

Dispute Resolution Process

Also see "A Template for Managing Inspections".

I. INTRODUCTION

This document is intended to provide guidance for animal facilities on procedures for resolving disputes that cannot be resolved at the time of an Animal Welfare Inspection conducted by the USDA. Dispute resolution is a vitally important process for the registered facility to follow through on. Although the USDA provides a mechanism whereby a registered facility can seek resolution of a dispute all the way up to the level of the Animal Care Deputy Administrator

(<http://www.aphis.usda.gov/ac/inspectionconcerns.html>),

NJABR believes that the process described herein is more robust. We have provided sound guidance for formally appealing your dispute to the Office of the Animal Care Headquarters, and for submitting information to assist Animal Care (AC) officials in resolving the issue(s) presented.

These guidelines borrow heavily from those that have been published by other government agencies (e.g., FDA). It is important to recognize that disputes will inevitably arise during the USDA inspection process and can involve complex judgments and issues that are critical to the operations of the animal facility. It is critical that there be procedures in place that will encourage open, prompt discussion of such disputes, which will usually lead to their resolution. The procedures described in this guidance document are intended to promote rapid resolution of disputes between the registered facility and the USDA.

Each registered facility should recognize that any dispute that occurs during an inspection can be appealed. If the issue is not resolved at the primary inspector level, the interested person may request that the matter be reviewed at the next higher supervisory level. This process may continue through the Agency's chain of command that includes the Inspector, the Supervisory Animal Care Specialist at the regional office, the Regional Director, then the AC Deputy Administrator. The registered facility should also request, if necessary, that AC seek the advice of outside experts. The registered facility may wish to include their own experts in this process when resolving a matter.

II. FORMAL DISPUTE RESOLUTION

As described above, the registered facility should initially seek resolution of any dispute at the Inspector level, using formal or informal mechanisms as appropriate. If these mechanisms do not lead to resolution, the facility may formally request reconsideration of the matter at the next level up through the Deputy Administrator.

III. PROCEDURES FOR SUBMITTING A REQUEST FOR FORMAL DISPUTE RESOLUTION

A. How to Request Formal Dispute Resolution

A registered facility that is interested in requesting formal dispute resolution by the AC Deputy Administrator should do so only if an attempt for resolution at the previous supervisory level was unsuccessful.

B. Supporting Information

To make the most efficient use of Agency and registered facility resources, any request for formal dispute resolution should include adequate information to explain the nature of the dispute and to allow the Agency to determine the necessary steps to resolve the matter quickly and efficiently. Each request should include the following:

1. A cover sheet that clearly identifies the submission as **FORMAL DISPUTE RESOLUTION REQUEST** in bold, capital letters.
2. Facility Identifier: Registration or Facility Number.
3. A brief, but comprehensive statement of each issue to be resolved:
 - Clearly describe the issue to be resolved.
 - Identify the issue : Animal care, Facilities, IACUC, Veterinary Care, etc.
 - State the steps that have been taken to resolve the issue, including informal dispute resolution.
 - Include the date(s) that these steps were taken.
 - Identify possible solutions.
 - State your expected outcome.
4. A statement identifying the AC Inspector who issued the original decision on the matter and, if applicable, all of the Agency officials who have formally attempted to resolve the matter.
5. A list of all documents previously submitted to the Agency that are deemed necessary for resolution of the issue(s). If a registered facility prefers, copies of such documents may be resubmitted to the Agency. Mark any document that is provided to the agency as "confidential."
6. A statement that the previous supervisory level received and has had the opportunity to review all of the requisite materials.
7. Name, title, and telephone, email and fax numbers of facility contact.
8. Name & location of facility, and the date(s) of the inspection.

Use an institutional letterhead to submit the information included in the dispute. Send the package as registered mail or "return receipt" to document the delivery & receipt of the package to the Agency.

IV. EXPECTED AGENCY ACTION

The due process necessary for resolving an inspection finding dispute with AC, knowing that the disputed finding may become available to the public through FOIA, is not clear. Likewise, the time frame, steps and retraction of inaccurate information, and redaction of confidential or proprietary information released by the USDA to the public through FOIA has not been discussed, nor is it outlined in any substantive manner by the USDA. For this reason, it is imperative that the registered facility clearly states in writing their expectations when disputing an inspection finding. Those expectations, at minimum, should be that AC will forward the formal request to the appropriate official (the Official) to respond to

the formal appeal, enter the necessary information into the appropriate tracking system, and send an acknowledgment letter to the registered facility. State that the expected time frame for a response from the USDA or other Agency is 30 days upon receipt of letter.

The Official is then expected to review the matter and provide a response prior to releasing the inspection finding to FOIA. The response could be a decision on the matter, but could also be a decision to seek advice from an advisory committee or other internal or external experts, or to ask the registered facility for more information. The decision can also be disputed further by the registered facility.

A. Written Response

The USDA is expected to send a written response to a registered facility that requests formal dispute resolution. The written response should specifically agree or disagree with the outcome desired by the registered facility, agree or disagree with parts of the proposed outcome, or indicate a resolution that is different from that proposed by the registered facility. If the Agency does not agree with the registered facility's position, the response should include reasons for the disagreement and any actions that the registered facility can take to address issues the Agency has raised, including time frames.

This guidance document has been prepared by the Animal Care Council of New Jersey Association for Biomedical Research and is our current thinking on dispute resolution.

Should you require clarification on any point contained in this guidance document or examples, contact the Animal Care Council through NJABR. As this document is considered a work in progress, the ACC encourages facilities to share case studies that illustrate the strengths or weaknesses of this process as outlined or provide comments.

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