SOP Log Sheet

ID # S00283

Region: NER

State: NJ **City:** Pittstown

Location: NER Field Snyder

FRD/LRD: Fisher
Submitter

Effective Date: 2/5/21

Description of Material (s): 2021 SOPs

Reviewed By: Julie Thomas 3/10/21
Sign/Date

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Sign: [signature]

Comment:

S: Facility Files- SOP Cover Sheet

9/13/16 JT

Juliet Thompson

From: Marylee Ross <mross@umd.edu>
Sent: Thursday, February 25, 2021 3:41 PM
To: Juliet Thompson; Jane Forder; Johanna Mazlo (NCSU IR-4)
Cc: Megan James
Subject: 2021 SOPs for Jennifer Fisher
Attachments: 2021_02_25_15_23_34.pdf; Fisher SOPs Feb 2021 (1).pdf

Hi Juliet,

Attached are Jennifer Fishers SOPs for 2021. The full set does not have the signatures on the cover page. The signed cover page is a separate attachment.

Thank you for taking good care of us :)
marylee

--
Marylee Ross
IR4 NE Region Coordinator/Field Research Director
University of Maryland, LESREC
27664 Nanticoke Road
Salisbury, MD 21801
410-742-8788 ext. 310

STANDARD OPERATING PROCEDURES

FOR

MAGNITUDE OF THE RESIDUE STUDIES

CONDUCTED UNDER GOOD LABORATORY PRACTICES

Jennifer Fisher
Rutgers University
Snyder Research and Extension Farm
140 Locust Grove Road
Pittstown, NJ 08867

Revision No.: 5

Effective Date: February 15, 2021

Field Research Director: Jennifer Fisher _____ (Signature) JF (Initials) 2/16/21 (Date)
Jennifer Fisher

Approving Official: Marylee Ross _____ (Signature) ML (Initials) 02/15/21 (Date)
Marylee Ross
NE Regional Field Coordinator

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

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

Effective Date: March 15, 2017 Revision Number: 1

Author: Jennifer Fisher

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 GLP field studies under the IR-4 Project

Procedures:

1. This facility shall develop 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 on a yearly basis and revised as needed. The SOPs shall be reviewed by the Field Research Director (FRD) or assigned personnel, and approved by the Regional Field Coordinator (RFC).

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 RFC 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 FRD 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 (SD). Please note that copies of approved SOP deviations are generally not returned to the 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 may be reactivated by the addition of a procedure statement to that effect, indicating the date of reactivation. In rare cases, SOPs may be retired/inactivated, with some or all of the points incorporated into other SOPs. In that case, a statement to that effect shall be placed behind the revision number with the date and SOP into which the points have been incorporated.

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

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

9. Each SOP page shall contain the FRD's name, the number of the SOP, and the page number. The revision number is included after the SOP number. This identification shall be located at the bottom of the page. For example:

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SOP #1.2 **Numbering system for SOPs**

Effective Date: April 22, 2016 Revision Number: 0

Author: Jennifer Fisher

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

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

Procedures:

The numbering system for SOPs by section is as follows:

1. General
2. Personnel
3. Test Substance and Pesticide Handling
4. Equipment and Calibration
5. Agronomic Practices
6. Residue Sample Handling
7. Data Handling
8. EPA Audit Procedures

Each SOP within a section shall be numbered sequentially in the suffix, for example: 1.1, 1.2, 1.3, etc. This allows for the addition of new SOPs to the section to which they pertain.

Some common abbreviations used in these SOPs are:

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

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

Effective Date: April 22, 2016 Revision Number: 0

Author: Jennifer Fisher

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

Scope: Applies to all SOPs developed by FRD for use in GLP trials

Procedures:

Name of Test Facility (centered)
Address (centered)
Space
SOP Number: (General category section number of individual SOP) followed by Title
Space
Effective Date: (Date when SOPs take effect, can be date of approval) then
Revision Number: (sequential beginning with 0 for new SOPs) on same line
Space
Author: (Name of person developing the SOP, not always the FRD)
Space
Purpose: (Brief description of the purpose of the SOP)
Space
Scope: (Determines where and when the SOP is applicable)
Space
Procedures: (Describe the operating procedures in numerical order from beginning to end so that an intelligent person with knowledge of the process can carry out the procedures without any verbal input from other sources.)

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

Effective Date: March 16, 2020 Revision Number: 1

Author: Jennifer Fisher

Purpose: To provide information on how a FRD is designated and outline their responsibilities

Scope: IR-4 Project GLP Trials

Procedures:

1. The FRD is designated by the SD, based on the recommendation of the RFC. The FRD 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 RFC shall work with Rutgers University Snyder Research and Extension Farm (RUSREF) personnel to provide a replacement or ensure the completion of ongoing trials.

2. The FRD has the responsibility for the following:

    a. Ensure that the GLP trials are carried out according to an approved protocol signed and dated by the SD.

    b. Ensure 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 RFC, Quality Assurance Officer (QA), SD, and/or lab personnel on important critical phase dates and events. Coordinate in-life inspections with QA.

    e. Ensure that all comments/questions from the QA, RFC, and SD are responded to in writing or direct contact (telephone, e-mail, etc.).

f. Ensure all raw data, summaries and other items connected with the GLP research are transferred to IR-4 HQ for archiving.

g. Maintain certified copies of the FDB until the data are submitted to the U.S. Environmental Protection Agency (EPA).

h. Maintain a file of current resumes, job descriptions and training records for all key personnel engaged in the trial. Ensure the information is archived at IR-4 HQ when personnel leave or other changes occur.

i. Ensure that a copy of the Master Study Schedule for all GLP projects under his/her direction is maintained in a file at the facility. This schedule is available on the IR-4 web site, or may be generated by IR-4 HQ.

j. Designate trial locations for the facility and ensure that crops are established, grown, and maintained under good agricultural practices.

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SOP #2.2 **Personnel**

Effective Date: April 22, 2016 Revision Number: 0

Author: Jennifer Fisher

Purpose: To provide information to personnel concerning requirements under GLP

Scope: All personnel working on research under GLP at this facility

Procedures:

1. The field test facility shall have on file information for each person currently supervising any phase of a MOR trial, and collecting and/or entering data under GLP. The information shall include a current summary of the experience and training of the worker, as well as a brief description of their duties or responsibilities. Each person so engaged in the conduct of trials shall have read and understood those sections of the protocol and SOPs that pertain to their responsibilities. Documentation of training adequate to complete the task under GLP is sufficient for personnel assisting in GLP activities under close supervision. In the latter case, the FRD or designated personnel shall record the names of the personnel and the dates that the SOPs or task were explained to them. This information shall be placed in the personnel file and sent to IR-4 HQ for archiving as needed. Alternately, the documentation can be placed directly in the FDB to which it pertains.

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

3. Personnel handling pesticides shall be trained in accordance with the current policies and guidelines of their institution, or see SOP 3.10.

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 RUSREF regulations, pesticide labels or the trial protocol.

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140 Locust Grove Road
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SOP #2.3 **Documentation of training**

Effective Date: April 22, 2016 Revision Number: 0

Author: Jennifer Fisher

Purpose: To ensure that training for personnel involved in GLP research is properly documented

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

Procedures:

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

2. All other training shall be documented in some form of training log.
   a. Training received from workshops, conferences, etc. shall be noted. Include the name of the person, the event and the dates attended. A copy of any type of training certificates issued shall also be retained in the personnel files at the location.

   b. Any form of verbal instruction shall be documented in writing and placed in the personnel files to show that the person received on-the-job training to conduct the task. Record the name of the person giving the instruction, the name of the person receiving the instruction, the date given and a concise statement of the instruction (i.e. Dr. X explained to Mr. Y how to label the sample bags as per SOP xx on 6/2/93).

3. Each person engaged in the conduct of the trial (i.e. collecting or entering data) shall have read and understood those sections of the protocol and the SOPs that pertain to their responsibilities. The FRD shall record the names of the personnel and dates that the SOPs were explained to them. This information shall be placed in the personnel file.

4. For personnel who are not collecting and/or entering data, but who might have an impact on the trial (for example casual labor involved in the harvest), a general statement of oral or written training by the FRD or designated supervisor shall be sufficient. The document shall be placed directly into the FDB to which it pertains.

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

6. The original CV or resume shall be included in one of the FDBs for each given year. Alternately, the originals may be submitted in the Common Data Book (CDB) for the testing facility.

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

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SOP #2.4 **Organizational chart**

Effective Date: April 22, 2016 Revision Number: 0

Author: Jennifer Fisher

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

Scope: All field test sites conducting GLP trials for the IR-4 Project

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), SD, (individual responsible for the overall conduct of the study), QA, Testing Facility Management (RFC in the case of IR-4) and Testing Facility (person who actually uses the test substance in the test system = the IR-4 FRD).

   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 HQ in the CDB each year.

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140 Locust Grove Road
Pittstown, NJ 08867

SOP #3.1 **Test Substance receipt and handling**

Effective Date: March 15, 2018 Revision Number: 1

Author: Jennifer Fisher

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

Scope: All GLP Test Substances for MOR field trials

Procedures:

1. Arrival of GLP Test Substance (TS) shall be checked for on a daily basis. When a TS is received, the product shall be unpacked, checked, and placed directly into the IR-4 pesticide cabinet in the pesticide storage building.

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

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

4. All TS containers shall be properly labeled with, at a minimum, the name of TS/active ingredient, lot/batch number, expiration date, and storage conditions. (See IR-4 Advisory #2003-04) The person receiving the TS shall add any missing information to the label. If more than one container of TS is received, each container shall be identified with the Field ID # or other unique identifier (i.e.: Container 1 of 2). The container of product used shall be clearly identified in the FDB.

5. The unique identifier used to identify a TS is the Field ID number.

6. Arrival information shall be recorded on the chemical inventory, and shall include, at a minimum, the name of the TS or active ingredient, batch/lot number, date of arrival, unique identifier when used, and the initials of person recording the information. Current pesticide inventory records shall be maintained by the FRD and kept in the IR-4 office.

7. All GLP TS are stored in a locked cabinet (IR-4 pesticide cabinet) within the limited access pesticide storage facility. Authorized IR-4 personnel shall have keys to this area.

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

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

When Test Substance is capitalized it is referring to GLP characterized material.

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140 Locust Grove Road
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SOP #3.2 **Storage of GLP Test Substance**

Effective Date: March 16, 2020 Revision Number: 3

Author: Jennifer Fisher

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

Scope: All GLP TS

Procedures:

1. TS shall be stored in accordance with current policies and guidelines of the institution. All unused TS including empty containers shall be returned to the storage facility at the completion of their use.

2. All TS containers shall be retained until the trial in which the product was used is submitted to the EPA, the trial dropped, or the study cancelled. See SOP 3.11 for detailed information on container disposal.

3. The RUSREF pesticide storage facility is a separate building from offices and laboratories and maintained in accordance with Rutgers University guidelines. The facility is dry, well ventilated, and temperature controlled with heaters to prevent freezing and ventilation fans to prevent overheating. The entire pesticide storage facility is locked and accessible only to authorized farm staff.

4. Storage conditions shall be monitored using a uniquely identified and verified HOBO data logger from the time the TS is placed in the cabinet until after the final application has been made. The HOBO shall be monitored periodically and downloaded and re-launched monthly. A uniquely identified and verified min/max thermometer shall be used as back-up, and the temperatures recorded in the event of a failure of the HOBO data logger.

5. The TS shall then be stored in the pesticide storage facility until it is needed for use in the trial. The storage conditions of the TS shall be recorded in the FDB or provided in other documents. Storage information shall be added to the label, if not included on original label. The SD shall be notified immediately upon determining the storage conditions were not within the label's recommended storage limits.

6. A log shall be kept on the contents of the storage facility indicating when a TS is removed and when it is returned to the facility, along with the purpose for which it is removed. This log shall be called the "Pesticide Removal Log".

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

8. The telephone numbers and names of personnel responsible for and knowledgeable of the contents of the storage facility are posted on a bulletin board outside the east door of the pesticide storage facility.

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

10. Steps in the mixing and handling of TS shall be taken to ensure no cross-contamination occurs. These measures shall include, but are not limited to: using clean paper or plastic on the counters; a new plastic tray to weigh out each TS; a new syringe/pipette or clean graduated cylinder for liquid measurements.

11. TS shall be stored in a manner to prevent any possibility of contamination, deterioration, or damage during the conduct of the trial.

12. Excess TS not used for study purposes may be logged out and used, once the last application has been completed. The product shall be used by trained personnel for maintenance (labeled uses) or experimental purposes at the discretion of the FRD or research personnel. The removal of the TS shall be noted on the Pesticide Removal Log. The container shall be retained until disposal is authorized (SOP 3.11).

13. This location does not ship hazardous chemicals. As a result, no TS shall be returned to the registrant, even if required in the protocol. In this case, a protocol deviation shall be written.

14. If the TS container is transferred to someone else (another testing facility, the registrant, etc.) the name and address of the new storage facility shall be documented in the chemical log.

15. Adjuvants used for GLP TS applications shall:
    a. be stored in accordance with current guidelines
    b. have a label, and the label shall be included in the FDB
    c. be designated to the IR-4 trials
    d. assigned an expiration date of 5 years after the purchase date
    e. once expired, new adjuvant shall be purchased and remaining material shall be transferred to farm maintenance program.

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

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140 Locust Grove Road
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SOP #3.3 **Calibration and use of an electronic scale used to weigh GLP Test Substances**

Effective Date: March 15, 2017 Revision Number: 1

Author: Jennifer Fisher

Purpose: To ensure accurate weighing of dry TS formulations

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

Procedures:

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

2. As soon as possible after servicing the scale, 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 certified copies of the information included in the FDB of all trials where needed, along with a copy of the service certificate. The original raw data shall be forwarded to IR-4 HQ with the CDB.

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

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

5. TS shall be weighed on a new plastic tray, or other clean weighing container. Appropriate safety equipment shall be selected and worn or used while handling pesticides. TS shall be weighed in a tared tray or container. Small quantities of excess may be returned to original pesticide container, if this procedure does not affect the integrity of the contents. Disposal of large quantities of excess shall be handled by using appropriate methods for hazardous wastes.

6. If taring the container is not possible, the weight of the container shall be recorded before adding the desired amount of pesticide to be weighed.

7. The contents of the weighing tray shall be washed into the sprayer using some of the measured carrier to ensure all the product is added to the tank. If using a container, make a slurry of the TS with the carrier before adding it to the tank. Triple rinse the container into the tank using a portion of the measured carrier.

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

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SOP #3.4 **Measuring a liquid pesticide formulation**

Effective Date: April 22, 2016 Revision Number: 0

Author: Jennifer Fisher

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

Scope: All liquid formulations of GLP pesticides

Procedures:

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

1. For most applications, a disposable syringe or pipette shall be used to measure the liquid. Select a syringe/pipette large enough to hold the volume of pesticide needed for the treatment, but small enough to measure the needed TS at an accuracy within +/- 5% of the total volume.

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

3. If the liquid cannot be removed from the container directly with the syringe or pipette, pour an adequate amount into a clean beaker or other container. Returning the unused product to the original container is not recommended as it may result in contamination of the TS.

4. A graduated cylinder may also be used to measure liquid TS. Use cylinders that typically have graduation increments of < +/-5% (e.g., at least 5 ml increments for a 100 ml cylinder) that is acceptable for GLP trials. Reusable cylinders shall be washed with ammonia then triple rinsed with clean water after each use to ensure that the cylinder is clean and cross-contamination shall not occur with future use.

5. The liquid TS is placed directly into the spray tank. Make sure that as much as possible of the liquid is transferred to the spray tank. If using a graduated cylinder or alternate container, triple rinse it into the spray tank.

6. 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 TS is used for more than one trial, all records must be maintained on a single log. The original shall be placed in the book for one trial and an exact copy for the other trial.

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SOP #3.5 **Adding pesticide concentrate to the water carrier in a spray tank**

Effective Date: March 16, 2020 Revision Number: 3

Author: Jennifer Fisher

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

Scope: All locations conducting GLP field trials

Procedures:

1. After the sprayer has been inspected and calibrated, empty the water from the tank. Open the sprayer lid. Measure the amount of water needed to dilute the measured amount of concentrate (based on the specific application calculations). Make sure the spray mix will be enough to cover the entire plot plus sufficient overage to ensure uniform coverage. If the plot is too large, the application may be made with two (or more) separate tank mixes, one for each subdivided area of the plot. Make sure the spray tank holds the entire mix (carrier, TS and adjuvant where required) needed for the area to be sprayed.

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

3. For dry formulations it is recommended to first make a slurry mix. Make the slurry by adding a small amount of carrier water to the concentrate and mixing 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 the rinse water to the spray tank.

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

6. Add adjuvants, when indicated, after all pesticide products have been added.

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

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

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140 Locust Grove Road
Pittstown, NJ 08867

SOP #3.6 **General procedures in the mixing and application of pesticides**

Effective Date: April 22, 2016 Revision Number: 0

Author: Jennifer Fisher

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

Scope: All locations where pesticides are applied

Procedures:

1. All personnel involved in the mixing, application, storage and cleanup of pesticides shall possess a current New Jersey Commercial Pesticide Applicator's License.

2. Equipment used in the application of the pesticides shall be inspected and calibrated as indicated under SOP 4.1.

3. Personnel mixing and applying the pesticide shall wear appropriate protective clothing as stated on the pesticide label or as indicated under SOP 3.10.

4. The pesticide concentrate shall be measured out as indicated under SOPs 3.3, 3.4 and 3.5.

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

6. If the pesticide application involves the TS, then procedures for handling the TS as indicated in SOPs 3.3, 3.4, and 3.5 shall also be followed.

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SOP #3.7 **Procedures for the application of the Test Substance(s) in the field**

Effective Date: April 22, 2016 Revision Number: 0

Author: Jennifer Fisher

Purpose: To ensure that the TS(s) are applied uniformly to the plots

Scope: All GLP field trials at this location

Procedures:

1. Application equipment shall be inspected and calibrated as described under SOP 4.1. Make sure all settings for pressure, speed, etc. are the same as those used in the calibration as previously performed.

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

3. Follow protocol for maximum wind speed during spray operation. Measure wind speed and direction 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).

4. Adjust the boom height and position.

5. 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.

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

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

8. 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 overplanting, designated non-crop area, or according to current policies and guidelines of the research testing facility.

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

10. Dispose of excess tank mix and clean equipment as described in SOP 3.8.

11. Collect any additional information for each application, if required by FDB and/or protocol.

12. 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.

13. The SD and/or RFC shall be informed of any events that might affect the integrity of the trial.

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SOP #3.8 **Cleanup of application equipment**

Effective Date: March 16, 2020 Revision Number: 2

Author: Jennifer Fisher

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

Scope: All locations where pesticides are used under GLP

Procedures:

1. All personnel involved in the mixing, application, storage and cleanup of pesticides shall possess a current New Jersey Commercial Pesticide Applicator's License and be properly trained.

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

3. Excess pesticides, pesticide rinse water, and other dilute pesticide waste shall be disposed of in the field per label directions or applied to non-crop area of field. After triple rinsing in the field, spray tanks shall then be washed with ammonia and triple rinsed. Hoses and nozzles shall be flushed with ammonia wash, then clean water, then air.

4. Disposable protective clothing items shall be placed in a container for incineration or landfill. Chemical resistant suits may be reused if not damaged or contaminated. Non-disposable items shall be cleaned with soap or ammonia and water as appropriate.

5. Once application equipment is dry, it shall be maintained per manufacturer's instructions and the equipment returned to storage.

6. Cleanings, calibrations, lubrications, etc. shall be recorded in the sprayer maintenance log.

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SOP #3.9 **Procedures to follow when a problem occurs in the application of the Test Substance**

Effective Date: April 22, 2016 Revision Number: 0

Author: Jennifer Fisher

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

Scope: All GLP TS applications

Procedures:

1. During application, the applicator shall observe the process to make sure that the TS 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. Stop immediately, turn off the boom, and pause/stop the stopwatch.

3. The affected portion of the plot shall be carefully marked off and staked to indicate the area affected. This portion shall not be used for obtaining samples of the commodity for residue analysis.

    a. If mixing and applying another tank of spray to the unsprayed area of the plot can save a trial, document the activities as if it were another treatment. Clearly explain what was done and where, to ensure no problems arise, such as a double application. If not sure if this is a legitimate resolution, contact the SD or RFC.

    b. If the unaffected area is too small to obtain the samples required for analysis, then contact the SD immediately for the decision whether or not to discontinue the trial.

4. The SD, RFC, and other appropriate individuals shall be notified immediately of the incident, and details shall be recorded in the raw data notebook.

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

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SOP #3.10 **Handling pesticides safely**

Effective Date: April 22, 2016 Revision Number: 0

Author: Jennifer Fisher

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

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

Procedures:

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

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

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

4. Appropriate weather conditions for the application of the pesticide shall prevail; otherwise the pesticide applications shall be delayed. For example, applications shall not be made if wind speed is excessive.

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 overplanting of the commodity or non-crop area. The equipment shall be washed off both inside and outside and all pesticides and pesticide containers shall be returned to the 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 should be posted. If the protocol requires reentry before the labeled REI, proper protective measures shall be taken as per the label. For persons who regularly handle organophosphates and/or large quantities of carbamates, cholinesterase levels shall be monitored throughout the pesticide application season.

9. Unauthorized persons shall not be permitted in the pesticide storage area.

10. Pesticides shall not be stored 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. Unlined chemical resistant gloves shall be worn while handling containers and mixing or measuring pesticides.

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

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

15. Plots shall be marked with labels that include the trial ID #, active ingredient, target crop, and treatment number.

16. Pesticide storage areas shall be properly ventilated.

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SOP #3.11 **Disposal of pesticides**

Effective Date: April 22, 2016 Revision Number: 0

Author: Jennifer Fisher

Purpose: To ensure the TS 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 where institutional guidelines for disposal of pesticides do not exist

Procedures:

1. The containers for GLP TS used in support of an EPA tolerance shall be retained at the facility until the data package is submitted to the EPA, the trial dropped, or the study cancelled.

    a. Excess TS can be used in other crops, once the applications are completed, as long as the product is registered in that crop and the container is retained. If the TS 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 IR-4 Advisory #2005-01).

    c. Notification many also be sent by the RFC, SD, 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 (IR-4 Advisory #2003-02).

    d. Container disposal is NOT acceptable if the TS from the same container was also used in another study, and that study has not yet been canceled or completed.

2. When disposing of pesticide concentrates or containers, personnel shall follow current policies and guidelines of their institution. Where institutional guidelines do not exist, the following procedures shall be followed. This applies to the TS only when permission has been received from the SD.

    a. Follow label directions for disposal of the pesticide.

    b. If no label directions exist for disposal, arrangements shall be made with Rutgers Environmental Health and Safety (REHS) for pickup and disposal of the pesticide and/or the empty containers.

3. When the TS or container is disposed of, an entry shall be made in the chemical inventory, logging out the product and/or container. These records shall be retained and archived.

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

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

    b. Dispose of the dilute pesticide waste and rinse water in the field by spraying on an overplanting of the crop where this procedure does not violate any laws or regulations. Excess dilute pesticide solutions may be applied to non-crop areas for disposal. All pesticide solutions shall be mixed with the intent of limiting the problem of excess solutions.

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SOP #3.12 **Storing and maintaining adjuvants**

Effective Date: February 15, 2021 Revision Number: 1

Author: Jennifer Fisher

Purpose: To define procedures for receiving and storing adjuvants for use in IR-4 GLP studies

Scope: All GLP field studies under the IR-4 Project requiring an adjuvant

Procedures:

1. GLP labeling requirements for reagents (i.e. adjuvants, spray additives) are: name, concentration, lot or batch number if available, storage conditions, date of purchase or initial opening of the container and expiration date.

2. Spray additives shall be stored in a location that has limited access and is temperature monitored.

3. Spray additives shall 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:

    a. Spray additives shall be dispensed into a temporary container (such as a beaker) prior to being used in a GLP residue trial. The spray additive, once dispensed, shall not be used for a different trial or returned to the original or secondary container; it shall be discarded.

    b. Spray additives shall be dispensed from the original or secondary spray additive container using a newly opened factory sealed syringe or pipette. After this syringe or pipette is used, it never returns to the spray additive container, is discarded and never used again. The TS is also dispensed by a different newly opened syringe or pipette, discarded after use.

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SOP #4.1 **Calibration and application with a CO_2 backpack or tractor-mounted boom sprayer**

Effective Date: February 15, 2021 Revision Number: 4

Author: Jennifer Fisher

Purpose: To provide accurate and documented application of TS using CO_2 backpack or tractor-mounted boom sprayers

Scope: All GLP trials where a CO_2 backpack or tractor-mounted boom sprayer is used

Procedures:

Calibration

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

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

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

4. All sprayers used for GLP trials shall have a pressure gauge. Sprayer pressure gauges shall be observed throughout the season for consistent readings. Observe the pressure reading when uniform discharge from all nozzles is achieved. Record the pressure.

5. Measure out the length of the test plot and clearly mark the two ends of that distance with a flag or other such marker.

a. If using a backpack sprayer, establish a comfortable, safe pace to walk that distance with the backpack equipment and spray tank. Make several practice runs and measure the pass times with a stopwatch. Record the time it takes to travel that distance at the desirable pace.

b. If using a tractor sprayer, choose an adequate spray speed and record the length of time it requires to cover the distance. Make several practice runs and measure the pass times with a stopwatch. Record the gear and RPMs used in travelling that distance.

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

7. Do mathematical calculations based on the treated area of the application type (IR-4 Advisory #2004-02). Multiply the calculated carrier needed before overage (ml) by 43,560 sq ft/A, then divide by treated area (sq ft); divide by 3785 (ml/gal) to determine gallons per acre.

8. Choose a rate at which to spray within protocol specifications. If recommended gallons per acre is given in the protocol, adjust walking or tractor speed, pressure, nozzle size or combination thereof until the desired gallonage is collected. A complete calibration (three runs) shall be conducted after any of the above parameters are changed.

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

10. Calculate the amount of TS to add to water. Calculations vary depending on application type. Calculations shall be shown in Part 6 of the FDB.

Application

1. Always wear personal protective equipment. Use the product Safety Data Sheet (SDS) for precautionary information on the active ingredient.

2. Adjust boom height in the field for proper nozzle overlap on the target (soil vs. foliar applications). Boom must be level for uniform application.

3. Monitor the spray pattern visually to ensure uniform coverage.

4. Dilute spray solutions must be uniformly mixed in the spray container.

5. Follow protocol for maximum wind speed during spray operation. If no guidelines are given, winds greater than 6 mph are generally regarded as excessive for a GLP application.

6. The travel time for each spray pass in the treatment plot shall be recorded by the sprayer operator or an assistant. The direction of travel shall be recorded unless otherwise noted. The spray delivery system shall be completely purged with compressed gas to remove the calibration carrier water before the dilute spray solution is applied. Uniform delivery of the dilute spray from each nozzle shall be verified before the sprayer moves into the treatment area. The spray system shall be completely charged with the dilute spray solution before entering the plot.

7. Calculation of the actual rate of TS application shall be based on the total travel time of each spray pass in the plot, the calibrated discharge rate, the area of application and the amount of TS mixed with the carrier to provide the total dilute spray volume at the start of the application.

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SOP #4.2 **Verification of flow meter**

Effective Date: March 15, 2017 Revision Number: 1

Author: Jennifer Fisher

Purpose: To establish procedures used when verifying flow meter

Scope: The SOP is to be followed by IR-4 participating personnel when verifying flow meter.

Procedures:

1. Prior to use, visually inspect the measuring device for cleanliness and that it is in good working condition. Check the power supply (if applicable, batteries shall be replaced when display area begins to dim). Record inspection and any maintenance performed in appropriate logs. Use the following methods or document the methods used in the field data.

2. The flow meter shall be verified once a year. Prior to verification, the flow meter shall be purged of air by turning the system on and dispensing water until the flow stream is full and steady. A calibration container clearly marked with a designated volume, such as 5 gallons, shall be used to catch discharge from flow meter. The flow meter shall be turned on until the desired volume (from display) has been discharged. If meter does not give an accurate reading, it shall be replaced.

SOP HAS BEEN INACTIVATED – March 15, 2017

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SOP #4.3 **Verification and use of temperature measuring devices**

Effective Date: March 16, 2020 Revision Number: 4

Author: Jennifer Fisher

Purpose: To establish procedures used to verify and read temperature measuring devices

Scope: The SOP is to be followed by IR-4 participating personnel when verifying thermometers and other temperature monitoring devices.

Procedures:

1. All temperature measuring devices used for GLP trials, including, but not limited to, mercury and min/max thermometers and electronic devices shall be identified by a unique number or code. The identification number or code shall be placed on the measuring device such that it can easily be cross-referenced to verification log records. If the device breaks or is otherwise retired, its fate shall be recorded and the unique identifier not used again. Records of devices shall be maintained in a log.

2. Prior to use, visually inspect the measuring device for cleanliness and to determine that it is in good working condition. Check the power supply (if applicable, batteries shall be replaced when display area begins to dim). Record inspection and any maintenance performed in appropriate logs. Use the following methods or document the methods used as raw data. All temperature measuring devices used for GLP trials or equipment associated with trials shall be checked for accuracy at least once a year, either directly, or against a reference thermometer, by a recorded traceable chain.

3. The reference thermometers shall be verified by placing in both an ice bath and warm water bath or in varying air temperature conditions. Temperature readings taken from the reference thermometers may be rounded to whole numbers (e.g. If reference reads 38.2°F, the recorded value shall be 38°F).

4. All other temperature measuring devices (i.e., Min/Max and soil thermometers, electronic data recording units, pocket weather meters, etc), shall be checked against the reference thermometer at two different temperature ranges (such as freezing and room temperature) to verify accuracy.

a. Water Bath Method

If using water bath method, at least two water baths shall be used for verification of reference thermometers and/or other temperature measuring devices. Examples of temperature ranges to test may include:

i. Boiling (212°F)
ii. Warm (approx. 104 to 131°F)
iii. Room temperature (approx. 70°F)
iv. Ice (approx. 32°F)

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

b. Air Method

If using air method, at least two air temperature conditions shall be used for verifying reference thermometers and/or other temperature measuring devices. Examples of temperature ranges to test may include:

i. Warm, i.e. 104 to 120°F (drying oven may be used)
ii. Room temperature (approx. 70°F)
iii. Cool, i.e. 42 to 50°F (refrigerator may be used)
iv. Cold, i.e. 23 to -4°F (freezer may be used)

5. The temperature measuring device(s) and the reference thermometer shall remain in the verifying environment until a constant reading is reached. When the analyst feels confident that the reading(s) is constant, the values shall be recorded in the pertinent log(s). The following information shall be documented:

a. date of verification
b. initials of person doing verification
c. reference thermometer reading
d. temperature measuring device reading
e. Identification (ID) or code number of the thermometer/measuring device being verified

6. If the reading of the device being verified is ± 2°F of the reference thermometer reading, no temperature adjustment shall be made. If the reading is more than ± 2°F in relation to the reference thermometer, the proper adjustment shall be made or the instrument retired. For example: If the thermometer reads 20°F and the reference reads 23°F, the adjustment would be + 3°F at 20°F. When this thermometer is used, the individual would add 3°F to the 20°F observed reading and 23°F would be recorded as the temperature reading.

7. Remedial action to be taken in case of failure or malfunction shall include immediately reporting any problem to the FRD or designated personnel, documenting, and placing in the records for non-routine procedures. Any repairs or replacements resulting from malfunction during application shall be documented as non-routine maintenance in the appropriate log(s). The loss or replacement of a measuring device shall be documented and the log for that device sent for archiving.

8. Designated personnel currently operating the equipment are responsible for the maintenance and remedial action taken in case of malfunction.

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SOP #4.4 **Verification and use of wind speed and relative humidity measuring devices**

Effective Date: April 22, 2016 Revision Number: 0

Author: Jennifer Fisher

Purpose: To establish procedures used when verifying wind speed and relative humidity measuring devices

Scope: The SOP is to be followed by IR-4 participating personnel when verifying and using wind speed and relative humidity meters.

Procedures:

1. Prior to use visually inspect the measuring device for cleanliness and that it is in good working condition. Check the power supply (if applicable, batteries shall be replaced when display area begins to dim). Use the following methods or document the methods used in the field data.

2. Use: Just prior to application, check the wind speed in the area to be treated. The measurement shall be taken 2 to 3 ft above the nozzle height when using a boom sprayer. If using an air blast sprayer, measurement shall be taken 5 to 6 ft above the soil surface. Record the wind speed as raw data.

3. Verification check: The wind speed meter shall be verified for accuracy once/year. Two or more measuring devices shall be read side by side under conditions appropriate to the intended use to verify their accuracy. Record the reading from each unit as raw data. If the measured speeds from each unit are within ± 2 mph of each other, then each unit is reading accurately and is acceptable for use. If the measured speed from the units differ more than ± 2 mph, then the units need to be serviced or replaced.

4. Verification check: The relative humidity meter shall be verified for accuracy once/year. Two or more measuring devices shall be read side by side under conditions appropriate to the intended use to verify their accuracy. Record the reading from each unit as raw data. If the measured relative humidity from each unit is within ± 5% of the other, then each unit is reading accurately and is acceptable for use. If the measured relative humidity from the units differ more than ± 5%, then the units need to be serviced or replaced.

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SOP #4.5 **Verification of pressure gauges**

Effective Date: March 15, 2017 Revision Number: 1

Author: Jennifer Fisher

Purpose: To establish procedures used when verifying pressure gauges

Scope: The SOP is to be followed by IR-4 participating personnel when verifying pressure gauges.

Procedures:

1. Replace every year, or verify as follows. Prior to use visually inspect the gauge for cleanliness and that it is in good working condition. Record inspection and any maintenance performed in appropriate logs. Use the following methods or document the methods used in the field data.

2. Verification check: The pressure gauge shall be checked for accuracy once a year.

3. The pressure gauge shall be verified by recording sequential pressure from the same equipment under conditions appropriate to intended use.

4. If the measured reading from the unit to be verified is within ± 4 psi of the reference meter reading, then unit is reading accurately and is acceptable for use. If the measured reading from the unit to be verified differs more than ± 4 psi of the reference meter reading, then the unit needs to be serviced before future use.

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

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

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

SOP HAS BEEN INACTIVATED – March 15, 2017

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SOP #4.6 **Verification and use of temperature data logger devices**

Effective Date: February 15, 2021 Revision Number: 5

Author: Jennifer Fisher

Purpose: To establish procedures for verification and use of temperature data loggers

Scope: The SOP is to be followed by IR-4 participating personnel when verifying and using data loggers.

Procedures:

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

2. All temperature measuring devices used for GLP studies shall be verified at least once a year directly against a verified thermometer. Records of thermometer verification shall be maintained in a log.

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

4. Data logger(s) to be verified and the reference thermometer shall be placed side by side under conditions appropriate to the intended use. All readings should be within ± 5°F of reference. If a data logger records data outside of that range it shall be deemed inaccurate and not used until appropriate repairs have been made or the unit is replaced.

5. Air Method. At least two air temperature conditions shall be used. Examples of temperature ranges to test may include:

    a. Warm, i.e. 104 to 120°F (drying oven may be used)
    b. Room temperature (approx. 70°F)
    c. Cool, i.e. 42 to 50°F (refrigerator may be used)
    d. Cold, i.e. 23 to -4°F (freezer may be used)

6. The data logger(s) and the reference thermometer shall remain in the verification environment until a constant reading is reached. When the analyst feels confident that reading is constant, the values shall be recorded in the log. The following information shall be documented in the log:

a. date of verification
b. initials of person doing verification
c. reference thermometer number and reading
d. data logger reading
e. Identification (ID) or code number of the data logger being verified

7. If the reading of the data logger is ± 2°F of the reference thermometer reading, no temperature adjustment shall be made. If the reading is more than ± 2°F in relation to the reference thermometer, the proper adjustment shall be made or the unit repaired or replaced. For example: If the data logger reads 20°F and the reference reads 23°F, the adjustment would be + 3°F at 23°F. When this data logger is used, the individual would indicate on the printout to add 3°F to the 20°F observed reading and 23°F would be recorded as the temperature reading.

8. **Launch unit:** Select the duration of time which best suits the use (i.e. 30 ± 5 days for chemical storage cabinet). If provided, in the 'Legend', type in the location of the data logger during use.

9. **Downloading unit**: At the end of the data collection period (30 ± 5 days), the data should be transferred to a storage system and immediately printed out (hard copy). This hard copy shall be retained in a file as raw data. The following information should be included on the printout:

a. date
b. initials of individual conducting the activity
c. data logger ID or code number
d. temperature sensor location at the time of reading(s)
e. units of measurements

10. The hard copy of the data from the data logger(s) should be legible to persons with normal vision. The first and only printing shall by initialed and dated by the person printing it. This shall be used as the original.

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

12. Designated personnel currently operating the equipment are responsible for the maintenance and remedial action taken in case of malfunction.

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SOP #4.7 **Operation and maintenance of freezers**

Effective Date: February 15, 2021 Revision Number: 3

Author: Jennifer Fisher

Purpose: To ensure that freezers are in proper condition so as to maintain integrity of residue samples

Scope: All GLP trials under the IR-4 Project

Procedures:

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

    a. If temperature measured is within the sample storage range, then the unit is approved for use.

    b. If temperature measured is not within the sample storage range, generally below 0°F, then adjust the temperature control until the unit maintains the correct temperature range.

    c. If after adjustment, the unit cannot maintain a temperature range within the sample storage range, then the unit must be serviced by a trained technician prior to use or be replaced.

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

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

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

5. Temperature monitoring devices shall be checked annually using a verified reference thermometer (-40 to 120 degrees F) and deviations shall be recorded. Deviations in excess of 5°F shall be deemed sufficient to adjust or replace recording instrument.

6. In the event of a freezer malfunction, samples shall be relocated to a properly functioning IR-4 designated freezer. If an IR-4 freezer is not available then any alternative freezer free of pesticide contamination shall be acceptable.

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

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

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

8. Designated personnel operating the equipment are responsible for the maintenance and remedial action taken in the case of malfunction.

9. The IR-4 freezers at RUSREF are on a standby generator that comes on automatically in the event there is a power outage. The generator is programmed to run once weekly on Monday at approximately 7:00 a.m. as a test. If there is any malfunction, a code is sent to the control panel. The farm maintenance personnel check the control panel periodically and appropriate action is taken to remedy the cause for any code displayed on the panel. While samples are being held in the IR-4 freezers, the FRD will perform periodic checks of the generator to ensure that it is functioning properly and that there are no error codes. The generator may also be tested manually as needed. The freezer temperature data loggers are checked periodically.

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SOP #4.8 **Operation and maintenance of farm equipment**

Effective Date: March 15, 2017 Revision Number: 1

Author: Jennifer Fisher

Purpose: To ensure that the crop or commodity under study is grown under simulated commercial conditions, in a quantity sufficient for the trial and in a reasonably good state of health

Scope: All studies where the farming operation is under the general guidance of the FRD

Procedures:

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

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

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

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

5. A written record shall be maintained for each piece of equipment used and under the full control of the FRD. This equipment includes, but is not limited to, CO_2 backpack and tractor sprayer booms used to make GLP applications. The record shall contain maintenance dates and what was done, repair dates and type of repair.

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140 Locust Grove Road
Pittstown, NJ 08867

SOP #4.9 **Borrowed or seldom used equipment**

Effective Date: April 22, 2016 Revision Number: 0

Author: Jennifer Fisher

Purpose: To ensure that borrowed or seldom used equipment is in satisfactory working order for accurate applications in GLP studies

Scope: All GLP field trials for the IR-4 Project

Procedures:

1. List the manufacturer, source, age and condition of said equipment.
2. Inspect equipment for obvious problems, i.e. loose connections, cracked hoses, etc.
3. Ascertain, if possible, last known use and document.
4. Clean equipment before use and after each use.
5. If a sprayer, calibrate before use and adjust or replace those parts not functioning properly. Record all actions.
6. Enter dates equipment was borrowed, used, and returned to original source.

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SOP #5.1 **Site selection for GLP field trials**

Effective Date: February 15, 2021 Revision Number: 2

Author: Jennifer Fisher

Purpose: To ensure plots are of suitable design to obtain the required data or samples with sufficient uniformity

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

Procedures:

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

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

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

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

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

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

7. Each plot shall be laid out using a suitable measuring device to accurately locate plots on the site. The length and width of the plot shall be measured.

Measurements shall be made from a permanent field marker to the closest corner of the plot. From there, measurements shall be made from another corner of the plot to a permanent field marker. Buffer zones between plots shall be measured to ensure acceptable space exists between plots.

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

9. The fields involved in GLP field trials at RUSREF shall be identified with a unique field number. The corners shall also be marked with flags so a visual marker is available. The flags shall be replaced when they are worn out or lost.

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

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

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SOP #5.2 **Site selection for established fruit GLP field trials**

Effective Date: March 15, 2017 Revision Number: 1

Author: Jennifer Fisher

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

Scope: Locations conducting GLP field trials

Procedures:

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

2. Site shall simulate commercial conditions and be large enough to accommodate the required number of duplicate samples, buffer zones and treatments in accordance with an approved trial protocol.

3. Locate site with sufficient isolation to minimize contamination from other plots within the same trial, other research trials and/or external sources such as commercial operations. A minimum of 15 feet shall be between plot ends within trials if no other option is possible. For perennial fruit, much larger buffer zones shall be employed when plots are side by side. A protocol change shall be submitted if the buffer zones specified in the protocol cannot be met.

4. Where samples for residue trials are required, locate a second site within the same area but with enough isolation to produce untreated, uncontaminated samples.

5. Prepare a plot map showing the location of each plot on the site with the direction and percent slope and the north azimuth. The plot map shall contain distances to permanent reference points so that the plots can be located after the trial is terminated. Adjacent plots or crops shall be noted. Follow the FDB for further directions.

6. Lay out each plot on the site using an appropriate measuring device to accurately locate the plots on the site, by the distance to a permanent marker, such as irrigation valve, telephone pole, etc. The untreated plot shall be separated from the treated plots by a buffer at least 15 ft. wide, (untreated plots shall be on side predominant winds come from and up slope, if possible).

7. The plot map and a summary of the cultural practices shall be part of the FDB.

8. The soil where trials are to be conducted shall be tested annually for nutrients, pH, and organic matter. The above data shall be recorded in the files for all trials.

9. For soil texture determination, analysis performed up to 15 years prior to the trial shall be considered acceptable.

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SOP #5.3 **Commodity establishment and maintenance**

Effective Date: March 15, 2017 Revision Number: 1

Author: Jennifer Fisher

Purpose: Ensure that commodities are grown under good agricultural practices and provide a uniform crop for trial

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

Procedures:

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

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

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

4. Till the field as specified for the commodity.

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

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

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

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

9. If needed, apply as appropriate, pesticides as specified in the *New Jersey Commercial Vegetable Production Recommendations*, *New Jersey Commercial Tree Fruit Production*

Guide or other applicable resources. Do not apply maintenance pesticides that are not registered for the commodity unless there is no registered product for the pest and approval is granted by the SD. Document application of pesticides.

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

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140 Locust Grove Road
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SOP #6.1 **Residue sample collection and storage**

Effective Date: February 15, 2021 Revision Number: 4

Author: Jennifer Fisher

Purpose: To ensure that residue samples are collected and stored in a proper fashion

Scope: Locations where trials are conducted to obtain GLP samples for residue analysis under the IR-4 Project

Procedures:

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

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

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

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

    a. Project and/or Field ID Number
    b. Commodity (Crop)
    c. Chemical
    d. Sample ID
    e. Date Sampled
    f. FRD: Name/Phone #

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

6. Take special care to do the following in the sample collection process:

   a. Avoid contamination of the field sample with the pesticide under study during the sampling, labeling, storage and shipping processes.
   b. Avoid taking diseased or undersized crop parts.
   c. Take care not to remove surface residues during handling, packaging or preparation.
   d. Be certain tools are clean.
   e. Do not remove any plant parts or trim the commodity unless it is specified in the research protocol.

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

8. Measure samples to determine compliance with the protocols as pounds/sample and/or number of plant parts/sample. A field balance shall be used to weigh samples and shall be maintained in good working order. The field balance will not be maintained under GLP.

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

10. When sample collection is completed, the samples shall be removed from the field and transported in a project vehicle as soon as possible to frozen storage. The project vehicle shall be cleaned or lined with plastic sheeting prior to placement of samples in the vehicle. Maintain separation between treated and untreated samples while in the project vehicle and place immediately into designated freezers. If samples must be held for more than one hour, place samples in a cooler on ice. Separate, designated coolers may be used for the treated and untreated samples. If a single cooler is used, place treated and untreated samples in separate plastic bags to maintain separation.

Prevent water contact with the sample bag and the sample by adequately containing the samples in plastic bags. The samples shall be placed in frozen storage within 2 hours after collection unless samples were collected off station. Separate, designated freezer units shall be used for the treated and untreated samples.

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

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

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

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

15. Each freezer shall be equipped with the Sensaphone 400 Remote Monitoring System. The alarm shall be programmed to call up to 4 phone numbers if the temperature in the freezer rises above 25°F. The alarm shall be programmed to call up to 4 numbers if the power to the freezer fails and remains off for more than 5 minutes.

16. The alarm shall be tested annually just prior to sample storage and may be tested periodically to ensure all functions are operating properly with the following procedures:

    a. The alarm shall be tested for temperature monitoring by removing the sensor from the freezer or otherwise raising the temperature of the sensor (i.e. placing sensor in warm water). After the programmed delay time has elapsed verify that all phone numbers programmed received the call alerting to a temperature rise.

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

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

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

17. The freezers where the samples are stored shall be secure with limited access. At the RUSREF facility there are two upright freezers dedicated to GLP residue samples. They are located in Building 6343. Freezer UT-1 is dedicated to untreated samples. Freezer TRT-1 is dedicated to treated samples. The freezers shall remain locked when not in use and available to authorized personnel only.

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

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

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

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140 Locust Grove Road
Pittstown, NJ 08867

SOP #6.2 **Sample shipping procedures**

Effective Date: February 15, 2021 Revision Number: 1

Author: Jennifer Fisher

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

Scope: All residue samples for GLP trials

Procedures:

1. Prior to shipment of samples, contact the residue laboratory and notify them of the shipment dates and method of shipment including the carrier and carrier schedule. Ask them for any special instructions for shipping the samples. Air freight shipments shall be made early in the week to avoid potential weekend layovers. Notify the designated person from the analytical laboratory and the SD when a shipment date is established. With air shipments, talk directly with lab personnel before shipping.

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

3. The residue samples shall be shipped by freezer truck (ACDS) unless otherwise specified in the protocol or requested by the lab or if ACDS cannot pick up the samples in acceptable time. Use boxes of sufficient size and quantity to hold the untreated and treated residue samples in separate containers. If containers need to be shipped with dry ice, either REHS shall be required to come to the farm or someone from RUSREF shall need to be trained by REHS for the proper procedure for shipping with dry ice.

4. Distribute copies of the Residue Sample Chain of Custody Form to the RFC, Laboratory Research Director and to IR-4 HQ. Include one in each samples box with the shipment. Retain the original form in the FDB. The form shall be signed and dated by the FRD upon transfer of sample to the carrier.

5. Label shipping container with the following information:

   a. Return Name and Address of the sender
   b. Name and Address of the residue laboratory receiving the samples
   c. Number of the container if more than one is used
   d. Where used, affix "Dry Ice" on two sides of container

6. Tape lids of each container firmly in place.

7. Provide carrier with the phone number of the residue laboratory receiving the samples and request the carrier to notify the laboratory when the samples arrive at a remote terminal for pickup where appropriate.

8. Provide the carrier with the samples for shipment.

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140 Locust Grove Road
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SOP #7.1 **Collection and recording of raw data**

Effective Date: February 15, 2021 Revision Number: 5

Author: Jennifer Fisher

Purpose: To ensure that raw data collected and recorded is correct and recorded accurately

Scope: All GLP trials under the IR-4 Project

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 FDB, following a careful review of the protocol.
   2. Raw data/information collected for trials conducted under GLP shall include, but not be limited to:
      a. Equipment logs, descriptions and/or diagrams (spray equipment, freezers, scale/balance used to weigh TS, 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 TS, equipment used to collect application weather data)
      c. Sprayer calibration and application rate calculation worksheets
      d. Monitored temperatures for chemical and freezer storage
      e. E-mails, notes, memoranda, pictures, worksheets, dictated observations and activities that relate directly to the conduct or integrity of the trial
      f. Recorded data from automated instruments, or exact copies thereof, such as weather data
      g. Document of anything that supports or explains events during the course of the trial

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

II. Recording Data:

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

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

3. No pages or forms shall be removed from the FDB (unless they are optional pages as indicated in *General Instructions*) or AAFC RDFN as provided by the Sponsor. The pages and forms shall not be placed out of order.

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

5. Blank forms may be photocopied as needed.

6. Data shall be assembled as completely and accurately as possible. All data and documentation that pertains to each trial shall be placed in the FDB 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 FDB. If original supporting data are relevant to multiple trials it shall be placed in the CDB for that trial year and a certified copy shall go into all FDBs to which it is relevant. The CDB shall be sent to IR-4 HQ for archiving.

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 are recorded in pencil, the page shall be photocopied and certified, since photocopies cannot be altered. The original document shall still be included.

9. Typewritten or electronic data shall be signed and dated on date that it is printed. More detail on electronic data is in SOP 7.2.

10. Information shall not be entered in advance, with a few exceptions. Not entering data in advance is especially true of application, calibration and other data where the information might change before the end of the event. In some cases, where information shall not change before the end of the event or trial, it may be entered in advance. Examples include the FRD's name and address on the personnel form (2A), or the name and address of the residue lab (8A).

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 are not available, the response shall be written out as such.
    c. The one exception is when the question starts with 'if'. As a recognized conditional in Standard English, no response is needed as long as the condition is met. e.g., If the answer is no, and the conditional prompt is for no. However, if the conditional and prompt do not agree (the answer is yes, but the prompt is for no) then the question shall be answered.

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

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 to 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 FDB. Anything not listed there shall be defined in Part 3 of the FDB. For example: CDB = Common Data Book.

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

18. Transcribing data for 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 #7.3 for more details.

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

III. Completion and final review of FDBs:

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 have been collected and recorded, i.e. all the forms and data prompts (blank spaces) have been filled out or properly crossed out, initialed and dated.

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

5. All supporting data have 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 SD.

7. The GLP compliance statement accurately reflects the study. All procedures not conducted in accordance with GLP shall be noted in the FDB, Part 1, GLP Compliance Information. Raw data/information not conducted/collected under GLP at this site may include, 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 FDB 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.

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

10. Pagination should not be done until the FDB 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 two-sided document, such as a SDS, 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 two-sided page may then be crossed out. If, for any reason, two-sided pages are included in the FDB, they shall be identified with the Field ID Number and paginated on both sides.

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140 Locust Grove Road
Pittstown, NJ 08867

SOP #7.2 **Collection of raw data electronically**

Effective Date: April 22, 2016 Revision Number: 0

Author: Jennifer Fisher

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

Scope: All GLP trials under the IR-4 Project

Procedures:

1. All remote sensing and other automatic data collecting and/or recording devices shall be inspected and verified as described under SOP 4.6.

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

3. Each data sheet from a monitoring device 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) 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 FDBs of any trials to which they pertain.

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140 Locust Grove Road
Pittstown, NJ 08867

SOP #7.3 **Data storage during the active life of the project**

Effective Date: March 16, 2020 Revision Number: 2

Author: Jennifer Fisher

Purpose: To ensure that all data resulting from the trial is retained and usable

Scope: All locations conducting GLP trials

Procedures:

1. It is the responsibility of the FRD to see that all raw data, summaries and other items are retained during the active life of each project for which he/she is responsible. All original raw data supporting the registration of a pesticide use pattern shall be retained in the archives in-perpetuity as specified in the GLP Standards Subpart J, Section 160.195. This Testing Facility does not maintain this archive; all data are sent to IR-4 HQ for archiving: IR-4 Project Headquarters, Rutgers, The State University of NJ, 500 College Road East, Suite 201W, Princeton, NJ 08540. Tel.: (732) 932-9575, Fax: (609) 514-2612

2. The protocols, FDBs, and supporting data shall be stored in a limited access area in office 102C in building 6346 during the active life of the trial. The area shall be locked when not in use.

3. The FRD or designated personnel shall make a copy of the completed original FDB. This entire copy shall be certified as a true copy by initialing and dating the title page. The true copy of the FDB shall be retained in the Historical Files at this research Testing Facility at least until the data are submitted to the EPA.

4. Original information and data pertaining to all or several trials being conducted at this site shall be kept in a notebook designated as Common Data Book. Verified copies of these data shall be made and placed in the pertinent FDBs citing the location of the original. At the end of each season, that year's CDB is sent to IR-4 HQ for archiving.

The information/data to be included in the CDB may include, but is not limited to:

a. Personnel records, including original CVs and training records

b. TS storage temperature data

c. Equipment maintenance logs and calibration/verification information, excluding application calibration information

d. Original signed SOPs

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140 Locust Grove Road
Pittstown, NJ 08867

SOP #7.4 **Historical files**

Effective Date: April 22, 2016 Revision Number: 0

Author: Jennifer Fisher

Purpose: To ensure a designated area for historical files of FDBs and CDB pertaining to the field research studies conducted under the IR-4 Program

Scope: All ongoing facility studies under the IR-4 Project

Procedures:

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

2. The FRD shall be responsible for seeing that the files are placed in the historical file at the end of each season. Files containing the copies of the CDB and certified copies of the FDBs may also be kept in the historical files.

3. The Historical Files may be used only by those persons so authorized by the FRD.

4. An historical file has been established in Building 6346 in office 102C Rutgers University Snyder Research and Extension Farm, 140 Locust Grove Road, Pittstown, NJ 08867.

5. Historical files are maintained in a file cabinet in a room denoted as office 102C.

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SOP #8.1 **Procedures to follow prior to an announced EPA inspection**

Effective Date: February 15, 2021 Revision Number: 1

Author: Jennifer Fisher

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

Scope: All locations conducting GLP field trial(s)

Procedures:

1. Notify the SD, QA, and other interested personnel of the pending audit or review as soon as possible.

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

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

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

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

    b. Discuss possible questions that may likely come up about the trial(s) or facility and make sure everyone understands what to expect.

    c. Request personnel to answer the questions only to the extent needed and not to provide extraneous information. Do not volunteer information; keep answers direct and to the point.

    d. Make certain that technical personnel know the safety precautions needed for the work area.

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

i. Master schedules for the Field Research Personnel at the regional and IR-4 HQ.

ii. Study Protocol and SOPs.

iii. Raw data, correspondence and logs.

iv. Training records, CVs, job descriptions, etc. of personnel assigned to the trial(s).

v. Appropriate chain of custody documents for samples and freezer logs and storage temperature documentation.

vi. Documentation of the characterization of the TS, receipt and handling, and storage records.

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

viii. Storage of historical records.

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

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SOP #8.2 **Procedures to follow during an EPA inspection**

Effective Date: April 22, 2016 Revision Number: 0

Author: Jennifer Fisher

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 more smoothly.

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

6. Explain any housekeeping rules such as the use of safety equipment in work areas, etc. to avoid any possible misunderstandings.

7. Proceed with the inspection.

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

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SOP #8.3 **Procedures to follow after the EPA inspection**

Effective Date: April 22, 2016 Revision Number: 0

Author: Jennifer Fisher

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

Scope: All locations conducting GLP field trial(s)

Procedures:

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

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

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

4. Have someone present during the close-out 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 SD with an explanation of any problems found.

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

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