SOP Log

ID # S00128

Region: NE

State: NY City: Ithaca

Location: Field NE Cowell

FRD/LRD: Robin Bellinder
Submitter

Effective Date: 4/15

Received at HQ: 8/14/16 Date to Reviewer: 8/15/16
Sign/Date

Reviewed By: D. D'Angelo

Description of Material (s): 2016 SOPs

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

Electronic copy ok to use: (Y) or No (Circle one) If no, indicated what needs to be done But replace cover page File #S00089

Date from Reviewer: 8/22/16

Date Posted: 8/23/16 Archive Date: ~~Archive~~ (WE) 8/23/16

Archive Location: Active File Rm. ~~Active~~ (WE) 8/23/16 Cabinet 6 Drawer 2

Sign: AA

Comment:

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STANDARD OPERATING PROCEDURES FOR

MAGNITUDE OF THE RESIDUE-FIELD TRIALS CONDUCTED

UNDER GOOD LABORATORY PRACTICES

Revision No.: 2

Effective Date: April 2015

Field Research Director:

Robin R. Bellinder Robin R. Bellinder RRB 4/15/2015
(Signature) (Initials) (Date)

Approving Official: Regional IR-4 Field Coordinator

Edith L Lurvey [signature] ell 4/9/2015
(Signature) (Initials) (Date)

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

Reviewed by Marylee Ross - no revisions
Marylee Ross MR April 12, 2016
Northeast Region Field Coordinator

EXACT COPY OF
ORIGINAL DOCUMENT
MR 04/12/16
original sent to
Zvonko Jacimovski

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SOP #: **1.1** Revision Number: 1

Submitted by: R.R. Bellinder Effective date: April 2014

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

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

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

Procedures:

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

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

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

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

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

6. Any SOP which is no longer applicable may be inactivated/retired by the addition of a procedure statement at the end of the SOP indicating that the SOP has been inactivated and the date that the inactivation takes effect. Inactivated SOPs shall be noted in the list of revisions for the year in which the inactivation takes place. Inactivated SOPs may be reactivated by the addition of a procedure statement to that effect, indicating the date of

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reactivation. In rare cases, SOPs may be retired/inactivated, with some or all of the points incorporated into other SOP's. In that case, a statement to that effect shall be placed behind the revision number with the date and SOP into which the points have been incorporated.

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

8. Original signed SOP sets shall be sent to IR-4 Headquarters yearly for archiving as a part of the Facility File. Certified copies will be maintained at the facility for the researcher use.

9. If there are no new revisions the newest certified copy will be in use (up to three years, see 2 above). The certified copy shall be sent to IR-4 Headquarters for archiving as a part of current Facility File, yearly.

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SOP #: **1.2** Revision Number: 1

Submitted by: R.R. Bellinder Effective date: April 2015

Title: Numbering system for SOP categories

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

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

Procedures:

1. The category numbering system for SOPs is as follows:

    1. General
    2. Personnel
    3. Agronomic Practices
    4. Pesticide and Adjuvant Handling and Storage
    5. Test Substance Applications
    6. Residue Sample Collection, Storage and Shipment
    7. Data Collection, Recording, Retention and Disposition
    8. EPA Audit Procedures

2. The category number shall be followed by a period, then the SOP number (in numerical order [1 to n]). The revision number and effective date are located in the upper right side of the first page of each SOP. The revision numbers are serial, beginning with 0 for the first edition. SOP numbers can also be written as Category #. SOP #: Revision#, for example SOP 1.1:0.

    Some common abbreviations used in these SOPs are:

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

    Please note that a significant revision of the SOPs for this location was made for 2011. This included changes in the numbering system and location of individual SOPs. To avoid confusion, this SOP set is being considered completely new, restarting with Revision 0 and an April 2011 Effective Date. This revision supersedes the previous set of SOPs from this location.

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SOP #: **1.3** Revision Number: 0

Submitted by: R.R. Bellinder Effective date: April 2011

Title: Format for use in developing SOPs

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

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

Procedures:

1. The following format shall be used for each Standard Operating Procedure:

   A header (centered) with the name and location of the test site.

   SOP #: (In accordance with numbering system) Revision Number:

   Submitted by: (Name of person developing the SOP) Date:

   Title: (Brief title of the SOP)

   Purpose: (Brief description of the purpose of the SOP)

   Scope: (Determines where and when the SOP is applicable)

   Procedures: (Describe the operating procedures in numerical order from beginning to end so that a person with some knowledge of the situation can carry out the procedures without any verbal input from other sources.)

2. SOPs shall be numbered in sequential order. Page numbers shall be inserted on each page in sequential order.

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SOP #: **2.1** Revision Number: 0

Submitted by: R.R. Bellinder Effective date: April 2011

Title: Designation of Field Research Director and responsibilities

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

Scope: Field test sites conducting GLP research

Procedures:

1 The Field Research Director (FRD) is designated by the Study Director, based on the recommendation of the Regional Field Coordinator. The Field Research Director shall be a scientist with appropriate training and experience to conduct the work. If the FRD cannot continue with the assigned IR-4 research, then the Regional Field Coordinator shall work with the Department of Horticulture at Cornell University personnel to provide a replacement or insure the completion of ongoing trials.

2 The Field Research Director has responsibility for the following:

a. Assure that the trial is carried out according to an approved protocol signed and dated by the Study Director.
b. Assure that personnel, resources, facilities, equipment, materials and methods are available as scheduled for the conduct of the project.
c. Make sure that all personnel conducting a GLP trial understand the protocol and SOPs for any portion of the project in which they are directly involved.
d. Communicate with the Regional Field Coordinator (RFC), Quality Assurance Officer (QA), Study Director (SD) and/or lab personnel on important critical phase dates and events. Coordinate in-life inspections with QA.
e. Assure that all comments/questions from the QA, RFC and SD are responded to in writing, or direct contact (telephone, e-mail, etc.).
f. Insure all raw data, summaries and other items connected with the GLP research are transferred to IR-4 Headquarters for archiving.
g. Maintain certified copies of the Field Data Book until the data is submitted to the U.S. EPA.
h. Maintain a file of current resumes, job descriptions and training records for all key personnel engaged in the trial. Assure the information is archived at IR-4 Headquarters when personnel leave or other changes occur.
i. Designate trial locations for the facility and maintain perennial crops under good agricultural practices.

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SOP #: **2.2** Revision Number: 0

Submitted by: R.R. Bellinder Effective date: April 2011

Title: Personnel and documentation of training

Purpose: Information concerning personnel requirements under GLP's. To assure that training is adequate and properly documented for GLP research.

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

Procedures:

1. 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.

2. Personnel handling pesticides shall be trained in accordance with the current policies and guidelines of Cornell University.

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

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

5. The field testing facility shall have on file information for each person currently supervising any phase of a GLP residue trial, and collecting and/or entering data under GLPs.

6. The personnel information for each person so engaged in the conduct of GLP trials shall include a current summary of the experience and training of the worker, as well as a brief description of their duties or responsibilities, along with other pertinent information:.
    a. Documentation of formal training at an institution of higher learning may consist of a CV or a notation that the person received a degree, and the year graduated noted. If a degree was not awarded then the years of attendance, credit hours and specialty shall be noted. Years of experience may serve in lieu of some or all of the formal education. These shall be documented in the files at the field facility.
    b. Documentation of training for each person shall include, but not be limited to:
        i. Records that those sections of the protocol and Standard Operating Procedures that pertain to their responsibilities have been read and understood. The Field Research Director or designated personnel shall record the names of the personnel and dates that the SOPs and protocols were read or explained.
        ii. Notations of training received from workshops, conferences, etc. A copy of any type of training certificate issued shall also be retained in the personnel files.
        iii. 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 6/2/11).

iv. Include the name of the person and/or the event and the dates for all training listed above.

c. All educational and training documentation shall be placed in the personnel file and sent to IR-4 headquarters for archiving as needed.

7. 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. In this case, supervising personnel shall record the names of the personnel and the dates that the SOPs or task were explained to them. This documentation shall be placed directly in the FDB to which it pertains.

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

9. An exact copy of each original CV or resume, along with the training logs shall be included in each Field Data Book. The original CV or resume and training records shall be submitted with the Facility File to IR-4 headquarters for archiving, yearly.

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SOP #: **2.3** Revision Number: 0

Submitted by: R.R. Bellinder (R.R.B.) Effective date: April 2011

Title: Organizational Chart

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

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

Procedures:

1. An organizational chart shall be developed which reflects the lines of communication and responsibility for conduct of GLP studies. Show the line of reporting between the Sponsor (entity that initiates and finances the study and submits the report to the EPA), Study Directors (individual responsible for the overall conduct of the study), Quality Assurance, Testing Facility Management (Regional Field Coordinator in the case of IR-4) and Testing Facility (person who actually uses the test substance in the test system, the 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 separate line, but this 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 GLP trials are shown on the chart with lines of responsibility indicated. Direct and indirect lines of communication and accountability shall be shown as follows:

    a. Direct lines as solid
    b. Indirect lines as dashes

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

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SOP #: **3.1** Revision Number: 0

Submitted by: R.R. Bellinder Effective date: April 2011

Title: Site selection for GLP field studies

Purpose: To assure plots are large enough to obtain the required data or samples with sufficient uniformity

Scope: All GLP field research studies

Procedures:

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

2. Site shall be large enough to accommodate the required number of duplicate samples, buffer zones and treatments, in accordance with an approved protocol and the given commodity, in order to yield samples of sufficient size for analysis.

3. There shall be a minimum of 15 ft between plots of annual crops or low - growing perennials (e.g. strawberries). The buffer shall be increased, if required in the protocol, or a protocol change shall be requested. Buffers for caneberries, grapes and tree fruit shall be of an adequate distance or positioned in such a way to insure there is no cross contamination.

4. Site shall be situated to insure that the untreated plot cannot be contaminated by applications to the treated plots, and to minimize contamination from external sources.

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

6. The soil where studies shall be conducted shall be tested every two years for nutrients, pH, and organic matter, and this shall be recorded in the files for all studies. For soil texture determination, analysis performed no more than 15 years prior to the study shall be considered acceptable.

7. Cultural practices (plowing, planting, etc.) shall be performed prior to plot layout and marking, unless there are pre-plant applications.

8. A plot map showing the location of each plot on the field shall be prepared. Appropriate measurements, from a permanent marker, shall be made to denote the trial within the larger field area so that the plots can be relocated after the study is terminated. Some notation of what is around the plots shall be included where possible.

9. The outside boundaries of the study shall be triangulated using the Pythagorean Theorem and each plot, using a suitable measuring device, shall be accurately sited within the study boundaries. See SOP# 3.2

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10. Boundaries of each plot shall be identified at both ends with markers. Plot stakes shall be written in permanent ink and replaced as necessary to ensure that the information remains clearly visible.

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SOP #: **3.2** Revision Number: 1

Submitted by: R.R. Bellinder (R.R.B.) Effective date: April 2014

Title: Plot Lay-out for Field Trials

Purpose: To provide guidance how to lay-out plot, mark it, select and measure distances of permanent markers on field and orchards

Scope: All GLP field research studies.

Procedures:

1. This site lays out more than one plot at a time. First a large rectangle is laid out in one of the fields using the Pythagorean Theorem to insure that the corners are square. In some cases, this rectangle may encompass the entire field and serves to establish a number of actual plots and studies. Not all the plots within a given rectangle are necessarily GLPs trial plots. The rectangle is subdivided into plots that may vary in size, depending on the crop to be planted or other considerations. The plot corners of all the plots to be included in the area are marked along the axes of the large rectangle, based on measurements (in feet), and the sizes may vary.

2. The name of trial, treatment and Field ID are on the front left stake. The other three corner stakes will be blank, unless a GLP trial plot, in which case the labeled stake is also placed at the rear left corner. The corner stakes may be placed in row once the crop is planted for protection from equipment damage.

3. For annual crops, plot width may differ from the row widths or treated area width. For example, a measured plot width for snap bean might be 12 ft. Even though 4 bean rows per plot with 30 inches row widths is 10 ft, the plot dimensions are as measured. The treated area will be based on the numbers of rows and row width.
4. Plot plan shall be made using a permanent marker (such as telephone poles, gas pipes, irrigation pipes, buildings corner, fence post, etc.) as reference. Distances from permanent marker shall be measured following requests defined by protocol and Field Data Book.
5. For perennial fruit crops, the plot area width is defined as being equal to the row width if it reflects commercial practices. For fruit tree plots at this site, the plot extends from the row middle to the row middle and that is the width used in calculations. For instance, in cherry block with row spacing of 18 feet, the plot width is 18 feet (from row middle to row middle). Each plot in the test system shall be identified with flags, stakes, marking tape, etc. that will last for the term of the testing period. At a minimum, the markers will include the trial number and name and the treatment number. If the test protocol contains specific instructions for plot identification, those instructions will supersede the instructions in this SOP.

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SOP #: **3.3** Revision Number: 1

Submitted by: R.R. Bellinder Effective date: April 2014

Title: Seeding, transplanting, and maintenance of commodities

Purpose: To assure that commodities are grown under good agricultural practices and provide a uniform crop for study

Scope: All GLP studies developing data on vegetable and fruit crops

Procedures:

1. Determine standard production practices for the commodities to be grown for all trials conducted under GLPs, as specified by the most recent volume of the "Cornell University Integrated Crop and Pest Management Guidelines for Vegetable and Fruit Crops".
    a. Determine the correct species and variety to use, as specified by the study protocol. If the variety is not specified, select a variety commonly used by commercial producers.
    b. Determine pH and soil fertility requirements of the commodity. Soil tests shall be conducted on all fields once every two years. Each crop shall be fertilized annually as recommended for the commodity.
    c. If a commercial producer is providing plants for transplanting, select uniform, healthy stock. Record what is available about seed used, etc.
    d. If transplants are grown by the investigator, pertinent information (e.g. time of seeding, variety, seed source, growing conditions, chemical applications, etc.) shall be documented and included in the appropriate Field Data Book.
    e. Determine appropriate in-row and between-row spacing, and seeding or transplant depth. Plant the seed or transplant in accordance with these measurements.
    f. Perform other agricultural practices as necessary (e.g. Irrigate, fertilize) to aid in crop establishment.
    g. Annual crops usually will be planted 3 or more rows per plot. The inside row(s) only will be harvested unless the Study Director approved differently. Plot may consist of 2 rows and be harvested from both rows if more practical (tomato, pumpkins...).
    h. For perennial crops plot may consists of one or more row(s).

2. Till the field and prepare the seedbed or transplant area as specified for the commodity.

3. Apply appropriate maintenance pesticides (herbicides, insecticides, fungicides, etc.). Approval of the Study Director will be requested when possible. No pesticide should be applied that would interfere with the chemical analysis of the pesticide.

    a. Maintenance pesticides used will be applied by either the Farm Manager, the Cornell Orchards Manager or designated personnel under the Farm Manager or Field Research Director. Documentation of these applications shall be recorded into the Field Data Books or transcribed from farm records that are stored in the office of the Farm Manager.
4. Maintain the commodity in a healthy state throughout the study duration. Document in the FDB any unusual conditions.

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SOP #: **3.4** Revision Number: 2

Submitted by: R.R. Bellinder Effective date: April 2015

Title: Crop Destruction

Purpose: To assure that there is no potential for the public to be exposed to crops treated with agricultural pesticides that have not obtained final registration

Scope: All GLP studies involving edible crops

Procedures:

1. All tree fruit and vine crops are grown inside locked, high-fenced fields where the general public is prohibited. After appropriate samples have been collected, the remaining treated fruit shall be allowed to abscise naturally. Treated plots shall be clearly marked with treatment stakes and/or red flagging. The fruit will be left to rot on the ground.

2. Strawberries shall be mowed shortly after sampling, usually within 7 days, unless circumstances intervene to lengthen the interval. If practical, all fruit can be collected and removed to designated place (compost) and the plots saved for the next year trial (e.g.; day-neutral strawberries produce flowers and fruit from summer continuously through fall in mild to hot weather; the fruit can be collected and destroyed periodically).

3. Vegetable crops are grown on university property where public access is by-permission only. Vegetable crops shall be mowed, disked, or rototilled (destroyed) within 7 days of sampling unless circumstances intervene to lengthen the interval.

4. If practical, fruit or entire plants can be removed to designated place – compost (e.g., onion plants, to prevent insects developing in field).

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SOP #: **4.1** Revision Number: 1

Submitted by: R.R. Bellinder Effective date: April 2014

Title: Test Substance handling and storage

Purpose: To assure that all Test Substances and pesticides are stored in a safe manner

Scope: Locations conducting GLP field trials

Procedures:

1. Arrival of GLP test materials shall be checked daily, and as they arrive, each shall be dated and recorded in the GLP chemical inventory log.

    a. Chemicals shall be stored in a locked, fireproof file cabinet in 148 Plant Science Bldg., until transferred to a locked file cabinet in H. C. Thompson Vegetable Research Laboratory (room # 5).

    b. Storage temperatures shall be monitored at both sites using either a HOBO temperature data logger or a Min/Max thermometer. If using a Min/Max, temperatures shall be recorded at least once a week. If using a HOBO data logger, temperatures shall be downloaded at least once every 30 days (+/- 5 days). A Min/Max thermometer shall be used as a back-up. Verification of temperature monitoring devices are done according to SOP#6.4. Please note that historically, chemical storage temperatures have ranged between 45˚F to 100˚F.

    c. All pesticides in storage shall be properly labeled (see Advisory #2003-04). Name of Test Substance (active ingredient or trade name as per protocol), CAS/code number, batch/lot number, expiration date, and storage conditions shall be added to the label, if not already there. The person receiving the Test Substance shall initial and date the label and add any missing information. If more than one container of Test Substance is received, each container shall be identified with the Field ID# and assigned ID # (i.e.: ID#2011/ 7 and ID# 2011/ 8). Containers shall be clearly identified in the field data book.

    d. As GLP test materials arrive, the condition of the container shall be examined and recorded as intact (no breaks, holes, or leaks) or otherwise (specific defect shall be detailed). Labeling by manufacturer shall be inspected, and non-compliant labeling shall be amended. If storage conditions or expiration date are not included on the label, they shall be added. If the name of the test substance does not match the protocol or no expiration date is provided in any of the documentation from the manufacturer, the Study Director shall be notified immediately.

    e. Shipping documents shall be retained in the Field Data Books.

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

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3. During the field season, all GLP chemicals shall be stored at the H. C. Thompson Vegetable Research Laboratory, and shall be accessible only to the Field Research Director, research personnel, and the Farm Manager.

4. After finishing use of a Test Substance, the GLP Test Substance containers are transferred to the Pesticide Storage Facility (building code 1229E) at the H.C. Thompson Vegetable Research Farm, where they are kept until the final report is completed and submitted to EPA, or the trial dropped, as per IR-4 Advisories 2003-02 and 2005-01. Storage temperatures shall be that of ambient air, except during winter months when temperatures shall be maintained at or above 45 °F

5. Excess chemicals not used for study purposes may 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 log for that chemical. The container must be retained until the final study report (Pesticide Tolerance Petition) has been signed by the Study Director (study completion date). However, disposal is NOT acceptable if the test substance from the same container was also used in a trial in a different study that has not yet been canceled or completed.

6. Adjuvants used with test substances shall be assigned an expiration date of five years from the date of receipt, unless instructed otherwise.

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SOP #: **4.2** Revision Number: 1

Submitted by: R.R. Bellinder Effective date: April 2014

Title: Calibration and use of an electronic scale to weigh GLP Test Substances

Purpose: To assure an accurate dosage in the application of pesticides

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

Procedures:

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

2. As soon as possible after servicing the balance, and prior to its initial use, the Standard Weights shall be verified on the serviced scale. The verification of the Standard Weights shall be recorded and the information included in the FDB of all trials where needed as a certified copy. The original raw data shall be forwarded to IR-4 HQ with the Facility File.

3. Immediately prior to weighing the Test Substance for an application, the balance shall be verified using the standardized weights. For each of verifications two weights shall be chosen to bracket the target weight: one slightly smaller and one slightly larger than the amount of Test Substance to be weighed. (Example: if amount of Test Substance to be weighed equals 6.52 g then weights equal to 5 g and 10 g would be used for calibration.)

4. Test Substances shall be weighed on a new plastic tray, or other clean weighing container. Select and wear or use appropriate safety equipment while handling pesticides. Weigh the Test Substance in a tared tray or container. Return excess to original pesticide container, if this procedure does not affect the integrity of the contents or dispose of the excess by using appropriate methods for handling hazardous wastes.

5. Dry Test Substances shall be pre-weighed in building and the tank mix made at that time. For remote sites the TS shall be transported to trial site in alternate container. This pre-weighing shall be done on the day of application, or no more than 24 hours ahead of time. The container shall be labeled with Test Substance name, lot #, expiration date, project ID #, amount, treatment number, initialed and dated.

6. Wash the weighing tray into the sprayer using some of the measured carrier to insure all the product is added to the tank. If using an alternate container, make a slurry of the Test Substance with the carrier, before adding it to the tank. Triple rinse the container into the tank.

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

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SOP #: **4.3** Revision Number: 1

Submitted by: R.R. Bellinder Effective date: April 2014

Title: Measuring a liquid formulation.

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

Scope: All liquid formulations of GLP pesticides.

Procedures:

1. Appropriate safety equipment shall be used while handling pesticide concentrates.

2. When measuring pesticides, clean graduated cylinders, syringes, pipettes or micro-pipettes large enough to hold the volume of pesticide needed shall be used.

3 For accurate measuring of small quantities of pesticides, pipettes, ranging in volume from 0.1 to 10 ml, or syringes ranging from 1.0 to 10.0 ml shall be used. Measured quantities shall be expelled directly into spray tank. Graduated cylinders of appropriate size (accuracy within +/- 1% of the total volume) may be used.

4 Take the reading of the liquid at the bottom of the meniscus where appropriate. Syringes provide complete transfer of liquid Test Substances and do not require rinsing. Pipettes are not a good choice for viscous liquids.

5 A graduated cylinder may also be used to measure liquid Test Substances. Use cylinders that typically have graduation increments of <+/-5% (e.g., at least 5 ml increments for a 100 ml cylinder) which is acceptable for GLP trials. Cylinders shall be triple rinsed into the spray tank and then washed with soap and water after use to ensure that they are clean and cross-contamination of pesticides shall not occur in future use.

6 The liquid shall be poured or expelled directly into the spray tank, making sure that as much of the liquid as possible is transferred. Cylinders shall be triple rinsed into the spray tank.

7 If the opening of the cylinder is too restricted to allow pouring of the pesticide from the original container without danger of spillage, then:
   a. Use a clean glass container with a pour lip as an intermediate and fill the cylinder from it or;
   b. Use a clean funnel that is large enough to allow filling the cylinder with a minimum of spillage.

   If the pesticide container neck is too small for syringe use clean beaker as an intermediate and discard any product not used.

8 A written record of each volume of the pesticide removed from the original container shall be maintained. If more than one amount is measured out for a single application, each amount shall be entered separately. If the same Test Substance is used for more than one trial, all records must be maintained on a single log; the original of the log would be placed in the book for one trial and an exact copy in the other.

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SOP #: **4.4** Revision Number: 1

Submitted by: Robin R Bellinder Effective date: April 2014

Title: Adding pesticide concentrate to the carrier (water)

Purpose: To insure proper mixing of the concentrate and carrier in a spray tank

Scope: All GLP field trials involving application of a pesticide concentrate in water

Procedures:

1. After the sprayer has been inspected and calibrated, per SOP# 5.2, empty the tank. Confirm that the spray tank shall hold the entire mix volume (carrier, Test Substance and surfactant, if required). Measure the amount of water needed to dilute the measured amount of concentrate. Make sure the quantity of spray shall be enough to cover the entire plot plus sufficient overage. If the plot is too large or too wide, the application may be made with two separate tank mixes.

2. Add roughly 1/2 the water to the spray tank before adding the Test Substance.

3. For dry formulations, making a slurry mix first is recommended. Make the slurry by adding a small amount of mix water to the concentrate and shaking well. Once well mixed, add the slurry to the water in the spray tank.

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

5. Add surfactant, after all pesticide products have been added or when indicated.

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

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

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SOP #: **4.5** Revision Number: 0

Submitted by: R.R. Bellinder Effective date: April 2011

Title: Cleanup of application equipment

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

Scope: All locations where pesticides are used under GLP

Procedures:

1. Excess spray material shall be applied to a similar crop or non-crop area or disposed according to current facility policy. This location shall be far enough away from the untreated plot to prevent any possibility of contamination.

2. In the designated area or suitable location away from aquatic areas or danger of aquatic contamination, hose down the sprayer/applicator to remove pesticide residuals from inside of the equipment. Wash the tank and all spray systems with 50% ammonia solution and triple rinse with water after each application. Apply each tank of wash or rinse solution to the over-planting of the crop or non-crop area. If a crop/non-crop area is not available, then follow the disposal procedures for pesticide rinse water in accordance with current policies and guidelines of this institution. If the same TS need to be applied on different rates on the different plots the lower rate shall be applied first. The equipment will be washed between treatments/plots as same as between different Test Substances.

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

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

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

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SOP #: **4.6** Revision Number: 1

Submitted by: R.R. Bellinder Effective date: April 2014

Title: Disposal of pesticides

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

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

Procedures:

1. The containers for GLP Test Substances used in support of an EPA tolerance shall be retained at the facility until the data package is submitted to the US EPA, the trial dropped or the study cancelled.
    a. Excess Test Substance can be used in other crops, once the applications are completed, as long as the container is retained. If the Test Substance is used elsewhere, the transfer should be noted in the use log.
    b. Containers approved for disposal are listed on the IR-4 website (see advisory #2005-01).
    c. Notification many also be sent by the Regional Field Coordinator, Study Director or other authorized IR-4 personnel, either stating that the containers may be discarded or documenting that the study has been forwarded to the EPA (Advisory #2003-02).

2. Occasionally the protocol requires that unused product be returned to the company. This site does not ship pesticides, therefore, a protocol change will be written, while the remaining product shall be handled as below.

3. When disposing of pesticide concentrates or containers, personnel shall follow current policies and guidelines of their institution. Where institutional guidelines do not exist, the following procedures shall be followed. This applies to the Test Substances only when permission has been received from the Study Director.
    a. Follow label directions for disposal of the pesticide.
    b. 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.

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

5. Disposal of pesticides concentrates shall be done by the special Cornell University unit charged with the task.

6. Disposal of pesticide rinse water, unused spray solutions and other dilute pesticide waste shall be done as indicated in SOP# 4.5.

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SOP #: **4.7** Revision Number: 1

Submitted by: R.R. Bellinder Effective date: April 2014

Title: Handling pesticides safely

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

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

Procedures:

1. Personnel shall follow current policies and guidelines of their institution. 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 study protocol shall be worn in the handling of pesticides for storage, mixing and application. Emergency personal protective equipment (e.g. coveralls, filters, etc.) shall 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.

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. All pesticides shall be mixed in quantities that are adequate for the job and avoid excess dilute solutions after the application is completed. Cleanup procedures shall be established whereby excess sprays can be safely discarded, preferably by spraying the material on an over-planting of the commodity or non-crop area. The equipment shall be washed off as indicated in SOP# 4.5 and all pesticides and pesticide containers shall be returned to a storage area immediately after use.

8. A pesticide-treated area shall not be reentered until adequate time has elapsed, as specified on the label of the pesticide. Treated plots are posted as per New York regulations.

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

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10. 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.

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

12. Wear protective gloves while handling containers and mixing or measuring pesticides.

13. Pesticide storage areas shall be properly ventilated.

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SOP #: **4.8** Revision Number: 1

Submitted by: R.R. Bellinder (R.R.B.) Effective Date: April 2014

Title: Rounding.

Purpose: To provide a general outline for rounding (when and how to round)

Scope: All field studies.

Values will not be rounded until the end of a calculation.

All steps to generate a number will be done in one equation, if it is possible and practical.

Numbers will be rounded to a value that can actually be measured. For example, the calculated amounts of product, carrier and adjuvant needed for a tank mix need to be accurately measurable (as long as the rounding does not result in a % deviation greater than 1%).

$$\frac{618 \text{ ml product / acre}}{43560 \text{ ft}^2 \text{ / acre}} \times 700 \text{ ft}^2 \text{ / plot} \times 1.1 \text{ overage factor} = 10.92424242 \text{ ml} = 10.9 \text{ or } 11 \text{ ml product / tank mix}$$

Other numbers that need to be rounded are the calibrated values for discharge rate (ml / sec / boom, GPA), and speed (sec / foot and mph). These numbers will be rounded to values to reflect what can be timed or measured. For example, the ml / sec / boom will be rounded to two decimals if the stopwatch is that accurate.

For the back calculations, the values that correspond to protocol requirements (such application rates (ml or g product per acre and / or lb active ingredient per acre), GPA, etc.) shall be rounded to no more than one decimal point greater than the value expressed in the protocol. Plot area shall be rounded to feet (for example: 400 ft^2 instead of 400.2 ft^2).

The following rules and examples illustrate the rounding in all cases:

1. If the digit to the right is less than 5, leave digit unchanged.

   4.1282 rounds to 4.128

2. If the digit to the right is 5 or greater than 5, than increase the digit by 1.

   4.1286 rounds to 4.129

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SOP #: **4.9** Revision Number: 0

Submitted by: R.R. Bellinder Effective date: April 2015

Title: Storing and Maintaining Adjuvants (Spray Additives) for Use in IR-4 Field Residue Studies

Purpose: To establish a procedure that defines the labeling, handling, and storage of adjuvants (spray additives), along with appropriate supporting data and documentation as part of IR-4 GLP residue studies.

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

Procedures:

Note: The use of adjuvants (spray additives) with the test substance must be approved in the protocol or in a protocol amendment.

1. GLP labeling requirements for reagents (i.e. adjuvants, spray additives) are: name, concentration, storage conditions and expiration date. These will be required on all spray additives used for IR-4 GLP Residue Studies beginning with 2015 field trials and beyond.
    a. If temporary containers are used (i.e. a subsample dispensed from the purchased container or a properly labeled secondary container (see b. below) they should be used only for the purpose of measuring or preventing contamination. They should be adequately labeled to insure the product is uniquely identified, but need not be labeled per GLP as required for the original or secondary containers. Excess material poured into a temporary container should be discarded, not used, for subsequent trials and not returned to the original or secondary container.
    b. Secondary containers are permitted for storage (e.g. a 1 gallon container subdivided into 100 ml containers for ease of use and transport to remote sites), but must be properly labeled per the original container and now take on all the requirements and properties of an "original container".
2. Spray additives will be stored in a location that has limited access and is temperature monitored. The temperature can be monitored with a min/max thermometer or electrical data logger. If monitored with the electronic data logger, logging interval shall be four hours or less (i.e., one hour during the season, stored with the Test Substances and four hours out of the season, stored in the long-term, temperature controlled storage).
3. Spray additives will be in good condition prior to use - the physical characteristics of the additive should not have changed from purchase or be compromised (i.e. different color, consistency [cloudy, darkened] or have the appearance of rancidity).
4. Spray additives must be handled in a manner to prevent cross contamination with test substances and other spray additives. Two suggested options are provided below.
    a. Spray additives will be dispensed into a temporary container (such as a beaker) prior to being used in a GLP residue trial. The spray additive once dispensed will not be used for a different trial or returned to the original or secondary container; it will be discarded.
    b. Spray additives will be dispensed from the original or secondary spray additive container using a factory sealed newly opened pipette or syringe. After this pipette or syringe is used it is discarded and never used again. This pipette or syringe never returns to the spray additive

container. The test substance is also dispensed by a different newly opened pipette or syringe, and discarded after use.

The critical element in both these examples is: no "double-dipping" into an original or secondary container. No measuring device will be placed directly into a spray adjuvant original or secondary container, and then directly into a spray tank or container intended to hold GLP test substance, and then back into the spray adjuvant container. Other methods that prevent double dipping into original or secondary containers are also acceptable.

5. Spray additives which have not been monitored and labeled per above (the reagents received before this SOP) can be moved into current use:
    a. Spray additives that have been directly dispensed with a measuring device that has been placed directly into a container with GLP Test substance, or any pesticide tank mix and placed again into a spray additive container will no longer be used for GLP residue studies.
    b. All spray additives must be labeled per GLP reagent requirements (name, concentration, storage conditions and expiration date). If an expiration date is not available (i.e. on the label or SDS) then the FRD should assign one that does not exceed 5 years from the purchase date. It is also recommended that the FRD include the date the container was opened as a helpful reference date.
    c. Spray additives will be in good condition prior to use - the physical characteristics of the additive should not have changed or be compromised (i.e. different color, consistency [cloudy, darkened] or appearance of rancidity). If the spray additive demonstrates any of these characteristics it should be removed from use in GLP residue trials.
    d. Monitoring of spray additives, to document and thus assure that storage conditions have been met, should be in place for 2015 GLP field trials and beyond.
    e. If there are any questions or concerns about the integrity or condition of the spray additive, it should be removed from use for GLP residue trials.

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SOP #: **5.1** Revision Number: 1

Submitted by: R.R. Bellinder Effective date: April 2014

Title: General information & documentation on the John Deere 4110 and Kubota 2320DT tractor & Offset Mounted Spray Bar (OMSB)

Purpose: To determine the procedures of making adjustments as necessary to ensure an accurate application of the pesticide.

Scope: All GLP trials using The John Deere 4110 or Kubota 2320DT tractor, OMSB and IR-4 dedicated spray system

Procedures:

1. The John Deere 4110 and Kubota 2320DT tractor are equipped with an Offset Mounted Spray Bar (or OMSB) to which the appropriate spray booms can be attached, depending on the application type.
    a. The booms and CO_2 tank used to apply GLP test substances are used exclusively for IR-4 test substances, and are individually identified.
    b. The same John Deere 4110 tractor or Kubota 2320DT and OMSB may be used for maintenance and other non-IR-4 research when equipped with other 'non –GLP' booms and delivery systems.

2. Maintenance logs for booms and spray systems used for GLP applications are kept by the Field Research Director in the Facility File. General maintenance or repairs to the John Deere 4110 and Kubota 2320DT tractor or the non-IR-4 spraying systems are recorded by the Farm Manager and logs are kept in his office.

3. The GLP system consists of CO_2 tank, pesticide's solution tank, boom and nozzles.

    The unique identifiers for the GLP parts are the next:

    Broadcast boom: B-1
    Directed boom: GD-2
    Offset mounted spray bar: OMSB
    CO_2 tank: #1 (big tank for tractor's applications)
    Pesticide's solution tank: No.1
    Pesticide's solution tank: No.2
    Pesticide's solution tank: No.3
    Pesticide's solution tank: No.4

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SOP #: **5.2** Revision Number: 1

Submitted by: R.R. Bellinder Effective date: April 2014

Title: Maintenance and calibration of a CO_2 sprayer and accompanying speed calibration.

Purpose: To describe the procedure for maintaining and calibrating the CO_2 backpack or tractor-mounted sprayer, and the speed calibrations for this equipment.

Scope: All GLP broadcast, banded or foliar-directed applications with a CO_2 sprayer

Procedures:
The majority of trials conducted at this site require broadcast, banded or directed applications to crops in the field, using a water carrier and CO_2 propellant spray system. The maintenance and calibration of CO_2 backpack and tractor mounted sprayers are the same. Speed calibrations are the same principle, with some modifications.

1. Check and clean CO_2 spray equipment before each use.
   a. The nozzle assemblies shall be disassembled to verify cleanliness and to clean the screens and nozzle bodies within at least 7 days of a full discharge calibration.
   b. The application boom shall be inspected for leaks. Booms, with nozzles and screens removed, shall be flushed with 50% ammonia solution and triple rinsed with water before the season. Nozzles and screens shall be cleaned with a 50% solution of ammonia and then triple rinsed with water before the season. The equipment is cleaned after each application as per SOP# 4.5.
   c. The CO_2 propellant tank connections shall be inspected for leaks and repaired if necessary.
   d. All gauges shall be inspected to insure proper operation and be replaced if necessary.
   e. Verify that the nozzles and screen size provides the desired spray volume within the recommended range of pressure and area of application, as recommended by the manufacturer. The screen size shall be compatible with the test substance and the nozzle size.
   f. Unique identifiers for each spray boom shall be checked and renewed, if needed.
   g. Any faulty components shall be replaced before calibrations.
   h. Maintenance shall be recorded on the appropriate equipment log with a notation as routine or non-routine work.
   i. All calibrations, applications and other routine and non-routine activities shall be recorded on the equipment log.

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2. Calibrate the discharge rate of the spray equipment.

   a. A complete discharge/output calibration consists of a minimum of three consecutive, documented checks for output at each nozzle.

   b. A complete discharge/output calibration of the spray equipment must be conducted just prior to the first application of the test substance. If more than one application will be made in a given day, a recheck shall be conducted between each application. Just prior to an application includes the day before. If more than one full day elapses between the calibration and an application, another calibration must be conducted. Discharge data from a full calibration from another trial performed on the day of or day prior to the application in a trial may be used if in compliance with a protocol. However, a recheck (single output check and speed recheck) must be performed just prior to the application in the second and all subsequent applications on that day.

   c. A single recheck of the discharge may be conducted for subsequent applications in the same trial between multiple applications, as long as no changes have been made to the equipment and the application parameters have not changed. A single output check shall be conducted to confirm consistent delivery (±5% of the last complete calibration; show calculation) just prior to each subsequent application. Use the discharge rate from the most recent full calibration for calculations. A full calibration preferred.

   d. Calibrate discharge uniformity of the spray boom by measuring each nozzle's output. Fill the spray tank with a sufficient quantity of water and discharge it into containers (one container per nozzle) for a period of time, such as 10 seconds, timed with a stopwatch. Measure and record the captured output with a graduated cylinder of appropriate size. Record the discharge value and the cylinder used, including its incremental units. For any nozzle tip that has greater than a 5% variation from the average, clean or replace screens and/or replace the tip with a new one. Conduct this test three times using the same method to ensure that spray tips are discharging uniformly.

      Show calculations in ml/sec/boom.

$$\text{Volume (ml/sec/boom)} = \frac{\text{Average total output (ml) of \_\_\_* nozzle(s)/boom}}{\text{Average time (sec)}}$$

      * Number of nozzles per boom

   e. Complete the discharge calibration prior to calculating the amount of carrier as the average discharge/output is issued for the calculation.

   f. Empty the spray delivery system with compressed gas to remove any water left in the system from the calibration before connecting the tank with the dilute spray solution.

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3. Calibrate the speed of the application equipment (tractor mounted or backpack)

   a. A Full speed calibration consists of a minimum of three consecutive, documented checks for equipment speed or walking speed. A full speed calibration shall be performed prior to the first test substance application in a trial and before any subsequent applications if the equipment or any of the applications parameters have changed.

   b. Full speed calibration data from one trial may be used for other applications performed on the same day. A recheck of the speed shall be done prior to each subsequent application on that day. A speed recheck may also relate back to the original speed calibration in the trial.

   c. The speed of the application equipment needs to be estimated prior to calibration, to ensure that protocol parameters are met.
      i. The estimated speed shall be based on commercial application practices, unless other specifications are given. For example: 2.5 to 3.5 miles/hour = 3.67 to 5.13 ft/sec for tractor applications; or about 1.36 miles/hour = 2 ft/sec for walked-on applications.

   d. Complete the speed calibration before calculating the amount of carrier, as the calculations are based on the calibrated speed.

   e. Calibrate the speed of application equipment in the field, on terrain similar to the plot.
      i. Tractor speeds are calibrated on the same track as used for the application.
      ii. Determine what tractor gear and throttle setting are needed to attain the estimated speed.
      iii. Several practices runs are made to establish wheel tracks and compact the soil prior to the calibration, recheck and application passes. This facilitates a uniform travel speed for the calibration and application passes.

   f. When determining a walking pace, simulate the application by carry all the application equipment and positioning the boom at a height as for an application

   g. Once the estimated speed has been attained, make three passes through the plot or test track. Runs at the to-be-used speed.
      i. Travel the length of the plot or track, measuring the pass time from when the boom crosses the markers at the beginning and at the end of the plot with a stop-watch.
      ii. Record the times (Part 6.D. Field Data Book) including Gear and Throttle Setting (if applicable), Track Length (ft.), and Time (sec.).
      iii. The three pass times shall be within ± 5 % of the mean value.
      iv. A recheck shall also be within ± 5 % of the mean calibrated value.
      v. Calculate average pass time per plot (in seconds) and use this for calculations of the amount of carrier and test substance. Show average speed in ft/sec.

   h. Note that branches of fruit trees or bushes that might interfere with the application should be moved, tied or cut prior to speed calibration.

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SOP #: **5.3** Revision Number: 1

Submitted by: R.R. Bellinder Effective date: April 2014

Title: Calibration of mist blower discharge rate and speed

Purpose: To describe the procedure for maintaining and calibrating the Solo Mist Blower, and the speed calibrations for this equipment. Application techniques specific to the mist blower are also described

Scope: GLP foliar-directed applications in tree fruit with a mist blower

Procedures:
This location uses a SOLO 450 motorized air-assisted mist blower (identification number M-1) to apply foliar directed applications in tree fruit.

1. Check and clean the mist blower before application.

    a. The mist blower shall be examined for damage and proper functioning prior to each application. Maintenance, care and operation shall be performed according to the manufacturer's operating manual.

    b. Before the first application of each year, and following each use, the mist blower's tank, tubes, nozzle and screen (if applicable) shall be cleaned with a 50% ammonia solution and triple rinsed with water.

    c. Routine and non-routine activities shall be entered in the mist blower equipment log.

2. Calibrate the mist blower discharge/output.

    a. Fill the mist blower tank with a specified amount of water (e.g. 3 L), using a graduated cylinder. Record graduated cylinder size and incremental units.

    b. Choose appropriate throttle. Run the mist blower for a specified time (e.g. 60 seconds), while spraying an actual tree (well outside the tested area), moving the mister arm attachment in a uniform up and down motion, mimicking an actual application.

    c. Shut off the mist blower immediately when the specified time-interval is reached.

    d. Measure the water remaining in the tank by disconnecting the tube from the sprayer arm and slowly emptying the water into a container of adequate size. Measure the water from the container using a graduated cylinder. Deduct the unused water from the original amount (ex. 3 L), to obtain the output. Record output in the discharge calibration table (ml).

    e. Repeat this procedure a minimum of three times. Each run must be within +/- 5% of the mean value. The average discharge rate of three separate events is the discharge calibration.

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3. The calculations for both the test substance need and the estimated amount of carrier (water) for the application are based on the area of the plot to be treated. These calculations are covered in more detail in SOP #5.4.

$$\text{Volume of carrier (ml } H_2O) = \frac{\text{Treated Area (ft}^2) \times \text{GPA desired}}{43560\ (\text{ft}^2/\text{A})} \times 3785\ \text{ml/gal} \times \text{Overage}$$

a. The minimum overage factor for mist blower applications is 1.2, the same overage factor used for calculation of the test substance amount.

b. Use the GPA specified by the protocol. If not specified, use a GPA common to local commercial practices with an identical commodity. Note that the mist blower tank's size (a maximum volume of 11.5 l) limits applications to $\leq$ 120 GPA in plots with 8 trees. That is, a total of 8 trees can be sprayed, on both sides of the row, for a 60 GPA, without refilling the tank. For spray volumes between 60 and 120 GPA the mist blower tank can be refilled between passes. For larger GPA, refills would be needed during passes. A recheck of the discharge output is not needed between passes.

4. Speed calibration (pass time/plot).

A targeted speed, based on the volume to be applied, is used for mist blower applications.

a. The targeted pass time/plot (sec) is calculated using the volume of tank mix (ml), discharge rate (ml/sec), and the 1.2 overage factor as shown below. Round to two decimal places.

$$\text{Total Pass Time (sec/plot)} = \frac{\text{Volume of Tank Mix (ml)} \div \text{Overage Factor}}{\text{Discharge Rate (ml/sec)}}$$

b. Full walking speed calibration shall consist of three consecutive runs per one side of a row. In order to make the walking speed uniform through the entire plot, do the following:

i. Divide the pass time per one plot side by the number of trees/bushes, in order to get the elapsed time per one side of one tree/bush. If there are no trees/bushes, divide the plot into subunits and mark them. For example, divide a 90 ft long raspberry row into 9 subunits of 10 ft.

ii. Walking speed during a mist blower application shall match the calculated pass times per one side of one subunit. For example, if the calculated total pass time per plot is 659 sec, the pass time per one row side is 329.5 seconds. The pass time per one side of one tree for a plot of 8 trees is 329.5 ÷ 8 = 41.2 seconds/per one side of one tree.

iii. Show calculations in seconds and minutes separately for each tree side. The column with minutes is necessary for timing with a stopwatch.

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For example:
Pass time per one side of one tree

Tree #	Seconds	Minutes
1	41.2	00:41:20
2	82.4	01:22:40
3	123.6	02:03:06
...	...	...

iv. Make three consecutive runs per one side of row, simulating spraying, following the above table, and recording the pass time per one side of row. Calculated passing time(s) per subunits shall be adhered to by the applicator himself, preferably, with the aid of an assistant. The assistant shall tap the applicator on the shoulder one second before the pass time for the actual subunit would be met, giving the applicator a second to move to the next subunit on that side with no stop in spraying. On the last subunit, the sprayer shall be turned off. The time shall be recorded. If only the applicator is present, a note card, specifying the times to switch from one sub-unit to the next shall replace the second person. In this case, the applicator shall hold the card while spraying and watching the stopwatch.

v. The mean value of these three consecutive runs per one side of row, with no more than ± 5 % discrepancy, shall be considered the calibrated walking speed.

vi. Note that branches of fruit trees or bushes that might interfere with the application should be move, tie or cut prior to speed calibration. If branches are too big to be cut stop spraying, record time, move to appropriate position, and then continue spraying and timing.

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SOP #: **5.4** Revision Number: 1

Submitted by: R.R. Bellinder Effective date: April 2014

Title: Application Calculations

Purpose: To describe calculations used at this location to determine treated area and tank mix quantities: carrier volume; milliliters or grams of test substance;

Scope: All applications of GLP test substance. Can also be used for non-GLP applications.

Procedures:
The majority of trials conducted at this site require broadcast, directed or banded applications to crops in the field, using a water carrier and CO_2 propellant spray system or air assisted mist blower. The tank mix calculations are dependent on the type of application, not the equipment. Descriptions of the calculations and formulae used are give below. With few exceptions, the test substance and carrier calculations are based on the area to be treated

1. Calculate the amount of Test Substance needed for one treated plot. The required amount of pesticide/tank mix calculation is based on: Treated Area*: the application rate required by protocol; and the amount of active ingredient in product.

   Calculate Treated Area*(ft^2). Use the following formulae to determine the required amount of formulated product per tank mix:

   a. Broadcast applications:

   *Treated Area (ft^2) = number of nozzles (#) x nozzle spacing (ft) *x* plot length (ft) x # passes

   b. Banded applications
   if the protocol request is " do not concentrate the application rate into the treated swath" (usual for herbicides):

   *Treated Area (ft^2) = number of nozzles (#) *x* swath per nozzle (ft) *x* plot length (ft)

   If the protocol requires "a banded application applied at full per acre rate" (usually fungicides, insecticides and fertilizers). A.k.a as soil directed application.

   *Treated Area = Row Width (Commercial) x Row Length x Number of Rows/Plot).

   c. Soil (also banded ii.) **or foliar directed applications**:

   Directed applications (soil or foliar), do not proportionally reduce the application rate. The entire per-acre rate is directed at and concentrated on the crop, planting furrow, etc. Use row widths as per local commercial practice.

   *Treated Area (ft^2) = crop/commercial row width (ft) *x* number of rows (#) x plot length (ft)

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2. Use the following formulae to determine the required amount of formulated product per tank mix:

a. Solid formulations:

$$\text{Product (g)} = \frac{\text{Treated Area (ft}^2\text{) x Rate (lb ai/A)}}{\text{\% Active ingredient}} \times 1.0413^* \times \text{Overage}^1$$

1.0413 is a conversion factor and is derived as follows: $\frac{453.6 \text{ g/lb}}{43560 \text{ ft}^2\text{/A}} \times 100$

b. Liquid formulations:

$$\text{Product (ml)} = \frac{\text{Treated Area (ft}^2\text{) x Rate (lb ai/A)}}{\text{Active Ingredient (lb ai/gal product)}} \times 0.08689^* \times \text{Overage}^1$$

0.08689 is a conversion factor and is derived as follows: $\frac{3785 \text{ ml/gal}}{43560 \text{ ft}^2\text{/A}}$

For **ae/acre (acid equivalent/acre)** applications, calculate the amount of product using the protocol rate of formulated product in ml/acre or g/acre as per the following formulae:

c. Solid formulations:

$$\text{Product (g/Treated Area)} = \frac{\text{Protocol rate of formulated product (g/acre) x Target Area (ft}^2\text{)}}{43560 \text{ ft}^2} \times \text{Overage}^1$$

d. Liquid formulations:

$$\text{Product (ml/Treated Area)} = \frac{\text{Protocol rate of formulated product (ml/acre) x Target Area (ft}^2\text{)}}{43560 \text{ ft}^2} \times \text{Overage}^1$$

When calculating application rates, rounding (# of decimal places) should reflect the parameters of the measuring equipment to be used. **Rounding** shall take place at the end of calculations for critical values such as amounts to be measured for tank mixes, actual application rates of product/acre or # a.i./acre.

[1] Use the same **overage factor** for calculating the amount of formulated product and amount of carrier for each tank mix. For example, use a overage factor of 1.1 for CO_2/ backpack applications, 1.2 for the mist blower applications (backpack), and 1.3 for tractor-boom applications. Use a higher overage factor for extremely long plots and/or applications requiring multiple passes.

3. Calculate the required amount of carrier (water).

a. Determine the required amount of carrier (ml) by calculating the calibrated discharge rate and the average time (sec) from the speed calibration section. Always use the mean value from a full discharge/output calibration and speed calibration data not the recheck results. Multiply the

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calibrated discharge rate and the speed calibration average time by the number of passes needed to cover the entire treated area (usually 1 or 2). Use the same overage factor that was used in the calculation of the test substance amount.

$$\text{Carrier (ml)} = \underset{\text{(ml/sec/boom)}}{\text{Calibrated Discharge Rate}} \times \underset{\text{(sec/plot)}}{\text{Calibrated Speed}} \times \frac{\quad}{\text{(\# passes)}} \times \text{Overage}$$

Round to a value that can accurately be measured (basis on equipment increments).

4. Calculate the resulting spray volume and compare with the spray volume range required by the protocol (GPA, gallons per acre). If necessary, make adjustments (e.g. nozzle size, pass time) and recalculate until the to-be-used spray volume falls within the accepted range.

$$\text{GPA*} = \underset{\text{(ml/sec/boom)}}{\text{Calibrated Discharge Rate}} \times \underset{\text{(sec/plot)}}{\text{Calibrated Speed}} \times \text{\# passes} \div \underset{\text{(ft}^2\text{)}}{\text{Treated Area}} \times \frac{43560\ \text{ft}^2}{3785\ \text{ml/gal}}$$

GPA= gallons per acre

Note: When the liquid test substance and adjuvant volumes are large, remove an equal volume (ml) of carrier. This volume adjustment is not needed if the % deviation in total volume, with the addition of the Test Substance and any adjuvants, is less than 1%. To calculate the % deviation in the volume of the carrier, and/or to show that the carrier volume does not need adjusted, use the following formula.

$$\%\ \text{Deviation} = \frac{\text{No adjusted rate (ml)} - \text{Adjusted rate (ml)}}{\text{Adjusted rate (ml)}} \times 100$$

Confirm accuracy of the actual applied rate of the Test Substance through post-application calculations.

Calculate the actual application rate using the following formula:

Liquid formulations:

$$\underset{\text{(lb ai/A)}}{\textbf{Actual Rate}} = \underset{\text{(ml/sec/boom)}}{\textbf{Boom Discharge Rate}} \times \underset{\text{(sec)}}{\textbf{Total Pass Time}} \times \frac{\textbf{43560 ft}^2\textbf{/A}}{\textbf{Treated Area (ft}^2\textbf{)}} \times \frac{\textbf{Product (ml)}}{\textbf{Volume Mix (ml)}} \div \textbf{3785 ml/gal} \times \frac{\textbf{No. lb ai}}{\textbf{gal product}}$$

If the Protocol Rate of formulated product in ml/acre was used to calculate the Actual Rate in ml/acre, then do not use the following part of the formula:

$$\div 3785\ \text{ml/gal} \times \frac{\text{No. lb ai}}{\text{gal product}}$$

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Solid formulations:

$$\text{Actual Rate (lb ai/A)} = \text{Boom Discharge Rate (lb ai/A)} \times \text{Total Pass Rate (ml/sec/boom)} \times \frac{\text{43560 ft}^2\text{/A}}{\text{Time (sec)}} \times \frac{\text{Product (g)}}{\text{Treated Area (ft}^2\text{)}} \div \text{453.6 g/lb} \times \frac{\text{\% a.i. / lb Product}}{\text{100 lb Product}} \div \text{Volume Mix (ml)}$$

If the Protocol Rate of formulated product in g/acre was used to calculate the Actual Rate in g/acre, then do not use the following part of the formula:

$$\div \text{ 453.6g/lb} \times \frac{\text{\% a.i. / lb Product}}{\text{100 lb Product}}$$

Round the actual applied rate to the number of decimal points used for the target rate in the protocol, or a maximum of one more (e.g., 986 vs. 985.6).

Calculate the deviation of the actual applied rate from the Protocol rate (either lb ai/A or ml or g formulated product/acre) with the following formula:

$$\text{\% Deviation} = \frac{\text{Actual Rate (lb ai/A)} - \text{Protocol rate (lb ai/A)}}{\text{Protocol rate (lb ai/A)}} \times 100$$

Round to an integer for the % deviation. If the actual applied rate is less than the PROTOCOL rate by 5%, or more than the PROTOCOL rate by 10%, the study director shall be immediately notified.

On rare occasions, applications will differ from those discussed above.

Granular applications where the test substance is applied dry and undiluted.

If the entire substance is to be applied in the treated area, the calculation is using only the treated area.

$$\text{Product (g)} = \frac{\text{Treated Area (ft}^2\text{)} \times \text{Rate (lb ai/A)}}{\text{\% Active ingredient}}$$

To make the application, divide the plot into sections, applying the amount of product needed for that section, then move on to another section.
Neither discharge rate or speed calibrations are needed for this type of application, although the application to the section will be practiced by applying the product on plastic of the same area as one section in the field.

The Test substance (TS) is applied as a volume of carrier or amount of treated crop. For example:

lb. ai TS, or ml or g formulated product per 100 gallons of mix

lb. ai TS, or ml or g formulated product per 2000 lbs. of crop (e.g., potatoes)

No SOPs have been developed for these types of applications.

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SOP # **5.5** Revision Number: 1

Submitted by: R.R. Bellinder Effective date: April 2014

Title: General procedures for the application of GLP pesticides in water carrier.

Purpose: To describe the practices common to all types of pesticide applications

Scope: All locations where GLP field trials are conducted

Procedures:

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

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

3. If the pesticide application is for maintenance of the plots, and not the Test Substance, then apply the pesticide to all the plots in the trial according to the directions on the pesticide label.

4. If the pesticide application involves the Test Substance, then procedures for handling the Test Substance as indicated in SOP#4.1 shall also be followed.

    a. Application equipment shall be inspected and calibrated as described in SOP#5.2 or 5.3

    b. The pesticide concentrate shall be measured out as indicated in SOP#4.2 and 4.3

    c. Preparing tank mixes shall be done as indicated in SOP#4.4

    d. Follow protocol for maximum wind velocity during spray operation. Measure wind velocity and direction on the boom level just before application and record it. If no guidelines are given, winds greater than 6 mph are generally regarded as excessive for a GLP application. Do not spray if wind direction endangers other plots (if drift is possible).

    e. Adjust the boom height and position.

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

    g. The spray system shall be completely charged with the dilute spray solution before entering the plot. Uniform delivery of the dilute spray from each nozzle shall be visually verified before the sprayer moves into the treatment area.

    h. Just before entering each plot make sure that you are traveling at the correct speed. Prepare stopwatch and turn on the sprayer.

i. Start application. Measure time required for boom to pass from start stake to end stake of plot with a stop-watch. Visually monitor the spray pattern during application to ensure uniform coverage.

j. In case of mechanical malfunctions, follow instructions as described in SOP#5.6.

k. Turn off the sprayer just after leaving the plot.

l. The travel time for each spray pass in the treatment plot shall be recorded by the sprayer operator, or an assistant. Record to two decimal places.

m. Dispose of excess tank mix and clean equipment as described in SOP # 4.5 and SOP # 4.6

n. Collect any additional information for each application, if required by Field Data Book and/or protocol.

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

p. The calculation of the actual application rate shall be completed immediately. Before leaving the field if possible, if not, at least on the same day.

q. The Study Director and/or Regional Field Coordinator will be informed of any events that might affect the integrity of the trial.

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SOP #: 5.6 Revision Number: 1

Submitted by: R.R. Bellinder Effective date: April 2014

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

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

Scope: All GLP Test Substance applications

Procedures:

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

2. If something goes wrong, such as a plugged nozzle or a hose breaks, then the operator shall take immediate action to correct the situation.

3. Stop immediately; turn off the boom, and pause/stop the stopwatch.

4. 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.

    a. If mixing and applying another tank of spray to the unsprayed area of the plot can save a trial, document the activities as if it were another treatment. Clearly explain what was done and where, to insure no problems arise, such as a double application. If unsure if this is a legitimate resolution, contact the Study Director or RFC.

    b. If the unaffected area is too small to obtain the samples required for analysis, then the trial shall be discontinued.

5. The Study Director, Regional Field Coordinator and other appropriate individuals shall be notified of the incident immediately, and details shall be recorded in the raw data notebook. Special attention shall be given to this point if there is a possibility the trial might be lost.

6. If there is time and resources the trial may be repeated. **However, the new field trial must not be initiated until the new trial is added to the protocol, and a new ID number is issued.**

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SOP #: **6.1** Revision Number: 1

Submitted by: R.R. Bellinder Effective Date: April 2014

Title: Residue sample collection

Purpose: To assure that representative residue samples are obtained, identified, and the records made by requests defined by protocol in a timely fashion

Scope: All GLP field research studies with residue sampling

Procedures:

1. Consult the study protocol for specific instructions for the collection of samples.

2. Estimated dates may be established and entered on this location's Project Study Master Timetable. If a preharvest interval (PHI) is required, estimate the dates to agree with the applications. If sampling is based on uncontrolled events (plant size, fruit maturity, etc.), then tentative dates should be established and refined as necessary. If unforeseen circumstances radically change the timetable of a trial, the Quality Assurance Unit and the Regional Field Coordinator shall be kept informed.

3. Determine sample size and any special instructions and/or possible modifications for the commodity such as shelling, pitting or cutting to reduce sample weight.

4. Harvest Date is the date the samples are picked, cut or dug from the soil. Sampling Date is the date samples are placed in the residue bags. Dry bulb onions are an example of commodity routinely dried at this site, and, therefore, may have different harvest and sampling dates.

5. Prior to sample collection, a sufficient number of IR-4 plastic lined cloth residue sample bags shall be obtained from the Regional Field Coordinator.

6. Residue sample bags shall be used for samples going directly to the analytical laboratory. Other bags or containers shall be used for samples delivered for processing. These containers will be identified as in #7.

7. Before harvesting, each sample bag shall be labeled using waterproof ink with the following information:
    a. Field ID #
    b. Crop fraction
    c. Test substance
    d. Sample ID
    e. Treatment #
    f. Harvest date
    g. Sample date
    h. FRD name/ phone number

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8. Representative samples of the commodity shall be taken from each plot by the procedure requested in the protocol. Description of the complete procedure used shall be written in Field Data Books for each study.

9. The original Residue Sample chain of custody form, initialed and dated, shall be retained in the Field Data Book. Copies will be included in each shipping container.

10. Each duplicate sample shall be harvested individually, avoiding the ends of the plot and plot edges. The collection of the each sample, including any modifications, shall be completed before proceeding to the next sample. Untreated samples shall be completed first, and then the treatments shall be harvested in the order of increasing dosage rates. Clean gloves shall be used and changed between treatments. Completing the modifications to the untreated samples before proceeding to treated samples, unless not possible for reasons that shall be explained in the FDB, such as unfavorable weather conditions or samples from remote sites.

11. Each treated and untreated plot shall consist of an adequate amount of harvestable crop so that the protocol requirements are met. If there is not enough crop to provide duplicate samples of the required size without harvesting more that 50% of the crop, the Study Director and RFC shall be notified immediately.

12. Samples should not be taken during periods of inclement weather, unless absolutely necessary.

13. Be certain tools are clean. Equipment (knives, pruning shears, cutting boards etc.) shall be cleaned with 50/50 ammonia/water solution. Equipment (knives, pruning shears, cutting boards, etc.) shall be cleaned with 50/50 ammonia/water solution and well rinsed with clean water one-three days before harvest. Clean equipment shall be used between treatments; or different clean equipment shall be used.

14. Special care shall be taken to avoid contamination of the field sample with the pesticide under study during the sampling, labeling, storage and shipping processes.
    a. Avoid taking diseased or undersized crop parts.

15. Take care not to remove surface residues during handling, packing or preparation.

16. If loose soil or other debris adheres to fruit/vegetable, remove it by lightly brushing. Document what is used to remove the soil or debris, e.g. a clean brush (preferred), clean gloved hand, clean dry towel, or similar method.

17. If necessary, and allowed by the protocol, lightly rinse of sample with a minimal amount of clean running water (do not scrub), or dip briefly in a bucket of clean water. Pat lightly with clean paper towels. While rinsing or drying the fruit/vegetable, avoid rubbing of surfaces.

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18. Samples shall be placed into labeled IR-4 plastic lined cloth residue sample bags; secured; then, the bagged samples shall be placed into new clear plastic bags.
    a. In some cases, such as when the samples are to be modified, the commodity may first be harvested into other bags or receptacles for transport and modification. Any receptacles used shall be clean, such as plastic bins lined with a new plastic bag.
    b. Samples, such as juicy commodities and/or cut fractions, may first be collected directly into clean, clear plastic bags which are sealed, then placed into IR-4 residue sample bags.

19. Residue sample bags shall always be placed on clean surfaces or in clean receptacles. Sample bags shall not be placed on the ground within the plot, but rather carried, in a clean bag or receptacle, if needed. Surfaces the bags may come in contact with shall be cleaned or covered with a clean protective material.

20. If samples are harvested mechanically, then the duplicate samples are separate subsamples of the total harvest, if subsampling is not specified in the protocol, an amendment shall be submitted.

21. Processing samples shall be collected directly into clean container(s) suitable for shipment or delivery to the processing site.

22. A 3 x 5 index card or similar material/size with all information from Procedure # 7 above may be placed in a moisture-proof container (e.g. sandwich zip lock bag), and then placed inside the sample bag.

23. After each sample has been collected, it shall be weighed, placed in a new plastic bag, and then placed in a cooler with ice. The scale/balance used for these weights is not maintained under GLP.

24. Residues samples shall be placed in separate treated and untreated coolers, with ice, for transport, if elapsed time will exceed 1 hour.

25. Residue samples shall be stored in locked freezers, with untreated and treated samples placed in different freezers. If samples are placed in the same freezer, the treated and untreated samples shall be kept in different areas of the freezer. See sop #6.2 for storage details.

26. Samples shall be modified as required or allowed by the protocol. Some modifications commonly required in protocols are: the removal of dead and senescing leaves; the removal of roots and other unwanted parts; plant or crop fraction drying; and pitting of fruit such as peaches and cherries. If the protocol contains specific instructions for modification of harvested crop, those instructions will supersede the instructions in this SOP.

27.
    a. Senescing leaves are pulled off in the field, when required by the protocol. Otherwise, they are left on the commodity sample.
    b. Cutting roots, stems, leaves and other unwanted parts from the commodity samples (e.g., beets, onions and garlic, etc.) are usually required in the protocol. The unwanted parts may be cut off in the field while harvesting, or the commodity harvested and carried back to the lined Gator or pick-up tailgate and modified there. To cut unwanted parts from the plant or fruit, a clean knife or pruning shears are used. The later is generally used if two parts of a commodity are to be sampled separately (e.g., radish roots and tops).

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c. Oven drying, e.g., herbs: The plants or parts of plants shall be harvested into clean receptacles or bags and transported to the driers in the lab. At H.C.Thompson Research Farm, Freeville. The parts to be dried shall be placed into new paper bags, labeled with, at a minimum the Field ID number, treatment and sample number, and any other information needed accurately identify the samples as they dry. Plants from the untreated plot shall be placed into drier# 1; Plants from treated plot(s) shall be placed into drier#2. The temperature shall be set at 120°F and monitored during the drying process. The plants will stay in a drier as long as needed, unless a time is specified in the protocol.
d. Greenhouse drying , e.g., onions, legume plants and/or pods for forage and shelling, as needed. The plants or parts of plants shall be harvested into clean receptacles or bags and transported to the greenhouse at H.C.Thompson Research Farm, Freeville. Trays will be lined with new paper bags. The bulbs, pods or entire plants shall be placed on those trays in one layer, one sample per one tray, clearly marked. Plants shall remain in the same place over the next seven-ten days. The plants are left until dry, unless the protocol specifies a length of time. The temperature in the greenhouse shall be monitored with Min/Max thermometer during the drying process.
    1. If not already done, unwanted leaves, roots and other parts are removed.
    2. Pea and bean pods to be shelled are then shelled by hand using clean gloves between treatments. Once a seed is shelled, it is placed in a free of any foliage or pod fragments the seed shall be placed directly into IR-4 residue sample bag. Then, the IR-4 residue bag with clean seed shall be weighed (non-GLP scale).
e. Whole plants or fruit may be cut to reduce gross sample weight if the total weight of the required numbers of plants or fruit is considerably larger than the suggested weight, and the protocols allows it. Unless other instructions are given in the protocol, each plant/fruit shall be cut into quarters longitudinally from stem end to opposite end, and opposite quarters retained and placed in the sample bag the plant/fruit shall be cut using a clean knife and plastic cutting board. A Separate board and knife shall be used for treated and untreated samples.
f. The protocol usually requires that the pits be removed from peaches. Whole fruit, shall be cut in half, as above, and the pit removed. If necessary and allowed by the protocol, the fruit may than be cut into quarters to reduce gross sample weight. Cut peaches will normally be placed into a plastic bag before being placed into the residue bag, because of the juice.
g. Cherries also usually need to be pitted, but are too small to cut. This site harvests cherries into a clear plastic Ziploc bag. The bag containing fruits with pits and stems shall be weighed. Then, stems and pits shall be removed, by hand, while still in the bag, to retain the juice. Once all the trash has been removed and the cherries pitted, the plastic bag is weighed, sealed and placed into a labeled ir-4 residue bag.

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SOP #: **6.2** Revision Number: 1

Submitted by: R.R. Bellinder Effective date: April 2014

Title: Packing and storage procedures

Purpose: To assure the integrity of the samples after collection

Scope: All GLP field research studies where residue samples are collected

Procedures:

1. Harvested samples shall be taken directly to the IR-4 Freezers. Freezer identifiers and maintenance information are in SOP# 6.6.

    a. Freeville and Cornell Orchards (Lansing and Ithaca sites) samples shall be transported directly to the Guterman freezers on the day they are harvested, unless noted otherwise in the field data book. Samples are placed in separate treated and untreated coolers with ice for transport.

    b. Freeville trials may also be harvested and placed in the on-site freezer for temporary (one day) or longer-term storage. Frozen untreated and treated samples shall then be transferred in separate coolers with ice to the Guterman freezers and held there prior to shipping.

    c. Elapsed time between harvest and placement in a freezer shall be recorded. Elapsed time shall also be recorded for the transport of samples frozen at Thompson Research Facility to the Guterman Bioclimatic Research Facilities.

2. Field harvested samples shall be stored as per protocol, generally at or below -18° C (0 ° F), excluding defrost spikes, until shipped to a designated laboratory. Temporary increases in freezer temperature up to 20° F due to the addition of samples at field temperatures shall be deemed acceptable if the temperature returns to 0° F or below in no more than 24 hours. Greater temperature increases or a delay of greater than 24 hours in returning to 0° F shall be treated as a deviation from the SOP's and the Study Director shall be immediately notified.

3. Samples identified for post-harvest processing shall not be frozen unless specified in the protocol. They shall be shipped or delivered to the processor as soon after collection as possible, preferably within 24 hours. This site will deliver the processing samples within 24 hours of harvest, if being processed by ACDS. Notify the Study Director if the time specified in the protocol is exceeded.

4. All freezers shall have temperatures monitored with a 7-day thermograph or electronic data logger to ensure that the temperature is maintained within the limits established in the study protocol. Freezers at our Guterman facility are equipped with a power-out alarm monitoring device. The system automatically calls up to five different owner-programmed phone numbers in the event of a power failure, including the Field Research Director, the principal IR-4 technician, other assigned IR-4 personnel and the Guterman facility's managers. The IR-4 Freeville freezer is equipped with an audible alarm system should temperatures go above set limits. If the power failure persists for

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more then 24 hours samples will be transported to other freezers on the Cornell campus or ACDS will be called to pick up samples immediately (SOP#6.6).

5. A log of the samples kept inside the IR-4 freezers, indicating the PR No., sampling date, and number of sample bags for each project shall be kept adjacent to each freezer. A maintenance log of the freezers and a brief description of any calibration, maintenance and repair work done on the freezers shall be kept in the Facility File. In case of failure of Guterman freezers the samples will be immediately transported to IR-4 Freeville freezer.

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SOP #: **6.3** Revision Number: 1

Submitted by: R.R. Bellinder Effective Date: April 2014

Title: Sample shipping procedures

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

Scope: All GLP field research studies where residue samples are necessary and the samples are to be shipped to laboratories.

Procedures:

1. The residue laboratory shall be notified of the shipment dates and their expected date of arrival.

   a. If a freezer truck carrier, such as ACDS, is to be used, contact the carrier to arrange for sample pick-up. Once a tentative date has been set, notify the lab. Notification on the same day as pick-up is acceptable with ground shipments.

   b. If Airfreight is to be used, make the shipment early in the week to avoid potential weekend layovers. Contact the lab person via telephone prior to shipment to coordinate sample arrival. Prior to shipment, the residue sample chain of custody form shall be completed. Exact copies shall be made, and one copy shall be packed with the samples in each box along with a blank copy of the sample arrival check sheet (8C). Copies shall also be sent to the Study Director and Regional Field Coordinator, either via US mail, fax or email

2. Determine special packing instructions that are required to preserve sample integrity.
   a. For airfreight, determine the amount of dry ice needed to maintain sample integrity and insure that it will not exceed the limits on quantities of dry ice etc. that may be required by the carrier. Be sure that you have a valid Dry Ice shipment certificate.

   b. Sufficient dry ice shall be used to insure the arrival of frozen samples. A minimum ration of 1 lb sample: 3 lb dry ice may be deemed sufficient for shipments within the continental US. A greater ratio should be used for Canadian or Hawaiian shipments.

   c. For dry ice shipment, the package and/or Unit Load Device must be designed and constructed to allow release of sublimed CO2 to prevent dangerous built-up of pressure.

3. Pack the samples when a freezer truck carrier comes (not in advance). Obtain insulated containers of sufficient size and quantity to hold the residue samples and dry ice (where required). The containers should have a sufficient bursting strength so as to withstand normal handling in shipping and storage.

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4. Label each shipping carton with the following information:
    a. Return Name and Address of the sender.
    b. Name and Address of the residue laboratory receiving the samples.
    c. Number of the carton if more than one is used (e.g. 1 of 2, 2 of 2).
    d. Affix "Experimental Samples-Perishable" on each carton.
    b. Where used, affix "Dry Ice" on two sides of the container.

5. A copy of the completed residue sample chain of custody form and blank copy of the sample arrival check sheet (8C) shall be placed in every shipping container.

6. Tape lids of each container firmly in place (except dry Ice shipping; see 2.c above).

7. Provide carrier with the phone number of the residue laboratory receiving the samples.

8. Retain original shipping documents in Field Data Book. When necessary, make exact, certified copies of documents to insert in the Field Data Books of other studies' residue samples which were shipped at the same time. It is, however, preferable to use a different shipping form for each trial.

9. When samples are destined for processing at A.C.D.S Research Inc. North Rose, NY, the Field Research Director or a staff member may personally deliver the samples. The field personnel shall work with the processing facility to identify a date acceptable to both parties to insure that the samples do not need to be stored for long periods between harvest and processing. If not delivered within 24 hours, some arrangement shall be made for refrigerated storage.

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SOP #: **6.4** Revision Number: 1

Submitted by: R.R. Bellinder (R.R.B.) Effective date: April 2014

Title: Verification of temperature monitoring devices.

Purpose: To assure that all temperature monitoring devices are accurate and in good working order.

Scope: All GLP field research studies.

Procedures:

1. Each temperature monitoring device used in GLP field research studies will be periodically verified to determine that they are accurate.

2. Procedures for all temperature monitoring devices:

   a. Accuracy of the IR-4 reference thermometer (R#1) will be verified by reading the resulting temperatures, after submersion in an ice-water bath and a boiling water bath.

   b. Accuracy of other temperature monitoring devices (min/max thermometers, soil thermometers, Bacharach sling psychrometer etc.) will be checked by comparing each with the IR-4 reference thermometer (R#1), at two different temperatures (such as ice-water bath and room temperature), preferably bracketing the expected temperature(s) to be monitored. The deviations for min/max thermometer, soil thermometer and Bacharach sling psychrometer of +/- 4°F will be accepted.

   c. Electronic data loggers will be verified by comparing each one to the IR-4 reference (R#1), at two different temperatures (such as freezer temperature and room temperature). The reference thermometer and logger being calibrated / verified should be maintained at the same temperature as long as needed to insure that the temperatures have stabilized. The deviations for electronic data loggers of +/- 2 °F will be accepted.

   d. All above temperatures will be recorded and placed in the Facility File for that year.

   e. Temperature monitoring devices that give inconsistent results or are not accurate within the desired tolerances, will be repaired or replaced. If retired or broken, that event will be entered on the equipment log for that device.

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SOP#: 6.5 Revision Number: 1

Submitted by: R.R. Bellinder (R.R.B.) Effective date: April 2014

Title: Instruction for Testing, Launching, Reading Out and Data Collection with an Electronic Data Logger (such as Hobo Temperature Data Logger)

Purpose: To provide specific instructions for recording temperature and downloading data to a PC using a Hobo Data Logger. This SOP will also describe the procedure for documenting sample temperatures out of range.

Scope: All GLP research studies where temperature monitoring is necessary

1. Launch the electronic data logger using the instructions provided by manufacturer.
   a. Enter a study description for a file name, which will include the study number and a date.
   b. Next, select the time interval to be used between temperature readings. Choose the interval that will allow readings for the duration of the sampling trip. An interval of fifteen minutes will be considered the standard. Use other intervals if needed. For example, use one hour interval in the cabinet with the test substance stored. Check the battery level on a regular basis, and change the battery if necessary. Double check to insure the logger is ready for use.
2. Read data from the electronic data logger.
   a. To download information, follow equipment instructions.
   b. After the data is downloaded, the data will be plotted and saved under the same file name given when launched.
   c. To print the plotted temperature recording, print in landscape, not portrait mode. Initial and date printed copy. This printed copy becomes the original raw data.
3. Record out-of-range sample temperatures

Examine the plotted temperature printout. If the recorded maximum or minimum temperatures exceed protocols, these areas will be marked and reference made to the temperature deviation.

4. Troubleshooting

If an error window appears when trying to Launch or Readout a logger reading, "Check logger's connection or battery," open the logger's plastic case and replace the battery. Click on Retry after changing the battery. This error message can also mean the serial cable is not inserted completely into the data jack. Click on Retry after pushing the serial cable in snuggly. If an error window appears saying "Either the logger or the data file has been damaged," the logger is unusable. Do not use the logger.

5. Maintenance log will be kept for loggers in use – enter battery charges, verification, software updates.

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SOP #: **6.6** Revision Number: 2

Submitted by: R.R. Bellinder (R.R.B.) Effective date: April 2015

Title: Maintenance of freezers.

Purpose: To describe actions to be taken to ensure proper freezer operation and sample storage.
Scope: All GLP field research studies.
Procedures:

1. Prior to the growing season, the freezer (known as the IR-4 REVCO freezer, Freeville) located at H.C. Thompson Vegetable Research Farm and the three freezers (known as the IR4 FCCS151FW4 freezer #1, Serial # WB40358461 , IR4 FCCS151FW4 freezer #2, Serial # WB40358459 and IR4 FCCS151FW4freezer #3, Serial # WB40358446) all three located at Guterman Bioclimatic Research Facilities, Room 111, Cornell Campus, Ithaca, will be cleaned and temperatures monitored for one-three weeks, either with a 7 day-thermograph, changing the graph paper every 7 days, or with a electronic data logger. The temperature monitoring devices will be verified before use (SOP # 6.4). Routine cleaning and maintenance will be recorded on an equipment log kept in the Facility File.

2. A fluctuation of freezer temperature of +/- 6 °F will be acceptable as long as the maximum temperature does not exceed the temperature specified by protocol.

3. During use, freezer temperature will be monitored continuously. Data from loggers will be downloaded once in 10-15 days. If in use, thermograph charts will be replaced on a weekly basis. Each chart will be labeled with, at a minimum, device #, start and end dates. An attempt will also be made to explain spikes in temperatures outside the normal defrost cycle. Charts will be initialed and dated by the person collecting the chart and it will be stored in the Facility File.

4. An exact copy of the freezer temperature and maintenance logs will be placed in each Field Data Notebook to which it pertains.

5. IR-4 Freeville freezer (Revco Freezer serial number P23P-277698-PP) located at H.C. Thompson Vegetable Research Farm will be used to store samples on a short term basis, if necessary, until they can be moved to the Guterman Lab freezers. Occasionally, samples may be stored for longer periods, for example when the Guterman freezers are full.

6. Freezers at Guterman facility are connected to the facility central ARGUS Alarm Monitoring System. The ARGUS system monitors temperature inside the freezers. In the event of temperature above or below entered the temperature range into the ARGUS software the system automatically calls two Guterman Lab's managers. Then, they call the Field Research Director and the principal IR-4 technician.

7. Freezers at Guterman facility are in locked room#111. The access to the room #111 is allowed to Field Research Director, IR-4 principal technician, staff included in the organizational chart, and Guterman Lab's maintenance staff.

8. Should any freezer temperature malfunctions occur, the Study Director will be notified immediately and the following remedial actions taken. If samples have not begun to thaw, they will be transferred to another freezer under the control of the Field Research Director. If no freezer is

available, ACDS shipping company will be notified and they will pick the samples up with a freezer truck. If thawing has occurred the Study Director, RFC and designated analytical laboratory will be contacted immediately, to determine if sample salvage is possible.

9. If the freezer is repaired, that event will be entered in the log as a non-routine event. If the freezer is retired, that event will also be reported in the log as replaced or broken.

10. Freezer temperature in Guterman freezers connected to ARGUS alarm system shall be set at about -30°C (note: expect normal temperature oscillations in range of about +/- 4°C). Once temperatures stabilized in all freezers, the ARGUS alarm system shall be activated. It shall be done at least several weeks before expected first trial sampling.

11. ARGUS freezer alarm system shall be set to -19 °C. A 1 minute alarm prove time (delay) shall be programmed in order to avoid possible signal transients that are artifactual and unrelated to actual temperature. A 1 minute delay poses minimal risk to the safety of the samples, while significantly reducing the chances of spurious alarms. Additionally, the freezer alarm shall be set to call if the freezer temperature rises above -21°C for more than 5 minutes during the 7:30am to 6:00pm (Standard Time) period. This may help alert Guterman Laboratories staff to an impending or gradual failure during the day, when it is more practical and efficient to address the problem.

12. ARGUS freezer alarm system shall be tested before the current season (annually). The HOBO data loggers shall be launched before the testing. Take ARGUS sensors from freezers (one sensor per one freezer) and hold them in the palm of a warm hand until temperature increases past alarm settings (-21°C). Did ARGUS alarm system make calls for each of the freezers or not shall be documented on the freezers maintenance logs.

13. If ARGUS alarm system did not pass the testing, any malfunction of equipment and/or mistake in programming or any other mistake will be removed and the procedure restarted until testing is successful.

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SOP #: **7.1** Revision Number: 1

Submitted by: R.R. Bellinder Effective Date: April 2014

Title: Collecting and recording of raw data.

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

Scope: All IR-4 GLP trials.

Procedures:

I. Data: information that supports or explains events during the course of the trial.

1. All data required by the study protocol shall be collected and recorded in the Field Data Book, following a careful review of the protocol.

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

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

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

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.

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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. For more information see SOP# 7.2

5. Blank forms may be printed or photocopied as needed.

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

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

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

9. Typewritten or electronic data shall be signed and dated on date that it is printed.

10. Information shall not be entered in advance, with a few exceptions. Never enter a data in advance of an application, calibration and other data where the information might change before the end of the event. In some cases, where information will not change before the end of the event or trial, it may be entered in advance. Examples include the Field Research Director's name and address on the personnel form (1A), or the name and address of the residue lab (8A). For more information on templates see SOP # 7.2.

11. If a particular form or section of the form does not apply to the trial, or a customized form is being used, 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.

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

15. The narrative portion of the forms shall be used to summarize the activity or to explain anything that is unusual. If the space provided is not sufficient to adequately describe the activity, an additional, properly identified page 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). Any thing not listed there shall be defined in Part 3 of the FDB. For example: FRD MF = Field Research Director's Master File.

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 # 7.2 for more details.

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

III. Completion and final review of Field Data Books:

1. All forms shall be carefully checked to be certain all categories/blanks are completed and all appropriate data has been collected. The protocol shall be reviewed to be certain that all the necessary information has been provided.

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

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

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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.

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

10. Pagination should not be done until the Field Data Book is complete and has been checked. Paginate within each part of the raw data book separately; be sure to include the Part number (i.e. Part 1, pg. 1, Part 1, pg. 2 etc.). Each form and all pages of supporting data must be paginated, 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 #: **7.2** Revision Number: 1

Submitted by: R.R. Bellinder Effective Date: April 2014

Title: Handling data that transcend two or more trials and certified copies

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

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

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

Procedures:

Data Common to more than one trial:

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

2. This Testing Facility conducts 15 to 20 magnitude of residue trials under GLP's each year. Original data common to all or most of the GLP trials shall be kept in a Facility File. That is, the original raw data shall be placed in the current years Facility File. Certified copies of that data shall then be included in each Field Data Book to which the data pertains. The location of the original shall be cited on each copy. Original data that may be placed in the Facility File includes, but is not limited to:
    a. Original CV's, qualifications summaries, and training records
    b. Chemical storage inventories and temperature logs
    c. Scale/balance service and weight verification documents*
    d. Directions to the test site and plot area*
    e. Soil characterizations and test site histories*
    f. Sprayer equipment diagrams (6B) and equipment logs*
    g. Weather and irrigation records*
    h. Freezer logs, inventories, and temperature logs
    i. Calibration/verification of general equipment such as thermometers, thermographs, wind gauges, pressure gauges, etc. (not application calibrations)

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j. The current original, authorized SOP set, if the SOP set is retained and used for more than one year.

*Might be more appropriately placed in one of the FDB, depending on circumstances – limited number of dry TS, and remote sites with only one or two trials, etc.

Certified Copies

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

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

Templates

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

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

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2. Some FDB forms may be partially filled out in advance, and kept as templates. Because the forms are dated with the trial year, these templates shall be used for only the one year. Examples of these types of form templates are:
   a. The name and address of FRD on 2A.
   b. The directions and map to the testing facility and farm map, if using the forms 5A and B. This information can also be inserted into the FDB as a separate page (see #3).
   c. Calculation formulae in the applications section (e.g., 6 E, F and I). The formulae can also be included as a separate page.

   These templates should be kept in the Facility File and sent for archiving yearly.

   The templates we may use at this site include but are not limited to:

Part 2.A	Part 6.A
Part 4.A	Part 6.B
Part 4.C	Part 6.C
Part 4.D	Part 6.D
Part 5.A	Part 6.E
Part 5.B	Part 6.F
Part 5.D	Part 6.J

3. As with templates, some actual data, such as soil texture, is used for more than one year. In this case, the original soil texture analysis shall be kept in the FRD MF (Field Research Director's Master File). **This data shall be archived for the life of the registration supported by the data. As this location does not maintain an archive, the Field Research Director shall take full responsibility for ensuring that the original shall be sent to IR-4 Headquarters each year and an exact copy kept.**

4. Long or complex narrations may be prepared on a computer, as a type of template. An example of a template narrative would be the description of the sample harvest and/or modifications to the harvested crop where the researcher has multiple trials and does the same crops yearly, for example summer squash. The description can be written before or after the event. If written after the even, it shall be written immediately (within 24 hours) of the event. If prepared in advance, the description shall be reviewed after the event and modified, as necessary, to insure that it accurately reflects what was done. The narration shall only be printed after the event, when the information has been reviewed. When printed, the page shall be initialed and dated to verify that the information is accurate and complete. The narrative portions of the forms shall then be crossed out and the separate narration referenced. The narrative templates used at this site include but are not limited to: harvesting, sampling, directions to test site, procedure used to check discharge calibration.

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SOP #: 7.3 Revision Number: 1

Submitted by: Robin R Bellinder Effective date: April 2014

Title: Collection of raw data electronically.

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

Scope: All locations conducting GLP field trials.

Procedures:

1. All remote sensing and other automatic data collecting and/or recording devices shall be inspected and verified as described under SOP# 6.4 and 6.5

2. Check the power supply on portable units to see that it shall be adequate during the data collection and data transfer period.

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 #: **7.4** Revision Number: 0

Submitted by: Robin R Bellinder Effective date: April 2011

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

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

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

Procedures:

All original raw data supporting the registration of a pesticide use pattern shall be retained in the archives in-perpetuity as specified in the GLP Standards Subpart J, Section 160.195. This Testing Facility does not maintain an archive, all data 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

Active life of the trial:

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

2. The protocols, Field Data Books and supporting data shall be stored in limited access area (locked office) during the active life of the trial. The current Facility File and the Field research Director's Master File shall be stored with the Field Data Books during the season. The locked room is of sufficient size to contain all active records and data generated during the season. The room is in close proximity to the field and available for the Field Research Director or technician responsible during the conduct of the trials. Two offices are in use for this purpose the addresses are:

   H.C. Thompson Vegetable Research farm, Room#9, Freeville, NY, 13068 (during the growing season) and

   Plant Science Building, Room#148, Cornell University, Ithaca, NY, 14853 (before and after the growing season)

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

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f. Communications including e-mails, phone logs and other correspondence related to the trial

4. The Field Research Director or designated personnel shall make a copy of the completed original Field Data Book. This entire copy shall be certified as a true copy by the initialed and dated certification stamp on the title page. 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.

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

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

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

Facility File:

1. Once all the Field Data Books have been completed, the original raw data in the Facility File shall be sent to IR-4 Headquarters for Archiving. One certified copy of the Facility File shall be retained by the Field Research Director, a second copy shall be sent to the Regional Field Coordinator. The Facility File may include, but not be limited to:
    a. The current original authorized SOPs.
    b. The original signed and dated CVs and training records of personnel involved in the conduct of any GLP trials during the year.
    c. The personnel records of any personnel no longer involved in the project.
    d. Original Organizational Charts and floor plans being retired, as new ones are generated.
    e. Any Test Substance inventories and logs not place Field Data Books.
    f. Chemical and frozen residue sample storage temperatures.
    g. Irrigation records, weather data and soil analysis information.
    h. Personnel records of current employees engaged in GLP work.

Field Research Director's Master File:

1. Testing facility information required under GLP/FIFRA, but not required to be included in the Field Data Book, shall be kept in a FRD's Master File. Information may remain in the FRD's Master File for more than one year, as long as it is not revised. Data that may be placed in the FRD's Master File includes, but is not limited to:
    a. Organizational charts and floor plans,
    b. Soil Texture analysis
    c. Production guides used for the GLP trials. Retired guides shall be archived as they are replaced with newer edition.

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

3. It is the responsibility of the Field Research Director to ensure that any data that supports the registration of a pesticide is archived. Therefore, any data kept in the FRD's Master File shall be sent IR-4 Headquarters for archiving if any changes occur.

4. FRD's Master File shall be stored in locked offices with current FDB's.

Historical Files

1. IR-4 historical records shall be maintained by the Field Research Director or designated personnel. These records shall include, but are not limited to certified copies of:
    a. Retired Organizational Charts, floor plans and other facility information from FRD's Master File sent to IR-4 HQ
    b. Previous years Field Data Books
    c. Previous years Facility Files.

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

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

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SOP #: **8.1** Revision Number: 0

Submitted by: R.R. Bellinder Effective Date: April 2011

Title: Procedures to follow prior to an EPA inspection

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

Scope: All locations conducting field trial(s)

Procedures:

1. Notify the Study Director, Quality Assurance Officer, Regional IR-4 Field Coordinator and other interested personnel of the pending audit or review as soon as possible.

2. Arrange to have available the Field Research Personnel who may be associated with the trial(s) or facilities audit.

3. Make sure that the Field Research Director or personnel authorized to accept the Notice of Inspection shall 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 every one understands what to expect.
    c. Request personnel to answer the questions only to the extent needed and not to provide extraneous/additional information. Do not volunteer information; keep answers direct and to the point.
    d. Make certain that technical personnel know the safety precautions needed for the work area.
    e. Be certain that all documents pertaining to the trial(s)/facilities inspection are available, including:
        i. Study Protocol and Standard Operating Procedures
        ii. Raw data, correspondence and logs (certified copies are acceptable).
        i. Training records, CVs, job descriptions, etc. of personnel assigned to the trial(s) at the time of the trial conduct.
        ii. Appropriate chain of custody documents for samples and freezer logs and storage temperature documentation.
        iii. Documentation of the characterization of the test substance, receipt, and handling, and storage records (obtainable from IR-4 Headquarters).
        iv. Calibration logs on equipment, such as balances and application equipment.
        v. Master schedules for both the Field Research Director, Quality Assurance Unit Officer and possibly their counterparts at the regional and IR-4 headquarters.
        vi. Archives or storage of records and logs indicating removal and replacement of documents.

5. Have accessible signed and dated organizational charts, a map of the facility and any information specific to the facility or area that shall make the inspection go smoother.

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SOP #: **8.2** Revision Number: 0

Submitted by: R.R. Bellinder Effective Date: April 2011

Title: Procedures to follow during an EPA inspection

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)

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 shall accept the Notice of Inspection.

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

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.

4. 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 #: **8.3** Revision Number: 0

Submitted by: R.R. Bellinder Effective Date: April 2011

Title: Procedures to follow after the EPA inspection

Purpose: To provide guidance to study personnel after receiving a request for an EPA audit or review by OCM

Scope: All locations conducting field trial(s)

Procedures:

1. Make sure that all personnel involved in the inspection are present for the closeout conference, if possible.
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 noted in the inspector's logbook
4. Have someone present during the closeout 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 timely replies to the regulatory agency as necessary, and keep interested parties, such as management and the Study Director, apprised.