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4.5	07 (03/15)	Protocol Change (Amendment/Deviation) Development and Distribution
4.6	01 (03/15)	SOP Deviations – Documentations, Authorization and Distribution
4.7	01 (01/10)	Terminating an IR-4 Project GLP Field Trial
4.8	01 (01/10)	Canceling an IR-4 Project GLP Study
5.0	02 (01/10)	Responses to Quality Assurance (QA) Findings: Generation, Handling and Evaluation for GLP Compliance
5.1	05 (03/15)	Data Receipt and Log-In Procedures
5.2	Deleted	Combined with SOP 5.3 to generate SOP 5.4
5.3	Deleted	Combined with SOP 5.2 to generate SOP 5.4
5.4	00 (04/07)	IR-4 Headquarters Review of Study Documents
6.0	07 (03/15)	Final Report Development
6.1	07 (03/15)	Pesticide Petition Development and Review
6.2	Deleted	Incorporated in SOP 6.1
6.3	06 (03/15)	Draft Petition or Final Report Submission to Registrant(s) for Review
6.4	07 (03/15)	Pesticide Petition Submission to the United States Environmental Protection Agency (EPA)
6.5	04 (01/10)	Petition and Final Report Tracking
6.6	03 (01/10)	Amending Pesticide Petitions and Data Volumes
6.7	03 (01/10)	Communication and Tracking of EPA Responses Regarding IR-4 Project Tolerance Petitions

SOP #	Revision # (Date)	Title
7.1	11 (03/15)	Access and Archiving: Active Study Files, Archived Study Files, Facility Files, Certificate of Analysis Files, Confidential Files, and Characterization Reports of Test and Reference Substances
7.2	Deleted	Incorporated into SOP 7.1
7.3	Deleted	Incorporated into SOP 7.1
7.4	03 (09/07)	Archive Procedures: Study File Location, Study File Retrieval, Study File Re-entry, Archive Log Book, Archival Entry without Study File Retrieval
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8.0	03 (01/10)	Quality Assurance Unit (QAU), Terms and Responsibilities
8.1	~~07~~ (10/13)	QA Facility Inspections of the IR-4 Headquarters (Retired Oct.7)
8.2	07 (10/13)	Protocol Audit Procedures and Routing
8.3	07 (10/13)	Quality Assurance (QA) – Facility Inspections
8.4	06 (10/13)	Quality Assurance (QA) – In-Life Inspection of Field Trials
8.5	08 (10/13)	Quality Assurance (QA) – Field Raw Data Audits.
8.6	06 (10/13)	Quality Assurance (QA) – In-Life Inspection of the Analytical Phase of a Study
8.7	06 (10/13)	Quality Assurance (QA) – Analytical Raw Data Audits
8.8	05 (10/13)	Quality Assurance (QA) – The Analytical Summary Report Review (ASR)
8.9	07 (10/13)	Quality Assurance (QA) – The Final Reports and Study File Review
8.10	03 (04/07)	Quality Assurance (QA) – Training of New Quality Assurance Personnel

SOP #	Revision # (Date)	Title
8.11	06 (10/13)	Routing Of Incoming Quality Assurance Reports
8.12	04 (01/10)	Protocol / Protocol Change Distribution to the Quality Assurance Unit (QAU)
8.13	04 (01/10)	HQ Quality Assurance Files: Organization & Management
8.14	04 (10/13)	Quality Assurance Audit of Second Draft Final Reports, Preparation of the QA Statement and Metrics Evaluation
8.15	02 (03/15)	Scheduling by Headquarters (HQ) QA of Field Data Books (FDB) for Auditing at HQ or for Transfer of Books to External QA Auditors
8.16	00 (10/13)	Quality Assurance eQA system – Installation, maintenance, use and retention of records
8.17	00 (10/13)	Generation and distribution of QA reports using the eQA system
8.18	00 (10/16)	Quality Assurance (QA) – Contributing Scientists Report Audit
9.0	00 (07/06)	Conducting non IR-4 Sponsored Studies

SOP #: 1.1

AUTHORS: K. A. Hackett-Fields, J. J. Baron

REVISION #: 03

EFFECTIVE DATE: January 31, 2010

TITLE: **General Requirements for IR-4 Project Headquarters Standard Operating Procedures (SOP's) for Good Laboratory Practice (GLP) Research Projects.**

PURPOSE: To provide information common to all IR-4 Project Headquarters SOP's for GLP Research Projects and define terms common to these SOP's.

SCOPE: All IR-4 Project Headquarters SOP's for GLP Research Projects. The purpose of the SOP's is to: (1) ensure the quality and integrity of data, (2) maintain compliance with EPA requirements for Good Laboratory Practice Standards for all studies conducted by the IR-4 Project that support or are intended to support applications for research or marketing permits for pesticide products regulated by the EPA, and (3) maintain consistency in operations at IR-4 Project Headquarters.

PROCEDURES:

1) The following definitions apply to all IR-4 Headquarters SOP's for GLP Research Projects:
IR-4, IR-4 Project – The Interregional Research Project No. 4.
SOP, SOP's – IR-4 Project Headquarters Standard Operating Procedure(s) for GLP Research Projects
EPA – United States Environmental Protection Agency
GLP – Good Laboratory Practice
GLP Research Projects – studies conducted that support or are intended to support applications for research or marketing permits for pesticide products regulated by the EPA.

2) IR-4 Project Headquarters SOP's will be reviewed at a minimum of once every two years to determine if revisions are needed. Revisions will follow current version of IR-4 Headquarters SOP # 1.4.

3) Training on these SOP's will be provided by IR-4 Project Headquarters Management or their designee(s).

4) IR-4 Project Headquarters Management or their designee must authorize all deviations from the IR-4 Project Headquarters SOP's that could significantly affect the integrity of GLP research projects conducted by IR-4. The deviation must be signed and dated by the person citing and preparing the deviation, then be approved, signed, and dated by the IR-4 Executive Director. The deviation will be filed in the IR-4 Project Headquarters SOP archive file and/or appropriate study file.

5) Minor revisions may be recommended at any time by staff members for consideration during the next scheduled review period. The current Chair of the SOP Committee will receive and make note of the recommendations.

Prepared by: K. Valentin-Le Date: Jan. 6, 2010

Approved by: Jerry J Baron Date: 8 JAN, 2010

SOP #: 1.2

AUTHORS: K. A. Hackett-Fields, W. P. Barney, J. S. Corley and J. J. Baron

REVISION #: 04

EFFECTIVE DATE: January 31, 2010

TITLE: **General Numbering System for IR-4 Headquarters Standard Operating Procedures (SOP's) for GLP Research Projects.**

PURPOSE: To provide information relevant to the numbering system used in organizing the IR-4 Headquarters SOP's.

SCOPE: All IR-4 Headquarters SOP's for GLP Research Projects.

PROCEDURES: SOP's are numbered and organized into subject groups in the following manner:

1. Standard Operating Procedures
2. Personnel
3. Miscellaneous
4. Protocol preparation, Study Conduct and Tracking
5. Data Handling
6. Petitions
7. Archives
8. Quality Assurance
9. Non IR-4 Sponsored Studies

When a new SOP is being developed, the Chair of the SOP Committee will assign an SOP number for the draft as appropriate. When a SOP is deleted, its number will remain in place in the Index, and will not be re-assigned.

Prepared by: _____ Date: Jan. 6, 2010

Approved by: _____ Date: 8 JAN 2010

SOP #: 1.3

AUTHORS: K. A. Hackett-Fields and J.J. Baron

REVISION #: 03

EFFECTIVE DATE: January 31, 2010

TITLE: **Format of IR-4 Project Headquarters SOP's for Use in GLP Research Projects.**

PURPOSE: To assure a uniform format in the development of IR-4 Headquarters SOP's for Use in GLP (Good Laboratory Practice) Research Projects.

SCOPE: All IR-4 Headquarters Standard Operating Procedures for GLP Research Projects.

PROCEDURES: 1) The heading, "IR-4 HEADQUARTERS STANDARD OPERATING PROCEDURES FOR GLP RESEARCH PROJECTS" will appear at the top left of each page of every SOP. The number of each page will be at the top right of each page, directly beneath the SOP #. The numbering of pages is to be expressed in the following manner: Page X of X

2) Specific sections of each SOP are to be titled and listed in the following manner and order:

SOP #:
AUTHOR(S):
REVISION #:
EFFECTIVE DATE:
TITLE:
PURPOSE:
SCOPE:
PROCEDURES:

3) The SOP # will be divided into three parts. The part of the SOP # before the period will refer to the general subject group as described in SOP # 1.2. The part of the SOP # following the period will denote the sequential number assigned to specific SOP's within each general subject group. A two-digit number following the colon (:) will be used to identify the version of the document (see point 5).

The SOP #, including the revision #, is to be used when referring to specific SOP's, and is to appear at the top right (just above the page number) of every page of the SOP.

4) The AUTHOR(S) of the SOP will be so noted, example J.M. Smith. Names will be added as "first author" when SOPs are revised by assigned personnel. If former authors are no longer employed at IR-4 HQ, their names will be dropped.

5) The REVISION # is a two digit number that identifies the SOP as either an original version or an updated version. The number for original versions will be 00. All updates will be numbered to identify how many revisions have been made. For example, the first REVISION # for any SOP will be 01, the second will be 02, the third will be 03, and so on.

6) The EFFECTIVE DATE will be the date assigned by management for use of the SOP.

7) The TITLE is a brief statement identifying the topic of the SOP and shall be in bold type.

8) The PURPOSE is a brief statement identifying the operational result of adherence to the subject SOP.

9) The SCOPE identifies the extent to which the SOP applies.

10) The section, PROCEDURES, describes exactly how each activity addressed by the SOP will be conducted. As appropriate, number each paragraph (1, 2, 3, etc.) and specific steps if necessary (as a), b), c), etc.) for reference purposes.

11) The last page of each SOP will have prompts for the signature of the person preparing or revising the SOP and the approval signature of the IR-4 Executive Director, including the signature dates.

12) An SOP is approved when signed and dated by the IR-4 Executive Director, regardless of its EFFECTIVE date.

Prepared by: K. Kuhlman-L Date: Jan. 6, 2010

Approved by: Jerry J. Baron Date: 8 JAN 2010

SOP #: 1.4

AUTHORS: D. Carpenter, W.P. Barney, T. W. Barkalow, and J. J. Baron

REVISION #: 07

EFFECTIVE DATE: April 8, 2015

TITLE: **Reviewing, Creating, Revising or Amending IR-4 Project Headquarters' SOPs for GLP Research Projects.**

PURPOSE: To assure IR-4 Project Headquarters' SOPs for GLP Research Projects accurately represent the conduct of administrative, technical and regulatory compliance aspects of IR-4 Project GLP Research Projects at IR-4 Project Headquarters.

SCOPE: All current and potential IR-4 Headquarters' SOPs for GLP Research Projects.

PROCEDURES:

1) All current IR-4 Project Headquarters' SOPs will be reviewed overall at least once every three years. The IR-4 Project Executive Director has the authority to direct SOP revision outside of the 3-year cycle.

2) Establishment, revision or review of IR-4 Project Headquarters' SOPs will be coordinated by the IR-4 Project SOP Committee, as designated by Management. The following guidance will assist the Committee in carrying out the operations when an SOP update is directed by Management:

a) Any SOP with an amendment since the prior review period will be updated to include the change(s) in the body of the SOP, after assuring the amended language is current.

b) An all-Staff invitation for comment on any procedure and/or suggestion of any new SOPs; a two-week period is recommended.

c) Following this, Primary Author reviews for updates, or suggestions for a new SOP, will be requested. Any comments received from all-Staff or other sources will also be forwarded to the Primary Author at this time.

3) The Committee then reviews input and develops drafts to include appropriate revision(s) in bold italics or similar means, to distinguish the proposed change(s).

4) For each SOP that the Committee determines does not require revision, a confirming review must be performed by Management. This will be documented using initials and date adjacent to the SOP title, on a specially-formatted Index. The original of this review index will be maintained in the SOP Archive File. See Appendix A for an example of the index.

5) Management will determine whether a consensus meeting (peer review) is needed. If needed, it will be scheduled by the SOP Committee Chair. Where appropriate due to the nature of the SOP, a limited staff review will be offered instead. Input by other staff will be incorporated into the draft(s) to reflect the group consensus. Attendance is optional but this is the opportunity for suggesting changes.

Following review of the changes, an updated copy of the new or revised SOP(s) will be submitted to the staff electronically for final review.

6) As determined by the Executive Director, Management will conduct a review of the proposed SOP modifications with the SOP Chair.

7) The SOP is approved when signed and dated by the IR-4 Project Executive Director. To ensure compliance with the new or revised SOP, a training session will be scheduled with attendance documented on a form listing applicable SOPs. This form will be copied and placed in individual training record files.

a) The Effective Date is the date after which a SOP must be followed. The Effective Date may or may not be the day which the SOP is approved. The effective date can be proposed by members of the IR-4 HQ SOP Committee and approved by Management.

b) The original, paper copy of all IR-4 Project Headquarters' SOPs, historic and current, must be archived in the Archive SOP File. The Archive SOP File shall be maintained by the QA Manager.

c) Paper copies of IR-4 Project Headquarters' SOPs must be distributed to IR-4 Project Headquarters staff having responsibility as Management, Study Director and Quality Assurance staff as necessary. See the current version of SOP 1.5 for specific distribution instructions.

8) Amending an SOP

a) An IR-4 Project Headquarters' SOP may be amended at any time. When problems or the need to update a procedure are noted by any Staff member, the IR-4 Project Executive Director will be notified. It will then be determined by the Executive Director whether this amendment needs to be made.

b) The change must be clearly explained in a memo that includes the word "Amendment" at the top of the page, the SOP number and revision number, and date that the amendment becomes effective. This will be distributed to appropriate Staff in accordance with the current version of SOP 1.5.

c) The original of the SOP amendment must be archived in the Archive SOP File with the original SOP.

d) Paper copies of IR-4 Project Headquarters' SOP amendment must be distributed to IR-4 Project Headquarters staff having responsibility as Management, Study Director and Quality Assurance staff as necessary.

9) Creation of New SOPs

a) Creation of new IR-4 Headquarters' SOPs will also be coordinated by Management with the IR-4 HQ SOP Committee Chair. This may or may not be part of the routine cycle of SOP review. The SOP Committee Chair will verify with the Executive Director that a new procedure is appropriate.

b) Once the new SOP is approved, the SOP Committee Chair will assign an SOP number. A draft copy will be prepared following the format described in the most current version of IR-4 Project Headquarters' SOP # 1.3.

c) The draft of any new or revised SOP will be distributed to those IR-4 Project staff having responsibility as Management, Study Director, staff for GLP Research Projects, and to Quality Assurance staff as necessary for peer review. If the SOP is a QA SOP that affects members of the IR-4 QAU staff not at IR-4 HQ, the draft will also be distributed to QA Coordinators and full time QA personnel.

d) The process for final revision, training and distribution of a new SOP are the same as described above.

Prepared by: Debra Carpenter Date: March 23, 2015

Approved by: Jerry J Baron Date: 20 March 2015

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1.3	03 (01/10)	Format of IR-4 Headquarters SOP's for Use in GLP Research Projects
1.4	07 (03/15)	Review, Creating, Revising or Amending IR-4 Project Headquarters' SOP's for GLP Research Projects
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2.2	05 (03/15)	Personnel Training and Experience Records
2.3	03 (01/10)	Personnel Job Descriptions
2.4	01 (01/10)	Qualifications and Hiring of Temporary Professional Staff
3.1	Delete	- -
3.2	Delete	- -
3.3	04 (03/15)	Procedures To Follow For Decommissioning of IR-4 Test Sites
3.4	04 (03/15)	EPA Inspection Procedures
4.1	09 (03/15)	Protocol Development and Distribution for GLP Research Projects
4.2	03 (01/10)	Protocol Development and Distribution for Pesticide Performance Studies
4.3	Delete	Incorporated into SOP 4.1:03

SOP #	Revision # (Date)	Title
4.4	07 (03/15)	Master Study Schedule (Master Schedule)
4.5	07 (03/15)	Protocol Change (Amendment/Deviation) Development and Distribution
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5.3	Deleted	Combined with SOP 5.2 to generate SOP 5.4
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6.0	07 (03/15)	Final Report Development
6.1	07 (03/15)	Pesticide Petition Development and Review
6.2	Deleted	Incorporated in SOP 6.1
6.3	06 (03/15)	Draft Petition or Final Report Submission to Registrant(s) for Review
6.4	07 (03/15)	Pesticide Petition Submission to the United States Environmental Protection Agency (EPA)
6.5	04 (01/10)	Petition and Final Report Tracking
6.6	03 (01/10)	Amending Pesticide Petitions and Data Volumes
6.7	03 (01/10)	Communication and Tracking of EPA Responses Regarding IR-4 Project Tolerance Petitions

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7.3	Deleted	Incorporated into SOP 7.1
7.4	03 (09/07)	Archive Procedures: Study File Location, Study File Retrieval, Study File Re-entry, Archive Log Book, Archival Entry without Study File Retrieval
7.5	00 (06/11)	Off-Site Archiving & Access: Archived Study Files
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8.1	~~07~~ (10/13)	QA Facility Inspections of the IR-4 Headquarters (Retired Oct.7)
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8.3	07 (10/13)	Quality Assurance (QA) – Facility Inspections
8.4	06 (10/13)	Quality Assurance (QA) – In-Life Inspection of Field Trials
8.5	08 (10/13)	Quality Assurance (QA) – Field Raw Data Audits.
8.6	06 (10/13)	Quality Assurance (QA) – In-Life Inspection of the Analytical Phase of a Study
8.7	06 (10/13)	Quality Assurance (QA) – Analytical Raw Data Audits
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8.9	07 (10/13)	Quality Assurance (QA) – The Final Reports and Study File Review
8.10	03 (04/07)	Quality Assurance (QA) – Training of New Quality Assurance Personnel

SOP #	Revision # (Date)	Title
8.11	06 (10/13)	Routing Of Incoming Quality Assurance Reports
8.12	04 (01/10)	Protocol / Protocol Change Distribution to the Quality Assurance Unit (QAU)
8.13	04 (01/10)	HQ Quality Assurance Files: Organization & Management
8.14	04 (10/13)	Quality Assurance Audit of Second Draft Final Reports, Preparation of the QA Statement and Metrics Evaluation
8.15	02 (03/15)	Scheduling by Headquarters (HQ) QA of Field Data Books (FDB) for Auditing at HQ or for Transfer of Books to External QA Auditors
8.16	00 (10/13)	Quality Assurance eQA system – Installation, maintenance, use and retention of records
8.17	00 (10/13)	Generation and distribution of QA reports using the eQA system
9.0	00 (07/06)	Conducting non IR-4 Sponsored Studies

SOP #: 1.5

AUTHORS: K. A. Hackett-Fields, W.P. Barney and T. Barkalow

REVISION #: 02

EFFECTIVE DATE: January 31, 2010

TITLE: **Notification, Distribution and Acknowledgement of Receipt of IR-4 HQ SOPs for GLP Research Projects.**

PURPOSE: To assure IR-4 Project Headquarters' SOPs are distributed to and acknowledged by the appropriate persons in the IR-4 Program.

SCOPE: All current and potential IR-4 Headquarters' SOPs for GLP Research Projects.

PROCEDURES:

1) Once a HQ SOP has been approved by Management it is to be distributed to appropriate IR-4 personnel, the new SOP inserted and/or the old SOP removed and the revised SOP inserted, into individual's SOP manual.

2) When an SOP is issued or revised the SOP index will be updated and distributed along with the recently approved SOP. The old index is to be removed and the new SOP index inserted into each individual's SOP manual.

3) It is the responsibility of the IR-4 HQ SOP Committee Chair to distribute the copies of the newly approved SOPs, the updated SOP index along with an SOP Alert notification and an acknowledgement of receipt document to the appropriate individuals.

4) The newly approved SOPs and updated SOP index are to be forwarded to staff as hard copies. An SOP Alert cover letter is to be forwarded with the SOPs which will act as an inventory of what is being sent (see Appendix A for an example letter). A SOP acknowledgement letter is also forwarded with the SOP package (see Appendix B for an example acknowledgement form).

5) Upon receipt of the SOP distribution package the contents should be verified against the inventory. The new SOP index is to replace the current index and the new and/or revised SOP(s) inserted into the manual. The acknowledgement form is to be signed and dated by the recipient and returned to the HQ originator as verification of receipt of the SOP package. A SOP distribution tracking list (Appendix C has an example form) will be generated when SOP packages are forwarded. These distribution lists will be reviewed periodically and the individuals that have not completed their acknowledgement forms will be contacted for update information.

6) The original SOP alert cover sheet, the completed SOP acknowledgement signature forms and the SOP distribution tracking form will be archived for retention in the SOP files in the Archive Room.

7) The recipients fall into two groups: 1) IR-4 HQ GLP participating employees (This group will receive all HQ SOPs generated or revised); 2) Other IR-4 participants (This group might receive a full set of HQ SOPs or the QA portion only). See Appendix D for details.

Prepared by: _____ Date: Jan. 6, 2010

Approved by: _____ Date: 8 JAN 2010

Date Here

TO:

FROM:

CC:

SUBJECT: Revised SOPs : AN SOP ALERT

The following SOP(s) have been signed by Management. Replacement copies for your SOP manuals are enclosed. Please insert all new and replace all old SOPs in your SOP manuals. Please read the new and updated SOP(s).

Please sign and date the enclosed receipt form and forward it back to my attention for retention.

Please review the SOP Index and confirm that your QA SOP packages contain the latest versions of the SOPs.

This package contains the following SOPs (identified by SOP number and revision)

If you have any questions, please contact me. Thank you.

These SOPs were issued/revised in order to (add reason here)

SOP Distribution of New/Revised SOPS – (Date Here)

SOP .....was/were approved by Management. The revised SOP and revised index is being issued as part of this update.

Please indicate below the date you installed the revised SOP and the new index into your SOP binders. Provide your dated signature and printed name (replaced by). Return this acknowledgement form to my attention for retention.

Thank you

Date Replaced: _____

Replaced By: _____
Signature and Date

_____
Printed Name

Documentation of training will be generated and placed into the personnel training file. Please return signed acknowledgement form to my attention.

Thank you,

Bill Barney, IR-4

SOP Distribution of New/Revised SOP – (Enter Date Here)

SOP(s):

Date of return of signature page

IR-4 Headquarters

Arsenovic
Barkalow
Baron
Barney
Braverman
Burke
Carpenter
Corley
Dorschner
Ferrazoli
Forder
Harrison
Homa
Hackett-Fields
Infante
Kunkel
Leonard
Lennon
Malamud-Roam
Nagahiro
Patel
Samoil
Sims
Starner
Switek
Thompson, D
Thompson, J.

IR-4 QAU and Canadian partners:

Adkins
Anderson
Beran
Chen
Knight
Kanagalingam
E. M. Lopez
McFarland
Penny
Raghavan

Other QA lab or field receive QA SOPs only

J. Campbell
Hornbuckle
Jensen
Killilea

IR-4 HQ full SOP sets

B. Anderson
M. Arsenovic
T. Barkalow
B. Barney
J. Baron
M. Beran
M. Braverman
U. Burke
D. Carpenter
Z. Chen
J. Corley
K. Dorschner
C. Ferrazoli
J. Forder
L. Harrison
K. Hackett-Fields
K. Homa
D. Infante
K. Knight
D. Kunkel
R. Leonard
G. Lennon
J. McFarland
K. Malamud-Roam
S. Nagahiro
B. Patel
K. Samoil
K. Sims
V. Starner
T. Switek
D. Thompson
J. Thompson

Laboratory, Contract or Canadian QA Participants

R. Adkins - Full set of HQ SOPs
J. Campbell - QA SOPs only
R. Hornbuckle - QA SOPs only
B. Jensen - QA SOPs only
K. Kanagalingam - Full set of HQ SOPs
D. Killilea - QA SOPs only
E.M. Lopez - Full set of HQ SOPs
H. Penny - Full set of HQ SOPs
S. Raghavan – QA SOPs only

SOP #: 2.1

AUTHORS: K.A. Hackett-Fields, V. R. Starner, and K. W. Dorschner

REVISION #: 03

EFFECTIVE DATE: January 31, 2010

TITLE: **Personnel Qualifications.**

PURPOSE: To ensure that personnel involved in the activities and functioning of IR-4 Headquarters (HQ) have the proper education, training, and experience necessary for them to carry out the jobs for which they have responsibility.

SCOPE: This SOP applies to all employees at IR-4 HQ who are performing duties directly involved with the Good Laboratory Practice Standards.

PROCEDURES:

1) It is the responsibility of the IR-4 Executive Director to ensure that individuals hired to work for IR-4 HQ have the proper education, training, and experience necessary for them to carry out the jobs for which they have responsibility as outlined in the applicable job description.

2) It is the responsibility of the IR-4 Executive Director to determine that the number of employees at IR-4 HQ is sufficient to ensure the quality of pesticide data packages and pesticide petitions that are processed and generated at and/or through IR-4 HQ.

3) It is the responsibility of the IR-4 Executive Director to ensure that employees understand their job responsibilities.

   a) Job descriptions will be reviewed, with the employee documenting the date when the qualifications were read and understood.

3), continued

b) SOPs applicable to the position will be thoroughly reviewed, with the employee documenting the date when the procedure was read and understood.

c) Specific training will be provided as necessary over the course of employment.

Prepared by: _____ Date: Jan. 6, 2010

Approved by: _____ Date: 8 JAN 2010

SOP #: 2.2

AUTHORS: K. W. Dorschner and V. R. Starner

REVISION #: 05

EFFECTIVE DATE: April 8, 2015

TITLE: **Personnel Training and Experience Records.**

PURPOSE: To ensure that adequate personnel records are maintained at IR-4 Headquarters (HQ), verifying that requirements specified in the current version of SOP # 2.1 are being satisfied.

SCOPE: This SOP applies to all personnel employed at the IR-4 HQ, as specified in the current version of SOP # 2.1.

PROCEDURES: 1) The IR-4 Executive Director is responsible for ensuring that a file of up-to-date training and experience records is maintained for all personnel at IR-4 HQ. Typical records may include:

- CV and/or Resume
- Job description (see current version of SOP 2.3)
- IR-4 HQ SOP training documentation; prior training records
- Certificates of attendance/participation from training sessions

2) The IR-4 Executive Director has designated the Assistant Director, HQ QA as the custodian of the training and experience records. The Assistant Director, HQ QA will ensure that:

a) At a minimum, each IR-4 HQ employee reviews his/her training and experience records at least once every year (generally during the time of performance evaluation). If necessary, the employee will update these records to provide an accurate representation of his/her actual training records and CVs.

b) Records are initialed/dated after each review and/or updating. Prior versions will remain in the employee's folder.

3) Personnel training and experience records may be in any format, providing all information is accurate and up-to-date. Updated records and new certificates of training may be filed by the employee, or provided to the QAU via the routing bin for filing.

Prepared by: _____ Date: 3/20/2015

Approved by: _____ Date: 20 March 2015

SOP #: 2.3

AUTHORS: K.A. Hackett-Fields, V. R. Starner and K.W. Dorschner

REVISION #: 03

EFFECTIVE DATE: January 31, 2010

TITLE: **Personnel Job Descriptions.**

PURPOSE: To describe the creation and handling of the job responsibility and scope descriptions for the IR-4 Headquarters (HQ) Staff.

SCOPE: This SOP is to apply to all personnel employed at the IR-4 HQ, as specified in the current version of SOP # 2.1.

PROCEDURE:

1) It is the responsibility of the IR-4 Executive Director to ensure that accurate job descriptions are maintained at IR-4 HQ. Detailed descriptions of all routine duties and responsibilities of a position will be developed and utilized during interviews, hiring, training, performance review, or as needed to maintain a common awareness of expectations.

2) Job descriptions will be maintained in each employee's personnel file at IR-4 HQ.

3) Management and the employee's supervisor will approve, and each employee will initial/date their job description confirming that they understand their responsibilities. This will be done during the first few days of employment and after any revision in the job description.

Prepared by: _____ Date: Jan. 6, 2010

Approved by: _____ Date: 8 JAN 2010

SOP #: 2.4

AUTHOR: K. A. Hackett-Fields

REVISION #: 01

EFFECTIVE DATE: January 31, 2010

TITLE: **Qualifications and Hiring of Temporary Professional Staff**

PURPOSE: To ensure that all personnel involved in the activities and functioning of IR-4 Headquarters (HQ) have the proper education, training, and experience necessary for them to carry out their assignments.

SCOPE: All Temporary Professional Staff (TPS) including consultants and staff involved in the review and/or auditing of data and in data package and/or petition preparation. Exempted from the scope of this SOP are computer consultants and others responsible only for clerical duties.

PROCEDURES:

1. If there is a need for additional professional services and the Executive Director concurs that the number of employees at HQ is not sufficient to ensure data/report quality and adherence to schedule, the process of hiring TPS may be authorized.

2. It is the responsibility of the Executive Director to ensure that TPS hired to work for HQ are qualified to perform, or assist with, a given job description. Documentation of education, training, and experience for the individual(s) will be supplied to the Executive Director, or designate, for review by the Manager of the HQ section requesting support.

3. The Executive Director will approve or make the selection, and authorize funds for the contracted work. In addition, a standard letter of agreement will be prepared, to include the following points:

(1) The first assignment performed by the assisting professional will be reviewed by the Manager requesting assistance.

(2) HQ has the right to terminate the arrangement at any time based upon need, or dissatisfaction with the performance of the contracted individual(s).

4. In order to evaluate performance, the initial assignment to the TPS may be evaluated by the Manager of the department requesting assistance, and a verbal report will be given to the Executive Director or designee.

5. All those hired for assisting in any of the functions outlined in this SOP will provide HQ with at least the following documents for the permanent file of employee qualifications, prior to beginning work:

a. Resume and/or Curriculum Vita (CV).
b. Full contact information (address, phone, e-mail, fax).
c. Emergency contact information (individuals working at HQ).

Prepared by: K. Juliette-Le Date: Jan. 6, 2010

Approved by: Jerry J. Baum Date: 8 Jan 2010

SOP #: 3.3

AUTHORS: T. W. Barkalow and J. Forder

REVISION #: 04

EFFECTIVE DATE: April 8, 2015

TITLE: **Procedures to follow for Decommissioning of IR-4 Project Test Sites.**

PURPOSE: To establish procedures for decommissioning an IR-4 Project test site, documenting the event, and notifying the EPA.

SCOPE: Regional Offices and all IR-4 test sites conducting GLP research solely for IR-4, and IR-4 HQ personnel.

PROCEDURE:

1) The decommissioning process is not appropriate for instances of routine personnel changes. It is only to be used when a test site (Defined as a location where a Research Director is present and operating under their own SOP's.) will no longer be conducting GLP research, and does not have a legacy process in place. In this case, continuity is lost between past and future testing endeavors.

2) The Regional/ARS Director or designee responsible for the placement of any IR-4 work at a test site will be responsible for preparing the official notification to the IR-4 Executive Director, or designee, of the closure of a test site. The Regional/ARS Director will forward a letter to the participating Research Director and request that all raw data be forwarded to IR-4 Headquarters for archiving (see Appendix A, IR-4 Advisory 2006-01, for requirements).

3) Raw data can include any and all observations made during study conduct, memoranda, communication logs, equipment maintenance records, experience and training records, floor plans, field plot maps, SOPs (historical and current), original weather data, freezer records, test material receipt and storage data (if not previously forwarded as originals), and any other records needed to reconstruct research conducted at the test site.

4) Procedures in Advisory #2006-01 should be followed to provide IR-4 HQ with a detailed index and chain of custody documentation. It is important to clearly document who sent the data, where it was sent and who received the data at the end point, regardless of format.

5) Upon receipt, the data will be transferred to the IR-4 HQ archives or active files, as appropriate.

6) The IR-4 Executive Director will notify the EPA of the test site closure and transfer of data to IR-4 HQ archives. The letter will state the name and address of the test site, the name of the Research Director (see example in Appendix B), and a copy of the index of transferred raw data, if appropriate. This letter will serve as notification of test site decommissioning and closure and will be sent to the EPA's Office of Compliance, Agriculture and Ecosystems Division, Laboratory Data Integrity Branch. This letter will serve to fulfill the requirement of notification of EPA as required in 40 CFR 160.195(g) or current version.

7) The decommissioning letter will be distributed to the appropriate IR-4 Project Management Committee member, and Regional/ARS Coordinators.

Prepared by: T Barkalow Date: March 2015

Approved by: Date: 20 March 2015

IR-4 Advisory #2006-01 (Dec. 22, 2006)

Title: Inventory and Transfer of GLP Raw Data and Other Records to IR-4 Headquarters (HQ)

Issue/ Question: What documentation and data security mechanisms are needed when transferring raw data (other than Field Data Books) and other GLP records from IR-4 test sites to IR-4 HQ?

Background:

Original GLP data, SOPs and other applicable GLP records (facility or study related) are periodically transferred from IR-4 test sites (field and lab) to IR-4 HQ for archival (Field Data Books are routed directly to the Regional/ARS Field Coordinator). When received at HQ, the materials come with various forms of chain of custody and inventory records, or none at all. In order to check in the materials and maintain chain of custody, an inventory is generated at HQ so we have a record of what was received. But, without an inventory from the sender, we do not know if all documents intended to be transferred were actually received.

Resolution:

Transfer of GLP raw data and related GLP records should be done in an organized, traceable, secure and well documented fashion. An inventory of the materials being transferred must be generated and chain of custody verified at point of origin and at the receiving location. The sender will receive verification of the completed shipment. Any discrepancies or problems will be addressed prior to document storage at HQ.

Before shipping, be certain to make and keep a copy of all materials being transferred, including the inventory and chain of custody. The IR-4 Raw Data/Documents Transfer Form (see Attachment A as an example) can be used to document inventory and chain of custody information (see Attachment B as an example inventory).

Because handling of data is an element to be addressed in SOPs, any data transfer procedures specific to a test site should be detailed in a site-specific SOP, which should be sent to the Regional/ARS Field/Lab Coordinator, as appropriate, for approval.

Transfer to IR-4 HQ can be by hand or through a courier service, and should be addressed to the Registrations Manager. If a courier service is used, the documentation should include the identity of the courier service and the tracking number provided by the service so that packages can be traced if necessary. Raw data and GLP related records should not be transferred using regular, non traceable US postal service mail, but by certified mail or other traceable mechanism. Materials should be packaged appropriately to protect them during transport.

(If you have any questions, please contact your Regional/ARS Field/Lab Coordinator or HQ QA for further guidance.)

ATTACHMENT A

IR-4 RAW DATA/DOCUMENTS TRANSFER FORM

SENDER NAME: _____
PRINT

_____
SIGNATURE DATE

_____
PHONE# FAX#

TRANSFER INVENTORY: List data/documents description here, using additional pages as needed, or attach your own documentation, or use an Inventory form such as presented in Attachment B. Please show PR numbers and field or ID numbers where appropriate. Inventory should include a complete listing of materials being transferred; be as specific as possible so verification of receipt will be inclusive.

INVENTORY:

PLEASE SEND THE ORIGINAL TRANSFER FORM TO HQ, AND KEEP A COPY FOR YOUR RECORDS.

COURIER: _____

COURIER TRACKING NUMBER: _____

TRANSFERRED TO: _____

RECEIVED BY: _____
PRINT

_____
SIGNATURE DATE

Completed Transfer Form was returned to Sender on: _____ by: _____
Date Print name

ATTACHMENT B

(EXAMPLE INVENTORY)

Inventory for Data, Documents and/or Facility Files sent to IR-4 HQ

IR-4 test site location: _____
_____
_____
_____

Items	# of Pages*
Record of Data in Archive – inventory for 1997-2003	12
Calibration of Hobo loggers – 2005	15
Organization charts (2004-2006)	3
Maintenance log forms – 2004	
VWR digital humidity/temperature meter	2
Kenmore freezer	2
Hobos – 18161-18164, 18166, 18168	10
Turbo meter	2
Taylor soil probe	2
Hobo Standardization records, 2004	15
Pesticide Inventory (2/5/2004)	2
SOP originals, dated 6/3/02	35
Modular building floor plan, 5/9/05	2
Job description (7/28/99), training, and CVs (4/4/05, 3/18/05) for _____	5
Job description (2/25/02), training, and CV (4/19/02) for _____	7

***# of pages is desired, but not required**

The IR-4 Project

Pest Management Solutions
for Specialty Crops and
Minor Uses

IR-4 Headquarters
Rutgers, The State University of New Jersey
500 College Road East, Suite 201W
Princeton, NJ 08540
732.932.9575 fax 609.514.2612
www.ir4.rutgers.edu

SAMPLE LETTER on IR-4 Letterhead to provide contact information

Ms. Francisca E. Liem
Laboratory Data Integrity Branch
Agriculture and Ecosystems Division
Office of Compliance , USEPA
William Jefferson Clinton South Building 2227A
1200 Pennsylvania Ave. N. W.
Washington DC 20460

October 7, 2014

Dear Ms. Liem,

This letter is to inform the USEPA that the research test site of The analytical laboratory at Cornell University, formerly headed by _____ is no longer conducting GLP research. This notification serves to fulfill the requirement of 40 CFR 160.195(g). Please consider this laboratory decommissioned.

The test site address:

All raw data, correspondence and miscellaneous facilities information from this test site has been transferred to the IR-4 Headquarters for permanent archival (Please see attached letter from Dr. _____). Any inquiries about studies submitted to the EPA that contain data from this test site will need to be addressed here at IR-4 HQ. If you have any questions, please feel free to call.

Respectfully Submitted,

Dr. Jerry Baron
Executive Director, the IR-4 Project

_ attachments (__ pages)

Cc:
Regional Director
Regional Coordinators (F or L and QA)
Test Site QA folder

Major funding for IR-4 is provided by Special Research Grants and Hatch Act Funds from USDA-NIFA, in cooperation with the State Agricultural Experiment Stations, and USDA-ARS.

RUTGERS
THE STATE UNIVERSITY

SOP #: 3.4

AUTHORS: T.W. Barkalow, K. S. Samoil and J. Forder

REVISION #: 04

EFFECTIVE DATE: April 8, 2015

TITLE: **EPA Inspection Procedures.**

PURPOSE: To provide guidance to Headquarters and study personnel in responding to a notice of an inspection by Office of Enforcement & Compliance Assurance (OECA), U.S. Environmental Protection Agency.

SCOPE: IR-4 Headquarters, and all locations conducting GLP field trials, processing or laboratory analyses.

PROCEDURES:

Notification of an EPA inspection is received at IR-4 HQ (normally by email). Instructions will be provided in the notification as to whether to send all appropriate data to the EPA address stated in notification (data inspection) or to the site being audited (on-site inspection).

1. Procedures prior to an EPA inspection.

a. When notice of an EPA inspection is received at IR-4 Headquarters other responsible parties will also be notified. Immediately following notification by the EPA of intent to inspect, the QA Manager or any other member of the HQ QA unit will be made aware of the inspection. Headquarters QA will review the instructions provided by the Agency regarding the planned event (see Appendix A for example). Notification of other personnel, including (but not limited to) Study Director(s), Regional Director, Regional local Quality Assurance Officer(s), and appropriate Coordinators will be verified by HQ QA.

b. IR-4 Headquarters QA will assure that appropriate materials are removed from the Archives and prepared for shipment to the address specified in the notification.

i) Depending on the nature of the inspection (field, HQ or laboratory) described in the notice, the original raw data, study file and other materials are shipped by traceable carrier to the test site or certified copies of data, records and reports and shipped to the EPA inspector's office. Generate an inventory for use in documenting custody of the material (see Appendix B for example).

ii) The HQ QAU or the Study Director will arrange for the necessary information on the reference and/or test substances to be shipped separately to the address specified in the notification. Please request that the certification statement in the notice of inspection is signed by the registrant/sponsor, as appropriate (see Appendix C for example of request email).

iii.) The records of QA inspection (routing sheets or printouts of eQA workflows) will be copied for inclusion in the package for the EPA inspector. As needed, QA records (pertinent QA audits, memos, correspondence, etc) from the "Green folder" will be sent "for QA eyes only" to the QA assisting with the test site inspection.

2. Procedures for preparing for data audit (EPA office data audit or at Test site)

a. IR-4 Headquarters QA will assure that appropriate materials are removed from the Archives and shipped to the specified address. Typically 15 business days (see specifics in EPA notification letter) are allowed for getting the materials to the EPA inspector. In the event of an on-site data audit, materials will be sent as needed to the FRD /LRD at the site. Appropriate materials to send include, but may not be limited to the following:

i. Master schedules for the Research Director and previous FRD's at the test site, as necessary.
ii. Standard Operating Procedures relevant to the audited data, for QA, Field, Processing, Lab, etc. These can be made available from HQ or the test site (i.e., the analytical lab if they are sending the data to the inspector.)
iii. Raw data, correspondence and logs.
iv. CVs and job descriptions, etc. of HQ personnel assigned to the studies. A list of persons to contact and the information will be provided as outlined in the EPA notice (see appendix D for contact list example).
v. Appropriate chain of custody documents for samples and freezer logs, and storage temperature documentation.
vi. Documentation of the characterization of the test substance, receipt, handling, and storage records. The HQ QA or the Study Director will request, from the registrant, that characterization data and reports, or other documentation related to the test and/or reference substance(s), be made available at the inspection site. If the registrant is unable to provide the information in time for the inspection, they will be requested to contact IR-4 and the EPA and explain why the information is unavailable. The inspector will be referred to the registrant if this documentation is not provided in time for the inspection.
vii. Calibration logs on equipment such as balances, temperature measuring devices, and application equipment.
viii. A cover letter will be generated and included in the package shipped to the EPA inspector (see Appendix E for examples) and cc'd to the appropriate parties.

b. IR-4 Headquarters QA will ensure that site specific personnel as well as regional QA are available via phone to speak to an EPA inspector during the dates of the audit as specified in the notification.

3. Procedures During an On-Site Inspection:

a. Personnel who have been associated with the trial(s) should be available for the inspection, if schedules permit. A representative from the IR-4 QA Unit will be appointed to serve as the primary contact for the EPA and site personnel. Unless otherwise directed by Management (or the Field or Laboratory Research Director or other responsible party), this representative can accept the Notice of Inspection-from the Investigator, as can the Field or Lab Research Director or other responsible party. Should the data be inspected at the EPA, personnel who have been associated with the trial(s) should be available via phone.

b. The Quality Assurance Unit or other representative (hereafter known as the IR-4 Representative) will help to prepare trial and/or facility personnel for the inspection by the following steps:

i. Review position descriptions with technical personnel so they understand and can explain their role in the trial(s). Inform on site personnel about the nature of the inspection and request that whoever greets the Investigator that he/she wait for an escort to the designated area.

ii. Discuss issues that may come up about the trial(s) or facility and ensure that everyone understands what to expect. This preparation can include the technical staff and any others who might be on-site at the time, especially during the walk-through, if conducted.

iii. Request personnel to answer the inspector's questions only to the extent needed and not to provide extraneous information. Personnel should not volunteer information; answers should be direct and to the point.

iv. Be certain that all documents pertaining to the trial(s)/facility inspection will be available especially those specifically requested by the inspection letter of notice. Personnel should be able to explain how each document was developed and is maintained. Documents on site or brought by the FRD/LRD may include those listed in section 2 and additionally:

1. Updated Master schedules for the Research Director and previous FRD's at the test site, as necessary.
2. Current Standard Operating Procedures

3. Current up to date raw data, correspondence and logs (EPA inspector routinely chooses recent data to audit as part of test site inspection).
4. Training records, CVs, GLP training, job descriptions, etc. of personnel assigned to the trial(s). CVs for study-related HQ personnel will we forwarded from HQ.
5. Other facility records as needed

c. An introductory packet containing organizational charts, a map of the facility and any information specific to the facility will be compiled by the test site personnel. This will assist the inspector who may not be familiar with the surroundings or personnel. The person responsible to accept the Notice of Inspection will be identified prior to arrival of the EPA.
While each EPA inspection is unique, recommendations are provided in this Section which should be followed to the fullest extent possible. The inspection team will be greeted by the IR-4 representative, and will be provided with any institutional procedures for signing in/out, safety, confidentiality, etc. An appropriate location should be established and identified for use for the duration of the inspection.

d. Assign one person as scribe to keep notes of observations and of all interviews if this will not be done by the IR-4 representative. At the opening of the conference ask the lead inspector for credentials (identification) and for any opening statements. A general timeframe will be requested from the Investigator so that any potential conflicts in staff schedules can be smoothed out in advance.

e. Introduce the facility personnel present and state their function in the facility or trial(s).

f. Distribute organizational charts, map of the facility, and any other information previously prepared to assist the inspector.

g. Ask the lead inspector if any personnel not present will be required for interview during the inspection, so that appropriate time may be allotted.

h. Explain any "housekeeping" information such as the use of safety equipment in work areas, location of bathrooms, coffee, fire exits, etc.

i. Proceed with the inspection.

i. Provide documents only as they are requested and provide explanations only as necessary (or requested), to be sure the information is understood.

ii. Keep management informed of the progress of the inspection and the findings.

iii. Ensure that someone is available to assist the inspector throughout the inspection. If the inspector wishes to work alone for periods of time, let him or her know how the assistant can be contacted.

iv. At the end of each day, ask the Inspector if there are any questions, so that any misunderstandings are clarified before his or her report is written.

j. If possible, have all personnel involved in the inspection present for the exit conference.

k. Have someone present during the exit conference to take accurate notes.

l. Obtain a copy of the list of documents or other materials that the inspector(s) will take as exhibits.

m. At the exit conference, review the observation sheet developed by the inspectors, if any, to make sure that any corrections already made to problems found during the inspection are properly noted as corrected. Obtain a copy of the observation sheet.

n. Determine if discrepancies between the inspector's findings and actual situations exist and provide inspectors with any additional data needed to clarify those discrepancies.

4. Procedures after the EPA inspection

a. Management's designee (usually the Regional QA Coordinator) will distribute to Management, Staff, and the Study Director a written report of the inspection with an explanation of any problems found. This summary of the inspection may be more widely distributed for use as a training tool for IR-4 personnel.

b. Management will assign responsibility for preparation of possible solutions to problems and obtain time estimates for implementation.

c. Management will prepare any replies to the regulatory agency as necessary within a timely basis and keep all affected parties informed.

Prepared by: _____ Date: March 20, 2015

Approved by: _____ Date: 20 March 2015

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Office of
Enforcement and
Compliance Assurance

SENT BY E-MAIL
RETURN RECEIPT REQUESTED

February 6, 2014

Ms. Tammy W. Barkalow
Rutgers University
IR-4 Project Headquarters
500 College Road East, Suite 201 W
Princeton, NJ 08540
E-mail: White@aesop.rutgers.edu

Re: GLP Data Audit Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act

Dear Ms. Barkalow:

The United States Environmental Protection Agency (EPA) has chosen to conduct a data audit of the following study under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Good Laboratory Practice (GLP) regulations, 40 CFR Part 160.

Study Title	MRID	Lab Project No.
MANDIPROPAMID: MAGNITUDE OF THE RESIDUE ON BASIL	48992002	10124.09-NC17
HALOSULFURON-METHYL: MAGNITUDE OF THE RESIDUE ON CANEBERRY (RASPBERRY and BLACKBERRY)	48856702	09793.08NC-10
Diquat - Magnitude of The Residue on Canola	48839501	10091.09-NC24

The Final Study Reports were submitted to EPA in support of a registration or marketing permit and indicates that the IR-4 Program was the sponsor for these studies and that NCSU IR-4 Field Research Center was the testing facility. As the study sponsor, EPA is requesting that you submit exact copies of records, reports and data required to maintained by 40 CFR Part 160 and 169.2(k).

The purpose of the data audit is to further examine the Final Report and to determine whether the Final Report complies with the Agency's GLP regulations. Please note that under the GLP regulations at 40 CFR 160.15(b), EPA will not consider reliable for purposes of supporting an application for a research or marketing permit any data developed by a testing facility or sponsor that refuses to permit inspection.

Furthermore, under 40 CFR 160.17(a) EPA may refuse to consider reliable for purposes of supporting an application for a research or marketing permit any data from a study which was not conducted in accordance with the GLP regulation.

Please send all data needed to verify and support the findings in the Final Report for each study, along with the study protocol including any protocol deviations and/or amendments. Please include the index of Standard Operating Procedures (SOP) in use at the time of study and Quality Assurance inspection records. The EPA inspector assigned to this data audit will identify the relevant SOPs and will request copies. Identify all personnel associated with these studies and include their contact information, such as telephone number and e-mail address. Copies of records may be sent in paper format and must be certified as exact copies of the original. A certification form is enclosed.

In addition to the data mentioned above, we request specific information regarding the test substance. Please include source and lot number, record of receipt, storage, usage data, test substance inventory logs, and custodial procedures. Usage data include evidence of correspondence between test substance received and tested, weights, and preparation of dosages and/or dilutions. In addition, please obtain a statement from the sponsor indicating the origin of the test substance, namely, if it was sampled from a batch for contemporary commercial use or was synthesized or manufactured for the specific study for which the raw data are being audited. In either case, the statement should include chemistry data, i.e., all data to prove the identity and purity of the test substance, the identity of any and all impurities detected by sponsor or manufacturer, and data to prove storage stability of the test substance during the lifetime of the study.

You may, if you desire, assert a business confidentiality claim covering all or part of the information requested, in the manner described by 40 C.F.R. Section 2.203(b). EPA will disclose information covered by such a claim only to the extent and only by means of the procedures set forth in 40 C.F.R. Part 2, Subpart B. See 41 Fed.Reg. 36902 (September 1, 1976); 43 Fed.Reg. 4000 (December 18, 1985). If no such claim accompanies the information when EPA receives the information, then EPA may make the information available to the public without further notice to you. You should read carefully the above-cited regulations before asserting a business confidentiality claim, since certain categories of information are not properly the subject of such a claim. If you claim information submitted in response to this request as confidential, then also provide a second, redacted copy of the information with all confidential business information deleted.

In addition to this data audit, the inspector will conduct a facility compliance inspection at a later date to determine compliance with the FIFRA GLP regulations at the laboratory. Both the data audit and the facility compliance inspection are part of the GLP inspection being conducted. The inspector assigned to this data audit will coordinate this facility compliance inspection.

You are requested to provide the Agency with the information and documents identified above within 15 business days of your receipt of this letter by sending them to:

By U.S. Mail:

Daniel Myers
EPA, Office of Compliance
Denver Federal Center
Bldg 25, E2, Box 25227
Denver, CO 80225

By Hand Delivery:

Daniel Myers
EPA, Office of Compliance
Denver Federal Center
Bldg. 25, E3, Room 2246
Denver, CO 80225

At the conclusion of the data audit and facility inspection, the Inspector will provide a Receipt for Samples for any copies made and retained as part of the inspection file. EPA will destroy submitted documents and complete a certificate of destruction that will be kept in the inspection file. Alternatively, at your written request and expense, the documents may be returned.

Please direct any questions concerning this data audit to Mr. Daniel Myers, EPA, Office of Compliance, GLP Program, at 303-462-9392.

Sincerely,

Francisca E. Liem, Director
Good Laboratory Practice (GLP) Program

Cc: Daniel Myers
Mr. Roger Batts, NCSU IR-4 Field Research Center

CERTIFICATION

I certify under penalty of law that I have personally examined and am familiar with the documents and other information submitted in response to this information request; that based on my inquiry of the persons directly responsible for gathering the information the information is true, accurate and complete; and that all documents submitted herewith are true, accurate and complete. I am aware that there are significant penalties for submitting false information to the United States Government, including the possibility of fine or imprisonment under 18 U.S.C. 1001.

_____

Signature

_____

Name

_____

Title

_____

Company

_____

Date

IR-4 RAW DATA TRANSFER FORM

TRANSFER INVENTORY (list records/data description here, use additional pages as needed. Please show PR numbers and field id numbers where appropriate):

Participant's list and contact information

Certified Copies:

Universityof Maryland, M. Ross

Field SOPs – 2010

Test material data for:

Triflumizole – lot # is BO8M15P034 characterized in Feb of 2009 as provide by the manufacturer

Mandipropamid – provided directly to Ms. Liem by Syngenta -The lot # is 554552 characterized in March 2010

Final reports for

09299 Triflumizole/Tomato (GH)

10485 Mandipropamid/Tomato (GH)

QA routing sheets for PR#s – 09299 and 10485

HQ files – Correspondence and records for PR#s – 09299 and 10485

Field Data Books –

09299.10MD01
10485.10MD14

* Each study is set up as a series of records. The Final report, followed by the QA routing coversheets, then the HQ correspondence and the field data

TRANSFERRED BY: Tammy W. Barkalow

SIGNATURE DATE

COURIER:

TRANSFERRED TO:

Francisca Liem
US EPA – William Jefferson Clinton Bldg. South
Room 5109, Tel. 202-564-2365
1200 Pennsylvania Avenue NW
Washington DC 20004

RECEIVED BY:

PRINT

SIGNATURE DATE

PLEASE RETURN THE ORIGINAL TRANSFER FORM TO HQ, KEEP A COPY FOR YOUR RECORDS.

Tammy White

Subject: FW: Request for characterization data for Difenoconazole for an upcoming EPA insepction

Attachments: EPA inspection of ARS Salinas and Artichoke Research Dr. Bari Oct 14 2014.pdf; Fin_Rpt_Difen_Cyprod_Artichoke_10387_batch 520131.pdf

Hello,

We have been notified of an upcoming EPA inspection at Artichoke Research field test site in Salinas CA. The study is PR# 10387 Difenoconazole + cyprodinil/artichoke and it has been selected studies to be audited and we are preparing to send the data to the EPA inspector, Dan Meyer in Denver Colorado.

The lot # xxxx was characterized by xxxx.

I have attached the C of A and our notice of inspection. The EPA data certification form is the last page of the EPA announcement and will need to be signed by xxxx personnel making any copies for the EPA.

You can either send the materials to Dan Meyers at the Denver EPA offices, please reference the IR-4 studies listed above and let us at HQ know the data has been sent.

OR, you can send the materials to me at IR-4 HQ and I will include them in the package I send to Mr. Meyers. If sending to HQ please have them arrive before Oct. 31 so we have time to get them to Mr. Meyers by Nov. 4. The actual site visit will be on Nov. 18, 2014.

Thank you. Please feel free to call if there are any questions.

Tammy White Barkalow, RQAP-GLP
The IR-4 Project
Assistant Director, Quality Assurance
500 College Ave, Suite 201W
Princeton, NJ 08540
Phone - 732-932-9575, ext. 4607
Fax – 609-514-2612
white@aesop.rutgers.edu

Participants List and Contact Information for University of Maryland, Salisbury EPA Inspection

Ms. Marylee Ross, Univ. of MD/LESREC, 27664 Nanticoke Rd., Salisbury, MD, 21801

Phone: 410-742-8788 , ext. 310, mross@umd.edu

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The IR-4 Project

Pest Management Solutions
for Specialty Crops and
Minor Uses

IR-4 Headquarters
Rutgers, The State University of New Jersey
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www.ir4.rutgers.edu

Feb. 24, 1014

TO: Dan Meyers

FROM: Tammy Barkalow

CC: QA folders (10124, 09786, 10091)
J. Baron
D. Kunkel
D. Carpenter
M. Arsenovic
R. Leonard
K. Knight
R. Batts

RE: Transfer of materials for EPA inspection of the NC State Field test site in Raleigh, NC

Please find the enclosed materials to utilize during the upcoming EPA GLP compliance inspection. An inventory is provided on the raw data transfer form. Please review the inventory and sign it for acknowledgement of receipt of the materials.

Thank you. Please call if you have any questions or we can be of further assistance.

Major funding for IR-4 is provided by Special Research Grants and Hatch Act Funds from USDA-NIFA, in cooperation with the State Agricultural Experiment Stations, and USDA-ARS.

RUTGERS
THE STATE UNIVERSITY

SOP #: 4.1

AUTHOR: D. Carpenter, K. Samoil, D.K. Infante, V. R. Starner, K. W. Dorschner and D. L. Kunkel

REVISION#: 09

EFFECTIVE DATE: April 8, 2015

TITLE: **Protocol Development and Distribution for GLP Research Projects.**

PURPOSE: To establish a standard procedure for the development and distribution of protocols for IR-4 research in studies conducted according to the current version of US EPA GLP.

SCOPE: This SOP applies to all protocols and protocol changes issued for IR-4 GLP Research Projects.

PROCEDURES:

1. Definitions:

Personnel: Study Director: The individual designated by the IR-4 Executive Director to fulfill the requirements found in the current version of US EPA GLP and who has overall responsibility for the conduct of the study. Sponsor Representative: The individual(s) designated by the Sponsor (IR-4 Project Management Committee) who will sign the protocol and protocol changes. Sponsor designates are noted in Appendix A for protocols and protocol changes (see the latest version of SOP 6.0 for Testing Facility Management designates for final reports, GLP Compliance Statements and QA reports).
Regional/ARS Field Coordinator: The individual as designated by the Sponsor who has the duty to coordinate the field trials conducted by scientists within their region or ARS facilities.
Regional/ARS Laboratory Coordinator: The individual as designated by the Sponsor who has the duty to coordinate the laboratory trials conducted by scientists within their region or ARS facilities.
Field Research Director: The individual with sufficient training and experience to conduct the field trial at his/her testing site.
Laboratory Research Director: The individual with sufficient training and experience to direct the analytical analysis of the samples generated from the field portion of the study.
Terms and Definitions: PHI, preharvest interval (i.e. last treatment to harvest); Harvesting, the actual cutting or collecting of a bulk sample from the field; Sampling, the act of placing a sample in a sample bag.

2. Protocol development will be based on the requested use pattern contained in the appropriate Project Clearance Request Form or other sources of information such as EPA's *Residue Chemistry Test Guidelines OPPTS 860*, preliminary performance data, label text, use rates for related crops and recommendations or restrictions imposed by the registrant(s). At a minimum, IR-4 protocols will contain information required per the current version of US EPA GLP, excluding information that pertains to animal studies, including (at a minimum): project (study) title, justification and objectives, sponsor/testing facility name and address, Study Director, proposed experimental start date, experimental termination date, study completion date, location of test sites and residue research facilities, identification of test system (crop) and test substance, plot requirements, application of treatments and timings, residue sample collection and handling, inventory of residue samples, designation of project personnel, analytical methodology, statistical method, a description of records that must be maintained, and raw data handling and reporting.

3. Interested parties (at a minimum the registrant and IR-4 Registrations Manager) will be given an opportunity to review the draft protocol. The Registrations Manager may designate additional IR-4 Headquarters personnel to review draft protocols. Protocols for non-routine studies (post-harvest, seed treatment, foliar dislodgeable, etc.) or studies which include activities beyond the regular magnitude of residue requirements (processing, declines, etc.) as determined by the Registrations Manager will be provided to QA for review and auditing. All suggested changes will be considered by the Study Director who will make the final decision on protocol content.

4. ***PR Number.*** Project Clearance Request Number (a.k.a. Pesticide Clearance Request Number and PCR) is a unique number assigned to a clearance request.

5. ***Study Number.*** Each study protocol is assigned a unique identification number. For studies with assigned PR numbers below 10000, the first digit of the identifier is assigned "Zero (0)" when the study is the first study under a particular PR number. The second study has "A" as the first character, the third study is assigned "B", the fourth study is "C"; each additional study associated with the same PR number is assigned the next letter in the alphabet. For studies with assigned PR numbers 10000 and higher, additional studies will have the letter placed before the five digit number, resulting in a six-character code. See current version of SOP# 9.0 when conducting non IR-4 Sponsored Studies.

6. Each testing site of the study is assigned a specific identification number. The **"FIELD ID. NO."** is in the following format: Study Number.XX-YY# where XX is a two-digit numerical value representing the year the field trial was authorized for this portion of the study. "YY" is the state, territory, country, or province designation for the field site. When an asterisk (*) appears directly after this, the field trial site is a US Department of Agriculture/Agriculture Research Service trial. The final notation ("#") is a number that is an unique (up to three digits) field trial identification number assigned by Database Manager or their designee. Once assigned, the number will not be reused within the calendar year of the trial.
The **"LAB ID. NO."** is in the following format: Study Number.XX-YYY# where XX is a two-digit numerical value representing the year the laboratory was authorized for this portion of the study. When XX is other than a two-digit numerical value, the nature of the study is other than a Magnitude of the Residue. For example, SS designates a storage stability study and MV designates a method validation study (prior to the effective date of this SOP, AA designated storage stability studies and BB designated method validation studies). "YYY" is the designation of Laboratory ID Code for the cooperating laboratory. The final section ("#") in the **"LAB ID. NO."** is a unique number. See the current version of SOP # 4.4 Appendix A for a list of acceptable Nature of the Study and Laboratory ID Codes.

7. A protocol is approved once it has been signed by the Sponsor Representative and Study Director. The Study Director's signature must be the final signature, indicating "study initiation." If the study director is not at the same location as sponsor management, the study director may sign the protocol first, after receiving documentation, (such as an email) from sponsor management indicating the protocol has been approved for signature by management.

8. A true copy of the protocol is provided to the Field Research Director(s), Laboratory Research Director(s), Official Registrant Contact, appropriate Regional/ARS Coordinators, and the IR-4 Quality Assurance Unit. The original of the protocol is placed in the blue folder for the study file.

Prepared by: Deborah Carpenter Date: March 23, 2015

Approved by: Jerry Baron Date: 20 March 2015

RE: Routing of IR-4 Protocols at HQ and delegation of authority

In order to facilitate the handling of IR-4 protocols and protocol changes, any of the following headquarters managers may sign as sponsor representative.

Deborah Carpenter

Dan Kunkel

Van Starner

Jerry Baron

When none of the above managers is available, and there is an urgent need to sign a protocol or protocol change, the following individuals may sign as sponsor representative.

William Barney

Kenneth Samoil

SOP #: 4.2

AUTHORS: K. S. Samoil, D. C. Thompson, K. W. Dorscher, M. Arsenovic, and D. K. Infante

REVISION #: 03

EFFECTIVE DATE: January 31, 2010

TITLE: **Protocol Development and Distribution for non-GLP Product Performance Studies.**

PURPOSE: To provide guidance for the development and distribution of performance protocols for IR-4 research in non-GLP studies designed to collect product performance data (phytotoxicity, efficacy, and yield or quality data).

SCOPE: This SOP applies to all new research protocols on crops for which the IR-4 Project intends to submit the results to the potential registrant for the purposes of gaining support to pursue product registration.

Performance protocols requiring GLP will be addressed under SOP 4.1. These encompass pesticides used in public health and when EPA requires the submission of performance data. All others do not need to be conducted following GLP.

PROCEDURES: 1. Performance Protocols will be drafted based on the requested use pattern contained in the appropriate Project Clearance Request Form (PCR Form) and other sources of information such as preliminary data, label text, use rates for related crops, and recommendations or restrictions imposed by the registrant(s). Information contained on performance protocols includes (but is not limited to): title, justification and objectives, Research Coordinator name and address, identification of test site (crop) and test substance, test system design and statistical method, application treatments and timings, a description of records which must be maintained (such as disease incidence, insect counts, weed counts, and phytotoxicity ratings and descriptions), and raw data handling/reporting. A list of Field Research Directors may also be included in the protocol, at the option of the Research Coordinator who prepares the protocol. Appendix A has an example of a generic performance protocol template that includes a requirement for recording phytotoxicity in the plots. Appendix B has a performance protocol template that has been modified for fungicide studies.

2. Sponsor representative, registrant contact and other interested parties will be given a reasonable opportunity to review the draft performance protocol. All suggested changes will be considered. However, the sponsor representative has the final decision on content of the performance protocol.

3. Each performance protocol is assigned a unique identification number, consisting of the PR number with a P at the beginning. If the PR number is below 10000, then the initial 0 is replaced by a P; otherwise, P is added before the first digit. A single protocol may be used to cover multiple trials, or may cover just one trial, at the discretion of the Research Coordinator who prepares the protocol.

4. Each trial of the study is assigned a specific identification tag. The "FIELD ID. NO." is in the format PNNNN.YY-XX##. NNNN is a four or five digit number representing the PR number. YY is a two digit numerical value representing the year the protocol authorizing the field trial(s) is issued. "XX" is the state or territory designation for the field site. US Postal Service codes for states will be used. When an "asterisk (*)" appears directly after the postal service code, the field site is a US Department of Agriculture/Agriculture Research Service site. The final section "##" is the trial number, where the ## starts with "1" and increases in numerical order by 1 for each trial authorized in the state for that year.

5. Sponsor signature is not required for non-GLP performance protocols.

6. Copies of the performance protocol should be made and distributed to appropriate individuals. A copy should be provided to the Field Research Director(s), Official Registrant Contact and appropriate Field Research Coordinator(s). The original performance protocol should be placed in the study file.

Prepared by: _____ Date: 1/6/10

Approved by: _____ Date: 8 Jan 2010

APPENDIX A

IR-4 NATIONAL PESTICIDE CLEARANCE EFFICACY AND PERFORMANCE PROTOCOL

PR. NO.: NNN
DATE:

1. PROJECT TITLE:
PPP: Nature of Performance on CCC

2. JUSTIFICATION AND OBJECTIVES:
IR-4 has received a request for the minor use of ppp on ccc for control of @@@. The purpose of this research is to collect performance data to support pesticide registration according to parameters outlined in the request.

3. IR-4 RESEARCH COORDINATOR:
@@ IR-4 Project Headquarters, 500 College Road East, Suite 201 W, Princeton, NJ 08540, (732) 932-9575 X####, FAX# (609) 514-2612, E-mail: x@aesop.rutgers.edu

4. TEST SYSTEM/CROP:
CCC - Use a commercial variety and report: variety/source, lot number, etc. Field trials will be conducted at the appropriate sites to determine performance of ppp on ccc.

5. TEST/CONTROL SUBSTANCE:
Use @@@. IR-4 Personnel will arrange procurement of the test substance. Upon receipt, document the lot/batch number. Store the test substance in a secure, clean, dry area at temperature ranges noted in the product label.

6. TEST SYSTEM DESIGN and STATISTICAL METHOD:
Each test site will consist of four replicates of one untreated and 2 treated plots. Arrange plots in a randomized complete block design. The individual plots will be large enough to permit accurate application of the test substance in a manner that represents the major application technique that will be used commercially. Conduct appropriate statistical analysis to determine if significant differences exist between treatments.

7. TEST SITE PREPARATION:
Prepare test site following good local agricultural practices for the production of ccc including fertilization, irrigation, if necessary and available, and other practices that ensure good crop production. The test site should have a known pesticide and crop treatment history of a minimum of 1 year.

8. TEST SUBSTANCE APPLICATION:
Use application equipment that will provide uniform application of the test substance and simulates the intended commercial application technique as specified below. To ensure accurate delivery, calibrate test application equipment just prior to application of the test substance.

9. APPLICATION TREATMENTS AND TIMING:

Trt#	Treatment	Target Rate of active ingredient	Target Rate of formulated product*	Application Type	Spray Volume Range**
01	Untreated	Not Applicable	Not Applicable	Not Applicable	Not Applicable
02	Registered Standard				
03	PPP	@@ lbs ai/acre (@@ grams ai/hectare)	@@ grams ml/acre (@@ grams ml/hectare)	@@	@@ GPA (@@ LPH)

*The nominal formulation concentration of the test substance will be used in calculating application rates (see Section 13 for the nominal concentration).
**GPA=gallons per acre, LPH=liters per hectare

Make @@ applications at @@ day intervals.

IR-4 NATIONAL PESTICIDE CLEARANCE
EFFICACY AND PERFORMANCE PROTOCOL

PR.

NO.: NNN

DATE:

10. SUPPLEMENTAL CROP TREATMENTS:

The integrity of the study should be protected by managing pests causing significant damage to the test crop. Only EPA-registered maintenance pesticides should be used at labeled rates. Document all supplemental crop treatments.

11. FIELD DOCUMENTATION AND RECORD KEEPING:

All operations, data and observations, appropriate to this study should be recorded directly and promptly into the IR-4 MINOR USE PERFORMANCE FORM or equivalent raw data notebook. At a minimum, collect and maintain the following raw data:

- Test site information
- Plot maps
- Information regarding calibration, and use of application equipment
- Treatment application data
- Crop maintenance pesticides and cultural practices
- Meteorological/Irrigation records
- Other data requested in the IR-4 MINOR USE PERFORMANCE FORM which is appropriate

This trial requires collection of CROP PHYTOTOXICITY DATA, EFFICACY and YIELD DATA.

NOTE:
Please take phytotoxicity ratings on all plots during study conduct and at its conclusion. Specify the type of injury (stunting, stand loss, leaf burn, leaf cupping or twisting, chlorosis, etc.). Record if any delay in maturity occurred. With the last rating evaluate if the crop is stunted and provide an overall assessment (if the level of phytotoxicity would be acceptable in commercial production).

12. PROTOCOL/MODIFICATIONS:

Consult with the IR-4 Regional/ARS Field Research Coordinator and IR-4 HQ Research Coordinator regarding desired changes in this protocol prior to occurrence.

13. FIELD RESEARCH REPORT/ARCHIVING:

The Field Research Director should send the completed originals of the IR-4 MINOR USE PERFORMANCE FORM and other raw data to the Regional/ARS Field Research Coordinator. Short summary of the results should be included in the report. The Field Research Director will maintain a complete copy of these field documents. The original IR-4 MINOR USE PERFORMANCE FORM and other raw data will be sent to IR-4 Headquarters for reporting and archiving.

APPENDIX B

IR-4 NATIONAL PESTICIDE CLEARANCE
EFFICACY AND PERFORMANCE PROTOCOL

PR. NO.: NNN
DATE:

1. PROJECT TITLE:

Efficacy and Phytotoxicity of PPP on CCC for the control of DDD.

2. JUSTIFICATION AND OBJECTIVES:

IR-4 identified the use of ppp on ccc as a useful tool to control ddd. The purpose of this efficacy and crop safety trial is to determine the level of ddd control provided by ppp and to determine whether there is a negative impact of ppp on plant and yield variables.

3. IR-4 RESEARCH COORDINATOR:

@@, IR-4 Project Headquarters, 500 College Road East Suite, 201W, Princeton, NJ 08540,
Phone: (732) 932-9575, ext. 4613, FAX: (609) 514-2612, e-mail: x@aesop.rutgers.edu

4. TEST SYSTEM/CROP:

CCC – use a ccc cultivar that is susceptible. Report the cultivar and source.

5. TEST/CONTROL SUBSTANCE:

Use the @@ formulation of ppp (EPA Reg. No. ; CAS#). IR-4 personnel will arrange procurement of the test substance. Upon receipt, document the lot/batch number. Store the test substance in a secure, clean, dry area at temperature ranges noted in the product label.

6. TEST SYSTEM DESIGN and STATISTICAL METHOD:

Each test site should consist of **a minimum** four replicates of each treatment. Arrange plots in a randomized complete block design. The individual plots should be large enough to minimize the impact of the non-uniform distribution of this disease. It is suggested that plots be a minimum of 4 rows that are 30 feet long. Conduct appropriate statistical analysis to determine if significant differences exist between treatments.

7. TEST SITE SELECTION:

Select a test site that is appropriate for growing ccc and encouraging ddd.

8. TEST SUBSTANCE APPLICATION:

The test substance should be applied in a spray to the foliage, flowers and pods. Adequate pressure and equipment should be used to penetrate the crop canopy. The sprays should be applied at the rate of approximately 25-75 gallons per acre.

9. TREATMENTS:

TRT #	Test material (registrant)	Active ingredient	Rate	Timing
1 UTC	Untreated	--	--	--
2.	PPP (1X)			
3.	PPP (2X)			
5.STANDARD				

The foliar sprays should be made at approximately 7-day intervals. Make at least 4 applications and preferably 6 applications. Design the spray boom so that there is good coverage of the foliage and other plant parts.

IR-4 NATIONAL PESTICIDE CLEARANCE
EFFICACY AND PERFORMANCE PROTOCOL

PR. NO.: NNN
DATE:

10. DISEASE AND YIELD EVALUATION:

DDD incidence and severity on the foliage should be determined at least twice.

11. SUPPLEMENTAL CROP TREATMENTS:

The integrity of the study should be protected by managing pests causing significant damage to the test crop. Only EPA-registered maintenance pesticides should be used at labeled rates. **Document all supplemental crop treatments**.

12. FIELD DOCUMENTATION AND RECORD KEEPING:

All operations, data and observations, appropriate to this study should be recorded directly and promptly into the IR-4 MINOR USE PERFORMANCE FORM or equivalent program. It is recommended that at a minimum, collect and maintain the following raw data:

- Test site information
- Plot maps
- Information regarding calibration, and use of application equipment
- Treatment application data
- Crop maintenance pesticides and cultural practices
- Meteorological/Irrigation records
- Other data requested in the IR-4 MINOR USE PERFORMANCE FORM, which is appropriate

13. PROTOCOL/MODIFICATIONS:

Consult with the IR-4 Regional/ARS Field Research Coordinator and IR-4 Headquarters Research Coordinator regarding desired changes in this protocol prior to occurrence.

14. FIELD RESEARCH REPORT/ARCHIVING:

A short summary of one to two pages should be submitted. Statistical analysis of the data is required. We encourage you to publish the results in Fungicide and Nematicide Tests. Copies of the data from each evaluation are requested. The Field Research Director should send the report and evaluation data to the Regional Field Coordinator.

15. FIELD PERSONNEL:

Trial ID#	FRD	Address	Phone	Email

SOP #: 4.4

AUTHORS: D. L. Kunkel and T.W. Barkalow

REVISION #: 07

EFFECTIVE DATE: April 8, 2015

TITLE: IR-4 Master Schedule

PURPOSE: To provide an accurate and orderly system for the development and maintenance of a database that tracks the research conducted by IR-4 under Good Laboratory Practice standards.

SCOPE: This SOP applies to the IR-4 Master Schedule (MS) developed and updated by personnel at IR-4 Headquarters.

PROCEDURES:

1) The IR-4 Executive Director shall designate who shall maintain the MS (see Appendix A).

2) The MS shall contain all the items identified as required in EPA GLP's. The MS shall be able to be indexed by test substance and contains the test system, nature of the study (all IR-4 studies are magnitude of the residue (MOR) unless designated in LAB ID field), date study was initiated, current status, identity of the Sponsor (The IR-4 Project, represented by the IR-4 Project Management Committee or their designee) and name of the Study Director. Additional elements that comprise the MS are also explained in this SOP. To assure understanding and compliance, the following explanations and definitions are provided.

   The title "IR-4 MASTER SCHEDULE (ESTIMATED DATES), (IR-4=SPONSOR (unless designated as per section 5 or SOP 9.0)), (ACT. = Actual Dates)" was present on the official MS prior to July 15, 2009. The new title is "IR-4 MASTER SCHEDULE (IR-4=SPONSOR) All Studies MOR unless coded otherwise; Estimated Dates except for ACT (=ACTUAL DATE); Good Laboratory Practice (GLP) Studies" is present on the current version. Both include all studies initiated after 1989 for which the IR-4 Project is the Sponsor. Studies not sponsored by IR-4 will be entered on this MS as described in the current version of SOP 9.0 or in the case of Canadian sponsored studies, in section 5 of this SOP. The date in the upper left of the page is the date the MS is printed off the IR-4 database. The term "field" is defined as the columnar area on the printed form of the MS in which the same type of information is regularly recorded. The term "PR#" is the Project Clearance Request number that is assigned to each study. The MS fields are comprised as follows:

   a) The field "PR#" (study #) is a character value identifier for the study. When a number is the first character, this represents the first study for a particular request. When a letter precedes the PR#, this represents a project for which there are two or more studies.
   b) The field "CHEMICAL" is the common name of the test substance used in the IR-4 sponsored study.

Periodically, changes to the name used in the protocol or changes for clarification in the name used in the master schedule need to be performed (i.e., when the manufacturer changes from a code name to a chemical name). The following scenarios will be utilized when making changes:

If the study is active (the final report is not yet signed) the protocol will be amended to indicate that the chemical name will be changed from the current "name" (usually a code number) to the new chemical name with the old "name" immediately following the new name, in parenthesis. For example. BYI 02960 will become Flupyradifurone (BYI 02960).

If the chemical names being changed in the master schedule are found in studies that have been completed, the master schedule will be changed to reflect the naming convention provided as above. The final report for the study will not be amended.

All studies whose protocols have not yet been signed at the time of a name change will use the common name (ie flupyradifurone) or may use the combination name (ie, Flupyradifurone (BYI 02960)), dependent on whether the manufacturer has made a specific request.

For studies conducted with the active ingredient Halosulfuron-methyl or Fluazifop, the master schedule will list them using the chemical name of Halosulfuron or Fluazifop-p-butyl, respectively.

c) The field "COMMODITY" is the common name of the commodity used in the test system.

d) The field "FIELD RESEARCH DIRECTOR"(FRD) is the person supervising/conducting the individual GLP trial. See Appendix B.

e) The field "FIELD ID#" is the specific identifier for IR-4 sponsored field trials. The "FIELD ID#" follows the current format from the current version of SOP# 4.1.

f) The field "FIELD START' is the estimated date of the first test substance application as provided by the Field Research Director (FRD) and remains on the MS. The estimated date is not replaced with an actual date once the activity occurs.
The procedure followed for when the postcard or FDB or Field Data Summary were received at IR-4 Headquarters prior to July 15, 2009, had replaced the estimated date with an "*"; or when the trial was terminated, "---" replaced the estimated date; or when a final report had been signed, submitted to EPA and archived the field was replaced with "A-COMP." or when a study was canceled and archived, the field was replaced with "A-CANCEL".

g) The field "COLLECT SAMPLE" is the estimated date when the residue samples are to be collected as provided by the FRD and remains on the MS. The estimated date is not replaced with an actual date once the activity occurs and remains on the MS.
The procedure followed for when the postcard or FDB or Field Data Summary were received at IR-4 Headquarters prior to July 15, 2009, had replaced the estimated date with an "*" or when the trial was terminated, "---" would replace the estimated date.

h) The field "SAMPLES SHIPPED" is the estimated date when residue samples are to be shipped to the analytical laboratory as provided by the FRD and remains on the MS. The estimated date is not replaced with an actual date once the activity occurs.
The procedure followed for when the postcard or FDB or Field Data Summary were

received at IR-4 Headquarters prior to July 15, 2009, had replaced the estimated date with an "*" or when the trial was terminated, "---" replaced the estimated date.

i) The field "FIELD COMP." is the estimated date when IR-4 Field Data Book (FDB) is completed and will be forwarded to IR-4 as provided by the FRD and remains on the MS. The estimated date is not replaced with an actual date once the activity occurs.
The procedure followed for when the postcard or FDB or Field Data Summary were received at IR-4 Headquarters prior to July 15, 2009, had replaced the estimated date with "RECD"; or if the original IR-4 FDB needed to be returned to the FRD, "COPY" would be entered into the field; or when the trial was terminated, "DROPPED" would replace the estimated date; or when notification to HQ was made that an IR-4 FDB had been completed and sent to the Regional office, the appropriate Regional Code would be entered (see Appendix A) or when notification to HQ was made that the IR-4 FDB had been sent to the monitoring Quality Assurance Auditor, "TO QA" would replace the estimated date.

The above fields "FIELD START", "COLLECT SAMPLE", "SAMPLES SHIPPED" and "FIELD COMPLETE" are estimated dates entered into the database once these proposed dates are provided by the FRD. This information is received from the FRD after (s)he receives a protocol, reviews the protocol, fills in the estimated dates and sign the GLP acknowledgement on the IR-4 Research Director Agreement cover letter. These dates will remain there as of July 15, 2009.

All trials that had followed the old procedure prior to July 15, 2009 and have removed the estimated dates will continue to follow the old procedure used for "FIELD COMPLETE" but will also add the actual date of occurrence to the new fields added to the MS noted in Section j, k & l (RFC, TO QA, HQ RECD). The cover letter is returned to the IR-4 HQ, preferably via the Field Regional/ARS Coordinator. The dates are not replaced with an actual date once the activity occurs. They are only replaced with new dates if circumstances (such as unfavorable weather) require that the trial initiation be delayed to later in the year.

j) The field "RFC" has been added to the MS as of July 15, 2009 that indicates when IR-4 HQ has been notified that the FDB has been shipped to the Regional Field Coordinator (RFC) or other location (see Appendix A for codes used).

k) The field "TO QA" has been added to the MS as of July 15, 2009 that indicates when IR-4 HQ has been notified that the FDB has been shipped to the QA Auditor.

l) The field "HQ RECD" has been added to the MS as of July 15, 2009 that indicates when IR-4 HQ has received the FDB. Those that were received prior to this date may be indicated with the wording "RECD"; other values found in this field are: "LOST", "DROPPED", "NA" & "TRANS." (Note "TRANS." is the abbreviation for transferred)

m) The field "LAB ID#" is an identifier for the IR-4 laboratory/processing/seed treatment laboratory portion of the study and follows the current format from SOP# 4.1 paragraph #6 and Appendix C. Studies begun in 1989 and 1990 do not contain this laboratory trial number.

n) The field "LAB START" is the estimated date the laboratory will receive the first residue samples and is entered into the database once the proposed dates are provided by the Laboratory Research Director (LRD). The date is not replaced with an actual date.

o) The field "LAB COMP" is blank until the Analytical Summary Report (ASR) has been received at IR-4 HQ. Codes or data information used in the section can be found in Appendix A of this SOP.

p) The field "ACT. STUDY INIT." is the Actual Study Initiation date when the study protocol has been signed by the Study Director. Studies completed and submitted to EPA have an actual date containing month, day & year. Studies that have been canceled prior to July 15, 2009 contain only a month and year date. As of July 15, 2009 all entries will be specific dates containing month, day and year.

q) The field "EXP. START" is an estimated date provided by the protocol that relates to the first application of test substance in the study. The estimated date is not replaced with an actual date once the activity occurs.

r) The field "EXP. TERM." is an estimated date provided by the protocol that relates to the date of last collection of data for the study. The estimated date is not replaced with an actual date once the activity occurs.

s) The field "ACT. STUDY COMP." is the Actual Study Completion date that the final report is signed by the Study Director or the Actual Study Completion date that the study has been canceled. Those studies that have been completed or submitted to EPA have an actual date containing month, day & year. Studies that have been canceled prior to July 15, 2009 contain only a month and year date. As of July 15, 2009 all entries (submitted or canceled) will be specific dates containing month, day and year.

t) The field "STUDY DIRECTOR" is the last name of the Study Director. Generally, this individual is located at IR-4 Headquarters. See Appendix A for list of acceptable codes relating to this field.

u) The field "AUDITOR " is the monitoring Quality Assurance Auditor (Location) assigned to the study (See Appendix A). This is located after the Study Directors name.

3) The individual(s) responsible for the MS should update the database on an "as needed" basis.

4) Individuals responsible for coordination of IR-4 research (IR-4 Headquarters Staff, Regional/ARS Coordinators, and IR-4 Quality Assurance Unit) will have access to the information in the database. Other individuals or organizations can request the MS by contacting the individual responsible for the MS or the IR-4 Executive Director or by accessing the IR-4 web site.

5) Adding Canadian Sponsor studies to the IR-4 master schedule

The collaboration of the IR-4 Project with the Canadian Pest Management Centre (PMC) began in the late 1990's. In the beginning, all studies conducted collaboratively were done so as part of IR-4 protocols (with IR-4 study directors (SDs) and testing facility management (TFM)). In recent years the PMC has taken on the role as SD and TFM and IR-4 personnel have participated in these studies. However, the Canadian Sponsored studies were never listed in the IR-4 master schedule thereby omitting some of the trials each Field Research Director (FRD) was conducting. In order to keep a more accurate accounting of the Canadian trials placed with each FRD, the IR-4 master schedule will now list the Canadian studies.

Listing the Canadian studies on the IR-4 master schedule does require a revision to the required data points listed for Canadian studies, an explanation/modification of some Canadian used terms to fit into

the IR-4 database and an omission of some items that are not listed in the Canadian master schedule. The Canadian studies portion of the master schedule will be updated quarterly and will be based on updated printouts received of the PMC's master schedule. The printout will be sent, printed if necessary and the hard copy archived at IR-4 for retention of the records used to update the IR-4 master schedule.

The IR-4 master schedule fields for Canadian studies will be populated as follows:

a. The study # will use the PR# which is a character value identifier for the study. When a number is the first character, this represents the first study for a particular request. When a letter precedes the PR#, this represents a project for which there are two or more studies. The IR-4 master schedule will not use the Canadian study #.

b. The field "CHEMICAL" is the active ingredient name of the test substance used in the Canadian sponsored study.

c. The field "COMMODITY" is the common name of the commodity used in the test system and is called the Crop in the Canadian master schedule. .

d. The field "FIELD RESEARCH DIRECTOR"(FRD) is the person conducting the individual GLP trial and is called the Principal Investigator (PI) in the Canadian master schedule. The nomenclature will follow the examples presented in Appendix B.

e. The field "FIELD ID#" is the specific identifier for field trial. The "FIELD ID#" will follow the following format: (XXCYYZZZ) XX equals the last two digits of the year, C equals Canadian sponsored study, YY equals the state, province or national abbreviation and ZZZ equals the Canadian field trial number from the Canadian master schedule.

f. The field "FIELD START' is the actual date of the first application of the test substance, from the Canadian master schedule.

g. The field "COLLECT SAMPLE" is the "Harvest date" as presented on the Canadian master schedule.

h. The field "SAMPLES SHIPPED" is the actual date when last residue samples have been shipped to the analytical laboratory, from the Canadian master schedule.

i. The field "FIELD COMP." is the date of receipt of the Raw Data Field Notebook (RDFN), from the Canadian master schedule.

j. The field "RFC" may or may not be filled in for Canadian studies

k. The field "TO QA" may or may not be filled in for Canadian studies

l. The field "HQ RECD" will be the date the RDFN is received at PMC headquarters, from the Canadian master schedule.

m. The field "LAB ID#" is an identifier for the laboratory portion of the Canadian sponsored study. The lab ID # will follow the format; XXYYYCZZZ. The XX is the year the laboratory work has been assigned. The YYY is the laboratory abbreviation as provided for in Appendix

C. The letter C is used in the format to designate it as a Canadian study and ZZZ is the laboratory trial # and is taken from the Canadian master schedule.

n. The field "LAB START" is the actual date when the method validation is complete, as per the Canadian master schedule.

o. The field "LAB COMP" is blank until the Analytical Report has been received at PMC HQ. The date in the field "Complete FAR to PMC" will be taken from the Canadian master schedule. Any other codes used in this section can be found in Appendix A of this SOP.

p. The field "ACT. STUDY INIT." is the Actual Study Initiation date when the study protocol has been signed by the Study Director. This date is in the Canadian master schedule.

q. The field "EXP. START" is an estimated date provided in the Canadian master schedule labeled "Proposed Experimental Start Date". Only the month and year designations of MM/YY will be presented.

r. The field "EXP. TERM." is an estimated date provided by the Canadian master schedule labeled "Proposed Experimental End Date". Only the month and year designations of MM/YY will be presented.

s. The field "ACT. STUDY COMP." is the Actual Study Completion date that the final report is signed by the Study Director or the Actual Study Completion date that the study has been canceled. This study completion date is taken from the Canadian master schedule.

t. The field "STUDY DIRECTOR" is the last name of the Study Director. This individual is taken from the Canadian master schedule for Canadian sponsored studies. See Appendix A for list of acceptable codes relating to this field.

u. The field "AUDITOR "is the monitoring Lead Quality Assurance entity for Canadian studies and will be designated by CAN. This is located after the Study Directors name.

Prepared by: _____ Date: 20 MAR 2015

Approved by: _____ Date: 20 March 2015

CONTENTS

Individual Responsible for Master Schedule: **Susan Bierbrunner**

Nature of Study Codes (other than a MOR)

See Current format of SOP 4.1

CODE	Description
*DF	Dislodgeable Foliar
*MA	Metabolite Analysis
*MV	Method Validation (Prior to 01/06/10 code was *BB)
*RA	Re-Analysis
*RC	Reference Characterization
*SS	Storage Stability (Prior to 01/06/10 code was*AA)
*ST	Seed Treatment
*VD	Verification Data
*TS	Test Substance Characterization

Field Research Directors(s) Codes

See attached pages - Appendix B

Laboratory ID Codes

See attached pages - Appendix C

Study Director Codes

CODE	Description
"Last Name*"	On going Study
XX-"Last Name"	Archived Study
XC-"Last Name"	Canceled Study
H-"Last Name"	Study on Hold
TT-"Last Name"	Study Transferred (no longer sponsored by IR-4)

* This is the last name of the Study Director

Regional Office Codes

CODE	Regional Office
NCR	North Central
NER	Northeastern
WSR	Western
SOR	Southern
ARS	USDA/ARS
CANADA	Canada
NORTON	Jack Norton

Auditor Codes

CODE	Auditor Location
HQ	IR-4 Headquarters
NCR	East Lansing, MI
NER	Geneva, NY
WSR	Davis, CA
SOR	Gainesville, FL
NOV	MFG Syngenta, Greensboro, NC
HIR	Hawaii
CAN	Canada
AGR	MFG AGRI
FMC	MFG FMC Corporation
OLD	Multi Auditors, Not Assigned at Start

Associate Codes

None utilized

Field: LAB COMP

Keyword	Description
MM/YY	Date received; MM=2 digit month & YY= last 2 digit year
RECD	ASR Received
DROPPED	The research is terminated and the samples have not been received
DISCARD	Residue samples associated with the particular field trial were not analyzed and were disposed of
LOST	Residue Samples associated with the particular field trial were lost
COPY	ASR was returned to the LRD
TRANS	The study has been transferred to an outside Sponsor

Code	Field Research Director (NCR)	State
C+B9	Bennett, David	IA
C71	Clayton, Mr. Paul	IA
C+F3	Shepherd, G.	IA
C+D1	Keith, Stephen	IL
C53	Scheirer, Dr. Douglas	IL
C66	Weinzierl, Dr. Richard	IL
C41	Francis, Mr. John A.	IN
C16	Green, Dr. Ralph J.	IN
C12	Latin, Dr. Richard X.	IN
C05	Weller, Dr. Stephen	IN
C10	York, Dr. Alan	IN
C64	Jardine, Dr. Douglas	KS
C75	Nord, Cathy	KS
C+D5	Nord, Douglas	KS
C60	Wilde, Dr. Gerald	KS
C14	Grafius, Dr. Edward J.	MI
C37	Hanson, Dr. Eric J.	MI
C56	Hausbeck, Dr. Mary K.	MI
C25	Johnson, Dr. James W.	MI
C06	Jones, Dr. Alan L.	MI
C52	Putnam, Dr. Al R.	MI
C07	Ramsdell, Dr. Donald	MI
F25	Van Woerkom, Anthony	MI
C+B8	Waldecker, Mark	MI
C67	Wise, Dr. John C.	MI
C04	Zandstra, Dr. Bernard H.	MI
C55	French, Mr. Lee K.	MN
C45	Hertz, Dr. Leonard	MN
C58	Noetzel, Dr. Dave	MN
C31	Oelke, Mr. Ervin	MN
C81	Viger, Paul	MN
C22	Finn, Dr. Chad	MO
C23	Keaster, Dr. Armon	MO
C32	Moore, Dr. Justin F.	MO
C27	Ahrens, Dr. Bill	ND
C79	Ciernia, Mr. Mark	ND
C02	Eriksmoen, Mr. Eric	ND
C76	Henson, Dr. Bob	ND
C74	Jenks, Dr. Brian	ND
C77	Knodel, Janet J.	ND
C48	Lamey, Dr. H. Arthur	ND
C80	Lee, Curt	ND
C28	Lorenze, Dr. James	ND
C+D9	Markle, D.	ND
C20	Meyer, Dr. Dwain	ND
C26	Nalewaja, Dr. John	ND
C30	Riveland, Mr. Niel	ND
C69	Tyess, Ms. Debbie	ND
C29	Weiss, Dr. Mike	ND
C72	Zollinger, Dr. Richard	ND
C98	Harveson, R.M.	NE
C34	Kamble, Dr. Shripat	NE
C65	Kerr, Dr. Eric D.	NE
C61	Mayo, Dr. Z.B.	NE

Code	Field Research Director (NCR)	State
C68	Wilson, Dr. Robert G.	NE
C57	Witkowski, Dr. John F.	NE
C59	Wright, Dr. Robert	NE
C01	Ellis, Dr. Michael A.	OH
C03	Gorski, Dr. Stanley F.	OH
C39	Hoy, Dr. Casey W.	OH
C84	Miller, Dr. Sally Ann	OH
C13	Riedel, Dr. R.M.	OH
C08	Williams, Dr. Roger N.	OH
C+D4	Auch, Duane	SD
C40	Clay, Dr. Sharon	SD
C78	Irwin, Roger	SD
C70	Baldock, Dr. Jon	WI
C+D2	Bellman, Susan	WI
C18	Harvey, Dr. R. Gordon	WI
C62	Koenig, Dr. John P.	WI
C49	Mahr, Dr. Dan	WI
C21	Parke, Dr. Jennifer	WI
C83	Peever, Michael J.	WI
C51	Perry, Dr. Robert S.	WI
C38	Roper, Dr. Teryl	WI
C42	Stevenson, Dr. Walter	WI
C19	Wyman, Dr. Jeff A.	WI

Code	Multiple FRD Same Location	State
+CC	**Midwest Research**	**NE**
+CC2	Spontanski, Jess J.	NE
+CC1	Spotanski, Ron	NE
+CA	**Univ. of WI**	**WI**
+CA5	Binning, Dr. Larry	WI
+CA2	Chapman, S.	WI
+CA3	Heider, Daniel J.	WI
+CA4	Hopen, Dr. Herb J.	WI
+CA1	Michaelis, Mr. Bruce	WI

Code	Field Research Director (ARS)	State
W2B	Benzen, Ms. Sharon D.	CA
S3A	Chandler, Dr. Laurence D.	GA
S5B	Payne, Dr. J.A.	GA
C4A	Wax, Dr. Loyd M.	IL
E1B	Frank, Mr. J. Ray	MD
S5A	Smith, Dr. Barbara J.	MS

Code	Multiple FRD Same Location	State
+CB	**USDA - Wooster**	**OH**
+CB2	Giovannini, Michele	OH
+CB3	Horst, Leona	OH
+CB1	Tappan, Mr. Craig	OH
XX1	Krause, Charles	OH
+SF	**USDA - Tifton**	**GA**
+SF1	Fraelich, Ben	GA
+SF3	Johnson, Dr.Carrol	GA
+SF2	Johnson,Dr. Alva W.	GA
+SI	**USDA - Charleston**	**SC**
+SI1	Simmons, Dr. A.M.	SC
+SI3	Wade, Paul	SC
+SI2	Wrenn, Michele M.	SC
S7B	Harrison, Dr. Howard F.	SC
S+Q9	Fenn, Kristina	SC
+SD	**USDA - Weslaco**	**TX**
+SD2	Coleman, Randy	TX
+SD1	McCommas, Mr.David	TX
+WG	**USDA - Prosser**	**WA**
+WG1	Birch, Mr. Lyle M.	WA
+WG2	Boydston, Dr. Rick A.	WA
+WL	**USDA - Wapato**	**WA**
+WL3	Harvey, John	WA
+WL1	Toba, Dr. Harold H.	WA
+WL2	Treat, Mr. Thomas	WA
+WU	**USDA- Maricopa**	**AZ**
W+W6	Alexander, Patrick	AZ
W+Y1	De Stefano, Neil	AZ
W+Y4	Miller, Barry	AZ

Code	Field Research Director (NER)	State
E44	Ahrens, Dr. John	CT
E31	LaMondia, Dr. James	CT
E77	Bewick, Dr. Thomas	MA
E49	Kusek, Dr. Chuck	MA
E58	Beste, Dr. Ed	MD
E+G1	Collins, J.	ME
E65	Drummond, Dr. Frank	ME
E32	Forsythe, Dr. H.Y.	ME
E34	Plissey, Mr. Edward	ME
E33	Porter, Dr. Greg	ME
E35	Yarborough, Dr. Dave	ME
E37	Bowman, Dr. James	NH
E36	Lord, Dr. William	NH
E38	Wells, Dr. Otho	NH
E22	Baron, Dr. Jerry J.	NJ
E80	Choban, Dr. R.G.	NJ
E+B5	Freiberger, Tom	NJ
E19	Polk, Dr. Dean	NJ
E21	Rabin, Mr. Jack	NJ
E20	Stretch, Dr. Allen W.	NJ
E46	Abawi, Dr. George	NY
E10	Agnello, Dr. Arthur	NY
E01	Bellinder, Dr. Robin	NY
E11	Burr, Dr. Thomas	NY
E02	Eckenrode, Dr. Charles J.	NY
E12	Ellerbrock, Dr. Leroy	NY
E09	Merwin, Dr. Ian	NY
E61	Palmer, Mr. W.H.	NY
E47	Pearson, Dr. Roger	NY
E08	Pritts, Dr. Marvin	NY
E13	Rosenberger, Dr. David A.	NY
E06	Senesac, Dr. Andrew	NY
E05	Shelton, Dr. Anthony	NY
E54	Shields, Dr. Elson	NY
E03	Sieczka, Dr. Joseph	NY
E43	Straub, Dr. Richard	NY
E42	Wilcox, Dr. Wayne	NY
E07	Wilcox-Lee, Dr. Darlene	NY
E14	Wise, Ms. Alice	NY
E12	Ellerbrock, Dr. Leroy	NY
F42	Smart, Kris	NY
E66	Demchak, Kathleen	PA
E29	Goulart, Dr. Barbara	PA
E79	Smith, Dr. Christine	PA
E26	Travis, Dr. Jim	PA
E82	White, Mr. Tim	PA
E27	Wuest, Dr. Paul J.	PA
E64	Teillon, Dr. Brent	VT
E40	Weaver, Dr. Joseph	WV

Code	Multiple FRD Same Location	State
+EF	**U of MD/LESREC**	**MD**
+EF1	Linduska, Dr. James	MD
+EF2	Ross, Marylee	MD
+EG	**Rutgers Bridegton**	**NJ**
+EG3	Ghidiu, Dr. Jerry	NJ
+EG2	Johnston, Dr. Steve	NJ
+EG1	Majek, Dr. Brad	NJ
+EB	**A.C.D.S. Res.**	**NY**
+EB2	Humphreys, Harry	NY
+EB1	Jordan, Mr. Grant	NY
+EH	**LAB Services**	**PA**
+EH2	Landis, Donna	PA
+EH1	Steffel, Mr. Jim	PA
+ED	**USMASS Cranberry Station**	**MA**
+ED1	Averill, Dr. Anne	MA
+ED4	Caruso, Dr. Frank	MA
+ED5	Devlin, Dr. Robert	MA
+ED3	Sandler, Ms. Hilary	MA
+ED2	Sylvia, M.	MA
+EA	**Bridgeton Center**	**NJ**
+EA2	Bonham, Melissa	NJ
+EA1	Rossell, Mr. Larry	NJ
+EA3	Hitchner, Ms. Erin	NJ

Code	Field Research Director (SOR)	State
S45	McInnes, Mr. T. Bond	AL
S66	Zehnder, Dr. Geoff W.	AL
S+Q3	Burgos, N.	AR
YY3	Estorninos, L.(Jun)	AR
S09	McLeod, Dr. Paul J.	AR
S+A4	Shoffner, Ms. Wendy	AR
S14	Talbert, Dr. Ron E.	AR
S94	Baranowski, Dr. Richard	FL
S+A9	Curry, Dr. Wayne	FL
S02	Datnoff, Dr. Lawrence	FL
S33	Espaillat, Mr. Jose	FL
S+B9	Green, Mr. Michael E.	FL
S92	Howard, Dr. Charles	FL
S05	Johnson, Mr. Robert R.	FL
S32	Kucharek, Dr. Tom A.	FL
S43	Lambe, Dr. R.C.	FL
S21	Locascio, Dr. Sal	FL
S83	McGuire, Dr. Ray	FL
S97	McMillan, Dr. Robert	FL
S53	Meister, Dr. Charles W.	FL
S+A1	Minter, Mr. Tom	FL
S69	Noegel, Dr. Ken (FL)	FL
S+B7	O'Hair, Dr. Stephen K.	FL
S+A8	Remick, Mr. Dean	FL
S24	Saxena, Dr. Gopal K.	FL
S+A7	Scott, Mr. Jeff	FL
S61	Shuler, Mr. Kenneth	FL
S+S3	Sutherland, Dudley	FL
S75	Watson, Dr. Bill	FL
XY0	Vallad, Gary	FL
S+O1	Brenneman, T.B.	GA
S01	Chalfant, Dr. Richard B.	GA
S72	Dutcher, Dr. Jim	GA
S+R1	Eadie, Mell	GA
S98	Easton, Dr. Ford	GA
S+B5	Henry, Louise	GA
S+A5	Jones, Dr. Galin	GA
S+M0	Ji, Pingsheng	GA
S23	Vincelli, Dr. Paul C.	KY
S90	Clark, Dr. Chris	LA
F40	Ivey, Melanie	LA
S82	Griffin, Dr. James L.	LA
S58	Porter, Dr. Wayne C.	LA
S74	Rolston, Dr. Larry H.	LA
S93	Story, Richard	LA
S+Q2	Wright, Denise	LA
S68	Bailey, Dr. Jack	NC
S+G2	Garvey, Dr. Paul	NC
S07	Meyer, Dr. John R.	NC
S57	Monaco, Dr. T.J.	NC
S39	Skroch, Dr. Walt	NC
S08	Sutton, Dr. Turner B.	NC
S41	Walgenbach, Dr. James F.	NC
S49	Cartwright, Dr. Robert	OK
S65	Edelson, Dr. Jonathan	OK
S+G4	Musick, Roger	OK
S34	Acin, Ms. Nilsa M.	PR
S35	Acosta, Dr. Nelia	PR
S89	Almodovar, Mr. Luis	PR
S30	Armstrong, Mr. Aristide	PR
S03	Cabrera, Ms. Irma	PR
S70	Gonzalez, Mr. Wigmar	PR
S50	Ingles, Mr. Rafael	PR
S11	Liu, Tong-Xian (T.-X.) (PR)	PR
S+B2	Pantoja, Dr. Alberto	PR
S99	Semidey, Dr. Nelson	PR
ZZ7	Robles, Vazquez, W.	PR
S29	Keinath, Dr. Anthony P.	SC
S+G1	McCarty, Dr. Mike	SC
S28	Reighard, Dr. Greg	SC
S86	Walker, Mr. Tommy	SC
F23	Phillips, Mike	TX
S80	Dainello, Dr. Frank	TX
S78	Felker, Dr. Peter	TX
S73	Harris, Dr. Marvin	TX
S8B	Hickman, Dr. Michael	TX
S13	Holloway, Dr. Rodney L.	TX
S+B1	Krupala, Mr. Frank J.	TX
S96	Locke, Mr. James	TX
S81	McCutchen, Mr. Bill	TX
S+D6	Miller, M.E.	TX
S37	Philley, Dr. George	TX
S+Q8	Ripple, B.	TX
S31	Sparks, Dr. Alton M.	TX
S38	Tannahill, Dr. Harold	TX
S91	Wiese, Dr. Ann	TX
S+G3	Wilde, Dr. David	TX
F27	Splichal, Raquel	TX
S18	Baldwin, Dr. Robert E.	VA
S44	Derr, Dr. Jeff F.	VA
S67	Yoder, Dr. Keith	VA

Code	Field Research Director (WSR)	State	Code	Field Research Director (WSR)	State
W94	Kilby, Dr. Michael	AZ	W87	Ogawa, Dr. Joseph M.	CA
W+I4	Matheron, Dr. Michael E.	AZ	W+P3	Olsen, Nora	CA
W29	Palumbo, Dr. John	AZ	W81	Olson, Mr. William H.	CA
XX2	Young, P.	AZ	W63	Orloff, Mr. Steve B.	CA
W+D4	Adaskaveg, Dr. James	CA	W+O2	Peterson, Steve	CA
W06	Agamalian, Dr. Harry	CA	W79	Reil, Mr. Wilbur O.	CA
W+A2	Andris, Mr. Harry	CA	W+X3	Rivera, Sylvia	CA
W+H9	Attaway, J	CA	W+P1	Robbins, Mr. Sean	CA
W+D6	Autotte, Barbara A.	CA	W+G1	Rodriguez, Dr. Ben	CA
W04	Bailey, Dr. Blair	CA	W+I7	Roncoroni, Mr. John	CA
W92	Bari, Dr. Mohammad H.	CA	W68	Salmon, Mr. Terrill	CA
W+G8	Bayramian, Laurie	CA	W+O9	Schlesselman, Mr. Jack	CA
W+G6	Beevers, Dr. Michael	CA	W03	Smith, Dr. Richard	CA
W83	Bender, Mr. Gary	CA	W+X9	Stewart, D.	CA
W+B9	Blechman, Mr. Matt	CA	W22	Teviotdale, Dr. Beth	CA
W+P2	Bolda, Mr. Mark	CA	W+B8	Trabuco, Mr. Ray	CA
W+O3	Campbell, Ms. Marsha	CA	F37	Turner, B (Woodland)	CA
W33	Chaney, Mr. William	CA	W39	Van Steenwyck, Dr. Robert	CA
W80	Connell, Mr. Joseph	CA	W+G4	Vickery, Craig	CA
W+G2	Corkins, Dr. John	CA	W+F2	Villasenor, Raymond	CA
W+F9	DaSilva, Mr. Alfredo	CA	F16	Watkins, S.	CA
W19	Davis, Dr. Michael R.	CA	W+D2	Zalom, Dr. Frank	CA
W+P5	Diaz, Mr. Doug	CA	ZZ4	Zapien, R.	CA
W32	Elmore, Dr. Clyde	CA	W53	Cranshaw, Dr. W.S.	CO
W+I8	Farrar, Mr. Chuck	CA	W+B7	Defoliart, Ms. Linda	CO
W10	Ferguson, Dr. Louise	CA	W+A8	Westra, Dr. Philip	CO
W74	Ferguson, Mrs. Mary	CA	W+D9	Wingfield, Sandi	CO
W54	Fohner, Dr. George	CA	+W11	Oman, Clark (CAT)	CO
W+I1	Galt, Dan	CA	W71	Chang, Mr. Vincent	HI
W47	Godfrey, Dr. Larry	CA	W35	DeFrank, Dr. Joseph	HI
W08	Gubler, Dr. Douglas	CA	W31	Etheridge, Ms. Myoung-Hee	HI
W49	Hale, Mr. Roy	CA	W69	Santo, Mr. Lance	HI
W58	Hickman, Mr. Gary	CA	W+P6	Willis, Dr. Hong	HI
W30	Hulst, Dr. David	CA	W+D5	Barbour, Jim	ID
W96	Keenan (Stoffel), Debra	CA	W+I3	Cervantes, Dan E.	ID
W99	Kelley, Ms. Kathleen	CA	W38	Dorschner, Dr. Keith	ID
W57	Kempen, Dr. Harold L.	CA	W12	Hafez, Dr. Saad L.	ID
W26	Koike, Dr. Steve	CA	W+B2	Meeks, Mr. Will	ID
W+G5	Ksander, Tim	CA	W+A5	Olson, Ms. Debi	ID
W13	Laemmlen, Mr. Franklin	CA	W+P3	Olsen, Nora	ID
F34	Kyser, Guy	CA	W+O6	Smith, Ms. Jo Anne	ID
W+F1	May, Mr. Bryan Vander	CA	W28	Thomson, Mr. Craig	ID
W+H3	Middleton, Michael	CA	W+B5	Noel, Mr. Wes	MT
W+H8	Mitchell, Michelle	CA	W+H7	Banks, Phil (Marathon)	NM
W95	Morris, Ms. Mona L.	CA	W+F6	Lee, Dr. Richard	NM
W23	Mullen, Mr. Robert	CA	W50	Lewis, Mr. Brad	NM
W76	Noegel, Dr. Ken (CA)	CA	W40	Schroeder, Dr. Jill	NM

Code	Field Research Director (WSR)	State
F33	Hamilton, Cary	NM
W34	Anderson, Dr. Dave	OR
W18	Appleby, Mr. Arnold	OR
W82	Burr, Dr. Ronald J.	OR
W97	Calkin, Mr. Jim	OR
W85	Collins, Mr. Craig	OR
W89	Collins, Mr. Ron	OR
W88	Crabtree, Dr. Garvin	OR
W+O7	Curtis, Mr. Dan	OR
W20	DeFrancesco, Mr. Joe	OR
W90	Fischer, Mr. Vernon	OR
W45	Ingham, Dr. Russell E.	OR
W98	Kloft, Mr. Paul	OR
W48	Pscheidt, Dr. Jay	OR
W02	Stanger, Dr. Charles	OR
W17	William, Dr. Ray	OR
ZZ5	Sturman, P.	OR
W+A6	Vokler, Dr. K.C.	WA
W93	Askham, Dr. Leonard R.	WA
W+A4	Boerboom, Dr. Chris	WA
W15	Bristow, Dr. Peter	WA
W+G3	Britt, Ron	WA
W01	Buchholz, Dr. Carl	WA
F32	Zasada, I.A.	WA
W86	Dean, Dr. Bill	WA
W+D8	Miller, Tim (Mosses Lake)	WA
W36	Parker, Dr. Robert	WA
W05	Patten, Dr. Kim	WA
W91	Qualls, Mr. Mick	WA
W75	Santo, Dr. Gerald	WA
W21	Schultz, Dr. Tom	WA
W16	Shanks, Dr. Carl	WA
W78	Grove, Mr. Gary	WA
W84	Johnson, Dr. Dennis A.	WA
+W21	Schreiber, Mr. Alan (ADG)	WA

CODE	Field Research Director (Canada)	State
K73	Abiola, Tola	AB
F28	Heptonstall, L.	AB
K54	Welford, Michael	AB
K01	Fitzpatrick, Dr. Sheila	BC
K05	Elmhirst, Dr. Janice	BC
K07	Brookes, Ms. Victoria	BC
K16	van den Berg, Cornelius	BC
K34	Bedford, Karen	BC
K43	Wright, Brent	BC
K65	Clodius, Markus	BC
K66	Wardle, Douglas	BC
K68	McMillan, Grant	BC
K72	Nield, David	BC
K78	MacDonald, Jesse	BC
K*	TBD-CANADA	K*
K02	Rourke, Mr. David	MB
K21	Pankhurst, Dave	MB
K57	De Koninck, A.	MB
K60	Fuchs, Melissa	MB
K50	Leblanc, S.	NB
K44	Peill, Heather	NS
K03	Walker, Mr. Gerald	ON
K04	O'Sullivan, Dr. John	ON
K06	Hovius, Ms. Marilyn	ON
K09	Chaput, Mr. Jim	ON
K5	Dombrowsky, Maria	ON
K10	McFadden-Smith, Wendy	ON
K11	Vaugh, Fred	ON
K12	Jotcham, Jim	ON
K13	O'Neill, Greg	ON
K17	Kerr, Brian J.	ON
K19	Grohs, Robert	ON
K22	Hamill, Al	ON
K29	Weber-Henricks, Mary	ON
K30	Riddle, Geoff	ON
K33	Ardiel, K.	ON
K36	Pogoda, Mitch	ON
K37	Penner, Julie	ON
K39	Davis, Justin	ON
K42	Vander Wilp, Kelly	ON
K45	White, Peter	ON
K70	Wismer, R.J.	ON
K25	Howatt, Steve	PE
K40	Harris, Matthew	PE
K14	Asselin, Mario	QC
K15	Audette, Charles	QC
K20	Bouffard, Sylvie-Anne	QC
K26	Bastiani, Celia	QC
K38	McArthur	QC
K46	Rancourt, Benoit	QC
K51	Hadd, Renaud	QC
K53	Trudeau, M.	QC
K61	Jobin, Tristan	QC
K71	Dubuc, Jean-Fracois	QC
K63	Ulrich, Daniel	SK
K67	Redekop, J.	SK

Code	Multiple FRD Same Location	State
+SA	**U of FL**	**FL**
F41	Carrillo, D.	FL
S40	Crane, Dr. Jonathan H.	FL
+SA4	Crocker, Dr. Tim E.	FL
+SA3	Johnson, Dr. Fred A.	FL
+SA1	Stall, Dr. William M.	FL
+SA6	Studstill, David	FL
+SA5	Tanner, Berry	FL
+SA2	Taylor, Mr. Scott	FL
S40A	Olzack, Reed	FL
S56	Lamberts, Dr. Mary	FL
YY1	Palmateer, A	FL
+SB	**NC State**	**NC**
+SB1	Averre, Dr. Charles	NC
+SB2	Batts, Roger B.	NC
+SB5	Cline, Mr. William	NC
+SB3	Mitchem, Wayne	NC
+SB4	Monks, Dr. David W.	NC
+SB6	Sorensen, Dr. Kenneth	NC
+SG	**U of TN - Crossville**	**TN**
+SG1	Mullins, Dr. Charles	TN
+SG2	Shamiyeh, Dr. William	TN
+SH	**TN-Jackson & Crossville**	**TN**
+SH4	Smith, Brent	TN
+SH1	Thompson, A.	TN

Code	Multiple FRD Same Location	State
+SJ	**TX A& M**	**TX**
+SJ1	Dela Garza, Mr. Rudy	TX
+SJ2	Gregg, Ms. Lori	TX
F17	Bauer, Arin	TX
S48	Braverman, Dr. Michael	TX
F36	Marconi, C.	TX
F20	Rodriguez, Alfredo	TX
F24	Saldana, Robert	TX
+SJ3	Amador, Dr. Jose M.	TX
+SA		**FL**
S26	Pena, Dr. Jorge E.	FL
S27	Ploetz, Dr. Randy	FL
S04	Raid, Dr. Richard	FL
+$S1		**FL**
+$S1	Booker, Bradley	FL
F2	Yates, S.	FL
S+U8	Huffman, B.	FL

Code	Multiple FRD Same Location	State
+WD	**Excell - Fresno**	**CA**
+WD2	Jones, Pat	CA
+WD1	Miller, Mr. Michael	CA
+WA	**Research for Hire**	**CA**
+WA3	DeCarli, Paul	CA
+WA1	Ennes, D. (RFH)	CA
+WA5	Patterson, F.	CA
+WA2	Scheufele, Scott	CA
+WA4	Turner, Blaine (Porterville)	CA
+WQ	**Imperial County**	**CA**
+WQ1	Bell, Mr. Carl	CA
+WQ2	Boutwell, Brent	CA
+WB	**UC Kearney Res.**	**CA**
+WB4	Carpenter, Francislene	CA
+WB2	Ennes, D. (Kearney)	CA
+WB1	Prather, Dr. Tim	CA
+WB5	Skiles, Keri	CA
+WB3	Straugh, Mr. Michael	CA
+WO	**Plant Science - Ripon**	**CA**
+WO1	Allan, Mr. Mike	CA
+WO2	Fekete, Mr. David	CA
+$	**Pacific Ag Research**	**CA**
+$W1	Sances, Mr. Frank	CA
+WJ	**Res. Designed for Agri**	**AZ**
+WJ2	Paden, Mr. Ron	AZ
+WJ1	West, Mr. Steve	AZ

Code	Multiple FRD Same Location	State
+WN	**CO State Univ**	**CO**
+WN3	Loiz, Meghan	CO
+WN1	McDonald, Dr. Sandra	CO
+WN2	Oman, Clark (CSU)	CO
+WR	**U of HI**	**HI**
+WR3	Coughlin, Julie	HI
+WR2	Kam, James	HI
+WR1	Kawate, Dr. Mike K.	HI
+WF	**NM State Univ.**	**NM**
+WF2	Banks, Phil (NMSU)	NM
+WF1	Craig, Maury (NMSU)	NM
+WF3	Morris, Edward (NMSU)	NM
+WM	**NWREC - OR State Univ**	**OR**
+WM2	Cornwell, Chris	OR
+WM3	Koskela, Ms. Gina	OR
+WM1	McReynolds, Mr. Robert	OR
+WI	**Excell - Mt. Vern**	**WA**
+WI1	Al-Khatib, Dr. Kassim	WA
+WI2	Miller, Mr. Tim (MT Vern)	WA
+WP	**WA State U - IAREC**	**WA**
+WP3	Groenendale, D.	WA
+WP1	Schreiber, Mr. Alan (WAU)	WA
+WP2	Wight, Ron	WA
+WH	**UC Coop Ext - Fresno**	**CA**
+WH1	Fischer, Mr. Bill	CA
+WH2	Hembree, Mr. Kurt	CA

APPENDIX C to SOP# 4.4:07

CODE	*LABORATORY*
ABC	*ABC - ABC Lab Missouri*
ACD	*ACD - A.C.D.S. Res., Inc. (Processing)*
ADP	*ADP - ADPEN Labs., Inc.*
AGR	*AGR - Agrolinz Agrarchemikalien Ges.m.b.H.*
ALS	*ALS - ALS Laboratory Group*
ARR	*ARR - U of Arkansas*
BAR	*BAR - BASF Corporation*
BER	*BER - USDA-ARS Beltsville*
BIO	*BIO - Biospherics*
BOL	*BOL - Bolsa Res. Assoc.*
BYP	*BYP - Bayer Corp. (Residue & Processing)*
CANADA	*CANADA - Canadian To Be Determined*
CAR	*CAR - U of California*
CEM	*CEM - CEM Analytical Services Ltd.*
CER	*CER - Cerexagri, Inc.*
CIR	*CIR - Novartis*
CLR	*CLR - Centre Lab*
CNR	*CNR - Enviro-Test Lab*
COL	*COL - Columbia Labs*
COR	*COR - Pyxant labs Inc.*
CPR	*CPR - Critical Path Services*
DEL	*DEL - Del Monte Res. Center*
DOR	*DOW - Dow AgroSciences*
DPR	*DPR - E.I. DuPont de Nemours & Co.*
ECR	*ECR - En-Cas Analytical Lab.*
EFP	*EFP - Englar Food Lab., Inc. (Processing)*
EPA	*EPA*
EPL	*EPL - EPL Bioanalytical Services*
ETL	*ETL - ETL Enviro-Test*
FLR	*FLR - U of Florida*
FMC	*FMC - FMC*
GAR	*GAR - River Res. Center*
GPR	*GPR - Golden Pacific Laboratories, LLC.*
GUS	*GUS - Gustafson Res & Dev. Center (Seed Treatment)*
GXP	*GLP Technologies (Processing)*
HAS	*HAS - Huntington Analytical Services*
HIP	*Univ. of Hawaii at Manoa (Processing)*
HIR	*HIR - U of Hawaii*
HLS	*HLS - Huntingdon Life Sciences*
HOR	*HOR - Horizon Lab., Inc.*

CODE	LABORATORY
HSR	HSR - Environmental Science Dept.
IDP	University of ID (Processing)
IDR	IDR - U of Idaho
ILR	ILR - IL Natural History Survey
JAN	JAN - Janssen Pharmaceutics, N.V.
JRF	JRF - JRF America
LSR	LSR - Vineland Station, Canada
MCK	MCK - McKenzie Lab., Inc.
MI/FL	MIR & FLR Split AI's
MIR	MIR - Michigan State U
MNR	MNR - MN Valley Testings Labs
MON	MON - Monsanto Company
MOR	MOR - Morse Laboratories
MSD	MSD - Merck Res. Labs.
MSR	MSR - MS State U
MTR	MTR - Maxim Technologies Inc.
NCR	NCR - NC State U
NDR	NDR - ND Pesticide Analytical Lab
NFL	NFL - The National Food Laboratory (Processing After 7/1/03)
NFP	The National Food Laboratory (Processing-Prior to 8/1/03)
NONE	Performance Study
NOR	NOR - Novartis Crop Protection
NRR	NRR - MI Dept. of Env Quality, Joint Lab
NYP	NYS Agricultural Experiment Station (Processing)
NYR	NYR - Cornell - NYSAES
ONR	ONR - University of Guelph, Canada
ORR	ORR - OR State U
PAR	PAR - Penn State U
PER	PER - PTRL East, Inc.
PTR	PTR - PTRL West, Inc.
PXR	PXR - Pixant Lab, Canada
RCR	RCR - Ricerca Inc.
RHR	RHR - Biodevelopment Lab. Inc.
RPR	RPR - Rhone-Poulenc Ag. Co.
SANDOZ	SANDOZ - Sandoz Crop Protection Corp.
SGS	SGS - SGS North America, Inc. (Seed Treatment)
SRI	SRI - Southwest Research Institute
STR	STR - SynTech Research Laboratories Service
SVR	SVR - Smithers Viscient
SYM	SYM - Symbiotic Research
SYN	SYN - Syngenta Crop Protection, NC

CODE	*LABORATORY*
SYS	*SYS - Syngenta Seeds, MN*
TBD	*TBD - To Be Determined*
TIR	*TIR - USDA-ARS Tifton*
TOR	*TOR - Trace Organic & Pesticide Section, Canada*
TOX	*TOX - Toxikon*
TSF	*TSF - The South Farm (Seed Treatment)*
TXP	*Texas A&M University (Processing)*
UCR	*UCR - Crompton Co*
UOG	*UOG - University of Guelph*
VAL	*VAL - Valent USA Corporation*
VPI	*VPI - VA Polytech. Institute*
WAR	*WAR - WA, Chemical & Hop Lab*
WIR	*WIR - Hazeleton Laboratories*
WUR	*WUR - Tri Cities, Food & Env. Quality Lab*
YAR	*YAR - USDA-ARS Wapato*
ZER	*ZER - Zeneca, Inc.*

SOP #: 4.5

AUTHORS: W.P. Barney, V. R. Starner and D. L. Kunkel

REVISION# 07

EFFECTIVE DATE April 8, 2015

TITLE: **Protocol Change (Amendment/Deviation) Development and Distribution.**

PURPOSE: To establish a standard procedure for the development, authorization and distribution of protocol changes for IR-4 research in studies designed to be conducted according to Good Laboratory Practice (GLP) standards. To provide instruction when the deviation involves a non-compliant laboratory reference substance.

SCOPE: This SOP applies to all protocol changes issued on IR-4 projects conducted under GLP.

PROCEDURES: 1) Protocol amendments are planned changes to the protocols that are made and documented by the Study Director prior to occurrence. Protocol amendments may be proposed by anyone involved in the study. These proposed changes must be communicated to the Study Director. If the proposed change is acceptable, then the change is documented by the Study Director and Sponsor Representative. The documentation of the protocol amendment should contain, at a minimum: Study Number (PR Number), change number, test substance/crop, description and reason(s) for the change, a brief statement on the impact of the change on the study, and room for the signature and date of the Study Director and Sponsor Representative to authorize the amendment(s).

If deemed appropriate by the Study Director, affected individuals will be given an opportunity to review the draft protocol amendment(s). All suggested changes will be considered; however, the Study Director has the final decision on acceptance of the protocol amendment(s).

2) Protocol deviations are unplanned changes to the protocol. The appropriate Research Director or other study participant should contact the Study Director as soon as possible after it has been recognized that a protocol deviation has occurred. The Study Director may informally approve the deviation if circumstances require immediate response. However, the Study Director must at a minimum document the approval *via* phone log, e-mail, or fax, etc. and insure that the deviation is documented. The deviation must be authorized by the Study Director and Sponsor Representative as soon as possible after receipt at Headquarters. If a protocol deviation is recognized by the Study Director, then the Study Director may generate the deviation form. Items required in a protocol deviation form are the same as outlined for protocol amendments (see procedure 1).

3) Study protocols designate use of GLP characterized reference substances. However, if laboratory personnel request the use of a reference substance that has not been characterized in accordance with GLP by a reputable manufacturer; IR-4 will do everything in its power to get this reference substance characterized. If characterization is not possible, then the specific procedure in Appendix D will be followed.

4) Emergency Case Only (e.g. trial termination and new trial needed immediately): If the Study Director cannot be reached concerning a protocol change, a member of HQ management or a Study Director will provide guidance regarding the change/deviation. Either will prepare documentation for the absent Study Director. This Emergency Change Form (See Appendix A) will be signed and dated by testing facility management or the registration manager. Upon return the Study Director will sign and date this emergency change form and if acceptable, this form will then be redistributed to the appropriate people.

5) Tracking protocol amendments and deviations: Each protocol amendment and deviation will be assigned a unique identification (change) number. These numbers will be consecutive whole numbers assigned by the Study Director, or other appropriate person at Headquarters, after checking the number of previous change(s) on file at Headquarters. Approved protocol changes will be assigned a numerical value beginning with 1. The change number is noted on

the inside cover of the protocol folder located in the study file (see SOP 4.1, section 8). To correct an error in numbering of protocol changes, use the next sequential number following the most recent change number (e.g., if there are two protocol

changes No. 4, and the most recent change is No. 8, correct the 2nd [chronological] Change No. 4 [as per GLP correction procedures] to be Change No. 9, and redistribute as appropriate).

6) A protocol amendment or deviation is officially approved once the Study Director and the Sponsor Representative sign and date the change. Any handwritten changes after the approved signatures must be initialed and dated by SD and Sponsor Representative.

7) Certified exact copies of the document authorizing protocol changes are made and distributed to the IR-4 Headquarters Quality Assurance Unit and other individuals indicated by the Study Director. The QAU will be responsible for distribution to appropriate QA personnel. The original of the protocol change is placed in the protocol folder located in the study file.

8) Examples of the protocol amendment and deviation forms are provided as Appendix B and C, respectively.

Revised by: W. P. Barney Date: 3/20/15

Approved by: Jay Bar Date: 25 March 2015

IR-4 PROJECT HEADQUARTERS, 500 COLLEGE ROAD EAST, SUITE 201 W, PRINCETON, NJ 08540
PHONE: (732) 932-9575; FAX#: (609) 514-2612

EMERGENCY IR-4 PROTOCOL CHANGE/DEVIATION*

CHANGE # ___

Project Title: _____ **PR No.**: _____

Field I. D. No.: _____

Laboratory I.D. No.: _____

Description of Change:

Reason for Change:

Impact on Study:

EMERGENCY Authorization:

_____ _____

HQ Study Director (DATE) Management (DATE)

cc: IR-4 QA Unit
Laboratory Research Director(s)
Field Research Director(s)
Regional Field Coordinator(s)

*** Study Director could not be reached; approval was granted by the above HQ Study Director and Sponsor**

Authorization of the Study Director upon return**

_____

Study Director (Date)

**** Redistribute Study Director Authorization**

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PHONE: (732) 932-9575; FAX#: (609) 514-2612

CHANGE # ____

IR-4 PROTOCOL AMENDMENT FORM

Project Title: _____ **PR No.**: _____

****Field I. D. No.**: _____

****Laboratory I.D. No.**: _____

Description of Change:

Reason for Change:

Impact on Study:

Authorization:

_____		_____	
Study Director	(DATE)	Sponsor Representative	(DATE)

cc: IR-4 QA Unit
Laboratory Research Director(s)
**Field Research Director(s)
**Regional Field Coordinator(s)

**Note items that are optional

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CHANGE # ____

IR-4 PROTOCOL DEVIATION FORM

Project Title: _____ **PR No.**: _____

****Field I. D. No.**: _____

****Laboratory I.D. No.**: _____

Description of Change:

Reason for Change:

Impact on Study:

Authorization:

_____		_____	
Study Director	(DATE)	Sponsor Representative	(DATE)

cc: IR-4 QA Unit
Laboratory Research Director(s)
**Field Research Director(s)
**Regional Field Coordinator(s)

**Note items that are optional

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Appendix D to SOP 4.5:07

The GLP regulations (40 CFR 120.105), the IR-4's Magnitude of the Residue study protocols and the IR-4 Operational Handbook state that the reference substance must be characterized under GLPs. However, there are times when study personnel (usually the Study Director) are notified that the reference substance has been characterized by a reputable manufacturer, but not characterized under GLP. The following procedure will apply in this situation.

a) Testing facility management (TFM) will be notified by the Study Director (or other personnel) as soon as possible.

b) Study personnel (usually the Study Director) will request the user or supplier (for example, the lab director or registrant) to provide the COA and any other available characterization data. Characterization data is needed for the IR-4 files and to determine if sufficient information is available to assess the validity of the material and to support "Books and Records" requirements.

c) The COA and other characterization data will be provided to TFM, who will make a final decision on whether the available data is sufficient to establish identity and purity of the reference substance to support the study.

d) TFM or designee will communicate to the Study Director whether the data provided is sufficient to proceed with the analysis, or whether additional action (such as analysis of the reference substance) is needed prior to acceptance of use of the reference substance in the study.

e) If the characterization data is deemed acceptable by TFM, a protocol deviation is still needed to document the use of the non-GLP reference substance (and a statement added to the GLP compliance statement of the final report).

f) If the reference substance has already been used in the study, the above steps apply as soon as study personnel are notified.

SOP#: 4.6

AUTHOR: V. R. Starner

REVISION#: 01

EFFECTIVE DATE: April 8, 2015

TITLE: **Test Site SOP Deviations - Documentation, Authorization, and Distribution**

PURPOSE: To establish a standard procedure for the documentation, authorization and distribution of test site SOP deviations for IR-4 research in studies designed to be conducted according to Good Laboratory Practice (GLP) standards.

SCOPE: This SOP applies to all SOP deviations issued on IR-4 studies conducted under GLP.

PROCEDURES:

1) Definition: an SOP deviation is a change from established facility SOPs

2) All deviations to facility SOPs (Field Researcher, Residue Laboratory. Processing Facility, HQ, Seed Treatment Facility) and the reasons thereof shall be documented, signed/dated by the Study Director, and maintained in the study file.

3) The appropriate Field/Lab Research Director (or other appropriate facility person) should contact the Study Director as soon as possible after it has been recognized that an SOP deviation has occurred. The Study Director may informally approve an SOP deviation if immediate response is needed. However, the Study Director must at a minimum document the approval via phone log, e-mail, or fax, etc., and request a written SOP deviation be submitted to the Study Director. The SOP deviation must be authorized by the Study Director after receipt at Headquarters. If an SOP deviation is recognized by QAU or the Study Director, then the Study Director can document the deviation on his or her own initiative.

4) If the Study Director cannot be reached concerning an SOP

deviation, the Sponsor Representative or another Study Director at Headquarters may provide guidance regarding the deviation and prepare documentation for the absent Study Director. Upon return, the Study Director will be responsible for processing the appropriate documentation.

5) The SOP deviation form (see an example form - Appendix A) should contain, at a minimum, the PR#, Test Substance and Crop, Field, Laboratory, Processor or Seed Treatment I.D.#, Facility and SOP# affected, description and reason for the deviation, impact of the deviation, and Study Director signature/date. For all SOP deviations, the Study Director will provide a brief assessment regarding the impact of the deviation on the study.

6) An SOP deviation is officially approved once the Study Director signs and dates the deviation.

7) The signed, original SOP deviation should be filed with the study raw data. Certified copies of the deviation can be distributed to individuals indicated by the Study Director.

Revised by: Van R. Stanger Date: 3/19/15

Approved by: Jerry Baron Date: 20 March 2015

APPENDIX A

IR-4 SOP DEVIATION FORM

Test Substance/Crop: _____ PR No.:

*Field I. D. No.:

*Laboratory I. D. No.: _____

Test Site SOP# deviated from:
(e.g. Headquarters SOP# 5.1)

Description of the SOP Deviation:

Reason(s) for the SOP Deviation:

Study Director's assessment regarding the impact of this SOP deviation on the study:

Authorization:

_____
Study Director Date

cc: Regional Field/Laboratory Research Coordinator - as needed
Field/Laboratory Research Director - as needed

*Notes items that are optional.

.....
.....

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Page 1 of 1

SOP #: 4.7

AUTHORS: K. S. Samoil

REVISION: 01

EFFECTIVE DATE: January 31, 2010

TITLE: **Terminating an IR-4 Project GLP Field Trial**

PURPOSE: To outline the procedure to follow when terminating an IR-4 Project GLP Field Trial.

SCOPE: This SOP applies to all IR-4 Project GLP Field Trials to be terminated, regardless of reason.

PROCEDURES:

1) Immediately after a Study Director has determined that a GLP Field Trial must be terminated, he/she must prepare an amendment terminating the field trial. The amendment must follow the current version of IR-4 Headquarters SOP # 4.5; however, it must include (1) the reason the field trial is terminated, (2) the statement that data from the field trial (including the Field Data Book) will not be audited by QA after the date the amendment is signed, and (3) the impact of the field trial termination on the study. A copy of the amendment must be distributed to the Field Research Director, the appropriate Regional/ARS Field Coordinator, and the appropriate Laboratory Research Director.

2) The Study Director will request that the Field Data Book be sent to the Registrations Manager at IR-4 Project Headquarters, following established routing procedures, so the receipt of the book can be documented in the IR-4 Project database.

3) Once the Field Data Book is at IR-4 Headquarters, the cover sheet must indicate that the field trial was terminated.

4) The Field Data Book and all associated documentation for the terminated GLP Field Trial must be archived with the study file at study completion.

Prepared by: _____ Date: 1/6/10

Approved by: _____ Date: 8 JAN 2010

SOP #: 4.8

AUTHOR: T. W. Barkalow and Diane Infante

REVISION: 01

EFFECTIVE DATE: January 31, 2010

TITLE: **Cancelling an IR-4 Project GLP Study**

PURPOSE: To outline the procedure to follow when canceling an IR-4 Project GLP Study.

SCOPE: This SOP applies to all IR-4 Project GLP Studies to be canceled.

PROCEDURES: 1) A Study Director (SD) can make the decision to cancel a study only with the authorization of IR-4 Testing Facility Management (TFM) or their designate (see appendices to current version of SOP # 6.0 for designates). To cancel a study two different scenarios may apply. Utilize the procedures that fit the current scenario of the study needing to be cancelled. Scenario A: If all of the data is at HQ or in their appropriate archive, then the SD may use the amendment in Appendix A and issue the cancelling amendment. Scenario B: If all the data is not at HQ or in an archive, then utilize the following procedure.

Utilize the first part of the amendment form in Appendix B indicating that the study will be cancelled and request all data be forwarded to IR-4 HQ for archival or that an acknowledgment that the data is in their appropriate archive be sent to HQ. The second portion of this amendment will cancel the study. The study will remain active on the Master Schedule until the second portion of the amendment is signed by the SD and TFM.

The amendment indicating the pending and/or actual cancellation of the IR-4 Project GLP study must be prepared following the current version of IR-4 Headquarters SOP # 4.5 with the exception of final signature(s) from TFM. In addition, the amendment in scenario B must contain: (A) A statement that the study is going to be canceled, and that the outstanding data for the study is to be forwarded to the IR-4 HQ Registration Manager for archival or archived on site; or (B) A statement indicating that all the raw data has been received at IR-4 HQ, that the analytical data at an IR-4 regional laboratory, has been archived, or that the majority of the raw data has been received at IR-4 HQ and the exceptions are listed and (C) The amendment will serve as the final report for the study and that the report does not contain all required final report elements. The bottom portion of this amendment will definitively state that the study is cancelled.

2) If field trials or analytical work are in progress, the appropriate Field Research Director(s), Regional/ARS Field Coordinator(s), Laboratory Research Director, and IR-4 QAU must be notified immediately that the study is being canceled.

3) If field trials are in progress, all data generated as of the date of notice of cancellation must be current. The Study Director will request that any outstanding Field Data Books immediately be sent to the Registrations Manager at IR-4 Project Headquarters, following established routing procedures, so the receipt of the book can be documented in the IR-4 Project database. If any Field Data Books from the study are in queue to be audited by QA, they will be immediately removed from the queue and forwarded to the Registrations Manager.

4) If the analytical work is in progress, all data generated as of the date of cancellation must be current. If the Analytical Summary Report for the study is in queue to be audited by QA, it must be immediately removed and archived. Analytical data can be archived at the analytical laboratory or at IR-4 Project Headquarters, following established procedures.

5) All documentation (includes protocol with any changes, other records and raw data) associated with the study must be archived at study completion following specific instructions in the protocol and a copy of the completed archive inventory sheet provided to the SD. After 45 days the Study Director will make a determination if the raw data is available.

Prepared by: Tommy W Barker Date: 1/6/2010

Approved by: Jerry Baron Date: 8 JAN 2010

IR-4 Project Headquarters, 500 College Road East, Suite 201W, Princeton, NJ 08540. TEL. #: 732-932-9575, FAX. #. 609-514-2612

Change #

IR-4 PROTOCOL AMENDMENT FORM

Project Title: **PR No.**:

Description of Change:

This study is cancelled. The cancellation date will be the date this amendment is signed by the study director.

Reason for Change:

This study is being cancelled because [give reason for cancellation].

Impact on Study:

This amendment will serve as the final report. This report will not contain all required final report elements. All raw data, protocol and changes, and correspondence have been archived (with the following exceptions [list all exceptions]). Please see attached completed archive inventory as provided from the archivist.

Authorization:

Study Director	(DATE)	Testing Facility Management	(DATE)

cc: IR-4 QA Unit, FRDS, RFCs, LRD, etc.

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Change #

IR-4 PROTOCOL AMENDMENT FORM

Project Title: **PR No.:**

Description of Change:

This study is going to be cancelled. In preparation for cancellation of the study, all data must be archived and at this time we do not have all data received at IR-4 Headquarters.

The following data is outstanding: (***list all data that is outstanding***).

All data should be sent to the IR-4 Registration Manager per standard routing procedures (all field and lab data and records). The regional labs (Michigan State, University of California-Davis, University of Florida) may archive any and all data generated for this study and must provide acknowledgement of the archival to the study director.

Reason for Change:

This study is being cancelled because [give reason for cancellation].

Impact on Study:

The Quality Assurance Unit will not audit any additional data/reports generated from this study, including the field data books and the analytical data/summary report.

Authorization:

Study Director	(DATE)	**Testing Facility Management**	(DATE)

cc: IR-4 QA Unit
LRD:
FRDS:
RFCs:

All outstanding data has been received at IR-4 Headquarters, this study is now canceled, the study will be archived and this amendment will serve as the final report. This report does not contain all required final report elements.

Study Director Authorization _____ Date _____

Testing Facility Management_____ Date _____

Note that after cancellation, this amendment will be re-distributed.

THIS PROTOCOL CHANGE FORM COPIED ON COLORED PAPER IS AN EXACT COPY OF THE ORIGINAL

SOP #: 5.0

AUTHOR: W. P. Barney and Kathryn A. Hackett-Fields

REVISION #: 02

EFFECTIVE DATE: January 31, 2010

TITLE: **Responses to Quality Assurance (QA) Findings: Generation, Handling and Evaluation for GLP Compliance.**

PURPOSE: To provide guidance to QA and Study Directors (SDs) for handling the documentation of responses for recordkeeping purposes and for GLP compliance. To provide guidance to SDs in responding to QA findings, and evaluating the responses of others. To provide an explanation to outside entities (e.g. EPA) of the IR-4 process for making responses to QA findings.

SCOPE: All IR-4 HQ personnel concerned with project oversight, management and QA, including Administrative functions.

PROCEDURES: The procedures cover routine operations. For any QA finding of a critical nature, the only difference is immediate routing to the Study Director and Testing Facility Management, using separate reports.

QA findings in audit and inspection reports should be written in such a way as to specify the necessary action, termed the *response*. The response will be made in one of several ways, depending on the nature of the finding:

- an answer to a question
- the provision of additional information in the text of the response (see B.3.)
- the provision of additional information via an altered copy (or made to the original) of the raw data at the research site
- new documents to be attached to the original raw data
- the generation of an SOP and/or protocol deviation
- deferral of the response to the Study Director (SD).

In general, responses come from two main sources: 1) research personnel from field, laboratory, processing and other sites, and 2) Study Directors. Original responses are to be sent to IR-4 HQ, for routing by QA to SDs.

A. QAU Handling of Responses

1. Since the original audit, to which the response will be attached, may not be in the active QA PR folder, it will be necessary to contact individual SD's in order to retrieve outstanding documents. This may be done directly or via e-mail, which may be more efficient when requesting several audits.

2. When documents are provided as the means of making a response, a photocopy will be made for permanent attachment to the audit. The original, which is sent to the SD, may be tagged as "Data" with a "Post-It" note as an alert.

3. Periodically, each SD with outstanding audits awaiting finalization may receive a report from QA, listing the audits of interest. SD's are encouraged to handle responses and audits in a timely manner, especially since audit cover pages may be signed without inferring that the SD considers the audit to be satisfactorily addressed.

B. Responses made by Research Personnel: Areas to Consider

1. Unless the finding is specifically noted for response by the SD, the personnel at the research site will be expected to handle the response. It may be necessary for them to contact the SD, who has access to the raw data, or the QA auditor, to decide upon an appropriate response. If pages from final contributing scientist reports are amended by the SD in the process of responding to the audit, a copy of each will be returned to the research personnel for their project file. Minor changes to field documents can be made directly to the documents by using GLP compliant change procedures. A major change to the data requires notification of the appropriate Field Research Director(s). It is the responsibility of the Study Director to determine if a change is major or minor.

2. For facility inspection audit reports, for which more than one SD may be affected, findings will be addressed by the research personnel. It will be the responsibility of the IR-4 QAU to monitor facility compliance to SOPs, GLP and generally accepted scientific practices. Adverse findings in facilities will be a particular focus for discussion and action among Regional/ARS directors, Testing Facility Management and the QA Manager. During annual QA Planning Meetings, discussion will be held to assure that facilities are properly targeted for follow-up inspections. Study Directors with a particular concern about any research site are encouraged to discuss this with QA and/or the registrations manager, since there may be additional issues for consideration.

3. Generally, responses will fall into one of these 4 categories: a) the answering of a question, b) the provision of additional documentation, c) the generation of a protocol and/or SOP amendment or deviation, or d) deferral of the response to the SD.

    a. Answers to questions, as appropriate, may also require documentation in the raw data, since QA records cannot be made part of the study file. Answers may also provide information that would reveal a deviation from GLP or an SOP. (For example, the auditor might have questioned the existence of a training record on file at the research site. If no documentation was available, the deviation from GLP would need to be added to the final report.) It will be permissible for a SD to make additional entries to the raw data to document deviations from GLP regulations. This may be added to Part 1.C in the field data books.

    b. For provision of an altered (or new) attachment, the appropriate changes, annotations and additions to the copy of the raw data (or to the original as appropriate) are done in accordance with GLP. As an attachment to the QA audit, the research personnel will forward these *original* altered copies to IR-4 HQ, and maintain a copy of whatever was sent to HQ.

    c. Any additions to the field data book will be uniquely paginated according to the procedure found in General Instructions.

    d. When the QA finding suggests that a deviation from a SOP or the protocol has occurred, the research personnel may state that a deviation form has been sent to the SD or appropriate person. Generally, the deviation is sent under separate cover, and may or may not have been copied to the audit response. These instances will be handled in accordance with IR-4 HQ SOP #s 4.5, 4.6 and 8.12 (current versions), as appropriate.

    e. When the research personnel defer the response to the SD or other person, the SD will evaluate the situation and determine the proper action. Some situations may require a team approach to come to a satisfactory resolution.

4. All responses will be dated and initialed, at minimum, by the person(s) involved in making and/or authorizing the remedial action. (For audits returned to the SD without the required response, see SOP # 8.11, current version).

C. Responses made by the Study Director

1. Generally, the SD or designee makes responses to QA audits of final reports, both primary and secondary. Appropriate measures will be taken; findings or comments that are unclear should be discussed with the QA auditor.

2. Some situations may require a team approach to arrive at a satisfactory solution. The SD or designee is permitted to make changes to the raw data on behalf of research personnel, as noted above. In cases when the research personnel are not available, the SD may respond to the best of their ability; this should be noted in the response.

3. After all responses have been made, the audit will be brought to the QA office for review, and routing of the responses to Management.

D. General Considerations

1. Given the limitations of written communication, care will be taken by all parties to provide clear direction and use a neutral (versus adversarial) tone in order to expedite the response and review process. Direct communication is advised when written findings, comments or responses are unclear to the reader.

Prepared by: W. C. Barney Date: 1/6/10

Approved by: Jerry Baron Date: 8 JAN 2010

SOP #: 5.1

AUTHORS: D. L. Kunkel and J.J. Baron

REVISION#: 05

EFFECTIVE DATE: April 8, 2015

TITLE: **Data Receipt and Log-in Procedures**

PURPOSE: To provide an accurate and orderly system for the receipt, log-in, and transfer of data for review routing.

SCOPE: This SOP is to apply to all data to be used by IR-4 Headquarters in the development of pesticide petitions or other submissions to the EPA for the purpose of establishing tolerances, performance, and/or registering labels for various pesticide uses. This SOP does not apply to data received at IR-4 Headquarters for QA review.

PROCEDURES:

1. All data will be placed at the location found in Appendix A.

2. Upon receipt of all field study specific GLP data and/or reports (including processing data), the person receiving the data will acknowledge receipt. At minimum, the chain of custody records should include the name of the person receiving the data, the date received and date when the data is transferred to the Study File. Other "non-GLP" studies do not require a "Chain of Custody" form.

3. Upon receipt of all ASR (Analytical Summary Report) reports, the report will be verified that all pages are as numbered and are readable. If a problem is found the ASR will be brought to the attention of the Study Director who will contact the laboratory. Once the report is corrected the SD will bring the ASR in for the review process.

4. Acceptable ASR reports will be scanned and saved in the Shared directory as: EPA Submission/Final Reports, with the document saved using the Lab ID number. The assigned Study Director will be notified of the ASR receipt via e-mail.

5. The initial action of the person responsible for the coordination of data receipt (or designee) is to attach the "Preliminary Data Review" sheet to all incoming data to IR-4 Headquarters. The form to be filled out can be found in Appendix B.

6. Pertinent information from the received data is entered on the Food Use Data Log, (see Appendix C).

7. The IR-4 Food Use database for data tracking status is updated.

8. The data are added to the study file.

Prepared by: _____ Date: 20 MAR 2015

Approved by: _____ Date: 20 March 2015

Appendix A to SOP# 5.1:05

Location of Incoming Data Box:	In basket in Active File Room designated office at IR-4 Headquarters
Person responsible for the Coordination of Data receipt:	Susan Bierbrunner

Appendix B to SOP# 5.1:05

PRELIMINARY DATA REVIEW

PRODUCT/CROP: _____ PR#: _____

DATE RECD: _____ ASR is □ Complete □ Readable _____ FIELD/LAB ID#: _____

Note Problems if ASR is not Complete or Readable:

_____

Appendix C to SOP# 5.1:04

Food Use Data Log

Month/Year:_____ Page ____

PR#	PRODUCT	CROP	Field/Lab ID#	Day Recd

SOP #: 5.4

AUTHOR: D. Carpenter, K. S. Samoil, J. S. Corley, K. Hackett-Fields

REVISION #: 00

EFFECTIVE DATE: April 15, 2007

TITLE: **IR-4 Headquarters Review of Study Documents**

PURPOSE: To ensure that study documents are reviewed to determine their scientific merit.

SCOPE: This applies to study documents (including but not limited to field data books (FDB) and other supporting field documentation, analytical summary reports (ASR) and other laboratory documentation, and other contributing scientist documents such as processing reports when applicable) received at IR-4 Headquarters for which the IR-4 Project intends to submit the results to the registrant and/or EPA for the purposes of supporting a pesticide tolerance or expanding or maintaining a registration.

PROCEDURES: The Study Director in collaboration with other reviewers examines study documents as received together with appropriate parts of the protocol to determine if the resulting residue samples and associated analytical data are complete and sufficient and will meet the objectives of the study. When the Study Director determines that significant data/information is not available to reconstruct the research and requested data/information cannot be obtained, termination of a trial and/or additional research may be necessary. The Registration Manager and the Database Manager will be informed of the need to update the appropriate IR-4 databases by noting the need for additional data. Review will be completed before submission of the draft study report for QA audit.

A) FIELD DOCUMENTATION:

1) Items which should be checked in the FDBs during the review include, but are not limited to:

Accuracy of test substance application calculations

Test substance application adhered to protocol

Unusual rainfall and environmental events/conditions

Residue sample collection(s) agree with protocol

Sample storage conditions maintain sample integrity

Residue sample shipping agrees with protocol

2) Minor changes to the field documents can be made directly to the documents by using GLP compliant change procedures. A major change to the data also requires notification of appropriate Field Research Director(s). It is the responsibility of the Study Director to determine if a change is major or minor. The chain of custody form in the FDB(s) will be signed by the study director.

3) If the reviewer and/or Study Director determines that necessary information is not available in the field documents or if significant deviation(s) from the protocol occurred, the appropriate Regional/USDA-ARS Field Research Coordinator or Field Research Director shall be contacted to obtain the necessary information and/or assist in the appropriate follow-up actions.

4) Once the review is completed, the FDBs and other field documents should be filed in the study file.

B) ANALYTICAL DOCUMENTATION:

1) The Study Director (SD) in collaboration with other reviewers will conduct a preliminary examination of the ASR as received, together with appropriate parts of the protocol, to determine if the resulting residue data meet the objectives of the study. A more detailed review of the ASR should be conducted during data package/final report development if it was not done at the time of the initial review

2) Items that should be checked in the ASR during review include, but are not limited to those found in the protocol (Section 33):

All data and information are clear and legible

Reference Substance(s) maintained under conditions specified by the Registrant (or supplier)

Clear cross-reference between the unique laboratory Sample ID # and the field Sample ID # listed in the Sample Inventory and History section

Samples maintained frozen (generally less than 0°F, -18°C) until extraction, unless otherwise noted in the protocol

Description of sample processing and preparation of fortifications and storage stability spikes

A complete copy of the analytical Working Method along with the changes/modifications to the Reference Method

MV conducted as per protocol, applicable data included

Storage stability study conducted as per protocol and covers or nearly approximates the storage interval (longest interval from field sampling to extraction in the laboratory) of the field samples, applicable data included

Residue levels for control and treated samples with concurrent fortified recoveries included

Concurrent recoveries were within acceptable range (or the out of range values have been acknowledged by the SD) and are comparable to MV recoveries

Any modifications or deviations from the protocol and/or Working Method have been documented and approved

The GLP Compliance Statement and the QA inspection reports should be checked for non-compliance issues.

3) If the reviewer and/or Study Director determines that necessary information is not available in the analytical documents or if significant deviation(s) from the protocol occurred, the appropriate Laboratory Research Director shall be contacted to obtain the necessary information and/or assist in the appropriate follow-up actions.

4) Once the review is completed, the analytical documentation should be filed in the study file.

5) Minor changes to the ASR can be made directly to the document by using established change procedures[1]. Major changes to the ASR should be made in coordination with the LRD. The LRD should be sent those pages to which any change has been made for the laboratory's archives. For major changes requested, the cover letter should be copied to the QAU of the Laboratory. It is the responsibility of the SD to determine if a change is major or minor. Any page added or changed by the LRD/SD should be marked as such and a copy of the unrevised version marked and placed in the raw data.

6) A summary of items found deficient in the preliminary review, along with any suggested follow-up actions, should be noted.

---

1 A single line is to be drawn through the incorrect information using indelible ink, the correct information is then entered and the reviewer is to initial, date and provide a brief explanation or code documenting why the change was made

C) OTHER CONTRIBUTING SCIENTIST REPORTS (If applicable):

Contributing Scientist Reports will be reviewed with the appropriate sections of the protocol to determine that the data presented is complete and sufficient. If the reviewer and/or Study Director determines that necessary information is not available or if significant deviation(s) from the protocol occurred, the appropriate Contributing Scientist shall be contacted to obtain the necessary information and/or assist in the appropriate follow-up actions. Once the review is completed, the Contributing Scientist Report should be filed in the study file.

D) QA DOCUMENTATION:

The QA documentation will be checked and any outstanding items from QA audits will be addressed.

E) PRE-REPORT SURVEYS

Review of study documentation may be carried out by someone other than the study director. This is called a pre-report survey.

1) The Registration Manager will determine if a study receives a pre-report survey and assigns the reviewer.
2) The reviewer examines study documents as described above. The reviewer is authorized to make minor changes to field raw data, and to insert raw data pages provided in response to QA audits, in accordance with applicable FDB instructions. The chain of custody form in the FDB(s) will be signed by the reviewer.
3) Documentation will be prepared by the reviewer to provide the study director with a list of the items reviewed and results of the review, such as application calculations. This documentation will note any items which require follow-up. An example Pre-Report Survey is included in Appendix A. The study director will address items requiring follow-up, or will direct the reviewer to do so. Once the pre-report survey is completed, it will be stored in the study file.
4) The Study Director maintains the responsibility to determine whether the data is complete and sufficient and will support the objectives of the study.

Prepared by: Deborah Carpenter Date: April 2, 2007

Approved by: Jerry J Barry Date: 4-2-07

APPENDIX A

Cover Page, Pre-report Survey

PR#: [Chemical/Crop] Study Director:
This section completed by Reviewer
Dates:

_____Begin Survey

_____End Survey

_____ Raw data replaced in Active file (if not, ID location)

_____ Submitted to SD or designee

Attachments in addition to PRS summary:

_____Calculations spreadsheet for review, comments

_____

This section to be completed by Study Director in addition to notes on inner pages.

Instruction re. issues reported and/or instructions for submittal of data package for report writing:

_____

_____

_____

_____

_____

_____ Date of return by SD

A. Items to Address Prior to Sendout
1. Item: Calculations spreadsheet

Suggested action: Review and make changes or accept as presented; sign & date.

SD action/direction/decision:

Other findings: cut and paste frame below and repeat as needed for additional item(s); add number(s):

Item:

Suggested action:

SD action/direction/decision:

Resolution (by Reviwer):

B. Test and Reference Substance Information
(Not necessary to complete if no issues exist with T/C/R Substances)

Field Lot(s) used:

Laboratory Lot(s) used:
Parent:
Metabolite:

C. Items found that may be of interest to report writer:
[Identify as appropriate]

D. Items found for reporting to:
E.g., QA Manager, Registrations Manager, etc.

[Identify as appropriate and note date of transmittal]

PRS Prepared by:_____ Date:_____

Approved by:_____ Date:_____

SOP #: 6.0

AUTHORS: T.W. Barkalow, K. S. Samoil, D. L. Kunkel, J. J. Baron

REVISION#: 07

EFFECTIVE DATE: April 8, 2015

TITLE: **Final Report Development.**

PURPOSE: To provide a uniform system of final report development.

SCOPE: This SOP applies to the data from studies sponsored by IR-4 for which IR-4 intends to submit the results to potential registrants and/or EPA for the purposes of supporting a pesticide tolerance or expanding or maintaining a registration.

PROCEDURES:

1) The Study Director (SD) will determine the adequacy and completeness of the study data (including the Field Data Books, contributing scientists' reports and any other relevant data in the facility files) that have been received at IR-4 Headquarters.

2) When the SD has determined that adequate information is available or can be readily obtained, a first draft of the final report (data volume) will be prepared. Each final report should contain, but is not limited to:

- Title page (See EPA PR Notice 2011-3 {Appendix A} for guidance)
- Statement of "no confidentiality" claims (See Appendix A)
- GLP compliance statement - items for consideration may be found in each Field Data Book Part 1.C, GLP statements in contributing scientist reports, and the QA audit reports. An example for the statement's format is shown in Appendix A)
- Quality assurance statement(s) will be prepared by a QA reviewer during the second report audit for inclusion after the GLP compliance statement
- Study identification/performing laboratory

information
- Study Timetable
- Signatures & approval
- Location of raw data
- Table of contents
- Field and analytical information (see below)
- Copies of the protocol and changes
- Copies of certificates of analysis

The Field/Analytical information part of the final report should contain the majority of the study details. This part should include, but is not limited to: Text that summarizes significant features of the field and analytical trials; Field Data Summaries (see Appendix B, for an example); EPA Recommended Tables, or similar tables (see Appendix C, for examples); and a copy of the Analytical Summary Report(s) (ASR). Please note that for Table A.2., this table may be intentionally left blank.

3) The SD should determine if the Limit of Detection (LOD) and the Limit of Quantitation (LOQ) have been calculated or estimated by the Laboratory Research Director (LRD) and reported in the ASR or in a letter. If the LOD/ LOQ have been calculated by the LRD, then the SD should check to see if the calculations have been adequately explained. If the LOD/LOQ has not been calculated, then the SD should determine if it is necessary to calculate them. If estimated values have been reported and are adequate, then no further action is necessary.

If the SD determines that a calculated LOD/LOQ is necessary, then the attached method (see Appendix D) may be used to calculate the LOD/LOQ. If this method is used, then the SD should ensure that only the recoveries (conc., ppm) at the lowest level of method validation (LLMV) are used in calculating the Standard Deviation (Std. Dev.) and in determining the one-tailed t statistic (t_{n-1}) for (n-1) replicates. This method should be used only if the number of recovery check spikes (MV + Concurrent Recoveries) at the LLMV is >5 (preferably >7). If the number of spikes at the LLMV is <5 then this method should not be used or the SD may report

it as an estimated value. It is acceptable for the SD or the LRD to use a different method to calculate the LOD/LOQ; however, the method/calculations should be clearly explained. Calculations performed by the Study Director for LOD/LOQ should be documented and the spreadsheet provided in the study file.

4) A draft of the final report may be prepared by the Study Director with or without assistance from another designated person. When someone other than the Study Director assists in the preparation of the first (or any subsequent) draft of the final report, the other person's name shall be included on the study identification/performing laboratories page with a notation that their participation occurred during final report preparation. When the final report is complete, the signatures and approval page must be signed by the Study Director and a representative of IR-4 Project Management. Refer to Appendix E for sponsor designates for QA report and for final reports.

Prior to being signed, the final report must undergo Quality Assurance (QA) audit(s).

a. Interim Final Reports

Only final reports assigned to IR-4 HQ will be considered for the interim report review process.
The interim report auditing will be limited to:

i. The GLP statement as it applies to the compliance issues of the field data/field data books
ii. field data summaries appendix
iii. The B Tables of the final report
iv. Other presented areas that QA identifies and communicates as auditable.

All other sections of the final report that may be presented will not be audited in association with this interim audit. The auditing of interim reports will be focused on priority/expedited reports as determined by the Registrations

manager. The QA Manager and Registrations Manager will determine the timelines associated with the interim studies submitted and monitor progress.

When presenting the Interim report for audit, all previous QA inspection reports performed on the field portion activities should have been closed (or, this can be waived via email by the Registrations Manager if needed, cc to QA Manager)

The QA auditor will attach all materials to their report presented for interim audit so it is available for direct comparison to the complete draft final report that will be submitted for final report audit 1 (FRA1) (see section 4b). Following Petition 1 audit **response**, the pages attached to the Interim audit report may be reduced to only those requiring correction, to save file/archival space.

The response to the Interim audit will be completed prior to the submission of the complete final report draft for FRA1, or may be worked on simultaneously with authorization by the Registrations Manager. However, it is highly recommended that the corrective actions be taken prior to submission of the complete report for FRA1. This will save the Study Director the amount of additional actions needed to be reviewed at the conclusion of the FRA1 audit.

When logging in the interim reports the current report tracking log book will be utilized and an "I" placed into the "report type" column to permit tracking (see current SOP 8.9 Appendix A).

If new additions or changes are made to the material audited in the Interim stage following the Study Director's response, they will be presented in a list with the complete Draft 1 final report and identified as additions/changes not previously audited so that FRA1 audit will include them.

b. Completed draft Final Reports

The final report shall not be forwarded for QA review until all Field Data Books have been reviewed by QA and all findings from all prior QA reports in the study have been addressed, unless Management approval has been obtained to proceed in a different sequence.

In order to proceed with the final report prior to completion (findings addressed) of the QA review of all Field Data Books, a Field Data Book Review Expedition Request Form must be completed (see Appendix F). The Study Director must indicate on the form each of the Field Data Books that are to be expedited. Option d authorizes the Study Director to submit a draft final report for QA review before the listed field data books have been audited. If an audit has occurred, but all findings have not been addressed, then option e may be chosen, with an explanation written below. This form must be signed by 1) the Study Director, 2) the Registrations Manager, 3) the QA Manager and 4) Testing Facility Management. Once the request has been approved, copies of the form must be sent to the appropriate Regional Field, Laboratory, and Quality Assurance Coordinators; the original is filed in the study red folder.

The Study Director must make available to the designated QA reviewer a copy of the draft final report, copies of the field data, copies of any raw analytical data that have been sent to IR-4 Headquarters, copies of any QA reports pertinent to the study and any other supporting documents (such as application calculation spreadsheets, seed treatment report, processing data report, etc.) The Study Director shall receive from the designated QA reviewer a QA report that indicates whether the draft final report accurately reflects the raw data of the study.

5) The Study Director and any appropriate personnel shall respond to the QA report and make whatever revisions are deemed appropriate (by the Study Director) to the draft final report, the analytical summary report, or the raw data as a result of the findings in the QA report. The revised final report shall then be submitted to the IR-4 Headquarters QAU

(regardless of where the initial final report review was conducted) for a second audit ("FRA2" audit).

QA shall then generate another report which is submitted to the Study Director for responses and confirmation that the study file (including the raw data associated with the study) has been archived. A draft QA statement shall accompany this second audit report. The second QA report with responses, accompanied by the revised final report, is returned to QA for a closing check, ensuring all changes have been made. The Study Director will receive an electronic version of the QA statement once the data have been presented for archival, and the signature of management on the second QA report has been obtained. It will be necessary to obtain a signature from QA on the original statement, and a copy made for the QA green folder.

6) Once the signed QA statement has been inserted into the final report, and the report has been signed by the Study Director and a representative of IR-4 Project Management, the Study Director must ensure that the final report is properly paginated (according to EPA guidelines) and, if appropriate, that a New Jersey Agricultural Experiment Station publication number is assigned to the report (refer to SOP 6.5). An electronic copy of the signed final report will be placed in the appropriate folder in the IR-4 Shared Directory.

Prepared by: _____ Date: March 20 2015

Approved by: _____ Date: 20 March 2015

US Environmental Protection Agency
Office of Pesticide Programs

Pesticide Registration (PR) Notice 2011-3
Standard Format for Data Submitted Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Certain Provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA)

November 30, 2011

Pesticide Registration (PR) Notice 2011-3

Notice To: Manufacturers, Producers, Formulators, Distributors and Registrants

Attention: Persons Responsible for Federal Registration of Pesticides Products

Subject: Standard Format for Data Submitted Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Certain Provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA)

I. PURPOSE AND APPLICABILITY

This PR Notice updates and replaces Pesticide Registration Notice 86-5 and discusses both the recommended and the required procedures for submitting FIFRA and FFDCA data. All required procedures contained within this document, generally indicated by use of the word "must," were previously made mandatory by statute or regulation; this document creates no new legally binding requirements. Where indicated by the use of non-mandatory language such as "may," "should" and "can," this document provides recommendations or guidance.

The PR Notice applies to all data that are submitted to EPA to support any application, petition, or submission intended to persuade EPA to grant, modify or leave unmodified a registration or other approval required as a condition of sale or distribution of a pesticide. Such submissions may include, but are not limited to, the following: an application for registration or amended registration of a pesticide product under FIFRA section 3 or 24; a submission of data required in conjunction with reregistration of a currently registered product under FIFRA section 4 (or its registration review under FIFRA section 3); an application for an experimental use permit under FIFRA section 5; a submission of data in response to a notice issued by EPA under FIFRA section 3(c)(2)(B); a petition to establish or modify a tolerance or an exemption from the requirement of a tolerance for a pesticide chemical residue under FFDCA section 408 as well as studies submitted under FIFRA section 6(a)(2). (See generally, 40 CFR parts 150 – 189; specifically, 40 CFR parts 158, 160, 161 and 174.)

II. EFFECTIVE DATE

Effective immediately.

III. BACKGROUND

PR Notice 86-5 has served as the Office of Pesticide Programs' (OPP's) data formatting guidance since its publication on July 29, 1986. At the time PR Notice 86-5 was originally issued, the only acceptable medium for data submission was paper. Today, advances in information technology, statutory and regulatory changes, and new policy initiatives make this an opportune time to update the guidance. This new guidance gives registrants the option of submitting electronic submissions and provides a flexible but still acceptable format for data submission, regardless of the medium in which the data are submitted. Attachment 5 contains a listing of glossary terms used in this guidance.

IV. OVERVIEW OF CHANGES

The following list is a summary of the changes recommended by this guidance. A more detailed description of the changes to the guidance is described in sections IV and V.

- Electronic submission on CD or DVD is now an option for some types of data submissions. OPP plans to make this option available to more types of submissions. Check the e-Submission website (http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm) for the latest information.

- Since the inception of PR Notice 86-5, Master Record Identifiers (MRIDs) have been assigned only to data documents that comply with its formatting instructions. One major process change being planned by OPP is that MRIDs will no longer be assigned after these documents have been screened. MRIDs are already being pre-assigned, in the case of electronic submissions. Similarly, MRIDs will be assigned to all of the data documents in a paper submission prior to our format screening process. Submitters will continue to be notified if a document does not meet the mandatory formatting elements.

- Currently, three identical copies of all applicable data are required. This applies to submissions that are entirely paper. Please note that as OPP phases in its up-front imaging of paper submissions, we expect to reduce this requirement to a single copy. For the latest information on the status of the up-front imaging effort and number of copies required please continue to check the e-Submission website (http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm).

- Previous language discouraging double-sided printing and color printing has been eliminated.

- Section G of PRN 86-5, Special Requirements for Submitting Data to the Docket, is obsolete and has been eliminated.

- Information on asserting claims of data confidentiality has been updated in accordance with the latest edition of 40 CFR sections158, 161 and 174.

- The information on flagging of studies for potential adverse effects has been updated in accordance with the latest edition of 40 CFR sections 158 and 161.

- OECD dossier format is an option that did not exist when PRN 86-5 was written.

- References to the data requirements for antimicrobial pesticides, which have been redesignated in new 40 CFR 161, have been inserted as appropriate.

V. RELATIONSHIP OF THIS NOTICE TO OTHER OPP POLICY AND GUIDANCE FOR SUBMITTING DATA

A. Test reports and study profile templates

This notice contains guidance for organizing and formatting submissions of supporting data but does not address the substance of test reports themselves. Consult the OPP website at http://www.epa.gov/pesticides/regulating/studyprofile_templates/studyprofile_templatelist.htm for information on study profile templates and at http://www.epa.gov/ocspp/pubs/frs/home/guidelin.htm for information on harmonized test guidelines.

B. Adverse effects reporting

Detailed guidance on adverse effects reporting under FIFRA section 6(a)(2) is available at http://www.epa.gov/pesticides/fifra6a2/.

C. Electronic submissions

At this writing, electronic submission on CD or DVD is an option for some, but not all, types of data submissions. Electronic submission guidance is available on OPP's website at http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm. However, OPP continues to accept all types of data submissions in paper form.

D. OECD dossier format

There is an alternative to the overall submission format presented in this Notice for submitters who are planning a multi-national electronic submission on CD or DVD. Information on the OECD dossier format can be found at http://www.oecd.org. Submitters who use this format should arrange individual documents as described in this Notice, with the exception of the placement of any information claimed as confidential. Instead of preparing a confidential attachment for an individual document, all confidential information should be compiled in Document J of the dossier.

E. Technical amendments for antimicrobial pesticides, 40 CFR part 161

EPA has redesignated certain pesticide data requirements formerly located in 40 CFR 158 into a new part 161. The data requirements that have been transferred apply to antimicrobial pesticides. EPA has made conforming changes and cross-reference revisions to the re-designated material, including re-designation of 40 CFR part 158.32, 158.33, and 158.34 as 161.32, 161.33 and 161.34, respectively. These technical amendments, published in the Federal Register on October 24, 2007, (72 FR 60251) preserve the original data requirements for use with antimicrobial pesticides until such time as a final rule for antimicrobial pesticides can be promulgated and made effective.

F. Clarification of plant-incorporated protectants data submissions

The characteristics of plant-incorporated protectants (PIPs), such as their production and use in plants, their biological properties, and their ability to spread and increase in quantity in the environment, distinguish them from traditional chemical pesticides. Therefore, PIPs are subject to different regulatory requirements and procedures than traditional chemical pesticides. 40 CFR 174 sets forth regulatory requirements, criteria, and procedures applicable to PIPs under FIFRA and FFDCA. When applied to PIPs, the definitions and regulations in 40 CFR 174 supersede the regulations found in 40 CFR parts 150 through 180 to the extent that the regulations conflict.

VI. FORMAT

A submission consists of all the documents sent to OPP at the same time in support of a single regulatory action or a group of related actions, such as a product amendment and a related tolerance petition. The documents should be accompanied by a transmittal document and related administrative material (e.g., EPA Forms 8570-1, 8570-4, etc.) as appropriate. For actions subject to a registration service fee (see FIFRA section 33), failure to comply with this guidance may result in rejection of the action during the 21-day completeness screening. This transmittal document and administrative material should be grouped together in the first physical volume if the submission is on paper. Consult the e-submission XML guidance document at http://www.epa.gov/pesticides/regulating/registering/submissions/XMLsubmissions/e-submission_xml_guidance_document_v1.pdf for specific information on the format of these documents as files on a CD/DVD.

A detailed discussion of format elements appears below and samples of some of the elements are attached. Except for the language of the two alternative forms of the Statement of Data Confidentiality that can not be altered (see 40 CFR 158.33), these samples are illustrative. As long as the required information is included and clearly identifiable, then the form of the samples may be altered to reflect the submitter's preference.

A. Organization of the data submission package

The following physical format guidance applies to the transmittal document and data documents in a **paper** data submission. Consistency of electronic data submissions with the data submission requirements cited in this notice will be verified electronically.

- 8.5 x 11-inch white paper
- High contrast and good resolution
- Easily removable bindings*
- Pages in good condition
- No fold-out or oversize pages
- All pages present, consecutively paginated and in the correct order
- Double-sided printing acceptable, color printing acceptable

*Two examples of adequate binding are: 1) a staple in the upper-left corner of a small document or 2) plastic covers held together by two metal prongs. Transparent covers are preferred. Three-ring binders are discouraged.

B. Transmittal Document (Sample provided in Attachment 1)

The transmittal document is the first item in each submission. This document discusses basic information-- i.e., who is submitting the information, what regulatory actions are involved, the date of transmittal, a list of documents in the package and the contact information. Specifically, this document identifies:

- the submitting company's name and address, its EPA-assigned company number(s) if one has been previously assigned, and contact information, preferably including fax number and email address in addition to name and phone number and the regulatory or other action(s) identified by EPA-assigned number (such as the EPA registration number, case number or decision number) in support of which the package is being submitted. If no number has been assigned by EPA, describe the type of request: data call-in notice of MM/DD/YY, experimental use permit, etc.;

- the transmittal date; and

- a list of all documents included in the package in the order of their appearance. They should be grouped by discipline (e.g., product chemistry, toxicology, environmental fate) and arranged in ascending order by guideline number within each discipline.

Submitters commonly provide this information in a cover letter. This is adequate so long as all of the elements above are included.

C. Individual documents

A data document is most commonly the report of a single scientific investigation including all supporting analyses required for logical completeness. It may also be a compilation of product chemistry data, a summary document that relates to two or more other documents in the submission, a rationale for a data waiver request, or any other document that addresses a data requirement. If a study is a commentary on or supplement to another previously submitted document, or if it responds to EPA questions raised with respect to an earlier document, then submitters should include on the title page the EPA MRID of the earlier document, if known. Previously submitted documents should not be resubmitted unless specifically requested by OPP.

Each document should be consecutively paginated beginning with the title page and continuing throughout the document, including any appendices. If it is extremely long, binding in multiple volumes may be necessary. In this case, the pagination should continue consecutively through all of the physical volumes. Each physical volume should be plainly identified by its title and its position in the multi-volume sequence (e.g., volume 1 of N, 2 of N, etc.). An English translation must be provided for any information in another language, as specified in 40 CFR 158.32(c)(4).

Currently, three identical copies of all applicable data are required. This applies to submissions that are entirely paper. Please note that as OPP phases in its up-front imaging of paper submissions, we expect to reduce this requirement to a single copy. For the latest information on

the status of the up-front imaging effort and number of copies required, please continue to check the e-Submission website (http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm).

1. Document Title Page (Sample provided in Attachment 2)

Contains the following information for unpublished documents*:

- Document title. This should be as descriptive as possible and include the substance(s) or product tested.
- Test guideline(s) http://www.epa.gov/oppts/pubs/frs/home/guidelin.htm
- Author(s). Submitters should cite only individuals with primary intellectual responsibility for the content of the document.
- Study completion date, if applicable; otherwise submitters should use the date on which the document was created.
- Performing laboratory(ies). If the document reports work done by one or more labs, submitters should include on the title page the name and address of the performing lab(s) and the lab's internal project number(s) for the work
- Laboratory project identifier. Submitters should clearly distinguish between the lab's project identifier and any other reference numbers provided by the sponsor or submitter.
- Total page count for the document (Page 1 of xx).

*Published documents should be identified by the relevant facts of publication, such as journal title, volume, issue, page range and publication date.

2. Statement of Confidentiality Claim

The regulations that address data confidentiality requirements are specific to the three categories below. The first category represents the majority of documents submitted to the Office of Pesticide Programs.

- All pesticides other than antimicrobial pesticides and plant-incorporated protectants,
- Antimicrobial pesticides, and
- Plant-incorporated protectants (PIPs).

A. Documents supporting all pesticides other than antimicrobial pesticides and plant-incorporated protectants (See 40 CFR 158.33):

One of the two statements below must appear on the second page of each data document. The wording of these statements is prescribed by 40 CFR 158.33. Neither deviations from the text of these two statements nor claims or markings on the document or its attachments other than the statement provided on page 2 of the document will be recognized as asserting a claim of confidentiality. The statement must be signed and dated by an authorized representative of the submitter.

1) NO CLAIM OF CONFIDENTIALITY

No claim of confidentiality, on any basis whatsoever, is made for any information contained in this document. I acknowledge that information not designated as within the scope of FIFRA sec. 10(d)(1)(A), (B), or (C) and which pertains to a registered or previously registered pesticide is not entitled to confidential treatment and may be released to the public, subject to the provisions regarding disclosure to multinational entities under FIFRA 10(g).

Submitter: _____*signature*_____ Date: _____
Typed Name of Signer: _____
Typed Name of Company: _____

2) CLAIM OF CONFIDENTIALITY

Information claimed as confidential has been removed to a confidential attachment.

Submitter: _____*signature*_____ Date: _____
Typed Name of Signer: _____
Typed Name of Company: _____

Use of the statement above requires that all information claimed as confidential be submitted in a separate confidential attachment to the document and cross referenced to the specific location from which it was removed. The confidential attachment must have its own title page and be paginated separately from the non-confidential document.

In the confidential attachment, information claimed confidential under FIFRA 10(d)(1)(A), (B) and (C) must be individually identified.

- FIFRA 10(d)(1)(A): Information that consists of (or whose disclosure would in turn disclose) manufacturing or quality control processes.

- FIFRA 10(d)(1)(B): Information that consists of (or whose disclosure would in turn disclose) the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide.

- FIFRA 10(d)(1)(C): Information that consists of (or whose disclosure would in turn disclose) the identity or percentage quantity of any deliberately added inert ingredient of a pesticide.

Sample cross references between the non-confidential document and its confidential attachment are provided in Attachment 3.

3) VOLUNTARY RELEASE OF INFORMATION TO STATES AND FOREIGN GOVERNMENTS (40 CFR 158.33(c)(4))

In addition to the required use of one of the two confidentiality statements above, submitters are encouraged to include an additional statement to allow EPA to share information with state and foreign governments to facilitate coordination of pesticide reviews. EPA will not consider such a statement to be a waiver of confidentiality or proprietary claims for the information. The statement is as follows:

> **I authorize the Environmental Protection Agency to release any information contained in this document to State and foreign governments, without relinquishing proprietary rights or any confidentiality claims asserted above.**
>
> Submitter: _____*signature*_____ Date: _____
> Typed Name of Signer: _____
> Typed Name of Company: _____

Information designated as releasable to state or foreign governments in accordance with the above statement may be released to those governments without further notice to the submitter. EPA will inform the state or foreign government of any confidentiality claims associated with the information.

B. Documents supporting antimicrobial pesticides (See 40 CFR 161.33):

40 CFR 161.33 is the regulation that currently governs the procedures for claims of confidentiality of data in antimicrobial pesticide documents. One of the two statements below must appear on the second page of each data document. The statement must be signed and dated by an authorized representative of the submitter.

1) NO CLAIM OF CONFIDENTIALITY

If no claim of confidentiality is being made for information described by FIFRA section 10(d)(1)(A), (B), (C), or if such information is not contained in the body of the study, the Statement of Data Confidentiality Claims must include the following statement. This statement must bear the name, title and signature of the submitter or his properly designated agent, and the date of signature:

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA sec. 10(d)(1)(A), (B), or (C).

Submitter: _____*signature*_____ Date: _____

Typed Name of Signer: _____
Typed Name of Company: _____

2) CLAIM OF CONFIDENTIALITY

Any information claimed to be confidential under FIFRA 10(d)(1)(A) through (C) must be contained in a separate attachment to the study. If any information is included in the body of the study rather than in the confidential attachment, the submitter waives a claim of confidentiality for such information under FIFRA section 10(d)(1)(A), (B) or (C). The attachment must have a cover page that is clearly marked to indicate that the material contained in the attachment falls within the scope of FIFRA section 10(d)(1)(A), (B) or (C). Each item in the attachment must be numbered. For each item, the submitter must cite the applicable portion of FIFRA section 10(d)(1)(A), (B) or (C) on which the claim of confidentiality is based. In addition, for each item, the submitter must provide a list of page numbers in the study where the item is cited (*i.e.*, identified by number). Each item in the attachment must be referenced in the body of the study by its number in the attachment.

The following statement must appear on the Statement of Data Confidentiality Claims and must bear the name, title, and signature of the submitter or his properly designated agent, and the date of signature:

Information claimed as confidential on the basis of its falling within the scope of FIFRA sec. 10(d)(1)(A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.

Submitter: _____*signature*_____ Date: _____
Typed Name of Signer: _____
Typed Name of Company: _____

Sample cross references between the non-confidential document and its confidential attachment are provided in Attachment 3.

Any information not described by FIFRA section 10(d)(1)(A), (B), or (C) for which a claim of confidentiality is made must be submitted in accordance with the following procedures:

- The information must be clearly marked in the body of the study as being claimed confidential.
- A separate Supplemental Statement of Data Confidentiality Claims must be submitted, identifying by page and line number the location within the study of each item claimed confidential, and stating the basis for the claim.
- The Supplemental Statement of Data Confidentiality Claims must bear the name, title and signature of the submitter or his properly designated agent, and the date of signature.

C. Documents supporting plant-incorporated protectants (PIPS) (See 40 CFR 174.9):

Although it is strongly recommended that the submitter minimize the amount of data and other information claimed as Confidential Business Information, a submitter may assert a claim of confidentiality for all or part of the information submitted to EPA in a submission for a plant-incorporated protectant. To assert such a claim, the submitter must comply with all of the following procedures:

- Any claim of confidentiality must accompany the information at the time the information is submitted to EPA. Failure to assert a claim at that time constitutes a waiver of confidentiality for the information submitted, and the information may be made available to the public, subject to section 10(g) of FIFRA, with no further notice to the submitter.

- Any claim of confidentiality must be accompanied, at the time the claim is made, by comments substantiating the claim and explaining why the submitter believes that the information should not be disclosed. The submitter must address each of the following points in substantiation. EPA will consider incomplete all plant-incorporated protectant submissions containing information claimed as CBI that are not accompanied by substantiation and will suspend any applicable review of such submissions until the required substantiation is provided.

    1. The portions of the information that are alleged to be entitled to confidential treatment;
    2. The period of time for which confidential treatment is desired by the business (e.g., until a certain date, until the occurrence of a specified event or permanently);
    3. The purpose for which the information was furnished to EPA and the approximate date of submission, if known;
    4. Whether a business confidentiality claim accompanied the information when it was received by EPA;
    5. Measures taken by the business to guard against undesired disclosure of the information to others;
    6. The extent to which the information has been disclosed to others, and the precautions taken in connection therewith;
    7. Pertinent confidentiality determinations, if any, by EPA or other federal agencies, and a copy of any such determination, or reference to it, if available;
    8. Whether the business asserts that disclosure of the information would be likely to result in substantial harmful effects on the business's competitive position, and if so, what those harmful effects would be, why they should be viewed as substantial and an explanation of the causal relationship between disclosure and such harmful effects; and
    9. Whether the business asserts that the information is voluntarily submitted information as defined in §2.201(i), and if so, whether and why disclosure of the information would tend to lessen the availability to EPA of similar information in the future.

3. Statement of compliance or non-compliance with good laboratory practice (GLP) standards (40 CFR 160)

Sample compliance statements are provided in Attachment 4. This statement is required only if a document meets the following definition of a study:

> S*tudy* means any experiment at one or more test sites, in which a test substance is studied in a test system under laboratory conditions or in the environment to determine or help predict its effects, metabolism, product performance (efficacy studies only as required by 40 CFR 158.400 or 161.640, as applicable), environmental and chemical fate, persistence and residue, or other characteristics in humans, other living organisms, or media. The term "study" does not include basic exploratory studies carried out to determine whether a test substance or a test method has any potential utility. [Excerpt from 40 CFR 160.3]

4. Flagging of studies for potential adverse effects (See CFR 158.34 and 161.34)

Any study of a type listed in tables 1 and 2 below must include the appropriate one of the two statements below, together with the signature of the authorized representative of the submitter and the date of signature on its fourth page.

1) If the study does not meet or exceed criteria listed in the table:

I have applied the criteria of 40 CFR 158.34/40 CFR 161.34 for flagging studies for potential adverse effects to the results of the attached study. This study neither meets nor exceeds any of the applicable criteria.

Submitter: _____*signature*_____ Date: _____
Typed Name of Signer: _____
Typed Name of Company: _____

2) If the study meets or exceeds criteria listed in the table:

I have applied the criteria of 40 CFR 158.34/40 CFR161.34 for flagging studies for potential adverse effects to the results of the attached study. This study meets or exceeds the criteria numbered [insert all applicable reporting codes].

Submitter: _____*signature*_____ Date: _____
Typed Name of Signer: _____
Typed Name of Company: _____

Table 1 - Flagging Criteria for All Pesticides other than Antimicrobials (See 40 CFR 158.34)

Study Types	Guideline No.	Criteria: Treated animals show any of the following:	Criteria No.
Carcinogenicity or combined chronic feeding study	870.4200 870.4300	An incidence of neoplasms in males or females which increases with dose (positive trend $p \leq 0.05$); or	1
		A statistically significant (pairwise $p \leq 0.05$) increase of any type of neoplasm in any test group, males or females at any does level, compare to concurrent control animals of the same sex; or	2
		An increase in any type of uncommon or rare neoplasms in any test group, males or females animals at any dose level, compared to concurrent controls of the same sex; or	3
		A decrease in the time to development of any type of neoplasms in any test group, males or females at any dose level, compared to concurrent controls of the same sex.	4
Prenatal developmental toxicity Reproduction and fertility Developmental neurotoxicity	870.3700 870.3800 870.6300	When compared to concurrent controls, treated offspring show a dose-related increase in malformations, pre- or post-natal deaths, or persistent functional behavioral changes on a litter basis in the absence of significant maternal toxicity at the same dose level.	5
Neurotoxicity	870.6100 870.6200	When compared to concurrent controls, treated animals show a statistically or biologically significant increase in neuropathological lesions or persistent functional or behavioral changes.	6
Chronic feeding Carcinogenicity Reproduction and fertility Prenatal developmental toxicity Developmental neurotoxicity Acute or 90-day neurotoxicity	870.4100 870.4200 870.3800 870.3700 870.6300 870.6200	The no observed adverse effect level (NOAEL) from one of these studies is less than the NOAEL currently used by the Agency as the basis for either the acute or chronic reference dose.	7

Table 2 - Flagging Criteria for Antimicrobial Pesticides
(See 40 CFR 161.34)

Toxicity studies	Pesticide assessment guideline No.	Criteria	Reporting code
Oncogenicity [or combined oncogenicity/chronic feeding study]	83-2	Treated animals show any of the following:	
		An incidence of neoplasms in males or females which increases with dose;	1
or		or	
Subchronic feeding study	82-1	A statistically significant ($p \leq 0.05$) incidence of any type of neoplasm in any test group (male or female animals at any does level), compared to concurrent control animals of the same sex;	2
		or	
		An increase in any type of uncommon or rare neoplasms in any test group (male or female animals at any dose level) compared to concurrent control animals;	3
		or	
		A decrease in the time to development of any type of neoplasms in any test group (male or female animals at any dose level) compared to concurrent control animals	4
Teratogenicity	83-3	When compared with concurrent controls, treated animals show a dose-related increase in malformations (or deaths) on a litter basis in the absence of significant maternal toxicity at the same dose levels.	5
Neurotoxicity	81-7	When compared with controls, treated animals show a response indicative of acute delayed neurotoxicity	6
Chronic feeding study or combined chronic feeding/oncogenicity study	83-1	Cholinesterase inhibition NOEL less than 10 times the current existing ADI.	7
		or	
		General (systemic) toxicity NOEL less than 100 times the current existing ADI.	8
Reproduction study	83-4	Reproductive effects NOEL less than 100 times the current ADI	9
Subchronic feeding study	82-1	Cholinesterase inhibition NOEL less than 100 times the current ADI.	10
		or	
		General (systemic) toxicity NOEL less than 1000 times the current existing ADI.	11

VII. PAPERWORK REDUCTION ACT NOTICE

The information collection activities associated with the activities described in this PR Notice are already approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq. The corresponding Information Collection Request (ICR) documents for the pesticide application process have been assigned under the following ICRs: Application for New and Amended Pesticide Registration EPA ICR number 0277.15 approved OMB control number 2070-0060; Submission of Unreasonable Adverse Effects Information under FIFRA Section 6(a)(2), EPA ICR number 1204.11 approved OMB control number 2070-0039; Tolerance Petitions for Pesticides on Food/Feed Crops and New Inert Ingredients, EPA ICR number 0597.10 approved OMB control number 2070-0024; Experimental Use Permits (EUPs) for Pesticides, EPA ICR number 0276.14 approved OMB control number 2070-0040; Notice of Pesticide Registration by States to Meet a Special Local Need (SLN) under FIFRA Section 24(c), EPA ICR number 0595.10, approved OMB control number 2070-0055; and the Pesticide Data Call-in Program, EPA ICR number 2288.01, approved OMB number 2070-0174.

Under the PRA, "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For this collection, it is the time reading the regulations, planning the necessary data collection activities, conducting tests, analyzing data, generating reports and completing other required paperwork, and storing, filing, and maintaining the data.

Under the PRA, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations codified in Chapter 40 of the CFR, after appearing in the preamble of the final rule, are listed in 40 CFR part 9, are displayed either by publication in the Federal Register or by other appropriate means, such as on the related collection instrument or form, if applicable.

VIII. SUBMISSION OF INFORMATION

See http://www.epa.gov/PR_Notices/pr2006-1.pdf for instructions on transmitting information to the Office of Pesticide Programs.

IX. FOR FURTHER INFORMATION

If you have questions or need further information about this notice, you may contact Teresa Downs, Information Technology and Resources Management Division, at downs.teresa@epa.gov or (703)305-5363.

Dated: November 30, 2011

Steven Bradbury, Ph.D., Director
Office of Pesticide Programs, OCSPP
U.S. Environmental Protection Agency

ATTACHMENT 1
SAMPLE TRANSMITTAL DOCUMENT

Submitter:

Smith Chemical Corp.
1234 West Smith Street
Cincinnati, OH 98765

Company Contact: _____*(signature)*_____
Typed Name of Signer: _____

Phone: _____
Fax: _____optional_____
Email address: _____ optional_____

Regulatory Action in Support of Which this Package is Submitted:

EPA registration number: 98765-1, My Flea Product
Amendment to add ticks to the label.

Submission date:

MM/DD/YY

List of Submitted Documents:

Volume 1 Administrative materials (This list is for illustration purposes and does not attempt to list all of the necessary forms to support a specific regulatory action.)
- Amendment form
- Data Matrix
- Proposed label text
- Confidential Statement of Formula

Volume 2 Title of first data document (Guideline No.)

Volume 3 Title of second data document (Guideline No.)

ATTACHMENT 2
SAMPLE TITLE PAGE

TITLE

Product ABCXYZ
Acute Oral Toxicity in Rats

TEST GUIDELINE

OPPTS 870.1100

AUTHOR

John C. Davis

STUDY COMPLETION DATE

01/22/2008

PERFORMING LABORATORY

ABC Agricultural Laboratories
940 West Bay Drive
Wilmington, DE 33445

LABORATORY PROJECT ID

ABC 08-34

PAGE COUNT

1 of 35

ATTACHMENT 3
SAMPLE CROSS REFERENCES TO A CONFIDENTIAL ATTACHMENT

Reference on page 12 of the non-confidential text:

> *Information claimed confidential has been removed to the confidential attachment. See Cross Reference 1.*

Reference on page 18 of the non-confidential text:

> *Information claimed confidential has been removed to the confidential attachment. See Cross Reference 2.*

Complementary reference in the confidential attachment:

> Cross Reference 1, page 12
> FIFRA reference: 10(d)(1)(A)
>
> *Reproduce the deleted text here.*

Complementary reference in the confidential attachment:

> Cross Reference 3, page 18
> FIFRA reference: 10(d)(1)(B)
>
> *Reproduce the deleted text here.*

ATTACHMENT 4
SAMPLE GOOD LABORATORY PRACTICE COMPLIANCE STATEMENTS

Example 1:

This study was conducted in accordance with 40 CFR 160.

Study Director: _____*signature*_____ Date: _____
Typed Name of Signer: _____
Typed Name of Laboratory: _____

Sponsor: _____*signature*_____ Date: _____
Typed Name of Signer: _____
Typed Name of Company: _____

Submitter: _____*signature*_____ Date: _____
Typed Name or Signer: _____
Typed Name of Company: _____

Example 2:

The following is a detailed description of all differences between the practices used in the study and those required by 40 CFR 160:

_____
_____

Study Director: _____*signature*_____ Date: _____
Typed Name: _____
Typed Name of Laboratory: _____

Sponsor: _____*signature*_____ Date: _____
Typed Name of Signer: _____
Typed Name of Company: _____

Submitter: _____*signature*_____ Date: _____
Typed Name of Signer: _____
Typed Name of Company: _____

Example 3:

The submitter of this study neither sponsored this study nor conducted it and does not know whether the study was conducted in accordance with 40 CFR 160.

Submitter: _____*signature*_____ Date: _____
Typed Name of Signer: _____
Typed Name of Company: _____

ATTACHMENT 5
GLOSSARY

Applicant:	Any person or entity who sends any application, petition, or other submission to OPP with the intention to persuade OPP to grant, modify, or leave unmodified a registration or other approval required as a condition of sale or distribution of a pesticide. (See 40 CFR 158.3).
Author(s):	Individual(s) primarily responsible for the intellectual content of a document. In the case of a document that meets the definition of a "study' in 40 CFR 160.3, the study director should be identified as the author.
Authorized Agent:	A person residing in the United States who is designated by an applicant to act as his agent. If an applicant wishes to designate an agent, he must send the Agency a letter stating the name and U.S. mailing address of his agent. (See 40 CFR 152.50(b)(3).) If an authorized agent signs any of the statements described in this notice, then it should be made clear that he is doing so as the applicant's (submitter's) authorized agent.
Data:	Information submitted by an applicant to satisfy an Agency data requirement such as those published in 40 CFR parts 158 and 161, or any other information requested by EPA or presented by the applicant in support of a scientific or regulatory decision by OPP. Includes, but is not limited to, data to support registration review, adverse effects information submitted under FIFRA 6(a)(2), information supporting applications for new or amended registration, experimental use permits, tolerance petitions and tolerance exemption petitions. This information is contained in documents that are collectively referred to as data. Studies (see definition below) are a subset of data. Studies are subject to the requirements of 40 CFR 160, OPP's Good Laboratory Practice Standards (GLPs).

MRID:	**M**aster **R**ecord **I**dentifier. A unique 8-digit number assigned to each document submitted to OPP. These documents are permanent records; you do not need to resubmit any document that has already been assigned a MRID unless specifically requested to do so by OPP. Use the MRID to cite a previously submitted document that supports a new regulatory action. Never re-use an MRID; EPA assigns a new MRID to an amended document in order to preserve the integrity of the records in our database.
OECD Dossier:	The Organization for Economic Co-operation and Development (OECD) has developed a format for pesticide data submissions that is accepted by numerous countries including the United States. See http://www.oecd.org.
Performing Laboratory:	Facility/facilities where a study or part of a study is conducted.
Person:	Includes an individual, partnership, corporation, association, scientific or academic establishment, government agency, or organizational unit thereof, and any other legal entity. (See 40 CFR 160.3.)
Plant-incorporated protectant (PIP):	A pesticidal substance that is intended to be produced and used in a living plant, or in the produce thereof, and the genetic material necessary for production of such a pesticidal substance. It also includes any inert ingredient contained in the plant, or produce thereof. (See 40 CFR 174.3)
Sponsor:	A person who initiates and supports, by the provision of financial or other resources, a study. (See 40 CFR 160.3.)
Study:	Any experiment at one or more test sites in which a test substance is studied in a test system under laboratory conditions or in the environment to determine or help predict its effects, metabolism, product performance, environmental and chemical fate, persistence and residue, or other characteristics in humans, other living organisms or media. The term "study" does not include basic exploratory studies carried out to determine whether a test substance or a test method has any potential utility. (See 40 CFR 160.3.)
Study Completion Date:	Date the final report is signed by the study director. (See 40 CFR 160.3.)
Study Director:	Individual responsible for the overall conduct of a study. (See 40 CFR 160.3 and 160.33.)
Study Profile Template:	A study profile records basic study information such as materials, methods, results, and the applicant's conclusions in a standard format

	known as the template that mirrors the template used by EPA science reviewers in preparing their Data Evaluation Records (DERs).
Submission:	Consists of all the documents sent to OPP at the same time in support of a single regulatory action or a group of related actions, such as a product amendment and a related tolerance petition by an Applicant (see definition above). The documents should be accompanied by a transmittal document and related administrative material (e.g., EPA Forms 8570-1, 8570-4, etc.) as appropriate. This transmittal document and administrative material should be grouped together in the first physical volume if the submission is on paper. Consult the e-submission XML guidance document at http://www.epa.gov/pesticides/regulating/registering/submissions/XMLsubmissions/e-submission_xml_guidance_document_v1.pdf for specific information on the format of these documents as files on a CD/DVD.
Submitter:	Any person making a submission to OPP.
Test Guideline:	Number that identifies a published testing procedure. The OCSPP harmonized test guidelines are available at: http://www.epa.gov/ocspp/pubs/frs/home/guidelin.htm
Transmittal Document:	Provides the who, what, when and why of the data submission by identifying the submitter, submission date, regulatory action being supported, and a list of the documents included in the submission. See 40 CFR 158.32(b), 161.32(a).

APPENDIX B

The attached document is an example of a completed field data summary. The summary tables may be modified as needed to best express the specifications of the subject study.

FIELD DATA SUMMARY

Pesticide/Commodity/Field ID No.: Novaluron/Pepper(Bell & Non-Bell)/08985.06-CA20

Field Research Director (FRD): Chuck Farrar

Affiliation of FRD: Dept. of Entomology, University of California-Riverside
Riverside, CA 92521

Other Field Personnel: Sylvia Rivera

TEST SUBSTANCE RECORDS				
Test Substance (Trade Name):	Rimon 0.83 EC			
Batch/Lot No.:	50110342	Date Received:	March 30, 2006	
		Expiration Date:	June 10, 2007	
Test Substance (Trade Name):	Pedestal			
Batch/Lot No.:	MC3C31P002	Date Received:	May 1, 2006	
		Expiration Date:	April 19, 2008	
Spray Additives (Adjuvants) Used:	None			
Storage Location:	Room 226, Entomology Bldg., University of California-Riverside Riverside, CA			
Storage Temperature Range (from receipt of Rimon 0.83 EC to last application)[1]:			19.8-26.8	°C
Storage Temperature Range (from receipt of Pedestal to last application):			19.8-23.2	°C

[1]Temperature range includes storage of Rimon 0.83 EC at "room temperature" during the period 3/30/06-4/4/06.

TRIAL SITE INFORMATION					
Test Site:	South Coast Research & Extension Center, 7601 Irvine Blvd., Irvine, CA				
Soil Type/Texture:	Sandy clay loam				
% Sand:	49.4	% Silt:	25.8	% Clay:	24.8
% Organic Matter:	1.2	Soil pH:	7.6	CEC:	38.8 meq/100 g
Crop Variety:	Taurus	Bell or Non-Bell:	Bell		
Row Width:	3'4"	Date Transplanted:	6/8/06		
No. Rows/Plot:	5	Plant Spacing:	12"		
Control Plot Dimensions:	16'8" x 65'	Trt 02 and 03 Plot Dimensions:	16'8" x 65'		

Maintenance Fertilizers and Pesticides (does not include adjuvants)	
Treflan HFP herbicide, 6/6/06	20-20-20 fertilizer, 6/26/06, 7/5/06, 7/26/06
Asana XL insecticide, 6/23/06, 7/11/06	Admire 2 F insecticide, 7/5/06

Field Data Summary

Application No.: 1 of 3 (Treatments 02 and 03)

Pesticide/Commodity/Field ID No.:	Novaluron/Pepper(Bell & Non-Bell)/08985.06-CA20

APPLICATION RECORDS			
Application Date:	8/1/06	Days From Last Application:	Not applicable
Application Equipment:	CO_2 backpack sprayer		
Type of Application:	Foliar directed spray		
Plot Length (feet):	65	Number of Passes:	5
Number of Nozzles:	3	Spray Swath Width (inches):	Not applicable
Screen Mesh:	50	Nozzle Spacing (inches):	Not applicable
Nozzle Brand/Type/Size:	TeeJet 60-8002 twin fan		
Equipment Calibration Date:	8/1/06	Treated Area (ft^2):	1083
Boom Discharge Rate (mL/sec):	30.153	Trt 02 Total Pass Time (sec):	127.89
		Trt 03 Total Pass Time (sec):	126.68
Trt 02 Calculated Delivery of Spray Solution (GPA):	41		
Trt 03 Calculated Delivery of Spray Solution (GPA):	41		

Tank Mix Amounts for Treatment:	02	03
Carrier (Water) (mL):	5800	5800
Formulated Product (mL):	14	14
Adjuvant (mL):	0	0
Total Mix Volume (mL):	5814	5814

Actual Application Rate(s): (Based on: sprayer output and applicator pass times)

Treatment No.	Protocol Rate (lb ai/A)	Actual Rate (lb ai/A)	% Dev. From Protocol Rate
01	0	NA	NA
02	0.08	0.082	2
03	0.08	0.081	1

Air Temperature (°C):	28.1
Wind Speed (mph):	<4
Crop Height:	18-24"
Commodity Growth Stage:	Fruiting
Date of First Rain after Application:	None before harvest
Amount of First Rain after Application (inches):	---
Time after Application of First Rain:	---
Date of First Irrigation after Application:	8/1/06
Amount of First Irrigation after Application (inches):	0.58
Time after Application of First Irrigation:	Simultaneous drip irrigation

Field Data Summary **Application No.: 2 of 3 (Treatments 02 and 03)**

Pesticide/Commodity/Field ID No.:	Novaluron/Pepper(Bell & Non-Bell)/08985.06-CA20

APPLICATION RECORDS			
Application Date:	8/9/06	Days From Last Application:	8
Application Equipment:	CO_2 backpack sprayer		
Type of Application:	Foliar directed spray		
Plot Length (feet):	65	Number of Passes:	5
Number of Nozzles:	3	Spray Swath Width (inches):	Not applicable
Screen Mesh:	50	Nozzle Spacing (inches):	Not applicable
Nozzle Brand/Type/Size:	TeeJet 60-8002 twin fan		
Equipment Calibration Date:	8/9/06	Treated Area (ft^2):	1083
Boom Discharge Rate (mL/sec):	31.264	Trt 02 Total Pass Time (sec):	123.97
		Trt 03 Total Pass Time (sec):	125.60
Trt 02 Calculated Delivery of Spray Solution (GPA):	41		
Trt 03 Calculated Delivery of Spray Solution (GPA):	42		

Tank Mix Amounts for Treatment:	02	03
Carrier (Water) (mL):	5800	5800
Formulated Product (mL):	14	14
Adjuvant (mL):	0	0
Total Mix Volume (mL):	5814	5814

Actual Application Rate(s): (Based on: sprayer output and applicator pass times)

Treatment No.	Protocol Rate (lb ai/A)	Actual Rate (lb ai/A)	% Dev. From Protocol Rate
01	0	NA	NA
02	0.08	0.082	3
03	0.08	0.083	4

Air Temperature (°C):	24.1
Wind Speed (mph):	<4
Crop Height:	24-26"
Commodity Growth Stage:	Fruiting
Date of First Rain after Application:	None before harvest
Amount of First Rain after Application (inches):	---
Time after Application of First Rain:	---
Date of First Irrigation after Application:	8/11/06
Amount of First Irrigation after Application (inches):	0.58
Time after Application of First Irrigation:	2 days

Field Data Summary

Application No.: 3 of 3 (Treatments 02 and 03)

Pesticide/Commodity/Field ID No.:	Novaluron/Pepper(Bell & Non-Bell)/08985.06-CA20

APPLICATION RECORDS

Application Date:	8/16/06	Days From Last Application:	7
Application Equipment:	CO_2 backpack sprayer		
Type of Application:	Foliar directed spray		
Plot Length (feet):	65	Number of Passes:	5
Number of Nozzles:	3	Spray Swath Width (inches):	Not applicable
Screen Mesh:	50	Nozzle Spacing (inches):	Not applicable
Nozzle Brand/Type/Size:	TeeJet 60-8002 twin fan		
Equipment Calibration Date:	8/16/06	Treated Area (ft^2):	1083
Boom Discharge Rate (mL/sec):	30.422	Trt 02 Total Pass Time (sec):	123.00
		Trt 03 Total Pass Time (sec):	123.50
Trt 02 Calculated Delivery of Spray Solution (GPA):	40		
Trt 03 Calculated Delivery of Spray Solution (GPA):	40		

Tank Mix Amounts for Treatment:	02	03
Carrier (Water) (mL):	5800	5800
Formulated Product (mL):	14	14
Adjuvant (mL):	0	0
Total Mix Volume (mL):	5814	5814

Actual Application Rate(s): (Based on: sprayer output and applicator pass times)

Treatment No.	Protocol Rate (lb ai/A)	Actual Rate (lb ai/A)	% Dev. From Protocol Rate
01	0	NA	NA
02	0.08	0.079	-1
03	0.08	0.080	0

Air Temperature (°C):	27.8
Wind Speed (mph):	<4
Crop Height:	16-20"
Commodity Growth Stage:	Maturing fruit
Date of First Rain after Application:	None before harvest
Amount of First Rain after Application (inches):	---
Time after Application of First Rain:	---
Date of First Irrigation after Application:	8/16/06
Amount of First Irrigation after Application (inches):	0.77
Time after Application of First Irrigation:	Simultaneous drip irrigation

FIELD DATA SUMMARY	HARVEST NO. 1
Pesticide/Commodity/Field ID No.:	Novaluron/Pepper(Bell & Non-Bell)/08985.06-CA20

SAMPLE COLLECTION AND STORAGE					
Harvest Date:	8/17/06	Sample Date:	8/17/06	PHI (days):	1
Crop Fraction Sampled:	Commercially mature pepper fruit				
Sampling Equipment:	Rubbermaid tubs				
Sampling Procedures:	Twelve fruit were picked for each sample from separate, impartially chosen plants in the middle three rows of the plot. Fruits were taken from high and low, inside the foliage and exposed areas. Untreated samples were collected first, then Trt 02, then Trt 03.				
Trimming, Cleaning, Cutting, Drying, Composting, etc:	None				
Sample Handling between Field and Freezer (or Field and Shipment):	Sample bags were held in separate Rubbermaid tubs during harvest, and then placed in coolers with blue ice during transport.				
Maximum Length of Time from Treated Sample Collection to Frozen Storage:	1 hour, 53 minutes				
Samples were kept frozen from sampling to shipment:	Yes	X	No		
"Kept frozen" indicates storage at temperatures generally <0 °F (-17 °C).					
If "No" is indicated, explain:	---				
Shipped: Frozen					
Shipped Via:	ACDS freezer truck	Shipment Date:	9/11/06		

METEOROLOGICAL INFORMATION	
Were the test plots irrigated?	Yes
Type of Irrigation:	Drip
Was the weather during this field trial normal for this test site?	Yes
Describe any unusual weather occurrences:	---

PHYTOTOXICITY, EFFICACY & YIELD	
Were any phytotoxic effects seen?	No
Describe the severity & symptoms of any phytotoxic effects:	---
If efficacy/yield data were recorded, describe any differences between treatment(s) and controls:	None recorded

APPENDIX C

The attached documents are examples of completed EPA Recommended Tables. The tables may be modified as necessary to best express the specifications of the subject study.

Table A.1: Test Compound Nomenclature

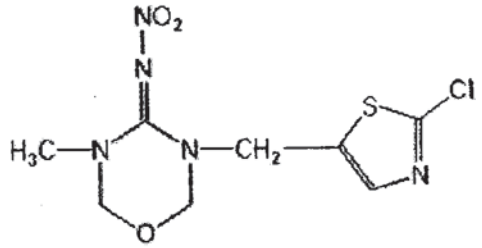
Compound: Thiamethoxam	Chemical Structure:	
Common Name:	Thiamethoxam	
Company Experimental Name:	CGA-293,343	
IUPAC Name:	(*EZ*)-3-(2-chloro-1,3-thiazol-5-ylmethyl)-5-methyl-1,3,5-oxadiazinan-4-ylidene(nitro)amine	
CAS Name:	3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-*N*-nitro-4*H*-1,3,5-oxadiazin-4-imine	
CAS #:	153719-23-4	
End-Use product/EP:	Actara® 25WG and Platinum™ 2SC	

Table A.2. Physicochemical Properties

Parameter	Value	Reference
Chemical:		
Melting point/range		
pH		
Density		
Water Solubility (C)		
Solvent Solubility (mg/L at C)		
Vapour Pressure at C		
Dissociation Constant (pK_a):		
Octanol/Water Partition Coefficient Log (K_{ow}):		
UV/visible Absorption Spectrum:		

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Table B.1.1 Soil Characterization and Summary of Meteorological Conditions

Trial ID	Trial Location (City, State or Province)	Trial Start Year	Soil characteristics				Meteorological Comments	
			Type	%OM	pH	CEC (meq/100 g)	Rainfall	Temperatures
-ME05	Jonesboro, ME	2001	Sandy Loam	0.15	4.8	17.6	Above normal in April and June. Much below normal in May.	Below normal in April. Above normal in May and June.
-NJ28	Bridgeton, NJ	2001	Sandy Loam	2.1	6.5	4.4	Normal	Normal
-NJ29	Bridgeton, NJ	2001	Sandy Loam	2.1	6.5	4.4	Normal	Normal
-NC22	Castle Hayne, NC	2001	Sand	4.2	3.9	7.0	Normal	Normal
-NC23	Castle Hayne, NC	2001	Loamy Sand	5.8	3.4	13.6	Normal	Normal
-MI34	Fennville, MI	2001	Loamy Sand	6.2	4.7	6.5	Normal	Normal
-MI35	Fennville, MI	2001	Loamy Sand	6.2	4.6	4.5	Normal	Normal
-MI36	Fennville, MI	2001	Loamy Sand	6.2	4.6	6.6	Normal	Normal
-OR20	Aurora, OR	2001	Loam	3.2	4.4	8.2	Below normal in June	Below normal in June

Table B.1.2.1: Study Use Pattern

Trial ID	Trial Location (City, State)	Trial Start Year	EP[1]	Application							
				Timing	Rate lb a.i./A	RTI[2] (days)	Treat. No.	Method	Total Rate lb a.i./A	Tank Mix Adjuvants	Harvest Procedures[3]
-ME05	Jonesboro, ME	2001	Actara® 25WG	Fruiting	0.066	--	1 of 3	Broadcast Foliar	0.198	None	NA
				Fruiting	0.067	6	2 of 3	Broadcast Foliar			
				Fruit	0.065	7	3 of 3	Broadcast Foliar			
-NJ28	Bridgeton, NJ	2001	Platinum 2SC	Bud break	0.195	NA	1 of 1	Soil Applied Surface Band	0.195	None	NA
-NJ28	Bridgeton, NJ	2001	Actara® 25WG	Ripening Fruit	0.065	--	1 of 3	Directed Foliar	0.198	None	NA
				Coloring Fruit	0.066	6	2 of 3	Directed Foliar			
				Ripening Fruit	0.067	7	3 of 3	Directed Foliar			
-NJ29	Bridgeton, NJ	2001	Platinum 2SC	Bud break	0.191	NA	1 of 1	Soil Applied Surface Band	0.191	None	NA
-NJ29	Bridgeton, NJ	2001	Actara® 25WG	Ripening Fruit	0.066	--	1 of 3	Directed Foliar	0.197	None	NA
				Coloring Fruit	0.065	6	2 of 3	Directed Foliar			
				Ripening Fruit	0.066	7	3 of 3	Directed Foliar			

[1]EP = End-use Product [2] Retreatment Interval [3] Only applicable for cotton commodities.

Table B.1.2.2: Study Use Pattern

Trial ID	Trial Location (City, State)	Trial Start Year	EP[1]	Application							
				Timing	Rate lb a.i./A	RTI[2] (days)	Treat. No.	Method	Total Rate lb a.i./A	Tank Mix Adjuvants	Harvest Procedures[3]
-NC22	Castle Hayne, NC	2001	Platinum 2SC	Bud (3-4 stage)	0.197	NA	1 of 1	Soil Applied Surface Band	0.197	None	NA
-NC22	Castle Hayne, NC	2001	Actara® 25WG	Fruiting	0.064	--	1 of 3	Directed Foliar	0.198	None	NA
				Fruiting	0.066	7	2 of 3	Directed Foliar			
				Fruiting	0.068	7	3 of 3	Directed Foliar			
-NC23	Castle Hayne, NC	2001	Platinum 2SC	Treatment lost due to frost damage. See protocol change 1.							
-NC23	Castle Hayne, NC	2001	Actara® 25WG	Fruiting	0.066	--	1 of 3	Directed Foliar	0.198	None	NA
				Fruiting	0.066	7	2 of 3	Directed Foliar			
				Fruiting	0.066	7	3 of 3	Directed Foliar			

Table B.1.2.3: Study Use Pattern

Trial ID	Trial Location (City, State)	Trial Start Year	EP[1]	Application							Harvest Procedures[3]
				Timing	Rate lb a.i./A	RTI[2] (days)	Treat. No.	Method	Total Rate lb a.i./A	Tank Mix Adjuvants	
-MI34	Fennville, Michigan	2001	Platinum 2SC	Green Tip	0.197	NA	1 of 1	Soil Applied Surface Band	0.197	None	NA
-MI34	Fennville, MI	2001	Actara® 25WG	Immature Fruit	0.066	--	1 of 3	Directed Foliar	0.198	None	NA
				Immature Fruit	0.066	7	2 of 3	Directed Foliar			
				Immature Fruit	0.068	7	3 of 3	Directed Foliar			
-MI35	Fennville, MI	2001	Platinum 2SC	Green Tip	0.187	--	1 of 1	Soil Applied Surface Band	0.187	--	NA
-MI35	Fennville, MI	2001	Actara® 25WG	Immature Fruit	0.066	--	1 of 3	Directed Foliar	0.197	None	NA
				Immature Fruit	0.065	7	2 of 3	Directed Foliar			
				Immature Fruit	0.066	7	3 of 3	Directed Foliar			

[1]EP = End-use Product [2] Retreatment Interval [3] Only applicable for cotton commodities.

Table B.1.2.4: Study Use Pattern

Trial ID	Trial Location (City, State)	Trial Start Year	EP[1]	Application							Harvest Procedures[3]
				Timing	Rate lb a.i./A	RTI[2] (days)	Treat. No.	Method	Total Rate lb a.i./A	Tank Mix Adjuvants	
-MI36	Fennville, MI	2001	Platinum 2SC	Green Tip	0.197	NA	1 of 1	Soil Applied Surface Band	0.197	None	NA
-MI36	Fennville, MI	2001	Actara® 25WG	Immature Fruit	0.066	--	1 of 3	Directed Foliar	0.196	None	NA
				Immature Fruit	0.065	7	2 of 3	Directed Foliar			
				Immature Fruit	0.065	7	3 of 3	Directed Foliar			
-OR20	Aurora, OR	2001	Platinum 2SC	Pink Bud	0.218	--	1 of 1	Soil Applied Surface Band	0.218	--	NA
-OR20	Aurora, OR	2001	Actara® 25WG	Fruit beginning to blush pink	0.069	--	1 of 3	Directed Foliar	0.204	None	NA
				Most green berries, a few blue	0.066	6	2 of 3	Directed Foliar			
				Ripe and green fruit	0.069	7	3 of 3	Directed Foliar			

[1]EP = End-use Product [2] Retreatment Interval [3] Only applicable for cotton commodities.

Table B.1.3: Trial numbers and geographical locations

NAFTA Growing Region	Crop: Blueberry			
	Canada		US	
	Sub	Req	Sub	Req
1			1	1
1A				
2			4	3
3				
4				
5			3	3
5A				
6				
7				
7A				
8				
9				
10				
11				
12			1	1
13				
14				
15				
16				
17				
18				
19				
20				
21				
Total			9	8

Sub = Submitted Req = Required

Table C.1.1: Summary of Recoveries

Matrix	Analyte	Spike level (ppm)	Sample size (n)	Type of Recovery [1]	Recoveries (%)	Mean	±Std Dev.
Blueberry	Thiamethoxam (CGA-293343)	0.01003	11	MV	92	91	9
				MV	74		
				MV	86		
				CR	89		
				CR	106		
				CR	97		
				CR	88		
				CR	84		
				CR	89		
				CR	100		
				CR	97		
Blueberry	Metabolite (CGA-322704)	0.01003	11	MV	87	90	8
				MV	81		
				MV	90		
				CR	93		
				CR	99		
				CR	98		
				CR	79		
				CR	82		
				CR	85		
				CR	99		
				CR	102		

[1] MV = Method Validation Recoveries; CR = Concurrent Recoveries

Table C.1.2: Summary of Recoveries

Matrix	Analyte	Spike level (ppm)	Sample size (n)	Type of Recovery [1]	Recoveries (%)	Mean	±Std Dev.
Blueberry	Thiamethoxam (CGA-293343)	0.1003	6	MV	81	90	12
				MV	81		
				MV	79		
				CR	96		
				CR	92		
				CR	109		
Blueberry	Metabolite (CGA-322704)	0.1003	6	MV	85	89	8
				MV	84		
				MV	84		
				CR	94		
				CR	85		
				CR	103		
Blueberry	Thiamethoxam (CGA-293343)	5.015	4	MV	113	104	15
				MV	109		
				MV	112		
				CRSS	82		
Blueberry	Metabolite (CGA-322704)	5.015	4	MV	88	83	4
				MV	80		
				MV	84		
				CRSS	79		

[1] MV = Method Validation Recoveries; CR = Concurrent Recoveries; CRSS = Concurrent Recoveries, Storage Stability

Table C.2: Summary of Storage Conditions

Matrix (RAC or Extract)	Analyte(s)	Storage Stability Recoveries (%)	Storage Temp. (°C)	Maximum Actual Sample Storage Duration (days)	Limit of Demonstrated Storage Stability (days)
Blueberry	Thiamethoxam (CGA-293343)	93	-4 to -28	430	430
		91			
		93			
Blueberry	Metabolite (CGA-322704)	95	-4 to -28	430	430
		93			
		96			

Table C.3.1: Residue Data from Crop Field Trials

Trial ID	Trial Location (City, State)	NAFTA Growing Region	Trial Start Year	Crop	Variety	Commodity	Total Rate lbs a.i./A [1]	PHI	Residues from Treated Samples				
									Thiamethoxam (CGA-293343) (ppm)		Metabolite (CGA-322704) (ppm)		Total Max. (ppm)
-ME05	Jonesboro, ME	1	2001	Blueberry	Lowbush	Fruit	0.198 **(Trt 02)**	3	0.06	0.06	0.02	0.03	0.09
-NJ28	Bridgeton, NJ	2	2001	Blueberry	Duke	Fruit	0.198 **(Trt 02)**	3	0.07	0.06	0.01	<0.01 (0.008)	0.08
-NJ28	Bridgeton, NJ	2	2001	Blueberry	Duke	Fruit	0.195 **(Trt 03)**	76	<0.01	<0.01	<0.01	<0.01	<0.01
-NJ29	Bridgeton, NJ	2	2001	Blueberry	Blueray	Fruit	0.197 **(Trt 02)**	3	0.07	0.06	0.01	0.01	0.08
-NJ29	Bridgeton, NJ	2	2001	Blueberry	Blueray	Fruit	0.191 **(Trt 03)**	72	<0.01	<0.01	<0.01	<0.01	<0.01
-NC22	Castle Hayne, NC	2	2001	Blueberry	Croatan	Fruit	0.198 **(Trt 02)**	3	0.06	0.07	0.02	0.02	0.09
-NC22	Castle Hayne, NC	2	2001	Blueberry	Croatan	Fruit	0.198 **(Trt 02)**	7	0.05	0.03	0.02	0.02	0.07
-NC22	Castle Hayne, NC	2	2001	Blueberry	Croatan	Fruit	0.198 **(Trt 02)**	10	0.02	0.01	0.01	0.01	0.03
-NC22	Castle Hayne, NC	2	2001	Blueberry	Croatan	Fruit	0.197 **(Trt 03)**	78	<0.01 (0.001)	<0.01	<0.01	<0.01	<0.01

[1] Treatment 02 consisted of 3 directed foliar applications of Actara® 25WG with a 3 day PHI. Treatment 03 consisted of one soil applied surface band application (calculated on broadcast basis) of Platinum™ 2SC and sampled on the same day as Treatment 02.

Table C.3.2: Residue Data from Crop Field Trials

Trial ID	Trial Location (City, State)	NAFTA Growing Region	Trial Start Year	Crop	Variety	Commodity	Total Rate lbs a.i./A [1]	PHI	Residues from Treated Samples				
									Thiamethoxam (CGA-293343) (ppm)		Metabolite (CGA-322704) (ppm)		Total Max. (ppm)
-NC23	Castle Hayne, NC	2	2001	Blueberry	Blue Chip	Fruit	0.198 **(Trt 02)**	3	0.04	0.05	0.05	0.04	0.09
-MI34	Fennville, MI	5	2001	Blueberry	Rubel	Fruit	0.198 **(Trt 02)**	3	0.07	0.06	<0.01 (0.006)	<0.01 (0.005)	0.076
-MI34	Fennville, MI	5	2001	Blueberry	Rubel	Fruit	0.198 **(Trt 02)**	7	0.06	0.05	<0.01 (0.006)	<0.01 (0.005)	0.066
-MI34	Fennville, MI	5	2001	Blueberry	Rubel	Fruit	0.198 **(Trt 02)**	10	0.04	0.05	<0.01 (0.005)	<0.01 (0.007)	0.057
-MI34	Fennville, MI	5	2001	Blueberry	Rubel	Fruit	0.197 **(Trt 03)**	86	<0.01	<0.01	<0.01	<0.01	<0.01
-MI35	Fennville, MI	5	2001	Blueberry	Rubels	Fruit	0.197 **(Trt 02)**	3	0.11	0.10	<0.01 (0.010)	<0.01 (0.009)	0.12
-MI35	Fennville, MI	5	2001	Blueberry	Rubels	Fruit	0.187 **(Trt 03)**	94	<0.01 (0.001)	<0.01 (0.001)	<0.01 (0.001)	<0.01 (0.001)	<0.01

[1] Treatment 02 consisted of 3 directed foliar applications of Actara® 25WG with a 3 day PHI. Treatment 03 consisted of one soil applied surface band application (calculated on broadcast basis) of Platinum™ 2SC and sampled on the same day as Treatment 02.

Table C.3.3: Residue Data from Crop Field Trials

Trial ID	Trial Location (City, State)	NAFTA Growing Region	Trial Start Year	Crop	Variety	Commodity	Total Rate lbs a.i./A [1]	PHI	Residues from Treated Samples				
									Thiamethoxam (CGA-293343) (ppm)		Metabolite (CGA-322704) (ppm)		Total Max. (ppm)
-MI36	Fennville, MI	5	2001	Blueberry	Rubels	Fruit	0.196 **(Trt 02)**	3	0.06	0.06	<0.01 (0.006)	<0.01 (0.007)	0.067
-MI36	Fennville, MI	5	2001	Blueberry	Rubels	Fruit	0.197 **(Trt 03)**	94	<0.01 (0.001)	<0.01	<0.01	<0.01	<0.01
-OR20	Aurora, OR	12	2001	Blueberry	Bluecrop	Fruit	0.204 **(Trt 02)**	3	<0.01 (0.006)	<0.01 (0.009)	<0.01 (0.002)	<0.01 (0.004)	0.013
-OR20	Aurora, OR	12	2001	Blueberry	Bluecrop	Fruit	0.218 **(Trt 03)**	85	<0.01	<0.01	<0.01 (0.001)	<0.01 (0.001)	<0.01

[1] Treatment 02 consisted of 3 directed foliar applications of Actara® 25WG with a 3 day PHI. Treatment 03 consisted of one soil applied surface band application (calculated on broadcast basis) of Platinum™ 2SC and sampled on the same day as Treatment 02.

Table C.4: Summary of Residue Data from Crop Field Trials

Commodity	Treatment	Total Application Rate, lb a.i./A	PHI (days)	Analyte	Treated Sample Residue Levels (ppm)					
					n	Min.	Max.	HAFT [1]	Mean	Std. Dev.
Blueberry	Three directed foliar applications	0.196 to 0.204	3	Thiamethoxam (CGA-293343)	18	<0.01 (0.006)	0.11	0.105	0.06	0.02
Blueberry	Three directed foliar application	0.196 to 0.204	3	Metabolite (CGA-322704)	18	<0.01 (0.002)	0.05	0.045	0.015	0.013
Blueberry	Three directed foliar applications	0.198	7	Thiamethoxam (CGA-293343)	4	0.03	0.06	0.055	0.05	0.01
Blueberry	Three directed foliar application	0.198	7	Metabolite (CGA-322704)	4	<0.01 (0.005)	0.02	0.02	0.013	0.008
Blueberry	Three directed foliar applications	0.198	10	Thiamethoxam (CGA-293343)	4	0.01	0.05	0.045	0.03	0.02
Blueberry	Three directed foliar application	0.198	10	Metabolite (CGA-322704)	4	<0.01 (0.005)	0.01	0.01	0.008	0.002
Blueberry	One soil applied band application	0.187 to 0.197	72-94	Thiamethoxam (CGA-293343)	14	<0.01	<0.01	<0.01	<0.01	<0.01
Blueberry	One soil applied band application	0.187 to 0.197	72-94	Metabolite (CGA-322704)	14	<0.01	<0.01	<0.01	<0.01	<0.01

[1] HAFT = Highest Average Field Trial.

APPENDIX D

Example of Worksheet for Calculation LOD & LOQ

ATTACHMENT D

Please copy this file & save it to your folder before using. Delete contents of this Cell & Cells E7 to E13 before using. Enter in the correct information for Compound / Commodity in Row 4. Also, please enter the correct value for LLMV in cells E6 and F34.

Calculations for Determination of LOD / LOQ for TNT / Roadkill

degrees of freedom	Number of Replicates	One-tailed t-statistic
0	1	infinity
1	2	31.821
2	3	6.965
3	4	4.541
4	5	3.747
5	6	3.365
6	7	3.143
7	8	2.998
8	9	2.896
9	10	2.821
10	11	2.764
11	12	2.718
12	13	2.681
13	14	2.65
14	15	2.624
15	16	2.602
16	17	2.583
17	18	2.567
18	19	2.552
19	20	2.539
20	21	2.528
21	22	2.518
22	23	2.508
23	24	2.500
24	25	2.492
25	26	2.485

Amount Detected (Spiked at 0.1 ppm)
0.092
0.098
0.1
0.095
0.103
0.101
0.09

Avg. Recovery	0.097 ppm n = 7	LLMV = 0.1 ppm

For Lowest Spike Only:	Std. Dev.	One-tailed t-statistic
	0.00483046	3.143

For (n) Replicates = (n-1) Deg. of Freedom

MDL (LOD)

0.015182132

= (t-statistic) X (Std. Dev.)

PQL (LOQ)

0.045546397

= (MDL) X (3)

This method is based on the method described in Roy-Keith Smith's Handbook of Environmental Analysis, Fourth Edition, Genium Publishing Corporation.

APPENDIX E

RE: Routing of Final Reports and QA reports at HQ, delegation of authority

In order to facilitate the handling of Final Reports and FRA1 Reports, the Testing Facility Management signing responsibility is delegated as follows:

Primary: Dan Kunkel, Van Starner, Jerry Baron
Secondary: Chair, Project Management Committee

This prioritization list will permit routing of Final Reports and FRA1 reports to the secondary management delegate when the primary members of management are not available.

APPENDIX F

The attached document shall be used to request management approval for Field Data Books (dated 1997 or later) to be reviewed as part of the final report review. (See item d under Action Requested.) This document shall also be used to request management approval for other changes to the sequence of Field Data Book review at IR-4, as listed under Action Requested.

Field Data Book Review Expedition Request Form

PR# _____

Study Director: _____

Chemical/Crop: _____

Assigned QA: _____

Has the analytical summary report been received at HQ? YES NO (Circle)

CC: Regional Laboratory Directors: ARS NER NCR WSR SOR (Circle)

Regional Field Coordinators ARS NER NCR WSR SOR (Circle)

Regional Quality Assurance Coordinators: NER NCR WSR SOR (Circle)

Susan Bierbrunner

List individually: (attach additional pages if needed)

Field Trial ID #	Current Location	Action Requested*	Completed

*

a) Establish a QA priority.
b) Forward original FDB to QA; copy to HQ (Registration Manager). SD will generate the draft field summary, but this will not be incorporated into final report until QA complete.
c) Forward original FDB to HQ (Registration Manager). SD will review the FDB, contact the FRD and complete the raw data, then forward the original to QA for review.
d) Forward the original FDB to HQ (Registration Manager). SD will write the final report and FDB will be audited as part of the final report review.
e) Other, please explain in notes section.

Additional Notes:

_____

_____

_____

_____

Submitted by: _____

Reviewed by Registration Manager: _____

Reviewed by QA Manager: _____

Approved by Testing Facility Management: _____

Field Data Book Review Expedition Request Form

Field Trial ID #	Current Location	Status	Action Requested*	Completed

SOP #: 6.1

AUTHORS: D. Carpenter, K. S. Samoil, W. P. Barney, V. R. Starner, , M. P. Braverman and J. Baron

REVISION #: 07

EFFECTIVE DATE: April 8, 2015

TITLE: **Transmittal Letter and Administrative Volume (Petition) Development and Review.**

PURPOSE: To provide a uniform method and format for the preparation and review of administrative volumes and transmittal letters, requesting tolerances or exemptions from the requirement of a tolerance (tolerance exemptions) that are submitted by IR-4 Headquarters to the registrant(s) and EPA.

SCOPE: This SOP, which is not subject to GLP compliance, applies to all administrative volume (petitions) and transmittal letters prepared, reviewed, and submitted by IR-4 Headquarters to the registrant(s) and EPA proposing tolerances or tolerance exemptions for pesticide residues in or on food and feed commodities. This SOP does not apply to petition amendments. For reregistration packages, only the transmittal letter applies in this SOP.

PROCEDURES: 1) Refer to PR Notice 2011-3 or current notice for EPA format guidance for submission to EPA. See current SOP 6.0 for a copy of PR Notice 2011-3 or current version.
2) Transmittal Letter:
The transmittal letter is addressed as indicated in APPENDIX A, and identifies 6 items in the subject line (see example in APPENDIX B).

Active Ingredient Common Name (Trade Name(s) of Formulation(s))
Code of Federal Regulations chemical name of parent chemical or equivalent
EPA Registration No. from the label, if available
Whether the use is new or a reregistration
Crop(s) and/or Crop Group(s)
IR-4 Study Number(s) (PR Number(s))

The transmittal letter identifies IR-4 as the submitter on behalf of the Agricultural Experiment Stations who have requested the use or participated in the research and/or other interested parties who have formally requested IR-4's assistance in the clearance effort. It also identifies the pesticide that the submission covers, the pesticide's 40 CFR 180 series number (if available), and the Federal Food Drug and Cosmetic Act Section that is affected. Any additional information that will clarify what IR-4 is requesting (for example, Reduced Risk classification, status of immunotox and neurotox studies and public interest finding – see EPAs public interest web site) should be included in the letter. The transmittal letter contains a listing by volume title and PR number of studies submitted in support of the dossier.

The transmittal letter indicates who should receive a copy of the transmittal letter and a copy of the administrative volume (Volume 1), except for some reregistration packages; copies should go to Regional Field Coordinators and interested parties. The transmittal letter also indicates the registrant representative who should receive a copy of the dossier. A hard copy is also placed on a clipboard in the copier room for personnel involved in database updates and monthly logs.

3) Volume 1, the administrative volume, shall be submitted to EPA in the following form:

Administrative Volume (Petition):

The Administrative Volume (Volume 1) contains a Title Page, a Table of Contents, a Letter of Authorization (LOA), and Sections A through G (detailed descriptions below). The Title Page should contain the title, the author, author's address, the New Jersey Agricultural Experiment Station Publication Number and statement of support. The LOA is a letter that is sent by the registrant (see example LOA in APPENDIX C) that allows EPA to review pertinent data for this pesticide in conjunction with the submission. The Table of Contents indicates the pages on which the LOA and Sections A through G can be found.

Section A:

The pesticide formulations used in the studies and EPA Registration Numbers are listed.

Section B:

This section contains the complete, proposed pesticide label(s) including the requested new uses, with information on the formulation, application rate, frequency, target pest, and time of application of the pesticide. Any restrictions should be listed such as PHI (Preharvest Interval) and total amount per growing season. The directions for use in Section B reflect the general use pattern in the residue trials. (IR-4 cannot request a change to the label, once submitted, so assure that the use pattern suggested is

consistent with the residue study and will be useful to the grower.) Optionally, a summary of the instructions for the requested new uses, excluding the general label instructions and instructions for previously registered commodities, may be included in Section B (see example of EPA preferred format in APPENDIX D).

Note: (Generally, IR-4 cannot request a change to the label, once submitted, so assure that the use pattern suggested is consistent with the residue study and will be useful to the grower.)

Section C:

This section is for full reports of investigations made with respect to the safety of the pesticide. IR-4 usually covers this area by making reference to the LOA from the registrant allowing EPA to refer to data on file.

Section D:

This section contains the results of the studies on the amount of residue remaining. The IR-4 data summary (see current SOP 6.0) is included in this Section, unless it is a surrogate data petition. Section D, at a minimum, should include a description of what was actually done; e.g., where field trials were conducted, dosage rates, application intervals, PHI, a description of the analytical method used, and the results (maximum residues) of the study. Section D should include a discussion of the adequacy of the data and factors that may have had an impact on the study. Section D is usually a compilation of all of the summaries of each individual study contained in subsequent volumes. For non-data tolerance requests, Section D should include an explanation for the requested tolerance(s).

Section E:

This section involves a discussion of practicable methods for removing residue that exceeds the proposed tolerance. In most IR-4 submissions it is unlikely that residues of the test substance on the test crop will exceed the proposed tolerance, in which case a discussion of methods for removing the residues is unnecessary.

Section F:

This section includes the proposed tolerance or exemption from the requirement of a tolerance. When the submission is for a food or feed commodity, the wording in Section F should reflect the wording in the appropriate subpart of 40 CFR 180. Include in this section the submitter, IR-4, the Agricultural Experiment Stations who have requested the use, and/or other interested parties who have formally requested this activity for the test substance on the particular crop(s) or tolerance level(s). The following is an example:

"The petitioner, IR-4, on behalf of the Agricultural Experiment Stations of Massachusetts, Wisconsin, New Jersey, and Oregon, and the

Cranberry Institute which represents all cranberry growing states, requests the establishment of a tolerance for the residues of the fungicide, aluminum tris (*O*-ethylphosphonate), in or on the raw agricultural commodity cranberry at 0.5 ppm."

When multiple commodities or crop groups are involved, they may be listed in a table in Section F. When existing tolerances are being amended, such as crop group updates, raising tolerance level, etc., a separate table in this section should list the tolerances that are to be removed upon the establishment of the new tolerances. A draft of this section should be sent to EPA for assurance that the nomenclature is correct.

If EPA personnel are not available, consult with the Registration Manager or designee.

Section G:

This section includes summaries of the need for the new use(s) and study results, and additional information in support of the submission, such as Section 18s, PCR forms, letter(s) of support, results from the OECD MRL calculator and efficacy information.

4) After a draft administrative volume has been written and reviewed by the Study Director, they may request a review from IR-4 Management (for example, assistance with comparing existing MRLs to suggested US, Canadian and Codex tolerances). Alternatively, the Registrations Manager may request that a Study Director submit a petition for review. This review may be conducted by the Registrations Manager, or someone else designated by the Registrations Manager. When an administrative volume does not meet any of the critical requirements, or seems to be incomplete or unclear, then clarifications or corrections will be required before the internal review is considered to be complete.

Prepared by: Deborah Carpenter Date: March 23, 2015

Approved by: Jerry Baron Date: 25 March 2015

APPENDIX A

DOCUMENT PROCESSING DESK ADDRESSES FOR IR-4 PETITIONS

The following address should be used for all correspondence or data submissions to OPP that are hand-carried or sent by courier service (e.g., **UPS**) Monday through Friday, from 8:00 am to 4:30 pm, excluding Federal holidays:

Ms. Barbara Madden
US EPA OPP/Doc Proc Desk (REGFEE)
Room S-4900
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

The IR-4 Project
Pest Management Solutions for Specialty Crops and Minor Uses

IR-4 Headquarters
Rutgers, The State University of New Jersey
500 College Road East, Suite 201 W
Princeton, NJ 08540
732.932.9575
fax: 609.514.2612
www.ir4.rutgers.edu

DATE, YEAR

Ms. Barbara Madden
Minor Use Officer
US EPA OPP/Proc Desk (REGFEE)
Room S-4900
2777 S. Crystal Drive
Arlington, VA 22202

Dear Ms. Madden:

Submission of the IR-4 CHEMICAL AND TECHNICAL CHEMICAL NAME studies on CROPS.

RE: CHEMICAL
END USE PRODUCT®, EPA Reg. No. #

IR-4 Public Interest Finding:

(1) The CROP data being submitted was developed by IR-4.
(2) The active ingredient, CHEMICAL, is already registered on other food crops.
(3) The active ingredient/crop combinations of PR # CHEMICAL / CROP were pre-screened by EPA because these IR-4 studies were initiated in 2010.
(4) The use is for:
    a. a minor crop (≤ 300,000 acres) or a specialty crop (which the 2004 Specialty Crop Competitiveness Act defines to include fruits, vegetables, tree nuts, dried fruits and nursery crops (including floriculture))[1], or
    b. a major crop that is a representative commodity for a crop group/subgroup that is being submitted to establish tolerances for the minor uses/specialty crops in the crop group/subgroup, and where the accompanying label amendment adds at least one new minor use/specialty crop from that crop group to the label; or

[PLEASE NOTE: Additional guidance for public health submissions can be found on the EPA web page: http://www2.epa.gov/pria-fees/factors-ir-4-public-interest-finding.]

[1] Only those applications for specialty crops that would require the establishment of a tolerance or tolerance exemption would meet condition (i) "application is solely associated with a tolerance petition…" and therefore could qualify for exemption from the PRIA registration fee.

Major funding for IR-4 is provided by Special Research Grants and Hatch Act Funds from USDA-CSREES, in cooperation with the State Agricultural Experiment Stations and USDA-ARS.

Regarding the conversion of the existing CROP GROUP tolerance to the revised CROP GROUP tolerance, IR-4 believes the that technically these submissions are "agency initiated actions" since in the Crop Grouping Final Rule (FRN 77 No.163, August 22, 2012), EPA requests that petitioners seek tolerances under the new crop grouping system or, alternatively, EPA will address the conversion on its own. Secondly, stakeholders and the public will benefit from actions such as these because many additional minor use crops will be covered by the new crop grouping system tolerances. Third, the new crop group structure will enhance maximum residue limit (MRL) enforcement efforts by FDA since the new naming system is more precise than the old naming convention.

New Uses	**Supporting Data**	
Tolerance Requested	IR-4 PR Numbers	Source of New Tolerance
CROP GROUP	#	CROP residue data
CROP	#	ChemSAC decision
CROP SUBGROUP	#	Expansion of existing CROP tolerance to revised crop group or subgroup ####

Fee Category:
R-1XX
Registration Fee: $$$$$$ (See IR-4 exemption request below)

The undersigned, STUDY DIRECTOR, Coordinator, Interregional Research Project No. 4, The State University of New Jersey, Princeton, New Jersey 08540, on behalf of the IR-4 Project and the Agricultural Experiment Stations of the states of STATE (CROP), submits this petition pursuant to Section 408(e) of the Federal Food, Drug and Cosmetic Act, as amended, with respect to the pesticide chemical, CHEMICAL, (TECHNICAL CHEMICAL NAME) (40 CFR 180.###).

As per the Pesticide Registration Improvement Act, the IR-4 tolerance petition for CHEMICAL in/on (LIST CROPS) is in the public interest and therefore exempt from the registration services fee. IR-4 in cooperation with the registrant, (REGISTRANT NAME), requests an exemption of the registration services fee for this tolerance petition.

List of Studies Submitted with this letter in Support of Proposed Tolerances for (CHEMICAL) in/on (LIST CROPS):

Vol. #	Volume Title	MRID No. / PP No.
1	Petition (Administrative Volume) Supporting data for CHEMICAL on CROP, CROP GROUP, CROP SUBGROUP and Crop Group Expansion or Conversions	---
2	CHEMICAL: Magnitude of the Residue on CROP	*Obtain MRID# from EPA*

Major funding for IR-4 is provided by Special Research Grants and Hatch Act Funds from USDA-CSREES, in cooperation with the State Agricultural Experiment Stations and USDA-ARS.

The entire submission is being made as an electronic submission only using EPA's e-submission XML format described in the e-Submission XML Guidance Document Version 1.2 dated July 21, 2008.

Enclosed in this submission as an electronic copy on CD are the Administrative Volume, the Data Volumes, Notice of Filing, the Letter of Authorization (DATE) and the following listed below:

For the technical product:

- EPA Form 8570-1 for CHEMICAL Technical (EPA Reg. No. #)
- EPA Form 8570-34 Certification with Respect to Citation of Data for CHEMICAL Technical (EPA Reg. No. #)
- EPA Form 8570-35 Data Matrix (EPA copy) for CHEMICAL Technical (EPA Reg. No. #)
- EPA Form 8570-35 Data Matrix (Public copy) for CHEMICAL Technical (EPA Reg. No. #)
- CHEMICAL Technical label (EPA Reg. No. #)

For the end use product:

- EPA Form 8570-1 Application for Pesticide for END USE PRODUCT® (EPA Reg. No. #)
- Form 8570-27 Formulator's Exemption Statement
- EPA Form 8570-34 Certification with Respect to Citation of Data for END USE PRODUCT® (EPA Reg. No. #)
- EPA Form 8570-35 Data Matrix (EPA copy) for END USE PRODUCT® (EPA Reg. No. #)
- EPA Form 8570-35 Data Matrix (Public copy) for END USE PRODUCT® (EPA Reg. No. #)
- Proposed Section 3 Supplemental label for END USE PRODUCT® (EPA Reg. No. #)

For the neurotoxicity study requirement, REGISTRANT NAME submitted a neurotoxicity study (MRID #) for CHEMICAL.

For the immunotoxicity study requirement, REGISTRANT NAME submitted an immunotoxicity study (MRID #) for CHEMICAL.

For questions pertaining to the 8570 forms, the labels and the notice of filing, please contact THE REGISTRANT, ADDRESS, TELEPHONE, EMAIL. For questions concerning the transmittal letter, petition and/or final study reports, please contact STUDY DIRECTOR, IR-4, Tel. No.: (732) 932-9575 ext. ; email: .

Yours very truly,
Interregional Research Project No. 4
Petitioner

Per_____

Major funding for IR-4 is provided by Special Research Grants and Hatch Act Funds from USDA-CSREES, in cooperation with the State Agricultural Experiment Stations and USDA-ARS.

STUDY DIRECTOR
Coordinator, IR-4 Project Headquarters
Rutgers, The State University of New Jersey
500 College Road East, Suite 201 W
Princeton, NJ 08540

Copies: REGISTRANT (REGISTRANT NAME, Uploaded letter, administrative & data volumes); Shirley Archambault, Shirley.Archambault@AGR.GC.CA (Agriculture & Agri-Food Canada, Uploaded letter, administrative & data volumes, IF JOINT CANADIAN SUBMISSION)
IR-4 Regional Coordinators (Uploaded letter & administrative volume)
Diane Infante, Ken Samoil, Debbie Carpenter, Dan Kunkel (IR-4, letter only)

Major funding for IR-4 is provided by Special Research Grants and Hatch Act Funds from USDA-CSREES, in cooperation with the State Agricultural Experiment Stations and USDA-ARS.

APPENDIX C

Example Letter of Authorization (LOA)

"REGISTRANT LETTERHEAD"

"Date"

Ms. Barbara Madden
US EPA OPP/Doc Proc Desk (REGFEE)
Room S-4900
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Dear Ms. Madden:

SUBJECT: "PRODUCT"/ "CROP(S)"/"PR#"
PETITION FOR TOLERANCE

"Registrant" herewith authorizes the Registration Division of the Office of Pesticide Programs of the Environmental Protection Agency to refer to all "product" data submitted by "Registrant" which are considered necessary to support the IR-4 petition for residue tolerance(s) of "product" on "crop(s)".

This authorization is qualified to the extent, however, that: (1) the applicant or any other person except your agency shall have access to said data unless specifically authorized in writing by "Registrant", or when in the opinion of your agency it is required in judicial or administrative proceedings; (2) this authorization shall not be construed as authorization to use or consider said data, directly or indirectly, in support of any subsequent application submitted by the applicant; and (3) this authorization shall not be transferred by the applicant in any manner whatsoever without the express prior consent of "Registrant".

Sincerely,

"John Doe"
"John Doe's Title"

cc: IR-4, etc.

APPENDIX D

SECTION B

THE AMOUNT, FREQUENCY AND TIME OF APPLICATION OF PYRACLOSTROBIN IN HEAD AND STEM BRASSICA

(Crop subgroup 5A) PRODUCTION
(includes broccoli, Chinese broccoli [gai lon], brussels sprouts, cabbage, Chinese cabbage [napa], Chinese mustard cabbage [gai choy], cauliflower, cavalo broccolo, kohlrabi)

Product: Cabrio™ EG Fungicide (20% WG) EPA Reg. No.: 7969-187

Firm Name: BASF Corporation

Crop/Site/Commodity: broccoli, Chinese broccoli [gai lon], brussels sprouts, cabbage, Chinese cabbage [napa], Chinese mustard cabbage [gai choy], cauliflower, cavalo broccolo, kohlrabi

Target Pest/Problem: alternaria leaf spot (*Alternaria* spp.), anthracnose (*Colletotrichum* spp.), black leg (*Phoma lingan*), cercospora leaf spot (*Cercospora brassicicola*), downy mildew (*Peronospora parasitica*), powdery mildew (*Erysiphe polygoni*), rhizoctonia blight (*Rhizoctonia solani*), ring spot (*Mycosphaerella brassicicola*), white rust (*Albugo candida*), white leaf spot (*Pseudocercosporella capsellae*)

Methods of Application: ground, aerial, through sprinkler irrigation

Dosage: Apply 0.15 to 0.20 lb active pyraclostrobin (12 to 16 oz. of Cabrio) per acre. Do not apply more than a total of 0.60 lb. ai (48 oz. of Cabrio) per acre per season.

Dilution Rate: For ground application use sufficient water to ensure thorough coverage of foliage for optimum disease control; for aerial application, use no less than 5 gallons of spray solution per acre.

Frequency/Timing of Applications: Begin applications of Cabrio™ fungicide prior to disease development and continue on a 7- to 10-day interval. Use the higher rate and shorter interval when disease pressure is high.

Resistance Management: To limit the potential for development of resistance, do not make more than three (3) applications of Cabrio or other strobilurin (QoI) fungicides per crop. Do not make more than two (2) sequential applications of Cabrio before alternating to a labeled non-strobilurin (non-QoI) fungicide with a different mode of action for at least one (1) application.

Restricted Entry Interval (REI): 12 hours

Preharvest Interval (PHI): 0 days

NOTE: See Cabrio™ EG Fungicide label in Section B for use directions and general product information

SOP #: 6.3

AUTHOR(S): D. Carpenter and K. S. Samoil

REVISION#: 06

EFFECTIVE DATE: April 8, 2015

TITLE: **Draft Petition Submission to Registrant(s) for Review and Request for Documents Needed for EPA Submission.**

PURPOSE: To list the documents that must be requested from the registrant(s), when a draft petition is sent for review, to be included in the submission to EPA.

SCOPE: This SOP, which is not subject to GLP compliance, applies to all draft petitions submitted to registrants(s) by IR-4.

PROCEDURES:

1) The Study Director should determine that the draft petition is ready for review by the registrant (See current version of SOP 6.1 for necessary components of a draft petition).

2) A copy of the draft petition is sent to the registrant(s) for review. The registrant is requested to provide IR-4 with a letter of authorization (LOA) to allow EPA to access all pertinent company data files related to the IR-4 petition, a Notice of Filing (NOF), and the following:
   - EPA Form 8570-1 (Rev. 3-94) (Registration Package Form) for formulated and technical materials.
   - Proposed label(s) for the use of formulated pesticide on requested commodities (two copies with one copy highlighting the proposed changes, or a supplemental label).
   - Proposed label(s) for the use of the technical material on requested commodities (two copies, with one copy highlighting the proposed changes).
   - EPA Form 8570-34 Certification with Respect to Proper Citation of Data (from the registrant) for the formulated product(s) and the technical material.
   - EPA Form 8570-35 for the formulated product(s) and the technical material.
   - EPA Form 8570-27 Formulator's Exemption Statement (if appropriate).

- Other regulatory requirements (discussion of the status of immunotoxicity and neurotoxicity studies) as needed.

Prepared By: Deborah Carpenter Date: March 23, 2015

Approved By: Jay Bern Date: 23 March 2015

SOP #: 6.4

AUTHORS: D. Carpenter, G. Lennon, K. W. Dorschner, D. L. Kunkel, and J. Baron

REVISION 07

EFFECTIVE DATE April 8, 2015

TITLE: Dossier **Submission to the United States Environmental Protection Agency (EPA).**

PURPOSE: To provide a uniform procedure for submitting a dossier to the United States Environmental Protection Agency (EPA).

SCOPE: This SOP applies to all electronic dossiers submitted by the IR-4 Project to EPA. These are not subject to GLP compliance.

PROCEDURES:

1) All documents as listed in SOP 6.3 need to be verified and available electronically in order to complete the submission. Note that each form and label need to be in a separate file and in pdf form, except for the notice of filing where the preferred format is in Microsoft Word.

2) All pages of all volumes are numbered per EPA policy, PR Notice 2011-3, or current version. An electronic copy of each volume to be submitted shall be placed in the appropriate folder in the IR-4 Shared Directory.

3) MRID numbers should be requested from EPA (Teresa Downs or current EPA contact). EPA provides the root number (currently 6 digits). The MRID for each data volume will be the root number followed by two digits starting at 01 and increasing sequentially. No dash is used in the MRID number (example: `49346901`). The MRID number is placed in the top right corner on the first page of each data volume.

4) EPA's e-dossier builder (or current version) will be used to compile this dossier. See details in the instruction manual in Appendix A.

5) A zip file is generated by the e-dossier builder. The exact location is listed under "settings" in the e-dossier builder program and it is usually located on your c: drive.

6)A copy of the zip file is copied on the shared directory (currently s: Karen\\EPA submissions and final reports). A disc label is generated by the submitter. See attached example in Appendix B. An email requesting preparation of the CD's is sent to the appropriate contact within IR-4.

7) A minimum of 3 CDs are prepared (EPA, registrant and archives). Additional CDs may be requested by the submitter.

8) The original signed transmittal letter along with the EPA disc are submitted to EPA by traceable carrier. Copies of the transmittal letter and CDs are provided to the registrant's (or registrants') contact person(s). The original is placed in the study file and archived at IR-4 Headquarters (see current version of IR-4 Headquarters SOP #7.1). A copy of the final Administrative Volume transmittal letter is placed in the study file.

At the time of submission to EPA, a copy of the signed transmittal letter and Volume 1 will be provided electronically to the IR-4 Regional Field Coordinators. A copy of the transmittal letter shall also be given to the IR-4 Database Manager and Monthly Log manager (currently K. Samoil). A copy of the transmittal letter shall also be sent via email, along with a Word version of the Notice of Filing and a copy of Volume 1, to the EPA Minor Use Coordinator. If Reduced Risk status is being requested, a copy of the Reduced Risk Request shall be sent via email to the EPA Reduced Risk Coordinator and the EPA Minor Use Coordinator. An electronic copy of the transmittal letter and submission documents will be placed in the appropriate folder in the IR-4 shared directory.

9) The following procedure may be used when submitting registrant data to satisfy an IR-4 priority. The approval of IR-4 Management and EPA must be received in advance of such a submission.

Additional pages shall be placed at the front of the registrant's final report. These pages will be numbered and will include at minimum a Title Page, an IR-4 Statement of No Data Confidentiality Claims an IR-4 Good Laboratory Practice Standards Compliance Statement, and a Table of Contents. Examples of additional pages are provided in

Appendix C.

5) At this time, paper submissions are allowed by EPA, but generally, IR-4 will use the above electronic submission procedure.

Prepared by: Deborah Carpenter Date: March 23, 2015

Approved by: Jay Bern Date: 20 March 2015

Introduction to Electronic Submissions

Obtain necessary documents from registrant(s), check list see appendix 1.

Obtain the MRID number from EPA, Teresa Downs, phone number and/or email is best also copy Barbara Madden. Note that non-data petitions have no MRID numbers.

Teresa Downs (703) 305-5363 email: downs.teresa@epa.gov

Barbara Madden (703) 305-6463 email: madden.barbara@epa.gov

Open the e-dossier Version 1.02, which is located on the shared directory under the ITS folder.

S:\ITS\e-Dossier_Builder\eDossier Builder User Guide v1.0.doc

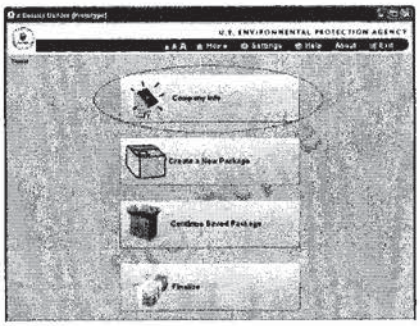
On the HOME page under Company Info set up a profile which includes all your information for the EPA with the submission once completed. Remember to hit "Add profile" so that your info appears on the company listing on top of this page, you can edit and/or delete profiles in the future if necessary by highlight the appropriate line. You do no need to set up your profile unless there is a change.

See example(s) of screens below taken from the EPA instruction manual.

Create, Edit, & Delete Company Profile

Create a Company Profile

From the *Home* screen, select the **Company Info** button.



The *Company Profile* screen appears. Complete all **required fields** (*) and any of the other fields as necessary, and then select the **Add** button.

Note: The Company and Contact Details are not meant to be the official company contact information.

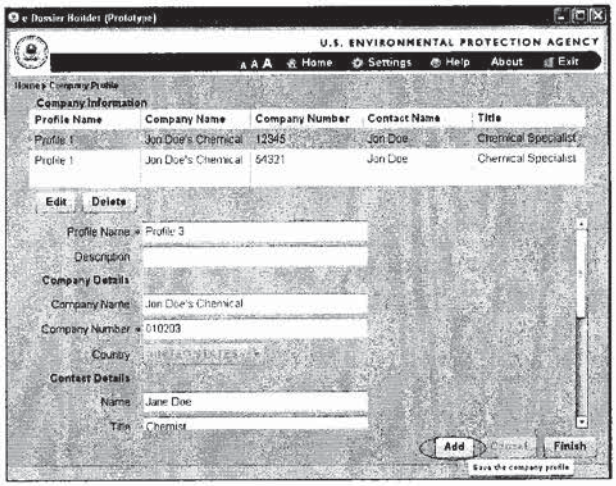


Figure 6-2: Company Info Screen

The information entered is now provided in the *Company Information* table as shown below. Repeat step 2 if you would like to provide additional profiles. If no other company profiles are needed, select **Home** from the tool bar provided at the top of the screen.

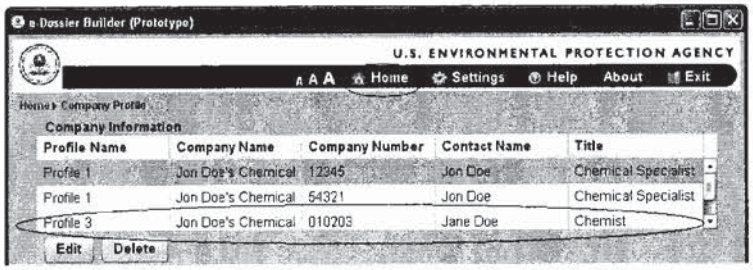


Figure 6-3: Company Info Added

Edit a Company Profile

From the *Company Profile* screen, select a profile that is provided in the *Company Information* table, and then click the **Edit** button.

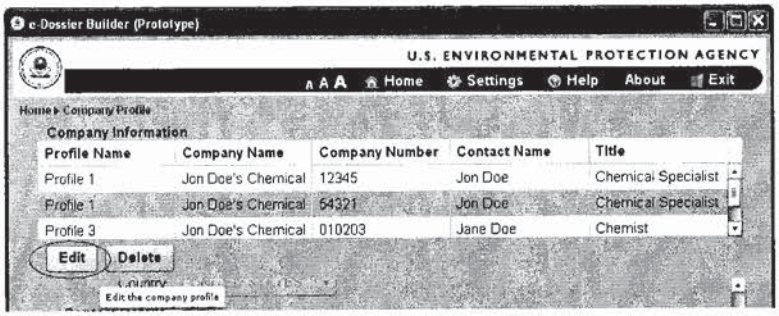


Figure 6-4: Edit Company Info

The previously entered profile name and company and contact details are provided in their associated fields located below the *Company Information* table. Make any **required changes**, and then select the **Save** button.

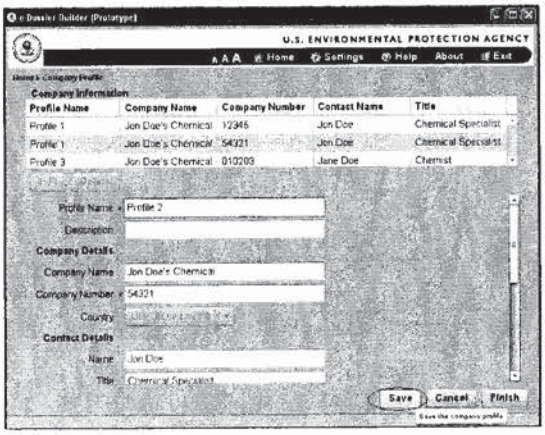


Figure 6-5: Save Company Profile Changes

The company profile changes are saved and the profile information is provided in the *Company Information* table.

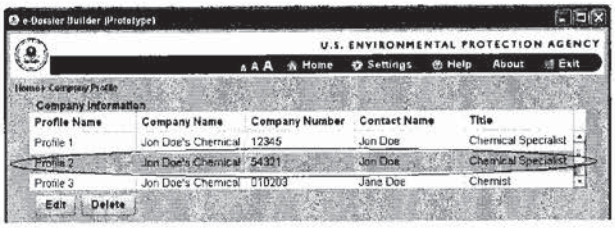


Figure 6-6: Updated Company Profile

Delete a Company Profile

From the *Company Profile* screen, select a profile that is provided in the *Company Information* table, and then click the **Delete** button.

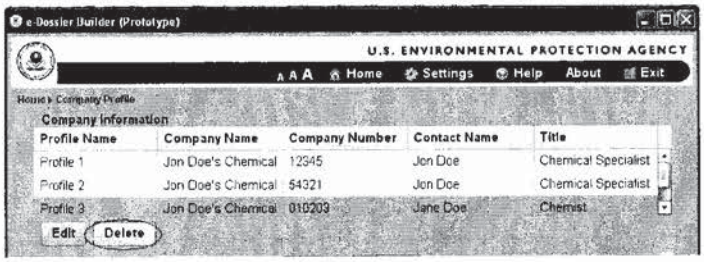


Figure 6-7: Company Profile Delete

The *Delete* window appears asking if you want to delete the profile. Select the **Yes** button.

Next you will go back onto the HOME page open "Create a New Package".

Create, Edit, and Delete a Package

Create a Package

From the *Home* screen, select the **Create a New Package** button.

Figure 7-1: Create a New Package

As you continue into this section you will be asked a few questions that will most likely have standard answers as far as IR-4 submission are concerned, BUT please note that there are always exceptions.

For instances: "EDSP (Endocrine Disruptor) submission Yes or No. In most cases for IR-4 MOR studies you should check "NO", there may come a time when we say yes.

The *New Package* screen appears. Complete all **required fields** (*) and any of the other fields as necessary, select the applicable **Regulatory** (i.e., Product Registration – Section 3) and **Application** (i.e., New Registration) **Types**, and then select the **Next>** button.

Under "package name" provide a name for the package (up to 45 characters).
Example; e.g. IR-4 Pyrimethanil Submission 2012 or IR4 Pyrimethanil Crop name 2012
Do not insert; , " " # * & etc. It is okay to put a space in the title

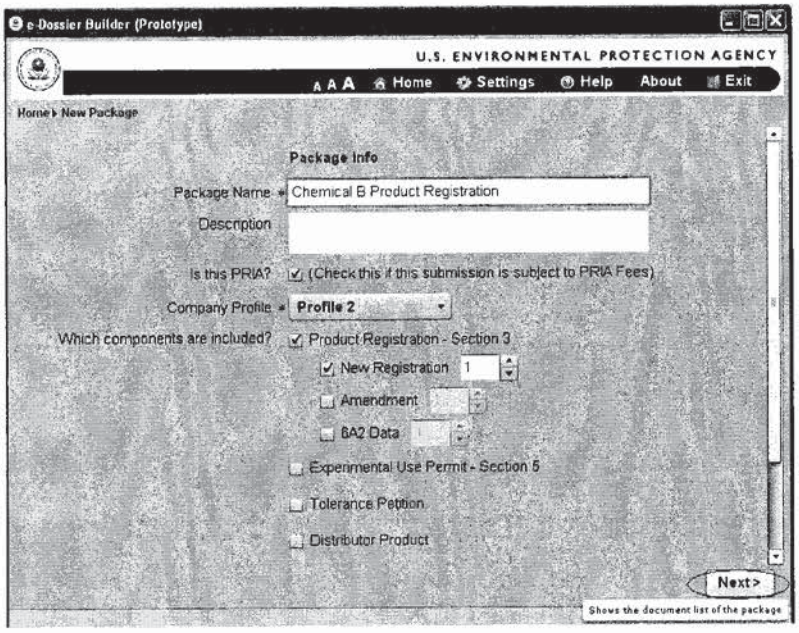


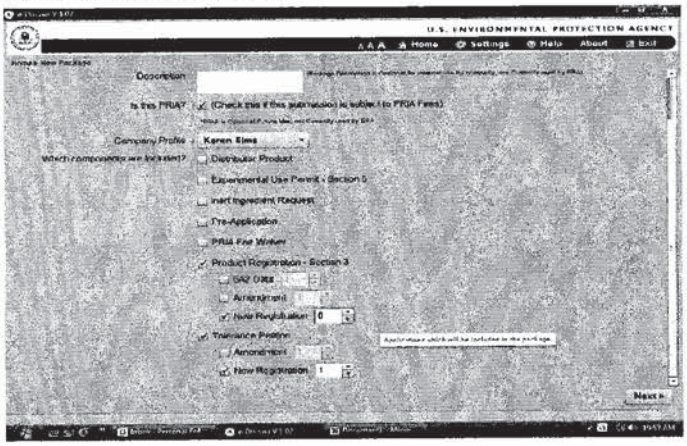
Figure 7-2: Package Info

On the question "Is this PRIA" ___ (check this box if this submission is subject to PRIA fees) Although IR4 submits a waiver letter for the fees, the PRIA Fees/payments are not tracked, recorded or processed electronically, but you should check this box.

Company Profile is a drop down box which will have your name since you created a company profile at the start.

Next section is called "What components are included"

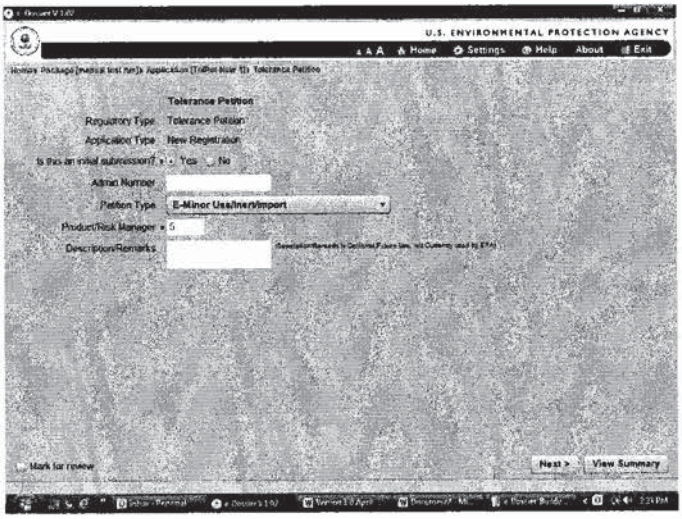
Check the product registration Section 3 box and a drop down list will appear.
Mark new registration(s) and indicate the total number of labels this will consist of all formulations and/or technical labels associated with this submission.



We then have to check the box next to Tolerance Petition – the sub-list here asks if it is an amendment of new registration, check the appropriated one and put the number of petitions in the box on the side. Note it is usually only one petition with each submission.

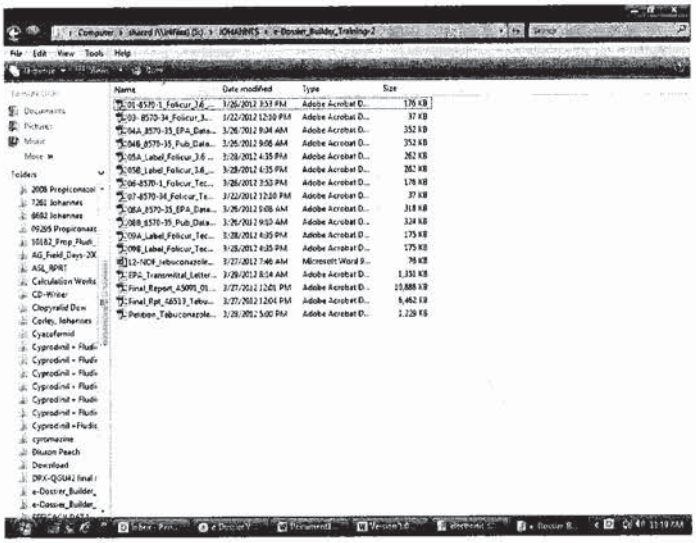
In the example that follows we had two labels and one petition

On the tolerance petition page you must answer a few more questions Mark the Initial submission as a yes. Petition type is E-Minor Use/Inert/Import. And note that Barbara Madden is our product risk manager and her number is five (5).

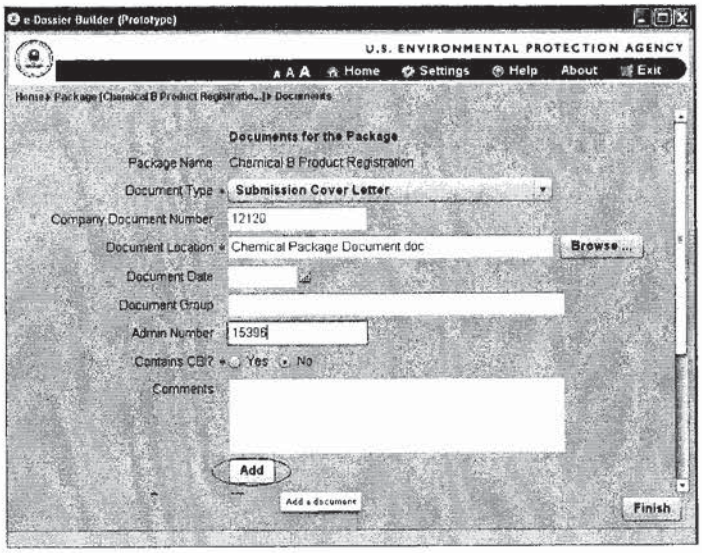


Next are the documents to be included –

In the training sessions we used an example from Johannes; included 2 section 3, and a tolerance petition.



The *Document for the Package* screen appears. Complete all **required fields** (*) and any of the other fields as necessary, and then select the **Add** button.



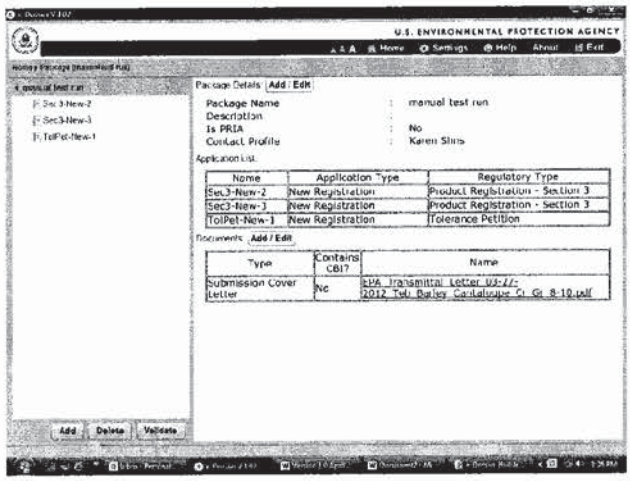
Add Package Document

The document information is provided in the *Documents* table as shown below.

Note: When adding multiple documents, the last document added will be placed at the bottom of the *Documents* table. Additionally, documents are not officially attached until the package is finalized.

Repeat if you would like to add additional documents to the package. Once you have added all of the documents, select the **Finish** button to continue.

The *Package [Title]* screen appears listing the package details, application information, and documents.

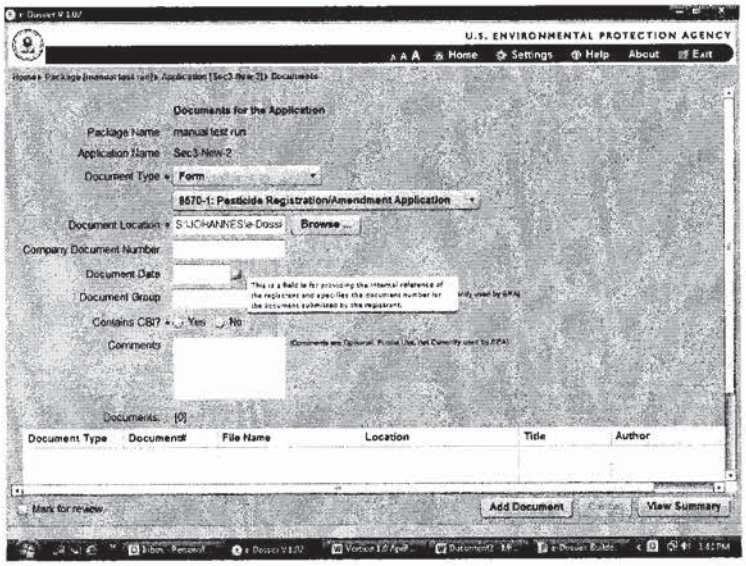


Package [Title] Screen

Quick cheat sheet of locations or which folder does this data go into

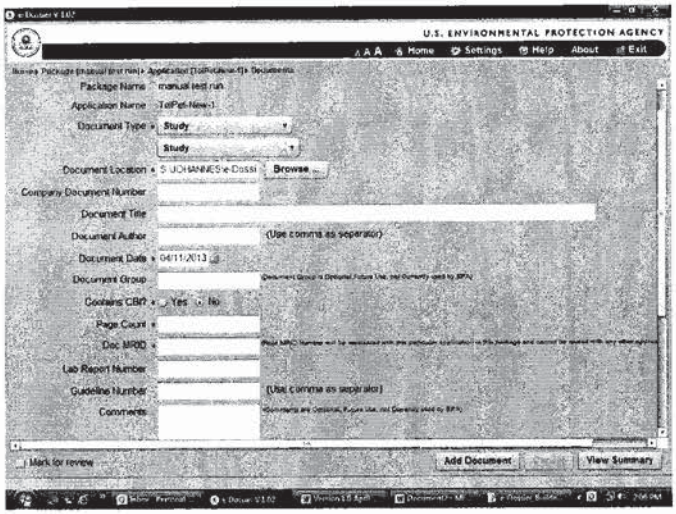
1. Main package name;
2. Sub-folders under package name
    a. Sec – 3; whatever name you give it lets say example "Sample 1"
    Contains forms, labels and data matrix that are associated with this example "Sample 1"
    b. Sec – 3; again whatever name you give it ; "Sample 2"
    Contains forms, labels and data matrix for this "Sample2"
    c. Tol Pet – 1
    Contains Transmittal, NOF, Petition and data volumes

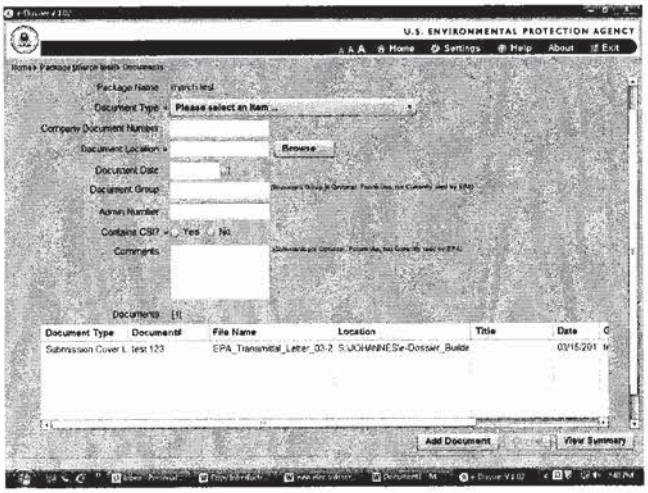
Highlight whichever folder you want to add additional documents to.
Best way is to run down appendix A adding 01, 02, 03 and so on, this will help you keep track of items added and also when you have to switch to the next folder (section 3 – 1 or section 3 -2)



When adding new documents to each folder you will be asked Contains CBI?
Usually it's a no unless you are adding the Data Matrix which is confidential

During this time if you need to view the listing of all folders you can hit View Summary in the bottom right hand corner and it will bring you back to your package listing.





After all forms and data are included Review your package.

Once complete you must Validate, button on summary page bottom left

Finalize your package:

Burn zip file to CDs –4 copies (1 CD EPA, 1 Registrant, 1 Archives and 1 SD.
Apply labels sample will be available on the shared drive
Ship to EPA
*Please note that if Karen isn't shipping out the CD/letters for you

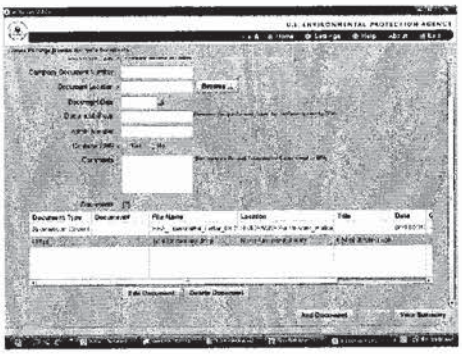
1. Copy of letter on clipboard for Diane/Ken
2. Copy of letter goes into binder on Karen's desk
3. Upload of letter and petition to RFC, some HQ staff
4. Copy of the UPS shipping slips to Karen for file attached to letter

Questions

Q -What happens if you have to stop in the middle, and how do you get back to something you were working on?
A-If not open, open e-dossier on the home page go to continue save package and pick the package you were working on via their title.

Q- If you get lost or confused?
A—Either click on the view summary tab bottom right of most pages or on the top tool bar click Home and continue on saved package.

Q- What if you have to replace an item prior to sending CD, like letter or label?
A—We'll use the example of changing the transmittal letter because the date isn't correct. Go to the summary page click the add/edit button by documents. The documents for package page will appear, highlight the letter that is to be replaced. Now underneath this listing is a choice to either edit or delete documents. If replacing name your new document exactly the same as the old one.



Most important thing to remember – before you finally complete your submission package it is wise to "mark for review" and go over the entire package/documents before you "validate" and burn CDs.

Appendix 1

Information that registrant's should provide for the section 3 registration packages submitted with an IR-4 petition
Formulation:

1. Form 8570-1 Application for Pesticide - for each end-use product
2. Form 8570-27 Formulator's Exemption Statement - for each end-use product
   (If this form is not applicable then please let me know why and I will add the following note to my letter)
   This form is not applicable to this submission since the sole active ingredient in the formulation Formulation® is A.I. (EPA Reg. No: XXX). The Confidential Statement of Formula, form 8570-4 was previously submitted to EPA and is currently on file. Please contact company contact at registrant if necessary.
3. Form 8570-34 Certification with Respect to Citation of Data - for each end-use product
4. Form 8570-35 Data Matrix – combined for end-use formulation and technical product (EPA only version, 4A & Public copy 4B)* (also see 13 below)
5. Five copies of draft labeling for each end-use product
   One copy of draft labeling (highlighted) for each end-use product

Technical Product:

6. Form 8570-1 Application for Pesticide - for technical product
7. Form 8570-34 Certification with Respect to Citation of Data - for technical product
8. Form 8570-35 Data Matrix – for technical product (EPA only version & Public copy) See 4 above
9. Five copies of draft labeling for technical product
   One copy of draft labeling (highlighted) for technical product

Petition:

10. Letter of Authorization
11. Current Label (end-use product) Not needed
12. Notice of Filing
13. *We also need the following information:

    "*Immunotoxicity (OPPTS Guideline 870.7800) and acute and subchronic neurotoxicity (OPPTS Guideline 870.6200) data MRID's (listed in the Data Matrix/8570-35) or an adequate justification statement (on company letterhead and signed by a responsible company representative) as to why those data are not needed.*"

    Please determine if data deficiencies exist that are likely to impact EPA's tolerance decision. If so, please resolve the deficiencies and let us know how we can help resolve these deficiencies.

    This is to satisfy EPA's latest requirements so that the package is deemed complete. Please see note below regarding the requirement:

    On December 26, 2007, changes to 40 CFR §158 made immunotoxicity (OPPTS Guideline 870.7800) and acute and sub-chronic neurotoxicity (OPPTS Guideline 870.6200) data required for pesticide registration. Please be aware that applications or requests submitted to the Agency now (i.e. after December 26, 2009), which lack either those data or an adequate justification as to why those data are not needed, may be considered to be incomplete and returned to the applicant. When submitting a petition for a chemical where these data are outstanding, the petition should include a schedule as to when these studies will be submitted as well as a discussion of the implications for the lack of these studies on the FQPA safety factor.

- ☐ Canadian Trials, Submit to Shirley
- ☐ CAL DPR Submission

IR-4 Fenamidone Submission 2013

Contents: MRID No.:
Sec. Pkg:
Petitions:
Final Reports:
Notice of Filing

Crops:
Chemical:

Magnitude of Residue

IR-4 Fenamidone Submission 2013

Contents: MRID No.:
Sec. Pkg:
Petitions:
Final Reports:
Notice of Filing

Crops:
Chemical:

Magnitude of Residue

Appendix C

Example of Cover Pages to be added to a Final Report
of a Study Not Sponsored by IR-4,
but will be Submitted to EPA by IR-4

TITLE PAGE

MAGNITUDE OF THE RESIDUE OF NOVALURON IN CUCUMBER RAW AGRICULTURAL COMMODITIES

Data Requirement

U.S. EPA OPPTS 860.1000 AND 860.1500

Study Director and Testing Facility

Tommy R Willard, PhD
American Agricultural Services, Inc.
404 E. Chatham Street
Cary, NC 27511

Sponsors

Makhteshim-Agan of North America
4515 Falls of Neuse Road
Raleigh, NC 27609

Chemtura Corporation
World Headquarters
Benson Road
Middlebury, CT 06479

Submitter

Kenneth S. Samoil
IR-4 Project
Rutgers, The State University of New Jersey
500 College Road East, Suite 201W
Princeton, NJ 08540

Report Date

August 3, 2007

AASI Study No. AA060702 Makhteshim-Agan Study No. R-20289

Facility Identification

Testing Facility: American Agricultural Services, Inc., 404 E. Chatham St., Cary, NC 27511
Analytical Facility: Pyxant Labs, Inc., 4720 Forge Road, Suite 108, Colorado Springs, CO 80907

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA Section §10 (d) (1) (A), (B), or (C).*

No claim confidentiality, on any basis whatsoever, is made for any information contained in this document. I acknowledge that information not designated as within the scope of FIFRA sec. 10 (d)(1)(A), (B), or (C) and which pertains to a registered or previously registered pesticide is not entitled to confidential treatment and may be released to the public, subject to the provisions regarding disclosure to multinational entities under FIFRA 10(g).*

Signature: _____ Date: _____

Kenneth S. Samoil
Technical Coordinator

* The above statement supersedes all other statements of confidentiality that may occur elsewhere in the report.

GLP COMPLIANCE STATEMENT

This study was not sponsored or conducted by the IR-4 Project. The IR-4 Project does not know whether the study meets current Good Laboratory Practice Requirements of 40 CFR Part 160.

Submitter (IR-4):

_____ DATE: _____

Kenneth S. Samoil
Technical Coordinator
IR-4 Project

TABLE OF CONTENTS

APPENDIX

MAGNITUDE OF THE RESIDUE OF NOVALURON IN CUCUMBER RAW AGRICULTURAL COMMODITIES

SOP #: 6.5

AUTHOR: K. S. Samoil

REVISION #: 04

EFFECTIVE DATE: January 31, 2010

TITLE: **Petition and Final Report Tracking**

PURPOSE: To monitor/track the progress of petitions and final reports sent to the registrant and EPA.

SCOPE: This SOP, which is not subject to GLP compliance, applies to all petitions and final reports being initially submitted to the registrant, QA, or EPA prepared by IR-4 Headquarters.

PROCEDURES: The **IR-4 Petition/Registration Package/Protocol log** (AKA the Monthly Activity Report) is maintained to track the food and feed use activities of IR-4 Headquarters during each month. For example, the activities may include: rules published in the Federal Register and favorable EPA opinion letters; proposed rules and Notices of Filing published in the Federal Register; the submission of petitions or final reports to the manufacturer/registrant, QA, or EPA; petitions withdrawn from EPA; Reduced Risk requests submitted to EPA; requests for the establishment of new or revised crop groups submitted to EPA; submissions to JMPR for the establishment of Codex MRL values; final reports that have been completed at IR-4 but have not yet been submitted; and other events that do not fit within the categories above. Entries to this log are made by the Technical Coordinator, Database Manager, or other designee of the Executive Director. Entries to this log generally include the following information for submissions: Pest Control Agent, Type (e.g. insecticide), Date, Commodity or Crop Group, PR#, and Numbers of Uses and Tolerances (for established tolerances and Notices of Filing). Additional comments, such as "replaces existing tolerance on peach", may be included. Examples of this log are attached as Appendix A (template log) and Appendix B (completed log).

Prepared by: _____ Date: 1/6/10

Approved by: _____ Date: 8 JAN 2010

APPENDIX A

IR-4 PETITION/REGISTRATION PACKAGE/PROTOCOL LOG

Template

IR-4 PETITION/REGISTRATION PACKAGE/PROTOCOL LOG
MONTHLY ACTIVITY REPORT (INCLUDES REREGISTRATION & FQPA ACTIONS)
FOOD AND FEED USES

DATE:

1) RULES PUBLISHED IN THE FEDERAL REGISTER

Permanent Tolerances

Pest Control Agent / Type*		Date	Commodity or Crop Group	PR#	No. of Uses	No. of Tolerances
				Totals		

*F=fungicide, H=herbicide, I=insecticide/acaricide, M=molluscide, P=plant growth regulator, R=rodenticide

Revised Tolerances

Pest Control Agent / Type*		Date	Commodity or Crop Group	PR#	No. of Uses	No. of Tolerances
				Totals		

*F=fungicide, H=herbicide, I=insecticide/acaricide, M=molluscide, P=plant growth regulator, R=rodenticide

Time-Limited Tolerances

Pest Control Agent / Type*		Date	Commodity or Crop Group	PR#	No. of Uses	No. of Tolerances	Expiration Date

*F=fungicide, H=herbicide, I=insecticide/acaricide, M=molluscide, P=plant growth regulator, R=rodenticide

New or Revised Crop Groups

Crop Group or Subgroup	Date	No. of Uses

Tolerances not previously reported

Pest Control Agent / Type*		Date	Commodity or Crop Group	PR#	No. of Uses	No. of Tolerances
				Totals		

*F=fungicide, H=herbicide, I=insecticide/acaricide, M=molluscide, P=plant growth regulator, R=rodenticide

2) NOTICES OF FILING (TOLERANCE PROPOSALS) PUBLISHED IN THE FEDERAL REGISTER

Pest Control Agent / Type*		Date	Commodity or Crop Group	PR#	No. of Uses	No. of Tolerances
				Totals		

*F=fungicide, H=herbicide, I=insecticide/acaricide, M=molluscide, P=plant growth regulator, R=rodenticide

3) SUBMISSIONS

Completed Petitions or Final Reports Submitted to EPA

Pest Control Agent / Type*		Commodity or Crop Group	PR#	Date

*F=fungicide, H=herbicide, I=insecticide/acaricide, M=molluscide, P=plant growth regulator, R=rodenticide

Completed Petitions or Final Reports WITHDRAWN from EPA

Pest Control Agent / Type*		Commodity or Crop Group	PR#	Date

*F=fungicide, H=herbicide, I=insecticide/acaricide, M=molluscide, P=plant growth regulator, R=rodenticide

Reduced Risk Requests for Petitions Submitted to EPA

Pest Control Agent / Type*		Commodity or Crop Group	PR#	Date

*F=fungicide, H=herbicide, I=insecticide/acaricide, M=molluscide, P=plant growth regulator, R=rodenticide

New or Revised Crop Groups

Crop Group or Subgroup	Date	No. of Uses

Commodities Requested in Submission to JMPR for Establishment of Codex MRL values

Pest Control Agent / Type*		Commodity	Date

*F=fungicide, H=herbicide, I=insecticide/acaricide, M=molluscide, P=plant growth regulator, R=rodenticide

Completed Final Reports Submitted to Registrant for Label Expansion or Conditional Registrations

Pest Control Agent / Type*		Commodity	PR#	Date

*F=fungicide, H=herbicide, I=insecticide/acaricide, M=molluscide, P=plant growth regulator, R=rodenticide

4) FINAL REPORTS THAT HAVE BEEN COMPLETED AT IR-4 BUT HAVE NOT BEEN SUBMITTED

Pest Control Agent / Type*		Commodity	PR#

*F=fungicide, H=herbicide, I=insecticide/acaricide, M=molluscide, P=plant growth regulator, R=rodenticide

5) DRAFT FINAL REPORTS AT IR-4 THAT HAVE BEEN SUBMITTED TO QA

Pest Control Agent / Type*		Commodity	PR#	Date of initial submission

*F=fungicide, H=herbicide, I=insecticide/acaricide, M=molluscide, P=plant growth regulator, R=rodenticide

APPENDIX B

IR-4 PETITION/REGISTRATION PACKAGE/PROTOCOL LOG

Completed Example

IR-4 PETITION/REGISTRATION PACKAGE/PROTOCOL LOG
MONTHLY ACTIVITY REPORT (INCLUDES REREGISTRATION & FQPA ACTIONS)
FOOD AND FEED USES

DATE: March 2009

1) RULES PUBLISHED IN THE FEDERAL REGISTER

Permanent Tolerances

Pest Control Agent / Type*		Date	Commodity or Crop Group	PR#	No. of Uses	No. of Tolerances
Dimethomorph	F	Mar 04 2009	Ginseng	08958	1	1
			Turnip, greens	07599	3	1
			Bean, lima (regional registration)	07261	1	1
			Bean, succulent (regional registration)	---	14	1
			Grape (regional registration)	06794	1	2
			Potato	---	1	2
Famoxadone	F	Mar 04 2009	Caneberry subgroup 13-07A (replaces tolerance on subgroup 13A)	08766	1	1
			Vegetable, leafy, except brassica, group 4, except spinach (replaces tolerance on head lettuce)	08499 08758	27	1
			Cilantro	---	1	1
			Spinach	08308	1	1
			Onion, bulb, subgroup 3-07A Onion, green, subgroup 3-07B	08303	26	2
Chlorimuron-ethyl	H	Mar 11 2009	Berry, low growing, except strawberry, subgroup 13-07H	03023	8	1
Fenpropathrin	I	Mar 25 2009	Caneberry subgroup 13-07A	08735	5	1
			Fruit, stone, group 12, except cherry	08962 08963	10	1
			Cherry	08016	1	2
			Nut, tree, group 14 Pistachio	08961	13	3
			Olive	09374	1	1
			Avocado Black sapote Canistel Mamey sapote Mango Papaya Sapodilla Star apple	07861 07858 07862 07863 07859 07856 07860 07857	8	8
Propiconazole	F	Mar 25 2009	Beet, garden	06352	2	2
			Cilantro	06371	1	1
			Parsley	06351	1	1
			Pineapple	06585	1	1
				Totals	128	36

*F=fungicide, H=herbicide, I=insecticide/acaricide, M=molluscide, P=plant growth regulator, R=rodenticide

Revised Tolerances

Pest Control Agent / Type*		Date	Commodity or Crop Group	PR#	No. of Uses	No. of Tolerances
Tebuconazole	F	Mar 04 2009	Cherry (pre- and post-harvest)	06554	1	2
				Totals	1	2

*F=fungicide, H=herbicide, I=insecticide/acaricide, M=molluscide, P=plant growth regulator, R=rodenticide

Time-Limited Tolerances

Pest Control Agent / Type*		Date	Commodity or Crop Group	PR#	No. of Uses	No. of Tolerances	Expiration Date
Pendimethalin	H	Mar 18 2009	Grasses	08310	3	2	Dec 31 2009
Pyraclostrobin	F	Mar 18 2009	Sugarcane	09901	1	2	Dec 31 2011
Dinotefuran	I	Mar 25 2009	Rice	10137	1	1	Dec 31 2009

*F=fungicide, H=herbicide, I=insecticide/acaricide, M=molluscide, P=plant growth regulator, R=rodenticide

2) NOTICES OF FILING PUBLISHED IN THE FEDERAL REGISTER FOR REQUESTS OF EXEMPTION FROM THE REQUIREMENT OF A TOLERANCE

Pest Control Agent / Type*		Date	Commodity or Crop Group	PR#	No. of Uses
Acetic acid	H	Mar 04 2009	All food commodities	---	Many
Aspergillus flavus AF36	F	Mar 16 2009	Pistachio	0327B	1

*F=fungicide, H=herbicide, I=insecticide/acaricide, M=molluscide, P=plant growth regulator, R=rodenticide

3) SUBMISSIONS

Completed Petitions or Final Reports Submitted to EPA

Pest Control Agent / Type*		Commodity or Crop Group	PR#	Date
Acetamiprid	I	Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F	09057	Mar 12 2009
		Clover (grown for seed)	09600	
		Tomato (greenhouse)	08354	
Novaluron	I	Vegetable, fruiting, group 8 Okra Cocona African eggplant Pea eggplant Scarlet eggplant Goji berry Garden huckleberry Martynia Naranjilla Roselle Sunberry Bush tomato Currant tomato Tree tomato	08985 08634	Mar 17 2009
		Vegetable, cucurbit, group 9	08988 08989 08990	
		Berry, low growing, subgroup 13-07G	09782 10050	
		Bean, snap	08128	
		Bean, dry	09781	
		Swiss chard	09745	
Diazinon	I	Mushroom	10262	Mar 20 2009
Clavibacter michiganensis subspecies *michiganensis*	F	Tomato	0430B	Mar 27 2009

*F=fungicide, H=herbicide, I=insecticide/acaricide, M=molluscide, P=plant growth regulator, R=rodenticide

Completed Petitions or Final Reports WITHDRAWN from EPA

Pest Control Agent / Type*		Commodity or Crop Group	PR#	Date
Cyprodinil	F	Leaf petioles subgroup 4B	09214	Mar 04 2009

*F=fungicide, H=herbicide, I=insecticide/acaricide, M=molluscide, P=plant growth regulator, R=rodenticide

Reduced Risk Requests for Petitions Submitted to EPA

Pest Control Agent / Type*		Commodity or Crop Group	PR#	Date
Acetamiprid	I	Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F	09057	Mar 12 2009
		Berry, low growing, subgroup 13-07G	09058	
		Clover (grown for seed)	09600	
		Tomato (greenhouse)	08354	
Novaluron	I	Vegetable, fruiting, group 8 Okra Cocona African eggplant Pea eggplant Scarlet eggplant Goji berry Garden huckleberry Martynia Naranjilla Roselle Sunberry Bush tomato Currant tomato Tree tomato	08985 08634	Mar 17 2009
		Vegetable, cucurbit, group 9	08988 08989 08990	
		Berry, low growing, subgroup 13-07G	09782 10050	
		Bean, snap	08128	
		Bean, dry	09781	
		Swiss chard	09745	
*F=fungicide, H=herbicide, I=insecticide/acaricide, M=molluscide, P=plant growth regulator, R=rodenticide				

Completed Final Reports Submitted to Registrant for Label Expansion or Conditional Registrations

Pest Control Agent / Type*		Commodity	PR#	Date
Carfentrazone	H	Onion, dry bulb	09034	Mar 16 2009
*F=fungicide, H=herbicide, I=insecticide/acaricide, M=molluscide, P=plant growth regulator, R=rodenticide				

4) FINAL REPORTS THAT HAVE BEEN COMPLETED AT IR-4 BUT HAVE NOT BEEN SUBMITTED

Pest Control Agent / Type*		Commodity	PR#
Bifenthrin	I	Grasses	09476
Glyphosate	H	Strawberry	01409
Sulfentrazone	H	Blueberry	09260
*F=fungicide, H=herbicide, I=insecticide/acaricide, M=molluscide, P=plant growth regulator, R=rodenticide			

5) DRAFT FINAL REPORTS AT IR-4 THAT HAVE BEEN SUBMITTED TO QA

Pest Control Agent / Type*		Commodity	PR#	Date of initial submission
Quinoxyfen	F	Hop	10084	Mar 05 2009
S-metolachlor	H	Spinach	09577	Mar 09 2009
Spirodiclofen	I	Lychee	09327	Mar 12 2009
Cyazofamid	F	Spinach	09265	Mar 16 2009
Cyazofamid	F	Cabbage	09082	Mar 20 2009
S-metolachlor	H	Tomato	09668	Mar 25 2009
*F=fungicide, H=herbicide, I=insecticide/acaricide, M=molluscide, P=plant growth regulator, R=rodenticide				

SOP #: 6.6

AUTHORS: K. S. Samoil and J. S. Corley

REVISION #: 03

EFFECTIVE DATE: January 31, 2010

TITLE: **Amending Pesticide Petitions and Data Volumes.**

PURPOSE: To provide a uniform procedure for amending pesticide petitions.

SCOPE: This SOP applies to all pesticide tolerance petitions and final reports that need to be amended by IR-4 Headquarters after submission to the EPA or after the final reports have been signed.

PROCEDURES: In some instances, after EPA reviews an IR-4 tolerance petition, they may request revision of certain sections or require additional data or information. Final reports must be amended after they have been signed but before they have been submitted, in order to make modifications other than those to meet submission requirements or because of a change in submission requirements that has occurred. Final reports may be revised to meet a submission requirement. The procedures for making these changes are listed below.

1) Amending the Administrative Volume:

- In the case of a Section B or F revision, where no data or supporting information are needed, the revision may be made and submitted directly to the EPA. The date of the amendment and Pesticide Petition No. should appear on the revised Sections B & F (e.g. Amended 05/15/95, Pesticide Petition No. XX@@XX).
- The procedure for more detailed petition amendments is similar to the procedure for pesticide petition development (see current version of IR-4 HQ SOP # 6.1), except, the information is included as references, and no section dividers are used. References should include, but not be limited to:
  - ➢ a copy of the EPA response letter
  - ➢ supporting information and/or a summary of attached data.
- The actual data should be submitted as an additional volume(s), similar to petition data volumes (see current version of the IR-4 HQ SOP # 6.0).
- The new data are subject to an internal review (see current version of the IR-4 HQ SOP # 6.2), and, if necessary a QA review[1].

[1] If any changes have been made to the data in the Data Volume

- It may also be submitted to the registrant for review if necessary[2].
- After approval by the registrant, the amended petition is archived and submitted to the EPA following the current version of IR-4 HQ SOP # 6.4. An electronic copy is placed in the appropriate folder in the IR-4 Shared Directory.

2) Amending the Data Volume (Final Report):

- Make all the necessary changes (corrections, additions, etc.) to the data volume clearly identifying the changes. (See example in Appendix A. In the example, all changes are marked in ***bold and italics*** and this is footnoted as such at the bottom of the page.)
- Mark clearly on the Title Page (under Study Title) that this is an Amended Report and state the MRID No. and/or Pesticide Petition No. of the report which is being amended, if the report has been submitted to EPA and such numbers have been assigned.
- Identify all the authors involved, including the original author and the amending author.
- Under Study Completion date, identify the original study completion date and the completion date for the amended petition. See attached example of Title Page for guidance (Appendix A, pg. 1).
- If additions are needed in the GLP Compliance Statement, identify these additions clearly. See attached example (Appendix A, pg. 2) for guidance.
- If a QA audit was performed on the amended report[3], a new Quality Assurance Statement must be generated and included in the amended petition.
- On a separate page, list the location of all the changes incorporated into the amended report and the reasons for the changes. See example (Appendix A, pg. 4) for guidance.
- On the Table of Contents, clearly identify pages containing changes. This may be done by using a different font for those titles (amended pages) or by marking with an asterisk or some other sign. See attached example (Appendix A, pg. 5) for guidance.
- The amended final report must be signed and dated by the Submitter, Study Director and IR-4 Testing Facility Management. If necessary, the IR-4 Quality Assurance Unit must generate and sign the new QA Statement[3].

---

[2] If any changes have been made to Sections B (use pattern) or F (proposed tolerance)

[3] A Quality Assurance Audit will be needed if any changes are made to the data volume of the petition.

- The cover letter addressed to the appropriate person (to whom the submission is being made) must include the reason(s) for the re-submission. See attached example of cover letter (Appendix B).

3) Submitting New (Additional) Data:

- If additional data are needed or requested by the EPA in reference to a petition submitted to the EPA, then the report containing this information must be submitted as new data volume(s).
- Follow the current version of SOP # 6.0 for developing the data volume(s).
- The new data volume(s) should be numbered sequentially in the cover letter starting with Volume 1.
- If the administrative volume needs to be modified, the amended sections should be submitted in accordance with the instructions in Section 1 of this SOP.
- In the cover letter, list the MRID No. and Pesticide Petition No. of the petition being amended, explain the reason for the new submission by referencing the EPA response letter and list the additions / amended sections to the petition.

Prepared By: _____ Date: 1/6/10

Approved By _____ Date: 8 JAN 2010

*Title Page**

ACETAMIPRID: MAGNITUDE OF THE RESIDUE ON TOMATO (GREENHOUSE)

AMENDED REPORT*

Data Requirement

U.S. EPA OPPTS 860 Series Guidelines

Author

Kenneth S. Samoil
IR-4 Project
Rutgers, The State University of New Jersey
500 College Road East, Suite 201W
Princeton, NJ 08540

Study Completed on

August 9, 2004

Amended: See page 7 for Study Director's signature

IR-4 PR No. 08354

Performing Laboratories

See page 6 for list of performing laboratories

Analytical Laboratory Identification Number

08354.02-NYR19

Field Identification Numbers

08354.02-TN15, 08354.02-TX26, 08354.02-ON06

All changes from the original final report are marked in Bold and Italics.

Statement of No Data Confidentiality Claims

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA Section §10 (d) (1) (A), (B), or (C).*

Interregional Research Project Number 4

Kenneth S. Samoil
Technical Coordinator

Date: _____

Signature: _____

* The above statement supersedes all other statements of confidentiality that may occur elsewhere in the report.

GLP Compliance Statement

This study as indicated by responsible individuals, meets current Good Laboratory Practice Requirements of 40 CFR Part 160, except as noted below. The Canadian trial was conducted in accordance with the OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring. These deviations do not affect the conclusions presented in this report.

GLP deviation declarations:

1. Supporting data such as soil characteristics, weather, irrigation, cultural practices, site history records, and maintenance chemical applications were not collected in full compliance with 40 CFR 160.
2. At the TX trial, the scale used to weigh the samples after harvest was not calibrated in full compliance with GLP.
3. The test and reference substances were characterized by Bayer CropScience. All of the characterization information has been transferred to Nisso Chemical in Japan. The retention sample has been transferred to LABServices in Pennsylvania.
4. Maintenance of and controlled access to storage freezers and coolers at Cornell University do not meet GLP requirements. Due to Cornell University policy, freezers for storage of GLP samples at the analytical laboratory are shared with other members of the department and are not locked. The walk-in freezers and coolers are cared for by the University Maintenance Department; no training records are retained on the employees of this department.
5. In the TN trial, no calibration of the syringe used for applications is recorded, as per 40 CFR 160.63.
6. In the ON trial, the balance calibrations did not bracket the amount of test substance weighed for the first two applications.

Submitter
and Study Director (IR-4): _____ DATE: _____

Kenneth S. Samoil
Technical Coordinator
IR-4 Project

Sponsor (IR-4): _____ DATE: _____

Dr. Jerry Baron
Executive Director
IR-4 Project

Quality Assurance Statement

LIST OF CHANGES INCORPORATED INTO THE AMENDED REPORT

The following pages were changed in the final report titled "Acetamiprid: Magnitude of the Residue on Tomato (Greenhouse)":

Original report page #	Amended report page #	Change
1	1	Deletion of "Volume 1 of 1". Addition of indication that this is an amended report. Corrected address for IR-4 Headquarters. Completion date entered for the original report. Deletion of New Jersey Agricultural Experiment Station Publication Number.
2	2	New page with fresh signature.
3	3	New page with fresh signatures. Jerry Baron replaces Robert Holm as Executive Director.
4	4	New QA Statement with additional QA audit date added (11/3/08) and fresh signature of QA reviewer. Date Reported to Study Director/Testing Facility Management changed to reflect new routing procedure. Dates for one audit that had been misfiled were corrected because of the discovery of the original audit with original dates.
---	5	Addition of this list of changes incorporated into the amended report.
5	6	Corrected address for IR-4 Headquarters.
6	7	New page with fresh signatures. Jerry Baron replaces Robert Holm as Executive Director.
7	8	Corrected address for IR-4 Headquarters.
8	9	Updated Table of Contents.
138-211	---	Deletion of Appendix 4: Reference Analytical Method
212	139	Revision of Appendix Number for Protocol and Amendments/Deviations (formerly Appendix 5)
---	155	Addition of Protocol Change #9.

All of the changed pages are marked by an asterisk (*) in the Table of Contents.

The pages in the amended report are designated at the bottom or the right side of the page as "Amended IR-4 Acetamiprid/Tomato(GH)/08354 Final Report".

Study Identification/Performing Laboratories

Study Title:	Acetamiprid: Magnitude of the Residue on Tomato (greenhouse)
Study Number:	08354
Test Substance:	Assail 70 WP
Sponsor Testing Facility:	IR-4 Project Rutgers, The State University of New Jersey ***500 College Road East, Suite 201W*** ***Princeton, NJ 08540***

Laboratory Research Director/Analytical Testing Facility (Laboratory)/Other Personnel:

Pim Larsson-Kovach / Cornell Analytical Laboratories, New York State Agricultural Experiment Station, Department of Food Science and Technology, Cornell University, Geneva, NY 14456-0462 / Jane DeCann, Mary Beth Sterling, Mary Townley

Field Research Directors/ Testing Facilities:

TN15 Bill Shamiyeh
Entomology & Plant Pathology
University of Tennessee
205 Plant Science Bldg.
Knoxville, TN 37901

TX26 Lori Gregg
Texas A&M Agricultural Experiment Station
2415 East Highway 83
Weslaco, TX 78596

ON06 Greg O'Neill
G. O. Research, Inc.
64 Westbury Cres.
Cambridge, ON N3C 3G2
Canada

See Field Data Summaries in Appendix 1 for other field personnel involved in the study.

Study Timetable

Study Initiation Date:	May 13, 2002
Experimental Start Date:	October 14, 2002
Experimental Termination Date:	May 9, 2003
Study Completion Date:	See Study Director's dated signature on this page.

Signatures and Approval

Prepared and Approved by:

Kenneth S. Samoil Study Director	Date

Approved by:

Jerry Baron, Ph.D. Testing Facility Management	Date

Location of Raw Data

The final report, protocol, protocol amendments and deviations, the majority of the field and laboratory (originals or true copies when originals are at facility) raw data are maintained at:

IR-4 Project Headquarters
Rutgers, The State University of New Jersey
500 College Road East, Suite 201W
Princeton, NJ 08540

Some facility related Analytical Raw Data are maintained at:

Cornell Analytical Laboratories, New York State Agricultural Experiment Station, Department of Food Science and Technology, Cornell University, Geneva, NY 14456-0462

A small amount of facility-associated raw data is maintained at the following sites:

Entomology & Plant Pathology
University of Tennessee
205 Plant Science Bldg.
Knoxville, TN 37901

G. O. Research, Inc.
64 Westbury Cres.
Cambridge, ON N3C 3G2
Canada

Texas A&M Agricultural Experiment Station
2415 East Highway 83
Weslaco, TX 78596

ACDS Research Inc., 1649 Lester Rd., Phelps, NY 14532

The test/reference substance was characterized by Bayer CropScience. All of the characterization data were transferred to Nisso Chemical in 2003:

Nisso Chemical Analysis Service Co., Ltd.
345 Takada Odawara City
Kanagawa 250-216, Japan

The retention sample was transferred to LABServices in 2004:

LABServices
342 South Third Street
Hamburg, PA 19526

table of contents

PAGE

*An asterisk indicates that the content of the marked page or section is changed from the original report.

March 31, 1999

REREGISTRATION

Ms. Kathleen Meier
Chemical Review Manager
OPP/SRRD (7508C)
U.S. Environmental Protection Agency
Office of Pesticide Programs
401 M Street, SW
Washington, DC 20460

Dear Ms Meier:

Re: Diuron/Caneberry, Reregistration MRID No. 44447601, Amended Petition.

The undersigned, Johannes Corley, Ph.D., Associate Coordinator, Interregional Research Project No. 4 (IR-4), Rutgers, The State University of New Jersey, 681 US Highway # 1 South, North Brunswick, NJ 08902, on behalf of the IR-4 Project, re-submits this petition pursuant to Section 408(e) of the Federal Food, Drug and Cosmetic Act, as amended, with respect to the pesticide chemical, Diuron (3-(3,4-dichlorophenyl)-1,1-dimethylurea) (40 CFR 180.106).

List of Studies Submitted in Support of Reregistration for Diuron

Volume No. and Title:

Volume 1 - Diuron: Magnitude of the Residue in/on Caneberry (Reregistration), (Amendment, MRID No. 44447601).

Continued.....

Ms. Kathleen Meier (Con't.) March 31, 1999

Reason for Re-Submission:

This petition is being re-submitted incorporating the changes based on the Inspection Observations by Mr. Elmer Griffin, EPA Compliance Officer in his letter dated April 30, 1998 (Investigation Id. No. 983979941). These changes are listed on pages 6 and 378-379 of the amended petition. A few additional changes resulting from calculation and rounding errors has also been made to the petition. These changes are also listed on pages 6 and 378-379 of the amended petition.

Yours very truly,

Interregional Research Project No. 4
Petitioner

Per
IR-4 Associate Coordinator
Center For Minor Crop Pest Management
Technology Centre of New Jersey
Rutgers, The State University of New Jersey
681 U.S. Highway # 1 South
North Brunswick, NJ 08902-3390

Attachment – Amended Petition (4 copies)

copies: Robert Park, E.I. DuPont de Nemours & Co. (Petition)

SOP #: 6.7

AUTHORS: K. S. Samoil and J. J. Baron

REVISION: 03

EFFECTIVE DATE: January 31, 2010

TITLE: **Communication and Tracking of EPA Responses Regarding IR-4 Project Tolerance Petitions.**

PURPOSE: To inform the registrant(s) of a subject pest control product of action taken by the EPA regarding IR-4 Project tolerance petitions, and to provide the EPA with a projected time schedule for submission of requested data.

SCOPE: This SOP, which is not subject to GLP compliance, applies to all pest control product tolerance petitions and amendments submitted by the IR-4 Project for which a response from the EPA is received.

PROCEDURES:

1) A response from the EPA will be directed by the recipient to the Database Manager for archiving and updating the database. An electronic copy will be placed in the appropriate folder in the IR-4 Shared Directory. The recipient may confer with the Registrations Manager to determine if a response to EPA is needed.

2) If appropriate, EPA responses will be sent to the registrant(s) of the pest control product covered in the subject petition.

3) If the EPA response is a request for additional information or research, the IR-4 Project will cooperate in responding to the EPA as appropriate.

4) If warranted, the IR-4 Project will respond to the EPA prior to any deadline indicated in the EPA letter. The response will be coordinated with the registrant(s) if necessary. A copy of written correspondence will be provided to IR-4 Project Management and the Database Manager for inclusion in the appropriate IR-4 Project database.

5) When a final rule is published in the Federal Register, this will be recorded in the IR-4 Monthly Activity Report (see Appendices in SOP 6.5).

Prepared by: _____ Date: 1/6/10

Approved by: _____ Date: 8 JAN 2010

SOP #: 7.1

AUTHORS: K. S. Samoil and D. L. Kunkel

REVISION #: 11

EFFECTIVE DATE: April 8, 2015

TITLE: **Access and Archiving: Active Study Files, Archived Study Files, Facility Files, Certificate of Analysis Files, Confidential Files, and Characterization Reports of Test and Reference Substances.**

PURPOSE: To explain the procedure for access to the unique file for each Pesticide Use/Crop/Pest combination and to the confidential file cabinets, as well as the procedure for archiving studies when appropriate. To provide a method for the orderly storage and expedient retrieval of all raw data, documentation, and final reports for studies located in the IR-4 Headquarters (HQ) Active and Archive files.

SCOPE: This SOP applies to all IR-4 Personnel.

PROCEDURES:

1) The study file areas are located in three locations in the space that is occupied by IR-4 HQ at 500 College Road East, Suite 201 W, Princeton, NJ 08540 (See Appendix A).

2) All Project Clearance Request (PCR) forms, protocols, protocol changes, raw field and analytical data, analytical summary reports, correspondence (mail, faxes, email, and telephone log pages) and associated documentation are to be filed in the assigned study files.

   For all studies initiated prior to January 1, 2009, filing for each assigned study file (PR#) subject to GLP Standards is as follows:

   Manila folder:
   *Non-GLP documentation, including:
   *PCR forms
   *Documentation of registrant's approval to proceed with the study
   *Other correspondence that precedes the date of signing of the protocol, and all non-study-related correspondence

Blue folder:
*Original protocol
*Original protocol changes (true copies of protocol changes may be used when a change affects more than one study)
[When a change form is approved by the Study Director a notation on the inner folder cover of the blue folder will note (at a minimum) the change form number and date.]

Red folder:
*IR-4 Research Director Agreement Letters
(Estimated study dates/GLP acknowledgement)
*Field Data Book completion cards
*Quality Control reports of Field Data Books
(These may also be retained in the Field Data Books)
*Residue Sample Chain-of-Custody forms
*Sample Arrival Check Sheets
[The documents listed above should be brought to the Database Manager when they are first received at IR-4 Headquarters prior to filing.]
*GLP-study related documentation including:
*Emails and faxes
*Telephone log entries
*SOP deviation forms
*Certificate(s) of Analysis for the test and reference substances
*Application rate calculation sheets
*Miscellaneous raw data
[Materials that are too large to fit in the red folder will immediately follow the red folder. Two or more red folders may be used to hold the appropriate materials if one folder cannot hold all of the documents.]

For all studies initiated on or after January 1, 2009, the preferred filing system for each assigned study file (PR#) subject to GLP Standards is as follows:

Manila folder:
*Non-GLP documentation, including:
*PCR forms
*Documentation of registrant's approval to proceed with the study
*Other correspondence that precedes the date of signing of the protocol, and all non-study-related correspondence

Blue folder:
*Original protocol
*Original protocol changes (true copies of protocol changes may be used when a change affects more than one study)
[When a change form is approved by the Study Director a notation on the inner folder cover of the blue folder will note (at a minimum) the change form number and date.]

Red folder:
*Any miscellaneous correspondences relating to the study (i.e MFG etc) not included below.
[These documents noted below in this section should be brought to the Database Manager when they are first received at IR-4 Headquarters prior to filing.]
*IR-4 Research Director Agreement Letters
(Estimated study dates/GLP acknowledgement)
*Field Data Book completion cards
*Quality Control reports of Field Data Books
(These may also be retained in the Field Data Books)
*Residue Sample Chain-of-Custody forms
*Sample Arrival Check Sheets

Purple folder:
*GLP-study related documentation related to field trials and processing trials including:
*Emails and faxes (except for those belonging in the red folder)
*Telephone log entries
*SOP deviation forms
*Certificate(s) of Analysis for the test substance(s)
*Application rate calculation sheets
*Miscellaneous raw data not included in the red folder contents

Gray folder:
*GLP-study related documentation related to the analytical laboratory including:
*Emails and faxes (except for those belonging in the red folder)
*Telephone log entries
*SOP deviation forms
*Certificate(s) of Analysis for the reference substance(s)
*Miscellaneous raw data not included in the red folder contents

Materials that are too large to fit in the red, purple, or gray folder will immediately follow the gray folder. Two or more of any color folder may be used to hold the appropriate materials if one

folder cannot hold all of the documents. The Study Director shall determine whether GLP-study related documentation will be filed in the purple or gray folder.

For active studies initiated prior to January 1, 2009, the Study Director or a colleague designated to provide assistance may re-file the contents of the red folder into red, purple, and gray folders at his or her own discretion.

3) Active & Inactive Study Files are located in Room 234.
   a) When data or folders are removed from the active file room, an OUT card labeled with the name of the person removing the materials must be placed in the study file. GLP data should be maintained under fire suppression as much as possible. GLP data can be stored overnight in bins in the active file room without the need to re-file.
   b) When returning data or folders, either re-file it or place the material on the designated table in Room 234 to be re-filed by personnel designated by management. The designated table in Room 234 contains bins indicating where material should be returned (Manila, Blue, Red, Purple, or Gray). If the entire study is being returned, leave it on the table for re-filing. For active studies initiated prior to January 1, 2009, in which the data have not been re-arranged into the red/purple/gray folder system, materials left in the bin for purple or gray folders will be re-filed in the red folder.
   c) The OUT card will be removed by the returnee when the material is returned.

3) Transfer of Files to Archives - Archived Study Files are located in Room 235 (see Appendix B). Just prior to study completion (study completion is defined as when the Study Director signs the final report), the entire study file except for the final report shall be transferred to the Archives. The Study Director must fill out an Archive Inventory Sheet (See Appendix C). This transfer shall be documented in the Archive Log (Appendix D).

a) the process starts by placing the materials along with the AIS in the archive bin located in the active file room.

b) The designated Archives staff is identified in Appendix E.

c) Rack 1 to 128 on the floor design contains Non-GLP and GLP Studies (see Appendix B).

5) Facility Files will be kept in Room 235, along the wall (locations A-J) and in the Active File Room (in designated filing cabinets along wall which is shared with the archive). If the facility files are stored in the active file room they are to be locked at all times and treated as they would if they were part of the main archive. Requests for these files will be made in the same manner noted in SOP 7.4, Section 2 on page 2 of 2. A copy of many of the facility files/SOPs are maintained on the shared (s: facility files/electronic facility files) directory. Identity of the files and their file number is maintained on a database supported by the Facility/SOP archivist.

6) Confidential and/or proprietary information will be kept in a confidential file cabinet(s) in Room 234. The keys for these file cabinets can be obtained from the Archivist. The Biopesticide Manager shall also retain keys to the cabinets. A log book is maintained for the file cabinets. The person removing information must enter in the log book the materials removed, date removed (and subsequently, date returned), and his/her initials.

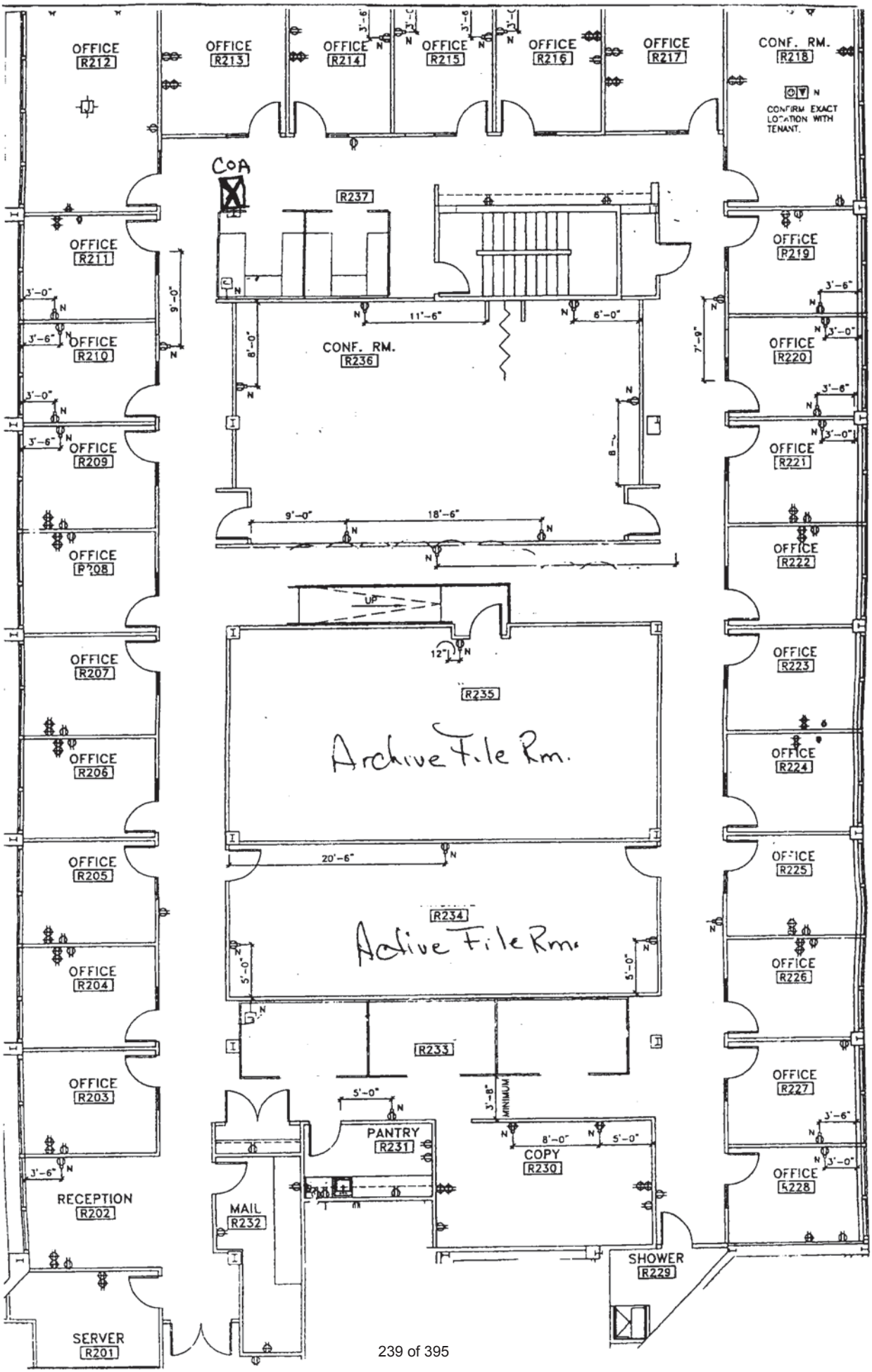
7) Upon receipt of a test and/or reference substance characterization report or Certificate of Analysis (COA), the report or COA will be filed in the secured characterization files located across from Room 213 in the hallway. Access is available by request to the Archivist.

8) Prior to the close of a study, a copy of all test and reference substance characterization reports or COA pertaining to that project will be archived with the final report. If a test/reference substance characterization report has not been received at IR-4 Headquarters, then the location of the characterization report(s) will be provided in the study file.

Prepared by: _____ Date: 20 March 2015

Approved by: _____ Date: 20 March 2015

APPENDIX A to SOP # 7.1

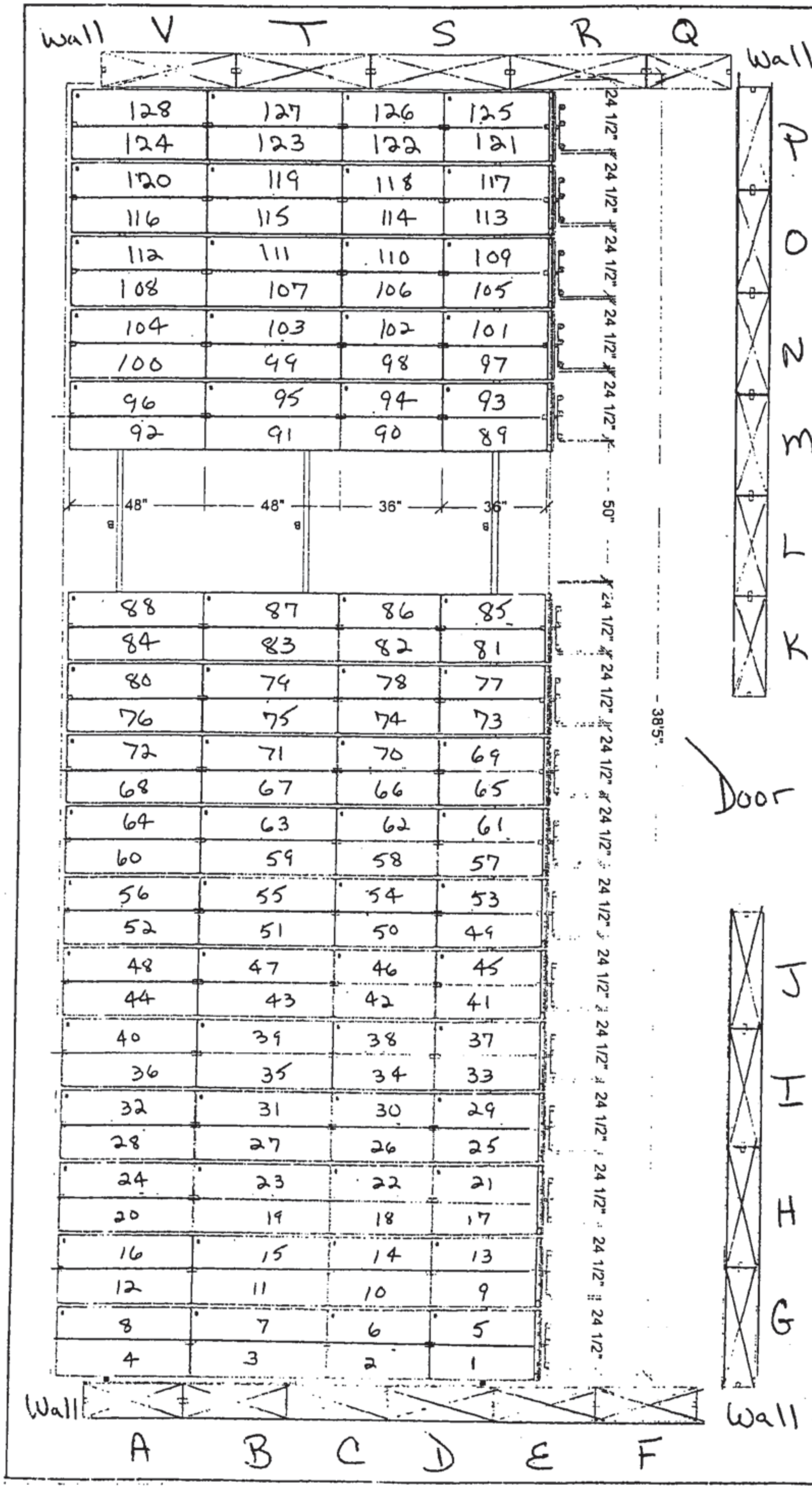


Appendix B to SOP# 7.1 (Room 235)

Racks 1 to 128
(each rack has 7 rows)
Study Files

Wall Section A to J
Facility Files

Wall Section K to V
QA Files



APPENDIX C to SOP#7.1:11

Archive Inventory Sheet

List the PR# used for Archive filing as the **first PR number**
(Also list all PR #'s if more than one):

PR#:_____

All items are to be listed, or documentation stapled to this form

Check off **only the materials presented for archiving:**

_____ **Manila Folder**

_____ **Blue Folder**

_____ **Purple Folder**

_____ **Gray Folder**

_____ **Red Folder**

_____ **Field Data Books** as listed:

_____ **ASR** from laboratory

_____ **Laboratory Raw Data** as listed (include # of folders, notebook names, etc.):

_____ Other Materials:

_____ **Final Report**

Submitter: Init/Date: _____ **Study Director:** Init/Date: _____
(Initial and date only if different than the submitter)

Archivist Use Only:

Archivist: Init/Date:_____ **File Location**: *(Rack-Row)* _____

CC: IR-4 Headquarters QA (completed form with initials/dates)

11/1/08
Form SOP 7.1.A
(s:\shared\ir4forms\sop 7.1.A)

ARCHIVED RECORDS – CHECK IN/CHECK OUT

PR#	Brief Description or Using Code (NE=New Entry - F=Final Report R=Return)	Entry Archivist Initial-Date	Transfer To Name-Date	Returned To Archivist Initial - Date	File Location Rack/Row (or Box/Year)

Appendix E to SOP# 7.1:11

Designated Archives Staff for GLP Studies& All Pre-GLP Studies.

In order to facilitate the handling of the Archives, the Designated Archives Staff responsibility will be delegated as follows:

Archivist	Susan Bierbrunner
Backup Archivist	Karen Sims
Backup Archivist	Van Starner
Backup Archivist	Debbie Carpenter
Backup Archivist	Daniel Kunkel
Backup Archivist	Jerry Baron

Designated Archivist for QA & Facility Files Only:

Archivist	Juliet Thompson

SOP #: 7.4

AUTHORS: D. K. Infante and D. L. Kunkel

REVISION #: 03

EFFECTIVE DATE: September 7, 2007

TITLE: **Archive Procedures: Study File Location, Study File Retrieval, Study File Re-entry, Archive Log Book, Archival Entry Without Study File Retrieval**

PURPOSE: To outline the procedure to: 1) post a study file into the Archive Log Book, 2) locate where the study file is placed in the archives, 3) retrieve and return the file after archiving and entry into the Archive Log Book, and 4) access the archives without removal of the study file.

SCOPE: This SOP applies to all IR-4 Personnel.

PROCEDURES:

1) The IR-4 Headquarters Archives are organized according to date prior to January 1, 2003, see current version of SOP# 7.1 for study file archives room assignment. The room key is the responsibility of the Archivist, and other designated staff members as shown in Appendix E to SOP# 7.1. At the end of the business day, the key must be secured in its location. The key location may be locked at the discretion of the Archive Staff, if this becomes necessary, as a control mechanism.

2) New entries for the Archive Room are posted in the Archive Log Book and filed accordingly.

   a) Prior to archiving a study file, the Archive Log Book is documented to show the new entry (NE) and the Archivist will indicate the PR#, initial, date and enter NE. The Inventory Sheet must be completed by the Study Director, which is checked by the Archivist and will be initialed and dated prior to archiving the materials (see Appendix D to current version of SOP# 7.1).

   b) When there are multiple PR#'s (i.e. multiple studies submitted in the same petition) all study files are filed together by the lowest PR# of the submission. In the IR-4 Food Use Database a note will be placed in the comment field indicating the PR# location.

3) To retrieve an Archived Study File or to just view an Archived Study File, a request must be made to the Archivist (identified in current version of SOP# 7.1).

   a) The Archivist may be accompanied by the person making the request to the Archived Study File.

   b) If the file is not removed (only viewed), no entries are made in the Archive Log Book.

   c) If a file, or any portion thereof, is to be removed, the Archivist or the requestor will fill out an Authorization Removal Form (See Appendix A). If material needs to be removed for longer than 7 days, the Archivist will have Management authorize the removal. The Archivist will also document the removal in the Archive Log Book.

   d) The archivist will periodically review the archive log and Authorization Removal Forms and follow-up to inquire as to the status of checked out materials.

   e) When the material is returned to the Archivist, the date will be entered in the Archive Log Book. If an Authorization Removal Form was initiated, then this form will be certified by the person returning the material that no data has been added or removed or changed. This form will be placed in archives.

4) Removal of other items stored in the archives, such as Facility Files, Test and Reference Substance Characterization, and QA files is covered by separate procedures outlined in the current version of SOP# 7.1 and the current version of SOP#8.13.

Prepared by: _____ Date: 9/4/07

Approved by: _____ Date: 9-4-07

Appendix A to SOP# 7.4:03

Authorization Form
Checkout and Return of Study Files/Data

Study Number: _____ Archive Location: _____ Archivist Initials & Date _____

Date of Log-Out: _____ Date Due (7 days from date of removal): _____

Description of Materials Removed:

The individual designated below may sign the above material out of the Archives:

_____

Designee Name (print) Signature Date

If the Designee needs to have the above out longer than 7 days, Management must authorize approval:

_____

Management Name (print) Signature Date

I certify that I (designee above) did not remove or add data or make any changes to the contents of this material returned to the archives*:

_____

Signature Date

Date Returned/Archivist Initials _____

*Alteration or addition of data to archived files will require written authorization from management, and will be coordinated with the Archivist.

12/12/06

SOP #: 7.5

AUTHORS: D. K. Infante, T.W. Barkalow

REVISION #: 00

EFFECTIVE DATE: June 14, 2011

TITLE: **Off –Site Archiving & Access: Archived Study Files**

PURPOSE: To explain the procedure for access to the unique file for each Pesticide Use/Crop/Pest archived study. To provide a method for the orderly storage and expedient retrieval of any archived study located at DucuSafe, 3 Applegate Drive, Robbinsville, NJ 08691.

SCOPE: This SOP applies to only the authorized Archive Archivist IR-4 Personnel, identified in SOP 7.1 Appendix E.

PROCEDURES:

1) The Off-Site archival area is located at DocuSafe, Data and Records Management, 3 Applegate Drive, Robbinsville, NJ 08691, Telephone: 609-259-8290, FAX# 609-259-8291.

2) A Study can be either a GLP study or a Non-GLP study.

3) Contents may consist of file Folders that are Manilla/Blue/Red/Purple/Gray, there may be Field Data Books/ASR/Raw Data or other records.

4) The procedure to transfer off site is to box the entire study into as many boxes that are needed to store the entire archived study.

   a) Bar codes are provided by DocuSafe, which are made up of our 4 digit account code and then followed by a six digit unique tracking number.
   b) The six digit unique tracking number will be noted in the IR-4 database in the field "Archive Location" and also in the log book "Off-Site Archived Records-Removal from HQ" as the "Box Identifier". See Appendix B.
   c) An "Off-Site Inventory Sheet" will be completed of what materials are boxed. The six digit unique tracking number will be noted on this sheet as the "Box Identifier". This sheet will remain at IR-4 HQ in a 3-ring notebook. See Appendix A.

5) Pick-up and Removal from DocuSafe can only be done by a authorized Archive Archivist IR-4 Personnel who each must know their user name and password. Each shall receive training on the DocuSafe system.

Prepared by: Dina Infante Date: 6/14/11

Approved by: Jerry J Brunner Date: 14 June 2011

Off-Site Inventory Sheet

PR#: _____

Check off **only the materials boxed for off-site archiving:**

- ☐ **Manila Folder**
- ☐ **Blue Folder**
- ☐ **Red Folder**
- ☐ **Gray Folder**
- ☐ **Purple Folder**
- ☐ **Field Data Books** as listed:
- ☐ **ASR** from laboratory
- ☐ **Laboratory Raw Data**
- ☐ **Final Report**
- ☐ **Other, explain**

Archivist Use Only:

Number of Boxes _____

Box Identifier _____
Box Identifier _____
Box Identifier _____
Box Identifier _____
Box Identifier _____
Box Identifier _____

Archivist: Init/Date:_____

OFF SITE ARCHIVED RECORDS – REMOVAL FROM HQ

PR#	Archivist Initial & Transfer Date (Ready for Removal)	Box Identifier (s)	Archivist Initial & Date of Removal From HQ

SOP #: 8.0

AUTHOR: T. W. Barkalow

REVISION #: 03

EFFECTIVE DATE: January 31, 2010

TITLE: **Quality Assurance Unit (QAU), Terms and Responsibilities**

PURPOSE: To ensure that the IR-4 Quality Assurance Unit is operating according to the US EPA Good Laboratory Practice Standards (GLPS) requirements and the IR-4 GLP Operational Handbook.

SCOPE: This SOP applies to all IR-4 GLP research projects that are to be submitted to the US EPA. The IR-4 QAU includes Headquarters (HQ) Quality Assurance Officers (QAOs), Regional QAOs, Laboratory QAOs (University and ARS), and QAOs of facilities participating in IR-4 research projects.

PROCEDURES:

1. The IR-4 Project shall have a Quality Assurance Unit (QAU) which shall be responsible for monitoring each study to assure the Testing Facility Management that the following are in conformance with the US EPA GLPs:

-facilities	-practices
-equipment	-records
-personnel	-controls
-methods	

The Project Management Committee has appointed the IR-4 Executive Director and any designees as their representative(s). See Appendix A of current SOP # 6.0 for specifics.

The QAU shall be entirely separate from and independent of the personnel engaged in the direction and conduct of the study monitored.

1. cont.

The QAU shall conduct inspections and maintain records appropriate to the study. Specific inspection and reporting procedures will be outlined in QA SOP's that will include the appropriate QA checklist. An outside QAU may be used for monitoring an IR-4 study and will be monitored by the IR-4 QAU.

2. The IR-4 QAU shall:

A. Maintain a copy of the master schedule for all studies conducted for IR-4, indexed by Test Substance, and containing at a minimum:

a) test substance
b) test system
c) nature of the study
d) date study initiated (date protocol is signed by the Study Director)
e) current status of each study (proposed experimental and study completion dates, and date archived)
f) identity of Sponsor
g) name of Study Director

B. Maintain copies of all protocols pertaining to all studies for which the QAU is responsible, indexed by PR # (Study No.) or other mechanism to expedite retrieval.

C. Inspect/audit each study at intervals adequate to ensure the integrity of the study and maintain written and properly signed records (indexed by PR # or other method) of each periodic inspection/audit showing the following:

a) date of inspection/audit
b) study inspected/audited
c) phase or segment of the study inspected/audited
d) person performing the inspection/audit
e) findings and problems

2. cont.C.

f) action(s) recommended and taken to resolve existing problems
g) scheduled date for reinspection (if appropriate)

D. Bring to the attention of the Study Director and Testing Facility Management immediately any problems which are likely to affect the study integrity; which, were found during the course of an inspection/audit. Examples of critical items that may adversely affect the integrity of a study (and may be reported immediately) include, but are not limited to:

a) lack of test system or test substance storage records
b) application parameters as specified in the protocol are not met
c) expired test or reference substances used for test system dosing or sample quantitation
d) test or reference substances integrity is jeopardized by inappropriate storage conditions
e) failure to retain raw data

E. Periodically provide to the Testing Facility Management and Study Director written status reports on each study, noting any problems and the corrective actions taken.

F. Determine that no deviations from approved protocols or SOPs were made without proper authorization and documentation.

G. Review the field data, lab report and lab data following approved QA procedures. Review the final report to assure that the reported results accurately reflect the raw data of the field and laboratory phases of the study.

H. Prepare and sign a QA statement to be included with the final report which shall specify the dates inspections/audits were made and findings reported to the Testing Facility Management and Study Director.

3. All records required to be maintained by the QAU are indexed by PR/Study No. except the master schedule, which is indexed by test substance and cross referenced to the PR/Study No.

The IR-4 QAU shall maintain written records of the following:

A. Responsibilities and procedures applicable to the QAU

B. The records maintained by the QAU

C. Method of indexing such records. These items including the following shall be made available for inspection to authorized employees or duly designated representatives of EPA or FDA:

a) inspection/audit dates

b) study inspected/audited

c) phase or segment of the study inspected

d) name of the individual performing the inspection

e) dates reported to Study Director and Management

4. An authorized employee or duly designated representative of the EPA or FDA shall have access to the SOP's for QA inspections and audits and may request the testing facility management to certify that inspections/audits are being implemented, performed, documented and followed up in accordance with this SOP.

Prepared by: T. W. Barkdoll Date: 1/6/2010

Approved by: Jerry J Bann Date: 8 JAN 2010

SOP #: 8.1

AUTHOR: T. W. Barkalow

REVISION #: 07

EFFECTIVE DATE: January 31, 2010

TITLE: **Quality Assurance Facility Inspection of the IR-4 Headquarters**

PURPOSE: This document details the procedures to be followed by IR-4 QA personnel, or those contracted to perform QA duties, when conducting facility inspections at IR-4 Headquarters.

SCOPE: This SOP applies to all QA personnel inspecting the IR-4 Headquarters for GLP, or other regulatory requirements and practices.

PROCEDURES: The IR-4 Headquarters Quality Assurance Unit (QAU) Manager will assign a QA Officer (QAO) to conduct facility inspections of IR-4 Headquarters.

1. During the facility inspection, the QAO will inspect/audit the HQ facilities for the following:

   A) Organizational Chart
   B) Master Study Schedule
   C) Personnel Records
   D) SOP's
   E) Study Files
   F) Document Archives
   G) Facilities (incl. space, housekeeping, availability of SOP's and use)
   H) Safety Equipment and Procedures

   A checklist and comment/recommendations forms which will facilitate and record the inspection results can be found in Appendix A.

2. During the inspection, the QAO will check to see that each member of the research staff at IR-4 Headquarters has access to a complete and current version of IR-4 HEADQUARTERS STANDARD OPERATING PROCEDURES FOR GLP RESEARCH PROJECTS.

   The QAO may monitor selected staff members and/or will review documents to ensure that SOP's are being followed and that GLP regulations and all other applicable standards are being met.

3. The QAO will prepare the written report of the facility inspection and place it in the QAU Routing Bin for forwarding to the members of the Management Team, which will address QA findings and recommendations. The original inspection report, with a Routing Page, will be given to the Executive Director. Other team members will receive a full copy of the inspection report.

   The Executive Director will be responsible for generating the written response, which will be returned to the QAU Routing Bin.

4. Re-inspection will be scheduled as necessary.

5. All facility inspection checklists, along with QA findings, comments and Managements' responses will be maintained in the Headquarters QA files.

6. Internal audits are not to be shown to persons outside of the IR-4 program, unless written authorization is received from the Executive Director.

Revised By: _____ Date: 1/6/2010

Approved By: _____ Date: 8 JAN 2010

The IR-4 Project

Providing Safe and Effective Pest Management Solutions for Specialty Crop Growers

IR-4 PROJECT

Facility Inspection

A) Research Director:

Name: _____

Address: _____

_____

Phone: ( ) _____

E-mail: _____

B) Quality Assurance Inspector:

Name: _____

Address: _____

Phone: ( ) _____

E-mail: _____

C) Test Site Location: _____

_____

D) Inspection Date: _____

E) Re-inspection Date: _____

F) Please fill out the following checklist.

Provide a narrative on any items marked No and provide suggestions and recommended actions to be taken as appropriate for QA findings. Use additional forms if needed. The Executive Director or Study personnel, as appropriate, must respond to QA findings.

Please Note:

Any problems which are likely to affect the study's integrity found during the course of the review must be brought to the attention of the Study Director (SD)/Testing Facility Management (TFM) **immediately**.

Facility Inspection

Test Site: _____

A. Facilities	**YES**	**NO**	**N/A**
* 1. Facility is of suitable size.			
* 2. Adequate working areas.			
* 3. Facility appears clean / well maintained.			
4. Satisfactory facilities for sanitation.			
B. Test, Control and Reference Substances	**YES**	**NO**	**N/A**
* 5. Are there separate areas for:			
a. Receipt and storage of test/control/reference substances.			
b. Storage of test/control/reference substances mixtures.			
c. Test substance mixing.			
* 6. Receipt and usage:			
a. Receipt and condition upon receipt documented.			
b. Bulk inventory log maintained.			
c. Adequate usage / accountability documentation.			
d. SOP followed.			
* 7. Storage:			
a. Limited access.			
b. Environmentally controlled if necessary.			
c. Is temperature continuously monitored?			
d. Calibration of temperature monitoring device per SOP.			
e. Temperature range adequate for compound integrity.			
f. Storage area adequately ventilated.			
* 8. Test/control/reference substances properly labeled.			
a. Name, CAS or code number.			
b. Batch number.			
c. Expiration date.			
d. Storage conditions.			
*9. Test/control/reference substance storage neat and organized.			

*** Minimal GLP requirements.**
Facility Inspection Checklist
N/A = Not applicable

Comments

Facility Inspection

Test Site: _____

C. Equipment	YES	NO	N/A
*10. Equipment cleaned as per SOP.			
*11. Equipment designed as per SOP.			
*12. Equipment located as per SOP.			
*13. Equipment appears to be in good repair.			
*14. Equipment adequately stored when not in use.			
*15. Maintenance logs on equipment up-to-date.			
a. Contains standardization / calibration records.			
b. Specifies routine and non routine maintenance.			
c. Specifies whether or not SOP was followed for routine maintenance.			
d. Specifies nature of defect or routine maintenance.			
e. Specifies how and when defect was discovered.			
f. Specifies remedial action taken in response to defect.			
*16. Maintenance / calibration / standardization / cleaning per SOP.			
*17. Owner's manual easily accessible.			
*18. Maintenance logs easily accessible.			

***Minimal GLP requirements.**
Facility Inspection Checklist
N/A = Not applicable

Comments

Facility Inspection

Test Site: _____

D. Test System Sample Storage	YES	NO	N/A
*19. Separate from test/control/reference standard storage area.			
*20. Clean, organized free from contamination.			
*21. Limited access.			
*22. Tracking / accountability system in place and adequate.			
*23. Control / treated adequately separated.			
*24. Temperature continuously recorded.			
*25. Recording devices adequately calibrated / standardized.			
*26. Maintenance logs on freezers up-to-date.			
a. Specifies routine and non routine maintenance.			
b. Specifies whether or not SOP was followed for routine maintenance.			
c. Specifies nature of defect for non routine maintenance.			
d. Specifies how and when defect was discovered.			
e. Specifies remedial action taken in response to defect.			
*27. Maintenance log readily available.			

*** Minimal GLP requirement.**
Facility Inspection Checklist
N/A = Not applicable

Comments

Facility Inspection

Test Site: _____

E. General Laboratory	YES	NO	N/A
*28. Work area neat, clean and uncluttered.			
*29. Proper storage of clean glassware.			
*30. SOP book available in work areas.			
*31. Appropriate dress procedures are followed.			
*32. All reagents / solutions properly labeled.			
a. Identity			
b. Titer / concentration.			
c. Storage conditions.			
d. Expiration date.			
*33. No reagents / solutions out of date.			
*34. Proper storage maintained for all reagents/solutions.			
*35. Have SOPs addressing safety issues been followed.			

*** Minimal GLP requirement.**
Facility Inspection Checklist
N/A = Not applicable

Comments

Facility Inspection

Test Site: _____

F. Standard Operating Procedures	YES	NO	N/A
*36. Have SOPs been approved by management according to IR-4 Operational Handbook. (IR-4 Regional Management)			
*37. Is there an effective date for each SOP? a. Did CRO TFM review SOP?			
*38. Is there a revision number.			
*39. Are SOPs appropriately retained after revision?			
40. Are there procedures in place for replacing revised SOPs and ensuring that old SOPs are not available for use.			
*41. Are required SOPs in place (160.81).			
a. Test system area preparation.			
b. Test system care.			
c. Receipt, ID, storage, handling, mixing & method of sampling test/control/reference substances.			
d. Test system observations.			
e. Laboratory or other tests.			
f. Handling of test system found dead during study.			
g. Necropsy.			
h. Collection & ID of specimens.			
i. Histopathology.			
j. Data handling, storage & retrieval.			
k. Maintenance & calibration of equipment.			
l. Transfer, proper placement & ID of test systems.			
42. Do SOPs accurately reflect current procedure?			
*43. a. Are there procedures in place for periodic review of SOPs to maintain accuracy.			
b. Are SOP review intervals being followed?			
44. Is there an index for the SOPs?			
45. SOP available on each piece of equipment.			
a. Routine inspection / maintenance intervals specified.			
b. Calibration / standardization procedures specified.			
c. Remedial action to be taken in case of malfunction or power failure specified.			
d. Person responsible for performance of each operation.			
46. SOPs readily available.			

*** Minimal GLP requirement.**
Facility Inspection Checklist
N/A = Not applicable

Comments

Facility Inspection

Test Site: _____

G. Personnel Records	YES	NO	N/A
*47. Training records:			
a. Are current			
b. Are being reviewed periodically as per SOP.			
c. Document recent GLP training.			
d. Document procedural training, as per SOP.			
*48. CV's.			
a. Provide adequate detail of past experience.			
b. Provide adequate detail of education.			
c. Provide adequate detail of "formalized" training / meetings.			
d. Have been updated according to SOP.			
*49. Current job descriptions available for all personnel.			
50. GLP personnel files maintained after departure.			
H. Management of Facility	**YES**	**NO**	**N/A**
51. Had an EPA / FDA inspection.			
52. Have all deficiencies been corrected.			
53. Is organizational chart available.			
54. Does organization chart adequately describe reporting structure?			
55. Is a floor plan available?			
56. Is the facility adequately staffed?			
I. Archives	**YES**	**NO**	**N/A**
*57. Are the archives adequate:			
a. Limited access.			
b. Neat and orderly.			
c. Environmentally controlled.			
*58. Have precautions to prevent deterioration of the raw data been addressed.			
*59. Are procedures in place for logging data in and out?			
*60. Is the material indexed to expedite retrieval?			
*61. Is there a designated archivist.			
*62. Is a backup archivist designated?			
*63. How long are raw data maintained?			

*** Minimal GLP requirement.**
Facility Inspection Checklist
N/A = Not applicable

Comments

Facility Inspection

Test Site: _____

J. Quality Assurance	YES	NO	N/A
*64. Is there an independent QA unit reporting directly to Management.			
*65. Does the QA conduct periodic facility inspections?			
*66. How often?			
*67. Does QA inspect critical phases of each study			
*68 Does QA audit all reports?			
*69. How much of a data check is done (comment).			
*70. Are Study Directors and testing facility management allowed to see all QA findings			
*71. Does the QA maintain a copy of the Master Schedule			
*72. Is the status of each study adequately documented?			
*73. . Are all required elements on the Master Schedule?			
a. Indexed by test substance.			
b. Test substance identified.			
c. Nature of the study.			
d. Date study was initiated.			
e. Current status.			
f. Identity of sponsor.			
g. Name of Study Director			
*74. Are all QA records easily accessible and properly indexed?			
*75. Is the QA statement included in the report?			
*76. Are QA SOPs adequate?			
*77. Does the QA offer periodic GLP training.			
*78. Is the QA adequately staffed?			
*79. Does the QA appear to have management support?			
*80. Does the QA maintain a copy of all signed approved protocols?			
*81. Does the QA have a copy of the final regulation?			

*** Minimal GLP requirement.**
Facility Inspection Checklist
N/A = Not applicable

Comments

Facility Inspection

Test Site: _____

List Personnel involved with inspections and their title:

Name	Title
1. _____	_____
2. _____	_____
3. _____	_____
4. _____	_____
5. _____	_____
6. _____	_____
7. _____	_____
8. _____	_____
9. _____	_____
10. _____	_____

Comments

Testing Facility: _____

Findings, Responses and Actions Taken*:

_____

_____

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_____ _____

Quality Assurance Date Responder** Date

* Place responses/ explanation of corrective action in space provided between findings or use a separate sheet of paper.

** Responder(s) are to assure they have identified themselves either by signing the bottom of this page or by initialing and dating the written response(s).

Testing Facility: _____

QA Findings	Response/Actions Taken*

_____ _____

Quality Assurance Date Responder **Date

* Place responses/ explanation of corrective action in space provided to the right of the findings or use a separate sheet of paper.

** Responder(s) are to assure they have identified themselves either by signing the bottom of this page or by initialing and dating the written response(s).

SOP #: 8.2

AUTHORS: T. W. Barkalow and J.D. Forder

REVISION #: 07

EFFECTIVE DATE: October 7, 2013

TITLE: **Protocol Audit Procedure and Routing.**

PURPOSE: To assure that protocols meet all requirements set forth in the most current version of the U.S. EPA Good Laboratory Practice Standards (GLP).

SCOPE: This SOP applies to protocols generated by IR-4 Study Directors (SD) as well as any protocols supplied to IR-4 personnel on cooperatively managed studies, which are assigned for auditing by IR-4 Headquarters (HQ's)/Regional Quality Assurance Units (QAUs).

This procedure does not apply to the protocol review done by a QAO prior to starting audit of a critical phase, field or laboratory data books or other study documents.

PROCEDURES: Protocol audits consist of reviewing and auditing draft or final protocols and documenting the audit with comments and/or findings. Utilize the forms in the eQA system. The protocol checklist in Appendix A may be used for notes/as a reference.

Special Needs Protocols

1. The IR-4 QAU will review draft protocols having special needs (those protocols with study requirements that are not considered routine residue studies).

2. A special needs protocol will be determined by the Registration Manager or the Study Director and verified as being audited by QA before approval by the Sponsor Representative. Once identified during the Study Director's review process, the draft protocol will be provided to the IR-4 HQ QA office for review. This protocol will receive a preliminary review by QA. It will not receive a formal audit at this time. The QA comments will be provided to the Study Director for consideration. Just prior to finalization, the previously reviewed protocol with any changes or corrections made based upon the informal review, will be presented to IR-4 HQ QA for audit. QA will audit this protocol utilizing the forms in the eQA system and the

checklist (paper form for note taking, Appendix. A) as described in the most current version of SOP 8.17. The cover sheet's header will contain the information "PA Chem/Crop and PR#". If the audit is not completed, Sponsor reserves the right to not sign the protocol.

The protocol checklist in the eQA system encompasses items detailed in the most current version of the GLPs, as well as specific study requirements.

General Comments:

Protocol audits performed at non-IR-4 test sites (contract facilities or cooperating laboratories) may use the QA auditing procedures in their SOPs provided they meet the requirements as defined in the most current version of the EPA GLPs.

Prepared By: _____ Date: 9/27/13

Approved By: _____ Date: 9/27/13

Protocol Audit Checklist

Study Title:

Study Number (PR#):

Packet ID: PA-000

Audit Type Chem/Crop/PR#(ID) :

Location:

Date:

A. General

Yes No or N/A

1. Study title (descriptive):
2. Purpose / objective of study:
3. Sponsor name and address:
4. Testing facility management name and address:
5. Identity of study participants/test sites complete:
6. Proposed start date:
7. Proposed termination date:
8. Name & dated signature of Study Director:
10. Records/specimens to be maintained:
9. Dated approval signature of Sponsor Representative:
11. Archival location for raw data accurate:
12. Description of proposed statistics:
13. Parameters to be statistically analyzed:

B. Test System

Yes No or N/A* GLP required element

14. Description of the test system:

I. Field Studies:

a. Crop/soil:

b. Variety:

c. Source of supply:

d. Age of test system:

e. Plot size and description:

f. Greenhouse trials required:

II. Analytical Studies:

a. Matrix/Method described:

b. Spiking levels assigned:

c. Number of samples for assay:

III. Animal Studies:

a. Number and sex:

b. Body weight range and/or age:

c. Species strain and sub strain:

d. Source of supply:

e. Description of diet used:

Study Title:

Study Number (PR#):

15. *Method of plot identification:

16. Justification for the test system selection:

C. Test, Control & Reference Article

Yes No or N/A

17. *Name, CAS number or code number:

a. Test Substance:

b. Control Substance:

c. Reference Substance:

18. Supplier of test, control & ref. substance:

19. Solvent and/or adjuvant used to solubilize or suspend the test, control or reference substance:

20. Archival of retentions sample addressed:

21. Storage condition information for the test, control and / or ref. substance:

22. Stability under testing conditions:

D. Dosing

Yes No or N/A

23 *Route or administration:

24. Frequency of administration:

25. Justification for route od administration:

26. *Preparation of dosage form:

27. *Identity of carrier or vehicle:

28. *Concentration of test material:

29. *Method to assure uniformity of mixture:

E. Sample Collection and Shipment

Yes No or N/A

30. *Interim sampling points (if applicable):

a. # of samples per plot/ per trt. group:

b. Number of treatments and control groups:

31. *Terminal sampling points:

32. *Description/number of samples required:

33. *Method of control bias:

34. *Handling, shipment and storage of samples:

35. *Sample prep for analysis:

36. *Archival/disposition of samples. :

37. *Parameters to be statistically analyzed:

F. Sample Analysis

Yes No or N/A

38. Identity of analytical reference method:

39. Method validation requirements:

40. Analysis acceptance criteria provided:

41. Storage stability requirements:

SOP #: 8.3

AUTHORS: T. W. Barkalow

REVISION #: 07

EFFECTIVE DATE: October 7, 2013

TITLE: **Quality Assurance (QA) - Facility Inspections.**

PURPOSE: To detail the procedures followed when conducting facility audits at current Regional Leader Laboratories, Field Research sites, Processing sites, Contract Research Organizations (CRO), and facilities/sites being considered for IR-4 research.

SCOPE: This SOP applies to all IR-4 Quality Assurance Unit (QAU) personnel or designees inspecting facilities on behalf of the IR-4 Project.

PROCEDURES:

1. The appropriate QAU personnel will conduct facility inspections of IR-4 cooperating facilities at a minimum of once every three years, for test sites in good standing. All new IR-4 cooperators' facilities should be inspected prior to study placement, or as soon as possible after assignment of a study. If possible, the facility inspection may be scheduled to coincide with an in-life study phase.

2. The facility inspection can be facilitated using the checklist in Appendix A, as a note taking tool. The facility inspection will include, but not be limited to:

   A) Organizational Chart
   B) Master Schedule
   C) Personnel Records (CV's, training records and job descriptions)
   D) SOP's
   E) Study Raw Data Files, (if available)
   F) Archives
   G) Facilities (i.e., appropriate equipment, test

substance and sample storage, test system care facilities, working areas, and safety equipment and procedures, etc.). A checklist which reflects the above parameters and associated facility requirements can be found as Appendix A.

QA findings and requests for corrective actions will also be recorded as part of the QA inspection report. Fully explain any GLP deficiency, using references as appropriate.

3. The QAO will check to see if each member of the research staff at the facility has access to a copy of the approved SOP's at the test site. The QAO will also observe the activities of the staff and may review any additional documents to ensure that SOPs are being followed and that GLP Standards are being met. Inspect the SOPs for adherence to the facility's procedure(s) regarding SOPs.

4. Once the Facility inspection has been completed, discuss the findings with the Field Research Director (FRD), Laboratory Research Director (LRD) or Processing Research Director (PRD). Use this as a training experience, to help prevent similar findings in the future. The QAO will prepare the audit report within 6 weeks utilizing the Facility Inspection Form in the eQA system and the availability of the report will be communicated to the parties as prescribed in the current version of SOP 8.17. The Study Directors and the Regional/ARS Coordinator will be notified of the audit report being available for viewing as per the form's workflow in eQA.

5. Once the FRD/LRD/PRD has responded to the inspection report, via the eQA system, the system will notify the TFM that the responses are available and the TFM will be prompted to complete the audit report (as per current version of SOP 8.17).

6. Any adverse inspection findings likely to affect the integrity of any current or proposed study must be reported to the SD and TFM, immediately. This can be done by documented telephone conversations, e-mail or by fax.

7. Re-inspection will be scheduled as necessary, add any date for re-inspection entered on front sheet.

8. Inspections performed at non-IR-4 test sites (e.g., Private Contract Facilities, Cooperating Laboratories) may use the QA auditing procedures in their SOPs, provided they meet the requirements as defined in the current version of the EPA GLPs. These audits will be routed using the eQA system and identified as "external" QA reports as described in the current version of SOP 8.17.

9. Internal audits are not to be shown to persons outside of the IR-4 program, unless written authorization is received from IR-4 Management (i.e., the Executive or Regional Director).

Prepared By: _____ Date: 9/27/13

Approved By: _____ Date: 9/27/13

Form Group: Facility Inspection
Packet ID: FI-
Location:
Date:
Closed:

A. Facilities
Yes, No, N/A

1. Facility is of suitable size:
2. Adequate working areas:
3. Facility appears clean/well maintained:
4. Satisfactory facilities for sanitation:

B. Test Control and Reference Substance
Yes, No, N/A

5. Are there separate areas for: :
   a. receipt and storage of test/control/reference substances?:
   b. storage of test/control/reference substances mixtures? :
   c. test substance mixing? :
6. Receipt and usage:
   a. receipt and condition upon receipt documented:
   b. bulk inventory log maintained:
   c. adequate usage/accountability documentation:
   d. SOP followed:
7. Storage::
   a. limited access:
   b. environmentally controlled if necessary:
   c. Is temperature continuously monitored? :
   d. calibration of temperature monitoring device per SOP.:
   e. temperature range adequate for compound integrity:
   f. storage area adequately ventilated:
8. Test/control/reference substances properly labeled. :
   a. name, CAS or code number:
   b. batch number:
   c. expiration date:
   d. storage conditions:
9. Test/control/reference substance storage neat and organized:

C. Equipment
Yes, No, N/A

10. Equipment cleaned as per SOP.:
11. Equipment designed as per SOP:
12. Equipment located as per SOP. :

13. Equipment appears to be in good repair:
14. Equipment adequately stored when not in use:
15. Maintenance logs on equipment up-to-date:
a. contains standardization/calibration records:
b. specifies routine and non-routine maintenance:
c. specifies whether or not SOP was followed for routine maintenance:
d. specifies nature of defect or routine maintenance :
e. specifies how and when defect was discovered:
f. specifies remedial action taken in response to defect:
16. Maintenance/calibration/standardization/cleaning per SOP. :
17. Owner's manual easily accessible:
18. Maintenance logs easily accessible:

D. Test System Sample Storage
Yes, No, N/A

19. Separate from test/control/reference standard storage area:
20. Clean, organized free from contamination:
21. Limited access:
22. Tracking/accountability system in place and adequate:
23. control/treated adequately separated:
24. Temperature continuously recorded:
25. Recording devices adequately calibrated/standardized:
26. Maintenance logs on freezers up to date:
a. Specifies routine and non-routine maintenance:
b. Specifies whether or not SOP was followed for routine maintenance:
c. Specifies nature of defect for non-routine maintenance:
d. specifies how and when defect was discovered:
e. specifies remedial action taken in response to defect.:
27. Maintenance log readily available:

E. General Laboratory
Yes, No, N/A

28. Work area neat, clean, uncluttered:
29. Proper storage of clean glassware:
30. SOP book available in work areas:
31. Appropriate dress procedures are followed:
32. All reagents/solutions properly labeled:
a. identity:
b. titer/concentration:
c. storage conditions:
d. expiration date:

33. No reagents/solutions out of date:

34. Proper storage maintained for all reagents/solutions:

35. Have SOPs addressing safety issues been followed?:

F. Standard Operating Procedures
Yes, No, N/A

36. Have SOPs been approved by management according to IR-4 Operational Handbook (IR-4 Regional Management)?:

37. Is there an effective date for each SOP?:

a. Did CRO TFM review SOP?:

38. Is there a revision number? :

39. Are SOPs appropriately retained after revision?:

40. Are there procedures in place for replacing revised SOPs and ensuring that old SOPs are not available for use?:

41. Are required SOPs in place (160.81)?:

a. test system area preparation:

b. test system care:

c. receipt, ID, storage, handling, mixing & method of sampling test/control/reference substances:

d. test system observations:

e. laboratory or other tests:

f. handling of test system found dead during study:

g. necropsy:

h. collection and ID of specimens:

i. histopathology:

j. data handling, storage & retrieval:

k. maintenance & calibration of equipment:

l. transfer, proper placement & ID of test systems:

42. Do SOPs accurately reflect current procedure?:

43. a. Are there procedures in place for periodic review of SOPs to maintain accuracy?:

b. Are SOP review intervals being followed?:

44. Is there an index for the SOPs?:

45. SOP available on each piece of equipment:

a. routine inspection/maintenance intervals specified:

b. calibration/standardization procedures specified:

c. remedial action to be taken in case of malfunction or power failure specified:

d. person responsible for performance of each operation:

46. SOPs readily available:

G. Personnel Records

Yes, No, N/A

47. Training Records:
a. are current:
b. are being reviewed periodically as per SOP:
c. document recent GLP training:
d. document procedural training as per SOP. :
48. CV's:
a. provide adequate detail of past experience:
b. provide adequate detail of education:
c. provide adequate detail of formalized training/meetings:
d. have been updated according to SOP:
49. Current job descriptions available for all personnel:
50. GLP personnel files maintained after departure:

H. Management of Facility

Yes, No, N/A

51. Had an EPA/FDA inspection:
52. Have all deficiencies been corrected?:
53. Is organization chart available? :
54. Does organization chart adequately describe reporting structure?:
55. Is a floor plan available?:
56. Is the facility adequately staffed?:

I. Archives

Yes, No, N/A

57. Are the archives adequate?:
a. limited access:
b. neat and orderly:
c. environmentally controlled:
58. Have precautions to prevent deterioration of the raw data been addressed?:
59. Are procedures in place for logging data in and out?:
60. Is the material indexed to expedite retrieval?:
61. Is there a designated archivist? :
62. Is a backup archivist designated?:
63. How long are raw data maintained?:

J. Quality Assurance

Yes, No, N/A

64. Is there an independent QA unit reporting directly to management?:
65. Does the QA conduct periodic facility inspections:
66. How often?:
67. Does QA inspect critical phases of each study?:
68. Does QA audit all reports? :

69. How much of a data check is done (comment)?:	
70. Are Study Directors and testing facility management allowed to see all QA findings?:	
71. Does the QA maintain a copy of the Master Schedule?:	
72. Is the status of each study adequately documented? :	
73. Are all required elements on the Master Schedule?:	
a. indexed by test substance:	
b. test substance identified:	
c. nature of the study:	
d. date study was initiated:	
e. current status:	
f. identity of sponsor:	
g. name of study director:	
74. Are all QA records easily accessible and properly indexed?:	
75. Is the QA statement included in the report?:	
76. Are QA SOPs adequate?:	
78. Is the QA adequately staffed?:	
77. Does the QA offer periodic GLP training?:	
79. Does the QA appear to have management support?:	
81. Does the QA have a copy of the final regulation?:	
80.Does the QA maintain a copy of all signed approved protocols?:	

SOP #: 8.4

AUTHOR: J.D. Forder, T. W. Barkalow

REVISION #: 06

EFFECTIVE DATE: October 7, 2013

TITLE: **Quality Assurance (QA) - In-Life Inspection of Field Trials**

PURPOSE: To detail procedures followed by IR-4 Quality Assurance Unit (QAU) or their representative(s), when conducting in-life inspections of IR-4 field studies.

SCOPE: This SOP applies to IR-4 QAU participants.

PROCEDURES:

1. The Quality Assurance Officer (QAO) will coordinate with the Field Research Director (FRD) as to times for the inspection. Field trials will be scheduled for inspection based on targeting plans made during the IR-4 QAU planning meeting typically held in the first quarter of the calendar year. Additional or substitute trials may be selected for inspection as determined by the QAO conducting the inspections.

2. The number of audits conducted on a study will depend on the length of the study and whether a re-inspection is warranted to assure the integrity of the study. Each study will receive at a minimum, one critical phase inspection during the in-life portion of the study. This can be done during the field portion or the laboratory portion of the study, but the QAU will audit as many in-life phases as necessary to assure study integrity. Field in-life phases may include, but not be limited to:

   A) Test substance application
   B) Equipment calibration
   C) Sample collection
   D) Sample storage and handling
   E) Sample shipment

3. Key items for QA personnel to focus on may include:

A) Has the protocol been signed by the study director and sponsor?

Take the QA copy of the protocol on all audits and monitor to see that it is being followed. Verify that the study personnel have a copy of the approved protocol and any necessary protocol changes.

B) Determine if there have been any protocol deviations and if those deviations have been properly authorized by the Study Director.

C) Check to see that the initial point of entry of raw data is into the IR-4 Field Data Book or other appropriate media. Check to see that each set of entries are signed/initialed and dated at the time of entry.

D) Independently check representative calculations for accuracy. Determine if the calibration(s) and application(s) procedures are conducted according to the protocol and the SOP for that piece of equipment.

E) Check the plot map to see it adequately describes the location and the setup of the test plot.

F) Check to see that the amount of test substance used has been recorded and that all forms for test substance shipment, receipt, storage, etc., have been retained/generated and are up-to-date.

G) Check to see that all problems encountered are documented, and that any SOP deviations have been reported and authorized by the Study Director.

H) Check the field data book for timeliness and completeness of entries.

I) Check that any observed applications met protocol with respect to the amount of test substance applied.

The inspection may be conducted utilizing IR-4 Project Field In-Life Inspection checklist (App. A for eQA checklist for note taking, App. B for paper QA reports. Inspection findings will be documented by fully explaining the finding(s) using the eQA form FCPI as described in the current version of SOP 8.17 If the FCPI is on a non IR-4 Sponsored study (eg, Sponsored by the Canadian PMC) then the paper version of the checklist and QA audit report maybe used (App. B).

3. Once the inspection has been completed (but possibly before the QA report has been generated) discuss the findings with the FRD or investigator at the test site, if possible. Use this as a training event, to prevent similar findings in the future. The QAO will prepare the audit report within 6 weeks and forward the report as prescribed in the current version of SOP 8.17 or send the report to the Sponsor QA.

4. The FRD will receive an email notifying them of the availability of the eQA audit report (packet). Please respond to the findings promptly (reminders will be sent via email if the response period has elapsed) and attach a copy of any corrected or newly generated data/memos or communications to the report/ packet. All originals are to remain in the study file.

5. Any findings likely to affect the integrity of the study must be reported to the Study Director and TFM, immediately. This can be done by documented telephone conversations, e-mail, or by fax. Examples of critical items that may adversely affect the integrity of the study include, but are not limited to:

   A) Misapplication of the test substance.

   B) Application interval as specified in the protocol was not met, for whatever reason.

   C) Sample collection could not be performed within the parameters of the protocol.

   D) Sample shipment could not take place according to the protocol.

   E) Sample integrity was jeopardized.

   F) Data collection did not occur in a timely manner, and it is observed that the data are not being recorded in a timely fashion.

G) The unlikely event that fraudulent data are encountered.

H) Documentation of GLP test substance characterization is incomplete.

6. If problem areas are deemed to exist, re-inspection will be scheduled and conducted.

7. Inspections performed by test site QA at non-IR-4 test sites (e.g., Contract Research Organizations, Cooperating Laboratories) may use the QA auditing procedures in their SOP's, provided they meet the requirements as defined in the US EPA GLPs. These audits will be routed using the eQA system and identified as "external" QA reports as described in the current version of SOP 8.17.

8. Audits are not to be shown to persons outside of the IR-4 program, unless written authorization is received from IR-4 Management (i.e., Executive or Regional Director).

Prepared By: _____ Date: 9/27/13

Approved By: _____ Date: 9/27/13

Study Title:
Field ID Number:

Form Group: Field Critical Phase Inspection
Packet ID: FCPI
Audit Type Chem/Crop/PR#(ID) :
Location:
Date:

Study Title:
Field ID Number:

A. General
Yes, No, N/A

1. Study protocol on site:
a. Signed and dated by Study Director (SD):
b. Signed and dated by Sponsor:
c. All protocol changes (amendments / deviations) properly authorized:
2. Field Raw Data Book or appropriate forms at site:
3. SOPs on site during procedures:
a. SOPs accurately reference current procedures:
b. Have been approved by management:
c. Contains provisions for remedial action (equipment malfunction):
d. If > 1 year old, been reviewed to be adequate:
4. Adequate number of personnel:
a. Personnel proficient in their duties:
5. Equipment:
a. Meet protocol requirements:
b. Properly cleaned and cleaning documented:
c. SOP available for the equipment used:
d. Log(s) available, up-to-date, GLP complaint:
e. In good working condition.:
6. Protective clothing worn:
7. Field data book:
a. Personnel have signed the field data book:
b. Field data being checked at the time of activity:
c. Were field data GLP complaint:

B. Test System
Yes, No, N/A

8. Plot Design proper size/meets protocol:
9. Plot adequately identified and flagged:
10. Control upslope/upwind from treated:
11. Plot layout:
a. Is neatly drawn:
b. Includes sufficient detail:
c. Reflects an actual design:
d. includes a fixed point of reference:

Study Title:
Field ID Number:

e. Dimensions given in proper units:
f. Direction of slope indicated:
g. North direction indicated:
h. Distance between treated and utc. shown:
12. Crop state as specified in the protocol:
13. SOP available and followed for establishment of test plots:
14. SOP available for maintenance of test plots:

C. Test Substance
Yes, No, N/A

15. Adequate & accurate calculations (units specified and correct):
16. Measuring techniques accurate and according to SOPs:
a. Proper measuring device used:
b. Data recorded to correct significant figures:
c. Calibration adequately documented (if required):
17. Weighing techniques accurate:
a. Balance check completed and within SOP range:
b. Scale/balance and/or weights certified within time frame outlined in SOP.:
C. Equipment log up-to-date and complete:
d. Data recorded to correct significant figures and accuracy of instrument:
e. Equipment appears in good repair:
18. Application equipment calibration acceptable:
a. Technique:
b. Calculations:
c. SOP available and followed:
19. Pass times taken:
20. Application problems (if any) documented:
21. Time of mixing and application documented and is within protocol limits:
22. Batch/lot number recorded:
23. Test substance stored according to label or stability information:
24. Test substance adequately labeled:
a. Name or CAS or code number:
b. Batch number:
c. Expiration date:
d. Storage conditions:
e. GLP status of test substance documented:
25. Test substance use log completed and correct:
26. Application interval as per protocol:
27. Application met protocol specified rate:
28. Environmental parameters at application recorded:
29. Environmental equipment used according to SOP:

Study Title:
Field ID Number:

D. Sampling
Yes, No, N/A

30. Sampling as per protocol, proper PHI maintained:
31. Methods to control bias documented:
32. Samples collected in proper order:
33. Description of collection, harvest, cleaning, trimming, and/or cutting documented:
34. Prevention of contamination addressed:
35. Sample handling post- harvest according to SOP. Transportation containers clean/free from contamination:
36. Elapsed time of collection to freezer recorded and within protocol range:
37. Gloves worn during collection:
38. Sampling equipment properly cleaned:
39. Sampling equipment stored separate from test substance:
40. Adequate separation between test substance and sample storage areas:

E. Storage and Shipping
Yes, No, N/A

41. Freezer inventory maintained and available at site:
42.Treated and untreated adequately separated.:
43. Sample handling in proper order:
44. Prevention of cross contamination addressed:
45. Shipping as per protocol:
46. Shipping equipment and supplies kept separate from test substance:
47. Shipped by:
a. Freezer truck (i.e. ACDS, Inc.):
b. Truck with dry ice:
c. Commercial carrier with dry ice:
d. Other (list method):
48. Data book pages and forms properly:
a. Signed:
b. Dated:
c. Sample ID consistent with plot plan and protocol:
d. Chain of custody form included in shipping box:
49. Maintenance logs on storage equipment maintained and up-to-date:
50. Storage conditions adequately maintained according to SOP and protocols:
51. Storage temperature monitoring equipment properly calibrated/standardized:

The IR-4 Project

Providing Safe and Effective Pest Management Solutions for Specialty Crop Growers

IR-4 PROJECT

Field In-Life Inspection

☐ **Circulate to TFM/SD simultaneously**

A) Study Title: _____

Field I.D. Number: _____

***Phase of the Study Reviewed:** _____

Inspection Date: _____

B) Field Research Director:

Name: _____

Address: _____

_____

Phone: ( ) _____

E-mail: _____

C) Regional / ARS Field Research Coordinator:

Name: _____

Address: _____

_____

Phone: ( ) _____

E-mail: _____

D) Quality Assurance Inspector:

Name: _____

Address: _____

_____

Phone: ( ) _____

E-mail: _____

E) Study Director: _____

E-mail: _____

F) Test Site Location: _____

_____

G) Please fill out the following checklist.

Provide a narrative on any items marked No and provide suggestions and recommended actions to be taken as appropriate for QA findings. Use additional forms if needed. Study personnel must respond to QA findings.

Please Note:

Any problems which are likely to affect the study's integrity found during the course of the review must be brought to the attention of the Study Director/Testing Facility Management at IR-4 HQ **immediately**.

***Phase of the study is very important:** Please indicate on the line provided. Each study must have at least one phase inspection. Use one QA review form per phase per study.

Field In-Life Inspection

ID #_____

A. General	YES	NO	N/A
*1. Study protocol on site.			
a. Signed and dated by Study Director (SD).			
b. Signed and dated by Sponsor.			
c. All protocol changes (amendments / deviations) properly authorized.			
*2. Field Raw Data Book or appropriate forms at site.			
*3. SOPs on site during procedures.			
a. SOPs reference accurately current procedures.			
b. Have been approved by management.			
c. Contains provisions for remedial action (equipment malfunction).			
d. If >1 year old, been reviewed to be adequate.			
*4. Adequate number of personnel.			
a. Personnel proficient in their duties.			
*5. Equipment.			
a. Meet protocol requirements.			
b. Properly cleaned and cleaning documented.			
c. SOP available for the equipment used.			
d. Log(s) available, up-to-date, GLP compliant.			
e. In good working condition.			
*6. Protective clothing worn.			
*7. Field data book.			
a. Personnel have signed field data book.			
b. Field data being checked at the time of activity.			
c. Were field data GLP complaint.			

*** Minimal GLP requirements associated with Series 860 and research protocol.**
N/A=Not Applicable

Comments

Field In-Life Inspection

ID #_____

B. Test System	YES	NO	N/A
* 8. Plot design proper size / meets protocol.			
* 9. Plot adequately identified and flagged.			
10. Control upslope / upwind from treated.			
*11. Plot layout.			
a. Is neatly drawn.			
b. Includes sufficient detail.			
c. Reflects actual design.			
d. Includes a fixed point of reference.			
e. Dimensions given in proper units.			
f. Direction of slope indicated.			
g. North direction indicated.			
h. Distance between treated and utc shown.			
*12. Crop state as specified in the protocol.			
*13. SOP available and followed for establishment of test plots.			
*14. SOP available for maintenance of test plots.			

*** Minimal GLP requirements associated with Series 860 and research protocol.**
N/A=Not Applicable

Comments

Field In-Life Inspection

ID #_____

C. Test Substance	YES	NO	N/A
*15. Adequate & accurate calculations (units specified and correct).			
*16. Measuring techniques accurate and according to SOPs.			
a. Proper measuring device used.			
b. Data recorded to correct significant figures.			
c. Calibration adequately documented (if required).			
17. Weighing techniques accurate.			
a. Balance check completed and within SOP range.			
b. Scale / balance or weights certified within time frame outlined in SOP			
c. Equipment log up-to-date and complete.			
d. Data recorded to correct sig. figures and precision of instrument			
e. Equipment appears in good repair.			
*18. Application equipment calibration acceptable.			
a. Technique.			
b. Calculations.			
c. SOP available and followed.			
*19 Pass times taken.			
*20. Application problems (if any) documented			
*21. Time of mixing and application documented.			
*22. Batch / lot number recorded.			
*23. Test substance stored according to label or stability information.			
*24. Test substance adequately labeled.			
a. Name or CAS or code number.			
b. Batch number.			
c. Expiration date.			
d. Storage conditions.			
e. GLP status of test substance documented.			
*25. Test substance use log completed and correct.			
*26. Application interval as per protocol.			
*27. Application met protocol specified rate.			
*28. Environmental parameters at application recorded.			
*29. Environmental equipment used according to SOP.			

*** Minimal GLP requirements associated with Series 860 and research protocol.**
N/A=Not Applicable

Comments

Field In-Life Inspection

ID #_____

D. Sampling	YES	NO	N/A
*29. Sampling as per protocol. a. PHI met.			
*30. Methods to control bias documented.			
*31. Samples collected in proper order.			
*32. Description of collection, harvest, cleaning, trimming, and/or cutting documented.			
*33 Prevention of contamination addressed			
*34. Sample handling post harvest according to SOP. a. Transportation containers clean / free from contamination			
*35. Elapsed time of collection to freezer recorded and within protocol range.			
36. Gloves worn during collection			
*37. Sampling equipment properly cleaned.			
*38. Sampling equipment stored separate from test substance.			
39. Adequate separation between test substance and sample storage areas.			

*** Minimal GLP requirements associated with Series 860 and research protocol.**
N/A=Not Applicable

Comments

Field In-Life Inspection

ID #_____

E. Storage & Shipping	YES	NO	N/A
*40. Freezer inventory maintained and available at site.			
*41. Treated and untreated adequately separated.			
*42. Sample handling in proper order.			
*43. Prevention of cross contamination addressed.			
44. Shipping as per protocol.			
*45. Shipping equipment and supplies kept separate from test substance.			
*46. Shipped by [circle appropriate method(s)].			
a. freezer truck (i.e. ACDS, Inc.).			
b. truck with dry ice.			
c. commercial carrier with dry ice.			
d. other (list method).			
*47. Data book pages and forms properly.			
a. signed.			
b. dated.			
c. sample ID consistent with plot plan and protocol.			
d. chain of custody form included in shipping box.			
*48. Maintenance logs on storage equipment maintained and up to date.			
*49. Storage conditions adequately maintained according to SOP and protocols.			
*50. Storage temperature monitoring equipment properly calibrated / standardized.			

*** Minimal GLP requirements associated with Series 860 and research protocol.**
N/A=Not Applicable

Comments

Study Title: _____

Study No.:_____ Study Dir.: _____

Findings/Actions

QA Findings	Response/Actions Taken*

_____ _____

Quality Assurance Date Responder** Date

* - Place responses/ explanation of corrective action in space provided between findings or use a separate sheet of paper.

** Responder(s) are to assure they have identified themselves either by signing the bottom of this page or by initialing and dating the written response(s).

Study Title: _____

Study No.: _____ Study Director: _____

Findings, Responses and Actions Taken*:

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____ _____

Quality Assurance Date Responder** Date

* - Place responses/ explanation of corrective action in space provided to the right of the findings or use a separate sheet of paper.

** Responder(s) are to assure they have identified themselves either by signing the bottom of this page or by initialing and dating the written response(s).

SOP #: 8.5

AUTHOR: J.D. Forder and T. W. Barkalow

REVISION #: 08

EFFECTIVE DATE: October 7, 2013

TITLE: **Quality Assurance (QA) - Field Raw Data Audits**

PURPOSE: To detail procedures followed by IR-4 Quality Assurance Unit (QAU) or their representatives, when conducting field raw data audits of IR-4 field trials.

SCOPE: This SOP applies to all IR-4 facilities, and all IR-4 QAU authorized personnel auditing an IR-4 cooperating facility.

PROCEDURES:

1. An interim audit of the field raw data may take place at any time during the in-life portion of a field trial. Audits may occur at the time of a facility inspection, or an in-life phase inspection. There will be a raw data audit by the "assigned" QA at the conclusion of the trial, before the final report is completed. The assignment of a QA to a particular study will be done at the annual QA planning meeting, and will be reflected on the IR-4 Master Schedule.

2. Raw data will be checked for compliance to the protocol, GLP Standards and applicable SOPs, and for completeness and clarity. A summation of the current protocol requirements may be prepared and filed in the QA PR folder to be used for subsequent audits. All transcribed entries will be audited back to the original point of entry. If this cannot be done, provide comment on the location of the original entries in the QA report.

3. The audit may be conducted using the IR-4 Project Field Raw Data checklist (Appendix A) as a prompt and note taking tool. QA findings will be documented using the eQA system following the procedures in the current version of SOP 8.17. Explain all findings and questions fully. If appropriate, provide a recommended course of action. Be specific in the description of the finding or question and reference where it can be found in the raw data or checklist as appropriate. This will permit expeditious correction. Comments, if any, will be listed separately and do not require a response (a separate area can be found in section 3 for QA comments.

4. When conducting field raw data audits, the following items should also be reviewed:

   a) Have any data been electronically generated? If so, check SOP's and request assurance that system validation packages are complete and in compliance with GLP.

   b) Check to see the initial point of entry of raw data is the IR-4 Field Data Book or other appropriate form and that each set of entries is dated and initialed on the date of entry. When data from another study is photocopied and inserted, be sure the copy has been clearly identified with the location of the original.

   c) Verify that any protocol changes have been properly documented and authorized by the Study Director and Sponsor, and that the finalized protocol change forms have been received at the field site (or included in the final notebook).

   d) Check representative calculations independently of the raw data equations. If there are discrepancies or questions about the calculations, the reviewer's calculations must be presented as part of the QA report. Make sure the equipment calibration(s), rechecks and application(s) are within SOP and protocol specifications.

   e) Check to see that all problems encountered (GLP, SOP or protocol deviations) have been properly documented.

   f) Check to see that data entries are made in a timely manner (as the procedures are being performed).

   g) Check to see that all study related activities have been documented and provide clear and complete reconstruction. This is not an exhaustive list; the audit will take direction from the study protocol and its changes.

5. Any findings likely to affect the integrity of the study found during the audit of the data will be communicated to the Study Director and Testing Facility Management (TFM) immediately.

   This can be accomplished by a documented phone conversation, email, or other appropriate mechanism. Issues that may affect the integrity of the study include, but are not limited to:

   a) misapplication of the test substance
   b) incomplete documentation of GLP test substance characterization c) the PHI is out of protocol range
   d) serious lack of data that prevents study reconstruction
   e) lack of test substance storage records
   f) sample integrity is jeopardized by inappropriate storage temperatures or lack of storage temperature records

6. Note, responses may be made by either the FRD/technical staff or the Study Director depending on the availability of the field staff and the priority of the project, but if the FRD or his/her designate is assigned an activity, they must complete this activity or the administrator must alter the packet removing this requirement

7. Inspections performed at non-IR-4 test sites (e.g., Private Contract Facilities, Cooperating Laboratories) may be performed in accordance with the QA auditing procedures in their SOP's, provided they meet the requirements as defined in the current EPA GLPs. All audits generated outside of the IR-4 QAU will be handled as "external" audits as described in the current version of SOP 8.17.

8. Internal audits are not to be shown to persons outside of the IR-4 program, unless written authorization is received from IR-4 Management (i.e., Executive or Regional Director).

Revised By: _____ Date: 9/27/13

Approved By: _____ Date: 9/27/13

Study Title:
Field ID Number:

Form Group: Field Raw Data Audit
Packet ID: FDB-
Audit Type Chem/Crop/PR#(ID) :
Location:
Date:
Closed:

A. General
Yes, No, N/A

1. Protocol and applicable amendments(s)/deviations(s)present and approved:
2. Pages identified with field ID #:
3. Study personnel signatures complete:
4. Training documents sufficient:
5. All in use pages/entries signed and dated:
6. Data changes GLP compliant as per SOP:
7. Notes with sufficient detail:
8. Timeliness of documentation adequate:
9. Raw data complete:
10. All known exceptions to GLP included in compliance statement(If not please list):
11. a. All unused pages lined out, dated and initialed:
b. Pages properly numbered:
12. SOP deviations approved by Study Director:

B. Test Substance Receipt, Use & Disposition
Yes, No, N/A

13. Chemical receipt documents complete:
14. Chemical use log completed:
15. Balance calibration adequately recorded/bracketing weights used:
16. Chemical storage conditions (exact copy) covers through last application :
17. Location of test substance container during trial recorded:
18. Disposition of test substance container after trial conclusion explained :
19. Test substance characterized to meet GLP standards:

Study Title:
Field ID Number:

C. Test System Maintenance
Yes, No, N/A

20. Site map (location map) included:
21. Plot layout (detailed, accurate & neatly drawn):
22. Test system description adequately documented:
23. Buffer zone according to protocol:
24. Pesticide / fertilizer history documented:
25. Soil characterization included:
26. Soil characterization according to GLP:
27. Cultural practices recorded:
28. Maintenance chemicals use recorded:
29. Irrigation dates & amounts recorded:
30. Weather data included (exact copy):
a. Covers protocol specified period:

D. Test Substance Application
Yes, No, N/A

31. Application intervals per protocol:
32. Application type per protocol:
33. a. Application calibration according to protocol:
b. Application calibration according to SOP:
34. Material and application calculations correct:
35. Application description section complete:
36. Unique spray mix used for each trial:
37. Test substance applied within 2 hours of mixing:
38. Application rate met protocol requirements:
39. Environmental conditions at application recorded:
40. Was sticker / spreader adjuvant used?:
a. Expiration (if any):
b. Receipt data provided:

E. Sample Collection and Shipment
Yes, No, N/A

41. Sample collection and/or harvest information complete:
a. Sample weights recorded:
b. Cleaning, cutting, etc. documented:
c. Sample PHI/size/quantity met protocol requirements:
42. a. Shipping forms in raw data:
b. FedEx receipt / ACDS bill of lading included:

Study Title:
Field ID Number:

43. Sample storage conditions (exact copies):	
44. Custody of samples adequately documented:	
45. a. Sample storage in accordance with protocol:	
b. Sample storage in accordance with SOP:	
46. a. Sample shipment in accordance with protocol:	
b. Sample shipment in accordance with SOP:	
47. Crop destruction adequately documented:	
48. Lab notification of sample shipment documented:	

SOP #: 8.6

AUTHOR: J.D. Forder and T. W. Barkalow

REVISION #: 06

EFFECTIVE DATE: October 7, 2013

TITLE: **Quality Assurance (QA) - In-Life Inspection of the Analytical Phase of a Study.**

PURPOSE: To detail procedures followed by IR-4 Quality Assurance Unit (QAU) or their representative, when conducting in-life inspections of the analytical phase of an IR-4 study.

SCOPE: This SOP applies to all IR-4 facilities, and all QAU authorized personnel auditing an IR-4 cooperating facility.

PROCEDURES:

1. The Quality Assurance Officer (QAO) will coordinate with the Laboratory Research Director (LRD) and the Chemist doing the analysis as to potential times for inspection.

2. The number of audits conducted on a study will depend on the length of the study, the number of matrices, and complexity of the method. A re-inspection maybe warranted to ensure the integrity of the study. Each study will receive a critical phase inspection at least once while the analytical phase is in progress at the laboratory test site. The QAU will audit as many in-life phases as necessary to assure study integrity.

   In-life phases may include, but not be limited to:

   A) Sample Receipt
   B) Sample Processing
   C) Standard Preparation
   D) Dilutions
   E) Spike Preparations
   F) Derivatizations
   G) Extractions
   H) Sample Clean Up
   I) Instrument setup and analysis of samples

3. Key items for QA personnel to focus on include the following:

   A) Check to see that the protocol has been signed by the Study Director and Sponsor Representative. Take the complete protocol (including all changes) on all audits and document that it is being followed.

   B) Check to see the initial point of entry of raw data is the laboratory raw data book or other appropriate forms and that each set of entries are dated and initialed on the date of entry.

   C) Check to see that protocol changes have been properly authorized and documented by the Study Director and Sponsor. All pertinent protocol changes should be available at the test site. Pay special attention to assure that the method has been validated according to the protocol and that all changes to the validated method are documented and approved by the required personnel (the LRD and the Study Director).

   D) Check representative calculations independently of the raw data, if appropriate, for the audit being performed.

   E) Check to see that all problems encountered are documented, as well as any SOP and protocol deviations. All SOP deviations must be authorized in writing by the Study Director.

   F) If time permits, conduct an interim raw data review for completeness and documentation.

   G) Assure that personnel are properly trained and that the training is documented.

4. The analytical inspection may be conducted utilizing the IR-4 Project Lab Critical Phase Inspection checklist (Appendix A) as a note taking tool. Findings will be documented using the eQA Laboratory Critical Phase Inspection form as per the current version of SOP 8.17. If appropriate, provide a recommended course of action. If appropriate, reference findings to the item on the in-life checklist form (e.g., B.14).

   Once the inspection has been completed, and as appropriate, discuss the findings with the LRD and/or Chemist. Use this as a training event, to prevent similar findings in the future. QAO is to prepare the audit report within 6 weeks.

5. Any adverse QA findings likely to affect the integrity of the study must be reported to the Study Director and Testing Facility Management (TFM), immediately. This can be done by documented telephone conversations, e-mail, or by fax. Examples of critical items that may adversely affect the integrity of the study include, but are not limited to:

   A) Changes to the method after validations that have not been signed off by the LRD and Study Director.

   B) Sample integrity in storage has been jeopardized.

   C) Expired or incorrect standards have been used for analysis or spiking.

   D) Incomplete documentation of GLP reference substance characterization is incomplete

   The LRD will respond to the findings within the time frame set in eQA system according to the current version of SOP 8.17.

6. Inspections performed at non-IR-4 test sites (e.g., Private Contract Facilities, Cooperating Laboratories) may use the QA auditing procedures in their SOP's, provided they meet the requirements as defined in the current US EPA GLPs. These external audits will be routed via eQA according to the current version of SOP 8.17.

7. Internal audits are not to be shown to persons outside of the IR-4 program, unless written authorization is received from IR-4 Management (i.e., Executive or Regional Director).

Revised By: _____ Date: 9/27/13

Approved By: _____ Date: 9/27/13

Study Title:
Lab ID Number:

Form Group: Lab Critical Phase Inspection
Packet ID: LCPI-
Audit Type Chem/Crop/PR#(ID) :
Location:
Date:
Closed:

A. General
Yes, No, N/A

1. Protocol and method available to appropriate personnel:
2. Discovered changes/revisions of approved protocol documented:
3. Procedures, as listed in the protocol, being followed:
4. Modifications to the validated method documented and approved by the LRD and Study Director:
5. Lab operations relating to study conducted according to SOPs:
6. SOPs available to lab personnel:
7. SOP deviations documented in the raw data:
8. SOP deviations approved by the Study Director:
9. Adequate number of trained personnel:
10. Observed procedures relating to study:
11. Observed procedures conducted for protocol:

B. Equipment/Instrument
Yes, No, N/A

12. Equipment calibrated/standardized:
13. Equipment cleaning/maintenance is documented:
14. Logbooks up-to-date:
15. SOP for equipment in place and current:

Study Title:
Lab ID Number:

C. Samples
Yes, No, N/A

16. Sample is uniquely identified to::
a. Protocol:
b. SOP:
17. Sample ID appears on container:
18. Sample container is identified by:
a. Test System:
b. Field ID Number:
c. Nature of the sample:
d. Date of collection/ site:
Test Substance:
19. Samples are maintained under proper storage:
a. Sample storage location documented:
b. Temperature and maintenance records up-to-date:
20. Sample preparation (ie, processing, extraction, analysis, etc.) is properly recorded:
21. Sub-samples are properly identified during:
a. Sample Processing/grinding:
b. Weighing/subsampling:
c. Sample extraction(s) and cleanup(s):
22. Sample integrity maintained during preparation:

D. Reagents, Solvents and Solutions

23. Reagents, Solutions, Solvents are labeled:
a. Identity/concentration/storage requirements:
b. Expiration date:
24. Standard Solutions:
a. Have been prepared according to SOPs/method:
b. Have been properly labeled:
i. Identity/concentration:
ii. Date prepared/prepared by (if applicable):
iii. storage conditions/expiration date:
c. Are not out-of-date:
d. Are properly stored:

Study Title:
Lab ID Number:

E. Recording of Data

25. Hand generated data are properly recorded:

a. Directly, promptly, legibly:

b. In indelible ink:

c. On an appropriate form or in lab raw data:

26. Entries are dated and initialed appropriately:

27. Analytical standards used are properly identified in the raw data:

28. Changes to raw data. Do not obscure the original entry:

a. Explained:

b. Dated:

c. initialed:

29. Computer generated data:

a. Program has been validated:

b. Input personnel identified:

c. Data calculation verified:

30. Lab raw data stored according to SOP:

SOP #: 8.7

AUTHOR: J.D. Forder, T. W. Barkalow

REVISION #: 06

EFFECTIVE DATE: October 7, 2013

TITLE: **Quality Assurance (QA) - Analytical Raw Data Audits**

PURPOSE: To detail procedures followed by IR-4 Quality Assurance Unit (QAU) or their representative, when conducting analytical raw data audits of IR-4 studies.

SCOPE: This SOP applies to all IR-4 facilities, and all QAU authorized personnel auditing an IR-4 cooperating facility.

PROCEDURES:

1. An audit of the analytical raw data may take place at any time during the in-life portion of the analytical phase of a study. Audits may occur at the time of a facility inspection, an in-life phase inspection or in conjunction with the analytical summary report. This will typically be done at the laboratory location, prior to the analytical summary report being forwarded to the IR-4 HQ.

2. Raw data will be checked for compliance, completeness and clarity. Transcribed entries will be audited back to the original point of entry. A minimum of an approximately 10% check of the data will be performed. This will include an audit of the laboratory bench books or other forms where sample preparation is documented, the calculation spreadsheets or printouts, dilution records, storage temperatures, etc. If errors (e.g., calculation errors, incomplete entries, transcription inaccuracies, etc,) or GLP compliance issues are discovered, the auditor will decide if they should do additional auditing or return the raw data for corrections before continuing.

3. When conducting analytical raw data audits, the following items should be reviewed, but not necessarily limited to:

   A) Review the data to see if it has been electronically generated/collected. If so, check SOP's and system validation packages for completeness and compliance.

   B) Check to see that hand entered data has been recorded on an appropriate form or into a laboratory bench book. See that each set of entries is entered in ink, dated and initialed on the date of entry.

   C) Check to see that all pertinent protocol changes have been properly authorized and documented by the Study Director and Sponsor.

   D) Check representative calculations independently of the raw data equations. See that they are within SOP and protocol specifications.

   E) Check dilution records and reference substance distribution documentation.

   F) Check to see that all problems encountered are documented. Verify that all SOP deviations have been documented and approved by the Study Director.

   G) Check to see that data entries are made in a timely manner (as the procedures are being performed).

4. The raw data audit may be conducted utilizing the IR-4 Project Quality Assurance Analytical Raw Data Audit Checklist (Appendix A) for note taking purposes. Findings will be documented using the Analytical Raw Data Audit form in the eQA system following the current version of SOP 8.17. Explain all findings fully.

   If appropriate, provide a recommended course of action. Be specific in the description of the finding and reference where it can be found in the raw data. This will permit expeditious correction. If appropriate, reference QA findings to the item on the raw data review checklist form (e.g., B.11).

5. Any findings likely to affect the integrity of the study found during the audit of the data will be communicated to the Study Director and Testing Facility Management (TFM) immediately. This can be accomplished by a documented phone conversation or fax, or other appropriate mechanism.

6. Issues that are likely to affect the integrity of the study include, but are not limited to:

   A) Lack of sample or reference material storage records.

   B) Sample integrity is jeopardized by inappropriate storage temperatures.

   C) Changes to the validated method have been made without having been communicated to the Study Director. This can be in the form of a planned modification or an inability to meet the specifications of the validated method.

   D) Documentation of GLP reference substance characterization is incomplete

7. Once the QA inspection report has been completed, discuss the findings with the Laboratory Research Director (LRD) and/or Chemist, if appropriate. Use this discussion as a training event to prevent similar findings in the future. Prepare the audit report within 6 weeks. The LRD will respond within the time frame set in the eQA system according to the current version of SOP 8.17.

8. For reporting purposes, the inspecting QAO will use the date the report was completed by QA and forwarded to the TFM for the QA statement in the analytical summary report. The final report (generated at IR-4 HQ) will contain a QA statement that will reflect the actual date the Study Director and TFM were informed of QA findings via the eQA system.

9. Inspections performed at non-IR-4 test sites (e.g., Private Contract Facilities, Cooperating Laboratories) may use the QA auditing procedures in their SOP's, provided they meet the requirements as defined in the US EPA GLPs. These external

audits will be routed via eQA according to the current version of SOP 8.17.

10. Audits are not to be shown to persons outside of the IR-4 program, unless written authorization is received from IR-4 Management (i.e., Executive or Regional Director).

Revised By: _____ Date: 9/27/13

Approved By: _____ Date: 2 Oct 2013

Study Title:
Lab ID Number:

Form Group: Analytical Raw Data Audit
Packet ID: ARDA-
Audit Type Chem/Crop/PR#(ID) :
Location:
Date:
Closed:

A. General
Yes, No, N/A

1. Approved protocol and method included in raw data package:
2. Changes were authorized by the Study Director, as per protocol:
3. Method used for analysis was validated per protocol prior to us in analyzing study samples:
4. All modifications to the referenced method were documented, validated, signed and dated by the LRD (working method):
5. All SOP deviations listed in the raw data:
6. All SOP deviations authorized by Study Director:
7. Appropriate personnel signatures included in raw data:
8. All data corrections properly explained, initialed and dated:
9. All pages properly identified:
10. Procedures used in generating raw data were described in the SOPs, protocol and /or study raw data:

B. Sample Storage and Preparation
Yes, No, N/A

11. Samples traceable through chain of custody documentation:
    a. Receipt:
    b. Storage:
    c. Distribution:
12. Sample preparation according to SOP:
13. Sample preparation adequately recorded:
14. Sample preparation followed validated method:
15. Sample storage location(s) documented:
16. Sample storage temperatures documented:
17. Date and times samples taken in and out of the freezer are logged and within SOP requirements:
18. Storage duration and conditions of storage of samples & stability samples are the same:

Study Title:
Lab ID Number:

C. Analytical Reference Standards and Fortification Solutions
Yes, No, N/A

19. Check all analytical standard used, source, batch numbers and expiration dates for acceptability:
20. Certified copy of certificate of analysis for standard(s) is in the study file:
21. Standard(s) solution was used prior to their expiration dates:
22. Accountability of reference standards:
a. Records and receipts:
b. Use logs up-to-date (distribution and disposal):
c. Storage logs:
d. Storage location(s):
e. Storage conditions:
23. Laboratory raw data documents the standard used (proper identification maintained):
24. Retention sample of the standard in the IR-4 Laboratory chemical archive or other archive facility is documented:
25. Logbook(s) for balance(s) contain calibration documentation:
26. Standard solutions documentation adequate:
a. Stock:
b. Analytical standards:
c. Fortification solutions:

D. Data Inspection
Yes, No, N/A

27. Raw data properly recorded:
a. Promptly and legibly in ink:
b. Dated on day of entry and signed or initialed:
c. Changes to entries did not obscure the original:
d. Corrections were explained, dated, and signed or initialed.
28. Computer generated data:
a. Program has been validated:
b. Input personnel identified:
c. Printout signed:
d. Printout dated:
29. Numerical results reported were consistent for significant figures, rounding-off numbers, etc. with SOPs:
30. Units of concentration were clearly identified:
31. Instrument parameters were documented for each set of runs:
a. Instrument conditions /date:

Study Title:
Lab ID Number:

b. Study number:	
c. Lab sample/standard concentration:	
d. Analyst(s) / operator(s) initials:	
e. Injection volume:	
32. Injection sequence. All chromatograms retained in continuous sets per run:	
33. Samples fall within standard curve range:	
34. Chromatograms and standard curves audited:	
35. Integrator chromatograms and /or computer generated chromatograms compared to data report:	
36. Analytical instrument logbooks showed proper documentation and operation:	
37. Analytical sets, including standards and fortifications according to SOPs and protocol:	
38. Limits of quantization and detection (LOQ and LOD) were clearly defined:	
39. Calculations were accurate:	
40. Recoveries outside of 70 - 120 % range documented and authorized by the LRD and the Study Director:	

SOP #: 8.8

AUTHOR: J.D. Forder, T. W. Barkalow

REVISION #: 05

EFFECTIVE DATE: October 7, 2013

TITLE: **Quality Assurance (QA) - The Analytical Summary Report Audit (ASR).**

PURPOSE: To detail procedures followed by IR-4 Quality Assurance Unit (QAU) or their representative, when conducting analytical summary report audits of IR-4 sponsored studies.

SCOPE: This SOP applies to all IR-4 facilities, and all QAU authorized personnel auditing an IR-4 study, except as noted.

PROCEDURES:

1. Upon receipt of the draft analytical summary report, a member of the Quality Assurance Unit will log it into the Quality Assurance Log for ASR Tracking (Appendix A) or comparable tracking system. The information entered at this time will be study number, test/reference substance, crop, and the date received by QA. The author will also ensure that all raw data are presented with the report, or will be made available to the auditor. In the rare event that the ASR audit is conducted without access to the data, the inability to access the data will be noted on the QA audit report.

2. When the report is reviewed, QA may utilize the checklist (Appendix B) for note taking. The protocol will be reviewed in its entirety and the report reviewed for compliance with SOPs, GLPs, the protocol and all protocol change forms.

   A minimum of approximately 10% of the data presented in the text of the report and the tables/calculation sheets in the report will be audited back to the original data. This percentage may be increased at the discretion of QA or the auditor may return the report for further review and correction before continuing with the audit.

QA will assure that the report reflects the methods, the SOP's, the raw data of the study, and that all circumstances that may affect the quality or integrity of the data are discussed in the text of the report.

At this time, all analytical inspections done on the study should be reviewed to ensure that all findings previously identified were addressed and documented. If the final audit of the raw data has not yet been performed, this should be conducted in association with the analytical summary report audit following the current version of SOP 8.7.

3. The results of the report audit will be documented using the IR-4 Project Analytical Summary Report Audit form in the eQA system following the current version of SOP 8.17. Any suspected GLP, SOP, or protocol deviations or findings will be documented. All findings should be fully explained. If appropriate, provide a recommended course of action. If appropriate, reference findings to the item on the review checklist form(s) (e.g., B.10). Any findings likely to affect the integrity of the study found during the audit of the ASR will be communicated to the Study Director and Testing Facility Management (TFM) immediately. This can be accomplished by a documented phone conversation or fax, or other appropriate mechanism.

4. Once the inspection report has been completed discuss the findings with the LRD or investigator at the test site, as appropriate. Use this as a training event, to prevent similar findings in the future

5. The QAO is to complete the audit report form within 6 weeks and request that the LRD document their responses and corrective actions taken.

6. The LRD will respond within the time frame set in the eQA system according to the current version of SOP 8.17.

7. All raw data and the analytical summary report must be archived at the time of completion of the analytical report at the test site (at or before the time the LRD signs the analytical summary report), unless provided for in the protocol. At this time a notation will be made on the master schedule at the test site, indicating that the lab phase of the study is completed.

8. For reporting purposes, the inspecting QAO will use the date the QA portion of the eQA report was completed and forwarded to the TFM for the QA statement in the analytical summary report. The final report (generated at IR-4 HQ) will contain a QA statement that will reflect the actual date the Study Director and TFM were informed of QA findings and the actions taken via the eQA system.

9. Inspections performed at non-IR-4 test sites (e.g., Private Contract Facilities, Cooperating Laboratories) may use the QA auditing procedures in their SOP's, provided they meet the requirements as defined in the US EPA GLPs. These external audits will be routed via eQA according to the current version of SOP 8.17.

   Audits are not to be shown to persons outside of the IR-4 program, unless written authorization is received from IR-4 Management (i.e., Executive or Regional Director).

Revised By: _____ Date: 9/27/13

Approved By: _____ Date: 9/27/13

Appendix A, SOP 8.8:05

Quality Assurance Log for Analytical Summary Report Tracking

Study No.	Pesticide/Crop	Date in to QA	Date returned to LRD/Chemist	Date back to QA	Date returned	Comments

QAASRLOG800

Study Title:
Lab ID Number:

Form Group: Analytical Summary Report Audit
Packet ID: ASRA-
Audit Type Chem/Crop/PR#(ID) :
Location:
Date:
Closed:

A. Cover Page
Yes, No, N/A

1. PR#:
2. Title:
3. Author(s):
4. Report Date:
5. Sponsor:
6. Study Director (Name):
7. Laboratory Research Director (Name/Location):
8. Laboratory ID#:
9. Field ID #s:
10. Study Timetable:
a. Initiation date:
b. Experimental termination date:

B. Good Laboratory Practice (GLP) Statement
Yes, No, N/A

11. Exceptions to the GLP standards listed:
12. Analyst's and Laboratory Research Director's signatures:

C. Quality Assurance Statement
Yes, No, N/A

13. Complete (includes date of inspection, person inspecting, date reported to SD & TFM):
14. Signed & dated:

D. Study Participants
Yes, No, N/A

15. All study participants listed:

E. Table of Contents
Yes, No, N/A

16. Index contains all sections of report:
a. List of tables:
b. List of Figures:
c. Appendices:
d. Page numbers included and accurate:

Study Title:
Lab ID Number:

F. Archive Statement
Yes, No, N/A

17. Data archive location provided & according to the protocol:

G. ASR Content
Yes, No, N/A

18. Objective(s) / Introduction included:
19. Sample Inventory History:
a. Test System:
i. Commodity:
ii. Field ID#s:
iii Field Research Director name(s):
iv. Total # of samples:
v. Form of sample (whole, ground, etc.):
b. Lab ID Number(s):
c. Storage (storage period & temperature for samples & extracts):
d. Relevant dates (e.g., harvest, sampling, application(s), processing, fortifications, extractions, analyses, etc.):
e. Test substance:
f. Were storage samples stored in the same form as samples (same container? ground?):
20. Materials/Methods:
a. Working method with modifications to reference method presented. :
b. Analytical standard(s) (Name, source, lot#, purity, expiration date [if any], storage conditions):
c. Reagents:
d. Equipment used:
e. Preparation of standards and fortification solutions adequately documented:
f. Preparation of reagents:
g. Description of sample preparation (sub-samples, chopping or grinding used for analysis):
h. Fortification procedures - concurrent, storage & validation:
i. Analytical procedure:
j. Instrument(s) and parameters used:
k. Limits of detection and quantitation (defined in SOP?):
l. Method of quantitation (e.g., software used) sample calculation provided. :
21. Results and Discussion:
a. Analytical results have been accurately transcribed to the study report. :
b. All relevant raw data were presented in the report:

Study Title:
Lab ID Number:

c. Use of correction factors clearly presented. If corrected values reported the apparent values are also present?:

d. Explanation/description of calculation technique presented, if an automated data calculation method used:

e. Sample calculations for fortified control, at a minimum:

f. Calibration curves or bracketing standard values presented:

g. Clearly labeled representative chromatograms/spectra.:

i. If ten or less treated samples, all?:

ii. Greater than 10, a min. of 10 treated sample chromatograms present:

iii. Min. of 3 chromatograms of each fortified control and control samples:

iv. Standard (min of 3 chromatograms) per analyte or as per protocol:

h. Dates test sample prep, test compound(s) prep and residue analyses. :

H. Summary Tables

22. Analytical recovery Samples (method validation and concurrent):

a. Residue Data Report Analysis Sheet(s):

b. Fortification recoveries were within 70 to 120%:

23. Treated Samples:

a. Time samples stored before analysis:

b. Time between preparation and quantitation:

c. Residue Data Report Analysis Sheet(s):

24. Storage Stability:

a. Sample forms in storage reported (intact, chopped, extracted, etc.):

b. Storage conditions specified (temperatures and containers, etc):

c. Dates of fortification, extraction and analysis:

d. Residue Data Report Analysis Sheet(s):

I. Appendices

25. Reference Substance Characterization:

a. Contains GLP status and archival location:

b. Copy of Certificate of Analysis presented:

SOP #: 8.9

AUTHOR: J.D. Forder, T. W. Barkalow

REVISION #: 07

EFFECTIVE DATE: October 7, 2013

TITLE: **Quality Assurance (QA) - The Final Draft Report and Study File Audit.**

PURPOSE: To detail procedures followed by IR-4 Quality Assurance Unit (QAU) or their representative, when conducting draft final report and raw data audit of IR-4 sponsored studies.

SCOPE: This SOP applies to all IR-4 facilities and all QAU authorized personnel auditing an IR-4 study, except as noted.

PROCEDURES:

1. When submitting an interim or draft final report to the QAU, the Study Director (SD) /Author will log it into the Quality Assurance Final Report Log (Appendix A) at IR-4 HQ. The information entered will include the Study No., Pesticide/Crop, Type of Report (see footer of log for report types), Lab, QA (to whom report was sent to), SD, and the date submitted to QA. The log will be updated as the report moves in and out of QA. The author will ensure that all raw data are presented with the final report, or will be made available to the auditor. If the package is not complete, (as may happen on occasion) the SD will be notified and the data will be made available to the QAO prior to the audit completion.

2. An audit of the interim report will be documented using the eQA system Final Report Audit 1 as per the current version of SOP 8.17 (see Appendix B for note taking checklist). See the current version of SOP 6.0 section 4.a for specifics involved with the auditing and reporting of interim final reports.

3. When the completed draft final report is to be audited the Quality Assurance Officer (QAO) may use the checklist in Appendix B for note taking purposes and report the audit using

the eQA form Final Report Audit 1 as per the current version of SOP 8.17. If the eQA audit form is to have the SD and another person assigned an activity, then the report must be sent to QA accompanied by a cover letter (or other communication) that indicates this and that contains the identity of the person that will be assisting the SD.

The protocol will be reviewed in its entirety and the report reviewed for compliance with SOP's, GLP's, the protocol and all protocol change forms. The data presented in the text of the report and the tables/calculation sheets in the report will be audited back to the raw data. The auditor may return the report for further review and correction before continuing with the audit if numerous omissions/errors are found in the package. QA will assure that the report describes the methods and SOP's, that the reported results accurately reflect the raw data of the study, and that all circumstances that may affect the quality or integrity of the data are discussed in the text of the report. At this time, all inspections done on the study should be reviewed to assure that all findings previously identified by QA were addressed and documented. If the final audit of any of the raw data has not yet been performed, this should be conducted in association with the final report review following the current version of the appropriate SOP.

4. The report shall also be reviewed for compliance to the requirements of the US Environmental Protection Agency (EPA) PR 2011-3 or current policy.

5. The results of the audit will be documented using the eQA system form "Final Report Audit 1"following the procedures in the current version of SOP 8.17. Any suspected GLP, SOP, protocol deviations, or findings will be documented. All findings should be fully explained. If appropriate, provide a recommended course of action. If appropriate, reference QA findings to the item on the review checklist form(s) (e.g., B.15).

6. Any findings likely to affect the integrity of the study found during the audit of the data will be communicated to the Study Director and Testing Facility Management (TFM) immediately. This can be accomplished by a documented phone conversation or fax, or other appropriate mechanism.

7. Inspections performed at non-IR-4 test sites (e.g., Private Contract Facilities, Cooperating Laboratories) may use the QA auditing procedures in their SOP's, provided they meet the requirements as defined in the current version of the US EPA GLPs. These external audits will be routed via eQA according to the current version of SOP 8.17.

8. Audits are not to be shown to persons outside of the IR-4 program, unless written authorization is received from IR-4 Management (i.e., Executive or Regional Director).

Revised By: _____ Date: 9/27/13

Approved By: _____ Date: 9/27/13

Quality Assurance Final Report Log

Study No.	Pesticide/Crop	Type* Of Report	Lab	QA	SD	Date Submitted To QA	Date Back To SD	Date Back To QA	Date Back To SD	Date Back To QA	Date Returned To SD	Comments

*Type of Report P = data volume to accompany a petition. R = re-registration data volume. L = data volume to support a label change.

A = amended final report. ASR = Analytical Summary Report I = Interim Report

Created on 8/8/2013 4:06:00 PM . Updated 3/15/12

SOP 8.9 R7 App. A

Study Title:
PR Number:

Form Group: Final Report Audit 1
Packet ID: FRA1-
Audit Type Chem/Crop/PR#(ID) :
Location:
Date:
Closed:

A. General
Yes, No, N/A

Meets EPA formatting requirements:
a. Are all pages of the final report readable?:
2. Name and address of all testing sites included:
3. Name and address of Sponsor:
4. Study initiation date:
5. Experimental start date:
6. Experimental completion date:
7. Study completion date (completion, terminated or discontinued :
8. Quality Assurance statement accurate and complete:
9. Names on GLP Compliance Statement :
a. Study Director:
b. Applicant/Submitter:
c. Sponsor/Management:
10. GLP Compliance Statement accurately reflects study compliance:
11. Names of all scientists/professionals involved. :
12. names of supervisory personnel. :
13. Objectives and procedures as stated in approved protocol present. :
a. Protocol changes all documented, authorized and available:

B. Test, Control and Reference Substances
Yes, No, N/A

14. Name, CAS or code number of::
a. Test substance:
b. Control substance:
c. Reference substance:
15. Chemical Characteristics (Analytical and Field):
a. Strength:
b. Purity:
c. Composition:
d. Stability/solubility under test conditions:
16. Storage condition of test/reference

Study Title:

PR Number:

materials monitored:	
a. Analytical reference standards:	
b. Field trial test material (Each Site):	
17. Archival of retention sample(s). (Test, Control and Reference):	
18. Date of test material receipt & expiration (if applicable):	
a. Analytical:	
b. Field trial (each site):	
19. Test material application:	
a. Description of application(s):	
b. Application intervals given. :	
c. Type of application given (foliar, ground, etc):	
d. Number of applications:	
e. Sample calculations:	

C. Test System Description
Yes, No, N/A

20. Description of test system (field):	
a. Source of seeds, transplants, etc.:	
b. Species of seeds, transplants, etc. :	
c. Procedure for identification of plots:	
d. Age of the test system (crop):	
e. Plot size:	
f. Soil type/characteristics (protocol requirement):	
21. Description of methods used (fields):	
a. Plot pesticide history meets protocol:	
b. Cultivation/agriculture techniques:	
c. Maintenance chemicals used:	
d. Irrigation amounts/schedule:	
e. Sampling and collection intervals(s):	
f. Procedures used to control bias:	
g. Shipping documentation:	
22. Test environmental conditions:	
a. Weather at field sites:	
b. On-site observations of unique occurrences:	
23. Description of all circumstances affecting the quality and integrity of the data:	
24. Test system analysis:	
a. Equipment used are described:	
b. Method used/description presented:	
c. Description of standard solution prep.:	
d. Description of spike prep. :	
e. Calculations/transformation to the data explained (example calculation shown):	
f. Method problems explained:	
25. Final report contains all details necessary to summarize the study procedures and conclusions. :	

Study Title:
PR Number:

26. All contributing scientist's reports included. :

D. Data Analysis
Yes, No, N/A

27. Raw data completeness (See Raw Data Checklists for field and lab work):
a. Analytical:
b. Field Trials:
28. All relevant raw data reported and omissions explained. :
29. Description of::
a. Data transformations:
b. Operations performed on data:
c. Recoveries:
d. Summary of analysis of data:
e. Conclusions drawn from data:
30. Statistical methods employed:

E. Data/Specimen Storage and Archival
Yes, No, N/A

31. Location identified for::
a. Final Report (Required to be maintained by Sponsor and test facility):
b. Raw Data (Original?) (Field and Lab?):
c. Archival of specimens (if not archived, disposition noted):
d. test material characterization data:
e. test material retention sample archived?
f. reference material characterization data:
g. reference material retention sample archived? :
32. All QA audit/inspection reports complete with findings addressed. :

SOP #: 8.10

AUTHOR: Jane D. Forder, K. A. Hackett-Fields and T. L. White

REVISION #: 03

EFFECTIVE DATE: April 15, 2007

TITLE: **Quality Assurance (QA) - Training of New Quality Assurance Auditors**

PURPOSE: To detail procedures followed by the IR-4 Quality Assurance Manager when training Quality Assurance Auditors.

SCOPE: All IR-4 QA auditors concerned with auditing and inspecting project data, reports and IR-4 cooperating facilities.

PROCEDURES:

1. All QA auditors will be properly trained in accordance with their job description and GLP requirements. Training will be documented using the Quality Assurance Training Record (Appendix A), and by use of any records available from previous employment. Attendance at seminars, meetings and any other training sessions will be documented by certificates received, but should also be added to the employee's CV.
   These records are to be maintained in the personnel file of the QAA at their facility.

2. When training to be an IR-4 QA Auditors (and therefore a member of the cooperative IR-4 QAU), the following materials will be reviewed:

   a) The current US EPA Good Laboratory Practice Standards

   b) Preambles to the FDA and EPA GLP Standards

   c) EPA GLP Advisories, to-date

   d) The EPA Question and Answer Document of May 12, 1992

   e) The EPA FIFRA GLP Enforcement Response Policy

   f) The "Operational Handbook of the IR-4 Project To Fulfill the Requirements of EPA for Good Laboratory Practices (current version)

   g) IR-4 QA SOP's, especially Sec. 8. In addition, a typical SOP set from a field site in each region will be reviewed.

   h) Documents from Training Workshops

   i) IR-4 Advisories

   j) QA Peer Review 2002 – Results and Implementation

3. Following these initial reviews, the QA Manager or designee will review the IR-4 Master Schedule with the new employee, in conjunction with its SOP. Particular emphasis should be placed on the use of the electronic version and obtaining information via the database.

4. It is recommended that arrangements be made for new QA auditors to spend as much time as necessary in the laboratory and/or field, observing various procedures, to gain a more thorough understanding of study conduct.

5. Depending on the experience level of the new employee, raw data audits will generally be a primary focus of initial training. Prior to auditing any report, protocol or raw data, it is recommended that the new QA auditor become familiar with the following for that particular type of report:

   a) Office of Pesticide Programs Testing Guidelines (Series 860.1000, 860.1380, 860.1500 860.1520, or as applicable). Refer to: http://www.epa.gov/opptsfrs/OPPTS_Harmonized/860_Residue_Chemistry_Test_Guidelines/Series/

   b) Standard Evaluation Procedures (SEP's), Appendix B.

   c) Individual Report/protocol/raw data checklist(s)

   Until the QA Manager is satisfied that audits are being properly conducted, discussion (or review of the work) with the new auditor of her/his findings will be routine, and documented on the audit. This will permit proper documentation on the QA Statement as the project nears completion.

6. Whenever possible, new QA auditors should accompany experienced QA Auditors on inspections of testing facility sites. This should be followed up by periodic reviews and training to assist the new QA auditor in building his/her expertise in Quality Assurance.

7. Final reports will be reviewed by a new QA Auditor at the discretion of the trainer and/or supervisor. As with raw data, these initial attempts should also be reviewed with an experienced QA Auditor, until such time that the QA Manager authorizes the new QA auditor to work independently.

8. Other training will be provided for duties agreed upon and documented in the position requirements. Training specific to the QA Auditor's University or other work site will be provided as appropriate.

9. Training and certification appropriate to Quality Assurance will be determined by the employee's supervisor and/or Management. This may include attendance at seminars, meetings, workshops given by qualified entities and individuals, as well as in-house and University-provided training. Active membership in the Society of Quality Assurance and/or its chapters and specialty sections will be maintained, if deemed necessary by QA or TFM management.

Revised By: _____ Date: 3/30/07

Approved By: _____ Date: 4-2-07

Training Record, IR-4 QAU

Employee Name, Title: **Change in Title, as of:**

Date	Subject/Skill	Initials	Trainer or Site	Proficient[a] (Y/N, or detail)	Notes
	Working knowledge, GLP				
	Review of IR-4 SOP				
	RQAP status				
	Regulatory Inspection Prep.				
	Regulatory Document Reviews				
	SOP 8.10 Appendix B				
	SOP 8.10 Appendix C				
	A copy of the SOP may be used to document reviews of all other listed reference materials; enter date of review, and verification of proficiency (understanding)				
	Audit Procedures				
	Protocols				
	Field Raw Data				
	Reports – "secondary"				
	Preparation of Report QAS				
	Lab Raw Data				
	Reports – "primary"				
	ASR – typical format				
	ASR – in-depth review				
	Inspection Procedures				
	Field Facility				
	Greenhouse				
	Post Harvest Trtmt. Facility				
	Processing				
	Specialty grower(s)				
	Analytical Laboratory				
	Others (list) _____				
	_____				
	_____				

Training Record, IR-4 QAU

Employee Name, Title:

Date	Subject/Skill	Initials	Trainer or Site	Proficient[a] (Y/N, or detail)	Notes
	Administrative				
	[left open for specifics in each Region/HQ]				
	Other Training (specify)				
	[left open for specifics in each Region/HQ]				

[a] If previous experience warrants, reference "Exp." and include sufficient documentation.

United States
Environmental Protection
Agency

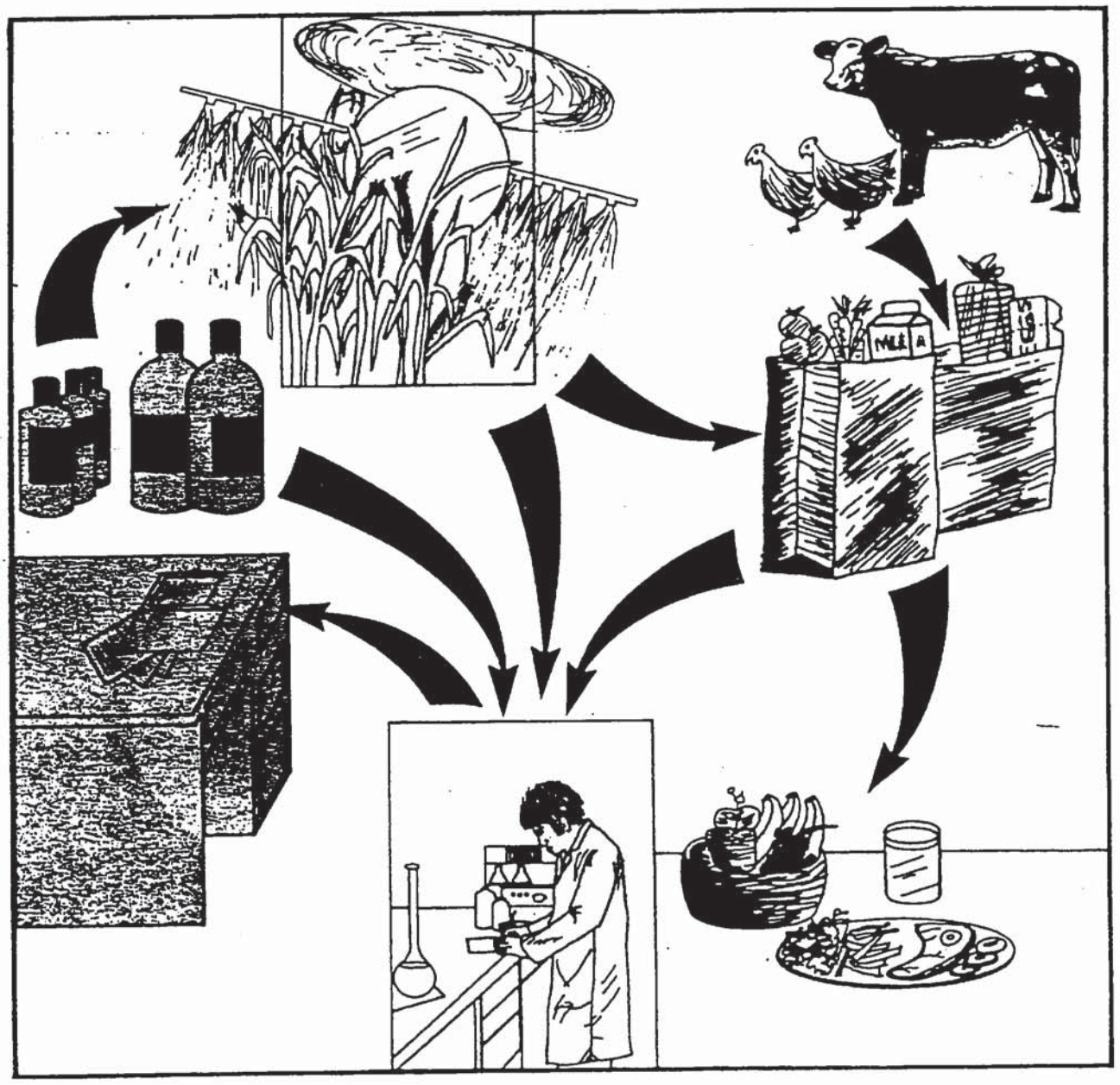
Office of Pesticides Programs
Washington, DC 20460

EPA-540/9-85-021
June 1985

EPA

Hazard Evaluation Division
Standard Evaluation Procedure

Magnitude of the Residue: Crop Field Trials



EPA-540/9-85-021
June 1985

HAZARD EVALUATION DIVISION

STANDARD EVALUATION PROCEDURE

MAGNITUDE OF THE RESIDUE:

CROP FIELD TRIALS

Prepared by

M. J. Nelson, Ph.D.

Standard Evaluation Procedures Project Manager
Stephen L. Johnson
Hazard Evaluation Division
Office of Pesticide Programs

United States Environmental Protection Agency
Office of Pesticide Programs
Washington, D.C. 20460

STANDARD EVALUATION PROCEDURE

PREAMBLE

This Standard Evaluation Procedure (SEP) is one of a set of guidance documents which explain the procedures used to evaluate environmental and human health effects data submitted to the Office of Pesticide Programs. The SEPs are designed to ensure comprehensive and consistent treatment of major scientific topics in these reviews and to provide interpretive policy guidance where appropriate. The Standard Evaluation Procedures will be used in conjunction with the appropriate Pesticide Assessment Guidelines and other Agency Guidelines. While the documents were developed to explain specifically the principles of scientific evaluation within the Office of Pesticide Programs, they may also be used by other offices in the Agency in the evaluation of studies and scientific data. The Standard Evaluation Procedures will also serve as valuable internal reference documents and will inform the public and regulated community of important considerations in the evaluation of test data for determining chemical hazards. I believe the SEPs will improve both the quality of science within EPA and, in conjunction with the Pesticide Assessment Guidelines, will lead to more effective use of both public and private resources.

John W. Melone, Director
Hazard Evaluation Division

TABLE OF CONTENTS

MAGNITUDE OF THE RESIDUE: CROP FIELD TRIALS[1,2]

I. INTRODUCTION

A. Purpose of the Standard Evaluation Procedure

This Standard Evaluation Procedure is designed to aid Residue Chemistry Branch data reviewers in their evaluations of crop field trial studies submitted by petitioners/ registrants. This particular Standard Evaluation Procedure document addresses crop raw agricultural commodities.[1]

B. Background Information

Crop field trials to provide residue chemistry data on the magnitude of the residue are required by 40 CFR 158.125 to support the registration of any pesticide intended for use on a food or feed crop under the amended Federal Insecticide, Fungicide, and Rodenticide Act.

Residue chemistry data on raw agricultural commodities (r.a.c.'s) are used by the Agency to estimate the exposure of the general population to pesticide residues in food, and for setting and enforcing tolerances for pesticide residues in or on raw agricultural foods or feeds under provisions of Section 408 of the Federal Food, Drug, and Cosmetic Act. [Note: Processed foods and feeds are regulated under Section 409 of the Act.]

Residue chemistry data are also needed to support the adequacy of one or more methods for the enforcement of the tolerance, and to support practical methods for removing residues that exceed any proposed tolerances.

C. Objective of Crop Field Trials

Crop field trial studies should answer the following question: What is the maximum level of "total toxic residue" that will

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1/ Other aspects of the Magnitude of the Residue [see 40 CFR 158.125: processed food/feed; meat/milk/poultry/eggs; fumigation uses; dermal uses; post-harvest treatment] will be addressed in separate Standard Evaluation Procedure documents (to be developed in FY 85).

2/ This Standard Evaluation Procedure is to be used in conjunction with the Standard Format for Preparation of Tolerance Petition Reviews (now under development) that describes the content and considerations of a Residue Chemistry Branch data review memorandum.

likely result in or on the raw food or feed commodity as a result of application of the pesticide formulated product according to the proposed label directions for use.

The term "total toxic residue" is used to describe the sum of the parent pesticide and its degradation products, metabolites (free or bound), and impurities that are considered to be of toxicological significance, and therefore warrant regulation.

II. INFORMATION TO BE SUPPLIED

The petitioner/registrant's report on crop field trials on a raw agricultural commodity should include all information necessary to provide a complete and accurate description of field trial treatments and procedures; sampling (harvesting), handling, shipping, and storage of the r.a.c.; storage stability validation of the test chemical [and metabolite(s) of special concern]; residue analyses of field samples for the "total toxic residue" [and for individual components of special concern]; validation (recovery studies) of the residue analytical methodology; reporting of the data and statistical analyses; and, quality control measures/precautions taken to ensure the fidelity of these operations.

A guideline of specific information that should be included in the petitioner/ registrant's report of crop field trials is provided in the Residue Chemistry Branch Data Submission Guideline on the Magnitude of the Residue: Crop Field Trials[3], that complements this Standard Evaluation Procedure. Related information on Nature of the Residue: Processed Food/Feed, Analytical Method(s), and Storage Stability are found in the Standard Evaluation Procedures[3] and Data Submission Guidelines[3] on those subject areas.

III. THE DATA EVALUATION PROCESS

A. Prepare a Summary

The initial step in the evaluation process of crop field trials on a raw agricultural commodity is for the reviewer to carefully examine and summarize the information/data supplied by the petitioner/registrant in his submission to the Agency. Statistical treatments of the data should be independently verified and the quality control precautions noted.

3/ Concurrently in preparation, FY 85.

B. Identify Data Gaps

Using the Data Submission Guideline on Magnitude of the Residue: Crop Field Trials as a guide (in conjunction with the related Guidelines on Analytical Method(s) and Storage Stability), the reviewer should then look for data gaps--omissions in the information supplied by the petitioner/registrant in his report. These should be duly noted in the reviewer's report, and a judgment made as to which are considered significant enough to adversely affect the review process. Those so identified should be communicated back to the petitioner/registrant by the Product Manager for corrective action.

C. Assess the Appropriateness and Adequacy of the Data

The data reviewer then considers the appropriateness (vis-a-vis the intended use) and adequacy of the data/information that has been supplied. The aforereferenced Data Submission Guidelines are a useful guide to the various parameters that need to be considered. Appendix 1 of this document discusses specific aspects of those parameters that warrant consideration.

As an adjunct to these, the reviewer should draw upon the technical guidance in the reviewer aids materials that are available to him, such as the Residue Chemistry Guidelines (a.k.a. Subdivision O of the Pesticide Assessment Guidelines). A listing of some suggested source materials is located in Appendix 2 to this document.

Any perceived deficiencies in the data/information supplied should be identified and explained, with a statement as to what steps should be taken to resolve the deficiencies, so that this information can be relayed back to the petitioner/registrant by the Product Manager for appropriate action.

Note: As stated in Footnote 1, other aspects of the Magnitude of the Residue, such as processed food/feed and meat/milk/poultry/eggs considerations are to be addressed in separate Standard Evaluation Procedure documents (to be developed in FY 85). Those considerations are applicable whenever a r.a.c. (or parts thereof) may be utilized as an item of livestock or poultry feed, or may be processed into feed items or human foods.

D. Determine the Need for Deferral/Referral(s) to Other HED Branches

In considering the appropriateness and adequacy of the data/information that have been supplied, the data reviewer must also determine if deferral/referral(s) to other HED Branch(es) are germane to reaching that decision.

If so, the specific nature of the deferral/referral(s) should be clearly and succinctly stated and directed to the specific Branch(es) whose input is sought. In the interim period until the response(s) to such deferral/referral(s) are received, final judgment on the issue(s) in question should be withheld.

E. Conclude if the Requested Action is Supportable

As the last step in the data evaluation process, the data reviewer makes a judgment as to whether the submitted data/information support the requested action (tolerance/registration) of the data submitter.

If the data are not supportive, possible alternative action(s) that may be taken by the petitioner/registrant are suggested.

If deficiencies/omissions exist in the submitted data base, the reviewer may have to defer judgment until such time as appropriate corrective action has been rendered by the petitioner/registrant.

(Note: As stated in D above, if deferral/referral(s) to other HED Branch(es) have been made, final judgment will need to be held in abeyance pending the response to such deferral/referral(s).)

IV. REVIEWER AIDS

There are a large number and variety of source materials that are available to assist the data reviewer in the evaluation process. A listing of some of the more useful references that reside within the Branch is provided in Appendix 2 to this document.

APPENDIX 1

MAJOR POINTS TO CONSIDER IN EVALUATING CROP FIELD TRIAL DATA

Include the following:

A. Field Treatments and Harvesting

1. The R.A.C.

- Has the r.a.c. been adequately identified in all the field trials?
- Are an adequate number of types and varieties represented?
- Are the commercially important varieties represented?
- Is it clear what specific plant part(s) were harvested?
- Have the developmental stage(s) and general condition (e.g., immature/mature, green/ripe, fresh/dry, etc.) of the r.a.c. at time of pesticide application(s) and at harvest been specified?
- Were the r.a.c. samples in any way trimmed, cleaned, or otherwise subjected to a means of residue removal at time of harvest? If so, were the recommended procedures of P.A.M. I, §§ 141-2 followed?
- Are there livestock or poultry feed items associated with the r.a.c.? If so, are animal metabolism and feeding studies available? (Note: these concerns will be addressed in separate Standard Evaluation Procedures to be developed in FY 85.)
- Is the r.a.c. normally processed into feed or food items? If so, have processing studies been conducted? (Ref. Footnote 1, page 1, this document.)
- Is supplementary information available for the pesticide in other reports by the petitioner/registrant on this r.a.c. or botanically related r.a.c.'s that can be translated to support the data base, if needed?
- Are data for the pesticide under similar use conditions available on the representative r.a.c.'s of the crop group to which this r.a.c. belongs and, if so, should a crop group action be considered?
- Are the typical growing seasons (summer/winter; wet/dry) of the r.a.c. represented, especially by field trial data from CA and/or FL?

- Have geographically representative data been submitted for the major growing areas of the r.a.c. (ref. USDA Agricultural Statistics)?

(Note: Determining factors as to what constitutes "adequate geographic representation" include how widespread the crop is grown, its economic importance and national acreage, the range of conditions under which it is grown, whether a minor crop or minor use is involved, what the intended use pattern is, what data and tolerances exist on botanically related crops treated with the same pesticide via a similar use pattern, and the general concern over the toxicity of the pesticide.)

- Is this r.a.c. considered a "minor crop" (i.e., limited acreage and low exposure)?
- Have there been experimental use permits/temporary tolerances, Section 18 exemptions, or Section 24(c) registrations for the r.a.c. treated with this pesticide? Permanent tolerance petition requests?
- Are there Codex/FAO Monograph data available for this r.a.c. or botanically related r.a.c.'s treated with this pesticide? - Are there international residue limits (IRL's) established for use of this pesticide on this r.a.c. and, if so, upon what use(s) were they established and what components of the residue are regulated? What would be required for harmonization with any such IRL's?
- Is there any other unpublished or published information known to us re this pesticide and r.a.c. use that must be taken into consideration?
- Are all the important dates relative to the growing and harvesting of the r.a.c. reported?

2. <u>The Pesticide</u>

- Does each field trial specify what pesticide formulated product(s) were applied?
- Has each pesticide formulated product been adequately identified? (Detailed consideration of this should be addressed in evaluating the formulation(s); this will be the subject of a separate Standard Evaluation Procedure to be developed in FY 85.)
- Has the EPA Registration Number been given?
- Has the type of formulation (WP, EC, G, etc.) been specified?
- Has the active ingredient (a.i.) in the formulated product been identified?
- Is the purity of the a.i. known? Are there impurities of concern?
- Is the percent a.i. in the formulated product stated?

- Is the amount of a.i. per gallon, pound, etc. of formulated product given? Are metric equivalents given?
- Is the photochemical stability of the pesticide formulated product known?
- Are the registered label(s) and proposed supplemental label(s) provided (or available somewhere in the over-all data package; e.g., Section B of a petition)?
- Were the field trials conducted with the proposed commercial pesticide formulation(s) of intended use?
- Were spray adjuvants used with the formulation and, if so, are they identified as to nature and amount? Does the proposed use indicate spray adjuvants are intended to be used?
- Were there any tank-mates or other pesticides applied to the r.a.c. and, if so, have they been adequately identified?
- Was there any special carrier involved in the application of the pesticide (e.g., encapsulating polymer, cigarette filter tips, etc.)?
- Is information available (e.g., Section A of a petition) on the stability and solubility of the formulated product(s)?
- Has this chemical been RPAR'd and, if so, what is the current status?
- Is there a Registration Standard on this chemical and, if so, is it being used in the evaluation of these data?

3. <u>The Experimental Design</u>

- Were field trials carried out in the major areas of cultivation or production of the r.a.c. and sited to cover the range of representative conditions (climatic, seasonal, soil, cropping system, farming practice, etc.) under which it is normally grown?
- Are the field trial lay-outs sufficiently described and of adequate design (i.e., inclusion of control plots, large enough plots, etc.)?
- Are there data for successive crop years?
- Are trials properly identified and the collected samples adequately labeled, dated, and coded?
- Is the method of harvesting (mechanical/hand; from the plant/ground/flotation, etc.) described?
- What steps were taken to assure random and representative sampling?
- Is the intended use considered a "minor use" in terms of exposure?

- Were there a sufficient number of field trials conducted on the r.a.c. to support the requested action of the data submitter?

(Note: This is a judgment call and is influenced by the economic importance of the r.a.c., national acreage of the r.a.c., the range of conditions under which it is grown, how widespread it is grown, how closely the trials corresponded with the intended use pattern(s), whether exaggerated rate and residue decline data are available, whether a minor crop or minor use is involved, the data and established tolerances already available on botanically related crops treated with the pesticide under similar conditions of use, the nature of the requested action of the data submitter, and the general concern over the toxicity of the pesticide.)

4. Application of the Pesticide

- Do the field trials reflect the intended use (proposed labeling) of the pesticide on the r.a.c.?
- Are data available reflecting the maximum proposed use conditions (e.g., maximum dose rate(s), maximum number of applications, minimum application intervals, minimum preharvest interval (PHI), etc.)? If not, are the available data sufficient to allow for extrapolation?
- Do the method(s) of application (air/ground) and the type of application(s) [band/broadcast, soil/foliar/directed, ultralow volume (ULV)/concentrate/dilute, etc.) reflect the intended use?
- Are data available reflecting the minimum spray gallonage per acre, especially for ULV intended uses?
- Are label restrictions needed?
- Are exaggerated rate and residue decline data (varying PHIs) available?
- Was a description of the pesticide application equipment provided?
- Was the application equipment used similar to that in local commercial practice?
- Are dose rates and spray volumes reported in a manner (e.g., lbs a.i./A or, for tree crops, for example, X lbs a.i. per Y gallons, use Z gallons per acre) that is consistent with normal practice and with the directions on the proposed labeling? Are metric equivalents provided?
- Are the dates, number(s) and timing of the application(s) given? Is this information tied in with the developmental stage(s) of the r.a.c.?
- Is information provided on tank-mates or other pesticide(s applied, if applicable (formulation(s), rate(s), date(s) applied, etc.).

5. Quality Control

- Are quality control measures to ensure the fidelity of the crop field trials described?
- Were proper records (e.g., field trial/sample history, dates, weather, etc.) kept and duly reported?
- Are responsible personnel adequately identified? Was a petitioner/registrant contact person identified and a telephone number provided?
- Was the application equipment calibrated?

B. Handling, Pre-Shipping Storage, and Shipping Procedures for Harvested R.A.C. Samples

1. The R.A.C.

- Were the r.a.c. samples in any way trimmed, cleaned, or otherwise subjected to a means of residue removal during these operations? If so, were the procedures recommended in P.A.M. I, §§ 141-2 followed?
- How were the r.a.c. samples stored between harvesting and shipping (temperature, humidity, container type(s)/size(s), etc.)?
- How soon after harvesting did the r.a.c. samples enter storage?
- How long between harvesting and shipping?
- Were specific dates given for each of these operations for each of the field trials?
- Was any sample compositing or subsampling done at these stages? If so, were details given?

2. General Procedure

- What were the method(s) of packaging samples for shipment (container type(s)/ size(s); sample sizes; ambient/ iced; labeling/dating/coding)?
- What was the means of shipping the samples to the laboratory?
- Were the dates of harvesting, entry into storage before shipping, and shipping given?

3. Quality Control

- What quality assurance measures were taken to ensure the fidelity of harvested r.a.c. samples?
- Were adequate records kept and has sufficient information been submitted?
- Were responsible personnel identified? Was a petitioner/registrant contact person identified and a telephone number provided?

C. Conditions and Length of Storage of Harvested R.A.C. Samples (following their receipt in the laboratory and prior to residue analysis)

1. The R.A.C.

- Were the r.a.c. samples in any way trimmed, cleaned, or otherwise subjected to a means of residue removal upon their receipt in the laboratory and prior to entering storage? If so, were the recommended procedures of P.A.M. I, §§ 141-2 followed?
- Were the r.a.c. samples stored whole, chopped, as an extract, etc.?
- Was any sample compositing or subsampling done prior to storage? If so, were details given? Were the same sample code numbers maintained?

2. General Procedure

- What were the conditions of storage (temperature, humidity, container type(s)/size(s), sample weights, etc.)?
- What was the extraction procedure (if applicable)?
- What dates were samples received in the laboratory; subsampled/composited (if applicable); chopped or extracted (if applicable); and entered into storage?

3. Quality Control

- What quality assurance measures were taken to ensure the fidelity of harvested r.a.c. samples?
- Were adequate records kept and has sufficient information been submitted?
- Were responsible personnel identified? Was a petitioner/registrant contact person identified and a telephone number provided?

D. Storage Stability Validation Testing

Refer to the Standard Evaluation Procedure on Storage Stability[4] for guidance on this subject area.

E. Analyses to Determine the "Total Toxic Residue" in Samples From Supervised R.A.C. Field Trials

1. The R.A.C.

- What specific plant part(s) were subjected to residue analysis for a determination of the "total toxic residue"?

4/ Concurrently in preparation, FY 85.

- Were all the appropriate plant part(s) subjected to residue analysis? (Ref. Table II, Residue Chemistry Guidelines.)
- Are there food or feed items associated with the r.a.c.? (If so, refer to the Standard Evaluation Procedure dealing with that topic (to be developed in FY 85).)
- Were the r.a.c. samples in any way trimmed, cleaned, or otherwise subjected to a means of residue removal in preparation for the analysis of the "total toxic residue"? If so, were the recommended procedures of P.A.M. I, §§ 141-2 followed?
- Was any sample compositing or subsampling done in preparation for analysis of the "total toxic residue"? Is so, were details given? Were the same sample code numbers maintained?
- Was the sample/laboratory coding sufficiently clear so that the history of the r.a.c. sample(s) could be traced (e.g., treatment regimen, harvest date, length of storage, extraction date, etc.)?
- Were control samples (field blanks, reagent blanks) carried through the analytical procedure?
- Were there replicate r.a.c. samples per field treatment regimen per plant matrix?

2. Residue Methodology and Instrumentation

Refer to the Standard Evaluation Procedure on Analytical Method(s)[5] for guidance on this subject area.

3. Analytical Methodology Residue Results

- Were blank values reasonably low? If not, is an explanation provided?
- Are all the raw data reported rather than just average values?
- Were any correction factors [e.g., method recovery, extraction efficiency, field blanks, storage stability] applied to the residue values reported?
- Is the method of calculating the residue values adequately described [formulae, standard curves, etc.], and illustrated, and the raw data sufficiently detailed so that independent calculations to verify the reported results can be made?
- Were the residue values reasonably uniform for replicate samples?

5/ Concurrently in preparation, FY 85.

- Does the petitioner/registrant claim any of the residue values are outliners and, if so, can this claim be supported?
- How do these residue results compare with those on related botanical r.a.c.'s treated with this same pesticide via the same, or similar, use pattern(s) [provided such data are available]?
- How do these residue results compare with previously submitted data [e.g., EUP/temporary tolerance, Section 18 or 24(c) exemptions] for this r.a.c. treated with this same pesticide via the same, or similar, use pattern(s) [provided such data are available]?
- Do these residue results support the action requested by the data submitter? If not, what action(s) should the data submitter undertake to resolve the perceived deficiencies?
- Are residue decline data [residues (ppm) vs. time (PHI)] provided?
- Can harmonization with international residue limits be achieved [if applicable]? If not, why not?
- Is there a Registration Standard for this pesticide and, if so, is it being used by the reviewer in the evaluation of these data?

4. Quality Control

- What quality assurance measures were taken to ensure the fidelity of the analytical methodology residue analyses?
- Was the sample/laboratory coding sufficiently clear so that the history of the sample(s) used could be traced?
- Were the analyst's worksheets provided? Are they sufficiently detailed?
- Were the person(s) [supervisor, analyst] responsible for the analytical methodology residue analyses identified [name, title, organization, address, and telephone number]?
- Were the analytical methodology residue analyses test report(s) authenticated (signed) by the responsible personnel?
- Is a contact person for the petitioner/registrant given with title, address, and telephone number?
- Were representative chromatograms, spectra, etc., as applicable, provided? Are adequate clean-up and determination [i.e., low background "noise", adequate signal-to-noise ratio, well-defined peaks rather than shoulder bands, etc.] of the test compound(s) indicated? The level of claimed sensitivity valid?

- Was the methodology tested for possible interference(s) from other registered pesticides?
- Are the calibration procedures for the instrumentation described?
- Were tests performed for interference from storage containers, reagents, plant substrates, plastic labware, etc.?
- If statistical analyses were performed and applied to the results of the analytical methodology residue determinations, is sufficient information provided to independently validate the results?
- Is a need for a laboratory audit indicated?

F. Analytical Methodology Validation/Recovery Testing

1. The R.A.C.

- What specific plant part(s) were subjected to analytical methodology validation/recovery testing?
- Were the r.a.c. samples in any way trimmed, cleaned, or otherwise subjected to a means of residue removal in preparation for the analytical methodology validation/recovery testing? If so, were the recommended procedures of P.A.M. I, §§ 141-2 followed?
- Was any sample compositing or subsampling done in preparation for analytical methodology validation/recovery testing? If so, were details given? Were the same sample code numbers maintained?
- In what form [whole, chopped, extract, etc.] were the r.a.c. samples [i.e., plant matrices] when they were fortified?

2. The Test Compound(s)

- Were analytical reference grade standards of the parent pesticide and any metabolite(s) of especial concern [normally those which, in addition to the parent, comprise the "total toxic residue", unless present in very minor amounts] used for fortifications? Was the purity of these standards given?
- Is it clear what test compound(s) were used for fortification? For each of the plant matrices tested?
- Were the fortification ["spiking"] level(s) given for each test compound? For each of the plant matrices tested?

- Is it described how the test compound(s) were prepared for the fortification process [i.e., what solute(s), concentration of the standard solution(s), dilution factors, etc.]?
- If "spiking" with a mixture of test compounds, was testing done to ensure interference would be no problem?

3. The Experimental Design

- Were all the necessary compounds [parent plus metabolite(s) comprising the "total toxic residue"] and plant matrices [specific r.a.c. parts] tested for analytical methodology validation/recovery?
- Were the number and magnitude of the fortification levels adequate and appropriate?
- Was there a fortification level to establish a validated sensitivity level?
- Was there a fortification level near the proposed tolerance level?
- Were control samples [field blanks, reagent blanks] carried through the procedure?
- Were the analytical methodology validation/recovery tests conducted in conjunction with the analyses of residues in r.a.c. samples from each of the supervised crop field trials, or as a separate study?
- Were there replicate samples per test compound per fortification level per plant matrix?
- Are all the significant dates given [date of samples receipt in laboratory; dates and length of storage, if applicable; dates of test sample preparation (chopping, extraction, etc.); date of test compound(s) preparation (standard reference solutions); residue analysis, including the determinative step]?

4. Residue Methodology and Instrumentation

- Was more than one analytical method used in the analysis of r.a.c. field trial samples for the "total toxic residue" [i.e., a "total" residue method and perhaps separate method(s) for the metabolite(s) of concern] and, if so, were each of those methods subjected to validation/recovery testing?
- Was the analytical methodology adequately identified [e.g., title/designation/date and source]?
- Is a complete copy [non-CBI] of each analytical method that was used in the validation/recovery study testing provided [or available in the over-all data package] with a description of the principles and the stepwise procedure [extraction/clean-up, derivatization, determination], and is it clear what chemical species could be determined?

- Is it clear if modifications were made in the analytical procedure(s) and, if so, are they adequately described?
- Is it clear at what step in the analytical procedure(s) the fortification occurred, and how this was accomplished?
- Was the extraction efficiency of the analytical methodology demonstrated [especially if dry r.a.c. substrates were used or if the presence of "bound" residues is suspected]?
- Were method sensitivity and the limit of detection given? Were they suitably low?
- Was an internal standard used?
- Were any difficulties encountered in the procedure [e.g., emulsions, etc.] and, if so, were they adequately described and overcome?
- Were any esoteric reagents/equipment/instrumentation used?
- Are the instrumentation [type, type/specificity of detector(s), column(s) (size, packing materials), carrier gas(es), etc.] and operating parameters [flow rate(s), temperature(s), voltage, etc.] specified? Adequately described?
- How long did it take the analyst to run a sample completely through the analytical procedure, including the determinative step?

5. Analytical Methodology Validation/Recovery Results

- Do the results indicate the recoverability of the test compound(s) in the plant matrices?
- Are recovery values acceptably high [$\geq$ 70%, except in special cases; ref. Residue Chemistry Guidelines]?
- Were blank values reasonably low? If not, is an explanation provided?
- Are all the raw data reported rather than just average values?
- Were any correction factors [e.g., extraction efficiency, field blanks, etc.] applied to the residue values/recovery values reported?
- Are the methods of calculating the residue level and percent recovery adequately described [formulae, standard curves, etc.], and illustrated, and the raw data sufficiently detailed so that independent calculations to verify the reported results can be made?

6. Quality Control

- What quality assurance measures were taken to ensure the fidelity of the analytical methodology validation/recovery testing?

- Was the sample/laboratory coding sufficiently clear so that the history of the sample(s) used could be traced?
- Were the analyst's worksheets provided? Are they sufficiently detailed?
- Were the person(s) [supervisor, analyst] responsible for the analytical methodology validation/recovery testing identified [name, title, organization, address, telephone number]?
- Were the analytical methodology validation/recovery test report(s) authenticated (signed) by the responsible personnel?
- Is a contact person for the petitioner/registrant given with title, address, and telephone number?
- Were representative chromatograms, spectra, etc., as applicable, provided? Are adequate clean-up and determination [i.e., low background "noise", adequate signal-to-noise ratio, well-defined peaks rather than shoulder bands, etc.] of the test compound(s) indicated?
- Were the recovery values reasonably uniform for replicate samples?
- Are the calibration procedures for the instrumentation described?
- Were tests performed for interference from storage containers, reagents, plant substrates, plastic labware, etc.?
- If analytical methodology validation/recovery tests were performed in conjunction with the analyses of residues in r.a.c. samples from each of the supervised crop field trials, were the reference standards solutions freshly prepared each day? If not, was their stability monitored?
- If statistical analyses were performed and applied to the results of the analytical methodology validation/recovery testing, is sufficient information provided to independently validate the results?
- Is a need for a laboratory audit indicated?

APPENDIX 2

REVIEWER AIDS MATERIALS[6]

Following is a listing of some of the more useful source materials within the Residue Chemistry Branch that could prove helpful in reviewing crop field trial studies:

(1) Federal Food, Drug, and Cosmetic Act, as amended, §§ 408-409;

(2) Federal Insecticide, Fungicide, and Rodenticide Act, as amended;

(3) Subdivision O [Residue Chemistry] of the Pesticide Assessment Guidelines, § 171-3 and § 171-4, prepared by OPTS/EPA, Washington, D.C. (1982);

(4) Subdivision D [Product Chemistry] of the Pesticide Assessment Guidelines, prepared by OPTS/EPA, Washington, D.C. (1982);

(5) Code of Federal Regulations [40 CFR 158 and 180; 21 CFR 193 and 561], General Services Administration, Washington, D.C., updated annually;

(6) Pesticide Chemical News Guide, R. E. Duggan, editor, Food Chemical News, Inc., Washington, D.C., 1982, updated monthly;

(7) "Guidelines on Pesticide Residue Trials to Provide Data for the Registering of Pesticides and the Establishment of Maximum Residue Limits", FAO Plant Protection Bulletin, 29:1/2, pp. 12-27 (1981);

(8) "Guidelines for Data Acquisition and Data Quality Evaluation in Environmental Chemistry", Anal. Chem. 52, 2242-2248 (1980);

(9) Acceptable Common Names and Chemical Names for the Ingredient Statement on Pesticide Labels, 4th ed., C. R. Blalock, et al., editors, OPP/EPA, 1979, available from National Technical Information Service, Springfield, VA;

6/ A comprehensive listing is to be compiled in future.

(10) Farm Chemicals Handbook, Meister Publishing Co., Willoughby, OH, updated annually;

(11) Nanogen Index: A Dictionary of Pesticides and Chemical Pollutants, K. Packer, editor, Nanogens International, Freedom, CA, 1975 (updated periodically by supplements);

(12) U.S.D.A. Agricultural Statistics, U.S. Government Printing Office, Washington, D.C., updated annually;

(13) Crop Grouping Classification [40 CFR 180.34(f), as revised 6/29/83 (48 FR 29855)];

(14) F.D.A. Pesticide Analytical Manual, Volumes I and II, available from the National Technical Information Service, Springfield VA;

(15) Plants Consumed by Man, B. Brouk, Academic Press, NY (1975);

(16) Principles of Field Crop Production, 3d ed., J. H. Martin, W. H. Leonard, and D. L. Stamp, Macmillan Publishing Co., Inc., NY (1976);

(17) Crop Production, 4th ed., R. J. Delorit, L. J. Greub, and H. L. Ahlgren, Prentice-Hall, Inc., NJ (1974);

(18) Food and Feed Crops of the United States, J. R. Magness, G. M. Markle, and C. C. Compton, Rutgers University, NJ (1971);

(19) McGraw-Hill Encyclopedia of Food, Agriculture & Nutrition, D. N. Lapedes, editor-in-chief, McGraw-Hill Book Company, NY (1977);

(20) "Guide for Estimating Toxic Residues in Animal Feeds or Diets" prepared for the E.P.A. by Lorin E. Harris, available from National Technical Information Service, Springfield, VA;

(21) Feeds and Feeding, Abridged: The Essentials of the Feeding, Care, and Management of Farm Animals, Including Poultry, F. B. Morrison, 9th ed., The Morrison Publishing Co., Ithaca, NY (1958);

(22) Statistical Methods Applied to Experiments in Agriculture and Biology, 7th. ed., G. W. Snedecor, Iowa State College Press, Ames, IA (1980);

(23) Foods and Food Production Encyclopedia, D. M. Considine and G. D. Considine, Van Nostrand Reinhold Company, NY (1982);

(24) Registration Standards on various individual pesticides, prepared by OPTS/EPA, (several issued each fiscal year);

(25) Residue Chemistry Branch files: petition and registration files; cultural practices; reviewer aids; policies; foreign uses; subject files; reading files; card catalogue; et al.;

(26) Various reference texts and journal publications of a scientific or agricultural nature, including FAO/Codex Monographs.

SOP#: 8.11

AUTHORS: J.D. Forder and T.W. Barkalow

REVISION #: 06

EFFECTIVE DATE: October 7, 2013

TITLE: **Routing of Incoming Quality Assurance Reports.**

PURPOSE: To detail the procedures to be followed when Quality Assurance inspection/audit reports are received for routing to the Study Director (SD) and Testing Facility Management (TFM).

SCOPE: This SOP applies to TFM, all Headquarters (HQ) Study Directors, and members of the HQ Quality Assurance Unit (QAU).

PROCEDURES:

1. This SOP will be retired pending the completion of routing of ongoing paperbased QA inspections reports once the eQA system has been implemented. Once TFM determines the routing of audits has been completed (via email received by IR-4 HQ QA) the paper based routing system will no longer be used. All paper audits will be maintained in the Green QA folders and archived after the close of the study. The QA Routing database will remain available on the IR-4 server but will also be copied onto disk and the disk placed in the IR-4 archive for retention.

   Follow the procedures provided in this SOP to complete the QA reports already using the paper based system at the time of the implementation of the new eQA system. Future paper based or electronically received audit reports will be distributed in the eQA system as external audits as described in the current version of SOP 8.17.

2. Initial Receipt and Routing to SD

   A. When a QA audit report is received by the HQ QAU office, the contents are briefly reviewed and then placed in the "To Be Routed" bin and will be stamped with the receipt date.

   B. If a QA report is received by the Study Director (SD) or Testing Facility Management (TFM) it should be brought to the QAU for proper routing.

   C. A routing cover sheet (Appendix A) will be completed and attached to the QA audit report with its cover letter, if supplied. If a report is to be returned to the source QA, the Return Requested space on the cover sheet should be checked as a reminder.

   D. QA audit reports entering the HQ QA routing system will be tracked using the Data Tracking System (DTS). The DTS is an

electronic Access database. The format of the reporting form used for this application can be found as Appendix B. The column headings represent prompts or a drop down list to enter information.

The columns in the database (refer to Appendices B & C) are:

1) ID # - This number is assigned sequentially by the software to each row and is to be used as the QA report tracking number entered on Appendix A.
2) PR# - The study number will be entered into this cell. Begin the entry with a zero if the number is ≤ 9999. If the study number begins with a letter, begin the entry with the letter (e.g., A4953).
3) SD – Chose the appropriate SD initials from the drop down list (Appendix C).
4) Pesticide - Enter the identity of the test substance as presented in the protocol.
5) Crop - Enter the identity of the crop common name as presented in the protocol.
6) FRD/LR/PRD - type in the name of the Field or Laboratory Research Director.
7) Field/Lab/Processor ID# - Enter the IR-4 trial, lab or processor identification here.
8) QA – Choose the appropriate QA initials or "Contract" from the drop down list (Appendix C).
9) Assigned QA – Choose the appropriate region from the drop down list (Appendix C).
10) Audit date- enter the 1st date of the audit, in the following format – mm/dd, the year will be supplied by the system.
11) Phase inspected – chose from the drop down list (Appendix C).
12) Date to HQ. This represents the date that is stamped onto the audits HQ receives from elsewhere or the date that HQ auditors put the audit into the routing bin. Enter mm/dd and year will be supplied by system
13) Date to SD. This is the date the audit was given to the SD. Enter mm/dd and year will be supplied by system.
14) SD Sign – enter the date (mm/dd) the SD signed the audit.

15 -23) All dates. Enter in mm/dd format and yy if not supplied by system.

24) Comments – add comments as needed.

25) Archive Date

26) Archive Location

E. Upon each update, the file is to be saved after each session of entry by replacing the file on the network. The network is backed up to a tape to add another level of security to the system. This tracking system is a tool and is not to be used as the sole mechanism in the generation of the QA Statement to verify date of reporting the notification of SD and TFM.

F. After entering the information into the DTS, the cover page is attached to the audit and the audits are routed to the TFM. Routing to the TFM should be done within 5 business days of receiving the audit reports, if possible.

3. Routing to SD and TFM

A. QA audits received from an outside QA or performed by HQ QA auditors will be reviewed prior to routing to TFM and SD to determine if additional action is required or if special circumstances are evident that requires the audit to be sent to the TFM and SD simultaneously as indicated by a check mark in the box on the audit forms. If it is a routine audit, the following steps will apply.

1) The QA audit is logged into the DTS and is given to TFM who will sign the audit off as read, then return it to the QAU to be routed to SD. The SD will sign the audit off as read and indicate its finalization status and return to the QAU.

2) If responses are needed from the FRD, LRD or PRD the audit is first circulated to the TFM who will sign off as read, then return the audit to HQ QAU to be routed to the SD. The SD may elect to wait for up to 8 weeks for responses or may sign the audit without responses, indicating that it is not final and return the audit to HQ QAU. At this time the SD may also indicate on the routing sheet, that they request the audit be returned to them. The DTS will be updated indicating the status of the audit. The audit will either be filed in the QA study folder or returned to the SD pending additional action.

3) When responses are received by QA, they will be attached to the original audit report. Any original data sent with the responses will be copied and clipped to the QA audit report. The original audit report (with cover page), responses, original and copied data, will be brought to the SD and the DTS system will be updated. SD will review the responses, sign the audit form and return it to the QAU bin. It will then be circulated to

TFM who will review the responses and sign the audit. The SD will indicate on the cover page whether or not the audit is now finalized.

B. After TFM has signed the report, the DTS system is updated and the audit report is filed in the QA study file.

4. Returns to Source and Assigned QAUs

A. Since each contract or registrant source will have its own SOPs, the instructions provided by them for returning their audits will be followed by HQ QA. All completed audits will be copied and forwarded with a descriptive cover letter to the Assigned QA (Assigned QAs are assigned for audits performed on 1997 trials or later.). Any photocopies will be appropriately stamped.

B. The Assigned QA will be informed of the receipt and movement of QA audits at HQ by periodically sending them copies of completed routing cover sheets.

Prepared By: _____ Date: 9/27/13

Approved By: _____ Date: 9/27/13

The IR-4 Project

Providing Safe and Effective Pest Management Solutions for Specialty Crop Growers

☐ Circulate to TFM/SD simultaneously

IR-4 QA REPORT ROUTING FORM

Tracking# N_____

PR#_____ Study Director: _____

Chemical/Crop: _____

FRD/LRD: _____ ID#: _____

_____

QAO: _____ Assigned QA _____ Audit Date(s): _____

PHASE: Protocol ☐ CPI- Field ☐ Lab ☐ Data- Field ☐ Lab ☐ ASR ☐ Seed Trt. ☐ Pet-1☐ Pet-2 ☐ Process ☐ Other ☐

DATE TO HQ: _____ DATE TO TFM: _____

ACTION REQUIRED: ___Review report(s) ___ No Findings ___ Findings ___ Comment (s) only

_____ Response needed from Researcher Date Response Received _____

_____ Response needed from Study Director

FINDINGS ADDRESSED: _____ Date Response to SD: _____

DOCUMENTATION OF RECEIPT: (sign & date all entries)

Management I: _____

Date to Study Director I: _____; Study Director I: Finalized: Yes/No_____

(SD must circle one, initial & date)

_____ Request for return to SD

Study Director II: Finalized: _____

(SD, initial & date when audit finalized)

Date to Management II: _____; Management II: _____

For HQ QAU only

____*Send cover sheet + responses to contract QA: _____; date copied: _____*

____*Send to IR-4 QA personnel: _____: date copied: _____*

Form A8:11, revised 07/02/09
Directory: Shared/Juliet/form A 8.11
SOP 8.11 r6, App. A

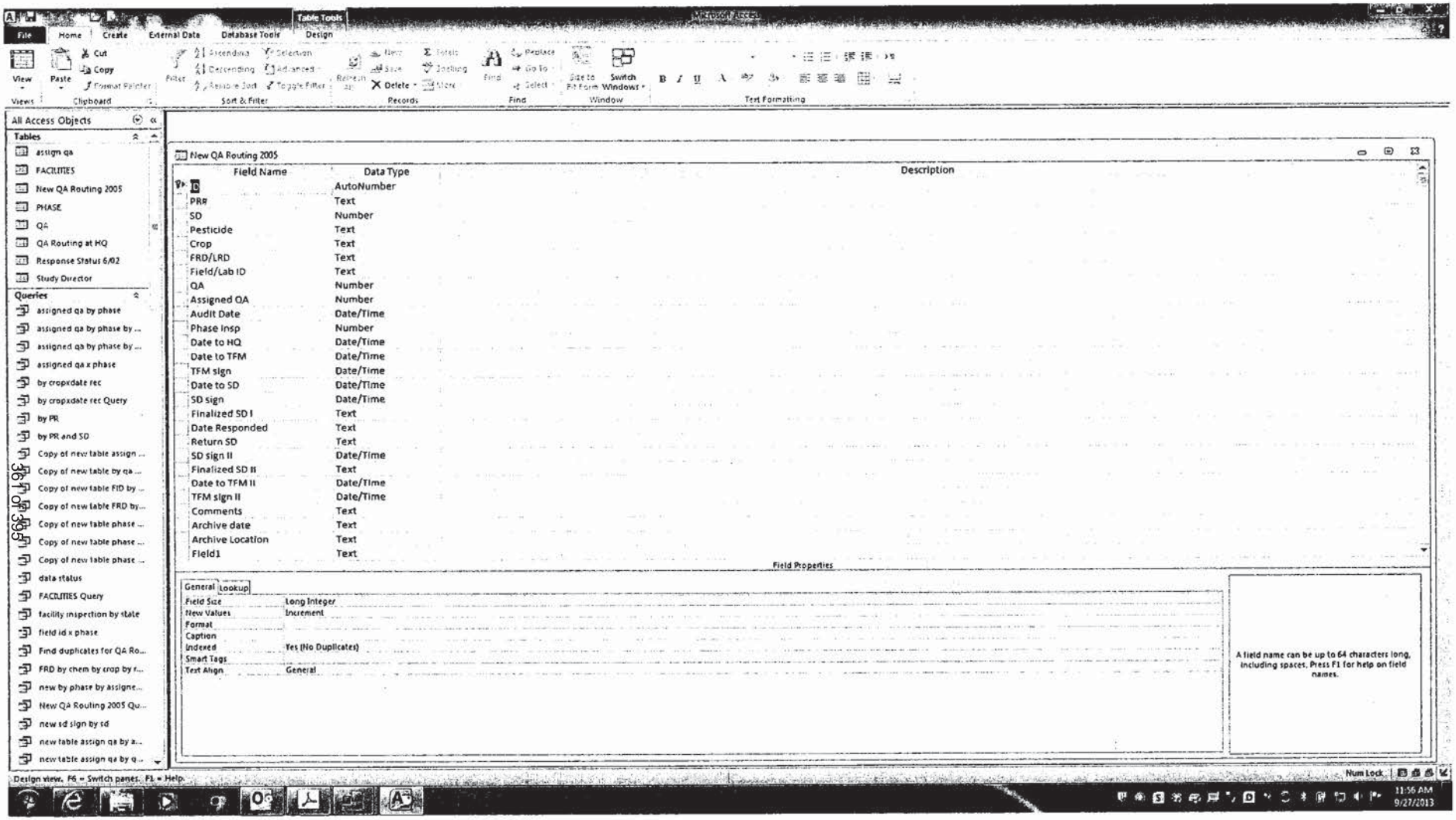
Table Tools
File
Home
Create
External Data
Database Tools
Design
All Access Objects
Tables
assign qa
FACILITIES
New QA Routing 2005
PHASE
QA
QA Routing at HQ
Response Status 6/02
Study Director
Queries
assigned qa by phase
assigned qa by phase by ...
assigned qa by phase by ...
assigned qa x phase
by cropxdate rec
by cropxdate rec Query
by PR
by PR and SD
Copy of new table assign ...
Copy of new table by qa ...
Copy of new table FID by ...
Copy of new table FRD by...
Copy of new table phase ...
Copy of new table phase ...
Copy of new table phase ...
data status
FACILITIES Query
facility inspection by state
field id x phase
Find duplicates for QA Ro...
FRD by chem by crop by r...
new by phase by assigne...
New QA Routing 2005 Qu...
new sd sign by sd
new table assign qa by a...
new table assign qa by q...
New QA Routing 2005
Field Name
Data Type
Description
ID
AutoNumber
PR#
Text
SD
Number
Pesticide
Text
Crop
Text
FRD/LRD
Text
Field/Lab ID
Text
QA
Number
Assigned QA
Number
Audit Date
Date/Time
Phase Insp
Number
Date to HQ
Date/Time
Date to TFM
Date/Time
TFM sign
Date/Time
Date to SD
Date/Time
SD sign
Date/Time
Finalized SD I
Text
Date Responded
Text
Return SD
Text
SD sign II
Date/Time
Finalized SD II
Text
Date to TFM II
Date/Time
TFM sign II
Date/Time
Comments
Text
Archive date
Text
Archive Location
Text
Field1
Text
Field Properties
General
Lookup
Field Size
Long Integer
New Values
Increment
Format
Caption
Indexed
Yes (No Duplicates)
Smart Tags
Text Align
General
A field name can be up to 64 characters long, including spaces. Press F1 for help on field names.
Design view. F6 = Switch panes. F1 = Help.
Num Lock
11:56 AM
9/27/2013

Appendix C

Drop Down List

Study Directors - Max 2 characters – Use in Old QA Routing Database

MA	Marija Arsenovic
WB	Bill Barney
JB	Jerry Baron
WB	William Biehn
MB	Michael Braverman
HC	Hong Chen
JC	Johannes Corley
HC	Hong Chen
KD	Keith Dorschner
DK	Dan Kunkel
GM	George Markle
JN	Jack Norton
KS	Ken Samoil
VS	Van Starner
FS	Fred Salzman
DT	Dave Thompson
DC	Debbie Carpenter

Study Director abbreviations to choose from in New, 2005 Routing Database Drop Down Menu

MA	Marija Arsenovic
WB	Bill Barney
MB	Michael Braverman
DC	Debbie Carpenter
HC	Hong Chen
JC	Johannes Corley
KD	Keith Dorschner
KH	Kathryn Homa
KF	Kathryn Hackett-Fields
DK	Dan Kunkel
RL	Ray Leonard
KS	Ken Samoil
TS	Tracey Switek
VS	Van Starner
FS	Fred Salzman
DT	Dave Thompson
CJ	Carolyn Jolly
GL	Grace Lennon

Quality Assurance Personnel - Max 3 characters for use in old Database

BA	Barbara Anderson	MB	Martin Beran
JBB	John B. Bourke	VDB	Virginia DeBose
ZC	Zhongxiao (Michael) Chen	MKE	Mary K. Erickson
SF	Sam Fernando	DG	Debi Garvin
BG	Bonnie Glazier	JC	Janet Campbell
KHF	Kathryn Hackett-Fields	RH	Regina Hornbuckle
BJ	Bryan Jensen	DMJ	Donna M. Johnston
KK	Ken Kanagalingam	DK	Derek Killilea
EML	E. Maria Lopez	ML	Maria Lugo
JCM	Jay C. Maitlen	MR	Maria A. Ralat
PM	Pat Messick	JMM	James M. McFarland
JO	John Obrist	LO	Laurie O'Reilly
DLS	Denise L. Snook	TLW	Tammy L. White

TW	Trina Witter	JDF	Jane D. Forder
CON	Contract QA		

Quality Assurance Personnel Codes to choose from in New, 2005 Routing Database

BA	Barbara Anderson	BJ	Bryan Jensen
DB	Diane Bradway	DMJ	Donna M. Johnston
MB	Martin Beran	EML	E. Maria Lopez
ZC	Zhongziao (Michael) Chen	MR	Maria A. Ralat
JDF	Jane D. Forder	JO	John Obrist
JMF	James M. McFarland	TW	Trina Witter
KHF	Kathryn Hackett-Fields	BG	Bonnie Glazier
SF	Sam Fernando	DMR	Doria M. Rogers
TWB	Tammy W. Barkalow	RH	Regina Hornbuckle
KK	Ken Kanagalingam	BP	Bharti Patel
KKn	Kathleen Knight	DD	Diane D'Angelo
DK	Derek Killilea	MH	Michele Humiston
CON	Contract	ML	Mary Lynn

Phase Inspected - Max 13 characters for use in Old Database

Protocol
CPI (critical phase inspection)
Data-Field
Data-Lab
ASR
Petition-1
Petition-2
Amnd-Rpt (audit of an amended, final report prior to re-submission to EPA)

Phase Inspected –Drop Down Menu to choose from in New, 2005 Routing Database

DATA,FIELD	PROCESSING
CPI,FIELD	SEED TRT
DATA,LAB	PROTOCOL
CPI,LAB	OTHER (PLACE INFO IN COMMENTS)
ASR	
PETITION-1	
PETITION-2	

Abbreviations to choose from in New, 2005 Routing Database for Assigned QA

HQ	Headquarters	NCR	North Central Region
WSR	Western Region	NER	North Eastern Region
SOR	Southern Region		

SOP#: 8.12

AUTHOR: J. D. Forder, T. W. Barkalow, J. Thompson, J. D. Forder, K. A. Hackett-Fields and K. Sims

REVISION#: 04

EFFECTIVE DATE: January 31, 2010

TITLE: **Protocol / Protocol Change Distribution to the Quality Assurance Unit (QAU)**

PURPOSE: To provide the assigned QA with copies of approved protocols and protocol changes for his/her projects, and to notify all appropriate QA personnel of approved changes made to protocols.

SCOPE: This SOP pertains to Headquarters (HQ) personnel that are responsible for protocol distribution to the QAU.

PROCEDURES:

1. Initial Receipt and review of Protocols/ Protocol Changes

   A. One copy of each protocol or change form generated at Headquarters will be left in the labeled basket. At least once every three weeks, copies will be made as needed for distribution to appropriate field and/or laboratory Quality Assurance Officers (QAO), and one for the QA PR file at HQ.

   B. Each new protocol or protocol change form will be checked for appropriate approval signatures and dates.

2. To determine which QAU members receive copies of the new protocols and/protocol changes, utilize the IR-4 database:

   A Using the IR-4 data base, enter the PR number and locate the necessary information to determine the assigned QA.
   - select "Reports," then "Master Schedule"
   - enter the PR number

   click on the print button to bring up the master schedule report.

Based upon the field, processing lab and residue lab ID numbers, determine the assigned QA (located by abbreviation after the study director's name/ for the region who should receive a copy of the new protocol and/or protocol change. Several states also utilize other QA personnel, as indicated on a national map. (For example, the QA Officer for the University of Wisconsin's test site would receive a protocol or change form, which would also be sent to the North Central Region QA Coordinator). Contract facility sites also have QA personnel to which amendments and protocols will be sent.

B. On the reverse side of the protocol/change provided to HQ QA of each document, a list of initials for appropriate QA personnel will be written to enable distribution of a copy to each. The original document, with the initials on the reverse, is the HQ QA copy. File these copies in the appropriate green PR folders in the QA hallway. All protocols and protocol changes will be directed to the Regional QA Coordinators and appropriate auditors.

3. Preparation of Cover Letters to QA Coordinators and Other Personnel

A "form" letter (Appendix A) will include a list of the enclosures provided to each person. One copy will remain at HQ and will be provided to QA for filing in the correct PR folder. A copy of each letter sent, with its attached list, will be filed appropriately (see current SOP 8.13).

4. Preparing Package and Cover Letters to Regional QA Coordinators and other QA auditors.

The RQACs will receive copies of their own protocols and changes.

Prepared by: Jan Ford Date: 1/7/10

Approved by: Jerry J Baron Date: 8 JAN 2010

IR-4 Headquarters
Rutgers, The State University of New Jersey
500 College Road East, Suite 201W
Princeton, NJ 08540
732.932.9575
fax 609-514-2612
www.ir4.rutgers.edu

The IR-4 Project
Providing Safe and Effective Pest Management Solutions for Specialty Crop Growers

Date

To: _____

From: _____

Enclosed, please find a listing of Protocol (s) /Protocol Amendment (s) for which your QA Unit is responsible. Contact our office immediately if your representative has been replaced so that we may update our records.

PR #	Protocol Change #

PR #	Protocol Change #

Major funding for IR-4 is provided by Special Research Grants and Hatch Act Funds from USDA-CSREES, In cooperation with the State Agricultural Experiment Stations, and USDA-ARS.

SOP#: 8.13

AUTHOR: J. A. Thompson and J. D. Forder

REVISION #: 04

EFFECTIVE DATE: January 31, 2010

TITLE: **HQ Quality Assurance Files: Organization & Management**

PURPOSE To provide a method for orderly storage and expedient retrieval of all Active and Archive files.

SCOPE: All HQ QA personnel and those who interact with QA.

PROCEDURES: **1. Maintenance of the files is as follows**:

A. **Active Study Files**
To distinguish QA files, green folders will be used to enclose active, completed projects and facility files. QA files will be kept in file cabinets. Each file drawer will be labeled as to its contents. Numbered files should be filed by PR number.

When a Folder is removed from active files, an out card must be placed in the study file. The out card must have the initials of the person removing the files, along with a description of what is being removed.

B. **Facility Records**
Facility Inspection Records will be removed from the QA files at a minimum of every four years and placed in the designated QAU section of archive, room 235 A new index will then be prepared. The index will show the facility name and the applicable year(s) of archived materials. The current index and all revisions will be filed in a drawer labeled as such in the QA cabinets.

C. **Canceled Studies**
When a study is canceled the entire green folder is to be removed and placed in the canceled study drawer. These folders will then be transferred to archive within four years.

All other files will be moved out of their original location and archived whenever filing space is needed.

2. **Archiving QA Records at Headquarters**

A. As of the current SOP date, all QA files transferred to archives (Room 235, Wall Section K-V) are to be archived by date and file location. Archive date and file location will be documented in the Archive Log (Appendix D to SOP 7.1) as well as QA routing database by the Archivist. All files filed prior to SOP effective date are filed by PR # order with exceptions as noted in SOP deviation.

B. Completed studies are to be transferred from the active filing drawer and placed in the completed study drawer. The QA Auditor lists PR# and date transferred on the Finalized Index (Appendix A) located in a red folder at the beginning of the drawer). Prior to archiving, the archivist must verify that a signed QA Statement is included in each study folder. The finalized index will be verified against the actual file drawer contents. After contents are verified, the Archivist must sign and date the index. The original index is retained in the IR-4 HQ archive Log **(Appendix D to SOP 7.1) and a copy is place in designated area in QA.** .

C. Files in archive are maintained by the QAU Archivist. When a file is removed, an out card must be written up, with the initials of the archivist along with a description of what is being removed. Only designated Archivist can remove files from archive. When the file is returned the card is to be removed and the entries crossed out. All transfers must be documented in the Archive Log **(Appendix D to SOP 7.1).**

Prepared By: _____ Date: 1/6/10

Approved By: _____ Date: 8 JAN 2010

Complete QA Folders Index – Transfer to Archive Bi-Monthly

PR #	Date In/by	Archive Location	PR #	Date In/by	Archive Location

1/8/08

SOP #: 8.14

AUTHOR(S): Tammy W. Barkalow and J.D. Forder

REVISION #: 04

EFFECTIVE DATE: October 7, 2013

TITLE: **Final Quality Assurance Audit of Second Draft Final Reports (Final Report 2) and Preparation of the QA Statement**

PURPOSE: To provide guidance to Study Directors (SD); to outline the QA procedures for assigning auditing priorities, to provide assurance that all items of non-compliance with current Headquarters' SOPs and/or EPA GLPs have been addressed; and to provide instruction on preparing the QA Statement.

SCOPE: This SOP will apply to QA auditors. The "final" audit is the second one performed; a "closing check" is a review of the responses done to assure accuracy.

PROCEDURES: Section I - Initiation of Second Draft Report Audit Process

1. Study Directors (SD) will bring revised final reports (Final Report 2) to the HQ QAU and leave them in the area designated for Second Reviews. The primary QA audit of the final report will need to have been completed prior to bringing final report into QA for second round audit. The review tag will be updated, and the transfer to QA will be documented in the Final Report Tracking Log.

2. Using the most current EPA priority list for Final Report submittal, the available drafts will be assigned new or revised audit priorities by the QA Manager as necessary. Internal priority is typically based upon the most recent submittal date and the date that the draft was received in the QA office. An "A, B" letter/number system will be used to denote priorities (i.e., A_1 , B_1, etc.). However, priorities are subject to change based on Testing Facility Management (TFM) directives.

   As priority assignment changes are made on a review tag in response to such directives, they will be dated. If the SD or designee feels that a changed priority will present a problem, QA Manager should be contacted.

2. cont.

The QA Manager (or designee) will review the status of the Final Report 1 audit, and assign the final report 2 review to QA auditor. It will be the responsibility of the QA Manager to monitor the priority assignments, make changes and obtain outstanding corrected drafts, referring to the PR numbers on the whiteboard.

Section II. QA Procedures for Audit of Second Draft

1. Second reviews are performed by any trained QA auditors, generally at HQ, or done in tandem as part of the training process for new auditors.

In accordance with the priority schedule, the highest priority draft, its corresponding QA folder, and the available raw data including colored folders, are taken from their respective locations ("out" cards will be used).

The following will also be done:

- the Master Schedule for the project will be printed for review
- all project records from the QA routing database will be sorted and printed for review and the eQA system will be sorted by PR# and the audits reviewed.
- verification of complete response to all other QA audits will be done (if not done previously)
- the protocol and all changes will be reviewed

2. The revised second draft and the first draft are compared, to verify that corrections were made based upon findings noted in the first audit. If they were not, the primary audit is reviewed for the SD's explanation, since the SD may have elected not to make the change.

3. The current Master Schedule for the project is then examined to be certain it accurately reflects the project information. Raw data from terminated trials must be available for archiving in accordance with GLP. If any problems are noted with the Master Schedule, they will be brought to the attention of the Database Manager immediately.

4. The auditor, will then read through the final report up to Appendix 1, paying special attention to these areas:

A) overall format (GLP elements, IR-4 specific elements, compliance with PR 2011-3 (or current EPA OPP

requirements), correct Volume number (wherever shown)
B) accuracy of the Table of Contents as compared to the petition 2
C) spelling and grammar
D) dates of study initiation, experimental start and termination
E) residue values presented compared to the ASR tables
F) accuracy of any references to Figures, Tables or Appendices
G) archival location of raw data, test and reference substances
H) any other areas that appear incorrect or illogical

5. Utilize the Final Report Audit 2 form in eQA to generate the report as per the current version of SOP 8.17. The write-up will begin with any items left unaddressed from the primary audit. Using the original auditor's reference numbers will be helpful for the response and review process.
Findings generated by the second auditor will then be listed in numerical order.

Section III – Areas of GLP, SOP or Protocol Deviation

If findings stating non-compliance to GLP, an SOP or the protocol are in dispute between the SD and auditor, supporting documentation and/or discussion will be useful in setting precedent for guidance in similar situations.

Section IV – Preparation of the QA Statement

1. The Shared directory file, *QA Statements*, contains draft and final versions, indexed by year, of all QA statements generated at HQ. Save the QA statement, named for the PR#, in the draft folder of the current year. QA Statements can also be typed up after final report 1 audit if the audit was done at HQ.

2. The draft QA statement is prepared by using the audits from the QA green folder and QA audits generated and completed in the eQA system.

   Note: When utilizing paper QA reports the first "set" of reporting dates to the SD and TFM are used for reporting purposes. If other dates are used, the explanation must be added to the routing cover page, which may be viewed by EPA investigators. When utilizing the eQA system the reporting dates will be:

   For TFM – The date QA signs the QA report (this is the date

the email to TFM is generated that notifies them to acknowledge receipt of the new inspection report).

For SD: the date the TFM acknowledges receipt of the eQA generated audit (this is the date the SD is notified that a new audit is available that contains an action for them to complete).

There are two formatted footnotes in the draft QA statement. Additional ones will be added as necessary. The draft of the QA Statement will be verified to the original documents (if paper) or to the eQA system for accuracy, and also compared against contributing scientist QA statements.

3. The Final Report Audit 2 form in the eQA system will be completed by QA following procedures in the current version of SOP 8.17.

Note: QA conducting the audit will include a standard finding requesting the SD provide the date the raw data was transferred to the archivist.

4. After the Study Director or designee has completed all responses, the corrected final report is returned to the QAU for a "closing check," (the raw data will have been presented to the Archivist prior to the report being presented to QA for finalizing). The purpose of the closing check is to ensure that raw data are archived, and that all responses have been made. After all QA reports are finalized (in the eQA system or via paper) the QA statement may be finalized and sent electronically to the SD.

5. When the final QA Statement is brought to the QA for signing, a copy is made for filing in the QA green folder, which can then be removed from the active QA files and transferred for archival ("Completed" file drawers). The holding drawer begins with a central index that will be updated whenever files are added.
In the QA Final Report Tracking Log, the QA auditor will enter the date of transfer of the signed QA Statement to the SD, noting "Done" on the appropriate line.

Prepared by: _____ Date: 9/27/13

Approved by: _____ Date: 9/27/13

FINAL/AMENDED REPORT CHECKLIST

Study Title: _____

Study/PR Number:_____ Study Director:_____

QA Inspector: _____ Inspection Date: _____

To Be Completed by the QA Inspector

1. I have reviewed the amended report against the original audit performed by:

_____

_____ In addition, the corrections/additions/deletions that are shown on the following page(s) must be addressed.

Additional Comments:

2. Draft QA Statement Attached: _____ Yes (If not, explain:)

To Be Completed by the Study Director

Final archiving has been performed in accordance with current version of IR-4 SOP # 7.1 – Index will accompany the data.

Date the Raw Data/Study Folder was presented for Archiving:

_____ (SD initials:)

SOP #: 8.15

AUTHORS: J. Forder and J. Thompson

REVISION#: 02

EFFECTIVE DATE: April 8, 2015

TITLE: **Scheduling by Headquarters (HQ) QA of Field Data Books (FDB) for Auditing at HQ or for Transfer of Books to External QA Auditors**

PURPOSE: To provide instruction for the scheduling of field data book audits when Headquarters QA is the monitor. To provide instructions for transfer and security of field data books to contract auditors when services are used to meet proposed timelines.

SCOPE: IR-4 HQ QA staff involved in auditing and transferring field data books

PROCEDURES:

A. Scheduling of Raw Data Book Audits

1) The QA manager will prepare a monthly schedule of field data books for auditing by each HQ QA auditor. Whenever possible, there should be some commonality among the assigned books (same PR#, same researcher, etc.) to expedite the audit process. See Appendix A for the form to use. The completed form will be given to each auditor.

2) The target due date for completion of the FDB audit will be six weeks from the date of receipt of the book at HQ.

3) Auditors will be responsible for communicating to the QA Manager any problems in meeting their monthly deadlines.

B. Transfer from Headquarters

1) As directed by the QA Manager, Field Data Books will be sent to contract QA Reviewers.

2) The transfer process will be documented:
   - in the Field Data Log,
   - on each book's Chain of Custody page,
   - in a cover letter, accompanied by a Data Transfer Form.

3) Field Data Log:

   a) The Field Data Books to be transferred will be selected on the basis of common characteristics, or priority known or communicated to the QAU. (The auditing process is made more efficient when a maximum number of books from the same PR and/or researcher can be provided to the contractor.)
   b) In the comment field, the name of the receiving auditor or company will be entered.

4) Chain of Custody Page:

   Each field book's chain of custody page will be updated as the selected field books are removed from the QA holding drawer.

5) The FDBs to be transferred will be scanned. They will be brought to the copy room for scanning with a request indicating the date of request, name of person requesting scanning and the priority desired.

6) Copies of each project's protocol, protocol changes and applicable SOPs will be made to send with the field data books.

7) Cover letter and Data Transfer Form: A copy of the cover letter sent with the FDBs will be placed in the contractor's file, and the appropriate QA PR folder(s).

C. Return of Audited Books

When an external QA returns the original field data books, the date of return is entered in the Field Data Log. The original books are transferred in accordance with the current version of SOP# 5.1. The scanned versions of the returned field data books are deleted.

Prepared by: _____ Date: 20 March 2015

Approved by: _____ Date: 20 March 2015

Field Data Book Schedule for Month of

Field ID Number	Date Rec'd. at HQ	Target // Actual Date

Notes for the month:

Primary:

Processing reports/data:

Secondaries:

****High Priority***

SOP#: 8.16

AUTHOR: T. Barkalow

REVISION #: 00

EFFECTIVE DATE: October 7, 2013

TITLE: **Quality Assurance eQA system – Installation, maintenance, use and retention of records.**

PURPOSE: To provide an overview on the installation, maintenance, use and retention of records from the eQA system, and define a method for orderly storage and expedient retrieval of all Active and Archive files.

SCOPE: All IR-4 QA personnel, (QA Cooperators and QA contractors as needed) and those who interact with QA.

PROCEDURES:

1. **Installation of eQA software:**

The installation of the eQA software purchased from Quality Systems Integrators, (QSI) was performed on Rutgers servers (development and production) by QSI IT representatives in association with Rutgers' School of Environmental and Biological Sciences' IT staff assigned to the support of IR-4 computer systems.

2. **Maintenance of eQA software - Software maintenance**

Updates, patches and software revisions will be downloaded from QSI periodically. When updates, patches or revisions occur this change to the software will be recorded into the eQA installation and maintenance records and a printout of the email confirming the "change to the software has been made" will be retained.

3. **Use of eQA software**

   a. **Administration of eQA** – the eQA administrators are responsible for assuring the user lists, logins and QA report forms/workflows are properly designed, tested and maintained. Each form type is described and its workflow documented as part of the individual SOPs on the different types of QA inspections.

b. Contents of User Lists

User lists and logins – each user will be entered into the eQA user list. All items prompted for will be filled in. This is to include:

1. **Full name**
2. **Last name**
3. **First name**
4. **Employee number** –will be assigned by one of the administrators and are to be assigned as follows:
   a. ADMIN (ADMIN, ADM + HQ + phone extension)
   b. Mgmt + (F for field or HQ) + Region (CAN, NER, NCR, WSR, SOR) or ARS + either the phone extension # at HQ or the next assigned sequential number from the TMS User list.
   c. QA + (Region (CAN, NER, NCR, SOR or WSR) or HQ) + phone extension # at HQ or the next assigned sequential number from the TMS User list.
   d. FRD, LRD, QA or R+XC (Where X =F, L or QA for coordinators) + Region (CAN, NER, NCR, WSR, SOR) + the next assigned sequential number from the TMS User list.
   e. SDHQ + phone extension number
   f. TFMHQ (testing facility management headquarters HQ) + phone extension number
   g. IR4+ Region (CAN, NER, NCR, WSR, SOR or ARS) + the next assigned sequential number on the TMS User List

5. **Position/Title** – Position name can be from Rutgers job descriptions or assigned for regional/cooperating staff using the following naming structure. Their general system capabilities and structure are explained below:

   a) HQ Systems Administrator – assigned to person from Rutgers IT assigned to IR-4 and persons at QSI as deemed necessary. This entity will have full editing and software change control authorization.
   b) HQ Unit Coordinator - Rutgers position – will be assigned as an eQA administrator.
   c) QA HQ Assist. Director –IR-4 designation – will be assigned as an eQA administrator
   d) FRD or LRD + Region (CAN, NER, NCR, WSR, SOR or ARS) – these users may receive packet activities or be notified when new packets are available for viewing.
   e) QA + Region (CAN, NER, NCR, WSR, SOR or ARS) –

these users will be report generators, may have access to all packets in the system or be defined to only those locations as is necessary for their job function.

f) HQ Testing Facility Management or Mgmt – these users will have overall responsibility for acknowledgement of all generated packets and with their e-signature, verify that the packet (QA report) has been successfully completed.

g) SD HQ – will have access to all packets in the system and be assigned activities for inspections/ audits performed on their studies.

h) Region Field Mgmt – will have access to packets for their regional cooperators (locations) and maybe notified when new packets are generated for them.

i) RLC or RFC + Region (CAN, NER, NCR, WSR, SOR or ARS) - will have access to the packets for their regional cooperators (locations) and will be notified when new packets are generated for them.

j) Tech + Region (CAN, NER, NCR, WSR, SOR or ARS) – may be assigned activities associated with packets (but may not), but will be permitted to have read only access to packets for their location.

k) Asst. + Region CAN, NER, NCR, WSR, SOR or ARS) – will have read only access to packets for their regional locations.

l) RQAC + Region (CAN, NER, NCR, WSR, SOR or ARS) - these users will be report generators and will have access to all packets in the system.

m) PMC – PMC + Region (CAN, NER, NCR, WSR, SOR or ARS) – will have read only access to packets for their regions.

6. **Network Logon** – A network logon is to be assigned to each user. It will be in the form of their CITS login as assigned by IT for HQ personnel or will be cits\ (first initial) + last name, also assigned by IR-4 HQ IT. All login passwords will be chosen by the user for the eQA production system and manually administrated via the IR-4 HQ IT personnel. All passwords are to be kept secure and are not to be shared.

7. **Document Edit Path – c:\temp**

8. **E-Mail Address – as provided by the user**

9. **E-Mail Notify – yes, permits eQA to use email notifications to the user**

10. **Active – yes for active users, no for retired users**

11. Location (default IR-4 Project Headquarters)

c. Permission groups

Individual users will be assigned various permissions allowing them only the ability to read or read/write to the system as assigned by the administrators. Various Permissions groups and departments have been established to define and control what users can and cannot do in the eQA system. Access to packets (QA reports) will be assigned by the administrators depending upon what level of read or read/write access the user requires.

d. Location Lists

All test sites and IR-4 operational units will have a location established in the eQA system that will have two permission groups assigned, one a read only and the other a read/write. Additional permission groups are added to the system by the administrators when a new location is established/identified. Before a user can be added to eQA, their location(s), and it's permission groups, must also be available so they can be assigned the level of access they require.

e. Training of eQA Users –

All users will receive formal training that will be provided by eQA administrators or subject matter experts (SME's) that have received the TMS three day training program. The training will be differentially targeted for those users that are: 1) Receivers of eQA activities; 2) Receivers of eQA notification; and 3) those that are Report generators, (ie. QA). A successful completion of a test packet that has been generated by QA will be documented for all persons to be completing activities. The successful completion of the generation of a test packet will be documented for Report Generators to verify they can use the system. Specific overviews of packet/QA report contents will be presented in the specific SOPs on the QA activity.

A Frequently Asked Questions (FAQ) document will be kept and periodically updated (check for need to update twice a year). This FAQ will be found on the IR-4 website, under the Quality Assurance tab.

4. Archival/Retention of eQA records

a. Packet Integrity/security

The eQA system is designed that once a packet (a QA report) is finalized it is locked and cannot be altered unless specifically reopened by an administrator.

b. Server security and back up of eQA files

A copy of the eQA software was purchased from QSI and loaded onto two different servers at Rutgers University (production and development). The development server will be used for customization and testing of the eQA forms (QA Audit report forms software) prior to their being transferred to the production server for use. The IR-4 IT Systems Administrator and an administrator at QSI will be the only individuals that can alter the software code of eQA located on the Rutgers servers. All upgrades, patches or code changes will be recorded into the eQA installation and maintenance records and a printout of the email confirming the "change to the software" has been made will be retained. The eQA Administrators at IR-4 HQ are the only individuals that can create or alter the eQA forms, workflows, make changes to activity assignments or alter the workflow of a packet.

The Rutgers servers are currently backed up nightly to the server itself and then to tape the following night. The web files are backed up incrementally to tape each night and differentially to tape each week. Rutgers IT does a full backup monthly. The tape is swapped every month and placed in a fireproof locker in the server room.

IR-4 HQ will create a CD back up of the eQA data from the production server weekly. This CD will be presented to the archivist and logged into the archive weekly.

c. Periodic Testing of Back Up Systems

The eQA data will be backed up to CD and this backup system will be tested semi-annually to assure the backup can be used to recover the system. A CD that was archived the previous week of

the test will be removed from the archive and uploaded onto a "dummy" version of the software to verify that it is possible to restore the system from this archived copy of the software data. The testing of the system will be recorded into the eQA installation and maintenance records.

Prepared By: _____ Date: 9/27/13

Approved By: _____ Date: 9/27/13

SOP#: 8.17

AUTHOR: T. Barkalow

REVISION #: 00

EFFECTIVE DATE: October 7, 2013

TITLE: **Generation and distribution of QA reports using the eQA system**

PURPOSE To provide an overview on the generation and distribution of reports (packets) using the eQA system, and define a method for preparing the packets with all required elements.

SCOPE: All IR-4 QA personnel, (QA Cooperators and QA contractors as needed) and those who interact with QA.

PROCEDURES:

1. Definitions

a. Icons:

Forms Activity icon. Designates an activity for a form. Clicking this link from the activity displays the specific form on which the activity originated. If a user has Read/Write permission to the form, they will be able to enter information into the form. If a user has Read-Only permission, they will only be allowed to view information on the form. The description attached to the activity and icon will explain specific tasks that the recipient is requested to perform.

Signature icon. Designates that an e-signature is required. This icon is the standard signature icon used throughout the TMSWeb application.

Edit Icon. Allows for entering data into a free-use field (text editor) in a packet.

Workflow Icon. Allows the user to view the status of the packet's workflow progress.

b. SD – The Study Director
c. TFM – Testing Facility Management
d. FRD/LRD/PRD – Field, Laboratory or Processing Research Director
e. Packet – a QA report written using the eQA software.

f. eQA – The software system purchased from Quality Systems Integrators (QSI) that has been customized to provide a mechanism to write, respond to, distribute and retain QA inspections/audit reports in compliance with 40 CFR Part 160.35 criteria.

g. eQA forms – Specific report forms will/have been created that will be used to generate the report for the defined types of QA inspections. Information on the content and use of the individual forms can be found in the SOP that covers the type of inspection/audit.

These include, but are not limited to:

i. Protocol Audit (PA)
ii. Field Critical Phase Inspection (FCPI)
iii. Lab Critical Phase Inspection (LCPI)
iv. Field Raw Data Audit (FRDA)
v. Analytical Raw Data Audit (ARDA)
vi. Analytical Summary Report Audit (ASRA)
vii. Final Report Audit 1(FR1)
viii. Final Report Audit 2 (FR2)
ix. Facility Inspection (FI)

h. Assigned Activity – this terminology is used when describing that a user has been assigned an action that is required.

i. Text editor – This is the mini word processor that is part of the eQA system. By having the capabilities of a word processor the information being added to the database can be formatted for easy reading, but retain its search ability within the system.

j. User – eQA users are sorted into three categories:

i.Report Generators -QA personnel who create packets

ii. Receivers of eQA activities – persons identified by QA who will have responsibility to respond to QA findings and take all appropriate actions to activity assignments.

iii. Receivers of eQA notifications – these individuals will receive notice of packet availability for viewing on a read only basis.

Any user of the system can participate in any of the user categories dependent on their role in the generation and completion of the QA report or their need to know its content. Generators are limited to QA personnel

or their support staff whose function is to generate and or administer the system to assure the system is working and packets/ reports are being completed.

2. Using the eQA software system

a. Creation of customized forms used in eQA

i. The IR-4 eQA forms will consist of 5 sections (however the FR2 report will only have 4 sections as there won't be a checklist for the FR2 QA form).

These sections for PA, FCPI, FRDA, LCPI, ARDA, ASRA, FR1 or FI QA report forms include:

- Section 1: Cover Sheet
- Section 2: Checklist
- Section 3: QA Findings/Recommendations
- Section 4: Response to QA Findings
- Section 5: SD/TFM or TFM Approval

The sections for the FR2 QA report form include:

- Section 1: Cover Sheet
- Section 2: QA Findings/Recommendations
- Section 3: Response to QA Findings
- Section 4: SD/TFM Approval

ii. The contents of each of the customized forms and their associated workflows will be printed out, signed and dated and retained with the eQA installation and maintenance records. These records will be archived at least yearly in the IR-4 archive for long term retention. When a form is altered, the new form will be printed, signed, dated and retained.

b. Generation of eQA packets using specific customized forms for specific types of QA inspections/audits

i. QA conducts audit/inspection
ii. Log in to the eQA
iii. Choose the form type appropriate to report your QA activity (use left hand side menu to select appropriate type of form from the +Forms Module)
iv. Click button to add a new packet
v. Section 1: Complete Cover sheet

Note: Once added, the packet cannot be deleted except by an administrator. Always save your work before switching to another section in the form.

Note: Once a packet section has been saved all changes to that section are captured by an eQA internal audit trail (that is captured within packet sections).

a) Header - Audit type Chem/Crop PR# (with FID or LID as appropriate). Field ID (FID) and Laboratory ID (LID) are defined in current HQ SOP 4.1.

Example: FRDA Happy Bug Spray/Tomato 03333.13-CA43

Note: the correct acronym for the audit type will be displayed in the packet ID

Example: FRDA000001 or FCPI000022

b) Location - Select the Test Site/location (from the drop down menu) where the person (FRD, LRD, SD, etc) who carried out the activity or action being reported resides (for a FRDA audit select the location at which the FRD resides, as appropriate).

c) Date – this date is assigned by the system as the date the packet is first created.

d) Study Title – Chemical/Crop at a minimum (as per protocol)

e) (Field, Lab or Study) ID Number – enter the full FID, LID or PR# as appropriate

f) Origin of Audit – All audits generated by IR-4 QAU personnel using the eQA system to generate the QA report are considered internal audits. Those audits performed by non IR-4 test site QA and provided to IR-4 for reporting to SD and TFM in paper form or electronically (via email, etc.) will be considered external audits and handled according to procedures found elsewhere in this SOP.

g) Inspection Date – select the date or dates that activities of the audit took place. Multiple dates can be selected that will document when QA was working on the audit and report.

h) Notification of Activity (as per the prompts in the form) – The users who are responsible for corrective action/responses will be named here. They will receive notification via email when they have activities available for follow up.

i) Notification (read only) - The users who will receive notice that a new packet is available for review, but will not be required to complete an activity. They will receive email notifications that the new packet is available on the eQA system for viewing.

j) Quality Assurance Inspector – the user captured automatically by the system, as being the individual who created the packet.

k) Study Director (SD) – This individual is identified in the study protocol

l) Testing Facility Management (TFM) – These individuals are identified in IR-4 SOP 6.0, appendix E. The primary TFM designate for different forms are noted on the cover sheet of the form, however, any TFM designate can receive and complete activities as needed.

vi. Section 2: Complete QA Checklist – select the appropriate response from the drop down menu or entry prompt as provided on the form checklist. When complete be sure to save your work in a section before moving to the next section or moving to a different packet. (Not applicable for FR2 report forms).

vii. Section 3: Complete the QA Findings/Response section – QA findings for FRDs/LRDs, and or SD are entered in this section. Attach any documents containing example calculations, demonstration pages, etc. to this section using the "attachment" function. Refer and explain all attachments in the findings or comments sections. Be sure to save your work frequently. While in the text editor select the icons "submit" then "save" when closing and saving your work. This section is identified as Section 2 for FR2 report forms.

Note: Attempting to use the attachment functions while the text editor is open may result in a loss of entries if not properly saved.

As needed, attach a Word document copy (or other word processors that can be universally used) containing all findings and comments captured in this section. Once QA has completed this section they will acknowledge

they are finished (click on the "finished" icon) and move to signature. By e-signing the QA section of the eQA form the QA generating the report is verifying that they certify the entries are theirs and that their e-signature is equivalent to a wet signature. Once signed, Sections 1 through 3 of the packet are locked and cannot be opened, altered or deleted (except by an administrator with authorization and proper documentation as to why changes were made).

Once QA has completed their report the TFM is notified via email that a new QA report is available to view. TFM will be required to log on to the system and acknowledge receipt of the audit/inspection report by clicking on a receipt icon in the packet. An acknowledgement of receipt is required before the system will notify the SD and other users about the availability of the new packet.

viii. Section 4: Complete the Response to QA Findings section - The users assigned activities for a packet will be notified of the availability of the audit via an email and are to respond to the findings in section 4. Users will log into the eQA system and go to their "my activities" page for a listing of the eQA reports requiring their attention. Note: if users link to the eQA packet via the email notification ,be sure that: 1) you do not open multiple tabs of your browser in eQA. If this happens, close all tabs but one and go to your "my activities" page to access the packet you wish to work on; 2) if you encounter a notice that" the packet is no longer available or has been deleted", go to your "my activities" page and access the packet there via the "FA" page icon. The responses must be entered into the system and saved in the text editor provided in section 4. Each response line is to be dated and initialed by the person entering the response. The user assigned the activity may choose to respond utilizing the Word document copy of the findings, but the findings, responses, initials and dates must be saved into the appropriate text editor for proper inclusion in the database. When exiting the text editor users will need to click on the "submit" button then click the "save" icon to save their work in the eQA system. Failure to properly close the text editor may result in the loss of the entries made to the text editor since it was last saved. Users responding to QA findings will need to attach any clarifying memos, corrected pages or other materials generated as part of their responses using the attachment function in Section 4. This section is identified as Section 3 for FR2 report forms.

Note: Providing a response to QA findings is not sufficient to correct a problem. Be sure that documentation or memos needed to be added to the

data are generated.

Users will need to send all originals, corrected pages or other materials to IR-4 HQ (can use the preaddressed envelopes provided) for inclusion into the FDB or appropriate data files. Users will have a length of time to complete their activities after which time the eQA system will begin notifying them that their work is overdue by sending out emails. The timing of these emails and identity of who will receive the emails will be identified in the eQA system.

Once the users have completed their responses and the needed attachments have been made to Section 4, the users will need to click the "finished" icon. Once this icon is selected, the user(s) assigned the activity will not be able to edit the section further. If this icon is selected accidently, please contact an administrator and they can roll back the packet to the step in the work flow that will permit further entry.

Please remember that all corrected pages, memos , notes to files, etc must be retained in the data or forwarded to IR-4 HQ for inclusion in the data package if located there.

ix. Section 5: SD/TFM approval –

Once all activities are completed and the "finished" icon selected the SD will be prompted (notified by email) to review the responses and attachments for completeness. If the SD finds the actions appropriate they will click the "Finished with review, OK to sign" icon indicating the review is complete. If the actions are insufficient, the SD will click the icon "reject" and roll the system back to reopen Section 4 for further follow up. The SD will be prompted for the reason for the rejection and this will be captured within the packet. Further actions will be taken until parties are satisfied, the section is complete, the SD will review and when complete, the SD will select the "Finished with review, OK to sign" icon. This section is identified as Section 4 for the FR2 report form.

The SD will then be prompted to sign the packet using the e-sign function. This e-sign function verifies the identity of the individual based on their logging into the system and the prompt for signature attests to their entry of the password confirming their identity and is comparable to a wet signature.

Once the SD signs the packet the TFM is notified (via email) of the need

for their review. If the TFM finds the actions appropriate they will click the "Finished with review, OK to sign" icon indicating the review is complete. If the actions are insufficient, the TFM will click the icon "reject" and roll the step back to the SD review, the SD will then address the issue or reject at this step and roll the activity back to the response step which will permit additional entry into section 4 (reopens the text editors for additional entries). The TFM will be prompted for the reason for the rejection and this will be captured within the packet. Further actions will be taken until parties are satisfied, section 4 is complete, the SD will review and when complete, the SD will select the "Finished with review, OK to sign" icon. The TFM will be re-notified of the need to review the packet. The TFM will click the "Finished with review, OK to sign" will then e-sign the packet, thereby approving its contents and closing the packet from any further additions, edits or changes. An email notification will be sent to the Quality Assurance personnel that created the packet that the packet has been completed and all signatures are complete. They will be required to click the "I have been notified of closed audit" icon, verifying they have received and viewed the closed packet.

3. Distribution of packets -

a. **Internally generated packets** – All packets generated by IR-4 participating QA will be termed as internally generated packets.

b. Externally generated QA reports – All packets (QA reports) received from non IR-4 eQA participating QA will be routed as externally generated QA reports.

i. An Administrator of the eQA system will add a new packet and fill in the cover page using information from the externally submitted QA report. An activity will be assigned to the SD (as noted in the protocol for the study) for seeing the responses and corrective actions are completed as necessary. If regional personnel (Field, Laboratory or QA Coordinators) have a need to be notified of the availability of the inspection report, they will be identified in the "Notification, read only" entry line on the coversheet.

ii. Once the new packet is created, the Packet ID number will be written on the printout/paper copy of the audit received at IR-4 HQ. This will link this audit to the electronic routing of it in the eQA system.

iii. By selecting "external" on the cover page the checklist is automatically bypassed and will not be used.

iv. The administrator/QA Personnel creating the external packet will be the "Quality Assurance Inspector" identified, however the actual auditor's identity can be viewed by looking at the audit report itself (this will be attached in section 3, QA Findings/Recommendations).

v. The administrator will go to Section 3 and in the text editor explain that the audit report can be found as attachment " X" of this section. Also, they will direct the SD to provide any needed responses and or corrective actions in the text editor in Section 4 as per normal procedures and to include the responses as an attachment to Section 4 that may be sent back to the originating QA as needed. A hard copy of the audit, with its assigned eQA packet number will be placed into the QA green folder.

vi. Reviews and approvals to these external audits will use normal procedures as described in Section 2.ix.of this SOP.

Note: Because external test site's QA may also require proof of SD and TFM review it may be necessary to deliver their paper audit (or copy sent) by hand to the SD and TFM for their signature or printouts from the executed packet sections be made and sent back to the originating QA as proof of receipt.

Note: printouts from the eQA system to be used to verify receipt of SD and TFM receipt and approval may include the workflow, cover sheet and signature page.

Prepared By: _____ Date: 9/27/13

Approved By: _____ Date: 9/27/13

SOP #: 8.18

AUTHORs: T. W. Barkalow and M. Beran

REVISION #: 00

EFFECTIVE DATE: October 3, 2016

TITLE: **Quality Assurance (QA) – Contributing Scientists Report Audit**

PURPOSE: To detail procedures followed by IR-4 Quality Assurance (QAU) or their representative, when conducting contributing scientist report (to include processing reports, seed treatment reports, and others as applicable) audits of IR-4 sponsored studies.

SCOPE: This SOP applies to all IR-4 facilities, and all QAU authorized personnel auditing an IR-4 study of an IR-4 cooperating facility. This form does not replace the Analytical Summary report audit for use with analytical data/reports. Contributing scientist's reports audited by qualified QA at the site of origin may not need to be audited by IR-4 QA.

PROCEDURES:

Upon receipt of the draft or completed contributing scientists report , a member of the QAU unit will log it into a Quality Assurance tracking log. The information entered at this time will be, but not limited to, study number, date received by QA, audit type, and author. The author will ensure that all raw data are presented with the report, or will be made available to the auditor.

The audit will be conducted using the IR-4 Project Contributing Scientists report/data checklist (Appendix A) as a prompt and note taking tool. QA findings will be documented using the eQA system following the procedures in the current version of SOP 8.17. Explain all findings and questions fully. If appropriate, provide a recommended course of action. Be specific in the description of the finding or question and reference where it can be found in the raw data or checklist as appropriate. This will permit expeditious correction. Comments, if any, will be listed separately and do not require a response.

Approximately 50% of the data presented in the text of the report and tables/calculations sheets in the report will be audited back to the original data. This percentage may be decreased or increased at the discretion of the QA or the auditor may return the report for further correction before continuing with the audit.

QA will audit the report/data to assure that it reflects the methods, the SOPs, and the raw data of the study, and that all circumstances that may affect the quality or integrity of the data are discussed in the text of the report and report any discrepancies.

Verify that any protocol changes have been properly documented and authorized by the Study Director and Sponsor, and that the finalized protocol change forms have been received at the test site.

Check to see that all problems encountered (GLP, SOP or protocol deviations) have been properly documented. Check to see that data entries are made in a timely manner (as the procedures are being performed).

Verify that all study related activities have been documented and provide clear and complete reconstruction. This is not an exhaustive list. The audit will take direction from the study protocol and its changes.

Any findings likely to affect the integrity of the study found during the audit of the data will be communicated to the Study Director and Testing Facility Management (TFM) immediately.

Inspections performed at non-IR-4 test sites (e.g., Private Contract Facilities, Cooperating Laboratories) may be performed in accordance with the QA auditing procedures in their SOP's, provided they meet the requirements as defined in the current EPA GLPs. All audits generated outside of the IR-4 QAU will be handled as "external" audits as described in the current version of SOP 8.17. Note: QA in-life inspections of non-field treatment activities (processing, controlled seed treatments, etc. will be routed as LCPI reports).

Internal audits are not to be shown to persons outside of the IR-4 program, unless written authorization is received from IR-4 Management (i.e., Executive or Regional Director).

Written By: Tammy W Baker Date: Sept 26, 2016

Approved By: [signature] Date: 26 Sept 2016

Study Title:
Lab ID Number:

Form Group: Contributing Scientist Report/Data Audit
Packet ID: CSRA-
Audit Type Chem/Crop/PR#(ID) :
Location:
Date:
Closed:

A. Cover Page
Yes, No, N/A

Study Title:
Lab/Processing/Seed Treatment ID#:
1. PR# on Report:
2. Title of Report Accurate:
3. Author (s) Presented:
4. Report Date:
5. Sponsor Named:
6. Study Director (Name):
7. Research Director (Proc, Seed Trt., etc) (Name & Location):
8. Study Timetable:
a. Initiation Date:
b. Experimental Termination Date:

B. Good Laboratory Practice (GLP) Statement
YES,NO,N/A

9. Exceptions to the GPL Standards listed:
10. Research Director's Signature (s):

C. Quality Assurance Statement
YES,NO,N/A

11. QA Statement Complete:
a. Date (s) of Inspection (s):
b. Name of Person (s) Inspecting:
c. Date Reported to SD and TFM:
d. Signed and Dated:
12. Signed & dated:

D. Study Participants
YES,NO,N/A

13. All Study Participants Listed:

E. Table of Contents
YES,NO,N/A

14. Table of Contents to contain all Sections of Report:
a. List of Tables:
b. List of Figures:
c. Appendices:

Study Title:
Lab ID Number:

d. Page numbers included and accurate:

F. Archive Statement

15. Data Archive Location Provided & According to the Protocol:

G. CSR Content YES,NO,N/A

16. Objective(s) / Introduction included:

17. Materials/Methods:

a. Methods of Trt. /Processing, etc. Presented :

b. Test/Reference substance(s) (Name, Source, lot#, Purity, Expiration Date, Storage:

c. Reagents:

d. Equipment (s) used Identified:

e. Preparation of Test/Reference Substance(s) and Fortification Solutions Adequately Documented:

f. Preparation of Reagents Described:

g. Description of Sample Preparation (sub-samples, chopping or grinding used for analysis):

h. Analytical Procedure Named and Available:

i. Instrument(s) and Parameters Used:

j. Limits of Detection and Quantitation (defined in SOP):

k. Method of Quantitation (e.g., software) Sample Calculation Presented. :

18. Sample Inventory and History:

a. Test System:

i. Commodity (ies) of Fractions:

ii. Field ID#s:

iii. Field Research Director name(s):

iv. Total # of Samples:

v. Form(s) of Sample (whole, ground, etc.):

b. Storage (storage period and temp.) for Samples & Extracts:

C. Relevant Dates (e.g., harvest, sampling, application(s), Processing, Fortifications, Extractions, Analyses, etc.):

d. Were samples stored in appropriate form :

19. Results and Discussion

a. Processing flow chart/mass balance presented, as applicable:

b. Results have been accurately transcribed to the study report:

c. All relevant raw data were presented:

d. Use of correction factors clearly presented.

e. Explanation/Description of Calculation Technique Presented (if automated?) are formulas visible:

f. Sample Calculations for Fortified Control Presented (at a minimum):

g. Calibration curves or bracketing standard(s) values presented:

h. Clearly labeled and representative chromatograms/spectra presented:

i. If corrected values reported are the apparent values are also presented?:

Study Title:
Lab ID Number:

H. Appendices
YES,NO,N/A

20. Test/Reference Substance Characterization:
a. Contains GLP Status and Archival Location:
b. Copy of Certificate of Analysis Presented:

I. Data
YES,NO,N/A

21. Data properly signed/initialed and dated:
22. Data changes GLP compliant:
23. Data Pages is Identified by Study # and Paginated:
24. Raw Data Complete:

J. Protocol/SOP
YES,NO,N/A

25. Protocol and all Applicable Changes Present:
26. Protocol Followed or All Deviations Issued and Approved:
27. All SOPs Followed or Deviations Issued and Approved:

SOP #: 9.0

AUTHORS: T. White

REVISION #: 00

EFFECTIVE DATE: July 21, 2006

TITLE: Conducting non IR-4 Sponsored studies

PURPOSE: To provide a uniform procedure and document specific SOP needs associated with conducting non IR-4 sponsored GLP studies.

SCOPE: This SOP applies to studies conducted for which IR-4 HQ at Rutgers University is the Testing Facility and maintains study directorship, but is not the Sponsor of the research. Where noted, this SOP will supersede the procedures as noted in other IR-4 HQ SOPS for those studies being sponsored by organizations other than the IR-4 Project.

PROCEDURES:

1) Protocol – this section is to address needed changes to sections of SOP 4.1 to accommodate for non IR-4 Sponsored studies.

4.1.1 Definitions:

Personnel – All sections are relevant for non IR-4 Sponsored studies with the following additions:

Sponsor Representative (SR) – The individual(s) designated by the Sponsor who will sign the protocol, protocol changes and final reports The Sponsor identity will be designated on the master schedule by an alphabetic letter incorporated into the PR # (see section update in this SOP for SOP 4.1.5)

Field Program Manager (FPM) – This term is to be used synonymously with Regional/ARS Field Coordinator and is designated in the protocol.

Laboratory Program Manager (LPM) – This term is to be used synonymously with Regional/ARS Laboratory Coordinator and is designated in the protocol where appropriate.

Principal Investigator (PI) – This term is to be used interchangeably with the term Field Research Director.

4.1.5 Study Number:

Each study is assigned a unique identification number. The first digit of the identifier is assigned a letter (beginning with Z and working backward through the alphabet through M) that will be used to designate the identity of the Sponsor of non IR-4 Sponsored studies. The first such designation will be the letter Z, which will designate Cerexagri, Inc as the Sponsor of the study. All further use of other alphabetic designations will be assigned via a SOP amendment to this SOP.

4.1.6 Field ID number

Each testing site will be assigned a specific identification number. The FIELD ID. NO is in the following format for non IR-4 sponsored studies:

XX-YY$NNN

XX = year for the trial to be conducted

YY = the state, territory or province designation for the test site

$ = identifying this trial as a non IR-4 sponsored study

NNN = the sequential number of the particular field trial being conducted in a given state.

4.1.7 Approval

The protocol is approved once it has been signed by the Sponsor Representative and the Study Director. All non IR-4 Sponsored study protocols will also be signed by IR-4 Testing Facility Management and the Study Director Management (which in the case of non IR-4 Sponsored studies are to be the same individuals who act as Sponsor Representative as designated in Appendix A of SOP 4.1). The Study Director signs the protocol last.

2) Protocol Changes (Amendments/Deviations)

This section addresses the differences in procedures relating to SOP 4.5 and the amendments and deviations.

4.5.5 Protocol amendments and deviations are officially approved once the Study Director has signed the document. Other required signatures on these documents will include that of the Sponsor Representative and Study Director Management.

3) Master Schedule

This section addresses differences in procedures relating to SOP 4.4 on the IR-4 master schedule for non-IR-4 sponsored studies

4.4.2

a) The master schedule shall use the Study Number designation for non-IR-4 sponsored studies as outlined in section 4.1.5 of SOP 4.1.

b) The term Principal Investigator will be used synonymously with the term Field Research Director.

c) The use of the Regional Code to be used to track the movement/status of the field data notebook/trial conduct will include the use of FPM to stand for Field Program Manager.

4) Final Reports

This section addresses differences in procedures relating to SOP 6.0 concerning the final report for non IR-4 sponsored studies.

6.0.7 The final report will need to be signed by the Study Director, Sponsor (non IR-4 personnel) and Testing Facility Management to be considered finalized for non IR-4 sponsored studies. The Study Director signs the final report last.

5) QA procedures

This section addresses those issues from SOP Section 8 (QA SOPs) for non IR-4 sponsored studies.

Facility inspection reports will be forwarded to IR-4 HQ QA for routing to the study director and testing facility management. When applicable, the Sponsor can request to also be provided a copy of this inspection. The facility inspection reports will not be provided to the FPM unless the FPM needs to carryout follow up actions or correction.

Prepared By: _____ Date: 7/17/2006

Approved By Robert E. Hahn Date: 7/7/2006