SOP Log Sheet

ID # SOO302

Receive Date: 3/3/22

Region: NER

State: MA **City:** East Wareham

FRD/LRD: Martha Sylvia
Submitter

Effective Date: 2/10/22

Description of Material (s): 2022 SOPs

File Format: E-mail ☑ **Hard Copy** ☐

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

(Circle one)

Date Post to Website: 2/4/22 **Archive Date:** 3/7/22

Archive Location: 66-1

Sign: _____

Comment: _____

1/19/2022 JT

STANDARD OPERATING PROCEDURES
FOR MAGNITUDE OF THE RESIDUE-FIELD TRIALS
CONDUCTED UNDER GOOD LAB PRACTICES
(IR-4 FIELD TRIALS)

MARTHA SYLVIA

UNIVERSITY OF MASSACHUSETTS
CRANBERRY STATION

ONE STATE BOG ROAD
EAST WAREHAM, MA 02538

SET REVISION NO.: 7

Set Effective Date: February 25, 2022

Martha Sylvia	Martha Sylvia	Martha Sylvia	MMS	2/11/22
Field Research Director	Martha Sylvia	Signature	Initials	Date

APPROVED BY:

Marylee Ross	Marylee Ross			02/16/22
Regional Field Coordinator	Marylee Ross	Signature	Initials	Date

The above signatures, initials and dates constitute approval of the entire set of Standard Operating Procedures as reviewed.

University of Massachusetts, Cranberry Station, East Wareham
Sylvia

STANDARD OPERATING PROCEDURES
TABLE OF CONTENTS
SET REVISION NO.: 6
Set Effective Date: May 15, 2014

University of Massachusetts, Cranberry Station, East Wareham
Sylvia

SOP Number: 100.02
Page: 1 of 2
Effective date: May 15, 2014
Author: Martha Sylvia

Title: APPLICATION OF GLP REGULATIONS, SOP DEVELOPMENT AND REVIEW

Purpose: To define the status of GLP (GOOD LABORATORY PRACTICES) for all studies to be submitted to the EPA in support of registration.

Scope: GLP field studies at UMass Cranberry Station

Procedures:
APPLICATION OF GLP REGULATIONS.

1. Magnitude of Residue studies (MOR) that are conducted in the support of the registration of pesticides shall have SOP's for all phases of the research. Studies that need to be conducted under Good Laboratory Practice Standards (GLP) shall be periodically inspected and audited by the regional QA unit, or designated representatives, to determine if the studies are being conducted per these Procedures. The University of Massachusetts is dedicated to achieving full compliance with GLP regulations. Standard Operating Procedures (SOP) have been established to verify that these standards exist and are practiced. These procedures are applied for IR-4 work done at the UMass Cranberry Station.

2. A standard operating procedure may be written to document procedural steps to be followed for any task that shall be routinely performed or that is important in obtaining accurate, reproducible results.

REVIEW and APPROVAL OF SOP's:

3. Each SOP shall be reviewed and/or revised by the Field Research Director or assigned personnel as needed, at least every five years. This review shall take place before the initiation of GLP trials.

4. The SOP's for the UMass Cranberry Station shall generally be approved as a set, when reviewed. 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 Research Site, the SOP set Revision Number and Effective Date, and the dated signatures of the Field Research Director and approving official. SOP's revised or generated after the SOP set has been approved, shall be signed and dated separately and incorporated into the SOP set for subsequent revisions.

5. Any change to an individual SOP shall be considered a revision. This includes correcting grammatical and/or typographical errors, as well as technical changes.

6. The revision number of the individual SOP shall be changed to reflect the change and a new effective date assigned. The revision number shall also be altered in the table of contents to reflect the change.

7. Please note that individual SOP revision numbers and effective dates may not always be the same as those of the Set. As the revision number and effective date on individual SOPs are only changed when that SOP has been revised. Set Revisions and Effective dates reflect the timing and approval of the entire set.

8. Original signed SOP's shall be sent to IR-4 Project Headquarters, Rutgers University, 500 College Road East, Suite 201, Princeton NJ 08540 for archiving at the end of each season. Certified copies shall be filed in the Historical File, a locked filing cabinet in Room 118.

9. RETIRED SOP'S: Any SOP that is no longer applicable may be retired by the addition of a dated statement to the SOP declaring that it has been retired. The SOP shall keep its number and continued to be listed in the contents, but marked there as retired. Retired SOPs may be reactivated by the addition of a procedure statement to that effect, indicating the date of reactivation.

10. DEVIATIONS: Any deviations from the SOP's shall be noted in the Field Data Book (FDB) and approved by the Study Director. The Study Director shall be notified in a timely manner and the Regional Field Coordinator copied. Please note that copies of approved SOP deviations are generally not returned to the Field Research Director (FRD).

University of Massachusetts, Cranberry Station, East Wareham
Sylvia

SOP Number: 101.03
Page: 1 of 2
Effective date: May 15, 2013
Author: Martha Sylvia

Title: SOP ORGANIZATION, REVIEW, AND DISTRIBUTION

Purpose: To provide information relevant to the organization and use of Standard Operating Procedures (SOP's).

Scope: Applies to all SOP's developed for use in the conduct of GLP field research studies.

Procedure:
SOP NUMBERING:

1. Standard Operating Procedures are organized into subject groups in the following manner:

SOP #	TITLE
1XX.XX	General and personnel
2XX.XX	Agronomic Practices, Test Substance and Sample Handling
3XX.XX	Equipment
4XX.XX	Data Handling
5XX.XX	EPA Inspection

2. The SOP number consists of the three digits immediately preceding the decimal point. The first digit is the subject number. The next two digits are sequential within each subject, starting with zero, and represent individual SOP's. The two digits following the decimal point represent the revision number. Zeros in this position indicate the original issue.

   Example: 200 address test substance handling, while 201 covers the field plots. 200.00 is the SOP as originally issued. If it were to be revised, the number for the first revision would be 200.01, the second revision 200.02, etc.

IDENTIFICATION OF SOP'S:

3. All SOP's shall be identified with a header that includes the Research Site and Field Research Directors currently active at the site, centered at the top. Then each SOP shall start with the SOP number, page numbers, and effective date.

Continued.....

University of Massachusetts, Cranberry Station, East Wareham
Sylvia

SOP Number: 101.03
Page: 2 of 2
Effective date: May 15, 2013
Author: Martha Sylvia

FORM OF SOP's:

4. The following is the format to be used for each Standard Operating:

University of Massachusetts, Cranberry Station, East Wareham
Field Research Directors currently active

SOP Number: (XXX.XX)
Page: (# of total #)
Effective date: (date SOP becomes effective)
Author: (Name of person who wrote the SOP)
Line
Title: (brief title of the SOP)
Line
Purpose: (brief description of the purpose of the SOP)
Line
Scope: (determines where and when the SOP is applicable)
Line
Procedures: (describe the procedures in order from beginning to end so that a person with some knowledge of the situation can carry out the procedures without any verbal input from other sources.)

5. SOP's of more than one page shall be identified on each page. This identification shall be justified left at the top of each page. For example:

SOP Number: 101.02
Page: 2 of 2
Effective date: May 15, 2013

COMMON ABBREVIATIONS:

6. Common abbreviations used in these SOP's are:

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

University of Massachusetts, Cranberry Station, East Wareham
Sylvia

SOP Number: 102.03
Page: 1 of 1
Effective date: May 15, 2014
Author: Martha Sylvia

Title: RESPONSIBILITIES OF FIELD RESEARCH DIRECTOR

Purpose: To provide information on the designation and responsibilities of the Field Research Director.

Scope: Studies conducted under GLP

Procedure:

1. The Field Research Director (FRD) is designated by the Study Director, based on the recommendation of the Regional Field Coordinator. The FRD 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 UMass Cranberry Station 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. Assure 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, Quality Assurance Officer, Study Director 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 Regional Field Coordinator, Quality Assurance Officer and Study Director are responded to in writing, or direct contact (telephone, e-mail, etc.) in a timely manner.
   f. Assure that all raw data, summaries, and other items connected with the trial that need to be retained, are transferred to IR-4 Headquarters for archiving.
   g. Maintain certified copies of the Field Data Book until data is submitted to U.S. EPA.
   h. Maintain a file of current resumes, job descriptions, and training records for all key personnel currently engaged in the trial. Ensure the information is archived at IR-4 Headquarters when personnel leave or other changes occur.
   i. Designate the trial location for the facility and maintain perennial crops under good agricultural practices.
   j. Assure that safety equipment is in working order and sufficient to protect the health and safety of personnel connected with the project.

University of Massachusetts, Cranberry Station, East Wareham
Sylvia

SOP Number: 103.02
Page: 1 of 2
Effective date: May 15, 2013
Author: Martha Sylvia

Title: GENERAL PERSONNEL AND TRAINING

Purpose: To provide information concerning requirements under GLP for personnel and to assure that training is properly documented

Scope: Studies conducted under GLP

Procedure:

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

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

3. Personnel handling pesticides shall be trained in accordance with the current policies and guidelines of the University of Massachusetts. General personnel shall have Worker Protection Standard training as a handler. Where the application of restricted use pesticides is required in the trial, the applicator shall be a certified applicator.

4. The field site facility shall have a supply of safety equipment in working order and sufficiently clean to protect the health and safety of the personnel connected with the project as required by Worker Protection regulations, UMass Cranberry Station regulations, pesticide labels or the trial protocol.

PERSONNEL

1. The field test facility shall have on file information for each person currently supervising any phase of an MOR trial, as well as those collecting and/or entering data under GLPs. This information shall include, but not be limited to documentation of:
    a. Formal training. If at an institution of higher learning a CV or a notation that the person received a degree, and the year graduated noted. If a degree was not awarded then the years of attendance, credit hours and specialty shall be noted. Years of experience may serve in lieu of some or all of the formal education.
    b. A GLP Training Log. A log shall kept for each employee recording that:
        i. those sections of the protocol, Standard Operating Procedures and other materials that pertain to their responsibilities have been read and understood.

Continue . . .

ii. The date and brief description of the training shall be entered in a log for each employee.
iii. Verbal instruction and informal training, such as site visits from the Regional Field Coordinator and/or Quality Assurance Officer shall also be recorded and placed in the log or other written record 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).
iv. NOTATIONS OF formal training received from workshops, conferences, etc. shall be noted either on the CV or training log. A copy of any type of training certificate issued shall also be retained in the personnel files.
v. A brief job description outlining the individual's duties as they pertain to MOR trials.

b. The above personnel records shall be forwarded to IR-4 Headquarter for archiving on a regular basis, or, at a minimum, when the employee leaves the project. Certified copies shall be retained in the Historical File.

2. The Curriculum Vitae (CV) shall be revised, printed, initialized and dated every year, with the original included in the Field Data Book. If more than one Field Data Book is being generated in the same year, the original CVs along with the training records shall be placed one book with certified copies in each additional book, citing the location of the original.

3. For personnel who are not collecting and/or entering data involved in critical phases of the study, 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. A list of these personnel, along with some notation of what was explained shall be included in the Field Data Book.

4. Personnel who are only involved in routine maintenance and other non-critical duties do not need to be included as this is covered under the statement of non-GLP compliance in the FDB.

University of Massachusetts, Cranberry Station, East Wareham
Sylvia

SOP Number: 104.00
Page: 1 of 1
Effective date: May 15, 2013
Author: Martha Sylvia

Title: ORGANIZATIONAL CHART

Purpose: To provide information the lines of communication concerning GLP Studies

Scope: Studies conducted under GLP

Procedure:
GLP COMMUNICATIONS FLOW CHART

1. An organizational chart shall be developed which reflects lines of communication and responsibility for GLP studies, i.e., the various individuals/entities directly involved in the conduct of the GLP studies. Specific entities shall include, but not be limited to: the Sponsor that initiates and finances the study and submits the report to the EPA; the Study Directors who have individual responsible for the overall conduct of the study; Quality Assurance; Testing Facility Management who oversees the GLP work and personnel and approves SOP's (Regional Field Coordinator in the case of IR-4); and Testing Facility the site where the trials are located and the person who actually uses the test substance in the test system (IR-4 Field Research Director).

2. The relationship of the Test Facility personnel to the departmental and college level administrators within UMass may also be included.

Each block in the chart shall show the title of entity and the name and of specific personnel, where appropriate, starting with the Sponsor (IR-4 HQ, Debbie Carpenter, Sponsor Representative) at the top.

3. 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

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

University of Massachusetts, Cranberry Station, East Wareham
Sylvia

SOP Number: 200.02
Page: 1 of 2
Effective date: May 15, 2013
Author: Martha Sylvia

Title: TEST COMPOUND RECEIPT AND DOCUMENTATION, STORAGE FACILITY, AND STORAGE CONDITIONS

Purpose: To outline the procedures for receipt, storage, and documentation of test compounds.

Scope: Studies conducted under GLP

Procedure:

1. Arrival of GLP Test Substance shall be checked for daily: When a Test Substance is received, it shall be checked according to points 2-4 below and then placed directly into the chemical storage building at the Cranberry Station. The storage facility is a weatherproof, locked enclosure with limited access. It is called the UMass Cranberry Station Pesticide Storage Room.

2. Upon receipt, the shipping container is opened and 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. 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. Arrival information shall be recorded in the chemical inventory log, 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. A chemical inventory log shall be maintained by the Field Research Director and kept in the locked IR-4 cabinet inside the locked pesticide storage facility at the Cranberry Station. Removal and return of the Test Substances shall be recorded in the chemical inventory log. The disposal of the Test Substance and/or its container shall also be entered in the chemical inventory log.

Continued . . .

6. Adjuvants used with Test Substances shall be stored in the locked pesticide storage facility at the Cranberry Station. They shall be assigned an expiration date of five years from the date of receipt. A copy of the label will be included in the FDB.

7. The max/min temperatures in the chemical storage building shall be monitored and recorded from within two days of its arrival through the time of the last application. Readings shall happen at a minimum of once a week when there is an active project with Test Substance present.

8. Test Substance removal shall be recorded in real time (i.e. at the time compound was removed). If the same container of Test Substance is used for multiple trials, one form shall be used and certified copies placed in other books.

9. All Test Substance containers shall be stored in the locked IR-4 cabinet inside the locked pesticide storage facility at the Cranberry Station. The containers shall be accessible only to the Field Research Director, research personnel, and the Farm Manager. The storage of the Test Substances shall be separate from areas where the pesticide is mixed. All Test Substance containers shall be retained in the locked pesticide storage facility at the Cranberry Station until the final study report (Pesticide Tolerance Petition) has been signed by the Study Director (study completion date), the trial canceled or dropped. The IR-4 website (Advisory 2005-01) shall be consulted prior to disposal.

10. 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.

11. 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.

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

University of Massachusetts, Cranberry Station, East Wareham
Sylvia

SOP Number: 201.02
Page: 1 of 2
Effective date: April 22, 2019
Author: Martha Sylvia

Title: FIELD PLOT PREPARATION, SET-UP, CARE, AND OBSERVATION.

Purpose: The purpose of this SOP is to provide general methods of field plot preparation, set-up, care, and observation. It shall be used as a guideline for preparing field plots, setting up plots, care of field plots, and observations of field plots.

Scope: Studies conducted under GLP

Procedure:
1. FIELD PLOT PREPARATION and SET-UP: After determining the field plot location, size, and arrangement, prepare the plots according to the protocol and/or local agronomic practices. These practices may include several different methods of fertilization, weeding, pruning, and maintenance with pesticide application. Prepare a plot map showing the location of each plot, using permanent reference points (sprinkler heads). Measure at least 2 corners of plot and mark all 4 corners with colored flags or other markers. The front and back of each plot shall be marked with a permanent label as per protocol (usually labeled wooden stake).

2. FIELD PLOT CARE: Once the field plots have been marked out, provide adequate care for the cranberries to simulate a commercial crop or maintain according to protocol requirements. Test system care would include provisions for adequate moisture through irrigation, a relatively weed-free condition, and little or no pressure from insects and diseases. Provide cultural practices, mechanical or chemical, to alleviate a less than desirable condition that may develop. Any chemicals used for maintenance shall be labeled for the crop and chemicals that might interfere with a residue analysis shall be approved by the Study Director. Records shall be kept of all chemicals used for maintenance.

3. FIELD PLOT OBSERVATION: Observe the test system frequently for pests and environmental conditions that may not be conducive to normal plant growth and development. These observations can be made at the time of test substance applications, samplings, or as needed for a given crop. No specific guidelines regarding the frequency of observation are provided since several factors such as environmental conditions, type of crop, stage of growth, and time of the season shall determine the frequency required. Field plot observations are useful for determining crop stage of growth and subsequent applications or samplings that are needed.

4. DOCUMENTATION: Record test system preparation, care, and observation comments in the IR-4 Field Data Book under the appropriate section.

Continued…

Cranberries in Massachusetts are grown in large beds averaging 1 to 20 acres. The vines are a monoculture, with uprights and runners intermingled and spread across the bed. Generally the vine stands about 10-16 cm (4-6"). While the uprights tend to be biennial bearing, the overall production of a bed is annual. The beds are divided by land dikes and within a bed there are often crossing drainage ditches. The beds are otherwise contiguous vine with no alleys, rows or pathways dividing them. Plants within sections are generally all of a single cultivar.

Plots for research (treated and untreated) shall be set up within one section of a cranberry bed of the same cultivar, separated by a buffer of at least 15 feet. Generally, a spray plot is 18' x 18', divided into 3 spray sections and spray lanes flagged for ease of application.

Irrigation is commonly used throughout the growing season. Commonly, the vines require an inch per week from either rain, capillary action from groundwater, irrigation, or some combination of these. If provided by irrigation, it is about a tenth of an inch an hour applied in the early morning for several hours.

Most cranberry bogs are harvested in water and sold as processed fruit. A harvest flood is applied for several days as each bog is picked. During water harvest, the berries float and are corralled using floating booms. The berries are removed from the flood via a conveyor or vacuum hose. More than 90% of the cranberries in Massachusetts are wet harvested.

Sanding is a commonly used cultural practice that most cranberry growers use. Growers apply thin (1/2 to 2 inch) layers of sand on the surface of producing cranberry beds at 2- to 5-year intervals to promote growth, improve productivity, suppress disease and weeds, and reduce insect populations. Sanding is particularly well suited to the cranberry system. The layers of sand anchor runners and cover bare wood at the base of uprights (vertical stems), promoting rooting and the production of new uprights. The preferred method of sand application is on the ice of a flooded bog during the winter months (ice sanding). This prevents vine injury caused by sanding equipment operating on the bog (dry sanding). Sanding improves soil drainage and may physically strengthen peat soils so that mechanical operations on the farm are easier.

A winter flood is usually applied by cranberry growers for several weeks in the winter months to protect the bogs from winterkill (desiccation). This flood may be applied as early as December 1 and remains on the bog as long as winterkill conditions are present or forecast. Generally, floods are not held longer than a month due to oxygen deficiency conditions. A new flood may be reapplied if necessary. Generally, a flood should not need to be held any later than March 15.

University of Massachusetts, Cranberry Station, East Wareham
Sylvia

SOP Number: 202.02
Page: 1 of 1
Effective date: May 15, 2013
Author: Martha Sylvia

Title: PROCEDURES FOR APPLICATION OF TRIAL PESTICIDES

Purpose: To assure that the trial pesticides are applied uniformly to the plots.

Scope: Studies conducted under GLP

Procedure:
1. A complete discharge calibration (three complete discharges or runs) is required for the first application. Ensure all settings of pressure, speed, granular flow etc. are set according to specifications. Although complete calibrations for each application are recommended, discharge and speed calibrations can be confirmed with at single recheck, as long as none of the application parameters or equipment components have been changed. Rechecks shall be within +/- 5% of original calibration or a complete calibration shall be run. See SOP 303.03 for details of calibration.

2. Just before entering each plot make sure you are traveling at the correct speed and turn on the sprayer or release granules. Maintain the correct speed through the plot. Be sure to record time. See SOP 303.02 for speed calibrations.

3. Apply the material according to the directions in the protocol or as specified on the label. Calculations shall be made to minimize the amount of spray material left in the spray equipment. This residue shall be sprayed to a similar crop, overplant, or a non-crop area.

4. During application, the operator shall observe the process to make sure that the test substance is being evenly distributed to the commodity. If something goes wrong, for example, a nozzle is plugged or a hose breaks, then the operator shall take immediate action to correct the situation. The Field Research Director shall ascertain if the integrity of the project has been damaged. The final decision rests with the Study Director. 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. If the unaffected area is too small to obtain the samples required for analysis, then the trial(s) shall be discontinued and the Study Director contacted immediately. The Regional Field Coordinator and the Study Director shall be notified of the incident with details recorded in the raw data notebook. A new field ID number is needed to restart a trial after the first application has been made.

5. Equipment shall be cleaned after every use according to SOP 304.00

University of Massachusetts, Cranberry Station, East Wareham
Sylvia

SOP Number: 203.01
Page: 1 of 1
Effective date: May 15, 2008
Author: Martha Sylvia

Title: COLLECTING RESIDUE SAMPLES

Purpose: To assure that samples taken for residue analysis are representative of the treated area and their integrity remains intact during the sampling process.

Scope: Studies conducted under GLP

Procedure:
1. Follow protocol instructions for obtaining residue samples, including timing of sampling, size of sample, type of sample, and any special requirements unique to that study.

2. A cranberry scoop (full size 22" x 16", ½ size 12" x 20.5", or ¼ size 8" x 12.5") shall be used to harvest commercially ripe cranberries. Berries do not need to be completely red to be commercially ripe, but shall be fully sized. The scoop has long wooden tines that rake through the cranberry vine and collect the cranberry fruits. The scoop is raked through the vine in a rocking motion until sufficient fruits are collected. Twigs, leaves, vine, bramble and obviously rotten berries are removed by hand. The berries are emptied into the labeled IR-4 bags, which is then tied closed.

3. If there is absolutely no way to avoid harvesting wet berries in order to meet the pre-harvest interval required in the protocol, then, after scooping, the wet berries may be dumped into a shallow pan lined with paper towels in order to get rid of any excess moisture before going into bags. Permission shall be obtained from Study Director before harvesting wet berries.

4. Always sample control plot first, followed by the plot treated with the lowest dosage rate or longest treatment-to-harvest interval and working toward the plot treated with the highest dosage rate or shortest treatment-to-harvest interval. Complete one set of duplicate samples before starting the harvest of another treatment. Avoid contamination of samples during the harvest process from tools, vehicles, soil, hands or clothing, containers or other samples.

5. The scoop is washed with soap and water before the start of sampling. Control samples are collected first. Treated samples are harvested last, in ascending order of largest application rate last. Each sample is made up of scoops from 12 or more separate areas within each plot. The samples are taken every three steps up plot rows and back again. No samples are taken from within 1 foot of the edges or ends of the plot.

6. Samples are placed in freezers as soon as possible. Freezers are generally within one mile of plots. Use a cooler with blue ice or other coolant, if samples cannot be placed in freezers within one hour. Treated and control samples are placed in separate coolers.

7. The remaining crop in the treated plot shall be harvested and destroyed if product tested is not registered in cranberries.

University of Massachusetts, Cranberry Station, East Wareham
Sylvia

SOP Number: 204.01
Page: 1 of 2
Effective date: May 15, 2008
Author: Martha Sylvia

Title: SAMPLE SHIPPING PROCEDURES

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

Scope: Studies conducted under GLP

Procedure:

1. Consult protocol for specific instruction on shipping samples.

2. PREPARATION: Samples will be completely frozen prior to shipping unless written dispensation has been given by the Study. Prior to the samples being shipped, contact the personnel (as specified in protocol) at the residue lab and notify him/her of the shipment dates and method of shipment including the carrier and carrier schedule. Ask him/her for any special instructions in shipping the samples. Air freight shipments shall be made on Monday or Tuesday to avoid potential weekend layovers.

3. Sample shipments from the UMass Cranberry Station are usually via air-carriers, but ground transport (such as ACDS) shall be contracted to first to determine if they may be available. Make arrangements with the carrier for shipment of the samples and determine any special packing instructions that are required to preserve sample integrity. Note any limits on quantity of dry ice etc. that may be set by the carrier.

4. Obtain insulated containers, if necessary, of sufficient size and quantity to hold the residue samples and dry ice when shipping by air. Pack the commodity samples with enough dry ice to insure sample integrity (usually a 1:3 weight ratio) just prior to shipment. The containers shall have a sufficient bursting strength so as to withstand normal handling in shipping and storage. Coolers may be used for air shipments.

5. Copy the completed residue sample shipping form (8A) and the chain of custody form (8B) and place in a waterproof container with the storage samples. Include a sample arrival check sheet (8C). Place the copy of these 3 forms in every container. Distribute copies of the residue sample shipping form as indicated on the form.

6. Label each shipping carton with the following:
   Return name and address of the sender
   name and address of the residue lab receiving the samples
   number of containers if more than one is sent
   affix "experimental samples - perishable" on each carton
   where used, affix "DRY ICE" on two sides of the container

continued...

7. Tape lids of each container firmly in place.

8. Provide carrier with the phone number of the residue lab receiving the samples and request the carrier to notify the lab if the samples arrive at a remote terminal for pickup. Provide the carrier with the samples for shipment.

University of Massachusetts, Cranberry Station, East Wareham
Sylvia

SOP Number: 300.03
Page: 1 of 2
Effective date: May 15, 2014
Author: Martha Sylvia

Title: VERIFICATION OF THERMOMETERS AND OTHER TEMPERATURE MEASURING DEVICES

Purpose: To provide guidance to personnel on calibrating and verifying temperatures of thermometers other temperature monitoring devices.

Scope: Studies conducted under GLP

Procedure:

1. A certified thermometer is used for verification of all thermometers used in GLP studies. Other temperature monitoring devices, such as ibuttons or electronic devices, are also verified in the same manner. The certification papers are in the historical files in the locked fireproof facility file cabinet (Room 118, Entomology Office). The certified thermometer is checked once a year using an ice water bath and a boiling water bath.

2. Once a year, all temperature measuring devices used in GLP studies at the Cranberry Station shall be checked against the reference certified thermometer to verify the correctness of recorded temperatures. This once-a-year check shall be recorded and this verification check shall be sent in with the raw data. Copies may be retained in the historical file.

3. A unique number shall identify all temperature monitoring devices. The identification number shall be placed on the measuring device such that it can easily be cross-referenced to verification paperwork. Spare verified max-min thermometers shall be kept on hand in the eventually of breakage or incorrect readings. When replaced the date and reason are recorded in the log for the device being replaced.

4. VERIFICATION: Measuring devices to be checked and the reference thermometer shall be read side by side in water under conditions appropriate to the intended use. At least two water baths shall be used. Examples of temperature ranges to test may include: boiling, warm (approx. 55°C), room temperature (approx. 22°C), or ice (approx. 0°C). Water baths shall be 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. The temperature monitoring devices shall be verified in the water baths from warm to cold. The temperature monitoring devices and the reference thermometer shall remain in the water bath until a constant reading is reached. When the

analyst feels confident that reading is constant, the value shall be recorded. The following information shall also be documented: date of verification, initials of person doing verification, reference thermometer reading at each temperature, temperature monitoring device reading at each temperature, ID number of the device being checked.

5. Temperature readings taken from the reference thermometer may be rounded to whole numbers (e.g.: If reference reads 38.2°C, the recorded value can be 38°C). 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. When recording a thermometer reading, the following information shall always be included in the entry: date, initials of reader, and thermometer number.

University of Massachusetts, Cranberry Station, East Wareham
Sylvia

SOP Number: 301.03
Page: 1 of 1
Effective date: May 15, 2014
Author: Martha Sylvia

Title: COLLECTION AND RECORDING OF DATA FROM ELECTRONIC MONITORING DEVICES

Purpose: To describe methods for handling data from remote sensing and other data collecting devices, such as hobos and other temperature monitors.

Scope: Studies conducted under GLP

Procedure:

1. All remote sensing and other automatic data collecting and/or recording devices shall be inspected and verified as described under SOP 300.03

2. The first printout is the original and shall be initialed (or signed) and dated. If this information is needed in more than one trial, certified copies of the original shall be made, citing the location of the original. Prints or plots of data from these devices shall be legible to persons with normal vision.

3. Hard copies of computerized data and/or other written, typed or plotted data sheets shall be retained in the file folder of the project and included in the Field Data Book or otherwise sent to IR-4 Headquarters for archiving.

4. 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.

4. Each data sheet from a monitoring device shall be marked in ink with the device name or identifier, dates (day, month, year) of occurrence of the event measured, verified dates, units of measurement and signed by the individual who generated them.

University of Massachusetts, Cranberry Station, East Wareham
Sylvia

SOP Number: 302.03
Page: 1 of 1
Effective date: May 15, 2014
Author: Martha Sylvia

Title: COLLECTION AND PRESENTATION OF WEATHER DATA

Purpose: This outlines the kind of weather data that shall be collected

Scope: Studies conducted under GLP

Procedure:

1. Temperature, humidity, rainfall, and wind speed data shall be recorded DAILY for each trial conducted under GLP.

2. For trials conducted at the UMass Cranberry Station, weather information is collected by hand daily by the farm manager.

3. The weather station shall be no more than 10 miles from the study site. For sites more than 10 miles from the Station, local weather reports shall be used.

4. Weather data shall be collected for the full growing season, app. May 1- Oct. 1.

5. Each page of weather data shall be properly marked as true and exact copies. Signatures and dates are also necessary to verify that all the weather data on a page is a certified copy of the computer or written record. The certified copy shall state the location of the original.

6. If weather data are provided from any source other than on site collection, the location of the data collection site shall be referenced on the data provided. When these data are submitted, they shall be true and exact copies and marked as such.

7. If remedial action is needed to fix the weather station, a specialist shall be brought in.

8. Hand-held equipment used to collect application day weather data shall be verified (e.g. wind meter, verified thermometers, etc.). This equipment shall be verified as per SOP 300.03 (thermometers) and 308.00.

University of Massachusetts, Cranberry Station, East Wareham
Sylvia

SOP Number: 303.03
Page: 1 of 2
Effective date: April 1, 2019
Author: Martha Sylvia

Title: CALIBRATION OF A CO-2 POWERED SPRAYER

Purpose: A standard calibration technique for use with a CO-2 powered sprayer and discharge calculations

Scope: Studies conducted under GLP

Procedure:
INTRODUCTION:
This SOP describes a possible calibration procedure for a CO_2 powered backpack sprayer and provides for documentation of this procedure. This SOP is to be used by those individuals in charge of calibration and sprays with the CO_2 powered backpack sprayer.

CLEAN AND CHECK EQUIPMENT

1. Clean spray equipment according to SOP 304.00 and examine spray equipment for proper working condition. If any maintenance is required, record in the Field Data Book.

2. Select the best nozzle based on desired spray pattern.

3. Install nozzles, strainers, caps, etc. on boom.

4. Fill the tank partially with water. Operate sprayer and set pressure to desired level. Observe sprayer for any leaks etc., and correct any such situations.

5. Record the number of nozzles, type and size, nozzle spacing, and spray pressure used during calibration in the Field Data Book.

COLLECT OUTPUT FOR DISCHARGE CALIBRATION

1. Using a set period of time (e.g. 30 seconds), collect the output from each nozzle and record in milliliters (ml). If the high and low output varies more than $\pm$5% from the mean, replace the appropriate nozzles(s).

2. Calculate total output using the output of all nozzles from three runs, mls/sec total output as follows:
   Average Nozzle Output (mls/sec. catch time) = total nozzle output from 3 runs ÷ total number of nozzles (e.g. a 4 nozzle boom with 3 discharge calibration runs = 12).
   Nozzle Discharge (ml/sec./nozzle) = (Average Nozzle Output (mls/sec. catch time) ÷ catch time (sec))

Discharge Rate (ml/sec./boom) = Avg. Nozzle Output (mls/sec. catch time) ÷ x seconds catch time × # of nozzles
Swath Width (ft) = number of nozzles/boom ×nozzle spacing (inches) ÷ 12 inches/ft
GPA = [Discharge Rate (ml/sec) ÷ by 3785 ml/gal] x [43,560 ft² / A ÷ Pass Time {target speed (ft/sec) x distance (ft)}]
GPM = Nozzle Discharge (ml/sec/nozzle) x 60 sec/min. ÷ by 3785 ml/gal.

WALKING SPEED

Make practice runs outside the plot area (calibration distance (CDS) = length of plot). Adjust walking speed until the time (CDS), as measured with a stopwatch, to cover the plot length is consistently within ±5% of the calculated CDS. After the appropriate walking speed is obtained, make three additional walking speed calibration runs beside the plot and record these times in the Field Data Notebook.

University of Massachusetts, Cranberry Station, East Wareham
Sylvia

SOP Number: 304.00
Page: 1 of 2
Effective date: March 15, 2005
Author: Martha Sylvia

Title: CLEANUP OF APPLICATION EQUIPMENT

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

Scope: Studies conducted under GLP

Procedure:

1. It is the responsibility of the person making the application under GLP to clean spray equipment after each use as described below.

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

3. In a suitable area away from aquatic areas or danger of aquatic contamination, hose down the sprayer to remove pesticide dust or residue from the inside and outside. Triple wash spray machines and apply each wash to the overplanting of the crop with crop destruct or non-crop area.

4. Excess spray solutions, pesticide rinse water and other dilute pesticide waste shall be disposed of in the field on overplant with crop destruct or on non-crop area.

5. APPLICATION EQUIPMENT CLEANING
All application equipment shall be cleaned after completion of applications. The sprayer shall be broken down into its major components and cleaned as defined below:

(A) Appropriate screens, tips, diaphragms, or other components to be used shall be selected and cleaned with an acceptable cleaning solution (such as ammonia). For these small components, a solvent is suggested followed by a triple rinse with water.

(B) Spray tanks shall have been cleaned with an acceptable cleaning solution (such as ammonia) and adequately rinsed with water before use. Depending on spray tank size (commercial or backpack), the appropriate washing solution shall be selected.

(C) The spray boom shall be flushed with the appropriate cleaning solution (such as ammonia). The selection shall be based on the sprayer size and type.

(D) The sprayer (spray tank, boom, and nozzles) shall then be flushed with water. This shall be repeated until all evidence of cleaning solution residues has been removed (at least 3 times).

(E) The method of sprayer equipment cleaning shall be described in the Field Data Book including the date, the method of cleaning, cleaning solution used, equipment ID, and the users' initials.

6. ACCEPTABLE CLEANING METHODS

The following are some examples of acceptable cleaning solutions: solvents (for small components), bleach or ammonia, detergent and water, or soap and water.

The choice of an acceptable cleaning solution shall be based first on component size and second on availability. Multiple water rinses alone are not acceptable

The minimum number of water rinses following the use of any cleaning solution is three.

7. Use common sense when disposing of expendable protective clothing. Clean nondisposable items with soap and water as appropriate.

University of Massachusetts, Cranberry Station, East Wareham
Sylvia

SOP Number: 305.02
Page: 1 of 2
Effective date: May 15, 2014
Author: Martha Sylvia

Title: ELECTRONIC BALANCE USE AND VERIFICATION

Purpose: This outlines the procedure for proper calibration of an electronic balance that shall be done before weighing chemicals used in residue trials.

Scope: Studies conducted under GLP

Procedure:
The balance shall be operated on a level, vibration-free, solid support away from direct sunlight and drafts. The balance and weighing pan shall be kept clean -- never weigh chemicals directly into the pan. If the balance is moved, make sure all arresting mechanisms are properly engaged and that the balance is stored in a case designed to prevent damage.

The scale shall be serviced every year in which dry formulation pesticide work is to be done. The Field Research Director doing the GLP trial(s) is responsible for this.

A standard mass set with a forceps is needed for verification. The entire Standard Mass set shall be verified every year in which dry formulation pesticide work is done. After a professional servicing of the scale, the Standard Masses shall be weighed and these weights recorded. This data shall be included with the raw data in the Field Data Book. The Field Research Director doing the GLP trial(s) is responsible for this.

Before weighing chemicals, verify balance by using standard weights to bracket amount to be weighed. If chemicals for more than one trial or application are weighed on the same day, the verification procedure need only be done before the first weighing of that day. Original verification data shall be placed in one Field Data Book while certified copies (with location of the original) shall be placed in the other Field Data Books.

1. Turn on the balance, check the level, and allow the machine to reach internal equilibrium according to the manufacturer's operating manual.

2. Tare the balance.

3. Select two Standard Masses to bracket the weight of the chemicals to be weighed (e.g. if the test chemical ranges from 1.5 to 4.5 g., use 1 and 5 g. Standard Masses). Always use forceps or tweezers when handling Standard Masses.

4. Record the following information in the Field Data Book: Date, Balance, Model Number, Test Number being weighed, Standard Mass Set Number, Weights of Standard Masses used, Weight measured for each Standard Mass and the Signature (or Initials) of individual doing calibration.

If the measured weights of both Standard Masses are within ± 2% of the Standard Mass size, proceed with weighing of the chemicals.

If the measured weight of either Standard Mass differs by more than ± 2% from the Standard Mass size, recalibrate the balance.

If after recalibration, the measured weight of both Standard Masses are within ± 2% of the Standard Mass sizes, record the weights in the Field Data Book and proceed with weighing of chemicals.

If after recalibration, the measured weight of either Standard Mass still differs by more than ± 2%, weigh a third Standard Mass (one as close as possible to the 'problem' Standard Mass) to determine if the problem is the Standard Mass rather than the balance. If the measured weight of the third Standard Mass and at least one of the two original Standard Masses are within ± 2% of the Standard Mass sizes, record the weights in the Field Data Book and proceed with the chemical weighing. Replace the defective weight with a new Standard Mass or have the defective Standard Mass recalibrated.

If after recalibration, the measured weights of at least two of the three Standard Masses differ by more than ± 2% from the Standard Mass sizes, record the measured weights in the Field Data Book and DO NOT use the balance for weighing until it has been professionally serviced.

University of Massachusetts, Cranberry Station, East Wareham
Sylvia

SOP Number: 306.02
Page: 1 of 1
Effective date: May 15, 2014
Author: Martha Sylvia

Title: WEIGHING/MEASURING TEST SUBSTANCES

Purpose: This outlines the procedure for proper weighing out of test materials using a balance or measuring of a liquid material using pipettes or graduated cylinders.

Scope: Studies conducted under GLP

Procedure:

For Dry Materials:

Follow directions specified in SOP 305.02 when using an electronic balance to weigh out materials. Always verify the balance on the day it is to be used. When verifying the balance, be sure to use standard weights that are both heavier and lighter than the target weight of the material (bracket the weights). When weighing out the materials use a clean plastic weight dish or other receptacle appropriate to the amount of material needed.

For Liquid Materials:

For proper measurement of liquid materials, use a pipette, syringe or graduated cylinder that shall give accurate measurement of the appropriate amount needed. For example, if the test required 6 ml of material, disposable pipette/syringe (preferred) or a 10 ml graduated cylinder shall be used. If the test requires 0.6 ml of materials a disposable 1 ml pipette/syringe shall be used. Be sure the glassware is clean and is properly rinsed after the work is complete. A clean bulb can be used to aspirate the materials.

Be sure to read pipettes and cylinders correctly, reading at the base of the meniscus.

For measuring the water carrier, be sure to use an appropriately-sized graduated cylinder for best accuracy.

Record the amount that can actually be measured along with the increments of cylinder.

Triple rinse cylinder and pipettes used in measurement of pesticides.

University of Massachusetts, Cranberry Station, East Wareham
Sylvia

SOP Number: 307.02
Page: 1 of 2
Effective date: May 15, 2014
Author: Martha Sylvia

Title: MAINTENANCE OF FREEZER STORAGE FACILITIES FOR RESIDUE SAMPLES

Purpose: This document outlines the procedures to be followed for maintaining storage freezers and includes procedures for freezer temperature monitoring.

Scope: Studies conducted under GLP

Procedure:

1. FREEZER REQUIREMENTS

Freezers shall be of sufficient capacity to maintain a temperature of approximately 0°F (-18°C) when fully loaded with residue samples as stated by the protocol. One freezer shall be dedicated to holding treated samples and another separate freezer shall be maintained for holding non-treated samples. Starting at least one week prior to placing samples into a freezer, temperatures shall be monitored and recorded. Temperature monitoring and recording shall continue until samples are shipped. If freezer fails (e.g. about 10°F for more than 24 hours), sample shall be moved (see 4. below).

2. DOCUMENTATION OF TEMPERATURES

Daily data loggers shall be preferentially used. Dataloggers shall take a reading every hour and downloaded monthly when a sample is present. At a minimum, maximum and minimum temperatures shall be monitored and recorded at least once a week when freezers are holding a sample. Monitoring shall begin at least one week prior to samples being placed in a freezer. Monitored temperatures and the freezer serial numbers shall be recorded into the raw data of the Field Data Book. A physical indicator, such as a plug of ice in an inverted test tube, can be kept in each freezer as a backup device to quickly check sample integrity.

3. MAINTENANCE OF FREEZERS

Maintenance and repair of all freezers and storage areas at the Cranberry Station are under the control of University of Massachusetts Buildings and Properties and this service is not carried out under GLP. Freezer maintenance shall be written into the raw data of each project. Normal maintenance, including calibration and inspection shall be noted during the period of use by a project.

4. EMERGENCY SITUATIONS (such as freezer breakdown or power outage)

When samples are being held, daily (visual) checks to verify freezers running properly must be made. There is a high temp alarm on the freezers that would be heard. In the case of any emergency situation, the Field Research Director or technician shall be notified immediately (FRD cell phone number shall be posted on freezers during critical holding times, Station Director cell phone will also be posted).

Appropriate actions shall be taken to rectify the situation (i.e. Move samples to best available freezer without mixing treated and untreated). The Field Research Director shall ascertain if the integrity of the project has been damaged and if deviations have occurred.

The final decision rests with the Study Director who would be notified. The Regional Field Coordinator and the Study Director shall be notified of the incident with details recorded in the raw data notebook.

If a freezer unit shall fail for any reason, note the following in the project raw data.

(1) the day on which the problem was first noticed
(2) whether the samples had thawed
(3) remedial action taken
(4) time at which samples were refrozen

If the alternate chest freezer (another chest freezer used for general cranberry project use) needs to be used until the IR-4 freezer is repaired, double bag samples, monitor temperatures, and record name and serial number of freezer. When repairs have been completed, attach the service invoice or provide a description of corrective actions taken into the Field Data Book. There are 2 other reliable chest freezers available at the station in case of breakdown.

There is a generator at the UMass Cranberry Station, and it is understood in a case of power outage, that the freezers get priority.

University of Massachusetts, Cranberry Station, East Wareham
Sylvia

SOP Number: 308.01
Page: 1 of 1
Effective date: May 15, 2014
Author: Martha Sylvia

Title: 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

Procedure:

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. 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.

University of Massachusetts, Cranberry Station, East Wareham
Sylvia

SOP Number: 309.00
Page: 1 of 1
Effective date: May 15, 2013
Author: Martha Sylvia

Title: 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.

Procedure:

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).

University of Massachusetts, Cranberry Station, East Wareham
Sylvia

SOP Number: 400.02
Page: 1 of 1
Effective date: April 22, 2019
Author: Martha Sylvia

Title: MAKING CERTIFIED COPIES OF RAW DATA

Purpose: This outlines procedures on how to make and use certified copies.

Scope: Studies conducted under GLP

Procedure:
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 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.

University of Massachusetts, Cranberry Station, East Wareham
Sylvia

SOP Number: 401.03
Page: 1 of 5
Effective date: May 15, 2014
Author: Martha Sylvia

Title: DATA HANDLING AND STORAGE

Purpose: To assure that all data resulting from the study is retained and usable.

Scope: Studies conducted under GLP

IR-4 Headquarters provides a Field Data Book (FDB) to each of the cooperators for each trial undertaken. Detailed instructions are provided in the book. The Field Data Book instructions shall be followed at all times and are superseded only by the protocol. The FDB is new each year and shall be reviewed in advance of the trial.

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

5. Blank forms may be photocopied as needed.

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

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

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

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

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

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). Any thing 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.

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 shall 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 shall 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 label, is received, it can be converted to one-sided document by photocopying. If the page or document is actual data, the second page shall be photocopied as a one sided page and certified as a true copy. The second side of the 2-sided page may then be crossed out. If, for any reason 2 sided pages are included in the FDB, they shall be identified with the Field ID Number and paginated.

University of Massachusetts, Cranberry Station, East Wareham
Sylvia

SOP Number: 402.02
Page: 1 of 1
Effective date: May 15, 2013
Author: Martha Sylvia

Title: Handling data that transcends two or more trials

Purpose: To explain how raw data that pertains to more than one trial shall be included in each Field Data Book.

Scope: Studies conducted under GLP

Background:
In some year, this site conducts multiple trials. 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 shall have the original placed in one Field Data Book (FDB) include, but are not limited to:
   a. Sprayer calibrations for applications on the same day using the same equipment and settings (Part 6C and D)
   b. Plot plans including more than one trial
   c. Shipping and sample receipts for more than one trial
   d. Test substance receipt and use logs and documentation for more than one trial

University of Massachusetts, Cranberry Station, East Wareham
Sylvia

SOP Number: 403.01
Page: 1 of 3
Effective date: May 15, 2014
Author: Martha Sylvia

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

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

Scope: Studies conducted under GLP

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

ACTIVE LIFE OF THE TRIAL:

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

2. The protocols, Field Data Books and supporting data shall be stored in limited access area (locked office) during the active life of the trial. The current 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. For the UMass Cranberry Station, the Field Data Books are kept in Room 118, a locked office.

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

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

5. The original of the completed, assembled Field Data Books shall be forwarded to the Field Research Coordinator within 4 weeks 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, confirm 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 will be retained of studies, which have been cancelled.

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

FACILITY FILE:

1. 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. For the UMass Cranberry Station, this is information is kept in the active drawer of the locked fireproof file cabinet in the locked office, Room 118. 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
   e. Production guides used for the GLP trials shall be archived as they are replaced with newer additions.

2. At the end of one season, or at the beginning of the next, Facility File original information that has changed or been revised (e.g. workers leaving, new SOP's, 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.

HISTORIC FILES:

1. IR-4 historical records shall be maintained by the Field Research Director or designated personnel. No original data is kept in this file. For the UMass Cranberry Station, these records are kept in the historic files drawers of the locked fireproof file cabinet in the locked office, Room 118. Historical Files shall include, but are not limited to certified copies of:
   a. Retired Organizational Charts, floor plans and other facility information
   b. Old CVs and training records
   c. Previous SOP sets
   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 shall be contacted, to assure that the original is archived.

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

University of Massachusetts, Cranberry Station, East Wareham
Sylvia

SOP Number: 501.00
Page: 1 of 3
Effective date: May 15, 2013
Author: Martha Sylvia

Title: PROCEDURES TO FOLLOW PRIOR TO, DURING, AND FOLLOWING AN EPA INSPECTION

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

Scope: Studies conducted under GLP

Procedure:

PRIOR TO AN ANNOUNCED EPA INSPECTION

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

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

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

4. Prepare trial(s) and/or facilities personnel for the inspection.
   a. Review position descriptions with technical personnel so they understand and can explain their role in the trial(s).
   b. Discuss possible questions that may likely come up about the trial(s) or facility and make sure everyone understands what to expect.
   c. Request personnel to answer the questions only to the extent needed and not to provide extraneous information. Do not volunteer information; keep answers direct and to the point.
   d. Make certain that technical personnel know the safety precautions needed for the work area.
   e. Be certain that all documents pertaining to the trial(s)/facilities inspection are available. This would include: 1) Master schedules for the Field Research Director, Quality Assurance Research Officer and possibly their counterparts at the region and IR-4 headquarters. 2) Study Protocol and Standard Operating Procedures. 3) Raw data, correspondence, etc. 4) Training records, CVs, job descriptions, etc. of personnel assigned to the trial(s). 5) Appropriate chain of custody documents for samples and freezer data and storage temperature documentation. 6) Documentation of the characterization of the test substance, receipt, and handling, and storage records. 7) Calibration paperwork on equipment such as balances and application equipment. 8) Storage of records

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

DURING AN EPA INSPECTION

1. Greet the inspection team and follow any institutional procedures for signing in. Introduce and escort the entire group to the station library.

2. At the opening of the conference ask the lead inspector for his credentials and for any opening statements.

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

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

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

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

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.

FOLLOWING AN EPA INSPECTION

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

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

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

4. Have someone present during the close-out take accurate notes.

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

6. Debrief management, staff, and the 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.