

IR-4 HANDBOOK

DAN KUNKEL

IR-4 Advisories

- #2015-01 Storing and Maintaining Adjuvants (Spray Additives) for Use in IR-4 Field Residue Studies (Amended September 10, 2015)
- #2014-01 Maintaining Freezer Storage Systems at IR-4 Field and Laboratory Research Sites
- #2007-01: Shipping with Dry Ice and Training/Certification Guidance
- #2006-01: Inventory and Transfer of GLP Raw Data and Other Records to IR-4 Headquarters (HQ)
- #2005-02: Field Research Director Disposal of Field Data Book Copies
- #2005-01: Test Substance Container Disposal Website Approval Procedure (Amended Nov. 21, 2008)
- #2004-02: IR-4 Application Type Definitions
- #2004-01: Foliar Broadcast Spray Swath vs. Plot Width
- #2003-05: Weighing Field Trial and Processing Trial Residue Samples
- #2003-04: Test/Reference Substance Container Labels - Required Information
- #2003-03: Conflicting Chemistries in IR-4 Studies
- #2003-02: Test Substance Container Disposal
- #2003-01: Responding to FDB QA Findings

Training

- IR-4 Education and Training Committee (TC)- objective, composition, membership responsibilities
- Phoenix Proceedings February 2006
- GLP Training Opportunities
- San Antonio Workshop Results
- Operational Handbook
- 2004 Southern/North Central Region GLP Training Session
- IR-4 Field Data Book (FDB) Guidance Document
- Laboratory Guidance Document

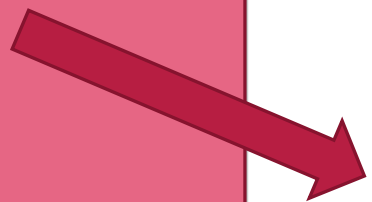
IR-4 Advisories/Training Events Links Upload Files

**OPERATIONAL HANDBOOK
OF IR-4
TO FULFILL THE
REQUIREMENTS OF EPA
FOR
GOOD LABORATORY PRACTICES**



The
IR-4
Project

Providing Safe and Effective Pest
Management Solutions for
Specialty Crop Growers



VERSION 7.0 01/06

THE FDB REVIEW TEAM...FROM IR-4 ASSESSMENT..

- Re-doing many of the sections relating to Field work..and responsibilities.

- **PREFACE**

- **PERSONNEL GUIDELINES FOR GLP COMPLIANCE**

- **GLP DEFINITIONS**

- Archives
- Protocol
- Quality Assurance Unit
- Sponsor
- Study
- Study Director
- Testing Facility

- **IR-4 DEFINITIONS**

- Field Research Director
- Laboratory Research Director
- Quality Assurance Coordinator
- Research Test Site
- Regional Field Coordinator
- Regional Laboratory Coordinator

- **INTER-RELATIONSHIPS**

- **SPECIFIC RESPONSIBILITIES**

- Non-compliance
- Generally Correctable
- Non-Correctable

- **INTERACTIONS OF PROGRAM PERSONNEL**

- **PROGRAM GUIDELINES FOR GLP COMPLIANCE**

- **STANDARD OPERATING PROCEDURES**

- **DATA REVIEW**

- **Field Data Book flow chart**

- **IR-4 GLP TRAINING PROGRAMS**

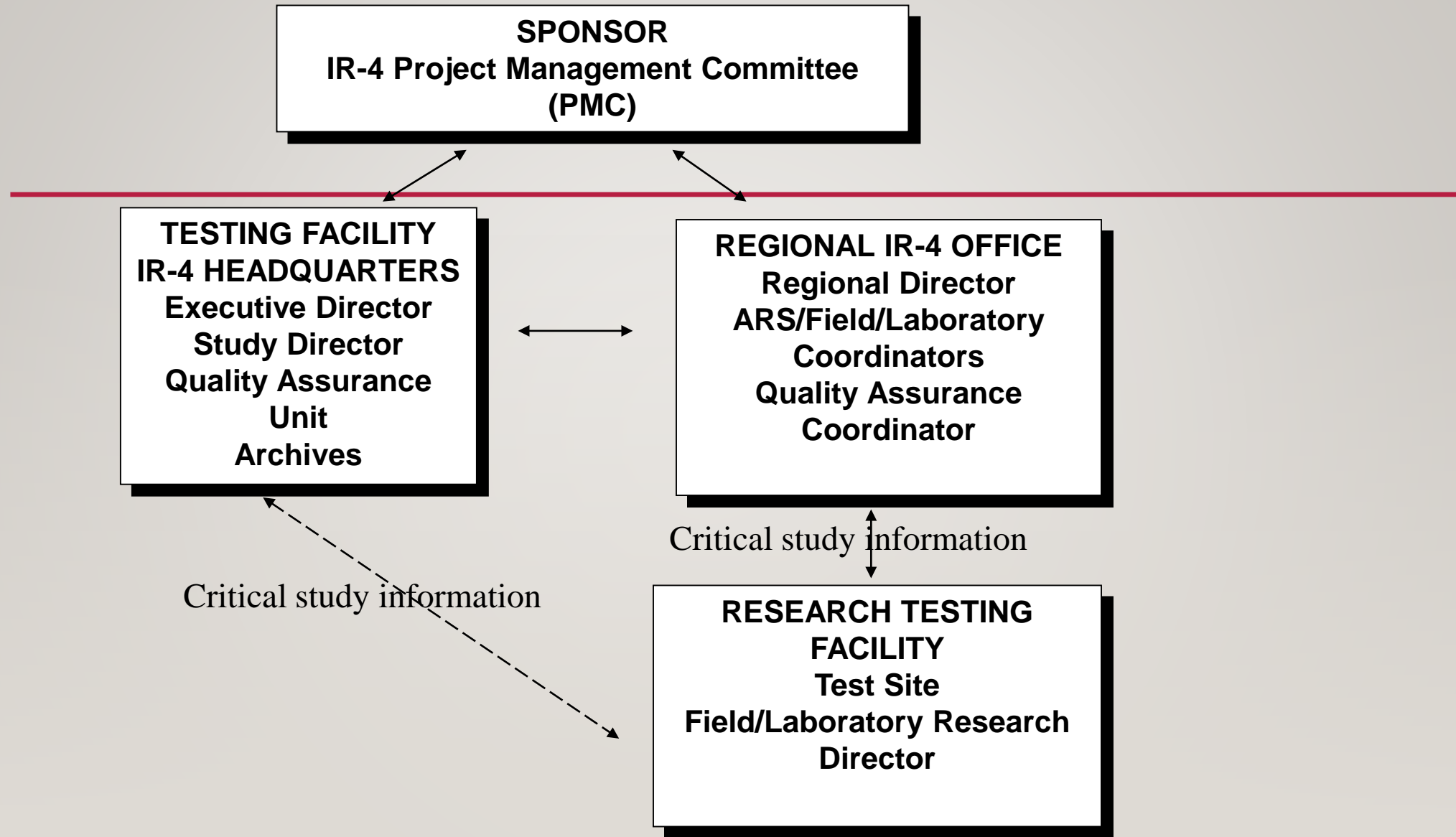
- **CHART 1: HIGHLIGHTS OF GLP RESPONSIBILITIES**

- **CHART 2: GLP COMMUNICATIONS FLOW CHART**

- **Appendix 1: GUIDELINES FOR ROLES & RESPONSIBILITIES**

- **Appendix 2: 30-MONTH TIMELINE**

GLP COMMUNICATIONS FLOW CHART



REGIONAL LABORATORY COORDINATOR

- This person assigns laboratory-testing sites within his/her region for residue analyses conducted by the leader laboratory, its satellites, and private contract laboratories

LABORATORY RESEARCH DIRECTOR

- A person with sufficient training and experience to be able to conduct the laboratory analysis and appoint adequate personnel to assure this function will be carried out for all studies. The LRD will report all deviations from the protocol or the SOPs to the SD.
- Do we want to add... Are responsible for maintaining a GLP compliant Facility

Now that there are no more satellite labs, RLC and LRD are usually the same person

- **SPECIFIC RESPONSIBILITIES**

- To assist SDs in meeting their responsibilities, the following personnel will be held accountable that the data generated by IR-4 personnel fulfill the requirements of GLP:

- I. **Regional Laboratory Coordinator (RLC)** for residue analyses conducted by the regional laboratory, its satellites, and private contract laboratories.

- A facility that cannot conduct research in compliance with GLP will be terminated as a test location for IR-4. Assurances must be made that a facility can meet the requirements of GLP and Residue Chemistry Test Guidelines OPPTS 860.1500 Crop Field Trials before any IR-4 GLP research is initiated; determinations will be made based on QA monitoring audits/reports as well as Regional Field coordinator assessment.

- **Non-compliance: Generally Correctable:** some examples...

- X. Failure to document the replacement of the Field or Laboratory Research Director.

- X. Failure to have evidence of a characterization of the test, control, or reference substances. This information may be held by the company or IR-4 HQ but some documentation must be available to show possession.

- X. Failure to record some of the required raw data.

- **Non-compliance: Non-Correctable:**

- X. Failure to designate a Field or Laboratory Research Director when study is in progress.

- X. Starting or completing a trial without an authorized protocol.

LABORATORY:

- The laboratory facilities are to be designated as acceptable for the procedures required by the Regional Director or the ARS chemist in charge at the location where the analysis are to be conducted. Since these facilities are under the control of the institution where the research is being performed, no uniform equipment requirements are possible. The regulations only require that separate space be provided as needed for the performance of the procedures required.

OTHER

- **Test/Reference Substances**
- **Supply Storage**
- **Devices to Measure or Record Weather Data**
- **Pesticide Application Equipment**
- **Scales**

DATA REVIEW

- *ANALYTICAL SUMMARY REPORTS*: The LRD completes analysis of the residue samples and prepares the Analytical Summary Report (ASR). The ASR is audited by the Regional or Laboratory QAC who generates an audit and sends it via eQA to LRD/SD for responses and corrections as needed, to TFM for review. Findings are addressed by the Laboratory Research Director. The LRD can consult with the SD to address findings. Once corrections and responses are completed, accepted and signed by SD and TFM, QA is notified of a closed audit and acknowledges that it's closed. After completion, the ASR is sent to the Registration Manger at IR-4 HQ. For ARS reports, after the QA audit is complete and findings addressed, the ASR will be sent to the ARS IR-4 Director for review, then on to the Registration Manger at IR-4 HQ. At IR-4 HQ, the ASR is forwarded to the SD for review, used in preparation of the final report, and archiving.



IR-4 REQUIRED TRAINING FOR NEW FRDS

BEFORE CONDUCTING GLP RESEARCH

- Basic GLP training required as soon as possible, before beginning any field trials. Follow up with a second basic GLP training after new FRD has gained some experience to help solidify understanding and GLP perspectives.
- Visit one relevant established FRD and the RFC for hands-on training and question/answer time (repeat as needed or desired).
- Regional QA personnel meets with the new FRD for the purpose of training and orienting them to the GLP procedures and expectations related to IR-4 field trials
- Make FDBs available as teaching tools and references regarding applications, crops, methodologies.
- Create a support system for answering questions and providing mentoring and guidance (FRDs, RFC, QA, others)
- Provide “quick” QC reviews on “first” notebooks to insure understanding of trial notebook and requirements.
- Training references and IR-4 orientation documents for FRD training and orientation to IR-4 are available at:
<http://ir4.rutgers.edu/trainingadvisories.html>
- Attend training as available, such as webinars, hands on training at national and regional level.

Do we need something like this for new lab folks ???

APPENDIX I: GUIDELINES FOR ROLES & RESPONSIBILITIES OF IR-4 PERSONNEL

- **Role of the RLCs/Laboratory Chemists at Satellite and ARS Labs**
 - Coordinate and monitor residue analyses
 - Provide leadership and oversight for laboratory personnel at local facilities
 - Ensure lab capabilities and facilities are adequate
- **Responsibilities of the RLC and Laboratory Chemists**
 - Supervise analyses
 - Maintain GLP compliance in labs (generate SOPs, training records, etc.)
 - Select projects for the region
 - Manage laboratory budget and resources
 - Prepare Analytical Summary Reports
 - Communicate study status and progress to RDs and SDs