National Alliance of Independent Crop Consultants

EPA Regulatory Inspection
Field Site Preparation
Memphis, TN
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Content

- Targeting
- Pre inspection procedures
- GLP points of interest:
  - Equipment
  - SOPs
  - Electronic data
LDIB Access to Studies

- OPP accepted studies entered into OPPIN data base
- LDIB accesses OPPIN data base for FIFRA studies
- LDIB data base LISA
Targeting

- Neutral Scheme
  - Most Common
  - Random facility selection

- Directed / For Cause
  - Requested inspection from OPP/ OCE

- Informant
Target Selection Criteria

- Last date of inspection
- Compliance history
- OPP, OCE, OECA priority list
  - Type of chemicals
  - Types of studies
- Number of studies submitted
- Date of receipt of study at EPA
- Geographical location
First Contact with the EPA Inspection Authority

- EPA sends a letter to the field site and study sponsors which specifies:
  - Studies to be audited
  - The nature and purpose of the inspection
  - The dates of inspection
  - We will choose one or more ongoing study(s)
EPA Letter Requirements

- Suitable space for the audit
- Have available & in good order, all original data (certified copies sometimes accepted)
- Copies of the protocol & amendments and any reports to sponsor
- Correspondence with study personnel including the study director
EPA Letter Requirements

- Study personnel should be available for the inspection
- Relevant SOPs must be available
- Test substance information available
  - Characterization data
  - Purity and lot number information
  - Records of receipt, storage, usage including chain of custody procedures
Call From the Inspector

- Introduce ourselves and inspection team if relevant
- Clarify the “nature” of the inspection
  - neutral scheme or directed
- Answer any questions from EPA letter
- We’ll ask for:
  - Floor Plan and site map of your facility
  - Organization chart (sponsor down)
Call From the Inspector

- In addition, we’ll ask for:
  - A discussion of your facility, (past, present, and future plans)
  - Quality assurance routing forms
  - Master schedule
  - Personnel C.V.’s and records of training
Call From the Inspector

- We verify your address and request directions to your site
- We provide you with our phone information, and encourage you to contact us with any questions that may arise prior to inspection
Equipment in the Field

Subpart D
What Exactly is Equipment?

- Global Positioning System (GPS)
- Computer/ software
- Spray equipment
- Tractor
- Balance
- Pipette
Equipment Design
§ 160.61

Equipment used for the generation, measurement, or assessment of data and equipment used for facility environmental control shall be:

- Appropriate design and capacity to function according to the protocol
- Suitable located for “proper” operation, inspection, cleaning, and maintenance
Maintenance and Calibration of Equipment § 160.63(a)

- Equipment shall be adequately inspected, cleaned and maintained.
- Equipment used for the generation, measurement, or assessment of data shall be adequately tested, calibrated, and/or standardized.
Equipment Standard
Operating Procedures

§160.63(b)

- Methods, materials, and schedules used in the routine inspection, cleaning, maintenance, testing, calibration / standardization of equipment should be documented in an SOP.
- Specify remedial action taken in event of failure or malfunction.
- Person designated as responsible for performance of above operations.
Standard Operating Procedures (additional points)

- Are SOPs current and properly approved?
  - Rubber stamp approval by management?

- Do they reflect current practices?

- Accurate with appropriate detail?

- Are they available at each work area, are they followed?

- Are historical SOPs available?
Written Records

§ 160.63 (c)

- Records shall be maintained for equipment.
  - Inspection
  - Maintenance
  - Testing
  - Calibration / standardization / verification
  - Retirement of equipment
Written Records (continued)

- Also must include:
  - Dates of operations
  - Type of maintenance operations - routine
    - Standard Operating Procedure followed
  - Type of maintenance operation – nonroutine
    - Describe problem
    - How and when problem discovered
    - Action to correct the problem
Fundamental Requirements for Electronic Records
Fundamental Requirements for Electronic Records

- Must establish the following record keeping requirements:
  - Ability to generate and maintain accurate and complete copies of records for potential review, and protect them against alteration
  - Computer systems (including software and hardware) must be available for agency inspection
Protection of e-signature(s) so that record is not compromised (i.e.) copied, detached, altered
Electronic Signatures

- Individual entering data shall be identified
  - Biometric or user name / password
- Certified letter stating the electronic signatures are legally binding and equivalent to a hand written signature
- Employee training on use and security
Use of computer-generated, time stamped audit trails...provides record of actions *(key element during agency review)*
Electronic Records and the Audit Trail

- When a change is made the audit trail must establish:
  - When change was made (date & time)
  - Who made the change
  - The original data without overwriting
  - The new entry
  - Reason for the change
Fundamental Requirements for Electronic Records (Continued)

- Records are retrievable for legal proceedings and data audits
- Electronic records must be archived in such a way to preserve data integrity
Electronic Data Archives

- Data retention should be compliant with predicate rule.
- Limited access
- Minimize deterioration
- Have evidence of reliability for electronic data transfer to archives