

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.

