SOP Log

these are 4 yrs old but what she is using for 2014

ID # S 00020 ~~NE~~

Region: NE

State: ME City: Orono

Location: University of Maine

FRD/LRD: Judith Collins
Submitter

Effective Date: 4/14/10

Received at HQ: 8/7/14 Date to Reviewer: 8/8/14
Sign/Date

Reviewed By: Dave DiAngelo

Description of Material (s): 2010 SOPs & Index

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

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

use this hard copy for a scan

Date from Reviewer: 8/8/14

Date Posted: 8/8/14 Archive Date: 8/8/14

Archive Location: Active File Rm (AFR) Cabinet 1 Drawer 1

Sign: [signature]

Comment:

S: Facility Files- SOP Cover Sheet

7/31/14 JT

10637.11-ME01
BYI02960/Blueberry
Collins

STANDARD OPERATING PROCEDURES

FOR

MAGNITUDE OF THE RESIDUE FIELD TRIALS

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Set Revision 2

EXACT COPY OF
ORIGINAL DOCUMENT
ell 1/13/12

Effective Date: 14 April 2010

Field Research Director: Judith A. Collins (Signature) (Initials) 3/30/2010 (Date)

Approving Official: Edith L. Lurvey (Signature) ell (Initials) 4/14/2010 (Date)
Regional/ARS 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.

No changes to SOP's in 2011 JAC 7/25/11
Judith A Collins

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Table of Contents Set Revision 2 Effective date: 1 June 2010

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Table of Contents Set Revision 2 Effective date: 1 June 2010

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 June 2010
Author: Judith A. Collins

SOP# 1.1:2 General requirements for the development and use of Standard Operating Procedures (SOPs)

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

Scope: All GLP field studies.

Procedures:

1. Studies that are conducted in support of the registration of pesticides will develop SOPs for all phases of the GLP research.

2. Each SOP will be reviewed and/or revised, at least every three years. The effective date and revision number shall be changed to reflect revision and the new effective date assigned.

3. The SOPs for researchers in the IR-4 Northeast Region will generally be approved as a set, when reviewed. Approval will consist of the dated signature of the Regional Field Coordinator on the title page. The title page shall also show, at a minimum, the set revision number, set effective date, with the dated signatures of the Field Research Director or assigned personnel, and approving official. SOPs revised or generated after a SOP set has been signed, will be signed and dated separately and incorporated into the SOP set when next revised.

4. Please note that individual SOP revision numbers and effective dates will 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.

5. Original signed SOP sets of all revisions and individual SOPs will be sent to IR-4 Headquarters for archiving. Certified copies will be retained in the facilities historical file.

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

7. SOPs shall be identified on each page. Each page shall contain the name of Field Research Director, the number of the SOP, and the page. This identification will be located at the bottom of the page. For example:

   Judith A. Collins SOP# 1.1:1 Page 2 of 2

8. Any deviations from the SOPs shall be noted in the Field Data Book by completing a deviation form and sending the original to the Study Director for approval. A certified copy will be kept in the Field Data Book.

9. 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 will 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.

10. The location of an SOP may be moved within the SOP set, as long as a note is added citing its previous location. The Revision Number and Effective Date continue as they were. For example: "Formerly SOP 9.9:9". This statement may be removed the next time the SOP is revised in its new location.

11. In some cases, to reduce redundancies, an SOP may be retired as the information is already covered in another SOP. In that case, in addition to the inactivation/retired statement the SOP with the information should be cited. For example; "This SOP is inactivated as of May 21, 2009. The information can be found in SOP 9.9".

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

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 June 2010
Author: Judith A. Collins

SOP# 1.2:2 Numbering system for SOPs

Purpose: To provide a general outline for SOPs.

Scope: All GLP field studies.

Procedures:
1. SOPs will be grouped by category. Categories of SOPs will be identified as follows:

    1. General
    2. Personnel
    3. Test Site and Agronomic Practices
    4. Test Substance Handling
    5. Test Substance Application and Equipment Calibration
    6. Equipment Verification/Calibration and Maintenance
    7. Residue Sampling Handling
    8. Data Handling
    9. EPA Audit Procedures

2. Numbers of individual SOPs within a category will be written as a decimal as follows: Category #. SOP#: Revision #, for example 1.1:1.

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 June 2010
Author: Judith A. Collins

SOP# 1.3:2 Format for use in developing SOPs

Purpose: To insure a uniform format for the development of SOPs.

Scope: All GLP field studies.

Procedures:
1. The following format is to be used for each SOP.

TEST FACILITY	Name of the Test facility and Field Research Director (Centered) Address of the Test facility (Centered)
EFFECTIVE DATE	Date the revision or new SOP becomes effective
AUTHOR	Name of person developing the SOP
SOP #	Category #. SOP#: Revision # Tab title
PURPOSE	Brief description of the purpose of the SOP
SCOPE	Description of when and where the SOP is applicable
PROCEDURES	Description of the operating procedures in numerical order from beginning to end so that a person with some knowledge of the situation can carry out the procedures without any verbal input from other sources
PAGE IDENTIFIER	Field Researcher's name, SOP#, and Page# if more than one page.

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 June 2010
Author: Judith A. Collins

SOP# 2.1:2 Field Research Director and responsibilities

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

Scope: Field test sites conducting pesticide registration research under GLP.

Procedures:

1. The Field Research Director is designated by the Study Director based on the recommendation of the Regional Field Coordinator. The Field Research Director shall be a scientist with appropriate training and experience to conduct the trial. If the Field Research Director cannot continue with the project, then the Regional Field Coordinator will work with the University of Maine, School of Biology and Ecology to provide a replacement, or insure the completion of ongoing research.

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. Assure that all comments reported by the Regional Field Coordinator, Quality Assurance Officer and/or Study Director are responded to in writing, or direct contact (telephone, e-mail, etc.).
    e. 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.
    f. Maintain certified copies of the Field Data Book until the data is submitted to the U.S. EPA.
    g. Maintain resumes, job descriptions, and training records for all key personnel currently engaged in the trial, and send originals to IR-4 Headquarters for archiving on an annual basis or when the individual leaves the program.
    h. Maintain a copy of the Master Schedule for all GLP projects under his/her direction, as supplied by IR-4 Headquarters.
    i. Designate the location for the facility and historical files.
    j. Assure that safety equipment is in working order and sufficient to protect the health and safety of personnel connected with the project.

k. Assure that any deviations from protocol or standard operating procedures, or equipment malfunctions are reported to the Study Director and Regional Field Coordinator.
l. Insure that all original raw data and test site information is transferred to IR-4 Headquarters for archiving on a regular basis.

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Effective Date: 31 May 2008
Author: Judith A. Collins

SOP# 2.2:1 Organizational chart

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

Scope: Field test sites conducting pesticide registration research under GLP.

Procedures:

1. An organizational chart shall be developed which reflects the management of the facility and the reporting lines of the personnel engaged in the GLP trials.

2. Each block in the chart shall show the name and title.

3. At the top of the chart, show the head of the unit (Department Chair, Director etc.), i.e. the person(s) to whom the Field Research Director reports.

4. Personnel engaged in the conduct of the trials are shown on the chart with lines of supervision indicated.

5. The Field Research Director's interaction with IR-4 shall also appear in the diagram.

6. The charts should be signed or initialed and dated. As they are revised, a certified copy of retired charts should be retained in the facilities historical files. Original charts will be forwarded to IR-4 Headquarters.

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Effective Date: 31 May 2008
Author: Judith A. Collins

SOP# 2.3:1 Personnel

Purpose: To provide information concerning requirements for personnel under Good Laboratory Practices.

Scope: Field test sites conducting pesticide registration research under GLP.

Procedures:

1. The field test site will have on file a current summary of the training and experience and a brief description of duties or responsibilities for each person supervising any phase of the trial or collecting and/or entering data. Each person so engaged in the conduct of trials shall have read and understood those sections of the protocol and SOPs that pertain to their responsibilities. The Field Research Director or designated personnel shall record the names of the personnel and the dates that the SOPs were explained to them. This information shall be placed in the personnel file.

2. The Field Research Director or designated personnel will 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 the University of Maine and State of Maine Board of Pesticides Control.

4. The field site facility will 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 Standards, the Health and Safety SOPs, other institution regulations, pesticide labels, or the trial protocol.

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

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 June 2010
Author: Judith A. Collins

SOP# 2.4:2 Documentation of training

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

Scope: Field test sites conducting pesticide registration research under GLP.

Procedures:

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

2. Training received from workshops, conferences, etc. shall be noted as to the name of the event and dates of attendance. A copy of any type of training certificates issued shall be retained in the personnel files at the field facility.

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

4. Each person engaged in the conduct of the trial shall have read and understood those sections of the protocol and the standard operating procedures that pertain to their responsibilities. The Field Research Director or designated personnel 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.

5. For personnel who are not collecting and/or entering data, but who might have an impact on the trial, (for example casual labor involved in the harvest), a general statement of oral or written training, by the Field Research Director or designated supervisor, will be sufficient. Personnel who are only involved in routine maintenance and other non-critical duties do not need to be included if a statement of non-GLP compliance is made.

6. Copies of all training documents will be retained in the facility Historical Files; originals will be sent to IR-4 Headquarters annually.

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 June 2010
Author: Judith A. Collins

SOP# 3.1:2 Site selection for field trials

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

Scope: Field test sites conducting pesticide registration research under GLP.

Procedures:

1. Site selection will be made in accordance with acceptable commercial practices for lowbush blueberries.

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

3. Locate site with sufficient isolation to minimize contamination from external sources such as commercial operations or other research trials. Place individual plots with enough isolation (at least 15-ft or in accordance with trial protocol) to produce uncontaminated control and treated samples.

4. 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 site of the plots can be located after the trial is terminated. Follow the Field Data Book for further directions.

5. Lay out each plot using a suitable measuring device to accurately locate the plots on the site even after the trial has been completed. Identify both ends of each plot with a marker of sufficient visibility to be seen easily throughout the duration of the trial. At a minimum, the marker shall include the Field ID number and treatment number or treatment name. Follow the study protocol for further requirements. The plot map and a summary of the cultural practices shall be part of the Field Data Book.
6. The soil where trials will be conducted shall be tested for nutrients, pH, and organic matter in the year in which trials will be conducted on that site. The above data will be recorded in the files for all trials. For soil texture determination, analysis performed no more that 15 years prior to the trial will be acceptable. Alternatively, USDA soil characterizations may be used. Original soil test reports must be sent to HQ for archiving, either separately or in one of the field books.

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 June 2010
Author: Judith A. Collins

SOP# 3.2:2 Commodity maintenance

Purpose: To assure that the commodity is grown under good agricultural practices and to provide a uniform crop for trial.

Scope: Field test sites conducting pesticide registration research under GLP.

Procedures:

1. Use an up-to-date publication on the production of wild lowbush blueberries or consult with an agricultural specialist familiar with local commercial production.

2. Do not apply pesticides that are not registered for the commodity. If absolutely necessary to apply a non-registered pest management product to save the crop, contact the Study Director and for a protocol deviation. If pesticides are applied to the commodity to prevent losses due to pests, they shall be applied to all plots within the trial using standard agricultural practices. For residue trials, no pesticide shall be applied that would interfere with the chemical analysis of the pesticide under trial. If in doubt, contact the Study Director or analytical chemist/analytical laboratory identified in the protocol to receive the residue samples for guidance

3. Irrigate and perform other agricultural practices as necessary.

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

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Effective Date: 31 May 2008

Author: Judith A. Collins

SOP# 3.3:1 Borrowed/rented/leased equipment.

Purpose: To identify procedures for the use of borrowed, rented, or leased capital equipment in the application, harvest or other critical phase operation.

Scope: Field test sites conducting pesticide registration research under GLP.

Procedures:

1. When protocols approved by the Study Director and Sponsor require the use of equipment not under the direct control of the Field Research Director, appropriate equipment may be borrowed, rented, or leased.

2. Such equipment will include, but not be limited to, tractors, air blast sprayers, or any other equipment not under the direct control of the Field Research Director. This also includes any equipment operated by the Maine Agriculture and Forest Experiment Station.

3. The owner will be responsible for routine maintenance of the equipment.

4. Before use, in a regulated study, equipment will be inspected, repaired, cleaned, and calibrated to bring it into compliance with GLP. All such tasks will be documented in the raw data.

5. The following information shall be documented for borrowed/leased/rented equipment and maintained in the Field Data Book:

    a. Owner/source
    b. Description of equipment, e.g. type, make, model
    c. Year of manufacture (when available)
    d. Year acquired (when available)
    e. Last known use and purpose
    f. Study identification
    g. Condition of equipment on receipt
    h. Maintenance performed (when applicable)
    i. Date equipment was returned to original source
    j. Modifications required (when applicable)
    k. Cleaning/decontamination procedures performed

l. Principal investigators statement of suitability for use
m. Date of use

6. The person entering the information must initial and date the entries.

7. If a sprayer, calibrate before use and adjust or replace those parts not functioning properly - record actions in Field Data Book.

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

9. This SOP deactivated effective 1 June 2010.

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 June 2010
Author: Judith A. Collins

SOP# 4.1:2 Test substance receipt and storage.

Purpose: To explain the procedures required in the receipt, removal, use, return, and transfer of the test substances.

Scope: Field test sites conducting pesticide registration research under GLP.

Procedures:

1. Test substances are delivered to the Field Research Director at the School of Biology and Ecology, University of Maine, Orono, ME. While in Orono, the test substances are stored in the flammables cabinet in room 308. While in storage at Orono, temperatures will be monitored with a HOBO® TidBit temperature logger and storage temperature will be documented in the Field Data Book.

2. When logging in a test substance, the responsible person will assign an appropriate log number consisting of the last two digits of the current year, the first and last initials of the Field Research Director, and a sequential number beginning with 01. For multiple containers of the same test substance a sequential letter beginning with "A" will also be added to the log number. The log number will be written prominently on the test substance container(s). An ID sticker provided with the Field Data Book will also be attached to each test substance container.

3. If the name on the Test Substance container does not match the protocol, the Study Director shall be notified.

4. As soon as practical, the test substance will be transferred to Blueberry Hill Farm Experiment Station, Jonesboro, ME, and the transfer will be documented in the Field Data Book. During transport temperature will be monitored with a HOBO® TidBit temperature logger and temperatures will be documented in the Field Data Book.

5. Information provided with the test substance or its label shall be consulted and followed for storage conditions. If storage conditions are not on the container label, they will be added. The Study Director will be notified immediately upon determination the storage conditions were not within the label's recommended storage condition limits.

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

7. All pesticides will be stored in a locked area of the Blueberry Hill Farm pesticide storage building, separate from areas where the pesticide is mixed and where mixtures are stored.

8. All test substance containers must be stored until the study in which the material was used is submitted to the U.S. EPA or the trial canceled. Test substance container disposal shall follow IR-4 Advisories.

9. Place highly visible, waterproof identification signs on doors, gates, buildings, and fences indicating the hazardous nature of the storage facility's contents.

10. Post the telephone numbers and names of personnel responsible for and knowledgeable of the contents of the storage facility.

11. Check containers of pesticides 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.

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

13. Pesticides in containers that could be damaged by moisture or water should be kept off the floor.

14. All pesticides in storage must be properly labeled.

15. A Storage Facility Log shall be kept indicating when a test substance is added or removed, and when it is returned to the facility, and the purpose for which it is removed.

16. A Test Substance Use Log will be kept in the Field Data Book.

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 June 2010
Author: Judith A. Collins

SOP# 5.1:2 Measuring and mixing a pesticide formulation

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

Scope: All field studies under GLP.

Procedures:

1. Wear or use appropriate safety equipment while handling pesticide concentrates. This may include, but is not limited to, gloves, respirator, goggles, boots, and coverall.

2. Maintain a written record of each volume or weight of the pesticide removed from the original container. Whenever a test material is used, record in the log provided in the Field Data Book the following information: the amount of material used, date, initials of responsible person, and purpose (including Field ID number).

3. If the pre-weighed or measured test substance is transported to the trial site in an alternate container, the containers shall be labeled with the Field ID number, test substance name, lot number, and appropriate treatment or plot numbers. The containers shall also be labeled with the identity of the person who weighed or measured the sample and the date weighed or measured.

I. Measuring a liquid formulation

1. Select a disposable pipette or graduated cylinder large enough to hold the volume of pesticide needed for the treatment and graduated in increments small enough to measure the needed test substance and to read to accuracy within +/- 1% of the total volume.

2. When measuring the liquid in a graduated cylinder or pipette take the reading of the liquid at the bottom of the meniscus.

3. Add the liquid pesticide directly into the spray tank. An alternate method is to place the test substance in a clean, non-reactive container, fit with a liquid-proof lid and label as outlined in #3 above.

1-20

II. Measuring a dry formulation

1. The balance/scale used to weigh test substances for GLP trials must be serviced and calibrated once every one to two years. Standard Weights shall be verified by weighing the weights immediately after servicing, and recording the values. The verification of the Standard Weights shall be recorded and the original included as raw data in one of the Field Data Books and certified copies included in the books for any other trials where it is needed. A certified copy will also be maintained in the Historical Files.

2. The balance shall be checked and calibrated prior to weighing test substance for use in the trial. Make sure that the balance is on a solid base, level and clean. Avoid drafts. Calibrate by recording the values of known standard weights that bracket the quantity to be measured.

3. Weigh the test substance in a tarred tray or container (new paper, plastic or aluminum trays, or other containers as appropriate). Return excess to the original pesticide container, if this procedure does not affect the integrity of the contents. Or, dispose of the excess by using appropriate methods for handling hazardous wastes.

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

5. The balance should be inspected for cleanliness after use.

III. Mixing a pesticide formulation

1. The spray delivery system will be completely purged with compressed gas to remove the calibration carrier water before adding the dilute spray solution.

2. Use pH paper or other means to measure the pH of the dilution water and record in the raw data.

3. Measure into a separate container the amount of water needed to dilute the measured amount of concentrate. Add approximately half the water to the spray tank. If necessary, i.e. for a wettable powder formulation, make a slurry mix first by adding the concentrate to a small volume of water in a separate, clean container. Add the pesticide concentrate or slurry to the water in the spray tank.

4. Using the second half of the carrier water, triple rinse the container, except if a pipette or syringe, that held the pesticide concentrate/slurry into the spray tank.

5. Add adjuvant, if required.

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 June 2010
Author: Judith A. Collins

SOP# 5.2:2 Calibration of a CO_2-propelled boom sprayer

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

Scope: All field studies under GLP.

Procedures:

I. Sprayer Preparation and Maintenance

1. The application boom will be inspected for leaks and the dilute spray container and spray boom will be cleaned. The nozzle assemblies will be disassembled to verify cleanliness or to clean the screens and nozzle bodies.

2. The CO_2 propellant connections will be inspected for leaks and repaired if necessary.

3. Inspect all gauges to insure proper operation and replace if necessary.

4. 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.

5. Any faulty components will be replaced before calibrations.

6. Adjust the CO_2 pressure regulator to the desired pressure with the CO_2 tank valve in the fully open position. Be sure that the pressure has stabilized before proceeding.

II. Sprayer Calibration

1. Calibration shall be done no more than 24 hours prior to an application and no other uses of the equipment will occur between the calibration and application. If significant time elapses within those 24 hrs, and the sprayer has not been used, a single spray output determination may be used to verify the previous calibration within the tolerances as follows. If the sprayer is not used within 24 hours of the full calibration, and it is to be used for a first application, the sprayer must be recalibrated. If the equipment is used for a not GLP application, recalibration must be performed before test substance application.

2. Water delivery from the nozzles will be collected for a designated time period, such as 30 sec. The conditions of calibration will be recorded including, but not limited to: sprayer ID number, number of nozzles, nozzle type, boom pressure, nozzle spacing, calibration time, calibration distance, and desired output. To determine compliance for +/- 5%, multiply the average nozzle output by 0.95 and 1.05 to obtain the maximum acceptable range of nozzle output. Change nozzle and screens until uniform nozzle discharge is obtained. The delivery rate (discharge calibration) will be averaged for three determinations or as specified in the protocol.

3. Determine the travel speed required for the application. This walking pace will be practiced before application of the test substance in the trial site with a metronome calibrated to emit a tone at each step. The final practice speeds will be made on the same soil surface as the test site. Other walking paces may be utilized to achieve the desired application rates. A metronome shall be used for assistance in maintaining a uniform walking speed. The tempo shall be adjusted for the desired pace.

4. The spray volume and sprayer nozzle configuration to use for the application will be in compliance with the protocol requirements. If the spray volume and method are unspecified, a 4-nozzle, CO_2-propelled sprayer will be used.

5. Sample calculations for application of a fixed spray volume are given below.

III. Discharge Calibration (Record this information on template and include in Field Data Book)

a. Operate sprayer for designated time period (such as 20 seconds) and record the discharge from each nozzle. Repeat 3 times and calculate the discharge (mls/sec/boom) and (mls/sec/nozzle) using the formula with example below.

$$\text{Discharge (ml/sec/boom)} = \frac{\text{Average Discharge collected}}{\text{Average time}} = \frac{891.3 \text{ mls}}{20.08 \text{ sec}} = 44.4 \text{ ml/sec/boom}$$

$$\text{Discharge (ml/sec/nozzle)} = \frac{\text{Average discharge (ml/sec/boom)}}{\text{Number of nozzles}} = \frac{44.4}{4} = 11.1 \text{ ml/sec/nozzle}$$

IV, Calculation of Travel Speed and Target Pass Time (Record this information on template and include in Field Data Book)

Formulae with example calculation: PLEASE FIX CASE – I PUT IN CAPS TO SHOW

Speed Z ft/sec = Track (X ft) ÷ Y sec/pass = 19 ft ÷ 20 sec = 0.95 ft/sec

mph = Z ft/sec ÷ 5280 ft/mile * 3600 sec/hour (60 sec/min * 60 min/hour)
= 0.95 ft/sec * 3600 sec/hour ÷ 5280 ft/mile = 0.65 mph

ml/plot = Y GPA targeted * 3785 ml/gal ÷ 43560 sq ft/A * X sq ft/plot
= 25 GPA targeted *3785 ml/gal ÷ 43560 sq ft/A * 361 sq ft/plot
= 784 mls/plot

Targeted Speed (sec/pass) = ml/plot ÷ 3 passes ÷ ml/sec/boom
= 784 mls/plot ÷ 3 ÷ 44.4 ml/sec/boom = 5.89 sec/pass

V. Calculation of Amount of Test Substance, Carrier, and Adjuvant

a. The amount of test substance, carrier, and adjuvant 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 20% greater than the amount of solution required to spray the entire plot.

TEST SUBSTANCE

Test substance (ml or g/acre) ÷ 43560 sq ft/acre * treated area (sq ft) * 1.20 overage

= ml or g of test substance to add to tank mix

CARRIER

mls carrier/plot = Y GPA targeted * 3785 ml/gal ÷ 43560 sq ft/A * X sq ft/plot
mls carrier/plot * 1.2 overage = mls carrier for tank mix

ADJUVANT

(ml final carrier + ml final product) * (% volume of adjuvant)

= ml adjuvant required

VIII. Documentation

1. Record all necessary information into the Field Data Book in enough detail to reconstruct the application. Document calibration as an event in the maintenance log.

2. Calculations shall be entered in a logical manner showing all steps and conversions so that they can be easily followed and reconstructed. Calculation shall clearly show the actual GPA and amount of active ingredient or product applied.

3. If the amount of test substance (a.i. or product/A) differs by more than +10% - 5 % from the protocol values, the Study Director shall be notified within 24 hrs.

4. Protocol instructions for reporting application events and deviations will have precedence over this SOP.

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 June 2010
Author: Judith A. Collins

SOP# 5.3:2 Procedures for the application of test substances

Purpose: To assure that test substances are applied uniformly to the plots.

Scope: Field test sites conducting pesticide registration research under GLP.

Procedures:

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

2. Personnel mixing and applying pesticides should wear appropriate protective clothing; this may include, but is not limited to, gloves, respirator, goggles, boots, and coverall.

3. Equipment used in the application of pesticides should be inspected and calibrated according to SOP# 5.2

4. The pesticide concentrate should be measured out as indicated in the SOP# 5.1

5. 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. Just prior to application check the wind speed in the area to be treated. The measurement shall be taken 2-3 ft above the canopy. Record the wind speed as raw data.

6. The spray delivery system will 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 will be verified before the sprayer moves into the treatment area. The spray system will be filled with the dilute spray at about 10 ft from the plot edge and down wind from the trial site.

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

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

9. Just before entering each plot, make sure you are traveling at the correct speed. Maintain the correct speed through the plot.

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

11. Calculations shall be made to minimize the amount of spray material left in the spray tank. This residue shall be disposed of according to current policies and guidelines of the University of Maine.

12. If an equipment malfunction or other problem occurs which effects the application the Field Research Director or designated personnel will inform the Study Director and Regional Field Coordinator.

13. Record each calibration and use in the equipment log.

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

Verification of Application Rate (Record this information on template and include in Field Data Book)

1. Calculation of the actual rate of test substance (TS) application will be based on the total travel time of each spray pass in the plot, discharge rate, number of nozzles, area of application, and amount of test substance mixed with the carrier to provide the total dilute spray volume at the start of the application. The formulas may be used as follows:

a. mls or g test substance/acre = Total pass time (sec) * discharge (ml/sec/nozzle) * number of nozzles ÷ mls tank mix * ml or g TS/tank mix * ÷ Treated area sq ft * 43560 sq ft/A

b. (Amount of TS applied per acre – Protocol TS per acre) ÷ (Protocol TS per acre) = ± % deviation

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 June 2010
Author: Judith A. Collins

SOP# 5.4:2 Cleanup of application equipment

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

Scope: Field test sites conducting pesticide registration research under GLP.

Procedures:

1. Drain all the pesticide from the sprayer. 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. A variety of cleaning agents can be used including, but not limited to, a commercial tank cleaner, household detergents and ammonia, sudsy ammonia, or acetone.

2. Agitate the system until the sides of the spray tank are wet. Drain the tank and flush with clean water as in step 1, above, least 3 times.

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

4. Dispose of expendable protective clothing by placing the items in a container for incineration. Clean non-disposable items with soap and water as appropriate. After the application equipment is dry, return to storage.

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 June 2010
Author: Judith A. Collins

SOP# 5.5:1 Procedures to follow when a problem occurs in the application of the test substance

Purpose: To explain the procedures required when something goes wrong during the application of the test substance in the trial.

Scope: Field test sites conducting pesticide registration research under GLP. For the purposes of this SOP, test substance also applies to control and reference substances.

Procedures:

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

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

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

4. The Study Director and Regional Field Coordinator 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. Details shall be recorded in the Field Data Book.

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

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 June 2010
Author: Judith A. Collins

SOP# 6.1:2 Verification of instruments and gauges

Purpose: To assure that all instruments used in GLP field studies are accurate and in good working order.

Scope: All field studies under the GLP.

Procedures:

1. All measuring devices (except marked, calibrated graduated cylinders, syringes, pipettes, etc.) 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/verification 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. Each instrument used in a GLP trial shall be tested yearly to determine that it is accurate. If the item is used continuously, it might be tested more frequently to assure its continued accuracy. If the item is used infrequently, it shall be tested before it is first used in a GLP trial and as often thereafter as necessary to assure its accuracy.

3. A written record shall be kept of the dates and results of the tests and of the acceptable tolerance for each instrument. Acceptable tolerances and verification methods will be determined from the manual for the instrument being tested.

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

5. Written records (maintenance logs) shall be kept on routinely used equipment. These records shall include, but not be limited to, the person doing the maintenance, the date, whether the activity is routine or non-routine, and the tolerances for that piece of equipment. Certified copies of the logs will be maintained in the facility Historical Files. The original logs will be submitted with the Field Data Books.

6. When a piece of equipment maintained under GLPs is replaced or retired, its fate will be noted in the relevant equipment log.

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

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 June 2010
Author: Judith A. Collins

SOP# 6.2:2 Verification of thermometers

Purpose: The purpose of this SOP is to establish procedures used when calibrating and reading thermometers.

Scope: The SOP is to be followed when calibrating thermometers for GLP work.

Procedures:

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

2. All temperature-measuring devices used for GLP trials will be checked for accuracy at least once a year against a reference thermometer, either directly or by a recorded traceable chain. A reference thermometer will be verified by placing it in an ice bath and a boiling bath. All other thermometers will be read side-by-side with the reference thermometer to verify accuracy.

3. Records of thermometer verification will be maintained in a log.

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

5. Measuring devices to be verified and the reference thermometer will be read side by side under conditions appropriate to the intended use. For example: thermometers used to measure temperatures of liquids shall be verified in water baths.

Water Bath Method

1. At least two water baths will be used. Examples of temperature ranges to test may include:

   a. Boiling (100 ^{o}C)
   b. Warm (approx. 40 to 55^{o}C)
   c. Room temperature (approx. 22^{o}C)
   d. Ice bath (approx. 0^{o}C)

2. Water baths will 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.

Air Method

1. At least two air temperature conditions will be used, briquetting the temperatures it will be used to monitor, if possible. Examples of temperature ranges to test may include:

    a. Warm, i.e. 40 to 60°C (drying oven may be used)
    b. Room temperature (approx. 22°C)
    c. Cool, i.e. 5 to 10°C (refrigerator may be used)
    d. Cold, i.e. -5 to -20°C (freezer may be used)

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

    a. Date of verification
    b. Initials of person doing verification
    c. Reference thermometer reading
    d. Laboratory thermometer reading
    e. Identification (ID) or code number of the thermometer being verified

3. Temperature readings taken from the reference thermometer may be rounded to whole numbers (e.g.: If reference reads 38.2°C, the recorded value will be 38°C).

4. If the difference between the reference thermometer and the thermometer being checked is greater ± 5%, it will be labeled as not suitable for trials conducted under GLP and the % difference will be noted on the logger label.

5. If possible, each measuring device will be labeled following verification and will include:

    a. ID or code number
    b. Date of verification
    c. Initials of person doing the verification
    d. Temperature adjustment

6. When recording a thermometer reading, the following information shall also be included in the entry:

    a. Date
    b. Initials of individual conducting the activity
    c. Thermometer ID or code number

7. Calibrated thermometers may be used to verify other temperature recording devises as long as they can be traced back to a reference verification. These devices may include continuous thermographs used for walk-in digital displays on up-right freezer/refrigerator units, etc.

8. Remedial action to be taken in case of failure or malfunction shall include:

    a. Any problem shall be immediately reported to the facility director or designated personnel, documented, and placed in the records for non-routine procedures.
    b. Any repairs or replacements resulting from malfunction during application will be documented as non-routine maintenance in the appropriate log(s).

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

10. In the event of a malfunction or other incident that may affect the integrity of the trial, the Study Director and other appropriate individuals shall be notified and details shall be recorded in the Field Data Book.

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 June 2010
Author: Judith A. Collins

SOP# 6.3:2 Verification and use of temperature data loggers

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

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

1. Prior to use, visually inspect the data logger for cleanliness and that it is in good working condition. Check the power supply. Record inspection and any maintenance performed in appropriate logs.

2. The accuracy of temperature data loggers used for GLP studies will be verified at least once a year against a reference thermometer which as been calibrated according to SOP# 6.2:2. Records of thermometer verification will be maintained in a log.

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

4. Data logger(s) to be verified and the reference thermometer will be read side by side under conditions appropriate to the intended use.

5. Air Method. At least two air temperature conditions will be used. When possible, an attempt will be make to bracket the temperatures the device will monitor. Examples of temperature ranges to test may include:

    a. Warm, i.e. 40 to 60°C (drying oven may be used)
    b. Room temperature (approx. 22°C)
    c. Cool, i.e. 5 to 10°C (refrigerator may be used)
    d. Cold, i.e. -5 to -20°C (freezer may be used)

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

a. Date of verification
b. Initials of person doing verification
c. Reference thermometer reading
d. Data logger reading
e. Identification (ID) or code number of the data logger being verified

7. Temperature readings taken from the reference thermometer may be rounded to whole numbers (e.g.: If reference reads 38.2°C, the recorded value will be 38°C).

8. If the difference between the reference thermometer and the data logger is greater ± 5%, it will be labeled as not suitable for trials conducted under GLP and the % difference will be noted on the logger label.

9. Each measuring device will be labeled following verification and should include:

a. ID or code number
b. Date of verification
c. Initials of person doing the verification
d. Temperature adjustment (if appropriate)

10. Launch unit. Select the duration of time that best suits the use (i.e. 30 days for chemical storage cabinet). If provided, in the 'Legend', type in the location of the datalogger during use.

11. Downloading unit. At the end of the data collection period, 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 will be initialed and dated and retained as original raw data in the Field Data Book. A certified copy will be maintained in the facility Historical File. The following information should be included on the printout:

a. Date
b. Initials of individual conducting the activity
c. Data logger ID or code number
d. Temperature sensor location at the time of reading(s)
e. Units of measurements

12. The hard copy of the data from the data logger(s) should be legible to persons with normal vision.

13. Remedial action to be taken in case of failure or malfunction should include:
a. Any problem should be immediately reported to the facility director or designated personnel, documented, and placed in the records for non-routine procedures.
b. Any repairs or replacements resulting from malfunction during use will be documented as non- routine maintenance in the appropriate log(s).
c. If a data logger is retired or broken, that event will be noted on the corresponding equipment log

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

15. In the event of a malfunction or other incident which may affect the integrity of the trial, the Study Director and other appropriate individuals shall be notified and details shall be recorded in the Field Data Book.

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 June 2010
Author: Judith A. Collins

SOP# 6.4:2 Verification of wind speed measuring devices and RH meters

Purpose: The purpose of this SOP is to establish procedures used when calibrating wind speed measuring devices and RH meters.

Scope: The SOP is to be followed by IR-4 participating personnel when calibrating and using wind speed measuring devices and RH 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. Record inspection and any maintenance performed in appropriate logs.

2. The accuracy of wind monitoring devices used for GLP studies will be verified at least once a year by a side-by-side comparison with at least two other devices. Records of verification will be maintained in a log.

3. If the measured wind speed of any one unit is +/- 2 mph of the average wind speed of all the devices being tested, then unit is reading accurately and is acceptable for use.

4. If the measured RH of any one unit being tested is +/- 3% of the average RH of all the devices being tested, then the unit is reading accurately and is acceptable for 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 use will be documented as non-routine maintenance in the appropriate log(s).
   c. If a data logger is retired or broken, that event will be noted on the corresponding equipment log

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

7. In the event of a malfunction or other incident that may affect the integrity of the trial, the Study Director and other appropriate individuals shall be notified and details shall be recorded in the Field Data Book.

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 June 2010
Author: Judith A. Collins

SOP# 6.5:2 Operation and maintenance of freezers

Purpose: The purpose of this SOP is to establish procedures when using a freezer.

Scope: All field studies conducted to develop samples for residue analysis under GLP.

Procedures:

1. Prior to use clean the unit and visually inspect that it is in good working condition. Document inspection(s) and any maintenance performed in appropriate logs.

2. Temperature within the unit should be checked prior to sample storage. A data logger should be placed in the unit. The temperature range recorded by the device should be within the limits as required by the protocol for storage of the sample.
   a. If temperature measured is within the sample storage range, then unit is approved for use.
   b. If temperature measured is not within the sample storage range, then adjust the temperature control until the unit maintains the correct temperature range.
   c. If after adjustment, the unit cannot maintain a temperature range within the sample temperature storage range, then the unit must be serviced by a trained technician prior to use.

3. When unit is being actively used for storage, the temperature should be monitored with a data logger set to record every 2 hours. If no samples are being stored in the unit, no records of the temperature need to be maintained. During use enough ice will be stored in the unit in insure that the samples remain frozen in the event of a malfunction or power outage.

4. Remedial actions to be taken in case of failure or malfunction include:
   a. Any problem should be immediately reported to the facility director or designated personnel and then documented in the maintenance log.
   b. Any repairs or replacements resulting from malfunction during use should be documented as non-routine maintenance in the appropriate log(s).
   c. If a data logger is retired or broken, that event will be noted on the corresponding equipment log

5. In the event of a malfunction, the samples will be temporarily stored in the freezer located in Deering Hall, room 311. The transfer will be documented in the Field Data Book. Remedial actions will be taken as stated in #6 below. The temperature will be monitored and the samples returned to the trial designated freezers as soon as repairs have been completed.

6. Personnel currently operating the equipment are responsible for the maintenance and remedial action taken in case of malfunction. In the event of a malfunction or other incident that may affect the integrity of the trial, the Study Director and Regional Field Coordinator shall be notified and details shall be recorded in the Field Data Book.

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 June 2010
Author: Judith A. Collins

SOP# 6.6:1 Verification and use of optical range-finder

Purpose: The purpose of this SOP is to establish procedures used when verifying and using an optical range-finder

Scope: All field studies conducted to develop samples for residue analysis under GLP.

Procedures:

1. Verification of the optical range-finder shall be done annually to determine if it is within the desired tolerance.

2. Ensure that the unit displays information when activated by pressing the POWER button. If so, continue to Step 4. If no display occurs or the battery image is blinking or not present, continue to Step 3.

3. Check and replace battery, if necessary

4. Establish a known distance that measures in whole yards (i.e., 100 yds) using a tape measure or other accurate measuring device. Place an object, large enough for optical display to find in its crosshairs, at the determined distances above. Ensure that the object has a flat surface that will reflect the laser directly back to the optical range-finder.

5. Make sure the display is reading in yards. If not, use the MODE function to switch to the appropriate unit of measurement.

6. Record distance values from the range-finder.

    a. Stand with range-finder at one end of the pre-measured distance for whole yards, aim at the object placed at other end of this distance and press the POWER button to gain a read out of the distance. Repeat at least once for consistency and accuracy. Record the displayed value in the Maintenance Log. If values for whole yards do not match the measured distance, do not use range-finder for determining distances. Use some other device.

7. Repeat #6 above for a second pre-measured distance (i.e. 200 yds).

Safety Precautions:

1. Never look directly at the laser beam or directly at the sun when using the range-finder.
2. Do not operate with other optical elements, such as binoculars, lenses, etc.
3. Do not disassemble unit.
4. If unit's body cover is damaged, or if it emits a strange sound due to dropping or from some other cause, immediately remove the battery and stop using.
5. Do not press POWER button when not using the unit.
6. Do not leave within reach of small children.
7. Remove water, sand, or mud immediately with soft, clean, dry cloth.
8. Do not attempt to use range-finder under water.
9. Do not swing by lanyard or leave in unstable situation. Both could result in damage to the unit.
10. Do not leave unit in direct sunlight of in situations of extreme heat.

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 June 2010
Author: Judith A. Collins

SOP# 7.1:2 Residue sample collection and storage

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

Scope: All field studies conducted to develop samples for residue analysis under GLP.

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, Regional Field Coordinator and Quality Assurance Research Officer shall be kept informed when the dates are changed.

2. Prior to sample collection obtain a sufficient number of sample bags from the Regional Field Coordinator to collect all the samples. Before entering the field, label each sample bag with waterproof ink as instructed in the protocol.

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

4. A commercial blueberry rake shall be used to collect the samples. Separate rakes will be used for treated and untreated plots.

5. Prior to sample collection, the rakes and collecting boxes will be thoroughly cleaned with soap and water and stored in plastic bags for transport to the field site.

6. Sample each plot individually beginning with the untreated plots and work up to the highest dosage. Samples from each plot shall be individually packaged and labeled.

7. For each plot, begin raking in one corner and move diagonally across the plot avoiding plot boundaries. Avoid overfilling the rake since this can damage the fruit. Air-winnow the fruit into a clean 1-quart collecting box (1 qt = ca. 1 lb of fruit) to remove leaves. Repeat until a sufficient quantity of fruit as specified in the protocol has been collected.

8. Place the collected fruit into the sample bag. Avoid sample bag contact with the soil or plant parts during sampling. Berry samples may be placed in a plastic bag within the sample bag to avoid loss of juice if not prohibited by the protocol.

9. Briefly describe the procedures and methods used in the Field Data Book.

10. Blueberry Hill Farm Experiment Station is about a 2-hour drive from Orono, ME, where the samples are frozen. Therefore, the treated and untreated samples will be placed in separate coolers with blue ice for transport. Temperature within the coolers will be monitored prior to and during transport.

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 June 2010
Author: Judith A. Collins

SOP# 7.2:2 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 field studies conducted to develop samples for residue analysis under GLP.

PROCEDURES -

1. Prior to shipping, contact the residue laboratory and notify them of the shipment dates and method of shipment including the carrier and carrier schedule. Ask them for any special instructions in shipping the samples.

2. 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.

3. Treated and untreated samples should be packed in separate containers. The containers should have a sufficient bursting strength so as to withstand normal handling in shipping and storage.

4. If shipping by air, obtain insulated containers of sufficient size and quantity to hold the residue samples and dry ice (where required) in a 1:1 to 1:3 weight ratio to commodity and pack the samples and dry ice in the containers just prior to shipment. Airfreight shipments should be made on Monday or Tuesday to avoid potential weekend layovers.

5. A residue sample shipping and identification form should be completed, a copy made, and the copy packed with the samples.

6. Retain the original of the residue sample shipping form in the Field Data Book.

7. Label each shipping carton with the following information.
   a. Return name and address of the sender.
   b. Name and address of the residue laboratory receiving the samples.
   c. Number of the container if more than one is used.
   d. Affix "Experimental Samples-Perishable" to each carton.
   e. Where used, affix "Dry Ice" on two sides of the container.

8. Tape lids of each container firmly in place.

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, where appropriate.

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 June 2010
Author: Judith A. Collins

SOP# 8.1:2 Recording of raw data

Purpose: To assure that raw data collected and recorded is accurate and available for audit.

Scope: Field test sites conducting pesticide registration research under GLP.

Procedures:

1. Data shall be assembled as completely and accurately as possible. All data and documentation that pertains to each trial shall be placed in the Field Data Book for the 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.

2. Use the forms provided in the Field Data Book or develop new forms where needed. No forms will be removed from the Field Data Book. Blank forms may be photocopied as needed. The new forms or supplementary data shall be placed in the Field Data Book behind the existing forms. All supporting data or certified copies shall be included in the Field Data Book.

3. If a particular form or section of the form does not require a response, make a diagonal line 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 at the bottom of the page. If the requested data are not applicable, give an explanation; otherwise refer to the page where the data is provided. For example, 9A shall be lined out, initialed and dated with a notation such as "See following pages."

4. Mistakes shall be lined through once, a reason for the change given, initialed and dated. The correction explanation with the date and initials may be circled. Explanation codes used for corrections shall be defined, either in the instructions or in Part 3 of the Field Data Book.

5. Transcribing data is not acceptable, unless absolutely necessary, such as general farm records. Transcribed data shall be clearly identified as transcribed, the location of the original cited, and be dated and initialed by the person doing the transcription. If possible, someone else should verify transcribed data. Raw data shall not be transcribed to forms and then the forms submitted as raw data.

6. Where raw data is needed for more than one trial (for example sprayer calibrations, logs of various types, weather data, pesticide and freezer storage logs and temperature records, equipment logs, etc.), the original will be placed in one of the Field Data Books, with certified copies in all the other affected books, citing the location of the original. In the case of application calibrations used for more than one application in a given day, the original will be placed in one of the Field Data Books and certified copies will be placed in the other affected Field Data Books.

7. To certify that a copy is a true copy of the original, the copy will be stamped "Exact copy of original document", initialed and dated. The certified copy must contain a notation as to the location of the original the raw data. For example: "Original in ID#_____."

8. Date entries and sign each completed page, and elsewhere as prompted. This is to verify that the data in question is true and accurate. Therefore, do not sign prior to completely the task

9. A hard copy of electronic data, computerized summaries etc., shall be placed with the raw data and referenced as to source as soon as possible after the information is generated. Print outs or plots of data from these devices must be legible. Initial and date the print out when it is printed. The initialed and dated hard copy then becomes the original. When a print out is not possible, a written log shall be recorded throughout the duration of the trial or portion of the trial where the information is required. Each entry to the log shall be dated and initialed by the person collecting the data.

10. The narrative portion of the forms shall be used to summarize the activity and to explain any unusual events so that someone else can reconstruct the event. If more space is needed, attach a second page behind the first.

11. All notebooks, data sheets, summaries, etc. shall be clearly marked with the name of the project, dates generated, name of research personnel and other information that may be needed to understand the data and its sources. All pages will be one-sided only.

12. Number each form and supporting data within each part of the raw data book.

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

14. The original signed SOPs will either be included in one of the Field Data Books for that year, or sent separately to IR-4 Headquarters for archiving. Testing facility information required under GLP/FIFRA, but not required to be included in the Field Data Book, does need to be archived for the duration of the registration. A Facility File will be kept with this original information, including but not limited to: Organizational charts, floor plans, Personnel records such as job descriptions, training records, etc.

15. The information mentioned in #14 will be sent to IR-4 Headquarters for archiving when changes are made, or personnel leave.

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Effective Date: 1 June 2010
Author: Judith A. Collins

SOP# 8.2:2 Historical files and the disposition of data

Scope: Field test sites conducting pesticide registration research under GLP.

Purpose: To assure that each location conducting GLP trials has a designated area for active and historical records pertaining to the program.

Procedures:

1. A limited access facility (i.e. locked room or cabinet) of sufficient size to contain all active records and data generated during the trial, shall be available at or in close proximity to the location of the Field Research Director or technician responsible for the conduct of the trial. The cabinet will be locked and accessible only to the Field Research Director and designated personnel. At the Blueberry Hill Farm research facility, the Field Data Book will be kept in the "Scientist's Office" in the main building. Following the completion of the critical phases of the research, i.e. applications and harvest, and prior to submission to the Regional Field Coordinator, the Field Data Book will be stored at the University of Maine, School of Biology and Ecology, room 307, Deering Hall, Orono, Maine.

2. All raw data and final reports pertaining to IR-4 trials conducted at this site shall be archived at IR-4 Headquarters, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The Field Research Director or designated personnel is responsible for insuring that all the original raw data is included in the Field Data Books, or otherwise transmitted to IR-4 Headquarters.

3. Prior to sending the original Field Data Book to the Regional Field Coordinator, a copy of the completed book shall be made and certified as a true copy by stamp, initials and date on the title page. This certified copy should be used when corrections are needed to the Field Data Book. These copies of the Field Data Book will be retained in the Historical file until the petition that used the data is submitted to the US EPA, the study is cancelled, or the trial dropped.

4. Historical files will be maintained by the Field Research Director or designated personnel. These records will include, but not be limited to, copies of:

    a. Organizational charts and other facility information
    b. CVs, and training records
    c. Historical SOPs
    d. Certified copies of Field Data Books.

5. A facility file will be maintained by the Field Research Director or designated personnel. This file is for current records and information not sent for archiving. When changes are made, the older information will be sent to IR-4 HQ. As this is original information, the files will also be maintained under limited access. These records will include, but not be limited to:

    a. Organizational charts, floor plans and other current facility information
    b. CVs and training records of current personnel.

6. A historical file will be maintained by the Field Research Director or designated personnel for copies of records and information that has been submitted to IR-4 Headquarters for archiving. These records will include, but not be limited to copies of:

    a. Previous organizational charts, floor plans and other facility information
    b. CVs and training records for former personnel.
    c. Copies of historical SOPs
    d. Certified copies of Field Data Books.

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Effective Date: 31 May 2008
Author: Judith A. Collins

SOP# 9.1:1 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: Field test sites conducting pesticide registration research under GLP.

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:

1) Master schedule for the field research director
2) Trial Protocol and Standard Operating Procedures
3) Raw data, correspondence and logs
4) Training records, CVs etc. of personnel assigned to the trial
5) Appropriate chain of custody documents for samples and freezer logs and storage temperature documentation
6) Documentation of the characterization of the test substance, receipt and handling
7) Calibration logs on equipment such as balances and application equipment.
8) Archives or storage of records and logs indicating removal and replacement of documents.

5. Have accessible organizational charts, a map of the facility and any information specific to the facility or area that will facilitate the inspection (restaurants, motels etc.).

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Effective Date: 31 May 2008
Author: Judith A. Collins

SOP# 9.2:1 Procedures to follow during an EPA inspection (Field trial site inspection/outside agency)

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

Scope: Field test sites conducting pesticide registration research under GLP.

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/her 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 will accept the Notice of Inspection.
4. Distribute organizational charts, map of the facility and any other previously prepared information.
5. Ask the lead inspector for his/her agenda for the inspection as well as a list, if possible, of personnel needed for interviews 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.
8. Provide documents requested and provide explanations needed.
9. Keep notes of observations and of all interviews.
10. Keep management informed of the progress of the inspection and the findings.

University of Maine
Judith A. Collins
School of Biology and Ecology
5722 Deering Hall
Orono, ME 04469

Effective Date: 31 May 2008
Author: Judith A. Collins

SOP# 9.3:1 Procedures to follow after an EPA inspection

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

Scope: Field test sites conducting pesticide registration research under GLP.

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 closeout 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 closeout take accurate notes or record the conference on tape if taping is acceptable to the inspectors.
5. 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.