SOP Log

ID # S000 80

Region: NE

State: Maine City: ORONO

Location: Field U of Maine

FRD/LRD: David Yarborough
Submitter

Effective Date: 3/10/15

Received at HQ: [signature] 6/30/15 Date to Reviewer: 6/30/15
Sign/Date

Reviewed By: [signature]

Description of Material (s): 2015 SOPs & Index

File Format: E-mail ☐ CD ☐ Hard Copy ☒

Electronic copy ok to use: (Y) or No If no, indicated what needs to be done
(Circle one)

Date from Reviewer: 6/30/15

Date Posted: 7/2/15 Archive Date: 7/2/15

Archive Location: Active File Rm. Cabinet 3 Drawer 2

Sign: [signature]

Comment: —

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

STANDARD OPERATING PROCEDURES FOR

MAGNITUDE OF THE RESIDUE-FIELD TRIALS CONDUCTED

UNDER GOOD LABORATORY PRACTICES

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Revision No.: 1

Effective Date: 10 March 2015

Field Research Director: David E Yarborough DEY 3/1/15
David E. Yarborough (Signature) (Initials) (Date)

Approving Official: Edith L Lurvey EL 3/10/2015
Edith L. Lurvey (Signature) (Initials) (Date)
Regional Field Coordinator

The above signatures, initials and dates constitute approval of the entire set of Standard Operating Procedures for the specified revision and effective date.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Table of Contents Set Revision 1 Effective date: 10 March 2015

NUMBER TITLE

1. GENERAL
- 1.1:0 General requirements for the development and use of Standard Operating Procedures (SOPs)
- 1.2:0 Numbering system for SOPs
- 1.3:0 Format for use in developing SOPs

2. PERSONNEL
- 2.1:0 Designation of Field Research Director and responsibilities
- 2.2:0 Personnel
- 2.3:1 Documentation of Training
- 2.4:0 Organizational Chart

3. TEST SITE AND AGRONOMIC PRACTICES
- 3.1:0 Field location selection for field trials
- 3.2:0 Commodity maintenance

4. TEST SUBSTANCE HANDLING AND STORAGE
- 4.1:1 Test Substance receipt and handling
- 4.2:1 Storage of GLP Test Substances
- 4.3:0 Handling pesticides safely
- 4.4:1 Disposal of pesticides
- 4.5:0 Reagent receipt and handling

5. TEST SUBSTANCE APPLICATION AND EQUIPMENT
- 5.1:0 Calibration of a CO_2-propelled boom sprayer
- 5.2:0 Measuring a liquid pesticide formulation
- 5.3:0 Calibration and use of an electronic scale used to weigh GLP Test Substances
- 5.4:0 Adding pesticide concentrate to the water carrier in a spray tank
- 5.5:0 Procedures for the application of the Test Substance(s) in the field
- 5.6:0 Cleanup of application equipment
- 5.7:0 Procedures to follow when a problem occurs in the application of the Test Substance

6. OTHER EQUIPMENT VERIFICATION/CALIBRATION AND MAINTENANCE
- 6.1:0 Calibration/verification of instruments and gauges
- 6.2:0 Verification and use of thermometers
- 6.3:0 Verification and use of temperature data loggers

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Table of Contents Set Revision 1 Effective date: 10 March 2015

NUMBER TITLE

7. RESIDUE SAMPLE HANDLING
- 7.1:0 Residue sample collection and storage
- 7.2:0 Sample shipping procedures

8. DATA COLLECTION, HANDLING AND RETENTION
- 8.1:0 Collecting and recording of raw data
- 8.2:0 Handling data that transcend two or more trials, and certified copies
- 8.3:0 Collection of raw data electronically
- 8.4:0 Disposition of raw data and documents for GLP trials

9. EPA AUDIT PROCEDURES
- 9.1:0 Procedures to follow prior to an announced EPA inspection
- 9.2:0 Procedures to follow during an EPA inspection (Field trial site inspection/outside agency)
- 9.3:0 Procedures to follow after an EPA inspection

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 March 2013

Author: Jennifer Cote

Title: 1.1:0 General requirements for the development and use of Standard Operating Procedures.

Purpose: To provide guidance to scientists in the development and use of Standard Operating Procedures (SOPs) when conducting research under Good Laboratory Practices (GLP).

Scope: All Studies and/or trials conducted under Good Laboratory Practices (GLPs) at this location

Procedures:

1. This facility shall develop Standard Operating Procedures (SOPs) for studies conducted under Good Laboratory Practices (GLP), and shall cover all phases of that research. These SOPs shall cover all the magnitude of residue (MOR) studies and/or trials conducted to generate data in support of the registration of pesticides.

2. Each SOP shall be reviewed and/or revised as needed, at least every three years. The SOPs shall be reviewed by the Field Research Director or assigned personnel, and approved by the Regional Field Coordinator.

3. The SOPs for researchers in the IR-4 Northeast Region shall generally be approved as a set before the initiation of GLP trials. Approval shall consist of the dated signature of the Regional Field Coordinator on the title page. The title page shall show, at a minimum: the test site location covered by the SOPs; the revision number; effective date; dated signature of the Field Research Director or assigned personnel; and the dated signature of the Regional Field Coordinator as approving official. Any SOP revised or generated in a given year, after the SOP set has been signed, shall be signed and dated separate from the set and incorporated into the SOP set when next revised..

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

4. The effective date and revision number shall be changed to reflect any revisions; both on the title page for the SOP set, and on the individual SOP being revised. The revision number shall begin with 0 and increase sequentially with each revision. If revisions are made to individual SOPs, the revision number and effective date shall be changed to reflect the revision, and the title page shall be signed and dated accordingly. Please note that if an individual SOP is not revised, the revision number and effective date shall not be changed, even though the set is being revised. If the SOP set is reviewed, but not revised, the title page shall retain the original revision number and effective date. A statement may be added to the title page, if the SOPs are being used for another year.

5. Any deviations from the SOPs shall be noted in the Field Data Book (FDB) and approved by the Study Director. Please note that copies of approved SOP deviations are generally not returned to the Field Research Director (FRD).

6. Any SOP which is no longer applicable may be inactivated/retired by the addition of a procedure statement at the end of the SOP indicating that the SOP has been inactivated and the date that the inactivation takes effect. Inactivated SOPs shall be noted in the list of revisions for the year in which the inactivation takes place. Inactivated SOPs may be reactivated by the addition of a procedure statement to that effect, indicating the date of reactivation. In rare cases, SOPs may be retired/inactivated, with some or all of the points incorporated into other SOPs. In that case, a statement to that effect shall be placed behind the revision number with the date and SOP into which the points have been incorporated.

7. Corrections of simple typographical errors shall still be considered a revision, and shall change the Revision Number and Effective Date.

8. Original signed SOP sets should be sent to IR-4 Headquarters for archiving, while maintaining certified copies at the facility for researcher use.

9. SOPs of more than one page shall be identified on each page. Each additional page shall contain the Field Research Director's name, the number of the SOP, and the page number. The revision number is included after the SOP number. This identification shall be located at the bottom of the page. For example:

David E. Yarborough	SOP 1.1:0	Page 1 of 1
David E. Yarborough	SOP 1.1:0	Page 2 of 2

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 March 2013

Author: Jennifer Cote

Title: 1.2:0 Numbering system for SOPs.

Purpose: To provide a general outline for SOPs via a numbering system.

Scope: All SOPs shall follow the numbering system to provide uniformity in the system.

Procedures:
The numbering system for SOPs by section is as follows:

1. General
2. Personnel and Facilities
3. Agronomic Practices
4. Pesticide Handling and Storage
5. Test Substance Application and Equipment
6. Calibration and Maintenance of Other GLP Equipment
7. Residue Sample Handling
8. Data Collection, Handling and Retention
9. EPA Audit Procedures

Each SOP within a section shall be numbered sequentially after the period behind the SOP number, for example 1.1, 1.2, 1.3 etc. This allows for the addition of new SOPs to the section to which they pertain.
The Revision Number shall be numbered sequentially starting at zero (0). Note that the individual SOP revision number changes only when that SOP has been revised.

Some common abbreviations used in these SOPs are:

FDB = Field Data Book	FRD = Field Research Director
GLP(s) = Good Laboratory Practices	RFC =Regional Field Coordinator
MOR = Magnitude of Residue	SD = Study Director
SOP(s) = Standard Operating Procedures	

Please note that a significant revision of the SOPs for this location was made for 2013. This included changes in the numbering system and location of individual SOPs. To avoid confusion, this SOP set is being considered completely new, restarting with Revision 0 and 2013 Effective Dates. This revision supersedes the previous set of SOPs from this location.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 March 2013

Author: Jennifer Cote

Title: 1.3:0 Format for use in developing SOPs.

Purpose: To assure a uniform format in the development of SOPs.

Scope: Applies to all SOPs developed by Field Research Director for use in GLP trials.

Procedures:
Header for each page: University of Maine, David E. Yarborough, Plant, Soil and Environmental Sciences Dept., 5722 Deering Hall, Orono, ME 04469
Space
Effective Date: (date when SOPs take effect, can be date of approval).
Space
Author: (Name of person developing the SOP, not always the FRD).
Space
Title: Tab SOP Number: (General category section. number of individual SOP) Tab SOP title.
Space
Purpose: (Brief description of the purpose of the SOP).
Space
Scope: (Determines where and when the SOP is applicable).
Space
Procedures: (Describe the operating procedures in numerical order from beginning to end so that an intelligent person with knowledge of the process can carry out the procedures without any verbal input from other sources).

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 March 2013

Author: Jennifer Cote

Title: 2.1:0 Designation of Field Research Director and responsibilities.

Purpose: To provide information on how a Field Research Director is designated and outline their responsibilities.

Scope: Field test sites conducting GLP research.

Procedures:

1. The Field Research Director (FRD) is designated by the Study Director, based on the recommendation of the Regional Field Coordinator. The Field Research Director shall be a scientist with appropriate training and experience to conduct the work. If the FRD can not continue with the assigned IR-4 research, then the Regional Field Coordinator shall work with Rutgers Fruit Research & Extension Center personnel to provide a replacement or ensure the completion of ongoing trials.

2. The Field Research Director has the responsibility for the following:
    a. Assure that the trial is carried out according to an approved protocol signed and dated by the Study Director.
    b. Assure that personnel, resources, facilities, equipment, materials and methods are available as scheduled for the conduct of the project.
    c. Make sure that all personnel conducting a GLP trial understand the protocol and SOPs for any portion of the project in which they are directly involved.
    d. Communicate with the Regional Field Coordinator (RFC), Quality Assurance Officer (QA), Study Director (SD) and/or lab personnel on important critical phase dates and events. Coordinate in-life inspections with QA.
    e. Assure that all comments/questions from the QA, RFC and SD are responded to in writing, or direct contact (telephone, e-mail, etc.).
    f. Ensure all raw data, summaries and other items connected with the GLP research are transferred to IR-4 Headquarters for archiving.
    g. Maintain certified copies of the Field Data Book until the data are submitted to the U.S. EPA.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

h. Maintain a file of current resumes, job descriptions and training records for all key personnel engaged in the trial. Ensure the information is archived at IR-4 Headquarters when personnel leave or other changes occur.
i. Assure that a copy of the Master Study Schedule for all GLP projects under his/her direction is maintained in a file at the facility. This schedule is available on the IR-4 web site, or may be generated by IR-4 HQ.
j. Designate trial locations for the facility and maintain crops under good agricultural practices.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 March 2013

Author: Jennifer Cote

Title: 2.2:0 Personnel

Purpose: Information concerning personnel requirements under GLPs.

Scope: All personnel working on research under GLPs at this test facility.

Procedures:

1. The field test facility shall have on file information for each person currently supervising any phase of an MOR trial, collecting and/or entering data under GLPs. The information shall include a current summary of the experience and training of the worker, as well as a brief description of their duties or responsibilities. Each person so engaged in the conduct of trials shall have read and understood those sections of the protocol and Standard Operating Procedures that pertain to their responsibilities. This information shall be placed in the personnel file and sent to IR-4 headquarters for archiving as needed.

2. Documentation of training adequate to complete the task under GLPs is sufficient for personnel assisting in GLP activities under close supervision. The Field Research Director or designated personnel shall record the names of the personnel and the dates that the SOP or task was explained to them. This documentation shall be place directly in the FDB to which it pertains.

3. The Field Research Director or designated personnel shall determine that the person or persons conducting the trial are of sufficient number to carry out the trial to its completion and are sufficiently trained to conduct their portion of the trial.

4. Personnel handling pesticides shall be trained in accordance with the current policies and guidelines of their institution, or see SOP# 4.4.

5. Where the application of restricted use pesticides is required in the trial, the applicator shall be certified.

6. The field site facility shall have a supply of safety equipment in working order and sufficiently clean to protect the health and safety of the personnel and are to follow University of Maine regulations, pesticide labels or the trial protocol.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 10 March 2015

Author: Jennifer Cote

Title: 2.3:1 Documentation of Training

Purpose: To assure that training for personnel involved in GLP research is adequate and properly documented.

Scope: All personnel working on research under GLPs at this test facility.

Procedures:

1. Formal training at institution of the personnel engaged in the GLP trials shall be documented in the files at the field facility. This may consist of a CV or a notation that the person received a degree, and the year graduated noted. If a degree was not awarded then the years of attendance and credit hours and specialty shall be noted, or years of experience.

2. All other training shall be documented in some form of training log.
    a. Training received from workshops, conferences, etc. shall be noted. Include the name of the person, the event and the dates of attended. A copy of any type of training certificates issued shall also be retained in the personnel files at the location.
    b. Any form of verbal instruction shall be documented in writing and placed in the personnel files to show that the person received on-the-job training to conduct the task. Record the name of the person giving the instruction, the name of the person receiving the instruction, the date given and a concise statement of the instruction (i.e. Dr. Y explained to Ms. C how to label the sample bags as per SOP xx on 6/2/07).

3. Each person engaged in the conduct of the trial (i.e. collecting or entering data) shall have read and understood those sections of the protocol and the Standard Operating Procedures that pertain to their responsibilities.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

4. For personnel who are not collecting and/or entering data, but who might have an impact on the trial, (for example casual labor involved in the harvest), a general statement of oral or written training, by the Field Research Director or designated supervisor shall be sufficient.

5. Personnel who are only involved in routine maintenance and other non-critical duties (field preparation, planting, maintenance activities) do not need to be included if a statement of non-GLP compliance is made.

6. The original CV or resume will be included in one of the Field Data Books for each given year. Alternately, the originals may be submitted in the common data book for the testing facility.

7. All records (CV/resume, training records, etc.) for personnel no longer involved in GLP research shall be sent to IR-4 headquarters for archiving.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 March 2013

Author: Jennifer Cote

Title: 2.4:0 Organizational chart

Purpose: To assist locations in the development of an organizational chart.

Scope: All testing facilities conducting trials for the registration of pesticides.

Procedures:

1. An organizational chart shall be developed which reflects the lines of communication and responsibility for conduct of GLP studies. Show the line of reporting between the Sponsor (entity that initiates and finances the study and submits the report to the EPA), Study Directors (individual responsible for the overall conduct of the study), Quality Assurance, Testing Facility Management (Regional Field Coordinator in the case of IR-4, and Testing Facility (person who actually uses the test substance in the test system = IR-4 Field Research Director).
    a. The management of the institution (i.e. Department Chair, Director, etc.) where the field testing facility is located may be included as a separate line, but is not essential.

2. At the top of the chart, show the Sponsor (IR-4) and head of the institution, if being included.

3. Each block in the chart shall show the unit, name and title.

4. Personnel engaged in the conduct of the trials are shown on the chart with lines of supervision indicated. Direct and indirect lines of communication and accountability shall be shown.
    a. Direct lines of responsibility are solid;
    b. Indirect lines as dashes.

5. The charts must be signed or initialed and dated. As they are revised, the retired copies should be sent to IR-4 Headquarters.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 March 2013

Author: David E. Yarborough

Title: 3.1:0 Field location selection for field trials.

Purpose: To assure plots are large enough to obtain the required data or samples with sufficient uniformity and can be relocated after the trial is terminated.

Scope: Field test locations conducting pesticide registration research under GLP.

Procedures:

1. Field location selection shall be made in accordance with acceptable commercial practices for the crop being treated.

2. Each location shall be large enough to accommodate the required number of duplicate samples, buffer zones, and treatments, in accordance with an approved trial protocol and for the commodity to be grown under simulated commercial conditions yielding samples of sufficient size for analysis. Plots shall be of sufficient size so that no more than 50% of the plot is harvested to produce the required samples.

3. Locate the field location with sufficient isolation to minimize contamination from external sources such as commercial operations or other research trials. Place individual plots with enough isolation (at least 15-ft or in accordance with trial protocol) to produce uncontaminated control and treated samples.

4. Standard cultural practices should be performed prior to plot layout and marking.

5. Lay out each plot using a suitable measuring device to accurately locate the plots on the field location even after the trial has been completed. Identify both ends of each plot with a marker of sufficient visibility to be seen easily throughout the duration of the trial. At a minimum, the marker shall include the Field ID number and treatment number of treatment name. Prepare a plot map showing the location of each plot on the field location with the direction and degree of slope, the North azimuth, and distances of buffer zones between treated and untreated plots. The plot map shall contain distances to permanent reference points so that the site of the plots can be located after the trial is terminated. Follow the Field Data Book for further directions.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

7. The soil where trials shall be conducted shall be tested for pH, CEC, and organic matter in the year in which trials shall be conducted on that site. The above data shall be recorded in the files for all trials. For soil texture determination, analysis performed no more that 15 years prior to the trial shall be acceptable or the USDA soil characterizations may be used. Original soil test reports must be sent to HQ for archiving, either separately or in one of the field books.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 March 2013

Author: David E. Yarborough

Title: 3.2:0 Commodity maintenance.

Purpose: To assure that the commodity is grown under good agricultural practices and to provide a uniform crop for trial.

Scope: Field test locations conducting pesticide registration research under GLP.

Procedures:

1. Use an up-to-date publication, such as the Wild Blueberry Grower's Guide, or consult with an agricultural specialist familiar with the local commercial production.

2. Maintain the commodity in a healthy state and good growing condition throughout the life of the trial.

3. Do not apply maintenance pesticides that are not registered for the commodity. If absolutely necessary to apply a non-registered pest management product to save the crop, contact the Study Director and ask for a protocol deviation. If pesticides are applied to the commodity to prevent losses due to pests, they shall be applied to all plots within the trial using standard agricultural practices. For residue trials, no pesticide shall be applied that would interfere with the chemical analysis of the pesticide under trial. If in doubt, contact the Study Director or analytical chemist/analytical laboratory identified in the protocol to receive the residue samples for guidance.

4. Irrigate if necessary and perform other agricultural practices to maintain crop in good commercial condition.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 10 March 2015

Author: Jennifer Cote

Title: 4.1:1 Test Substance receipt and handling.

Purpose: To explain the procedures and documentation required for the receipt, use and handling of GLP Test Substances.

Scope: All GLP Test Substances for MOR field trials.

Procedures:

1. Arrival of GLP Test Substance shall be checked for daily. When a Test Substance is received, the product will be unpacked, checked and placed directly into the Roger Clapp Greenhouse Pesticide Storage Facility at the University of Maine campus.

2. Upon receipt or when the shipping container is opened, the condition of the container shall be examined. The condition shall recorded as intact (no breaks, holes, or leaks) or otherwise (specific defect will be detailed). If the condition might adversely affect the integrity of the material, the Study Director shall be contacted.

3. The name and formulation of the product shall be checked against the protocol, if they are different the Study Director shall be informed immediately. If no expiration date or GLP status is provided in any of the documentation from the manufacturer, the Study Director shall be notified. Shipping documents shall be retained in the FDB.

4. All Test Substance containers shall be properly labeled with, at a minimum, the name of Test Substance/active ingredient, lot/batch number, expiration date, and storage conditions (See Advisory #2003-04). The person receiving the Test Substance shall initial and date the label and add any missing information.

5. Each Test Substance container shall also be labeled with a unique identifier consisting of the last two digits of the year received, the initials "IR", and a two digit code denoting the consecutive order in which it was received that year (order is of all IR-4 pesticides and reagents received at the testing facility). For example: 15IR01.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

6. Arrival information shall be recorded in the appropriate Field Data Book, and will include, at a minimum, the name of the Test Substance, the active ingredient, batch/lot number, date of arrival, and expiration date. The Test Substance shall also be recorded in the chemical inventory, and will include, at a minimum, the Test Substance name, active ingredient, unique identifier, expiration date, amount received, IR-4 trial number, and manufacturing company. Current pesticide inventory records shall be maintained by the Field Research Director and/or GLP research personnel and kept in the IR-4 office.

7. All GLP Test Substances are stored in a fire-safe cabinet within the limited access pesticide storage facility. IR-4 Pesticide Storage Authorized IR-4 personnel shall have keys to this area.

8. Temperatures for each GLP Test Substance shall be monitored from within two days of its arrival through the time of the last application. A log for the removal and return of the Test Substances shall be maintained and shall be located in the pesticide storage facility. The disposal of the Test Substance and/or its container shall be entered in the log.

9. A certificate of analysis (COA) may arrive with the Test Substance or be supplied later by the SD or registrant. In some cases it may not have arrived before the FDB is forwarded to the RFC. In that case, the SD shall include the COA at a later date.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 10 March 2015

Author: Jennifer Cote

Title: 4.2:1 Storage of GLP Test Substances.

Purpose: To explain the procedures required in the receipt, removal, use, return and transfer of the GLP Test Substances.

Scope: All GLP Test Substances

Procedures:

1. Test Substances shall be stored in accordance with current policies and guidelines of the institution. All unused Test Substances including empty containers shall be returned to the storage facility at the completion of their use (see SOP# 4.1, item 7).

2. All Test Substance containers shall be retained until the trial in which the product was used is submitted to the US EPA, the trial was dropped or the study canceled. See SOP# 4.4 for detailed information on container disposal.

3. The Roger Clapp Greenhouse Pesticide storage facility is a separate building from offices and laboratories and maintained in accordance with University of Maine guidelines. The facility is dry, well ventilated and temperature controlled with heaters to prevent freezing and ventilation fans to prevent overheating. The entire pesticide storage facility is under lock and key and accessible only to authorized staff.

4. Storage conditions shall be monitored using a uniquely identified and verified HOBO Temperature Data Logger from the time the Test Substance is placed there until after the final application has been made. The HOBO shall be monitored and downloaded and re-launched approximately monthly. A uniquely identified and verified min/max thermometer shall be used as back-up, and the temperatures recorded every time the data logger is downloaded.

5. The Test Substance shall then be stored in the pesticide storage facility until it is needed for use in the trial. The Study Director shall be notified immediately upon determining the storage conditions were not within the manufacturer-supplied recommended storage limits.

6. A log shall be kept on the contents of the storage facility indicating when a Test Substance is removed and when it is returned to the facility, along with the purpose for which it is removed. Included in the log shall be the log-out and log-in dates, trial ID, in-house ID, active ingredient, purpose and users initials.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

7. The Pesticide Storage facility is labeled with highly visible, waterproof identification signs on the doors to advise of the hazardous nature of the storage facility's contents.

8. Pesticides containers are checked regularly for corrosion and leaks. If such is found, the contents shall be transferred to a sound, suitable container and be properly labeled, or the container and its contents shall be disposed of properly.

9. Mixing and handling of Test Substances will normally take place in a separate area; however, in the event that a Test Substance must be mixed or handled (e.g., measured) in the storage facility, steps shall be taken to ensure no cross contamination occurs. These measures shall include, but are not limited to: using clean paper or plastic on the counters; a new plastic tray or clean metal scoop to weigh out dry measurements, and/or a clean graduated cylinder for liquid measurements.

10. Test Substances shall be stored in a manner to prevent the possibility of contamination, deterioration, or damage during the conduct of the trial.

11. Excess Test Substance not used for study purposes may be logged out and used, once the last application has been completed. The product shall be used by trained personnel for maintenance (labeled uses) or experimental purposes at the discretion of the Field Research Director or research personnel. The removal of the Test Substance shall be noted on the Test Substance inventory log. The container shall be retained until disposal is authorized (SOP# 4.4).

12. This location does not ship hazardous chemicals. As a result, no Test Substance shall be returned to the registrant, even if required in the protocol. In the latter case, a protocol deviation will be written.

13. If the Test Substance is transferred to someone else (another testing facility, the registrant, etc.) the name and address of the new storage facility shall documented in the chemical log.

14. See SOP# 4.5 for Reagent Receipt and Handling (adjuvants, etc.).

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 March 2013

Author: Jennifer Cote

Title: 4.3:0 Handling pesticides safely.

Purpose: To assure that personnel handling pesticides are doing so in a safe manner and if an accident occurs, danger is minimized.

Scope: All locations conducting field trials where guidelines for handling pesticides do not exist.

Procedures:

1. Personnel shall follow current policies and guidelines of the University of Maine. Where institutional guidelines do not exist, the following procedures shall be followed.

2. A supply of soap/detergent and water shall be readily accessible for clean-up in the case of an emergency.

3. All personal protective equipment and clothing as required by the label or written SOPs shall be worn in the handling of pesticides for storage, mixing and application. Emergency personal protective equipment (e.g. coveralls, respirator, etc.) must be available when handling hazardous pesticides such as restricted use pesticides.

4. Inspect all pesticide containers for leaks, tears, or holes before handling. Do not mishandle or abuse containers and thereby create hazards and/or emergencies by carelessness.

5. Precautions shall be taken to avoid applying pesticides to or near sensitive areas or where drift to these areas may occur.

6. All pesticides shall be mixed in quantities that are adequate for the job and avoid excess dilute solutions after the application is completed. Cleanup procedures shall be established whereby excess sprays can be safely discarded preferably by spraying the material on an over-planting of the commodity or non-crop area. The equipment shall be washed off both inside and outside and all pesticides and pesticide containers shall be returned to a storage area as soon as possible after use.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

7. A pesticide-treated area shall not be reentered until adequate time has elapsed, as specified on the label of the pesticide. Treated plots should be posted.

8. Do not permit unauthorized persons in the pesticide storage area.

9. Do not store pesticides next to food, feed, seed, fertilizer, or other articles intended for consumption or use by humans or animals. Do not store food, beverages, tobacco, clothing, eating utensils, or smoking equipment in any area where pesticides are present.

10. Do not drink, eat food, smoke, or use tobacco in areas where pesticides are present.

11. Wear unlined rubber, nitrile, etc. gloves while handling containers and mixing or measuring pesticides.

12. Do not put fingers in mouth or rub eyes while working with pesticides.

13. Wash hands thoroughly with soap and water immediately after handling pesticides and, especially before eating, smoking, or using the toilet. The local fire department shall be provided with a floor plan of the pesticide storage area indicating where different pesticide classifications are regularly stored.

14. Pesticide storage areas shall be properly ventilated.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 10 March 2015

Author: Jennifer Cote

Title: 4.4:1 Disposal of pesticides.

Purpose: To assure the Test Substances containers, pesticide concentrate, spray solutions, and rinse water are disposed of with minimal environmental contamination and in accordance with federal, state and local regulations.

Scope: All locations conducting GLP field trials and where institutional guidelines for disposal of pesticides do not exist.

Procedures:

1. The containers for GLP Test Substances used in support of an EPA tolerance shall be retained at the facility until the data package is submitted to the US EPA, the trial dropped or the study cancelled.
    a. Excess Test Substance can be used in other crops, once the applications are completed, as long as the product is registered in that crop and the container is retained. If the Test Substance is used elsewhere, the transfer should be noted in the use log.
    b. Containers approved for disposal are listed on the IR-4 website (see advisory #2005-01).
    c. Notification that the study has been forwarded to the EPA may also be sent by the Regional Field Coordinator, Study Director or other authorized IR-4 personnel (Advisory #2003-02).
    d. Container disposal is not acceptable if the test substance from the same container was also used in another study, and that study has not yet been canceled or completed.

2. When disposing of pesticide concentrates or containers, personnel shall follow current policies and guidelines of their institution. Where institutional guidelines do not exist, the following procedures shall be followed. This applies to the Test Substances only when permission has been received from the Study Director.
    a. Follow label directions for disposal of the pesticide.
    b. alternately, arrangements may be made with a licensed waste disposal firm for pickup and disposal of the pesticide and/or the empty containers.

3. When the Test Substance or containers is disposed of, an entry shall be made in the chemical inventory, logging out the product and/or container. These records shall be retained and sent to IR-4 Headquarters for archiving.

4. Disposal of pesticide rinse water, unused spray solutions and other dilute pesticide waste (see also SOPs 5.5 and 5.6).
    a. Dispose of the dilute pesticide waste in the field by spraying on an overplanting of the crop or non-crop area and/or pouring it onto a bare area immediately adjacent to the treated area, where this procedure does not violate any laws or regulations. All pesticide solutions shall be mixed with the intent of limiting the problem of excess solutions.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 10 March 2015

Author: Jennifer Cote

Title: 4.5:0 Reagent receipt and handling.

Purpose: To explain the procedures and documentation required for the receipt, use and handling of reagents for use in IR-4 trials.

Scope: All reagents used for MOR field trials.

Procedures:

1. When a reagent used for GLP studies (e.g., adjuvant, spray additive, etc.) is received, the product will be unpacked, checked for damage, and placed directly into the Roger Clapp Greenhouse Pesticide Storage Facility at the University of Maine campus.

2. Upon receipt or when the shipping container is opened, the condition of the container shall be examined. The condition shall recorded as intact (no breaks, holes, or leaks) or otherwise (specific defect will be detailed). If the condition might adversely affect the integrity of the material, the Study Director shall be contacted.

3. All reagent containers shall be labeled with, at a minimum, the name of the reagent, concentration, expiration date, and storage conditions (See Advisory #2015-01). The person receiving the reagent shall add any missing information. Expiration date can be assigned by FRD or designated person. The reagent will only be use in the year it was obtained and then transferred to regular storage so that it may be used on non-GLP trials.

4. Each reagent container shall also be labeled with a unique identifier consisting of the last two digits of the year received, the initials "IR", and a two digit code denoting the consecutive order in which it was received that year (order is of all IR-4 pesticides and reagents received at the testing facility). For example: 15IR01.

5. Arrival information shall be recorded in the appropriate Field Data Book, and will include, at a minimum, the name of the reagent, the type, batch/lot number if available, date of arrival, condition on arrival, expiration date and storage conditions. The reagent shall also be recorded in the chemical inventory, and will include, at a minimum, the reagent name, active ingredient, unique identifier, expiration date, amount received, IR-4 trial number, and manufacturing company. If an expiration date is not available, one shall be assigned that is no longer than 5 years from the manufacturing/packaging/arrival date (the earliest date of whichever are available). Current pesticide inventory records shall be maintained by the Field Research Director and/or GLP research personnel and kept in the IR-4 office.

6. All reagents are stored in a fire-safe cabinet within the limited access pesticide storage facility. IR-4 Pesticide Storage Authorized IR-4 personnel shall have keys to this area. Reagents are stored in the same manner as Test Substances (see SOP# 4.2, Storage of GLP test substances).

7. Temperatures for each reagent shall be monitored from within two days of its arrival through the end of the treatments for the trial.

8. Secondary containers (e.g. a 1 gallon container subdivided into 100 ml containers for ease of use and transport to remote sites) may be used to store, transport and dispense reagents. The secondary container shall be labeled and stored in the same manner as the original container and now take on all the requirements and properties of an "original container".

9. Reagents dispensed into any temporary container or measuring device shall not be returned to the original or secondary container, but shall be disposed of in a manner that prevents cross-contamination. The temporary container or measuring device shall not have direct contact with the reagent container once it has had direct contact with the spray tank or any container used to mix the Test Substance spray solution.

10. The reagent shall be examined for changes to physical characteristics prior to use, i.e. changes in color, consistency, etc. If reagent quality is compromised, it shall be removed from use in GLP trials.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 March 2013

Author: David E. Yarborough

Title: 5.1:0 Calibration of a CO_2-propelled boom sprayer

Purpose: To determine the delivery rate of sprayer and make adjustments as necessary to assure an accurate application of the pesticide.

Scope: All field studies under GLP.

Procedures:

I. Sprayer Preparation and Maintenance

1. The application boom shall be inspected for leaks and the dilute spray container and spray boom shall be cleaned. If necessary, the nozzle assemblies shall be disassembled to verify cleanliness or to clean the screens and nozzle bodies.

2. The CO_2 propellant connections shall be inspected for leaks and repaired if necessary.

3. Inspect all gauges to ensure proper operation and replace if necessary.

4. Verify the nozzle and screen size and that the nozzles shall provide the desired spray volume within the recommended range of pressure and area of application as required by the protocol or recommended by the manufacturer. The screen size shall be compatible with the test substance and the nozzle.

5. Any faulty components shall be replaced before calibrations.

6. Adjust the CO_2 pressure regulator to the desired pressure with the CO_2 tank valve in the fully open position. Be sure that the pressure has stabilized before proceeding.

7. Maintain an equipment log documenting all inspections, calibrations, cleaning and maintenance. An entry must be made to the log when all or part of the sprayer is retired.

8. The applicator is responsible for calibrating the sprayer.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

II. Sprayer Calibration

1. Calibration shall be done no more than 24 hours prior to an application and no other uses of the equipment shall occur between the calibration and application. If, after 24 hrs, the sprayer has not been used, a single spray output determination may be used to verify the previous calibration within the tolerances as follows. If the equipment is used for another purpose, recalibration must be performed before test substance application. If making a number of applications under GLP, the equipment must have a single recheck done between each application from different trials.

2. Water delivery from the nozzles shall be collected for a designated time period, such as 30 seconds. The conditions of calibration shall be recorded including, but not limited to: sprayer ID number, number of nozzles, nozzle type, boom pressure, nozzle spacing, calibration time, calibration distance, and desired output. To determine compliance for +/- 5%, multiply the average nozzle output by 0.95 and 1.05 to obtain the maximum acceptable range of nozzle output. Change nozzle and screens until uniform nozzle discharge is obtained. The delivery rate (discharge calibration) shall be averaged for three determinations or as specified in the protocol.

3. The spray volume and sprayer nozzle configuration to use for the application shall be in compliance with the protocol requirements. If the spray volume and method are unspecified, a typical local agricultural application spray method and spray volume, for an application similar to the proposed test substance use in the protocol shall be used.

III. Walking Speed

1. Prior to determining walking speed, calculate the amount of solution required to spray the test plot at the volume and pressure specified in the research protocol.

2. Fill the sprayer with water to the volume calculated in step 1 and measure the time it takes from when the spray leaves the nozzle tips to when it stops.

3. Practice walking speed beside the plot with the sprayer and adjust your speed until the time is within 5% of the time required to spray the material out in step 2. Repeat and if necessary adjust pressure, speed or nozzle tips until you are sure you are applying the correct volume of spray/acre. A metronome may be used to assist in regulating walking speed.

IV. Documentation

1. Record all necessary information into the Field Data Book in enough detail to reconstruct the application. Document calibration as an event in the maintenance log.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

2. Calculations shall be entered in a logical manner showing all steps and conversions so that they can be easily followed and reconstructed. Calculation shall clearly show the actual GPA and amount of active ingredient or product applied.

3. If the amount of test substance (a.i. or product/A) differs by more than +10% - 5 % from the protocol values, the Study Director shall be notified within 24 hrs.

4. Protocol instructions for reporting application events and deviations shall have precedence over this SOP.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 March 2013

Author: Jennifer Cote

Title: 5.2:0 Measuring a liquid pesticide formulation

Purpose: To assure an accurate dosage in the application of a pesticide.

Scope: All liquid formulations of GLP pesticides.

Procedures:
Liquid (SC, EC, FL, L, etc.)

1. A graduated cylinder shall be used to measure the liquid. Select a graduated cylinder large enough to hold the volume of pesticide needed for the treatment, but small enough to measure the needed Test Substance an accuracy within +/- 5 % of the total volume (i.e. if 10 ml graduated cylinder is used the smallest division shall be 0.5 ml or less).

2. Take the reading of the liquid at the bottom of the meniscus where appropriate.

3. The liquid Test Substance is placed directly into the spray tank or bottle. Make sure that as much as possible of the liquid is transferred to the spray tank or bottle. If using a graduated cylinder or alternate container, triple-rinse it into the spray tank or bottle. Wash with soap and water after use to ensure that the cylinder is clean and cross-contamination of pesticides shall not occur with future use.

4. A written record of each volume of the pesticide removed from the original container shall be maintained. If more than one amount is measured out for a single application, each amount shall be entered separately.

5. Table of measuring equipment with increments:

Graduated cylinder
1,000 ± 10 mls
500 ± 10 mls
250 ± 5 mls
100 ± 5 mls
50 ± 2 mls
25 ± 2 mls
10 ± 1 mls

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 March 2013

Author: Jennifer Cote

Title: 5.3:0 Calibration and use of an electronic scale used to weigh GLP Test Substances.

Purpose: To assure an accurate Test Substance application.

Scope: Applicable to GLP trials where a dry material is weighed and used.

Procedures:

1. The electronic scale used to weigh Test Substances for GLP trials shall be serviced and calibrated at a minimum of every two years.

2. Immediately prior to weighing a Test Substance for an application, the balance will be verified using the Standardized weights. To verify, two weights will be chosen to bracket the target weight: one slightly smaller and one slightly larger than the amount of Test Substance to be weighed. (Example: if amount of Test Substance to be weighed equals 6.52 g then weights equal to 5 g and 10 g would be used for calibration). The verification of the Standard Weights shall be recorded and the original raw data shall be included in one FDB of a trial where needed, along with a copy of the service certificate; certified copies shall be included in additional FDBs where needed.

3. Dry Test Substances shall be pre-weighed in building and transported to trial site in alternate container, unless the building is close enough for mix to be made inside. This pre-weighing should be done on the day of application, or no more than 24 hours ahead of time. The container shall be labeled with Test Substance name, Field ID Number, amount, treatment number, initialed and dated.

4. Test Substances shall be weighed on a new plastic tray, or other clean weighing container. Select and wear or use appropriate safety equipment while handling pesticides. Weigh the Test Substance in a tared tray or container. Small quantities of excess may be returned to original pesticide container, if there is no chance this procedure might result in contamination of the Test Substance. Dispose of large quantities of excess by using appropriate methods for handling hazardous wastes.

5. If taring the container is not possible, then record the weight of the container before adding the desired amount of pesticide to be weighted.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

6. A written record of the amount of the pesticide removed from the original container must be maintained for each application and each trial. Record each amount weighed and the trial for which it was used, initial and date, at the time of weighing. If more than one amount is weighed out for a single application, each amount shall be entered separately. If the same Test Substance is used for more than one trial, all records shall be maintained on a single log. Then the original shall be placed in one of the books, and an exact copy for any other.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 March 2013

Author: Jennifer Cote

Title: 5.4:0 Adding pesticide concentrate to the water carrier in a spray tank.

Purpose: To ensure proper mixing of the concentrate into the spray mix.

Scope: All locations conducting GLP field trials.

Procedures:

1. After the sprayer has been inspected and calibrated, empty the water from the tank or dedicated plastic bottle. Measure the amount of water needed to dilute the measured amount of concentrate. Make sure the spray mix shall be enough to cover the entire plot plus sufficient overage to ensure uniform coverage. If the plot is too large, the application may be made with two separate containers of spray solution, one for each side of the row or plot.

2. Use pH paper or other means to measure the pH of the dilution water and record in the raw data.

3. Add roughly 1/2 the water to the spray tank or bottle before adding the Test Substance, except: For dry formulations making a slurry first is recommended. Make the slurry by adding a small amount of mix water to the concentrate and shaking well. Once well mixed, add the slurry to the water in the spray tank. If making the tank mix in a bottle, measure a small amount of mix water into the bottle and add the dry formulation; shake well to make a slurry before adding the rest of the tank mix components.

4. Triple rinse alternate containers holding the pesticide concentrate using the second 1/2 of the water and add the wash water to the spray tank.

5. If adding more than one product to the tank mix, the products should be added in order of solubility, starting with the least soluble and ending with the most soluble product.

6. Add adjuvants, when indicated, after all pesticide products have been added, unless the label specifies otherwise.

7. Add the remaining water to the spray tank. Close and tighten the lid.

8. Agitate the spray mix before and during application to ensure an even mix of the pesticide and water, unless contrary to the labeled directions.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 March 2013

Author: Jennifer Cote

Title: 5.5:0 Procedures for the application of the Test Substance(s) in the field.

Purpose: To assure that the Test Substance(s) are applied uniformly to the plots.

Scope: All GLP field trials at this location.

Procedures:

1. Application equipment shall be inspected and calibrated as described under SOP 5.1. Make sure all settings for pressure, speed, granular flow etc. are the same as those used in the calibration as previously performed.

2. Appropriate weather conditions for the application of the pesticide shall prevail; otherwise the pesticide applications shall be delayed. For example, applications shall not be made if wind velocity is > 10 mph.

3. Where possible, apply the material beginning with the lowest concentration and work up to the highest concentration.

4. Just before entering each plot make sure you are traveling at the correct speed and turn on the sprayer or release the granules. Maintain the correct speed through the plot.

5. Turn off the sprayer or stop granular flow just after leaving the plot.

6. Calculations shall be made to minimize the amount of spray material left in the spray tank. Dispose of any excess spray mix by spraying out on over-planting, designated non-crop area, or according to current policies and guidelines of the research testing facility.

7. Make a separate tank mix for each plot to be treated. One spray mixture shall never be used for more than one plot.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 March 2013

Author: Jennifer Cote

Title: 5.6:0 Cleanup of application equipment

Purpose: To assure that pesticide application equipment is decontaminated without adversely affecting personnel or the environment.

Scope: All locations where pesticides are used under GLP.

Procedures:

1. Granules: Remove any excess granules and dispose of them properly using appropriate methods for handling pesticides, or apply to a similar crop or non-crop area. Do not return them to the original container as that might affect the integrity of the contents.

2. Spray: Excess spray material shall be applied to a similar crop or non-crop area or disposed according to current facility policy.

3. In the designated area or suitable location away from aquatic areas or danger of aquatic contamination, hose down the sprayer/applicator to remove pesticide residuals from inside and outside. Wash the application equipment with commercial tank cleaner or detergent. Apply each tank of wash or rinse solution to the over-planting of the crop or non-crop area, or an immediately adjacent bare area. At a minimum, triple rinse all apparatus with clean water. Dedicated dilute spray solution plastic bottles shall be maintained for each test substance for the duration of the trial and shall be disposed of after the last application. If a crop/non-crop area is not available, then follow the disposal procedures for pesticide rinse water in accordance with current policies and guidelines of the institution.

4. Dispose of expendable protective clothing by placing the items in a container for incineration or landfill. Clean non-disposable items following the manufacturer's instructions or with soap and water as appropriate.

5. After the application equipment is dry, lubricate those parts requiring lubrication and return the equipment to storage.

6. Record cleanings, calibrations, lubrications, etc. in the sprayer equipment log.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 March 2013

Author: Jennifer Cote

Title: 5.7:0 Procedures to follow when a problem occurs in the application of the Test Substance.

Purpose: To explain the procedures to follow when something goes wrong during the application of the Test Substance in the trial.

Scope: All GLP Test Substance applications.

Procedures:

1. During application, the applicator shall observe the process to make sure that the Test Substance is being uniformly distributed to the commodity or trial site.

2. If something goes wrong, such as a plugged nozzle or hose breaks, then the operator shall take immediate action to correct the situation. Stop immediately, turn off the boom, and pause/stop the stopwatch.

3. The affected portion of the plot shall be marked off and staked to indicate the area affected. This portion shall not be used for obtaining samples of the commodity for residue analysis.
    a. If mixing and applying another tank of spray to the unsprayed area of the plot can save a trial, document the activities as if it were another treatment. Clearly explain what was done and where, to ensure no problems arise, such as a double application. If not sure if this is a legitimate resolution, contact the Study Director or RFC.
    b. If the unaffected area is too small to obtain the samples required for analysis, then the trial shall be discontinued. Contact the SD and RFC immediately.

4. The Study Director, Regional Field Coordinator and other appropriate individuals shall be notified of the incident immediately, and details shall be recorded in the raw data notebook.

5. If there is time and resources the trial may be repeated. However, a new trial shall only be initiated with a signed protocol amendment and new Field ID Number.

6. Protocol instructions for reporting application events and deviations shall have precedence over this SOP.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 March 2013

Author: David E. Yarborough

Title: 6.1:0 Calibration/verification of instruments and gauges

Purpose: To assure that all instruments used in GLP field studies are accurate and in good working order.

Scope: All field studies under the GLP.

Procedures:

1. All measuring devices (except marked, calibrated graduated cylinders, syringes, pipettes, etc.) shall be identified by a unique number or code. The identification number or code shall be placed on the measuring device such that it can easily be cross-referenced to log records. If the device breaks or is otherwise retired, its fate shall be recorded and the unique identifier not used again. Records of devices shall be maintained in a log.

2. Written records (maintenance logs) shall be kept on routinely used equipment. These records shall include, but not be limited to, the person doing the maintenance, the date, whether the activity is routine or non-routine, and the tolerances for that piece of equipment. Certified copies of the logs shall be maintained in the facility Historical Files. The original logs shall be submitted with the Field Data Books.

3. Personnel currently operating the equipment are responsible for the maintenance and remedial action taken in case of malfunction.

4. In the event of a malfunction or other incident that may affect the integrity of the trial, the Study Director and other appropriate individuals shall be notified and details shall be recorded in the Field Data Book. Any repairs or replacements resulting from malfunction during use shall be documented as non-routine maintenance in the appropriate log(s).

<u>Wind speed measuring devices and RH meters</u>

1. Prior to use, visually inspect the measuring device for cleanliness and that it is in good working condition. Check the power supply. Record inspection and any maintenance performed in appropriate logs.

2. The accuracy of wind monitoring devices used for GLP studies shall be verified at least once a year by a side-by-side comparison with at least two other devices. Records of verification shall be maintained in a log.

3. If the measured wind speed of any one unit is +/- 2 mph of the average wind speed of all the devices being tested, then unit is reading accurately and is acceptable for use.

4. If the measured RH of any one unit being tested is +/- 10% of the average RH of all the devices being tested, then the unit is reading accurately and is acceptable for use.

5. Remedial actions to be taken in case of failure or malfunction include:
   a. Any problem shall be immediately reported to the facility director or designated personnel, documented, and placed in the maintenance log records for non-routine procedures.
   b. Any repairs or replacements resulting from malfunction during use shall be documented as non-routine maintenance in the appropriate log(s).
   c. Any device that does not meet the parameters above shall be retired and its removal from GLP work shall be noted in the appropriate log.

Storage Freezer

1. Prior to use clean the unit and visually inspect that it is in good working condition. Document inspection(s) and any maintenance performed in appropriate logs.

2. Temperature within the unit should be checked prior to sample storage. A data logger should be placed in the unit. The temperature range recorded by the device should be within the limits as required by the protocol for storage of the sample.
   a. If temperature measured is within the sample storage range, then the unit is approved for use.
   b. If temperature measured is not within the sample storage range, then adjust the temperature control until the unit maintains the correct temperature range.
   c. If after adjustment, the unit cannot maintain a temperature range within the sample temperature storage range, then the unit must be serviced by a trained technician prior to use.

3. When unit is being actively used for storage, the temperature should be monitored with a data logger and recorded. If no samples are being stored in the unit, no records of the temperature need to be maintained. During use enough ice shall be stored in the unit in ensure that the samples remain frozen in the event of a malfunction or power outage.

4. Remedial actions to be taken in case of failure or malfunction include:
   a. Any problem should be immediately reported to the facility director or designated personnel and then documented in the maintenance log.
   b. Any repairs or replacements resulting from malfunction during use should be documented as non-routine maintenance in the appropriate log(s).
   c. If a freezer cannot be repaired, it shall be retired and its removal from GLP work shall be noted in the equipment log.

5. In the event of a malfunction, the samples shall be temporarily stored in the freezer located in Deering Hall, room 311. The transfer shall be documented in the Field Data Book. Remedial actions shall be taken as stated in #6 below. The temperature shall be monitored and the samples returned to the trial designated freezers as soon as repairs have been completed.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 March 2013

Author: David E. Yarborough

Title: 6.2:0 Verification and use of thermometers

Purpose: The purpose of this SOP is to establish procedures used when verifying and reading thermometers.

Scope: The SOP is to be followed when verifying thermometers for GLP work.

Procedures:

1. Prior to use, visually inspect the measuring device for cleanliness and that it is in good working condition. Record inspection and any maintenance performed in appropriate logs. Use the following methods and document the methods used as raw data.

2. All temperature-measuring devices used for GLP trials shall be checked for accuracy at least once a year against a reference thermometer, either directly or by a recorded traceable chain. A reference thermometer shall be verified by placing it in an ice bath and a boiling bath. All other thermometers shall be read side-by-side with the reference thermometer to verify accuracy.

3. Records of thermometer verification shall be maintained in a log.

4. All thermometers shall be identified by a unique number or code. The identification number or code shall be placed on the measuring device such that it can easily be cross-referenced to log records.

5. Measuring devices to be verified and the reference thermometer shall be read side by side under conditions appropriate to the intended use. For example: thermometers used to measure temperatures of liquids shall be calibrated in water baths. An attempt shall be made to bracket the temperature the device shall be used to monitor, as the design of the device allows.

6. If a measuring device breaks or is retired, its removal from GLP use shall be noted in the appropriate log.

7. Verified thermometers may be used to verify other temperature recording devices as long as they can be traced back to reference verification. These devices may include continuous thermographs used for walk-in digital displays on up-right freezer/refrigerator units, etc.

8. Remedial action to be taken in case of failure or malfunction shall include:
   a. Any problem shall be immediately reported to the facility director or designated personnel, documented, and placed in the records for non-routine procedures.
   b. Any repairs or replacements resulting from malfunction during application shall be documented as non-routine maintenance in the appropriate log(s).
   c. Any temperature monitoring device that does not meet the 2^0 C differential shall be retired and its removal from GLP work shall be noted in its log.

9. Personnel currently operating the equipment are responsible for the maintenance and remedial action taken in case of malfunction.

10. In the event of a malfunction or other incident that may affect the integrity of the trial, the Study Director and other appropriate individuals shall be notified and details shall be recorded in the Field Data Book.

Water Bath Method

1. At least two water baths shall be used. Examples of temperature ranges to test may include:
   a. Boiling (100 ^{O}C)
   b. Warm (approx. 40 to 55^{O}C)
   c. Room temperature (18 to 24^{O}C)
   d. Ice bath (approx. 0^{O}C)

2. Water baths shall be contained in a pan or beaker deep enough for adequate immersion of the instrument. The ice bath shall be made with chopped ice in water to form a tightly packed slush, without floating ice.

Air Method

1. At least two air temperature conditions shall be used. Examples of temperature ranges to test may include:
   a. Warm, i.e. 40 to 60^{O}C (drying oven may be used)
   b. Room temperature (18 to 24^{O}C)
   c. Cool, i.e. 5 to 10^{O}C (refrigerator may be used)
   d. Cold, i.e. -5 to -20°C (freezer may be used)

2. The thermometer(s) and the reference thermometer shall remain in the verifying environment until a constant reading is reached. When the analyst feels confident that reading is constant, the values shall be recorded in the log. The following information shall be documented in the log:
    a. Date of verification.
    b. Initials of person doing verification.
    c. Reference thermometer reading.
    d. Laboratory thermometer reading.
    e. Identification (ID) or code number of the thermometer being verified.

3. Temperature readings taken from the reference thermometer may be rounded to whole numbers (e.g.: If reference reads 38.2^{O}C, the recorded value shall be 38^{O}C).

4. If the difference between the reference thermometer and the thermometer being checked is greater $\pm$ 2^{0} C it shall be labeled as not suitable for trials conducted under GLP and the device shall be retired and that event entered in the log and/or in Part 7C of the Field Data Book.

5. If possible, each measuring device shall be labeled following verification and shall include:
    a. ID or code number.
    b. Date of verification.
    c. Initials of person doing the verification.
    d. Temperature adjustment.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 March 2013

Author: David E. Yarborough

Title: 6.3:0 Verification and use of temperature data loggers

Purpose: The purpose of this SOP is to establish procedures for use and verification of temperature data loggers.

Scope: The SOP is to be followed for dataloggers used to collect GLP data.

Procedures:

1. Prior to use, visually inspect the data logger for cleanliness and that it is in good working condition. Check the power supply. Record inspection and any maintenance performed in appropriate logs.

2. The accuracy of temperature data loggers used for GLP studies shall be verified at least once a year against a reference thermometer which as been verified according to SOP# 6.2:1. Records of thermometer verification shall be maintained in a log.

3. All data loggers shall be identified by a unique number or code. The identification number or code shall be placed on the measuring device such that it can easily be cross-referenced to verification log records.

4. Data logger(s) to be verified and the reference thermometer shall be read side by side under conditions appropriate to the intended use.

5. Dataloggers shall be verified according to the Air Method described in SOP #6.2.

6. Launch unit. Select the duration of time that best suits the use (e.g. 30 days for chemical storage cabinet). If provided, in the 'Title', type in the location of the data logger during use.

7. Downloading unit. At the end of the data collection period, the data should be transferred to a storage system (i.e. computer disc labeled 'Data logger' and year of entries) and the data immediately printed out (hard copy). This hard copy shall be initialed and dated and retained as original raw data in the Field Data Book. A certified copy shall be maintained in the facility Historical File. The following information should be included on the printout:
    a. Date.
    b. Initials of individual conducting the activity.
    c. Data logger ID or code number.
    d. Temperature sensor location at the time of reading(s).
    e. Units of measurements.

8. The hard copy of the data from the data logger(s) should be legible to persons with normal vision.

9. Remedial action to be taken in case of failure or malfunction should include:
    a. Any problem should be immediately reported to the facility director or designated personnel, documented, and placed in the records for non-routine procedures.
    b. Any repairs or replacements resulting from malfunction during use shall be documented as non- routine maintenance in the appropriate log(s).

10. Personnel currently operating the equipment are responsible for the maintenance and remedial action taken in case of malfunction.

11. In the event of a malfunction or other incident which may affect the integrity of the trial, the Study Director and other appropriate individuals shall be notified and details shall be recorded in the Field Data Book.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 March 2013

Author: David E. Yarborough

Title: 7.1:0 Residue sample collection and storage

Purpose: To assure that residue samples are collected in a timely fashion.

Scope: All field studies conducted to develop samples for residue analysis under GLP.

Procedures:

1. Consult the trial protocol to establish specific dates for the collection of samples. If these dates are based on uncontrolled events (fruit size, spray applications, etc.), then tentative dates shall be established and refined as necessary. The Study Director, Regional Field Coordinator and Quality Assurance Research Officer shall be kept informed when the dates are changed.

2. Prior to sample collection obtain a sufficient number of sample bags from the Regional Field Coordinator to collect all the samples. Before entering the field, label each sample bag with waterproof ink as instructed in the protocol.

3. Samples shall not be taken during periods of inclement weather unless absolutely unavoidable.

4. Take special care to do the following in the sample collection process:
   a. Avoid contamination of the field sample with the pesticide under study during the sampling, labeling, storage and shipping processes.
   b. Avoid taking diseased or undersized crop parts.
   c. Take care not to remove surface residues during handling, packing or preparation.
   d. Be certain tools are clean.
   e. Harvest the untreated plots first and then proceed to the treated plots.
   f. Clean, disposable gloves should be worn and changed between harvest of the untreated control samples and the treated samples. Clean hands are also acceptable as long as they are washed between harvest of the untreated and treated samples.
   g. Never place residue sample bags on the ground.

5. Carefully place each sample in the appropriate individual sample bag.

6. Excess air should be expelled from the bag, then securely close the sample bag.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

7. Briefly describe the procedures and methods used in the Field Data Book.

8. When sample collection is completed, the samples shall be placed in a plastic cooler with ice or blue ice for transport to frozen storage. The samples should be removed from the field as soon as possible to frozen storage.

9. Consult the research protocol for the method, temperature and maximum length of time for storage. In general, samples should be air-shipped as soon as possible, preferably within two weeks of harvest. If a pickup by ACDS can be scheduled, or Canadian samples delay shipping, then samples can be stored until pickup can be arranged.

10. Samples identified for post-harvest processing should be processed or shipped unfrozen to the processor as soon after collection as possible, preferably within 24 hours.

11. Access to the freezers is limited to those authorized by the Field Research Director as the freezers are locked.

12. Attached to the storage facility (i.e. freezer) should be a log of the items inside indicating field ID#, sample collection dates, and number of samples for each project. Removal of samples prior to shipment should be recorded on the log sheet as to the name of the person removing them, what sample bags or parts thereof were removed, date removed, and date returned. On shipment, include the date of removal for shipping and individual responsible for removal.

13. If a freezer malfunction or other problem occurs which requires remedial action or which may affect the integrity of the samples, the Field Research Director shall inform the Study Director and shall immediately transfer the samples to non-GLP freezers in the same building. To minimize the effect of a freezer malfunction, gallon jugs of water shall be placed in GLP freezers to maintain temperature.

The following procedures are specific to lowbush blueberry samples:

14. For wild blueberries a commercial blueberry rake shall be used to collect the samples. Separate rakes shall be used for treated and untreated plots.

15. Prior to sample collection, the rakes and collecting boxes shall be thoroughly cleaned with soap and water and stored in containment for transport to the field site.

16. For each plot, begin raking in one corner and move diagonally across the plot avoiding plot boundaries. Avoid overfilling the rake since this can damage the fruit. Repeat until a sufficient quantity of fruit as specified in the protocol has been collected. Sample weight will be estimated by weighing the sample on a non-GLP analog scale.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

17. Samples shall be air winnowed and/or the larger leaves and stems shall picked out by hand, to provide the cleanest samples possible.

18. Place the collected fruit into the sample bag. Avoid sample bag contact with the soil or plant parts during sampling. Berry samples may be placed in a plastic bag within the sample bag to avoid loss of juice if not prohibited by the protocol.

19. The remaining treated crop shall remain marked until it is disposed of in such a way that it does not get into the food supply, e.g. harvesting and discarding, or mowing to the ground.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 March 2013

Author: David E. Yarborough

Title: 7.2:0 Sample shipping procedures.

Purpose: To assure that residue samples are removed from storage and shipped to the residue laboratory with a minimum loss of integrity.

Scope: All field studies conducted to develop samples for residue analysis under GLP.

Procedures:

1. Prior to shipping, contact the residue laboratory and notify them of the shipment dates and method of shipment including the carrier and carrier schedule. Ask them for any special instructions in shipping the samples. Air freight shipments should be made on Monday or Tuesday to avoid potential weekend layovers. When air shipping, notify the laboratory via phone; when shipping by ACDS, notification by phone or email is acceptable.

2. Make arrangements with the carrier for shipment of the samples and determine any special packing instructions, etc. that are required to preserve the sample integrity. Note any limits on quantity of dry ice, etc. that may be set by the carrier.

3. Treated and untreated samples could be packed in separate containers or in the same container if divided by a barrier and put in separate plastic bags, or if the untreated samples are placed above the treated samples. The containers should have a sufficient bursting strength so as to withstand normal handling in shipping and storage.

4. If shipping by air, obtain insulated containers of sufficient size and quantity to hold the residue samples and dry ice (where required), such as a 1:3 weight ratio to commodity and pack the samples and dry ice in the containers just prior to shipment. Airfreight shipments should be made on Monday or Tuesday to avoid potential weekend layovers.

5. A residue sample shipping and identification form should be completed, copies made, and a certified copy placed in each packed container of samples.

6. Retain the original of the residue sample shipping form in the Field Data Book.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

7. Label each shipping carton with the following information.
    a. Return name and address of the sender.
    b. Name and address of the residue laboratory receiving the samples.
    c. Number of the container if more than one is used.
    d. Affix "Experimental Samples-Perishable" to each carton.
    e. Where used, affix "Dry Ice" on two sides of the container.

8. Tape lids of each container firmly in place.

9. Provide carrier with the phone number of the residue laboratory receiving the samples and request the carrier to notify the laboratory when the samples arrive at a remote terminal for pickup, where appropriate. Send tracking number to the Laboratory Director or samples officer, so they can track the shipment if needed.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 March 2013

Author: Jennifer Cote

Title: 8.1:0 Collecting and recording of raw data.

Purpose: To assure that all information necessary to a trial is collected, reported and archived. To explain the use of the IR-4 report forms (Field Data Book) and other raw data notebooks for recording raw data.

Scope: All IR-4 GLP trials.

Procedures:

I. Data: information that supports or explains events during the course of the trial.
   1. All data required by the study protocol shall be collected and recorded in the Field Data Book, following a careful review of the protocol.

   2. Raw data/information collected for trials conducted under GLP's shall include, but not be limited to:
      a. Equipment logs, descriptions and/or diagrams (spray equipment, freezers, scale/balance used to weigh Test Substance, chemical and freezer inventory logs, etc.).
      b. Calibration/verification logs for equipment used during critical phases of a GLP trial (temperature monitoring devices, scale/balance for weighing Test Substance, equipment used to collect application weather data).
      c. Sprayer calibration and application rate calculation worksheets.
      d. Monitored temperatures for chemical and freezer storage.
      e. E-mails, notes, memoranda, dictated observations and activities that relate directly to the conduct or integrity of the trial.
      f. Recorded data from automated instruments, or exact copies thereof, such as weather data.
      g. Documentation of anything that supports or explains events during the course of the trial.

   3. Please note that some data required for GLP trials may not be collected under GLPs. See III for specific details.

   4. The raw data may be in the form of worksheets, records, memoranda, notes, dictated observations, computer printouts, pictures, magnetic media, recorded data from automated instruments, or exact copies thereof, which are the result of original observations and activities of a study.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

II. Recording Data:

1. Data shall be collected and recorded in real time, i.e., as the activity is completed or the data generated or downloaded.

2. Please note that when Field Data Book or FDB is used in the SOPs for this researcher, it is understood to include the Canadian (AAFC) Raw Data Field Notebook (RDFN), or any other raw data notebook for the collection of GLP data.

3. No pages or forms shall be removed from the Field Data Book or Canadian (AAFC) Raw Data Field Notebook as provided by the Sponsor. The pages and forms shall not be placed out of order.

4. The forms provided in the Field Data Book (FDB)/Canadian (AAFC) Raw Data Field Notebook (RDFN) should be used, or new/custom forms may be developed. The new forms shall contain all the data required on the original form. These new forms or other supporting data shall be placed in the FDB/RDFN behind the existing forms. For example, weather data shall be placed behind Part 9A.

5. Blank forms may be photocopied as needed.

6. Data shall be assembled as completely and accurately as possible. All data and documentation that pertains to each trial shall be placed in the raw data book for that trial, as that information becomes available. Sufficient detail or appropriate reference shall be provided as to the data and collection methods so that someone else can reconstruct the trial.

7. All original supporting data or certified copies shall be included in the raw data notebook.

8. The forms and all other raw data shall be written with indelible ink. Blue ink, as long as it photocopies and does not smudge, is preferable as it helps distinguish original from copied pages. If, for some reason, data is recorded in pencil, the page shall be photocopied and certified, since photocopies cannot be altered. The original document shall still be included.

9. Typewritten or electronic data shall be signed and dated on date that it is printed. More detail on electronic data in SOP# 8.3.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

10. Information shall not be entered in advance, with a few exceptions. Not entering data in advance is especially true of application, calibration and other data where the information might change before the end of the event. In some cases, where information will not change before the end of the event or trial, it may be entered in advance. Examples include the Field Research Director's name and address on the personnel form (1A), or the name and address of the residue lab (8A). See SOP 8.2 templates section for more detail.

11. If a particular form or section of the form does not apply to the trial, or a customized form is being use, a single diagonal line shall be made from the top of the page or field to the bottom. Initial, date, and give a reason on the line or in the space provided. For example, Part 9A for weather data shall be lined out, initialed and dated with a notation such as "See following pages".

12. Unused portions of tables and pages shall also be lined out, if more than three lines/cells are not used. For example, the unused lines in the 4B table shall be lined out, initialed and dated.

13. All blanks or prompts on the provided forms shall have a response.
    a. If the prompted question does not apply to the trial, use NA.
    b. If the data is not available, the response shall be written out as such.

14. Date entries and sign each completed page, and elsewhere as prompted. If more than one person enters data on the same page, the different entries shall be identified with the initials and dates of person entering the information.

15. The narrative portion of the forms shall be used to summarize the activity or to explain anything that is unusual. If the space provided is not sufficient to adequately describe the activity, an additional, properly identified page may be used.

16. All abbreviations or codes used in the raw data shall be defined. Common codes are already defined in the instructions, which are a part of the Field Data Book (FDB). Anything not listed there shall be defined in Part 3 of the FDB.

17. Changes to the raw data shall be lined through once, a reason given, initialed and dated. The correction explanation and/or code may be circled. Codes used for reasons shall be defined, as per #16, above.

18. Transcribing data for a GLP field trials is not acceptable, unless absolutely necessary, for example, general farm records.
    a. Transcribed data shall be clearly identified as transcribed, the location of the original cited, and dated and initialed by the person doing the transcription.
    b. Verification of accuracy by an independent reviewer is recommended.
    c. Raw data shall not be transcribed to forms and then the forms submitted as raw data. Instead, a certified copy of the original shall be submitted, citing the original's location.

19. Raw data may apply to two or more trials. In that case, certified copies shall be used as needed. See SOP# 8.2 for more details.

20. The first printing of a hard copy of electronic data, computerized summaries, etc. shall be initialed/signed and dated. This verified first printing then becomes the original. When the same data is needed in other locations, a certified copy of the data will be used, citing the location of the original.

III. Completion and final review of Field Data Books:
1. All forms shall be carefully checked to be certain all categories/blanks are completed and all appropriate data has been collected. The protocol shall be reviewed to be certain that all the necessary information has been provided.

2. All notebooks, data sheets, summaries, etc. shall be clearly marked with the name of the trial, date generated, name of research personnel and other information that may be needed to understand the data and its sources. Everything that needs to be has been signed/initialed, and dated. All copies have been certified and the location of the original cited.

3. All data required by the trial protocol and on the FDB forms has been collected and recorded, i.e. all the forms and data prompts (blank spaces) have been filled out or properly crossed out, initialed and dated.

4. Each data sheet from an electronic monitoring device shall be identified in ink with the instruments unique identifier, the dates (day, month, and year) of occurrence and units of measurement, if applicable.

5. All supporting data shall be added to the book, including SOPs, personnel information, equipment logs, weather data, chemical and sample storage temperatures, etc.

6. All protocol and SOP deviations have been documented and submitted to the Study Director.

7. The GLP compliance statement accurately reflects the study. All procedures not conducted in accordance with GLPs will be noted in the FDB, Part 1, GLP Compliance Information. Raw data/information not conducted/collected under GLPs at this site may include, but is not limited to:
    a. Weather data, irrigation records, and soil sampling and characterization not done under GLP guidelines.
    b. Residue sample weights measured on a scale/balance that is not maintained under GLP.
    c. Application and recording of maintenance pesticides and fertilizer not conducted or recorded under GLP.
    d. Crop cultural practices and plot histories not collected under GLP.

8. Within each part of the Field Data Book, supplementary documentation shall be placed behind the page it supports. For example, weather data behind 9A. If there is no prompt, place data behind the page to which it is most relevant. For example, Test Substance shipping documentation behind 4A.

9. There are no real prompts for equipment calibration/verification logs. Place them at the back of the part of the FDB where they first support data. For example, if a log includes the calibration information for the device used to monitor Test Substance temperatures, the back of Part 4 might be a good choice. If the logs cover a number of different parts, Part 6 is always a good choice.

10. Pagination should not be done until the Field Data Book is complete and has been checked. Paginate within each part of the raw data book separately; be sure to include the Part number (i.e. Part 1, pg. 1; Part 1, pg. 2, etc.). Each form and all pages of supporting data must be paginated. Once a part has been paginated, enter the total number of pages on page one of that Part.

11. Two sided pages are not acceptable in the raw data notebooks. If a two-sided document is received, it can be converted to one-sided document by photocopying. If the page or document is actual data, the second page shall be photocopied as a one sided page and certified as a true copy. The second side of the 2-sided page may then be crossed out. If, for any reason 2 sided pages are included in the FDB, they shall be identified with the Field ID Number and paginated.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 March 2013

Author: Jennifer Cote

Title: 8.2:0 Handling data that transcend two or more trials, and certified copies.

Purpose: To explain how raw data that pertain to more than one trial shall be included in each Field Data Book. How to make and use certified copies of original raw data.

Scope: All IR-4 GLP trials at this site.

Background:
This site may conduct multiple trials during the year. As a result, some data collected may pertain to more than one trial and one data form can be utilized in the Field Data Books for more than one trial. There are provisions within the GLPs for substitution of true (certified) copies in place of original records. However, the original raw data still need to be retained and archived. The following procedures are designed to meet the GLP and FIFRA requirements where copies of data are used.

Procedures:
Data common to more than one trial:

1. Specific raw data may apply to two or more trials. In that case, the Field Research Director shall designate one Field Data Book to contain the original of the data. Certified copies of the data shall then be placed in all other books to which those data pertain, citing the location of the original. The types of data which should have the original placed in one Field Data Book (FDB) include, but are not limited to:
    a. Sprayer calibrations for applications on the same day using the same equipment and settings (Part 6C and D);
    b. Plot plans including more than one trial;
    c. Shipping and sample receipts for more than one trial;
    d. Test substance receipt and use logs and documentation for more than one trial;
    e. Freezer logs;
    f. Site soil characterization.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Certified Copies:

1. All copies of forms/supplementary data placed in a Field Data Book shall be certified true copies of the original. Certification shall be done with a red stamp "Exact Copy of the Original Document" which shall then be initialed and dated.
    a. On those occasions when the stamp in not available, the same information may be written in by hand.
    b. Only the first page of multipage documents needs to be certified, if the pages are numbered, or there is some other indication of pages that belong together, for example a SOP set.
    c. In some cases it may be necessary to reduce the scale of the page for all the information to make it onto the photocopy. The copy shall still be certified as a true copy, with the addition of the information that it is a 'reduced scale' copy.

2. The certified copy shall also have a notation as to the location of the original raw data.
    a. When the original is in another FDB and already has that Field ID No., a simple arrow to the original's ID#, stating "original in" is sufficient.
    b. Other examples for citing the original may include: "Original in ID# _____.".
    c. A blank statement is provided at the bottom of some pages that are commonly copied. When filled in, no other certification is needed.
    d. Although 2A has such a blank statement, only the name and contact information of the Field Research Director shall be copied. The signatures, initials and dates shall be original for each Field Data Book and only have entries for personnel actually involved in the conduct of that study.

Templates:

1. Templates may be used for certain recurring information that is used often at the same location and will not change during the course of the trial. In many cases the information does not change for years. Examples include farm maps and directions, perennial crop maps and spray equipment diagrams. For guidance on what can be a template, the Regional Field Coordinator shall be consulted. Templates do not need to be signed and dated until:
    a. added to a specific book as raw data, for example maps and directions; or
    b. information specific to a trial is added, such as the crop drawn into in a spray equipment diagram, or the plot added to a perennial crop map.

   Again the signature and date verify that the information correctly reflects what occurred for the trial. The originals of these templates may be kept in the facility file and only sent for archiving when the template is no longer needed.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

2. Some FDB forms may be partially filled out in advance, and kept as templates. Because the forms are dated with the trial year, these templates shall be used for only the one year. Examples of these types of form templates are:
    a. the name and address of FRD on 2A.
    b. the directions and map to the testing facility and farm map, if using the forms 5A and B. This information can also be inserted into the FDB as a separate page.
    c. calculation formulae in the applications section (e.g., 6 E, F and I). The formulae can also be included as a separate page.

    These templates should be kept in the Common Data Book and sent for archiving at the end of the year.

3. As with templates, some actual data, such as soil texture, is used for more than one year. In this case, the original soil texture analysis shall be kept in the Facility File. This data shall be archived for the life of the registration supported by the data. As this location does not maintain an archive, the Field Research Director shall take full responsibility for ensuring that the data is forwarded to IR-4 Headquarters for archiving.

4. Long or complex narrations may be prepared on a computer, as a type of template. An example of a template narrative would be the description of the sample harvest and/or modifications to the harvested crop where the researcher has multiple trials and does the same crops yearly. The description can be written before or after the event. If written after the event, it shall be written immediately (within 24 hours) of the event. If prepared in advance, the description shall be reviewed after the event and modified, as necessary, to ensure that it accurately reflects what was done. The narration shall only be printed after the event, when the information has been reviewed. When printed, the page shall be initialed and dated to verify that the information is accurate and complete. The narrative portions of the forms shall then be crossed out and the separate narration referenced.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 March 2013

Author: Jennifer Cote

Title: 8.3:0 Collection of raw data electronically.

Purpose: To assure that raw data collected electronically is verifiable if audited.

Scope: All locations conducting GLP field trials.

Procedures:

1. Hard copies of computerized data (e.g. HOBO) and/or other written, typed or plotted data sheets must be initialed/signed, and dated. This initialed/signed and dated data then become the original raw data and shall be retained in the appropriate file. When a print out is not possible, a written log shall be recorded. Each entry to the log shall be dated and initialed by the person collecting the data.

2. Certified copies of computerized data and/or other written, typed or plotted data sheets shall be placed in the Field Data Books of any trials to which they pertain.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 March 2013

Author: Jennifer Cote

Title: 8.4:0 Disposition of raw data and documents for GLP trials.

Purpose: To assure that raw data are maintained during the active life of the trial and archived after the completion of the trial.

Scope: All GLP data and documents generated at this location in support of pesticide registrations.

Procedures:
All original raw data supporting the registration of a pesticide use pattern shall be retained in the archives in-perpetuity as specified in the GLP Standards Subpart J, Section 160.195. This Testing Facility does not maintain an archive; all data are sent to IR-4 Headquarters for archiving: IR-4 Project Headquarters, Rutgers, The State University of NJ, 500 College Road East, Suite 201, W. Princeton, NJ 08540. Tel.:732.932.9575, fax: 609.514.2612

Active life of the trial:

1. It is the responsibility of the Field Research Director to see that all raw data, summaries and other items are retained during the active life of each project for which he/she is responsible. After the end of the season, the Field Research Director shall see that these data are submitted to IR-4 for archiving.

2. The protocols, Field Data Books and supporting data shall be stored in limited access area (e.g., locked office) during the active life of the trial. The current Facility File shall be stored with the Field Data Books during the season. The locked room is of sufficient size to contain all active records and data generated during the season. The room is available for the Field Research Director or technician responsible during the conduct of the trials. This limited access area is located at the University of Maine, 5722 Deering Hall room 411, Orono, ME. Original freezer temperature logs are kept by another Field Research Director (at this time, Judy Collins), whose Facility File is located in Deering Hall room 307.

3. Information retained during the course of a trial includes, but is not limited to:
    a. The Field Data Books and any other forms used during the season;
    b. Supplementary raw data and information, such as personnel qualifications and training, test substance documentation and logs, pesticide storage and freezer temperature charts, site maps, soil characterization, weather data, equipment logs, etc.;
    c. All protocol and SOP changes and deviations, and documentation of their submission to the Study Director;
    d. Calibrations and original calculations;
    e. Citations of sources of information used (such as production guides); and/or
    f. Communications including e-mails, phone logs and other correspondence related to the trial.

4. The Field Research Director or designated personnel shall make a copy of the completed original Field Data Book. This entire copy shall be certified as a true copy by the initialed and dated certification stamp on the title page. A true copy of the Field Data Book shall be retained in the Historical Files at this Research Testing Facility at least until the data is submitted to the EPA.

5. The original of the completed, assembled Field Data Books shall be forwarded to the Field Research Coordinator within two months of sample shipping. If a Lab Receipt has not been received by the time the FDB is ready to be forwarded, the lab shall be contacted. If no receipt is available, confer with the Regional Field Coordinator. Special attention shall be paid to Studies that are on a fast track < 30 month time lines, as noted in the protocol.

6. FDBs from cancelled trials shall only be completed up to the time that the trial was dropped. These books may be sent directly to IR-4 Headquarters. No copy will be retained for studies which have been cancelled.

7. The Field Research Director shall respond to comments, questions, etc., posed by the Field Research Coordinator, Quality Assurance unit, and/or Study Director within two weeks of receipt, if possible. Responses should be in writing (letter, e-mail, etc.) or personal contact (e.g. phone).

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Facility File:

1. Testing facility information required under GLP/FIFRA, but not required to be included in the Field Data Book, shall be kept in a Facility File. Information may remain in the Facility Files for more than one year, as long as it is not revised. Data that may be placed in the Facility File includes, but is not limited to:
    a. Original authorized SOPs for the year;
    b. Organizational charts and floor plans; and/or
    c. Current personnel records (CV, Qualifications statement or resume, training records, job description, etc.).

2. At the end of one season, or at the beginning of the next, Facility File original information that has changed or been revised (e.g. workers leaving, new SOPs, etc.) shall be sent to IR-4 for archiving and a copy saved in the Historical File.

3. It is the responsibility of the Field Research Director to ensure that any data that support the registration of a pesticide is archived. Therefore, any data kept in the Facility Files shall be sent IR-4 Headquarters for archiving if any changes occur.

Historical Files:

1. IR-4 historical records shall be maintained by the Field Research Director or designated personnel. These records shall include, but are not limited to certified copies of:
    a. Retired Organizational Charts, floor plans and other facility information;
    b. Old CVs and training records;
    c. Previous SOP sets; and
    d. Previous years' Field Data Books.

2. Field Data Book copies shall be held until the data package is submitted to the U.S. EPA, the trial is dropped, or the study cancelled. Other copies of historical data shall be kept at least 4 years, but preferably until all the data packages in which the data were used go to the U.S. EPA. Before discarding documents from the Historical File, IR-4 HQ should be contacted, to assure that the original is archived.

3. The Historical Files shall be under limited access. The Historical Files shall be in a building with adequate fire protection and shall contain fire protection devices within the room.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 March 2013

Author: David E. Yarborough

SOP# 9.1:0 Procedures to follow prior to an announced EPA inspection.

Purpose: To provide guidance to trial personnel in responding to a request for an EPA audit or review by OCM.

Scope: Field test sites conducting pesticide registration research under GLP.

Procedures:

1. Notify the Study Director and other interested personnel of the pending audit or review as soon as possible.

2. Arrange to have available the personnel who may be associated with the trial or facilities audit.

3. Make sure someone who is authorized to accept the Notice of Inspection is going to be present at the start and finish of the inspection.

4. Prepare trial and/or facilities personnel for the inspection.
   a. Discuss position descriptions with technical personnel so they understand and can explain their role in the trial.
   b. Discuss possible questions that may likely come up about the trial or facility and make sure everyone understands what to expect.
   c. Request personnel to answer the questions only to the extent needed and not to provide extraneous information. Do not volunteer information; keep answers direct and to the point.
   d. Make certain that technical personnel know the safety precautions needed for the work area.
   e. Be certain that all documents pertaining to the trial/facilities inspection are available. This would include:
      1) Master schedule for the field research director;
      2) Trial Protocol and Standard Operating Procedures;
      3) Raw data, correspondence and logs;
      4) Training records, CVs etc. of personnel assigned to the trial;
      5) Appropriate chain of custody documents for samples and freezer logs and storage temperature documentation;
      6) Documentation of the characterization of the test substance, receipt and handling;
      7) Calibration logs on equipment such as balances and application equipment; and
      8) Archives or storage of records and logs indicating removal and replacement of documents.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

5. Have accessible organizational charts, a map of the facility and any information specific to the facility or area that shall facilitate the inspection (restaurants, motels etc.).

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 March 2013

Author: David E. Yarborough

SOP# 9.2:0 Procedures to follow during an EPA inspection (Field trial site inspection/outside agency).

Purpose: To provide guidance to trial personnel in responding to a request for an EPA audit or review by OCM.

Scope: Field test sites conducting pesticide registration research under GLP.

Procedures:

1. Greet the inspection team and follow any institutional procedures for signing in. Escort the entire group to a conference or meeting room.
2. At the opening of the conference ask the lead inspector for his/her credentials and for any opening statements.
3. Introduce the facility personnel present and state their function in the facility or trial. Identify the person responsible who shall accept the Notice of Inspection.
4. Distribute organizational charts, map of the facility and any other previously prepared information.
5. Ask the lead inspector for his/her agenda for the inspection as well as a list, if possible, of personnel needed for interviews during the inspection.
6. Explain any housekeeping rules such as the use of safety equipment in work areas, etc. to avoid any possible misunderstandings.
7. Proceed with the inspection.
8. Provide documents requested and provide explanations needed.
9. Keep notes of observations and of all interviews.
10. Keep management informed of the progress of the inspection and the findings.

University of Maine
David E. Yarborough
School of Food and Agriculture
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 March 2013

Author: David E. Yarborough

SOP# 9.3:0 Procedures to follow after an EPA inspection.

Purpose: To provide guidance to trial personnel in responding to a request for an EPA audit or review by OCM.

Scope: Field test sites conducting pesticide registration research under GLP.

Procedures:

1. Make sure that all personnel involved in the inspection are present for the closeout conference.

2. If the inspector's comments are in error, call this to the inspector's attention. Remember the closeout conference is not the forum for any debate.

3. If you have corrected any problems during the inspection make sure the corrections are so noted in the inspector's logbook.

4. Have someone present during the closeout take accurate notes or record the conference on tape if taping is acceptable to the inspectors.

5. Obtain a copy of the list of documents or other materials that may be taken as exhibits by the inspectors.

6. Debrief management, staff, and the Study Director with an explanation of any problems found.

7. Assign responsibility for preparation of possible solutions to problems and obtain time estimates for implementation.

8. Prepare any replies to the regulatory agency as necessary within a timely basis, and keep interested parties such as management and the Study Director informed.