



August 6, 2021

Via Submission to Federal eRulemaking Portal at
<https://www.regulations.gov/commenton/APHIS-2020-0101-0001>

Regulatory Analysis and Development
PPD, APHIS, Station 3A-03.8
4700 River Road, Unit 118
Riverdale, MD 20737-1238

RE: Docket No. APHIS-2020-0101; Comments in Response to Notice of Proposed Rulemaking
- Handling of Animals; Contingency Plans

To Whom It May Concern:

The Council on Governmental Relations (COGR) is an association of 190 public and private U.S. research universities and affiliated academic medical centers and research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions. One area of significant interest and expertise among COGR member institutions is the appropriate conduct of basic and applied animal research to ensure proper protections for animal health, safety, and welfare, while reducing unnecessary burden on researchers and research institutions.

COGR appreciates the opportunity afforded by the U.S. Department of Agriculture Animal and Plant Health Inspection Service (USDA APHIS) to comment on the above-captioned proposed rule published on June 25, 2021 at [86 FR 33567](https://www.federalregister.gov/documents/2021/06/25/86-fr-33567). The COVID-19 pandemic has driven home the need for contingency planning across all types and sectors of institutions and enterprises. COGR institutions support the proposed rule and fully recognize that proper preparation for natural and manmade disasters and emergencies is critical to ensuring the health, safety, and welfare of research animals. In fact, the vast majority of academic research institutions already include contingency planning in their animal care and use programs, and such emergency preparedness is required both by [The Guide for the Care and Use of Laboratory Animals](#) ("Guide") and AAALAC International accreditation standards (which, in large part, are based on the Guide). For these reasons, COGR institutions support the purpose and intent of the proposed rule, and our comments below are directed to provisions of the proposed rule regarding training and harmonization, as well as a request to reconsider the estimates of the time to comply with the rule.

COGR also supports the template form that accompanies the proposed rule. Although the form will not fit the circumstances of all institutions, it does provide a starting place for plan development. The key to successful implementation of any contingency plan, however, is to ensure the plan is flexible enough to permit adaptation to the unique circumstances of each emergency. Although it is difficult to include this concept of flexibility in a template form, COGR

urges the USDA to consider plan adaptability when reviewing submitted plans and associated training. Additionally, we hope that USDA also will recognize that while contingency plans are developed to provide advance guidance on how to respond to an emergency, the actual response may vary from the plan depending on the unique circumstances of the event. Such variations from a written contingency plan should not be viewed as “violations” or failures to follow the plan, but as on-the-ground efforts to tailor the plan to specific events. Further, these types of variations often form the basis for future modifications based on “lessons learned.”

Training:

Section 2.38(l)(1)(iv)(3) of the Proposed Rule states as follows:

The facility must provide training for its personnel regarding their roles and responsibilities as outlined in the plan. For current registrants, training of facility personnel must be completed within 60 days of the research facility putting their plan in place; for research facilities registered after [DATE 180 DAY AFTER EFFECTIVE DATE OF FINAL RULE] training of facility personnel must be completed within 60 days of the facility putting its contingency plan in place. To fulfill this training requirement, employees hired 30 days or more before the contingency plan is put in place must be trained by the date the facility puts its contingency plan in place. For employees hired less than 30 days before the date or after that date, training must be conducted within 30 days of their start date. Any changes to the plan as a result of the annual review must be communicated to employees through training which must be conducted within 30 days of making the changes.

(a) Content of Training and Coverage of Personnel -- For medium and large research facilities, especially those with multiple facility sites, the number of personnel who may play a role in the plan can be quite large, with great diversity in the types of employees encompassed by the plan. Accordingly, the content of the training, as well as the types of trainees, can vary tremendously depending on trainees’ physical location and responsibilities, as well as the nature of the emergency. For example, in a natural disaster scenario, roles and responsibilities may include not only animal care technicians and veterinarians, but physical plant personnel who have responsibility for emergency water and power supplies and public security personnel with responsibility for evacuating and securing buildings. Although the proposed rule states that training for personnel must be provided “regarding their roles and responsibilities,” the verbiage should make clear that it is up to the institution to determine who is covered by the plan, the content of the training that various types of personnel will be provided, and the mechanism(s) by which the training will be delivered. We suggest inserting the following text as a new second sentence in §2.38(l)(1)(iv)(3): “The facility shall be solely responsible for determining which personnel are encompassed by the plan and the content of, and delivery mechanism(s) for, the training that they will receive at both initial training regarding the plan and at any training required when changes are made to the plan.”

(b) Timing of Training -- As noted, the number and types of personnel who require training may be extensive, diverse, and situated at multiple locations. Additionally, the type of training required may range from content that easily could be presented via online methods/communications, to training that requires in-person demonstrations. For these reasons, COGR believes that the 30 and 60-day training timelines specified in the proposed rule are unrealistic. We suggest that a 90-

day period be allowed both for initial and subsequent training of personnel. Additionally, we note that there may be a non-substantive change to a contingency plan (e.g., a change in a responsible party's title) that does not require training. As written, however, the proposed rule requires training subsequent to “*any* changes to the plan as a result of the annual review,” and we suggest that this wording be modified to read “any *substantive* changes to the plan . . .” (emphasis added).

Harmonization:

As noted, the vast majority of, if not all, academic research facilities currently have emergency preparedness plans in place per the aforementioned provisions of the Guide. COGR urges USDA to explicitly recognize in the proposed rule that preparedness plans developed for compliance with the Guide are acceptable as contingency plans required by the proposed rule.

Estimates of Time Required for Compliance:

The preamble to the proposed rule states that USDA APHIS estimates that it will take “1-2 hours per entity to complete the plan, which includes the time to collect and document the required information.” It further estimates that it “will take up to 1 hour to train employees on the operations of the plan.” Both estimates are unreasonably low when considered in the context of an academic research center, many of which have multiple animal care and use facilities (frequently at diverse geographic locations) and, as previously noted, when the proposed rule does not recognize the acceptability of plans developed for compliance with the Guide.

First, institutions must involve personnel from multiple units (e.g., veterinary care, physical plant, environmental health and safety, building maintenance, animal care and use, public safety, legal counsel) to develop and draft a comprehensive contingency plan. Further, outside entities such as city/county public safety units, animal transportation providers and/or other animal care facilities frequently must be consulted in planning, such as for cases when animals may need to be transferred to other facilities if an institution's animal facilities become uninhabitable.

Second, the development of a contingency plan is a multi-phased process. The [Federal Emergency Management Act \(FEMA\) Comprehensive Preparedness Guide \(CPG\) 101 Version 2.0 \(Nov. 2010\)](#) outlines the six basic steps in developing a preparedness plan: (1) forming a collaborative planning team; (2) understanding the situation; (3) determining goals and objectives; (4) plan development; (5) plan preparation, review and approval; and (6) plan implementation and maintenance. At a medium to large-size research institution, identifying and assembling the necessary parties for an initial meeting to kick off the first step of the process will take one to two hours, let alone performing all six steps! Based on institutions' experience in developing existing contingency plans, it takes approximately 100-150 person hours over an average of two to three months to develop a new contingency plan. The process entails following the FEMA recommended procedure of identifying stakeholders, determining the risk scenarios for which plans must be developed, developing plans to address each scenario, ensuring that plans are integrated across institutional units, and developing training. The review of an existing contingency plan to ensure that it is up to date in terms of risks addressed and incorporated modifications based on changed circumstances and/or lessons learned takes an average of 20-30 person hours per year.

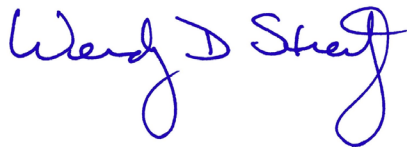
Third, although it may be possible to train personnel with very limited responsibilities under the plan in an hour, training for persons with multiple responsibilities, of necessity, will take longer. For example, veterinary and animal care personnel can be expected to have multiple plan responsibilities, which may change depending on the type of disaster involved. The training required to familiarize such personnel with their responsibilities increases incrementally with the number of tasks they are required to perform, making a blanket one hour estimate of training time inaccurate.

Conclusion:

COGR institutions understand the need for rigorous contingency planning and support the proposed rule's goal of ensuring that all types of animal care facilities have an appropriate preparedness plan in place. We believe that our foregoing suggestions will improve the content and clarity of the rule, as well as providing more realistic estimates of the time that it will take for institutions to meet the proposed rule's requirements.

We very much appreciate the opportunity to submit these comments and stand ready to answer any questions that you may have regarding this submission. In this regard, please feel free to contact Kris West, Director, Research Ethics and Compliance by email at kwest@cogr.edu.

Sincerely,

A handwritten signature in blue ink that reads "Wendy D. Streit". The signature is fluid and cursive, with the first and last names being more prominent than the middle initial.

Wendy D. Streit
President