The Legal Administration Documents for Laboratory Animal in People's Republic of China and Being Municipality

Beijing Administration Office of Laboratory Animal

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The Introduction of Beijing Administration
Office of Laboratory Animal
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Beijing Administration Office of Laboratory Animal

The Office of Beijing Laboratory Animal Administration Committee, which established in 1991 by Beijing Municipal Government, is an administration institution for laboratory animal in Beijing municipality. In 1998, after promulgated of 《Regulation of Beijing Municipality for Administration of Laboratory Animals》 by the Standing Committee of Beijing People’s Congress, the office was redirected to Beijing Administration Office of Laboratory Animal (BAOLA).

BAOLA is an institution directly under the Beijing Municipal Commission of Science and Technology.

According to the 《Regulation of Beijing Municipality for Administration of Laboratory Animals》, Beijing Municipal Commission of Science and Technology is in charge of administering laboratory animal fare in Beijing municipality. The Beijing Administration Committee of Laboratory Animal is in charge of coordinating the administration of laboratory animal fare in Beijing municipality. The Consultant Committee of Beijing administration committee of laboratory animal is nominated by the Office of Beijing Municipal Government. The Consultant Committee can provide their consultation and many technological services for promoting laboratory animal science and socialization production of laboratory animal in Beijing municipality. BAOLA, as a standing body, is in charge of routine administration works of laboratory animals for Beijing municipality.
The main duties of BAOLA:

1. To carry out the 《Regulation of Beijing Municipality for Administration of Laboratory Animals》.

2. The management of license of laboratory animal production or experiment.

3. The management of laboratory animal quality control.

4. The management of training agencies of laboratory animal.

5. The management of quality monitoring agencies of laboratory animal.

6. To organize the consulting activities for design and construction of laboratory animal facilities.

7. To organize the domestic and abroad scientific communication activities cooperating with Chinese (or Beijing) Society of Laboratory Animal Science.
The Progress of Legal Administration of Laboratory Animal in China and Beijing
The Progress of Legal Administration of Laboratory Animal in China and Beijing

I. In China, laboratory animal science progresses along with the development of nature science and biological medicine industries. Since 1981, the State Commission of Science and Technology organized several surveys relating to research work, animal care, and experimentation of laboratory animal respectively. The conclusions were not optimistic as backward management, less investment, poor condition of animal facility and etc. By analysis, lack of unified standard (criterion) for laboratory animal quality control and legal regulation were the main reasons. Afterwards, the State Commission of Science and Technology held the 1st National conference of laboratory animal and some symposiums during 1982. All the participants reached an identity of views. That was necessary to constitute a regulation for laboratory animal administration as quickly as possible. After the 2nd National Conference of Laboratory animal in 1985, The State Commission of Science and Technology started to constitute the 《The Regulation for Administration of Laboratory Animal 》. On 31st October of 1988, 《 The Regulation for Administration of Laboratory Animals 》 was approved by The State Council and issued by the State Commission of Science and Technology. State Commission of Science and Technology cooperating with relating Ministries took big efforts to develop laboratory animal sincere very quickly. Afterwards, Beijing, Shanghai, Tianjin, Guangdong and other provinces and municipalities had also set up the
administration institutions and set down the detail implementing rules one after another. All of these measures have maximally promoted the development of laboratory animal science in China.

Recently, except the 《The Regulation for Administration of Laboratory Animal》, the Ministry of Health has constituted the 《Implementing Detail rules of Medical Laboratory Animal Administration》, the Ministry of Agriculture, State Administration Bureau of Pharmacy, PLA and other relating bureaus have also set down the regulations and rules. In 1994, The State Technology Supervision Administration issued National standards for laboratory animal including Grades for microbiological and parasitological monitoring of laboratory animals (rodent and rabbit), Genetic quality control of mammalian laboratory animal, Full-nutrient diets for laboratory animals and Requirements of environment housing facilities for laboratory animals. The Ministry of Science and Technology (MOST), i.e. State Commission of Science and Technology, has set up the rodent-breeding center in 1998 for improving the quality of strain maintenance and unifying genetic quality of laboratory animal for whole China. The MOST and The State Technology Supervision Administration has constituted the 《Administration rules of laboratory animal quality》 for improving quality control of laboratory animals. The systems of training and checkup of personnel engaged in laboratory animal field, monitoring net of laboratory animal quality, and accrediting rules of environment of laboratory animal breeding and experiment have been set up.

According to the incomplete statistic, there are more than 2,000 institutions that
are using 10 million pieces of animals each year. Chinese scientists have already bred several new strains of laboratory animal such as Chinese mini-pig, albino Chinese hamster, inbred Chinese hamster and etc. There are 4 periodical journals of laboratory animal in China. Chinese scientist also wrote and published many editions of textbooks and training reference books. The laboratory animal science, as a new knowledge, is vigorously growing up in China.

II. Beijing is the capital and the economic and cultural center of China. Beijing Municipal Government cooperating with the MOST, PLA and other relating ministries makes enormous efforts to promote the laboratory animal science for meeting the need of high-tech industry development and improving the health of citizens.

As early as 1991, Beijing Municipal Government has issued the 《Provisional Rules of Beijing municipality for Administration of Laboratory Animals》. After 4 years’ implementing, Beijing Municipal Commission of Science and Technology, Beijing Municipal Office of Legality and The Standing Committee of Beijing Municipal People’s Congress started to investigate and research the necessity and possibility for constituting a district regulation for administration of laboratory animal. On 17th October of 1996, The Standing Committee of Beijing Municipal People’s Congress examined and approved 《Regulation of Beijing Municipality for Administration of Laboratory Animals》. This is the first Chinese (maybe in worldwide) district law in laboratory animal field.

For strict implementing 《Regulation of Beijing Municipality for Administration of Laboratory Animal》, Beijing Municipal Commission of Science
and Technology has established a well-operating administration system (see figure 1).

Now, Beijing laboratory animal administration is executing the system of license for laboratory animal breeding and experiment institutions. There are 78 institutions have already gain the licenses in which 48 institutions have set up barrier system to keep their animals. The construction and equipment of animal facility is closed the standard of developed countries. But we still have a long way to go for improving management of facility and reaching the world standard. Beijing Municipal Government is energetically educating and training the personnel who engaged in taking care and using the laboratory animals. A training net including 7 agencies has established. Till August of this year, more than 7000 personals have taken part training, passed examination and gained the certification. The management flow chart of license is shown as figure 2.
Fig. 1 The Chart of Policy and Regulation of Laboratory Animal

The management measure of training and checkup for the personnel engaged in laboratory animal field of Beijing municipality

The management measure of Laboratory animal license of Beijing municipality

The management measure of laboratory animal quality test institution of Beijing

The notice of follow out (Regulation of Beijing Municipality for Administration of Laboratory Animals) in scientific research administration
The progress of legal administration of laboratory animal in China and Beijing

Fig 2  The Chart of Administration of Laboratory Animal License of Beijing municipality

- **Institutions support**
  - 5 agencies for laboratory animal quality test

- **Policy support**
  - 1. Accrediting rules
  - 2. Application procedure
  - 7 agencies for training personnel engaged in laboratory animal science

- **Quality test**
  - 1. Test the quality of animal and feed
  - 2. Provide the environment test data for accreditation

- **Personnel training**
  - 1. The training and checkup of administration rules for the directors of institutions
  - 2. The training and checkup of all personnel engaged in animal care and experimentation

- Submitting application form

- Beijing Administration Office of Laboratory Animal

- Form examination

- Field accreditation

- Draft the conclusion of accrediting group

- Passed

- non-passed

- Report to Beijing Municipal Commission of Science and Technology

- License

check up again
Regulations of People's Republic of China for Administration of Laboratory Animals
ORDER OF THE STATE SCIENCE AND TECHNOLOGY COMMISSION OF THE PEOPLE'S REPUBLIC OF CHINA

No. 2

A Regulation of the People's Republic of China for Administration of Laboratory Animals had been approved by the State Council on October 31, 1988 and is hereby promulgated.

Minister: Song Jian

November 14, 1988
REGULATIONS OF PEOPLE’S REPUBLIC OF CHINA FOR ADMINISTRATION OF LABORATORY ANIMALS

Chapter I
General Provisions

Article 1

These Regulations are formulated for strengthening the administration of laboratory animals and for guaranteeing the quality of laboratory animals to fit in with the needs of scientific researches, economic construction and social development.

Article 2

The term of "Laboratory Animals" used in these Regulations refers to the artificially raised and bred animals with controlled microbes and parasites and definite genetic background and clear sources that are used in scientific researches, teaching, production, examinations and other scientific experiments.

Article 3

These Regulations apply to all the organizations and individuals engaged in researches, species maintenance, raising, breeding, supply, check and supervision of the laboratory animals.

Article 4

The administration of laboratory animals shall be coordinated, energized in administration and rationally labor-interfaced to make it beneficial to improvement of the scientific researches and to use of laboratory animals.

Article 5

The State Science and Technology Commission shall be responsible for administration of laboratory animal management.

The science and technology commissions under the governments of provinces, autonomous regions and municipalities directly under the Central Government shall be responsible for the administration of laboratory animals within their jurisdiction.

Related departments under the State Council shall be responsible for the administration of laboratory animals within their respective jurisdictions.

Article 6

The State exercises the system of quality monitoring and authentication of
laboratory animals. The State Science and Technology Commission shall formulate specific measures for its implementation additionally.

Article 7

The national standards of genetics, microbiology, nutriology and raising environment etc. of laboratory animals shall be formulated by the State Technology Supervision Administration.

Chapter II
Administration of Raising and Breeding of Laboratory Animals

Article 8

The organizations engaged in raising and breeding of laboratory animals shall carry out regular quality surveys of the laboratory animals in accordance with standards of genetics, microbiology, nutriology and raising and breeding environment etc. Various manipulations and data shall be completely and accurately recorded and a sound system of statistical reporting shall be established.

Article 9

The raising and breeding houses and laboratories of the laboratory animals shall be constructed in different blocks strictly isolated.

There shall be scientific administrative system and operation procedures established for the raising and breeding houses and laboratories of the laboratory animals.

Article 10

Species and strains commonly accepted at home and abroad shall be adopted in the species maintenance, raising and breeding of laboratory animals. Valid certificate of quality shall also be available for the animals.

Article 11

The laboratory animals of different sources, species and strains and for different experimental purposes shall be raised separately.

Article 12

The laboratory animals are divided into four grades: Grade I, conventional animals; Grade II, clean animals; Grade III, specific pathogen-free animals; Grade IV, germ-free animals.

The laboratory animals of different grades shall be managed in accordance with respective standards of microbial control.
Article 13

The laboratory animals shall be well fed. The mildewed and rotted, deteriorated, worm-damaging and contaminated forages shall not used in laboratory animal feeding. The vegetables and fruits directly used as the forages shall be washed and disinfected and kept fresh.

Article 14

The drinking water for laboratory animals of grade I shall be in conformity with the hygiene standards for drinking water in cities. The drinking water for laboratory animals of grades II, III and IV shall be in conformity with the hygiene standards for drinking water in cities and be sterilized.

Article 15

The bedding materials for laboratory animals shall be managed in accordance with respective requirements of the materials for the animals of different grades. They shall be kept clean, dry, water sucking, non-poisonous, parasites-free, infection-free and contamination-free.

Chapter III
Quarantine and Control of Infectious Diseases in Laboratory Animals

Article 16

The introduced laboratory animals shall be isolated for quarantine.

The wild animals caught for supplementing species sources or developing new species shall be isolated for quarantine inspection to obtain the certificate issued by local departments for animal quarantine. Upon transported to the place for raising and breeding of laboratory animals, the wild animals shall be isolated for quarantine inspection before being put into the raising and breeding houses of laboratory animals.

Article 17

If the prophylactic vaccination is necessary for a laboratory animal, the animal shall undergo preventive inoculation in accordance with the experimental requirements or related provisions of the Regulations for Epidemic Prevention of Livestock and Poultry. However, the laboratory animals used as the raw materials for production of biological products shall not undergo the preventive inoculation.

Article 18

Should a laboratory animal die of diseases, the reasons shall be identified as
soon as possible and the animal corpse are appropriately disposed. All these shall be kept in records.

Should a laboratory animal be found to suffer from infectious diseases, it shall be immediately eliminated or isolated for treatments in accordance with the status of disease. The laboratory animals that might be infected shall undergo emergency preventive inoculation and the might-be-contaminated areas inside and outside the raising and breeding houses shall be carefully disinfected. Meanwhile, the situations shall be immediately reported to higher authorities responsible for administration of laboratory animals, agencies responsible for animal quarantine and sanitation and to anti-epidemic stations. Consequently, the emergency anti-epidemic measures can be taken to prevent the diseases from spreading.

Chapter IV
Use of Laboratory Animals

Article 19

The experiments involved with animals shall use qualified laboratory animals in accordance with their respective purposes. The approval of sci-tech projects and appraisal of sci-tech achievements shall regard the use of qualified laboratory animals as an elementary condition. The results of examinations or safety evaluation through use of unqualified laboratory animals shall be considered invalid. The products manufactured on basis of such results and evaluation shall not be approved.

Article 20

The following information shall be provided for animals for laboratory use:
1) Exact names of species, strains and sub-strains.
2) Genetic background or sources.
3) Conditions of microbial detection.
4) Certificates of quality.
5) Signature of the person-in-charge of the raising and breeding organizations.

The laboratory animals not accompanied with the above-mentioned information shall not be used.

Article 21

There shall be special personnel being responsible for transportation of laboratory animals. The transporting facilities shall be safe and reliable. The laboratory animals of different species, strains or grades shall not be mixed during transportation.
Chapter V
Administration of Import and Export of Laboratory Animals

Article 22

If the stock original species of the laboratory animals are imported from foreign countries, they shall be accompanied with information such as the names of strains and sub-strains as well as genetic and microbial situations etc. signed and issued by the person-in-charge of the raising and breeding organizations.

The laboratory animals not accompanied with the above-mentioned information shall not be imported and used.

Article 23

The organizations involved in the management of laboratory animals shall complete registration procedures at the agencies specializing in species maintenance, breeding and quality control of the laboratory animals that are assigned by the State Science and Technology Commission when importing stock original species of the laboratory animals from foreign countries.

Article 24

The export of the laboratory animals shall be reported to and approved by the State Science and Technology Commission before the nominal exportation procedures.

The procedures of export of the laboratory animals developed from the species of wild animals under special state protection shall be completed after the export licenses have been obtained in pursuance with statutory regulations.

Article 25

The quarantine of the imported and exported laboratory animals shall be performed in accordance with the provisions set forth in the Regulations for Quarantine of Imported and Exported Plants and Animals of the People’s Republic of China.

Chapter VI
Personnel Engaged in Management of Laboratory Animals

Article 26

The organizations engaged in management of the laboratory animals shall recruit professionals and professionally trained personnel for raising and breeding of the animals. All these personnel shall observe all the rules for raising, breeding and management of the laboratory animals and familiarize
with and acknowledge the working specifications.

Article 27

The departments under local governments administering the management of laboratory animals shall exercise the system of certification for all the personnel engaged in management of laboratory animals.

Article 28

The organizations engaged in management of laboratory animals shall organize physical examinations among staff on regular basis. Any staff member who is not suitable for the post he/she holds because of infectious disease(s) shall be transferred to another post immediately.

Article 29

The personnel engaged in management of laboratory animals shall take good care of the animals but not play tricks on or ill-treat them.

Chapter VII
Reward and Punishment

Article 30

The administrative departments shall commend or reward the significant achievements made by organizations or individuals engaged in management of laboratory animals for a long time.

Article 31

The administrative departments may, depending on severity of the misconduct, give any organization violating the provisions herein the administrative sanction of warning, instruct an immediate remedy or order a close-up therefor.

Article 32

Any staff member violating the provisions herein shall be, based on severity of his/her misconduct, given the administrative sanction by his/her employer in pursuance with the statutory regulations.

Chapter VIII
Supplementary Provisions

Article 33

Governments of different provinces, autonomous regions and municipalities
as well as related authorities under the State Council may, based on the actual situations, work out specific measures for implementation of these Regulations.

The management of laboratory animals in constituents of the Chinese People's Liberation Army shall be implemented in accordance with these Regulations.

Article 34

The right to interpret these Regulations resides with the State Science and Technology Commission.

Article 35

These Regulations will be enforced as of the date of promulgation.
Regulations of Beijing Municipality for Administration of Laboratory Animals
REGULATIONS OF BEIJING MUNICIPALITY FOR ADMINISTRATION OF LABORATORY ANIMALS

(Adopted at the Thirty-first Plenary Session of the Standing Committee of the Tenth Beijing Municipal People's Congress)

Chapter I
General Provisions

Article 1

These Regulations are formulated in accordance with related laws and regulations of the People’s Republic of China and in accommodation with the actual situation in Beijing Municipality, for the purpose of guaranteeing the quality of laboratory animals to fit in with the needs of scientific researches, economic construction, social development and opening to the outside world.

Article 2

The term of “Laboratory Animals” used in these Regulations refers to the artificially raised and bred animals with control of microbes and parasites carried by them and definite genetic background and clear sources that are used for scientific researches, teaching, production, examinations and other scientific experiments.

Article 3

These Regulations apply to all organizations and individuals engaged in researches, species maintenance, raising, breeding, supply and check of the laboratory animals within the administrative precincts of Beijing Municipality. In case of any discrepancy between this document and laws or regulations of China, the latter shall prevail.

Article 4

The administration of laboratory animals shall be coordinated, energized in administration and rationally labor-interfaced to make it beneficial to market cultivation and to improve the scientific researches and use of laboratory animals.

Article 5

Beijing Municipal Science and Technology Commission (abbreviated as MSTC hereinafter) shall be responsible for administration of laboratory animals in Beijing Municipality.

Beijing Municipal Laboratory Animals Administration Committee shall be responsible for coordination in the administration of laboratory animals within the administrative precincts of the Municipality.
Related departments under the Municipal Government shall be responsible for the administration of laboratory animals in accordance with related regulations of the State and Beijing Municipality.

Article 6

The system of quality monitoring and authentication of laboratory animals shall be exercised within the Municipality. National standards shall be executed in the quality monitoring of laboratory animals. If the national standards are not available, professional ones shall prevail. If both the national and professional standards are not available, local standards shall apply.

Article 7

The organizations and individuals engaged in management of laboratory animals shall take good care of the animals and prevent environmental pollution in research, species maintenance, raising, breeding, supply and use of the laboratory animals.

Article 8

The departments in charge of the management of laboratory animals shall commend and award those organizations and individuals that have made outstanding contribution in research, species maintenance, raising, breeding, supply and use of the laboratory animals.

Chapter II
Organizations and Personnel Engaged in Management of Laboratory Animals

Article 9

The organizations engaged in species maintenance, raising, breeding and supply of laboratory animals, the organizations using laboratory animals in production of drugs and other biological products and those carrying out researches of laboratory animals must obtain the license conferred by MSTC.

If the organizations using laboratory animals in production of drugs and other biological products need to complete other approvals, the procedures shall be gone through in accordance with related regulations.

Article 10

The organizations engaged in management of laboratory animals shall appoint professional and technical personnel or administrative agencies employing professional and technical personnel to take charge of the management of laboratory animals in the organizations and formulate corresponding administrative regulations.
Article 11

The organizations engaged in management of laboratory animals shall be responsible for professional training for their staff. Those not undergone professional training shall not be involved in management of laboratory animals.

Article 12

The organizations engaged in management of laboratory animals shall organize the technical workers to take part in technical competence assessment. The professional and technical positions of the personnel engaged in management of laboratory animals shall be conferred and promoted in line with the characteristics of their posts.

Chapter III
Raising and Breeding of Laboratory Animals

Article 13

The laboratory animals are divided into four grades: Grade I, conventional animals; Grade II, clean animals; Grade III, specific pathogen-free animals; Grade IV, germ-free animals.

The laboratory animals of different grades shall be managed in accordance with respective standards.

Article 14

The organizations engaged in species maintenance and breeding of laboratory animals shall employ those species and strains recognized internationally and apply standard breeding approaches.

Article 15

The organizations engaged in breeding of laboratory animals shall conduct regular quality monitoring in accordance with the standards of genetics, parasitology, microbiology, nutriology, and environment and housing facilities. Various manipulations and data shall be completely and accurately recorded.

Article 16

The organizations engaged in raising and breeding of laboratory animals shall present the certificate of quality upon supplying or selling the animals. The certificate shall bear the exact names of species and strains, grades, genetic background or sources, results of detection of microbes and parasites of the laboratory animals. Meanwhile, it shall also bear sales date and the signature and seal of the person-in-charge.

Article 17
There shall be special personnel responsible for transportation of laboratory animals. The transporting facilities shall be in conformity with requirements for grades of microbe control and be safe and reliable. The laboratory animals of different species, strains or grades shall not be mixed upon transportation.

Article 18

It is unnecessary for the organizations engaged in raising and breeding of dogs for scientific researches to pay for registration of dog breeding and annual registration. MSTC shall be responsible for completing all application procedures for dog breeding for all these organizations to the Municipal Bureau of Public Security.

Article 19

The administration on import and export of laboratory animals shall be carried out in accordance with related statutory regulations.

Chapter IV
Use

Article 20

The environment and facilities in the animal laboratory shall be in conformity with respective grading standards of laboratory animals. The laboratories with special requirements associated with radioactivity and infection etc. shall be constructed and equipped in accordance with related regulations.

The experiments using different species and grades of animals and those with mutual interference shall not be simultaneously performed in the same laboratory.

Article 21

An experiment using animals shall employ laboratory animals of the corresponding standard in accordance with its target.

The approval of sci-tech projects and appraisal of sci-tech achievements shall regard the use of qualified laboratory animals as the basic condition. The results of examinations or safety evaluation through use of unqualified laboratory animals shall be considered invalid.

The use of unqualified laboratory animals in production of drugs and other biological products shall be prohibited.

Article 22

The personnel performing animal experiments shall finish the experimental design beforehand and employ appropriate approaches but not ill-treat the
animals.

Article 23

The corpses of laboratory animals shall be burned in cinerators or undergo harmless disposal.

Chapter V
Quality Test

Article 24

The quality test agencies of laboratory animals in the Municipality shall be approved and annually supervised by MSTC and by departments for technology supervision administration.

The quality test agencies shall accommodate the following conditions:

1) An agency shall have professional and technical personnel and 50% or more of the personnel shall have medium and above professional and technical titles.
2) An agency shall possess laboratories and auxiliary rooms necessary for the test.
3) An agency shall possess instruments and facilities necessary for the test.
4) An agency shall have established scientific manipulation rules and a sound supervision system.

Article 25

The quality test agencies shall be responsible for tests of the quality of laboratory animals and MSTC-organized annual supervision on the organizations engaged in raising, breeding and use of laboratory animals.

The quality test agencies shall strictly execute the standards, approaches and rules of the quality test and provide objective, fair, authentic and reliable test reports.

Chapter VI
Epidemic Prevention

Article 26

Laboratory animals shall not undergo prophylactic vaccination. The laboratory animals that must undergo prophylactic vaccination shall be treated in accordance with experimental requirements or related provisions of the Regulations for Epidemic Prevention of Livestock and Poultry.

Article 27

When the epidemic situation occurs in laboratory animals, the organization
shall timely isolate the animals, make diagnosis and take emergency measures to prevent spread of the epidemic situation; perform strict examinations, monitoring, prevention and treatment in the personnel concerned; report to authorities at higher levels, MSTC and the local departments of health, veterinary medicine and epidemic prevention at the same time.

MSTC shall immediately notify all the organizations concerned to take corresponding measures upon receiving the report about the epidemic situation.

Chapter VII
Legal Responsibility

Article 28

MSTC shall ask an organization engaged in management of laboratory animals to correct in definite time limit and give a warning or revoke the license according to the severity of its misconduct in any of the following cases:

1) The environment and facilities related to laboratory animals do not reach the standards or do not undergo the annual inspection.
2) The personnel engaged in management of laboratory animals have not been well trained.
3) Use of unqualified laboratory animals in production of drugs and other biological products.
4) The certificate of quality is not presented upon supply or sales of laboratory animals or the contents of the certificate of quality are no in conformity with related regulations.
5) The transportation of laboratory animals is not in conformity with related regulations.

Article 29

MSTC shall ban the species maintenance, raising, breeding, supply and use of laboratory animals by an organization failing to acquire a license as specified in Article 9 herein.

Article 30

If a quality test agency violates Article 25 to forge testing data or conclusions, MSTC and departments of technology supervision administration shall cancel its qualification of quality test. Meanwhile, his/her employer or authorities at higher levels shall give the responsible person the disciplinary sanction.

Article 31

An organization or person violating the First Clause of Article 27 shall be punished in accordance with Regulations on Epidemic Prevention of Livestock
and Poultry.

Article 32

If a person engaged in management of laboratory animals neglects his/her duties, abuses his/her authority and plays favoritism and commits irregularities, he/she shall be given the disciplinary sanction by his/her employer or authorities at higher levels. If he/she violates the laws, he/she shall be given the criminal sanction.

Chapter VIII
Supplementary Provisions

Article 33

The right to interpret application of these regulations resides with MSTC.

Article 34

These Regulations will be enforced as of January 1, 1997.
Management Measures of Beijing
Municipality for the License of Laboratory
Animals (Provisional)
MANAGEMENT MEASURES OF BEIJING MUNICIPALITY FOR THE LICENSE OF LABORATORY ANIMALS (PROVISIONAL)

Article 1

These Measures are formulated for purpose of strengthening the administration over the License of Laboratory Animals (called License for short hereinafter) and guaranteeing the quality of laboratory animals and animal experiments, in accordance with Regulations of Beijing Municipality for Administration of Laboratory Animals.

Article 2

Beijing Municipal Science and Technology Commission (abbreviated as MSTC hereinafter) shall be responsible for conferring and administration of the License within the administrative precincts of Beijing Municipality. Beijing Municipal Administrative Committee of Laboratory Animals shall coordinate the License conferring and administration. Beijing Municipal Administrative Office of Laboratory Animals shall be responsible for routine administration of the License.

Article 3

All the organizations and individuals engaged in management of laboratory animals and animal experiments within the administrative precincts of Beijing Municipality shall apply for the License from MSTC.

Article 4

The organizations and individuals engaged in species maintenance, breeding and supply of laboratory animals should accommodate the following conditions when applying for the License:

1) The semen of laboratory animals shall be from the State Laboratory Animal Semen Center or state-certified agencies for species maintenance. Before the construction of the State Laboratory Animal Semen Center or state-certified agencies for species maintenance are established, the semen of laboratory animals shall have clear sources and its genetic features and control of microbes be in conformity with the national standards.

2) The environment and housing facilities for raising and breeding of laboratory animals shall be in conformity with the national standards.

3) There shall be the fundamental instruments and measures for detection of microbes and parasites in laboratory animals. Meanwhile, the detecting approaches shall be in conformity with the national standards.

4) The feed, drinking water and padding materials shall be in conformity with the national standards.

5) They shall have established a sound administrative system and standard manipulation rules.

6) The personnel engaged in management of laboratory animals shall have
undergone professional training and obtained the Post License for Management of Laboratory Animals in Beijing Municipality.

Article 5

The organizations and individuals using laboratory animals in production of drugs and other biological products and conducting animal experiments shall accommodate the following conditions when applying for the License:

1) The laboratory animals shall be from the licensed organizations and individuals.
2) The environment and facilities for raising laboratory animals shall be in conformity with the national standards.
3) The forages, drinking water and bedding materials for raising laboratory animals shall be in conformity with the national standards.
4) They shall have established a sound administrative system and standard operation procedure.
5) The personnel engaged in management of laboratory animals shall have undergone professional training and obtained the Post License for Management of Laboratory Animals in Beijing Municipality.
6) The conduction of experiments involved with chemically toxic substances, radioactivity and infections shall be approved by related administrative departments.

Article 6

The procedure of application and conferring of the License are as follows:

1) The organizations and individuals applying for the License shall simultaneously provide the application and testing reports issued by Beijing Municipal Quality Test Agencies of Laboratory Animals to MSTC. The contents of these two documents shall be in conformity with the regulations set forth in Articles 4 and 5 herein.
2) MSTC shall entrust Beijing Administration Office of Laboratory Animals to organize members of Experts Commission of Beijing Municipal Laboratory Animal Administration Committee and other experts concerned to carry out the acceptance in accordance with the Regulations on Check of the License (see Appendix) and write comments and sign their names. To those proven qualified, MSTC shall examine and verify the results and confer the License.

The organizations and individuals that do not pass the first acceptance shall improve their conditions in definite time limit. Those not passing the second acceptance shall no be conferred the License in the same year.

3) The organizations shall apply for license respectively for their raising facilities of laboratory animals at different places.

Article 7

The period of validity of the License is five calendar years and the License
shall be examined and verified and renewed upon expiration. The license-holders that wish to renew the License shall apply to MSTC within six months before the expiration date.

Article 8

The organizations and individuals that had been conferred the license shall complete procedures of annual inspection by MSTC within the period of validity. The licensed organizations and individuals to be checked shall present the following documents: 1) records of personnel training, assessment to and physical examination report of the persons involved; 2) Certificate of Quality of Laboratory Animals and records of quality test of the animals; 3) records of sources and use of laboratory animals and the report on management of the facilities.

MSTC shall carry out regular or casual inspection on the organizations and individuals that had obtained the License.

Article 9

The organizations and individuals that had obtained the License shall not lend, transfer or rent the License to any third party. Meanwhile, they shall not act as an agent to sell animals and related products produced by unlicensed organizations and individuals.

Article 10

If the organizations and individuals that had obtained the License wish to alter the registered items of the License or terminate activities defined in the License, they shall complete procedures of the alteration or return the License within one month after such alteration or termination. Loss of the License shall be reported and the License shall be conferred again.

Article 11

If the organizations and individuals are proven unqualified through the annual inspection or do not complete procedures of the annual inspection in time, they shall improve in definite time limit or complete procedures of the annual inspection within one month. If they fail to reach the requirement or do not complete procedures of the annual inspection within the time limit, MSTC shall revoke the License and proclaim the decision.

Article 12

If none License has been obtained for a research project in which the laboratory animals are involved, departments of sci-tech research administration shall not approve the project and appraise its achievements. In addition, its results of examinations and safety evaluation shall be deemed invalid.
MSTC shall ban the species maintenance, breeding, supply and use of laboratory animals by the organization and individuals that had not obtained the License.

Article 13

If the organizations and individuals that had obtained the License violate Article 9 of these Measures, MSTC shall revoke the License upon verification.

If the organizations and individuals violate the provisions herein to reprint and forge the License, MSTC shall take over this License. If the misconduct is of serious nature and causes severe effects, the organizations and individuals shall be investigated and affixed for the administrative responsibility and given criminal sanctions in accordance with the law.

Article 14

The departments and their staff responsible for verifying and conferring the License shall strictly observe the provisions in Regulations of Beijing Municipality for Administration of Laboratory Animals and this document.

Article 15

The right to interpret these Measures resides with MSTC.

Article 16

These Measures will be enforced as of the date of promulgation.

Beijing Municipal Science and Technology Commission (Stamp)

July 7, 1997
Measures of Beijing Municipality for Administration of Quality Test Agencies of Laboratory Animals (Provisional)
MEASURES OF BEIJING MUNICIPALITY FOR ADMINISTRATION OF QUALITY TEST AGENCIES OF LABORATORY ANIMALS (PROVISIONAL)

Article 1

These Measures are formulated for the purpose of strengthening the administration over quality test agencies of laboratory animals in the Municipality, in accordance with related national laws and regulations and Regulations of Beijing Municipality for Administration of Laboratory Animals.

Article 2

Beijing Municipal Science and Technology Commission (abbreviated as MSTC hereinafter) and departments of technology supervision administration shall be responsible for certification and administration of quality test agencies of laboratory animals (abbreviated as QTA hereinafter). Beijing Administration Office of Laboratory Animals shall be responsible for the routine administration.

Article 3

The term of “Quality Test of Laboratory Animals” used in these Measures refers to quality test on the laboratory animals, environment, housing facilities, special feed and other related products.

Article 4

QTA shall perform their tasks in accordance with the national standards. If the national standards are not available, professional standards shall be applied. If both the national and professional standards are not available, local standards shall prevail.

Article 5

The major tasks of QTA are as follows:
1) They shall be responsible for implementation of the quality test needed in conferring the License of the Management of Laboratory Animals in Beijing Municipality (called License for short hereinafter).
2) They shall be responsible for the quality test applied by the organizations engaged in production and use of laboratory animals and related products.
3) They shall be responsible for technical test in annual supervision on License organized by MSTC and quality test of laboratory animals.
4) They shall carry out researches on test approaches and techniques and be involved in technical communication and cooperation.
5) They shall be responsible for renewing knowledge of their staff and organize training for staff in charge of the test and the quality test.
6) They shall provide statistical reports for the test and related information and materials in accordance with requirements claimed by the administrative departments. They shall report to MSTC, competent authorities at higher levels and the municipal departments of health,
veterinary medicine and epidemic prevention.
7) They shall be responsible for other tests authorized by MSTC.

Article 6

QTA shall accommodate the following conditions:
1) They shall pool necessary professional and technical competence and
   50% or more of the personnel shall have medium and above professional
   and technical titles.
2) They shall possess laboratories and auxiliary rooms necessary for the test.
3) They shall have equipment and facilities necessary for the test.
4) They shall have established standard manipulation rules and a sound
   administrative system.

Article 7

All the organizations possessing the necessary conditions for the quality test
of laboratory animals within the administrative precincts of Beijing Municipality
and the following conditions for the quality test of laboratory animals by
presenting the following documents:
1) The application form for being a quality test agency of laboratory animals
   of Beijing Municipality.
2) The curriculum vitae of the person-in-charge of the quality test agency.
3) The list of staff members of the quality test agency.
4) The list of instruments and facilities of the quality test agency.
5) The analysis of professional competence of the quality test agency.
6) The Quality Certificate of Metrological Authentication conferred by
   competent department for technology supervision administration.

Article 8

MSTC and departments of technology supervision administration shall
organize the experts concerned to conduct authentication within one month
after receiving the applications. They shall confer the Certification of Quality Test
Agencies of Laboratory of Beijing Municipality (called Certification for short hereinafter) to an organization if it is authenticated to be qualified.

Article 9

The period of validity of the Certification is five years. Before expiration,
MSTC and departments of technology supervision administration shall check
eligibility of the certificate-holders on regular basis. Only those proven to be
qualified can be conferred the updated Certification.

MSTC and departments of technology supervision administration shall carry
out annual inspection on the quality test agencies in November each year.

The organizations proven to be unqualified through the annual inspection or
those failing to complete procedures of the annual inspection in time shall
improve within a definite time or complete procedures of the annual inspection
within one month. If an organization fails to reach the requirement or does not complete procedures of the annual inspection within the time limit, MSTC shall deprive it of its qualification of quality test and proclaim the decision.

Article 10

The quality test agencies shall be responsible for the careful, timely and accurate tests of the samples and those for random examination. The reports of the tests shall be objective, fair, authentic and reliable. The behaviors of practicing fraud, intending to delay tests, damaging samples and forging results or conclusions of the test shall be punished according to the severity of the misconduct. The organizations committing severe misconduct shall be deprived of the qualifications.

Article 11

The quality test agencies should evade the quality test of their own-bred laboratory animals except for the routin test.

Article 12

Inconsistent opinions about the testing results between the testee and quality test agencies shall be coordinated by MSTC.

Article 13

The right to interpret these Measures resides with MSTC.

Article 14

These Measures will be enforced as of the date of promulgation.

Beijing Municipal Science and Technology Commission (stamp)

July 7, 1997
Measures of Beijing Municipality for Administration of Training and Checkup of Personnel Engaged in Management of Laboratory Animals (Provisional)
MEASURES OF BEIJING MUNICIPALITY FOR ADMINISTRATION OF TRAINING AND CHECKUP OF PERSONNEL ENGAGED IN MANAGEMENT OF LABORATORY ANIMALS (PROVISIONAL)

Article 1

These Measures are formulated for strengthening the administration over the post competence and for promoting the quality of personnel engaged in management of laboratory animals, in accordance with the Regulations of Beijing Municipality for Administration of Laboratory Animals.

Article 2

Beijing Municipal Science and Technology Commission (abbreviated as MSTC hereinafter) shall be responsible for the administration over the training and checkup of personnel engaged in management of laboratory animals within the administrative precincts of the Municipality. Beijing Municipal Administrative Committee of Laboratory Animals shall be responsible for coordination of the administration over the training and checkup of personnel engaged in management of laboratory animals. Beijing Administration Office of Laboratory Animals (abbreviated as BAOLA hereinafter) shall be responsible for the routine administration.

Article 3

The term of "Personnel Engaged in Management of Laboratory Animals" in these Measures refers to the scientific and technical personnel, managerial personnel and skilled workers engaged in management of laboratory animals and animal experiments.

Article 4

The personnel engaged in management of laboratory animals shall undergo substantive training on related laws, regulations and professional skills and obtain the "Post Certificate of the Personnel Engaged in Management of Laboratory Animals in Beijing Municipality" (called "Post Certificate" for short hereinafter) conferred by MSTC before performing their duties.

Article 5

The post orientation to the personnel engaged in management of laboratory animals shall be carried out at the "Training Agencies of the Management of Laboratory Animals of Beijing Municipality" (called "Training Agencies" for short hereinafter) authorized by MSTC. The personnel shall take part in the unified examinations organized by MSTC and only those who pass the examinations will be conferred the "Post Certificate".

Article 6

The period of validity of the "Post Certificate" is five years. A person who
holds the “Post Certificate” shall undergo the training and checkup before the expiration. The renewal “Post Certificate” shall not be conferred until he/she is proven to be qualified.

Article 7

The “Training Agencies” shall accommodate the following conditions:
1) Sound teaching conditions.
2) The trainers shall command medium and above professional and technical titles and necessary teaching experience.
3) Strict enrollment administration and checkup system.

Article 8

The “Training Agencies” shall complete the following duties:

1) Training to the personnel engaged in management of laboratory animals in Beijing Municipality.
2) Rigorous training in accordance with the teaching plan and syllabus to guarantee teaching quality.
3) Organizing the students to take part in the unified examinations and being responsible for completing procedures of “Post Certificate” conferring at MAOLA.
4) Tracing sci-tech evolution at home and abroad, continuously renewing knowledge and strengthening academic exchange.

Article 9

The contents of training are as follows:
1) The basic knowledge and evolution of management of laboratory animals and related laws and regulations.
2) Selection and use of laboratory animals.
3) Quality control of laboratory animals.
4) Commonly used laboratory animals and their raising and management.
5) Factors affecting laboratory animals and animal experiments.
6) Basic knowledge and skills of animal experiments.
7) Creation and application of animal models.
8) Management of facilities for animal raising and breeding.
9) Professional ethics of the personnel engaged in management of laboratory animals.

The class hour of the training course shall not be less than 25.

Article 10

In any of the following events, MSTC shall give the training agency warning, ask it to improve in definite time limit and deprive it of its qualification of training respectively in accordance with the severity of the misconduct:

1) Chaos in enrollment administration that lead to fake identifying and trick
practicing.
2) Trainers are not competent to the teaching tasks.
3) The teaching is not carried out in accordance with the teaching plan and syllabus, the nominal courses are arbitrarily omitted and teaching quality is inferior.

Article 11

The personnel without the "Post Certificate" shall not be engaged in management of laboratory animals and animal experiments.

Article 12

The organizations engaged in management of laboratory animals shall strengthen the post administration and prevent those without the "Post Certificate" being involved in the management of laboratory animals and animal experiments.

Article 13

The right to interpret these Measures resides with MSTC.

Article 14

These Measures will be enforced as of the date of promulgation.

Beijing Municipal Science and Technology Commission (Stamp)

July 7, 1997
NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA
Requirements of Environment and Housing
Facilities for Laboratory Animals
NATIONAL STANDARD OF THE PEOPLE’S REPUBLIC OF CHINA

GB/T 14925 — 94

Requirements of Environment and Housing Facilities for Laboratory Animals

Promulgated on January 11, 1994 | Enforced since October 1, 1994

Promulgated by the State Technology Supervision Administration
1. Themes and Scope of Application

This Standard stipulates the technical requirements of environment and housing facilities for laboratory animals and requirements and experimental approaches for the buildings, classification of housing facilities, distribution of housing facilities, padding materials, drinking water and cages etc.

This standard applies to the environment and housing facilities for raising, breeding, experiments and production of laboratory animals.

2. Nominative Standards

GBJ 243  The Specification for Construction and Acceptance of Ventilation and Air Conditioning Engineering

GB 3095  The Standard for Quality of the Air and Environment

GBJ 232  The Specification for Construction and Acceptance of Electrical Installation Engineering

GB 3096  The Standard of Environmental Noise in the Urban Area

GBJ 68  The Unified Standard for Design of the Building Structures

GBJ 73  The Standard for Design of Clean Factory Buildings

GB 5749  The Hygiene Standard for Drinking Water

3. Building Facilities

3.1 Site selection

It shall be conducted in accordance with the provisions set forth in GBJ 68.

3.2 Requirements of construction

3.2.1 The construction of the raising and breeding houses for laboratory animals shall be in conformity with the provisions of GBJ 68-84 and GBJ 73-84. The surface of the inner wall shall be smooth and flat and both the convex and concave angles shall be arc-shaped so that they can be easily washed and disinfected. The wall surface shall be plastered with materials
less prone to fall-off, resistant to erosion, non-light-reflecting and resistant to strikes. The floor shall be non-slip, resistant to abrasion and leakage. The ceiling shall be resistant to water and erosion. The raising and breeding houses shall feature sound airtightness. The corridor shall be wide enough. The width of door shall not be less than 1 m. The blowing-in of the air shall be in conformity with the requirements for cleanliness of different grades of raised animals. The blowing-out of the air shall be in conformity with the requirements for the air exhaustion.

3.2.2 The electrical devices in the animal raising and breeding houses shall be in conformity with the provisions set forth in GBJ 73-84 and the emergency power source shall be configured.

4. Classification and Technical Requirements for Housing Facilities

4.1 Open System: suitable for raising and breeding of laboratory animals of grade I.

4.2 Sub-barrier System: suitable for raising and breeding of laboratory animals of grade II.

4.3 Barrier System: suitable for raising and breeding of laboratory animals of grade III (SPF).

4.4 Isolation System: suitable for raising and breeding of laboratory animals of grade IV (GF).

4.5 Technical requirements

The environmental indexes listed in the below table shall be accommodated in the raising and breeding of laboratory animals.
<table>
<thead>
<tr>
<th>Item</th>
<th>Index</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Open S.</td>
</tr>
<tr>
<td>Temperature, °C</td>
<td>18~29</td>
</tr>
<tr>
<td>Temperature Difference during one day, °C ≤</td>
<td>3</td>
</tr>
<tr>
<td>Relative Humidity, %</td>
<td>40~70</td>
</tr>
<tr>
<td>Air changing times, /h</td>
<td>10~20</td>
</tr>
<tr>
<td>Air velocity, m/s ≤</td>
<td>0.18</td>
</tr>
<tr>
<td>Pressure Difference, Pa</td>
<td>20~50</td>
</tr>
<tr>
<td>Class</td>
<td>100 000</td>
</tr>
<tr>
<td>Falling Bacteria Number, /plate/hour ≤</td>
<td>12.2</td>
</tr>
<tr>
<td>Ammonia Concentration, mg/m³ ≤</td>
<td>14</td>
</tr>
<tr>
<td>Noise, dB ≤</td>
<td>60</td>
</tr>
<tr>
<td>Working Illumination, lx</td>
<td>150~300</td>
</tr>
<tr>
<td>Brightness-darkness alternation cycle, h/h</td>
<td>12/12 or</td>
</tr>
</tbody>
</table>

5. Partitioning of Housing Facilities

5.1 Front Block: Isolation & Quarantine Room, Offices, Repair Room, Storeroom, Feed storage Room and Ordinary Corridor.


5.4 The barrier and sub-barrier systems shall be in conformity with the requirements for single-way flow and there shall be air-lock devices at the site of pressure changes.

5.5 Deployment of the Animal Experiment Block shall be in conformity with the respective microbial grades of the animals used. Meanwhile, the Block shall be separated from the systems for raising and breeding of laboratory animals.

5.6 Experiments in connection with radioactivity shall be conducted in conformity with the enforcing Regulations for Protection of Radioactive Injury.

Animal experiments with infectious effects shall be performed under the condition of negative pressure or in the equipment under strict protection. In addition, effective measures shall be taken to prevent poisonous substances from going out of the experimental block.
6. Disposal of Wastes

All the wastes shall undergo the harmless treatment and come up to the standards for discharge of “three-wastes”. The corpses of the animals shall be burned in an environment-friendly manner.

7. Measurements

7.1 Temperature

It shall be measured as per provisions set forth in GBJ 243.

7.2 Relative humidity

It shall be measured as per provisions set forth in GBJ 243.

7.3 Air changing times

7.3.1 Calculation of air changing times

\[ N = \frac{L}{V} \]

In the formula: \( N \) — Air changing times, /h;
\( L \) — Volume of the blowing-in air, m³/h;
\( V \) — Indoor net volume, m³.

7.3.2 Volume of ventilation

It shall be measured as per provisions set forth in GBJ 243.

7.4 Air velocity

It shall be measured as per provisions set forth in GBJ 243.

7.5 Cascading pressure difference

It shall be measured as per provisions set forth in GBJ 73.

7.6 Air class

It shall be measured as per provisions set forth in GBJ 73.

7.7 Falling bacteria number

When the laboratory animals are not raised in a room, the uncovered culture plates (one plate with a diameter of 9 cm per 5~10 m² floor space) were put into the room for 30 min. Then the plates were incubated at 37°C for 48 h to count the number of bacterial colonies.

7.8 Noise

It shall be measured as per provisions set forth in GB 3096.
7.9 Working illumination

It shall be measured as per provisions set forth in GBJ 232.

7.10 Ammonia concentration

It shall be measured as per provisions set forth in GB 3095.

8. Requirements for Bedding Materials, Cages and Drinking Water

8.1 Bedding materials

Materials featuring high water-sucking capacity, less dusts, absence of peculiar smell, nontoxicity and absence of fat shall be chosen. Meanwhile, the materials shall be used after disinfesting, disinfecting and sterilization.

8.2 Cages

The cages shall be made of materials that are non-toxic, resistant to erosion, resistant to high temperature and easy to wash, disinfect and sterilize.

8.3 Drinking water

Domestic drinking water shall be used in raising and breeding of the laboratory animals of grade I; while sterilized water shall be used in raising and breeding of the laboratory animals of grade II, III and IV shall take the.

Additional Remarks:

This Standard is lodged by the State Science and Technology Commission.

This Standard is construed and governed by China Biological Engineering Development Center.

This Standard is jointly drafted by Shanghai Medical University, Shanghai Laboratory Animal Center of Chinese Academy of Sciences, Shanghai Laboratory Animal Research Center, Shanghai Municipal Institute of Family Planning Studies, Shanghai Institute of Biological Products of the Ministry of Health and Shanghai Municipal Technology Supervision Administration etc.

Main drafters: Yang Youming, Zhang Fan, Xing Zhenghong, Wang Changjiang, Chen Hongshu, Chen Tianpei and Xiao Qigang.