



Date: December 09, 2024

Division of Global Migration Health (DGMH) Policy Statement: Enforcement options for CDC-registered animal care facilities (ACFs)

Subject: Enforcement options for CDC-registered animal care facilities (ACFs)

Under 42 CFR 71.51, CDC-registered animal care facilities (ACFs) are defined as facilities registered by CDC for the purpose of providing veterinary care and temporary housing to animals imported into the United States. ACFs serve an important role in protecting public health and CDC seeks to work collaboratively with ACFs whenever possible. The intention of this document is to provide information regarding how CDC conducts oversight to ensure that ACFs comply with requirements for the care, handling, processing, housing, and treatment of animals imported into the United States, consistent with the regulations and relevant agency policies. The examples provided in this document are illustrative in nature and may not necessarily reflect the full range of scenarios where CDC may seek to take an enforcement action against an ACF.

Authority:

CDC's animal import regulations at 42 CFR 71 are enacted under the authority of sections 361-369 of the Public Health Service Act, 42 U.S.C. §§ 264-272. Pursuant to these authorities, CDC seeks to prevent the introduction, transmission, and spread into the United States of zoonotic diseases of public health concern, including dog-maintained rabies virus variants (sometimes referred to as dog rabies), and other zoonotic diseases adversely affecting human health.

ACFs are facilities registered by CDC for the purpose of providing veterinary care and temporary housing to animals imported into the United States. To maintain their registration, ACFs must comply with a variety of requirements including those at 42 CFR 71.51(k-q). These include requirements relating to licensing; maintenance of facilities; document review and recordkeeping; granting of reservations to the public; veterinary services; animal quarantine; transportation; and health reporting. CDC may also seek to further explain these regulatory requirements through a variety of formats including through memoranda, policy statements, technical instructions, and training materials.

Unless revoked, a registration certificate issued to an ACF is valid for two years. 42 CFR 71.51(l). An ACF must apply to CDC for renewal of the registration certificate not less than 60 days and not more than 90 days before the existing registration expires. 42 CFR 71.51(l). CDC may revoke an ACF's registration at any time if the CDC Director (or the Director's designee) determines that it has failed to comply with any applicable provisions of 42 CFR 71.51, the facility's standard operating procedures, U.S. Department of Agriculture's (USDA) Animal Welfare standards (9 CFR parts 1, 2, and 3), or other standards as outlined in CDC's Technical Instructions for CDC-registered Animal Care Facilities. 42 CFR 71.51(r).

Policy Statement:

It is the policy of CDC to enforce compliance whenever it becomes aware that an ACF has failed to comply with applicable regulations under 42 CFR 71.51 including those for the care, handling, processing, housing, and treatment of animals imported into the United States. When feasible, CDC will work collaboratively with an ACF so that the ACF may come into compliance with CDC's animal import requirements. The enforcement options listed below are ordered in severity from least to most severe. However, CDC is not obligated to complete these steps sequentially and reserves the right to determine the appropriateness of any enforcement option based on individual circumstances.

1. *Reminder letter.* Reminder letters are meant to remind an ACF of applicable regulatory requirements, as well as relevant policies, procedures, technical instructions, or standards for operations. Upon receipt of a reminder letter, the ACF should familiarize itself with its contents and adjust its practices if needed to ensure compliance. A reminder letter may be appropriate if the violation is procedural or technical in nature and unlikely to create a public health risk or represents a low public health risk, *or* if the violation is of a "first time" nature or based on excusable error. A reminder letter can also form the basis for other actions as explained in this document.
2. *Warning letter.* A warning letter is similar to a reminder letter but is considered more serious. A warning letter may be appropriate if the violation is procedural or technical in nature and unlikely to create a public health risk or represents a low public health risk,¹ *or* if an ACF has repeated the same violation in the past or should know or be aware of CDC's requirements, e.g., based on previous reminders, memoranda to ACF, or based on training. Upon receipt of a warning letter, the ACF should adjust its practices to ensure that further non-compliance does not occur. The warning letter can also form the basis for other actions as explained in this document.
3. *Non-compliance letter.* A non-compliance letter is appropriate if the violation creates a public health risk or may create a public health risk if left uncorrected, *or* if the ACF has repeated the same violation after receiving a reminder and/or warning letter, *or* if the violation appears deliberate, intentional, willful, or is otherwise of a serious nature. This includes violations of applicable regulatory requirements, as well as relevant policies, procedures, technical instructions, or standards for operations. Upon receipt of a non-compliance letter, the ACF must adjust its policies, procedures, or practices to remedy the non-compliance and ensure that future violations do not occur. The non-compliance letter will typically require the ACF to respond in writing within a certain timeframe (e.g., 5 business days) to acknowledge that they understand that a violation has occurred and describe the remedial steps the ACF will take to prevent future violations. The non-compliance letter may also request additional information to further investigate the

¹ CDC, in its discretion, may choose to issue a warning letter for more serious violations potentially affecting public health, instead of a non-compliance letter, if, for instance, CDC believes that some aspect of its regulations or procedures may have been unclear and the non-compliance predated CDC's issuance of a memoranda, policy statement, training material, letter to the ACF, etc., clarifying its policies and practices.

violation or assess the need for further remedial action, e.g., written explanation for why violation occurred, photographs of signage indicating the parameters of an animal quarantine area.

4. *Non-compliance letter requiring a Corrective Action Plan (CAP)*. Based on individual circumstances, e.g., seriousness of the violation, failure to remedy or recurrence of non-compliance, CDC may require the ACF to respond with a formal written plan for corrective action. A CAP is a written document submitted by the ACF for CDC's approval describing the specific remedial steps the ACF will take to ensure that further non-compliance does not occur. Such corrective steps would depend on the individual circumstances but may, for instance, include staff retraining, reassignment of staff duties, changes to the ACF's standard operating procedures, or changes to facility layout to ensure proper quarantine. CDC may also place conditions on its approval of a CAP to ensure compliance, e.g., examination of animals or inspection of records, ACF facilities, or vehicles used to transport animals.
5. *Temporary suspension of ACF*. A temporary suspension means that although an ACF retains its registration for the remainder of the registration period, it is not permitted (for the duration of the time specified) to house dogs (or cats) or accept reservations for imported dogs under 42 CFR 71.51. A temporary suspension may be carried out in whole or in part meaning that based on individual circumstances CDC may, for instance, allow the ACF to continue to house dogs currently in its possession for the duration of the quarantine period but not accept new reservations. CDC may also direct that dogs currently housed be moved to an alternate location such as another ACF or veterinary clinic for the duration of their quarantine. The duration of a temporary suspension will be determined based on individual circumstances.
6. *Revocation of status as registered ACF*. A revocation represents the CDC Director's decision to revoke an ACF's registration. CDC will follow the procedures required by 42 CFR 71.51(r), including those relating to notice, review, and for issuing a final agency decision. The CDC Director may appoint a designee for purposes of deciding whether to revoke an ACF's registration. In accordance with 42 CFR 71.51(l), the revocation period may last up to 5 years.

PLEASE SEE ATTACHED CHART FOR FURTHER EXPLANATION OF ENFORCEMENT OPTIONS

Effective Date:

This policy statement is effective December 09, 2024. This policy statement will be posted on the CDC website and may be revised as needed.

Any questions concerning this policy may be addressed by contacting cdcanimalimports@cdc.gov.