A TEMPLATE FOR

MANAGING INSPECTIONS

Developed by a Work Group at Inspecting the Process II
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MANAGING INSPECTIONS

INTRODUCTION

In addition to training staff to oversee the animal care and use program on a day to day basis, staff must also be trained in how to manage any type of programmatic audit, be it announced or unannounced. The purpose of this document is to provide a guideline for preparing for and managing the audit. It was developed for members of the New Jersey Association for Biomedical Research (NJABR) in June 2000, and has since been revised by NJABR's Animal Care Committee, which agreed that the regulated community and regulators share a common objective: to assure that the highest standards of animal care are maintained.

IMPORTANT NOTE: The term “inspection” and "Inspector" are used generically in this document. The concepts of Managing Inspections can be applied to an USDA Inspection, AAALAC Site Visit, or any other state, local or federal audit of your facility.

In addition to operating your program day-to-day, staff must be trained to manage any type of programmatic review, announced or unannounced.

BEFORE THE INSPECTION

1. For security reasons, each registered animal facility should consider establishing a P.O. Box as their official vivarium mailing address. By so doing, the address listed on official documents will not specify the location of your facility.

2. On an annual basis, consider sending the inspecting agency a letter that contains the following:
   a. Facility contact person's name and phone number. This person should be knowledgeable of your programs and trained in managing inspections.
   b. Company hours and holidays
   c. A request for the name of the facility's Inspector for the year
   d. Entry rules (48-72 hour entry rules)
   e. Safety supplies the Inspector should bring (i.e., respirator)
   f. Requirements for the Inspector to be TB tested, and any other medical evaluations/vaccinations the Inspector should have.

3. Develop a written SOP or Procedure document that outlines your process for managing inspections. You may wish to include the following in your guidelines:
   a. Provide the main receptionist with a list of key contacts within the animal care group to notify when the Inspector arrives.
   b. Identify at least one key contact and alternate within the vivarium who would be responsible for immediately notifying individuals within the organization of the inspection. This contact list may include:
      • Vivarium Staff
      • Security
      • Legal
      • Public Relations
      • Attending Veterinarian/Designee
      • IACUC Chair and Committee
      • Investigators
      • Senior Management
• Institutional Official
• Quality Assurance Unit

c. Identify the Inspection walk-through team up front. Each member of this team should be trained in how you will manage your inspections.
d. Determine who receives the Inspector and where s/he is received.
e. If the Inspector is new, call the home office to verify that this person is an Inspector for that agency. Photocopy the Inspector’s badge for your records.
f. Include who should be notified post-inspection of the inspection results. Note what you want included in the Inspection summary (Inspector’s name, time of arrival, inspection participants, areas of the facility visited, documents reviewed or taken, documents provided to management by the Inspector, findings, etc.).

BEFORE YOU START THE FACILITY TOUR

1. When you are notified that an inspection is taking place, it is critical that your staff is notified and becomes involved in the inspection. This is particularly important for unannounced inspections, because the inspector may arrive before your staff has completed their morning rounds. It is their program that is being assessed, and they are key stakeholders in the inspection outcome. As per the program requirements, ways your staff can become involved are:
   a. Preparing an updated species count
   b. Listing procedures being performed that day
   c. Listing new programs or changes at facility since the last site visit
   d. Touring rooms to check conditions, i.e., temperature, humidity, animals/cage
   e. Checking the pharmacy veterinary supplies for dates

2. Reserve a conference room for the duration of the inspection. During the pre-tour conference, discuss:
   a. What the Inspector wants to see during the visit
   b. The facility tour and appropriate traffic patterns
   c. New programs or recent changes in programs at your facility
   d. Changes in staff
   e. Corrections or responses to issues noted at the last inspection
   f. Recent correspondence with the Inspector’s main office or headquarters
   g. New information, policies and procedures or relevant handouts from Inspector’s agency — ask for copies
   h. Opportunities for the Inspector to convey changes in programs to your staff. It is sometimes helpful for them to hear these changes directly from the Inspector.

   Remember: Inspectors are experts in conducting inspections. They can help your staff understand what they are looking for as well as help you convey to staff the importance of your programs and procedures.

3. Request that the Inspector inform you of any finding that s/he intends to cite as soon as it is identified. Begin immediately to correct any finding.

4. Include staff in the tour. Be sure to introduce them to the Inspector and have your staff represent their area of responsibility.
**THE WALK-THROUGH**

It is important that staff involved in the walk through are knowledgeable about your programs and are able to discuss them with the Inspector.

1. During the inspection, describe your program and its unique points for the Inspector.
   a. Remember, the primary focus is the health and well-being of the animals
   b. Be prepared to share/reference IACUC discussions on topics that may become relevant

2. Be prepared to represent your program thoroughly by:
   a. **Knowing the law and understanding the spirit of the law completely**
   b. Remaining professional at all times (You all have a job to do.)
   c. Clarifying any issues raised during the tour

3. If a deficiency is being raised, you need to know the law and be prepared to separate out for discussion purposes what is:
   a. Law
   b. Policy/Guidelines
   c. Best Practices
   d. Opinion

3. If you do not feel that the proposed citation is warranted, discuss the issue thoroughly. Review the program that covers the area of concern and recognize that if you do not take the time to explain your program, the Inspector:
   a. may not understand your program
   b. may not realize that you are following the program
   c. or, may come to realize through your explanation that your program meets applicable laws and guidelines

**THE EXIT INTERVIEW (SOMETIMES CALLED A DEBRIEFING)**

Recognize that the best way to prevent information from becoming available to the public through FOIA is to prevent the information from being listed on the inspection report.

The opportunity to sit down and discuss the inspection is extremely important and should not be over looked.

1. Consider routinely including Legal and/or QA in the Exit Interview.
   a. They lend expertise to discussions
   b. They help distinguish between regulations and policies as well as mediate differences of opinion as to interpretation
   c. They will help educate senior management about the issues and may gain internal support for your programs

2. Discuss finding(s) with the Inspector.
   a. Be sure to clarify any findings not raised during the tour.
   b. Review findings in enough detail to understand the issues
   c. Take time to explain your programs related to the finding, and how you comply with the law or guidelines. Once again, when discussing the issues, focus on what is:
      - Law
d. If, after discussing the issue with the Inspector, you cannot resolve the issue, initiate the dispute resolution process.

3. If any documents are to be removed:
   • Stamp them as "Proprietary Information"
   • Make sure they are accurately labeled
   • Record them on a log form that you require the Inspector to sign, indicating that they are aware of the proprietary and confidential nature of these items

4. Closely review the write-up. There may be errors. Be certain that the wording is neutral and not prejudicial. Descriptions should be specific without putting the facility at risk and should accurately reflect the weight of the citation, i.e., the rate of occurrence or the actual impact on animal welfare.

5. Determine if you will or will not sign the report. Recognize that by signing the report, you are not indicating that you agree with the conclusion. Also recognize that if the report is released to the public through FOIA, your signature may also be released without your approval.

6. Thank the Inspector at the end of the inspection.

7. Write your post-Inspection summaries, letters, etc. immediately.
   a. Write a post-inspection communication to the Regional Office
      • to appeal finding(s)
      • If not appealing, to assess the inspection process. Strive for a fair and useful critique.
   b. Distribute copies internally as appropriate

Should you require clarification on any point contained in this guidance document or examples, contact the Animal Care Council through NJABR.

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DISPUTE RESOLUTION PROCESS

Discuss Issue with Inspector

- Cannot resolve issue with site Inspector
  - Call Regional/Main Office and discuss with both Inspector & Inspector's Supervisor
  - ASK FOR A DECISION / RULING

  - Indicate your intention to appeal
  - Follow an appeal process
  - You may also ask for revisit
  - You may ask for a Supervisor to visit

  UNSATISFACTORY OUTCOME

  SATISFACTORY OUTCOME

- Resolve issue at that time
- Correct finding later

SATISFACTORY OUTCOME