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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 2, 3, and 4

[Docket No. APHIS–2019–0001]

RIN 0579–AE54

AWA Research Facility Registration Updates, Reviews, and Reports

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the Animal Welfare Act (AWA) regulations governing facilities that conduct research, experimentation, teaching, and testing by removing duplicative and unnecessary reviews and requests for information. We are removing the requirement that registered research facilities update their registration information every 3 years because the information is already collected by other means. We are also removing a redundant requirement for the Institutional Animal Care and Use Committee at each facility to conduct a continuing review of research activities involving animals and instead requiring a complete resubmission and review of such activities at least every 3 years. We will also no longer require that research facilities request an inactive status if they no longer use, handle, or transport AWA covered animals. In addition, we are clarifying the duration of a registration and conditions for its cancellation and will no longer require that the Institutional Official or Chief Executive Officer sign the annual report. We are also making miscellaneous changes to improve readability. These changes will reduce duplicative requirements and administrative burden on facilities while continuing to ensure the integrity and credibility of research findings and the protection of research animals.

DATES: This rule is effective December 27, 2021.

FOR FURTHER INFORMATION CONTACT: Dr. Lance H. Bassage, VMD, Director, National Policy Staff, Animal Care, APHIS, 4700 River Road, Unit 84, Riverdale, MD 20737; *lance.h.bassage@usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

Under the Animal Welfare Act (AWA or the Act, 7 U.S.C. 2131 *et seq.*), the Secretary of Agriculture is authorized to promulgate standards and other requirements governing the humane handling, care, treatment, and transportation of certain animals by dealers, exhibitors, operators of auction sales, research facilities, and carriers and intermediate handlers.

The Secretary has delegated responsibility for administering the AWA to the Administrator of the U.S. Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS). Within APHIS, the responsibility for administering the AWA has been delegated to the Deputy Administrator for Animal Care. Definitions, regulations, and standards established under the AWA are contained in 9 CFR parts 1, 2, and 3 (referred to below as the regulations).

Part 1 contains definitions for terms used in parts 2 and 3. Part 2 provides administrative regulations and sets forth institutional responsibilities for regulated parties. Part 3 provides standards for the humane handling, care, treatment, and transportation of covered animals. Part 4 addresses rules of practice governing proceedings under the AWA.

On September 17, 2020, APHIS announced in the **Federal Register** (85 FR 57998–58002, APHIS–2019–0001) [1] proposed changes to 9 CFR part 2 in order to address reforms called for in Title II, Section 2034(d) of the 21st Century Cures Act (21CCA). The 21CCA tasked the National Institutes of Health (NIH), the USDA, and the U.S. Food and Drug Administration (FDA) to identify inconsistent, overlapping, and unnecessarily duplicative regulations and policies associated with research using laboratory animals and to consider modifying, streamlining, or repealing those that are unnecessary or impose administrative burdens or excessive costs on regulated entities.[2] These changes will reduce or remove redundant registration, reporting, and review requirements of activities involving animals at AWA-registered research facilities while ensuring that research animals continue to receive humane care.

We solicited comments concerning our proposal for 60 days ending November 16, 2020. We received 61 comments by that date.[3] They were from animal welfare organizations; public and private universities, hospitals, and biomedical and other research institutions; a veterinary association; and members of the public. They are discussed below by topic.

Registration of Research Facilities

Section 2.30(a)(1) currently requires that each research facility other than a Federal research facility register with the Secretary by completing and filing an initial registration form.[4] Facilities are also required to update their registration every 3 years by filing a registration update form [5] with the registrant's name, address, and contact information; USDA registration certificate numbers; and names of partners, officers, and the Institutional Official (IO) as applicable.

We proposed to eliminate the requirement in § 2.30(a)(1) to update the research facility registration every 3 years after the facility's initial registration. We proposed this change because § 2.30(c)(1) already requires such a facility to notify APHIS within 10 days of any change in the name, address, ownership, or any other change in operations affecting its status as a research facility. We also considered the registration update to be unnecessary

[1] *https://www.federalregister.gov/documents/2020/09/17/2020-20512/awa-research-facility-registration-updates-reviews-and-reports.*

[2] Found at *https://www.congress.gov/bill/114th-congress/house-bill/34/.* An August 2019 report issued jointly by the NIH, the USDA, and the FDA, titled ''Reducing Administrative Burden for Researchers: Animal Care and Use in Research,'' is available at *https://olaw.nih.gov/sites/default/files/21CCA_final_report.pdf.* The report identifies ways in which Agencies can reduce regulatory and administrative burden consistent with requirements under the AWA.

[3] To view the proposal, supporting documents, and the comments we received, go to *www.regulations.gov.* Enter APHIS–2019–0001 in the Search field.

[4] APHIS Form 7011A: Application for Registration, New Registration.

[5] APHIS Form 7011: Application for Registration, Registration Update.

because name, address, contact information, and registration certificate numbers are included in the annual report [6] that facilities are required to submit to APHIS in accordance with § 2.36 of the regulations. Eliminating the registration update requirement reduces administrative burden on institutions, removes needless duplicative procedures for providing information, and is consistent with the reforms mandated in the 21CCA.

A commenter disagreed with eliminating the registration update and asked that we provide data to help them assess the basis for this proposed change, particularly how it addresses USDA's claim of needless duplication. The commenter also questioned whether research facilities were complying with the requirement to report changes in operations to APHIS within 10 days and suggested that rather than being a redundant requirement, the registration update is an opportunity for research facilities to make up for changes that they had not otherwise reported to APHIS.

The registration update is duplicative and therefore unnecessary because a facility is already required under § 2.30(c)(1) to provide this information whenever there is a change in the name, address, or ownership, or other change in operations affecting its status as a research facility. Regarding the question of whether facilities are complying with reporting requirements, our records indicate consistent and substantial compliance with the requirement to report changes to facility operations within 10 days of the changes. We disagree with the commenter's implication that research facilities use the registration update to report changes to operations, as the update form does not include fields for such data and APHIS would consider any such changes to be improperly submitted.

Notification of Change of Operation

As noted above, the current requirement in § 2.30(c)(1) for research facilities to notify the APHIS Animal Care Deputy Administrator in writing [7] 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 a change would remain in the regulations. We proposed to add language to the requirement stating that a new Notification of Change form (APHIS Form 7033) [8] may be used to provide that information. In addition, we proposed to add a new provision to § 2.30 that clarifies the duration of a research facility's registration and conditions for its cancellation.

One commenter stated that eliminating the 3-year facility registration update form (APHIS Form 7011) and instead relying on the proposed APHIS Form 7033 risks losing certain information not required by the latter form, such as the checklist for the types of animals used at a facility. Other commenters stated that even though facilities are already required to notify APHIS within 10 days of any change in the name, address, or ownership, or any change in operations affecting its status as a research facility, facilities are not specifically required to let APHIS know of changes to types of animals used.

We disagree with the commenters. Neither the current registration update form nor the new change notification form is intended to capture changes to types of animals used. APHIS will continue to obtain detailed information about the types of animals used at facilities from the semiannual reviews and annual report, and through inspections of facilities during business hours.

Two commenters asked that APHIS clarify what constitutes a ''change of operations'' as the term appears in § 2.30(c)(1). One commenter added that it is unclear that any facility changes will compel the facility to complete APHIS Form 7033 or otherwise submit the required information without having more detail about what a change of operations means.

A change of operations includes any change affecting a facility's status as a research facility, including but not limited to whether the facility is conducting teaching, testing, or research activities using regulated species. Regarding the commenter's concern about research facilities completing proposed APHIS Form 7033, we note that under § 2.30(c)(1) they are already required to report changes in operations that affect their status as a research facility. The new form is intended to make it easier for facilities to provide the required information.

Duration of Registration and Conditions for Cancellation of a Registration

We noted in the proposed rule that a small number of research facilities become inactive each year. We determined that requiring inactive facilities to request inactive status and continue filing annual reports in accordance with § 2.30(c)(2) constitutes an unnecessary burden because these facilities are no longer using animals covered under the AWA or otherwise functioning as a research facility as the term is defined in § 1.1. For this reason, we proposed to remove the provisions requiring such facilities to request inactive status and file an annual report. Under the proposed change, facilities would no longer be identified as active or inactive, but instead be registered or unregistered. Accordingly, under proposed § 2.30(d)(1), a research facility that goes out of business or otherwise ceases to function as a research facility can request to have its registration canceled by writing to the Deputy Administrator.

Some commenters suggested that we revise the heading of proposed § 2.30(d) to read, ''Cancellation and Resumption of a Registration'' instead of ''Duration of a Registration and Conditions for Cancellation of a Registration'' to reflect more accurately the content of the paragraph.

We are making no changes in response to the commenters. The heading of paragraph (d) appropriately emphasizes the main point of the paragraph with respect to conditions of registration. We added the new paragraph to clarify the duration of a research facility's registration and conditions for its cancellation.

We proposed to add a provision in § 2.30(d)(2) stating that the Deputy Administrator may cancel a registration without a written request from the research facility, if he or she has reason to believe that a research facility has ceased to function as a research facility.

A commenter expressed concern about the provision that the Deputy Administrator may initiate a cancellation of a research facility's registration. The commenter noted that various reasons exist why a facility may choose to remain in active status without having animals, such as an inactive academic institution that has used non-covered species at one time and anticipates using covered species again. The commenter asked that we include language in the regulations explaining how a facility would provide this information if they chose to remain active.

We are making no changes in response to the commenter. Facilities would no longer be identified as having active or inactive status, but instead be either registered or unregistered. While facilities may have their reasons for wishing to remain in active status, one

[6] APHIS Form 7023: Annual Report of Research Facility.

[7] Send changes to USDA/APHIS/AC, 4700 River Road, Unit 84, Riverdale, MD 20737–1234, or email *animalcare@usda.gov.*

[8] While APHIS recommends use of Form 7033 for licensees and registrants, locally developed formats may also be used for submitting a notification of change if desired.

that ceases to function as a research facility, or has changed its method of operation so that it no longer uses, handles, or transports animals, does not need to be registered for regulatory purposes. Whenever it plans to resume activities as a research facility, the facility can submit a registration form in accordance with § 2.30(c)(3) at least 10 days prior to using, handling, or transporting animals again. We intend to provide for such a facility to be able to retain its previous registration number upon registering.

One commenter recommended that APHIS define the term ''evidence of business activity'' in greater detail.

We assume the commenter is referring to the phrase ''evidence of business inactivity'' we used in the preamble to the proposed rule when discussing duration of registration and conditions for cancellation. We noted in the preamble that such evidence of inactivity could include but not be limited to multiple unsuccessful attempts to contact the facility by phone or mail, or no activity apparent at the physical address listed in the registration.

A few commenters indicated that it is unclear how the USDA would formally notify the facility that their registration was under consideration to be cancelled or was actually cancelled. Another commenter suggested that APHIS should attempt to notify the facility with a letter stating that the registration will be canceled within a certain timeframe if there is no response challenging the cancellation. One commenter proposed that APHIS make at least four documented attempts to contact the facility, with the fourth being by certified mail, and allow four months for a response.

APHIS will make multiple attempts in writing and by phone during business hours to establish contact with a research facility before considering canceling its registration due to evidence of inactivity. Once we have determined that a facility is no longer functioning as a research facility as the term is defined in § 1.1, there is no regulatory need for the facility to remain registered.

Two commenters requested that the USDA provide a more tangible standard for cancelling a registration than ''has reason to believe.'' One commenter recommended that a potential standard could be when the Deputy Administrator ''has developed credible evidence that demonstrates a research facility has ceased to function as a research facility.''

In the preamble of the proposed rule, we explained that the Deputy Administrator may cancel a registration if sufficient evidence exists that a facility has ceased to function as a research facility. However, in the regulatory text of proposed § 2.30(d)(2), we used the words ''reason to believe.'' We agree with the commenter's suggestion that the language should be more tangible and will amend paragraph (d)(2) accordingly by replacing ''reason to believe'' with ''sufficient evidence showing''.

The same commenter asked that we include a provision by which a facility can contest or appeal the cancellation of a registration that it believes has been made in error.

We are making no changes in response to the commenter. APHIS will cancel a registration if the research facility requests it, or if we have sufficient evidence showing that a facility has ceased to function as a research facility. This evidence includes but is not limited to failure to submit an annual report or respond to multiple contact attempts. We note above that we will make several attempts in writing and by phone during business hours to establish contact with a facility before deciding to cancel its registration based on sufficient evidence of inactivity, so accordingly we see no need to include a provision to contest a cancellation. If a facility has questions about cancellations, they are encouraged to contact APHIS Animal Care.[9]

We included in proposed paragraph (d)(3) the provision that if a research facility registration has been canceled but the facility wishes to resume operations or otherwise conduct regulated activities in the future, it is responsible for submitting an application to reregister at least 10 days prior to it using, handling, or transporting animals. No fees would be associated with reregistration.

A commenter requested that the USDA streamline the registration process so that it may be consistently completed within 10 business days of receipt in order to ensure that reregistration does not jeopardize funding or research plans.

We acknowledge the commenter's request but are making no changes to the process. APHIS typically completes the process of registering a facility within 10 business days of receiving the application for registration and intends to continue doing so.

The commenter also asked that we outline the steps we will take to provide flexible options for electronic registration and other measures to ensure timely processing and notification of registration status.

We are currently developing an electronic registration option that will provide greater flexibility and efficiency for stakeholders. We will inform the regulated community when electronic registration is available and where to access it.

A commenter recommended that APHIS place limitations on reregistration by requiring that research facilities pay the costs of their reregistration. The commenter suggested that without such a fee, research facilities unable to comply consistently with the AWA could use the cancellation and reregistration processes to avoid being cited for noncompliance.

We are making no changes in response to the commenter's recommendation. The AWA is silent on authorizing the Secretary to charge a fee for registration. Regarding the commenter's concern, if a facility is out of compliance with the regulations or otherwise has pending citations, canceling its registration will neither cancel the citations nor eliminate the possibility of APHIS taking enforcement action, as enforcement is a process distinct from registration.

Proposed § 2.30(d)(3) includes registration requirements for formerly registered facilities wishing to resume regulated activity. A few commenters recommended revising § 2.30(d)(3) to read ''If a research facility plans to resume activity,'' presumably to replace ''If a research facility resumes operation or otherwise wishes to conduct regulated activities in the future . . . ''.

We did not intend to imply that formerly registered facilities could resume operation of regulated activities prior to registering again, so we agree with the language suggested by the commenters and will replace the proposed wording with ''plans to resume regulated activity'' in § 2.30(d)(3). We emphasize that unregistered facilities wishing to engage in regulated activities must submit APHIS Form 7011A at least 10 days prior to using, handling, or transporting animals. We intend to allow formerly registered facilities to retain their original registration number if they are registering again.

IACUC Facility Reviews

We noted in the proposed rule that § 2.31 requires the Institutional Animal Care and Use Committee (IACUC) for each registered research facility to assess the facility's animal program, facilities, and procedures and evaluate proposed research activities or

[9] USDA/APHIS/AC, 4700 River Road, Unit 84, Riverdale, MD 20737–1234, or email *animalcare@usda.gov.*

significant changes in ongoing activities related to the care, treatment, housing, and use of research animals. In accordance with this section, the IACUC reviews the research facility's programs and facilities to determine compliance with AWA and institutional requirements. The IACUC also reviews proposed animal research activities or significant changes to ongoing activities and notifies the principal investigator (PI) and the research facility of its decision to approve or withhold approval.

Section § 2.31(c)(1) requires the IACUC of each research facility to review, at least once every 6 months, the research facility's program for humane care and use of animals using the AWA regulations as a basis for evaluation. Under § 2.31(c)(2), the IACUC is also required to inspect all of the research facility's animal facilities, including animal study areas, again using the AWA regulations as a basis for evaluation. The IACUC reports the outcome of these semiannual evaluations to the Institutional Official of the research facility in accordance with requirements in § 2.31(c)(3). In addition, the IACUC's functions under § 2.31(c)(4) include reviewing and investigating reports of noncompliance received from facility personnel, as well as public complaints, involving the care and use of animals at the research facility. If noncompliance with the AWA is found during these reviews and inspections, the IACUC is authorized to require modifications or suspend an activity involving animals in accordance with the specifications set forth in § 2.31(d)(6).

In order to approve newly proposed research activities or proposed significant changes in ongoing activities, the IACUC is also required to conduct a review of components of the proposed activities or significant changes related to the care and use of animals and determine that they meet the requirements listed in § 2.31(d)(1). Once a research activity or a significant change to an ongoing activity has been approved, paragraph (d)(5) of this section requires the IACUC to conduct continuing reviews of activities covered under the regulations at 9 CFR 1.1, *et seq.,* at appropriate intervals as determined by the IACUC, but not less than annually.

We proposed to amend § 2.31(d)(5) by removing the continuing review requirement and adding the requirement for a complete review of activities at appropriate intervals as determined by the IACUC, but not less than every 3 years. As we noted in the proposed rule, we made this change in order to harmonize the USDA AWA regulations with the NIH requirement for a complete review of IACUC-approved activities at 3-year intervals.

Several commenters disagreed with our proposal to remove the continuing review requirement in § 2.31(d)(5) and add the requirement for a complete review. One commenter stated that an annual review of research activities and protocols is crucial to maintain transparency and accountability in animal research, and many expressed the view that these changes create too long of an interval between reviews to ensure animal welfare oversight. Another commenter stated that allowing IACUCs to conduct complete reviews ''at appropriate intervals'' no less than every 3 years would give IACUCs far too much leeway in reviewing activities and animal welfare oversight, and one stated that we provided no data to support a 3-year complete review, noting that it is unclear how the expanded review period comports with annual and semiannual inspections. One commenter stated that APHIS does not elucidate how it will ensure that the AWA standards of treatment will be adhered to with a relaxed review standard.

We acknowledge the concerns expressed by these commenters over whether IACUC reviews at research facilities are sufficiently frequent and thorough to ensure animal welfare. However, we emphasize that the two review types have different objectives, and that removing the continuing review and adding a complete review, as we have proposed, will actually enhance the thoroughness of review of animal activities with no effect on frequency and oversight—we explain this point below.

The purpose of the continuing review required in paragraph (d)(5) of the current regulations is not specified. In practice, however, it has consisted of the IACUC determining whether significant changes impacting animal welfare have occurred in a research activity since the time it was originally approved or last reviewed. We consider the continuing review to be redundant because, under § 2.31(c) and (d), any significant changes to an ongoing activity are already required to be reviewed by the IACUC. Further, the semiannual review of a research facility's program for humane care and use of animals covers animal use in all facility research activities to ensure that the approved activity continues to comply with regulatory and institutional requirements, and under paragraph (c)(3) any departures from the regulations found by the IACUC are required to be reported and addressed appropriately. In addition, under § 2.31(c)(4), the IACUC is required to review, and, if warranted, investigate complaints by the public or facility personnel involving the care and use of animals at the research facility at any time. Finally, removing the continuing review requirement has no effect on the IACUC approval process for new activities and significant changes to animal activities.

The complete review required by NIH at federally funded facilities involves a full evaluation of each new animal research activity—including all elements pertaining to animal welfare listed under § 2.31(d) and (e)—with resubmission and complete review of that activity every 3 years thereafter as if it were a new activity. The NIH requires the complete review of the entire activity protocol even if no significant changes have been made to it in that 3-year period, the rationale being that regulations or scientific developments germane to the activity may have changed during the period between reviews. The complete review does not affect the IACUC's authority under § 2.31(c)(3) to determine the best means of conducting the evaluations required by paragraphs (c)(1) and (2) of the facility's programs and facilities. A facility's programs include the animal activities, and the IACUC's evaluations required by paragraphs (c)(1) and (2) include monitoring after approval.

Based on the results of the complete review, the IACUC grants or withholds approval, or requires modifications to the activity. The purpose of the complete review is to ensure that all elements of animal use in a research activity, or changes to an ongoing activity, are humane and designed to minimize animal distress, and that alternatives to painful and distressing procedures have been considered and implemented to the extent possible.

We proposed harmonizing our review requirements with NIH by adding the complete review requirement because it ensures that every component in a research activity that uses animals is thoroughly evaluated. We note that under the current AWA regulations, no such equivalent review requirement exists. In other words, once approved, an animal research activity using AWA species that is not funded by the Public Health Service [10] can continue

[10] The Public Health Service is a collection of agencies with the Department of Health and Human Services that includes NIH. NIH requires that a complete IACUC review of research protocols be conducted at least once every 3 years for facilities conducting research funded by the Public Health Service.

indefinitely without ever being fully revisited to ensure its underlying design or foundational assumptions are in step with current science and regulatory policy relating to animal welfare. The continuous review was never intended to serve this purpose, as it involves only periodic checks sufficiently covered by other reviews discussed above.

For the complete review, the PI will provide the IACUC with a written description of all current activities that involve the care and use of animals for review and approval. Changes such as but not limited to personnel, species, study objectives, and frequency of sample collections may be reviewed by the IACUC as frequently as necessary, but not less than every 3 years.

A commenter expressed concern that any violation of IACUC-approved protocols, such as performing procedures on animals beyond what was initially approved or experiencing more animal mortalities than was initially approved, would not necessarily be brought to the attention of the IACUC until the 3-year review, by which time it could be too late to take appropriate action.

We note the commenter's concern but reiterate that, under § 2.31(c), the IACUC is required to review the research facility's program for humane care and use of animals at least once every 6 months, which includes animal use in all facility research activities, and under paragraph (c)(3) any departures from the regulations found by the IACUC at any time are required to be reported and addressed appropriately. The IACUC may approve, require modifications, or withhold approval of such changes, using the AWA regulations as the basis for its decision. Requirements for submitting a proposal to make significant changes to an ongoing activity are listed in § 2.31(e). Furthermore, the IACUC may review animal use in an ongoing activity at any time if there are indications that it deviates from initially approved procedures.

One commenter stated that an annual review is essential for ensuring that when new alternatives in animal use become available, the IACUC and the PI can promptly consider them. Similarly, several commenters noted that advances in scientific knowledge are emerging so quickly that refinements for improving the humane treatment of animals in research activities may go unused in the long period between reviews.

In the interim 3-year period before a complete review occurs, the semiannual review, and the IACUC review and approval process for significant changes, remain in place for raising concerns about changes in a scientific method or the existence of alternatives that reduce or replace live animal use. In addition, the Animal Welfare Information Center remains a resource for the PI to consult regarding the latest alternatives. The AWA regulations under § 2.32(c)(5) require training of PIs and other facility staff in using this resource or that of the National Library of Medicine. If the PI decides to implement an alternative in a research activity based on new knowledge, then he or she can submit an amendment to the IACUC for review and approval at any time.

Two commenters cited a 2014 audit report by the USDA Office of Inspector General (OIG) that found a substantial number of research facilities reviewed in fiscal years 2009–2011 misreported animal use and that IACUCs did not approve, monitor, or report adequately on experimental procedures on animals. Citing these issues in the OIG audit, the commenters indicated that a full IACUC continuing review on at least an annual basis is needed to ensure compliance and protect animals.

We acknowledge the conclusions of the audit report, in which USDA–OIG recommended that APHIS provide research facilities with training or best practice guidelines for IACUC protocol reviews and approvals regarding experimental procedures. As noted in the audit report, APHIS agreed with the OIG recommendation and has since developed guidance for research facilities on protocol review and approval, including updating the Animal Care Inspection Guide with additional guidance on IACUC best practices. In addition, NIH and APHIS formed the Interagency Collaborative Animal Research Education Project, which involves frequent trainings to empower IACUCs and their institutions to improve animal welfare and increase compliance with Federal standards.

We reiterate that eliminating the continuing review does not affect the frequency or depth of reviews required to ensure the humane care and use of animals, and that addition of the complete review further addresses the commenter's concerns.

A few commenters indicated that reducing the frequency of protocol review will diminish efforts to follow the ''Three R's''—reduction, refinement, replacement—thus undermining the spirit and intent of the independent policing inherent to the current AWA enforcement structure and limiting the IACUC's role.

We are making no changes in response to the comment. The IACUC's role is not limited or diminished as the result of removing the continuous review requirement, and addition of the complete review provides the committee with an additional strategy for ensuring animal welfare. We add that the IACUC has the authority to review the humane care and use of animals and all the research facility's animal facilities whenever deemed necessary to ensure compliance with the AWA.

A commenter stated that the proposed changes in review hamstring Congressional review and related agency reporting, as both reporting and funding may rely upon outdated data.

The annual continuing review is distinct from the annual report that facilities will still be required to submit to APHIS. The annual report provides data about the animals used by species and the level of pain and distress experienced during the annual reporting period. Furthermore, agency funding is not dependent on the annual report of animal use by research facilities.

One commenter stated that revising the review requirements lies outside the scope of the statutory source, explaining that APHIS does not explain whether the protection of animals would be adversely affected by reducing administrative burden in accordance with 2034(d) of the 21CCA.

We disagree with the commenter. The 21CCA tasked the NIH, in collaboration with the USDA and the FDA, to review regulations and policies for the care and use of laboratory animals and revise them appropriately to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals. The reduction in administrative burden will have no effect on animal welfare in research facilities, as there will be no change in the degree of IACUC and APHIS oversight.

A few commenters stated that harmonizing the IACUC review requirement with NIH requirements is insufficient to ensure animal welfare at research facilities, with one noting that serious animal welfare violations have been documented at NIH facilities in the past few years. Another commenter suggested that, instead of changing the USDA review, the NIH should conform to USDA's stronger annual review requirement. Another commenter stated that the proposal to align with the NIH review timeframe is based purely on convenience and is an inadequate reason to put animals in harm's way.

We reiterate that APHIS' addition of the complete review as a regulatory requirement ensures a thorough evaluation of research activity design and development with respect to

maintaining animal welfare and is independent of NIH oversight activities. Together with semiannual inspections, monitoring of animal activities at an interval deemed necessary for each facility, and investigation of complaints as warranted, the level of animal welfare oversight at facilities will not be diminished by this change.

Another commenter suggested changing the requirement to a 2-year or less review interval, explaining that it would relieve burden while matching the NIH requirement of a complete review of IACUC-approved activities.

We are making no changes in response to the commenter. In keeping with the reforms of the 21CCA, our proposed changes eliminate the redundancy of the continuous review while retaining the semiannual review. Regarding the complete review, we reiterate that the IACUC may choose to review ongoing activities more frequently than 3 years as part of a program review.

In the proposed rule, we noted that the complete review would result in approval of an activity using animals for an interval approved by the IACUC, not to exceed 3 years after the review, unless the IACUC suspends the activity for nonconformance with the description of that activity as provided by the PI and approved by the IACUC under § 2.31(d)(6).

A commenter stated that in addition to a protocol expiring after 3 years or being terminated, it is likely that research facilities have methods to terminate an approved IACUC protocol other than those cited in the regulations. The commenter noted as one example a voluntary termination by the PI or the IACUC for a reason other than that described in § 2.31(d)(6), or suspension by the IO.

We are making no changes in response to the comment. However, we acknowledge the commenter's point that a facility may choose to terminate a research activity voluntarily for reasons not included in the regulations.

A commenter suggested we consider the way protocols are renewed on an annual basis in Canada following a full review.

We are making no changes in response to the commenter. We note that under the regulations, research facilities are currently required to submit an annual report and under the proposed regulatory changes will undertake the 3-year complete review. Consistent with the aims of the 21CCA, this change harmonizes our review requirements with NIH requirements for Public Health Service-funded studies.

As a final note on our proposed addition of the complete review to § 2.31(d)(5), we are amending the language we originally proposed to read ''all activities'' instead of ''proposed activities'' pertaining to requirements for submitting written descriptions of activities to the IACUC involving the care and use of animals. This change more accurately reflects what we intended and reinforces commenter concerns that both proposed and ongoing activities involving animal care and use fall under the review requirement.

Annual Report Signature

We proposed to amend § 2.36(a) to eliminate the requirement for Chief Executive Officer (CEO) and IO signatures on a paper copy of the annual report. We noted that this guards against identity theft and allows for the facility representative to electronically submit the annual report on behalf of the CEO or IO while maintaining requirements for the facility annual report and practices. We also proposed to modify § 2.36(a) to inform registered research facilities and Federal research facilities that APHIS Forms 7023, 7023A, and 7023B may be used to submit the annual report information required in § 2.36(b).

Several commenters indicated that requiring the CEO or IO to sign the annual report makes them legally accountable and connected to the IACUC process and recommended against eliminating the requirement. One such commenter advised against eliminating the requirement for a signed paper copy of the report. Another commenter stated that, since the CEO or IO is ultimately responsible for making modifications to a facility and for ensuring that research protocols are modified as necessary for animal welfare purposes, his or her signature on the report confirms the awareness that such modifications are needed. The commenter added that if the annual report was submitted by the facility representative electronically, the CEO or IO may not be aware that modifications are needed for the facility to conform with the AWA. The commenter supported digital signature and electronic submission of the report but asked that we require CEO or IO signature.

We note that under the definition in § 1.1, the IO is the individual at a research facility who is authorized to legally commit on behalf of the research facility that the requirements of 9 CFR parts 1, 2, and 3 will be met. The IACUC is required to prepare a report of findings from the semiannual inspections to be given to the IO. The CEO and IO of the facility are legally responsible for facility and activity conformance with the AWA regardless of whether they actually sign the annual report.

Another commenter stated that changing the signature requirement is arbitrary and recommended against it, as APHIS does not consider its costs or alternatives to the revision.

We disagree that it is arbitrary because the change is consistent with the reforms called for in the 21CCA to reduce administrative burden. The costs of this change to the regulations are considered in the supporting economic analysis (see footnote 3 for a link to the analysis).

Other Comments

One commenter stated that IACUCs at taxpayer-funded State universities should open their meetings to the public.

This comment is beyond the scope of the rulemaking as we proposed no changes to IACUC meetings.

A commenter stated that we failed to show the cost savings to facilities of the proposed changes.

Information about costs can be found in the economic analysis prepared for this rulemaking.

Another commenter stated that cost savings and relief from regulatory burden would be achieved by moving away from animal experiments toward human-relevant research.

The comment is beyond the scope of this rulemaking as we did not address the topic of whether animal experimentation should be eliminated.

A commenter questioned whether the Secretary of Agriculture has the authority to delegate administration of the AWA to the APHIS Administrator. The commenter also stated that while the Administrative Procedure Act requires a ''reasoned explanation'' for finalizing proposed changes, the proposed rule does not explain how reducing duplicative requirements and administrative burden on research facilities, maintaining research integrity and oversight, and ensuring that research animals continue to receive humane care would result from the proposed provisions in the rule.

The delegation authority of the USDA Secretary is established by statute.[11] As for the relationship between reducing administrative burden while maintaining oversight and humane animal care, we respond that the reduction in burden does not impede current processes in place to ensure oversight, such as evaluating, at least

[11] 5 U.S.C. 302—Delegation of authority.

semiannually, the research facility's program for humane care and use of animals, conducting reviews as determined necessary, and investigating public complaints as warranted.

Miscellaneous

In parts 2, 3, and 4 of the current regulations, we proposed and are making minor corrections in punctuation and wording to improve readability. In paragraphs (f)(6) and (7) of § 3.111, we are removing extraneous punctuation and wording. In §§ 4.10 and 4.11, we are adding pronouns that are more inclusive.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule with the changes discussed in this document.

Executive Order 12866 and Regulatory Flexibility Act

This final rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities.The analysis is summarized below. Copies of the full analysis are available on the *Regulations.gov* website (see footnote 3 in this document for a link to *Regulations.gov*) or by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

APHIS is amending five requirements in the following three sections of the Animal Welfare Regulations. The five amendments in these three sections are summarized as follows:

Section 2.30—Registration

- Paragraph (a)(1): Eliminate the requirement for research facility registration updates at 3-year intervals;
- Paragraph (c): Eliminate the requirement for a research facility to request being placed on inactive status if the facility has not used, handled, or transported animals for a period of at least 2 years;
- Paragraph (d): Clarify the duration of a registration and conditions for cancellation of a registration;

Section 2.31—IACUC

- Paragraph (d)(5): Replace continuing annual reviews of activities involving animals approved by the IACUC with reviews and approval by the IACUC at intervals not exceeding 3 years; and

Section 2.36—Annual Report

- Paragraph (a): Eliminate the requirement for Chief Executive Officer and Institutional Official signatures on the reporting facility annual report.

APHIS solicited public comments concerning these amendments for 60 days ending November 16, 2020 and received 61 comments. Three commenters raised concerns that were specific and relevant to the Initial Regulatory Flexibility Analysis (IRFA). The commenters expressed concern that the changes could compromise humane animal care at research facilities. Processes in place under the regulations by which IACUC monitors animal activities will not be affected by the changes. These processes include semiannual inspections and the authority to investigate any complaints where warranted under 9 CFR 2.31.

APHIS has quantified annual savings for facilities that total approximately $80,000 from the changes in § 2.30(a)(1) and approximately $11,000 from the change in § 2.36(a). APHIS also expects that the changes to § 2.30(c)(2) and (3) will reduce administrative burden of certain inactive research facilities. APHIS expects that the change in § 2.31(d)(5) will be cost neutral; no quantifiable public information is available to show expected net cost savings from the change.

These changes are intended to reduce administrative burden on investigators, IACUC members, attending veterinarians, and other related facility staff, and will not affect the Animal Welfare regulations that ensure humane animal care during research, testing, experiments, or teaching. Facilities covered by this final rule include small entities.

Based on our review of available information, the APHIS Administrator has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR chapter IV.)

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. The Act provides administrative procedures which must be exhausted prior to a judicial challenge to the provisions of this rule.

Paperwork Reduction Act

This rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The information collection activities in this rule are approved under the Office of Management and Budget control number 0579–0036.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this rule, please contact Mr. Joseph Moxey, APHIS' Paperwork Reduction Act Coordinator, at (301) 851–2483.

List of Subjects

9 CFR Part 2

Animal welfare, Pets, Reporting and recordkeeping requirements, Research.

9 CFR Part 3

Animal welfare, Marine mammals, Pets, Reporting and recordkeeping requirements, Research, Transportation.

9 CFR Part 4

Administrative practice and procedure, Animal welfare.

Accordingly, we are amending 9 CFR parts 2, 3, and 4 as follows:

PART 2—REGULATIONS

■ 1. The authority citation for part 2 continues to read as follows:

Authority: 7 U.S.C. 2131–2159; 7 CFR 2.22, 2.80, and 371.7.

■ 2. Section 2.30 is amended as follows:
■ a. By revising paragraphs (a)(1) and (c);
■ b. By redesignating paragraph (d) as paragraph (e);
■ c. By adding a new paragraph (d); and
■ d. By adding a heading for newly redesignated paragraph (e).

The revisions and addition read as follows:

§ 2.30 Registration.

(a) * * *

(1) Each research facility, other than a Federal research facility, shall register with the Secretary by completing and filing a properly executed form which will be furnished, upon request, by the Deputy Administrator. The registration form shall be filed with the Deputy Administrator. Except as provided in

paragraph (a)(2) of this section, where a school or department of a university or college uses or intends to use live animals for research, tests, experiments, or teaching, the university or college rather than the school or department will be considered the research facility and will be required to register with the Secretary. An official who has the legal authority to bind the parent organization shall sign the registration form.

* * * * *

(c) *Notification of change of operation.* 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.

(d) *Duration of a registration and conditions for cancellation of a registration.* (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.

(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.

(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.

(e) *Non-interference with APHIS officials.* * * *

■ 3. In § 2.31, paragraph (d)(5) is revised to read as follows:

§ 2.31 Institutional Animal Care and Use Committee (IACUC).

* * * * *

(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.

* * * * *

■ 4. In § 2.36, paragraph (a) is revised to read as follows:

§ 2.36 Annual report.

(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.

* * * * *

PART 3—STANDARDS

■ 5. The authority citation for part 3 continues to read as follows:

Authority: 7 U.S.C. 2131–2159; 7 CFR 2.22, 2.80, and 371.7.

§ 3.111 [Amended]

■ 6. Section 3.111 is amended in paragraphs (f)(6) and (7) by removing ‘‘, which’’.

PART 4—RULES OF PRACTICE GOVERNING PROCEEDINGS UNDER THE ANIMAL WELFARE ACT

■ 7. The authority citation for part 4 continues to read as follows:

Authority: 7 U.S.C. 2149 and 2151; 7 CFR 2.22, 2.80, and 371.7.

§ 4.10 [Amended]

■ 8. In § 4.10, paragraph (a) is amended by removing the words ‘‘he’’ and ‘‘his’’ and adding the words ‘‘he or she’’ and ‘‘his or her’’ in its places, respectively.

§ 4.11 [Amended]

■ 9. In § 4.11, paragraph (a) introductory text is amended by removing the word ‘‘his’’ and adding the words ‘‘his or her’’ in its place.

Done in Washington, DC, this 18th day of November 2021.

Mark Davidson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2021–25614 Filed 11–23–21; 8:45 am]

BILLING CODE 3410–34–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

[NRC–2021–0135]

RIN 3150–AK68

List of Approved Spent Fuel Storage Casks: Holtec International HI-STAR 100 Cask System, Certificate of Compliance No. 1008, Renewal of Initial Certificate and Amendment Nos. 1, 2, and 3

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is confirming the effective date of December 15, 2021, for the direct final rule that was published in the **Federal Register** on October 1, 2021. This direct final rule amended the Holtec International HI-STAR 100 Cask System listing in the ‘‘List of approved spent fuel storage casks’’ to renew, for an additional 40 years, the initial certificate and Amendment Nos. 1, 2, and 3 of Certificate of Compliance No. 1008.

DATES: The effective date of December 15, 2021, for the direct final rule published October 1, 2021 (86 FR 54341) is confirmed.

ADDRESSES: Please refer to Docket ID NRC–2021–0135 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0135. Address questions about NRC dockets to Dawn Forder; telephone: 301–415–3407; email: *Dawn.Forder@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ‘‘Begin Web-based ADAMS Search.’’ For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The final certificates of compliance, final changes to the technical specifications, and final safety