FAQs: AWA Research Facility Registration Updates, Reviews, and Reports

Last Modified:

Registration requirements: updates, duration, and cancellation

The requirement to update a research facility’s registration every 3 years has been eliminated.

- **Purpose:** This reduces regulatory burden, since updated information is already provided on APHIS Form 7023-Annual Report or on APHIS Form 7033-Change of Operations.
- **§ 2.30(c):** A research facility shall notify the Deputy Administrator in writing of any change in the name, address, or ownership, or other change in operations affecting its status as a research facility, within 10 days after making such change. The Notification of Change form (APHIS Form 7033) may be used to provide the information.

The requirement to request inactive status has been eliminated.

- **Purpose:** Facilities will no longer be on active or inactive status. They will now either be registered or unregistered

Duration of registration and criteria for registration cancellation has been clarified.

- **Purpose:** Clarify conditions of cancellation.
    - A facility can cancel registration by written request.
        - **§ 2.30(d)(1):** A research facility that goes out of business or ceases to function as a research facility, or that changes its method of operation so that it no longer uses, handles, or transports animals, and does not plan to use, handle, or transport animals at any time in the future, may have its registration canceled by making a written request to the Deputy Administrator.
    - A registration can be cancelled by the Deputy Administrator when evidence exists of no regulated activity
        - **§ 2.30(d)(2):** If the Deputy Administrator has sufficient evidence showing that a research facility has ceased to function as a research facility, then the Deputy Administrator may cancel the registration on its own, without a written request from the research facility.
- **Purpose:** Clarify conditions for registration after cancellation.
    - A facility with a cancelled registration, can register again.
        - **§ 2.30 (d)(3):** If a research facility plans to resume regulated activity, the facility is responsible for submitting a form (APHIS Form 7011A) to reregister at least 10 days prior to it using, handling, or transporting animals. There are no fees associated with such reregistration.

Frequently Asked Questions

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How can Animal Care obtain updated information without the 3-year registration renewal requirement?

- Animal Care already collects updated information through the Annual Report submitted online or using a hard copy of APHIS Form 7023.
- The information can also be collected from APHIS Form 7033-Change of Operations.

Can a facility request cancellation of its registration?

- Yes. A facility can voluntarily request cancellation by submitting a written request to the Deputy Administrator of Animal Care using the Fort Collins Office address or by email to AnimalCare@USDA.Gov.

How may a facility's registration be cancelled without a written request from the facility?

- Upon submission of APHIS Form 7033-Change of Operations, where it is apparent the facility is no longer functioning as a research facility.
- Upon evidence presented to the Deputy Administrator of Animal Care that there is sufficient evidence that a facility has changed its method of operation so that it no longer uses, handles, or transports animals, and does not plan to use, handle, or transport animals at any time in the future; upon evidence from the Annual Reports of no regulated activity for 3 consecutive years; or that otherwise no longer meets the definition of a research facility.

Will Animal Care contact a facility of pending cancellation of registration before it occurs?

- Yes. A letter will be issued, or a Veterinary Medical Officer will contact the facility ahead of time.

Can an involuntary cancellation be appealed before it occurs?

- Yes, in writing to the Deputy Administrator of Animal Care.

What is the process to become registered after cancellation?

- **Step #1**: A facility is required to contact Animal Care least 10 days prior to conducting regulated activity.
- **Step #2**: The facility will apply for registration by completing form 7011A-New Registration before conducting regulated activity and submit online or hard copy by mail to the Fort Collins Office.
- **Step #3**: Animal Care will issue a new registration number.

How will facilities already on inactive status be handled moving forward?

- Such facilities will be notified that they will be classified as unregistered unless they apply for registration using APHIS Form 7011A within 10 days of conducting regulated activity.

Complete Annual Review

The requirement for the IACUC to conduct continuing reviews of activities not less than annually has been eliminated and replaced it with a requirement for a complete review of approved activities every 3 years.

- **Purpose:** Reduce regulatory burden by harmonizing with Public Health Service (PHS) policy so all stakeholders operate under one requirement for review of animal activities.

- **§ 2.31 (d)(5):** The IACUC shall conduct complete reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC, but not less than every 3 years. The complete review shall address all requirements related to the care and use of animals under paragraphs (d) and (e) of this section. The IACUC shall be provided a written description of all activities that involve the care and use of animals for review and approval at the end of the term.

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How can a facility transition from an annual continuous review to a 3-year complete review of animal activities?

- Animal activities that are already on a 3-year cycle of complete review (e.g., PHS funded activities,) will require no change in practice. Many facilities already conduct a 3-year cycle of complete review as standard protocol.
- Animal activities not on the 3-year complete review cycle are to begin the practice after the last required annual continuous review under the Animal Welfare Act before the new rule took effect Dec 27, 2021.

  Examples:
  - If the last annual continuous review was conducted in December 2020, then the complete review should occur by December 2023.
  - If the last annual continuous was conducted in December 2021 the complete review should occur by December 2024.

Are all animal activities required to have a duration of activity for 3 years?

- No. It is up to the IACUC to determine the approval period of an activity. The new regulation requires a complete review after 3 years.

What should a facility do to prevent a noncompliance?

- Ensure an animal activity is placed on a 3-year complete review cycle after the last required annual continuous review under the AWA performed before the new rule took effect on December 27, 2021.

Does this mean post approval monitoring, including post approval monitoring (PAM) programs, are no longer necessary?

- No. The IACUC retains the authority under 9 CFR § 2.31 (c) to review an animal activity after approval at its discretion. As a result, we recommend continuing post-approval monitoring or PAM programs.

Does this change mean semiannual inspections conducted by the IACUC are sufficient means to monitor after approval?

- No. The IACUC retains the authority under 9 CFR § 2.31 (c) to review an animal activity after approval at its discretion. It is up to the IACUC to determine the method and frequency of monitoring.

Will past citations be removed from inspection reports – especially those on the public search tool? If so, how far back in years? Would they no longer be searchable?

- Past citation under § 2.31(d)(5) will not be removed. Citations will continue to be searchable.

Annual Report Signatures

The requirement for the Chief Executive Officer (CEO) or Institutional Official (IO) to sign the annual report has been eliminated.

- **Purpose:** This guards against identity theft of signatures. It also expedites processing and therefore reduces regulatory burden by allowing a facility representative to electronically submit the report on behalf of the CEO or IO without having a separate, signed, hard copy of the annual report to be submitted.

- **§ 2.36 (a):** The reporting facility shall be that segment of the research facility, or that department, agency, or instrumentality of the United States that uses or intends to use live animals in research, tests, experiments, or for teaching. Each reporting facility shall submit an annual report to the Deputy Administrator on or before December 1 of each calendar year. The report shall cover the previous Federal fiscal year. The Annual Report of Research Facility (APHIS Form 7023), Continuation Sheet for Annual Report of Research Facility (APHIS Form 7023A), and Annual Report of Research Facility Column E Explanation (APHIS Form 7023B) are forms which may be used to submit the information required by paragraph (b) of this section.

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What criteria are used to determine an individual's authority to sign on behalf of the CEO or IO on the Annual report?

- We allow the facility to set the criteria and identify persons authorized to sign the Annual Report.

Is a facility required to inform Animal Care about the person(s) authorized to sign?

- There is no regulatory requirement for the facility to inform Animal Care of the person or persons designated to sign the Annual report. For online submissions, it is up to the facility to ensure the signatory obtains eAuthentication credentials to access our online system.

Are persons that sign the Annual Report, who are not the IO or CEO, legally bound to commit on behalf of the research facility that the regulatory requirements under 9 CFR Parts 1, 2, and 3 are met?

- No. Only the person designated as the Institutional Official as described under 9 CFR § 1.1 is legally responsible.

Will there be a citation if the Annual Report is not signed?

- No. The Annual Report simply will not be processed until there is a signature.

Will there be changes to APHIS Forms 7023 and 7023A?

- The forms may be modified at a later date to remove the statement regarding IO and CEO signature.

Miscellaneous

Frequently Asked Questions

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Will new registrants receive hard copy manuals?

- Yes. The new regulations do not impact § 2.30(b), which requires APHIS to supply a copy of the regulations and standards with each registration form. This will apply to new research facilities and those reapplying after registration cancellation. The current manual will have inserts with updated materials. Research facilities are encouraged to consult the online version because it contains all updates.

When will new "Blue Book" manual be published?

- The next publication is to be determined.

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