

# National Alliance of Independent Crop Consultants



## EPA Regulatory Inspection Field Site Preparation

Memphis, TN  
*January 30, 2009*

# 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
  - Suitably 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

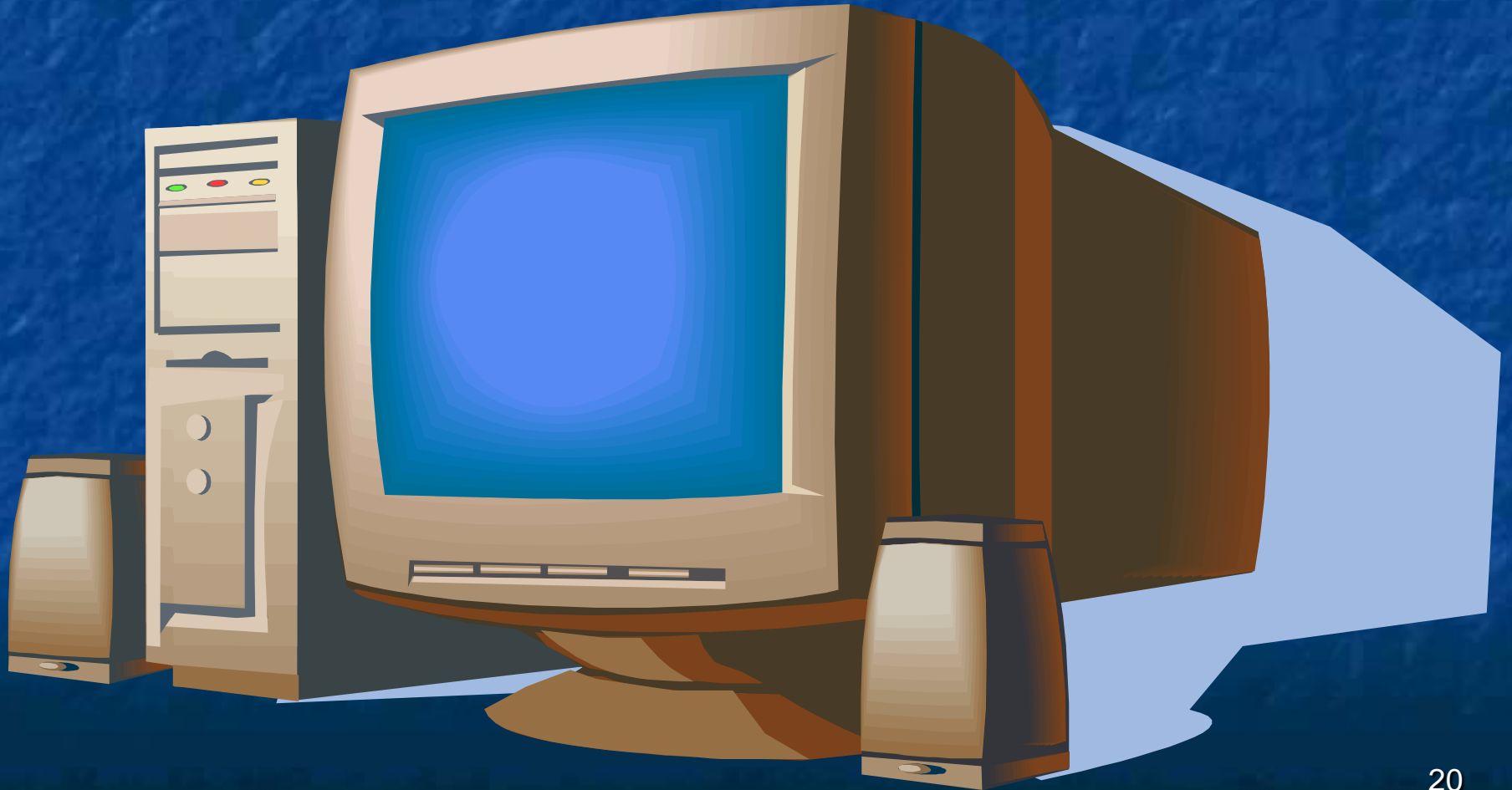
## § 160.63 (c)

- 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**

# Fundamental Requirements for Electronic Records (Continued)

- 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

# Fundamental Requirements for Electronic Records (Continued)

- 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



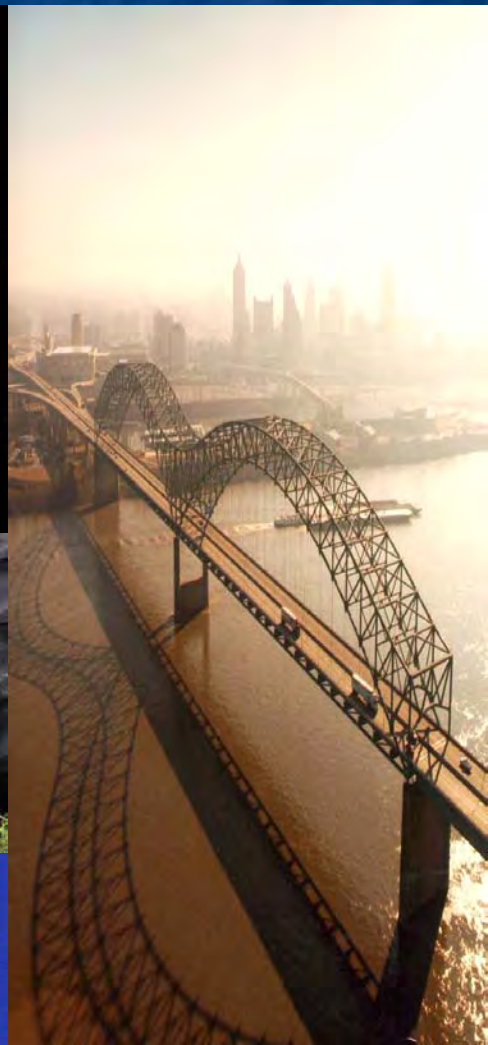
# Fundamental Requirements for Electronic Records (Continued)

- 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.
  - US EPA - 40 CFR 160.51, 160.190, 160.195, 169.2(k)
- Limited access
- Minimize deterioration
- Have evidence of reliability for electronic data transfer to archives

# NAIICC 2009 Annual Meeting



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