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STANDARD OPERATING PROCEDURES

FOR

MAGNITUDE OF RESIDUE STUDIES

CONDUCTED UNDER GOOD LABORATORY PRACTICES

Marylee Ross
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Revision No.: 12

Effective Date: March 02, 2016

Field Research Director: Marylee Ross ML March 29, 2016
Marylee Ross (Signature) (Initials) (Date)

Approving Official: Daniel Rossi DR March 2, 2016
Dr. Daniel Rossi (Signature) (Initials) (Date)
NE Regional Director

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

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REVISION NUMBER: 12
YEAR: 2016

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SOP #1.1 **General requirements for the development and use of Standard Operating Procedures (SOP).**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 8

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

SCOPE: All GLP field studies under the IR-4 Project.

SUBMITTED BY: Marylee Ross

PROCEDURES: SOPs developed for use in all phases of the GLP research where the trials are conducted in the support of the registration of pesticides shall be managed as follows:

1. The SOPs shall be reviewed by the Field Research Director or assigned personnel, and approved by the Regional Director. The SOPs for researchers in the IR-4 Northeast Region shall generally be approved as a set. 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 revision number, effective date, dated signature of the Field Research Director or assigned personnel, signature of the approving official, and the date signed by the approving official. SOPs revised or generated in a given year, after the SOP set has been signed, shall be signed and dated separately and incorporated into the SOP set for subsequent revisions. Original signed SOP sets shall be sent to IR-4 Headquarters in the Common Data Book for archiving upon completion and submission of all current Field Data Books and Quality Assurance Audits. Certified copies shall be maintained at the facility for researcher use.

2. Each SOP shall be reviewed and/or revised as needed, at least every three years. The effective date and revision number shall be changed to reflect revisions, both on the title page for the SOP set, and on the individual SOP revised. The revision number shall begin with 1 and increase sequentially with each revision.

3. Any change to an individual SOP shall be considered a revision. This includes correcting grammatical and/or typographical errors, as well as technical changes. Individual revised SOP shall be given a new revision number and effective date.

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4. SOP sets reviewed, but not revised shall retain the original revision number, signature and date of the approval on the title page, along with an added statement that the SOPs are being used for another year, with the year specified.

5. Any deviations from the SOPs shall be noted in the Field Data Book, by completing a deviation form (1C) and sending the original to the Study Director for approval, while keeping a copy of the form.

6. Any SOP that is no longer applicable may be inactivated by the addition of a procedure statement at the end of the SOP indicating that the SOP has been inactivated and the date the inactivation took place. Inactivated SOPs may be reactivated by the addition of a procedure statement to that effect, indicating the date of reactivation.

7. The location of a SOP within the SOP set may be changed by noting at the end of the SOP where that SOP was located in the previous revisions.

8. SOPs shall contain the name of the Field Research Director, the Effective Date the number of the SOP, the revision number and the page number. SOPs of more than one page shall be identified on each page. Each additional page shall contain the name of the Field Research Director, the number of the SOP and the page number. Example:
   Ross SOP#1.1 Page 2 of 2

9. The SOPs developed for the field trials also apply to greenhouse trials unless an SOP has been specifically developed for the greenhouse.

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SOP #1.2 **Numbering system for SOPs**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 5

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.

SUBMITTED BY: Marylee Ross

PROCEDURES: The numbering system for SOPs is as follows:

1. General
2. Personnel
3. Agronomic Practices
4. Test Substance and Pesticide Handling
5. Equipment and its Calibration
6. Application Calibrations
7. Residue Sample Handling
8. Data Handling
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.

Each SOP within a section will have a revision number that starts with 1 when it is created. Revisions to an individual SOP will be reflected in the Revision number by increasing that number by 1 with each revision. The revision number will follow a colon after the individual SOP number within a section. Example: 1.2:5 (Section 1. SOP2: revision 5).

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SOP #1.3 **Format for use in developing SOPs**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 4

PURPOSE: To assure a uniform format in the development of SOPs

SCOPE: Applies to all SOPs developed by Field Research Director for use in the conduct of studies under GLP.

SUBMITTED BY: Marylee Ross

PROCEDURES:

Name of Researcher and Test Facility (centered)
Address (centered)
Space
SOP Number: (SOP section and number as a decimal) (Tab) Title:
Space
EFFECTIVE DATE: (date of approval) (Tab) REVISION NUMBER: (sequentially beginning with 1 for first use)
Space
PURPOSE: (Brief description of the PURPOSE of the SOP.)
Space
SCOPE: (Determines where and when the SOP is applicable)
Space
SUBMITTED BY: (Name of person developing the SOP)
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.)

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SOP #2.1 **Designation and Responsibilities of Field Research Director**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 7

PURPOSE: To provide information on how a Field Research director is designated and to outline the responsibilities of the Field Research Director.

SCOPE: IR-4 Project GLP Trials

SUBMITTED BY: Marylee Ross

PROCEDURES:

1. The Field Research Director is designated by the Study Director based on the recommendation of the Regional Field Coordinator. The Field Research Director shall have appropriate training and experience to conduct the trial. If the Field Research Director cannot continue with the project, then the Regional Field Coordinator shall work with the institution to provide a replacement, or close the center.

2. The Field Research Director has the responsibility for the following:

   a. Assure that the GLP trials are carried out according to an approved research protocol signed and dated by the Study Director.

   b. Assure that personnel, resources, facilities, equipments, materials and methods are available as scheduled for the conduct of the project. Designate trial locations and assure that crops are established, grown and maintained under Good Agricultural Practice.

   c. Make sure that all personnel conducting the trial understand the research protocol and SOPs for any portion of the project in which they are directly involved. One person shall be familiar enough with the project to see it to its completion should the Field Research Director become unavailable to fulfill the requirements of the trial.

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d. Assure that all comments reported by the Regional Field Coordinator, Quality Assurance Officer and/or Study Director are responded to promptly in writing or direct contact (telephone, e-mail, etc.). Coordinate in-life QA inspections.

e. All raw data, summaries and other items connected with the trial need to be retained throughout the duration of the trial and sent to headquarters for archiving after completion of the trial.

f. Submit annually a projected timetable to the Field Research Coordinator before experimental start date. This is currently done by filling in the dates and signing the cover letter that accompanies each protocol. 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, and may be viewed, downloaded and printed as needed.

g. Maintain on file a current summary of the training and experience and a job description for all key people engaged in the trial.

h. Assure that all original records are transmitted to IR-4 Headquarters for archiving.

i. Maintain certified copies of the FDB until the data is submitted to the US EPA.

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SOP #2.2 **Personnel**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 7

PURPOSE: To provide information to Personnel concerning requirements under Good Laboratory Practices.

SCOPE: All GLP field(delete this word?) research trials.

SUBMITTED BY: Marylee Ross

PROCEDURES:

1. The Field Research Director shall have on file a current summary of the training and experience and a job description for each person collecting and/or entering data or supervising the GLP trials. 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. The Field Research Director or designated personnel shall record the names of the personnel and the dates that the SOPs were explained to them. This information shall be placed in the Common Data Book that shall be sent to IR4 HQ for archiving.

2. 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.

3. The Field Research Director shall have a supply of safety equipment in working order and clean to protect the health and safety of the personnel connected with the project as required by pesticide labels or the trial protocol.

4. Personnel handling pesticides shall be trained in accordance with the current policies and guidelines of LESREC.

5. Where the application of restricted use pesticides is required in the trial, the applicator must be certified or under the direct supervision of a certified applicator.

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SOP #2.3 **Organizational Chart**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 6

PURPOSE: To assist in the development of an organizational chart.

SCOPE: All field test sites conducting GLP trials for the IR-4 project.

SUBMITTED BY: Marylee Ross

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 shall be signed or initialed and dated. The original charts shall be sent to IR-4 Headquarters in the Common Data Book each year.

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SOP #2.4 **Documentation of Training**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 5

PURPOSE: To assure that training for personnel involved in the trial is properly documented.

SCOPE: All Personnel working on research under GLPs at this Field Research Center

SUBMITTED BY: Marylee Ross

PROCEDURES:

1. Training 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 discipline, year graduated and institution shall be noted. If a degree was not awarded then the years of attendance and credit hours and specialty and/or years of experience shall be noted. Experience may stand in lieu of formal education.

2. Training received from workshops, conferences, etc. shall be noted as to the name of the event and dates of attendance, either in their CV or in a training log. A copy of any type of training certificates issued shall be retained in the personnel files at the location. Certified copies of Job Descriptions for personnel no longer involved in the projects shall be sent to IR4 Headquarters for archiving.

3. 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. X explained to Mr. Y how to label the sample bags as per SOP xx on 6/2/93).

4. Each person engaged in the conduct of the trial shall have read and understood those sections of the protocol and the standard operating procedures that pertain to their responsibilities. The Field Research Director shall record the names of the personnel and dates that the SOPs were explained to them. This information shall be placed in the personnel file.

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5. 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.

6. Personnel (such as farm crew) who are only involved in routine maintenance and other non-critical duties (such as plowing, planting, pruning, hand weeding, etc.) do not need to be included, if a statement of non-GLP compliance is made for these activities.

7. Personnel files shall be maintained and updated annually for all persons involved in any GLP activities associated with GLP trials. The original, updated documents, including, but not limited to CV and Training Record shall be placed in the Common Data Book. A certified copy shall be placed in the Field Data Book for all GLP trials in which the person or persons are involved.

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SOP #3.1 **Site selection for GLP field trials**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 6

PURPOSE: To assure plots are of suitable design to obtain the required data or samples with sufficient uniformity.

SCOPE: All GLP field studies under the IR-4 Project

SUBMITTED BY: Marylee Ross

PROCEDURES:

1. Site selection will be made in accordance with the horticulturally acceptable practices for the commodity.

2. Each site shall be large enough to accommodate the required number of samples, buffer zones and treatments in accordance with an approved research protocol and for the commodity to be grown under simulated commercial conditions yielding samples of sufficient size for analysis where required.

3. Locate site with sufficient isolation to minimize contamination from external sources such as commercial operations or other research studies. A minimum 15 feet shall exist between plots of similar chemistries and/or untreated plots unless protocol dictates otherwise. Where samples for residue trials are required locate a site within the same area, but with enough isolation to produce untreated, uncontaminated samples. At LESREC, GLP trials will be performed with the untreated plot located north of the treated plot since we have NW prevailing winds.

4. If the commodity is not to be newly established, a site shall be selected that has a uniform stand for production.

5. Standard cultural practices shall be performed prior to plot layout and marking.

6. The experimental design, if specified by the research protocol, shall be used.

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7. Lay out each plot on the site using a suitable measuring device to accurately locate plots on the site. Measure from a permanent field marker to the closest corner of the plot. From there measure to the next corner of the plot and then to another permanent marker. Measure the length of the plot. Measure buffer zones between plots to assure acceptable space will exist between plots. Record the date the plots were laid out and the initials of the individual responsible for laying out the plots.

8. Prepare a plot map showing the location of each plot on the GLP trial site, direction and degree of slope and the north azimuth. The map should also show the number of rows, row spacing, row length, overall plot dimensions and distance from the farm entrance to the plot, and dimensions of the buffer zones. The plot map shall contain distance to plots from permanent reference points.

9. The fields involved in GLP field trials at the LESREC shall be identified with a unique number and the corners identified by a permanent marker. The permanent markers are metal poles or pieces of metal of sufficient size to be easily located using a metal detector and are buried approximately 12 inches deep at each corner. The corners are also marked with flags so a visual marker is available. The flags shall be replaced when they are worn out or lost. The metal pieces shall be replaced if they are disturbed or they rust away.

10. Identify each treatment plot as per the protocol, including, but not limited to the IR-4 Field ID Number and treatment number or treatment name. The marker shall be made in such a manner that it will be visible throughout the life of the trial.

11. The soil where the trials will be conducted shall be tested for nutrients, pH, and organic matter in the year in which trials will be conducted on that site. The above data will be recorded in the files for all trials. For soil texture determination, analysis performed no more than 15 years prior to the trial will be acceptable.

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SOP #3.2 **Commodity establishment and maintenance.**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 4

PURPOSE: Assure that commodities are grown under good agricultural practices and provide a uniform crop for trial.

SCOPE: All GLP field studies developing residue samples under the IR-4 Project.

SUBMITTED BY: Marylee Ross

PROCEDURES:

1. Document the practices followed to produce the commodity under simulated commercial conditions.

2. Obtain a soil test report for pH and soil fertility requirements annually and retain with raw data.

3. Lime, fertilize and/or condition the soil at the site as necessary to bring the soil within the requirements of the commodity.

4. Till the field as specified for the commodity.

5. Determine the correct species and variety to use as specified by the research protocol. If the variety is not specified, determine a variety commonly used in the area by commercial producers to use for trial. If a commercial producer is providing the plants, select plants as uniform in growth and color as possible.

6. Determine within and between row spacing and seed depth as specified. Plant the seed or transplant in straight rows with fairly accurate measurements to assure the commodity is planted according to specifications.

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7. Irrigate or perform other agricultural practices as necessary to get the commodity started.

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

9. If needed, apply as appropriate, pesticides as specified in the Maryland Commercial Vegetable Recommendations. Do not apply maintenance pesticides that are not registered for the commodity unless there is no registered product for the pest and approval is granted by the Study Director. Document application of pesticides.

10. If pesticides are applied to the commodity to prevent losses due to pests, they shall be applied to all plots in the trial using standard agricultural practices. If this is a magnitude of residue trial, no pesticide shall be applied that would interfere with the chemical analysis of the pesticide under trial. If in doubt, call the analytical chemist or analytical laboratory and/or Study Director as identified in the research protocol. Apply maintenance materials to both the untreated and the treated plots.

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SOP #3.3 **Greenhouse Facility**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 4

PURPOSE: To assure that greenhouse facility is properly maintained and in sufficient working order throughout the trial to obtain the required data and samples with sufficient uniformity

SCOPE: IR-4 Project Field Research Center Greenhouses, LESREC

SUBMITTED BY: Marylee Ross

PROCEDURES:

1. The greenhouses must be sufficiently large to contain the entire trial or a complete treatment of the trial with sufficient space between plots to prevent contamination. There shall be sufficient buffer space between the treated and untreated plots of a trial. If there is not sufficient space a barrier shall be in place during spray applications and until the application has completely dried. Treated and untreated plots may be placed in separate greenhouses.

2. Where more than one trial is conducted in the greenhouse there must be sufficient isolation between the trials to prevent contamination or interference between trials.

3. Lighting, temperature, humidity and shade will be sufficiently uniform at trial sites in the greenhouse to provide nearly uniform plant growth throughout the trial sites.

4. The walls, floors, and ceilings of the greenhouse will be maintained in good condition. Floors, benches and aisles shall be free of debris, weeds and superfluous equipment and be well drained to prevent the buildup of excess moisture.

5. Greenhouse shall be equipped to maintain temperature, lighting, and moisture conditions to simulate commercial greenhouse production techniques or to meet the requirements of the trial protocol.

6. Sufficient monitoring devices shall be installed, in good working order, and verified periodically to assure that the proper lighting, temperature and humidity are maintained throughout the trial. The climatic conditions will be measured and recorded on a regular basis for the entire length of the trial.

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SOP #4.1 Receipt, Handling and Storage of the Test Substance

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 9

PURPOSE: To explain the procedures required in the receipt, removal, use, return, and transfer of the test control and reference substances, and to assure that all pesticides are stored in a manner consistent with GLP requirements.

SCOPE: For GLP Studies Conducted at This Location

SUBMITTED BY: Marylee Ross

PROCEDURES:

1. When the test substance is received, lot/batch number, source, quantity, date of receipt, condition of the material, GLP status, expiration date and storage location shall be recorded in the FDB. Each entry shall be initialed and dated. To serve as a unique identifier, the protocol number(s) and crop(s) are recorded on the container. If storage conditions and expiration date are not already on the label, they shall be added at the time of receipt. 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. If other materials such as adjuvants and fertilizer are used as part of a GLP application date of receipt and expiration date shall be recorded if available See SOP #4.8.

2. Store pesticides in a dry, well-ventilated building, which is separate from offices and laboratories and where fire protection is provided. Protect from freezing or overheating. A thermostatically controlled forced air heater is installed in each room of the pesticide storage building. Heaters are set to prevent temperature from dropping below 50 degrees Fahrenheit.

3. Make accessible, materials such as absorptive clay, granulated activated charcoal, hydrated lime, and sodium hypochlorite for emergency treatment or detoxification of spills or leaks.

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4. All pesticides in storage must be properly labeled. If more than one container of test substance is received, each container shall be identified with a unique number consisting of the project number then the container number, starting with number 1. For example, if 3 containers are received they shall be numbered 1 of 3, 2 of 3 and 3 of 3.

5. Pesticides shall not be stored on the floor. GLP test substances are stored separate from pesticides for non-GLP use. GLP products are stored in a locked metal cabinet labeled for IR-4 use only, in room 20 in the LESREC chemical storage room. Access to the cabinet is limited to the Field Research Director and other authorized personnel.

6. The storage of the pesticides is in a separate room from the areas where the pesticide is measured and mixed.

7. Containers of pesticides 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. The Study Director shall be contacted to determine if the container or the contents can be disposed of properly.

8. A current inventory of all pesticides in the GLP storage unit is kept in the Field Research Director's office.

9. The telephone numbers and names of personnel responsible for and knowledgeable of the contents of the storage facility are posted on the door of the pesticide cabinet.

10. Highly visible, waterproof identification signs shall be placed on doors, gates, buildings and fences to advise of the hazardous nature of the storage facility's contents.

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11. A designated data logger shall be kept in the storage cabinet to record storage temperatures of the test substance during period from initial receipt of substance until trial's completion. The data shall be downloaded and printed periodically, for example, every four to six weeks. The original printout shall be dated and initialed and placed in the Common Data Book. Certified copies, properly referenced, shall be placed in the individual FDBs. A designated min/max thermometer shall also be kept in the storage cabinet as a backup in case the data logger fails. Minimum and maximum temperatures shall be recorded each time the data logger is downloaded. The data logger shall be replaced each year with a new one guaranteed by the manufacturer to be accurate.

12. If test substance is held in temporary storage at any time or is in transport there shall be a verified Min/Max thermometer with it to monitor storage temperature. The Minimum and maximum temperatures during temporary storage shall be recorded.

13. When a test substance is used, the date, amount used, purpose of use and initials/signature of the user shall be recorded in the FDB.

14. All unused pesticides and empty containers shall be returned to the storage facility at the completion of their use. Notification that the containers may be disposed of may come from the Regional Field Coordinator or occasionally the Study Director, and may be confirmed on the IR-4 website. 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 shall be written.

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15. 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. The container shall be retained until disposal is authorized.

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

17. Adjuvants used in GLP trials shall be stored in the same place as the test substances, and a record kept of when and where the adjuvant was obtained, along with any other information requested in the Field Data Book. See SOP # 4.8.

18. If a test substance must be transported to a trial site away from LESREC it shall either be kept in its original container or the amount needed may be premeasured, placed in a suitable container and properly labeled with test substance identifying name, lot number, expiration date, trial and treatment number, amount removed from the original container, initials and date. Dry material shall generally be pre-weighed to avoid transport of GLP balance. Container of test substance shall be transported in a zipper sealed plastic bag in a box with absorbent material. The test substance shall be protected from direct sunlight and extreme temperatures. Transport temperatures shall be recorded with data logger or max/min thermometer. Unused test substance shall be returned to IR-4 Pesticide Cabinet as soon as possible after use. Empty secondary containers shall be disposed of properly.

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SOP #4.2 **Measuring a pesticide formulation**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 7

PURPOSE: To assure an accurate dosage in the application of pesticides.

SCOPE: All GLP field studies.

SUBMITTED BY: Marylee Ross

PROCEDURES:

- Wear or use appropriate safety equipment while handling pesticides.

- Maintain a written record of each volume or weight of pesticide removed from the original container in the chemical log. If more than one amount is measured 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 must be maintained on a single log. The original is placed in the book for one trial and an exact copy in the other.

I. Liquid (SC, EC, FL, L, etc.)

1. If the material is fluid, then a disposable syringe or disposable pipette shall be used to measure the pesticide. If the volume being measured is >100 ml, then a graduated cylinder with increments small enough to read to accuracy required by the study (+/- 5%) shall be used.

2. If the liquid can not be measured without danger of spillage, then pour an adequate amount into a clean container from which the liquid can be extracted. If filling a cylinder, a container with a pour lip or clean funnel shall be used. Dispose of unused liquid properly, do not return it to the container.

3. Take the reading of the liquid in the cylinder or pipette at the bottom of the meniscus.

4. Pour the liquid directly into the spray tank. Make sure that as much as possible of the liquid is transferred to the spray tank. Cylinders shall be triple-rinsed into the spray tank, as indicated under SOP #4.3.

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5. Reusable cylinders shall be washed with ammonia then triple rinsed with clean water after each use to ensure that the cylinder is clean and cross-contamination of pesticides shall not occur with future use.

II. Dry

1. The balance shall be serviced and calibrated once a year and a copy of the certificate included in the Field Data Book. Immediately after servicing, the Standard Weights shall be weighed for verification and the data entered in a log.

2. Immediately prior to weighing a dry test substance the accuracy of the balance shall be verified by bracketing the weight of the test substance with Standard Weights of larger and smaller weight.

3. Select a clean container suitable to hold the desired amount of pesticide and tare it on the scale following the manufacturer's directions.

4. Weigh the test substance in the tared container.

5. If taring the container is not practical then record the weight of the container, add the weight of the desired amount of pesticide to it and weigh out this amount.

6. If mix is to be made at a later time, the weighed material may be kept in a suitable container and properly labeled with test substance identifying name, lot number, expiration date, trial and treatment number, amount removed from the original container, initials and date.

7. Transfer the pesticide directly into the spray tank. Triples rinse the container into the spray mixture.

8. If necessary, a slurry shall be made to suspend the material in water prior to addition to the spray mixture. An appropriate amount of the carrier shall be used to make the slurry in a suitable container. The container shall be triple rinsed into the spray mixture with an appropriate amount of the carrier.

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SOP #4.3 **Procedures in the application of pesticides.**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 7

PURPOSE: To describe the practices common to all types of pesticide application.

SCOPE: All GLP field studies under the IR-4 Project.

SUBMITTED BY: Marylee Ross

PROCEDURES:

1. All personnel involved in the mixing, application, storage and cleanup of pesticides shall be properly trained.

2. Personnel mixing and applying the pesticide shall wear appropriate protective clothing as stated on the pesticide label.

3. Equipment used in the application of the pesticides shall be inspected and calibrated as indicated under SOP #6.1, 6.2 or 6.3.

4. Remedial actions to be taken in case of failure or malfunction include:
   a. Any problem shall be immediately reported to the Field Research Director, documented and placed in the maintenance records for non-routine procedures.
   b. If the problem cannot be corrected by instructions from the manufacturer's manual, the service representative shall be notified. All corrective actions taken shall be documented.
   c. The Study Director shall be contacted, if the problem occurs during the GLP application or otherwise affects the integrity of the trial. See SOP # 4.4.

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

6. The test substance shall be measured out as indicated under SOP #4.2. Document as amount of product.

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7. Measure the amount of water needed to meet the requirements of the protocol. Document as amount of carrier. Add approximately ½ the water to the spray tank.

8. If needed, make a slurry mix (i.e. wettable powder formulation) first by adding the concentrate to a small volume of the measured carrier in a separate, clean container. Shake until completely mixed. Add the test substance or slurry to the water in the spray tank. Triple rinse the test substance measuring or slurry container (does not include pipettes or syringes) into the spray tank using the remaining carrier water.

9. If adjuvants are to be used, they should be added to the tank after the test substance unless the label or protocol establishes a specific mixing sequence.

10. Add the remaining water to the spray tank. Close and tighten the lid. Rinse the outside surface of the spray tank with clean water, when needed.

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

12. Make sure all settings of pressure, speed, etc. are set according to specification from the calibration as previously performed.

13. Apply the material beginning with the lowest concentration and work up to the highest concentration. Make a separate tank mix for each plot to be treated. One spray mixture shall never be used for more than one plot.

14. Just before entering the plot make sure that you are traveling at the correct speed and turn on the sprayer. Maintain the correct speed through the plot.

15. Turn off the sprayer flow just after leaving the plot.

16. Calculations shall be made to minimize the amount of spray material left in the spray tank.

17. If the pesticide application is for the maintenance of the plots, then apply the pesticide to all the plots in the study according to the directions on the pesticide label.

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SOP #4.4 **Procedures to follow when a problem occurs in the application of the Test Substance.**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 4

PURPOSE: To explain the procedures required when something goes wrong during the application of the Test Substance in the trial.

SCOPE: All locations where pesticides are used. For the purpose of the SOP, test substance also applies to control and reference substances.

SUBMITTED BY: Marylee Ross

PROCEDURES:

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

2. If something does go wrong such as a nozzle is plugged or a 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 carefully marked off and staked to indicate the area affected. This portion shall not be used for obtaining samples of the commodity for residue analysis.

4. If the unaffected area is too small to obtain the samples required for analysis, contact the Study Director for the decision whether or not to discontinue the trial. If a new trial can be initiated, a protocol amendment is needed with a new Field ID number. A new trial shall only be initiated once the protocol has been amended adding a new field trial.

5. The Study Director, Regional Director and other appropriate individuals shall be notified immediately of the incident and details shall be recorded in the Field Data Book.

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SOP #4.5 **Clean up of application equipment**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 5

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.

SUBMITTED BY: Marylee Ross

PROCEDURES:

1. All personnel involved in the mixing, application, storage and cleanup of pesticides shall be properly trained.

2. Personnel mixing and applying the pesticide shall wear appropriate protective clothing as stated on the pesticide label. If the label does not specify, then gloves and Tyvek suits shall be worn to protect personnel involved in the application.

3. Excess pesticides, pesticide rinse water and other dilute pesticide waste shall be disposed of in the field per label directions or applied to non-crop area of field. Spray tanks shall then be taken to the spray pad, rinsed once with water, washed with ammonia and triple-rinsed. Hoses and nozzles shall be flushed with ammonia wash then clean water then air. Drain each wash into designated rinsate containment area.

4. Dispose of expendable protective clothing by placing the items in a container for proper disposal. Clean non-disposable items with soap or ammonia and water as appropriate.

5. After application equipment is dry, maintain per manufacturer's instructions and return the equipment to storage.

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SOP #4.6 **Disposal of Pesticides**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 5

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

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

SUBMITTED BY: Marylee Ross

PROCEDURES:

GLP Test substance containers shall be kept until the study is submitted to the US EPA or canceled, the trial dropped.

Maryland Agricultural Experiment Station policy requires that each Principal Investigator shall be required to inventory their storage area yearly and maintain a neat and orderly site. Following each yearly inventory, each PI is responsible for disposing of unwanted and/or leftover materials including rinsates.

1. Disposal of pesticide concentrate and/or containers. The following applies to the test substance containers when permission has been received as per Advisories #2005-01 and/or #2003-02.

    a. Excess test substance may be used in other crops, as long as the product is registered in that crop.

    b. Follow label directions for the disposal of the pesticide.

    c. If no label directions exist for disposal, arrangements shall be made with a licensed waste disposal firm for pickup and disposal of the pesticide and/or the empty containers.

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2. Disposal of pesticide rinse water, unused spray solutions and other dilute pesticide waste.

   a. Check state and local laws and regulations to determine any procedures that may exist for proper disposal of pesticide solutions.

   b. Dispose of the dilute pesticide waste in the field by spraying on an over-planting of the crop where this procedure does not violate any laws and regulations. Excess dilute pesticide solutions may be applied to non-crop areas for disposal. Washing and rinsing of spray tank is performed on a designated rinse pad and drained into a pesticide drainage pond. All pesticide solutions shall be mixed with the intent of limiting the problem of excess solutions.

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SOP #4.7 **Handling pesticides safely.**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 2

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.

SUBMITTED BY: Marylee Ross

PROCEDURES:

1. Personnel shall follow current policies and guidelines of the University of Maryland, LESREC. 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, self-contained breathing apparatus, etc.) must be available when handling hazardous pesticides such as restricted use pesticides.

4. 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.

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

6. Prior to application, the equipment shall be checked to make sure there are no leaks in the pump or tanks, hose connections, or worn spots in the hoses. All spray tanks shall have lids. Filling the spray tank shall be done carefully so it does not run over. All machinery shall be shut down if necessary to adjust or repair any moving parts. Never blow out nozzles, hoses, or clogged lines by mouth. 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.

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. If the protocol requires reentry before the labeled REI, proper protective measures shall be taken as per the label.

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 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. The fire chief shall be furnished with the home telephone of the person responsible for the pesticide storage facility.

14. Pesticide storage areas shall be properly ventilated.

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SOP #4.8 **Storing and Maintaining Adjuvants**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 1

PURPOSE: To define procedures for receiving and storing adjuvants for use in IR4 GLP studies.

SCOPE: All GLP field studies under the IR4 Project requiring an adjuvant.

SUBMITTED BY: Marylee Ross

PROCEDURES:

Adjuvants are considered to be reagents, not test substances and are required by EPA to be treated as GLP reagents. No GLP characterization is expected.

1. All adjuvants for GLP studies will meet GLP labeling requirements for reagents which shall include, but not be limited to:

    a. Name
    b. Concentration
    c. Lot or batch number if available
    d. Storage conditions
    e. Date of purchase or initial opening of the container
    f. Expiration date
    If no expiration date is available the Field Research Director will assign an expiration date of no longer than 5 years from date of purchase.

2. Secondary containers are permitted for storage, but must be properly labeled as per the original container and shall take on all the requirements of the original container. Adjuvant dispensed into a secondary container shall not be returned to the original container.

3. Adjuvants shall be in good condition. The physical characteristics should not have changed since purchase or be compromised. Color, consistency and odor should be unchanged from purchase. If there are any concerns about the integrity or condition of an adjuvant it shall be removed from use in GLP studies.

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4. Store adjuvants in a dry, well-ventilated building, which is separate from offices and laboratories and where fire protection is provided. Protect from freezing or overheating. A thermostatically controlled forced air heater is installed in each room of the pesticide storage building. Heaters are set to prevent temperature from dropping below 50 degrees Fahrenheit. At LESREC adjuvant containers will be stored in a cabinet with access limited to authorized personnel. The cabinet is located in Building 601, room 20. It is labeled for IR4 personnel only and is kept locked.

5. Storage temperatures shall be recorded using a data logger. Data logger shall be downloaded periodically; graphs printed and placed in Common Data Book for the applicable year.

6. Adjuvants shall be handled in a manner to prevent cross contamination with any other substances. Adjuvants shall be dispensed from the original container or secondary container using a factory sealed disposable syringe or pipette, or by pouring directly into a measuring device such as a beaker or graduated cylinder. Syringes or pipettes shall not be used again for adjuvant or test substance and shall be properly disposed of. It is imperative that no measuring device will be used to dispense from an original or secondary adjuvant container, placed onto a mix tank and used to dispense from the adjuvant container again. Measuring devices such as beakers and graduated cylinders shall be cleaned by rinsing, washing with ammonia and at minimum; triple rinsing.

7. When necessary; adjuvant will be transported to and from test site in a manner to protest from overheating or freezing. A Min/Max thermometer will accompany the container and a log kept of transport temperatures. The log will be placed in the applicable year's Common Data Book and a true copy placed in relevant Field Data Books.

8. At LESREC, unless otherwise necessary and documented new adjuvant shall be obtained every year. The new adjuvant shall be used exclusively for IR4 studies. After completion of all studies requiring use of an adjuvant in a correspondent year the container shall be moved into farm maintenance materials storage.

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SOP #5.1 **Calibration and use of balances.**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 7

PURPOSE: To assure an accurate weighing of dry test substances.

SCOPE: All GLP field facilities where a dry material is weighed for use in a field, greenhouse or hothouse trial(s).

SUBMITTED BY: Marylee Ross

PROCEDURES: The methods, materials and schedules for routine inspection and cleaning and calibration shall be:

1. Prior to each use, the user shall visually inspect the balance for cleanliness. Any dirt or chemicals within the chamber or on the pan must be cleaned immediately.

2. Once each year a professional service technician shall perform a balance calibration. The technician shall clean, lubricate, adjust, test and calibrate to the balance manufacturer's specifications. The technician's reference weight sets shall be traceable to the National Institute of Standards and Technology. A Balance Certificate shall be issued on the date of calibration service. As soon as possible after calibration and before first use of the balance, the Field Research Director's standard weights shall be verified and recorded in a balance log. A true copy of the Balance Calibration Certificate and the balance calibration log shall be included in all Field Data Notebooks for projects where dry measure occurs. The original Balance Calibration Certificate and the balance calibration log shall be placed in the Common Data Book for that year and sent to IR-4 Headquarters for archiving.

3. Two balances shall be dedicated to IR-4 GLP and labeled with a unique identifying number. Only personnel directly involved in IR-4 trials shall use the balance. With each GLP use the balance accuracy shall be verified using test weights that bracket the amount of test substance to be measured. All uses shall be recorded in a balance log specific to that balance.

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SOP #5.2 **Calibration/Verification of instruments and gauges.**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 5

PURPOSE: To assure that all instruments and gauges used in GLP trials are reasonably accurate and in good working order.

SCOPE: All facilities where GLP field studies are conducted under the IR-4 Project.

SUBMITTED BY: Marylee Ross

PROCEDURES:

1. Each instrument used in GLP trial (i.e., thermometers, data loggers, etc.) shall be periodically tested/checked to determine that it is acceptably accurate. Each item shall be tested/checked at the beginning of the season, before it is first used in a GLP trial, and as often thereafter as necessary to assure its accuracy.

2. A written record shall be kept of the dates and results of the tests and of the acceptable tolerance for each instrument.

3. Sprayer pressure gauge shall be observed throughout the season for consistent readings.

4. Those gauges or instruments that give inconsistent results or are not accurate to within acceptable tolerances shall be repaired or replaced.

5. Refer to pages in the manual for the calibration method. If no method is available then cite how to proceed.

6. Written records (maintenance logs) shall be kept on routinely used equipment. These records shall include but not be limited to the date, the person(s) responsible for doing the maintenance, whether the activity is routine or non-routine, and the tolerances for that piece of equipment when available.

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SOP #5.3 **Calibration, operation and maintenance of thermographs and hygrothermographs.**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 3

PURPOSE: This document is for use by IR-4 personnel to define techniques used for calibrating, operating, and maintaining thermographs and hygrothermographs.

SCOPE: The SOP describes the proper procedures used by the IR-4 personnel to ensure that accurate calibration, operation, and maintenance of thermographs and hygrothermographs.

SUBMITTED BY: Marylee Ross

PROCEDURES:

1. To activate unit turn on the power switch or wind up unit with proper clock key. Some units can be set for using daily, weekly, or monthly removable charts.

2. Identify the chart with the unit location, equipment identifier, time on and initial and date.

3. When the reading period is over, remove chart and replace with a new one. Record time off and initial and date.

4. Additional information may be added to the recording chart as necessary (i.e., weekly high, low, etc.). These charts shall be deemed raw data and handled as such at all times.

5. Units shall be appropriately maintained. If the unit fails, it shall be serviced by a technician. The only exception is the changing of batteries and charts or the adjustment of sensor arms during calibration.

6. All problems encountered, calibration, and maintenance shall be documented in the appropriate log. In addition, completed charts shall be kept on file and sent to IR-4 Headquarters with corresponding Common Data Book or Field Data Books.

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7. All units shall be calibrated/standardized on a semiannual basis, using the following procedure:

   a. Place a calibrated laboratory thermometer beside the unit to be calibrated.

   b. Allow at least 15 minutes to assure thermometer equilibrium.

   c. Observe and record the temperature values of the laboratory thermometer and the recording thermograph or hygrothermograph into the appropriate log.

   d. The difference in temperature observed by these thermometers must not be greater than 2°F.

   e. If the temperature difference is greater than 2°F, adjust the thermograph or hygrothermograph. If the unit is being monitored with a laboratory thermometer, replace it with one that is newly calibrated against a reference thermometer.

   f. If the above correction fails, a serviceman shall be called to service the unit. Another appropriate monitoring device shall be used as a replacement until the unit is repaired.

   g. Logbooks shall be archived at IR-4 Headquarters.

   h. The relative humidity shall be calibrated against a sling psychrometer. The wet and dry bulb readings shall be documented in the appropriate log and the relative humidity determined by the use of a standard reference table.

   i. If the difference in relative humidity is greater than 1% adjust the hygrothermograph mechanically. Document the adjustment in the appropriate log.

This SOP inactivated effective February 10, 2005.

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SOP #5.4 **Verification and operation of temperature measuring and recording devices.**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 8

PURPOSE: The purpose of this SOP is to establish procedures used when verifying and reading temperature measuring devices.

SCOPE: The SOP is to be followed by IR-4 participating personnel when verifying temperature measuring and recording devices.

SUBMITTED BY: Marylee Ross

PROCEDURES:

1. All temperature measuring and recording devices at LESREC, Salisbury Facility used for GLP trials or equipment associated with these trials shall be verified at least one time a year against a reference thermometer, either directly or by a recorded traceable chain. Exceptions shall be data loggers that are not immersible. Data loggers that are not immersible shall be replaced each year with new ones. New devises need not be verified. They come from the manufacturer guaranteed to be accurate

2. Each measuring device shall be labeled with an ID or code number.

3. Records of temperature measuring and recording devices verification shall be maintained in a log.

4. A unique number or code shall identify all laboratory and min/max thermometers. The identification number or code shall be placed on the measuring device such that it can be easily cross-referenced for verification 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. Those devices shall be verified using 2 of the methods described in Procedure 6.

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6. Verify each thermometer in the temperatures that bracket the expected temperature range it shall encounter in use. Examples of temperature ranges to test may include:

   a. Boiling Water (212°F)
   b. Hot water (approx. 212°F)
   c. Warm water (approx. 131°F)
   d. Room temperature (approx. 71.6°F)To be tested in Building 601
   e. Ice water (approx. 32°F)
   f. Below Freezing such as in LESREC Walk-in Freezer
   g. Hot conditions such as in a greenhouse

   Location shall be identified in the log.

   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.

7. The devices shall be left in place for the time necessary to record enough data points to illustrate the level of accuracy between the devices. For thermometers and data loggers with current reading displays the readings shall be recorded on the log. Data loggers shall be downloaded and the printouts dated and initialed and placed in the Common Data Book. The original printouts shall be placed in the Common Data Book and a certified copy shall be placed in the appropriate Field Data Books.
   The following information shall be documented in the log.
   a. Date of reading and recording
   b. Initials of person recording
   c. Reference thermometer reading at each temperature
   d. Laboratory thermometer reading at each temperature
   e. ID code number of the thermometer

8. Temperature reading taken from the reference thermometer shall be rounded to whole numbers (e.g.: If reference reads 78.2°F, the recorded value shall be 78°F).

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9. If the reading of the laboratory thermometer is ±1 degree of the reference reading, no temperature adjustment shall be made. If the reading is ± 2 degrees or more different from the reference thermometer:
    a. proper adjustment shall be made. For example: If the thermometer reads 80°F and the reference reads 82°F, the adjustment would be +2° at 82°F. When this thermometer is used, the individual would add 2°F to the 80°F observed reading and 82°F would be recorded as the temperature reading. A tag shall be attached to the thermometer indicating the adjustment.
    b. The device may be retired. In this case the date and reason for removal shall be entered in the log.

10. When recording a thermometer reading, the following information shall also be included in the entry:
    a. Date
    b. Initials of individual conducting the activity
    c. Thermometer Number or Data Logger serial number

11. Thermometers may be used to reference other temperature recording devices as long as they can be traced back to reference. These devices may include continuous thermographs used for walk-in displays on upright freezer/refrigerator units, etc.

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SOP #5.5 **Operation and maintenance of farm equipment.**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 4

PURPOSE: To assure that the crop or commodity under study is grown under simulated commercial conditions, in a quantity sufficient for the study and in a good state of health.

SCOPE: All studies where the farming operation is under the general guidance of the Field Research Director.

SUBMITTED BY: Marylee Ross

PROCEDURES:

1. Much of the routine maintenance of the field plots is done by the LESREC farm crew. This machinery is not under the control of the Field Research Director and no claim of GLP compliance is made for these tasks (plowing, disking, planting, etc.). Just prior to the initiation of the use of the equipment (tractor, plow, disk, harrow, planters, harvester, etc.) the operator shall visually inspect the equipment to see that it is in good working order, properly lubricated, and in good mechanical condition. Routine maintenance and inspection of equipment is performed by the farm crew and documented in their facility records.

2. Any necessary repairs or adjustments shall be made prior to the use of the equipment in the trial.

3. The operator of the equipment shall be familiar with its operation and safety precautions.

4. Manuals on the operation and maintenance of the equipment and the name, address, and telephone number of a parts supply company shall be kept in a place accessible to the operator and the Field Research Director.

5. A written record shall be maintained for each piece of equipment used and under the full control of the Field Research Director. This equipment includes, but is not limited to the tractor and booms used to make GLP applications. The record shall contain maintenance dates and what was done, repair dates and type of repair.

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SOP #5.6 **Borrowed or seldom used equipment**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 5

PURPOSE: To assure that borrowed or seldom-used equipment is in satisfactory working order for accurate applications in GLP studies.

SCOPE: All GLP field trials for the IR-4 Project.

SUBMITTED BY: Marylee Ross

PROCEDURES:

1. Inspect equipment for obvious problems, i.e. loose conditions, cracked hoses, etc.
2. Ascertain, if possible, last known use and document.
3. Clean the equipment.
4. If to be used in spray application, calibrate and adjust or replace those parts not functioning properly. Record all actions.
5. Enter dates equipment was borrowed, used and returned to original source.

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SOP #5.7 **Operation and maintenance of Butterbean Sheller**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 2

PURPOSE: To assure that bean samples are properly shelled and protected from possibility of contamination.

SCOPE: All GLP trials where bean seed samples are required and the butterbean sheller shall be used to separate the seed from the pods.

SUBMITTED BY: Marylee Ross

PROCEDURES:

1. Inspect the sheller for any broken parts or debris that can easily be removed.

2. Repair or replace any broken parts. Grease or oil any moving parts as appropriate.

3. Thoroughly clean the sheller before use. Using clean water hose off the entire machine then spray with an ammonia and water wash. Thoroughly rinse with clean water and allow to air dry.

4. Test the machine with some untreated beans to make sure it is operating properly. If not make adjustments or repairs as necessary.

5. Use the sheller to separate seed from pods of untreated samples first, then treated samples in ascending order. If more than one treated plot is involved clean the sheller between each set of samples.

6. Thoroughly clean the sheller after completion of samples collection.

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SOP #6.1 **Calibration of a liquid sprayer – tractor mounted broadcast or directed spray boom.**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 11

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

SCOPE: All GLP field studies

SUBMITTED BY: Marylee Ross

PROCEDURES:

1. Visually inspect pumps, hose, pipes, fittings, regulators, gauges, and tanks for obvious wear or potential leaks and repair or replace as necessary.

2. Choose the appropriate nozzle tip in accordance with gallonage and spray pressure guidelines on approved research protocol or technical publications.

3. Determine whether all nozzles are discharging uniformly by spraying water through them at a uniform pressure and catching the discharge from each nozzle in a separate container for a given length of time such as; the time it will take to make one pass of the plot to be sprayed. Begin timing the discharge after the system is operating. If the discharge varies widely, replace all nozzle tips that give a much larger or much smaller discharge. Variation among nozzle tips shall be less than 5%. Repeat the above procedure until all nozzles are discharging within 5%.

4. Measure an area of the length of the plot to be sprayed. Choose a good spray speed and record the length of time it requires to cover that distance. Also record the gear and RPMs used in traveling that distance. All sprays will be applied at this speed. Thus, in calibrating tractor speed in feet per second will need to be checked each time that a spray is made.

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5. Determine the rate of delivery by using the following procedure:

   a. Collect the spray discharge from each nozzle for the same amount of time it takes for the tractor to cover the distance. The amounts collected will be measured in a graduated cylinder of appropriate size.

   b. Combine the discharge figures to give the total number of milliliters discharged for the boom.

   c. Calculate the linear acre you will be spraying. For broadcast applications use spray swath (number of nozzles x nozzle spacing), use row width if conducting a directed spray. Divide into 43,560 for linear acre. Multiply linear acre by the total milliliters collected then divide by feet of row length to give milliliters per acre. Divide this figure by 3785 ml/gal to give the gallons per acre.

   d. For directed applications calculate the portion of an acre you will be spraying. Multiply row width (commercial spacing used in the area) by distance traveled. Divide into 43,560. Multiply by the number of milliliters collected to give ml. per acre. Divide this figure by 3785 ml/gal to give the gallons per acre.

6. If recommended gallons per acre is given in the protocol, adjust the tractor speed, pressure, nozzle size or combination thereof until the desired gallonage is collected. A complete calibration (three runs) shall be conducted after any of the above parameters are changed.

7. Calculate amount of mix needed to spray the area to be treated. (Example: 34 gallons/acre = X gallons/treated area) Add sufficient amount extra to accommodate spray hoses, etc. and achieve the amount of mix necessary to assure coverage of entire treated area. Divide by 3,785 ml/gal to obtain ml. mix needed.

8. Calculate the amount of pesticide to add to the spray tank. Calculations vary depending on application type. Calculations shall be shown on Part 6 F of the Field Data Book.

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SOP #6.2 **Calibration of a CO_2 backpack sprayer**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 8

PURPOSE: To determine the delivery rate of sprayer and make adjustments as necessary to ensure an accurate application of the test substance.

SCOPE: All GLP trials where a backpack sprayer is used

SUBMITTED BY: Marylee Ross

PROCEDURES:

1. Visually inspect hoses, pipes, fittings, regulators, gauges, and tanks for obvious wear or potential leaks and repair or replace as necessary.

2. Determine whether all nozzles are discharging uniformly by spraying water through them at a uniform pressure and catching the discharge from each nozzle in a separate container for a given length of time such as the time it will take to make one pass over the plot. Begin by timing with a stopwatch; collection of the discharge after the system is primed and operating. Measure the discharge from each nozzle in a graduated cylinder of appropriate increments. If the discharge varies widely, replace all nozzle tips with variation of greater than 5% from the mean output of all nozzles. Variation among nozzle tips shall be less than 5%. Repeat the above procedure until all nozzles are discharging uniformly.

3. All sprayers used for GLP trials shall have a pressure gauge. Observe the pressure reading when uniform discharge from all nozzles is achieved. Record the pressure.

4. Measure out the length of the test plot and clearly mark the 2 ends of that distance with a flag or other such marker. Establish a comfortable, safe pace to walk that distance with the backpack equipment and spray tank. Make several practice runs and measure the pass times with a stopwatch. Record the time it takes to travel that distance at the desirable pace.

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5. Collect discharge from all nozzles at the recorded pressure for the amount of time it took to travel the distance. The amounts collected will be measured in a graduated cylinder. Record the discharge from each nozzle in milliliters. Add the amounts for total discharge. A longer time may be used if the distance is small for ease and accuracy of calculations.

6. Do mathematical calculations to convert area to be treated to portion of an acre.

7. Choose a rate at which to spray within protocol specifications.

8. Calculate amount of mix needed to spray the area to be treated. (Example: 34 gallons/acre = X gallons/treated area) Add sufficient amount extra to accommodate spray hoses, etc. and achieve the amount of mix necessary to assure coverage of entire treated area.

9. Calculate the amount of test substance to add to water. Calculations vary depending on application type. Calculations shall be shown on Part 6 F of the Field Data Book.

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SOP #6.3 **Calibration of a CO_2 vertical boom sprayer for use in greenhouse.**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 7

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

SCOPE: All GLP greenhouse trials where a vertical boom sprayer is used

SUBMITTED BY: Marylee Ross

PROCEDURES:

1. Visually inspect hoses, pipes, fittings, regulators, gauges, and tanks for obvious wear or potential leaks and repair or replace as necessary.

2. Determine whether all nozzles are discharging uniformly by spraying water through them at a uniform pressure and catching the discharge from each nozzle in a separate container for a given length of time such as the time it will take to make one pass of the plot. Begin by timing with a stopwatch; collection of the discharge after the system is primed and operating. Measure the discharge from each nozzle into a graduated cylinder of appropriate dimensions to fit the nozzles and of appropriate increments for amounts being collected. If the discharge varies widely, replace all nozzle tips that give a much larger or smaller discharge. Variation among nozzle tips shall be less than 5%. Repeat the above procedure until all nozzles are discharging uniformly.

3. All sprayers used for GLP trials shall have a pressure gauge. Observe the pressure reading when uniform discharge from all nozzles is achieved. Record the pressure.

4. Measure out the length of the test plot and clearly mark the 2 ends of that distance with a flag or other such marker.. Establish a comfortable, safe pace to walk that distance with the backpack equipment and spray tank containing water. Make several practice runs and measure the time with a stopwatch. Record the time it takes to travel that distance in feet at the desirable pace.

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5. Collect discharge from all nozzles at the recorded pressure for the amount of time it took to travel the distance. The amounts shall be collected into graduated cylinders and the amounts collected shall be recorded. Add the amounts for total discharge. A longer time may be used if the distance is small for ease and accuracy of calculations.

6. Determine the actual output in gallons/acre from the following formulae:

$$\frac{\text{Amount used}}{\text{spray swath (row width if directed spray) x sq. ft sprayed}} = \frac{x}{43560 ft^2 (1\ A)} = \text{oz or ml/A}$$

Divide by 128oz/gallon to obtain gal/A

Divide by 3,785 ml/gallon if measuring in ml instead of oz.

7. If the calculated gal/acre is within the spray volume range then the sprayer is calibrated and the same settings will be used in actual application. If it is not within this range then repeat steps 2 to 6 after adjusting the pressure or ground speed until you are sure you are applying the correct volume of spray/acre measured in ml/sec.

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SOP #7.1 **Residue sample collection and storage.**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 7

PURPOSE: To assure that residue samples are collected in a proper fashion.

SCOPE: All locations where GLP trials are conducted to develop samples for residue analysis under the IR-4 Project.

SUBMITTED BY: Marylee Ross

PROCEDURES:

1. Consult the research protocol to establish specific dates for the collection of samples. If these dates are based on uncontrolled events (plant size, fruit maturity, etc.) then tentative dates shall be established and refined as necessary. The Study Director shall be kept informed when the dates are changed.

2. Prior to sample collection, obtain a sufficient number of sample bags from the Field Research Coordinator to collect all the samples. Cloth laminated bags are preferred and the bags shall be fairly burst proof.

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

4. Before entering the field, label each sample bag using waterproof ink with the following:

    a. Project and/or Field ID Number
    b. Commodity (Crop)
    c. Chemical
    d. Sample ID
    e. Date Sampled
    f. Appl. Rate (#a.i./A)
    g. Field Research Director: Name/Address/Phone #

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5. Harvest samples of the crop as specified by the research protocol. Untreated samples shall be collected first followed by the lowest dosage rate and working toward the highest dosage rate. Each sample shall be collected on a separate run through the plot and be representative of the entire plot. Each sample shall be individually packaged and labeled. Briefly describe the procedures and methods used in the raw data.

6. 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, packaging or preparation.
    d. Be certain tools are clean.
    e. Do not remove any plant parts or trim the commodity unless it is so specified in the research protocol.

7. Whenever possible place the collected plant parts directly into the sample bag marked for that sample. Avoid sample bag contact with the soil or plants during sampling. If samples are not placed directly into sample bags document the sampling procedure.

8. Measure samples to determine compliance with the protocols as lbs. /sample and/or number of plant parts/sample. A field balance will be used to weigh samples. It will be maintained in good working order and will be calibrated by a certified service technician once each year. The field balance will not be maintained under GLP.

9. Excess air shall be expelled from the bag and the bag securely tied closed.

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10. When sample collection is completed, the samples shall be removed from the field and transported in a project vehicle as soon as possible to frozen storage. The project vehicle shall be cleaned or lined with plastic sheeting prior to placement of samples in the vehicle. Maintain separation between treated and untreated samples while in the project vehicle and place immediately into designated freezers. If samples must be held for more than one hour, place samples in a cooler on ice. Place treated and untreated samples in separate plastic bags to maintain separation. Prevent water contact with the sample bag and the sample by adequately containing the samples in plastic bags. The samples shall be placed in frozen storage within 2 hours after collection unless samples were collected off station. Separate, designated freezer units will be used for the treated and untreated samples.

11. Consult the research protocol for the method, temperature, and maximum length of time for storage. If specifications are not given in the research protocol use -20°C for frozen commodities until Agricultural Chemicals Development Services, Inc. (ACDS) pick up.

12. Samples identified for post-harvest processing shall be processed or shipped to the processor as soon after collection as possible (as per protocol).

13. Upon completion of the sampling, the Specific Sample Information and Inventory shall be completed.

14. Using a verified refrigerator/freezer temperature data logger, the storage temperature of the samples shall be continuously recorded and downloaded frequently to document that the temperature is maintained within the limits as prescribed by the research protocol. As a backup there will be a verified min/mix thermometer inside the freezer unit. Include any temperature documentation with raw data.

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15. Each freezer shall be equipped with and Emerson Climate Technologies Freeze Alarm model FA-I-CCA. The alarm shall be programmed to call up to 3 phone numbers if the temperature in the freezer rises above 10°F and remains above 10°F for more than 45 minutes. The alarm shall be programmed to call up to 3 numbers if the power to the freezer fails and remains off for more than 45 minutes. The first contact shall be the FRD's cell phone followed by the FRD's home phone followed by the FRD's assistant's cell phone.

16. The alarm shall be tested annually and may be tested periodically to assure all functions are operating properly with the following procedures:

    a. The alarm shall be tested for temperature monitoring by removing the sensor from the freezer. After the programmed delay time has elapsed verify that all phone numbers programmed received the call alerting to a temperature rise.

    b. The alarm shall be tested for power supply monitoring by unplugging the unit. After the programmed delay time has elapsed verify that the phone numbers received the alert to power failure.

    c. Document the testing on the Freezer Maintenance Log with information including, but not limited to date, time of test, temperature reached when alarm was sent, time messages were received and if all programmed phone numbers were contacted.

    d. If the system did not work properly repairs must be made as soon as possible. Document all corrective actions taken. Conduct a test of the system. If repairs are not possible the system must be replaced a soon as possible. Conduct a test of the new system and document all changes.

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17. The freezers where the samples are stored shall be secure with limited access. At the LESREC facility there are 2 chest style Deep Freeze freezers dedicated to GLP residue samples. Freezer UT is dedicated to untreated samples. Freezer TRT is dedicated to treated samples. They are located in Building 603 on the LESREC facility. The building is of limited access and is locked when not in use. The freezers will remain locked when not in use and available to authorized personnel only.

18. A log of the items inside the storage facility (i.e. freezer) shall be kept indicating Trial ID#, contents (samples placed in the freezer), day and time placed in the freezer. Each such entry shall be dated and initialed.

19. Removal of samples prior to shipment shall be recorded for each sample on the log sheet and be dated and initialed by the person removing them.

20. As soon as possible after sample harvest is complete, the crop will be destroyed by cutting, disking, plowing, or some suitable method.

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SOP #7.2 **Sample shipping procedures**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 7

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

SCOPE: All residue samples for GLP trials.

SUBMITTED BY: Marylee Ross

PROCEDURES:

1. Prior to shipment of samples, 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 for shipping the samples. Air freight shipments shall be made early in the week to avoid potential weekend layovers. Notify the designated person from the analytical laboratory and the Study Director when a shipment date is established. With air shipments, talk directly with lab personnel before shipping.

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

3. The residue samples will be shipped by freezer truck (ACDS) unless otherwise specified in the protocol or requested by the lab or if ACDS cannot pick up the samples in acceptable time. Use boxes of sufficient size and quantity to hold the untreated and treated residue samples in separate containers. For air freight use insulated containers of sufficient size and quantity to hold the untreated and treated residue samples in separate containers with dry ice in a 1:1 to 1:3 weight ratio to commodity depending on destination and pack the samples and dry ice in the containers just prior to shipment. All containers shall have a sufficient bursting strength so as to withstand normal handling in shipping and storage.

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4. Distribute copies of the Residue Sample Chain of Custody Form to Field Research Coordinator, Laboratory Research Director and to Headquarters. Include one in each samples box with the shipment. Retain the original form in the Field Data Notebook. The form shall be signed and dated by the Field Research Director upon transfer of sample to the carrier.

5. Label shipping container 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" on each carton
    e. Where used, affix "Dry Ice" on two sides of container

6. Tape lids of each container firmly in place.

7. 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.

8. Provide the carrier with the samples for shipment.

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SOP #7.3 **Operation and maintenance of freezers.**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 7

PURPOSE: To assure that freezers are in proper condition so as to maintain residue samples in frozen state.

SCOPE: All GLP trials under the IR-4 Project.

SUBMITTED BY: Marylee Ross

PROCEDURES:

1. Prior to use, freezers will be checked with temperature monitoring devices for a minimum 24 hours to detect any deleterious fluctuations in temperature. The temperature range recorded by the device shall be within the limits as required for storage of the samples.

    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, generally below 0°F 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 storage range, then the unit must be serviced by a trained technician prior to use or be replaced.

2. Temperatures will be monitored during the entire storage period for any and all residue samples. A temperature recording data logger and a verified min/max thermometer will also be in place as a further check for temperature increases that exceed 0°F for more than a few hours.

3. Temperature records will be kept during the storage period for all residue samples. If no samples are being stored in the unit, no records of the temperature need to be maintained.

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4. All freezers will be defrosted and cleaned annually and maintenance records will be kept.

5. Temperature monitoring devices will be checked annually using an ASTM-30/120F thermometer and deviations will be recorded. Deviations in excess of 5°F will be deemed sufficient to recalibrate or replace recording instrument.

6. Shall there be a freezer malfunction; samples will be relocated to a properly functioning IR-4 designated freezer. If an IR-4 freezer is not available then any alternative freezer free of pesticide contamination will be acceptable.

7. Remedial actions to be taken in case of failure or malfunction include:

    a. Any problem shall be immediately reported to the Study Director or designated personnel, documented, and documentation placed in the maintenance log records for non-routine procedures.

    b. Any repairs or replacements resulting from malfunction will be documented as non-routine maintenance in the appropriate log(s).

8. FRD is responsible for the maintenance and remedial action taken in the case of malfunction.

9. The IR4 freezers at LESREC are on a backup generator that comes on automatically in the event there is a power outage. The backup generator is under contracted routine inspection and maintenance. An inspection and test is performed by the contractor once monthly. The generator is programed to run once weekly on Tuesday as a test. If there is any malfunction a code is sent to the control panel. The farm maintenance manager checks the control panel each Tuesday and appropriate action is taken to remedy the cause for any code displayed on the panel. The freezer temperature data loggers are visually checked daily during the week to check that the temperatures are in acceptable range.

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SOP #7.4 **Greenhouse Drying of Samples**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 5

PURPOSE: To assure that techniques followed for drying of samples in greenhouse eliminate possibility of contamination and promote uniform drying of samples.

SCOPE: GLP field trials that need supplementary drying.

SUBMITTED BY: Marylee Ross

PROCEDURES:

1. When protocol states, or with the permission of the study director, some residue samples may be dried in the greenhouse.

2. The greenhouse shall be in clean and neat order before samples are taken into the greenhouse.

3. Tables shall be prepared for placement of samples by covering them with clean plastic or paper. The cover shall be fixed to stay for the duration of drying time. Tables will be labeled to represent the samples to be placed on them. The label shall include project number, commodity, sample ID and date.

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4. Untreated samples shall be harvested first and transported to the greenhouse in a clean project vehicle. The samples can be placed in clean, suitable containers or the bed of the vehicle can be lined with clean plastic and the samples placed on that. Untreated samples shall be taken into the greenhouse and placed on the appropriately labeled table(s). The sample shall be spread out to allow sufficient air circulation to result in uniform drying. Treated samples shall then be harvested and transported in the project vehicle. Treated samples shall then be taken into the greenhouse and handled in the same manner as the untreated samples. If additional treated samples are required clean the containers or use separate clean containers or replace the plastic lining with new clean plastic. Untreated and treated samples shall remain separate by placing them on separate tables and assuring a minimum distance of 15 feet between treatments. Duplicate samples may be dried on the same table if maintaining separation and each is labeled to identify it. Samples shall be rearranged periodically if necessary to permit uniform drying. Treated samples will be on the intake side of the greenhouse in relation to the untreated samples. Or the treated and untreated samples can be dried in separate greenhouses.

5. A notice shall be posted to inform any personnel entering the greenhouse that the samples shall not be touched or disturbed and that no pesticide applications will be permitted during the time the samples occupy the greenhouse.

6. Greenhouse temperature shall be controlled and monitored. Samples shall be observed daily. Any unusual occurrences will be documented.

7. When samples have dried sufficiently to satisfy protocol requirements they shall be collected. Untreated samples shall be collected first. Any modifications shall be recorded. Samples shall be placed directly into properly labeled residue bags. The bags shall be tied securely closed and taken immediately to IR-4 Freezer #1. Treated samples shall then be handled in the same manner and taken immediately to IR-4 Freezer #2. Times of sample collection completion and placement in freezers shall be recorded.

8. Upon completion of sample collection the table covers shall be discarded and postings removed.

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SOP #8.1 **Collection and Recording of Raw Data**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 8

PURPOSE: To assure that raw data collected and recorded is correct and recorded accurately.

SCOPE: All GLP trials under the IR-4 Project.

SUBMITTED BY: Marylee Ross

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, pictures, worksheets, 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. Document 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.

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 book. If original supporting data is relevant to multiple trials it shall be placed in the Common Data Book for that trial year and a certified copy shall go into all raw data books to which it is relevant. The Common Data Book shall be sent to IR4 Headquarters for archiving.

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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 in electronic data in SOP 8.2.

10. Information shall not be entered in advance, with a few exceptions. Not entering date 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 (2A), or the name and address of the residue lab (8A). See SOP 8.3. 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 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.
    c. The one exception is when the question starts with 'if'. As a recognized conditional in Standard English, no response is needed as long as the condition is met. E.g., If the answer is no, and the conditional prompt is for no. However, if the conditional and prompt do not agree (the answer is yes, but the prompt is for no) then the question shall be answered.

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.

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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 shall be used. No attempt shall be made write smaller or closer together to fit more in the space provided.

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. For example: CDB = Common Data Book.

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 #8.3 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.

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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 has been added to the book, such as 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 includes, but is not limited to:
    a. Weather data, irrigation records and soil sampling and characterization were not done under GLP guidelines.
    b. Residue sample weights were measured on a scale/balance that is not maintained under GLP.
    c. Application and recording of maintenance pesticides and fertilizer are not conducted or recorded under GLP.
    d. Crop cultural practices and plot histories were not collected under GLP.

8. Within each part, the Field Data Book forms shall be arranged alphabetically. 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.

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9. There are no real prompts for equipment calibration/verification logs. The originals shall be placed in the Common Data Book if they pertain to multiple GLP trials and a certified copy in the GLP section of the FDB. If it is a document only relevant to 1 or a few GLP trials the original shall be placed in 1 FDB and certified copies in all other FDBs to which it is relevant.

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, including both sides of two sided documents. 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 2-sided document, such as a MSDS, 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.

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SOP #8.2 **Collection of raw data electronically**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 5

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

SCOPE: All GLP trials under the IR-4 Project.

SUBMITTED BY: Marylee Ross

PROCEDURES:

1. All remote sensing and other automatic data collecting and/or recording devices shall be inspected and verified as described under SOP 5.4.

2. Check the power supply on portable units to see that it shall be adequate during the data collection and data transfer period. Make sure the correct program for data collection is ready and available.

3. Each data sheet from a monitoring device (e.g. thermograph) shall be marked on the front in ink with the name/unique identifier for the device, units of measurement, occurrence of the event measured (day, month, year of beginning and end of recording) and initialed by the person collecting the data.

4. Hard copies of computerized data (e.g. Hobo/StowAway) and/or other written, typed or plotted data sheets must be initialed/signed, and dated. This initialed/signed and dated data then becomes 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.

5. 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.

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SOP #8.3 Data storage during the active life of the project.

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 6

PURPOSE: To assure that all data resulting from the trial is retained and usable.

SCOPE: All locations conducting GLP trials.

SUBMITTED BY: Marylee Ross

PROCEDURES:

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. 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 is 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

2. The protocols, Field Data Books and supporting data will be stored in a limited access area in office 1102 in building 601 during the active life of the trial. The area will be locked when not in use.

3. 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 initialing and dating the title page. The 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

4. Original information and data pertaining to all or several trials being conducted at this site will be kept in a notebook designated as Common Data Book. Verified copies of these data will be made and placed in the pertinent Field Data Books citing the location of the original. At the end of each season, that year's Common Data Book is sent to IR-4 for archiving The information/data to be included in the Common Data Book may include, but is not limited to:
   a. Personnel records, including original CVs and training records.
   b. Test substance storage temperature data.

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c. Equipment maintenance logs and calibration/verification information, excluding application calibration information.
d. Original signed SOPs.

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SOP # 8.4 **Historical files**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 6

PURPOSE: To assure a designated area for historical files of Field Data Books and Common Data Book pertaining to the field research studies conducted under the IR-4 Program.

SCOPE: All ongoing facility studies under the IR-4 Project.

SUBMITTED BY: Marylee Ross

PROCEDURES:

1. The Field Research Director is responsible for all raw data files: designating a location, collecting the information for the files, maintaining the files and submitting all required raw data to IR-4 for archiving if the site becomes inactive. The Field Research Director may designate a Historical Files Librarian as appropriate.

2. The Field Research Director will be responsible for seeing that the files are placed in the historical file at the end of each season. Files containing the copies of the Common Data Book and certified copies of the Field Data Books may also be kept in the historical files.

3. The Historical Files may be used only by those persons so authorized by the Field Research Director.

4. An historical file has been established in Building #601 in office 1102 occupied by Marylee Ross, LESREC, 27664 Nanticoke Road, Salisbury, MD 21801.

5. Historical files are maintained in a file cabinet in a room denoted as office 1102.

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SOP #9.1 **Procedures to follow prior to an EPA inspection**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 4

PURPOSE: To provide guidance to study personnel in responding to a request for an EPA audit or review by Office Compliance Monitoring (OCM).

SCOPE: All locations conducting GLP field trial(s).

SUBMITTED BY: Marylee Ross

PROCEDURES:

1. Notify the Study Director, Quality Assurance Officer, 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(s) or facilities audit.

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

4. Prepare trial(s) and/or facilities personnel for the inspection.

    a. Review position descriptions with technical personnel so they understand and can explain their role in the trial(s).

    b. Discuss possible questions that may likely come up about the trial(s) 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.

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e. Be certain that all documents pertaining to the trial(s)/facilities inspection are available. This would include:

   1. Master schedules for the Field Research Personnel at the regional and IR-4 headquarters.

   2. Study Protocol and Standard Operating Procedures.

   3. Raw data, correspondence and logs.

   4. Training records, CV's job descriptions, etc. of personnel assigned to trial(s).

   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, and storage records.

   7. Calibration logs on equipment such as balances and application equipment.

   8. Storage of historical records.

5. Have accessible organizational charts, a map of the facility and any information specific to the facility or area that will make the inspection go more smoothly.

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SOP #9.2 **Procedures to follow during an EPA inspection**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 4

PURPOSE: To provide guidance to study personnel in responding to a request for any EPA audit or review by OCM.

SCOPE: All locations conducting GLP field trial(s).

SUBMITTED BY: Marylee Ross

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 credentials and for any opening statements.

3. Introduce the facility personnel present and state their function in the facility or trial(s). Identify the person responsible who will accept the Notice of Inspection.

4. Distribute organizational charts, map of the facility and any other information previously prepared to make the inspection go more smoothly.

5. Ask the lead inspector for his/her agenda for the inspection as well as a list, if possible, of personnel for interview 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.

    a. Provide documents requested and provide explanations needed.
    b. Keep notes of observations and of all interviews.
    c. Keep management informed of the progress of the inspection and the findings.

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SOP #9.3 **Procedures to follow after the EPA inspection.**

EFFECTIVE DATE: March 02, 2016 REVISION NUMBER: 4

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

SCOPE: All locations conducting GLP field trial(s).

SUBMITTED BY: Marylee Ross

PROCEDURES:

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

2. Clarify any discrepancies brought up during the exit interview and offer supporting documentation for clarification.

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 close-out to take accurate notes.

5. Be sure you 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.