National Alliance of Independent Crop Consultants

EPA Regulatory Inspection & Field Site Preparation

Orlando, Florida
January 2010

Content

- Targeting
- Pre inspection procedures
- GLP points of interest:
  - Test substance & equipment
  - SOPs
  - Electronic data

LDIB Access to Studies

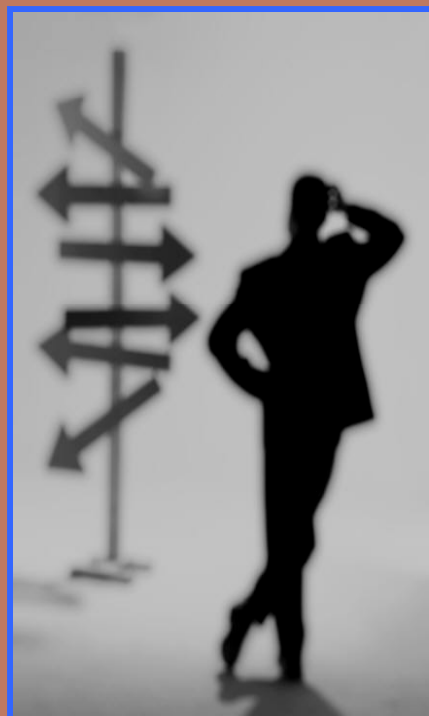
- Studies received by OPP entered into OPPIN data base
- LDIB accesses OPPIN data base for studies submitted under FIFRA
- LDIB's data base LISA

Targeting

- Neutral Scheme
  - Most common
  - Random facility selection
- For Cause
  - Requested inspection:
    - OPP/ OCE or foreign source
  - 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 study received 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 auditor**
- **Have available & in good order, all original data *(certified copies sometimes accepted)***

EPA Letter Requirements

- Copies of the protocol & amendments and any reports to sponsor
- 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 for cause
- 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
  - List of current and historical SOPs

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

Chemical Handling and Equipment

Chemical Substance Handling

- **Procedures established for storage & distribution:**
  - **Minimize contamination/deterioration**
    - **Environmental conditions (i.e. light, temperature, humidity, ventilation)**
  - **Identification throughout study distribution**
  - **Chain of Custody (COC)**
    - **Document amount used, when, and by whom**
    - **"Cradle to Grave" at the individual facility**

Substance Container Labeling

- Name
- CAS / code number
- Batch number
- Expiration date
- Storage conditions
- Storage containers assigned to minimize contamination

Test, Control & Reference Substance Characterization §160.105

- Records typically maintained and sent to audit by the study sponsor
  - Analysis for each batch to determine identity, strength, purity, composition…
  - Determined and documented before its use in the study

Test, Control & Reference Substance Characterization §160.105

- Records typically maintained and sent to audit by the study sponsor
  - Solubility when relevant
  - Stability shall be determined before experimental start date or concomitantly

How do we define "Equipment" for a GLP Study?

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**

Equipment Standard Operating Procedures

- 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 / verification
  - Retirement of equipment

Written Records (continued)

- Also must include:
  - Dates of operations
- Type of maintenance operations: *routine*
  - Standard Operating Procedure followed
- Repair / maintenance operation: *nonroutine*
  - Describe problem
  - How and when problem discovered
  - Action to correct the problem

Fundamentals of Electronic Records

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

Electronic Records

- **Protection of electronic 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

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

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

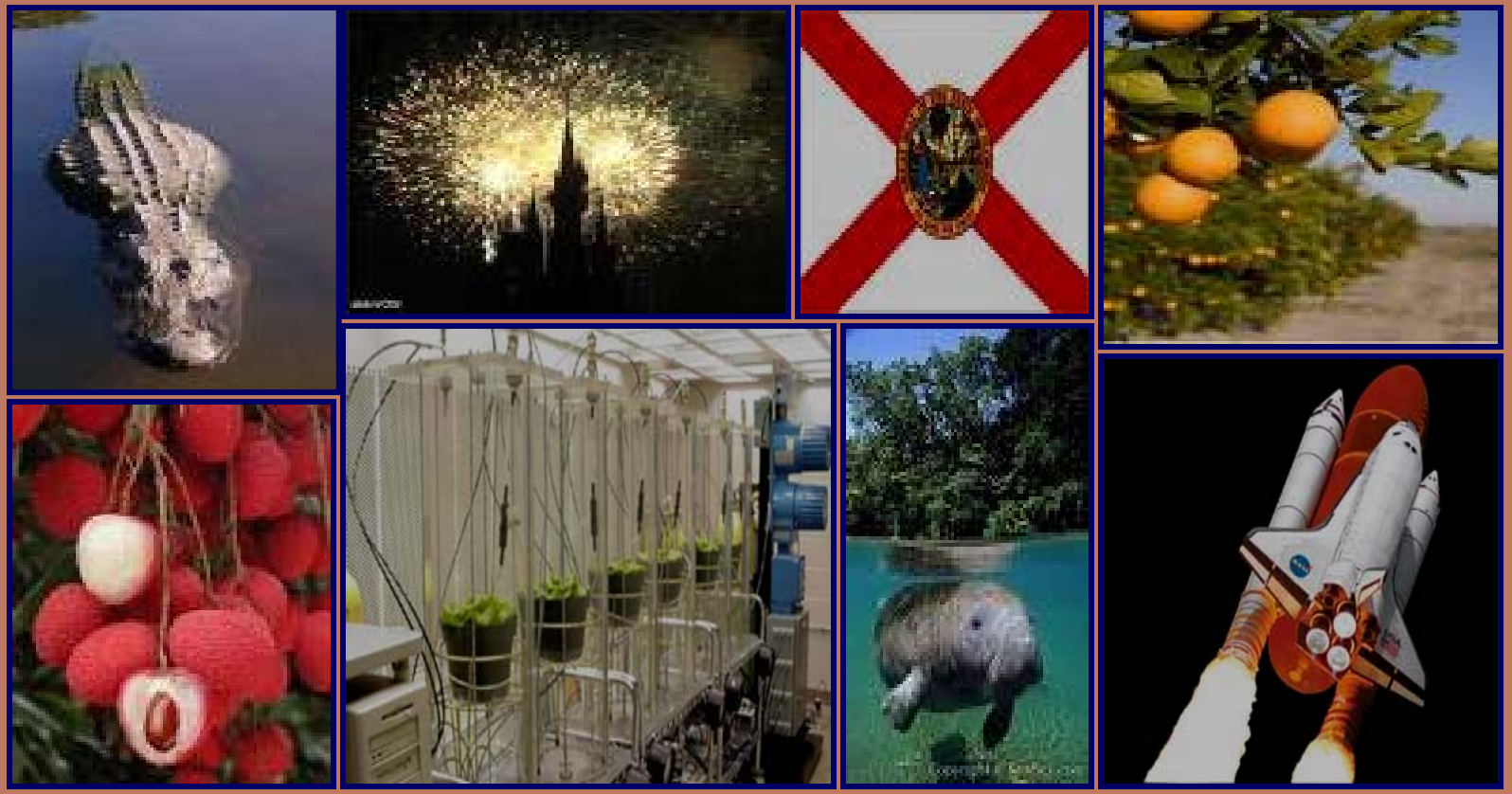
Electronic Data Archives

- Data retention should be compliant with the GLP regulations
  - 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

NAICC Annual Meeting

Orlando, Florida

January 21, 2010



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