



A TEMPLATE FOR MANAGING INSPECTIONS

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

The following template was developed for members of the New Jersey Association for Biomedical Research in June 2000, and has since been revised by NJABR's Animal Care Committee. Individuals from industry, academia and hospitals, large and small had input.

All agreed that the regulated community and regulators share a common objective: to assure that the well-being of the animals is provided.

NOTE: The term "Inspector" is used generically in this document. The concepts of **Managing Inspections** can be applied to a USDA Inspection, AAALAC Site Visit, or any other state, local or federal audit of your facility.

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 doing this, your address listed on inspection reports and other documents will not specify the location of your facility, should activists wish to have that information.
2. On an annual basis, consider sending the inspecting agency a letter that contains the following:
 - ◆ your faculty contact person's name and phone number (this person should be knowledgeable of your programs and trained in managing inspections)
 - ◆ Company hours and holidays
 - ◆ Request for the name of the facility's Inspector for the year
 - ◆ Entry rules (48-72 hour entry rules)
 - ◆ What safety supplies s/he should bring (respirator)
 - ◆ Requirements for TB test and other evaluations/vaccinations of Inspector
3. Have a written inspection SOP or Procedure document that outlines your process for managing inspections on site. You may wish to include the following guidelines for staff to follow or prepare:
 - ◆ Provide the main receptionist with a list of whom to call when the inspector arrives. In addition, create a telephone chain contact list, which may include the following:
 - a. Vivarium Staff
 - b. Security
 - c. Legal
 - d. Public Relations
 - e. Attending Veterinarian/Designee
 - f. IACUC Chair and Committee
 - g. Investigators

- h. Senior Management
- i. Institutional Official
- j. Quality Assurance Unit

◆ Define the Inspection walk-through team up front (this team should be trained in how you plan to run your inspections).

3. Determine who receives the Inspector and where s/he is received. If the Inspector is new, call the home office to verify that this person is an Inspector for that agency.
4. Photocopy the inspector's badge for your records.
5. Include who should be notified post-inspection of the inspection results. Note what you want included in the Inspection summary (name of Inspector, time of arrival, who from the company met with the Inspector, what areas of the facility were visited, documents reviewed or taken, documents given to the facility, findings, etc.).

DURING THE INSPECTION

1. When the inspector arrives, activate your staff to get them involved with the inspection. They can:
 - a. Provide an accurate species count
 - b. Provide a list of known procedures being performed that day
 - c. List a summary of new programs or changes at facility since the last site visit
 - d. Tour rooms and check cage sizes
 - e. Check the pharmacy
2. Reserve a conference room for the duration of the inspection.
3. Define the tour needs:
 - a. What does s/he want to see?
 - b. Discuss route—follow appropriate traffic patterns
 - c. Provide updated census as needed
4. Consider reviewing with the Inspector:
 - a. New programs at your facility
 - b. Changes in programs
 - c. Changes in staff in your area
 - d. Corrections or responses since the last inspection/visit
 - e. Provide the Inspector with any documents that may have been sent to the regional office.
5. Request a copy of any new information or handouts from the Inspector.
6. If desirable, ask the Inspector to meet with staff to review changes in programs or any information that it may be important for the staff to hear 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.

7. Request that the Inspector inform you of any finding that s/he feels may need to be cited when they identify that issue. If at all possible, you should begin to correct the finding immediately.
8. Plan to include your staff in the tour. Be sure to introduce them to the Inspector and have them represent their area.

THE WALK-THROUGH

1. Describe your program and its unique points for the Inspector.
 - a. Focus first on the well-being of the animals
 - b. Include others in the site visit where appropriate
 - c. Share/reference IACUC discussions on topics that may become relevant
2. Findings
 - a. Recognize that the best way to prevent information from becoming available through FOIA or eFOIA is to prevent the information from being listed on the inspection report.
 - b. Deficiencies: **KNOW THE LAW!** Separate out for discussion purposes what is:
 - Law
 - Policy/Guidelines
 - Best Practices
 - Opinion
 - c. If you have a deficiency, admit to it if it is not debatable, and begin corrective actions immediately, if possible.
 - d. If you do not feel that the proposed citation is warranted, debate it. Be prepared to discuss thoroughly any finding you disagree with. Emphasize that you have a program that covers the area, and recognize that if you do not take the time to explain your program, the Inspector:
 - may not understand your program
 - may not realize that you are following the program
 - and may come to realize through your explanation that your program meets all laws and guidelines
 - e. Defend your program by:
 - **Knowing the law and understanding the spirit of the law completely**
 - Remaining professional at all times (You all have a job to do.)
 - Clarifying any issue not raised during the tour

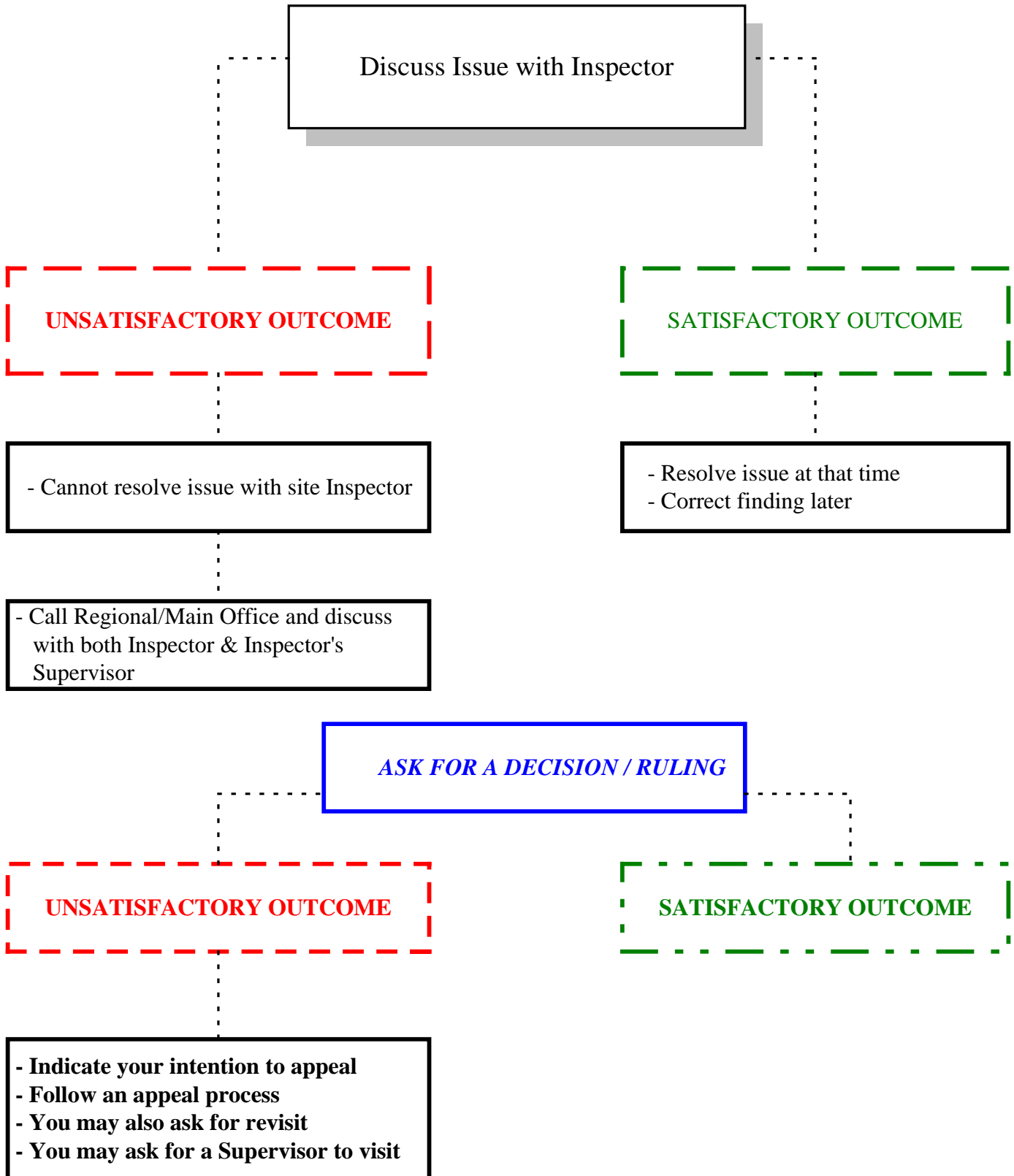
- f. When you become aware of an issue that could lead to a citation that was not raised during the inspection, you may want to revisit that area with the Inspector. There may be more to see or understand.

The Exit Interview or Inspection Write-up (sometimes called Debriefing)

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 can help distinguish between regulations and policies as well as mediate differences of opinion as to interpretation
 - c. They may help you gain internal support
 - d. They will help educate senior management about the issues
2. Discuss finding(s) with the Inspector
 - a. Review findings in enough detail to understand the issues
 - b. Take time to explain your programs when necessary
 - c. Initiate dispute resolution process as soon as possible, if necessary
 - d. Sign the report once inspection is completed
3. If you missed something during the Inspection that comes up at the Exit Interview, ask for a recap of how this item became an issue. Take the time to explain your program in a way that will help the Inspector understand how you comply with the law. **Be sure that you do comply with the law!**
4. Stamp any documents that are removed as "Proprietary Information."
5. Separate out for discussion purposes what is:
 - Law
 - Policy/Guidelines
 - Best Practices
 - Opinion
6. If you disagree with the decision made by an inspector, defend your program, and ultimately be prepared to follow a dispute resolution process.

DISPUTE RESOLUTION PROCESS



7. 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.
8. Thank the Inspector at the end of the inspection.
9. 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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