SOP Log Sheet

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FRD/LRD: Tom Freiberger
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STANDARD OPERATING PROCEDURES

FOR

MAGNITUDE OF THE RESIDUE-FIELD TRIALS

Tom Freiberger
Rutgers Fruit Research & Extension Center
283 Route 539
Cream Ridge, NJ 08514

Revision No.: 4

Effective Date: February 1, 2017

Field Research Director: Tom Freiberger TF 2-1-2017
Tom Freiberger (Signature) (Initials) (Date)

Approving Official: Marylee Ross MR 02/01/17
Marylee Ross (Signature) (Initials) (Date)
Regional Region 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.

Rutgers Fruit Research & Extension Center
283 Route 539
Cream Ridge, NJ 08514

Table of Contents- Revision: 4 Effective Date: February 1, 2017

SOP
No. TITLE

Rutgers Fruit Research & Extension Center
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Cream Ridge, NJ 08514

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SOP
No. TITLE

Rutgers Fruit Research & Extension Center
283 Route 539
Cream Ridge, NJ 08514

Effective Date: February 1, 2017 Revision Number: 4

Author: Tom Freiberger
Title: 1.1 General requirements for the development and use of Standard Operating Procedures.

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

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

Procedures:

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

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

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

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

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

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

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

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

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

Rutgers Fruit Research & Extension Center
283 Route 539
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Author: Tom Freiberger

Title: 1.2 Numbering systems for SOPs

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

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

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

1. General
2. Personnel
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 SOP's 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

Rutgers Fruit Research & Extension Center
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Author: Tom Freiberger

Title: 1.3 Format for use in developing SOPs

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

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

Procedures:
Name of Test Facility (centered)
Address (centered)
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 FDR)
Space
Title: SOP Number: (General category section number of individual SOP) followed by SOP title.
Space
Purpose: (Brief description of the purpose of the SOP.)
Space
Scope: (Determines where and when the SOP is applicable)
Space
Procedures: (Describe the operating procedures in numerical order from beginning to end so that an intelligent person with knowledge of the process can carry out the procedures without any verbal input from other sources.)

Rutgers Fruit Research & Extension Center
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Author: Tom Freiberger

Title: 2.1 Designation of Field Research Director and responsibilities.

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

Scope: Field test sites conduction GLP research.

Procedures:

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

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

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

Rutgers Fruit Research & Extension Center
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Author: Tom Freiberger

Title: 2.2 Personnel

Purpose: Information concerning personnel requirements GLPs.

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

Procedures:

1. The field test facility shall have on file information for each person currently supervising any phase of an MOR trial, and collecting and/or entering data under GLPs. The information shall include a current summary of the experience and training of the worker, as well as a brief description of their duties or responsibilities. Each person so engaged in the conduct of trials shall have read and understood those sections of the protocol and Standard Operating Procedures that pertain to their responsibilities. Documentation of training adequate to complete the task under GLPs is sufficient for personnel assisting in GLP activities under close supervision. In the latter case, the Field Research Director 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 headquarters for archiving as needed. Alternately, the documentation can be place directly in the FDB to which it pertains.

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

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

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

5. 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 Rutgers Fruit Research & Extension Center regulations, pesticide labels or the trial protocol.

Rutgers Fruit Research & Extension Center
283 Route 539
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Author: Tom Freiberger

Title: 2.3 Documentation of Training

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

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

Procedures:

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

2. All other training shall be documented in some form of training log.
   a. Training received from workshops, conferences, etc. shall be noted. Include the name of the person, the event and the dates of attended. A copy of any type of training certificates issued shall also be retained in the personnel files at the location.
   b. Any form of verbal instruction shall be documented in writing and placed in the personnel files to show that the person received on-the-job training to conduct the task. Record the name of the person giving the instruction, the name of the person receiving the instruction, the date given and a concise statement of the instruction (i.e. Dr. 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 Standard Operating Procedures that pertain to their responsibilities. The Field Research Director shall record the names of the personnel and dates that the SOPs were explained to them. This information shall be placed in the personnel file.

4. For personnel who are not collecting and/or entering data, but who might have an impact on the trial, (for example casual labor involved in the harvest), a general statement of oral or written training, by the Field Research Director or designated supervisor shall be sufficient. 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 will be included in one of the field data books for each given year. Alternately, the originals may be submitted in the common data book for the testing facility.

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

Rutgers Fruit Research & Extension Center
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Title: 2.4 Organizational Chart

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

Scope: All field test sites conducting trials for the registration of pesticides.

Procedures:

1. An organizational chart shall be developed which reflects the lines of communication and responsibility for conduct of GLP studies. Show the line of reporting between the Sponsor (entity that initiates and finances the study and submits the report to the EPA), Study Directors (individual responsible for the overall conduct of the study), Quality Assurance, Testing Facility Management (Regional Field Coordinator in the case of IR-4) and Testing Facility (person who actually uses the test substance in the test system, the IR-4 Field Research Director).

    a. The management of the institution (i.e. Department Chair, Director, etc.) where the field testing facility is located may be included as separate line, but this is not essential.

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

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

4. Personnel engaged in the conduct of the GLP trials are shown on the chart with lines of responsibility indicated. Direct and indirect lines of communication and accountability shall be shown as follows:

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

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

Rutgers Fruit Research & Extension Center
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Author: Tom Freiberger

Title: 3.1 Test Substance receipt and handling

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

Scope: All GLP Test Substances for MOR field trials.

Procedures:

1. Arrival of GLP Test Substance shall be checked for daily. When a Test Substance is received, the product will be unpacked, checked and placed directly into the Pesticide Storage Building "IR-4 Food Use cabinet #1" storage facility.

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

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

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

5. The unique identifier used to identify a test substance is the field ID number.

6. Arrival information shall be recorded on the chemical inventory, and will include, at a minimum, the name of the Test Substance 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 Field Research Director and kept in the IR-4 office.

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

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

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

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

Rutgers Fruit Research & Extension Center
283 Route 539
Cream Ridge, NJ 08514

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Author: Tom Freiberger

Title: 3.2 Storage of GLP Test Substance.

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

Scope: All GLP Test Substances

Procedures:

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

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

3. The Cream Ridge Pesticide storage facility is a separate building from offices and laboratories and maintained in accordance with Rutgers University/Cook College/Experiment Farm guidelines. The facility is dry, well ventilated and temperature controlled with heaters to prevent freezing and ventilation fans to prevent overheating. The entire pesticide storage facility is under lock and key and accessible only to farm staff.

4. Storage conditions shall be monitored using a uniquely identified and calibrated HOBO U10 Electronic Temperature Data Logger from the time the Test Substance is placed there until after the final application has been made. The HOBO U10 shall be monitored weekly and downloaded and re-launched monthly. A uniquely identified and calibrated min/max thermometer shall be used as back-up, and the temperatures recorded in case of a failure in the HOBO U10 Temperature Data Logger.

5. The Test Substance shall then be stored in the pesticide storage facility until it is needed for use in the trial. The storage conditions of the Test Substance shall be recorded in the raw data book or provided in other documents. Storage information shall be added to the label, if not included on original label. The Study Director 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 Test Substance is removed and when it is returned to the facility, along with the purpose for which it is removed. This log may 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 the front doors of the pesticide storage facility.

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

10. Separate areas shall be established for mixing and handling of the Test Substances. If space limitations preclude a separate space for measuring TS, steps shall be taken to ensure no cross contamination occurs. These measures shall include, but are not limited to: using clean paper or plastic on the counters; a new plastic tray to weigh out each Test Substance; a new syringe/pipette or clean graduated cylinder for liquid measurements.

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

12. Excess Test Substance not used for study purposes may be logged out and used, once the last application has be completed. The product shall be used by trained personnel for maintenance (labeled uses) or experimental purposes at the discretion of the Field Research Director or research personnel. The removal of the Test Substance shall be noted on the Pesticide Removal Log. The container shall be retained until disposal is authorized (SOP3.11).

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

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

15. Adjuvants used for GLP Test Substance applications shall:
    a. be stored in accordance with current guidelines
    b. have a label, and the label shall be included in the Field Data Book.
    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 will be purchased and remaining material shall be transferred to farm maintenance program

Rutgers Fruit Research & Extension Center
283 Route 539
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Effective Date: February 1, 2017 Revision Number: 4

Author: Tom Freiberger

Title: 3.3 Calibration and use of an electronic scale used to weigh GLP Test Substances.

Purpose: To assure an accurate Test Substance application.

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

Procedures:

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

2. 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 Common Data Book.

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

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

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

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

7. Wash the weighing tray into the sprayer using some of the measured carrier to insure all the product is added to the tank. If using a container, make a slurry of the Test Substance 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 weighted out for a single application, each amount shall be entered separately. If the same Test Substance is used for more than one trial, all records shall be maintained on a single log. Then the original shall be placed in one of the books, and an exact copy for any other.

Rutgers Fruit Research & Extension Center
283 Route 539
Cream Ridge, NJ 08514

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Author: Tom Freiberger

Title: 3.4 Measuring a liquid pesticide formulation

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

Scope: All liquid formulations of GLP pesticides.

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

1. 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 Test Substance an accuracy within +/- 5 % of the total volume (i.e. if 10 ml syringe/pipette is used the smallest division shall be .02 ml or less).

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

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 Test Substance.

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

5. The liquid Test Substance 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 Test Substance is used for more than one trial, all records must be maintained on a single log. Then the original is placed in the book for one trial and an exact copy for the other.

7. Table of measuring equipment with increments:

Graduated cylinder	Syringe	
100 ml ± 1 mls	3 ml ± 0.1 ml	
250 ml ± 2 mls	5 ml ± 0.2 ml	
500 ml ± 5 mls	10 ml ± 0.2 ml	
1000 ml ± 10 mls	20 ml ± 1 ml	
2000 ml ± 20 mls	30 ml ± 1 ml	
	60 ml ± 2 ml	

Rutgers Fruit Research & Extension Center
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Title: 3.5 Adding pesticide concentrate to the water carrier in a spray tank.

Purpose: To insure 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. Make sure the spray mix shall be enough to cover the entire plot plus sufficient overage to ensure uniform coverage. If the plot is too large, the application may be made with two separate tank mixes, one for each side of the row or plot. Make sure the spray tank holds the entire mix (carrier, Test Substance and surfactant where required) needed for the area to be sprayed.

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

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

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

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

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

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

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

Rutgers Fruit Research & Extension Center
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Cream Ridge, NJ 08514

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Title: 3.6 General procedures in the mixing and application of pesticides.

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, 4.2 and 4.3.

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, 3.4and 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 Test Substance, then procedures for handling the Test Substance as indicated in SOP 3.3, 3.4, and 3.5 shall also be followed.

Rutgers Fruit Research & Extension Center
283 Route 539
Cream Ridge, NJ 08514

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Author: Tom Freiberger

Title: 3.7 Procedures for the application of the Test Substance(s) in the field.

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

Scope: All GLP field trials at this location

Procedures:

1. Application equipment shall be inspected and calibrated as described under SOP 4.1, or 4.2. 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 velocity during spray operation. Measure wind velocity 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 over-planting, 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 Field Data Book 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 Study Director and/or Regional Field Coordinator will be informed of any events that might affect the integrity of the trial.

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Author: Tom Freiberger

Title: 3.8 Cleanup of application equipment

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

Scope: All locations where pesticides are used under GLP.

Procedures:

1. Granules: Remove any excess granules and dispose of them properly using appropriate methods for handling hazardous wastes. Do not return them to the original container as that might affect the integrity of the contents.

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

3. In the designated area or suitable location away from aquatic areas or danger of aquatic contamination, hose down the sprayer/applicator to remove pesticide residuals from inside and outside. Wash the tank with detergent or sudsy ammonia and triple rinse with water. Apply each tank of wash or rinse solution to the over-planting of the crop or non-crop area. If a crop/non-crop area is not available, then follow the disposal procedures for pesticide rinse water in accordance with current policies and guidelines of the institution.

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

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

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

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Author: Tom Freiberger

Title: 3.9 Procedures to follow when a problem occurs in the application of the Test Substance.

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

Scope: All GLP Test Substance applications.

Procedures:

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

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

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

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

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

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Author: Tom Freiberger

Title: 3.10 Handling pesticides safely.

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

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

Procedures:

1. Personnel shall follow current policies and guidelines of the Rutgers Fruit Research and Extension Center. Where institutional guidelines do not exist, the following procedures shall be followed.

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

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

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

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

6. Prior to application, the equipment shall be checked to make sure there are no leaks in the pump or tanks, hose connections, or worn spots in the hoses. All spray tanks shall have lids. Filling the spray tank shall be done carefully so it does not run over. All machinery shall be shut down if necessary to adjust or repair any moving parts. Never blow out nozzles, hoses, or clogged lines by mouth. Inspect all pesticide containers for leaks, tears, or holes before handling. Do not mishandle or abuse containers and thereby create hazards and/or emergencies by carelessness.

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

8. A pesticide-treated area shall not be reentered until adequate time has elapsed, as specified on the label of the pesticide. Treated plots should be posted. For persons who regularly handle organophosphates and/or large quantities of carbonates, a cholinesterase level shall be determined at least monthly throughout the pesticide application season.

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

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

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

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

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

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

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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Author: Tom Freiberger

Title: 3.11 Disposal of pesticides.

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

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

Procedures:

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

2. When disposing of pesticide concentrates or containers, personnel shall follow current policies and guidelines of their institution. Where institutional guidelines do not exist, the following procedures shall be followed. This applies to the Test Substances only when permission has been received from the Study Director.
    a. Follow label directions for disposal of the pesticide.
    b. If no label directions exist for disposal, arrangements shall be made with a licensed waste disposal firm for pickup and disposal of the pesticide and/or the empty containers.

3. When the Test Substance or containers is disposed of, an entry shall be made in the chemical inventory, logging out the product and/or container. These records shall be retained and 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. Dispose of the dilute pesticide waste in the field by adding to the spray tank and spraying on an overplanting of the crop or non-crop area, where this procedure does not violate any laws or regulations. All pesticide solutions shall be mixed with the intent of limiting the problem of excess solutions.

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Author: Tom Freiberger

Title: 3.12 Storing and maintaining adjuvants.

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

Scope: To be sure all adjuvants used in GLP trials are stored correctly and maintain their integrity.

1) GLP labeling requirements for reagents (i.e. adjuvants, spray additives) are: name, concentration, storage conditions and expiration date. These will be required on all spray additives used for IR-4 GLP Residue Studies.
2) Spray additives will be stored in a location that has limited access and is temperature monitored.
3) Spray additives will be in good condition prior to use - the physical characteristics of the additive should not have changed from purchase or be compromised (i.e. different color, consistency [cloudy, darkened] or have the appearance of rancidity).
4) Spray additives must be handled in a manner to prevent cross contamination with test substances and other spray additives. Two suggested options are provided below.
    a. Spray additives will be dispensed into a temporary container (such as a beaker) prior to being used in a GLP residue trial. The spray additive once dispensed will not be used for a different trial or returned to the original or secondary container; it will be discarded.
    b. Spray additives will be dispensed from the original or secondary spray additive container using a factory sealed newly opened pipette. After this pipette is used it is discarded and never used again. This pipette never returns to the spray additive container. The test substance is also dispensed by a different newly opened pipette, discarded after use.
5) New adjuvants will be purchased each year in early spring prior to first GLP application.

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Author: Tom Freiberger

Title: 4.1. Calibration and application with a CO2 sprayer.

Purpose: To provide accurate and documented application of test substances using CO_2 backpack sprayer.

Scope: All test sites with boom sprayers for GLP applications, generally for foliar directed applications in brambles and bushberries and broadcast strawberry, cranberry and most herbicide applications.

Procedure

1. Sprayer Preparation and Maintenance
   a. The application boom shall be inspected for leaks and cleaned. Ammonia and/or detergent shall be used for cleaning. The nozzle assemblies shall be disassembled to verify cleanliness or to clean the screens and nozzle bodies before the start of each trial.
   b. The CO2 propellant connections shall be inspected for leaks and repaired if necessary.
   c. Any faulty components shall be replaced before calibrations.
   d. Inspect all gauges to insure proper operation and replace if necessary
   e. Verify the nozzle and screen size and that the nozzles will provide the desired spray volume within the recommended range of pressure and area of application as recommended by the manufacturer. The screen size shall be compatible with the test substance and the nozzle size.

2. Operation.
   a. CO2 sprayers may be used for walking hand-held application.
   b. Adjust the CO_2 pressure regulator to the desired pressure with the CO_2 tank valve in the fully open position. Foliar (boom held at angle) to caneberries, blueberries, and grapes. Horizontal boom applications for herbicides, and/or strawberries, caneberries and cranberries. Boom may be held horizontally for foliar applications to younger or shorter plant material. Optimum pressure range 20- 50 psi.
   c. Attach the boom hose first then connect the CO_2 pressure hose. Reverse the order to disassemble the sprayer.

3. Calibration.

a. Complete calibrations (minimum of 3 times) of the spray equipment and travel speed shall be conducted just prior to the first application in a trial and just prior to any subsequent applications within a trial where application parameters (application type, gallons per acre, etc.), or equipment components (nozzles, pressure, etc.) have changed from the initial calibration, even if the equipment has been changed back to the parameters of the initial calibration. Just prior to an application includes the day before. If more than one day elapses between the full calibration and an application, another full calibration must be conducted.

b. The discharge rate of the spray equipment shall be completely calibrated just prior to each use, when possible. That is, just prior to the first application of a given day, a complete calibration shall be performed, with a single spray output recheck performed between each subsequent application of that day. Recheck outputs must agree within ±5% of the full calibration. The initial full calibration for that day, along with the pertinent recheck shall be included in each FDB. A discharge rate recheck is acceptable, if no changes have occurred to the equipment or the application parameters, and the output from the check is within ±5% of the most recent calibration from that trial.

c. Water delivery from nozzle shall be collected for a designated time period, such as 30 sec, and measured in an appropriate sized graduated cylinder. The conditions of calibration shall be recorded as follows: 1) nozzle type, 2) boom pressure, and 3) nozzle spacing. To determine compliance for ± 5% multiply the average nozzle output by 0.95 and 1.05 to obtain the approximately maximum acceptable range of nozzle output. Change nozzle and screens until uniform nozzle discharge is obtained. The delivery rate shall be averaged for three determinations or as specified in the protocol.

d. Travel speed shall be fully calibrated just prior to the first application in the trial. As long as there are not changes in the application parameters within a trial, a single pass recheck will be sufficient for all subsequent applications. The travel speed will usually be around 35 sec/100ft (2 mph) for hand-held applications. This walking pace shall be practiced before application of the test substance in the trial site. The practice speeds shall be made on the same travel surface as the test site. Other walking paces may be utilized to achieve the desired application rates. Once an appropriate walking speed has been chosen, three runs shall be made for a full speed calibration and recorded in FDB. For subsequent application if there have been no changes in the application parameters a recheck of the speed will be sufficient. (May need to change nozzle size if the walking speed is too slow or too fast)

e. For power applications, the time to traverse the length of the plot shall be determined under the actual field conditions of test site application. The travel speed shall be determined 3 times and the average speed shall be used for calibration calculations.

f. The spray volume and sprayer nozzle configuration to use for the application shall be in compliance with the protocol requirements. If the spray volume and method are unspecified, a typical local agricultural application spray method and spray volume, for an application similar to the proposed test substance use in the protocol shall be used. The typical calculation for a straight boom with 3 nozzles spaced 20 inches apart (5 ft. boom width), with measured output as shown, would be as follows:
Total discharge from 3 nozzles for 30 sec. is 1800 ml
Travel speed 35 sec/100 ft.

$$\frac{1800\ ml}{500\ sq\ ft} \times \frac{x\ ml}{43{,}560\ sq\ ft} = \frac{78{,}408{,}000}{500\ sq\ ft} = \frac{156{,}816}{3785\ ml/gal} = 41.4\ gal/A$$

g. The formula to verify the actual spray volume applied, as described above, may be used as a method of verification of the calibration spray volume.
h. Determination of Travel Speed for a Fixed Spray Volume:
i. The following formula may be used to calculate travel speed as follows:

$$\frac{\text{plot length (ft)} \times \text{3600 sec (1 hr)}}{\text{pass time(sec)} \times \text{5280 ft/mile}} = \text{Calculated Speed (mph)}$$

4. Test Substance
a. The amount of test substance to measure is dependent on the amount of extra dilute spray solution prepared to avoid depleting the solution before the entire plot area is sprayed. The suggested amount of spray solution to prepare is 5-10 % greater than the amount of solution required to spray the entire plot. The amount of spray solution to prepare is as follows:
Calculated to apply 1800 ml/500 sq ft
1800ml × 0.05 = 90 ml added to 1800 ml for extra 5%
The areas and volumes used in this example may be calculated with metric units and other methods of calculation may be used.
b. Calculation for the test substance:
To show the calculation of a test substance based on a formulated liquid product with 0.86 lb ai/gal shall be applied at 0.0672 lb ai /A as follows:

$$\frac{\text{amount ai/A} \times \text{acres used}}{\text{pounds ai/gal or lb}} = \text{Number of gal or lbs product to use/A}$$

Example: $\frac{0.0672\ lb\ ai/A \times 1\ Acre}{0.86\ lb\ ai/A\ gal} = 0.078\ gal\ product/A$
Convert gal to ml: 0.078 × 3785 ml/gal = 296 ml/A
This equation can be used for solids by using the decimal fraction of active ingredient in the product instead of lb ai/ gal and by using 453.6 grams / lb instead of 3785 ml / gal.

$$\frac{0.0672\ lb\ ai/A \times 1\ Acre}{0.75\ \%\ ai} = 0.0896\ lb\ product/A$$

Convert lbs to grams: 0.0896 × 453.6 ml/gal = 40.7g product/A
Do not round values until the last step.

5. Application
   a. Always wear personal protective equipment. Use the product MSDS for precautionary information on the active ingredient.
   b. Adjust boom height in the field for proper nozzle overlap on the target (soil vs foliar applications). Boom must be level for uniform application.
   c. Monitor the spray pattern visually to ensure uniform coverage.
   d. Dilute spray solutions must be uniformly mixed in the spray container.
   e. Follow protocol for maximum wind velocity during spray operation. If no guidelines are given, winds greater than 6 mph are generally regarded as excessive for a GLP application.
   f. 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 for the first.

6. Verification of Application Rate:
   a. Calculation of the actual rate of test substance 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 test substance mixed with the carrier to provide the total dilute spray volume at the start of the application. The following formulas may be used:
   Formula to verify liquid and dry formulations: (Can round these values)
   Total Pass Time (sec)× Discharge Rate (ml/sec/boom) = Amt. Carrier applied to plot

$$\frac{\text{Amt. Carrier applied} \times \text{Amt. Test Substance Used}}{\text{Volume of Tank Mix}} = \text{Amt. Test Substance Applied to Plot}$$

$$\frac{\text{Amt. Test Substance} / \times 43{,}560 \text{ sq. ft.}}{\text{Plot area treated (sq. ft.)}} = \text{Amt. Applied / A}$$

(Amt. Applied / A – Protocol Amt./A) / Protocol Amt./A * 100 = % deviation

b. Formula to verify spray volume (gallons) per acre:

$$GPA = \frac{\text{Time Traveled (sec)} \times \text{Total Liquid Collected (ml)} \times 43{,}560 \text{ sq ft}}{\text{Distance Traveled (ft)} \times \text{Collection Time(sec)} \times \text{Swath Width(ft)} \times 3785 \text{ ml/gal}}$$

7. Cleaning/Decontamination

a. Dilute spray for backpack applications shall be discharged at the end of the test plot or in an area not to be harvested. The disposal shall be downwind and downhill from the trial area on a non-crop area. Preferably, the dilute spray shall be removed from the site and sprayed on a non-crop or labeled crop area.

b. Drain all the pesticide from the sprayer.

c. Flush the system with clean water equal to about one-third the volume of the tank or, if using CO_2 system, use a full bottle of clean water.

d. A variety of cleaning agents can be used including, but not limited to a commercial tank cleaner, household detergents and ammonia, sudsy ammonia.

e. Agitate the system until the sides of the spray tank are wet, or in a circulating system, until the contents have made at least one cycle.

f. Discharge wash water from the tank and flush three times with clean water as in SOP 3.8.

g. Remove screens and tips and clean with a brush if necessary.

8. Mechanical Problems

a. If there is a problem with the sprayer during the application, stop immediately, turn off the boom, and stop the stopwatch. It shall be noted and flagged where the application ended. If the problem did not affect the application to that point, corrective action shall be taken and the application continued.

b. If a hose or a nozzle is plugged such that it is impossible to determine how much test substance was applied, that area shall be note and excluded from sampling.

c. The Study Director shall be notified immediately, preferably within 24 hours, with a description of the problem. The report shall indicate if the actual amount applied differs dramatically from protocol, or if the malfunction has affected the integrity of the trial.

9. Documentation

a. Record all necessary information into the trial notebook in enough detail to reconstruct the application. Document calibration as an event in the maintenance log if appropriate.

b. The following information shall be recorded at each application:
   i. SOPs followed
   ii. Operation pressure of sprayer such as, boom or nozzle pressure. The nozzle pressure is preferred.
   iii. Nozzles: number spacing, type, and size screens
   iv. The output of each nozzle and the length of time it was collected, if applicable
   v. Tractor gear, range, rpm (if applicable)
   vi. Time of passes during application and direction of travel and sequence of passes.
   vii. Nozzle height, if appropriate

c. Calculations shall be entered in a logical manner showing all steps and conversions so that they can be easily followed and reconstructed. Calculations shall clearly show the actual amount per acre applied and the percent deviated from protocol. However, if these differ by more than +10 % or -5% from the protocol values, the Study Director shall be notified within 24 hrs.

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

10. Tom Freiberger or designated personnel are responsible for the maintenance and remedial action taken in case of malfunction.

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Author: Tom Freiberger

Title: 4.2 Calibration and Application with an Airblast Sprayer

Purpose: To provide accurate and documented application of test substances.

Scope: All test sites with airblast sprayers for airblast applications.

Procedures:

1. Sprayer Maintenance and Repair

Sprayer shall be inspected for leaks and triple rinsed before usage. Optimum pressure setting, tips, whirlplates, nozzle position and pump rpm shall be set according to Pak-Blast manual. Any faulty components shall be replaced before calibrations. Inspect all gauges to insure proper operation and replace if necessary. The core size used for all nozzles in tree fruit applications shall be #45. The disk # for all tree fruit applications will usually be as follows: starting at the top, nozzle #1 disk#5, nozzles #2- #5 disk #7, nozzles #6- #7 disk #3. Other disk and core sizes may be substituted to meet protocol rate requirements.

2. Calibration

Calibration shall be done within 24 hours of application, and no other uses of the equipment shall occur between the calibration and application. If after 24 hours, the sprayer has not been used, a single output to verify the previous calibration is within ±5 % is acceptable. If the equipment is used for another purpose, recalibration must be performed before the test substance application. On the concrete pad outside the spray shed facing the same direction in the same location the tank shall be filled and sprayer shall be run to bleed air out of lines. Sprayer shall be checked to ensure it is in working order. Tank shall be refilled with flow meter and sprayed at selected rpm for a measured distanced and time. The exact amount needed to return tank to full level shall be measured with a flow meter. Divide amount needed to refill tank to full by the average time it took to spray, to determine the gal/sec delivered. For speed calibration, the rpm and gear to travel in shall be selected. The distance to be traveled between markers at the front and back of the plot shall be clocked with a stop watch on a surface similar to the actual application site and the time recorded. Calculate mph based on measured times.

3. Test substance:

The amount of test substance to measure is dependent on the 10% - 30% extra dilute spray solution prepared to ensure lines and pump are filled and to avoid depleting the solution before the entire plot is sprayed.

4. Application:
Always wear protective equipment. Use the product MSDS for precautionary information on the active ingredient. Monitor the spray pattern visually to ensure uniform coverage. Follow protocol for maximum wind velocity during spray operation. If no guidelines are given, winds greater than 6 mph are generally regarded as excessive for a GLP application. 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.

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

6. Tom Freiberger or designated personnel are responsible for the maintenance and remedial action taken in case of malfunction.

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Author: Tom Freiberger

Title: 4.3 Calibration and use of flow meter.

Purpose: The purpose of this SOP is to establish procedures used when calibrating flow meter.

Scope: The SOP is to be followed by IR-4 participating personnel when calibrating 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 calibrated once a year (refer to GPI Electronic Digital Meter Instruction Manual). Prior to calibration, 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 necessary, the flow meter readout can then be adjusted to correspond with the amount of water caught in the calibration container. Once the readout has been amended (if needed), hold the calibration key briefly, and calibration shall be complete.

3. Remedial actions to be taken in case of failure or malfunction include:
   a. Any problem shall be immediately reported to the Field Research Director or designated personnel, documented, and placed in maintenance log 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).

4. Tom Freiberger or designated personnel are responsible for the maintenance and remedial action taken in case of malfunction.

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Author: Tom Freiberger

Title: 4.4 Verification and use of temperature measuring devices.

Purpose: The purpose of this SOP is to establish procedures used to verify and read thermometers.

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, 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 calibration log records. If the devise breaks or is otherwise retired, its fate shall be recorded and the unique identifier not used again. Records of device shall be maintained in a log.

2. 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 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 thermometer shall be verified by placing it in both an ice bath and boiling bath. Temperature readings taken from the reference thermometer may be rounded to whole numbers (e.g.: If reference reads 38.2°F, the recorded value shall be 38°F). The reference thermometer must be within ± 2°F of the freezing and boiling points, or the thermometer will be retired.

4. All other temperature monitoring 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.

At least two water baths shall be used for verification of reference thermometer. 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 (a. 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.

At least two air temperature conditions shall be used for verifying reference thermometer. Examples of temperature ranges to test may include:

i. Warm , i.e. 104 to 131°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)

If ice and/or boiling baths cannot be used, an attempt will be made to verify at temperature close to those for which the monitoring device will be used.

5. The temperature monitoring 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 calibration/verification
b. initials of person doing calibration/verification
c. reference thermometer reading
d. laboratory thermometer reading
e. Identification (ID) or code number of the thermometer 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 and the label shall read "OK". 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 22°F, the adjustment would be + 2°F at 22°F. When this thermometer is used, the individual would add 2°F to the 20°F observed reading and 22°F would be recorded as the temperature reading.

7. Remedial action to be taken in case of failure or malfunction shall include:
Any problem shall be immediately reported to the Field Research Director or designated personnel, documented, and placed 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 monitoring device will be documented and the log for that device sent for archiving.

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

Rutgers Fruit Research & Extension Center
283 Route 539
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Effective Date: February 1, 2017 Revision Number: 4

Author: Tom Freiberger

Title: 4.5 Verification and use of wind speed and relative humidity measuring devices.

Purpose: The purpose of this SOP is 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). Record inspection and any maintenance performed in appropriate logs. 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 (OK) 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 ± 2 % of the other, then each unit is reading accurately (OK) and is acceptable for use. If the measured relative humidity from the units differ more than ± 2 %, then the units need to be serviced or replaced.

Rutgers Fruit Research & Extension Center
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Author: Tom Freiberger

Title: 4.6 Verification of Pressure gauges.

Purpose: The purpose of this SOP is 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 (OK) 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).

Rutgers Fruit Research & Extension Center
283 Route 539
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Author: Tom Freiberger

Title: 4.7 Verification and use of temperature data logger devices.

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

Scope: The SOP is to be followed by IR-4 participating personnel when 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 (if applicable, batteries should be replaced when the power indicator light does not blink while the unit is on). 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 calibration log records.
Freezers: #3 UTC logger # 2261257
#6 TRT logger # 2261259
Pesticide Storage: logger # 2261260
Extra data loggers may be used as back up: logger #2261256 , logger #2261261, and #2261258

4. Data logger(s) to be calibrated and the reference thermometer shall be read side by side under conditions appropriate to the intended use. All readings should be within +/- 5% 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:

5.1. Warm, i.e. 104 to 131°F (drying oven may be used)
5.2. Room temperature (approx. 70°F)
5.3. Cool, i.e. 42 to 50°F (refrigerator may be used)
5.4. Cold, i.e. 23 to -4°F (freezer may be used)

6. The data logger(s) and the reference thermometer shall remain in the calibrating 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:

6.1. date of verification
6.2. initials of person doing verification
6.3. reference thermometer number and reading
6.4. data logger reading
6.5. 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 reading, no temperature adjustment shall be made and the label shall read "OK". If the reading is more than ±2°F in relation to the reference thermometer, the proper adjustment shall be made. For example: If the data logger reads 20°F and the reference reads 22°F, the adjustment would be ± 2°F at 22°F. When this data logger is used, the individual would indicate on the printout to add ± 2°F to the 20°F observed reading and 22°F would be recorded as the temperature reading.

8. **Launch unit.** Select the duration of time which best suits the use (i.e. 30 ±5days 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 (i.e. computer diskette labeled 'Data logger' and year of entries) and the data 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:

9.1. date
9.2. initials of individual conducting the activity
9.3. data logger ID or code number
9.4. temperature sensor location at the time of reading(s)
9.5. 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. Tom Freiberger or designated personnel currently operating the equipment are responsible for the maintenance and remedial action taken in case of malfunction.

Rutgers Fruit Research & Extension Center
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Effective Date: February 1, 2017 Revision Number: 4

Author: Tom Freiberger

Title: 4.8 Operation and Maintenance of Freezers.

Purpose: The purpose of this SOP is to establish procedures used when using IR-4 freezers.

Scope: The SOP is to be for freezers used to store GLP residue samples.

Procedures:

1. At a minimum of two weeks prior to collecting the first set of GLP residue samples, the three IR-4 freezers shall be visually inspected to insure they are in good working condition. The freezer shall be cleaned if needed, or at least wiped out with a damp cloth. Document inspection(s) and any maintenance performed in appropriate logs. Individual freezer maintenance logs shall be kept for each year, i.e., starting when each unit is turned on and ending with the season end cleaning.

2. Each freezer should be clearly labeled with an ID that can be cross referenced to the maintenance logs.
   UTC Freezer #3 serial # WB63706062
   TRT Freezer #6 serial # GV139378
   Back Up Freezer #5 serial # ZG169131

3. Temperature within the unit shall be checked prior to sample storage. A temperature measuring device (such as a data logger) shall be placed in the unit, in a closed container or covered with ethylene glycol to keep the temperatures constant when doors are opened and closed. The temperature range recorded by the device shall be within the limits as required for storage of the sample.

4. If temperature measured is within the sample storage range, then unit is approved for use. If temperature measured is not within the sample storage range, then adjust the temperature control until the unit maintains the correct temperature range. If after adjustment, the unit cannot maintain a temperature range within the sample temperature storage range, then the unit must be serviced by a trained technician prior to use. Or contact SD.

5. When unit is being actively used for storage, the temperature shall be monitored and recorded once a month to ensure that the unit is working properly (i.e. data logger, min/max thermometer). If no samples are being stored in the unit, no records of the temperature need to be maintained.

6. Remedial actions to be taken in case of failure or malfunction include:
   a. Any problem shall be immediately reported to the Field Research Director or designated personnel, documented, and placed in the maintenance log 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).

   b. A beaker of frozen water with a BB on top or an inverted test tube of frozen water shall be placed in the freezer as a check of sample integrity if there is a malfunction. Or if there is a malfunction, all samples in the unit shall be checked to insure that they are still frozen.

   At the end of the season the freezers shall be shut off and thoroughly cleaned.

7. Tom Freiberger or designated personnel currently operating the equipment are responsible for the maintenance and remedial action taken in case of malfunction.

Rutgers Fruit Research & Extension Center
283 Route 539
Cream Ridge, NJ 08514

Effective Date: February 1, 2017 Revision Number: 4

Author: Tom Freiberger

Title: 4.9 Operation and maintenance of farm equipment used in GLP portion of trial (spray applications).

Purpose: To assure that the crop or commodity under trial is grown under conditions that simulate commercial practices, in a quantity sufficient for the trial and in a reasonably good state of health.

Scope: All locations where the farming operations are performed in GLP trials.

Procedures:

1. Farm crew or FRD performs maintenance pesticide application and are responsible for that machinery maintenance.

2. Just prior to the initiation of the use of the equipment for GLP applications, the Field Research Director or his/her designated representative shall visually inspect the equipment to see that it is in good working order, properly lubricated, and in good mechanical condition. Any maintenance procedures shall be noted in equipment log.

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

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

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

6. A portion of the record shall be maintained for each piece of equipment used in a GLP trial. The record shall contain maintenance service dates and what was done and repair dates and type of repair.

Rutgers Fruit Research & Extension Center
283 Route 539
Cream Ridge, NJ 08514

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Author: Tom Freiberger

Title: 4.10 Borrowed or seldom used Equipment.

Purpose: To assure that borrowed or seldom used equipment is in satisfactory working order for GLP trials.

Scope: All test sites where GLP trials are conducted.

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 enter into raw data notebook.

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 actions in raw data notebook.

6. Enter in raw data notebook the date equipment was returned to original source.

Rutgers Fruit Research & Extension Center
283 Route 539
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Effective Date: February 1, 2017 Revision Number: 4

Author: Tom Freiberger

Title: 5.1 Site selection for established fruit GLP field trials.

Purpose: To assure 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 will be employed when plots are side by side. A protocol change will 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 degree of 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 will be noted. Follow the Field Data Books for further directions.

6. Lay out each plot on the site using a tape measure 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. Identify both ends of each plot with identifiable markers containing a minimum of Field ID No., treatment number and treatment name that can be seen easily throughout the duration of the trial.

8. The plot map and a summary of the cultural practices shall be part of the raw data notebook.

9. The soil where trials ARE TO be conducted shall be tested for nutrients, pH, and organic matter on a bi-yearly basis. The above data shall be recorded in the files for all trials.

10. For Soil texture determination, analysis performed UP TO 15 years prior to the trial shall be considered acceptable.

Rutgers Fruit Research & Extension Center
283 Route 539
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Author: Tom Freiberger

Title: 5.2 Field preparation for annual strawberry/ vegetable transplanting

Purpose: Assure that strawberries/vegetables are grown with good agricultural practices and provide a uniform crop for trial.

Scope: All locations developing GLP data on strawberries/vegetables.

Procedures:

1. Have on hand a reasonably up-to-date publication (NJ Commercial Fruit and or vegetable Production Guide) or if no such publication is available, consult with an agricultural specialist familiar with the production practices for the commodity and document the practices required to produce the commodity under simulated commercial conditions

2. Determine pH and soil fertility requirements of the commodity. Obtain random samples of soil for testing from the trial site. Have the soil tested to determine how well it shall meet the requirements of the commodity and record the results in the raw data book (specify whether or not the testing was done under GLP).

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

4. Till and prepare the field as appropriate and prepare a uniform and consistant raised soil bed with black plastic (unless protocol prohibits) and "T"tape under the plastic for irrigation.

5. Apply appropriate pesticides (pre-plant herbicide, soil insecticide, fungicide drench, soil-incorporated nematicide etc.) as specified in the (New Jersey Commercial Fruit and or vegetable Production Recommendations). Apply and document application of pesticides as specified in other areas of these SOPs. Used materials registered in the crop and make sure they will not interfere with the chemical being studied (i.e., not in the same chemical family). If there is any doubt, check with the Study Director.

6. Irrigate and perform other agricultural practices as necessary to get the commodity started.

Rutgers Fruit Research & Extension Center
283 Route 539
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Author: Tom Freiberger

Title: 5.3 Method for strawberry/vegetable transplanting

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

Scope: All locations developing GLP data on strawberry/vegetables.

Procedures:

1. Determine the correct variety to use as specified by the trial protocol. If the variety is not specified, determine the variety most adapted to the needs of the trial and commonly used in the area by commercial producers. If a commercial producer is providing the plants, try to select plants as uniform in growth as possible.

2. Determine within and between row spacing as is practiced by local commercial agriculture. Use a hole punch to cut a round hole 2"- 4" in diameter in the plastic just prior to planting. Plant the transplant in reasonably straight lines or rows with fairly accurate measurements. If a different spacing is used to accommodate equipment, then record both the actual spacing used and the commercial row spacing.

3. Identify each treatment, front and back, with the IR-4 Field ID Number, treatment, include plot # and row # if necessary in such a manner so that it shall be visible throughout the life of the trial.

4. Irrigate and perform other agricultural practices as necessary to grow commercially acceptable crops.

Rutgers Fruit Research & Extension Center
283 Route 539
Cream Ridge, NJ 08514

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Author: Tom Freiberger

Title: 5.4 Commodity maintenance

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

Scope: All locations developing GLP data on fruit crops.

Procedures:

1. Maintain the commodity in a healthy state and good growing condition throughout the life of the orchard as directed in the New Jersey Commercial Fruit Production Recommendations.

2. Do not apply pesticides that are not registered for the commodity unless there is no registered product for the pest. If no labeled material is available consult with Study Director to determine what can be used so that there is no interference with the trial.

3. If pesticides are applied to the commodity to prevent losses due to pests, they shall be applied according to the relevant SOPs in this document. No maintenance pesticide shall be applied that would interfere with the chemical analysis of the residues of the pesticide under trial. If in doubt, contact the study director, analytical chemist, or analytical laboratory identified in the protocol to receive the residue samples and document any communication. Apply any maintenance chemicals to both the treated and untreated plots.

4. Irrigate, fertilize, prune and otherwise perform agricultural practices as necessary to maintain a healthy commodity.

Rutgers Fruit Research & Extension Center
283 Route 539
Cream Ridge, NJ 08514

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Author: Tom Freiberger

Title: 6.1 When to collect residue samples.

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

Scope: At locations where trials are conducted to obtain GLP residue samples.

Procedures:

1. Consult the trial protocol to establish specific dates for the collection of samples. If these dates are based on uncontrolled events (fruit size, spray applications, etc.), then tentative dates shall be established and refined as necessary. The Study Director and Quality Assurance Officer shall be kept informed when the dates are changed. The protocol PHI takes precedence over degree of ripeness, as long as the fruit are fully filled at harvest.

2. Samples shall not be taken during periods of inclement weather, unless absolutely necessary.

3. Untreated samples shall be collected first, followed by the lowest dosage rate and working toward the highest dosage rate.

Rutgers Fruit Research & Extension Center
283 Route 539
Cream Ridge, NJ 08514

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Author: Tom Freiberger

Title: 6.2 Method of sample collection.

Purpose: To assure the collection of representative samples of the commodity.

Scope: Locations where trials are conducted to produce samples for residue analysis.

Procedures:

1. Representative samples of the crop in each plot must be taken. Record how sampling was done (eg. Every 3 ft, zig zag, etc.)

2. Consult the trial protocol to determine sample size and special instructions for the commodity. Briefly describe the procedures and methods used in the raw data. Record number of fruit/plants harvested. How they were harvested (cut, pulled, etc.).

3. Each sample should be taken individually beginning with the untreated plots and working up to the highest dosage. Each duplicate sample shall be collected, packaged and labeled before starting on another sample, unless samples are being harvested by different people. As the protocols generally require that stone fruit be pitted and strawberries decapped, the fruit can be harvested into an alternative bag or clean container for transport prior to modification. If the sample is excessively fragile (e.g. caneberries) or juicy (e.g. cut ripe peaches) the fruit can be placed in a sealable plastic bag first to reduce the potential for juices to drip out of the IR-4 residue bag.

4. Take special care to do the following in the sample collection process:
   12.1. Avoid contamination of the field sample with the pesticide under trial during the sampling, labeling, storage and shipping processes.
   12.2. Avoid taking diseased or undersized fruit.
   12.3. Take care not to remove surface residues during handling, packing or preparation.
   12.4. Do not transport samples in a vehicle used to transport pesticides without proper precautions.
   12.5. Be certain tools are cleaned in detergent/ammonia/bleach and water rinses.
   12.6. Do not remove any soil or plant parts or trim the commodity (leave stem in cherry etc.) unless specified in the protocol or with permission from the SD.
   12.7. Avoid sample bag contact with the soil or plant parts during sampling.

5. When the number of fruit is specified in the protocol, that number shall be met or exceeded. Sample weight shall be taken to insure protocol compliance. Balance/scale does not need to be maintained under GLPs if that lack of compliance is noted in GLP statement. Sample weight and number shall be entered in the FDB.

6. Samples should not be held in the field at ambient temperature for more than one hour prior to transfer to the freezer. Ambient conditions at the time of sample collection may influence sample stability and the field storage interval shall be reduced if sample deterioration may occur under adverse conditions or if the sample is particularly fragile. If a longer period in the field is required, the samples shall be stored in an insulated chest, with dry ice, blue ice or wet ice of sufficient quantity to reduce the sample temperature while in transit. Melted water from wet ice shall be contained adequately in plastic bags to prevent water contact with sample bag and sample. The samples shall be placed in frozen storage within time frame specified in protocol.

7. The following sampling procedures shall be used when appropriate:
   a. Cranberries shall be harvested with a cranberry scoop. The cranberry scoop shall be washed with soap detergent and rinsed before usage. Fruit shall be harvested with the scoop into a labeled plastic bag lined basket. Fruit shall be harvested from all areas of the plot, except plot ends. Vines or other debris shall be removed by hand. Untreated samples shall be harvested first, followed by treated.
   b. Peaches shall be harvested into plastic bag lined baskets and taken to the plastic-lined tail gate of the truck or other work station and pitted over plastic sealable bags (such as ziploc) so that fruit and juices shall be collected in the ziplocs and then placed in sample bags. Pits shall be discarded. Clean equipment (knives, cutting boards, etc.) shall be used between each sample set.

8. Protocol instructions for reporting sample harvest events and deviations, shall have precedence over this SOP.

Rutgers Fruit Research & Extension Center
283 Route 539
Cream Ridge, NJ 08514

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Author: Tom Freiberger

Title: 6.3 Sample identification and records

Purpose: To specify how IR-4 samples are to be identified and the records needed.

Scope: All locations conducting field trials to obtain residue samples.

Procedures:

1. Plastic-lined cloth sampling bags with an identification tag sewn into the bottom stitching are usually provided to GLP cooperators for sample collection. If these bags have not been provided, a sampling bag suitable to protect the integrity of the sample shall be used. Sample bags shall be fairly burst proof. Cloth laminated plastic bags are preferred.

2. Prior to sample collection, have a sufficient number of sample bags to collect all the samples with the treatments stored individually by individual replicates and a separate untreated check sample as large as a single treatment combined over the replicates.

3. Before entering the field, use waterproof ink to fill in the label attached to the bottom of the bag and indicate the trial ID number and bag number on the tag if more than one is used for the plot sampled. If no tag has been provided, then label each sample bag with waterproof ink as per the protocol or the following:

   a. Trial identification number
   b. Commodity (Crop)
   c. Chemical
   d. Replicate Number
   e. Date sampled
   f. Application rate (#a.i./A)
   g. Investigator: Name/Address/Phone #
   h. Container Number (if more than 1 container for a plot indicates 1 of 2 etc.)
   i. Sample number

4. When samples are ready for shipping, a GLP shipping form(s) 8A, B & C shall be completed. The form shall be signed and dated by the Field Research Director. Retain the original of the residue sample shipping form(s) in the project file folder until the samples are shipped to the residue laboratory.

Rutgers Fruit Research & Extension Center
283 Route 539
Cream Ridge, NJ 08514

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Author: Tom Freiberger

Title: 6.4 Packing and storage procedures.

Purpose: To assure the integrity of the samples after collection.

Scope: All locations where residue samples are collected.

Procedures:

1. Samples shall be frozen, with the untreated control sample separated from the treated samples. Separate designated freezers shall be used for the treated and untreated samples. Record the time and quantity when placing samples in the freezers on the freezer contents log.

2. A data logger shall be placed in the freezer so that it indicates the sample storage temperature. A min-max thermometer shall be placed in the freezer as a back up indicator.

3. The generally accepted temperature for frozen raw agricultural commodities is -18°C (0°F), usually specified in the protocol. A temperature increase above - 7°C (20°F) for three hours is considered normal with the addition of other ambient temperature samples. However, if the temperatures go above -10 °C (14 °F) or remain above -7°C (20°F) for greater than 24 hours, a deviation shall be reported. Defrost cycles create short term temperature spikes. Sample storage temperatures in the protocol shall have precedence over this SOP. Put data logger in closed container or ethylene to reduce temperature spikes when the door is opened.

4. The Freezer Maintenance Log shall provide a chronological record of activity in the freezer. Samples placed in freezers shall be recorded in the Freezer Contents Log. The Freezer Contents Log shall provide times and dates samples are placed in the freezers. A Freezer Maintenance Log shall provide dates of cleaning, any other servicing, and dates that recording instruments are downloaded. Temperature monitoring devices shall be checked at 7 (±4) days to ensure they are still recording (blinking light, etc). At the time of download the min/max shall be recorded, and the min/max thermometer shall be reset. Temperature monitoring devices in the freezers shall be downloaded approximately every 4 weeks.

5. The Freezer Contents Log shall be designated for each freezer and samples shall be identified when added or removed from the freezer on a chronological basis.

6. Originals of the temperature records of each freezer shall be maintained in the Common Data Book, and a certified copy place in the pertinent Field Data Books.

7. The temperature records (print-outs, hand-written records, etc.) shall identify the freezer and temperature monitoring device used to obtain the records. They should also include the date the record started and ended. Note that the first print out from electronic data loggers becomes the original when initialed and dated.

8. Freezers shall not have any materials present except GLP residue samples. The freezers must be locked or have controlled access. The IR-4 freezers are locked to protect sample integrity in storage. The Field Research Director has primary responsibility for maintenance and sample storage. Two alternate key holders have access to the freezers.

FACILITIES

1. Freezer Units
   a. Freezer #3 - Frigidaire upright freezer (20 1/4 cubic feet), Serial # WB63706062. Designated for untreated samples
   b. Freezer #6- GE upright freezer (20 ¼ cubic feet), Serial #GV139378. Designated for treated samples.
   c. Freezer #5- GE upright freezer (20 ¼ cubic feet), Serial #ZG169131. Designated as a back-up freezer.

EMERGENCY CONDITIONS

1. The freezers are all connected to a manual generator for electric power backup. In case of power failure, FRD shall be contacted by monitoring alarm and shall start the gas powered generator.

Rutgers Fruit Research & Extension Center
283 Route 539
Cream Ridge, NJ 08514

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Author: Tom Freiberger

Title: 6.5 Sample shipping procedures.

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

Scope: All locations where GLP residue samples are stored.

Procedures:

1. For overland shipments, notify the chemist at the residue laboratory of the scheduled pick-up, once a date has been arranged with a freezer truck carrier, such as ACDS Inc., notify him/her of the project number, shipment date, number of boxes, and method of shipment, including the carrier. Ask for any special instructions in shipping the samples. Overnight shipments shall be made on Monday or Tuesday to avoid potential weekend layovers. Overnight shipments shall be verified with the lab to ensure that there shall be someone present to receive the shipment upon its arrival. Notify carrier of the shipment and schedule pick-up time.

2. Complete residue sample shipping form(s), make copies and send them to the Study Director, Regional Coordinator, and residue chemist.

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

4. If a shipment is by airplane or by non-refrigerated vehicle obtain insulated containers of sufficient size and quantity to hold the residue samples and dry ice (where required). Include enough dry ice to keep the samples frozen for the anticipated transit time, for example a 3:1 weight ratio of dry ice to commodity. Pack the samples and dry ice in the containers just prior to shipment. When approved by Study Director as a protocol amendment, samples may be shipped with U-Tek Refrigerant Packs with approximately the same weight ratio as dry ice. The samples shall be placed in plastic bags, the dry ice placed around them (sides, top and bottom). Blocks of dry ice are preferable to pellets.

5. If shipping via freezer truck such as ACDS Inc., the samples shall be placed in a plastic bag before being placed in the shipping container. The containers can be prepared for shipment then returned to the freezer prior to shipping.

6. The containers shall have sufficient bursting strength so as to withstand normal handling in shipping and storage. Apply adequate tape and strapping to prevent cartons from opening during shipment.

7. Place the copy of the residue sample shipping form in a waterproof container and place a copy in or on each sample shipping container.

8. Label each 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 containers if more than one is used.
   d. Where used, affix "dry ice" on two sides of the container with correct DOT labels affixed for dry ice shipments.

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

10. Provide the carrier with the samples for shipment with a completed way bill and record the Field ID No. on the way bill.

11. Some samples may be stored and shipped at ambient conditions, however, the sample containers and shipping cartons must be designed to prevent sample deterioration and instructions shall be in the protocol.

Rutgers Fruit Research & Extension Center
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Author: Tom Freiberger

Title: 6.6 IR-4 Freezer Alarm System

Purpose: To assure that residue samples remain frozen within IR-4 freezers.

Scope: All locations where GLP residue samples are stored.

Procedures:

1. All freezers where residue samples will be stored must be monitored for temperature and power supply to insure that samples will remain frozen during storage. A Sensaphone Model 800 monitoring system was installed January 2015 to monitor all IR-4 freezers. This system must be operational when samples are present in freezers.
2. To get a reading of temperature inside each freezer, phone number 609-758-0973 can be dialed and system will give current temperature readings. This can also be obtained using the monitoring system keyboard. (see model 800 user's manual for instructions) The Sensaphone Model 800 user's manual will be kept in IR-4 office.
3. The Sensaphone Model 800 can be tested by unplugging the power source to the monitor, with the battery back, the system will call the programed phone numbers to indicate there is an alarm.
4. In the event of an alarm, the FRD will be contacted to immediately resolve the problem. A backup generator may be started in case of a power failure or samples can be moved to a back-up freezer in case of a freezer failure. The back-up freezer #5 is always on and functional and is also connected to the Sensaphone monitoring system. In the case of a freezer failure the data loggers used to monitor temperature must also be moved with samples. In such event the freezer sample log must indicate what took place.
5. A "Freezer Alarm Maintenance Log" will be kept to document the testing of alarm system. The testing of backup generator will also be documented in this log.

Rutgers Fruit Research & Extension Center
283 Route 539
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Author: Tom Freiberger

Title: 7.1 Collecting and Recording of raw data.

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

Scope: All IR-4 GLP trials.

Procedures:

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

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

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

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

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

II. Recording Data:

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

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

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

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

5. Blank forms may be PRINTED OR photocopied as needed.

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

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

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

9. Typewritten or electronic data shall be signed and dated on date that it is printed. More detail ON electronic data in SOP 7.3.

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

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

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

13. All blanks or prompts on the provided forms shall have a response.
    a. If the prompted question does not apply to the trial, use NA.
    b. If the data is not available, the response shall be written out as such.
    c. The one exception is when the question starts with 'if'. As a recognized conditional in Standard English, no response is needed as long as the condition is met. E.g., If the answer is no, and the conditional prompt is for no. However, if the conditional and prompt do not agree (the answer is yes, but the prompt is for no) then the question shall be answered.

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

15. The narrative portion of the forms shall be used to summarize the activity or to explain anything that is unusual. If the space provided is not sufficient to adequately describe the activity, an additional, properly identified page shall be used. No attempt shall be made write smaller or closer together to fit more in the space provided.

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

17. Changes to the raw data shall be lined through once, a reason given, initialed and dated. The correction explanation and/or code may be circled. Codes used for reasons shall be defined, as per #16, above.
18. Transcribing data for a GLP field trials is not acceptable, unless absolutely necessary, for example, general farm records.
    a. Transcribed data shall be clearly identified as transcribed, the location of the original cited, and dated and initialed by the person doing the transcription.
    b. Verification of accuracy by an independent reviewer is recommended.
    c. Raw data shall not be transcribed to forms and then the forms submitted as raw data. Instead, a certified copy of the original shall be submitted, citing the original's location.

19. Raw data may apply to two or more trials. In that case, certified copies shall be used as needed. See SOP #7.2 for more details.

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

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

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

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

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

5. All supporting data has been added to the book, such as SOPs, personnel information, equipment logs, weather data, chemical and sample storage temperatures, etc.

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

7. The GLP compliance statement accurately reflects the study. All procedures not conducted in accordance with GLPs will be noted in the FDB, Part 1, GLP Compliance Information. Raw data/information not conducted/collected under GLPs at this site may 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 Field Data Book forms shall be arranged alphabetically. Supplementary documentation shall be placed behind the page it supports. For example, weather data behind 9A. If there is no prompt, place data behind the page to which it is most relevant. For example, Test Substance shipping documentation behind 4A.

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

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

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

Rutgers Fruit Research & Extension Center
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Author: Tom Freiberger

Title: 7.2 Handling data that transcend two or more trials and certified copies.

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

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

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

Procedures:
Data Common to more than one trial:

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

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

Certified Copies

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

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

Templates

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

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

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

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

Rutgers Fruit Research & Extension Center
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Author: Tom Freiberger

Title: 7.3 Collection of raw data electronically.

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

Scope: All locations conducting GLP field trials.

Procedures:

1. All remote sensing and other automatic data collecting and/or recording devices shall be inspected and calibrated as described under SOP 4.7.

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

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

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

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

Rutgers Fruit Research & Extension Center
283 Route 539
Cream Ridge, NJ 08514

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Author: Tom Freiberger

Title: 7.4 Disposition of raw data and documents for GLP trials.

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

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

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

Active life of the trial:

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

2. The protocols, Field Data Books and supporting data shall be stored in limited access area (locked office, and or within a locked fire proof cabinet) during the active life of the trial. The current Common Data Book and Facility File shall be stored with the Field Data Books during the season. The locked room is of sufficient size to contain all active records and data generated during the season. The room is in close proximity to the field and available for the Field Research Director or technician responsible during the conduct of the trials. All FDBs and supporting data for active trials are stored at the Rutgers Fruit Research Center 283 Rt 539 Cream Ridge, NJ 08514 in the main office room #102.

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

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

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

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

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

COMMON DATA FILES

1. Once all the Field Data Books have been completed, the original raw data in the Common Data Book shall be sent to IR-4 Headquarters for Archiving. One certified copy of the Common Data Book shall be retained by the Field Research Director, a second copy shall be sent to the Regional Field Coordinator. The Common Data Book may include, but not be limited to:

a. The current original authorized SOPs
b. The original signed and dated CVs and training records of personnel involved in the conduct of any GLP trials during the year
c. The personnel records of any personnel no longer involved in the project.

d. Original Organizational Charts and floor plans being retired, as new ones are generated.
e. Any Test Substance inventories and logs not place Field Data Books.
f. Chemical and frozen residue sample storage temperatures
g. Irrigation records, weather data and soil analysis information.

Facility File:

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

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

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

Historical Files

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

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

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

Rutgers Fruit Research & Extension Center
283 Route 539
Cream Ridge, NJ 08514

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Author: Tom Freiberger

Title: 8.1 Procedures to follow prior to an announced EPA inspection.

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

Scope: All locations conducting field trials.

Procedures:

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

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

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

4. Prepare trial and/or facilities personnel for the inspection.
   a. Discuss position descriptions with technical personnel so they understand and can explain their role in the trial.
   b. Discuss possible questions that may likely come up about the trial or facility and make sure everyone understands what to expect.
   c. Request personnel to answer the questions only to the extent needed and not to provide extraneous information. Do not volunteer information; keep answers direct and to the point.
   d. Make certain that technical personnel know the safety precautions needed for the work area.
   e. Be certain that all documents pertaining to the trial/facilities inspection are available. This would include:
      i. Master schedules for both the field research director, Quality Assurance Research Officer and possibly their counterparts at the region and IR-4 headquarters.
      ii. Trial Protocol and Standard Operating Procedures
      iii. Raw data, correspondence and logs.
      iv. Training records, CVs etc. of personnel assigned to the trial.

v. Appropriate chain of custody documents for samples and freezer logs and storage temperature documentation.
vi. Documentation of the characterization of the test substance, receipt and handling.
vii. Calibration logs on equipment such as balances and application equipment.
viii. Archives or storage of records and logs indicating removal and replacement of documents.
ix. 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 (restaurants, motels etc.)

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Author: Tom Freiberger

Title: 8.2 Procedures to follow during an EPA inspection.

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

Scope: All locations conducting field trials.

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. Identify the person responsible who shall accept the Notice of Inspection.

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

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

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

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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Title: 8.3 Procedures to follow after the EPA inspection.

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

Scope: All locations conducting field trials.

Procedures:

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

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

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

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

5. Be sure you obtain a copy of the list of documents or other materials that may be taken as exhibits by the inspectors.

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

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

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