned; no any institution or individual except the license-issuing authority can withhold and cancel the license.
4. Institutions holding license shall carry out production and operating activities within the scopes of license.
5. Application for changes in registration shall be submitted to original license-issuing authority when registration particulars of license change. Original and copy of license shall be sent back when business of Laboratory Animals is cancelled.
6. Institutions holding license shall be subject to annual inspections and license continues to be effective after pass the annual inspections.
7. License automatically becomes invalid after it is withdrawn by license-issuing authority.
## Usage License of Laboratory Animals

**License Number:**

**Name of Institution:**

**Legal Representative:**

**Location of Facilities:**

**Scope of Application:**

(Additionally affixed official seal of license-issuing authority)

(Date of Issue)

<table>
<thead>
<tr>
<th>Date of change</th>
<th>Item of change</th>
<th>Signature and seal</th>
</tr>
</thead>
</table>

Your license remains effective in ____ year after passing the annual inspections.

Official seal of inspection institution

MM/DD/YY

Your license remains effective in ____ year after passing the annual inspections!

Official seal of inspection institution

MM/DD/YY
Appendix 4

Coding Method for a Licence for Laboratory Animals

The production licence for Laboratory Animals is marked as an SCXK and usage licence for Laboratory Animals and is marked as SYXK. In addition, the content in the brackets is a Chinese abbreviation of the administrative region and a separate numbering is used for the army system. The following four-digit number is the year when the licence is issued. The four-digit number following the short transverse line is the licence number that is numbered according to the sequence of the licence issuance of each province, autonomous region, or municipality directly under the Central Government.

Graphic example:

License Classification (Abbreviation of administrative region) XXXX — XXXX

- Licence number (such as 0001)
- Year when licence is issued (such as 2000 indicates the year 2000)
- Such as (Jing) means Beijing City and (Jun) indicates the army system
- SCXK represents a production licence and SYXK represents a usage licence
Appendix 5

Sample of Certificate of Quality Conformity of Laboratory Animals

Certificate of Quality Conformity of Laboratory Animals

1. Receipt for seller

<table>
<thead>
<tr>
<th>Breed and strain of breed of animal</th>
<th>Grade</th>
<th>Specification of animal</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Weight/age in days</td>
<td>Gender of animal (♂/♀)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The latest date of quality inspection | Quality Inspection Institution |

Purpose
- ○ Scientific Research
- ○ Product Production
- ○ Inspection and verification
- ○ Teaching Experiment
- ○ Other

Seller (official seal): License Number:

QC responsible officer: Handling personnel: MM/DD/YY:

Being in duplicate, the certificate shall not be imitated and copy is invalid.

Certificate of Quality Conformity of Experimental Animals

2. Receipt for buyer

<table>
<thead>
<tr>
<th>Breed and strain of breed of animal</th>
<th>Grade</th>
<th>Specification of animal</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Weight/age in days</td>
<td>Gender of animal (♂/♀)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The latest date of quality inspection | Quality Inspection Institution |

Purpose
- ○ Scientific Research
- ○ Product Production
- ○ Inspection and verification
- ○ Teaching Experiment
- ○ Other applications

Seller (official seal): License Number:

QC responsible officer: Handling personnel: MM/DD/YY:

Being in duplicate, the certificate shall not be imitated and copy is invalid.
Remarks:

1. With this sample of the “certificate of quality conformity of laboratory animals”, each local competent authority can formulate the corresponding administration measures for the certificate of quality conformity for Laboratory Animals so as to determine the relevant affairs, such as the supervision department, institution responsible for the printing of the certificate, procedures for application and drawing, management, and supervision etc.

2. Based on operational needs, each local administration department shall decide whether stub, or other use stubs, shall be printed or not.
Documents Issued by the Ministry of Science and Technology
Notice No. 174 [1998] of the State Science and Technology Commission

The notice concerning the issuance of the 《Administrative Measures of the National Resource Centre for Laboratory Animals》

The Science and Technology Commissions of each province, autonomous region, and municipality directly under the Central Government, Technology Commission of The Production and Construction Corps of Xinjiang and various departments:

In order to strengthen the standardisation and normalisation of the quality administration of Laboratory Animals and scientifically maintain and manage China’s resource of laboratory animals, the 《Administrative Measures of the National Resource Centre for Laboratory Animals》 is formulated based on the 《Ninth Five-Year Plan of the People's Republic of China for Development of Scientific Research Conditions and the Outline of the Long-Term Target for the Year 2010》 and the 《Measures of Quality Administration of Laboratory animals》. This document is now issued to you and shall be implemented carefully and completely according to the actual conditions of the various places and departments.

Ministry of Science and Technology, the People’s Republic of China
12 May 1998
Administrative Measures of the National Resource Centre for Laboratory Animals

Section I  General Rules
Article 1 In order to completely implement the 《Measures of the Quality Administration of Laboratory Animals》 and scientifically protect and manage China’s resource of Laboratory Animals and guarantee the quality of breeds of the laboratory animals, these measures are formulated in order to strengthen the administration of the National Resource Centre for Laboratory animals.

Article 2 Based on the needs of the science and technology development of China and overall co-ordination of the Ministry and Science and Technology, the national resource centres for various breeds of Laboratory Animals shall be established by means of selection. When necessary, different centres, stations for the conservation of specific breeds and strains of breeds can be separately set up for national resource centres for various breeds of laboratory animals.

Article 3 National Resource Centres of Laboratory Animals are in the charge of the respective competent authorities, in which its businesses are subject to the instructions and supervision of the State Science and Technology Commission.

Section II  Missions
Article 4 Major missions of the National Resource Centre of Laboratory animals:
1. Introduction, collection, and conservation of the breeds and strains of breeds of laboratory animals;
2. Research into new technologies for the conservation of the breeds of laboratory animals;
3. Breeding of new breeds and strains of breeds of laboratory animals;
4. Supply of standard breeds of Laboratory Animals for customers nationally and abroad.

Article 5 The National Resource Centres of Laboratory Animals is responsible for unified introductions of Laboratory Animals from foreign countries and supplies of breeds of Laboratory Animals for customers.

Article 6 International communications and technical co-operation of the National Resource Centre of Laboratory Animals shall be subject to the approval of the State Science and Technology Commission.

Section III  Organisation
Article 7 The National Resource Centre of Laboratory Animals can be a relatively independent entity that is supported by research institutions or colleges and universities. It also can be an independent legal entity.
The National Resource Centre shall be responsible for instructing and co-ordinating the businesses of resource centre and station for the conservation of breeds.

Article 8 The National Resource Centre must meet the following basic conditions:
1. Long-term engagement in the conservation of the breeds of laboratory animals;
2. Relatively high technical competence with and good fundamental conditions of the research conducted with laboratory animals;
3. Acceptable facilities and inspection instruments for breeding laboratory animals;
4. Outstanding technological achievements and research findings in the conservation of the breeds of laboratory animals.

Article 9 Business operations of non-independent National Resource Centre of Laboratory Animals shall be supervised and examined by the institution by which it is supported. Furthermore, this institution also shall provide the necessary technical support and logistical support for the regular operations of the National Resource Centre of Laboratory animals. Appointment or removal of the major principals of the National Resource Centre of Laboratory Animals shall be reported to the Ministry of Science and Technology for filing.

Article 10 The National Resource Centre of Laboratory Animals shall establish an Academic Committee that shall determine the business objectives and evaluate the technological achievements for the National Resource Centre of Laboratory animals.

Article 11 Application and approval procedures of the National Resource Centre of Laboratory animals.
1. The Ministry of Science and Technology shall organise a specialist who is specialised in Laboratory Animals to recommend Candidate institutions for the National Resource Centre of Laboratory animals.
2. All institutions that are recommended by most of the specialists can file an application and fill out a «letter of application for the National Resource Centres of Laboratory Animals» that shall be reported to the Ministry of Science and Technology by Science and Technology Commission or industrial competent authorities of various provinces (autonomous regions and municipality directly under the Central Government) together with the relevant documents.
3. After the application is received, the Ministry of Science and Technology shall organise a specialist group to survey and evaluate the applicant. If necessary, an oral defence can be held.
4. Approval by the Ministry of Science and Technology.

Section IV  Finance and management

Article 12 The competent authorities shall provide the necessary capital expenditures and the Ministry of Science and Technology shall provide one-off subsidies for the approved National Resource Centre of Laboratory animals.

Article 13 Expenditures of the daily operations of the National Resource Centre of Laboratory Animals shall be raised by the centre itself or may be provided by the institution supporting the National Resource Centre of Laboratory animals. Operation expenditures can also be supplemented by income from social services.

Article 14 Charging scale for the supplies of breeds of Laboratory Animals shall be formulated by the National Resource Centre of Laboratory Animals according to the regulations of the relevant departments.

Article 15 The National Resource Centre of Laboratory Animals shall establish and improve the various strict managerial systems and systematic archives of the pedigrees of laboratory animals.
Moreover, monitoring of the qualities of the Laboratory Animals and the relevant facilities shall be strengthened.

Article 16 The National Resource Centre of Laboratory Animals shall take effective measures to maintain relative stabilities of backbones at different levels and the personnel involved with the affairs concerning the conservation and breeding of the breeds shall be subject to professional trainings. Additionally, these personnel must take a post with the relevant certificates.

Section V  Inspections and supervision

Article 17 The National Resource Centre of Laboratory Animals shall be subject to regular and irregular inspections that are to be performed by the National Quality Inspection Institution of Laboratory animals. The National Resource Centre of Laboratory Animals shall bring forward an improvement scheme aiming at the problems found during inspections and undergo reinspections after improvements are carried out within a limited period.

Article 18 The Ministry of Science and Technology shall give a warning to the National Resource Centre of Laboratory Animals, which have relatively serious problems but that do not have a corresponding improvement scheme. In the event that no improvement is carried out after the warning, the qualification of being a National Resource Centre of Laboratory Animals shall be cancelled.

Article 19 The National Resource Centre of Laboratory Animals shall pay compensation to customers and replace conforming breeds if it provides non-conforming breeds of Laboratory Animals and cause economic losses to customers. If the circumstances are serious, the principals shall be prosecuted for criminal liabilities according to the respective laws.

Section VI Supplementary Provisions

Article 20 The Measures shall enter into force on the date of promulgation.
The notice concerning the issuance of the 《Rules for the Implementation of Breed Introduction and the Supply of the National Resource Centre for Laboratory Experimental Rodents》

The Science and Technology Commissions of each province, autonomous region, and municipality directly under the Central Government, Technology Commission of The Production and Construction Corps of Xinjiang and various departments (bureaus):

For the purpose of the standardisation of breed introduction and the supply of experimental rodents, the 《Rules for the Implementation of Breed Introduction and the Supply of National Resource Centre for Laboratory Experimental Rodents》 is formulated in accordance with the 《Administrative Measures of the National Resource Centre for Laboratory animals》. This document is now issued to you and shall be implemented as a reference.

Department of Facilities and Finance of the Ministry of Science and Technology

30 September 1998
Rules for the Implementation of Breed Introduction
and the Supply of National Resource Centre for
Rodent Laboratory Animals

(1) For the purpose of the sound management of breed introduction and the supply of experimental rodents, these rules for the implementation are prepared based on the 《Measures of Quality Administration of Laboratory Animals》 and the 《Administrative Measures of the National Resource Centre for Laboratory animals》.

(2) The National Resource Centre for Laboratory Experimental Rodents shall be responsible for the overall businesses concerning the breed introduction of experimental rodents from foreign countries and the breed supply in China.

(3) The National Resource Centre for Laboratory Experimental Rodents shall determine the breeds of the rodents that are to be used. Moreover, the Ministry of Science and Technology shall organise specialists to verify the determinations of the rodents and confirm the breeds and strains of breeds, which conform to the respective quality requirements and that have complete data.

(4) To ensure that the breeds of animals can be supplied according to the needs of a production institution, the National Resource Centre for Laboratory Experimental Rodents shall be responsible for issuing a checklist of the breed supply of experimental rodents, which shall include the names of breeds and the strains of breeds as well as the quality grade of experimental rodents. The range of the breed conservation of Laboratory Animals shall be continuously added to and adjusted in the manner of the breed introductions from foreign countries and the collections at home, etc. so as to meet the requirements of the business development of the Laboratory Animals in China.

(5) Breed introduction and supply

A. Application for breed introduction

The institutions engaging in the production and breeding of Laboratory Animals shall, to the National Resource Centre for Laboratory Experimental Rodents, file a written application that shall describe the breeds, strains of breeds, gender of the animals, quantity of and quality requirements on as well as delivery time of the Laboratory Animals to be introduced. Production and breeding licences and the relevant documents granted and issued by the local administration department of Laboratory Animals shall be shown by the institutions that would like to introduce the breeds of laboratory animals. The National Resource Centre for Laboratory Experimental Rodents shall reply to the application within 10 days after the application is received.

B. Agreement on the breed supply

An agreement signed between the National Resource Centre for Laboratory Experimental Rodents and the institution requiring the breed introduction shall include the full names of the breeds and strains of the breeds of introduced laboratory animals, quality grade, quantity, gender of the animals, expenditures (such as the prices of the animals, fees of the packages and transportation, etc.), time and method of the breed supply, responsibilities and obligations assumed by both
parties, disputes on the qualities of animals and arbitrations etc. The agreement shall come into force after it is signed and affixed with the official seals by both parties.

C. Breed supply
When delivering breeds of animals to customers, the National Resource Centre of Experimental Rodents shall provide its customers with the following documents:
① A packing list that describes the names of the breeds and the strains of the breeds (number of reproductive generations of inbred strain animals), gender, quantity, quality grade of the animals, methods of packing and transportation, time of shipping out, principals, etc.
② Recent quality inspection reports of breeds, including a report of inspecting micro-organisms and parasites in the recent half year and the quality inspection results of the heredities of the inbred strain animals in the most recent year.
③ Information concerning the biological characteristics of the breeds, including the reproductive performances, growth curves, coefficients of major organs, physiological and biochemical indices and other properties of the clinical blood.

D. Disputes on the quality of the animals and claims
In the event of a dispute on the quality of the animals provided by the National Resource Centre for Laboratory Experimental Rodents, it shall be brought forward to the National Resource Centre for Laboratory Experimental Rodents within 20 days after the arrival of the animals. After verifying the customer’s economic losses that resulted from the non-conforming breeds of Laboratory Animals as provided by the National Resource Centre for Laboratory Experimental Rodents, compensation shall be made to the customer and the non-conforming breeds shall be replaced with conforming breeds by the National Resource Centre for Laboratory Experimental Rodents.

The National Quality Inspection Centre shall be responsible for arbitrating and inspecting the qualities of animals supplied by the National Resource Centre for Laboratory Experimental Rodents.

The National Competent Authorities of Laboratory Animals shall be the top arbitration agency to arbitrate disputes on the performance of the agreement of the breed supply.

(6) Breeds of Laboratory Animals that are introduced by the institutions shall be used by the institutions themselves for production and breeding and shall not be supplied to other institutions as breeds of laboratory animals. The Laboratory Animals introduced by the institutions themselves shall be reported to the National Resource Centre for Laboratory Experimental Rodents for filing. Moreover, these introduced Laboratory Animals shall only be used by the institutions themselves and shall not be supplied to other institutions as breeds of Laboratory Animals before being confirmed as breeds of animals to be used nationally.

(7) In order to strengthen the quality standardisation of laboratory animals, the institutions introducing animals shall report the production, breeding, quality, and usage of Laboratory Animals to the National Resource Centre for Laboratory Experimental Rodents after introducing the laboratory animals. As a general rule, Laboratory Animals that are used as breeds shall be regularly replaced as appropriate.

(8) In order to ensure the relative stability of the genetic heterogeneity and gene polymorphism of the closed colony animals in China, the National Resource Centre for Laboratory Experimental Rodents shall be primarily responsible for establishing an exchange system of closed colony
animals for important institutions engaging in the breeding of laboratory animals. Each institution shall actively support and participate in establishing an exchange system of closed colony animals in the manner of a reimbursable supply or exchange, etc.
(9) The rules for implementation shall be effective on the day of issuance.

Documents Issued by the Departments of the Ministry of Science and Technology

Notice No. 044 [1999] of State Science and Technology Commission

Disposal considerations of the current issues concerning the resources of laboratory animals during the issuance of a licence

The Science and Technology Commissions of each province, autonomous region, and municipality directly under the Central Government, Technology Commission of The Production and Construction Corps of Xinjiang and various departments (bureaus):
The following disposal considerations are brought forward in order to solve the relevant problems concerning the administration of the breeds of experimental rodents, which arise during the issuance of licences of laboratory animals, and to scientifically protect and manage the resources of Laboratory Animals in China and to enhance the implementation of the production licensing system of laboratory animals.
(1) In accordance with the regulations in the 《Measures of Quality Administration of Laboratory Animals》 and 《the Administrative Measures of National Resource Centre for Laboratory animals》, the National Resource Centre for Laboratory Animals shall be responsible for unified breed introduction from foreign countries and the breed supply to customers nationally. The institutions engaging in the production and breeding of Laboratory Animals shall introduce experimental rodents from the National Resource Centre for Laboratory Animals or from the Branch Centre for Laboratory Animals in Shanghai strictly in accordance with the regulations in the 《Rules for the Implementation of Breed Introduction and Supply of National Resource Centre for Laboratory Experimental Rodents》. When the introduction of experimental rodents is necessary, an application must be submitted to the National Resource Centre for Laboratory animals, which is responsible for the unified introduction of experimental rodents. Breeds of experimental rodents that are privately introduced by the institutions themselves will not be approved and these experimental rodents shall not be supplied to other institutions as breeds. As for non-breeding rodents brought back from foreign countries by researchers or that are presented by foreign countries due to the needs of researchers, they shall only be used for the
animal experiments of the institutions themselves and shall not be supplied to customers as breeds of laboratory animals.

(2) Each institution’s currently conserved breeds and strains of breeds, which belong to the following circumstances and are certified can be considered as in conformance with the requirements of the first subparagraph of Article 10 in the《Measures of Quality Administration of Laboratory Animals》.

A. The breeds and strains of breeds currently conserved belong to the breeds and strains of the breeds in the checklist of breed supply as published by the National Resource Centre for Laboratory Experimental Rodents. In light of a limited capacity of breed supply of the National Resource Centre for Laboratory Experimental Rodents, an application for confirmation that the aforesaid breeds and strains of breeds are temporally “treated as” that were introduced from the National Resource Centre for Laboratory Experimental Rodents can be submitted to the Science and Technology Commissions of the provinces (autonomous regions and municipalities directly under the Central Government) where the institution is located. After receiving the application, the Science and Technology Commissions of the provinces (autonomous regions and municipalities directly under the Central Government) shall organise specialists to examine the application documents in accordance with the “Necessary Documentation for Experimental Rodents used as Breeds” (refer to the appendix). After the applicant passes the examination, the breeds of the applicant can be “considered” acceptable and only used for production and breeding of the institution itself rather than for a breed supply to society.

Suggestions shall be collected from the National Resource Centre for Laboratory Experimental Rodents and the relevant documentation shall be supplemented for the breeds of Laboratory Animals that have been introduced from the National Resource Centre for Laboratory Experimental Rodents for less than 3 years before the publication of the checklist of the breed supply. Regarding the breeds of Laboratory Animals that have been introduced from the National Resource Centre for Laboratory Experimental Rodents for more than 3 years, a confirmation shall be made that the afore-mentioned breeds of Laboratory Animals, which are “treated as”, were introduced from the National Resource Centre for Laboratory Experimental Rodents.

The period of validity during which the breeds of Laboratory Animals are “considered” acceptable shall be less than or equal to 2 years. Furthermore, breeds shall be renewed by introducing new breeds from the Centre after the expiry date.

The breeds considered acceptable shall be reported to the National Resource Centre for Laboratory Experimental Rodents for filing by the Science and Technology Commissions of the provinces (autonomous regions and municipalities directly under the Central Government).

B. The breeds and strains of the breeds bred by the institutions themselves, introduced from foreign countries, or obtained through other channels shall be reported to the National Resource Centre for Laboratory Experimental Rodents for approval by the Science and Technology Commissions of the provinces (autonomous regions and municipalities directly under the Central Government).

A specialist group shall be organised by the National Resource Centre for Laboratory Experimental Rodents to review the relevant documentation. If necessary, random inspections can be performed on the qualities of the animals and the expenditures thereof shall be at the applicant’s expense.
A conclusion of whether the afore-mentioned breeds of Laboratory Animals are considered acceptable shall be made in the manner of written documents based on the examination results of specialists. The breeds of Laboratory Animals that are considered acceptable shall only be used for production at the institution itself and shall not be supplied to society as breeds of laboratory animals.

Usually, the period of validity of the certified breeds of Laboratory Animals is 5 years. When quality problems of experimental animals, which are caused by heredity, microbial contamination, or other factors are found during the period of validity, the National Resource Centre for Laboratory Experimental Rodents have the right to cancel the recognised qualification of the institution.

C. If the certified breeds as described in the above Articles are of great significance, they can be applied for incorporation into the networks of the National Resource Centre for Laboratory Experimental Rodents. In addition, the National Resource Centre for Laboratory Experimental Rodents shall be responsible for the unified publication of a checklist of breeds supply for experimental rodents, in which various institutions that introduce or conserve breeds shall be responsible for the conservation of these certified breeds. In accordance with the requirements of the 《Rules for the Implementation of Breed Introduction and the Supply of the National Resource Centre for Rodent Laboratory Animals》, various institutions that introduce or conserve breeds shall supply breeds for society. At the end of November in each year, the production, breeding, quality, usage, and supply of Laboratory Animals shall be reported and the relevant documentation shall be submitted to the National Resource Centre for Laboratory Experimental Rodents. When necessary, reinspections shall be performed by the National Resource Centre for Laboratory Experimental Rodents.

D. In a certain manner, the results of certification and examination shall be published by the National Resource Centre for Laboratory Experimental Rodents. The breeds during the period of validity of certification will be approved when a production licence is issued and reinspections are performed.

(3) These disposal considerations shall be implemented as of the date of promulgation.

17 November 1999
Animal Epidemic Prevention Law of the People’s Republic of China

(Adopted at the 26th Meeting of the Standing Committee of the Eighth National People’s Congress on 3 July 1997)

Section I General Provisions

Article 1 This Law is enacted for the purpose of intensifying the administration of animal epidemic prevention, as well as preventing, bringing under control, and exterminating animal epidemics, promoting the development of livestock, fish breeding, and poultry raising, and protecting human health.

Article 2 This Law is applicable to animal epidemic prevention activities within the territory of the People’s Republic of China.

For the quarantine of entry and exit animals or animal products, the 《Law of the People’s Republic of China on the Entry and Exit of Animal and Plant Quarantine》 shall apply.

Article 3 "Animal" when referred to in this Law means the livestock, poultry, and other animals that are raised by humans or that are caught legally.

"Animal product" when referred to in this Law means the animals’ raw hides, hairs, semen, embryos and breeder eggs as well as non-processed products such as trunks, fats, viscera, blood, down, bones, horns, heads and hoofs.

"Animal epidemic” when referred to in this Law means animal infectious diseases and parasitic diseases.

"Animal epidemic prevention" when referred to in this Law includes the prevention, control and extermination of animal epidemics as well as the quarantine of animals and animal products.

Article 4 Quarantine inspection and supervision shall be conducted pursuant to this Law over the trunks, heads, and viscera of slaughtered animals. Those up to standards for foods after quarantine inspection shall be subjected to hygienic inspection and supervision in accordance with the provisions of the Food Hygiene Law of the People’s Republic of China.

Article 5 The state institutes a policy of focusing on the prevention of animal epidemics.

Article 6 The animal husbandry and veterinary administrative department under the State Council shall be in charge of animal epidemic prevention throughout the country.

The animal husbandry and veterinary administrative departments under the local people’s governments at or above the county level shall be in charge of animal epidemic prevention within their respective administrative areas.

The supervising agencies for animal epidemic prevention under the people’s governments at or above the county level shall execute animal epidemic prevention and supervision on animal epidemic prevention.

The supervising agencies for animal epidemic prevention in the armed forces shall be responsible for epidemic prevention for active-duty animals in the armed forces and the animals raised by the armed forces for their own use.

Article 7 People’s governments at all levels shall strengthen the leadership over animal epidemic prevention.
Article 8 The state encourages and supports scientific research on animal epidemic prevention, spreads the advanced achievements of scientific research, popularises the scientific knowledge of animal epidemic prevention, and improves the level of animal epidemic prevention.

Article 9 Any unit or individual that has made achievements or contributions in animal epidemic prevention or scientific research on animal epidemic prevention shall be rewarded by the people’s government or the animal husbandry and veterinary administrative department.

Section II Prevention of Animal Epidemics

Article 10 In light of the seriousness of the damage caused by animal epidemics to the breeding production and human health, animal epidemics under the control of this Law comprise three classes:

(1) Epidemics of Class I refer to those that cause serious damage to humans and animals and need to take urgent, rigorous measures to compulsorily prevent, bring under control, or exterminate them.

(2) Epidemics of Class II refer to those that can cause great economic losses and need to take strict measures to bring under control or exterminate them and avoid their spread.

(3) Epidemics of Class III refer to those that are so common, and occur so frequently, that may cause great economic losses and, therefore, control and purifying measures are required.

A detailed catalogue of epidemics of the three classes that were mentioned in the preceding paragraph shall be fixed and published by the animal husbandry and veterinary administrative department under the State Council.

Article 11 The animal husbandry and veterinary administrative department under the State Council shall formulate the national plan for animal epidemic prevention.

The animal husbandry and veterinary administrative department under the State Council shall, in light of the animal epidemic situation abroad and nationally and in accordance with the requirements for the protection of the breeding production and human health, formulate and publish in a timely manner the measures for animal epidemic prevention.

The state practices a system of immunisation planning for the execution of compulsory immunisation against animal epidemics that cause serious damage to the breeding production and human health.

A catalogue of animal epidemics subjected to compulsory immunisation shall be formulated and published by the animal husbandry and veterinary administrative department under the State Council.

For other animal epidemics than those subjected to compulsory immunisation, the animal husbandry and veterinary administrative departments under local people’s governments at or above the county level shall formulate prevention plans and report them to the people’s governments at the same level for approval and implementation.

Article 12 The state should take measures to prevent and exterminate animal epidemics that cause serious damage to the breeding production and human health.

Medicine, biological products, or other relevant materials needed in the prevention and extermination of animal epidemics shall be reserved in a proper quantity and shall be included in the plan for national economy and social development.

Article 13 The supervising agencies for animal epidemic prevention shall strengthen animal epidemic prevention by conducting popularisation campaigns and education, technical advice,
technical training and consultancy services and shall organise the implementation of plans for immunisation against animal epidemics.

Animal epidemic prevention departments in townships, nationality townships, and towns shall organise, under the guidance of the supervising agencies for animal epidemic prevention, the prevention of animal epidemics.

Article 14 Units and individuals that engage in the raising or marketing of animals, or the production or marketing of animal products shall, pursuant to this Law and the relevant state provisions, complete planned immunisations against, and the prevention of, animal epidemics, and shall accept the monitoring and supervision from the supervising agencies for animal epidemic prevention.

Article 15 Any animal farm should exterminate animal epidemics in a timely manner. Stud stock and breeding poultry shall be kept healthy and up to the standards that are set by the State.

Article 16 Means of transport, padding materials and packing materials for animals or animal products shall meet the requirements for animal epidemic prevention as set by the animal husbandry and veterinary administrative department under the State Council.

Animals infected with epidemic diseases and their excrement, products made from animals infected with epidemic diseases, and carcasses of animals that died of illness or died due to an unidentified cause must be disposed of according to the relevant provisions of the animal husbandry and veterinary administrative department under the State Council and shall not be dealt with at will.

Article 17 The storage, use, and transportation of animal-borne pathogenic microorganisms shall conform to the management systems and operational rules as set by the state.

The transportation of animal epidemic materials for special needs in scientific research, teaching and epidemic prevention shall conform to the relevant state provisions.

Any unit engaging in scientific research on animal epidemics shall conduct, according to the relevant state provisions, strict management of Laboratory Animals in order to prevent the spread of animal epidemics.

Article 18 The marketing of any animal or animal product in the following categories shall be prohibited:

1. Those related to an animal epidemic disease occurring in a cordoned-off epidemic area;
2. Those susceptible to an epidemic disease in an epidemic area;
3. Those subjected to quarantine inspection according to the law but failing to undergo or pass the quarantine inspection;
4. Those infected with an epidemic disease;
5. Those that died of an illness or died due to an unidentified cause; or
6. Those not listed above but failing to conform to the state provisions regarding animal epidemic prevention.

Section III Control and Extermination of Animal Epidemics

Article 19 The animal husbandry and veterinary administrative department under the State Council shall exercise unified control over and publish animal epidemic information nationwide, or may, when necessary, authorise the animal husbandry and veterinary administrative departments under the people’s governments of provinces, autonomous regions and municipalities directly under the Central Government to publish animal epidemic information within their own
Article 20 Any unit or individual that finds an animal(s) having an epidemic disease or is suspected of having an epidemic disease shall in a timely manner report to the local supervising agency for animal epidemic prevention.

The latter shall promptly take measures and report the case to the higher authority according to the relevant state provisions.

No unit or individual may conceal, falsely report, or hinder another person from reporting animal epidemic information.

Article 21 In the case of an animal epidemic of Class I, the animal husbandry and veterinary administrative department under the local people’s government at or above the county level shall dispatch its personnel to the scene forthwith to delimit the epidemic point, the epidemic area and the threatened area, collect epidemic materials, investigate into the epidemic source, report in a timely manner to the people’s government at the same level for a decision for the cordon off of the epidemic area, and report the epidemic situation and the related information level by level to the animal husbandry and veterinary administrative department under the State Council.

The local people’s government at or above the county level shall organise the departments and units concerned without delay to take compulsory measures for the control and extermination of the animal epidemic such as isolation, massacre, destruction, disinfection, and emergency immunisation vaccination to exterminate the epidemic disease promptly, and shall inform the neighbouring areas of the case.

During the sanitary cordon, those animals or animal products having the epidemic disease or that are suspected of having the epidemic disease are prohibited from moving out of the epidemic area, and animals coming from outside the epidemic area shall be prohibited from entering the epidemic area. As required for the extermination of the animal epidemic, persons, means of transport and relevant articles that leave or enter the cordoned-off area shall be disinfected and have imposed upon them other restrictions.

Where the epidemic area involves two or more administrative regions, the decision on the cordon of the epidemic area shall be made by the common people’s government at the next higher level of the concerned administrative regions, or jointly by the people’s governments at the next higher level of the concerned administrative regions.

Article 22 In the case of an animal epidemic of Class II, the animal husbandry and veterinary administrative department under the local people’s government at or above the county level shall delimit the epidemic point, epidemic area, and threatened area.

The local people’s government at or above the county level shall, when necessary, organise the departments and units concerned to take control and extermination measures such as isolation, massacre, destruction, disinfection, emergency immunisation vaccination and imposition of restrictions upon entering and leaving of the epidemic area by animals, animal products and relevant articles that are susceptible to the epidemic disease.

Article 23 The disestablishment of the epidemic point, the epidemic area and the threatened area and the lifting of the cordon of the epidemic area shall be announced by the department that made the original decision.

Article 24 In the case of an animal epidemic of Class III, the people’s government at the county or township level shall organise the prevention and purification of the epidemic according to the plans for animal epidemic prevention and the provisions of the animal husbandry and veterinary
Article 25 The provisions of Article 21 in this Law shall apply if an animal epidemic of Class II or Class III spreads intensely.

Article 26 For the purpose of control or extermination of major animal epidemic situations, the supervising agencies for animal epidemic prevention may dispatch their personnel to the inspecting stations that have been set up according to law by the locality in order to undertake supervision and inspection.

When necessary, provisional supervising and inspecting stations for animal epidemic prevention may be set up subject to the approval of the people’s government of the province, autonomous region and municipality directly under the Central Government in order to perform supervision and inspection.

Article 27 In the case of an epidemic disease contracted commonly by both human beings and livestock, the animal husbandry and veterinary administrative department, the public health administrative department and other units concerned shall exchange information on the epidemic situation and shall take control and extermination measures in a timely manner.

Article 28 Any unit or individual within an epidemic area shall observe the stipulations of the people’s government at or above the county level and its animal husbandry and veterinary administrative department for the control and extermination of the animal epidemic.

Article 29 In the case of an animal epidemic, the transportation departments such as civil aviation, railways, highways, and waterways shall give priority to the transportation of personnel and related materials for the control and extermination of the epidemic situation, and the post and telecommunications departments shall deliver and transmit reports on the epidemic situation in a timely manner.

**Section IV Quarantine of Animals and Animal Products**

Article 30 Supervising agencies for animal epidemic prevention shall, in accordance with the national standards, the trade standards and quarantine measures as set by the animal husbandry and veterinary administrative department under the State Council, and in light of the objects to be quarantined, carry out the quarantine of animals and animal products.

Article 31 Supervising agencies for animal epidemic prevention shall have quarantine officers responsible for the quarantine of animals and animal products. Quarantine officers shall possess the necessary professional skills.

The detailed measures for qualifications and the issuance of qualification certificates shall be formulated by the animal husbandry and veterinary administrative department under the State Council.

The animal husbandry and veterinary administrative departments at or above the county level shall step up the training, evaluation, and administration of quarantine officers.

No quarantine officer may be permitted to take up the post for quarantine unless he or she has obtained the corresponding qualification certificate.

Quarantine officers shall observe the quarantine rules in carrying out the quarantine and bear liability for the quarantine results.

Article 32 The state exercises slaughter at designated points and the centralised quarantine of livestock such as pigs and other animals.

The people’s governments of provinces, autonomous regions and municipalities directly under the
Central Government shall set the categories of livestock and scopes of regions within their respective administrative regions to practice slaughter at designated points and the centralised quarantine.

Specific slaughterhouses (or points) shall be determined by the people’s governments in cities (including cities without districts) and counties after the studies by the departments concerned are organised by them.

Supervising agencies for animal epidemic prevention shall carry out the quarantine of animals slaughtered in slaughterhouses (or points) and affix to the slaughtered animals their uniform stamps for having been inspected.

Slaughter quarantine in slaughterhouses and joint meat processing factories, determined subject to consultation between the animal husbandry and veterinary administrative department and the commodity circulation department under the State Council, shall be handled pursuant to the relevant provisions of the State Council and shall be under supervision according to the law.

Article 33 For the quarantine of livestock such as pigs and other animals slaughtered by farmers themselves for their own use, the people’s governments of provinces, autonomous regions and municipalities directly under the Central Government shall formulate the control measures.

Article 34 Supervising agencies for animal epidemic prevention shall collect fees for their legal quarantine inspections according to the provisions of the financial and price control departments under the State Council and shall not collect other additional fees or repeat charging for the same item of quarantine.

Article 35 Supervising agencies for animal epidemic prevention shall not engage in business activities.

Article 36 Those who intend to introduce breeding animals and their semen, embryos and breeder eggs from another place in the country shall first apply to the supervising agency for animal epidemic prevention of the locality for the examination and approval of quarantine and shall be subject to quarantine inspection.

Article 37 Wild animals having been caught by humans, which are likely to spread animal epidemics, shall not be sold and transported before passing quarantine inspection by the supervising agency for animal epidemic prevention in the place where the wild animals were caught or where the wild animals are to be received.

Article 38 If any animal or animal product has passed quarantine inspection, the supervising agency for animal epidemic prevention shall issue a quarantine certificate and, at the same time for any animal product, affix thereto an inspection mark that is to be used by the supervising agency for animal epidemic prevention or seal it with the inspection mark.

If any animal or animal product has not passed quarantine inspection, the owner shall conduct disinfection for epidemic prevention or take other measures for innocent treatment. If innocent treatment cannot be carried out, the animal or animal product must be destroyed.

Article 39 Animals can be sold, transported, as well as put on display, shows, or contests on the strength of the quarantine certificate. Animal products can be sold or transported on the strength of the quarantine certificate and the inspection mark.

Article 40 The quarantine certificate shall not be transferred, altered, or forged.

The format and control measures for the quarantine certificate shall be formulated by the animal husbandry and veterinary administrative department under the State Council.
Section V Supervision over Animal Epidemic Prevention

Article 41 Supervising agencies for animal epidemic prevention shall conduct supervision on the work of animal epidemic prevention according to the law. In performing the duties of monitoring and supervision, supervising agencies for animal epidemic prevention may collect samples of animals or animal products, seize them for inspection or make sample inspections, conduct inspections retroactively or re-inspect animals or animal products with no quarantine certificates, and may isolate, seal up or dispose of animals having epidemic diseases or suspected of having epidemic diseases or animal products contaminated by epidemic diseases.

Article 42 Any consignor of animals or animal products to be transported by railway, highway, waterway or air must provide the quarantine certificate in consigning for shipment. Any consignee must undertake the shipment on the strength of the quarantine certificate. Supervising agencies for animal epidemic prevention shall have the right to supervise and inspect the transportation of animals and animal products according to law.

Article 43 The functionaries of animal epidemic prevention supervision shall produce their certificates in performing the duties of supervision and inspection. Any unit or individual concerned shall lend support and co-operation to them.

Supervising agencies for animal epidemic prevention and their staff shall not collect fees for the supervision and inspection of animal epidemic prevention.

Article 44 Selecting sites and designing for works of animal farms, warehouses, slaughterhouses, joint meat processing factories, other designated slaughterhouses or points and refrigeration sites for animal products shall conform to the requirements of animal epidemic prevention as stipulated by the animal husbandry and veterinary administrative department under the State Council.

Article 45 Raising and marketing of animals or production and the marketing of animal products by animal farms, slaughterhouses, joint meat processing factories and other designated slaughterhouses (or points) shall conform to the requirements for animal epidemic prevention as stipulated by the animal husbandry and veterinary administrative department under the State Council, and shall be subject to the supervision and inspection of supervising agencies for animal epidemic prevention.

The diagnosis and treatment of animals shall be engaged in by qualified professional technicians who possess the permit for the diagnosis and treatment of animals as issued by the animal husbandry and veterinary administrative departments.

Persons suffering from epidemic diseases contracted commonly by both human beings and livestock shall not directly engage in the diagnosis and treatment of animals, raising and marketing of animals or production and marketing of animal products.

Section VI Legal Liability

Article 46 Any violator of the provisions of this Law who commits any of the following acts shall be given a warning by the supervising agency for animal epidemic prevention. In case of the refusal by the violator to make corrections, the supervising agency for animal epidemic prevention shall deal with the case according to the law on the part of the violator who shall pay the expense thereof.
(1) Failing to timely vaccinate or disinfect for immunisation animals that he or she raises or markets as required by the compulsory immunisation plan against animal epidemics and the relevant state provisions;
(2) Failing to clean and disinfect means of transport, padding materials or packing materials for animals and animal products according to the relevant state provisions; or
(3) Failing to dispose of animals infected with epidemic diseases and their excrement, products made from animals infected with epidemic diseases, and carcasses of animals that died of an illness or died due to an unidentified cause according to the relevant state provisions.

Article 47 Any violator of the provisions of Article 17 of this Law who stores, uses or transports animal-borne pathogenic microorganisms, or transports animal epidemic materials shall be given a warning and may be concurrently fined not more than RMB 2,000 Yuan by the supervising agency for animal epidemic prevention.

Article 48 Any violator of the provisions of this Law who markets any of the following animals or animal products shall be ordered by the supervising agency for animal epidemic prevention to cease business operations and, with the illegal gains and animals and animal products having not yet been sold are to be confiscated, as well as to take effective measures to withdraw the animals and animal products having been sold. If the circumstances are serious, the offender may be concurrently fined less than five times the illegal gains.
(1) Those related to an animal epidemic occurring in a cordoned-off epidemic area;
(2) Those susceptible to an epidemic in an epidemic area;
(3) Those subjected to quarantine inspection according to law but failing to pass quarantine inspection;
(4) Those infected with an epidemic;
(5) Those that died of an illness or died due to an unidentified cause; or
(6) Those not listed above but failing to conform to the state provisions regarding animal epidemic prevention.

Article 49 Any violator of the provisions of this Law who markets animals or animal products subjected to quarantine inspection according to the law but without quarantine certificates shall be ordered, with the illegal gains confiscated, to cease business operations by the supervising agency for animal epidemic prevention. Animals or animal products having not yet been sold shall undergo quarantine inspection retrospectively according to the law and be dealt with according to the provisions of Article 38 of this Law.

Article 50 Any violator of the provisions of Article 42 of this Law who fails to implement the provisions for the shipment of animals or animal products on the strength of the quarantine certificate shall be given a warning and ordered to make corrections by the supervising agency for animal epidemic prevention. If the circumstances are serious, the consignor and consignee may be separately fined less than three times of the freight.

Article 51 If anyone transfers, alters, or forges the quarantine certificate, the supervising agency for animal epidemic prevention shall confiscate the illegal gains and withdraw the quarantine certificate. Anyone who transfers or alters the quarantine certificate shall be concurrently fined no less than RMB 2,000 Yuan and no more than RMB 5,000 Yuan; if the illegal gains exceed RMB 5,000 Yuan, the offender shall be concurrently fined no less than the amount of the illegal gains and no more than three times that amount. Anyone who forges the quarantine certificate shall be fined no less than RMB 10,000 Yuan and not more than RMB 30,000 Yuan; if the illegal gains
exceed RMB 30,000 Yuan, the offender shall be concurrently fined no less than the amount of the illegal gains and no more than three times that amount. If a crime has been constituted, the offender shall be investigated for criminal responsibility according to the law.

Article 52 If a unit engaging in raising or marketing of animals, or production or marketing of animal products, in violation of the provisions of the first paragraph of Article 45 of this Law, fails to conform to the requirements for animal epidemic prevention, the supervising agency for animal epidemic prevention shall give a warning and order it to make corrections. If it refuses to make corrections, the offender shall be fined no less than RMB 10,000 Yuan and no more than RMB 30,000 Yuan.

Article 53 If a unit, in violation of the provisions of this Law, conceals, falsely reports, or hinders another person to report animal epidemic information, the supervising agency for animal epidemic prevention shall give a warning and concurrently impose a fine of no less than RMB 2,000 Yuan and no more than RMB 5,000 Yuan. The person who is in charge and directly responsible and other persons directly responsible shall have administrative sanctions imposed on them according to the law.

Article 54 Any violator of the provisions of this Law who evades quarantine inspection, resulting in a serious animal epidemic that causes great losses to the breeding production or does serious harm to human health, shall be investigated for criminal responsibility according to the law.

Article 55 If any animal quarantine officer, in violation of the provisions of this Law, issues the quarantine certificate and affixes the inspection mark on animals or animal products having not undergone quarantine inspection or having not passed quarantine inspection, the unit to which he or she belongs or the competent authority at the next higher level shall give him or her a demerit or disqualify him or her as an animal quarantine officer. If the circumstances are serious, the offender shall be discharged from his or her office.

If the illegal act that is mentioned in the preceding paragraph causes damage to the interested party, the unit to which the animal quarantine officer belongs shall bear the liability for compensation.

Article 56 Any supervisor of animal epidemic prevention who abuses power, neglects duties, commits malpractices for selfish gains, conceals or delays the report on epidemic situations, or forges quarantine inspection results, if a crime has been constituted, shall be investigated for criminal responsibility according to the law. If a crime has not been constituted, the offender shall have administrative sanctions imposed on them.

Article 57 Whoever hinders a supervisor of animal epidemic prevention in the performance of duties according to the law shall, if a crime has been constituted, be investigated for criminal responsibility according to the law. If a crime has not been constituted, the offender shall be imposed administrative penalty for public security violations according to law.

Section VII Supplementary Provisions

Article 58 This Law comes into effect as of 1 January 1998.
Decree No.15 of the Ministry of Agriculture of the People’s Republic of China

《Measures on the Administration of Animal Epidemic Conditions》, which was deliberated and adopted at the eleventh executive meeting of the Ministry of Agriculture on 24 May 2002, is hereby promulgated.

Minister Du Qinglin

24 May 2002
Measures on the audit and management of the conditions concerning Animal Epidemic Prevention

Article 1 The present Measures are formulated in accordance with the relevant provisions in the 《Animal Epidemic Prevention Law of the People’s Republic of China》 for the purpose of intensifying the administration of animal epidemic prevention.

Article 2 The activities related to the raising and marketing of animals, production and marketing of animal products or animal epidemic prevention shall meet the requirements for animal epidemic prevention as formulated by the Measures and accept surveillance.

Article 3 The state institutes the system of 《Certificate of Animal Epidemic Prevention》 on the auditing and management of requirements for animal epidemic prevention.

Article 4 The animal husbandry and veterinary administrative departments under the people’s governments at or above the county level shall be in charge of the management of the requirements for animal epidemic prevention and auditing within their respective administrative areas.

The supervising agencies for animal epidemic prevention under the people’s governments at or above the county level shall execute the auditing and supervision on the requirements for animal epidemic prevention within their respective administrative areas.

Article 5 With the exception of rural households’ scatter breeding, all animal farms shall conform to the requirements for animal epidemic prevention in the following categories:
(1) The selection of sites and layout shall conform to the requirements of animal epidemic prevention, while the production area shall be separated from the living area;
(2) The design and construction of animal (poultry) houses shall conform to the requirements for animal epidemic prevention, complete lighting, ventilation, filth and sewage disposal facilities shall be equipped with, while the cleaning road and the pollution road shall be set separately;
(3) Shelters for animals who had been ill and non-polluting disposal facilities and equipment for animals that died of diseases, sewage, or filth shall be equipped with;
(4) Full-time personnel who are in charge of prevention shall be provided;
(5) Facilities and equipment for isolation and disinfection shall be set at the accesses;
(6) Persons who are in charge of raising, epidemic prevention, diagnosis, and treatment do not suffer from epidemic diseases contracted commonly by both human beings and livestock;
(7) The system of epidemic prevention is sound.

Article 6 Sire and embryo production sites shall conform to the requirements for animal epidemic prevention in the following categories:
(1) Selecting sites, layout, design, construction, facilities, equipment and appliances shall conform to the requirements of animal epidemic prevention;
(2) Raising area of breeding animals, semen collection area or embryo collection area shall be separated from the living area. Sites for animal introduction and diseased animal quarantine shall be set;
(3) Full-time personnel who are in charge of prevention shall be provided;
(4) Health certificates shall be secured for breeding animals;
(5) Non-polluting disposal, cleaning and disinfection facilities and equipment for sewage and filth shall be equipped;
(6) Persons who directly contact breeding animals, seminal fluid or embryo production do not suffer from epidemic diseases contracted commonly by both human beings and livestock;
(7) The system of epidemic prevention is sound.

Article 7 The hatchery shall conform to the requirements for animal epidemic prevention in the following categories:
(1) Selecting sites, layout, design, and construction shall conform to the requirements of animal epidemic prevention; the flow of hatchery workshop shall be unidirectional, in which crossing or recirculation is impermissible;
(2) Barrier is set to isolate the hatchery from the outside and it keeps a certain distance from the hatchery.
(3) Hatching facilities, equipment, special tools and appliances shall conform to the requirements of animal epidemic prevention;
(4) Fumigating and sterilising facilities for breeder eggs shall be equipped;
(5) Non-polluting disposal facilities and equipment for young birds that had been ill or dead, eggshells and deserted eggs shall be equipped with;
(6) Cleaning and disinfection facilities and equipment shall be equipped with;
(7) The system of epidemic prevention is sound.

Article 8 The slaughterhouses (plant or points) and joint meat processing factories shall conform to the requirements for animal epidemic prevention in the following categories:
(1) The selection of sites and layout shall conform to the requirements of animal epidemic prevention, while the production area shall be separated from the living area;
(2) The design and construction shall conform to the requirements for animal epidemic prevention, complete lighting, ventilation, filth and sewage disposal facilities shall be equipped;
(3) Quarantine room is set;
(4) Waiting pens, emergency slaughtering rooms and isolating rooms for diseased animals shall have the scopes that are in conformity with the slaughtering scopes;
(5) Non-polluting disposal facilities and equipment for animals die of illness, products made from animals infected with epidemic diseases, sewage, filth, and excrement shall be equipped;
(6) Means of transport and containers for animals or animal products shall meet the requirements for animal epidemic prevention and cleaning and disinfection facilities shall be equipped;
(7) Slaughtering facilities, tools, and appliances that conform to the requirements for animal epidemic prevention shall be equipped;
(8) Technical workers who are in charge of slaughtering and meat product inspectors do not suffer from epidemic diseases contracted commonly by both human beings and livestock or pyogenic dermatoses or effusive dermatosis that may pollute animal products;
(9) The system of epidemic prevention is sound.

Article 9 The places for storage and transportation, transfer and trading of animals shall conform to the requirements for animal epidemic prevention in the following categories:
(1) Selecting sites, layout, design, construction, facilities, and equipment shall conform to the requirements of animal epidemic prevention;
(2) Isolating rooms for diseased animals and disposal facilities for sewage, filth, and excrement shall be equipped;
Article 10 The sites for the marketing, processing and storage of animal products shall conform to the requirements for animal epidemic prevention in the following categories:

1. Selecting sites, layout, design, construction, facilities, equipment, tools, and appliances shall conform to the requirements of animal epidemic prevention;
2. Cleaning and disinfection facilities and equipment shall be equipped with;
3. Non-polluting disposal facilities and equipment for animals that die of an illness, products made from animals infected with epidemic diseases, sewage, and filth shall be equipped with;
4. Sound system of animal epidemic prevention that contains the registration of the quarantine situation for the procurement of animal products shall be provided;
5. Persons who are directly engaged in the marketing, processing, and distribution do not suffer from epidemic diseases contracted commonly by both human beings and livestock or pyogenic dermatoses or effusive dermatosis that may pollute animal products;

Article 11 Sites for the processing of hairs, raw hides, bones, and horns shall conform to the requirements of animal epidemic prevention in the following categories:

1. Selecting sites, layout, design, construction, facilities, equipment, and appliances shall conform to the requirements of animal epidemic prevention;
2. Fixed sites for raw material storage shall be provided;
3. Disposal facilities for sewage and filth shall be equipped;
4. Disinfection facilities and equipment shall be equipped;
5. The system of epidemic prevention is sound.

Article 12 Various types of animal quarantine farms shall conform to the requirements of animal epidemic prevention in the following categories:

1. Selecting sites, layout, design, construction, facilities, equipment, and appliances shall conform to the requirements of animal epidemic prevention;
2. The sites for the production, slaughtering and marketing of animals or for the processing and marketing of animal products must be kept away from;
3. Facilities and equipment for disinfection shall be equipped at the accesses of quarantine areas;
4. Non-polluting disposal, cleaning and disinfection facilities and equipment for sewage, filth, and animals that died of diseases, which are used for isolating the excretion of animals or other things, shall be equipped with;
5. Persons who are in charge of raising, diagnosis, and treatment do not suffer from epidemic diseases contracted commonly by both human beings and livestock;
6. The system of epidemic prevention is sound.

Article 13 The sites for the diagnosis and treatment of animals shall conform to the requirements of animal epidemic prevention in the following categories:

1. Selecting sites, layout, design, construction, facilities, equipment, and appliances shall conform to the requirements of animal epidemic prevention;
2. The sites for the production, slaughtering, and marketing of animals or for the processing and marketing of animal products must be kept away from;
3. Non-polluting disposal, cleaning and disinfection facilities and equipment for sewage, filth, and animals that died of diseases shall be equipped with;
4. Persons who are in charge of diagnosis and treatment do not suffer from epidemic diseases
contracted commonly by both human beings and livestock;
(5) The system of epidemic prevention is sound.

Article 14 The sites for the storage and use of animal-borne pathogenic microorganisms shall conform to the requirements of animal epidemic prevention in the following categories:
(1) Selecting sites, layout, design, construction, facilities, equipment, and appliances shall conform to the requirements of animal epidemic prevention;
(2) Processing facilities for laboratory animals, epidemic materials, waste products, sewage, filth and polluted air shall be equipped, which shall conform to the special requirements;
(3) Persons who can grasp professional knowledge on the storage and use of animal-borne pathogenic microorganisms shall be provided;
(4) Systems for the storage, use, and management of animal-borne pathogenic microorganisms shall be established;
(5) The contaminated area and clean area in the laboratory shall be strictly separated;
(6) Aseptic manipulation equipment shall be equipped, which shall conform to the requirements of animal epidemic prevention;
(7) A strict sterilisation system shall be established for the operation staff;
(8) Sites for the virulent vaccination and raising of Laboratory Animals shall be set independently;
(9) The system of epidemic prevention is sound.

Article 15 Written reports can be handed over to the supervising agencies for animal epidemic prevention under the people's governments at or above the county level by the sites listed in the Measures, which meet the above-mentioned requirements. 《Application Form for the Certificate of Animal Epidemic Prevention》 shall be filled out and the 《Certificate of Animal Epidemic Prevention》 shall be applied for.

The supervising agencies for animal epidemic prevention shall take on-site auditing and examination on the requirements of animal epidemic prevention in 30 working days after receiving the application report and the 《Application Form for the Certificate of Animal Epidemic Prevention》 shall be issued for those qualified in the course of auditing.

In the sites listed in the Measures and the special sites that closely associate with the control of animal infectious diseases, auditing on the requirements of animal epidemic prevention can be taken by the provincial supervising agencies for animal epidemic prevention. Specific measures for implementation shall be stipulated by the animal husbandry and veterinary administrative department of the people’s government in each province, autonomous region, and municipality directly under the Central Government.

Article 16 The 《Certificate of Animal Epidemic Prevention》 is valid for one year from the date of issuance. For an extension of the period of operations, an application shall be submitted 30 days before the expiration of the period.

An application to make the change shall be filed for the units or persons who have obtained the 《Certificate of Animal Epidemic Prevention》, but would like to change the relevant items confirmed during the issue of the Certificate and examination, 《Certificate of Animal Epidemic Prevention》 shall be applied for and received again.

Article 17 The supervising agencies for animal epidemic prevention shall periodically execute quality and technology monitoring of animal epidemic prevention for the units that have obtained the 《Certificate of Animal Epidemic Prevention》.

Article 18 The sites listed in the Measures, which fail to meet the requirements prescribed by the
Measures and that did not obtain the 《Certificate of Animal Epidemic Prevention》, cannot set up a business or put them into use. Any violator shall have a penalty imposed on them by the supervising agencies for animal epidemic prevention according to the prescription of Article 52 in 《Animal Epidemic Prevention Law of the People’s Republic of China》.

Article 19 The format of 《Certificate of Animal Epidemic Prevention》 shall be established by the Department of Agriculture.

Article 20 Issuance, checking and inspection of 《Certificate of Animal Epidemic Prevention》 shall be charged according to the current commodity prices and the standard fee as stipulated by the Department of Finance.

Article 21 The Measures come into effect as of 1 July 2002.

**Law of the People’s Republic of China on the Protection of Wildlife**

（Adopted at the Fourth Meeting of the Standing Committee of the Seventh National People's Congress and promulgated by Order No. 9 of the President of the People’s Republic of China on 8 November 1988, and effective as of 1 March 1989. Amendment of 《Decision on the Modification of Law of the People’s Republic of China on the Protection of Wildlife at the Eleventh Meeting of the Standing Committee of the Tenth National People’s Congress》 promulgated by Order No. 24 of the President of the People’s Republic of China on 28 August 2004, and effective as of the date of promulgation.）
In the sites that are listed in the Measures and the special sites that closely associate with the control of animal infectious diseases, the auditing on the requirements of animal epidemic prevention can be taken by the provincial supervising agencies for animal epidemic prevention. Specific measures for implementation shall be stipulated by the animal husbandry and veterinary administrative department of the people’s government in each province, autonomous region, and municipality directly under the Central Government.

Article 16 The 《Certificate of Animal Epidemic Prevention》 is valid for one year from the date of issuance. For an extension of the period of operations, an application shall be submitted 30 days before the expiration of the period.

If the units or persons who have obtained the 《Certificate of Animal Epidemic Prevention》 would like to change the relevant items that were confirmed during the issue of the Certificate and examination, they should file an application for a change and apply for obtaining a new 《Certificate of Animal Epidemic Prevention》 again.

Article 17 The supervising agencies for animal epidemic prevention shall periodically execute quality and technology monitoring of animal epidemic prevention for the units obtained 《Certificate of Animal Epidemic Prevention》.

Article 18 The sites listed in the Measures, which fail to meet the requirements as prescribed by the Measures and that did not obtain the 《Certificate of Animal Epidemic Prevention》, cannot be set up in a business or put into use. Any violator shall have a penalty imposed by the supervising agencies for animal epidemic prevention according to the prescription of Article 52 in the 《Animal Epidemic Prevention Law of the People’s Republic of China》.

Article 19 The format of the 《Certificate of Animal Epidemic Prevention》 shall be established by the Department of Agriculture.

Article 20 Issue, check, and survey the 《Certificate of Animal Epidemic Prevention》, charge according to the prices of our state and the standard checked and ratified by the Department of Finance.

Article 21 These Measures come into effect 1 July 2002.
Law of the People’s Republic of China on the Protection of Wildlife

（Adopted at the Fourth Meeting of the Standing Committee of the Seventh National People’s Congress and promulgated by Order No. 9 of the President of the People’s Republic of China on 8 November 1988, and effective 1 March 1989. The amendment of the 《Decision on the Modification of the Law of the People’s Republic of China on the Protection of Wildlife》 at the Eleventh Meeting of the Standing Committee of the Tenth National People’s Congress as promulgated by Order No. 24 of the President of the People’s Republic of China on 28 August 2004, and effective as of the date of promulgation.）

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Section I General Provisions
Article 1 This Law is formulated for the purposes of protecting and saving those species of wildlife that are rare or near extinction, protecting, developing, and rationally utilising wildlife resources and maintaining ecological balances.
Article 2 All the activities within the territory of the People’s Republic of China concerning the protection, domestication, breeding, development, and utilisation of species of wildlife must be conducted in conformity with this Law.
The wildlife protected under this Law refers to the species of terrestrial and aquatic wildlife that are rare or near extinction and the species of terrestrial wildlife that are beneficial or of important economic or scientific value.
The wildlife referred to in the provisions of this Law means the wildlife that shall enjoy protection as prescribed in the preceding paragraph.
As regards the protection of the species of aquatic wildlife other than those that are rare or near extinction, the provisions of the Fisheries Law shall apply.
Article 3 Wildlife resources shall be owned by the State.
The State shall protect the lawful rights and interests of those units and individuals engaged in the development or utilisation of wildlife resources according to law.
Article 4 The State shall pursue a policy of strengthening the protection of wildlife resources, actively domesticating and breeding the species of wildlife, rationally developing and utilising wildlife resources, as well as encouraging scientific research on wildlife.
Units and individuals that have made outstanding achievements in the protection of wildlife resources, in scientific research on wildlife, or in the domestication and breeding of wildlife shall be awarded by the State.
Article 5 Citizens of the People’s Republic of China shall have the duty to protect wildlife resources and the right to inform the authorities of or file charges against acts of seizure or destruction of wildlife resources.

Article 6 The governments at various levels shall strengthen the administration of wildlife resources and formulate plans and measures for the protection, development, and rational utilisation of wildlife resources.

Article 7 The departments of forestry and fishery administration under the State Council shall be respectively responsible for the nationwide administration of terrestrial and aquatic wildlife. The departments of forestry administration under the governments of provinces, autonomous regions, and municipalities directly under the Central Government shall be responsible for the administration of terrestrial wildlife in their respective areas. The departments in charge of the administration of terrestrial wildlife under the governments of autonomous prefectures, counties, and municipal governments shall be designated by the governments of provinces, autonomous regions, or municipalities directly under the Central Government. The departments of fishery administration under the local governments at or above the county level shall be responsible for the administration of aquatic wildlife in their respective areas.

Section II Protection of Wildlife

Article 8 The State shall protect wildlife and the environment for its survival, and shall prohibit the illegal hunting, catching, or destruction of wildlife by any unit or individual.

Article 9 The State shall provide special protection to those species of wildlife that are rare or near extinction. The wildlife under special state protection shall consist of two classes: wildlife under first class protection and wildlife under second class protection. Lists or revised lists of wildlife under special state protection shall be drawn up by the department of wildlife administration under the State Council and announced after being submitted to and approved by the State Council. The wildlife under special local protection, being different from the wildlife under special state protection, refers to the wildlife specially protected by provinces, autonomous regions, or municipalities directly under the Central Government. Lists of wildlife under special local protection shall be drawn up and announced by the governments of provinces, autonomous regions, or municipalities directly under the Central Government and shall be submitted to the State Council for the record. Lists or revised lists of terrestrial wildlife under state protection, which are beneficial or of important economic or scientific value, shall be drawn up and announced by the department of wildlife administration under the State Council.

Article 10 The department of wildlife administration under the State Council and the governments of provinces, autonomous regions, and municipalities directly under the Central Government shall, in the main districts and water areas where wildlife, under special state or local protection, lives and breeds, designate nature reserves and strengthen the protection and administration of wildlife under special state or local protection and the environment for its survival. The designation and administration of nature reserves shall be effected in accordance with the relevant provisions of the State Council.

Article 11 Departments of wildlife administration at the various levels shall keep watch of and monitor the impact of the environment on wildlife. If the environmental impact causes harm to wildlife, the departments of wildlife administration shall conduct an investigation and deal with
the matter jointly with the departments concerned.

Article 12 If a construction project produces adverse effects on the environment for the survival of wildlife under special state or local protection, the construction unit shall submit a report on the environmental impact. The department of environmental protection shall, in examining and approving the report, seek the opinion of the department of wildlife administration at the same level.

Article 13 If natural disasters present threats to wildlife under special state or local protection, the local governments shall take measures in a timely manner in order to rescue them.

Article 14 If the protection of wildlife under special state or local protection causes losses to crops or other losses, the local governments shall remit compensation for them. Measures for such compensation shall be formulated by the governments of provinces, autonomous regions, and municipalities directly under the Central Government.

Section III Administration of Wildlife

Article 15 The departments of wildlife administration shall regularly carry out surveys of wildlife resources and keep records of them.

Article 16 The hunting, catching, or killing of wildlife under special state protection shall be prohibited. Where the catching or fishing of wildlife under first class state protection is necessary for scientific research, domestication and breeding, exhibition or other special purposes, the unit concerned must apply to the department of wildlife administration under the State Council for a special hunting and catching licence; where the catching or hunting of wildlife under second class state protection is intended, the unit concerned must apply to the relevant department of wildlife administration under the government of a province, an autonomous region, or a municipality directly under the Central Government for a special hunting and catching licence.

Article 17 The State shall encourage the domestication and breeding of wildlife. Anyone who intends to domesticate and breed wildlife under special state protection shall obtain a licence. Administrative measures for such licences shall be formulated by the department of wildlife administration under the State Council.

Article 18 Anyone who intends to hunt or catch wildlife that is not under special state protection must obtain a hunting licence and observe the hunting quota assigned. Anyone who intends to hunt with a gun must obtain a gun licence from the public security organ of the county or municipality concerned.

Article 19 Anyone engaged in the hunting or catching of wildlife shall observe the prescriptions in their special hunting and catching licence or their hunting licence with respect to the species, quantity, area, and time limit.

Article 20 In nature reserves and areas closed to hunting, and during seasons closed to hunting, the hunting and catching of wildlife and other activities that are harmful to the living and breeding of wildlife shall be prohibited. The areas and seasons closed to hunting as well as the prohibited hunting gear and methods shall be specified by governments at or above the county level or by the departments of wildlife administration under them.

Article 21 The hunting or catching of wildlife by the use of military weapons, poison, or explosives shall be prohibited. Measures for the control of the production, sale, and use of hunting rifles and bullets shall be
Article 22 The sale and purchase of wildlife under special state protection or the products thereof shall be prohibited. Where the sale, purchase, or utilisation of wildlife under first class state protection or the products thereof is necessary for scientific research, domestication and breeding, exhibition or other special purposes, the unit concerned must apply for approval by the department of wildlife administration under the State Council or by a unit authorised by the same department. Where the sale, purchase or utilisation of wildlife under second class state protection or the products thereof is necessary, the unit concerned must apply for approval by the department of wildlife administration under the government of the relevant province, autonomous region, or municipality directly under the Central Government or by a unit authorised by the same department.

Units and individuals that domesticate and breed wildlife under special state protection may, by presenting their domestication and breeding licences, sell wildlife under special state protection or the products thereof, in accordance with the relevant regulations, to purchasing units designated by the government.

The administrative authorities for industry and commerce shall exercise supervision and control over wildlife or the products thereof that are placed on the market.

Article 23 The transportation or carrying of wildlife under special state protection or the products thereof out of any county must be approved by the department of wildlife administration under the government of the relevant province, autonomous region, or municipality directly under the Central Government, or by a unit authorised by the same department.

Article 24 The export of wildlife under special state protection or the products thereof, and the import or export of wildlife or the products thereof, whose import or export is restricted by international conventions to which China is a party, must be approved by the department of wildlife administration under the State Council or by the State Council, and an import or export permit must be obtained from the state administrative organ in charge of the import and export of those species that are near extinction. Customs shall clear the imports or exports after examining the respective import or export permit.

The export of the species of wildlife involving scientific and technological secrets shall be dealt with in accordance with relevant provisions of the State Council.

Article 25 The forgery, sale, or resale or transfer of special hunting and catching licences, hunting licences, domestication and breeding licences, and import and export permits shall be prohibited.

Article 26 Where any foreigner intends, within the territory of China, to make surveys of or to film or videotape wildlife under special state protection in the field, they must apply for approval by the department of wildlife administration under the State Council or by a unit authorised by the same department.

The establishment of hunting grounds open to foreigners must be approved by the department of wildlife administration under the State Council.

Article 27 Anyone engaged in the utilisation of wildlife or the products thereof shall pay a fee for the protection and administration of wildlife resources. The schedule of the fee and the procedure for collecting, it shall be formulated by the department of wildlife administration under the State Council jointly with the financial and pricing authorities and shall enter into force after being formulated by the department of forestry administration under the State Council jointly with the public security department, and shall enter into force after being submitted to and approved by the State Council.
submitted to and approved by the State Council.

Article 28 Anyone who has caused losses to crops or other losses while hunting or catching wildlife shall be held responsible for remitting compensation.

Article 29 The local governments concerned shall take measures to prevent and control the harm caused by wildlife so as to guarantee the safety of human beings and livestock and ensure agricultural and forestry production.

Article 30 The administrative measures for wildlife under special local protection and for other wildlife that is not under special state protection shall be formulated by the standing committees of the people’s congresses of provinces, autonomous regions, and municipalities directly under the Central Government.

Section IV Legal Responsibility

Article 31 Anyone who illegally catches or kills wildlife under special state protection shall be prosecuted for criminal responsibility in accordance with the supplementary provisions on punishing the crimes of catching or killing the species of wildlife under special state protection, which are rare or near extinction.

Article 32 If anyone, in violation of the provisions of this Law, hunts or catches wildlife in an area or during a season closed to hunting or uses prohibited hunting gear or methods for the purpose, their catch, hunting gear, and unlawful income shall be confiscated and shall be fined by the department of wildlife administration; if the circumstances are serious enough to constitute a crime, they shall be prosecuted for criminal responsibility in accordance with the provisions of Article 130 of the Criminal Law.

Article 33 If anyone, in violation of the provisions of this Law, hunts or catches wildlife without a hunting licence or in violation of the prescriptions of the hunting licence, their catch and unlawful income shall be confiscated and they shall be fined by the department of wildlife administration and, in addition, their hunting gear may be confiscated and their hunting licence revoked. If anyone, in violation of the provisions of this Law, hunts wildlife with a hunting rifle without a licence for the rifle, they shall be punished by a public security organ by applying mutatis mutandis the provisions of the Regulations on Administrative Penalties for Public Security.

Article 34 If anyone, in violation of the provisions of this Law, destroys in nature reserves or areas closed to hunting the main places where wildlife, under special state or local protection, lives and breeds, they shall be ordered by the department of wildlife administration to stop their destructive acts and restore these places to their original state within a prescribed time limit, and shall be fined.

Article 35 If anyone, in violation of the provisions of this Law, sells, purchases, transports, or carries wildlife under special state or local protection or the products thereof, such wildlife and products and their unlawful income shall be confiscated by the administrative authorities for industry and commerce and they may concurrently be fined. If anyone, in violation of the provisions of this Law, sells or purchases wildlife under special state protection or the products thereof, and if the circumstances are serious enough to constitute a crime of speculation or smuggling, they shall be prosecuted for criminal responsibility according to the relevant provisions of the Criminal Law.

The wildlife or the products thereof thus confiscated shall be, in accordance with the relevant provisions, disposed of by the relevant department of wildlife administration or by a unit authorised by the same department.
Article 36 If anyone illegally imports or exports wildlife or the products thereof, they shall be punished by the Customs according to the Customs Law; if the circumstances are serious enough to constitute a crime, they shall be prosecuted for criminal responsibility in accordance with the provisions of the Criminal Law on the crimes of smuggling.

Article 37 If anyone forges, sells, or resells or transfers a special hunting and catching licence, a hunting licence, a domestication and breeding licence, or an import or export permit, their licence or permit shall be revoked and their unlawful income shall be confiscated and they may concurrently be fined by the relevant department of wildlife administration or the administrative authorities for industry and commerce.

If anyone who forges, sells, or resells a special hunting and catching licence or an import or export permit, and if the circumstances are serious enough to constitute a crime, they shall be prosecuted for criminal responsibility by applying mutatis mutandis the provisions of Article 167 of the Criminal Law.

Article 38 Any staff member of a department of wildlife administration who neglects their duty, abuses their power or engages in malpractices for personal gains shall be subject to administrative sanctions by the department to which they belong or by the competent authority at a higher level; if the circumstances are serious enough to constitute a crime, they shall be prosecuted for criminal responsibility according to law.

Article 39 Any party who is dissatisfied with the decision on an administrative sanction may, within 15 days of receiving the notification on the sanction, make a request for reconsideration to the authority at the level next higher to the one that made the decision on the sanction; if they are dissatisfied with the decision on the reconsideration made by the authority at the next higher level, they may, within 15 days of receiving the notification on the decision on reconsideration, institute legal proceedings in court. The party may also directly institute legal proceedings in the court within 15 days of receiving the notification on the sanction. If the party neither makes a request for reconsideration nor institutes legal proceedings in court or complies with the decision on the sanction, the authority that made the decision on the sanction shall request the court to effect a compulsory execution of the decision.

If the party is dissatisfied with a Customs penalty or a penalty for violation of public security, the matter shall be dealt with in accordance with the provisions of the Customs Law or the Regulations on Administrative Penalties for Public Security.

Section V Supplementary Provisions

Article 40 If any international treaty concerning the protection of wildlife, concluded or acceded to by the People’s Republic of China, contains provisions differing from those of this Law, the provisions of the international treaty shall apply, unless the provisions are ones on which the People’s Republic of China has made reservations.

Article 41 The department of wildlife administration under the State Council shall, in accordance with this Law, formulate regulations for its implementation that shall go into effect after being submitted to and approved by the State Council.

The standing committees of the people’s congresses of provinces, autonomous regions, and municipalities directly under the Central Government may formulate, in accordance with this Law, measures for its implementation.

Article 42 This Law shall come into force 1 March 1989.
The Administrative Measures for the Domestication and Breeding Licence of Wildlife under Special State Protection

(Promulgated by Order No. 6 of the President of Ministry of Forestry in 1991 and effective as of 1 April 1991.)

Article 1 The Measures are formulated for the purposes of protecting, developing, and rationally utilising wildlife resources, strengthening the administration of domestication, and breeding of wildlife as well as maintaining the lawful rights and interests of those units and individuals engaged in the domestication and breeding of wildlife in accordance with the provisions of Article 17 of the 《Law of the People’s Republic of China on the Protection of Wildlife》.

Article 2 The units and individuals engage in the domestication and breeding of wildlife must obtain 《Domestication and Breeding Licence of Wildlife under Special State Protection》 (hereinafter referred to as the 《Domestication and Breeding Licence》). No unit or individual without obtaining the 《Domestication and Breeding Licence》 shall engage in the domestication and breeding activities of wildlife. “Wildlife” as mentioned in the Measures refers to the species of terrestrial wildlife under Special State Protection, while “domestication and breeding” as mentioned in the Measures refers to the domestication and breeding activities of wildlife that are taken for protecting, researching, scientific experiment, exhibition, and other economic purposes.

Article 3 The units and individuals who may apply for the 《Domestication and Breeding Licence》 shall fulfil the following requirements:

(1) Fixed places and necessary facilities that are suitable for the domestication and breeding of wildlife shall be provided;
(2) The funds and techniques of those personnel that are in conformity with the species and amount of domestication and breeding of wildlife shall be provided;
(3) The feed source provided for the domestication and breeding of wildlife shall be guaranteed.

Article 4 No 《Domestication and Breeding Licence》 shall be issued for those involved in any of the following circumstances:

(1) The resource information of wildlife is not clear;
(2) The domestication and breeding have not yet succeeded or the technology has not been perfected;
(3) The resources of wildlife are very limited, which cannot satisfy the requirements of the domestication and breeding resources.

Article 5 Those units and individuals for the domestication and breeding of wildlife must submit to the department of wildlife administration under the people’s governments at or above the county level a written application and fill in the 《Application Form for the Domestication and Breeding Licence of Wildlife under Special State Protection》. Those who are in charge of the domestication and breeding of wildlife under first class state protection shall be examined and approved by the Ministry of Forestry through the departments of forestry administration under the governments of provinces, autonomous regions, or municipalities directly under the Central Government. Those who are in charge of the domestication and breeding of wildlife under second
class state protection shall be examined and approved by the departments of forestry administration under the governments of provinces, autonomous regions, or municipalities directly under the Central Government. Once the units and individuals that domesticate and breed wildlife are approved, the 《Domestication and Breeding Licence》 shall be approved and issued by the departments of forestry administration under the governments of provinces, autonomous regions, or municipalities directly under the Central Government. The 《Domestication and Breeding Licence》 and 《Application Form for the Domestication and Breeding Licence of Wildlife under Special State Protection》 shall be uniformly printed by the Ministry of Forestry.

Article 6 The units and individuals for the domestication and breeding of wildlife that are mainly aimed at production and marketing shall apply for the registration from the administrative authorities for industry and commerce with the 《Domestication and Breeding Licence》. They can only engage in the domestication and breeding activities of wildlife after receiving the 《Business Licence for Enterprise as a Legal Person or Business Licence》.

Article 7 The units and individuals for the domestication and breeding of wildlife shall be in compliance with the following provisions:

1. Observe the national and local policies and regulations that relate to the protection and management of wildlife, as well as the concern and support of the protection of wildlife;
2. The source of wildlife that are for the domestication and breeding shall accord with the national regulations;
3. The supervision, inspection, and guidance from the department of wildlife administration shall be accepted;
4. Records and statistical system for the domestication and breeding of wildlife shall be established;
5. The domestication and breeding of wildlife and the products thereof shall be sold and utilised according to relevant provisions.

Article 8 Those units and individuals engaged in the domestication and breeding of wildlife must engage in the activities of domestication and breeding according to the species prescribed in the 《Domestication and Breeding Licence》. If it is needed to change the species of domestication and breeding of wildlife, they shall apply to the original approval authority for a change in the procedures in two months, mutatis mutandis, for the provisions of Article 5 in the Measures. If it is needed to terminate the activities of the domestication and breeding of wildlife, they shall apply to the original approval authority for the termination procedures in two months and hand back the original 《Domestication and Breeding Licence》.

Article 9 Since the resources are needed to be obtained from the fields for the domestication and breeding of wildlife, Article 16 in 《Law of the People’s Republic of China on the Protection of Wildlife》 and the relevant provisions shall be in accordance thereof.

Article 10 Those units and individuals that have obtained the 《Domestication and Breeding Licence》 and need to sell and utilise the wildlife under first class protection that they domesticate and breed and the products thereof must obtain approval from the Ministry of Forestry or its authorised units. Those who need to sell and utilise the wildlife under second class protection that they domesticate and breed and the products thereof must obtain approval from the departments of forestry administration under the governments of the provinces, autonomous regions, or municipalities directly under the Central Government or its authorised units. The units and individuals that have obtained Domestication and Breeding Licence cannot sell and utilise the
wildlife they domesticate and breed and the products thereof without approval.

Article 11 The department of wildlife administration under the people’s governments at or above the county level or its authorized units shall check the 《Domestication and Breeding Licence》 regularly. If the units and individuals conduct domestication and breeding activities of wildlife without obtaining the 《Domestication and Breeding Licence》, the wildlife that they domesticate and breed shall be confiscated by the department of wildlife administration under the people’s governments at or above the county level.

Article 12 In addition to the transaction in accordance with the relevant provisions as prescribed by the law and rule on the protection of wildlife, the 《Domestication and Breeding Licence》 that the units and individuals have obtained can be cancelled by the authority that approved the domestication and breeding of wildlife or the authority that approved and issued the 《Domestication and Breeding Licence》 and the administrative authorities for industry and commerce shall be suggested to confiscate the 《Business Licence for Enterprise as a Legal Person》 or 《Business Licence》, if those units and individuals are involved in any of the following circumstances:

1. Exceeding the species of the domestication and breeding of wildlife as prescribed by the 《Domestication and Breeding Licence》;
2. Obtaining the 《Domestication and Breeding Licence》 through concealing, making a false report, or other illegal methods;
3. Those who forge, alter, transfer, or sell or resell the 《Domestication and Breeding Licence》;
4. Illegally selling and utilizing the wildlife that they domesticate and breed and the products thereof;
5. Those who fail to engage in the activities of domestication and breeding in one year after obtaining the 《Domestication and Breeding Licence》. The units and individuals that are confiscated 《Domestication and Breeding Licence》 shall cease the activities of domestication and breeding immediately, in which the wildlife that they domesticate and breed shall be disposed of by the department of wildlife administration under the government at or above the county level or the authorized units thereof according to the relevant provisions.

Article 13 Examination, approval, and issue systems of the 《Domestication and Breeding Licence》 shall be established by the departments of forestry administration under the governments of provinces, autonomous regions, or municipalities directly under the Central Government, in which specially-assigned persons who are arranged for the management and special seals for the administration of wildlife shall be used. The appropriate cost of certificate and commission charges shall be charged while approving and issuing the 《Domestication and Breeding Licence》. The charging standard shall be put forward by the departments of forestry administration under the governments of provinces, autonomous regions, or municipalities directly under the Central Government and be submitted to the Commodity Price Department and Department of Finance at the same level for the check and ratification and shall also be submitted to the State Council for the record.

Article 14 The Measures shall be interpreted by the Ministry of Forestry.

Article 15 The Measures shall come into force as of 1 April 1991.
Decree No. 424 of the State Council of the People’s Republic of China

《Biosafety Management Regulation of Laboratories for Pathogenic Microorganisms》，which was adopted at the 69th executive meeting of the State Council on 5 November 2004, is hereby promulgated and shall be effective as of the date of its promulgation.

Premier Wen Jiabao

12 November 2004
Biosafety Management Regulation of the Laboratories for Microorganisms

Section I General Provisions

Article 1 This Regulation is formulated for the purposes of strengthening the biosafety and management of laboratories for pathogenic microorganisms (hereinafter referred to as “laboratories”) and protecting the health of the laboratories’ staff and the public.

Article 2 This Regulation shall apply to the laboratories within the territory of the People’s Republic of China and the biosafety and management that engage in laboratory activities.

The pathogenic microorganisms under this Regulation refer to the microorganisms that are pathogenic to people or animals.

The laboratory activities under this Regulation refer to the activities of research, teaching, detection, and diagnosis related to the seed cultures of bacteria (viruses) of pathogenic microorganisms and the samples that the laboratories handle.

Article 3 The competent health department under the State Council shall be in charge of the supervision over the biosafety of laboratories and laboratory activities that are related to human health.

The competent animal husbandry and veterinary department under the State Council shall be in charge of the supervision over the biosafety of laboratories and laboratory activities related to animals.

Other related departments under the State Council shall be in charge of the administration of the biosafety of laboratories and laboratory activities within the scope of their respective functions and duties.

The local people’s government at or above the county level and the related departments shall be in charge of the administration of the biosafety of laboratories and laboratory activities within the scope of their respective functions and duties.

Article 4 The State practices classified administration on pathogenic microorganisms and level-to-level administration on laboratories.

Article 5 The State shall apply the laboratory biosafety level on a uniform basis. The laboratories shall conform to the national standards or requirements.

Article 6 The units that are established by the laboratories and their competent departments shall be in charge of the administration of the daily activities of laboratories, take on the responsibilities of establishing and improving the safety management system, checking and maintaining laboratory facilities and equipment, and controlling laboratory infections.

Section II Classification and Management of Pathogenic Microorganisms
Article 7 The State classifies the pathogenic microorganism into four types as shown below according to the infectivity of pathogenic microorganisms and the extent of harm to individuals or groups after infection:

The pathogenic microorganisms in the first type refer to the microorganisms that can cause very serious diseases in people or animals and the microorganisms that have not been found or have been announced as being eliminated by our state.

The pathogenic microorganisms in the second type refer to the microorganisms that can cause serious diseases in people or animals and can be spread directly or indirectly more easily between people and people, animals and people, and animals and animals.

The pathogenic microorganisms in the third type refer to those microorganisms that can cause diseases in people or animals, but cannot constitute a significant risk to people, animals, or the environment in most cases. These microorganisms have limited propagation risks, they seldom cause serious diseases after laboratory infection, and they have effective therapeutic and preventive measures.

The pathogenic microorganisms in the fourth type refer to those microorganisms that cannot cause diseases of people or animals in more cases.

The pathogenic microorganisms in the first and second types refer to the microorganisms that are collectively called highly infectious pathogenic microorganisms.

Article 8 The List of Human Pathogenic Microorganisms is established, revised, and promulgated by the competent health department under the State Council after discussing with the related departments of State Council and the List of Animal Pathogenic Microorganisms is established, revised, and promulgated by the competent animal husbandry and veterinary department under the State Council after discussing with the related departments of State Council.

Article 9 To collect the samples of pathogenic microorganisms, the following requirements shall be met:

1. Equipment that is in conformity with the biosafety level that is needed by collecting the samples of pathogenic microorganisms shall be equipped;
2. Any staff member who grasps the relevant professional knowledge and operating skills shall be provided;
3. Measures that can effectively prevent the spread and infection of pathogenic microorganisms shall be provided;
4. Technical methods and measures that can ensure the quality of pathogenic microorganism samples shall be provided.

The staff members who are in charge of the collecting of highly infectious pathogenic microorganism samples shall prevent the spread and infection of pathogenic microorganisms during the process of collecting and make detailed records about the sources, collecting processes, and methods of samples.

Article 10 The seed cultures or samples of bacteria (viruses) of highly infectious pathogenic microorganisms shall be transported over land; if there are no land crossings, the pathogenic microorganisms or samples that must be transported over water can be transported over water. In an emergency or when the seed cultures of bacteria (viruses) of highly infectious pathogenic microorganisms or samples shall be transported abroad, civil aviation transportation can be introduced.
Article 11 To transport the seed cultures of bacteria (viruses) of highly infectious pathogenic microorganisms or samples, the following requirements shall be met:

(1) The transportation purposes, uses of highly infectious pathogenic microorganisms, and the accepting units shall be in conformity with the provisions of the competent health department or the competent animal husbandry and veterinary department under the State Council.

(2) The containers for the seed cultures of bacteria (viruses) of highly infectious pathogenic microorganisms or samples shall be sealed and the containers or packing materials shall also accord with the requirements of water proofing, breakage-proof, leak prevention, high (low) temperature resistance, and high voltage resistance;

(3) Biohazard symbols, warnings, and instructions as prescribed by the competent health department or the competent animal husbandry and veterinary department under the State Council shall approve the containers or packing materials.

The transportation of the seed cultures of bacteria (viruses) of highly infectious pathogenic microorganisms or samples shall be approved by the competent health department of the people’s government at or above the provincial level. The transportation within the administrative areas of provinces, autonomous regions, or municipalities directly under the Central Government shall be approved by the competent health department or the competent animal husbandry and veterinary department of the people’s government of provinces, autonomous regions, or municipalities directly under the Central Government. The transportation covering different provinces, autonomous regions, or municipalities directly under the Central Government or those need to be transport abroad shall be reported to the competent health department or competent animal husbandry and veterinary department of the Sate Council respectively after being examined primarily by the competent health department or the competent animal husbandry and veterinary department of the Sate Council.

The transportation of the samples of pathogenic microorganisms during the processes of inspection and quarantine taken by entry-exit inspection and quarantine departments shall be approved by the entry-exit inspection and quarantine departments of the Sate Council and reported to the competent health department or competent animal husbandry and veterinary department of the Sate Council at the same time.

The transportation of the seed cultures of bacteria (viruses) of highly infectious pathogenic microorganisms or samples through civil aviation shall be approved according to the provisions in the second and third paragraphs of this article and also be approved by the competent civil aviation authority under the State Council.

The competent departments concerned shall examine the application materials on the transportation of the seed cultures or samples of bacteria (viruses) of highly infectious pathogenic microorganisms as submitted by the applicants, in which those that meet the requirements in the first paragraph of this article shall be approved immediately.

Article 12 No less than two specially-assigned persons shall be in charge of the escorting and relevant protective measures shall be taken during the transportation of the seed cultures of bacteria (viruses) of highly infectious pathogenic microorganisms or samples.

No unit or individual may transport the seed cultures of bacteria (viruses) of pathogenic microorganisms or samples by public trams (buses) and urban railways.

Article 13 If the seed cultures of bacteria (viruses) of highly infectious pathogenic microorganisms or samples shall be transported by railway, highway, civil aviation, and other public transports, the
units that take charge of the transportation shall transport by the document of approval as prescribed in Article 11 of this Regulation. 
The units that take charge of the transportation shall take measures together with the staff that are in charge of the escorting so as to ensure the safety of the transportation of the seed cultures of bacteria (viruses) of highly infectious pathogenic microorganisms or samples and take strict precautions against being stolen, being robbed, being lost, or being leaked.

Article 14 The preservation centres or professional laboratories (hereinafter referred to as “preservation institutions”) for the seed cultures of bacteria (viruses) as appointed by the competent health department or competent animal husbandry and veterinary department under the State Council shall be in charge of the task of preserving the seed cultures of bacteria (viruses) of pathogenic microorganisms and samples.

The preservation institutions shall preserve the seed cultures of bacteria (viruses) of pathogenic microorganisms and samples delivered by the laboratories according to the provisions of the competent health department or competent animal husbandry and veterinary department under the State Council and provide the seed cultures of bacteria (viruses) of pathogenic microorganisms and samples to the laboratories.

The preservation institutions shall establish a strict safekeeping system, record of being in and out of the seed cultures of bacteria (viruses) of pathogenic microorganisms and samples, establish a filing system, and appoint specially assigned persons for the job. Special warehouses or cabinets shall be set up for storing the seed cultures of bacteria (viruses) of highly infectious pathogenic microorganism and samples individually.

The preservation institutions shall not be charged any fees during the storing or providing of the seed cultures of bacteria (viruses) of pathogenic microorganisms and samples, and the expenditures shall be protected in the unit budget by the fiscal budget at the corresponding level.

The measures for the administration of the preservation institutions shall be established by the competent health department and competent animal husbandry and veterinary department under the State Council.

Article 15 The preservation institutions shall provide the seed cultures of bacteria (viruses) of highly infectious pathogenic microorganisms and samples to the laboratories and register by the approval documents for the engagement of those laboratory activities related to the highly infectious pathogenic microorganisms obtained by the laboratories according to the provisions of the Regulation.

Article 16 The laboratories shall conform to the provisions of the competent health department or competent animal husbandry and veterinary department under the State Council, destruct the seed cultures of bacteria (viruses) of highly infectious pathogenic microorganisms and samples on the spot, or deliver them to the preservation institutions for being preserved.

The preservation institutions shall register and issue a certificate of acceptance while accepting the seed cultures of bacteria (viruses) of highly infectious pathogenic microorganisms and samples from the laboratories.

Article 17 If the seed cultures or samples of bacteria (viruses) of highly infectious pathogenic microorganisms are stolen, robbed, lost, or leaked during transport, the units that take charge of the transportation, the staff that are in charge of the escorting and the preservation institutions shall take the necessary control measures and report respectively to the competent departments of units that take charge of the transportation, the units of the staff that are in charge of the escorting
and the competent department of the preservation institution in two hours, at the same time, they shall report to the competent health department or the competent animal husbandry and veterinary department of the people’s government at the county level where the departments are located and they shall also report to the public security organs if stealing, robbing, and loss have occurred. The competent health department or the competent animal husbandry and veterinary department that receives the report shall report to the people’s government at the corresponding level in two hours and report to the competent health department or the competent animal husbandry and veterinary department of the people’s government at a higher level and the competent health department or the competent animal husbandry and veterinary department of the State Council.

The people’s government at the county level shall report to the people’s government of the municipalities divided into districts or the people’s government at the next higher level in two hours after receiving the report. The people’s government of the municipalities divided into districts shall report to the people’s government in each province, autonomous region, and municipality directly under the Central Government in two hours after receiving the report. In addition, the people’s government in each province, autonomous region, and municipality directly under the Central Government shall report to the competent health department or the competent animal husbandry and veterinary department of the State Council in one hour.

Any unit or individual that finds the containers or packing materials of the seed cultures of bacteria (viruses) of highly infectious pathogenic microorganisms or samples shall report to the competent health department or the competent animal husbandry and veterinary department nearby in a timely manner. The competent health department or the competent animal husbandry and veterinary department receiving the report shall organise investigations and verification in time and take the necessary control measures according to law.

Section III The Establishment and Management of Laboratories

Article 18 The State divides the classes of laboratories into Class One, Class Two, Class Three, and Class Four according to the biosafety levels of pathogenic microorganisms that the laboratories have and the provisions of the national standard on laboratory biosafety.

Article 19 The new construction, construction renovation, and expansion of the laboratories of Class Three and Class Four or the production and import of mobile laboratories of Class Three and Class Four shall conform to the prescriptions described below:

1. Conforming to the layout of national biosafety laboratory system and performing the relevant approval procedures according to law;
2. Being examined and approved by the competent science and technology department of the State Council;
3. Conforming to the technical code for the construction of national biosafety laboratories;
4. Evaluating the environmental impacts according to 《The Assessment of Environmental Impact in the People’s Republic of China》 and being examined and approved by the competent environmental protection department;
5. The biosafety levels shall be in conformity with the laboratory activities that they intend to engage in.

The layout of the national biosafety laboratory system mentioned in the preceding paragraph is established by the competent investment department and the relevant departments of the State Council. The layout of national biosafety laboratory system shall conform to the principles of total
quantity control, rational distribution, and resource sharing, hold hearings or conferences for
demonstration and listen to opinions from experts on public health, environmental protection,
investment management, laboratory management, and other aspects.

Article 20 The laboratories of Class Three and Class Four shall attain national accreditation for
laboratories.

The authorised institutions confirmed by the supervision and regulation departments of the State
Council for the authentication and approval shall confirm the laboratories of Class Three and
Class Four according to the national standards on laboratory biosafety. The laboratories that
receive authorisation can be issued the biosafety laboratory certificates at the corresponding levels.
The duration of validity for the certificates is five years.

Article 21 The laboratories of Class One and Class Two cannot engage in the laboratory activities
of highly infectious pathogenic microorganisms. The laboratories of Class Three and Class Four
shall meet the following requirements while they engage in the laboratory activities of highly
infectious pathogenic microorganisms:

(1) The experimental objectives and the laboratory activities that they intend to engage in shall
conform to the provisions of the competent health department or the competent animal husbandry
and veterinary department under the State Council;

(2) Getting national accreditation for laboratories;

(3) Staff members that are in conformity with the laboratory activities that they intend to engage in
shall be provided;

(4) The construction quality has passed the detection and acceptance inspection of the competent
construction department according to law.

The competent health department or the competent animal husbandry and veterinary department
under the State Council shall check whether the laboratories of Class Three and Class Four
conform to the requirements above according to their respective functions and responsibilities.
Those who meet the requirements shall be issued qualification certificates for engaging in the
laboratory activities of highly infectious pathogenic microorganisms.

Article 22 If the laboratories that have obtained the qualification certificates for engaging in the
laboratory activities of highly infectious pathogenic microorganisms need to engage in the
laboratory activities of some highly infectious pathogenic microorganisms or suspected highly
infectious pathogenic microorganisms, they shall report to the competent health department or the
competent animal husbandry and veterinary department of people’s governments at or above the
provincial level for approval according to the provisions as prescribed by the competent health
department or the competent animal husbandry and veterinary department under the State Council.
The results and working conditions of the laboratory activities shall be reported to the former
approving department.

The laboratories shall declare or accept the scientific research projects that are related to the
highly infectious pathogenic microorganisms according to the scientific research needs and
biosafety requirements. They shall have the relevant biosafety levels and be approved by the
competent health department or the competent animal husbandry and veterinary department under
the State Council.

Article 23 If highly infectious pathogenic microorganisms or suspected highly infectious
pathogenic microorganisms are found by the entry-exit inspection and quarantine departments, the
medical and health organisations and animal epidemic prevention institutions while they are
carrying out the detection and diagnosis in the laboratories and laboratory activities that are related to this type of highly infectious pathogenic microorganisms are needed to be further engaged in, they shall be authorised and approved according to the provisions of this Regulation and be taken in the laboratories that have the relevant qualification certificates.

The laboratories that exclusively engage in the detection and diagnosis shall strictly conform to the provisions of the competent health department or the competent animal husbandry and veterinary department under the State Council, establish and perfect rules and regulations and ensure the biosafety of laboratories.

Article 24 The competent health department or the competent animal husbandry and veterinary department of people’s governments at or above the provincial level shall make a decision whether to grant the approval or not within 15 days from the date of receiving the application on engaging in those laboratory activities related to the highly infectious pathogenic microorganisms.

The competent health department or the competent animal husbandry and veterinary department of people’s governments at or above the provincial level shall make a decision on whether to grant approval or not within 2 days from the date of receiving the application if the entry-exit inspection and quarantine departments apply for further carrying out the laboratory activities on the highly infectious pathogenic microorganisms or suspected highly infectious pathogenic microorganisms in the laboratories for the emergency requirements on the inspection and quarantine. If a decision is not made in two hours, relevant laboratory activities can be carried out in the laboratories.

The competent health department or the competent animal husbandry and veterinary department of people’s governments at or above the provincial level shall provide convenience for the applicants and ensure that they can apply through telegraph, telex, fax, electronic data interchange, email, or other methods.

Article 25 The new construction, construction renovation, or expansion of laboratories of Class One and Class Two shall register at the competent health department or the competent animal husbandry and veterinary department of people’s governments of the municipalities with districts for the record. The competent health department or the competent animal husbandry and veterinary department of people’s governments of the municipalities with districts shall compile the records and report them to the competent health department or the competent animal husbandry and veterinary department of people’s governments in each province, autonomous region, and municipality directly under the Central Government every year.

Article 26 The competent health department or the competent animal husbandry and veterinary department under the State Council shall regularly compile and report the number of laboratories and the establishment and distribution of laboratories as well as the conditions of the laboratories of Class Three and Class Four that have obtained the certificates for engaging in the laboratory activities of highly infectious pathogenic microorganisms and the relevant laboratory activities that they engage in with each other.

Article 27 The laboratories of Class Three and Class Four that have been established and obtain national accreditations for laboratories shall report to the competent environmental protection departments of the people’s government at the county level where the departments are located for records. The competent environmental protection departments shall conduct supervision and inspection on the disposal of the wastewater, exhaust gas, and other rubbish discharged by laboratories in accordance with the provisions of laws and administration regulations.
Article 28 No unit or individual is allowed to engage in laboratory activities that are related to pathogenic microorganisms that have not been found or have been announced as being eliminated by our state without approval.

If laboratory activities that are related to the pathogenic microorganisms in the preceding paragraph shall be engaged in for the purposes of preventing and controlling infectious diseases, they shall be approved by the competent health department or the competent animal husbandry and veterinary department under the State Council and be carried on in the professional laboratories appointed by the approval departments.

Article 29 The new technologies and methods that are used by the laboratories that engage in laboratory activities that are related to highly infectious pathogenic microorganisms shall prevent the spread of highly infectious pathogenic microorganisms, ensure biosafety and the personal security of the operators, as well as be scientifically demonstrated by the National Experts Committee on Biosafety in Laboratories Dealing with Pathogenic Microorganisms. The new technologies and methods are allowed only when they are demonstrated to be feasible.

Article 30 The laboratory activities that relate to highly infectious pathogenic microorganisms and that need to be carried out on animal bodies shall be carried out in those laboratories that are above Class Three and conform to the national standards for the biosafety of animal laboratories.

Article 31 The units established by the laboratories shall be in charge of the biosafety administration of laboratories.

The units established by the laboratories shall establish scientific and strict administration systems according to this Regulation, regularly inspect the implementation of the provisions related to biosafety, and regularly inspect, maintain, and update the facilities, equipment, and materials of the laboratories so as to ensure that they conform to the national standards.

The units established by the laboratories and their competent departments shall be in charge of the administration of the daily activities of laboratories.

Article 32 The principals of the laboratories are the first responsible persons for the biosafety of laboratories.

The laboratory activities carried out by the laboratories shall strictly conform to the relevant national standards and technical specifications and operating instructions of laboratories. The principals of the laboratories shall appoint specially assigned persons to conduct supervision and inspections on the implementation of the technical specifications and operating instructions of the laboratories.
Article 33 The units that set up the laboratories that engage in experimental activities related to the highly infectious pathogenic microorganisms shall establish and perfect security systems, take security measures, strictly prevent the highly infectious pathogenic microorganisms from being stolen, robbed, lost, or leaked and ensure the safety of the laboratories and the pathogenic microorganisms thereof. If the highly infectious pathogenic microorganisms of the laboratories are stolen, robbed, lost, or leaked, the units that set up the laboratories shall report in accordance with the provisions in Article 17 of the Regulation.

The laboratories that engage in the laboratory activities that relate to the highly infectious pathogenic microorganisms shall report to the local public security organs for records and accept the supervision and guidance on laboratory security from the public security organs.

Article 34 Laboratories or the units that set up the laboratories shall train the staff members regularly every year, so as to ensure that they can grasp the technical specifications of the laboratories, operating instructions, biosafety protection information, and practical operation skills, in which they shall also check the staff members. The staff members who have been qualified through examination may be permitted to take up the posts.

The laboratories that engage in the laboratory activities that are related to the highly infectious pathogenic microorganisms shall report the situations on the training and assessment of staff members thereof to the competent health department or the competent animal husbandry and veterinary department of the people’s government of provinces, autonomous regions, or municipalities directly under the Central Government once every six months.

Article 35 More than two staff members shall conduct the laboratory activities related to the highly infectious pathogenic microorganisms together.

The staff members or other relevant members who enter into the laboratories for relevant laboratory activities of highly infectious pathogenic microorganisms shall be approved by the principals of the laboratories. The laboratories shall provide protective articles that conform to the protection requirements and take other occupational protective measures. The laboratories that engage in laboratory activities related to highly infectious pathogenic microorganisms shall also monitor the health of the staff members who work in the laboratories, organise physical examinations for them and establish health records. If necessary, the staff members who work in the laboratories shall have preventive inoculations administered.

Article 36 In the same separated safe area of the same laboratory, only one laboratory activity related to the highly infectious pathogenic microorganisms can be engaged in at the same time.

Article 37 The laboratories shall establish experiment files and record the use and safety supervision of the laboratories. The retention time of the experiment files for the laboratories that engage in the laboratory activities related to highly infectious pathogenic microorganisms shall be no less than twenty years.

Article 38 The laboratories shall dispose of the wastewater, exhaust gas, and other rubbish discharged in accordance with the laws, administration regulations, and provisions of the departments concerned under the State Council of environmental protection and establish the appropriate environmental protection measures to prevent environmental pollution.

Article 39 Laboratories of Class Three and Class Four shall indicate the biohazard logos and level symbols of biosafety laboratories as prescribed by the competent health department or the competent animal husbandry and veterinary department under the State Council in visible locations.
Article 40 The laboratories that engage in the laboratory activities of highly infectious pathogenic microorganisms shall draw up emergency disposal proposals for laboratory infection and report to the competent health department or the competent animal husbandry and veterinary department of people’s governments in each province, autonomous region, and municipality directly under the Central Government where the laboratories are located for records.

Article 41 The competent health department or the competent animal husbandry and veterinary department under the State Council, together with the relevant departments under the State Council, organise the experts in the fields of etiology, immunology, laboratory medicine, epidemiology, preventive veterinary medicine, environmental protection, and laboratory management to form the National Experts Committee on Biosafety in Laboratories Dealing with Highly Infectious Pathogenic Microorganisms. This committee takes on the biosafety assessment, technical consultation, and appraisal on the setting up and operation of the laboratories that engage in the laboratory activities related to highly infectious pathogenic microorganisms.

The competent health department or the competent animal husbandry and veterinary department of the people’s government of provinces, autonomous regions, or municipalities directly under the Central Government, together with the related departments of the people’s governments at the same level, organise the experts in the fields of etiology, immunology, laboratory medicine, epidemiology, preventive veterinary medicine, environmental protection, and laboratory management to form the Local Experts Committee on Biosafety in Laboratories Dealing with Highly Infectious Pathogenic Microorganisms. This committee is to receive technical advice on the setting up and operation of local laboratories.

Section IV Control of Laboratory Infection

Article 42 The units that set up laboratories shall assign specialised institutions or persons for the control of laboratory infection and the regular inspection on the implementation of rules and regulations, including the biosafety containment of laboratories, preservation and use of the seed cultures of bacteria (viruses) of pathogenic microorganisms and samples, safe operation and disposal of the wastewater, exhaust gas, and other rubbish discharged by the laboratories.

The institutions or persons that take charge of the control of laboratory infection shall have a grasp of the knowledge needed for the prevention and treatment of infectious diseases related to pathogenic microorganisms handled in their laboratories, and shall regularly investigate and find out the health conditions of the persons who work in the laboratories.

Article 43 If the persons who work in the laboratories appear to have clinical symptoms or signs of the infection related to the laboratory activities of highly infectious pathogenic microorganisms that their laboratories engage in, the principals of the laboratories shall report to the institutions or persons that take charge of the control of laboratory infection and at the same time, appoint specially-assigned persons to accompany them to the hospitals in time. The persons who work in the laboratories shall truthfully inform the medical institutions for the diagnosis and treatment of the species and hazard degrees of the pathogenic microorganisms that they will be in contact with in the near future. The medical institutions for the diagnosis and treatment shall treat them in time.

The medical institutions that do not meet the relevant treatment requirements shall transfer those persons who work in the laboratories and are infectious to the medical institutions that have relevant infection treatment requirements. The medical institutions that meet the relevant treatment requirements shall accept those persons and shall not refuse treatment.
Article 44 When a leak of highly infectious pathogenic microorganisms is detected in the laboratories, those persons who work in the laboratories shall take control measures immediately, so as to prevent the spread of highly infectious pathogenic microorganisms and report to the institutions or persons that take charge of the control of laboratory infection at the same time.

Article 45 The institutions or persons that take charge of the control of laboratory infection, after receiving the reports as prescribed in Article 43 and Article 44 of this Regulation, shall start emergency disposal pre-arranged plans at once and organise persons to investigate the biosafety situations of the laboratories. When a laboratory infection or leak of highly infectious pathogenic microorganisms is confirmed, the institutions or persons shall report in accordance with the provisions in Article 17 of this Regulation and take control measures at the same time, provide medical observation or isolated treatment for the relevant persons, close the laboratories, and prevent proliferation.

Article 46 If the competent health department or the competent animal husbandry and veterinary department receives reports on the infectious accidents of the persons work in the laboratories or the leak of pathogenic microorganisms, or find laboratories that engage in the relevant laboratory activities of pathogenic microorganisms cause infectious accidents, they shall organise the disease prevention and control institutions, supervising agencies for animal epidemic prevention, medical institutions and other relevant institutions to take the following prevention and control measures according to law:

1. Close the laboratories that are contaminated by the pathogenic microorganisms or the places that may cause the spread of pathogenic microorganisms;
2. Carry out epidemiology research;
3. Provide isolated treatment for the patients and medical inspection for the relevant persons;
4. Carry out medical observation for the persons in close contact with them;
5. Conduct on-site disinfection;
6. Introduce isolation, killing, and other measures of the animals affected by a epidemic disease or the animals that are suspected to be affected by a epidemic disease;
7. Other prevention and control measures that shall be introduced.

Article 47 If the medical institutions or veterinary medical institutions and the medical personnel perform their duties, find infectious disease patients, suspected patients, and infectious or suspected animals that are affected by a quarantinable epidemic disease, the medical institutions or veterinary medical institutions for the treatment shall report to the competent health department or the competent animal husbandry and veterinary department of People’s Governments at the county level where the institutions are located in two hours. The competent health department or the competent animal husbandry and veterinary department that have received the report shall notify the competent health department or the competent animal husbandry and veterinary department of the People’s Governments at the county level where the laboratories are located in two hours. The competent health department or the competent animal husbandry and veterinary department that receive the notification shall take prevention and control measures according to the provisions in Article 46 of this Regulation.

Article 48 When the pathogenic microorganisms diffuse and some infectious diseases occur and even run rampant, the competent health department or the competent animal husbandry and veterinary department of People’s Governments at or above the county level shall, in accordance
with the provisions of the relevant laws, administrative regulations, and emergency disposal pre-arranged plans, end the laboratory infection.

**Section V Supervision and Management**

Article 49 The competent health department or competent animal husbandry and veterinary department of people’s governments at or above the county level shall conform to their work and perform the following duties:

1. Supervise and check the collection, transportation, and storage of the seed cultures of bacteria (viruses) of pathogenic microorganisms or samples;
2. Supervise and check whether the laboratories that engage in the laboratory activities related to highly infectious pathogenic microorganisms conform to the situations prescribed by this Regulation;
3. Supervise and check the training of the laboratories or the units that set up laboratories, as well as the assessment of their staff members and the persons in their positions;
4. Supervise and check whether the laboratories that engage in the laboratory activities related to pathogenic microorganisms in accordance with the relevant national standards, technical specifications, and operating instructions.

The competent health department or the competent animal husbandry and veterinary department of people’s governments at or above the county level shall earnestly implement the functions of supervision and management primarily through checking the records, files, and reports reflect the implementation of the relevant national laws, administrative regulations, and national standards and requirements by the laboratories.

Article 50 The competent health department, the competent animal husbandry and veterinary department or the competent environmental protection department of the People’s Government at or above the county level have the right to enter into the units under inspection and the leak or diffusion sites of pathogenic microorganisms for conducting an investigation and collecting evidence, collecting samples as well as consulting and copying the relevant information. Those who need to enter into the laboratories to engage in the relevant laboratory activities of highly infectious pathogenic microorganisms for conducting an investigation and collecting evidence as well as collecting samples shall appoint or consign professional organisations for implementation. The inspected units shall make co-ordinated actions and shall not refuse or obstruct it.

Article 51 The supervision and regulation departments of the State Council for authentication and approval shall supervise and check the activities authorised by the laboratories in accordance with the provisions of the 《Certification and Accreditation Regulation of the People’s Republic of China》.

Article 52 The competent health department, the competent animal husbandry and veterinary department or the competent environmental protection department shall perform the duties in accordance with the legal authority and processes and be just, fair, open, civilized, and efficient.

Article 53 More than two law enforcement officials in the competent health department, the competent animal husbandry and veterinary department or the competent environmental protection department shall be in for the performance of duties, they shall show certificates for law enforcement and fill out the law enforcement documents in accordance with the provisions. Check carefully to see if the on-site examination notes and sampling records are correct before the law enforcement officials, the persons being examined, or the persons who are taking samples sign their names. If the persons being examined or the persons who are taking samples refuse to sign
their names, the law enforcement officials shall indicate the situations after signing their own names.

Article 54 The competent health department, the competent animal husbandry and veterinary department or the competent environmental protection department and the law enforcement officials thereof shall voluntarily accept supervision from society and the citizens while performing their duties. The citizens, legal persons, and other organisations have the right to report the local people’s government and relevant competent departments that do not perform duties in accordance with the provisions to the people’s government at a higher level and the competent health department, the competent animal husbandry and veterinary department or the competent environmental protection department thereof. The relevant people’s government or the competent health department, the competent animal husbandry and veterinary department or the competent environmental protection department shall investigate and handle it in a timely manner.

Article 55 If the competent health department, the competent animal husbandry and veterinary department or the competent environmental protection department of the people’s government at a higher level find some items that shall be disposed of within the scope of the competent health department, the competent animal husbandry and veterinary department or the competent environmental protection department of the people’s government at a lower level shall inform the department for disposal. If the competent health department, the competent animal husbandry and veterinary department or the competent environmental protection department of the people’s government at a lower level does not dispose in a timely manner or perform its duties actively, the competent health department, the competent animal husbandry and veterinary department or the competent environmental protection department of the people’s government at a higher level shall order them to rectify the situation within a specified period. For the units that do not make the corrections after the time limit, the competent health department, the competent animal husbandry and veterinary department or the competent environmental protection department of the people’s government at a higher level has the right to dispose directly.

**Section VI Legal Responsibility**

Article 56 For the laboratories of Class Three and Class Four that do not have the qualification certificates for engaging in the laboratory activities of highly infectious pathogenic microorganisms according to the provisions of this Regulation, or those who have the relevant qualification certificates, but engage in the laboratory activities of some highly infectious pathogenic microorganism or suspected highly infectious pathogenic microorganisms without approval, the competent health department or the competent animal husbandry and veterinary department of the local people’s governments at or above county level shall order them to stop the relevant activities, supervise them to destroy the pathogenic microorganisms that are used for laboratory activities or send them to the preservation institutions and warm them in accordance with their respective functions and responsibilities. If the transmission and prevalence of infectious diseases or serious consequences have been caused, the principal persons, the persons in charge with direct responsibility or other personnel with direct responsibility shall be dismissed or fired according to law by the units that set up the laboratories. The qualification certificates of the laboratories shall be revoked directly. If the case constitutes a crime, criminal liabilities shall be investigated.
Article 57 The competent health department or the competent animal husbandry and veterinary department that violates the provisions of the Regulation and grants the laboratories that do not conform to the situations as prescribed by the Regulation to engage in the laboratory activities that relate to highly infectious pathogenic microorganisms shall revoke its former decision, order the relevant laboratories to stop the relevant activities, supervise them to destroy the pathogenic microorganisms that are used for laboratory activities or send them to the preservation institutions and place administrative sanctions on the persons in charge with direct responsibility or other personnel with direct responsibility. If the case constitutes a crime, criminal liabilities shall be investigated.

The competent health department or the competent animal husbandry and veterinary department that grants approval in violation of the law, harming the lawful rights and interests of concerned parties, shall be liable for the losses according to law.

Article 58 The competent health department or the competent animal husbandry and veterinary department that does not issue qualification certificates for engaging in the laboratory activities of highly infectious pathogenic microorganisms to the laboratories that conform to the legal conditions, or those who do not decide whether to grant approval or not to the entry-exit inspection and quarantine departments that apply to carry out further detection activities on highly infectious pathogenic microorganisms or suspected highly infectious pathogenic microorganisms for the emergencies of inspection and quarantine within the statutory time limit shall be ordered to remedy and be warned by the higher administrative authorities or supervisory organs. If the transmission and prevalence of infectious diseases or serious consequences have been caused, the persons in charge with direct responsibility or other personnel with direct responsibility shall be dismissed or fired according to law. If the case constitutes a crime, criminal liabilities shall be investigated.

Article 59 Anyone who, in violation of the Regulation, engages in the laboratory activities related to the pathogenic microorganisms that do not conform to the relevant biosafety requirements shall be ordered to stop the relevant activities, be supervised to destroy the pathogenic microorganisms used for the laboratory activities or send them to the preservation institutions and be warned by the competent health department or the competent animal husbandry and veterinary department of the local people’s government at or above the county level in accordance with their respective duties. If the transmission and prevalence of infectious diseases or serious consequences have been caused, the principal persons, the persons in charge with direct responsibility or other personnel with direct responsibility shall be dismissed or fired according to law by the units that set up the laboratories. If the case constitutes a crime, criminal liabilities shall be investigated.

Article 60 Any laboratory that has committed one of the following acts shall be given a deadline to correct and be given a warning by the competent health department or the competent animal husbandry and veterinary department of the local people’s government at or above the county level in accordance with their respective duties. If they do not make the corrections by the time limit, the persons in charge with direct responsibility or other personnel with direct responsibility shall be dismissed or fired according to law by the units that set up the laboratories. In addition, the relevant permission certificates of those who possess them shall be revoked by the original certificate-issuing departments:
(1) Failure to indicate biohazard symbols and class marks of biosafety laboratories as prescribed by the competent animal husbandry and veterinary department of the local people’s government under the State Council in the visible locations according to the provisions;
(2) Failure to report the results of laboratory activities and working conditions to the original approval departments;
(3) Failure to collect the samples of pathogenic microorganisms in accordance with the provisions, or failure to make full notes about the sources of the samples collected, the collection processes and methods;
(4) Failure to register the new construction, construction renovation, or expansion of laboratories of Class One and Class Two at the competent health department or the competent animal husbandry and veterinary department of the people’s governments of the municipalities with districts for the record;
(5) Failure to train the staff members regularly in accordance with the provisions, allow the staff members who fail in an evaluation to work or approve the persons who do not take protective measures to enter into the laboratories;
(6) The staff members in the laboratories who do not comply with the biosafety technical specifications and operating instructions of the laboratories;
(7) Failure to establish or keep the laboratory files in accordance with the provisions;
(8) Failure to draw up emergency plans for laboratory infections and to register for the record.

Article 61 If the units that set up the laboratories engage in the laboratory activities related to highly infectious pathogenic microorganisms in accordance with the law after approval do not establish and complete security systems or do not take security measures, the competent health department or the competent animal husbandry and veterinary department of local people’s government at or above the county level shall order them to rectify the situation within a specified period in accordance with their respective duties. For those units that do not make the corrections after the time limit, cause the stealing or robbery of the seed cultures of bacteria (viruses) of highly infectious pathogenic microorganisms or samples, or cause other serious consequences, the original certificate-issuing departments shall revoke the qualification certificates of the laboratories that engage in the laboratory activities related to highly infectious pathogenic microorganisms. For the units that cause the transmission and prevalence of infectious diseases, the competent departments of the units that set up the laboratories shall also demote, dismiss, or fire the persons in charge with direct responsibility or other personnel with direct responsibility in accordance with the law. If the case constitutes a crime, criminal liabilities shall be investigated.

Article 62 For the transportation units that transport the seed cultures of bacteria (viruses) of highly infectious pathogenic microorganisms or samples without the approval or those who fail to perform the protection obligations during the transportation of the seed cultures of bacteria (viruses) of highly infectious pathogenic microorganisms or samples and cause the stealing, robbery, loss, or leak of the highly infectious pathogenic microorganisms or samples, the competent health department or the competent animal husbandry and veterinary department of local people’s government at or above the county level shall order them to take measures, remove the hidden dangers, and give warnings in accordance with their respective duties. For the units that cause the transmission and prevalence of infectious diseases or other serious consequences, the competent departments of the consignment units and carriage acceptance units shall dismiss or fire the principal persons, the persons in charge with direct responsibility or other personnel with
Article 63 Any laboratory that has committed one of the following acts shall be ordered to stop the illegal activities at once by the competent health department or the competent animal husbandry and veterinary department of the local people’s government at or above the county level and supervised to destroy the pathogenic microorganisms or send them to the preservation institutions in accordance with their respective duties. For those that cause the transmission and prevalence of infectious diseases or other serious consequences, the departments to which they belong or the competent authorities at a higher level shall dismiss or fire the principal persons, the persons in charge with direct responsibility or other personnel with direct responsibility in accordance with the law. For those that have been issued permission certificates, their permission certificates shall be revoked by the original certificate-issuing departments. If the case constitutes a crime, criminal liabilities shall be investigated:

(1) The laboratories that fail to destroy the seed cultures of bacteria (viruses) of highly infectious pathogenic microorganisms and samples on the spot or send them to the preservation institutions for storage in time in accordance with the provisions after finishing the relevant laboratory activities;

(2) The laboratories that engage in the laboratory activities that relate to the highly infectious pathogenic microorganisms with new technology and new methods without demonstrating them to the National Experts Committee on Biosafety in Laboratories Dealing with Pathogenic Microorganisms;

(3) Discretionally engage in laboratory activities related to the pathogenic microorganisms that have not been found or have been announced as being eliminated by our State without approval;

(4) Engage in laboratory activities related to the pathogenic microorganisms that have not been found or have been announced as being eliminated by our State without approval in the professional laboratories that have not been designated;

(5) Engage in two types or more than two types of laboratory activities that relate to the highly infectious pathogenic microorganisms in the same separated security zone of the same laboratory at the same time.

Article 64 If the authorised institutions authorise the laboratories that don’t conform to the national standard on laboratory biosafety and the conditions prescribed by the Regulation, or fail to authorise the laboratories that conform to the national standard on laboratory biosafety and the conditions prescribed by the Regulation, the authorised institutions confirmed by the supervision and regulation departments of the State Council shall order them to rectify the situation within a specified period and issue warnings. For those that cause the transmission and prevalence of infectious diseases or other serious consequences, the authorised institutions confirmed by the supervision and regulation departments of the State Council shall disqualify their recognised qualification, as for those with the competent authorities at a higher level, their superior administrative departments shall dismiss or fire the principal persons, the persons in charge with direct responsibility and other personnel with direct responsibility in accordance with the law. If the case constitutes a crime, criminal liabilities shall be investigated.

Article 65 If the staff members who work in laboratories appear to have clinical symptoms or signs of infections related to the laboratory activities of pathogenic microorganisms engaged by their laboratories and a leak of highly infectious pathogenic microorganisms occurs in the
laboratories, the principals in the laboratories, the staff members in the laboratories, the specialised institutions or persons take charge of the control the laboratory infections fail to report or fail to take control measures in accordance with the provisions, the competent health department or the competent animal husbandry and veterinary department of the local people’s government at or above the county level shall order them to rectify the situation within a specified period and issue a warning. If the transmission and prevalence of infectious diseases or other serious consequences have been caused, the principal persons, the persons in charge with direct responsibility or other personnel with direct responsibility shall be dismissed or fired according to law by the units that set up the laboratories. For those that have been issued permission certificates, their permission certificates shall be revoked by the original certificate-issuing departments. If the case constitutes a crime, criminal liabilities shall be investigated:

Article 66 For those refuse to accept the activities of investigation and gathering for evidence related to the diffusion of highly infectious pathogenic microorganisms as carried out by the competent health department, the competent animal husbandry and veterinary department or relevant preventive and control measures taken in accordance with the provisions of this Regulation, the competent health department or the competent animal husbandry and veterinary department shall order them to rectify the situation and issue a warning in accordance with their respective duties. If the transmission and prevalence of infectious diseases or other serious consequences have been caused, the principal persons of the laboratories, the persons in charge with direct responsibility or other personnel with direct responsibility shall be demoted, dismissed, or fired according to law by the units that set up the laboratories. For those that have been issued permission certificates, their permission certificates shall be revoked by the original certificate-issuing departments. If the case constitutes a crime, criminal liabilities shall be investigated.

Article 67 If the transportation units, escorts, preservation institutions and the units that set up the laboratories do not report in accordance with the provisions of the Regulation when stealing, robbery, loss, or a leak of pathogenic microorganisms are detected, the competent health department or the competent animal husbandry and veterinary department of the people’s government at the county level where the departments are located shall issue warnings. If the transmission and prevalence of infectious diseases or other serious consequences have been caused, the principal persons, the persons in charge with direct responsibility or other personnel with direct responsibility shall be dismissed or fired according to law by the units that set up the laboratories, the competent authorities at a higher level of the transportation units and the preservation institutions. If the case constitutes a crime, criminal liabilities shall be investigated.

Article 68 For those preservation institutions that fail to store the seed cultures of bacteria (viruses) and samples sent by the laboratories in accordance with the provisions, or fail to provide seed cultures of bacteria (viruses) and samples, their designated departments shall order them to rectify the situation within a specified period, withdraw the seed cultures of bacteria (viruses) and the samples provided in violation of law and issue warnings. If the transmission and prevalence of infectious diseases or other serious consequences have been caused, the principal persons, the persons in charge with direct responsibility or other personnel with direct responsibility shall be dismissed or fired according to law by the units to which they belong or the competent authorities at a higher level. If the case constitutes a crime, criminal liabilities shall be investigated.
Article 69 The competent authorities of the people’s governments at or above the county level that fail to perform the supervision and inspection duties on laboratories and laboratory activities in accordance with the provisions of the Regulation shall be ordered to rectify the situation and circulate a notice of criticism by the relevant people’s governments within their respective duties. If the transmission and prevalence of infectious diseases or other serious consequences have been caused, the persons in charge with direct responsibility shall be given administrative sanctions in accordance with law. If the case constitutes a crime, criminal liabilities shall be investigated.

Section VII Supplementary Provisions
Article 70 The laboratories in the army shall be supervised and managed by the competent department of health of the Chinese People’s Liberation Army in accordance with the Regulation.
Article 71 The procedures of the laboratories set up before the implementation of the Regulation shall be handled in accordance with the provisions of the Regulation within six months as of the date of the implementation of the Regulation.
Article 72 The Regulation shall go into effect on the day of their promulgation.
Foreword

The compilation of the Standard mainly refers to ISO15190:2003 (E) 《Medical Laboratories —Safety Requirements》 and WHO 《Laboratory Biosafety Manual》 [Second Edition (Revised), 2003]. This Standard is different from ISO15190:2003 (E), in which it is not only used in the medical laboratories, but is also applicable to the various laboratories that perform operations with biological agents; in addition, it increases the biosafety requirements concerning laboratories. This Standard adopts the contents related to the laboratories that perform the operations of high-hazard
biological factors in WHO 《Laboratory Biosafety Manual》 and enhances the requirements for the facilities of this type of laboratories in consideration of the overall situations of the laboratory safety management of our State, so as to ensure security.

This Standard is put forth by the Ministry of Science and Technology of the People’s Republic of China and National Notarisation and Approval Supervision and Administration Committee.

This Standard is under the jurisdiction of the National Notarisation and Approval Standards Technical Committee.

The unit that is in charge of drafting this Standard: China National Accreditation Committee for Laboratories.

The units that take part in the drafting of this Standard: China Academy of Military Medical Sciences, Chinese Centre for Disease Control and Prevention, Beijing Military Area General Hospital, Guangdong Entry-Exit Inspection and Quarantine Bureau, and the National Animal Husbandry Veterinary Chief Station of the Ministry of Agriculture of the People’s Republic of China.

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### Laboratories—General Requirements for Biosafety

**1. Scope**

This Standard prescribes the biosafety management and construction principles of the laboratories and, at the same time, it also prescribes the requirements on the biosafety classifications, configurations of the facilities and equipment in the laboratories, personal protections, and safety behaviour in the laboratories. This Standard only prescribes the minimum requirements, in which this type of laboratories shall also conform to the requirements of the other relevant provisions of the State at the same time.

**2. Terms and Definitions**

The terms and definitions described below are applicable to this Standard.

2.1 **Biological Agents**

All of the microorganisms and bioactive substances.

2.2 **Pathogens**

The biological agents that are pathogenic to people, animals, and plants.

2.3 **Hazardous Waste**

All the waste that has potential biohazards or is flammable, combustible, corrosive, noxious, radioactive, destructive, or is harmful to people or the environment.

2.4 **Risk**

The integration of the probability of the injuries and the seriousness thereof.

2.5 **Aerosols**

The relatively stable dispersed systems formed by the tiny solid or liquid particles suspended in a gas medium, the diameters of which are generally approx. 0.001 micron to 100 microns.
2.6 **Biosafety**
Integrated measures to avoid the exposure of the persons who work in laboratories, the diffusion outwards of laboratories and the harm that is caused by dangerous biological factors.

2.7 **High Efficiency Particulate Air Filter (HEPA)**
The filter usually aims at the filtering of those particulates that have no less than 0.3 microns in diameter. Their filtering efficiency conforms to the relevant requirements.

2.8 **Safety Hood**
Negative pressure exhaust hood that is installed on the benches of the laboratories or the instruments and equipment for reducing the exposure hazards on the persons who work in the laboratories.

2.9 **Biological Safety Cabinet (BSC)**
Negative pressure filtering fume hood, which is used for preventing the operators and environment from being exposed to the bioaerosols produced in the process of conducting an experiment.

2.10 **Personal Protective Equipment (PPE)**
Equipment and appliances that are used to prevent persons from being hurt by injurious factors, such as chemical and biological factors.

2.11 **Laboratory Area**
The laboratory can be partitioned reasonably in accordance with the pollution probability of the biological factors.

2.12 **Buffer Room**
Buffer closed room that is set up between the two adjacent contaminated areas of the clean area, semi-contaminated area, and contaminated area. It has ventilation system; its two doors have an interlocking function and cannot be at the open state simultaneously.

2.13 **Air Lock**
An air-tight chamber, in which the air pressure in it can be regulated. It is used to connect two adjacent regions with different air pressures. Its two doors have an interlocking function and cannot be in the open state simultaneously. It is used as the specific channel in the laboratory.

2.14 **Directional Airflow**
The airflow that is controlled from the place with small pollution probability and high relative pressure to the place with high pollution probability and low relative pressure in the laboratories that the air pressure in them is lower than the atmospheric pressure of the outside environment.

2.15 **Material Safety Data Sheet (MSDS)**
Technical pamphlet that provides detailed information on the dangers and warnings.

3 **Classifications of Hazard Levels**
Four hazard levels can be divided in accordance with the hazard extent that the biological agents impose on individuals and groups.

3.1 Hazard Level I (Low Individual Hazard, Low Group Hazard)
Bacterium, epiphyte, viruses, parasites, and other biological agents that cannot harm healthy operators or make animals pathogenic.

3.2 Hazard Level II (Medium Individual Hazard, Limited Group Hazard)
The pathogens that can cause people or animals to become pathogenic, but cannot cause serious hazards to healthy operators, groups, domestic animals, or the environment in general cases. The laboratory infections cannot cause serious diseases; they have effective therapeutic and preventive measures and limited transmission risks.

3.3 Hazard Level III (High Individual Hazard, Low Group Hazard)
The pathogens that can cause serious diseases in people or animals or cause serious economic losses, but they cannot transmit in individuals through casual contact in general cases or be treated with antibiotics and antiparasitic drugs.

3.4 Hazard Level IV (High Individual Hazard, High Group Hazard)
The pathogens that can cause serious diseases in people or animals, they cannot be healed in general cases, and can be transmitted between people or between animals and people, or between people and animals or between animals because of direct contact, indirect contact, or casual contact.

4 Biohazard Assessments
Biohazard level assessments shall be taken while infectious biological agents or potential infectious biological agents are involved in the laboratory activities. The biohazard level assessments shall at least include the following contents: species of biological agents (biomaterials that are known, unknown, genetically modified or have unknown infectivity), sources, infectivity, pathogenicity, route of transmission, stability in the environment, infective doses, thickness, animal experimental data, prevention, and treatments.
The biohazard level assessments shall be performed by the proper experienced professionals.

5 Protective Barriers and Biosafety Level Classifications
5.1 Protective Barriers
5.1.1 Grade I Protective Barriers
Protective barriers formed by the biological safety cabinets and individual protective equipment of laboratories.

5.1.2 Grade II Protective Barriers
Protective barriers formed by the facility structures and ventilation systems of laboratories.

5.2 Biosafety Level Classifications
The biosafety levels can be divided into four levels in accordance with the hazard levels of the biological agents operated and the preventive measures that are taken. Grade I protection level is the lowest grade and Grade IV protection level is the highest grade. BSL-1, BSL-2, BSL-3, and BSL-4 are used to show the relevant biosafety protection levels of animal laboratories.

6 Facilities and Equipment Requirements
The facilities, equipment, and materials (including the protective barriers) used by the laboratories shall conform to the relevant standards and requirements of the State.
6.1 BSL-1 Laboratories
1) No special location is needed, just ordinary buildings. However, the designs for preventing the entering of arthropods and rodents shall be provided.
2) Washbasins shall be installed in each laboratory and they shall be installed near the exits.
3) Clothes hanging devices shall be installed at the doors of the laboratories, and personal casual clothes and laboratory clothing shall be stored separately.
4) The walls, ceilings, and floors of the laboratories shall be smooth, easy to clean, impervious and be able to resist the corrosion of chemicals and disinfectants. The floors shall prevent slipping, but they cannot be covered with carpet.
5) The surfaces of the laboratory benches shall resist water, corrosion, and heat.
6) The cabinets and benches in the laboratories shall be firm. A certain distance shall be kept between the cabinets and benches in order to facilitate cleaning.
7) If the windows in the laboratories can be opened, window screens shall be installed for the windows.
8) Operating illuminations shall be ensured in the laboratories and any unnecessary reflections and strong lights shall be avoided.
9) Proper sterilisation equipment shall be equipped.

6.2 BSL-2 Laboratories
1) Satisfy the requirements in 6.1.
2) The doors of the laboratories shall be equipped with locks and cannot be closed automatically. Visible windows shall be equipped in the doors of the laboratories.
3) Enough storage space shall be provided in order to place articles for the convenience of use. Long-term service of storage space shall be provided outside the work areas of the laboratories.
4) Special work clothes shall be used in the laboratories, and latex gloves shall be worn.
5) The conditions for the storage of personal clothes outside the work areas of the laboratories shall be provided.
6) High pressure steam sterilisers shall be equipped in the buildings where the laboratories are located, and inspect and validate them regularly to ensure them to conform to the requirements.
7) Biological safety cabinets shall be equipped in the laboratories.
8) Eye washing facilities shall be installed, and emergency spray equipment shall be provided, if necessary.
9) The laboratories shall be well ventilated, if windows are used for natural ventilation, insect screens shall be fitted on all the windows.
10) Reliable power supply and emergency lighting shall be provided. If necessary, a power supply shall be provided for the important equipment, such as incubators, biological safety cabinets, and refrigerators.
11) Symbols that can be identified definitively in the dark shall be provided at the exits of the laboratories.

6.3 BSL-3 Laboratories
Self-contained exclusion zones (such as access control) shall be set in the buildings or detached buildings.

6.3.1 Layout
1) BSL-3 laboratories are composed of clean areas, semi-contaminated areas, and contaminated areas. Buffer rooms are set between the contaminated areas and the semi-contaminated areas. If
necessary, buffer rooms shall be set between the semi-contaminated areas and the clean areas.
2) Emergency exits shall be set in the semi-contaminated areas for emergency evacuation.
3) Transmission windows shall be set between the contaminated areas and the semi-contaminated
areas or the semi-contaminated areas and clean areas. The two doors of the transmission windows
cannot be in the open state at the same time, and physical disinfection devices shall be set in the
transmission windows.

6.3.2 Exterior-protected Construction
1) The internal surfaces of the exterior-protected constructions for the laboratories shall be smooth
and resist corrosion and water, so that they can be easily sterilised and cleaned. All the cracks shall
be reliably sealed and be protected against earthquakes and fire.
2) The external walls of the exterior-protected constructions shall have proper earthquake
resistance and fire prevention abilities.
3) The intersection angles between the ceilings, floors, and walls are all in circular form and can
be sealed reliably.
4) All the floors shall be protected against leakage and bond lines, they shall be bright and clean
and prevent slipping.
5) All the doors in the laboratories shall be closed automatically. Symbols that can be identified
definitively in the dark shall be provided at the exits of the laboratories.
6) Windows cannot be equipped for exterior-protected constructions. The windows set inside shall
prevent breaking, prevent air leakage, and be safe.
7) The designs for preventing the entering of arthropods and rodents shall be provided with at all
the accesses.

6.3.3 Air Supply and Exhaust System
1) Independent air supply and exhaust systems shall be installed to control the airflow directions
and pressure gradients in the laboratories. The airflow in the laboratories shall be ensured to flow
from the clean areas to the contaminated areas and at the same time, the air in the laboratories
must be discharged from the dedicated exhaust pipes only after being filtered effectively.
2) The air supply outlets and the air vents shall be distributed oppositely, that is, in the up-supply
and opposite down-exhaust mode. The dead angles of the airflow and the vortexes in the
contaminated areas and the semi-contaminated areas shall be minimised.
3) Direct exhaust shall be introduced in the air supply and exhaust systems and air return system
cannot be introduced.
4) The air that is discharged from the biological safety cabinets after the internal efficient filter can
be directly discharged through the exhaust ducts of the system. The pressure in the biological
safety cabinets and air exhaust systems must be balanced.
5) The air supply of the laboratories shall be after triplex filters, primary filter, intermediate filter
and advanced filter. The static cleanliness of the pollution areas shall be ensured to reach Grade
Seven to Grade Eight.
6) The air exhaust of the laboratories shall be discharged to the air after efficient filtering. The
external air outlets shall be located away from the air supply outlets and be set towards the
downwind direction of the dominant wind direction. They shall be at least two metres higher than
the buildings where they are located and have designs for the prevention of rain, rats, and insects,
but they shall not direct the gas to discharge directly upward.
7) The high efficiency particulate air filters shall be installed at the end of the air supply ducts and
the front of the air exhaust ducts.

8) The installation of the filters in the ventilation system and the high efficiency particulate air filters shall be firm and conform to the requirements of gas tightness. The high efficiency filters shall be sterilised before being replaced or the filters that can be replaced in gas tight belt bags shall be introduced, in which the filters being replaced shall be sterilised or burnt at once. Each high efficiency filter shall be detected in accordance with the methods that have been confirmed after being installed, replaced, and maintained, in which after this, the detection shall be carried out at least once a year so as to ensure proper performance.

9) Air tight closed valves shall be installed at the main air supply ducts and main air exhaust ducts and can be completely closed when they are not needed, so that indoor chemical fumigation and disinfection can be carried out.

10) Install the automatic interlock devices for the start-up of the fans and the biological safety cabinets to ensure that positive pressure will not appear in the laboratories and ensure that the airflow in the biological safety cabinets shall not flow backwards. One of the exhaust blowers is for work and the other is for standby.

11) Split type air-conditioning, central heating, and electric fans shall not be installed additionally in the contaminated areas and semi-contaminated areas.

6.3.4 Environmental Parameters

1) Compared with the outdoor atmospheric pressure, the atmospheric pressure in the contaminated areas is -40pa (nominal value), and it keeps safe and reasonable pressure differences with the inner air pressure in the biological safety cabinets and other devices. Directional airflow shall be kept and the air pressure differences in each area shall be kept even.

2) The temperature and humidity in the laboratories shall conform with the work requirements and be fit for the work of the persons there.

3) The artificial illuminations of the laboratories shall conform with the work requirements.

4) The noise levels in the laboratories shall conform to the relevant national standards.

6.3.5 Special Equipment and Devices

1) The Grade II and Grade III biological safety cabinets that conform to the safety and work requirements shall be provided, and their installation positions shall be away from the entrances of the contaminated areas and the areas that people often move in and around.

2) Low temperature and high-speed centrifuges or other equipment that can produce aerosols shall be placed in negative pressure covers or other air exhaust devices (fume hoods, exhaust hoods, etc.), and the aerosols that may be produced shall be discharged after being filtered effectively. High pressure steam sterilisers that do not discharge steam or other disinfection devices shall be installed in the contaminated areas.
4) A display unit of indoor pressure with an alarm function shall be arranged in a conspicuous place at the entrance of the laboratory in order to indicate negative pressure in contaminated and semi-contaminated areas. When the value of negative pressure deviates from the control interval, alarms shall be given to the personnel outside the laboratory by means of acoustic and optical signals. Furthermore, a display unit shall also be provided for gas-flow resistance of a high efficiency filter.

5) A stand-by power supply shall be provided to ensure an uninterrupted power supply during the operational period of the laboratory.

6) Hand-washing facilities shall be provided at the exits of contaminated and semi-contaminated areas. Non-manual taps shall be employed for the water supply of hand-washing facilities. Anti-backflow devices shall be fitted for water supply pipes. Floor drains are prohibited from being installed in the laboratory. With eye-catching signs, sanitary sewers shall be completely isolated from the building’s sewer pipes. Effluents shall be directly sent to a separate liquid disinfectant system for centralised collection and shall be disposed of after effective decontamination.

6.3.6 Miscellaneous
1) Bench tops should be impervious to water and resistant to corrosion and heat;
2) Laboratory furniture shall be sturdy. For the purpose of convenient cleaning, laboratory equipment shall be reasonably spaced apart from each other;
3) Pressure equipment such as a pump and air compressor etc. as required by the laboratory shall not influence the effective gradient of the indoor negative pressure;
4) Laboratory shall be provided with a communication system;
5) Information such as experiment records shall be sent to outside of the laboratory by means of an electrograph or a computer;
6) Showers shall be provided in the decontamination area. If necessary, emergency disinfection showers shall be provided in the semi-contaminated area.

6.3 BSL-4 Laboratory
In accordance with the different types of biological safety cabinet and protective clothing, BSL-4 laboratory can be classified into cabinet laboratory, positive-pressure suit laboratory and laboratory by using a biological safety cabinet and protective clothing at the same time.

6.4.1 BSL-4 cabinet laboratory
6.4.1.1 Site selection
Laboratory shall be constructed in a separate building or in a completely isolated area in a building. Moreover, this building shall be located away from urban areas.

6.4.1.2 Arrangement
1) BSL-4 cabinet laboratory shall consist of a decontamination area, a semi-contamination area, and a contaminated area of Class III biological safety cabinet. The decontamination area includes an outer changing room, a shower room, and an inner changing room. An anteroom joins the adjacent areas with each other.
2) On the walls of or in the semi-contaminated area, the decontamination area and contaminated area, a double-door autoclave that does not discharge steam, dip-in disinfection flume, fumigation chamber, and pass-through window with decontaminating apparatus shall be provided for the exchange and disinfection of materials, articles, and apparatuses that cannot be brought in and out from the changing room.
2) The double-door autoclaves, which do not discharge steam and that are installed on the walls of the contaminated area and semi-contaminated area, shall be directly connected with a Class III biological safety cabinet;

3) The semi-contaminated area shall be provided with an emergency exit for which the anteroom and emergency disinfection room shall be arranged.

6.4.1.3 Building enclosure
Regulations of Article 6.3.2 shall be abided by.

6.4.1.4 Supply and exhaust systems
Exhaust air must be subject to the disposal of a series of two high efficiency filters and other requirements shall conform to Article 6.3.3.

6.4.1.5 Environmental parameters
Regulations of Article 6.3.4 shall be abided by.

6.4.1.6 Safety devices and special installations
Class III biological safety cabinet conforming to the safety and working requirements shall be provided.
Other requirements shall comply with Article 6.3.5.

6.4.1.7 Others
Regulations of Article 6.3.2 shall be abided by.

6.4.2 BSL-4 positive-pressure suit laboratory
BSL-4 positive-pressure suit laboratory is composed of BSL-4 laboratory facilities, Class II biosafety cabinets, and positive pressure suits with an air supply system that supports life.

6.4.2.1 Site selection
Regulations of Article 6.4.1.1 shall be abided by.

6.4.2.2 Arrangement
1) BSL-4 positive-pressure suit laboratory shall consist of a decontamination area, a semi-contaminated area and a contaminated area within which Class II biosafety cabinets are installed. Furthermore, an anteroom is to join the adjacent areas with each other. The decontamination area shall include an outer changing room, a shower room and an inner changing room (can also serve as an anteroom). In the anteroom between the contaminated area and semi-contaminated area, chemical showers shall be provided. When staff members leave the laboratory, the surfaces of positive-pressure protective suits shall be disinfected by chemical showers.

2) Other requirements shall comply with provisions 2) and 4) of Article 6.4.1.2;

6.4.2.3 Building enclosure
Regulations of Article 6.3.2 shall be abided by.

6.4.2.4 Supply and exhaust systems
Regulations of Article 6.4.1.4 shall be abided by.

6.4.2.5 Environmental parameters
Regulations of Article 6.3.4 shall be abided by.

6.4.2.6 Safety devices and special installations
1) Class E exhaust biological safety cabinet shall be used.

2) Staff entering into the contaminated area shall wear positive-pressure protective suits. A life support system consists of a positive-pressure air-supply device providing excessively clean breathing gas, an alarm, and a gas tank for emergency assistance. The
air pressure inside the protective suits shall be continuously positive in relation to the ambient pressure and shall conform to the relevant requirements. In addition, the life support system shall be provided with a self-starting emergency power supply.

3) Other requirements shall comply with the regulations of Article 6.3.5.

6.4.2.7 Others
Regulations of Article 6.3.2 shall be abided by.

6.4.3 BSL-4 laboratory using a biological safety cabinet and protective clothing at the same time.

In addition to BSL-4 laboratory facilities, a Class III biological safety cabinet and life support system (positive-pressure protective suits) are used at the same time. Meanwhile, all the requirements of Article 6.4.1 and 6.4.2 are met.

7 Biosafety of an animal laboratory
Containment facilities of an animal laboratory shall refer to the corresponding requirements of a BSL-1~BSL-4 laboratory (see section 6). Moreover, protections also shall be taken into account for potential biohazards that are caused by animal’s exhalation, excretion, hair, bites and scratches, struggles, escapes, animal experiments (such as contamination, medical examination, sampling, autopsy and inspection etc.) and animal feeding or whatever arises in the course of the disposal of carcasses and excretions. Particular attention shall be paid to protection from animal aerosol. For instance, the autopsy of infected animals shall be performed on an autopsy table with negative pressure.

According to the breeds, body sizes and life habits of animals as well as experimental objectives, a biological safety cabinet, animal feeding facility, animal experiment facility, disinfection facility and washing facility, which have suitable containment levels and conform to the relevant national standards, shall be selected and specially used for animals.

The buildings of a laboratory shall ensure that laboratory animals cannot escape from them and non-laboratory animals such as field mice and insects cannot enter into them. The design of the laboratory, such as spaces and accesses shall meet the demands of the used animals.

Air in the animal laboratory shall not be recirculated. Animal aerosol shall be discharged from the atmosphere without recirculation after being subject to the suitable high efficiency filtration and/or disinfection.

In case the animals need drinking sterile water, a water supply system can be safely disinfected.

The breeding environment including temperature, humidity, illuminance, noise and cleanness in the animal environment shall conform to the requirements of the relevant national standards.

7.1 ABSL-1 laboratory
In addition to satisfaction with the requirements of Article 6.1, the following requirements shall also be met:

1) Animal facilities in buildings shall be separated from the open activity areas of the staff;
2) An automatic door closer, which shall be in the status of being locked when there is a animal present, shall be installed;
3) Where a floor drain is installed, it shall always be sealed by water or a disinfectant;
4) Washing of animal cages shall meet the requirements for cleanness;
7.2 ABSL-2 Laboratory
In addition to satisfaction with the requirements of Article 6.2 and 7.1, the following requirements shall also be met:

1) An anteroom shall be provided at the access door;
2) The doors of the animal laboratory shall be provided with vision panels, which can automatically close and be equipped with a suitable fire alarm;
3) For the purposes of satisfying the requirements on the operation of animal laboratory and pollution control, the autoclaves used for disposing solid waste shall be specially designed and reasonably arranged and their maintenance shall be strengthened. Subject to a special design, an incinerator shall be equipped with afterburning and dust collecting equipment. Contaminated wastewater must be decontaminated.

7.3 ABSL-3 Laboratory
In addition to satisfaction with the requirements of Articles 6.3 and 7.2, the following requirements shall also be met:

1) Buildings shall be provided with the abilities of resisting earthquakes, rats, insects and burglary, which conform to the requirements;
2) An ABSL-3 Laboratory consists of a decontamination area, a semi-contaminated area and a contaminated area (animal feeding rooms). An anteroom shall be arranged between the contaminated area and the semi-contaminated area. If required, an anteroom also shall be provided between the semi-contaminated area and the contamination area;
3) In relation to outdoor atmospheric pressure, the air pressure in the contaminated area shall be 60 Pa (nominal value) and shall keep a safe and reasonable pressure difference from the internal air pressure of the equipment such as a biological safety cabinet. A directional airflow and average pressure differences among the various areas shall be maintained;
4) Manual or automatic disinfectors (such as dynalysor and ozonateur) and adequate disinfectants shall be provided in the laboratory rooms;
5) Where there is a infected animal in the laboratory room, a protective mask shall be worn;

7.4 ABSL-4 Laboratory
In addition to satisfaction with the requirements of Articles 6.4 and 7.3, the following requirements shall also be met:

1) Accesses shall be added for animals;
2) Infected animals shall be bred in isolators that have performances of a Class III biological safety cabinet;
3) Animals shall be bred in a way that animal aerosol shall be discharged to the atmosphere after high efficiency filtration and will not enter into the laboratory rooms;
4) Generally, operations on infected animals including vaccinations, blood collection, autopsy, change of bedding materials and pass-through shall be performed under the condition of physical protection. If practicable, all operations must be performed in a biological safety cabinet. In case of large animals that cannot be bred in a biological safety cabinet or a relatively large number of animals, a special design shall be carried out. For instance, comparatively large biosafety cabinets and operable physical protections are employed and operations with high contaminant concentration shall be performed in the large biosafety cabinets as much as possible.
8 Personal protective equipment

Any personal protective equipment used in the laboratory shall meet the requirements of the relevant national standards. Based on risk assessments, the appropriate personal protective equipment shall be selected according to the protection requirements at the different biosafety levels. Definite written regulations, procedures and use guides shall be prepared for the selection, use, maintenance of personal protective equipments in the laboratory.

8.1 Protective laboratory clothing

Sufficient, clean and available protective clothing with the appropriate biosafety level shall be provided for the laboratory. When not in use, only clean protective clothing shall be placed at a special storage location and contaminated protective clothing shall be placed into leak-proof bags properly labelled and then carried away.

Protective clothing shall be changed at regular intervals to ensure cleanliness and they shall be changed immediately when contaminated by hazardous materials. Protective clothing shall not be worn outside the laboratory.

Plastic aprons or anti-liquid coveralls shall be worn when it is necessary to protect the staff from possible splashes of potentially hazardous materials. If necessary, other personal protective equipments such as gloves, goggles, protective mask and safety face shield shall be worn under this working condition.

8.2 Face and body protection

Operations are performed within a biological safety cabinet if aerosols containing biological agents might be generated in the course of handling specimens.

Goggles, safety face shield and other eye and face protective equipment that are permitted to use shall be available when handling hazardous materials.

8.3 Gloves

During work in the laboratory, gloves shall be available so as to protect the personnel from biohazards, radiation contaminations, coldness and heat, product contaminations, puncture wounds, abrasions, bites and scratches from animals.

In relation to the characteristics of operations, gloves shall meet the requirements on comfort, appropriateness, flexibility, easiness to easier to hold, resistances to wear and tear. Furthermore, they shall be sufficient to protect the personnel from the hazards involved. Laboratory workers shall be trained on selecting gloves, putting on gloves before use and pulling the gloves off after use.

The following warnings shall be observed:

1) Gloves worn by laboratory workers shall be leak-free and undamaged;
2) Hands and wrists shall be completely covered after pulling on gloves; when required, laboratory coveralls or sleeves of laboratory coats can be used to cover hands and wrists;
3) Gloves shall be changed in cases of tearing, damage or suspicious internal contamination;
4) Gloves shall be dedicated for laboratory use only. After complete or terminated work, the gloves shall be decontaminated, pulled off, and disposed of safely;

8.4 Shoes

With a slip-resistant sole, shoes shall be comfortable. It is recommended that liquid-proof shoes made of leather or composite materials are to be used. Disposable waterproof shoe covers shall be worn when leakage may occur during operations. Dedicated shoes (such as disposable or rubber boots) are required when working in the special areas of the laboratory (such as the area where
electrostatic preventions are required) or in BSL3 and BSL-4.

8.5 Respiratory protection
When uses of respiratory protective equipment such as a protective mask, personal respirator and positive-pressure clothing etc. are required, use and maintenance guide of these respiratory protective equipments shall be included in safety or operations manual with respect to the corresponding activities. A personal respirator shall only be used in accordance with the requirements of the operational instruction and trainings.
In order to ensure the correct use of the respiratory protective equipments at any time, monitoring at the workplace, medical evaluations and supervision over the users of respirators shall be performed. A compatibility test shall be performed on respirators for individuals.
When operations that easily generate highly hazardous aerosols are performed, personal protective equipment, a biological safety cabinet and/or other physical protection equipment are required to be used at the same time.

9 Management requirements

9.1 Responsibilities of management
Laboratory managers shall be responsible for the safety of all staff and visitors. Final responsibility shall be borne by the laboratory director or other designated person taking a post equivalent to a laboratory director. A safety director of the laboratory with the appropriate competency and experiences shall be appointed to assist the laboratory managers to manage all the affairs concerning safety. The safety director shall prepare, maintain and supervise an effective laboratory safety programme that should include the procedures of education, position and training, examination and assessment and a procedure enhancing safe behaviour in laboratory.
The laboratory safety director is entitled to prevent unsafe behaviours. Where a safety committee is established, the laboratory director shall at least be a competent member of the committee if he or she is not a director of the committee.
The laboratory director shall develop regulations and procedures to ensure that the laboratory facilities, equipment, personal protective equipment and materials, etc. comply with the respective national safety requirements. Furthermore, regular inspections, maintenance and renewals shall be carried out so as to prevent the deterioration of design performance.

9.2 Health management of the staff
All the staff shall be evidenced in writing that they have been trained on the potential hazards that may be caused by operations or by all the laboratory facilities.
It is required that all staff be immunised according to the organisms with which they may come into contact with so that infections are thereby prevented. An immunisation record shall be kept in the archives.

9.3 Safety design
The appropriate national and local building codes, safety standards of buildings dedicated to the laboratory shall be observed when constructions of a new laboratory are under consideration or modifications of the structures of a completed laboratory are planned. Without a prior permit from the laboratory director or designated representative, construction or engineering works are prohibited from implementation.
The laboratory shall be designed to ensure the containment levels of biohazards, chemical hazards, radiation and physical hazards are controlled at corresponding assessed risk levels. Moreover, the laboratory shall also be designed in a way that a safe working environment is provided in the
associated office areas and adjacent public spaces. Corridors and accesses leading to the exits shall be free of obstacles.

For the purpose of sufficient vitalisation and prevention of potential infectious agents and hazardous gases from dispersion, routine monitoring of the airflow rate shall be carried out. Each entrance and exit of the laboratory can be identified. Signs, which include international warning symbols and signs (such as biohazard, fire and radiation signs) as well as other required signs, shall be provided at the entrance. A sign shall be provided for the emergency exit so as to distinguish them from the normal exits. Emergency evacuation routes shall be provided with signs that can be clearly recognised even in the darkness.

Lockable doors shall be arranged for the entrances of the laboratory, which shall not influence the emergency evacuation. Only authorised persons should be allowed to enter the laboratory working areas. Locks shall be installed on the doors inside the laboratory rooms, and access must be strictly controlled when highly hazardous specimens are being operated on. Other security measures such as lockable doors, freezers and restrictions on the access of special personnel also shall be taken for storages of highly hazardous specimens, cultures, chemical reagents, and supplies. Dangers that biomaterials, specimens, drugs, chemicals and confidential information are stolen and improperly used shall be assessed and the corresponding measures shall be taken to prevent the occurrences of such circumstances.

A special design shall be provided to guarantee the safety of the storage, transit shipment, collection, handling and disposal of hazardous materials. Indoor environment conditions such as temperature, humidity, luminance, noise and cleanliness, etc. shall meet the working requirements and relevant requirements.

9.4 Procedures
The corresponding standard procedures shall be prepared based on products, biohazard assessment, research contents, features of facilities, equipments. The standard procedures of the laboratory shall include detailed operation instructions that describe how to carry out activities under the condition of any involved hazard or minimum hazard. The management director responsible for the activities in the working areas shall evaluate, examine and renew these procedures at least once each year. A written plan including the following shall be prepared:

1) Surveillance of the health of the staff;
2) Implementation of hazard assessment, result record and arrangement of measures to be taken;
3) Identifications (including the appropriate labelling requirements), safe storage, handling and monitoring procedure of chemicals and other hazardous substances;
4) Procedures of safe behaviour when hazardous materials are being operated on;
5) Procedures preventing highly hazardous and contaminated materials from being stolen;
6) Methods adopted to identify the demands and teaching materials of training;
7) Procedures adopted to obtain, maintain and distribute the Material Safety Data Sheet (MSDS) for all the materials used in the laboratory;
8) Safe decontamination and maintenance procedure of the laboratory equipment;
9) Emergency procedures, including the leakage disposal procedure;
10) Recording, report and investigation of incidents;
11) Waste handling and disposal;

9.5 Verification and examination of the safety programme
9.5.1 Verification of the safety programme
Personnel appropriately trained shall annually perform verification and examination on the safety programme at least one time, including but not limited to the following essential factors:

1) Regulations regarding safety and health;
2) Written work procedure including safe work behaviour;
3) Education and training;
4) Supervision of the staff;
5) Routine examinations;
6) Hazardous materials and substances;
7) Surveillance of health
8) Services and equipment for first aid;
9) Investigations on accidents and the state of illness;
10) Verification and examination by the Health and Safety Committee;
11) Recording and statistics;
12) The programme that ensures the complete implementation of all the measures brought forward during verification and examination;
13) Check the tables that are specially prepared for each field to effectively assist verification and examination;

9.5.2 Safety inspection
Laboratory managers are responsible for ensuring the implementation of the safety survey. Work places shall be surveyed at least once per year so as to ensure:

1) Proper functions and states of emergency equipment, alarm system and evacuation procedures;
2) States of the procedures and articles including the emergency showers used for controlling the leakage of hazardous substances;
3) Appropriate containment and control of the storages of flammable, combustible, infectious, radioactive and poisonous substances;
4) States of the decontamination and waste disposal procedures;
5) States of the laboratory facilities, equipment and personnel;

9.5.3 Safety manual
The safety manual that all the staff are required to read shall be available in the working areas at all times. The contents of the safety manual shall aim at the demands of the laboratory and include but not limited to the following:

1) Biohazard;
2) Fire protection;
3) Electrical safety;
4) Chemical safety;
5) Radiation;
6) Handling and disposal of hazardous wastes;

The safety manual shall specifically describe the procedures for an evacuation from the working areas and for incident handling. Moreover, laboratory managers shall evaluate, examine and renew the safety manual at least each year. Other useful information resources in the laboratory also include (but not limited to) the Material Safety Data Sheet (MSDS) for all the materials involved in the laboratory and references such as schoolbooks and authoritative journals and articles.

9.6 Recording
9.6.1 Recording of occupational diseases, injuries and adverse incidents
A system shall be established to record and report occupational diseases, injuries, adverse incidents and corresponding measures taken. Meanwhile, individual privacy shall be respected. Training records shall be maintained for the staff, including safety instruction for each personnel member and annually renewed information regarding safety preparation.

9.6.2 Record of hazard assessment
A formal hazard assessment system shall be established. By means of a safety survey form, the course of hazard assessment can be recorded and documented. The records of a safety audit and analysis record of incident trend contribute to the preparation and implementation of remedial measures.

9.6.3 Record of hazardous waste
Records of hazardous waste handling and disposal shall be a part of the safety programme. Records of hazardous waste handling and disposal, hazard assessment, safety survey and actions taken accordingly shall be filed for reference during regulated period.

9.6.4 Hazard signs
Hazard areas shall be systemically and clearly identified and be applicable to the relevant hazards. In some cases, it is reasonable to label the hazard areas with signs and physical barriers at the same time. Specific hazardous materials that are used in the laboratory or on laboratory equipment shall be clearly labelled. All the entrances and exits leading to the working areas shall be labelled with hazards that may occur in these accesses. Special attention shall be paid to fire hazard, flammable, combustible, infectious, radioactive, harmful and biohazardous materials. In order to ensure applicability to the existing hazards, laboratory managers shall be responsible for regular evaluation, examination and renewing of the system of hazard signs. This activity shall be performed at least one time each year. Non-laboratory staff members such as maintenance personnel, contracting parties and subcontractors shall be informed of any hazards they may run into. The staff shall be trained and be familiar with the dedicated written instructions regarding emergency procedures. Potential hazards, which may influence the health of pregnant women and susceptible individuals, shall be labelled, evaluated and examined. Hazards shall be evaluated and recorded.

9.6.5 Reports of incidents, injuries, accidents and occupational diseases
A procedure shall be established to report incidents, injuries, accidents, occupational diseases and potential hazards in the laboratory. Reports of all the accidents (including injuries) shall be documented with specific descriptions of the incident, assessment on the causes, suggestions preventing the occurrences of similar incidents and measures taken to implement these suggestions. An incident report including remedial measures shall be subject to evaluations and examinations of the top managers, Safety Committee, or laboratory director.

9.7 Training
Focusing on safe work behaviour and a safety training programme shall be implemented by the laboratory director for all laboratory workers including those personnel engaging in transportation
and cleanness.

Begin with a written plan, in which an all-around training programme shall include instructions for new employees and periodic retrainings aiming at experienced employees. Before starting work belonging to a specific field, employees are required to read the appropriate safety manual. In writing, an employee shall acknowledge that he/she has been appropriately trained and has read and understand the safety manual including its executive date.

A safety training programme at least includes the states of fire protection and readiness as well as protections from chemical and radiological safeties, biohazards and infections. Taking into account pregnancy, immune deficiency and disability, training courses shall be prepared based on employees’ posts. A system shall be built to evaluate each employee’s understanding ability of the given information.

It shall be ensured that all laboratory workers are trained on first aid. Articles and procedures shall be provided to reduce any unfavourable effects and incident occurrences involving potentially infectious materials, chemicals and hazardous substances.

Instructions for initial care shall be provided. When necessary, suitable measures of emergency medical treatment shall also be provided with respect to hazards that may arise in the laboratory.

All the employees shall know very well those procedures that shall be performed after being subject to punctures.

9.8 Personnel responsibilities

9.8.1 Foods, drinks and similar articles

Foods, drinks and similar articles shall be prepared and eaten or drunk in the designated areas. Human foods or drinks shall only be stored at special positions designated in non-laboratory areas. Refrigerators shall be labelled with specified purposes and smoking in the laboratory is prohibited.

9.8.2 Cosmetics, hair and jewellery

Applying cosmetics and handling contact lenses is prohibited in the laboratory working areas. Long hair shall be tied up at the back of head. Rings, earrings, wristwatches, bracelets, necklaces and other jewellery shall not be worn in the laboratory working areas.

9.8.3 Immune state

It is required that all the staff be immunised according to those organisms with which they may come into contact with so that infections are thereby prevented. An immunisation record shall be kept in the archives.

Plans for immunisation shall be prepared for specific laboratory according to a documented hazard assessment of infections in the laboratory and to suggestions from the local public health authorities.

9.8.4 Personal belongings

Personal belongings, clothing and cosmetics shall not be placed in areas where these articles are prohibited and where contaminations may arise.

10 Good behaviour concerning cleanness and tidiness

Personnel shall be designated specially to supervise behaviours regarding cleanness and tidiness in the laboratory. Working areas should be kept neat, clean, and free of large numbers of disposable materials that may cause risks of obstacles and stumbles.

In case of any leakage or other contaminations, all equipment and working surfaces on which contaminated materials are handled shall be cleaned and disinfected by applying the appropriate
reagents at the end of each shift work.
After hazard assessments, leaked specimens, chemicals, radionuclide or cultures shall be cleaned out and involved areas shall be decontaminated. When cleaning, the approved safety precautions, methods and personal protective equipment shall be employed.
In order to avoid any unknown risks or hazards, changes in behaviour concerning cleanliness and tidiness shall be reported to the laboratory director.
Changes in behaviour, working habits and materials in the laboratory, which may result in potential hazards to personnel engaging in cleanliness and tidiness and/or maintenances, shall be reported to the laboratory director. Moreover, managers in charge of personnel engaging in cleanliness and tidiness and/or maintenances shall also be informed of these changes in writing.
A dedicated specification, which aims at decontamination, cleaning and disinfection of each equipment after biological, chemical and radioactive contamination caused by accidents or leakage and before maintenances or repairs of equipments, shall be prepared.

11 Safe work behaviours

11.1 Hand washing
After actually or possibly coming into contact with blood, bodily fluid or other contaminated materials, laboratory workers shall immediately wash their hands even if gloves were worn.
Routine hand washing shall be done after removing gloves, before and after entering into the toilet room, before leaving the laboratory, before eating and smoking as well as before and after contact with each patient.
Substitutes that are used for hand washing shall be provided for laboratory workers who are sensitive to or adversely affected by special chemical compounds contained in some disinfectants and preservatives.
Hand-washing basins shall not be used for other purposes. Where use of hand-washing basins is restricted, the use of ethanol-based water-free hand cleaning products is an acceptable alternative method.

11.2 Safe work behaviour involving contacts with organism-borne materials
Regulations and procedures for handling, examining and disposing of organism-borne materials shall make use of good behaviour standards related to microorganisms.
Work behaviour shall reduce the risk of contamination. Furthermore, work behaviour in contaminated areas shall prevent personal exposure to the risk of contamination.
In order to prevent leakage and generating aerosols in the case of damages or leakage of specimens upon receipt, specimen containers shall be opened by trained personnel wearing personal protective equipment. This kind of containers should be opened in a biological safety cabinet. When it is considered that specimens are excessively contaminated or unacceptably damaged, they shall be discarded in a safe manner and the specimen containers shall not be opened.
Mouth pipetting is prohibited.
Laboratory workers shall be trained on the safe operations of sharp instruments and devices.
It is prohibited that any sharp instruments are cut, bent, clipped, recapped or needles are removed from syringes by hand. Safe work behaviour shall reduce the opportunities of using sharp instruments or shall use substitutes as much as possible.
All sharp instruments including needles, glass and disposable scalpels shall immediately be put into puncture-proof/puncture-resistant containers after use. When they are two-thirds full, sharp
All specimens, cultures and wastes shall be assumed carrying infectious biological agents, therefore, they shall be handled and disposed of in a safe way.

All substances, which require quality controls on potential infectivity or toxicity, shall be treated as specimens carrying unknown risks when storing, handling and using them.

In the whole course of the operations of specimens, serum or cultures, personal protective equipment being true of the corresponding risk level shall be worn.

Bite and scratch proof and water-proof personal protective clothing and gloves, appropriate eye and face protective equipment, and respiratory protective equipment when required, shall be worn when laboratory animals are operated on. Moreover, operations shall be performed in a biological safety cabinet.

Hands shall be completely washed after removing gloves.

If possible, microbiological transfer loops shall be sterilised with an electric steriliser using the burning method.

11.3 Aerosols

Work behaviour in the laboratory shall be designed and performed in a way that personnel can reduce the opportunities of coming into contact with chemical and organism-borne hazardous aerosols.

Specimens shall be centrifuged in a protective shield with a cover.

Specimens mixed in a vortex stirrer shall be placed in a container with a cover.

Large analytical equipment generating aerosols shall be provided with local ventilation protection.

When a small apparatus is operated, a customised exhaust hood shall be used.

Where hazardous gases or organism-borne aerosols may be generated, the measure of local ventilation shall be taken.

Breeding and operations on animals shall be performed with aerosol protective equipment.

Meanwhile, the staff shall use the appropriate personal protective equipment.

Hazardous aerosols shall not be discharged directly.

11.4 Biosafety cabinet and protective shield

In the places where laboratory workers will be exposed to hazard level I and II, the air in a biological safety cabinet can be recirculated if it passes through high efficiency filters before discharging. In the places where laboratory workers will be exposed to hazard level III or above, the air in a biological safety cabinet is prohibited from recirculation. Air in an animal laboratory is prohibited from recirculation.

A new biological safety cabinet and protective shield and their high efficiency filters shall be installed and replaced by the competent personnel. After installations or replacement, biological and physical examinations shall be on site according to the approved methods and verification shall be performed each year.

Biosafety cabinets in the laboratory shall be monitored often so as to ensure their design performances can meet the corresponding requirements. Examination records and functional test results of biosafety cabinets shall be filed. Moreover, biosafety cabinets shall be labelled with signs as evidence of examination.

The placement, design and types of biosafety cabinets shall be appropriate for the containment level that is required by a safe work place.

All biological safety cabinets shall be used in a way that deteriorations in performance can be
avoided. Ventilation of biosafety cabinets and chemical protection shields shall conform to the microbiological and (or) chemical risk level and safety requirements.

12 Chemical safety
In the laboratory, the regulations and procedures for storage, handling, use and disposal of chemicals shall conform to the good behaviour standards of a chemical laboratory. According to the relevant standards, each storage container shall be labelled with each product’s hazardous properties and risks. Furthermore, a container of materials in use shall also be clearly labelled.

Adequate and available control measures shall be taken for chemical, physical and fire hazard. These measures shall be regularly supervised to ensure their effectiveness and availability. Additionally, supervision results shall be filed. All the staff shall be required to work according to the safety operation specification, including the use of safety equipment or installations that are deemed appropriate for their work. Written the procedures shall be available for discarding and the safe disposal of all chemicals used in the laboratory. Full and detailed descriptions on the relevant laws and regulations shall be included in these written procedures to guarantee complete conformity with the requirements, which enable these substances to separate from the controls of the laboratory.

13 Radiological safety
Before the approved use of radionuclide, the laboratory director shall evaluate the reason, limitation and place of use. Adequate records of the retrieval, use, and disposal of radionuclide shall be filed. Storages of all radioactive chemicals shall be safe and secure.

All laboratory workers who operate or come into contact with radionuclide shall be instructed and trained on the basic knowledge of radiation, relevant technologies and radioactivity protections so that they can follow regulations and procedures regarding radioactive safety. Written standard operation procedures and relevant laws and regulations that are appropriate and meet the demands of the work shall be available. The procedures shall include clear operation instructions, abstracts of operation instructions highlighted at the place where radionuclides are used and a detailed description of actions taken in the events of radiation accidents and leakages. Procedures shall describe in detail the methods that radioactive substances and materials mixed with or contaminated by radioactive substances are disposed safely. Approved warning and prohibiting symbols and signs shall be made public.

Laboratories engaging in radiation work shall consult the relevant competent authorities for radioactivity protection and legal requirements including all the requirements on laboratory design and equipment standards. Furthermore, appropriate measures shall be prepared to ensure abidance by these requirements. A safety supervisor shall be appointed by the laboratory to specially be responsible for the design, performance and maintenance of enforceable radioactivity protection programme. For the purpose of the performance of good behaviour concerning radioactivity protection, several supervisors shall be appointed to supervise the routines involving ionizing radiation.
A systematic supervision programme shall be prepared to ensure that the overall and regular supervision can be carried out at work places. Moreover, the supervision records shall be filed. Routine cleaning and decontamination specifications shall be prepared and implemented. Uses of radionuclides shall be regularly evaluated and examined and work behaviour shall be regularly supervised and renewed in a timely manner. Changes in remedial measures and programmes shall be filed for a regulated period. Radiological wastes shall be labelled with signs and stored in a dedicated, safe, and radiation-proof storage warehouse. Risk properties and groups shall be clearly labelled on each package to be discarded. Storage and disposal shall observe the relevant regulations.

14 Ultraviolet rays and laser sources (including light rays from a high-intensity light source)

Applicable and adequate personal protective equipment shall be provided and the appropriate signs shall be made public at places where ultraviolet rays and laser sources are used. Additionally, trainings shall be carried out for the safe use of the equipment. These light sources shall only be used for their designed purposes.

15 Electrical installations

Electrical installations shall be designed and manufactured in a way that the relevant safety standards are observed. In order to ensure safety, some electrical installations shall be connected with a standby power supply. Before electrical safety tests are performed by competent personnel (such as competent electricians or biomedical engineer) and conformities with operating requirements, new, modified and repaired electrical installations shall not be put into operation. Operators of electrical installations shall be trained for the proper operations and the operation mode shall not lower the electrical safety. Operators of electrical installations shall regularly inspect damages that may result in electrical failures. Only competent personnel are authorised to engage in works involving electrical equipment and circuits. Performances of any unauthorised works are prohibited. Measures shall be taken to decontaminate equipment and thereby the risk of chemical or biological contaminations can be reduced for the maintenance personnel.

16 Fire protection

The fire rating of the building shall be determined according to the hazards in the laboratory. A primary exit route shall be designated and auxiliary exits shall be provided to guarantee that the workers can safely evacuate from the laboratory. A specified emergency exit shall lead to a fireproof area. An automatic smoke and heat detection and alarm system shall be provided in all laboratory areas where combustible gases or liquids are used or stored. An alarm system shall be subject to regular inspections for its proper functions and all the personnel shall know very well its operations. All laboratory workers and personnel in buildings shall be instructed and trained in fire protection, including:

1) Identification and evaluations of fire risks;
2) A programme prepared to reduce fire risks;
3) All actions taken during an accidental fire;
Appropriate equipment, which meet the relevant requirements, shall be provided on site to extinguish a controllable fire disaster and help personnel evacuate from the fire. It is shall be emphasised that laboratory workers are responsible for ensuring that the personnel evacuate in a safe and orderly way rather than trying to extinguish the fire. Assistance from the fire department shall be sought if necessary.

17 Flood damage and other natural disasters
Emergency plans shall be prepared in advance for disasters. If possible, rescue workers shall, in advance, learn the properties, quantities, and storage locations of hazardous substances, including the layout and equipment of the laboratory.
In case of flood damage, earthquake or other natural disasters, measures shall be taken to isolate the contaminated areas and contamination sources based on the seriousness of the damages of the buildings and laboratories. Moreover, emergency measures such as effective disinfection and personnel evacuation etc. shall also be taken. Further measures shall be available according to the evaluations on the hazards. A disaster reporting system shall be established.

18 Emergency evacuation
An action plan shall be prepared for emergency evacuations. This action plan shall take into account the biological and chemical properties, accidental fire and other emergencies, including those measures that enable left buildings to be in a safe status.
All personnel shall learn the action plan, evacuation routes, and venues of an emergency evacuation.
All personnel shall participate in at least one fire drill each year.
The laboratory director shall ensure that the laboratory is provided with the available equipment that is required by first aid and emergency procedures.

19 Transport of specimens
The appropriate instructions and directions shall be made by the laboratory director for those places where specimens will be delivered to the laboratory.
All specimens shall be transported to the laboratory in a manner that workers, patients or the environment can be prevented from contamination.
Specimens shall be transported in approved, intrinsically safe, and leak-proof containers.
The transport of specimens within those buildings affiliated with the institution shall comply with the safety and transportation regulations. When specimens are transported to the outside of the institution, the prevailing laws and regulations concerning the transportation of infectious and other biological materials shall be observed.
Specimens, cultures, and other biological materials shall be transported between the laboratory rooms or between other institutions in a way that conforms to the corresponding safety regulations.
The relevant international and national requirements regarding road, railway and waterway transportations of hazardous materials shall be followed. When the materials that are considered hazardous according the national or international standards are planned to be transported by air at home or abroad, the packages, labels, and information shall be provided according to the requirements of the prevailing national or international standards.
Waste disposal

Waste disposal shall be managed according to the relevant national, regional and local requirements.

The purposes of the management of laboratory waste are as follows:
1) To minimise the risks of operating, collecting, transporting, handling and disposing of wastes;
2) To minimise the hazards of wastes on the environment;
All specimens, cultures and other biological materials that are not required any more shall be discarded and put into specially designed and labelled containers dedicated for disposing of hazardous wastes. Containers of biological wastes shall not be filled with wastes that are to go beyond its designed capacity.

Sharp objects including needles, knives, metals and glass shall be directly put into puncture-proof/puncture-resistant containers.

The laboratory managers shall ensure that the appropriate personal protective devices and equipment are used by properly trained personnel when hazardous wastes are handled.
Trashes and laboratory wastes are prohibited from piling up and full containers shall be carried away regularly. Before decontamination or final disposal, trash and laboratory wastes shall be stored at specified places that are usually located in the laboratory areas.
Before being taken away from the laboratory, all the discarded biological specimens, cultures and contaminated wastes of laboratory shall be made biologically safe.

Biological safety can be achieved by means of autoclaving or other approved technologies.
Laboratory wastes shall be placed in appropriately sealed and leak-proof containers and transported out of the laboratory.
Hazardous gases, aerosols, effluents and liquid wastes shall be discharged after innocent treatment conforming to the relevant national requirements.

Disposal and incineration of carcasses and tissues shall comply with the relevant national requirements.

References
[5] ISO15190:2003(E), Medical Laboratories - Particular Requirements for Quality and Competence
[8] GB 14925—2001 Laboratory Animals - Environment and Facilities
[9] GWKB 2—1999 Pollution Control Standards for Hazardous Wastes Incineration
General Biosafety Standard for Microbiological and Biomedical Laboratories

Health Industry Standards of the People's Republic of China (WS 233-2002)

Promulgated on 3 December 2002 and implemented on 1 August 2003
General Biosafety Standard for Microbiological and Biomedical Laboratories

1. Scope
As minimum requirements, the standard specifies the basic principles for biosafety containment for Microbiological and Biomedical Laboratories, as well as the laboratory level and basic requirements of laboratories at various levels.
The standard is applicable to Institutions of Disease Prevention and Control, Medical and health Institutions as well as Science and Research Institutions.

2. Documents referenced by the standard
The provisions in the following documents become a part of the standard by means of reference.
All the referenced documents with a date and all the following amendments (not including corrigenda) or revised edition are not applicable to the standard, meanwhile all the parties that are to reach agreements based on the standard are encouraged to investigate the feasibility of using the latest editions of these documents. As for referenced documents without a date, their latest editions are applicable to the standard.
GB 14925—2001 Laboratory Animals - Environment and Facilities
GB/T 16803—1997 Equipment of Heating, Ventilating, Air Conditioning and Air Cleaning Terminology
GB 50073—2001 Design Code for Clean Factory Buildings
JGJ 71—1990 Specification for the Construction and Acceptance of a Hygienic Room

3 Definitions
The following definitions are adopted by the standard.

3.1 Biosafety protection for laboratories
When target experiment objects that are handled by laboratory workers carry pathogenic microorganisms and toxins, integrated measures such as the construction and use of personal protective equipments in the laboratory, strict observance of standardised work and operation procedures and specifications shall be taken to prevent the laboratory workers from infections and surrounding environment from contaminations.

3.2 Hazard assessment for microbes
Assessments that are carried out on the hazards may be caused by the microorganisms and toxins that are used in the laboratory for personnel or environment.
3.3 Aerosol
A peptised and dispersed system that is formed by solid and liquid particles with 0.001\(\mu\)m~1000\(\mu\)m diameter suspended in gas media.

3.4 Biosafety cabinet
Cabinet-shaped safety equipment that is used to purify air when hazardous microorganisms are handled.

3.5 Class I Biosafety Cabinet
At least one high-efficiency particulate air filter is provided for purifying exhaust gas. During operations, a sliding glass window on the front face of a biological safety cabinet is half-opened. The upper part is a sight window and the lower part is an operating window and, therefore, the air outside can be sucked in and cannot escape from the operating window. When operating the cabinets, laboratory workers can be assured that they will not get hurt but it is not guaranteed that the target experiment objects are prevented from contaminations.

3.6 Class II Biosafety Cabinet
At least one high-efficiency particulate air filter is provided for purifying exhaust gas. A directional flow that is purified by the high-efficiency particulate air filter is generated in the workspace without air eddy. During operations, a sliding glass window on the front face of a biological safety cabinet is half-opened. The upper part is a sight window and the lower part is an operating window and, therefore, the air outside can be sucked in and cannot escape from the operating window. When Class II Biosafety Cabinets are operated according to the procedures, not only laboratory workers but also products can be assured that they will be prevented from infections or contaminations.

3.7 Class III Biosafety Cabinet
At least one high-efficiency particulate air filter is provided for purifying exhaust gas. A directional flow purified by the high-efficiency particulate air filter is generated in the workspace without air eddy. A sight window is arranged at the upper part of the front face and a glove-box operating opening is arranged at the lower part of the front face. A negative pressure to the surrounding laboratory shall be maintained to ensure a thorough isolation of humans from the articles in the biological safety cabinet.

3.8 Physical containment device
A device used to prevent pathogenic microorganisms from escaping by physical or mechanical means.

3.9 HEPA (high efficiency particulate air) filter
An air filter provided with collection efficiency of more than 99.97% for particles with a diameter larger or equal to 0.3\(\mu\)m and gas-flow resistance less than 245Pa when at the rated airflow.
3.10 Relative pressure
A value obtained by subtracting the absolute pressure from the atmospheric pressure.

4. Basic principles related to the biosafety containment of the laboratory.

4.1 General provisions
4.1.1 Biosafety containment of the laboratory shall include the safety equipments, personal protective equipments and measures, requirements for special design and construction of laboratory, strict management system and standardised procedures and specifications.

4.1.2 All the measures that involve biosafety containment throughout the process from the project approval, to the construction, use and maintenance of a specific laboratory, shall be included in the laboratory biosafety manual. A full-time biosafety director shall be appointed.

4.1.3 Based on different microorganisms and the protection requirements, the biosafety containment levels of the laboratory are classified into four levels.

4.2 Safety equipment and personal protective equipment
Safety equipment and personal protective equipment make up the first barrier to ensure laboratory workers who are directly in contact with pathogenic microorganisms and toxins thereof.

4.2.1 As the most important safety equipment, biosafety cabinets form a major protective barrier. Class I, II and III biosafety cabinets shall be respectively provided for the laboratory as required. All the operations that aerosols may be splashed or generated by pathogenic microorganisms and toxins, except those that are unenforceable, must be performed in biosafety cabinets. It is prohibited to use a clean-air workstation to substitute a biological safety cabinet.

4.2.2 If necessary, the laboratory shall be provided with other safety equipment, such as an exhaust hood that is equipped with an exhaust purification device or other safety equipment in turn preventing microorganisms from escaping.

4.2.3 Centrifuges equipped for the laboratory shall be used in a biological safety cabinet or in other safety equipment that is specified in provision 4.2.2, otherwise sealed centrifuge safety cups must be used.

4.2.4 Laboratory workers shall be provided with the necessary personal protective equipment.

4.3 Special requirements for the design and construction of the laboratory
These include special requirements for site selection and the layout of the laboratory as well as for the design and construction of the building enclosure, ventilation and air-conditioning, safety device and special equipment.

4.4 Safety operation specification
4.4.1 Safety operation specifications regulated for the biosafety containment laboratory, including the standard and special safety operation specifications (see annex A), must be clearly listed in the laboratory biosafety manual and be performed.
4.4.2 The special safety operation specifications, which shall be supplemented in turn aiming at different microorganisms and toxins, shall also be clearly listed in the various laboratory biosafety manuals and be subsequently implemented.

4.5 The transport of pathogenic microorganisms and toxins thereof between laboratories.
The transport of pathogenic microorganisms and toxins thereof between laboratories shall be performed strictly according to the prevailing and relevant national administrative measures.

4.6 Management system
4.6.1 Basic management of the laboratory
4.6.1.1 Admission and layout of the laboratory
a) Decontamination area, semi-contaminated area and contaminated area shall be reasonably arranged in the main laboratory;
b) No personnel or articles should be admitted other than those involved in the work of the laboratory;
c) No Eating, drinking or other activities are allowed other than those involved in the work of the laboratory;
d) Only after the approvals of the laboratory director, laboratory workers and co-operators from other institutions and the personnel engaging in advanced studies can enter into the laboratory and work places.
4.6.1.2 Competencies and trainings of laboratory workers.
a) Laboratory workers must be technicians who are professionally educated. They can start work only after undergoing pre-career trainings under the direction of intermediate and senior laboratory technicians and achieve the criterion of acceptability.
b) Laboratory workers shall be informed of the potential hazards in the laboratory and shall receive safety education concerning the laboratory. Moreover, they shall be voluntarily engaged in laboratory works.
c) Laboratory workers must follow all the regulations and operation specifications.
d) Before starting work, workers in containment laboratories – Biosafety Level 3 and 4 must leave background serum for the relevant inspections. Thereafter, regular inspections shall be performed. These workers must be subject to immunisation injections if the respective vaccines are available.
4.6.2 Laboratory special management

In order to avoid and handle accidents that are caused by unsafe operations, the following principles shall be strictly followed:

4.6.2.1 With respect to potential hazard factors, work procedures shall be prepared to guarantee safety.

4.6.2.2 Effective drills and simulation trainings shall be performed in advance.

4.6.2.3 In the event of accidents, measures including first aid and professional health and care shall be available to deal with any such emergencies.

4.6.2.4 The handling of laboratory accidents: all incidents arise during operations by workers, such as needle-stick injuries, cuts, contamination of skin, splashes of infectious specimens onto body surfaces or into the mouth, nose, or eyes, contamination of clothing and bench tops, shall all be considered as accidents. First aid shall be performed based on different situations such as the types of accidents. Specific measures shall be documented and strictly followed and performed. During first aid, the accident conditions, including a detailed record of the accidents and specific positions and seriousness of any damages, shall be reported to the relevant specialist and leaders who are responsible for evaluating the necessity of prophylactic treatments.

4.6.2.5 A formal accident record form shall be filled out and reported to the competent national Department of Health at the corresponding level.

4.7 Hazard assessment for microorganisms

Before the construction of laboratories that involve the use of infectious or potentially infectious materials, the hazards of microorganisms shall be assessed. The hazards of microorganisms shall be assessed based on the pathogenicity of microorganisms, transmission route, and stability of microorganisms, infective dose, concentration, and volume of the agent during operation, origin of product and other factors such as availabilities of data of animal experiments, precautions, and therapy methods etc.

4.7.1 By means of a hazard assessment for microorganisms, the biosafety level of containment laboratories wherein the microorganisms is operated shall be determined.

4.7.2 According to the results of the hazard assessment, corresponding operation specifications, management system of the laboratory and disposal methods of emergencies shall be prepared in written form and shall be strictly followed and performed.

5. Categorisation, classification, and the applicable scope of a laboratory

5.1 Categorisation

5.1.1 Normal biosafety containment laboratory (no laboratory vertebrates and insects are used)

5.1.2 Biosafety containment laboratory for laboratory vertebrates

5.2 Classification

Biosafety containment laboratories of each classification are classified into four levels according to the microorganisms and toxins thereof that are dealt with in the laboratory. The biosafety containment
requirements of laboratories at the various levels are as follows: lowest requirements for level 1 and the highest requirements for level 4.

5.3 Scope of application

5.3.1 General biosafety containment laboratory

5.3.1.1 Level-1 biosafety containment laboratory
Laboratory structures and facilities, safety operation specifications, and safety equipment are applicable to those microorganisms that are nonpathogenic for healthy adults, such as normal microbiological laboratories used for teaching.

5.3.1.2 Level-2 biosafety containment laboratory
Laboratory structures and facilities, safety operation specifications, safety equipment is applicable to microorganisms that are potentially and moderately hazardous to personnel and environment.

5.3.1.3 Level-3 biosafety containment laboratory
Laboratory structures and facilities, safety operation specifications, safety equipment are applicable to the microorganisms and toxins thereof that cause the personnel to be infected with serious or lethal diseases though the respiratory tract. In this case, vaccines are usually available to prevent infections. Research in AIDS related viruses (except serological experiments) shall be carried out in level-3 biosafety containment laboratories.

5.3.1.4 Level-4 biosafety containment laboratory
Laboratory structures and facilities, safety operation specifications, and safety equipment are applicable to those microorganisms and toxins thereof that are highly hazardous to humans and that are transferred through the route of aerosols or other unknown routes. Furthermore, no effective vaccines or therapy methods are available. Unknown microorganisms similar to those aforesaid also must be operated in level-4 biosafety containment laboratories. After the adequate data are available, these microorganisms or toxins are then determined to be handled in level-4 biosafety containment laboratories or in laboratories that have a lower level.

5.3.2 The applicable scope of microorganisms of biosafety containment laboratory for laboratory vertebrates is the same as that of a normal biosafety containment laboratory at the same level.

6. Basic requirements for normal biosafety containment laboratory

6.1 Level-1 biosafety containment laboratory

6.1.1 Safety equipment and personal protective equipment
6.1.1.1 Usually, no dedicated safety equipment such as a biosafety cabinet is required.
6.1.1.2 Laboratory workers shall wear smocks and goggles when working.
6.1.1.3 Laboratory workers shall wear gloves when there are damages or tetter on skin.

6.1.2 Special requirements for the design and construction of a laboratory.
6.1.2.1 Hand-washing basins, if possible, should be provided in each laboratory room, preferably near the exit door.

6.1.2.2 Inside surfaces of building enclosures of a laboratory shall be easy to clean. Without cracks, all floor surfaces shall be slip-resistant. No carpet shall be laid on the floors.

6.1.2.3 Bench tops should be impervious to water and resistant to corrosion and heat.

6.1.2.4 Laboratory furniture shall be sturdy. For the purpose of convenient cleaning, stages (racks) shall be remained at places between furniture and equipment.

6.1.2.5 When windows can be opened, they should be fitted with screens.

6.2 Level-2 biosafety containment laboratory

6.2.1 Safety equipment and personal protective equipment

6.2.1.1 All operations that aerosols may be splashed or generated by pathogenic microorganisms must be performed in biosafety cabinets (level II biosafety cabinet is preferable) or in other physical containment devices. Moreover, personal protective equipment shall also be used.

6.2.1.2 Large volumes and/or high concentrations of microorganisms shall be operated in biosafety cabinets (level II biosafety cabinet is preferable) or in other physical containment devices. Moreover, personal protective equipment shall also be used.

Such materials may be centrifuged in the open laboratory if sealed centrifuge rotors or centrifuge safety cups are used and if they are loaded and unloaded in a biosafety cabinet.

6.2.1.3 When microorganisms cannot be loaded in, and must be operated outside the biosafety cabinet, face protective equipment such as goggles, face shields, respiratory protections or other splash-proof protective equipment shall be used to prevent hazards caused by splashes or the atomisation of infectious materials.

6.2.1.4 Protective laboratory clothing such as a smock and coveralls shall be worn in the laboratory areas. When one leaves the laboratory, protective clothing must be taken off and left in the laboratory. It is prohibited to wear protective laboratory clothing outside the laboratory or to take them home. After use, the protective clothing shall be firstly disinfected in the laboratory and then be washed or discarded in a uniform way.

6.2.1.5 Gloves shall be worn when one’s hands may come into contact with infectious materials, contaminated surfaces or equipment. It is reasonable to wear double gloves when infectious materials may spill or splash. Gloves should not be worn outside the laboratory areas. Gloves shall be removed only after work. Gloves for one-time use shall not be washed and reused.

6.2.2 Special requirements for the design and construction of a laboratory.

6.2.2.1 Level-2 biosafety containment laboratories must meet the requirements of various provisions in article 6.1.2.

6.2.2.2 Facilities of various disinfection measures such as autoclave, chemical disinfection devices, etc. shall be provided to handle wastes.

6.2.2.3 Eyewash facilities shall be provided.
6.2.2.4 Self-closing laboratory doors shall be preferably provided with a lock.

6.2.2.5 Luminous indication signs shall be provided at all laboratory exits.

6.2.2.6 Times of ventilation and air change in the laboratory shall not be less than 3-4 in each hour.

6.3 Level-3 biosafety containment laboratory

6.3.1 Safety equipment and personal protective equipment.

6.3.1.1 Biosafety cabinet at Class II or above must be provided in the laboratory.

6.3.1.2 All operations with infectious materials are conducted within a biosafety cabinet. When this kind of operations has to be conducted outside the biosafety cabinet, integrated protection measures combining personal protection equipment and physical containment equipment shall be used.

6.3.1.3 When handling culture infectious tissues and performing operations that may generate infectious aerosols, personal protective equipment must be used.

6.3.1.4 When aerosols cannot be effectively contained within a limited area, respiratory protections shall be employed.

6.3.1.5 Before entering into laboratory working areas, laboratory workers shall wear back-opening smocks or other protective clothing in the dedicated changing rooms or anteroom. Smocks must be taken off after work and shall not be worn outside the laboratory. Reusable smocks must be firstly disinfected and then washed.

6.3.1.6 Gloves (double gloves are preferred) must be worn during work. Disposable gloves must be firstly disinfected before being discarded.

6.3.1.7 Effective disinfectants, eye cleaning agents or physiological saline, which are easily available, shall be provided in the laboratory. Moreover, medicines shall be provided for use in case of an emergency.

6.3.2 Special requirements for the design and construction of a laboratory.

6.3.2.1 Site selection

Level-3 biosafety containment laboratories can be located in a same building wherein the premises that are being used for other purposes are located, but it must be located in an area that is separated by a isolation door from the public corridor or public area.

6.3.2.2 Layout

a) Major areas of a level-3 biosafety containment laboratory shall consist of laboratory rooms and anterooms connecting with the laboratory rooms.

b) Anteroom also serves as an access to the laboratory room. Two interlocked doors must be provided. When one door is opened, the other door is to be automatically locked. In the case of dynamoelectric interlocking device, two doors must be openable when there is a power failure. Clothing can be changed for a second time in the anteroom.

c) When no automatic control devices are provided for the ventilation system of the laboratory, the area of the anteroom shall not be too large and shall not be more than one-eighth of the laboratory room’s area.

d) Safety devices of Class II and III Biosafety cabinets should be situated away from entrances of laboratory
rooms and from walking areas, which shall help form a directional airflow from “clean” areas to “contaminated” areas.

6.3.2.3 Building enclosure

a) Inside surfaces of the building enclosures of the laboratory shall be smooth, impervious to water and resistant to corrosion as well as easy to be disinfected and cleaned. All cracks must be sealed reliably.
b) All laboratory doors can be closed automatically.
c) Except for a sight window, no other windows shall be provided. With airproof structures, the sight window shall have shatterproof glass.
d) Floor surfaces shall be leak-proof, clean, and smooth, but not slippery. Floor surfaces made of ground tiles and terrazzo etc. and with cracks shall not be adopted.
e) Adjoining positions between the ceilings, floors, and walls shall take the form of an arc and be reliably sealed. During construction, insects and rats shall be prevented from entering into the basement.

6.3.2.4 Ventilation and air condition

a) Separate ventilation and air conditioning system shall be installed to control the direction and pressure gradient of the airflow in the laboratory. When the laboratory is being operated, the ventilation and air conditioning system must ensure that the indoor air is discharged through exhaust ducts rather than through other positions or gaps of the laboratory after it goes through high-efficiency particulate air filters. Meanwhile, it must be ensured that the air in turn flows from the decontamination area to the contaminated area in the laboratory. Arrangement of air inlets and outlets shall minimise the dead spaces in the laboratory areas.
b) Ventilation and air conditioning system shall be a non-recirculating ventilating system and no air return system shall be adopted as a part of the ventilation and air conditioning system.
c) Environmental parameters: a negative pressure shall be kept in the laboratory in relation to the air pressure outside the laboratory. Preferably, the relative pressure in the laboratory shall be kept at -30Pa～-40Pa and the relative pressure in anteroom shall be kept at -15Pa～-20Pa. It is reasonable that the temperature and humidity in the laboratory are kept at a comfort level for the human body or determined as per the process requirements. Air cleanliness in the laboratory shall be reasonably maintained at grade 7 or 8 as defined in GB 50073—2001 《Design Code for Clean Factory Buildings》. With illuminance equal to or higher than 500 lx, artificial illumination in the laboratory shall be even and shall not be dazzling.
d) For the purpose of the airflow direction from the decontamination area to the contaminated area, the layout that the air outlets are evenly arranged at both sides of the laboratory shall not be adopted. The ventilation system shall not be designed in a way that the air is sent or discharged upwards. After it passes through high-efficiency particulate air filters, the air discharged by biosafety cabinets can be directly discharged into the atmosphere or sent into the building’s exhaust system through exhaust ducts. Pressure balance between the biosafety cabinet and exhaust system shall be ensured.
e) The inlet air of the laboratory shall be subject to primary, intermediate, and high-efficiency filtration.
f) After being subject to high-efficiency filtration and disposed of by means of another method, the exhaust air of the laboratory shall be directly discharged into the atmosphere at a speed of no less than 12ms. This air outlet shall be kept away from air inlet. After treatment, the exhaust air can be discharged into the exhaust ducts, but shall not be sent back into any areas inside the building.

g) In order to avoid contaminating the exhaust ducts, high-efficiency filters of the inlet air and outlet air must be installed at the air ports of the building enclosure of the laboratory.

h) In the ventilation system of the laboratory, airtight modulating valves shall be installed at the inlet and exhaust header. If necessary, chemical fumigation can be performed in the laboratory after the airtight modulating valves are completely closed.

i) All of the components used in the ventilation system of the laboratory shall be airtight. No wood frames shall be used for high-efficiency particulate air filters.

j) An automatic interlocking device shall be installed for the starting of a fan to ensure that the exhaust fans are started and then supply fans are started when the laboratory is operated. After work, supply fans are stopped firstly and then exhaust fans are stopped.

k) No split air conditioner shall be installed in laboratory.

6.3.2.5 Safety devices and special installations

a) Main laboratory shall be provided with Class I, II, and III biosafety cabinets whose installation position shall meet requirements of provision d) in article 6.3.2.5.

b) Continuous centrifuges or other equipment that may generate aerosols shall be positioned in physical containment equipment, which can discharge any possibly generated aerosols after the filtration of high-efficiency particulate air filters. Air that is discharged by other exhaust devices such as a fume chamber and exhaust hood etc. that are required in the laboratory must be discharged after the filtration of high-efficiency particulate air filters. Arrangement in the laboratory shall be favourable to air flow direction from the decontamination area to the contaminated area.

c) Laboratory must be provided with autoclave or other disinfection devices that do not generate steam.

d) Pass-through window shall be arranged between the laboratory room and outside. Double doors of the pass-through window shall not be opened at the same time and the physical disinfection devices shall be arranged in the pass-through window. Infectious materials must be delivered through a pass-through window only after being placed in a closed container.

e) Pressure indication and alarm devices shall be arranged at prominent positions of the laboratory exits to show the negative pressure in the laboratory rooms and anterooms. When the indication of negative pressure deviates from the pre-set range, alarms can be sent to the personnel outside the laboratory acoustic and optical signals. Additionally, indicating devices can be supplemented to show the air flow resistances of high-efficiency particulate air filters of the supply and exhaust air.

f) Duplicate power supplies must be used because power failure is impermissible during the operations of the
laboratory. If it is impractical to use duplicate power supplies, stand-by or uninterruptible power supplies that can be automatically switched in the event of power failure shall be installed to supply power for major equipment such as a biosafety cabinet, fume chamber, and exhaust hood and lighting facilities, etc.

g) Anterooms shall be provided with hand-washing basins whose faucets shall be foot, elbow or automatically controlled. Where hand-washing basin is arranged in the main laboratory, sanitary sewers must be completely isolated from the building’s sewer pipes and shall be labelled with eye-catching signs. All the effluents must be subject to disinfections and disposals. Hand-washing basins are only used for hand washing and no infectious materials shall be dumped into them. Anti-backflow devices must be fitted for water supply pipes and no floor drains shall be installed in the laboratory.

6.3.2.6 Other requirements

a) Bench tops should be impervious to water and resistant to corrosion and heat.

b) Laboratory furniture shall be sturdy. For the purpose of convenient cleaning, laboratory equipment shall be reasonably spaced between each other; Stages (racks) dedicated to storing biological wastes shall be provided. Edges and protruding positions of furniture and equipment shall be smooth, free of burrs and preferably rounded.

c) The required vacuum pump shall be arranged in the laboratory. Vacuum pipelines must be provided with online high-efficiency particulate air filters.

d) Steel cylinders of compressed air shall be placed outside the laboratory. Positions between the pipes passing through the building enclosure and building enclosure must be sealed with unshrinkable sealing materials. Gas pipelines must be provided with online high-efficiency particulate air filters and anti-backflow devices.

e) Eyewash facilities shall be provided in the laboratory.

f) Luminous indication signs shall be provided at all laboratory exits.

g) A communication system must be provided outside the laboratory.

h) Information such as experiment records shall be sent outside the laboratory by means of electrograph.

6.4 Level-4 biosafety containment laboratory

Level-4 biosafety containment laboratory is classified into cabinet laboratory and positive-pressure suit laboratory. In a cabinet laboratory, all microorganisms shall be operated in Class III biosafety cabinets. When in a positive-pressure suit laboratory, all laboratory workers shall wear special positive-pressure protective suits.

6.4.1 Safety equipment and personal protective equipment

6.4.1.1 All infectious materials in the laboratory must be operated in Class III biosafety cabinets. Where laboratory workers wear integral positive-pressure suits with a air supply system supporting life, the relevant operations can be performed in Class II biosafety cabinets.

6.4.1.2 When entering into the laboratory, all workers shall change their daily clothing into a complete set of laboratory suits including underclothes, shirts or union suits, shoes and gloves. All of these protective suits
shall be taken off in the changing rooms before taking a shower or leaving the laboratory.

6.4.2 Special requirements for the design and construction of a cabinet laboratory.

6.4.2.1 Site selection. Laboratory shall be constructed in a separate building or in a separate area of a building.

6.4.2.2 Layout

a) The core areas of the laboratory shall consist of rooms in which Class III biosafety cabinets are installed and accessed. Access shall consist of at least three parts, including an outer changing room, a shower room and inner changing room. An automatic interlocking device shall be installed between any adjacent doors to prevent two adjacent doors from being opening at the same time. As for supplies, articles and materials that are not brought into the cabinet room through the changing area, a double-door autoclave, a liquid dunk tank, fumigation chamber or a pass-through window with disinfection devices shall be arranged on the walls of the biosafety cabinet so as to perform pass-through or disinfections of these supplies, articles and materials. An emergency exit with an airlock must be arranged.

b) Transition zone, which is a circular corridor or an anteroom and is a part of the core area, may be arranged around the biosafety cabinet room. Construction requirements of the transition zone shall be the same as that of a level-3 biosafety containment laboratory.

6.4.2.3 Building enclosure

a) Walls, floors and ceilings etc. of the biosafety cabinet room and inner changing room shall form a sealed inner enclosure. The floors shall be sealed as a whole and the corners of the walls shall take the form of an arc. Inside surfaces of the rooms shall be impervious to water and resistant to corrosion and all gaps or cracks in the enclosure shall be sealed. For the purpose of convenient disinfection, gaps or cracks surrounding a biosafety cabinet and inner changing room shall be reduced and can be sealed. All sanitary sewers on the floors of biosafety cabinet room shall directly lead to a liquid disinfectant system. High-efficiency particulate air filters shall be installed at the manholes of sanitary sewers and pipelines used for other services, in which hazardous insects shall be prevented from entering into these manholes.

b) Provided with a lock, a door through which workers enter into the laboratory can be automatically locked. Double doors, with an automatic interlocking device between two doors, must be provided for all facilities through which articles are passed between the inside and outside of the laboratory.

c) All windows must be break-resistant and sealed.

d) At the wall opening, a double-door autoclave shall be installed to disinfect the articles passed from Class III biosafety cabinet and biosafety cabinet rooms. The outer door shall be opened from outside the laboratory. All gaps or cracks must be sealed well.

6.4.2.4 Ventilation and air condition

a) A deliberately designed non-recirculating ventilating system shall be installed. Air supply and exhaust of the system shall be designed in a way that a directional airflow from the area of the least hazard to the area(s) of greatest potential hazard can be ensured. Arrangement of air inlets and outlets shall minimise any dead
spaces in the laboratory areas.

b) Pressure differences and airflow direction between adjacent areas shall be monitored and alarms shall be installed. At the entrance of the outer changing room, an instrument panel shall be installed to display and monitor the pressure, pressure difference and volumes of air supply and exhaust in various areas of the laboratory.

c) In order to avoid positive-pressure in the laboratory and maintain proper pressures in and the pressure differences among various rooms, an automatic control and alarm device shall be designed and installed. Air from Class III biosafety cabinet must be directly discharged into the exhaust ducts. Exhaust ducts shall be separately arranged without a connection with the exhaust system of the building.

d) Environmental parameters: biosafety cabinet rooms shall be kept at a maximum positive pressure and its relative pressure shall not be higher than -60Pa; Relative pressure in the biosafety cabinet rooms, inner changing rooms, shower rooms and outer changing rooms shall be increased in sequence. The pressure difference between 10Pa-15 Pa shall be maintained between the adjacent rooms. Air cleanliness in the core areas shall be reasonably maintained at grade 7 or 8. With illuminance equal to or higher than 500 lx, artificial illumination in the laboratory shall be even and shall not be dazzling.

e) A three-stage filtration system shall be arranged for the air supply and the supplier air must be subject to the filtration of high-efficiency particulate air filters.

f) Exhaust air from the whole core area must be subject to the continuous filtration of two high-efficiency particulate air filters. An air outlet shall be kept away from the laboratory working areas and air inlets.

g) In order to avoid contaminating the exhaust ducts, high-efficiency filters of inlet air and outlet air must be installed at the air ports of the building enclosure of various laboratory rooms. On-site disinfections must be carried out for the structures of air vents of high-efficiency particulate air filters before these high-efficiency particulate air filters are changed. In the case of a filter structure that can be replaced in a airtight bag, high-efficiency particulate air filters can be disinfected or incinerated later. Each high-efficiency particulate air filter must be inspected before and after installation. After put into operation, high-efficiency particulate air filters also shall be inspected one time each year.

6.4.2.5 Safety devices and special installations

a) Class III biosafety cabinets must be arranged in biosafety cabinet rooms.

b) Doors of the autoclave shall be automatically controlled; The outer door cannot be opened unless the autoclave has been first operated through a sterilisation cycle.

c) As regards articles that come from Class III biosafety cabinets and biosafety cabinet rooms and cannot be autoclaved, double-door liquid dunk tank and fumigation chamber or a airlock used for ventilation and disinfection shall be provided for the disinfection of these articles so as to guarantee safety.

d) In the case of a central vacuum pipeline system, it shall not be used in spaces outside the biosafety cabinet rooms. As much as possible, online high-efficiency particulate air filters shall be located at the positions close to each point of use or valve. High-efficiency particulate air filters shall be easily disinfected or replaced on-site. Anti-backflow devices shall be provided for air and water pipelines leading to biosafety cabinets.

e) Before discharged into sewers, the sewerages from changing rooms (including the toilets), water basins in biosafety cabinet rooms, floor drains and autoclave chambers and liquids from other resources shall be subject to disinfections, preferably heat disinfections. Floor drains must be filled with water seal of chemical disinfectants that are effective to infectious materials in the laboratory. Furthermore, these floor drains shall directly lead to disinfection system. High-efficiency particulate air filters shall be installed in the manholes of sanitary sewers and pipelines that are used for other services. Liquids discharged from the shower rooms, outer changing rooms and toilets can be directly charged into sewers without being subject to any treatment.
Disinfection effects on liquid wastes must be subject to confirmation.

f) Emergency power supplies started automatically shall be provided for the ventilation system, alarms, lighting and access control and biological biosafety cabinets in the laboratory’s core areas including the biosafety cabinet rooms, inner changing room, shower room and outer changing room.

6.4.2.7 Other requirements

a) Bench tops shall be free of cracks and sealed, impervious to water and resistant to corrosion and heat.
b) With an open structure, the laboratory furniture shall be simple and sturdy. Adequate spaces shall be kept between the benches, biosafety cabinets and other equipment for easy cleaning and disinfections. Non-fibrous materials shall be laid on the surfaces of chairs and other facilities so that disinfections can be performed easily. Edges and protruding positions of furniture and equipment shall be smooth, free of burrs and preferably rounded.
c) Non-manually operated or automatic hand-washing basins shall be installed close to the doors of inner and outer changing rooms of biosafety cabinet rooms.
d) A communication system (a closed circuit television system is preferable) shall be provided between the inside and outside of laboratory rooms.
e) Information such as experiment records shall be sent outside the laboratory by means of an electrograph.

6.4.3 Special requirements for the design and construction of positive-pressure suits laboratory.

6.4.3.1 Site selection: laboratory shall be constructed in a separate building or in a separate area of a building.

6.4.3.2 Layout

a) The core areas of laboratory shall consist of rooms (main laboratory rooms) in which Class III biosafety cabinets are installed and accessed. Access shall consist of a changing area and a decontamination area. The changing room consists of an outer changing room, a shower room and an inner changing room. The decontamination area shall be a chemical shower room. Before workers leave the main laboratory room, the surfaces of the positive-pressure suits shall be disinfected by chemical showers. An automatic interlocking device shall be installed between any adjacent doors in the core areas to prevent two adjacent doors from being opening at the same time. As for the supplies, articles and materials that cannot be brought into the main laboratory room through the changing area, a double-door autoclave, a liquid dunk tank, fumigation chamber or a pass-through window with disinfection devices shall be arranged on the walls of the main laboratory room so as to perform pass-through or disinfections of these supplies, articles and materials. An emergency exit with an airlock must be arranged.
b) The requirements are the same as those in provision b) of article 6.4.2.2.

6.4.3.3 Building enclosure: the requirements are the same as those in the provisions of article 6.4.2.3.

6.4.3.4 Ventilation and air condition

a) Laboratory areas shall be kept at a maximum positive pressure and its respective pressure shall not be higher than -80Pa; Relative pressure in the laboratory areas, chemical shower rooms, inner changing rooms, shower rooms and outer changing rooms shall be increased in sequence. The pressure difference between 10Pa-15 Pa shall be maintained between the adjacent rooms. Air cleanliness in the core areas shall be reasonably maintained at grade 7 or 8.
b) Except for the previously mentioned articles, other requirements are the same as those in the provisions of article 6.4.2.4.

6.4.3.5 Safety devices and special installations
a) Main laboratory room must be provided with at least Class II biosafety cabinets.
b) Workers entering into the main laboratory room shall wear positive-pressure protective clothing. Respiratory air shall be supplied by a life support system with high-efficiency particulate air filter. Life support system consists of a positive-pressure air-supply device providing excessive clean breathing gas, an alarm, and a gas tank for emergency assistance. Continuous positive pressure in relation to ambient pressure shall be kept in the protective clothing. An emergency power supply started automatically must be provided for the life support system.
c) Except for the previously mentioned articles, other requirements are the same as those in the provisions of article 6.4.2.5.

6.4.3.6 Other requirements are the same as those in the provisions of article 6.4.2.6.

7. Biosafety containment laboratory for laboratory vertebrates

7.1 Biosafety containment laboratory for laboratory vertebrates shall be designed in a manner that the requirements for the biosafety containment laboratory at the corresponding biosafety level in the standard and requirements in GB14925—2001《Laboratory Animal—Requirements of Environment and Housing Facilities》 are met at the same time.

7.2 When designing a biosafety containment laboratory for laboratory vertebrates, hazards (such as generation of aerosols and hazards to humans resulting from bites and scratches of animals) caused by animals' activities shall be fully taken into account. Moreover, the necessary measures shall be taken in the safety operation specification, safety equipment and personnel protective equipment as well as the design and construction of the laboratory.

7.3 Biosafety containment laboratory for laboratory vertebrates shall be isolated from conventional animal breeding facilities.

7.4 Animals used in the level-3 biosafety containment laboratory for laboratory vertebrates must be placed in a negative-pressure cage system with purification and ventilation devices.

7.5 Animals used in the level-4 biosafety containment laboratory for laboratory vertebrates must be placed in Class III biological biosafety cabinets in the event of a cabinet laboratory. As for the positive-pressure suits laboratory, laboratory workers must wear positive-pressure suits while animals must placed in negative-pressure cage system with the purification and ventilation system.

8. Biohazard signs and use

8.1 Biohazard signs

See the following figure 1.
**8.2. Use of biohazard signs**

8.2.1 Biohazard signs with an indicated biosafety level shall be posted at a prominent position of the entrance of a biosafety containment laboratory that is of level-2 or above.

8.2.2 Biohazard signs must be labelled at a prominent position on the surface of containers containing infectious materials and the corresponding biosafety level shall be indicated according to the biosafety level of the containment laboratory in which these containers are placed.

9. Acceptances of newly built level-3 and level-4 biosafety containment laboratories and inspections of existing biosafety containment laboratories.

9.1 Acceptances and putting into use of newly built level-3 and level-4 biosafety containment laboratory are divided into three phases such as final acceptance of construction, acceptance by a specialist group and putting into use after approval. After the final acceptance of the construction, newly built level-3 and level-4 biosafety containment laboratories shall be accepted by a specialist group firstly and an acceptance report shall be prepared, and then the respective laboratory can be put into use only after the approval of the competent authorities.

9.1.1 Acceptance by a specialist group

During acceptance, the specialist group shall perform document examination, on-site acceptance and inspections, random inspections and examinations with respect to the laboratory workers. In addition, an acceptance report shall be prepared.

9.1.1.1 Documents that must be examined during the acceptance of a specialist group:

a) Report and the relevant documents of the project approval;

b) Hazard assessment on laboratory microorganisms;

c) Design assignment, design descriptions and drawings; other necessary documents that are required by rgw procedures of capital construction if the project has been incorporated into the capital construction;

d) Final acceptance of the construction and inspection report can be partially referred to JGJ 71—1990 《Specification for Construction and Acceptance of Hygienic Room》.

e) Inspection report that is issued by the third party, involving with a pressure difference between various rooms, cleanliness, noise, and leakage detections on high-efficiency particulate air filters of exhaust air;

f) Service instructions of the laboratory;

g) Management system of the laboratory;

h) Operation specifications of the laboratory microorganisms (one specification for each kind of laboratory microorganism);

i) Emergency procedure;
j) Registration form for laboratory workers (including the signatures of the workers themselves);
k) Registration form for the instruments in the laboratory;
l) Training records of the workers;
m) Registration form for physical examinations (including the examination of the blood serum) and immunisation of the workers;

The above items from f to m shall be summarised and bound up with cover title “Biosafety Manual”. Adequate margins shall be left in the registration form and recording section for use in future.
n) Registration book (daily log) for laboratory use;
o) Record book for registering and handling an emergency;

9.1.1.2 Random inspections and examinations of laboratory workers
During the course of acceptance, random inspections shall be performed on workers in a manner of oral or written examinations and the number of randomly examined personnel shall not be less than one fourth of the total number of workers.

9.2 Inspections on level-3 and level-4 biosafety containment laboratories and Class Ⅱ biosafety cabinets that are in use
9.2.1 After repairing the protection structures of the existing level-3 and level-4 biosafety containment laboratories and the ventilation system (including replacement of high-effectiveness filters), or after relocating and checking biosafety cabinets, reinspections shall be conducted in accordance with the requirements of this standard and JGJ 71-1990 as well as the mission manual of design.
9.2.2 Annual inspection shall be performed each year on level-3 and level-4 biosafety containment laboratories that are in use currently.
9.2.3 An annual on-site inspection shall be conducted each year on Class Ⅱ biosafety cabinets serviced in at various levels of biosafety containment laboratories (see annex B).

10. Use and maintenance of level-3 and level-4 biosafety containment laboratories that are currently in use.
10.1 Use and maintenance of level-3 and level-4 biosafety containment laboratories that are currently in use shall be performed in accordance with the requirements of this standard and Laboratory Biosafety Manual.
10.2 No modification shall be conducted without permission on biosafety-related facilities and equipment of laboratory that have passed acceptance tests.
10.3 When modifications on the structures and equipment of the laboratory are really required, these modifications must be subject to the demonstrations of specialists and approvals of the competent authorities.
10.4 On the condition that safety is ensured, urgent and regular examinations and repairs and maintenances of the laboratory shall be conducted by professionals.
Annex A
(Normative annex)
Regulations on safety operation

A.1 Level-1 biosafety containment laboratory
A.1.1 Main points of safety operation in the regulations for the regular operation of microorganisms
A.1.1.1 Non-laboratory personnel are prohibited from entering into the laboratory; under special circumstances such as visit to the laboratory, non-laboratory personnel can enter into the laboratory only after the approval of the laboratory director.
A.1.1.2 In the event that laboratory workers have come into contact with microorganisms or articles containing microorganisms, their hands must be washed after removing their gloves and before leaving the laboratory.
A.1.1.3 Eating, drinking, smoking, applying cosmetics, handling contact lenses and storing foods are prohibited in the laboratory working areas.
A.1.1.4 A pipetting aid must always be used. Pipetting by mouth must be prohibited.
A.1.1.5 Safety operation specifications must be prepared for sharp instruments.
A.1.1.6 Splashes and generations of aerosols shall be reduced by operating according to the safety operation specifications of the laboratory.
A.1.1.7 Bench tops shall be disinfected one time each day and disinfections shall be performed at any time when active materials are splashed.
A.1.1.8 Before being transferred outside of the laboratory, all cultures and wastes must be deactivated by measures such as autoclave deactivation. Deactivated articles must be placed in dedicated closed containers before being transferred outside of the laboratory.
A.1.1.9 Effective measures shall be prepared to prevent rats and insects.

A.1.2 Special regulations on safety operation
There is no special regulation on safety operation.

A.2 Level-2 biosafety containment laboratories
A.2.1 Main points of safety operation in the regulations for regular operation of microorganisms
A.2.1.1 Same as those in annex A.1.1～A.1.9.
A.2.1.2 Biohazard signs shall be posted at the entrances of the laboratory and relevant biohazard information shall be posted at prominent positions inside the laboratory, including the names of the infectious materials used, names and telephone numbers of the principals.

A.2.2 Special regulations on safety operation
A.2.2.1 When infectivity experiments are being performed, other personnel shall be prohibited from entering into the laboratory or can only enter into the laboratory after the approval of the laboratory director. Workers subject to immunological tolerance or immunosuppression can work in the laboratory or animal rooms only after permission from the laboratory director.
A.2.2.2 Biohazard signs that indicate hazardous agents, biosafety levels, immunisations required, names and telephone numbers of the principals, special requirements for entry into the laboratory and the procedures for leaving the laboratory, shall be posted at the entrance of the laboratory.
A.2.2.3 Laboratory workers shall be subject to the necessary examinations and immunisations such as hepatitis B vaccine and BCG vaccine, etc.
A.2.2.4 When required, background serum shall be collected, preserved and serum samples shall be regularly
collected for workers engaging in hazardous works. Inspection reports shall be prepared and timely handling shall be conducted in case of any problems faced.

A.2.2.5 Biosafety procedures shall be included in the standard operation specification or the Biosafety Manual and shall be kept by the laboratory director. Laboratory workers shall read the operation specification before entering into the laboratory and the operations shall be conducted in accordance with the requirements of the specification.

A.2.2.6 Workers shall be trained for their knowledge of the potential hazards and shall know very well the measures for preventing exposures and disposal procedures conducted after exposures. Moreover, workers shall receive at least one update training each year.

A.2.2.7 The following regulations shall be strictly followed so as to avoid damages caused by sharp tools:

A.2.2.7.1 Except in special circumstances (such as parenteral injection and venesection, etc.), uses of needles, syringes and other sharp tools are prohibited in the laboratory. Plastic apparatuses shall be used to substitute for glass apparatuses as much as possible.

A.2.2.7.2 Disposable syringes shall be used as much as possible. It is prohibited to use needles that are bent, cut, clipped, recapped or needles to be removed from syringes directly by hand. Used needles must be placed into puncture-resistant containers. Non-disposable sharp tools must be placed into thick-walled containers and transported to special areas for disinfection. Autoclaving is preferred.

A.2.2.7.3 Hypospray and other safety equipment shall be used as much as possible.

A.2.2.7.4 It is prohibited to handle broken glass wares by hand. Before discarding, containers containing contaminated needles, sharp tools, and broken glass shall be disinfected.

A.2.2.8 Culture media, tissues, body fluids, and other potentially hazardous wastes must be put into leak-proof containers for storage, transportation, disinfection, and sterilisation.

A.2.2.9 Before being transported out for repairs or maintenance, laboratory equipment must be disinfected.

A.2.2.10 When staff members are exposed to infectious materials, they shall directly report to the laboratory director. Furthermore, they shall record the details of the accident and treatment proposals.

A.2.2.11 No animals should be admitted other than those involved in the work of the laboratory.

A.3 Level-3 biosafety containment laboratory

A.3.1 Main points of safety operation in the regulations for the regular operation of microorganisms

Same as the requirements in Annex A.2.1.

A.3.2 Special regulations on safety operation

A.3.2.1 Doors of the laboratory must be closed.

A.3.2.2 Entry of workers into the laboratory shall be subject to the approval of the laboratory director. It is prohibited to interfere with those workers who are operating or assisting other personnel. Workers subject to immunological tolerance or immunosuppression are prohibited from entering the laboratory; workers who are temporarily ill or have damages to their skin are prohibited from working in the laboratory. Minors are also
prohibited from entering the laboratory.
A.3.2.3 Biohazard signs indicating hazardous agents, biosafety levels, immunisation required, names and telephone numbers of the principals or other relevant principals, special requirements for entry into the laboratory and procedures for leaving the laboratory, shall be posted at the entrance of the laboratory.
A.3.2.4 Strict rules and regulations of the laboratory shall be established. When the relevant personnel enter into the laboratory, procedures for entering into and leaving the laboratory shall be clear and definite. A registration system shall be established for entering into and leaving the laboratory.
A.3.2.5 Laboratory workers shall be subject to the necessary immunisations such as hepatitis B vaccine and BCG vaccine etc. Furthermore, regular examinations shall be performed.
A.3.2.6 Background serum of the laboratory workers and other risk population shall be collected and preserved. Based on demands, serum samples shall be regularly collected. Inspection reports shall be prepared and timely handling shall be conducted in the case of any problem.
A.3.2.7 Biosafety procedures shall be included in the standard operation specification and the biosafety manual of the laboratory. All laboratory workers shall be provided with the biosafety manual and be advised of the special hazards that may arise in the laboratory. Moreover, all laboratory workers shall be required to read the safety or operations manual and follow the standard practices and procedures.
A.3.2.8 Laboratory workers and support personnel thereof shall be trained for their knowledge of the potential hazards and shall know very well the measures for preventing exposures and disposal procedures conducted after exposures. Moreover, the workers and support personnel thereof shall receive at least one update training each year.
A.3.2.9 Before laboratory workers enter into the laboratory, the laboratory director is responsible for providing all workers with the standard operation specifications and technologies of microbiology including the operation specifications of instruments. Special trainings shall be provided by specialists.
A.3.2.10 All the necessities for laboratory must be sent in through transmission windows.
A.3.2.11 The following regulations shall be strictly followed so as to avoid damages caused by sharp tools:
A.3.2.11.1 Except in special circumstances such as parenteral injection and venesection etc., the use of needles, syringes and other sharp tools are prohibited in the laboratory. Plastic apparatuses shall be used to substitute for glass apparatuses as much as possible.
A.3.2.11.2 One-time syringes must be used when injecting and pipetting. It is prohibited to use needles that are bent, cut, clipped, recapped or for needles to be removed from syringes directly by hand. These used needles shall be put into stainless steel containers. Non-disposable sharp tools must be placed into thick-walled containers and transported to special areas for disinfection. Final autoclaving shall be conducted.
A.3.2.11.3 Hypospray and other safety equipment shall be used as much as possible. Before discarding, containers containing contaminated needles, sharp tools, and broken glass shall be autoclaved. It is prohibited to handle broken glass wares with bare hands.
A.3.2.12 Operations of infectious materials, which shall be performed in biosafety cabinets or other physical containment devices, are prohibited from being conducted on open benches and in open containers. The tops of benches in biosafety cabinets shall be cleaned with the appropriate disinfectants.

A.3.2.13 Culture media, tissues, body fluids and other wastes must be put into leak-proof containers for storage and transportation.

A.3.2.14 After infectivity experiments are completed, especially after infectious materials are spilled and splashed, disinfections and cleanings shall be conducted by professionals or well-trained personnel. Procedures for dealing with spillage shall be available in the laboratory.

A.3.2.15 All contaminated equipment must be disinfected before being carried out from the laboratory for repairs. All wastes or articles must be disinfected before being discarded or reused.

A.3.2.16 A system shall be established to report all accidents and exposures in the laboratory. Following spillages and exposures to infectious materials, timely disinfections shall be conducted and all accidents shall be reported to the laboratory director. Additionally, the accident history and treatment process must be recorded.

A.3.2.17 No animals and plants should be admitted other than those involved in the work of the laboratory.

A.4 Level-4 biosafety containment laboratory

A.4.1 Main points of safety operation in the regulations for the regular operation of microorganisms

A.4.1.1 During experiment, the entries of non-laboratory personnel into the laboratory shall be subject to the approval of the laboratory director.

A.4.1.2 Safety operational regulations must be prepared for sharp instruments.

A.4.1.3 All operation procedures must be strictly followed to reduce or avoid the generation of aerosols.

A.4.1.4 After each experiment is completed, the bench tops must be disinfected. Timely handling and disinfections must be conducted after splashes and spillages of active substances.

A.4.1.5 All wastes shall be disinfected before being discarded by the appropriate measures such as autoclaving.

A.4.1.6 Effective measures shall be prepared to prevent the entry of rats and insects.

A.4.2 Special regulations on safety operation

A.4.2.1 Non-workers, personnel subject to immunological tolerance or immunosuppression, children and pregnant women are prohibited from entering into the laboratory. Temporarily ill workers (such as a person suffering from respiratory infection) also shall be prohibited from entering into the laboratory.

A.4.2.2 Emergency door with a lock shall be provided at the entrance of the laboratory. Laboratory director, biosafety director or director of equipment safety shall be responsible for entries of workers into the laboratory. Before entering into the laboratory, workers must understand the potential hazards in the laboratory and correct with protection measures.

A.4.2.3 Personnel who enter into the laboratory must follow the procedures for entering and leaving the laboratory. Date, time, and status of the laboratory when entering and leaving the laboratory shall be recorded.
A.4.2.4 Effective emergency measures shall be established.
A.4.2.5 Biohazard signs that indicate hazardous agents, names and telephone numbers of laboratory director, special requirements (such as immunisation and respirators, etc.) for entry into the laboratory, shall be posted at the entrance of the laboratory.
A.4.2.6 Laboratory director shall ensure that all workers are very familiar with the operation regulations and technologies of standard microorganisms and the microorganisms that are being studied in the laboratory, and that they must also understand the specific regulations and operations of the laboratory equipment.
A.4.2.7 Workers shall be immunised with respect to the relevant pathogenic agents.
A.4.2.8 Background serum of the workers shall be collected and preserved. Based on the actual demands, serum samples shall be regularly collected. A monitoring procedure shall be established for serology.
A.4.2.9 All laboratory workers shall be provided with the biosafety manual and be advised of the special hazards that may arise in the laboratory. In addition, all laboratory workers shall be required to read the safety or operations manual and follow the standard practices and procedures.
A.4.2.10 Workers shall be trained for their knowledge of the potential hazards and shall know very well the measures for preventing exposures and disposal procedures that are conducted after exposure. Moreover, the latest training shall be regularly provided for workers.
A.4.2.11 Workers can enter into and leave the laboratory only through the changing room and the passage of the shower room. Workers may leave the laboratory through the escape way of the airlock door only in the case of an emergency.
A.4.2.12 Laboratory workers shall change and store their own daily clothing in the outer changing room. When entering into the laboratory, all workers shall, in the cleaning suits room, change their daily clothing into a complete set of laboratory suits including underclothes, union suits, shirts, shoes and gloves. Workers must take a shower before leaving the laboratory. Prior to entering into the shower room, laboratory suits must be taken off in the non-cleaning suits room of inner changing room. These laboratory suits must be washed after autoclaved.
A.4.2.13 All the necessities for the laboratory shall be sent into through an autoclave chamber, a fumigation chamber or an airlock door.
A.4.2.14 The following regulations shall be strictly followed so as to avoid damages caused by sharp tools:
A.4.2.14.1 Except in special circumstances such as parenteral injection, uses of needles, syringes and other sharp tools are prohibited in the laboratory. Plastic apparatuses shall be used to substitute for glass apparatuses as much as possible.
A.4.2.14.2 Disposable syringes must be used when injecting and pipetting. It is prohibited to use needles that are bent, cut, clipped, recapped or for needles to be removed from syringes directly by hand. Non-disposable sharp tools must be placed into thick-walled containers and transported to special areas for autoclaving.
A.4.2.14.3 Hypospray and other safety equipment shall be used as much as possible.
A.4.2.14.4 It is prohibited to handle broken glass wares by hand. Before being discarded, containers containing contaminated needles, sharp tools, and broken glass shall be disinfected.

A.4.2.15 Biological substances transferred from Class III biosafety cabinet or level-4 biosafety laboratories must completely be put into an unbreakable, sealed into a Class I container and then packed with a Class II container. Finally, these biological substances shall be carried out from the laboratory through a disinfectant tank and an airlock door.

A.4.2.16 Moreover, biological substances must be kept in their original conditions, in which substances are prohibited from being taken out from a level-4 biosafety laboratory without autoclaving or fumigation.

A.4.2.17 After infectivity experiments are completed especially after infectious materials are spilled or splashed, disinfections shall be conducted by professionals or well-trained personnel. Before being transported out for repairs or maintenances, instruments must be disinfected. Procedures for dealing with spillage must be available in the laboratory.

A.4.2.18 A system shall be established to report accidents and exposures in the laboratory. Exposures of the personnel to infectious materials shall be directly reported to the laboratory director. Furthermore, an accident history shall be recorded and a disposal plan shall be prepared. Institutions responsible for the separation and medical care of infected personnel shall be established.

A.4.2.19 No goods should be handled in the laboratory other than those involved in the work of the laboratory.
Annex B

(Normative annex)

On-site inspections on a Class II biosafety cabinet

B.1 On-site inspections must be performed on Class II biosafety cabinets in any of the following cases:

B.1.1 After Class II biosafety cabinets are moved to specified positions during the construction of the laboratory;
B.1.2 After Class II biosafety cabinets are moved from specified positions;
B.1.3 After examinations and repairs of Class II biosafety cabinets are performed;
B.1.4 After high-efficiency particulate air filters of Class II biosafety cabinets are replaced;
B.1.5 Annual and routine on-site inspections of Class II biosafety cabinets.

B.2 Must test the items and methods during the on-site inspection

B.2.1 Determination of the vertical airflow rate at the cross-section

B.2.1.1 Instrument: hot wire anemometer with an accuracy of ±3% reading;
B.2.1.2 Method: evenly spaced measuring points are located at the position 0.15m beneath the air inlet of the biosafety cabinet; Space between the measuring points shall not be more than 0.15 m. No less than three rows of measuring points shall be arranged. A row of measuring points close to the inner wall of the biosafety cabinet shall be 0.15 m from the inner wall of the biosafety cabinet. Moreover, the number of measuring points in each row shall not be less than 7.
B.2.1.3 Determination: the difference between the mean air velocity measured in the uniform velocity zone of the vertical air flow and the value given by the manufacturer shall be less than ±0.025 m/s. Furthermore, it is acceptable that the air velocity measured at single measuring point deviates from the measured mean air velocity less than 20% of the mean air velocity.

B.2.2 Determination of the velocity of the inlet air at the operating window

B.2.2.1 Methods
Firstly, the volume of the inlet air is determined at the operating window. By dividing the volume of the inlet air by the area of the operating window of the biosafety cabinet, the velocity of the inlet air is figured out. Volume of the inlet air through the operating window is found by determining the volume of the exhaust air of the biosafety cabinet. As for the biosafety cabinet that draws in air only through the operating window, the volume of the exhaust air is equal to the volume of the inlet air. However, as regards the biosafety cabinet that draws in the air not only through the operating window but also through a separate air intake pipe, the volume of the inlet air through the operating window is figured out by subtracting the volume of inlet air through the air intake pipe from the total volume of the exhaust air through the air exhaust pipe.
Methods specified in JGJ 71—1990 shall be used to determine the air volume through the air intake pipe and
air exhaust pipe of the biosafety cabinet.

B.2.2.2 Determination: it is acceptable that the difference between the measure velocity of the inlet air and the value given by the manufacturer is less than ±0.025 m / s.

B.2.3 Smoke test: intuitive judgment is made by means of using an object producing smoke.

B.2.3.1 At a position above the middle line of the work surface and 0.15 m higher than the operating window, smoke is produced and flows from one end to the other end side plate. Without retention at the dead corner and without any back flow, smoke shall flow along a vertical line.

B.2.3.2 At a position 0.025m from the inner surface of the sight window and 0.15m higher than the operating window, smoke is produced and flows from one end to the other end side plate. Without retention at the dead corner and without any back flow, smoke shall flow along a vertical line. Moreover, the smoke shall escape from the biosafety cabinet.

B.2.3.3 When smoke is produced at the outer edge 0.04m from the operating window, no drawn in smoke escapes and retains on the work surface.

B.2.3.4 In the case of the sliding operating window, sealing along the edges shall be inspected by means of smoke formation.

B.2.4 Leak test of high-efficiency particulate air filters.

B.2.4.1 Methods regulated in JGJ 71—1990 shall be used to confirm that the high-efficiency particulate air filters in the biosafety cabinet are free of leakage.

B.3 Leak test of the biosafety cabinet (Non-must inspection item)

Before the leak test, the biosafety cabinet shall be completely closed, namely, the air pipes and the operating window are closed (seal tape can be used). After the power is cut off, the biosafety cabinet is charged and pressurised until the internal pressure reaches 500Pa, and then the pressure maintenance shall be observed. It is considered acceptable when the pressure drops below 10% after 30 min.

B.4 The electrical leakage test, grounding resistance test, and electrical polarity test shall be performed during the inspection. Moreover, the illumination photometry, vibration measurement, and noise measurement can be conducted according to the requirements of the customers.

B.5 Before announcing the implementation of the standards related to Class II biosafety cabinet in the country, imported Class II biosafety cabinet must conform to the corresponding standards of the country of origin. Where there is no relevant standard in the countries of origin, the product of these countries shall not be imported or used. Domestic manufacturers of Class II biosafety cabinets shall formulate the corresponding enterprise standards and the performance indices of Class II biosafety cabinets shall not be lower than the requirements in the foreign standards of like products. When leaving the factory, each set of biosafety cabinet shall be inspected according to the enterprise standards and the corresponding inspection reports shall be issued. Moreover, the inspections performed on biosafety containment by means of using microorganisms are a must.
Annex C

(Informative annex)

Table of the applicable level of microorganism and biosafety containment laboratory in the various countries

C.1 Definitions concerning the risk groups of microorganism and biosafety containment levels of various countries (organisations)

C.1.1 European Union (EU—96, October, 1993)

C.1.1.1 Risk Group 1 indicates those microorganisms that are unlikely to cause human disease.

C.1.1.2 Risk Group 2 indicates those microorganisms that can cause human diseases and are hazardous to workers. However, these diseases cannot spread into communities and effective precautions and disposal measures that are usually available.

C.1.1.3 Risk Group 3 indicates those microorganisms that can cause human diseases and result in serious harm to workers. These diseases involve the risk of spreading into communities, but effective precautions and therapy measures are usually available.

C.1.1.4 Risk Group 4 indicates those microorganisms that can cause serious human diseases and result in serious harm to workers. Moreover, these diseases involve a significantly high risk of spreading into communities, but effective precautions and therapy measures are usually unavailable.

C.1.2 Rules of Recombinant DNA (NIHrDNA—97) that are issued by the National Institutes of Health (NIH)

C.1.2.1 Microorganisms of Risk Group 1 (RG1) have nothing to do with the diseases of healthy adults.

C.1.2.2 Microorganisms of Risk Group 2 (RG2) relate to human diseases that are not serious. Precautions and therapy measures are available.

C.1.2.3 Microorganisms of Risk Group 3 (RG3) relate to serious or lethal human diseases, but precautions and therapy measures may be available.

C.1.2.4 Microorganisms of Risk Group 4 (RG4) may cause serious or lethal human diseases, meanwhile precautions and therapy measures are usually unavailable.

C.1.3 Laboratory Biosafety Guidelines of Canada (LCDC96, the second edition, 1996)

C.1.3.1 Microorganisms of Risk Group 1 (include low risk to individuals and communities) include those microorganisms such as bacterium, fungi, viruses, and parasites that are unlikely to cause diseases to healthy human or animals.

C.1.3.2 Infectious agent of Risk Group 2 (moderate risk to individuals and limited risk to communities) can cause human or animal diseases. Generally, these infectious agents are unlikely to cause serious hazards to healthy laboratory workers, communities, domestic animals, or environment. Exposures to these infectious agents seldom result in infections of serious diseases. Due to effective precautions and therapy measures, risk of spreading is limited.

C.1.3.3 Infectious agents of Risk Group 3 (high risk to individuals and low risk to communities) can cause
serious human or animal diseases or result in serious economic consequences, but accidental contact does not spread pathogens and antimicrobial or antiparasitic drugs can be used for therapies.

C.1.3.4 Infectious agents of Risk Group 4 (high risk to individuals and communities) can cause serious human and animal diseases that are usually incurable and are easy to spread between humans or between humans and domestic animals through direct, indirect, or accidental contact.

C.1.4 Biosafety in Microbiological and Biomedical Laboratories issued by the US CDC / NIH (BMBL.93—CDC, third edition, 1993)

C.1.4.1 Biosafety level 1 is applicable to work relating to microorganisms that have distinguishing characteristics and do not cause diseases in healthy adults and are not serious or potential hazards to laboratory workers and the environment.

C.1.4.2 Biosafety level 2 is applicable to work involved with microorganisms that cause moderate and potential hazard to individuals and the environment.

C.1.4.3 Biosafety level 3 is applicable to work involved with domestic or foreign microorganisms that may cause serious or potential fatal disease when handling exposures through respiratory route during clinic, diagnosis, teaching, scientific research and production.

C.1.4.4 Biosafety level 3 is applicable to work involved with microorganisms that cause high hazards to individuals and result in laboratory infections and life-threatening diseases through aerosols.

Note: Refer to new definitions in Biosafety in Microbiological and Biomedical Laboratories issued by the Centers for Disease Control and Prevention (CDC) of the US and the National Institutes of Health of the US (NIH) (fourth edition).

C.2 Table of the applicable level of microorganism and biosafety containment laboratories in various countries (omitted)

See tables C.1~ C.4

Tables C.1~ C.4 are cited from documentations publicised by the American Biological Safety Association (ABSA).
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Note: BL - biosafety level; RG - risk group; OP - opportunistic pathogens; V - means there are relevant vaccines; T - means producing toxins; AP - animal pathogens; HP - human beings

### Table C.2 Virus

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<td>Omsk (hemorrhagic fever) TBE</td>
<td>鄂木斯克（出血热）蜱传脑炎</td>
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<td>Oncornavirus B</td>
<td>致癌 RNA 病毒 B</td>
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Notes: 7BL-Biosafety Level; V-Vaccine Available; AP-Animal-borne Pathogen; HP-Human-borne Pathogen.
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Notes: BL-biosafety level; RG- Risk Group; AP-Animal-borne Pathogen; HP- Human-borne Pathogen; OP-Opportunistic Pathogen; EU-Europe Union.
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Note: BL-Biosafety Level; RG-Risk Group; AP-Animal-borne Pathogen; HP- Human-borne Pathogen.
Chapter II

Related policies and regulations of Beijing Municipalities
Regulations of Beijing Municipality for the Administration of Affairs Concerning Laboratory Animals

(Adopted at the 31st Session of the Standing Committee of the 10th Beijing Municipal People's Congress on 17 October 1996 and revised at the 17th Session of the Standing Committee of the 12th Beijing Municipal People's Congress on 2 December 2004)

Section I General Provisions

Article 1 In order to strengthen the administration of laboratory animals, guarantee the qualities of laboratory animals and animal experiments and meet the needs of scientific research, economic construction, social development as well as opening to the outside world, these regulations are formulated based on the related laws and regulations as well as in combination with the actual circumstances in Beijing.

Article 2 The term "laboratory animals" that is used in these Regulations refers to those animals that are artificially fed and bred, the microorganisms and parasites on or in whose bodies are kept under control, whose genetic backgrounds are definite or whose sources are clear, and that are to be used in scientific research, teaching, production, examination and verification and other scientific experiments. In accordance with the controls on microorganisms and parasites, laboratory animals are classified into conventional animals, clean animals, animals carrying no specific pathogens and animals carrying no bacteria.

Article 3 These Regulations shall apply to those institutions and individuals that are engaged in the research in, production and utilisation of, laboratory animals in the administrative regions of Beijing. When national laws or regulations provide for otherwise, the relevant provisions shall be complied with.

Article 4 The administration of laboratory animals shall be guided by the principle of unified planning, resource sharing, rational division of work and being beneficial to the specialisation of the market so as to promote the scientific research in, production and utilisation of, laboratory animals.

Article 5 Municipal Administrative Department of Science and Technology shall be in charge of those affairs regarding laboratory animals and responsible for preparing a development plan for the industry of laboratory animals. Moreover, the Municipal Administrative Department of Science and Technology also shall support scientific research in laboratory animals in a manner of allocating funds for science and technology projects. Under the leadership of the Municipal Administrative Department of Science and Technology, Beijing Administration Office of Laboratory Animal is responsible for routine management and supervision. Based on their own responsibilities, the relevant departments of Municipal People's Government shall carefully manage the affairs concerning laboratory animals well.

Article 6 Quality supervision system and licence system are adopted for laboratory animals in Beijing. Quality supervision and control on laboratory animals shall comply with the national standards. Trade standards shall be used in turn during the interim in cases that the relevant
Institutions and individuals engaging in affairs regarding laboratory animals shall obtain a production licence and usage licence for laboratory animals, which are issued by the Municipal Administrative Department of Science and Technology. The production licence and usage licence for laboratory animals shall not be transferred.

Article 7 Institutions and individuals engaging in affairs relating to laboratory animals shall safeguard the welfare of laboratory animals, guarantee biosafety and prevent environmental contaminations.

Article 8 Institutions and individuals that have scored remarkable achievements shall be praised or rewarded by the department in charge of the administration of the work with respect to laboratory animals.

Section II Institutions and Personnel Dealing with Laboratory Animals

Article 9 Institutions dealing with laboratory animals shall be staffed with technical personnel. There should be an administrative organisation for laboratory animals that is responsible for managing affairs involving projects with laboratory animals and for performing ethical reviews on animal experiments.

Article 10 Institutions dealing with laboratory animals shall organise employed persons to participate in specialised trainings. Any employee not subject to training shall not take up a post. Institutions dealing with laboratory animals shall organise technical personnel specialised in laboratory animals to participate in the further education of Laboratory Animal Science and relevant specialities.

Article 11 Institutions engaging in affairs relating to laboratory animals shall organise skilled workers to participate in examinations of skill grades; in accordance with the properties of posts and professional level, specialised technical personnel shall be evaluated for and promoted to the corresponding professional technical positions.

Article 12 Institutions dealing with laboratory animals shall take protective measures to ensure the health and safety of employed persons. Moreover, employed persons shall be physically examined each year. Persons who are unsuitable for undertaking affairs relating to laboratory animals due to health conditions shall change their positions.

Article 13 Personnel dealing with laboratory animals shall follow a variety of administrative provisions with respect to laboratory animals.

Article 14 Institutions and individuals who have obtained licences of laboratory animals are free of management and service fees if they produce or utilise laboratory dogs.

Section III Production of Laboratory Animals

Article 15 Institutions and individuals, which are engaged in the conservation of breeds, breeding, production, supply, transportation and commercial operations of laboratory animals, shall produce, supply or sell up-to-standard laboratory animals and the relevant products within the scopes authorised by a production licence for laboratory animals.

Article 16 Production environments and facilities of laboratory animals shall comply with the standard requirements on laboratory animals of different classes. According to the corresponding standards, laboratory animals of different classes and breeds shall be managed in different
environments and facilities. Up-to-standard supplies such as feedstuffs, cages and bedding materials etc. shall be used.

Article 17 Institutions and individuals dealing with the conservation of breeds, breeding of laboratory animals, shall adopt breeds, strains of breeds and standard feeding and breeding methods that are domestically and internationally accepted. The relevant national laws and regulations shall be observed if wild animals are captured for the purpose of supplementing the sources of breeds or developing new breeds or scientific research.

Article 18 Based on the relevant standards with respect to generics, parasitology, microbiology, nutriology and production environments and facilities, institutions and individuals dealing with producing laboratory animals and the relevant products shall regularly perform quality inspections. Complete and accurate records shall be made for the courses of various operations and test data.

Article 19 Institutions and individuals dealing with producing laboratory animals and relevant products, when supplying or selling laboratory animals and relevant products, shall provide a conformity certificate for laboratory animals. Conformity certificate for laboratory animals shall indicate the exact names of laboratory animals and products thereof, quality grade, quantity, quality inspection results, name of purchaser, sale date, number of licence, etc. and shall be signed by the principals of the seller and affixed with an official seal.

Article 20 The transfer facilities and cages used during the transportation of laboratory animals shall conform to the standards of microorganisms, environment and quality control with respect to transported laboratory animals. No laboratory animals of different breeds, strains, genders and classes may be mixed together in one cage during transportation.

Article 21 Import and export of laboratory animals shall be handled according to the relevant national regulations.

Section IV The Utilisation of Laboratory Animals

Article 22 Institutions and individuals, which are engaged in scientific research, productions, verifications, inspections and other activities by making use of laboratory animals, shall use up-to-standard laboratory animals within the scope authorised by a usage licence.

Article 23 Environments and facilities of laboratory animals shall conform to the requirements of corresponding classes of laboratory animals. Furthermore, up-to-standard feedstuffs, cages and bedding materials shall be used. Laboratories involving with radioactivity and infectivity that require special protective measures shall conform to the relevant regulations.

Article 24 Laboratory animals of corresponding classes shall be used for animal experiments in accordance with the purposes of experiments. Animal experiments, which involve with different breeds and classes of animals interfering with each other, shall not be performed in the same laboratory room.

Article 25 The use of up-to-standard laboratory animals and environments and facilities at the corresponding levels shall be taken as basic requirements in the research projects submitted for approval and in assessing the results of such projects, performances of verifications and inspections as well as in producing products with laboratory animals as productive materials. The results of animal experiments obtained by using non-conforming laboratory animals or in non-conforming laboratory environments are invalid. Moreover, products produced thereof shall not be sold.
Article 26 Individuals dealing with animal experiments shall design experiments based on the principles of substitution, reduction and optimisation. Laboratory animals shall be handled in an appropriate manner.

**Section V Epidemic Prevention of Laboratory Animals**

Article 27 Epidemic prevention of laboratory animals shall be carried out, in turn combining with the special requirements of laboratory animals.

Article 28 If an epidemic among laboratory animals occurs, the relevant national and municipal regulations shall be followed.

Article 29 Institutions and individuals dealing with laboratory animals shall perform innocent treatments on the carcasses of laboratory animals and on laboratory waste.

**Section VI Supervision and Inspections**

Article 30 The Municipal Administrative Department of Science and Technology shall supervise and inspect those institutions and individuals engaging in the production and utilisation of laboratory animals in Beijing. Moreover, the results of the supervision and inspection shall be publicised.

Article 31 Municipal Administrative Department of Science and Technology shall employ quality inspectors of laboratory animals to assist with the production and utilisation of laboratory animals in Beijing.

Article 32 The municipal authority shall establish a credit management system for those institutions and individuals dealing with the production and utilisation of laboratory animals. The Municipal Administrative Department of Science and Technology shall publicise credit information of these institutions and individuals.

Citizens are encouraged to report the illegal production and utilisation of laboratory animals to the Municipal Administrative Department of Science and Technology.

**Section VII Legal Liability**

Article 33 In the case of behaviours violating the provisions of this rule, laws and regulations, violators shall be penalised according to laws. Where there is no corresponding provision in laws and regulations, the following provisions of this section are applicable for penalise violators.

Article 34 When institutions and individuals that have obtained licences for laboratory animals violate the provisions of Article 10, 12, 16, 18, 19, 20, 23, 24 and 29 of this rule, the department in charge of the administration of the work with respect to laboratory animals shall, in accordance with the seriousness of the respective cases, impose on them such administrative sanctions as setting a deadline for them to improve their work, issuing a warning and temporarily withholding licences for laboratory animals.

Article 35 When institutions and individuals that have obtained licences for laboratory animals violate the 4th provision of Articles 6, 15 and 22, the Municipal Administrative Department of Science and Technology shall, in accordance with the seriousness of the cases, order them to stop their illegal activities and cancel their licences for laboratory animals.

Article 36 When institutions and individuals that have not obtained licences for laboratory animals are engaged in the production and utilisation of laboratory animals, the Municipal Administrative
Department of Science and Technology shall order them to stop their illegal activities and shall circulate a notice of criticism. Industrial and Commercial Administrative Departments shall penalise these institutions and individuals according to law. Those responsible personnel shall face administrative punishment that is imposed by their work institutions or the superior competent authorities.

Article 37 The management staff of laboratory animals, who commit dereliction, abuse of power or malpractice, shall be given disciplinary sanction by their work institution or the superior competent department. If the irregularities constitute a crime, the wrongdoer shall be prosecuted for his/her criminal liability according to law.

Section VIII Supplementary Provisions
Article 38 These regulations shall go into effect on 1 January 2005.
Measures of the Beijing Municipalities on 《Implementing the Law of the People's Republic of China on the Protection of Wildlife》

The Standing Committee of Beijing Municipal People's Congress
Issued on 2 April 1989 and implemented on 1 June 1989
(Adopted at the 10th Session of the Standing Committee of the 9th Beijing Municipal People's Congress)


Article 1 Combining with the actual circumstances in Beijing, these measures are formulated for the purpose of the implementation of 《Law of the People's Republic of China on the Protection of Wildlife》 (hereinafter referred to as the 《Law on the Protection of Wildlife》).

Article 2 Any activities involving protection, domestication, breeding and utilisation of wildlife in administrative regions of Beijing must follow 《Law on the Protection of Wildlife》 and these measures.

Article 3 Wildlife protected by these measures includes:

1. Wildlife that is approved by State Council and enjoys the priority of national protection;
2. Wildlife that is publicised by Beijing Municipality and is under municipal first class protection;
3. Wildlife that is publicised by Beijing Administrative Department of Wildlife and is under municipal second class protection;

Article 4 Citizens shall have the obligation to protect wildlife resources and are entitled to report and charge for those behaviours that encroach on and damage wildlife resources.

Article 5 Administrative department of Forestry and Administrative department of Fishery (hereinafter referred to as the Administrative Departments of Wildlife) in Beijing, various districts and counties are respectively in charge of the protection and management of terrestrial wildlife and aquatic wildlife.

Article 6 Administrative Departments of Wildlife at each level shall carry out surveys of wildlife resources and keep records of them every 10 years.

Article 7 In public parks, forest farms and scenic and tourist areas, nest boxes shall be hung up and platform bird feeders and water bathing places shall be arranged so as to artificially attract and protect wildlife.

Article 8 People's Governments or Administrative Departments of Wildlife at each level shall praise and reward institutions and individuals in any one of the following cases:

1. Save wildlife under special national and municipal protection;
2. Report and charge for the illegal catching and killing of wildlife under special national and municipal protection;
3. Outstanding achievements in protection, management, domestication and breeding of wildlife;
4. Outstanding achievements in scientific studies in wildlife;
5. Obvious performances in attracting birds;
(6) Highlighted achievements in performing 《Law on the Protection of Wildlife》 and these measures;

Article 9 The living environment of wildlife shall be protected and any institutions or individuals are prohibited from damaging the living environment of wildlife. If the main habitat and mating places of wildlife are damaged by institutions or individuals, the Administrative Department of Wildlife in each district and county shall order them to stop their act of destruction and restore it to the original state within a specified period. A fine of no less than 3 times of the costs required by restoration may be imposed on these institutions or individuals.

Article 10 All institutions and individuals are prohibited from illegally catching or killing wildlife under special national and municipal protection. The following regulations shall be observed if wild animals under special national and municipal protection are captured for the purpose of scientific research, domestication and breeding, exhibition or other special reasons.

(1) Capture of wild animals under national first class protection shall be subject to reviews and approvals of the Municipal Administrative Department of Wildlife. Moreover, a special hunting and catching licence shall be applied for from Department of Wildlife Administration under the State Council;

(2) A special hunting and catching licence shall be applied for from the Administrative Department of Wildlife for captures of wild animals under national second class protection and municipal first class protection.

(3) In the case of captures of wildlife under municipal second class protection, a hunting licence shall be applied for from the Administrative Department of Wildlife of administrative regions, counties where the hunting field is located.

Article 11 Anyone engaged in the hunting or catching of wildlife shall observe the directives in their special hunting and catching licence or their hunting licence with respect to the species, quantity, area and time limit.

Illegal catching or killing of wildlife under special national protection shall be dealt with in accordance with provision 31 of the 《Law on the Protection of Wildlife》.

When institutions and individuals illegally catch or kill wildlife under municipal first class protection, the Administrative Departments of Wildlife in administrative regions and counties shall confiscate captures and capture tools and cancel their hunting licences. Moreover, a fine of 5 to 10 times the costs of the captured may be imposed on these institutions and individuals. If the circumstances are serious enough to constitute a crime, criminal responsibility shall be investigated pursuant to law.

When institutions and individuals illegally catch or kill wildlife under municipal second class protection, the Administrative Departments of Wildlife in administrative regions and counties shall confiscate captured wildlife and a fine of no more than 5 times of cost of the captured shall be imposed. If the circumstances are serious enough to constitute a crime, criminal responsibility shall be investigated pursuant to law.

Article 12 Anyone who intends to hunt with a gun must obtain a gun licence from the public security organ of the county or municipality concerned. If anyone hunts wildlife with a hunting rifle without a licence for the rifle, they shall be punished by a public security organ according to provision 20 of the 《Regulations of the People's Republic of China on Administrative Penalties for Public Security》.

Article 13 Hunting is forbidden from March to May and from September to November each year. Hunting is prohibited in/at urban area, suburbs, outer suburbs, towns in counties, public parks, scenic and tourist areas, nature reserves, state owned forest farm and other suspended hunting
areas specified by the Administrative Departments of Wildlife of municipality, administrative districts and counties.

Tools such as ground bows, ground guns, sticky nets, poison baits, explosives, military weapons or large iron clamps and measures such as taking a nest, hollowing out, fire attack and fall traps shall be prohibited from use for hunting purposes.

In the event of violation of provisions 1, 2, and 3 in this article, the capture tools will be confiscated and a fine will be imposed according to the laws and administrative regulations. If the circumstances are serious enough to constitute a crime, criminal responsibility shall be investigated pursuant to law.

Article 14 Domestication and breeding of wildlife are encouraged by municipal authorities. Any institution and individual dealing with the domestication and breeding of wildlife under special national and municipal protection shall hold domestication and breeding licences. Domestication and breeding licences of wildlife under special national protection shall be reviewed and issued according to the regulations of the Department of Wildlife Administration under the State Council. The Municipal Administrative Department of Wildlife shall prepare the methods that are employed to review and issue domestication and breeding licences of wildlife under special municipal protection.

Article 15 Wildlife under special national and municipal protection and products thereof are prohibited from selling and purchasing. Under special circumstances such as scientific research, domestication, breeding and exhibition etc., selling, purchasing or utilisation of wild animals under national first class protection and products thereof shall be subject to reviews and permits of the Municipal Administrative Department of Wildlife and shall be reported to the Department of Wildlife Administration under the State Council or to authorised organisation for approval. Meanwhile, selling, purchasing or utilisation of wild animals under national first class protection or under special municipal protection and products thereof shall be approved by the Municipal Administrative Department of Wildlife or by authorised institutions.

Methods used to sell or manage domesticated and bred wildlife under national and municipal protection and products thereof shall be formulated by the Municipal People's Government.

Article 16 Activities such as selling, purchasing, transportation and carrying of wildlife and products thereof shall be supervised and managed by the Municipal Administrative Department of Industry and Commerce and Municipal Administrative Department of Wildlife at various levels. When those who violate the provisions in these measures illegally sell, purchase, transport or carry wildlife under special national and municipal protection and products thereof, wildlife and products thereof and illegal gains shall be confiscated. Moreover, a fine of no more than 10 times the costs of the physical goods may be imposed. If the circumstances are serious enough to constitute a crime, criminal responsibility shall be investigated pursuant to law.

Article 17 In the cases of forgery, sale or resale or transfer of special hunting and catching licences, hunting licences, domestication and breeding licences, and import and export permits, the certificates of the involved institutions and individuals shall be cancelled and any illegal gains shall be confiscated. Furthermore, a fine shall be imposed according to the laws and administrative regulations. Those whose acts constitute a crime shall be prosecuted for their criminal liability.

Article 18 The staff of the Administrative Department of Wildlife, who commit dereliction, abuse of power or malpractice during the protection and management of wildlife, shall be given disciplinary sanction by their work institution or the superior competent department. If the irregularities constitute a crime, the wrongdoer shall be prosecuted for his/her criminal liability according to law.

Article 19 If any party is not satisfied with the decision on administrative sanctions, it may, within 15 days after receipt of the notice of sanctions, apply for reconsideration to the organ at the next higher level over the one that has made the decision. Nevertheless, the decision that the captured
and capture tools are confiscated must be conducted. If the party is dissatisfied with the decision on the reconsideration made by the authority at the next higher level, it may, within 15 days of receiving the notification on the decision on reconsideration, institute legal proceedings in the court. A party may also bring a suit directly before a people's court within 15 days of receiving the notification of the sanction. If the said party neither files a request for reconsideration nor files a suit in a people's court, or does not comply with the punishment within the time limit, the authority that made the decision of punishment shall apply to the people's court for compulsory execution.

Article 20 Municipal Administrative Department of Wildlife is responsible for the interpretation of the specific application of these measures.

Article 21 These Measures shall become effective on 1 June 1989.
Measures of Beijing Municipality on Implementing the Animal Epidemic Prevention Law of the People's Republic of China

Announcement No. 27 made by the Standing Committee of Shanghai Municipal people's Congress on 22 October 2004)

Section I General Provisions

Article 1 With a view to prevent, control and exterminate animal epidemics, enhance development of livestock breeding and protect human health, these measures are made under the 《Animal Epidemic Prevention Law of the People’s Republic of China》 and in line with the actual circumstances of this Municipality.

Article 2 These measures are applicable for the prevention, diagnosis and treatment, control, extermination of animal epidemics, quarantine of animals and animal products and other activities involving animal epidemic prevention in the administrative regions in Beijing. If the entry & exit quarantine of animals and animal products, hygienic inspection and supervision on those up to the standards for food after quarantine inspection are regulated otherwise in the laws and regulations, the requirements in the laws and regulations shall be met.

Article 3 Municipal authorities institute a policy of focusing on the prevention of animal epidemics. The principles of integrated control, strict quarantine, selective control and supervision throughout the whole process shall be adhered to for animal epidemic prevention.

Article 4 People’s governments of Beijing, administrative districts and counties shall strengthen their leadership over animal epidemic prevention. Animal epidemic prevention shall be included in the National Economic and Social Development Plan and funds for animal epidemic prevention shall be listed in the fiscal budgets of Beijing, administrative districts and counties. Furthermore, the funds required by such routines concerning animal epidemic preventions as compulsory immunisation, monitoring of epidemic diseases, purification, quarantine and supervision etc. shall be guaranteed.

Article 5 Municipal Administrative Department of Animal Husbandry and Veterinary shall be in charge of animal epidemic prevention in Beijing. The Administrative Departments of Animal Husbandry and Veterinary in the administrative districts and counties shall be responsible for animal epidemic prevention in the administrative regions; when no Administrative Department of Animal Husbandry and Veterinary is established in a district, a Administrative Department specified by People’s governments of District shall be in charge of animal epidemic prevention in the administrative region. Moreover, the business of this Administrative Department in a district is subject to the leadership of Municipal Administrative Departments of Animal Husbandry and Veterinary.

A variety of departments involving commercial affairs, public security, industry and commerce administration, quality and technical supervision, traffic, entry-exit inspection and quarantine, etc., which are responsible for the supervision and management of animal epidemic prevention according to laws, shall supervise and manage animal epidemic prevention based on the relevant laws and regulations.
Various departments, which respectively involve rural affairs, development and innovation, environmental protection, municipal administration, science and technology, forestry, parks and gardens, water affairs, city management and supervision etc., shall manage the affairs concerning animal epidemic prevention based on the responsibilities as specified by the Municipal People's Government.

Article 6 Supervising agencies for animal epidemic prevention, which respectively belong to the city, administrative districts and counties, shall implement and supervise animal epidemic prevention. Meanwhile, these supervising agencies for animal epidemic prevention are under the leadership of the administrative department, which is at the same the administrative level and in charge of animal epidemic prevention.

Supervising agencies for animal epidemic prevention shall be responsible for the affairs relating to animal epidemic prevention in the corresponding administrative region and in charge of instructing animal epidemic prevention organs at villages and in towns to organise the animal epidemic prevention of corresponding villages and towns.

Supervising agencies for animal epidemic prevention shall be in charge of the quarantine of animals and animal products thereof in the corresponding administrative regions. As required, supervising agencies for animal epidemic prevention in administrative districts and counties may establish branch offices at villages and in towns.

Supervising agencies for animal epidemic prevention shall be responsible for animal epidemic prevention and supervision in corresponding administrative regions. Moreover, these supervising agencies shall enforce punishment for behaviours that violate laws and regulations relating to epidemic prevention.

Supervising agencies for animal epidemic prevention of city, administrative districts and counties shall strengthen their communications with supervising agencies for animal epidemic prevention in the same administrative regions so as to report the conditions of epidemic prevention in time and to organise epidemic prevention well.

Article 7 The municipality encourages and supports scientific research on animal epidemic prevention, spreads the advanced achievements of scientific research, popularises the scientific knowledge of animal epidemic prevention, and improves the level of animal epidemic prevention.

Section II Prevention of Animal Epidemics

Article 8 Based on the national plan for animal epidemic prevention and in combination with the actual circumstances of animal epidemic prevention in the city, Municipal People’s Government shall prepare municipal plan for animal epidemic prevention.

Based on the municipal plan for animal epidemic prevention and in combination with the actual circumstances of animal epidemic in corresponding administrative regions, Administrative Departments of Animal Husbandry and Veterinary of city, administrative districts and counties shall organise preparation of implementation plan of animal epidemic prevention, which shall be implemented after being approved by the People’s Government at the same administrative level.

Article 9 The Municipal Administrative Department of Animal Husbandry and Veterinary shall prepare a storage plan for machines, biological products, disinfection apparatuses and protective devices as required by the prevention and extermination of animal epidemics. Furthermore, this storage plan shall be implemented after being approved by the Municipal People’s Government.
Article 10 According to national catalogue of epidemics and municipal plan for animal epidemic prevention, a compulsory immunisation shall be enforced for animal epidemics that are seriously hazardous to animals and human health. Compulsory immunisation shall be organised and implemented by supervising agencies for animal epidemic prevention. Supervising agencies for animal epidemic prevention in the administrative districts and counties shall establish immunisation files for animals that require compulsory immunisation. Animals such as pigs, cattle, sheep, and deer etc., which have been subject to compulsory immunisation, shall wear signs of immunisation such as an ear tag, label plate or core plate etc. that are uniformly provided by the Municipal Administrative Department of Animal Husbandry and Veterinary.

Article 11 All the places that are involved with activities such as breeding, management, diagnosis and treatment of animals, production and management of animal products, storage of animals and animal products, innocent treatment and conservation and use of animal-borne pathogenic microorganisms, shall meet the requirements of animal epidemic prevention. After being considered acceptable after review and examination, a conformity certificate for animal epidemic prevention shall be issued by the supervising agency of animal epidemic prevention. Animal breeding farms, slaughter and processing factories, places for innocent treatment shall be arranged a safe distance from schools, kindergartens, residential areas, and water-source reserves. Meeting requirements on epidemic prevention, this safe distance shall be specified and publicised by the Municipal Bureau of Agriculture.

Article 12 Bred animals that are used as breeds or used to produce milk shall achieve the health standard and an animal vaccination certificate that is issued by supervising agencies for animal epidemic prevention shall be obtained. Epidemic supervision and purification shall be regularly performed by supervising agencies for animal epidemic prevention on those animals used as breeds or used to produce milk.

Article 13 The Administrative Department of Animal Husbandry and Veterinary shall strengthen the management on animal-borne pathogenic microorganisms. When it is necessary to store, use and transport pathogenic microorganisms due to the demands of scientific research, teaching, production and epidemic prevention, facilities and measures preventing spreads of pathogenic microorganisms shall be provided to achieve nationally specified conditions concerning animal epidemic prevention and a standard of biosafety containment. Moreover, a nationally regulated management system and operation specification shall be strictly performed. Storage, use and transportation of animal-borne pathogenic microorganisms shall be reported to the Municipal Supervising Agencies for Animal Epidemic Prevention for filing.

Article 14 Institutions dealing with the diagnosis and treatment of animals shall be provided with the following conditions and diagnosis and treatment licence for animals》 approved and issued by the local Administrative Department of Animal Husbandry and Veterinary shall be obtained.

1) Places meeting the requirements on animal epidemic prevention;
2) Specialised technical personnel in conformity with the diagnosis and treatment of the animal dealt with;
3) Instruments, equipment and medicine required for the diagnosis and treatment of animals;
4) Other conditions as stipulated by the laws, regulations and rules;

Institutions and personnel engaged in the diagnosis and treatment of animals shall, according to the approved items and scopes of practice, carry out diagnosis and treatment and strictly abide by the professional technical specifications.
Article 15 Places where the trade markets of animals are established and the trade fair, auction and exhibition of animals are held shall meet the requirements on animal epidemic prevention. In addition, a Conformity Certificate for Animal Epidemic Prevention as issued by the Supervising Agency for Animal Epidemic Prevention shall be obtained. Supervising Agency for Animal Epidemic Prevention shall strengthen the supervision on the trade markets of animals and trade fair, auction and exhibition of animals.

Article 16 Conveyance used for animals and animal products shall be cleaned and disinfected before loading and unloading. Moreover, a disinfection certificate for conveyance, which is issued by the Supervising Agency for Animal Epidemic Prevention at the place of departure, shall be obtained. During transportation, conveyance shall be kept clean and sanitary. Meanwhile, the animals’ excreta, bedding materials and contaminated articles shall not be unloaded, discarded or lost and thrown away.

Article 17 A Warehousing & Storage Checklist of animal products shall be established by the managerial staff of a cold storage house when animal products are stored in the cold storage house. When placing animal products into a cold storage house, the Conformity Certificate for Quarantine shall be reviewed; after animal products are sent out of a cold storage house, the original and copy of the Conformity Certificate for Quarantine shall be retained for 2 months.

Article 18 Service and management organisation of the market shall review the relevant certificates and check the relevant seals for animals and animal products sold on markets. When a Conformity Certificate for Quarantine has been obtained and the certificates and seals do not meet the requirements, the animals and animal products shall be handed over to the local Supervising Agency for Animal Epidemic Prevention for disposal.

Article 19 Conformity Certificates of Quarantine shall be checked for animals and animal products purchased by restaurants, hotels, dining-rooms and mess halls. Furthermore, originals and copies of Conformity Certificates of Quarantine shall be kept for 3 months.

Article 20 Innocent treatments shall be performed for animals, animal products and other articles.

1. Animals having an epidemic disease or suspected of having an epidemic disease and their excreta;
2. Animal products having an epidemic disease or suspected of having an epidemic disease;
3. Carcasses of animals that died of an illness or died due to an unidentified cause;
4. Articles that have come into contact with animals and animal products having an epidemic disease;
5. Clinical waste produced during diagnosis and treatment;
6. Food wastes produced by restaurant, hotel, dining rooms and mess halls;
7. Other articles that may cause the spread of animal epidemics;

Article 21 Places where innocent treatments are performed on animals and animal products shall be arranged and constructed by city, district and county people’s government in a uniform manner. Large breeding farms and slaughter and processing factories shall have the capability of innocent treatment. Institutions engaged in the production, operation, scientific research and education, which have no capability of innocent treatment, shall entrust innocent treatment to institutions with the corresponding capability.

According to the 《Control Regulations for Clinical Wastes》 as issued by the State Council, clinical wastes produced during the diagnoses and treatments of animals shall be subject to innocent treatments.
Implementation of innocent treatments on animals and animal products shall be supervised by the Supervising Agencies for Animal Epidemic Prevention. The Municipal Administrative Department shall be responsible for supervising the implementation of innocent treatments on food wastes produced at restaurants, hotels, dining rooms and mess halls. Article 22 Supervising Agencies for Animal Epidemic Prevention shall be responsible for accepting and treating discarded, confiscated and ownerless animals. Acceptance and handling of dogs shall be conducted according to the 《Administrative Provisions of Beijing Municipality on Dogs Raising》.

Article 23 Food wastes, which are produced by restaurants, hotels, dining rooms and mess halls, are prohibited from being used to feed animals without being subject to any innocent treatment.

Section III Control and Extermination of Animal Epidemics

Article 24 The Administrative Department of Animal Husbandry and Veterinary shall establish and improve a monitoring and reporting system for animal epidemics. In order to find, diagnose and report animal epidemics in time, Supervising Agencies for Animal Epidemic Prevention shall conduct overall monitoring, risk analysis, early warning and prediction for animal epidemics. In the case of animal epidemics, the Administrative Department of Animal Husbandry and Veterinary and Supervising Agencies for Animal Epidemic Prevention shall confirm and report according to the specified procedures and time limit. Publication of epidemic information shall follow the relevant national regulations.

Article 25 In the case of an animal epidemic of Class I, the Administrative Department Animal Husbandry and Veterinary of administrative districts and counties shall dispatch its personnel to the scene forthwith to delimit the epidemic point, the epidemic area and the threatened area, collect epidemic materials, investigate the epidemic source, report in due time to the people’s governments of administrative districts and counties for a decision of cordoning off the epidemic area, and report the epidemic situation and the related information to the Municipal Administrative Department of Animal Husbandry and Veterinary. District and County People’s Government shall publicise the decision of cordoning off the epidemic area in due time and shall immediately inform the neighbouring areas of the case. When an epidemic area covers more than two districts or counties, the Municipal Administrative Department of Animal Husbandry and Veterinary shall report to City People’s Government for the approval of a decision for cordoning off the epidemic area. The decision of cordoning off the epidemic area shall include contents such as scopes, objects of cordoning off and the measures to be taken.

Article 26 People’s Government, which publicises the decision of cordoning off the epidemic area, shall immediately organise the departments and institutions relating to husbandry and veterinary, public security, sanitation and traffic etc. shall take the following measures for the epidemic point to be cordoned off:

(1) The warning signs shall be arranged around the epidemic point to be cordoned off. Equipped with disinfection facilities, temporary inspection and disinfection stations (points) shall be arranged at the exit and entrance. Persons, means of transport and the relevant articles that leave or enter the cordoned-off area shall be disinfected and have imposed upon other restrictions.

(2) Animals or animal products having an epidemic disease or suspected of having an epidemic disease and animals that died of illness are prohibited from moving out of the epidemic area, and
animals coming from outside the epidemic area shall be prohibited from entering the epidemic area.

(3) Animals in the same group, which have an epidemic disease or suspected of having or being susceptible to an epidemic disease, shall be isolated and killed;

(4) Animals that were killed or died of an illness at the epidemic point, the animals’ excreta, bedding materials and contaminated articles shall be subject to innocent treatment. In addition, throughout disinfection shall be conducted at the epidemic point.

(5) Animals susceptible to an epidemic disease, which are not in the same group, shall undergo emergency immunisation and monitoring.

Article 27 People’s Government, which publicises the decision of the cordonning off of the epidemic area, shall immediately organise departments and institutions related to husbandry and veterinary, public security, sanitation and traffic etc. shall take the following measures for an epidemic point to be cordonned off:

(1) Warning signs shall be arranged around the epidemic area. Animals susceptible to the epidemic disease are prohibited from moving out and animals outside the epidemic area shall be prohibited from entering into the epidemic area;

(2) Animals suspected of having an epidemic disease and that died due to an unidentified cause, shall be isolated for inspections; when infections are diagnosed, Animals having an epidemic disease and other animals in the same group shall be isolated and killed. Moreover, these animals shall be handled according to the fourth provision in Article 26;

(3) Disinfection points shall be set up on the traffic roads leading to the epidemic area to disinfect all personnel entering into or leaving the epidemic area, their means of transportation and relevant articles;

(4) Stable breeding, fastening breeding or free breeding at a specified place shall be adopted for bred animals;

(5) Animals susceptible to an epidemic disease shall be monitored and be subject to emergency immunisation. Throughout, disinfection shall be carried out at the places involving animals susceptible to an epidemic disease;

(6) Trade involving animals susceptible to an epidemic disease and corresponding animal products shall be stopped;

Article 28 Administrative Department of Animal Husbandry and Veterinary organise the relevant departments to taken following measures for the threatened area:

(1) Emergency immunisation shall be performed on animals susceptible to an epidemic disease;

(2) Dynamic monitoring shall be conducted for animal epidemics;

(3) Necessary precautions such as restriction, isolation and disinfection shall be taken;

Article 29 In the event of an animal epidemic of Class II, the Administrative Departments of Animal Husbandry and Veterinary of administrative districts and counties shall delimit the epidemic point, the epidemic area and the threatened area. Meanwhile, compulsory measures for the control and extermination of the animal epidemic such as isolation, massacre, destruction, disinfection and emergency immunisation vaccination shall be taken to exterminate an epidemic disease.

In the case of an animal epidemic of Class III, the Administrative Departments of Animal Husbandry and Veterinary of administrative districts and counties shall organise epidemic prevention according to the regulations concerning animal epidemic prevention.
When an animal epidemic of Class II or Class III spreads violently or a new animal epidemic disease breaks out, measures aiming at the control and extermination of animal epidemic of Class I shall be taken.

Article 30 The municipality shall strengthen its monitoring of an epidemic disease contracted commonly by both human beings and livestock. The Administrative Department of Animal Husbandry and Veterinary and Administrative Department of Public Health shall communicate with each other. When an epidemic disease is contracted commonly by both human beings and livestock and in turn breaks out, the epidemic source shall be immediately investigated and the effective measures shall be taken so as to quickly exterminate the epidemic disease and prevent the spread of the epidemic disease.

Article 31 City, district and county people’s government shall organise to prepare an emergency preplan for major animal epidemic diseases. If a major animal epidemic disease breaks out in Beijing City or a major animal epidemic disease that may influence Beijing City breaks out outside the administrative districts of Beijing City, the Administrative Department of Animal Husbandry and Veterinary shall immediately perform a comprehensive assessment on animal epidemics. It shall be reported to the People’s Government at the same administrative level for approval when the start-up of an emergency preplan is required.

Headquarter of city, district and county people’s government, which is in charge of major animal epidemic diseases, shall coordinate the emergency control and extermination of major animal epidemic diseases.

Reserve teams shall be established by city, district and county people’s government for the emergency handling of major animal epidemic diseases. Consisting of the administration staff of animal husbandry and veterinary, supervisory personnel of animal epidemic prevention, relevant specialists, veterinarians, personnel of hygiene and disease control and public security officers etc., various reserve teams for emergency handling shall regularly attend trainings and carry out drills.

Article 32 When an outbreak of a major animal epidemic disease requires restrictive administrative measures to be taken outside the epidemic area of Beijing City, these administrative measures shall be approved by the city people’s government.

In order to prevent the spread of major animal epidemic diseases, the city, district and county people’s government can purchase animals susceptible to the epidemic disease outside the epidemic area.

Article 33 After all the animals having an epidemic disease, suspected of having an epidemic disease and products thereof are handled according to the regulations, monitoring shall be conducted on the epidemic disease breaking out for more than 1 latent period. If no new case appears, which has been reviewed and considered acceptable by the Supervising Agencies for Animal Epidemic Prevention, the People’s Government that publicised the decision of the cordon off shall announce the cancelling of the cordon off.

Article 34 The People’s Government shall compensate the owners for those animals that are killed to exterminate animal epidemic diseases. The Municipal Administrative Department of Animal Husbandry and Veterinary shall organise a specialist group to assess the economic damages resulting from killing animals. Based on the assessment result, compensation shall be paid for the owners of the animals according to the national and municipal regulations.

Section IV Quarantine of Animals and Animal Products

Article 35 Supervising agencies for animal epidemic prevention shall have quarantine officers responsible for the quarantine of animals and animal products. Quarantine officers shall possess
the necessary professional skills. In accordance with the national regulations, quarantine officers shall hold a relevant certificate to take a post after being reviewed and examined by the Municipal Administrative Department of Animal Husbandry and Veterinary. Quarantine officers shall observe quarantine rules in carrying out a quarantine and bear liability for the quarantine results.

Article 36 Before animals and animal products are sold or transported from producing areas, the owners shall report to the local Administrative Department of Animal Husbandry and Veterinary for inspections.

If all the animals or animal products have passed quarantine inspection, the Supervising Agency for Animal Epidemic Prevention shall issue a quarantine certificate and, which is nationally prepared and issued in a uniform manner, affix thereto an inspection mark used by the Supervising Agency for Animal Epidemic Prevention or seal it with the inspection mark.

Article 37 Animal products, animals that are supplied for slaughter or fattening shall be reported for inspections 3 days before they are sold, transferred and transported. Animals used as breeds, to produce milk or for epidemic prevention shall be reported for inspections before they are sold or transferred and transported. As for the animals and animal products sold, transferred and transported, carried due to the special demands of production and living, they shall be inspected upon report.

Before transporting animals to take part in exhibition, competition or performance, sell or transport legally captured wildlife, introduce animals used as breeds and genetic materials such as semen, embryos and breeder eggs of these animals, the owner shall report to the local Supervising Agency for Animal Epidemic Prevention for inspections. After arriving at the scheduled place, the owner shall report to the Supervising Agency for Animal Epidemic Prevention at the scheduled place for inspection with a Conformity Certificate for Quarantine.

Supervising Agencies for the Animal Epidemic Prevention of administrative districts and counties shall conduct a quarantine in isolation for animals introduced as breeds and shall follow and supervise the genetic materials of these animals such as semen, embryos and breeder eggs.

Article 38 The municipality exercises slaughter at designated places and the centralised quarantine of livestock such as pigs, cattle and sheep. Other species of animals requiring slaughter at designated points and centralised quarantine shall be reported by the Municipal Administrative Department of Animal Husbandry and Veterinary to City People’s Government to be approved and made public.

Complying with the plan, slaughterhouses (or points) at designated places shall meet the requirements of the national and municipal animal disease prevention, food hygiene and environmental protection.

Slaughterhouses (or points) of cattle, sheep, chicken and ducks shall draw a licence to slaughter at designated place. Administrative Departments of Animal Husbandry and Veterinary of administrative districts and counties shall review and the Municipal Administrative Departments of Animal Husbandry and Veterinary shall approve and issue the licence for the slaughter at the designated place.

The slaughter of live pigs at a designated place shall be managed according to the requirements of the 《Regulations for the Administration of Live Pig Slaughter》 as issued by the State Council.

Article 39 Supervising Agencies for Animal Epidemic Prevention shall dispatch quarantine officers to slaughterhouses (or points) at designated places to examine, review and withdraw Conformity Certificate for Quarantine, disinfection certificate for means of transportation and signs of immunisation. Furthermore, quarantines before and after slaughter shall also be conducted.
If any animal or animal product has passed quarantine inspection, the quarantine officers shall issue a quarantine certificate and, affix thereto an inspection mark or seal it with the inspection mark.

Article 40 Supervising Agencies for Animal Epidemic Prevention shall perform a quarantine according to the laws and collect fees for their legal quarantine inspections according to the national and municipal regulations and shall not collect other additional fees or repeat charges for the same item of quarantine. Fees collected for their legal quarantine inspections shall be turned in to the public purse at the same administrative level.

Supervising Agencies for Animal Epidemic Prevention is prohibited from dealing with profit-making business operations.

Section V Supervision and Administration

Article 41 Quarantine officers shall be arranged by the Supervising Agencies for Animal Epidemic Prevention to supervisions on animal epidemic prevention. The Municipal Administrative Departments of Animal Husbandry and Veterinary shall review and issue a certificate for quarantine officers.

Article 42 Animals and animal products shall be transported into Beijing City through the channels of quarantine as announced by the City People’s Government. The Municipal Supervising Agencies for Animal Epidemic Prevention shall review certificates, inspect and disinfect goods at the channels of quarantine as announced by the City People’s Government.

In case animals and animal products are transported into Beijing City via railway or air transportation, the Supervising Agencies for Animal Epidemic Prevention shall perform supervisions and examinations in due time after receiving notices from the relevant departments of railway and air transportation.

Article 43 Quarantine certificates, marks, signs and stamps for having been inspected are prohibited from transfer, obliteration, buying or selling as well as forgery.

It is prohibited to use forged quarantine certificates, marks, signs and stamps for having been inspected.

Section VI Legal Liabilities

Article 44 Any of following violations of the provision 1 of Article 12, provision 2 of Articles 13, 17, 18, and 19, the Supervising Agencies for Animal Epidemic Prevention shall issue a warning to violators and impose a fine of not less than 1,000 RMB and not more than 5,000 RMB on them:

1. Bred animals are used as breeds or to produce milk without obtaining an Animal Vaccination Certificate;
2. Animal-borne pathogenic microorganisms are stored, used and transported at will without being subject to filing;
3. Refrigerator warehouse, market, restaurant, hotel, dining room or mess hall do not examine, review or keep quarantine certificates in accordance with the regulations;

Article 45 Any of following violations of Articles 10, 16 or 20, the Supervising Agencies for Animal Epidemic Prevention shall order the violators to make corrections. Any violator who refuses to make corrections shall be punished by the Supervising Agencies for Animal Epidemic Prevention according to the laws and all the expenditures required by the punishment shall be at the violator’s account.

1. Compulsory immunisations are not performed on bred and managed animals according to the nationally specified checklist and the municipal plan for animal epidemic prevention;
(2) Pigs, cattle, sheep and (beerdeer???) that have undergone compulsory immunisation do not wear immunisation signs;

(3) Means of transportation that is used for animals and animal products are not cleaned and disinfected according to the relevant national regulations;

(4) Animals’ excreta, bedding materials, contaminated articles are unloaded, discarded or lost and thrown away during transportation;

(5) Innocent treatments are not performed, according to the regulations, on animals and animal products that shall be subject to innocent treatments;

Article 46 Those who violate provision 1 of Articles 11 and 15 of this chapter and deal with the relevant activities without obtaining a《Conformity Certificate for Animal Epidemic Prevention》shall be issued a warning and ordered to make corrections by the Supervising Agencies for Animal Epidemic Prevention. Any violator refusing to make corrections shall be imposed a fine of not less than 10,000 RMB and no more than 30,000 RMB.

Article 47 If one violates provision 2 of Article 14 and deals with the diagnosis and treatment without obtaining a《Diagnosis and Treatment Licence》, the Supervising Agencies for Animal Epidemic Prevention shall stop the violators' operations and confiscate their illegal earnings. Moreover, violators shall be imposed a fine of no less than 5,000 RMB and no more than 10,000 RMB.

Article 48 In the case of any of the violations of provision 2 of Articles 14 or 22, the violators shall be ordered to make corrections and have imposed a fine of no less than 1,000 RMB and no more than 5,000 RMB.

(1) Diagnosis and treatment of animals are not within the approved scopes;

(2) Animals are fed with food that is produced by restaurants, hotels, dining rooms and mess halls and not subject to innocent treatments.

Article 49 If institutions or individuals violate Article 36, provision 1 and 2 of Article 37 and produce and deal in animals and animal products that are not subject to quarantine or a quarantine certificate is not issued to, they shall be ordered to stop production, operations, and their illegal earnings shall be confiscated. All the animals and animal products shall be subject to reinspections or retroactive inspections. In the event of animal products on which reinspections or retroactive inspections cannot be performed, innocent treatments shall be carried out on these animal products according to the relevant national or municipal regulations. Moreover, the expenditures required by reinspections, retroactive inspections and innocent treatments shall be borne by the violators.

Article 50 If institutions or individuals violate provision 3 of article 38 and slaughter cattle, sheep, chicken and ducks etc. that shall be slaughtered at designated places without permission and obtaining a licence to slaughter at designated places, they shall be outlawed and their illegal earnings coming from the illegal slaughter of animal products shall be confiscated. Furthermore, violators shall have imposed a fine of no less than 5,000 RMB and no more than 30,000 RMB.

Article 51 If provision 1 of Article 42 is violated and animals and animal products are transported into Beijing City via the channels of quarantine that are not subject to the approval of City People’s Government, the Administrative Authorities of Industry and Commerce or Supervising Agencies for Animal Epidemic Prevention shall order the violators to perform retroactive inspections and each transportation vehicle shall have imposed a fine of 1,000 RMB.

Article 52 If provision 2 of Article 43 is violated and forged quarantine certificates, marks, signs and stamps for having been inspected are used, the Supervising Agencies for Animal Epidemic Prevention shall take over these forged quarantine certificates, marks, signs and stamps for having
been inspected and impose a fine of no less than 2,000 RMB and no more than 5,000 RMB on the violators.

Article 53 In the case of any of these behaviours, the quarantine officers and supervisors of animal epidemic prevention shall face administrative punishment imposed by their work institutions or the higher competent authorities. Where a crime has been constituted, criminal liability shall be investigated according to the laws.

(1) Operation specifications are violated;
(2) Forged quarantine certificates are issued;
(3) Quarantine certificates, seals and signs are sold;
(4) Relevant national and municipal regulations are violated for charging fees;
(5) Non-performance of the responsibilities of supervising animal epidemic prevention and other behaviours such as abuse of their power of office, neglect of their duties, or the practice of fraud for personal gains;

Section VII Supplementary Rules

Article 54 These Measures shall become effective on 1 January 2005. 《Regulations on the Quarantine of Livestock and Poultry in Beijing》, which was revised at the 40th Session of the Standing Committee of the 10th Beijing Municipal People's Congress on 15 October 1997 and revised again at the 26th Session of the Standing Committee of the 11th Beijing Municipal People's Congress on 18 May 2001, shall be repealed at the same time.
Handling procedures for the selling, buying, and making use of wildlife (terrestrial) under second class protection

Name of the approval project: Selling, buying, and making use of the wildlife (Terrestrial Animals) under second class protection
Acceptance scope of the approval:
Basis of the approval fees: Resource protection and management fees shall be charged in accordance with the《Notice on the Issue of the Charging Measures for the Protection Fees of Terrestrial Wildlife Resources from the Ministry of Forestry, Ministry of Finance and State Price Control Bureau》.
The total time limit of the approval: 20 working days (delivery time is not included)
Approval procedures:
I. Acceptance
Acceptance conditions: the sponsors shall provide the bidding materials as follows:
1. Applications
(According to: Article 25 of《Regulations for the Implementation of the People’s Republic of China on the Protection of Terrestrial Wildlife》)
2. Application forms (The basis is the same as stated above)
3. Copies of business licences of the enterprises (The basis is the same as stated above)
4. Copies of《Domestication and Breeding Licences》 (The basis is the same as stated above)
5. Certifications of lawful origins (The basis is the same as stated above)
6. Opinion letters from the local administrative departments in charge of forestry (The basis is the same as stated above)
7. Statement of the recognition capability that the business personnel have on the wildlife and its products (The basis is the same as stated above)
Acceptance standard: the application items are within the terms of reference of their respective administrative agencies, the application materials are completed and conform to the legal forms.
Principal of this position: Operations Section of Management Station for the Natural Protection Areas of Wildlife Protection in Beijing.
Duties and authorities of this position: Check the bidding materials in accordance with the acceptance standard. Those who conform to the standard will be issued《Acceptance Notification》 and the applicants shall be notified.《Check Records of the Administrative Licences》 shall be filled in and handed over to the audit personnel. Those who do not conform to the standard will not be accepted, in which a 《Rejection Notice》 shall be filled in and the applicants shall be
notified.
1. Processing methods that conform to the acceptance standard:
The acceptance must be carried out in five working days, in which 《Acceptance Notification》 shall be issued, 《Check Records of Administrative Licences》 shall be filled in and all the materials shall be handed over to the audit personnel.
2. Processing methods that do not conform to the acceptance standard:
   (1) 《Rejection Notice》 shall be issued if there is no need for the application items to obtain administrative licences or if the application items do not belong to the terms of reference of their respective administrative agencies, and the applicants shall be notified for their dismissal;
   (2) If mistakes that can be corrected on the spot are in the application materials, the applicants shall be permitted to correct them on-site. Those who conform to the acceptance standard after correcting shall be disposed in accordance with the processing methods that conform to the acceptance standard;
   (3) If the application materials are not completed or do not conform to the legal forms, 《One-time Notification》 shall be issued on the spot or within five days, in which the applicants shall be notified of all the contents that are needed to be supplied or corrected at one time. The total time limit of the acceptance: it shall be finished within five working days.
II. Auditing
Auditing standards
1. The application shall be within the authority scope of their respective bureaus.
   (Basis: Article 7 of the 《Law of the People’s Republic of China on the Protection of Wildlife》)
2. The application materials are completed, normal and effective.
   (Basis: Article 25 of the 《Regulations for the Implementation of the People’s Republic of China on the Protection of Terrestrial Wildlife》)
3. The sources of the wildlife and their products are legal.
   (Basis: Article 25 of the 《Regulations for the Implementation of the People’s Republic of China on the Protection of Terrestrial Wildlife》)
4. The identification ability that the business personnel have on the wildlife and their products.
The principal of this position: Station master of the Management Station for the Natural Protection Areas of Wildlife Protection in Beijing.
Duties and authorities of this position: Check in accordance with the auditing standards (experts shall be asked for a demonstration, if necessary). 《Check Records of the Administrative Licences》 shall be filled in for those who conform to the standards and audit opinions shall be signed and handed over to the audit personnel. 《Decision on not issuing Administrative Licences》 shall be issued and sent to those personnel who are in charge of delivery, checking, charging and issue as to those who do not conform to the final audit.
1. Disposal methods that conform to the auditing standards:
More than two staff members shall be assigned to have an on-site check of the sites for business operation. 《Notice for the Transaction Terms》 shall be issued to notify the applicants to verify the time limit and the 《Registration Forms for the Verification Materials》 shall be filled in after verifying. The 《Check Records of Administrative Licences》 shall be filled out within eight working days and the audit opinions shall be signed and handed over to the audit personnel (experts shall be asked for a demonstration, if necessary).
2. Disposal methods that do not conform to the auditing standards:
More than two staff members shall be assigned to have an on-site check of the sites for business operation.
operation. The 《Notice for the Transaction Terms》 shall be issued to notify the applicants to verify the time limit and the 《Registration Forms for the Verification Materials》 shall be filled in after verifying. The auditing shall be finished within eight working days and the 《Check Records of the Administrative Licences》 shall be filled out. The reasons shall be stated, and the 《Decision on not issuing Administrative Licences》 shall be sent to those personnel who are in charge of the delivery, checking and charging after signing names (experts shall be asked for a demonstration, if necessary).

The total time limit of the auditing: it shall be finished within eight working days.

III. Approval

Approval standard: it is the same as the auditing standards.

Person in charge of this position: Deputy Director of Bureau

Duties and authorities of this position: Examine and approve the 《Audit Opinions》 in accordance with the auditing standards (experts shall be asked for a demonstration, if necessary). The 《Check Records of Administrative Licences》 shall be filled in and sent to the personnel who are in charge of delivery, checking, charging and issue after the audit opinions are signed.

1. Processing methods for the approval of the audit opinions: The 《Check Records of Administrative Licences》 shall be filled out within seven working days and audit opinions shall be signed and sent to the personnel who are in charge of delivery, checking, charging and issue (experts shall be asked for a demonstration, if necessary).

2. Processing methods for the disapproval of the audit opinions: Communicate with the audit personnel within seven working days, listen to the opinions (experts shall be asked for a demonstration, if necessary), put forward approval opinions, fill in the 《Notice of Administrative Licences》 and then it is to be sent to the personnel who are in charge of the delivery, checking, charging and issue (experts shall be asked for a demonstration, if necessary).

The total time limit of the approval: it shall be finished within seven working days.

IV. Delivery, checking, charging and issue

Standards of delivery, checking, charging and issue:

1. The complete set of bidding materials is normal and integrated
2. 《Check Records of Administrative Licences》 are normal and integrated.
3. The names that the persons who are in charge of the acceptance, auditing and approval signed on the 《Check Records of Administrative Licences》 shall be completed.
4. 《Decision on not issuing Administrative Licences》 shall be issued without mistakes.
5. The approval documents of administrative licences shall be issued without mistakes.
6. The approval document (《Licence for the Management and Use of the Terrestrial Wildlife and Products in Beijing》) issued has no mistakes.
7. 《Administrative Licences Decision Dispatch》 shall be filled in without mistakes.
8. Fees for the protection and administration of resources shall be charged.

The principal of this position: Persons who are in charge of the delivery, checking, charging and issue in the Management Station for the Natural Protection Areas of Wildlife Protection in Beijing.

Duties and authorities of this position: Issue the approval document of administrative licences, 《Licence for the Management and Use of the Terrestrial Wildlife and Products in Beijing》 or
the 《Decision on not issuing Administrative Licences》 in accordance with the approval opinions and have a check. Notify the applicants to receive the approval document of the administrative licences, 《Licence for the Management and Use of the Terrestrial Wildlife and Products in Beijing》 or《Decision on not giving Administrative Licences》 and bidding materials, fill in the 《Administrative Licences Decision Dispatch》 and hand over to the applicants for signatures, charge fees for the protection and administration of resources and file all the materials.

1. Processing methods for the approval of the audit opinions:
Issue the approval document, 《Licence for the Management and Use of the Terrestrial Wildlife and Products in Beijing》 in accordance with the approval opinions. Fill in the 《Administrative Licences Decision Dispatch》 and hand it over to the applicants for their signatures. Charge fees for the protection and administration of resources and file all the materials.

2. Processing methods for the disapproval of the audit opinions:
Notify the applicants to receive a 《Decision on not issuing Administrative Licences》 and bidding materials, and inform the applicants about the relevant rights and complaint channels in writing. File all the materials.
The total time limit of the delivery, checking, charging and issue: it shall be finished within 10 working days.
Application form for the selling, buying, and making use of wildlife (Terrestrial Animals) under second class protection and its products

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<thead>
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<td>Legal representative</td>
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### Specific conditions

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<th>Production place and origin</th>
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<th>Purpose of operation</th>
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<th>Signature of the applicant (stamp)</th>
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<th>Opinions of the wildlife competent authorities of administrative districts and counties:</th>
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<td>Year Month Date</td>
<td></td>
<td>Year Month Date</td>
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Science and Technology Commission of Beijing Municipality

The notice of Beijing Municipalities concerning the issuance of the 《Administrative Measures of the Licence for Laboratory Animals》

All of the relevant units:
To implement the 《Regulations for the Administration of Affairs Concerning Laboratory animals》, strengthen the management of the licences for the laboratory animals in Beijing, the 《Measures for the Administration of Licences for Laboratory animals in Beijing》 were established by Beijing Municipal Science & Technology Commission. Now it is hereby printed and issued to you for implementation.

Attachment: Measures for the Administration of Licences for Laboratory animals in Beijing

23 July 2005

Key words: Laboratory animal, Licence, Management, Measure, Notice
Policy, Regulation and Institutional Reform Division of Beijing Municipal Science & Technology Commission	Printed and issued on 26 July 2005
200 pieces in total are printed
Administrative Measures of the Beijing Municipalities on the Licence for Laboratory Animals

Article 1 To implement the 《Regulations for the Administration of Affairs Concerning Laboratory animals》, strengthen the management of the licences for the laboratory animals in Beijing, the Measures are established in accordance with the 《Administrative Licence Law of The People's Republic of China》.

Article 2 The Measures are applicable to the application, approval, issue and management of the licences for the laboratory animals in the administrative areas of this city.

Article 3 Science and Technology Commission of Beijing Municipality (hereinafter referred to as the Science & Technology Commission of the Municipality) is the competent authority for the management of the licences for the laboratory animals in this city. The Administration Office of Laboratory animals of Beijing Municipality (hereinafter referred to as the Administration Office of Animals of the Municipality) shall take specific responsibility for the daily management of the licences for the laboratory animals.

Article 4 The licences for the laboratory animals include the 《Licences for the Breeding of Laboratory animals and Licences for the Use of Laboratory animals》. The same licence has two copies: the original and a duplicate, which have equal legal effects.

The organisations or individuals that engage in the manufacturing and supplying of laboratory animals and the products related to feedstuff, padding and cage and equipment for laboratory animals, or engage in the operation of laboratory animals shall obtain the 《Licences for the Breeding of Laboratory animals》.

The organisations or individuals that use laboratory animals and relevant products shall obtain the 《Licences for the Use of Laboratory animals》.

Article 5 The organisations apply for the 《Licences for the Breeding of Laboratory animals》 shall meet the following requirements:
(1) Having sound management and organisation institutions for the laboratory animals;
(2) Having sound quality management systems and standard operating rules;
(3) Having animal welfare and biosafety management systems;
(4) Having provisions for the professional training programmes and the health protection of the staff members;
(5) Having production environmental facilities that are in conformity with the production of laboratory animals and the relevant products, in accord with the national standards and relevant provisions, and having the relevant quality test ability of laboratory animals or signing formal entrustment detection agreements with the institutions that have a testing ability;
(6) The feedstuff, padding and cage and equipment and drinking water used for laboratory animals shall be in accordance with the national standards and relevant requirements;
(7) The employed people shall be familiar with the codes, standards and basic knowledge of laboratory animals and have passed the examinations.

Article 6 The organisations apply for the 《Licences for the Use of Laboratory animals》 shall meet the following requirements:
(1) Having sound management and organisation institutions for the laboratory animals;
(2) Having sound quality management systems and standard operating rules;
(3) Having animal welfare, ethical review and biosafety management systems;
(4) Having provisions for the professional training programmes and the health protection of staff members;
(5) Having the environmental facilities of animal experiments, which are in conformity with the national standards. Those who carry out infection, radiation, chemical contamination and other animal experiments that are related to the public security or who use wildlife directly shall be in accordance with the relevant provisions of the State and this city.
(6) The feedstuff, padding and cage and equipment and drinking water used for laboratory animals shall be in accordance with the national standards and relevant requirements;
(7) The employed people shall be familiar with the codes, standards and basic knowledge of laboratory animals and have passed all the examinations.
Article 7 The organisations that apply for the 《Licences for the Breeding of Laboratory animals》 shall submit the following materials:
(1) Application for the Breeding Licences of Laboratory animals;
(2) Management and organisation institutions of laboratory animals and the name list of their members;
(3) Feeding, breeding, facility management systems and the standard operating rules of laboratory animals;
(4) Testing reports for the environmental facilities that are issued by the legal quality inspection institutions;
(5) Name list of the employed people engaged in work with laboratory animals;
(6) Plans for the facilities of laboratory animals;
(7) Proof of medical examinations for the employed people who engage in work with laboratory animals in a year and the professional training programmes this year;
(8) Animal welfare and biosafety systems;
(9) List of quality inspection equipment for the laboratory animals and the relevant products and a name list of the people who are engaged in quality inspection, or copies of the agreements for the commission of the inspection.

Article 8 The organisations apply for the 《Licences for the Use of Laboratory animals》 shall submit the following materials:
(1) Application for the Use Licences for Laboratory animals
(2) Management and organisation institutions of laboratory animals and the name list of their members;
(3) Feeding of laboratory animals and facility management systems and standard operating rules of animal experiments;
(4) Testing reports for the environmental facilities that are issued by the legal quality inspection institutions;
(5) Name list of the employed people engaged in work with laboratory animals;
(6) Plans for the facilities of laboratory animals;
(7) Proof of medical examinations for the employed people who engage in work with laboratory animals in a year and the professional training programmes this year;
(8) Animal welfare, biosafety and ethical review systems of animal experiments;

Article 9 When those individuals who engage in work related to laboratory animals apply for licences for laboratory animals, the relevant provisions of Articles 5, 6, 7 and 8 in the Measures shall be referred to for the performance.

Article 10 The total time limit of the auditing for the laboratory animals is 20 working days. The process and time limit are as follows:
(1) Application and acceptance
The windows for accepting the licence application for laboratory animals of this city of the Science and Technology Commission of Beijing Municipality (hereinafter referred to as the Acceptance Windows of the Science and Technology Commission of the Municipality) are set at the Animal Management Office of the Municipality. The applicants can submit the application materials for the licences for laboratory animals through the mail, fax, email or carrier. Those persons who are in charge of acceptance shall check immediately as to whether the materials are completed, whether they accord with the legal forms and then issue acceptance forms to the applicants. Those who submit the applications through faxes or email shall supplement the original documents while the experts are assessing on-site.

(2) Checking
The office in charge of the Science and Technology Commission of the Municipality shall check as to whether the materials accord with the legal conditions and decide whether to submit them to the supervisor in charge for approval according to the on-the-spot assessment opinions from the experts. The time limit is seven working days.

(3) Approval
Those who have been approved by the office in charge of the Science and Technology Commission of the Municipality shall be approved by the executive leaders of the Science and Technology Commission of the Municipality. The time limit is thirteen working days.

Article 11 The Science and Technology Commission of the Municipality shall entrust the Animal Management Office of Municipality to organise experts for the on-the-spot assessment on the
conditions of those persons who apply for the licence for laboratory animals, and the Animal Management Office of Municipality shall notify the on-the-spot assessment opinions from the experts. The time limit for the on-the-spot assessment by the experts organised is ten working days.

Article 12 After the Science and Technology Commission of the Municipality makes the decision to grant the administrative licences, the Animal Management Office of Municipality shall make the certificates and deliver them to the applicants. The time limit is five working days.

Article 13 The valid period of the laboratory animal licences is five years, upon expiration, reinspection and licence renewal shall be conducted. The organisations or individuals that have obtained the laboratory animal licences shall apply for continuation towards the acceptance windows of the Science and Technology Commission of the Municipality in 30 working days before the expiration of licences.

Article 14 Those organisations or individuals that have obtained the laboratory animal licences and want to change the registered particulars of the licences shall apply to the acceptance windows of the Science and Technology Commission of the Municipality 30 working days ahead. Those who want to change the scope of the application or rebuild and expand the original facilities shall transact in accordance with the provisions of Articles 5, 6, 7 and 8 of the Measures. Those who want to stop work in the scope of application shall hand back the licences for laboratory animals within 30 working days after the stop. Those who lose their licences shall report the loss to the acceptance windows of the Science and Technology Commission of the Municipality in due time and apply for reissuance.

Article 15 The administrative law enforcement personnel of laboratory animals in Beijing and the quality inspectors of laboratory animals in Beijing (area) employed by the Science and Technology Commission of the Municipality shall carry out supervision and inspection of the organisations or individuals that have obtained the laboratory animal licences in the administrative areas of this city.

Article 16 The supervision and inspection of the laboratory animals shall carry out the principle that combines a random sample and self check together. The main contents of the inspection include:

1. The work records of the management and organisation institutions for the laboratory animals of the units;
2. Business training, evaluating and physical examination records of the employed people;
3. Whether the seed sources and animal transportation of the organisations and individuals that have obtained the production licences for laboratory animals accord with the relevant provisions of the State;
4. Whether the feedstuff, padding and cage and equipment that are used for the production or use of laboratory animals accord with the national standards and relevant requirements;
5. The implementation of the management systems and operating rules and the running conditions of the facilities of laboratory animals;
6. Performance of biosafety, animal welfare and ethical review systems of laboratory animals;
7. Whether the laboratory animals are provided or used beyond the range of the licences, and whether the conformity certificates of laboratory animals are used according to the provisions.

Article 17 The Science and Technology Commission of the Municipality shall proclaim the credit information of the organisations or individuals that have obtained the licences for laboratory animals through the media.

Article 18 The organisations or individuals that have obtained the 《Licences for the Breeding of Laboratory animals》 shall produce and provide laboratory animals and the relevant products in accordance with the scope of the application of the licences. 《Quality Certification of Laboratory animals in Beijing》 with the unified format in Beijing shall be enclosed during the provision or sale. The quality test results of microorganisms and parasites in a quarter shall also be enclosed during the provision or sale of laboratory animals. The organisations or individuals that have obtained the 《Licences for the Breeding of Laboratory animals》 shall not sell the laboratory animals or relevant products manufactured by those organisations or individuals that have not obtained the 《Licences for the Breeding of Laboratory animals》.
Article 19 Those organisations or individuals that undertake the production and operating activities of laboratory animals and the relevant products without the 《Licences for the Breeding of Laboratory animals》 shall be investigated and punished according to law by the Science and Technology Commission of the Municipality and their law-violating actions shall be reported to the Municipal Bureau of Industry and Commerce and be dealt with according to law. Those who forge licences for laboratory animals or the 《Quality Certification of Laboratory animals in Beijing》 shall be investigated for legal responsibility according to law.

Article 20 Those organisations or individuals that have obtained the 《Licences for the Use of Laboratory animals》 shall work in accordance with the scope of application of the licences. Those who use unqualified laboratory animals and the relevant products shall be notified by the Science and Technology Commission of the Municipality and their results of animal experiments shall be invalid while declaring the awards of achievements.

The organisations or individuals that have not obtained the 《Licences for the Use of Laboratory animals》 shall consign those who have obtained them for animal experiments, but both of the sides shall sign the written agreements and report to the Administration Office of Animals of the Municipality for records.

Article 21 Those organisations or individuals that have not obtained the 《Licences for the Use of Laboratory animals》 and those who do not transact according to the provisions of Paragraph Two in Article 20 of the Measures cannot declare the science and technology planning projects related to animal experiments.

The organisations or individuals that have not obtained the 《Licences for the Use of Laboratory animals》, but still engage in animal experiments shall be investigated and punished by the Science and Technology Commission of Municipality and their law-violating actions shall be reported to the relevant departments.

Article 22 The administrative licences for laboratory animals shall be written off according to law if those organisations or individuals that have obtained the licences for the laboratory animals have one of the following circumstances:

(1) The licences for the laboratory animals are not applied for in continuation after the expiration of their validity;
(2) Being terminated by the legal persons or other organisations according to law;
(3) The citizens who have obtained the licences for laboratory animals are dead;
(4) The licences for laboratory animals are revoked, withdrawn, or suspended according to law;
(5) The items related to the administrative licences of laboratory animals cannot be implemented owing to force majeure;
(6) Other conditions that shall be written off according to the provisions of laws and codes.

Article 23 The administrative law enforcement personnel of laboratory animals and quality inspectors who are negligent of their duties, abuse their powers or practice favouritism and malpractice shall be punished in accordance with the 《Regulations for the Administration of Affairs Concerning Laboratory animals in Beijing》.

Article 24 The parties who have objections to the approval, issue, and management of the licences for laboratory animals in the city can lodge administrative appeals to the legal departments of the municipal government or bring an administrative suit to the people’s courts.

Article 25 These measures come into effect as of 1 July 2005. Measures for the 《Implementation of Administrative Measures for the Licences of Laboratory animals (Trial) Implemented by Beijing》 as issued on 8 February 2003 shall be invalidated as of the same date.
Administrative Approval Procedure of the Science and Technology Commission of Beijing Municipality

Name of business: Laboratory Animals Licence
Type of business: licensing authority

Basis for handling:

《Regulations of Beijing Municipality for the Administration of the Affairs Concerning Laboratory Animals》 (Announcement No. 31 of the Standing Committee of Beijing Municipal people's Congress in 2004)
《Administrative Measures of the Licensing of Laboratory Animals (trial)》 (Notice No. 545 [2001] of State Science and Technology Commission)
《Administrative Measures of Beijing Municipality on the Licensing of Laboratory Animals》 (Notice No. 454 [2005] of Administrative Department of Science and Technology of Beijing Municipality)

Basis for charge: free
Charge standard: free

Specified total time period (in days): 20

Special explanations in terms of the time period: 10 workdays of the time period for the on-site acceptance of specialists; 5 workdays for the licence delivery, which is not included in the approval period.

Object of service: individuals and corporations
Object and scope of licence: individuals and corporations

Result from processing the business:

When an application for a licence for laboratory animals is handled, the working personnel responsible for accepting and handling the application shall examine and verify the completeness and conformities with the legal procedure of application documents, and then a handling form shall be issued to the applicant (《Handling Form of the Administrative Licence of the Science and Technology Commission of Beijing Municipality》).

When an application is accepted and handled, opinions on handling it thereby shall be written and a seal of the working personnel in charge of handling the application shall be affixed on the handling form. After the date is filled out, the handling form shall be issued to the applicant.

When an application is not accepted and handled, the reasons for the refusal of an application shall be written and a seal of the working personnel in charge of handling the application shall be affixed on the handling form. After the date is filled out, the handling form shall be issued to the applicant.

Opinions from the on-site evaluation shall be given by a specialist during the on-site acceptance. After these opinions are examined and approved by the Science and Technology Commission of Beijing Municipality, a written reply shall be given and an original and a copy of (production or usage) the licence for laboratory animals shall be issued to the applicant by the Science and Technology Commission of Beijing Municipality.

Handling Procedure:

Acceptance

(1) Requirements for the acceptance and handling of an application

The application documents, as submitted by an applicant, must be complete, conform to the regulations and be effective.
Time limit: immediate

(2) Positions and responsibilities

1. Application documents for the examination shall be reviewed for their completeness and conformity with legal form;
2. The applicant shall, for one time only, be informed of the incompleteness of their application documents, in which the relevant documents shall be prepared and issued. In the case of the non-conformity of application documents with the requirements, the application shall be refused and the reasons for this refusal shall be explained with the relevant documents that will be prepared and issued;
3. An application meeting the requirements shall be accepted and handled on time and the relevant documents shall be issued;

(3) Department in charge of the acceptance and handling of an application and its contact details

Department in charge: Beijing Administration Office of Laboratory Animals
Person in charge: Li Genping
Contact person: Liu Wenju
Address for accepting and handling applications: 6th Floor, Beike Building, No.27, Xisanhuan North Road, Haidian District, Beijing, China
Postal code: 100089
Telephone: 6872-2982 (2983) - extension 21
Fax: 6847-9601
Office hours: 8:30 - 12:00 PM and 1:00 - 5:00 PM, Monday to Friday

Examination

(1) Examination standard

Production Licence for Laboratory Animals:
1. Available and sound administrative organisation for laboratory animals;
2. Available and sound quality control system and standardised operation specifications;
3. Animal welfare system and biosafety management system are available;
4. Available professional training programme and regulations on the health protection of the staff;
5. Production environment and facilities that adapt to the production of laboratory animals, in which the relevant products shall be provided. Moreover, those institutions shall have the corresponding abilities of inspecting the quality of the laboratory animals or shall sign a formal entrustment agreement of inspection with an institution that has the corresponding inspection abilities;
6. The feedstuffs, bedding materials, cages and drinking water shall conform to the national standards and meet all the relevant requirements;
7. Employed persons shall be familiar with the laws and regulations, standards and possess basic knowledge concerning laboratory animals and shall pass all the examinations;

Usage Licence for Laboratory Animals:
1. Available and sound administrative organisation for laboratory animals;
2. Available and sound quality control system and standardised operation specifications;
3. Animal welfare system, ethical review system and biosafety management system are available;
4. Available professional training programme and regulations on the health protection of staff;
5. Environment and facilities that conform to the national standards shall be available for animal experiments. Implementation of animal experiments such as infection, radiation and chemical contamination that may influence public safety and the direct use of wildlife shall conform to the relevant national and municipal regulations;
6. The feedstuffs, bedding materials, cages and drinking water shall conform to the national standards and meet the relevant requirements;
7. Employed persons shall be familiar with the laws and regulations, standards and possess basic knowledge concerning laboratory animals and shall pass all the examinations;

(2) Basis for examination
Examinations are based on Article 6, 7, 9, 10, and 12 of the 《Regulations of Beijing Municipality for the Administration of Affairs Concerning Laboratory Animals》, Article 5, 6 of 《Administrative Measures of the Licence for Laboratory Animals (trial)》, Article 5, 6 of 《Administrative Measures of Beijing Municipality on the Licence for Laboratory Animals》 and opinions from the on-site acceptance of specialists.

(3) Position and responsibilities relating to an examination
Applications are examined for their conformities with the requirements and standards.

(4) On-site examination and acceptance of a specialist
On-site examination and acceptance of a specialist shall be performed according to the 《Regulation of the Inspection of Beijing Municipality on the Licence for Laboratory Animals》.

1. The supervisory staff of the applicant shall hold examinations concerning the polices, laws and regulations on laboratory animals;
2. Acceptance specialists shall carry out selective examinations on the knowledge and skills that shall be known and mastered by those employed persons dealing with laboratory animals;
3. Environments inside and outside the facilities, qualification certificates, records of bedding materials and the resources of bedding materials for laboratory animals, physical examination records of employed persons, continuing education programme of the employed persons, management system and standardised operation specification for laboratory animals, animal welfare system, ethical review system and biosafety management system as well as the repair and maintenance records of all the important equipment shall be examined on-site.

(5) Time period for examination: 7 workdays from the day that the application is accepted and handled.

5. Examination and approval

(1) Standards of the examination and approval
Production Licence for laboratory Animals
1. Available and sound administrative organisation for laboratory animals;
2. Available and sound quality control system and standardised operation specifications;
3. Animal welfare system and biosafety management system are available;
4. Available professional training programme and regulations on the health protection of the staff;
5. Production environment and facilities that adapt to the production of laboratory animals and the relevant products shall be provided. Moreover, institutions shall possess the corresponding abilities of inspecting the quality of the laboratory animals or shall sign a formal entrustment agreement of inspection with an institution that has the corresponding inspection abilities;
6. The feedstuffs, bedding materials, cages and drinking water shall conform to the national standards and meet all the relevant requirements;
7. Employed persons shall be familiar with the laws and regulations, standards and possess basic knowledge concerning laboratory animals and shall pass all the examinations;

Usage Licence for Laboratory Animals
1. Available and sound administrative organisation for laboratory animals;
2. Available and sound quality control system and standardised operation specifications;
3. Animal welfare system, ethical review system and biosafety management system are available;
4. Available professional training programme and regulations on the health protection of the staff;
5. Environment and facilities that conform to the national standards shall be available for animal experiments. Implementation of animal experiments such as infection, radiation and chemical contamination that may influence public safety, in which the direct use of wildlife shall conform to the relevant national and municipal regulations;
6. The feedstuffs, bedding materials, cages and drinking water shall conform to the national standards and meet the relevant requirements;
7. Employed persons shall be familiar with the laws and regulations, standards and possess basic knowledge concerning laboratory animals and shall pass all the examinations;

(2) Basis for examination and approval
Examinations and approvals shall be based on Article 6, 7, 9, 10 and 12 of the 《Regulations of Beijing Municipality for the Administration of the Affairs Concerning Laboratory Animals》, Article 5 and 6 of the 《Administrative Measures of the Licence for Laboratory Animals (trial)》, Article 5 and 6 of the 《Administrative Measures of Beijing Municipality on the Licence for Laboratory Animals》, opinions from specialists during on-site acceptance and opinions from departments and office in charge.

(3) Time period for examinations and approvals: 13 business days

Delivery
Time limit: 5 business days.
Method of delivery: applicants will be informed by telephone and the results will be recorded in the flow sheet of the examination and approval.
Remarks: Applicants shall faithfully submit the relevant application documents and be responsible for the authenticity of the application documents; otherwise, the applicants shall bear the corresponding legal consequences.
Application documents for a production licence for laboratory animals:

(1) 《Letter of application for a production licence for laboratory animals》 (in triplicate);
(2) A document concerning the administrative organisation of laboratory animals and a name list of its members;
(3) One document concerning the management system of raising, breeding and facilities of laboratory animals and one standardised operation specification;
(4) Inspection report of the environment and facilities as issued by the legal Quality Inspection Institution in triplicate (one is original);
(5) One document containing a name list of those persons who have obtained a 《Qualification Certificate for those Persons Engaging in the Industry of Laboratory Animals in Beijing》 and the corresponding certificate numbers;
(6) Layout drawings of the facilities of laboratory animals (in triplicate);
(7) One document concerning the physical examination certificate of the employed persons in the industry of laboratory animals within one year and one professional training programme in the current year;
(8) A document relating to the animal welfare system and biosafety system;
(9) One list of the quality inspection equipment for laboratory animals and the relevant products and one name list of the quality inspectors or one copy of the entrustment agreement of inspection;

Application documents for a usage licence for laboratory animals:

(1) Letter of application for a usage licence for laboratory animals (in triplicate);
(2) One document concerning the administrative organisation of laboratory animals and a name list of its members;
(3) One document describing the management system of the feeding and facilities of laboratory animals and one standardised operation specification;
(4) Inspection report of the environment and facilities as issued by the legal Quality Inspection Institution in triplicate (one is to be the original);
(5) One document containing a name list of those persons who have obtained a 《Qualification Certificate for those Persons Engaging in the Industry of Laboratory Animals in Beijing》 and the corresponding certificate numbers;
(6) Layout drawings of the facilities of laboratory animals (in triplicate);
(7) One document concerning the physical examination certificate of the employed persons in the industry of laboratory animals within one year and one professional training programme in the current year;
(8) Animal welfare system, ethical review system and biosafety management system;
Letter of application (sample) for a production licence for laboratory animals

Applicant (official seal): Integrated Biology Technology Development Co., Ltd of Beijing
Legal representative (signature): Liu Xiaoming
Date of Application: July 1, 2004
Contact Person: Wang Daming Contact telephone: 98562356
Department in charge of acceptance and handling of application: Beijing Administration Office of Laboratory Animal
Date of Acceptance: July 1, 2004
Explanations for Filling out the Form and Applying (Sample)

1. “Breed of Product” and “Quality Grade” in this letter of application refer to the breeds and monitoring levels of the applicable Laboratory Animals and relevant products thereof (such as a mouse, rat, shrewmouse, guinea pig, chicken, rabbit, dog, monkey, and feedstuffs, etc.) according to the national standards relating to experimental animals. Trade standards or local standards (such as cat and SPF pig, etc.) shall be used in turn during the interim in those cases that the relevant national standards have not yet been formulated.

2. “Facility Classification” in the letter of application means “Classifications of and Technical Requirements for Facilities” (such as an ordinary environment, a barrier environment, an isolation environment, etc.) as stipulated in the 《National Standards of the People’s Republic of China for Laboratory Animals—Environments and Facilities》.

3. Breeds of Laboratory Animals (such as reptiles, amphibians, fish, etc.) for which unified standards have not yet been formulated shall be governed by the various local competent authorities according to the local regulations.

4. Licences shall be respectively applied for and drawn for the facilities of Laboratory Animals that are set up at different places by the same institution.

5. The licence shall be applied and drawn for newly-built facilities after a trial run and before formal use.

6. The letter of application can be accepted as complete application documents only if submitted together with the following appendices.
   (1) Certificate proving that the resources of breeds of Laboratory Animals conform to the regulations;
   (2) Inspection report concerning environments and facilities and the qualities of the Laboratory Animals as issued by the Provincial Quality Inspection Institution of Experimental Animals;
   (3) Other relevant documentary evidence;

7. With legible writings, the letter of application shall be filled out in pen or with a computer;

8. Additional pages can be added in case there are insufficient spaces for filling the form out.

9. This letter of application is also applicable to the adding of scopes to the application.
1. Basic information of organisation

Name of organisation: Integrated Biology Technology Development CO., Ltd of Beijing
Address of organisation: 27 Xiwang Road, Haidian District, Beijing, China; Postal code: 100089
Contact Telephone: 98562356  Contact Person: Wang Daming
Legal Representative: Liu Xiaoming  Person in charge of animal facilities: Wang Daming
Location of facilities: Biology Lab building, 27 Xiwang Road, Haidian District, Beijing, China;

2. Application items

<table>
<thead>
<tr>
<th>Breed of Product</th>
<th>Quality Grade</th>
<th>Source of Breeds and Time of Introduction</th>
<th>Classification and Area (m²) of Facility as well as Production Capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCR mouse</td>
<td>SPF class</td>
<td>Charles River</td>
<td>Facilities: barrier environment Area: 500 m² Production capacity: 120,000/year</td>
</tr>
</tbody>
</table>

Sample
3. Product quality assurance condition

3.1 Major employees (including primary production management personnel, veterinarians, quality inspectors, etc.)

<table>
<thead>
<tr>
<th>Name</th>
<th>Professional and Technical Titles</th>
<th>Professional Qualification</th>
<th>Academic Qualification</th>
<th>Principle Duties</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

No need to fill out this table. Please directly fill out “Annex 2”.

3.2 Major instruments and equipment (or standard materials)

<table>
<thead>
<tr>
<th>Instruments and Equipment (or Standard Materials)</th>
<th>Quantity</th>
<th>Running Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air filter</td>
<td>5</td>
<td>normal</td>
</tr>
<tr>
<td>Refrigerator</td>
<td>10</td>
<td>normal</td>
</tr>
<tr>
<td>Autoclave</td>
<td>2</td>
<td>normal</td>
</tr>
<tr>
<td>Large isolator</td>
<td>1</td>
<td>normal</td>
</tr>
<tr>
<td>Electrophoresis magnetic stirring apparatus with timing and temperature keeping functions</td>
<td>2</td>
<td>normal</td>
</tr>
<tr>
<td>Mini bench vacuum pump</td>
<td>5</td>
<td>normal</td>
</tr>
<tr>
<td>High-speed desk centrifuge</td>
<td>5</td>
<td>normal</td>
</tr>
</tbody>
</table>

3.3 Important rules and regulations (facility management, equipment maintenance, personnel training, SOP, etc.)

1. Responsibilities of managerial personnel at various levels in the Department of Animal
2. Management rules for building of laboratory animals
3. Rules for clean-class animal laboratory
4. Procedures for entering and leaving clean-class laboratory
5. Environmental maintenance system for clean-class rats and mice
6. Management measures of testing laboratory
7. Measures for plan, management and supply of laboratory animals
8. Management measures of equipment and instruments

Sample
Resume of the Key Person in Charge of the Laboratory Animals Department

<table>
<thead>
<tr>
<th>Name</th>
<th>Wang Daming</th>
<th>Gender</th>
<th>Male</th>
<th>Date of Birth</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Education level</td>
<td>University</td>
<td></td>
<td></td>
<td>1960-01-07</td>
<td>Senior Engineer</td>
</tr>
<tr>
<td>Position</td>
<td>Laboratory Officer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Professional qualification</td>
<td>Medicinal Chemistry</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Graduate from</td>
<td>Beijing University</td>
<td></td>
<td></td>
<td></td>
<td>1984.07</td>
</tr>
<tr>
<td>Graduation Date</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Work experience and strengths:

CV
1980  Beijing University (former Medical Science University of Beijing). Major: Medical Chemistry
1985  Engaging in development of various new medicines for 5 years after graduation.
1990  Studied in the National Institutes of Health (NIH) in America.
1998 to present  Working for Integrated Biology Technology Development Co., Ltd of Beijing

Strengths: pharmacological test, technology of drugs and toxicology.

Sample
# Laboratory Animals Staff List (Sample)

<table>
<thead>
<tr>
<th>No.</th>
<th>Name</th>
<th>Gender</th>
<th>Date of Birth</th>
<th>Education qualification</th>
<th>Position</th>
<th>Title</th>
<th>Speciality</th>
<th>Principle Duties</th>
<th>Organisation Certificate number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Wang Daming</td>
<td>Male</td>
<td>1960-07-01</td>
<td>University</td>
<td>Laboratory Officer</td>
<td>Senior Engineer</td>
<td>Medicinal Chemistry</td>
<td>Management of laboratory animals</td>
<td>21111</td>
</tr>
<tr>
<td>2</td>
<td>Zhang Deming</td>
<td>Male</td>
<td>1960-06-01</td>
<td>University</td>
<td>Nil</td>
<td>Engineer</td>
<td>Laboratory Animals</td>
<td>Animal experiments</td>
<td>21112</td>
</tr>
<tr>
<td>3</td>
<td>Zhao Chunsheng</td>
<td>Male</td>
<td>1950-05-01</td>
<td>University</td>
<td>Nil</td>
<td>Senior Engineer</td>
<td>Biological Genetics</td>
<td>Studies of laboratory animals</td>
<td>21113</td>
</tr>
<tr>
<td>4</td>
<td>Wang Minzhe</td>
<td>Female</td>
<td>1980-04-01</td>
<td>University</td>
<td>Nil</td>
<td>Assistant engineer</td>
<td>Laboratory Animals</td>
<td>Feeding of laboratory animals</td>
<td>21114</td>
</tr>
<tr>
<td>5</td>
<td></td>
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</tr>
</tbody>
</table>
Letter of application (sample) for a licence for using laboratory animals

Applicant (official seal): Integrated Biology Technology Development Co., Ltd of Beijing
Legal representative (signature): Liu Xiaoming
Date of Application: 1st July, 2004
Contact Person: Wang Daming Contact telephone: 98562356
Department in charge of acceptance and handling of application: Beijing Administration Office of Laboratory Animal
Date of Acceptance: 1st July, 2004
Explanations for Filling out the Form and Applying (Sample)

1. “Facility Classification” in the letter of application means “Classifications of and Technical Requirements for Facilities” (such as an ordinary environment, a barrier environment, an isolation environment, etc.) as stipulated in the 《National Standards of the People’s Republic of China for Laboratory Animals—Environments and Facilities》.

2. Licences shall be respectively applied for and drawn for the facilities of Laboratory Animals that are set up at different places by the same institution.

3. The licence shall be applied and drawn for newly-built facilities after a trial run and before formal use.

4. The letter of application can be accepted as complete application documents only if submitted together with the following appendices.
   (1) Certificate proving that the resources of breeds of Laboratory Animals conform to the regulations;
   (2) Inspection report concerning environments and facilities and the qualities of the Laboratory Animals as issued by the Provincial Quality Inspection Institution of Experimental Animals;
   (3) Other relevant documentary evidence;

5. With legible writings, the letter of application shall be filled out in pen or with a computer;

6. Additional pages can be added in case there are insufficient spaces for filling the form out.

7. This letter of application is also applicable to the adding of scopes to the application.
1. Basic information of organisation

Name of organisation: Integrated Biology Technology Development Co., Ltd of Beijing
Address of organisation: 27 Xiwang Road, Haidian District, Beijing    Postal code: 100089
Contact telephone: 98562356    Contact Person: Wang Daming
Legal Representative: Liu Xiaoming    Person in charge of animal facilities: Wang Daming
Location of facilities: Biology Lab building, 27 Xiwang Road, Haidian District, Beijing

2. Application items

2.1 General experimental facilities of laboratory animals

<table>
<thead>
<tr>
<th>Facility Classification</th>
<th>Major subjects of animal experiments and the breed of animal being used</th>
<th>Area of Facility (m²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barrier environment</td>
<td>Inspection of abnormal toxicity and hypersensitive test, etc. on mice, rats and guinea pig</td>
<td>230 m²</td>
</tr>
</tbody>
</table>

2.2 Special laboratory facilities of laboratory animals

<table>
<thead>
<tr>
<th>Facility Classification</th>
<th>Major Subjects of Animal Experiments</th>
<th>Area of Facility (m²)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1. Animal experiment for radioactivity</td>
<td>Nil</td>
</tr>
<tr>
<td></td>
<td>2. Animal experiment for infectivity</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Animal experiment for chemical toxicity</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Other (explain in details)</td>
<td></td>
</tr>
</tbody>
</table>

Sample
3. Assurance of Facilities of Laboratory Animals

3.1 Major employees (including primary production management personnel, veterinarians and experimental technical personnel)

<table>
<thead>
<tr>
<th>Name</th>
<th>Professional and Technical Titles</th>
<th>Speciality</th>
<th>Academic Qualification</th>
<th>Principle Duties</th>
</tr>
</thead>
</table>

No need to fill out this table. Please directly fill out “Annex 2”.

3.2 Major instruments and equipment (or standard materials)

<table>
<thead>
<tr>
<th>Instruments and Equipment</th>
<th>Quantity</th>
<th>Running Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Thermodetector</td>
<td>2</td>
<td>normal</td>
</tr>
<tr>
<td>2) Microscope, OLYMPUS</td>
<td>10</td>
<td>normal</td>
</tr>
<tr>
<td>3) Microscope, Nikon</td>
<td>5</td>
<td>normal</td>
</tr>
<tr>
<td>4) Chamber electric oven</td>
<td>3</td>
<td>normal</td>
</tr>
<tr>
<td>5) Temperature controller of electric oven</td>
<td>6</td>
<td>normal</td>
</tr>
<tr>
<td>6) Microtome</td>
<td>5</td>
<td>normal</td>
</tr>
<tr>
<td>7) Electro-heating standing-temperature cultivator</td>
<td>2</td>
<td>normal</td>
</tr>
<tr>
<td>8) Vacuum drying chamber</td>
<td>2</td>
<td>normal</td>
</tr>
</tbody>
</table>

3.3 Important rules and regulations (facility management, equipment maintenance, personnel training, SOP, etc.)

1. Management system of laboratory;
2. Rules for experimenters;
3. Rules for laboratory workers;
4. Responsibilities of persons on duty;
5. Daily works of persons dealing with feeding of laboratory animals;
6. Hygiene and quarantine system;
7. Environmental monitoring system;
8. Management system of machine room;

Sample
Resume of the Key Person in Charge of the Laboratory Animals Department

<table>
<thead>
<tr>
<th>Name</th>
<th>Wang Daming</th>
<th>Gender</th>
<th>Male</th>
<th>Date of Birth</th>
<th>1960-01-07</th>
</tr>
</thead>
<tbody>
<tr>
<td>Education level</td>
<td>University</td>
<td>Position</td>
<td>Laboratory Officer</td>
<td>Title</td>
<td>Senior Engineer</td>
</tr>
<tr>
<td>Professional qualification</td>
<td>Medicinal Chemistry</td>
<td>Graduate from Beijing University</td>
<td>Graduation Date</td>
<td>1984.07</td>
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Work experience and strengths:

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1980 Beijing University (former Medical Science University of Beijing). Major: Medicinal Chemistry
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Strengths: pharmacological test, technology of drugs and toxicology.

Sample
## Laboratory Animals Staff List (Sample)

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<th>Date of Birth</th>
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<th>Title</th>
<th>Speciality</th>
<th>Principle Duties</th>
<th>Organisation Certificate number</th>
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<td>Management of laboratory animals</td>
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<td>Zhang Deming</td>
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<td>Laboratory Animals</td>
<td>Animal experiments</td>
<td>21112</td>
</tr>
<tr>
<td>3</td>
<td>Zhao Chunsheng</td>
<td>Male</td>
<td>1950-05-01</td>
<td>University</td>
<td>Nil</td>
<td>Senior Engineer</td>
<td>Biological Genetics</td>
<td>Studies of laboratory animals</td>
<td>21113</td>
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<tr>
<td>4</td>
<td>Wang Minzhe</td>
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<td>1980-04-01</td>
<td>University</td>
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<td>Feeding of laboratory animals</td>
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</tbody>
</table>
The Science and Technology Commission of Beijing Municipality

Notice No. 587 [2000] of the Administrative Department of Science and Technology of Beijing Municipality

The notice concerning the issue of the 《Measures of the Beijing Municipalities for the Implementation of Strengthening the Administrative Enforcement of the Law on the Affairs relating to Laboratory Animals》

To all the related departments and institutions:

In order to thoroughly implement the 《Regulations of Beijing Municipality for the Administration of the Affairs Concerning Laboratory Animals》, to strengthen the law enforcement and supervision on laboratory animals in Beijing and to standardise the behaviours of the administrative enforcement of law and enhance the publication of government affairs, the 《Measures of the Beijing Municipalities for the Implementation of the Strengthening of the Administrative Enforcement of the Law on the Affairs relating to Laboratory Animals》 is prepared and issued to you by the Science and Technology Commission of Beijing Municipality. It shall be implemented as a reference.

The Science and Technology Commission of Beijing Municipality
30 October 2000

Key words: Strengthening, laboratory animals, law enforcement, measures and notice
C.C.: Legal Office of Beijing Municipality
Science and Technology Commission of Beijing Municipality Printed on 30 October 2000
30 copies in total are to be printed
Measures of the Beijing Municipalities for the Implementation of the Strengthening of the Administrative Enforcement of the Law on the Affairs Relating to Laboratory Animals

Article 1 In order to strengthen the law enforcement on laboratory animals and standardise the behaviours of the administrative enforcement of the law in the administrative regions of Beijing, these measures are formulated according to 《The Law of the People’s Republic of China on Administrative Punishments》 and the 《Regulations of Beijing Municipality for the Administration of the Affairs Concerning Laboratory Animals》 (hereinafter referred to the “Regulations for the Administration of Laboratory Animals”).

Article 2 The Science and Technology Commission of Beijing Municipality (hereinafter referred to as “STCBM”) is in charge of the administrative enforcement of law in the administrative regions of Beijing. Entrusted by STCBM, the Beijing Administration Office of Laboratory Animal (hereinafter referred to as “BAOLA”) is specifically responsible for the daily management and law enforcement on laboratory animals in the administrative regions of Beijing.

Article 3 A qualification management system is carried out for the personnel engaged in the administrative enforcement of law. Being qualified after being subject to trainings for professional knowledge, laws and regulations, these personnel can take on a post with a law enforcement certificate that is issued by STCBM.

Article 4 STCBM employs quality supervisors in Beijing (region) to perform quality supervision over breeding, feeding, supply and utilisation of laboratory animals in Beijing.

Article 5 Quality supervisors shall be selected and employed from the personnel engaged in management and professional expertise involving laboratory animals.

Article 6 Persisting in impartiality, quality supervisors shall perform supervision and inspections according to the laws. In case violations of laws and regulations are discovered during follow-up visits to, and inspections of, institutions dealing with laboratory animals in Beijing, the quality supervisors shall report these violations to BAOLA in a timely manner.

Article 7 Personnel engaged in the administrative enforcement of law on laboratory animals shall investigate and punish all violations of the law according to the “Regulations for the Administration of Laboratory Animals”.

Article 8 Administrative enforcement of the law shall be carried out according to the following procedures for laboratory animals:

(1) Filing of a case: Upon the signatures of the personnel chiefly in charge of BAOLA, violations of the “Regulations for the Administration of Laboratory Animals” that are discovered via a report or during inspections can be filed as a case.

(2) Investigation and evidence collection: More than two law-enforcement personnel shall be designated by persons chiefly in charge of BAOLA to establish an investigation group that shall investigate and collect evidence with a law enforcement certificate within 3 workdays.
(3) Decision of the examination: the investigation group shall, in accordance with the verified unlawful practices and provisions of the laws and regulations, present written disposal considerations and submit these considerations to STCBM for approval.

(4) Delivery and execution: written decision on the punishment shall be delivered by law-enforcement personnel within 7 days after a decision is made by STCBM.

Article 9 Violations of the relevant national laws and regulations, which are found during the course of managing laboratory animals, shall be handled by STCBM with the relevant departments, according to the laws.

Article 10 Personnel engaged in the administrative enforcement of laws shall strictly abide by the following regulations:

(1) Personnel engaged in the administrative enforcement of laws shall carefully study the “Regulations for the Administration of Laboratory Animals” and be familiar with the municipal laws and regulations relating to laboratory animals so as to ensure strict conformity with the laws during law enforcement.

(2) Personnel engaged in the administrative enforcement of laws shall strictly enforce the law and handle affairs impartially. It is prohibited from figuring for illegal interests or accepting articles and services provided by persons under management by virtue of one’s position power.

(3) With neat appearances and civilized, polite speech and deportment, law-enforcement personnel shall respect the party concerned during civilized law enforcement. When unlawful practices are investigated, the principle that didactic education has precedence over punishment shall be adhered to.

(4) Devoting oneself to duties, law-enforcement personnel shall investigate unlawful practices in a timely manner according to the laws and are prohibited from playing during their duties or handing their duties off upon others, or bending the law for the benefit of relatives or friends.

Article 11 The Science and Technology Commission of Beijing Municipality shall be responsible for the interpretation of these measures.

Article 12 These Measures shall enter into force as of the date of promulgation.
Responsibility System of the Administrative Enforcement of the Law on the Affairs Relating to Laboratory Animals in the Beijing Region (trial)

In accordance with the requirements of the 《Regulations of Beijing Municipality for the Administration of the Affairs Concerning Laboratory Animals》, the Science and Technology Commission of Beijing Municipality (hereinafter referred to as “STCBM”) shall be responsible for the management of the affairs concerning laboratory animals in the administrative regions of Beijing. Authorised by STCBM, the Beijing Administration Office of Laboratory Animal shall manage the daily business of laboratory animals. Entrusted by STCBM, part-time law-enforcement personnel are employed to supervise behaviour that violates the 《Regulations of Beijing Municipality for the Administration of Affairs Concerning Laboratory Animals》.

1. Responsibility of law enforcement

Activities that involve laboratory animals and are performed by institutions and individuals dealing with laboratory animals shall be examined. Moreover, unlawful practices shall be punished according to the laws.

The main unlawful practices that shall be investigated and punished are as follows:

(1) Environment and facilities relating to laboratory animals that do not achieve the standards or fail to pass the annual inspection;
(2) Personnel engaged in affairs concerning laboratory animals take posts without being subject to proper trainings;
(3) Unacceptable laboratory animals are used to produce medicines or other biological products;
(4) Laboratory animals are supplied or sold without providing a conformity certificate or contents filled out in a conformity certificate that do not meet the requirements;
(5) Transportation of laboratory animals that does not conform to the regulations;
(6) Institutions or individuals that/who privately undertake the conservation of breeds, feeding, breeding, supply and utilisation of laboratory animals without obtaining licences;
(7) Inspection institutions forge data or inspection results;
(8) Working and managerial personnel laboratory animals abuse their power of office, neglect their duties or practice fraud for personal gains;
(9) Licences are lent, transferred or rented for the use of other institutions or individuals by those institutions or individuals that have obtained licences; organisations are commissioned to sell
laboratory animals and the relevant products produced by institutions or individuals without
obtaining licences;
(10) Disordered student status management of, imposture of and fraud practice of, training
institutions, incompetence of teachers in their teaching, teaching that does not conform to the
teaching programme, random deletion of and reduction in the curricula as well as inferior
education quality;
2. A System of Overall Responsibility of Chief Administrative Officers is practiced by the Beijing
Administration Office of Laboratory Animal and a leader is designated to directly undertake
organisation and implementation of this system.
Responsibilities of the chief administrative officers as follows:
(1) Law enforcement of laboratory animals shall be included in the agenda of the Beijing
Administration Office of Laboratory Animals;
(2) A politics and business learning system, an education system for honest and industrious
government affairs and a reward means shall be established for law-enforcement personnel;
(3) Chief administrative officers shall strictly enforce the laws by leading the way; a work
programme of inspections on law enforcement shall be implemented and cases shall be handled
according to the enforcement procedures; in addition, the relevant departments and
law-enforcement personnel shall be supported to exercise their functions and powers;
(4) An annual plan shall be prepared for law enforcement on the affairs concerning laboratory
animals; a work programme of law enforcement in the current year shall be submitted at the
beginning of the year and a work summary of law enforcement shall be reported at the end of the
year;
3. Beijing Administration Office of Laboratory Animal shall be responsible for the routine
management of law enforcement concerning laboratory animals and shall implement enforcement
procedures.
4. Procedures of administrative law enforcement concerning laboratory animals.
The Procedures concerning the Handling of Behaviour Violations《Regulations of Beijing
Municipality for the Administration of the Affairs Concerning Laboratory Animals》 shall be
strictly implemented (please refer to annex 1).
5. In case institutions and individuals violate the requirements of the《Regulations of Beijing
Municipality for the Administration of Affairs Concerning Laboratory Animals》, the relevant
disposal decisions shall be issued by STCBM after they are taken.
After being subject to trainings, evaluations, examinations and verifications by the Beijing
Administration Office of Laboratory Animals, law enforcement certificates shall be issued to all
eligible law-enforcement personnel.
6. Once the law-enforcement personnel who have obtained law enforcement certificates are
transferred from their original posts, the corresponding law enforcement certificates shall be
turned over to the higher authorities.
Law-enforcement personnel shall participate in trainings and examinations once per year. If the
personnel fail to pass examinations for 2 successive years, their law enforcement qualifications
shall be revoked.
7. Responsibilities of law-enforcement personnel concerning laboratory animals.
(1) Acceptance and handling of visits and incoming
correspondence;
(2) Interviews and investigations before a case is filed and inspections on
law enforcement after a case is filed;
(3) Report of case filling, investigation report and disposal opinions shall
be submitted;
(4) Initiative inspections and random examinations shall be performed on law enforcement
concerning laboratory animals in the Beijing regions at least 2 times each year. No less than 5
institutions shall be examined each time;
5. Work Regulations for the Law-Enforcement Personnel concerning Laboratory Animals in
Beijing shall be strictly followed (please refer to annex 2).

The Science and Technology Commission of Beijing Municipality
March 25, 1999

Keywords: laboratory animals, law enforcement, responsibility system

C.C.: Legal Office of Beijing Municipality
Legal Department of the Science and Technology Commission of Beijing Municipality

Printed and issued on March 25, 1999
15 copies in total are printed
Procedures concerning the Handling of Behaviour Violations of the Regulations of Beijing Municipality for the Administration of the Affairs Concerning Laboratory Animals

1. Case filing
In case behaviour violations 《Regulations of Beijing Municipality for the Administration of the Affairs Concerning Laboratory Animals》 (hereinafter referred to the 《Regulations for the Administration of Laboratory Animals》) occurs in the administrative regions of Beijing or if citizens, legal persons and other organisations in the administrative regions of Beijing violate the 《Regulations for the Administration of Laboratory Animals》, a registration form of a case filing shall be filled for these violations whether they are reported by which organisation or person or are found by the management departments of laboratory animals during inspections. After comments from responsible persons, a case can be filed after it is reported to and approved by the leaders of the Science and Technology Commission of Beijing Municipality.

2. Investigation
Within 1 week after a case is filed, those persons chiefly in charge shall designate the law-enforcement personnel to establish an investigation group that shall investigate and review the case. The investigation group shall begin, within 3 days after receiving notice, to carry investigations with the relevant certificates.

3. The investigation results shall be reported to those persons chiefly in charge by the investigation group in time and the investigation can be terminated after confirmation from the persons chiefly in charge. Furthermore, written disposal opinions shall be brought forward within 1 week based on the principle that “facts and laws serve as the basis and the minority is subordinate to the majority”. Treatment opinions shall include contents such as the names and addresses of persons who are going to receive a treatment, legal persons and their positions, factual basis determined by the investigation group, applicable laws and treatment decisions etc. In addition, all the members of the investigation group shall sign their names on a treatment opinion letter. The person chiefly in charge shall submit these treatment opinions, which are brought forward by the investigation group, to the Science and Technology Commission of Beijing Municipality for discussion during a director’s meeting. Finally, treatment decisions shall be issued by directors after they are made.

4. Notice of disposal decision
On behalf of the competent authorities, notice of a treatment decision shall be issued to those persons who are going to receive a treatment from the investigation group within 1 week after the treatment decisions are taken.

5. If any party is not satisfied with the treatment decision, it may apply, within 15 days after the receipt of the notice of disposal, for reconsideration to the Science and Technology Commission of Beijing Municipality. If the party is dissatisfied with the decision upon reconsideration being made by the Science and Technology Commission of Beijing Municipality, it may initiate, within 15 days of receiving the notification on the decision on reconsideration, legal proceedings in the court. The party involved may also file a lawsuit directly to the people's court.

The investigation group shall be responsible for supervising and urging the involved party to fulfil a disposal decision. If the said party neither files a request for reconsideration nor files a suit in a people's court, nor complies with the punishment, the Science and Technology Commission of Beijing Municipality shall apply, according to the opinions brought forth by the investigation group, to the people's court for compulsory execution.

The Science and Technology Commission of Beijing Municipality
Work Regulations for Law-Enforcement Personnel concerning Laboratory Animals in Beijing

1. In order to handle affairs strictly according to the laws during law enforcement, the law-enforcement personnel shall carefully study the national and municipal laws, regulations and policies concerning laboratory animals and shall be familiar with and master the "Regulations of Beijing Municipality for the Administration of the Affairs Concerning Laboratory Animals".

2. Law-enforcement personnel shall strictly enforce the laws and handle affairs impartially. It is prohibited from figuring for illegal interests or accepting articles and services that are provided by persons under management by virtue of a position of power.

3. With neat appearances and civilized, polite speech and deportment, law-enforcement personnel shall respect the party concerned throughout civilized law enforcement. When unlawful practices are investigated and handled, the principle that didactic education has precedence over punishment shall be adhered to.

4. Devoting oneself to duties, the law-enforcement personnel shall investigate unlawful practices in a timely manner according to the laws and be prohibited from playing at their duties and handing their duties off upon others, or bending the law for the benefit of relatives or friends.

5. The Procedures concerning the Handling of Behaviour Violations "Regulations of Beijing Municipality for the Administration of the Affairs Concerning Laboratory Animals", which is formulated by the Science and Technology Commission of Beijing Municipality, shall be strictly followed.

The Science and Technology Commission of Beijing Municipality
The notice concerning the issue of the Work Regulations on the Quality Inspector of Laboratory Animals in the Beijing Region

To every related department and institution:

In order to completely carry out the opinions and suggestions by the Education and Science Committee of the Standing Committee of Beijing Municipal people's Congress on further thorough the implementation of the 《Regulations of Beijing Municipality for the Administration of the Affairs Concerning Laboratory Animals》, the Science and Technology of Beijing Municipality prints and issues the 《Measures of Beijing Municipality for the Implementation of Strengthening Administrative Enforcement of the Law on the Affairs Relating to Laboratory Animals》. Moreover, some personnel specialising in the management and professional skills of laboratory animals are employed as quality inspectors of laboratory animals in the Beijing region so that the Beijing Administration Office of Laboratory Animals is assisted in supervising and inspecting those institutions and individuals dealing with laboratory animals in the administrative regions of Beijing for the thorough implementation of the laws and regulations relating to the administration of laboratory animals. To standardise the behaviour of the quality inspectors during assistance with law enforcement, the 《Work Regulations for Quality Inspector of Laboratory Animals in the Beijing Region》 is now issued. Various departments or institutions that are involved shall closely co-ordinate with quality inspectors and shall not refuse inspections for any reason. Meanwhile, the institutions that dispatch the quality inspectors shall greatly support the quality inspectors and ensure that there is sufficient time for the quality inspectors to participate in the investigation and the handling of unlawful practices and law cases.

According to these regulations, the work of the quality inspectors of laboratory animals can be supervised by the relevant institutions involved and any problems shall be reported to the Beijing Administration Office of Laboratory Animal when they are discovered.
Supervision hotline: 68722982

Annex:
1. Work Regulations for a Quality Inspector of Laboratory Animals in the Beijing Region
2. Registration Form of a Quality Audit and Inspection on Laboratory Animals in the Beijing Region

The Science and Technology Commission of Beijing Municipality
February 15, 2003

Keywords: issuance, laboratory animals, quality inspectors, regulations, notice
Send to: every related department and institution
Department of Facilities and Finance Preparation of the Science and Technology Commission of Beijing Municipality Printed and issued on February 17, 2003
200 copies in total are printed
Annex 1

**Work Regulations for a Quality Inspector of Laboratory Animals in the Beijing Region**

Article 1 In order to strengthen the administrative law-enforcement of the law on affairs concerning laboratory animals in the administrative regions of Beijing and to standardise the behaviour of the quality inspectors (hereinafter referred to as “inspectors”) of laboratory animals during their assisting with law-enforcement, these regulations are formulated based on the 《Measures of Beijing Municipality for the Implementation of Strengthening the Administrative Enforcement of the Law on the Affairs Relating to Experimental Animals》.

Article 2 Quality inspectors shall carefully study and familiarise themselves with the national and municipal laws, regulations and management measures related to laboratory animals and also shall master the prevailing national standards of laboratory animals.

Article 3 During supervisions and inspections, the quality inspectors shall offer consultations on the laws, regulations and business and provide suggestions on solving problems for institutions undergoing inspections.

Article 4 When following practices, violations of laws and regulations are discovered, the quality inspectors shall require the party involved to immediately stop such unlawful practices and a written report shall be sent to the Beijing Administration Office of Laboratory Animal in a timely manner.

(1) Production and laboratory facilities, feedstuffs and bedding materials fail to comply with the national standards;
(2) Personnel dealing with laboratory animals take a post without being subject to trainings and obtaining the 《Qualification Certificates for Employed Persons in the Industry of Laboratory Animals of Beijing》;
(3) Unacceptable laboratory animals are used for the production of medicines and biological products, scientific research, product testing and drug assays;
(4) Licences and conformity certificate of laboratory animals are not used in accordance with the regulations;
(5) Transportation of laboratory animals fails to meet the regulations;
(6) Handling and disposal of the carcasses of laboratory animals and wastes fail to meet the regulations;
(7) Institutions or individuals privately undertake the conservation of breeds, feeding, breeding, supply and utilisation of laboratory animals without obtaining licences;
(8) Data or inspection results are forged by a Quality Inspection Institution of Laboratory Animals;
(9) Disordered student status management, imposture and fraud practices as well as inferior education quality of training institutions concerning laboratory animals;
(10) Managerial personnel laboratory animals abuse their power of office, neglect their duties and practice fraud for personal gains;
(11) Other behaviour violating the national and municipal laws and regulations and rules relating to laboratory animals.

Article 5 Quality inspectors shall participate in investigation and evidence collection and bring forth the disposal of opinions for cases.

Article 6 With neat appearances and civilized, polite speech and deportment, the quality inspectors shall respect the party concerned and show the relevant certificates on their own initiatives throughout civilized law enforcement.

Article 7 During supervision and inspection, an inspection group consisting of 2 or more quality inspectors shall write a record.

Article 8 Quality inspectors shall participate in inspection activities organised by the Science and Technology Commission of Beijing Municipality (STCBM) on their own initiatives and the results of the assistance with law-enforcement shall be reported periodically.

Article 9 Quality inspectors shall strictly handle affairs impartially. It is prohibited from figuring for illegal interests or accepting articles and services provided by persons under supervision by virtue of their position of power.

Article 10 Quality inspectors shall actively participate in trainings on the laws, regulations and policies organised by the Science and Technology Commission of Beijing Municipality (STCBM) and the emphases of law-enforcement shall be mastered and adjusted in a timely manner. In addition, quality inspectors shall handle affairs according to the laws during supervisions and inspections on the qualities of laboratory animals.

Article 11 When a quality inspector cannot fulfil the responsibility of supervision and inspections of laboratory animals, the certificates of the quality supervisor shall be turned over to the Science and Technology Commission of Beijing Municipality (STCBM).
**Annex 2**

**Registration of a quality audit and inspection on laboratory animals in the Beijing Region**

<table>
<thead>
<tr>
<th>Institutions to be inspected</th>
<th>Number of the case filing:</th>
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<tr>
<td>Name:</td>
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<td>Postal code:</td>
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<td>Legal representative:</td>
<td>Tel:</td>
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<tr>
<td>Contact Person:</td>
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</tbody>
</table>

Inspection record (Priority shall be given to recording those circumstances of violations of the laws and regulations, meanwhile, the names and positions of the personnel involved, locations of the facilities, service properties, possession of licences, employed persons and qualification certificates, qualities of animals, feedstuffs, bedding materials and managerial system of institutions under inspections also shall be recorded.)

Signature of inspector: [DD/MM/YYYY]

DD/MM/YYYY
The notice concerning the complete implementation of the
《Regulations of the Beijing Municipalities for the Administration of
the Affairs Concerning Laboratory Animals》 during the
management of research and development

Notice No. 237 [1997] of the Administrative Department of Science and Technology of Beijing Municipality
Signer: Ren Ranqi

People’s governments, commissions, offices, bureaus (head offices) of every administrative district and county:
In order to thoroughly implement the 《Regulations of Beijing Municipality for the Administration of the Affairs Concerning Laboratory Animals》 that was reviewed and adopted at the 31st Session of the Standing Committee of the 10th Beijing Municipal People's Congress on October 17, 1996 and to take measures to exactly strengthen the management on those affairs concerning laboratory animals, we now notify the affairs involved with the management of scientific research as follows:
1. When scientific research subjects who are involved with laboratory animals or animals experiments, are reported for project approval, a Licence for Laboratory Animals in Beijing (hereinafter referred to as a “Licence for Laboratory Animals”) and Qualification Certificate for Employed Persons in the Industry of Laboratory Animals of Beijing (hereinafter referred to as a “Qualification Certificate”) hold by personnel participating in the scientific research subjects shall be issued in addition to the conformities with the requirements of project approval as specified by the competent authorities. Moreover, the contents of the scientific research subjects shall comply with the scopes of the licences.
2. As for the approved scientific research subjects involved with laboratory animals or animal experiments, the following inspection items must be added when in-process inspections, acceptances or appraisals are performed by the competent authorities on these scientific research subjects:
   (1) Laboratory animals or animal’s feedstuffs that are used by institutions responsible for scientific research subjects must come from organisations with a licence for laboratory animals and shall be issued with quality conformity certificates by these organisations;
   (2) Animal experiments must be performed in facilities with the relevant licences;
   (3) Personnel dealing with animal experiments shall hold the relevant qualification certificates to take posts.
3. When the award of the Science and Technology Progress of Beijing and other Technology Awards are applied for scientific research subjects involving laboratory animals and animal experiments, copies of the qualification certificates of personnel participating in these scientific research projects and copies of their conformity certificates for the animals used for these scientific research projects must be submitted at the same time.

4. All applications for project approval will be refused if the applications of these scientific research subjects fail to meet the requirements in provision 1 of the notice; scientific research subjects fail to pass acceptance and appraisals when the requirements in provision 2 of the notice are not met; qualifications to participate in the appraisal and selection of various awards will be automatically cancelled in case the requirements in provision 3 of the notice are not met.

5. During project approval and the achievement appraisal of organisations at various levels, these measures must be strictly followed when laboratory animals and animal experiments are involved. Notice is hereby given.

The Science and Technology Commission of Beijing Municipality

April 17, 1997

Keywords: thorough implementation, laboratory animals, regulations and rules, notice

Send to: the Standing Committee of the Beijing Municipal People's Congress, Municipal People’s Government and Mayor in charge

C.C.: competent departments and bureaus of the national relevant ministries and committees, relevant ministries and bureaus of the Chinese People's Liberation Army
The notice concerning the issue of the «Detailed Rules for Implementing the Measures of Science and Technology Awards in Beijing»

People’s governments of every administrative district and county, every ministry and commission and office of municipal government, every department and organisation subordinate to Beijing municipality:

For the purpose of the thorough implementation of the «Measures of Science and Technology Awards in Beijing», now the «Detailed Rules for Implementing the Measures of Science and Technology Awards in Beijing» is printed and issued to you for following and carrying out as a reference after it has been reviewed and approved at the executive meeting of Beijing municipality.

April 2, 2002
Detailed Rules for Implementing the Measures of Science and Technology Awards in Beijing

Article 1 These rules are formulated based on the 《Measures of Science and Technology Awards in Beijing》 (hereinafter referred to as the 《Measures of Awards in Beijing》).

Article 2 Scope of Science and Technology Awards in Beijing covers the natural sciences, technological invention and the development of science and technology.

Article 3 Municipal Administrative Department of Science and Technology shall be responsible for organising the assessment and review of Science and Technology Awards in Beijing, meanwhile the Administration Office of Science and Technology Awards in Beijing (hereinafter referred to as “AOSTAB”) is in charge of daily routines.

Article 4 Regional science and technology award as established by the social force in Beijing, which is mentioned in provision 7 in the 《Measures of Awards in Beijing》, means a regular science and technology award that is established in Beijing with funds raised by domestic and overseas organisations and individuals rather than the national department of finance.

Article 5 Originality, which is mentioned in provision 2 of Article 8 of the 《Measures of Awards in Beijing》, means that this technology has innovation or obvious progress compared to existing similar technologies at home and abroad. With respect to the effects and significance on accelerating progress in science and technology, the originality also indicates that major performance indices (characteristics) and economic indicators of this technology move ahead of those of similar technologies.

Article 6 Achievements of fundamental research, which is mentioned in provision 5 of Article 8 of the 《Measures of Awards in Beijing》, means that a new discovery in the field of the natural sciences is brought forward for the first time at home and abroad, or that the scientific theory of the technology is explained and its major treatise is published for the first time at home and abroad.

Article 7 Projects that involve with national defence and security cannot be disclosed due to national security and confidentiality, which is mentioned in provision 1 of Article 9 in the 《Measures of Awards in Beijing》, indicate that these projects come from army construction, scientific research of national defence, national security and other relevant activities and shall only be used for the purposes of national defence and securities.

Article 8 Projects under research, which are mentioned in provision 2 of Article 9 in the 《Measures of Awards in Beijing》, indicates that the technology is being researched and not completed yet or stage achievements of the technology has been gained but cannot be popularised and applied in other projects.

Article 9 Items that have been applied for other provincial (municipal) science and technology awards, which are mentioned in provision 4 of Article 9 in the 《Measures of Awards in Beijing》, means the same one item shall not be applied for an award in other provinces (cities) at the same time and it shall not win different awards repeatedly.
Article 10 An award can be given to an organisation according to an institution’s application, which is shown in provision 2 of Article 12 in the 《Measures of Awards in Beijing》, means that the names of specific principal personnel may not be filled out in the application if an agreement is reached by various institutions involved and the sequencing of major principal personnel is difficult to be determined.

Article 11 Application for withdrawal, which is mentioned in Article 21 in the 《Measures of Awards in Beijing》, means the corresponding specialists and working personnel do not participate in the assessment and review in the current year if an item involving themselves or their interests is applied for an award.

Article 12 Achievements recommended for an application of Science and Technology Awards in Beijing shall meet the following requirements:

(1) Items recommended for an application of Science and Technology Awards in Beijing belong to new products, technologies and processes, or to new technologies of diagnosis, therapy, disease prevention and recovery, or to medicine, biological products and medical apparatuses, or to new biological species, achievements of resource investigation and exploration, excellent design, significant engineering project, technical innovations, environmental protection and other achievements in the agriculture industry, forest industry, animal husbandry and fishery.

New products and materials: With original structures and new functions, resources in China can be fully used to produce these new products and materials; main technical indices reach an advanced level and reliable performance is proved by mass production; enterprise standards relating to these products and materials shall be available and product standards approved by the relevant competent authorities; with some economic and social benefits, the achievements of foods and cosmetics shall conform to the sanitary standards approved by the related competent authorities.

New technologies and processes: with advanced technologies, these technologies and processes are proved by practical applications that they play a significant role in cost reduction, enhancement of labour productivity and product quality, saving of raw materials, reduction of energy consumption, improvement of working conditions, pollution elimination, etc. Moreover, these technologies and processes shall bring about certain economic and social benefits.

New technologies of diagnosis, therapy, disease prevention and recovery: with an advanced level, these new technologies shall be proven to be safe and effective by a considerable number of clinical cases and scientific data. Furthermore, new technologies shall cause preferable social effects and their research papers must have been published in academic journals for more than 1 year.

Medicine (medicines for human use, pesticides and veterinary medicines) and biological products:

With advanced technical levels, Class I and II new medicines shall obtain approval documents of clinical research and Class III and IV new medicines shall obtain Certificates of New Medicine and an Approval Number of Production, meanwhile, biological products shall obtain a Certificate of a New Biological Product and an Approval Number of Production approved and issued by the National Department of Drug Safety & Inspection. In addition, these new medicines and biological products shall produce some economic and social benefits.
Medical apparatuses: With advanced technical level, Class III medical apparatuses shall obtain a Registration Certificate of Medical Apparatus approved and issued by the National Department of Drug Safety & Inspection and Class I and II medical apparatuses shall obtain a Registration Certificate of Medical Apparatus approved and issued by the Provincial (Municipal) Department of Drug Safety & Inspection.

New biological species (including animals, plants and microorganisms): new species, materials and combinations, which are found by researchers themselves and that fundamentally differ with the original species, shall be subject to strict scientific verification and determinations or approvals of special administrative departments. As for new species and materials developed by means of genetic engineering, they must comply with the requirements of the regulations on genetic engineering as issued by the national Administrative Departments of Science and Technology and competent authorities of the industry. In addition, these biological species shall have a certain scale of production and usage (regional tests of 3 years are required for new species of crops), and shall generate some economic and social benefits.

Achievements of resource investigation and exploration: with the aid of precise scientific verification and reliable data, the natural resources with some economic values are found and favourably influence the decision-making of the relevant departments of Beijing municipality. Moreover, some economic and social benefits are gained by developing and utilising these natural resources.

Achievements of excellent design, major engineering, technical innovation and environmental protection etc.: by the correct and complete implementation of the guidelines and policies of engineering construction, close combination of the actual conditions of Beijing with the properties of engineering, the initiative application of new technology, deliberate design and construction, requirements on production and use are all met. After the projects are put into service, certain economic and social benefits are achieved.

(2) Items recommended for an application for Science and Technology Awards in Beijing belong to those achievements of advanced sciences and technologies, which will be popularised and used in an integral manner.

By means of integration, major contributions are made to the promotion of industry or formation of new industry so as to achieve considerable economic and social benefits.

(3) Items recommended for an application for Science and Technology Awards in Beijing belong to research findings of basic theory and basic theory of applications.

New findings in nature, new understandings and explanations on natural laws shall have creativity and be at a high academic level. Research findings of basic theory and basic theory of applications have been published at professional academic conference or on professional academic journal at home or abroad for more than 1 year. Furthermore, these research findings shall be identified by the academic community at home and abroad and recommended by more than 5 specialists (specialists from other organisations must account for more than 80%) , who shall come from the same industry and hold professional title equivalent to assistant professors.
(4) Items recommended for an application for Science and Technology Awards in Beijing belong to those achievements of basic technologies serving for social and public benefits. Subject to official approval and adoption by the relevant national or local departments, these achievements shall include the national standards, specialized standards and enterprise standards that have been put into practice for more than 1 year and advices that are adopted by the International Standardization Organisation (ISO). In addition, these achievements play a considerable role in establishing mete wands and measurement standards (including Standard Productive Materials) at various levels, verification systems at a variety of levels, preparing the national measurement and verification specifications and unifying quantity value in China or in Beijing so that certain economic and social benefits are gained.

(5) Items recommended for an application for Science and Technology Awards in Beijing belong to those achievements of soft sciences enhancing scientific decision-making and the modernisation of management. These achievements shall include decision-making and consultation, plan of science and technology, policy, laws and regulations as well as management method, which are of great importance for promoting co-ordinated developments of science, economy and society. With a unique viewpoint, these achievements are adopted by the relevant departments and achieve economic and social benefits.

Article 13 The following documents shall be provided when Science and Technology Awards in Beijing are applied:
(1) Letter of recommendation for applying for Science and Technology Awards in Beijing;
(2) Appraisal certificate or report of scientific and technological achievements, certificate of a patent for invention or acceptance report as issued by the relevant organisation in the industry or certificate of literary property and copyright;
(3) Complete technical documentations and summary report of a test;
(4) Technical standards of products;
(5) Licence for a special industry, registration certificate of a product;
(6) Report for investigating new achievements in scientific research;
(7) Certificates for economic, social, environmental and ecological benefits;
(8) Other certificates required to be issued;

The afore-mentioned application documents shall be submitted in triplicate with a data diskette.

Article 14 Institutions and individuals, who apply for Science and Technology Awards in Beijing shall be recommended via the following channels:
(1) Achievements gained by an institution shall be recommended according to its relationship of administrative subordination:
(2) Achievements jointly completed by 2 or more institutions shall be recommended through the channels determined by negotiations.
(3) As for the achievements completed by a scientific research institution run by local people or completed by individuals (including non-service), they shall be recommended by the
Administrative Departments of Science and Technology in the administrative districts and counties based on the principle of territory.

(4) Achievements gained by institutions in Beijing subordinated to the Central Government can be directly submitted to the Administration Office of Science and Technology Awards in Beijing (AOSTAB) for applying for science and technology awards.

Article 15 Research projects, which are jointly completed by the relevant institutions or individuals in Beijing and overseas scholars, can be submitted for applying for science and technology awards according to Article 14 if their main academic ideologies are brought forth by these institutions or individuals and main research are completed by institutions or individuals at home and after a co-operation partner agrees and written evidence documents are provided.

Article 16 When an application item contains several subitems, some of which have been given awards after a separate application, these subitems given awards shall be deleted when the overall item is submitted for applying for science and technology awards.

Article 17 Institutions that recommend applications for science and technology awards shall be responsible for following reviews on the results of the applications:
(1) Conformities with the application scopes and conditions of science and technology awards;
(2) Completeness and qualification of the provided documentations and annexes;
(3) Trueness of technical information;
(4) Compliance with the regulations on the qualifications and sequencing of primary institutions and principal persons that complete research projects.

Article 18 Based on reviews on the results of applications, the institutions responsible for recommendation shall bring forward opinions and recommended levels of science and technology awards applied for.

Article 19 After formal reviews on the recommended achievements, the Administration Office of Science and Technology Awards in Beijing (AOSTAB) shall submit these recommended achievements to the Professional Review Committee of Judging Panel of Science and Technology Awards (hereinafter referred to as the “Professional Review Committee”) for preliminary assessment.

Article 20 Professional Review Committee shall review these recommended achievements according to the following procedures:
(1) 2 main reviewers shall be designated for each recommended achievement. The main reviewers shall carefully read the relevant application documents before review meeting and bring forth written review comments;
(2) In the case that the first award is applied, the Administration Office of Science and Technology Awards in Beijing (AOSTAB) shall organise specialists to carry out field surveys or investigations in other ways and arrange for the principal persons who completed the achievements to give a defence;
(3) When a professional review meeting is held, resolutions are effective only if the committee members attending the review meeting are more than two-thirds of the committee members who should attend the review meeting. Votes by secret ballots shall be performed by the Professional
Review Committee for reviewed achievements. During the vote, achievements applying for the first award shall be approved by more than two-thirds (including two-thirds) of the committee members attending the review meeting and achievements applying for the second or third award shall be approved by more than one half of (including one half) of the committee members attending the review meeting.
Article 21 The municipal science and technology awards include a first prize, second prize and third prize, which must be evaluated in conjunction with the scientific and technological levels, economic and social benefits and the functions and effects that promote scientific and technological progress.

The first prize: reaching the international advanced level of the same type of projects, the level of difficulty in techniques is demonstrably higher, the effect of promoting scientific and technological progress is very great, and attains particularly great economic or social benefits.

The second prize: approaching the advanced international standards or the lead position at the domestic level, the level of difficulty in techniques is higher, the effect of promoting scientific and technological progress is great, and attains particularly great economic or social benefits.

The third prize: reaching the domestic leading level of the same type of projects, the level of difficulty in techniques is higher, the effect of promoting scientific and technological progress is obvious, and attains particularly great economic or social benefits.

Article 22 The results of the preliminary accreditations of Science and Technology Awards in Beijing shall be proclaimed to the society by AOSTAB, all organisations or individuals can interpose objections to the results of the preliminary accreditations.

Objections can be divided into substantive objections and non-substantive objections. Substantive objections refer to having different opinions on the innovativeness, progressiveness and practicability of the key technology and the authenticity of the filling of recommendation letters and non-substantive objections refer to those objections to the primary units and persons that complete the projects and their sequences.

The opinions that the recommended organisations and the persons and units that complete the achievement have levels of accreditations that do not belong to the scope of meaning.

Article 23 The units and individuals that dissent shall indicate their real identities. Those who dissent in the name of units shall clearly state the names of the units, contact persons, contact phones and detailed addresses and stamp and those who dissent in the name of the individuals shall clearly state their real names, work units, contact phone numbers and detailed addresses as well as sign their names. Those who are required to keep secrets shall give a clear indication in the objection materials.

Article 24 Those who belong to the substantive objections after being handled by AOSTAB shall be investigated by AOSTAB and the recommended organisations shall assist in the investigation and bring forward treatment suggestions and those who belong to the substantive objections shall be investigated and shall bring forth forward treatment suggestions by the recommended organisations.

AOSTAB is responsible for submitting the treatment suggestions to the commission of review.

Article 25 The commission of review is responsible for reviewing projects that are raised objects and report the suggestions made during the reviews to the assessment committee.

Article 26 The Municipal Assessment Committee is responsible for examining and approving the assessment results that are submitted by the professional assessment committees and the commissions of review and make resolutions to the achievements of the awards of the first prize, second prize and third prize.

Article 27 Scientific and technical awards at the national level for the next year can be declared to the municipal administrative department of science and technology for those achievements that are awarded the first prize and the second prize of the Municipal Science and Technology Awards.
The municipal administrative department of science and technology performs the audit of the achievements declared according to the declaration conditions of the national science and technology awards and selectively recommends to the State in the respective limited amount.

Article 28 If the assessment experts and staff commit fraud, bend the law for personal gain or engage in fraud or have other behaviour that breaks the rules of the assessment, all the organisations or individuals shall report to AOSTAB or the discipline inspection department of the administrative department of science and technology in written form according to the facts. AOSTAB or the discipline inspection department of the administrative department of science and technology shall investigate the reports, handle them and inform of the decisions taken to the reporting organisations or informers.

Article 29 These detailed rules shall come into effect as of 8 May 2002.
The notice (revised edition 2001) concerning the full-scale implementation of the National Standards for Laboratory Animals

Notice No. 363 [2002] of the Administrative Department of Science and Technology of Beijing Municipality

All the related units:
The National Standards for Laboratory Animals was released in January 1994 for the first time and was revised in 1999. The revised National Standards were released in August 2001 by the General Administration of Quality Supervision, Inspection and Quarantine of the People’s Republic of China and were implemented as of 1 May 2002.
The most significant changes of the Revised Edition of the National Standards for Laboratory Animals are that it resets the levels of laboratory animals, correspondingly increases the microbiology monitoring projects of dogs and monkeys and redefines the amount of the samples, classifications of environmental conditions as well as the requirements of technologic indices are more scientific and the manoeuvrability is stronger; the levels of parasitology and detection are separated from the primary standard and in turn form an independent standard; the standard of feedstuff is changed to the《Laboratory Animals - General Quality Standard for Formula Feed》and the《Laboratory Animals — Hygienic Standard for Formula Feed》according to the unified terms of the national feed industry. The Revised Edition of the National Standards for Laboratory Animals is more in line with the actual conditions in China and is more feasible; it also reflects the latest levels of the science and technology of international laboratory animals.
In order to fully implement the Revised Edition 2001 of the National Standards for Laboratory Animals, further improve the quality of laboratory animals and provide solid support to the life science research and the development of the bioengineering and pharmaceutical industry in Beijing, the following decisions were taken:
1. All the relevant units in the city shall begin to implement the Revised Edition 2001 of the National Standards for Laboratory Animals from 1 May 2002.
2. International standard GB14922. 2-2001: the microbiological standards of mice and rats in the microbiological standards of laboratory animals and inspections are divided into clean grade, specific pathogen free (SPF) and sterile grade, in which the general grade is cancelled.
The Science and Technology Commission of Beijing Municipality prescribed that the production units of laboratory animals in the administrative areas of the city shall cease the production of the general grade of mice and rats before 31 December 2002.
3. The units that have not yet ceased the production and use of the general grade of mice and rats after 31 December 2002 shall be dealt with in accordance with the relevant provisions of the Science and Technology Commission of Beijing Municipality.

The Science and Technology Commission of Beijing Municipality
2 July 2002

Keywords: implementation, laboratory animals, national standards, notice
Send to: all the related units
C.C.: Beijing Bureau of Quality and Technical Supervision
Beijing Business
Administration Bureau
The notice concerning the issue of the Regulation of the Inspection of the Licence for Laboratory Animals

All the related units,

《Regulations of Beijing Municipality for the Administration of Affairs Concerning Laboratory Animals》 have been amended on 2 December 2004 at the 17th Meeting of the 12th Standing Committee of the National People's Congress. Science and Technology Commission of Beijing Municipality issued 《Administrative Measures of Beijing Municipality on the Licences of Laboratory Animals》 (Notice No. 454 [2005] of the Administrative Department of Science and Technology of Beijing Municipality). BAOLA organises experts to amend the existing 《Acceptance Rules of the Licences for the Use of Laboratory Animals in Beijing》 and Acceptance Rules of the Licences for the Breeding of Laboratory Animals in Beijing》 (Breeding)》 in order to specify the issue and acceptance of the licences for the laboratory animals. According to the opinions of experts, the acceptance regulations shall be established in accordance with the categories of the facilities, which include the 《Acceptance Rules of the Licences for the Use of Laboratory Animals in Beijing (Normal Environment)》 and 《Acceptance Rules of the Licences for the Use of Laboratory Animals in Beijing (Environment above the Barriers)》, 《Acceptance Rules of the Licences for the Breeding of Laboratory Animals in Beijing (Breeding and Normal Environment)》 and 《Acceptance Rules of the Licences for the Breeding of Laboratory Animals in Beijing (Breeding and Environment above the Barriers)》. At the same time, in order to strengthen the management of the cages of laboratory animals and the production of feedstuff, BAOLA organised experts to establish the 《Acceptance Rules of the Licences for the Breeding of Laboratory Animals in Beijing (Cages and Appliances)》 and amended the existing 《Acceptance Rules of the Licences for the Breeding of Laboratory Animals in Beijing (Feedstuff)》 according to the requirements of all the relevant units of laboratory animals. The acceptance rules mentioned above are hereby printed and distributed to you. Please implement them meticulously.

Annex: 1. 《Acceptance Rules of the Licences for the Use of Laboratory Animals in Beijing (Normal Environment)》
2. 《Acceptance Rules of the Licences for the Use of Laboratory Animals in Beijing (Environment above the Barriers)》

3. 《Acceptance Rules of the Licences for the Breeding of Laboratory Animals in Beijing (Breeding and Normal Environment)》

4. 《Acceptance Rules of the Licences for the Breeding of Laboratory Animals in Beijing (Breeding and Environment above the Barriers)》

5. 《Acceptance Rules of the Licences for the Breeding of Laboratory Animals in Beijing (Cages and Appliances)》

6. 《Acceptance Rules of the Licences for the Breeding of Laboratory Animals in Beijing (Feedstuff)》

30 August 2005

Keywords: printing and issuing, laboratory animals, licences, acceptance regulations, notice
Send to: all the related units
The Beijing Laboratory Animals Administration Office

Printed and issued on 30 August 2005
110 copies in total are printed
## Acceptance Rules of the Licences for the Use of Laboratory Animals

### in Beijing (Normal Environment)

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<td></td>
<td></td>
<td></td>
<td>Conform</td>
<td>Not conform</td>
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</table>
| 1   | Organisation                              | 1. ★ Leaders who are in charge of scientific research or conditions shall take charge of the laboratory animals of this unit. The leaders shall be familiar with the laws and codes related to the State, industries and Beijing as well as have passed all the examinations.  
2. There should be relevant departments that take charge of the management of the laboratory animals in the unit. |         |           |
| 1.1 | Supervising authorities and leaders       | 1. ★ Establish an administration committee of laboratory animals or leading group that is organised by the relevant leaders and professional technicians and ask for specially-assigned persons to take charge of the daily work.  
2. The administration committee or leading group shall have constitutions, hold meetings at regular intervals, discuss the major issues concerning the laboratory animals of the unit and maintain records. |         |           |
| 1.2 | Administrative organisations of laboratory animals | 1. ★ Have obtained “Position Qualification Certificates of the Laboratory Animal Practitioners in Beijing”.  
2. They shall receive legal education, professional moral education and the continuing education of professional skills, and shall have training plans and training records.  
3. The records of physical examinations for the current year shall be provided  
4. Measures for labour protection shall be provided. |         |           |
| 2   | Staff                                     | 1. They shall be a university graduate or above, with a relevant major such as medical science, biology, zootechnical science, veterinary medicine. |         |           |
| 2.1 | Working staff                             |                                                                                                                                            |         |           |
| 2.2 | Supervisory staff                         |                                                                                                                                            |         |           |
2. They shall have received a training on management of laboratory animals for more than half a year.

3. Environmental conditions and facility conditions

| 3.1 External environment | 1. The facilities shall be separated from the living quarters, for the facilities that cannot be separated, feasible isolation facilities shall be provided.  
2. No pollution sources that affect the breeding of animals shall exist within a radius of 50 metres from the facilities, or the facilities have effective pollution prevention measures.  
3. The outdoor environment shall be in good order and hygienic. No puddles, weeds, garbage diluvial soil or breeding ground for mosquitoes and flies shall exist. Disinfection, desinsection and deratization shall be regularly carried out in the outdoor environment.  
4. Disinfection measures shall be taken before the persons and vehicles enter the animal laboratory facilities. |
|---|---|
| 3.2 Internal environment | 1. ★ Cleaning and disinfection equipment shall be provided, facilities that are used to prevent wildlife from entering shall be provided.  
2. ★ Conformance to the code for fire protection.  
3. ★ The indices of the internal environment (static state) conformance to GB 14925-2001. |
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</table>
| 3.3 | Area layout                   | 1. ★ The animal breeding area and animal laboratory area shall be set up separately.  
2. The front area includes the offices, duty rooms, restrooms, maintenance rooms, power distribution rooms, monitoring rooms, warehouses, washrooms and normal corridors, etc.  
3. The animal experiment area can include isolation quarantine rooms, storerrooms for clean goods, laboratories, operation rooms, playgrounds for animals, etc.  
4. Auxiliary facilities: mechanical equipment rooms, veterinary rooms, rinsing and disinfection rooms, animal bathrooms, dissecting rooms and treatment rooms for animal wastes, etc. |
|     |                               |                                                                                                                                                                                                          |
| 3.4 | Treatment of animal carcasses | 1. Special rooms or equipment for the storage of animal wastes are provided.  
2. Closed freezing storage rooms or refrigerators for animal carcasses are provided.  
3. ★ The animal wastes and animal carcasses shall be handled without causing any harm. |
|     | and wastes                    |                                                                                                                                                                                                          |
| 3.5 | Construction requirements     | Construction requirements                                                                                                                                                                               |
|     | Exterior-protected construction | Nontoxic and nonradioactive materials that are waterproof and anti-corrosion shall be used.                                                                                                               |
| 3.5.1 | Interior wall                | 1. The surface is smooth and even, and the internal corner and external corner are in an arched shape, which can be cleaned and disinfected easily.  
2. Materials that are water resistant, anti-corrosion, shock resistant, anti-reflection and are hard to peel off shall be used for building interior walls. |
| 3.5.2 | Floor                        | Floor shall not be slippery and can resist abrasion and corrosion. It shall not have crack. Its surface should be smooth and even.                                                                      |
| 3.5.4 | Ceiling | It should be water and corrosion resistant with good air tightness. The net height from the ground shall be decided by considering the saving of energy and the comfort for the staff. |
| 3.5.5 | Corridor | Its width cannot be less than 1.5m and it shall be convenient for foot traffic. |
| 3.5.6 | Door | It shall be smooth and firm and must resist corrosion. The height of the door cannot be lower than 2m and the width cannot be less than 1m. |
| 3.5.7 | Activity area | Activity areas shall be provided for the bigger animals, such as dogs and monkeys. The height of the walls shall be enough to prevent the animals from running away. |
| 3.5.8 | Power supply | Installation of electrical appliances and laying of electric wires shall be implemented invisibly. |
| 3.5.9 | Air supply system and air discharge system | The air discharge shall conform to the requirements of environmental protection. Devices that are used to prevent against rain, birds, insects and headwinds shall be equipped at the air supply outlets and exhaust outlets towards the outside. |
| 3.5.10 | Water supply and sewage | 1. The inner diameter of the sewer pipelines in the washrooms shall not be less than 75mm (for rabbits, dogs and moneys, etc., it shall not be less than 200mm).  
2. The water supply pipelines shall conform to the requirements of domestic potable water.  
3. Detoxifying treatment shall be implemented for hazardous substances that enter into the sewer pipelines.  
4. Specialized septic tanks shall be provided. |
<p>| 3.5.11 | Indoor environment measuring instrument | Thermometers, hygrometers and other metres shall be provided. |</p>
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<tr>
<td>4</td>
<td>Articles for animal experiments</td>
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<tr>
<td>4.1</td>
<td>Animal</td>
<td>★ Users shall use laboratory animals of the corresponding level of breeding unit production that have “Licences for the Breeding of Laboratory Animals”. Quality conformity certificates for laboratory animals shall be kept for inspection.</td>
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<td>4.2</td>
<td>Padding materials</td>
<td>Padding materials should have the following properties: good hygroscopicity, little dust, no foreign smells, non-poisonous, no grease or impurities. They shall not be used before sterilisation and disinfection.</td>
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<tr>
<td>4.3</td>
<td>Feedstuff</td>
<td>★ Feedstuff that are produced by the units with “Licences for the Breeding of Laboratory Animals” shall be used. Quality conformity certificates for laboratory animals shall be kept for inspection.</td>
<td></td>
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<tr>
<td>4.4</td>
<td>Drinking water</td>
<td>★ The drinking water for animals shall conform to the sanitary requirements of domestic potable water in the city.</td>
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<tr>
<td>4.5</td>
<td>Cages</td>
<td>1. Cages shall be made of the materials that have no toxicity. They shall resist corrosion and high temperature and are easy to be cleaned, disinfected and sterilised. They shall also be resistant to impact. 2. They shall be firm and solid, and can prevent animals from escape. 3. ★ The sizes of the new cages shall conform to GBI 4925 2001 standard. 4. The cages and tools shall be placed in a correct location when being checked for acceptance.</td>
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<tr>
<td>5</td>
<td>Regulations and systems</td>
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<tr>
<td>5.1</td>
<td>Management</td>
<td>1. There should be an organisation and management framework, in which different departments and staff members shall have definite responsibility and divisions of work. 2. There should be environmental indices of facilities as well as a recording system for equipment operation and maintenance.</td>
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</table>
3. There should be a well designed management system and operation rules.
4. There should be provisions which ensure that the design of animal experiments shall pass the ethical reviews.
5. There should be animal welfare and biosafety safeguard measures.

<table>
<thead>
<tr>
<th>5.2 Laboratory</th>
<th>★ Animal experiments shall be carried out in different facilities (equipment) according to the requirements on different species.</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.3 Record</td>
<td>Index records for the living environments of laboratory animals and debugging and use records of the facilities and equipment shall be provided.</td>
</tr>
</tbody>
</table>

Acceptance opinions:

Signatures of the acceptance experts:  

Year  Month  Date

Note: ★ represents the one-vote-down item
## Acceptance Rules of the Licences for the Use of Laboratory Animals in Beijing (Environment above the Barriers)

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<tr>
<td>1</td>
<td>Organisation</td>
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<tr>
<td>1.1</td>
<td>Supervising authorities and leaders</td>
<td>1. ★ Leaders who are in charge of scientific research or conditions shall take charge of the laboratory animals of this unit. The leaders shall be familiar with the laws and codes related to the State, industries and Beijing as well as have passed all the examinations. 2. There should be relevant departments that take charge of the management of the laboratory animals in the unit.</td>
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<td>1.2</td>
<td>Administrative organisations of laboratory animals</td>
<td>1. ★ Establish an administration committee of laboratory animals or leading group that is organised by the relevant leaders and professional technicians and ask for specially-assigned persons to take charge of the daily work. 2. The administration committee or leading group shall have constitutions, hold meetings at regular intervals, discuss the major issues concerning the laboratory animals of the unit and maintain records.</td>
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<td>2</td>
<td>Staff</td>
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<td>2.1</td>
<td>Working staff</td>
<td>1. ★ Have obtained “Position Qualification Certificates of the Laboratory Animal Practitioners in Beijing”. 2. They shall receive legal education, professional moral education and the continuing education of professional skills, and shall have training plans and training records. 3. The records of physical</td>
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<tr>
<td>1</td>
<td>Organisation</td>
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<tr>
<td>1.1</td>
<td>Supervising authorities and leaders</td>
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<td>1.2</td>
<td>Administrative organisations of laboratory animals</td>
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<tr>
<td>2</td>
<td>Staff</td>
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<tr>
<td>2.1</td>
<td>Working staff</td>
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</table>
| 2.2 | Supervisory staff | 1. They shall be a university graduate or above, with a relevant major such as medical science, biology, zootechnical science, veterinary medicine.
2. They shall have received a training on management of laboratory animals for more than half a year.
3. Those people who are in charge of the barrier facilities shall have taken a training on management of barrier facilities. |
| 3. | Environmental conditions and facility conditions | 1. The facilities shall be separated from the living quarters, for the facilities that cannot be separated, feasible isolation facilities shall be provided.
2. No pollution sources that affect the breeding of animals shall exist within a radius of 50 metres from the facilities, or the facilities have effective pollution prevention measures.
3. The outdoor environment shall be in good order and hygienic. No puddles, weeds, garbage diluvial soil or breeding ground for mosquitoes and flies shall exist. Disinfection, desinsection and deratization shall be regularly carried out in the outdoor environment.
4. Disinfection measures shall be taken before the persons and vehicles enter the animal laboratory facilities. |
| 3.2 Internal environment | 1. The flow of people, goods and air shall be organised reasonably so as to avoid cross infection.  
2. Humidity control and temperature regulating systems shall be provided.  
3. Alarm systems for fire, malfunction, temperature and humidity as well as a pressure difference alarm system shall be set up in the facilities.  
4. ★ Cleaning and disinfection equipment shall be provided, facilities that are used to prevent wildlife from entering shall be provided.  
5. ★ Conformance to the code for fire protection.  
6. ★ The indices of the internal environment (static state) conformance to GB 14925-2001. |
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<td>3.3</td>
<td>Area layout</td>
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<td>1. ★ The animal breeding area and animal laboratory area shall be set up separately.</td>
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<td>2. The front area includes the offices, duty rooms, restrooms, maintenance rooms, power distribution rooms, monitoring rooms, warehouses, washrooms and normal corridors, etc.</td>
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<td>3. The animal experiment area can include isolation quarantine rooms, storerooms for clean goods, clean corridors, laboratories, operation rooms, filth corridors, playgrounds for animals, etc.</td>
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<td>4. Auxiliary facilities: mechanical equipment rooms, veterinary medicine laboratories, rinsing and disinfection rooms, animal bathrooms, dissecting rooms and treatment rooms for animal wastes, etc.</td>
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<td>3.4</td>
<td>Special animal experiment facilities</td>
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<td>1. The radioactive and infectious animal experiment facilities shall be separated from ordinary animal experiment facilities.</td>
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<td>2. The setting up of radioactive and infectious animal experiment facilities shall be approved by the relevant authorities.</td>
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<td>3. The toxicant exposure tests of chemical toxicant shall be carried out under negative pressure condition with protective facilities. These tests shall not create pollution. The persons engaged in the tests cannot be harmed.</td>
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<td>3.5</td>
<td>Treatment of animal carcasses and wastes</td>
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<td></td>
<td>1. Special rooms or equipment for the storage of animal wastes are provided.</td>
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<td>2. Closed freezing storage rooms or refrigerators for animal carcasses are provided.</td>
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<td>3. ★ The animal wastes and animal carcasses shall be handled without</td>
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<td>Description</td>
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<tr>
<td>3.6</td>
<td>Construction requirements</td>
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<tr>
<td>3.6.1 Exterior-protected construction</td>
<td>Nontoxic and nonradioactive materials that are waterproof and anti-corrosion shall be used.</td>
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<td>3.6.2 Interior wall</td>
<td>1. The surface is smooth and even, and the internal corner and external corner are in an arched shape, which can be cleaned and disinfected easily. 2. Materials that are water resistant, anti-corrosion, shock resistant, anti-reflection and are hard to peel off shall be used for building interior walls.</td>
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<tr>
<td>3.6.3 Floor</td>
<td>Floor shall not be slippery and can resist abrasion and corrosion. It shall not have crack. Its surface should be smooth and even.</td>
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<tr>
<td>3.6.4 Ceiling</td>
<td>It should be water and corrosion resistant with good air tightness. The net height from the ground shall be decided by considering the saving of energy and the comfort for the staff.</td>
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<td>3.6.5 Corridor</td>
<td>Its width cannot be less than 1.5m and it shall be convenient for foot traffic.</td>
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<tr>
<td>3.6.6 Door</td>
<td>It shall be smooth and firm and must resist corrosion. The height of the door cannot be lower than 2m and the width cannot be less than 1m. The doors of the barrier environment shall have good air tightness.</td>
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<td>3.6.7 Activity area</td>
<td>Activity areas shall be provided for the bigger animals, such as dogs and monkeys.</td>
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</table>
| 3.6.8 Power supply | 1. ★ Emergency power supply or duplicate supply shall be provided for the facilities. 2. Installation of electrical appliances and laying of electric wires shall be implemented invisibly. The pipelines that enter from the non-clean areas to the clean areas shall be sealed reliably.
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</table>
| 3.6.9 | Air supply system and air discharge system | 1. Pipelines shall be built for the air supply and discharge of the facilities. Positive pressure shall be kept. Short circuits, dead angles and discontinuous flows shall be avoided.  
2. Standby forced draft fans and exhaust blowers shall be provided.  
3. The air discharge shall conform to the requirements of environmental protection. Devices that are used to prevent against rain, birds, insects and headwinds shall be equipped at the air supply outlets and exhaust outlets towards the outside. Devices that are used to prevent the backflow of condensed water shall be provided at the exhaust ducts. | | |
| 3.6.10 | Communication | Internal and external communication systems shall be equipped for the facilities. | | |
| 3.6.11 | Water supply and water drain | 1. The inner diameter of the sewer pipelines in the washrooms shall not be less than 75mm (for rabbits, dogs and moneys, etc., it shall not be less than 200mm).  
2. ★ Sterile water shall be used inside the barriers of the facilities.  
3. The water supply pipelines and taps shall be made of those materials that are anti-rust, non-poisonous, anti-corrosion and will not cause secondary pollution of the sterile water. If sewage is set up, sealed water drain opening shall be installed. The sewer pipelines shall be antirust and anticorrosive.  
4. Detoxifying treatment shall be implemented for hazardous substances that enter into the sewer pipelines.  
5. Specialized septic tanks shall be provided. | | |
<p>| 3.6.12 | Indoor environment | Thermometers, hygrometers, and other metres shall be provided. Gradient | | |</p>
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<td>Padding materials</td>
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<td>4.3</td>
<td>Feedstuff</td>
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<td>4.4</td>
<td>Drinking water</td>
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| 4.5 | Cages | 1. Cages shall be made of the materials that have no toxicity. They shall resist corrosion and high temperature and are easy to be cleaned, disinfected and sterilised. They shall also be resistant to impact.  
2. They shall be firm and solid, and can prevent animals from escape.  
3. ★ The sizes of the new cages shall conform to GBI 4925 2001 standard.  
4. The cages and tools shall be placed in a correct location when being checked for acceptance. |
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<td>5</td>
<td>Regulations and systems</td>
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</table>
| 5.1 | Management                   | 1. There should be an organisation and management framework, in which different departments and staff members shall have definite responsibility and divisions of work.  
   |                               | 2. There should be environmental indices of facilities as well as a recording system for equipment operation and maintenance.  
   |                               | 3. There should be a well designed management system and operation rules.  
   |                               | 4. There should be provisions which ensure that the design of animal experiments shall pass the ethical reviews.  
   |                               | 5. There should be animal welfare and biosafety safeguard measures.                                                                                                                                 |         |
| 5.2 | Laboratory                   | ★ Animal experiments shall be carried out in different facilities (equipment) according to the requirements on different species.  
   |                               |                                                                                                                                                                                                             |         |
| 5.3 | Record                       | Index records for the living environments of laboratory animals and debugging and use records of the facilities and equipment shall be provided.                                                            |         |

Acceptance opinions:

Signatures of the acceptance experts: Year Month Date

Note: ★ represents the one-vote-down item
### Acceptance Rules of the Licences for the Breeding of Laboratory Animals in Beijing (Breeding and Normal Environment)

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<th>Opinion</th>
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<tbody>
<tr>
<td></td>
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<td>Conform</td>
</tr>
<tr>
<td>1.</td>
<td>Organisation</td>
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<tr>
<td>1.1</td>
<td>Supervising authorities and leaders</td>
<td>1. ★ Leaders who are in charge of scientific research or conditions shall take charge of the laboratory animals of this unit. The leaders shall be familiar with the laws and codes related to the State, industries and Beijing as well as have passed all the examinations. 2. There should be relevant departments that take charge of the management of the laboratory animals in the unit.</td>
<td></td>
</tr>
<tr>
<td>1.2</td>
<td>Administrative organisations of laboratory animals</td>
<td>1. ★ Establish an administration committee of laboratory animals or leading group that is organised by the relevant leaders and professional technicians and ask for specially-assigned persons to take charge of the daily work. 2. The administration committee or leading group shall have constitutions, hold meetings at regular intervals, discuss the major issues concerning the laboratory animals of the unit and maintain records.</td>
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<tr>
<td>2.</td>
<td>Working staff</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.1</td>
<td>Working staff</td>
<td>1. ★ Have obtained “Position Qualification Certificates of the Laboratory Animal Practitioners in Beijing”. 2. They shall receive legal education, professional moral education and the continuing education of professional skills, and shall have training plans and training records. 3. The records of physical examinations for the current year shall be provided 4. Measures for labour protection shall be provided.</td>
<td></td>
</tr>
<tr>
<td>Section</td>
<td>Description</td>
<td>Details</td>
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<tr>
<td>---</td>
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</tr>
</tbody>
</table>
| 2.2 Supervisory staff | 1. They shall be a university graduate or above, with a relevant major such as medical science, biology, zootechnical science, veterinary medicine.  
2. They shall have been engaging in technical jobs at intermediate level or above as well as professional jobs of laboratory animals for more than 3 years.  
3. Those staff who are in charge of the quality management shall have received professional trainings and will have registered at the Beijing Laboratory Animals Administration Office for records.  
4. Full-time or part-time veterinarians shall be employed. | |
| 3. Environmental conditions and facility conditions | 3.1 External environment | 1. The facilities shall be separated from the living quarters, for the facilities that cannot be separated, feasible isolation facilities shall be provided.  
2. No pollution sources that affect the breeding of animals shall exist within a radius of 50 metres from the facilities, or the facilities have effective pollution prevention measures.  
3. The outdoor environment shall be in good order and hygienic. No puddles, weeds, garbage diluvial soil or breeding ground for mosquitoes and flies shall exist. Disinfection, desinsection and deratization shall be regularly carried out in the outdoor environment.  
4. Disinfection measures shall be taken before the persons and vehicles enter the animal laboratory facilities. |
<table>
<thead>
<tr>
<th>No.</th>
<th>Item</th>
<th>Requirements</th>
<th>Opinion</th>
<th>Remarks</th>
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<td></td>
<td></td>
<td>Conform</td>
<td>Not conform</td>
</tr>
</tbody>
</table>
| **3.2** | Internal environment | 1. ★ Cleaning and disinfection equipment shall be provided, facilities that are used to prevent wildlife from entering shall be provided.  
2. ★ Conformance to the code for fire protection.  
3. Necessary medical equipments and medicines shall be ready in the veterinary medicine laboratories.  
4. ★ The indices of the internal environment (static state) conformance to GB 14925-2001. | | |
| **3.3** | Area layout | 1. ★ The animal breeding area and animal laboratory area shall be set up separately.  
2. The front area includes the offices, duty rooms, restrooms, maintenance rooms, power distribution rooms, monitoring rooms, warehouses, washrooms and normal corridors, etc.  
3. The animal breeding area can include isolation quarantine rooms, breeding rooms, extended group breeding rooms, group breeding rooms for production, waiting rooms for despatch, storerooms for clean goods, laboratories, playgrounds for animals, etc.  
4. Auxiliary facilities: mechanical equipment rooms, veterinary rooms, rinsing and disinfection rooms, animal bathrooms, dissecting rooms, etc. | | |
| **3.4** | Treatment of animal carcasses and wastes | 1. Special rooms or equipment for the storage of animal wastes are provided.  
2. Closed freezing storage rooms or refrigerators for animal carcasses are provided.  
3. ★ The animal wastes and animal carcasses shall be handled without causing any harm. | | |
<p>| <strong>3.5</strong> | Construction requirements | | | |
| <strong>3.5.1</strong> | Exterior-protected | Nontoxic and nonradioactive materials | | |</p>
<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>3.5.2</td>
<td><strong>Interior wall</strong>&lt;br&gt;1. The surface is smooth and even, and the internal corner and external corner are in an arched shape, which can be cleaned and disinfected easily.&lt;br&gt;2. Materials that are water resistant, anti-corrosion, shock resistant, anti-reflection and are hard to peel off shall be used for building interior walls.</td>
</tr>
<tr>
<td>3.5.3</td>
<td><strong>Floor</strong>&lt;br&gt;Floor shall not be slippery and can resist abrasion and corrosion. It shall not have crack. Its surface should be smooth and even.</td>
</tr>
<tr>
<td>3.5.4</td>
<td><strong>Ceiling</strong>&lt;br&gt;It should be water and corrosion resistant with good air tightness. The net height from the ground shall be decided by considering the saving of energy and the comfort for the staff.</td>
</tr>
<tr>
<td>3.5.5</td>
<td><strong>Corridor</strong>&lt;br&gt;Its width cannot be less than 1.5m and it shall be convenient for foot traffic.</td>
</tr>
<tr>
<td>3.5.6</td>
<td><strong>Door</strong>&lt;br&gt;It shall be smooth and firm and must resist corrosion. The height of the door cannot be lower than 2m and the width cannot be less than 1m.</td>
</tr>
<tr>
<td>3.5.7</td>
<td><strong>Activity area</strong>&lt;br&gt;Activity areas shall be provided for the bigger animals, such as dogs and monkeys. The height of the walls shall be enough to prevent the animals from running away.</td>
</tr>
<tr>
<td>3.5.8</td>
<td><strong>Power supply</strong>&lt;br&gt;Installation of electrical appliances and laying of electric wires shall be implemented invisibly.</td>
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</tr>
<tr>
<td>3.5.9</td>
<td>Air supply system and air discharge system</td>
</tr>
</tbody>
</table>
| 3.5.10| Water supply and sewage             | 1. The inner diameter of the sewer pipelines in the washrooms shall not be less than 75mm (for rabbits, dogs and moneys, etc., it shall not be less than 200mm).  
2. The water supply pipelines shall conform to the requirements of domestic potable water.  
3. Detoxifying treatment shall be implemented for hazardous substances that enter into the sewer pipelines.  
4. Specialized septic tanks shall be provided. |
| 3.5.11| Indoor environment measuring instrument | Thermometers, hygrometers and other metres shall be provided.                                      |
| 4     | Animal quality (species introduction certificates and the following reports must be provided before supplying animals) |                                                                                                 |
| 4.1   | ★ Quality control of microorganisms | Test reports that conform to the standard of GB 14922.2-2001                                    |
| 4.2   | ★ Quality control of parasites      | Test reports that conform to the standard of GB 14922.1-2001                                    |
| 4.3   | ★ Quality control of heredity       | Test reports that conform to the standard of GB 14923-2001                                      |
| 5     | Items for breeding                  |                                                                                                 |
| 5.1   | Padding materials                   | Padding materials should have the following properties: good hygroscopicity, little dust, no foreign smells, non-poisonous, no grease or impurities. |
| 5.2 Feedstuff | ★ Feedstuff that are produced by the units with “Licences for the Breeding of Laboratory Animals” shall be used. |
| 5.3 Drinking water | ★ Animals at common-level shall drink urban potable water. |
| 5.4 Cages | 1. Cages shall be made of the materials that have no toxicity. They shall resist corrosion and high temperature and are easy to be cleaned, disinfected and sterilised. They shall also be resistant to impact.  
2. They shall be firm and solid, and can prevent animals from escape.  
3. ★ The sizes of the new cages shall conform to GBI 4925 2001 standard.  
4. The cages and tools shall be placed in a correct location when being checked for acceptance. |
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<th>No.</th>
<th>Item</th>
<th>Requirements</th>
<th>Opinion</th>
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</table>
| 5.5 | Transportation tools   | 1. Special vehicles shall be equipped for the transportation of animals and specially-assigned persons shall also be responsible for it. The vehicles shall conform to the control requirements of safety, parasite, microorganism and environmental levels.  
2. The transportation cages shall be used after infection and sterilisation. |         |
| 6   | Regulations and systems| 6.1 Management 1. There should be an organisation and management framework, in which different departments and staff members shall have definite responsibility and divisions of work.  
2. There should be environmental indices of facilities as well as a recording system for equipment operation and maintenance.  
3. There should be a well designed management system and operation rules.  
4. There should be provisions which ensure that the design of animal experiments shall pass the ethical reviews.  
5. There should be animal welfare and biosafety safeguard measures. |         |
| 6.2 | Production             | 1. ★ Animals shall be produced and bred in different breeding facilities (equipment) according to the requirements on different species and different classification levels of microorganisms.  
2. Breeding methods that conform to the international and domestic standards shall be applied.  
3. Quarantine inspection facilities and equipment shall be provided. |         |
| 6.3 | Self-inspection        | 1. ★ Agreements for self-inspection of laboratories or agreements for inspection consignment shall be provided.  
2. There should be regulations to self-inspect the parasites and microorganisms carrying conditions of animals according to the requirements of |         |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th>2001 Edition of the National Standards for Laboratory Animals.</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.4</td>
<td>Record</td>
<td>Index records for the living environments of laboratory animals and debugging and use records of the facilities and equipment shall be provided.</td>
</tr>
</tbody>
</table>

Acceptance opinions:

Signatures of the acceptance experts: Year    Month    Date

Note: ★ represents the one-vote-down item
## Acceptance Rules of the Licences for the Breeding of Laboratory Animals in Beijing (Breeding Environment and Environment above the Barriers)

<table>
<thead>
<tr>
<th>No.</th>
<th>Item</th>
<th>Requirements</th>
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</table>
| 1.  | Organisation | 1. Leaders who are in charge of scientific research or conditions shall take charge of the laboratory animals of this unit. The leaders shall be familiar with the laws and codes related to the State, industries and Beijing as well as have passed all the examinations.  
2. There should be relevant departments that take charge of the management of the laboratory animals in the unit. |
| 1.1 | Supervising authorities and leaders | 1. Establish an administration committee of laboratory animals or leading group that is organised by the relevant leaders and professional technicians and ask for specially-assigned persons to take charge of the daily work.  
2. The administration committee or leading group shall have constitutions, hold meetings at regular intervals, discuss the major issues concerning the laboratory animals of the unit and maintain records. |
| 1.2 | Administrative organisation of laboratory animals | 1. Have obtained “Position Qualification Certificates of the Laboratory Animal Practitioners in Beijing”.  
2. They shall receive legal education, professional moral education and the continuing education of professional skills, and shall have training plans and training records.  
3. The records of physical examinations for the current year shall be provided. |
| 2.  | Working staff | 1. Have obtained “Position Qualification Certificates of the Laboratory Animal Practitioners in Beijing”.  
2. They shall receive legal education, professional moral education and the continuing education of professional skills, and shall have training plans and training records.  
3. The records of physical examinations for the current year shall be provided. |
| 2.2 Supervisory staff | 1. They shall be a university graduate or above, with a relevant major such as medical science, biology, zootechnical science, veterinary medicine.  
2. They shall have been engaging in technical jobs at intermediate level or above as well as professional jobs of laboratory animals for more than 3 years.  
3. Those staff who are in charge of the barrier facilities shall have taken a training on the management of barrier facilities.  
4. Those staff who are in charge of the quality management shall have received professional trainings and will have registered at the Beijing Laboratory Animals Administration Office for records.  
5. Full-time or part-time veterinarians shall be employed. |
| 3. Environmental conditions and facility conditions | 1. The facilities shall be separated from the living quarters, for the facilities that cannot be separated, feasible isolation facilities shall be provided.  
2. No pollution sources that affect the breeding of animals shall exist within a radius of 50 metres from the facilities, or the facilities have effective pollution prevention measures.  
3. The outdoor environment shall be in good order and hygienic. No puddles, weeds, garbage diluvial soil or breeding ground for mosquitoes and flies shall exist. Disinfection, desinsection and deratization shall be regularly carried out in the outdoor environment.  
4. Disinfection measures shall be taken before the persons and vehicles enter the animal laboratory facilities. |
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<tr>
<th>No.</th>
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<th>Requirement</th>
<th>Opinion</th>
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<td>Conform</td>
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</tbody>
</table>
| 3.2 | Internal environment  | 1. The flow of people, goods and air shall be organised reasonably so as to avoid cross infection.  
2. Humidity control and temperature regulating systems shall be provided.  
3. Alarm systems for fire, malfunction, temperature and humidity as well as a pressure difference alarm system shall be set up in the facilities.  
4. ★ Cleaning and disinfection equipment shall be provided, facilities that are used to prevent wildlife from entering shall be provided.  
5. ★ Fire-fighting equipment and emergency exits are provided.  
6. Necessary medical equipments and medicines shall be ready in the veterinary medicine laboratories.  
7. ★ The indices of the internal environment (static state) conformance to GB 14925-2001. |         |             |         |
| 3.3 | Area layout           | 1. ★ The animal breeding area and animal laboratory area shall be set up separately.  
2. The front area includes the offices, duty rooms, restrooms, maintenance rooms, power distribution rooms, monitoring rooms, warehouses, washrooms and normal corridors, etc.  
3. The animal raising area shall include isolation quarantine rooms, buffer rooms, breeding rooms, extended group breeding rooms, group breeding rooms for production, waiting rooms for despatch, storerooms for clean goods, clean corridors, laboratories, filth corridors, playgrounds for animals, etc.  
4. Auxiliary facilities: mechanical equipment rooms, veterinary rooms, rinsing and disinfection rooms, animal bathrooms, dissecting rooms, etc. |         |             |         |
### 3.4 Treatment of animal carcasses and wastes

1. Special rooms or equipment for the storage of animal wastes are provided.
2. Closed freezing storage rooms or refrigerators for animal carcasses are provided.
3. ★ The animal wastes and animal carcasses shall be handled without causing any harm.

### 3.5 Construction requirements

#### 3.5.1 Exterior-protected construction

- Nontoxic and nonradioactive materials that are waterproof and anti-corrosion shall be used.

#### 3.5.2 Interior wall

1. The surface is smooth and even, and the internal corner and external corner are in an arched shape, which can be cleaned and disinfected easily.
2. Materials that are water resistant, anti-corrosion, shock resistant, anti-reflection and are hard to peel off shall be used for building interior walls.

#### 3.5.3 Floor

- Floor shall not be slippery and can resist abrasion and corrosion. It shall not have crack. Its surface should be smooth and even.

#### 3.5.4 Ceiling

- It should be water and corrosion resistant with good air tightness. The net height from the ground shall be decided by considering the saving of energy and the comfort for the staff.

#### 3.5.5 Corridor

- Its width cannot be less than 1.5m and it shall be convenient for foot traffic.

#### 3.5.6 Door

- It shall be smooth and firm and must resist corrosion. The height of the door cannot be lower than 2m and the width cannot be less than 1m. The doors of the barrier environment shall have good air tightness.

#### 3.5.7 Activity area

- Activity areas shall be provided for the bigger animals, such as dogs and monkeys.

#### 3.5.8 Power supply

1. ★ Emergency power supply and duplicate supply shall be provided for the facilities.
<table>
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<tr>
<th></th>
<th>2. Installation of electrical appliances and laying of electric wires shall be implemented invisibly. The pipelines that enter from the non-clean areas to the clean areas shall be sealed reliably.</th>
</tr>
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</table>

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<th>No.</th>
<th>Item</th>
<th>Requirements</th>
<th>Opinion</th>
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</thead>
</table>
| 3.5.9 | Air supply system and air discharge system | 1. Pipelines shall be built for the air supply and discharge of the facilities. Positive pressure shall be kept. Short circuits, dead angles and discontinuous flows shall be avoided.  
2. Standby forced draft fans and exhaust blowers shall be provided.  
3. The air discharge shall conform to the requirements of environmental protection. Devices that are used to prevent against rain, birds, insects and headwinds shall be equipped at the air supply outlets and exhaust outlets towards the outside. Devices that are used to prevent the backflow of condensed water shall be provided at the exhaust ducts. | Not conform |
| 3.5.10 | Communication | Internal and external communication equipment shall be equipped for the facilities. | |
| 3.5.11 | Water supply and water drain | 1. The inner diameter of the sewer pipelines in the washrooms shall not be less than 75mm (for rabbits, dogs and moneys, etc., it shall not be less than 200mm).  
2. ★ Sterile water shall be used inside the barriers of the facilities.  
3. The water supply pipelines and taps shall be made of those materials that are anti-rust, non-toxic, anti-corrosion and will not cause secondary pollution of the sterile water. If sewage is set up, sealed water drain opening shall be installed. The sewer pipelines shall be antirust and anticorrosive.  
4. Detoxifying treatment shall be implemented for hazardous substances that enter into the sewer pipelines.  
5. Specialized septic tanks shall be provided. | |
| 3.5.12 | Indoor environment measuring instrument | Thermometers, hygrometers and other metres shall be provided. Gradient minute-pressure differential manometers shall be installed, or temperature sensors, | |
humidity sensors and indoor gas pressure transducers shall be equipped.

<table>
<thead>
<tr>
<th></th>
<th>Animal quality (species introduction certificates and the following reports must be provided before supplying animals)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>★ Quality control of microorganisms Test reports that conform to the standard of GB 14922.2-2001 test report.</td>
</tr>
<tr>
<td>4.1</td>
<td>★ Quality control of parasites Test reports that conform to the standard of GB 14922.1-2001 test report.</td>
</tr>
<tr>
<td>4.2</td>
<td>★ Quality control of heredity Test reports that conform to the standard of GB 14923-2001 test report.</td>
</tr>
</tbody>
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<thead>
<tr>
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<th>Goods for raising</th>
</tr>
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<tbody>
<tr>
<td>5</td>
<td>Padding materials</td>
</tr>
<tr>
<td>5.1</td>
<td>Feedstuff</td>
</tr>
<tr>
<td>5.2</td>
<td>Drinking water</td>
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<tr>
<td>5.3</td>
<td>Cages</td>
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<td>No.</td>
<td>Item</td>
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</tbody>
</table>
| 5.5 | Transportation   | 1. Special vehicles shall be equipped for the transportation of animals and specially-assigned persons shall also be responsible for it. The vehicles shall conform to the control requirements of safety, parasite, microorganism and environmental levels.  
2. The transportation cages shall be used after infection and sterilisation. |
| 6   | Regulations and systems |                                                                                                                                  |
| 6.1 | Management       | 1. There should be an organisation and management framework, in which different departments and staff members shall have definite responsibility and divisions of work.  
2. There should be environmental indices of facilities as well as a recording system for equipment operation and maintenance.  
3. There should be a well designed management system and operation rules.  
4. There should be provisions which ensure that the design of animal experiments shall pass the ethical reviews.  
5. There should be animal welfare and biosafety safeguard measures. |
| 6.2 | Production       | 1. ★ Animals shall be produced and bred in different breeding facilities (equipment) according to the requirements on different species and different classification levels of microorganisms.  
2. Breeding methods that conform to the international and domestic standards shall be applied. |
| 6.3 | Self-inspection  | 1. ★ Agreements for self-inspection of laboratories or agreements for inspection consignment shall be provided.  
2. There should be regulations to self-inspect the parasites and microorganisms carrying conditions of animals according to the requirements of 2001 Edition of the National |
| 6.4 | Record | Index records for the living environments of laboratory animals and debugging and use records of the facilities and equipment shall be provided. |

Acceptance opinions:

Signatures of the acceptance experts:

Note: ★ represents the one-vote-down item
## Acceptance Rules of the Licences for the Breeding of Laboratory Animals in Beijing (Cages and Appliances)

<table>
<thead>
<tr>
<th>No.</th>
<th>Item</th>
<th>Requirements</th>
<th>Opinion</th>
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<td>Conform</td>
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<tr>
<td>1.</td>
<td>★ The main items to be approved</td>
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<tr>
<td>1.1</td>
<td>Citizen</td>
<td>Can independently bear civil liability.</td>
<td></td>
</tr>
<tr>
<td>1.2</td>
<td>Corporation</td>
<td>Has an independent certificate of corporation, which is legal and effective.</td>
<td></td>
</tr>
<tr>
<td>1.3</td>
<td>Other organisations</td>
<td>Legal organisations that are established in accordance with the relevant laws and regulations of the State.</td>
<td></td>
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<tr>
<td>2</td>
<td>Requirements of facilities, equipment and materials.</td>
<td></td>
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<tr>
<td>2.1</td>
<td>Layout in plant</td>
<td>1. Has independent production areas.</td>
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<td></td>
<td></td>
<td>2. Has production and processing workshops, sample rooms, supply rooms and finished product warehouses, etc.</td>
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</tr>
<tr>
<td>2.2</td>
<td>Equipment</td>
<td>Plate shearing machines, bending machines, punching machines, argon arc welding machines, electric welding machines, spot welding machines, drilling machines, abrasive finishing machines and other basic equipment shall be provided.</td>
<td></td>
</tr>
<tr>
<td>2.3</td>
<td>Material</td>
<td>The source of the materials is clear and non-poisonous. The materials shall resist corrosion and high temperature and can be cleaned and disinfected easily.</td>
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</tr>
<tr>
<td>3</td>
<td>Conventional cages and appliances</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.1</td>
<td>★ Appearance</td>
<td>The internal and external edges and corners shall be smooth and have no orifices or burrs. The internal and external walls shall be smooth and even.</td>
<td></td>
</tr>
<tr>
<td>3.2</td>
<td>★ Size</td>
<td>The size shall be equal or greater than the minimum living space prescribed by GB14925-2001.</td>
<td></td>
</tr>
<tr>
<td>3.3</td>
<td>Drop impact strength</td>
<td>The products make a movement of free falling from heights of 1.8 or 2 metres from the ground, and they will not disintegrate, go out of shape or unsolder.</td>
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<tr>
<td>3.4</td>
<td>Tensile</td>
<td>Simulate the strength of animals, when</td>
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<tr>
<td><strong>3.5</strong></td>
<td><strong>Water bottle</strong></td>
<td>Fill the water bottle with water and fasten down the bottle plug and make sure there is no leakage. The water nozzle can resist gnawing.</td>
<td></td>
</tr>
<tr>
<td><strong>4</strong></td>
<td><strong>Special cages and appliances</strong> (besides for the basic requirements of conventional cages and appliances, the following requirements shall also be met).</td>
<td></td>
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</tr>
</tbody>
</table>
| **4.1** | **Transportation cage** | 1. It can keep the level requirements of animals and microorganisms and prevent the animals transported from running away or prevent other animals from entering into it. It shall also prevent the laboratory animals from being injured.  
2. It shall be easy to moved or fixed. |
<table>
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<th>Item</th>
<th>Requirements</th>
<th>Opinion</th>
</tr>
</thead>
</table>
| 4.2 | Isolation device                               | 1. Its material is transparent and it has no leakage. Its size is suitable for the operation.  
2. ★The frequency of air change, airflow speed, pressure difference, cleanliness of air, amount of bacteria and noises shall reach the GB14925-2001 isolation environmental requirements. | Not conform |
| 4.3 | Independent air change and laminar flow equipment | 1. The design is reasonable, the air change is even, and it is easy to be operated and observed.  
2. ★The frequency of air change, airflow speed, pressure difference, cleanliness of air, amount of bacteria and noises shall reach the GB14925-2001 isolation environmental requirements. |          |
| 5   | Production management                          |                                                                                                                                                                                                                                                                                                                                             |         |
| 5.1 | Staff                                          | 1. The supervisory staff and designers shall be familiar with the biological characteristics of laboratory animals and understand the national standard requirements.  
2. ★ The special types of work shall have relevant work certificates.  
3. Continuing education training and labour protection measures for the staff shall be provided. |          |
| 5.2 | System                                         | The following items shall exist: quality certificate establishment, amendment and keeping systems, a duty system for all kinds of staff members, a procurement and supply system, a research and development and assessment system, operating instructions for critical procedures, a maintenance, servicing and calibration system, an inspection system, a system for handling rejected products, a safety, sanitation and fire fighting system, etc. |          |
| 5.3 | Working procedure                              | The production flow is reasonable and the requirements of the working procedures are definite.                                                                                                                                                                                                                                               |          |
| 6   | Others                                         |                                                                                                                                                                                                                                                                                                                                             |         |
| 6.1 | ★                                              | It shall indicate that it is qualified by the                                                                                                                                                                                                                                                                                              |          |
Certificate inspection and give a clear indication of the inspectors and inspection dates.

<table>
<thead>
<tr>
<th>6.2</th>
<th>★ Product operation manual</th>
<th>It shall indicate the names, models and functions of products, installation instructions, purposes, precautions, manufacturers, contact persons, phone numbers, contact addresses and postal codes.</th>
</tr>
</thead>
</table>

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<tr>
<th>6.3</th>
<th>★ Warranty card</th>
<th>It shall give a clear indication of the warranty scope and conditions, warranty locations, terms of services, warranty approaches, warranty records and contact information, etc.</th>
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</thead>
</table>

Acceptance opinions:

Signatures of the acceptance experts: Year Month Date

Note: ★ represents the one-vote-down item
## Acceptance Rules of the Licences for the Breeding of Laboratory Animals in Beijing (Feedstuff)

<table>
<thead>
<tr>
<th>No.</th>
<th>Item</th>
<th>Requirements</th>
<th>Opinion</th>
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<tbody>
<tr>
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<tr>
<td>1.</td>
<td>★The main items to be approved</td>
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<tr>
<td>1.1</td>
<td>Citizen</td>
<td>Can independently bear civil liability.</td>
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<tr>
<td>1.2</td>
<td>Legal person</td>
<td>Has an independent certificate of legal person, which is legal and effective.</td>
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<tr>
<td>1.3</td>
<td>Other organisations</td>
<td>Legal organisations that are established in accordance with the relevant laws and regulations of the State.</td>
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<td>2</td>
<td>Staff</td>
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</tbody>
</table>
| 2.1 | Working staff | 1. They shall receive the laws and regulations, professional moral education and continuing education of professional skills. Continuous education shall be given.  
2. ★The production supervisors and technical supervisors shall obtain the “position certificates for the people who engage in the laboratory animals affairs in Beijing”.  
3. They shall take a physical examination once a year. With the diagnosis certificates, only those staff who satisfy the requirements prescribed in the 《Administrative Measures on the Physical Examinations of the People who engage in the Laboratory Animals Affairs in Beijing》 are suitable for the production of feedstuff. | | |
| 2.2 | Person in charge | 1. He/she shall be familiar with the laws and codes and has passed the examinations.  
2. He/she shall possess the knowledge on feedstuff processing, packing and disinfection. | | |
| 2.3 | ★Person in charge of production and technical affairs | 1. He/she shall be familiar with the professional knowledge on the nutrition of feedstuff.  
2. He/she shall have taken professional and safety production training. | | |
| 2.4 | Production staff | 1. ★ The production staff cannot breed the animals at the same time.  
2. They shall have received professional trainings and safe production trainings. |
|-----|------------------|------------------------------------------------------------------|
| 3   | Environment      | 1. The production areas shall be relatively separated from the living quarters.  
2. Cesspools, sewage drains and propagating grounds for mosquitoes, flies and insects shall not exist.  
3. Keep away from the pesticides, chemical fertilisers, refuse dumps and other pollutant sources.  
4. Protective screens for the epidemic prevention shall be set up in the newly-built feedstuff production areas and animal raising areas. |
| 3.1 | External environment of the plant area | 1. Tidy and safe.  
2. No puddles, weeds, garbage diluvial soils, propagating grounds for mosquitoes, flies and insects  
3. The production processes shall be arranged orderly.  
| 4   | Facilities and equipment | ★ Have production workshops, warehouses for raw materials, warehouses for finished feedstuff and drying equipment (facilities). |
| 4.1 | Fundamental conditions | 1. The feedstuff production workshops shall be clean and hygienic and ventilation equipment shall be provided.  
2. Equipment for breaking, agitating, metering, moulding, cooling, drying and packing shall be provided.  
3. Dustproof and explosion prevention measures shall be provided. The gauge and measuring tools shall be aligned and records shall be made. |
<table>
<thead>
<tr>
<th>No.</th>
<th>Item</th>
<th>Requirement</th>
<th>Opinion</th>
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<td>Conform</td>
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</table>
| 4.3 | Warehouses for raw materials and warehouses for finished feedstuff | 1. The warehouses for raw materials and the warehouses for finished feedstuff shall be set up separately. They shall be ventilated, clean and dry, and facilities for the prevention of insects, birds and field mice shall be provided. 
2. All kinds of raw materials in the warehouses shall stay away from the ground. The classification codes shall be placed in order and labels shall be provided. 
3. The packaging bags shall be in good condition and the raw materials cannot be cluttered on the ground. 
4. No poisonous substances, hazardous articles and sundries shall be stored in the warehouses. | | | |
| 4.4 | Storage of nutritive additives | 1. Be stored separately from the raw materials and finished products. 
2. All kinds of vitamins, mineral substances and amino acids shall be stored separately. 
3. The storage location shall be ventilated, dry and away from sunlight. 
4. Refrigerators shall be provided. | | | |
| 4.5 | Protective goods for labour | Protective goods for labours shall be provided: work clothes, shoes, caps, masks, gloves, noise protection goods, etc. | | | |
| 5   | Product quality | | | | |
| 5.1 | Production process | ★Each part of the feedstuff production shall have a completed SOP. | | | |
| 5.2 | Record of feedstuff production | The records shall be complete, clear and in detail. | | | |
| 5.3 | Raw grain | 1. All the raw grains shall conform to the national or industrial standards introduced by GB14924.1-2001. 
2. The raw grains shall have test reports of batches and be marked with batch labels. The purchase time and places of production shall be marked clearly on the labels. | | | |
### 5.4 Finished feedstuff

1. The olfactory indicators of the finished feedstuff shall conform to GB14924.1-2001 standard.
2. The health indicators of the compound feed shall conform to GB14924.2-2001 standard.
3. The nutritional ingredients of the compound feed for rats and mice shall conform to GB14924.3-2001 standard.
4. The nutritional ingredients of the compound feed for dogs shall conform to GB14924.7-2001 standard.
5. The nutritional ingredients of the compound feed for rabbits shall conform to GB14924.4-2001 standard.
6. The nutritional ingredients of the compound feed for shrewmice shall conform to GB14924.6-2001 standard.
7. The nutritional ingredients of the compound feed for guinea pigs shall conform to GB14924.5-2001 standard.
8. The nutritional ingredients of the compound feed for monkeys shall conform to GB14924.8-2001 standard.

### 5.5 Package

Shall conform to the provisions of GB14924.1-2001 standard.

### 5.6 Label

Shall conform to the provisions of GB14924.1-2001 standard.
<table>
<thead>
<tr>
<th>No.</th>
<th>Item</th>
<th>Requirements</th>
<th>Opinion</th>
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<tr>
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<td>Conform</td>
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<tr>
<td>5.7</td>
<td>Transportation</td>
<td>Shall conform to the provisions of GB14924.1-2001 standard.</td>
<td></td>
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<tr>
<td>6</td>
<td>Quality inspection</td>
<td></td>
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<tr>
<td>6.1</td>
<td>Self-inspection capability</td>
<td>The seven regular indices of inspection capability shall exist: (crude protein, crude fat, crude fibre, crude ash, water content, calcium and phosphorus) For those organisations that do not have an inspection capability, consignment of inspection is needed.</td>
<td></td>
</tr>
</tbody>
</table>
| 6.2 | Self-inspection method, system and record | 1. Self-inspection shall be carried out according to the method prescribed by GB14924.9-2001.  
2. The system shall be complete and the feasibility shall be high.  
3. The self-inspection records shall be normative, in detail and complete. They shall not be altered and shall be kept in a safe place. |         |             |         |
| 6.3 | Acceptance and inspection report  | 1. ★ Full inspection reports shall be provided by statutory inspection institutions.  
2. Indices that are deemed as unqualified will be inspected first. Qualified reports shall be subject to reinspection. |         |             |         |

Acceptance opinions:

Signatures of the acceptance experts:

Note: ★ represents the one-vote-down item
# Application form for changing a licence for laboratory animals

Name of applicant (seal): __________________________
Licence number: __________________ Issue date: __________

<table>
<thead>
<tr>
<th>Change item</th>
<th>Current registration status</th>
<th>Status planned to be changed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of unit</td>
<td></td>
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<tr>
<td>Legal representative</td>
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<tr>
<td>Address of the facilities</td>
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<td>Scope of application</td>
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<td>Reason of changes:</td>
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</table>

Name of person who fills out this form:
Date:
Contact telephone number:
Application form for an annual inspection of the licence for laboratory animals

For the year (       )

Application unit (seal):
Application date:

Beijing Laboratory Animals Administration Office
<table>
<thead>
<tr>
<th>Name of unit</th>
<th>Licence number</th>
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</thead>
<tbody>
<tr>
<td>Location of the facilities</td>
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<tr>
<td>Scope of application</td>
<td>Licence number</td>
</tr>
<tr>
<td>(Scope of the licence)</td>
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<tr>
<td>Legal representative</td>
<td>Contact Person</td>
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<tr>
<td>Conditions of working staff</td>
<td>Date of Training and Evaluation</td>
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<td>Continuous education</td>
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<td>Physical examination</td>
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<tr>
<td>Operating conditions of facilities</td>
<td>Operating or not (put a √ inside the bracket)</td>
</tr>
<tr>
<td>Time of coming into operation</td>
<td>Operated hours this year (in days)</td>
</tr>
<tr>
<td>If the operation is not normal, please explain the reasons.</td>
<td></td>
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</table>

Note: 1. The name of the unit, number of certificate, place of facilities, scope of application (licensing scope) and legal representative shall be the same with those in the “Certificate”. If there are changes, modification application shall be transacted at the same time.
2. Application form for the annual inspection shall be filled in respectively for each “Certificate”.
3. If the space of the form is not enough, attached sheets can be added.
<table>
<thead>
<tr>
<th>Conditions of animal production</th>
<th>Name of animal</th>
<th>Class</th>
<th>Production volume (number/year)</th>
<th>Amount for self-use (number/year)</th>
<th>Sales (number/year)</th>
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</table>

Is a Quality Conformity Certificate of laboratory animals in Beijing provided while selling animals? (put a ✓ inside the bracket)
Yes (✓) No ( ) According to the requirements of the buyer

<table>
<thead>
<tr>
<th>Conditions of feedstuff production</th>
<th>Name of feedstuff</th>
<th>Class</th>
<th>Production volume (T/year)</th>
<th>Amount for self-use (T/year)</th>
<th>Sales (T/year)</th>
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</table>

Is a Quality Conformity Certificates of laboratory animals in Beijing provided while selling feedstuff? (put a ✓ inside the bracket)
Yes (✓) No ( ) According to the requirements of the buyer
<table>
<thead>
<tr>
<th>Conditions of the user units</th>
<th>Conditions of the usage of animals</th>
<th>Name of the animals being used</th>
<th>Class</th>
<th>Source of the animals</th>
<th>Usage (number/year)</th>
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<tbody>
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</table>

Do you ask for a Quality Conformity Certificates of laboratory animals in Beijing while buying animals (put a √ inside the bracket)
Yes ( ) No ( ) According to the requirements of the task

<table>
<thead>
<tr>
<th>Conditions of the usage of feedstuff</th>
<th>Name of feedstuff being used</th>
<th>Class</th>
<th>Source of the feedstuff</th>
<th>Usage (T/year)</th>
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Do you ask for a Quality Conformity Certificates of laboratory animals in Beijing while buying feedstuff (put a √ inside the bracket)
Yes ( ) No ( ) According to the requirements of the task

<table>
<thead>
<tr>
<th>Opinions of the applicant</th>
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</table>

Signature of executive leaders
Year     Month     Date

<table>
<thead>
<tr>
<th>Conclusion of annual inspection</th>
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</table>

Organisation seal
Year     Month     Date
The notice concerning the issue of the 《Notice for Prolonging the Period of Validity of a Licence for Laboratory animals》

To all the related units,

In accordance with the provisions in the 《Administrative Permission Law of the People’s Republic of China》, 《Regulations of Beijing Municipality for the Administration of Affairs Concerning Laboratory Animals》 and 《Licence Administration of Laboratory Animals (Trial)》, the Licence of Laboratory Animals shall be checked and issued again after the expiry date of the Licence. Now, the Beijing Laboratory Animals Administration Office organises experts to establish 《Notice of Prolonging the Period of Validity of Licence of Laboratory Animals》， the units whose licences will expire soon shall go to the Beijing Laboratory Animals Administration Office to transact a licence replacement procedures on time in accordance with the 《Notice of Prolonging the Period of Validity of Licence of Laboratory Animals》.

20 January 2005

Keywords: issuance, licence, prolonging, points to note, notice
Send to: all the related units
The Beijing Laboratory Animals Administration Office Printed and issued on 20 January 2005
90 copies in total are printed
Points to note for the application of prolonging the period of validity of a licence for laboratory animals

In accordance with the provisions in the 《Administrative Permission Law of the People's Republic of China》, 《Regulations of Beijing Municipality for the Administration of Affairs Concerning Laboratory Animals》and 《Licence Administration of Laboratory Animals (Trial)》， the Licence of Laboratory Animals shall be checked and issued again after the expiry date of the Licence. In view of the environmental indicators in the national standard of laboratory animals are static parameters, but many units are in an active status when they replace their licences, Beijing Laboratory Animals Administration Office organises the members in the committee of experts to study carefully and put forward the basic requirements on the licence replacements of the Licence of Laboratory Animals. Now, we notify the relevant matters as follows:

I. Application of replacement of licence
Applications shall be submitted to the Beijing Laboratory Animals Administration Office 30 business days prior to the expiry.

II. Application materials
(1) Materials that are handed over while transacting the prolonging of validity period of licences for the breeding of laboratory animals:
1. The application of the breeding licences of laboratory animals shall be prepared in triplicate;
2. One name list of management and organisation institutions of laboratory animals and members shall be prepared;
3. The quality inspection reports on the environmental facilities and laboratory animals provided by the legal inspection institutions shall be prepared in triplicate, one of them shall be the original copy (the conditions of the facilities shall be kept good and they can be taken active acceptance without retransformation; the measurement indicators of active environment include: temperature, humidity, pressure difference, noise and the concentration of ammonia; if the licence replacement is after the retransformation of facilities, detection shall be taken in accordance with the requirements of initial licensing);
4. One name list of the working staff of laboratory animals and a list of numbers of position certificates shall be prepared;
5. The plans of facilities for the laboratory animals shall be prepared in triplicate;
6. One management system of laboratory animals and standard operating procedure shall be prepared;
7. Proof of medical examination of the working staff of laboratory animals in a year and professional training record shall be prepared;
8. A provision on animal welfare and a provision on biosafety;
9. A name list of technicians in the self-inspection laboratories or a copy of commissioned detection agreement.
(2) Materials that are handed over while transacting the prolonging of validity period of licences for the using of laboratory animals
1. The application of the using licences of laboratory animals shall be prepared in duplicate;
2. One name list of management and organisation institutions of laboratory animals and members shall be prepared;
3. The quality inspection reports on the environmental facilities and laboratory animals provided by the legal inspection institutions shall be prepared in triplicate, one of them shall be the original copy (the conditions of the facilities shall be kept good and they can be taken active acceptance without retransformation; the measurement indicators of active environment include: temperature, humidity, pressure difference, the noise and concentration of ammonia; if the licence replacement is after the retransformation of facilities, detection shall be taken in accordance with the requirements of initial licensing);
4. One name list of the working staff of laboratory animals and numbers of post certificates shall be prepared;
5. The plans of facilities for the laboratory animals shall be prepared in triplicate;
6. One management system of laboratory animals and standard operating procedure shall be prepared;
7. Proof of medical examination of the working staff of laboratory animals in a year and professional training record shall be prepared;
8. A provision on animal welfare, biosafety and ethical review of animal experiments shall be prepared;

III. Acceptance on the spot
The importance of on-site inspection includes: the function of the management and organisation institutions of laboratory animals in the unit, post certificates of working staff, quality inspection reports or resource records of laboratory animals and feedstuff, continuing education records of working staff, implementation of the internal and external environment of the facilities, management systems of laboratory animals and standard operating procedures, innocent treatment measures of waste, production and breeding records of laboratory animals or use records of facilities for the animal experiments, maintenance service records of important equipment, etc.

Annex:
Acceptance Rules of the Licences for the Breeding of Laboratory Animals in Beijing (production and breeding, active licence replacement)
Acceptance Rules of the Licences for the Use of Laboratory Animals in Beijing (active licence replacement)
## Acceptance Rules of the Licences for the Breeding of Laboratory Animals in Beijing (Production and Breeding, Active Licence Replacement)

<table>
<thead>
<tr>
<th>No.</th>
<th>Item</th>
<th>Requirement</th>
<th>Opinion</th>
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<td>Conform</td>
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<tr>
<td>1.</td>
<td>Organisation</td>
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</tbody>
</table>
| 1.1 | Supervising authorities and leaders | 1. ★ Leaders who are in charge of scientific research or conditions shall take charge of the laboratory animals of this unit. The leaders shall be familiar with the laws and codes related to the State, industries and Beijing as well as have passed all the examinations.  
2. There should be relevant departments that take charge of the management of the laboratory animals in the unit. |         |             |         |
| 1.2 | Administrative organisations of laboratory animals | 1. ★ Establish an administration committee of laboratory animals or leading group that is organised by the relevant leaders and professional technicians and ask for specially-assigned persons to take charge of the daily work.  
2.◆ The administration committee or leading group shall have constitutions, hold meetings at regular intervals, discuss the major issues concerning the laboratory animals of the unit and maintain records. |         |             |         |
| 2.  | Working staff |             |         |             |         |
| 2.1 | Working staff | 1. ★ Have obtained “Position Qualification Certificates of the Laboratory Animal Practitioners in Beijing”.  
2. ◆ They shall receive legal education, professional moral education and the continuing education of professional skills, and shall have training plans and training records.  
3. ◆ The records of physical examinations of the frontline staff for the current year shall be provided. |         |             |         |
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| 2.2 | Supervisory staff | 1. They shall be a university graduate or above, with a relevant major such as medical science, biology, zootechnical science, veterinary medicine.  
2. They shall have been engaging in technical jobs at intermediate level or above as well as professional jobs of laboratory animals for more than 3 years.  
3. Those staff who are in charge of the barrier facilities shall have taken a training on the management of barrier facilities.  
4. Those staff who are in charge of the quality management shall have received professional trainings and will have registered at the Beijing Laboratory Animals Administration Office for records.  
5. ◆ Full-time or part-time veterinarians shall be employed. |

<table>
<thead>
<tr>
<th>3.</th>
<th>Environmental conditions and facility conditions</th>
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</thead>
</table>
| 3.1 | External environment | 1. ◆ The facilities shall be separated from the living quarters, for the facilities that cannot be separated, feasible isolation facilities shall be provided.  
2. No pollution sources that affect the breeding of animals shall exist within a radius of 50 metres from the facilities, or the facilities have effective pollution prevention measures.  
3. ◆ The outdoor environment shall be in good order and hygienic. No puddles, weeds, garbage diluvial soil or breeding ground for mosquitoes and flies shall exist. Disinfection, desinsection and deratization shall be regularly carried out in the outdoor environment.  
4. ◆ Disinfection measures shall be taken before the persons and vehicles enter the animal laboratory facilities. |
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<td>Conform</td>
<td>Not conform</td>
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</tbody>
</table>
| 3.2 | Internal environment | 1. ◆ The flow of people, goods and air shall be organised reasonably so as to avoid cross infection.  
2. ◆ A Ventilation system as well as humidity control and temperature regulating systems shall be provided.  
3. ◆ Alarm systems for fire, malfunction, temperature and humidity as well as a pressure difference alarm system shall be set up in the facilities above the barriers.  
4. ★ Cleaning and disinfection equipment shall be provided, facilities that are used to prevent wildlife from entering shall be provided.  
5. ★ There should be fire protection equipment and emergency exits.  
6. Necessary medical equipment, devices and vaccines shall be ready in the veterinary medicine laboratories.  
7. ★ The temperature, humidity, pressure difference, the noise and thickness of ammonia that are stated in the indices of internal environment shall conform to GB 14925-2001 standard. | | |
| 3.3 | Area layout | ★ The animal breeding area and the animal experiment area shall be set up separately. | | |
| 3.4 | Treatment of animal carcasses and wastes | 1. ◆ Special rooms or equipment for the temporary storage of animal waste are provided.  
2. ◆ Closed freezing storage rooms or refrigerators for animal carcass are provided.  
3. ★ Animal wastes and animal carcasses shall be handled without causing any harm. | | |
| 3.5 | Power supply | 1. ★ Emergency power supply or duplicate supply shall be provided for the facilities above the barrier environment.  
2. Installation of electrical appliances and laying of electric wires shall be implemented invisibly. The pipelines that enter from the non-clean areas to the clean | | |
<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
<th>Details</th>
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<tbody>
<tr>
<td>3.6 Communication</td>
<td>Internal and external communication equipment shall be equipped for the facilities above the barrier environment.</td>
<td></td>
</tr>
<tr>
<td>3.7 Water supply and water drain</td>
<td>1. Sterile water shall be used in the barriers of the facilities above the barrier facilities. The water supply pipelines shall be made of the materials that are anti-rust, anti-corrosion and will not cause secondary pollution of the sterile water. If sewage is set up, sealed water drain outlet shall be installed and the sewer pipelines shall be antirust and anti-corrosion. 2. The water supply pipelines in the normal environment shall conform to the requirements of domestic potable water.</td>
<td></td>
</tr>
<tr>
<td>3.8 Indoor environment measuring instrument</td>
<td>Thermometers, hygrometer and other metres shall be provided. Gradient minute-pressure differential manometers shall be installed, or temperature sensors, humidity sensors and indoor gas pressure transducers shall be equipped.</td>
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<tr>
<td>4 Animal quality</td>
<td></td>
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</tr>
<tr>
<td>4.1 Quality control of microorganisms</td>
<td>Test reports that conform to the standard of GB 14922.2-2001.</td>
<td></td>
</tr>
<tr>
<td>4.2 Quality control of parasites</td>
<td>Test reports that conform to the standard of GB 14922.1-2001.</td>
<td></td>
</tr>
<tr>
<td>4.3 Quality control of heredity</td>
<td>Test reports that conform to the standard of GB 14923-2001.</td>
<td></td>
</tr>
<tr>
<td>5 Goods for breeding</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.1 Padding</td>
<td>Have good hygroscopicity, little dust, no foreign smell, toxicity, grease or impurities and can be used after sterilisation and disinfection.</td>
<td></td>
</tr>
<tr>
<td>5.2 Feedstuff</td>
<td>Feedstuff that are produced by the units with “Licences for the Breeding of Laboratory Animals” shall be used. The feedstuff for animals that are at clean-level or above shall be used after disinfection.</td>
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<td>No.</td>
<td>Item</td>
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<td>--------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>5.3</td>
<td>Drinking water</td>
<td>★ Animals at common level shall drink domestic potable water and animals above the clean-level shall drink sterile water.</td>
</tr>
</tbody>
</table>
| 5.4 | Cages                 | 1. Cages shall be made of the materials that have no toxicity. They shall resist corrosion and high temperature and are easy to be cleaned, disinfected and sterilised. They shall also be resistant to impact.  
2. They shall be firm and solid, and can prevent animals from escape.  
3. ◆ The sizes of the new cages shall conform to GBI 4925 2001 standard. |         |         |
| 5.5 | Transportation tools  | 1. ◆ Special vehicles shall be equipped for the transportation of animals and specially-assigned persons shall also be responsible for it. The vehicles shall conform to the control requirements of safety, parasite, microorganism and environmental levels.  
2. The transportation cages shall be used after infection and sterilisation. |         |         |
| 6   | Regulations and systems | 1. There should be an organisation and management framework, in which different departments and staff members shall have definite responsibility and divisions of work.  
2. ◆ There should be environmental indices of facilities as well as a recording system for equipment operation and maintenance.  
3. ◆ There should be a well designed management system and operation rules. They shall be firmly implemented.  
4. ◆ There should be animal welfare and biosafety safeguard measures. |         |         |
### 6.2 Production

1. ★ Animals shall be produced and bred in different breeding facilities (equipment) according to the requirements on different species and different classification levels of microorganisms.
2. ◆ Breeding methods that conform to the international and domestic standards shall be applied.
3. ★ The same animal feeder cannot feed the laboratory animals with different microorganism levels at the same time.
4. ◆ Quarantine inspection facilities and equipment shall be provided.
5. ◆ Measures that can ensure the health of working staff shall be provided.

### 6.3 Self-inspection

1. ★ Agreements for the self-inspection of laboratories or inspection consignment shall be provided.
2. Self-inspect the parasites and microorganisms carrying conditions of animals in accordance with the requirements of 2001 Edition of National Standards for Laboratory Animals every three months.

### 6.4 Record

◆ Index records for the living environments of laboratory animals and debugging and use records of the facilities and equipment shall be provided.

**Acceptance opinions:**

**Signatures of the acceptance experts:**

**Year** **Month** **Day**

**Note:** ★ represents the one-vote-down item. ◆ represents the three-vote-down item.
## Acceptance Rules of the Licences for the Breeding of Laboratory Animals in Beijing (Active Licence Replacement)

<table>
<thead>
<tr>
<th>No.</th>
<th>Item</th>
<th>Requirement</th>
<th>Opinion</th>
<th>Remarks</th>
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<td></td>
<td>Conform</td>
<td>Not conform</td>
</tr>
<tr>
<td>1</td>
<td>Organisation</td>
<td>1. Leaders who are in charge of scientific research or conditions shall take charge of the laboratory animals of this unit. The leaders shall be familiar with the laws and codes related to the State, industries and Beijing as well as have passed all the examinations. 2. There should be relevant departments that take charge of the management of the laboratory animals in the unit.</td>
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</tr>
<tr>
<td>1.1</td>
<td>Supervising authorities and leaders</td>
<td>1. Establish an administration committee of laboratory animals or leading group that is organised by the relevant leaders and professional technicians and ask for specially-assigned persons to take charge of the daily work. 2. The administration committee or leading group shall have constitutions, hold meetings at regular intervals, discuss the major issues concerning the laboratory animals of the unit and maintain records.</td>
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<tr>
<td>1.2</td>
<td>Administrative organisations of laboratory animals</td>
<td></td>
<td></td>
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<tr>
<td>2</td>
<td>Staff</td>
<td>1. Have obtained “Position Qualification Certificates of the Laboratory Animal Practitioners in Beijing”. 2. They shall receive legal education, professional moral education and the continuing education of professional skills, and shall have training plans and training records. 3. The records of physical examinations of the frontline staff for the current year shall be provided. 4. Measures for labour protection shall be provided.</td>
<td></td>
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</table>
2.2 Supervisory staff in the animal experiment department

1. They shall be a university graduate or above, with a relevant major such as medical science, biology, zootechnical science, veterinary medicine.
2. They shall have been engaging in technical jobs at intermediate level or above as well as professional jobs of laboratory animals for more than 3 years.
3. Those staff who are in charge of the barrier facilities shall have taken a training on the management of barrier facilities.

3 Environmental conditions and facility conditions

3.1 External environment

1. The facilities shall be separated from the living quarters, for the facilities that cannot be separated, feasible isolation facilities shall be provided.
2. No pollution sources that affect the breeding of animals shall exist within a radius of 50 metres from the facilities, or the facilities have effective pollution prevention measures.
3. The outdoor environment shall be in good order and hygienic. No puddles, weeds, garbage diluvial soil or breeding ground for mosquitoes and flies shall exist. Disinfection, desinsection and deratization shall be regularly carried out in the outdoor environment.
4. Disinfection measures shall be taken before the persons and vehicles enter the animal laboratory facilities.

3.2 Internal environment

1. The flow of people, goods and air shall be organised reasonably so as to avoid cross infection.
2. A Ventilation system as well as humidity control and temperature regulating systems shall be provided.
3. Alarm systems for fire, malfunction, temperature and humidity as well as a pressure difference alarm system shall be set up in the facilities above the barriers.
4. Cleaning and disinfection equipment shall be provided, facilities that are used to
prevent wildlife from entering shall be provided.
5. ★ There should be fire protection equipment and emergency exits.
6. ★ The temperature, humidity, pressure difference, the noise and thickness of ammonia that are stated in the indices of internal environment shall conform to GB 14925-2001 standard.
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<td></td>
<td>Conform</td>
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<tr>
<td>3.3</td>
<td>Area layout</td>
<td>★The experiment facilities and the animal breeding facilities shall be set up separately.</td>
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</tr>
<tr>
<td>3.4</td>
<td>Special animal experiment facilities</td>
<td>1. The radioactive and infectious animal experiment facilities shall be separated from ordinary animal experiment facilities. 2. The setting up of radioactive and infectious animal experiment facilities shall be approved by the relevant authorities. 3. The toxicant exposure tests of chemical toxicant shall be carried out under negative pressure condition with protective facilities. These tests shall not create pollution. The persons engaged in the tests cannot be harmed.</td>
<td></td>
</tr>
<tr>
<td>3.5</td>
<td>Treatment of animal carcass and wastes</td>
<td>1. ◆Special rooms or equipment for the temporary storage of animal waste are provided. 2. ◆Closed freezing storage rooms or refrigerators for animal carcass are provided. 3. ★Animal wastes and animal carcasses shall be handled without causing any harm.</td>
<td></td>
</tr>
<tr>
<td>3.6</td>
<td>Communication</td>
<td>◆Internal and external communication equipment shall be equipped for the facilities above the barrier environment.</td>
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</tr>
<tr>
<td>3.7</td>
<td>Power supply</td>
<td>1. ★Emergency power supply or duplicate supply shall be provided for the facilities above the barrier environment. 2. Concealed installation shall be implemented for the electrical appliances and concealed laying shall be implemented for the electric pipelines. The pipelines enter from the non-clean areas to the clean areas shall be sealed reliably.</td>
<td></td>
</tr>
<tr>
<td>3.8</td>
<td>Water supply and water drain</td>
<td>1. ★Sterile water shall be used in the barriers of the facilities above the barrier facilities. The water supply pipelines shall be made of the materials that are anti-rust, anti-corrosion and will not cause secondary pollution of the sterile water. If sewage is</td>
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<tr>
<td>3.9</td>
<td>Indoor environment measuring instrument</td>
<td>• Thermometers, hygrometers and other metres shall be provided. Gradient minute-pressure differential manometers shall be installed, or temperature sensors, humidity sensors and indoor gas pressure transducers shall be equipped.</td>
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</tr>
<tr>
<td>4</td>
<td>Articles for animal experiments</td>
<td></td>
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<tr>
<td>4.1</td>
<td>Animal</td>
<td>★ Users shall use laboratory animals of the corresponding level of breeding unit production that have “Licences for the Breeding of Laboratory Animals”. Quality conformity certificates for laboratory animals shall be kept for inspection.</td>
<td></td>
</tr>
<tr>
<td>4.2</td>
<td>Padding materials</td>
<td>Padding materials should have the following properties: good hygroscopicity, little dust, no foreign smells, non-poisonous, no grease or impurities. They shall not be used before sterilisation and disinfection.</td>
<td></td>
</tr>
<tr>
<td>4.3</td>
<td>Feedstuff</td>
<td>★ Feedstuff that are produced by the units with “Licences for the Breeding of Laboratory Animals” shall be used. Quality conformity certificates for laboratory animals shall be kept for inspection.</td>
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</tr>
<tr>
<td>4.4</td>
<td>Drinking water</td>
<td>★ Animals at the common level shall drink domestic potable water, while animals above the clean level shall drink sterile water.</td>
<td></td>
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</table>
| 4.5 | Cages | 1. Cages shall be made of the materials that have no toxicity. They shall resist corrosion and high temperature and are easy to be cleaned, disinfected and sterilised. They shall also be resistant to impact.  
2. They shall be firm and solid, and can prevent animals from escape.  
3. ◆ The sizes of the cages shall conform to the GBI 4925-2001 standard. |
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<tr>
<td>5</td>
<td>Regulations and systems</td>
<td></td>
<td>Conform</td>
</tr>
<tr>
<td>5.1</td>
<td>Management</td>
<td>1. There should be an organisation and management framework, in which different departments and staff members shall have definite responsibility and divisions of work. 2. ◆ There should be environmental indices of facilities as well as a recording system for equipment operation and maintenance. 3. ◆ There should be a well designed management system and operation rules. They shall be firmly implemented. 4. ◆ There should be animal welfare and biosafety safeguard measures. as well as regulations on ethic inspection for animal experiments.</td>
<td></td>
</tr>
<tr>
<td>5.2</td>
<td>Laboratory</td>
<td>1. ★ Animal experiments shall be carried out in different facilities (equipment) according to the requirements on different species, different strains of breeds and different classification levels of microorganisms. 2. ◆ The same animal feeder cannot feed the laboratory animals with different microorganism levels at the same time.</td>
<td></td>
</tr>
<tr>
<td>5.3</td>
<td>Record</td>
<td>◆ Index records for the living environments of laboratory animals and debugging and use records of the facilities and equipment shall be provided.</td>
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</tbody>
</table>

Acceptance opinions:

Signatures of the acceptance experts: Year Month Date

Note: ★ represents the one-vote-down item. ◆ represents the three-vote-down item.
Document of the Beijing Laboratory Animals Administration Office

Notice No. 09 [2006] of the Beijing Laboratory Animals Administration Office

The notice concerning the issue of the 《Administrative Measures of Beijing Municipalities on Credit Information in the Industry of Laboratory Animals (trial)》 and the 《Administrative Measures of the Beijing Municipalities on the Information Platform of Laboratory Animals (trial)》

All of the related units,

In order to implement the 《Regulations of Beijing Municipality for the Administration of Affairs Concerning Laboratory Animals》, regulate the management of credit information in the industry of laboratory animals, openly implement the system of making government affairs public, serve for the production and using units of laboratory animals much better and make working plans according to the technological regulations, administration statutes and policy measures of the Science and Technology Commission of Beijing Municipality, our office organises the experts to compile the 《Administrative Measures of Beijing Municipality on Credit Information in Industry of Laboratory Animals (Trial)》 and 《Administrative Measures of Beijing Municipality on Information Platform of Laboratory Animals (Trial)》. The two documents are hereby printed and distributed to you, please implement them throughout all work.

Annex: 1. 《Administrative Measures of Beijing Municipality on Credit Information in Industry of Laboratory Animals (Trial)》
2. 《Administrative Measures of Beijing Municipality on Information Platform of Laboratory Animals (Trial)》

Keywords: print and issue, credit, information, measure, notice
Send to: The Science and Technology Commission of Beijing Municipality
Beijing Laboratory Animals Administration Office Printed and issued on 28 March 2006
150 copies are printed in total
Administrative Measures of the Beijing Municipalities on Credit Information in the Industry of Laboratory Animals (trial)

Article 1 The Measures are established in accordance with the《The Measures for the Administration of the Collection and Promulgation of Enterprise Credit Information by the Administrative Organs of Beijing Municipality》 in order to implement the《Regulations of Beijing Municipality for the Administration of Affairs Concerning Laboratory Animals》, regulate the management of credit information in industry of laboratory animals and adapt to the development of science and technology and the requirements of social credit.

Article 2 “Credit information” as used in these Measures refers to the behaviour records related to credits during the business activities of the units of laboratory animals produced while the competent authorities of laboratory animals and other administrative organisations perform their duties in accordance with the law.

Article 3 The Measures are used for the collection, announcement, use and other activities of the information related to the credit that the Beijing Laboratory Animals Administration Office (hereinafter referred to as BAOLA) carries out to the units and individuals in the administrative regions of the municipality (hereinafter referred to as units of laboratory animals) while engaging in the work activities of laboratory animals.

Article 4 The Beijing Laboratory Animals Administration Office takes charge of the establishment and management of the credit information system in the industry of the laboratory animals in the municipality and provides credit management of industry and social inquiry services to the laboratory animals under the leadership of administrative departments for science and technology.

Article 5 The credit information management in the industry of laboratory animals have credit incentives, credit warning and credit supervision mainly through the dynamic collection and the credit information of the laboratory animal units that are openly demonstrated.

Article 6 The credit information in the industry of laboratory animals is formed by the basic information, good information, prompt information and warning information of the laboratory animal units.

Article 7 The following information of laboratory animal units shall be recorded as basic information:
(1) The basic information on the registration of the units;
(2) The administrative permission of the production and use of laboratory animals and the relevant products;
(3) Amount and professional component of the working staff of laboratory animals, conditions of the professional technical trainings on laboratory animals and the basic conditions of the principals of laboratory animal units and the technical leaders;
(4) Basic information related to the units of laboratory animals registered by other administrative organs according to law.

Article 8 The following information of laboratory animal units shall be recorded as good information:
(1) Paying attention to the credit and contract management and the implementation of systems, institutions and personnel, having no complaints on the faults of credit for three consecutive years during the business association;
(2) Being commended during the annual inspection;
(3) The working staff or principals of the laboratory animals are commended by the administrative authorities above the city level;
(4) The units that have the authorisation of the national or international quality standards and management;
(5) The units that have been awarded the “enterprises that abide by the contract and keep promises”, “AAA” credit rating, “enterprises that keep promises” and other titles of honour by relevant departments or laboratory animal industries of the State and Beijing;
(6) Other good information related to the credit that are recognised by Beijing Laboratory Animals Administration Office and can be recorded.

Article 9 The following information of laboratory animal units shall be recorded as prompt information:
(1) The units that get the penalties because of unruly and delinquent behaviours, the penalties include having rectification and reform within a definite time, warnings, amercement, confiscation, compelling to stop production and stop doing business and withholding the licences;
(2) The units that do not pass various types of special purposes or periodic inspection;
(3) The units that refuse to accept or escape from the supervision and inspection;
(4) The credit fault complaints of the laboratory animal products or technical services are more than 5 times in half a year;
(5) Other rule violation and unlawful acts that are recognised by the Beijing Laboratory Animals Administration Office as the acts that shall be notified.

Article 10 The following information of laboratory animal units shall be recorded as warning information:
(1) The units that seriously violate the standard of laboratory animals or refuse to produce laboratory animals or relevant products and use laboratory animals according to the tolerance range;
(2) The units that refuse to transact changes or refuse to transact cancellation of registration in the prescribed time limit when the registration or tolerance ranges of the units change;
(3) The units that are withdrawn, revoked or written off licences and business licences;
(4) The units that do not accept or do not pass the annual inspection;
(5) The staff work in the units of the laboratory units prevent the administrative law enforcement officials of laboratory animals and quality inspectors to perform public services and are subject to administrative sanctions or criminal responsibilities according to law;
(6) The units that get administrative penalty from the administrative services divisions or administrative law enforcement authorities because they produce and sell forged and fake laboratory animals and the relevant products, forge technical data, cheat users, release false advertising, interfere with the legal interests of customers and other violation behaviours;
(7) The units that are asked to straighten things up within the specified time or warned, are suspended licences, are asked to stop production or business, and are punished with penalty and confiscation and other penalties for more than twice because of the same kind of lawbreaking activities;
(8) The units or the principal persons who are investigated for criminal responsibility because of the serious violation of relevant trademarks, contract credit and other laws of the State.

Article 11 The time limit of credit information records shall be set up in accordance with the following provisions:
(1) The time limit of the record for the basic information is until the termination of the laboratory animal units;
(2) The time limit of the record for the good information is the valid period that the units attain commendation and win the titles;
(3) The time limit of the record for the prompt information is three years, the conditions of rectification and reform shall be publicised dynamically during the period;
(4) The time limit of the record for the warning information is three years, the conditions of rectification and reform shall be publicised dynamically during the period, the time limit of the record for the laws and regulations shall be applied except as otherwise provided for in the laws and regulations.
(5) Dynamic update and management are implemented for the credit information. After the time limit expires, the credit information publicised shall be released by the Beijing Laboratory Animals Administration Office and change into the information that shall be preserved permanently.

Article 12 The Beijing Laboratory Animals Administration Office takes charge of the setup and release of the credit stimulation and credit warning of laboratory animal units. 《Approval Form for the Setup or Release of Credit Information of the Beijing Laboratory Animals Administration Office》 (see the annex) shall be filled in while setting up or releasing the credit information and shall be approved by the principals of the Beijing Laboratory Animals Administration Office.

Article 13 The credit information set up or released by the units of laboratory animals shall be recorded or deleted in five working days by the Beijing Laboratory Animals Administration Office.

Article 14 The Beijing Laboratory Animals Administration Office shall award the units or principals of laboratory animals that have no prompt information or warning information and have two or more than two good information every two years and promulgate on the information network of laboratory animals.

Article 15 The Beijing Laboratory Animals Administration Office shall strengthen the supervision and management of the units of laboratory animals that have prompt information, take them as key units, inspect or have selective examinations on them and remind the users and society to beware. The units of laboratory animals that have had warning information shall not obtain all types of registrations and annual inspections, and credit warnings shall be issued to the society to remind the users to protect their legal rights and interests.

Article 16 Those persons who take charge of the credit information of laboratory animals shall manage and use credit information in accordance with the laws, regulations and the provisions of the Measures.

Article 17 Those persons who take charge of the credit information of laboratory animals shall promulgate the credit information of the units of laboratory animals. The contents that belong to individual privacy, involve in the commercial or technical secrets of units, as well as other contents that are clearly defined by laws, regulations and rules and cannot be open shall not be promulgated or disclosed.
Article 18 All the organisations and individuals can log in the credit information system in the industry of laboratory animals to inquire about relevant credit information system published, they shall not make any illegal activities or make profits by collecting, storing, counting and analysing the information generated through the credit information management system of laboratory animals and they shall supervise and report the behaviours that violate the Measures.

Article 19 The units of laboratory animals shall provide true and completed information timely and accurately in accordance with the requirements of the Beijing Laboratory Animals Administration Office and undertake corresponding legal liabilities.

Article 20 Those who think that the information of the unit released doesn’t conform to the facts shall present an application in written form to the Beijing Laboratory Animals Administration Office for the alternation or withdrawal of the credit records and provide corresponding evidence. The Beijing Laboratory Animals Administration Office shall make a decision in 15 working days after receiving the application and inform the applicants. The records that are regarded as really wrong shall be altered or withdrawn in a timely manner. The parties that have suffered damage due to the mistakes of the information shall have the right to demand compensation in accordance with law.

Article 21 The Measures enter into effect as of the day after its promulgation.
## Annex

### Approval Form for the Setup or Release of Credit Information of the Beijing Laboratory Animals Administration Office

<table>
<thead>
<tr>
<th>Name of unit</th>
<th>Legal representative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address of unit</td>
<td>Postal code</td>
</tr>
<tr>
<td>Contact person</td>
<td>Telephone</td>
</tr>
</tbody>
</table>

The contents and setup (release) of credit information are based on:

<table>
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<tr>
<th>Handled by:</th>
<th>Year</th>
<th>Month</th>
<th>Day</th>
</tr>
</thead>
</table>

Type of credit information:
1. Basic information ( )
2. Good information ( )
3. Prompt information ( )
4. Warning information ( )

Setup or release of credit information:
1. Setup ( )
2. Release ( )

Opinions from the person in charge:

<table>
<thead>
<tr>
<th>Signature:</th>
<th>Year</th>
<th>Month</th>
<th>Day</th>
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</thead>
</table>

Internet usage condition:

The credit information above has been registered ( )/withdrawn ( ) from the Beijing Information Network of Laboratory Animals

<table>
<thead>
<tr>
<th>Signature of the person in charge:</th>
<th>Year</th>
<th>Month</th>
<th>Day</th>
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</table>
Administrative Measures of the Beijing Municipalities on the
Information Platform of Laboratory Animals (trial)

Article 1 In order to reinforce the management of the information platform of laboratory animals of Beijing municipality (hereinafter referred to as the “information platform”) and to ensure its safe, reliable and efficient operation, these Measures are established according to the 《Administrative Measures on Internet Information Services》 and the requirement of the local standard, 《Specification of Construction and Administration for Government Websites》 in Beijing.

Article 2 Information platform is an information carrier to display the development of laboratory animal industry in Beijing. It mainly includes information network of laboratory animals in Beijing and credit information management system of laboratory animals (Beijing).

Information network of laboratory animals in Beijing is a window that can provide online consultation for the public, issue information on the administrative licensing and supervision and inspection of laboratory animals, publicise regulations and standards and popularise the scientific knowledge of laboratory animals.

Credit management information system of laboratory animals (Beijing) is an information system that can handle the production of laboratory animals, application (preliminary review of content) and annual inspection (preliminary review of form) through licences.

The information platform is built in accordance with the tenet that “making government affairs public, serving the public, issuing the information and sharing the resources”.

Article 3 The Beijing Laboratory Animals Administration Office (hereinafter referred to as BAOLA) is responsible for the construction, maintenance, operation and management of information platform.

Article 4 The units that obtain the licences of laboratory animals are the authorised users of information platform, they can use the resources of information platform and issue information in the scope of authority. Other units that use the information platform must apply towards Beijing Laboratory Animals Administration Office (BAOLA), they can only use the information platform after being authorised.

Article 5 The authorised users of the information platform shall be actively involved in the construction of information platform, update the content in a timely manner and serve for the public with enthusiasm. Beijing Laboratory Animals Administration Office (BAOLA) will award them depending on the circumstances.

Article 6 The authorised users of the information platform who are in violation of the Measures shall be circulated a notice of criticism and be ordered to correct by Beijing Laboratory Animals Administration Office (BAOLA).

Article 7 Beijing Laboratory Animals Administration Office (BAOLA) shall actively carry out the responsibilities and obligations that make government affairs public and issue relevant information without prejudice to relevant laws and regulations. Its functions are as follows:
(1) The construction of information platform shall comply with the laws, rules, regulations and related policies of the State and this Municipality.
(2) The principle of being open, fair and just shall be complied with during the release of credit information.
(3) Check the website contents of the authorised users of the information platform in a timely manner, access the contents with objection first and then inform the users of information platform as soon as possible.

(4) If the authorised users of the information platform are found filling malicious information and do not stop this after reminding, their right of use shall be stopped and relevant departments shall be informed in accordance with relevant provisions and procedures for further treatment.

(5) Set up perfect information security mechanisms, have routine maintenance to the hardware devices and ensure normal operation. Set up completed data monitoring systems and have digital storage to the contents of information platform at regular intervals.

(6) Have trainings to the authorise users and teach them how to use information platforms.

Article 8 The modules and columns established by the authorised users in the information platform shall be handled by specialised institutions or persons. Their functions are as follows:

(1) In order to ensure the stable operation of the information platform, the authorised users of the information platform shall comply with the relevant rules and regulations and standards promulgated during the construction of information platform and the application.

(2) A leader shall be confirmed to check the contents issued on the information platform, so as to ensure that the information is legal, true and effective. And they shall bear all the responsibilities caused by the false contents.

(3) A business personnel shall be designated to take charge of the detailed tasks of their unit in the information platform, carry out modular design, information input, layout adjustment and operation management, but they are not allowed to change the module framework of the information platform without authorisation.

(4) Browse the information released on the information platform in a timely manner and make adjustments in accordance with the requirements of the information platform. Pay attention to the feedback on the contents issued by the units, and answer the questions asked by the visitors in a timely manner.

(5) If there are some problems, preserve the erroneous contents, record the operation process and notify Beijing Laboratory Animals Administration Office (BAOLA) in a timely manner.

(6) Set up data backup system, make a backup of the online data regularly and provide backup data in a timely manner in accordance with the requirements of Beijing Laboratory Animals Administration Office (BAOLA).

(7) Set up perfect organisations and management systems of network information security, take appropriate information security technologies and approaches, and limit the content of on-line information in accordance with relevant laws and regulations on the confidentiality of the State.

Article 9 All the units and individuals have the rights to carry out supervision on the operation and management of information platform.

Article 10 The Measures enter into effect as of the day after its promulgation.
Document of the Beijing Laboratory Animals Administration Office

Notice No. 99 [2005] of the Beijing Laboratory Animals Administration Office

The notice concerning the issue of the supplementary documents of the 《Regulations of the Beijing Municipalities for the Administration of Affairs Concerning Laboratory Animals》

All of the related units,

《Regulations of Beijing Municipality for the Administration of Affairs Concerning Laboratory Animals》 has been amended on 2 December 2004 and came into operation on 1 January 2005. In order to implement the recently amended regulations, the Beijing Laboratory Animals Administration Office (BAOLA) organises experts to amend the current 《Assessment and Administrative Measures of the Training for the Working staff in Industry of Laboratory Animals of Beijing (Trial)》 and established 《Administrative Measures of the Quality Inspection of Laboratory Animals of Beijing》, 《Administrative Measures of the Physical Examination for the Working staff in Industry of Laboratory Animals of Beijing》 and 《Manual for the Welfare and Ethical Review of Laboratory Animals of Beijing》. The four management documents are hereby printed and distributed to you. Please implement them throughout all work.

Annex:
1. 《Assessment and Administrative Measures of the Training for the Working staff in Industry of Laboratory Animals of Beijing》
2. 《Administrative Measures of the Quality Inspection of Laboratory Animals of Beijing》
3. 《Administrative Measures of the Physical Examination for the Working staff in Industry of Laboratory Animals of Beijing》
4. 《Manual for the Welfare and Ethical Review of Laboratory Animals of Beijing》

21 December 2005

Keywords: print and issue, regulation, accompanying, regulation, circular
Send to: all of the related units
Beijing Laboratory Animals Administration Office
Printed and issued on 21 December 2005

150 copies are printed in total
Measures of the Beijing Municipalities on the Training, Evaluation, and Management of the working staff members in the Industry of Laboratory Animals

Article 1 The Measures are established for the purposes of strengthening and standardising the induction management of the working staff of laboratory animals, improving the professional qualities of the working staff of laboratory animals and ensuring the quality of laboratory animals and animal experiments and are in accordance with the provisions of the 《Regulations of the Beijing Municipality for the Administration of Affairs Concerning Laboratory Animals》.

Article 2 The working staff of laboratory animals as mentioned in the Measures refer to the scientific and technical personnel, professional management staff and skilled workers who are engaged in the production, supply and management of laboratory animals and animal experiments, as well as the persons who are responsible for the quality and technique on the production of the products related to the laboratory animals.

Article 3 The Beijing Laboratory Animals Administration Office (hereinafter referred to as BAOLA) is responsible for the professional training of the working staff of laboratory animals and the management of their assessment; the units that are engaged in the relevant work of laboratory animals shall take charge of the training and management of the working staff of laboratory animals in their respective unit.

Article 4 The Beijing Laboratory Animals Administration Office (BAOLA) is responsible for the drafting of examination syllabus for the working staff of laboratory animals and organizing examinations. The persons who pass the test shall be engaged in the work of laboratory animals.

Article 5 The Beijing Laboratory Animals Administration Office (BAOLA) sets up examination treasury according to the examination syllabus and takes examinations by randomly selecting examination questions.

Article 6 The candidates shall strictly comply with the rules of the examination sites and do not cheat.

Article 7 The management personnel who organise the examinations shall do their best to carry out their duties and strictly enforce the rules of examinations.

Article 8 The units that engage in relevant work of laboratory animals shall strengthen the post management of the working staff of laboratory animals; they shall not arrange the persons who do not pass the training assessment to engage in the relevant work of laboratory animals.

Article 9 The Measures enter into effect as of 1 January 2006.
Administrative Measures of the Beijing Municipalities on the Quality Inspections on Laboratory Animals

Article 1 The Measures are established for the purposes of ensuring the quality of laboratory animals and standardising the quality inspection of laboratory animals, and are in accordance with the 《Regulations of Beijing Municipality for the Administration of Affairs Concerning Laboratory Animals》 and the national standards of laboratory animals.

Article 2 The quality inspection of laboratory animals as mentioned in the Measures refer to the quality inspection of laboratory animals, environmental facilities, special feedstuff and other relevant products. The quality inspection of laboratory animals includes self-test, submittal for inspection, random inspection and other contents.

Article 3 The Beijing Laboratory Animals Administration Office (hereinafter referred to as BAOLA) is the organisation and co-operating agency for the quality inspection of laboratory animals in this city, it is in charge of the supervision and administration on the quality inspection of laboratory animals in this city.

Article 4 Each production unit of laboratory animals takes charge of the daily management on the quality of laboratory animals of its own unit and has regular inspection on the quality of laboratory animals in accordance with the national standards; the units that do not have detection ability must sign commission contracts with the relevant quality inspection institutions of laboratory animals, and have regular submittal for inspection. Quality inspection reports of laboratory animals are one of the conditions for the annual inspection of the licences for the breeding of laboratory animals.

Article 5 The Beijing Laboratory Animals Administration Office (BAOLA) commissions the quality inspection institutions of laboratory animals, which have quality inspection ability of laboratory animals, pass measurement attestation or are authorised by the accreditation committee of national laboratory to have sampling inspections, occasional surveys and other supervision inspections on the quality of laboratory animals.

Article 6 The institutions that accept consignments and carry out quality testing of laboratory animals shall bear the following responsibilities and obligations:

(1) Taking on the quality inspection tasks commissioned by the units that are in charge of the production and application of laboratory animals and relevant products;

(2) Taking on the on-site sampling and laboratory testing missions for the sampling inspections of the quality of laboratory animals through the commission of the Beijing Laboratory Animals Administration Office (BAOLA);

(3) Providing detection and statistical forms and relevant information in accordance with the requirements of the management departments, report to the Beijing Laboratory Animals Administration Office (BAOLA) if they find that the animals being inspected having zoonoses and fulminating infectious diseases of animals, the Beijing Laboratory Animals Administration Office (BAOLA) shall deal with in accordance with the relevant provisions of the State;

(4) Other work commissioned by the Beijing Laboratory Animals Administration Office (BAOLA).

Article 7 Quality inspection institutions of laboratory animals carry out national standards during
the inspection; industry standards shall be carried out if standards are not established by the State; local standards shall be carried out if standards are not established by the State and the industry.

Article 8 Certain amount of samples shall be collected based on relevant provisions of the national standards while the quality inspection institutions of laboratory animals are sampling randomly and the samples shall be collected, packed, transported and preserved in accordance with scientific procedures. Management procedures of each unit shall be respected while sampling in different units and cross infection shall be avoided to the maximum. All of the production units shall co-operate actively in order to provide convenience for the sampling.

Article 9 The quality inspection institutions of laboratory animals shall inspect the samples of submittal for inspection and random inspection in accordance with the inspection procedures, they shall be serious and responsible, timely and accurate, and issue the reports in the working days prescribed.

Article 10 The inspection report must be objective, fair, true and reliable, and its format must be standardised. The report shall include the names and numbers of the inspected articles, units of submittal for inspection, date, purposes of inspection, amount, inspection basis, inspection items, standard provisions, results, the technical leaders or authorised signatories and other basic elements.

Article 11 Quality inspection institutions of laboratory animals shall avoid the quality inspection of laboratory animals in their own units (united inspection and daily inspection are not included).

Article 12 The inspection results of the tasks commissioned by the Beijing Laboratory Animals Administration Office (BAOLA) shall be submitted to Experts Committee of Laboratory Animals in Beijing and be shown to the public after the auditing. However, the conditions described in Item 3 of Article 6 shall be not included.

Article 13 If the units being inspected and the quality inspection institutions of laboratory animals cannot agree with the inspection results, the third party shall have inspection again, if disagreement still exists, the Beijing Laboratory Animals Administration Office (BAOLA) shall coordinate for resolution, if the coordination fails, they can apply for arbitration inspection.

Article 14 The Measures enter into effect as of 1 January 2006.
Administrative Measures of the Beijing Municipalities on the Physical Examination of the working staff in the Industry of Laboratory Animals

Article 1 The Measures are established for the purposes of standardising the physical examinations and health management of the working staff of laboratory animals and ensuring the safety of laboratory animals and health of working staff, and are in accordance with 《Regulations of the Beijing Municipality for the Administration of Affairs Concerning Laboratory Animals》.

Article 2 The units that engage in the work of laboratory animals shall organise the working staff to have regular physical examinations every year and have category management of positions in accordance with the health conditions of the working staff.

Article 3 The working staff of laboratory animals who have the following diseases or physiological states are not suitable to engage in the work that shall contact the laboratory animals directly, such as conservation of breeds, breeding, production, supply, transportation, applications and feedstuff production, their units shall be responsible for the adjustment in a timely manner.

1. Tinea capitis, generalised tinea corporis, scabies, Chlamydia dermatitis and other infectious skin diseases or skin diseases that contaminate the environment of facilities during the healing of wounds.
2. Those who suffer from gonorrhoea, syphilis, chancroid, positive gonococcus of urethral secretions and condyloma acuminatum.
3. Those who suffer from acute exacerbation of chronic bronchitis, bronchial asthma, various types of tuberculosis, extra-pulmonary tuberculosis, tuberculous pleurisy and other infectious respiratory diseases and segmental atelectasis caused by a variety of reasons.
4. Acute pharyngitis accompanied by severe cough and acute exacerbation of chronic pharyngitis.
5. Parotitis accompanied by the excessive secretion of parotid gland and oral cavity, mixed tumour of parotid gland and oral diseases.
6. Bacillary dysentery, amoebic dysentery, acute enteritis and various types of dysentery or diarrhoea.
7. Febrile diseases, splenomegaly and enlargement of lymph nodes caused by unknown infectious diseases.
8. Those who suffer from various types of infectious hepatitis and are in the infective stages.
9. Infectious or acute conjunctivitis.
10. Epidemic hemorrhagic fever and other viral diseases that may be suffered from by people and animals.
11. Toxoplasma gondii and other parasitic diseases that may be suffered from by people and animals.
12. Severe paranasal sinusitis, severe rhinitis and anosmia.
13. Binaural hearing loss, the bilateral vision correction is lower than 0.5, severe colour vision defects or obvious damage of visual functions.
14. Those who suffer from cardiovascular diseases, high blood pressure, low blood pressure, history of epilepsy, history of psychopathy, enuresis, diabetes insipidus, history of syncope, abuse
and dependence of psychoactive substances, mental retardation and movement disorders and can’t engage in the normal work of laboratory animals.

(15) Having serious allergic diseases to the working environment of laboratory animals.

(16) In the trimester of pregnancy.

(17) Other diseases that may cause people cannot perform normal job responsibilities of laboratory animals.

Article 4 Other special requirements of the health management:

(1) People who may come in contact with the non-human primate laboratory animals need to have the inspection records of B virus and mycobacterium tuberculosis;

(2) People who may come in contact with laboratory dogs need to have the inoculability records of hydrophobia vaccine;

(3) People who may come in contact with laboratory sheep and laboratory dogs need to have the inspection records of Bacterium burgeri;

(4) People who may come in contact with laboratory cats need to have the inspection records of Toxoplasma gondii;

(5) The working staff of the units that suffer from zoonoses this year and the working staff who may have direct contact with the laboratory animals from the epidemic area of infectious diseases shall have the inspection records of the pathogeny.

Article 5 The units and individuals that engage in the work of laboratory animals in the city shall strictly comply with the provisions of the Measures and strengthen the labour protection measures and health management of the working staff.

Article 6 The Beijing Laboratory Animals Administration Office shall supervise the annual physical examination of the working staff, which is organised by the units that engage in the work of laboratory animals in the city, and list it into the content of annual inspection and supervision and inspection and its result shall be shown to the public.

Article 7 The Measures enter into effect as of 1 January 2006.
Examination Guideline for the Welfare and Ethics of Laboratory animals

Article 1 The Manual is established for the purposes of maintaining the welfare of laboratory animals in this city, regulate the ethical review of laboratory animals and the professional conduct of the working staff of laboratory animals, and is in accordance with the 《Regulations of Beijing Municipality for the Administration of Affairs Concerning Laboratory Animals》 and relevant laws, regulations of the State and refers to the international conventions.

Article 2 The Manual is applicable to the units and individuals that engage in the scientific research, production, management, transportation and application of laboratory animals in the administrative areas of the city. Where there are other stipulations in the laws or regulations of the State, the matter shall be handled in accordance with the relevant prescriptions of the State.

Article 3 The Beijing Laboratory Animals Administration Office is responsible for the coordination and management of the welfare and ethical review of laboratory animals of Beijing; it is also responsible for inviting relevant persons to form Welfare and Ethics Committee of Laboratory Animals in Beijing.

Welfare and Ethics Committee of Laboratory Animals in Beijing is responsible for the inspection of the welfare and ethical review system of laboratory animals and the implementation of the relevant units.

Article 4 The units that engage in the work related to laboratory animals shall set up a Welfare and Ethics Committee of Laboratory Animals (hereinafter referred to as the “Ethics Committee”), which can participated in by the management personnel, scientific and technical personnel, professional staff of laboratory animals and persons who are not members of the unit, the committee shall be responsible for the welfare and ethical review of laboratory animals and supervision and administration of its unit.

The units and individuals that do not have the conditions for the establishment of the Ethics Committee shall entrust the Ethics Committees of other units for review. Any other organisations may not substitute the duties of the Ethics Committee.

Article 5 Ethics Committee is composed of at least five people, one chairman, vice-chairmen and members. The chairman shall be occupied by the person, whose major is laboratory animals (major in veterinary surgeon is better). The term of office shall be 3 or 4 years. The units are responsible for the appointment, training before work, contract termination, and timely replenishment of the members. All the members shall commitment to preserve the welfare and ethics of laboratory animals.

Ethics Committee shall establish regulations, review procedures, supervision systems, regular meeting systems, reporting systems, work disciplines and professional training programmes, and report the list of members of the Ethics Committee to the Welfare and Ethics Committee of Laboratory Animals in Beijing.

Article 6 Ethics Committee shall work independently and perform the following duties: inspect and supervise whether the research, breeding, feeding, production, management and transportation of laboratory animals and the design developed by its unit and the implementation process of various kinds of animal experiments conform to the animal welfare and ethical principles.
Ethics Committee shall be based on the basic principles of the welfare and ethical review of laboratory animals, take into account the benefits of animal welfare and animal experimenters, have scientific assessment while comprehensively evaluating the injuries that animals suffer from and the necessity of using animals and provide reports of ethical review.

Article 7 The breeding of various types of laboratory animals and animal experiments shall be approved by the Ethics Committee before starting, and daily supervision and inspection shall be accepted.

Article 8 Formal application form shall be submitted to the Ethics Committee for the application of welfare ethics review. The application form shall include the following contents:
(1) Names and overviews of laboratory animals or animal experiment projects;
(2) Project leaders, names of executors, professional background resume, post certificate numbers of laboratory animal or animal experiments, licence numbers of environmental facilities;
(3) Significance and necessity of projects, purposes, breeding management or the disposal methods of experiments related to the laboratory animals in the project, anticipated harms to the animals, the ways to kill animals, detailed descriptions of animal welfare and ethical issues involved in the process of projects;
(4) Statement that complies with welfare and ethical principles of laboratory animals;
(5) Other documents that shall be supplemented according to the requirements of the Ethics Committee.

Article 9 Basic principles that the Ethics Committee is based on for the review:
(1) Animal protection principles: Necessity of the review of animal experiments, have assessment on the experiment purposes, the expected benefits and harm and death caused to animals. Meaningless indiscriminate breeding, misuse and ruthless killing of laboratory animals are forbidden. Animal experiments that have no scientific significance and social value or are unnecessary shall be prevented; optimise programmes of animal experiments, so as to protect laboratory animals, especially endangered species, reduce the amount of the animals used; introduce alternatives to animals, without prejudice to the scientificity and comparability of the experimental results and use low levels of animals instead of high levels of animals, use invertebrates instead of vertebrates, use histiocytes instead of the entire animals and use non-animal experimental methods, such as molecular biology, synthetic materials and computer simulation instead of animal experiments.
(2) Principles of animal welfare: Ensure that the laboratory animals enjoy the most fundamental rights during their survival, including the process of transportation, they shall be free from hunger, and thirst, they shall have comfortable and free life, enjoy good breeding and standardized living environment, and the management of various types of laboratory animals shall comply with the regulations for technical operations of the corresponding types of laboratory animals.
(3) Ethical principles: It shall give full consideration to the interests of animals, be kind to animals, prevent or reduce the stress, pain and injuries of animals, respect the lives of animals, stop the barbaric acts against animals and dispose animals through the methods that can produce the least pain; the projects of laboratory animals shall ensure the safety of working staff; and the methods and purposes of animal experiments shall conform to the moral and ethical standards of human beings and international customs.
(4) Principles of comprehensive scientific assessment:
1. Impartiality: Ethics Committee shall remain independent, impartial, scientific, democratic and transparent during the work of inspection, they shall not let out the secrets or be affected by the political interests, commercial interests and self interests;
2. Necessity: Good reasons shall be provided with as the premise of the breeding and application or disposal of all types of laboratory animals;
3. Balance of interests: Give consideration to the moral and ethical values recognised by the contemporary society and the benefits of both the animals and human beings; provide ethical review reports of laboratory animals or animal experiments responsibly based on comprehensively and objectively assessing the injuries suffered by the animals and the interests that the users can obtain

Article 10 Review processes of the Ethics Committee: Ethics Committee appoints members for the preliminary examination after receiving the application document of the projects related to laboratory animals. The conventional projects can be issued directly by the chairman or the vice-chairman authorised after the first assessment. Relevant experts shall be employed for the new projects or controversial projects, make comments in writing in five working days and submit to the Ethics Committee for consideration. The members that take part in the consideration cannot be less than half of the members. The applicants can apply for on-site question-and-answer and can submit that the members who may not keep the projects as secrets or may affect the impartiality of the review for avoidance. The Ethics Committee shall try to make resolutions through the consensus of method, where a decision cannot be arrived at by consensus, the principle of the minority being subordinate to the majority shall be followed, and the resolutions on the welfare and ethical review shall be made in 10 working days and be served in 3 working days after being signed and issued by the chairman or the vice-chairman authorised.

Article 11 The Ethics Committee shall have daily supervision and inspection of welfare and ethics on the projects of animal experiments approved, it shall provide specific reforming suggestions while finding problems and make resolutions on the suspension of laboratory animal projects at once if the problems are serious. At the end of the project, the principal of the project shall submit the final report of ethics of the project to the Ethics Committee and accept the final review ethics of the project.
Article 12 In the case of any of the following circumstances, applicants fail to pass the examination of the Ethics Committee:

1. Applicant’s items relating to laboratory animals are not subject to or duck out ethical reviews;
2. Inadequate evidences are adduced or application documents for reviews are incomplete or inauthentic;
3. Applicants are lack of objective justifications and necessities for implementing the projects of animal experiment or for injuring animals;
4. Personnel dealing with production, transportation, research and use of laboratory animals are not subject to specialised trainings or obviously violate requirements of principles concerning welfare and ethic of laboratory animals;
5. Production, transportation, experimental environment can’t conform to national standards associating with environments and facilities of laboratory animals at corresponding levels; feedstuffs, cages and bedding materials used for laboratory animals do not comply with the requirements of relevant standards;
6. Conservation of breeds, breeding, production, supply, transportation and management of laboratory animals are short of operation specifications which safeguards animal welfare and standardise ethical and moral conducts of working staff; standardised operation specifications are not followed; laboratory animals are maltreated so that unreasonable stresses, diseases and deaths of them are caused;
7. Design and implementation of animal experiments are unscientific; Existing data are not used to optimise design scheme and indices of animal experiments. Breeds, strains of breeds, modelling methods or animal models are not selected and used scientifically so as to improve success rates of experiments. Experiment methods used cannot fully make use of animals' tissues and organs or cannot obtain more experimental data by using less animals; the principle that laboratory animals are reduced and substituted are not embodied.
8. Humane treatments on and attentions to animals' life are not reflected during design and implementation of animal experiments; experimental procedures are not modified and improved so as to mitigate or reduce animals’ aches and pain and to avoid any unnecessary killing of animals and to decrease quantity of killing; Methods selected to kill animals can’t more effectively mitigate animals’ pain or shorten the time period during which animals are suffering pain;
9. Anaesthesia is not used when biopsies or operations are performed on animals; animal experiments that violate morality and ethic or use some extreme measures or bring about extensive disputes on ethic in society are performed on animals without considerations on their lives or deaths.
10. Methods and purposes of animal experiments do not conform to China’s traditional ethical and moral standards or international practices or these animal experiments belong to a variety of animal experiments which are expressly prohibited by China’s laws; Purposes and results of animal experiments violate expectations of contemporary society and scientific moralities and ethics;
11. A variety of animal experiments do not benefit human or any animals at all and cause extreme pain for laboratory animals;
12. Use of relevant new technologies of laboratory animals is lack of controls on morality and ethic; various experiments violate human traditional reproductive ethics, such as the experiment that zooblasts are implanted into human embryos or human cells are implanted into animal
embryos to cultivate hybrid animals; other animal experiments profane human’s dignity and might result in tremendous ethical conflicts in society;

(13) Other practices seriously violate principles of animal welfare and ethic review;

Article 13 in the event of disputes on decision on welfare and ethic review of laboratory animals, applicants may apply for re-examination after supplement of new documentation and improvement or appeal to the Welfare and Ethics Committee of Laboratory Animals in Beijing. After receiving an application for re-examination or appeal application, the Welfare and Ethics Committee of Laboratory Animals in Beijing shall give written reply within 10 workdays.

Article 14 The Welfare and Ethics Committee of Laboratory Animals shall specially designate persons for receiving and issuing documents and managing achieves. All the documents shall be kept for at least 3 years after animals experiments are completed. When the national laws or regulations provide otherwise, the relevant provisions shall be complied with.

Article 15 The Beijing Administration Office of Laboratory Animal shall circulate a notice of criticism and give an order of improvement to the Welfare and Ethics Committee of Laboratory Animals that fail to fulfil the duties.

Article 16 As regards units and individuals that seriously violate the requirements of the 《Manual for the Welfare and Ethical Review of Laboratory Animals of Beijing》, a decision that improvement shall be implemented within regulated time period shall be made by the Beijing Administration Office of Laboratory Animal according to the laws. Moreover, the decision shall be entered into the management system of credit information as warning information and a notice of criticism shall be circulated.

The Beijing Administration Office of Laboratory Animal shall give, according to the laws, an award to Welfare and Ethics Committee of Laboratory Animals that have outstanding achievements in the welfare and ethic review of laboratory animals. Furthermore, this award shall be entered into the management system of credit information as good information and a notice of commendation shall be circulated.

Article 17 This manual shall enter into force on 1 January 2006.
The notice concerning the issue of the 《Measures of Beijing Municipalities on the Administration of the Law Enforcement Documentation Relating to Laboratory Animals》

All related units:

In order to standardise the administration of law enforcement documentation relating to experimental animals in Beijing and service for scientific research, production, utilisation and management of laboratory animals, 《Measures of Beijing Municipality on Administration of Law Enforcement Documentation Relating to Experimental Animals》 is formulated based on investigations and research and according to the requirements of Science and Technology Commission of the Beijing Municipality and Beijing Municipal Archives Administration Bureau on strengthening standardised management of archives. Now, this document is hereby printed and distributed to you and it shall be carefully implemented as a reference.

With significance, the enhancement and standardisation of the management of law enforcement documentation relating to laboratory animals is a new measure to carry through and thoroughly implement scientific outlook (thinking) on development, promote level of scientific management of element tasks relating to laboratory animals in Beijing and innovate management of laboratory animals. For the purpose of thorough implementation of these measures, the management status of law enforcement documentation will, according to decisions after investigation and discussion, be listed as one item of annual supervision and inspection from this year so as to supervise and urge various departments and institutions to manage and utilise the law enforcement documentation of laboratory animals well and to standardise production and use of laboratory animals.

Annex: 《Measures of the Beijing Municipality on the Administration of the Law Enforcement Documentation Relating to Experimental Animals》

30 August 2005

Keywords: Printing and distribution, laboratory animals, law enforcement documentation, management methods, notice

Send to: all concerned units

C.C.: The Science and Technology Commission of Beijing Municipality, the Beijing Municipal Archives Administration Bureau, the Beijing Administration Office of Laboratory Animal

Printed and distributed on 30 August 2005

110 copies in total are printed
Measures of the Beijing Municipalities on the Administration of the Law Enforcement Documentation Relating to Laboratory Animals

Article 1 In order to thoroughly implement the 《Archives Law of the People's Republic of China》, 《Measures of the Beijing Municipality on Implementing the Archives Law of the People's Republic of China》 and 《Regulations of Beijing Municipality for the Administration of Affairs Concerning Laboratory Animals》, these measures are formulated to strengthen the management of law enforcement documentation relating to laboratory animals in Beijing and to service for scientific research, production, utilisation and management of laboratory animals in Beijing.

Article 2 Law enforcement documentation of laboratory animals are history records such as a variety of words, diagrams, sounds and images etc. which come into being during completely implement the 《Regulations of Beijing Municipality for the Administration of Affairs Concerning Laboratory Animals》 and are worthy of keeping. As a special kind of achieve, law enforcement documentation shall be included in the scope that a complete set of relevant documentation must be kept by the institutions dealing with scientific research, production and utilisation of laboratory animals. In addition, uniform system, requirements and standardised management shall be put into practice.

Article 3 Institutions engaged in affairs relating to laboratory animals shall emphasise management of law enforcement documentation of laboratory animals and specifically designate full-time and part-time personnel to manage these documentation so as to establish a sound documentation management system. Major tasks include collection, reorganisation, appraisal, safekeeping of documentation and handing over of documentation to Achieve Department of the institution, maintenance of completeness and safety of archives, exploration and utilisation of information resources of achieves as well as full exertion of functions of law enforcement documentation of laboratory animals.

Article 4 Documents, which come into being in the course of issuance, change of licences of laboratory animals and law enforcement inspections, belong to the law enforcement documentation that shall be placed on file. Moreover, safekeeping period of these documents is divided into long and short term. Archiving scope and safekeeping period refer to the annex.

Article 5 Collection of law enforcement documentation of laboratory animals shall be timely, complete and correct. After works concerning law enforcement inspections, issuance and changes of licences of laboratory animals, relevant personnel of institutions dealing with scientific research, production and utilisation of laboratory animals shall collect a complete set of related documentation at any moment. Moreover, these documentation shall be respectively put into archive boxes and folders to pre-establish different archive volumes, which lay a solid foundation for the systematic reorganisation of these documentation in the first quarter of the next year.

Article 6 Reorganisation and classification of law enforcement documentation shall follow rule in compliance with which these documentation come into being during science activities of laboratory animals so as to maintain organic links among these documentation and to sort this documentation in a standard manner. After classified according to year, documentation relating to issuance and changes of licences, recruitment of quality inspectors of laboratory animals, random
quality inspection on animals and feedstuffs, examinations and evaluations on working staff, annual inspection on licence and quality conformity certificates shall be classified and arranged to form different archive boxes and volumes for safekeeping and standardised reorganisation.

Article 7 Law enforcement documentation of laboratory animals shall be handed over for archiving and safekeeping. After kept by organisations dealing with affairs concerning laboratory animals for 1-2 years, law enforcement documentation shall be handed over to Archive Department of the institution with which the organisations are affiliated for archiving. Archives shall be stored in/on special file cabinets or shelves with safety precautions such as fire prevention, theft protection, insect prevention and moisture protection. After archiving period, institutions shall organise work staff engaged in laboratory animals and file clerks to identify these law enforcement documentation and to make the relevant detailed list. Out-of-date law enforcement documentation can be destroyed under supervision after approved by leaders of the institutions.

Article 8 Various institutions and file clerks dealing with affairs concerning laboratory animals shall carefully and responsibly keep and use law enforcement documentation of laboratory animals and keep national secrets and business secrets. When provided for use, procedures for borrowing shall be followed and borrowed archives shall be returned in a timely manner.

Article 9 Items such as archive box, cover and catalogue etc. of archives shall be handled as per requirements of Administrative Departments of Archives of China and Beijing.

Article 10 When supervise and inspect work activities of institutions engaged in production and utilization of laboratory animals, law-enforcement personnel and quality inspectors of laboratory animals in Beijing shall examine completeness, integrity and correctness. In case that any problem is found, institutions shall be ordered to improve according to regulations of these measures.

Article 11 The Beijing Administration Office of Laboratory Animal shall list management of law enforcement documentation of laboratory animals as one item of annual supervision and inspection and credit management. Additionally, supervision and inspection results shall be publicised.

Article 12 These Measures shall enter into force as of the date of print and distribution.

Note: individuals dealing with production and use of laboratory animals shall refer to these measures.
### Archiving Scope and Safekeeping Period of Law Enforcement Documentation of Laboratory Animals

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<td>1</td>
<td>Handling form of application for licences of laboratory animals</td>
<td>Long-term safekeeping</td>
</tr>
<tr>
<td>2</td>
<td>Document materials used for an application for licences of laboratory animals such as a letter of application, inspection report, organisation, name list of members, layout drawing, management system, operation specification and consignment agreement etc., comments on acceptance, acceptance result and improvement measure</td>
<td>Long-term safekeeping</td>
</tr>
<tr>
<td>3</td>
<td>Document materials such as originals and copies of licences and letter of application for changes in licences</td>
<td>Long-term safekeeping</td>
</tr>
<tr>
<td>4</td>
<td>Notice, reply letter, copy of engagement letter for recruiting quality inspectors and rules of conducts for quality inspectors</td>
<td>Short-term safekeeping</td>
</tr>
<tr>
<td>5</td>
<td>Registration form of supervision and inspection, notice movement, improvement plan and report etc.</td>
<td>Long-term safekeeping</td>
</tr>
<tr>
<td>6</td>
<td>Document materials used to determine the quality inspection institutions of laboratory animals</td>
<td>Short-term safekeeping</td>
</tr>
<tr>
<td>7</td>
<td>Inspection report of animals and feedstuffs, inspection report and opinions of specialists</td>
<td>Long-term safekeeping</td>
</tr>
<tr>
<td>8</td>
<td>Registration form and certificates of working staff for</td>
<td>Long-term safekeeping</td>
</tr>
<tr>
<td></td>
<td>Description</td>
<td>Storage Period</td>
</tr>
<tr>
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<td>------------------------------------------------------------------------------</td>
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<tr>
<td>9</td>
<td>Application form for annual inspections</td>
<td>Long-term safekeeping</td>
</tr>
<tr>
<td>10</td>
<td>Receipts of Quality Conformity Certificate of laboratory animals from those institutions that sell or purchase laboratory animals</td>
<td>Short-term safekeeping</td>
</tr>
<tr>
<td>11</td>
<td>Recordings concerning the operations of facilities, services and maintenance of equipment and innocent treatment of wastes</td>
<td>Long-term safekeeping</td>
</tr>
<tr>
<td>12</td>
<td>Document materials relating to administrative penalty</td>
<td>Long-term safekeeping</td>
</tr>
</tbody>
</table>