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Forest Service Handbook 4090.13 – Good Laboratory Practices Handbook
Chapter 90 – Inspections and Audits

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Responsible Staff:

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POSTING NOTICE. Amendments are numbered consecutively by Handbook number and calendar year. Post document in numerical order of chapters (1109.12, sec. 4.32, ex. 01). Remove entire national text of the Handbook and replace with this amendment. DO NOT REMOVE SUPPLEMENTS OR INTERIM DIRECTIVES. Retain this transmittal as the first page of this document.

Digest: Following is an explanation of the changes throughout the directive by section.

This Handbook provides direction on the principles and requirements of Good Laboratory Practice (GLPs) for Forest Service management and technical personnel. Any study that is performed with the intention of submitting the data to the U.S. Environmental Protection Agency or the U.S. Food and Drug Administration in support of a research or marketing permit must follow GLP standards.

01 - 06.5: Sets forth Authority (sec. 01), Policy (sec. 03), Responsibility (sec. 04), Definitions (sec. 05), and References (sec. 06) in the zero code chapter for the new Handbook on Good Laboratory Practices.

11 - 12.4: Establishes a new chapter that provides direction on the applicability of Good Laboratory Practices (GLPs) (sec. 11) and aspects of compliance (sec. 12).

20.3 - 22: Establishes a new chapter that provides direction on staffing requirements and training for personnel conducting, or involved with, Good Laboratory Practices.

30.3 - 35: Establishes a new chapter that provides policy and direction to determine requirements for test system care facilities (sec. 31); test system supply facilities (sec. 32); facilities for handling test, control, and reference substances (sec. 33); laboratory facilities (sec. 34); and archiving facilities (sec. 35) where Good Laboratory Practices are conducted or stored.

40.3 - 42.3: Establishes a new chapter that provides direction on equipment requirements including equipment design (sec. 41) and calibration and maintenance (sec. 42) for studies complying with Good Laboratory Practices.

50.3 - 55.33: Establishes a new chapter that provides direction on facility operations required for Good Laboratory Practices, including preparation of master schedule (sec. 51); standard operating procedures (sec. 52); reagents and solutions (sec. 53); test system care (sec. 54); and characterization, handling, and mixing with carriers of test, control, and reference substances (sec. 55).

61 - 62.32: Establishes a new chapter that provides direction on the preparation of protocols and collection of raw data for Good Laboratory Practices.

70.4 - 73.3: Establishes a new chapter, Records, Reports, and Archiving that provides direction on reporting study results (sec. 71), archiving (sec. 72).

80.1 - 81.2: Establishes a new chapter that provides direction on the requirements and duties of local and national Quality Assurance Units in support of Good Laboratory Practices.

90.1 - 93.38: Establishes a new chapter that provides direction on inspections conducted by local and national Quality Assurance Units (sec. 91 and 92) and the U.S. Environmental Protection Agency (sec. 93) in conjunction with Good Laboratory Practices.

This Handbook is now available electronically in the National Information Center in the same format as the paper copy. Henceforth, amendments to this Handbook will be issued to Forest Service units electronically on a document basis.

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90.1 - Authority

The local Quality Assurance Unit (QAU), whether internal or contracted, has authority to monitor and inspect studies and facilities under Title 40, Code of Federal Regulations, sections 160.35 (sec. 01, ex. 01) and 792.35. Inspections conducted by the National QAU follow the guidelines established in FSM 4085. Forest Service reviews are conducted under the guidelines of FSM 1410 and FSM 1470. The U.S. Environmental Protection Agency inspection requirements are set forth in 40 CFR 160.15 (sec. 01, ex. 01) and 40 CFR 792.15.

90.3 - Policy

Assess Forest Service compliance with Good Laboratory Practices (GLPs) during management or activity reviews and through inspections by national and local Quality Assurance Units (QAUs). The local QAU must review all GLP studies at least once while the study is in progress.

No facility shall refuse a U.S. Environmental Protection Agency inspection.

90.4 - Responsibility

90.41 - Deputy Chiefs for Research, State and Private Forestry, and the National Forest System

It is the responsibility of the Deputy Chiefs for Research, State and Private Forestry, and the National Forest System to assess Good Laboratory Practice compliance for studies conducted in their assigned areas during national management and activity reviews (FSM 1410).

90.42 - National Quality Assurance Unit Manager

(FSM 4085.04d).

90.43 - Regional Foresters, Station Directors, Area Director, Director of the Forest Products Laboratory, and Institute Director

It is the responsibility of Regional Foresters, Station Directors, the Area Director, the Director of the Forest Products Laboratory, and the Institute Director to assess Good Laboratory Practices compliance during management and activity reviews (FSM 1410).

90.44 - Local Quality Assurance Unit Manager

It is the responsibility of the manager of the local Quality Assurance Unit to schedule and implement facility inspections and data audits of all studies conducted at the facility that follow Good Laboratory Practices (sec. 91.2).

91 - Quality Assurance Unit Inspections

91.1 - National Quality Assurance Unit Inspections

Members of the national Quality Assurance Unit (QAU) should periodically inspect Forest Service facilities and conduct data audits to ensure compliance. Facility inspections and data audits should simulate U.S. Environmental Protection Agency (EPA) inspections (sec. 93) and can be done in conjunction with national management or activity reviews (FSM 1410).

A standardized list of questions or a checklist may be developed (ex. 01) to facilitate inspections and audits. Exhibit 01 provides a sample list of questions and topics that can be used by national and local quality assurance personnel to assess a testing facility's compliance with Good Laboratory Practice regulations. The questions and topics set forth in the exhibit are meant to serve as a guide and are not all inclusive. Individual quality assurance personnel or EPA inspectors may have additional concerns or areas of emphasis.

91.1 - Exhibit 01

Sample Questions for Facility Inspection and Data Audit.

This list of questions is based on material developed by the International Center for Health and Environmental Education, Alexandria, Virginia.

A. Personnel.

1. Who were the individuals (employees and contractors) who actually performed the studies?

2. Do they still work for the testing facility? If not, where are they and why did they leave?

3. Who can provide follow-up information on these individuals?

4. What role did they play in the study?

5. How critical was that role to the study results and reporting?

6. If they are still working for the testing facility, what is their present role and can they accept a personal interview?

7. A review of the documentation on each individual's background and experience before the personal interview is essential. This documentation can be in the form of a resume or personnel records.

8. Confirm each individual's level of experience in the initial phase of the interview with questions such as:

    a. What is their discipline/expertise?

    b. Where did they get their education/training?

    c. How long have they worked in this field?

    d. How long have they worked at this testing facility?

    e. What are their present responsibilities?

    f. Have they published or presented any of their work recently that is not in their resume or personnel records?

9. Have them describe their exact responsibilities in the study, starting from the receipt of the test substance.

10. What observations did they make?

11. In their opinion, what were the end results of their observations?

12. What do they think are the significance of these observations and results?

13. If they had to do this study over again, what would they do differently? How? Why?

B. Testing Facility Management.

1. Is there a Quality Assurance Unit (QAU)?

2. Where does the QAU fit into the administration of the organization?

3. Who is responsible for the QAU?

4. How do you communicate with the sponsor? Formally or informally?

5. Have there been any problems, from your point of view, with the laboratory's relationship with the sponsor? If yes, please describe.

C. Study Director.

91.1 - Exhibit 01--continued

1. What type of working relationship do you have with the sponsor?

2. Have you been asked by the sponsor to modify any data? If so, what were the modifications and what was the rationale?

3. Have you encountered any problems in conducting this study? If so, provide details.

4. In your opinion, what do the data suggest about the test substance?

5. How do you and this project relate to the Quality Assurance Unit?

6. How do you relate to upper management of this testing facility in terms of scheduling and overall support?

7. Have delays in the scheduling been documented?

8. Have any upper management decisions impacted this study? If so, please explain the details.

9. Have any amendments been made to the initial protocol? If so, why and when? What were the amendments?

10. Is the test system specified in the protocol actually as described?

D. Quality Assurance Unit.

1. Do you have a current copy of the master schedule of all studies conducted by the laboratory? Is it available?

2. Where does the QAU fit into the organization?

3. What type of support has upper management provided to the QAU to conduct its function?

4. Have there been any problems with respect to the study or the Study Director? Please explain.

5. Were there any changes in personnel during the course of the study? If so, please explain.

6. Where are the QAU records and staff housed?

7. Are QAU standard operating procedures available for inspections and audits?

8. Are there QAU records listing the following?

    a. Current master schedule for all studies?

    b. Protocols pertaining to all studies?

    c. Status reports on each study?

    d. A signed quality assurance statement of inspection dates and their findings?

9. Is there a training program for QAU staff and lab personnel in Good Laboratory Practices?

10. Is there a Standard Operating Procedure (SOP) for the inspection process?

11. If there were any problems that were likely to affect study integrity, were they brought to the attention of the Study Director and management?

E. Testing Facilities.

1. Are the facilities adequate to meet the objectives of the study plan?

2. Are the facilities adequate for handling the test and control substances?

3. Are the archives and other storage facilities adequate?

4. Have systems such as air ventilation, water quality, and environmental control been addressed?

5. Are there current SOPs available for the various facility functions? Are they adequate?

6. Do the freezers, incubators, and cold room temperatures meet the protocol requirements and are there SOPs for using and maintaining them?

7. Are contingencies addressed in the SOPs?

F. Equipment.

91.1 - Exhibit 01--continued

1. Is the equipment of an appropriate design to meet the requirements of the study plan?

2. Is there documentation of routine and unscheduled maintenance, calibration, and/or standardization and use of the equipment? When and how often?

3. Are the SOPs on equipment available? Are they current? Are they being followed?

4. Is new equipment validated?

G. Testing Facilities Operation.

1. Are there SOPs covering every aspect and phase of the study?

2. Is the current version of each SOP being followed?

3. Have all revisions of the SOPs been retained?

4. Are reagents properly stored and identified including the date generated?

5. How is the test system handled before, during, and after the study?

6. How is the test system disposed of?

H. Test and Control Substances.

1. Who is responsible for analyzing the test substance for purity and stability? Is this information supplied by the sponsor?

2. Are the analytical data present? If not, who has them (name, location/address, and telephone number)?

3. Is there an SOP for "chain of custody" documentation for test, control, and reference substances?

4. Are all test, control, and reference substances labeled to indicate identity, concentration, storage requirements, and expiration dates?

5. Are all samples uniquely identified by test number, notebook reference, and date of collection?

6. Is there an SOP for retaining or archiving test samples for future use or inspection?

91.1 - Exhibit 01--continued

7. Is there an SOP for the handling of test, control, and reference substances?

8. Is there an SOP for removal and disposal of test, control, and reference substances?

9. How are the test, control, and reference substances mixed with carriers?

10. How is the test substance analyzed in this mixture?

11. Is the test substance stable under all conditions of the study and storage? If not, how is this issue handled?

12. Are test, control, and reference substances stored separately from test samples and the test system?

13. For studies lasting more than 4 weeks, are reserve samples from each batch of test, control, and reference substance retained for a specified period of time?

I. Protocol and Conduct of the Study.

1. Does a protocol exist for the study?

2. Was the protocol approved and signed by the Study Director before it was initiated?

3. Does the protocol meet Good Laboratory Practice regulations?

4. Was the protocol followed? If not, why not? Are there protocol amendments?

5. When appropriate, does the protocol reference SOPs and validated methods?

6. Were there any protocol deviations and were they documented and justified?

7. Under what conditions were the test systems exposed to the test, control, or reference substances?

8. If animals or plants were used, who supplied them (including name, address, telephone number, date of receipt, condition upon receipt, handling records, and history of the test system)?

J. Records and Reports.

1. Are there records and reports?

91.1 - Exhibit 01--continued

2. Are there drafts of any of these documents?

3. How are raw data handled and stored?

4. Are notebook entries and handwritten data in permanent ink, free of erasures and white-outs?

5. Are pages signed and dated properly on the date the raw data were generated?

6. Are changes in entries signed and dated? Is there an explanation for why changes were made?

7. Are complete cross-references given?

8. Are entries coherent and complete?

9. Are SOPs for records and notebook entries available? Are they current?

10. Are all raw data retained and properly labeled? How are they stored?

11. Do transformed or computer-generated data correspond to raw data?

12. Can computer validation be demonstrated for hardware, software, and peripherals?

13. Are calculations correct?

14. Do data support observations and conclusions?

15. Is the study free from errors or practices which may impact the validity of the study?

16. Are back-up procedures for computer data followed?

17. Are copies of raw data certified as being exact copies?

18. Is the final report signed and dated by the Study Director?

19. Is there a statement from the QAU attached to the final report?

20. Is the report complete?

21. Will the report be finished by the scheduled completion date?

22. Does the report correctly describe the work performed?

23. Are previous audits from the QAU documented?

K. Computer Validation. Issues of computer validation arise when a facility uses computerized information management systems to gather and report study data. Adequate documentation must be available to demonstrate that these systems, including hardware, software, and peripherals have been validated.

1. Is there an inventory of all hardware, software, and peripherals?

2. Does the capacity of the hardware match its assigned function?

3. Have operational limits been identified?

4. Have "worst case" conditions been tested?

5. Have tests been repeated enough times to ensure a measure of consistency?

6. Is a computer validation protocol available? Has the validation program been thoroughly documented?

7. Can revalidation be initiated when significant changes are made to the system?

8. Are criteria for revalidation stated in SOPs?

9. Have the operational limits of the computer system been incorporated into an SOP?

10. What method of correction is used for input errors?

11. Are computer training manuals and current user manuals available?

12. Are historical data generated by the computer system available for review?

13. Where are the computer data stored?

14. Are SOPS available for such items as security systems, environmental conditions, shutdown, and recovery systems, edit control procedures, and archiving?

L. Archives.

1. Are there archiving facilities?

2. Who is responsible for the quality assurance of the archives?

3. Does the organizational chart indicate how the archives and its staff fit into the overall organization of the test facility?

4. Are SOPs present for the archives and are they being followed?

5. Are the archives secure from fire, pests, pesticides, and other conditions which may alter the quality and availability of the data?

6. Is access to the archives limited and controlled?

7. Are there SOPs for removing, returning, or discarding raw data from the archives?

8. When the final report is complete, have the following been archived?

    a. Raw data?

    b. Documentation?

    c. Records?

    d. Protocols?

    e. Test samples?

    f. Interim and final reports?

M. Field studies.

1. Is test site information available? Is it properly archived? This may include:

    a. Map of test sites or field plots, including topography.

    b. Weather records.

    c. Plot characteristics (soil, stand, target pest).

    d. Previous applications of fertilizer and pesticides.

    e. Previous crop (stand) history.

91.1 - Exhibit 01--continued

2. Are the locations and management records of the target crop (stand) documented?

3. Have the study initiation dates and experimental start dates been recorded?

4. Are protocols and SOPs in place for all aspects of the study, including:

    a. Information on application of the test substance?

    b. Quantity of pesticide or test substance applied?

    c. Application equipment?

    d. Application conditions?

    e. Target crop and target pest conditions at time of application?

    f. Deposit and/or residue analysis?

5. What are the cultural practices used for the target crop, including:

    a. Irrigation?

    b. Fertilizers?

    c. Cultural or silvicultural techniques?

    d. Pesticides (other than the test substance)?

6. Is there an SOP for sampling procedures? How are samples collected? Is there proper documentation of how and from where the samples were taken? Is there "chain of custody" documentation for samples?

91.2 - Local Quality Assurance Unit Inspections

Inspect each study at appropriate intervals to ensure that Good Laboratory Practices (GLPs) are being followed. Inspect each study at least once, preferably during critical phases of the study, such as administration of the test substance or during collection of specimens and other data.

The local Quality Assurance Unit inspections should ensure that:

1. Signed protocols exist and are followed.
2. Standard Operating Procedures (SOPs) have been developed and are being followed.
3. Training records are being properly maintained and updated.
4. Facilities and equipment are adequate for the job.
5. Test and control substances are being properly handled.
6. There are no safety violations.
7. Those involved in GLP studies are sufficiently aware of GLP procedures.
8. Record keeping is adequate.
9. Archiving is being done properly.

A standardized list of questions or a checklist may be developed to guide facility inspections and data audits (sec. 91.1, ex. 01).

91.3 - Inspection Records

Maintain written records of each inspection, whether conducted by the national or local Quality Assurance Unit (QAU). The QAU auditor must properly sign these records. The records should include the following information:

1. Date of inspection.
2. Study inspected.
3. Phase or segment of the study inspected.
4. Name and title of the person who performed the inspection.
5. Findings and problems detected during the inspection.

6. Actions recommended to correct such problems.

7. Scheduled date for reinspection if one is planned.

The national or local QAU must inform the Study Director and management immediately if any problems are detected during an inspection and may recommend corrective actions.

Internal QAU inspections are considered confidential. The U.S. Environmental Protection Agency (EPA) must be given access to inspection dates, the study inspected, phase or segment of the study inspected, name of the inspector, and a copy of the SOP covering QAU inspections. The EPA inspectors may request management to certify that inspections actually were conducted. Also, the EPA can petition a facility to open its QAU inspection records during litigation or in final adjudicatory hearings.

92 - Forest Service Reviews

Compliance with Good Laboratory Practices (GLPs) should be examined during management and activity reviews.

(FSM 1410), supervisory reviews (FSM 1410.44b), and national and local Quality Assurance Unit reviews (sec. 91). Reviewers must be familiar with the requirements of GLP regulations. A list of standardized questions or a checklist can be developed to assist in the evaluation (sec. 91.1, ex. 01).

92.1 - Management and Activity Reviews

Compliance with Good Laboratory Practices (GLPs) should be assessed during management and activity reviews (FSM 1410). A representative from the national Quality Assurance Unit (QAU) should take part in the reviews. If this is not possible, and areas of noncompliance are detected, the review panel can pass their concerns on to the national QAU. A field unit's compliance with GLP standards should be addressed in the review report.

92.2 - Supervisory Reviews

The degree of compliance of each field unit involved with Good Laboratory Practice research should be evaluated during the supervisory review (FSM 1410.44b). Areas not in compliance and possible corrective actions should be outlined in the review report.

93 - U.S. Environmental Protection Agency Inspections

93.03 - Policy

No Forest Service facility shall refuse a U.S. Environmental Protection Agency inspection.

93.1 - Refusal of Inspection

Although it is legally permissible to refuse a U.S. Environmental Protection Agency (EPA) inspection, this action can lead to dire consequences, and the Forest Service does not view it as an acceptable alternative. Refusal of an inspection automatically disqualifies a study and invalidates the data generated from it for EPA consideration. Although the study may not be considered by the EPA, the data could still be published in scientific or trade journals. However, rejection of a study by the EPA would cast a negative light on Forest Service research in general. This is not acceptable.

93.2 - Types of U.S. Environmental Protection Agency Inspections

The U.S. Environmental Protection Agency (EPA) can initiate inspections for the following reasons:

1. Random inspections. Random inspections can occur anytime after a final report has been filed with the EPA. Currently, facilities are inspected by the EPA about once every 2 years. Laboratories with a large number of studies, or with a history of noncompliance, may be audited more frequently (approximately once every 15 months).

2. For cause inspections. For cause inspections occur if a study is flagged for some particular reason. For example, this may occur if registration of the compound is of high priority or if inconsistencies are found in the final report.

3. Follow-up inspections. Follow-up inspections may be conducted if areas of noncompliance have been detected in previous inspections. Therefore, it is best to take corrective actions immediately after an inspection.

93.3 - Inspection Process

93.31 - Notification

The U.S. Environmental Protection Agency generally notifies a facility by certified letter that it shall be inspected and may list the specific studies that it wishes to audit. Unannounced inspections may also occur. Inspections are conducted under the Office of Compliance Monitoring.

93.32 - Preparation

All personnel involved in Good Laboratory Practice (GLP) studies should have a good understanding of the GLP regulations, including the preamble, positions, and opinions. All field units involved with GLP studies should have a copy of the U.S. Environmental Protection Agency

(EPA) Inspectors' Guide (sec. 06.2). Personnel involved with the inspection should have a working knowledge of this EPA guide.

Every field unit should have a written Standard Operating Procedure (SOP) for the inspection process. The SOP should address the following:

1. Duties and responsibilities of the key individuals during the inspection. Identify the responsibilities of all key staff involved in the inspection process, including line officers, the Study Director, and Quality Assurance Unit (QAU) personnel. Management should designate an individual who is responsible for signing all inspection forms, including receipts for samples and documents.

2. Permitted inspection areas. The permitted inspection areas can exclude other studies in progress, including those not following Good Laboratory Practices, that are confidential and should not be discussed.

3. Level of confidentiality requested for the study that is being audited. Most studies conducted by the Forest Service should not require confidentiality. If an outside sponsor requests confidentiality, two different levels are available: general confidentiality and confidential business information.

    a. General confidentiality. General confidentiality ensures that records shall not be made generally available to the public.

    b. Confidential business information. Confidential business information is the highest confidentiality possible and requires inspectors to keep all information in a special file in their possession at all times. Special clearance is required to gain access. Request for this degree of confidentiality should be made sparingly and usually applies only to formulation studies, not health and safety studies.

4. Inspection escort policies. A representative of the facility, designated by management, should escort the inspector at all times. This may be done by line officers, QAU staff, or the Study Director. Private companies often choose lawyers as the escort. The escort should be accommodating and should answer all questions asked, directly and honestly.

5. Use of cameras and tape recorders. All field units should set forth their policy on the use of cameras and tape recorders during the inspection process.

93.33 - Opening Conference

Inspections should occur during normal working hours. The inspector or the inspection team should be met at the door and escorted to an appropriate meeting room. The inspector's credentials should be confirmed and the appropriate introductions made. The inspector should

present notice on EPA Form 3540-2, Notice of Inspection, for Federal Insecticide, Fungicide, and Rodenticide Act inspections or FDA Form 7740-3, Notice of Inspection, for Toxic Substances Control Act inspections that may list suspected violations. During the opening conference, line officers should try to determine the exact nature and scope of the inspection, including the studies involved and the expected duration of the inspection. An agenda for the inspection should be set up at this time. The inspector should be informed of any in-house rules, including health and safety requirements. The policy on cameras and tape recorders should be discussed.

The inspector may request copies of the field unit's organizational chart, the layout of the facility, and resumes (Factor IVs) of key individuals. Raw data generated during the study, as well as copies of the Standard Operating Procedures, protocol, and final report, must be made available to the inspectors. Current personnel involved in the study should be available for discussion.

93.34 - Facility Inspection

During a facility inspection, the inspector should:

1. Assess whether Good Laboratory Practice (GLP) standards, as set forth in this Handbook, are being followed.

2. Interview people at all organizational levels at the field unit to determine whether they are qualified to perform their functions, follow the Standard Operating Procedures, and have a good grasp of GLP practices and regulations. The inspection process is enumerated in greater detail in the U.S. Environmental Protection Agency Inspector's Manual (sec. 06.2).

93.35 - Study (Data) Audit

The inspector should carefully compare the experimental protocol and raw data with the final report and should look for inconsistencies. The inspector should also look for missing data and any selective reporting of data. The raw data should be examined to see if they are properly recorded and whether changes are properly documented. Any deviations from the protocol and the Standard Operating Procedures should be noted. The inspector should determine whether the data support the conclusions of the study or if any unforeseen circumstances invalidate the study. The statement of compliance (sec. 12.2) and quality assurance compliance statement (sec. 80.44) should be assessed for accuracy and content.

93.36 - Closing Conference

After the inspection and audit are complete, the inspector should meet with field management and summarize the findings in a closing conference. Areas of noncompliance should be discussed and may also be summarized in a follow-up letter from the U.S. Environmental Protection Agency.

93.37 - Post-inspection Activities

All personnel involved in the study should meet after the inspection for a debriefing conference. The Standard Operating Procedures for the inspection process should be evaluated and rewritten, as necessary. Areas of noncompliance should be discussed along with possible solutions and actions to be taken to come into compliance. Corrections should be made as soon as possible since a follow-up inspection by the U.S. Environmental Protection Agency (EPA) may be held. Lack of compliance is handled by the Compliance Division of the EPA's Office of Compliance Monitoring. Cases are referred to the Office of Enforcement and ultimately to the Justice Department.

A letter should be prepared in response to the EPA's follow-up letter and should:

1. Address all of the points mentioned by the EPA,

2. Discuss how areas of noncompliance will be or have already been corrected,

3. Be returned to the EPA as soon as possible.

A facility can request that the response be filed with and released with EPA documents if they are requested under the Freedom of Information Act (5 U.S.C. 552; FSH 6209.13, Ch. 10).

93.38 - Routes of Appeal

Several routes of appeal can be used if field management feels that the conclusions reached during an inspection are incorrect or unfair. If an appeal is likely, document all conversations and actions pertaining to the study and include this information in a case file with the study in question.

1. Minor differences. Minor differences, such as a misinterpretation of data in the final report or an incorrect assessment of a field unit's facilities, should be discussed with the appropriate U.S. Environmental Protection Agency (EPA) officer, either in writing or on the telephone.

2. Serious conflicts. More serious conflicts, such as accusations of the falsification of data, records, and reports, must be resolved during a civil complaint. To do so, Forest Service personnel present their case in an informal hearing or settlement conference at the EPA. If the disagreement cannot be resolved, both parties must present their cases to an administrative law judge, who makes a final ruling.