

The "AAALAC International i-brief" (short for "Issue Brief"), is designed to help clarify specific elements of the accreditation process and is published as a service to accredited institutions. Feel free to distribute this i-brief to others at your organization.

Adverse Event Reporting: Strengthening Oversight While Focusing on Meaningful Risk

Adverse events comprise unexpected events or outcomes that impact animal health or well-being, human health or well-being, or institutional integrity. Such events may arise from natural disasters (also addressed in institutional disaster planning), animal welfare concern reports, unexpected outcomes of research procedures, research noncompliance, allegations reported in the media, or other circumstances that warrant institutional review.

Reporting of significant adverse events to the AAALAC Office has always been part of the Rules of Accreditation. However, there has been confusion and inconsistencies in how animal care and use programs define, assess, and report adverse events. To help address this confusion, AAALAC has recently issued a new Guidance Statement on Adverse Event reporting. This guidance statement clarifies when an accredited program is expected to report adverse events to AAALAC, but stresses that nothing has changed regarding an institution's responsibility to investigate and mitigate adverse events.

Accredited programs are expected to continue to maintain an adverse event assessment and reporting plan. This plan should define what constitutes an adverse event, describe how events are evaluated by the Institutional Animal Care and Use Committee or comparable Oversight Body (IACUC/OB), and outline procedures for risk assessment and mitigation to prevent recurrence. Programs are also expected to document events through mechanisms such as meeting minutes, reports, or internal tracking systems. Their plan should also include procedures for reporting adverse events to internal and external oversight bodies, as appropriate. Site visit teams will continue to evaluate how institutions manage adverse events, including internal and external reporting, as part of the triennial accreditation process.

Adverse event investigation and subsequent reporting should consider the following core principles.

Core Principle 1: Strong Local Oversight Is Still Essential

AAALAC accreditation continues to rely on effective institutional oversight of animal care and use programs. Accredited programs should demonstrate that potential adverse events are actively reviewed, discussed, and addressed by the IACUC/OB with appropriate mitigation strategies developed to minimize or prevent recurrence. Council will evaluate the effectiveness of this oversight during triennial accreditation reviews. AAALAC evaluates the process, not the number of instances.

This approach reinforces the expectation that programs maintain a thoughtful, well-documented process for identifying, investigating, and addressing adverse events while supporting continuous improvement and a strong culture of care.

Core Principle 2: Reporting Is Based on Risk

Historically, animal care programs interpreted "significant adverse events" differently, resulting in variability in reporting practices. However, adverse events that are being appropriately investigated and managed through programmatic oversight processes are expected to be addressed locally and do not require reporting to the AAALAC Office. The updated Guidance Statement clarifies that AAALAC International requires prompt reporting of events that carry potential external, regulatory, or legal implications for the animal care and use program. Each accredited program should maintain its own process for evaluating potential adverse events and determining what should be reported in accordance with the AAALAC Rules of Accreditation.



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Specifically, AAALAC International requires accredited programs to promptly report the following significant adverse events:

- Investigations by applicable external oversight bodies;
- Public records requests, particularly those involving AAALAC documents such as Program Descriptions or correspondence between AAALAC International and the accredited unit;
- Lawsuits alleging concerns regarding the animal care and use program, including the ethical conduct of studies involving animal models; or
- Events anticipated to attract external attention, such as those likely to elicit animal rights activities or media coverage.

If an animal care and use program is uncertain about whether or when an event should be reported, it is encouraged to contact the AAALAC Office for guidance. This contact can be via phone at +1-301-696-9626 or accredit@aaalac.org, contacting regional office staff, or using the online portal in the Unit Login area of the website to request a phone call. The Office has also created a series of Frequently Asked Questions, which will be updated as needed, to assist units in understanding the revised expectations.

Core Principle 3: Documentation Is Essential

AAALAC’s evaluation focuses on how animal care and use programs identify, review, and address adverse events rather than on the number of events that occur. Programs should be prepared to demonstrate that their oversight system is functioning effectively, which includes providing clear and complete documentation. Appropriate documentation may include documenting discussions of adverse events in meeting minutes, tracking trends over time, implementing and evaluating mitigation strategies, and demonstrating active engagement by the IACUC or Oversight Body in reviewing and managing events.

By maintaining clear documentation and evidence of review and corrective actions, animal care and use programs can show that adverse events are used as opportunities to strengthen their programs and improve animal welfare outcomes.

Summary

AAALAC International’s expectations for AE reporting emphasize meaningful oversight and transparency. Accredited programs should focus on maintaining a robust internal review process, ensuring adverse events are investigated and mitigated, reporting events that present external or regulatory risk, and demonstrating through documentation and oversight that their program continuously evaluates and improves animal care and use practices.



ADVERSE EVENT REPORTING:

What’s Changed—and What Hasn’t



What HAS Changed...

- You are **no longer required** to report every adverse event to the AAALAC Office.
- There is **no expectation** that the Executive Office be notified of routine adverse events or noncompliance incidents that are being appropriately investigated and managed locally.
- **The focus is now on risk-based reporting**, not volume-based reporting.



What Has NOT Changed...

Accredited units are still expected to:

- **Investigate** all adverse events and noncompliance incidents.
- Conduct **risk assessment**.
- Develop and implement **mitigation plans**.
- **Review** events through the IACUC or comparable Oversight Body.
- **Document** events and corrective actions (e.g., minutes, internal reports, tracking systems).
- **Be prepared** to discuss adverse events during site visits.

Site visit teams will continue to evaluate how your program identifies, investigates, and mitigates adverse events.



WHEN TO REPORT TO AAALAC
Consistent with the Rules of Accreditation, you MUST promptly report to AAALAC if there is...

- An **external investigation** by a regulatory or oversight body.
- **Anticipated external attention** including media coverage, animal rights activities, and events likely to create reputational risk.

- A **public records request**, especially those involving AAALAC documents.
- A **lawsuit** alleging concerns related to the animal care and use program.

If you are uncertain—contact the AAALAC Office.

REMEMBER! Documentation is essential even when not reported to AAALAC:

- Adverse events must be documented.
- Oversight bodies must review them.
- Mitigation and prevention steps must be recorded.
- Trends should be evaluated over time.

You should be able to show:

- What happened.
- How it was investigated.
- What corrective actions were taken.
- How recurrence risk was minimized.

The bottom line: Investigate locally. **Document** thoroughly. **Mitigate** proactively. **Escalate** when there is risk.



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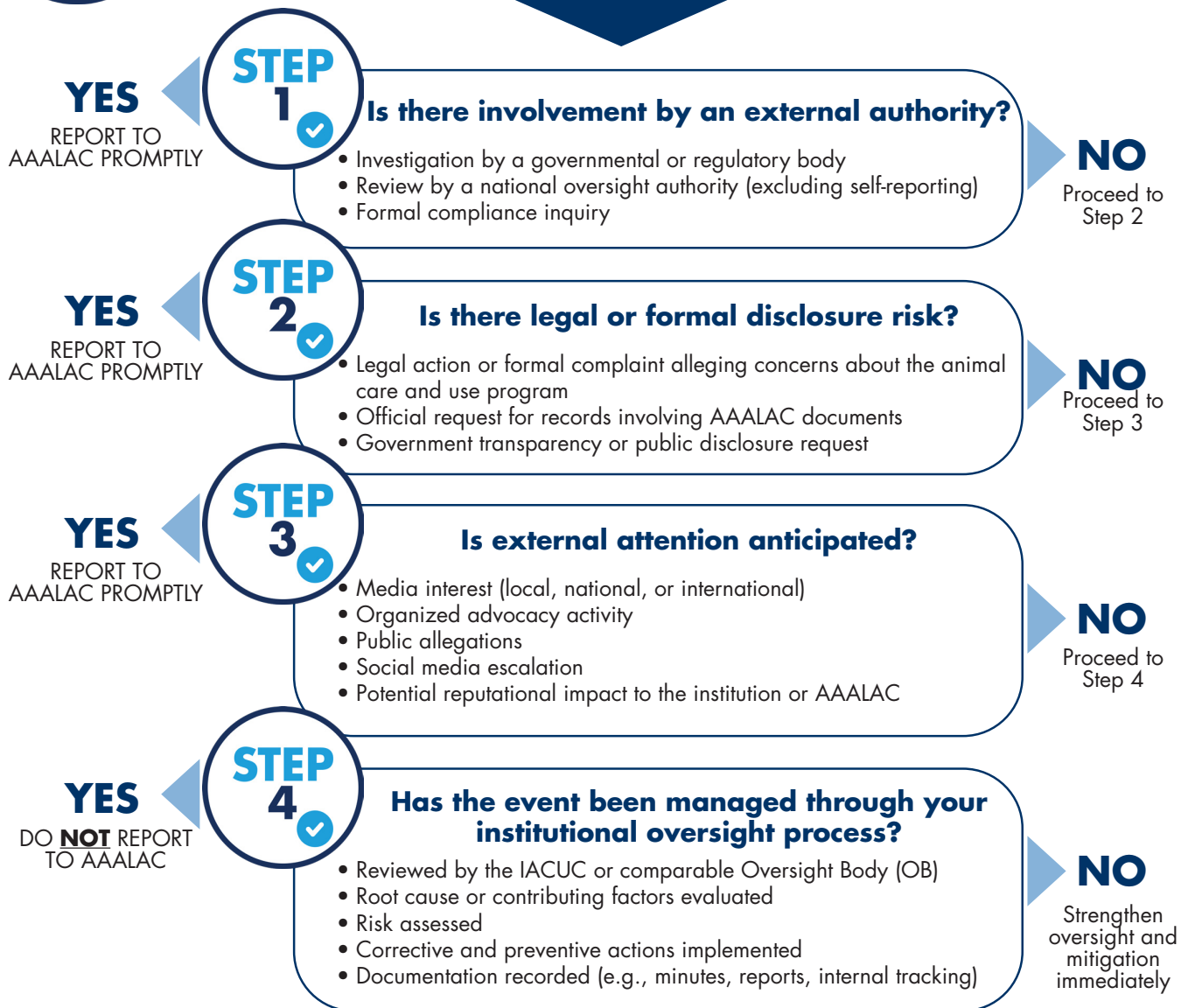
ADVERSE EVENT REPORTING DECISION TREE: Should we notify AAALAC?

START



An adverse event (AE) has occurred.

(An AE may impact animal welfare, human health, or institutional integrity.)



If the answers to steps 1-3 change at any time, revisit the flow chart and re-evaluate!

The bottom line: Investigate locally. **Document** thoroughly. **Mitigate** proactively. **Escalate** when there is risk.

