Forest Service Handbook
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Forest Service Handbook 4090.13 – Good Laboratory Practices Handbook
Chapter 80 – Quality Assurance Unit

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Approved by: David G. Unger, Acting Chief

Date approved:

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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80.1 - Authority

Authority to inspect and evaluate all Good Laboratory Practice (GLP) studies for compliance to GLP standards is given to the Quality Assurance Unit under the Federal Insecticide, Fungicide, and Rodenticide Act (40 CFR 160.35; sec. 01, ex. 01) and the Toxic Substances Control Act (40 CFR 792.35).

80.4 - Responsibility

80.41 - Deputy Chief for Research

(FSM 4085.04a).

80.42 - National Quality Assurance Unit Manager

It is the responsibility of the manager of the national Quality Assurance Unit (QAU) to:

1. Coordinate and promote information exchange among local QAUs. This can be done by collecting good examples of Standard Operating Procedures (SOPs), protocols, data collection forms, checklists, final reports, and archiving procedures and by making them available to field units that are establishing Good Laboratory Practice (GLP) programs. Members of the national QAU should be available to answer questions and provide guidance for field units involved with GLP studies.

2. Set qualification standards for quality assurance officers and provide direction on appropriate training.

3. Conduct routine field inspections to monitor GLP compliance in accordance with the same principles described in section 91.2 for local QAU inspections.

4. Report inspection results to field units and make recommendations on changes needed to correct any deficiencies. Conduct follow-up inspections to monitor corrective actions, when needed.

80.43 - Line Officers

It is the responsibility of line officers to provide quality assurance that satisfies Good Laboratory Practice compliance standards (sec. 0.1, ex. 01; 40 CFR 160.3 and 792.35) and training to quality assurance personnel when needed.

80.44 - Local Quality Assurance Unit Manager

(Sec. 0.1, ex. 01; 40 CFR 160.35). It is the responsibility of the manager of the local Quality Assurance Unit (QAU) to ensure that QAU personnel:

1. Monitor each study at a facility to ensure that it complies with Good Laboratory Practice (GLP) regulations.

2. Ensure, through periodic inspections, that facilities, equipment, personnel, Standard Operating Procedures (SOPs), methods, practices, records, controls, archives, and all other aspects of GLP studies comply with GLP regulations.

3. Provide certain facility administrative duties, including, but not limited to, the following:

    a. Master Schedule. Retain a current copy of the master schedule that lists the studies being conducted at the facility indexed by test substance (sec. 0.1, ex. 01; 40 CFR 160.35b1) (sec. 51).

    b. Protocols. Maintain copies of the protocols for all GLP studies.

    c. Inspections. Inspect each study at intervals to ensure that all GLP requirements are being met (sec. 91.2). Random inspection of studies is not adequate. Conduct general facility inspections, and keep written records of each inspection (sec. 91.3). Immediately inform the Study Director and line officers if any problems are detected during an inspection.

    d. Reports. Submit written, periodic status reports to line officers and the Study Director on each study. Include descriptions of any problems observed and recommendations for corrective actions.

    e. Deviations. Determine that deviations from approved protocols and SOPs were made with proper authorization and documentation.

    f. Final report. Review the final study report to ensure that it accurately describes the methods and SOPs, and that the results and conclusions accurately reflect the raw data. The final report is a major focus of U.S. Environmental Protection Agency (EPA) inspections. The QAU audit of a final report should be thorough so that any problems can be corrected before the report is submitted to EPA. The QAU should decide what percentage of data points must be audited, that is checked against the raw data, for each study. This percentage should be based on the complexity or overall quality of the final report. More data points should be audited in complex studies or when final reports appear to be of lower quality. The final report should be examined for completeness, reconstructability from raw data, internal consistency, conformance with the protocol, adherence to SOPs, and compliance with GLP regulations.

g. Quality Assurance Compliance Statement. Prepare and sign a statement that lists the dates of inspection and the findings reported to management and the Study Director. This is termed the "quality assurance compliance statement" and must be included in the final report.

h. Quality Assurance Verification. Inspect all fragile specimens and samples in the archives soon after their deposition to determine whether they need to be retained to preserve the integrity of the study. The specimens and samples should match what is described in the final report. Disposal is usually permissible if there are no inconsistencies in the data; no further data can be extracted from the material; and the material will decay rapidly.

i. Archiving. Maintain and archive records of QAU findings for each study. Make certain portions available to EPA officials upon request, as identified in sec. 91.3.

81 - Personnel

81.1 - National Quality Assurance Unit

Members of the national Quality Assurance Unit (QAU) should have a strong scientific background and be well trained in Good Laboratory Practices (GLPs) and quality assurance. They do not have to be based in the Washington Office but can be appointed regionally. Membership in the national QAU can be a collateral duty.

81.2 - Local Quality Assurance Unit

The local Quality Assurance Unit (QAU) personnel should be appointed by the Regional Forester, Station Director, Area Director, Director of the Forest Products Laboratory, or Institute Director (FSM 4085.04b).

1. Performance Standards. The QAU personnel should have sufficient training, education, or experience to perform this type of work. Also, the QAU personnel must be totally independent of the study, well-versed in Good Laboratory Practices and quality assurance procedures, and be able to critique and assess the study objectively. The QAU personnel must have a strong scientific background in the subjects that they inspect and audit so that they can accurately evaluate the study. All these performance standards may require extensive training.

2. Alternatives for Establishing a QAU. Several options exist, varying in cost, for the establishment of QAUs. All of the following options would satisfy the requirements of the U.S. Environmental Protection Agency if they are carried out properly.

   a. Utilize Industry or Private Organizations. The Forest Service can utilize the QAU of industry or other private organizations that fund Forest Service studies. Many

sponsors provide this service, especially if the testing facility they are funding has no established QAU. For example, a field unit could use Monsanto's QAU to analyze studies involving Monsanto products. The Forest Service must accept full responsibility for the quality assurance provided by the sponsor. If the sponsor cannot make this commitment, the Forest Service should not proceed with this option.

b. Establish Local Forest Service QAUs. The Forest Service can establish its own local QAUs. This can be done in several ways:

(1) Individual Responsibility. The QAU responsibilities can be given to a single individual, or individuals, who shall be responsible for monitoring all studies performed at that location. This individual cannot be involved in the direction or conduct of a particular study.

(2) Shared Responsibility. The QAU responsibilities can also be shared among personnel within or among Stations or Regions, in a situation similar to peer review. In this situation, a single person should be designated lead responsibility for quality assurance in order to ensure continuity in the QAU. Although this is probably one of the most cost-effective ways of establishing a QAU, it is also the most risky. All personnel must be thoroughly trained in GLPs and possess a strong commitment to doing a complete and objective assessment of each study. Quality assurance cannot be a rubber stamp operation. Inadequacies in the QAU would be exposed during an EPA audit and could lead to invalidation of a study (sec. 12.4 and 93). Proper implementation of quality assurance under this option is time-consuming, could significantly increase the workload, and decrease the time spent doing research.

c. Contract Independent Laboratories. The Forest Service may contract quality assurance to independent laboratories that specialize in this service. This is expensive but would guarantee objective analysis of each study and help ensure that quality assurance is properly done.