SOP Log Sheet

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Submitter

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1/19/2022 JT

STANDARD OPERATING PROCEDURES

Pesticide Residue Trials

Fruit and Vegetable Crops

Department of Horticulture
Michigan State University
East Lansing, Michigan 48824-1325

The following SOPs have been submitted by the Field Research Director and approved by the Regional Director.

Nicole Soldan Field Research Director	Nicole Soldan (Signature)	NS (Initials)	2-28-24 (Date)
Mary Hausbeck Regional Director	Mary Hausbeck (Signature)	MH (Initials)	3-1-24 (Date)

Revision: 6.7
These SOP's replace Department of Horticulture version 6.6 SOP

MICHIGAN STATE
UNIVERSITY

TO: Nicole Soldan
Michigan State University, Dept. of Horticulture A448 PSSB
East Lansing, MI 48824

FROM: Dr. Mary K. Hausbeck (IR-4 NC Regional Director)

SUBJECT: STANDARD OPERATING PROCEDURE (6.7) APPROVAL

EFFECTIVE DATE: March 1, 2024 Mary Hausbeck
Per 40CRF160 Good Laboratory Practice Standards (GLP), this is to notify you that your Standard Operating Procedure (SOP) in use is approved. Please retain this document with your SOP to fulfill GLP requirements.

SOP	REV #	REVISED DATE	SOP	REV #	REVISED DATE	SOP	REV #	REVISED DATE
1.1	6.0	1-5-18	6.2	6.0	1-5-18	9.5	6.2	2-28-24
1.2	6.1	1-7-19	6.3	6.0	1-5-18	9.6	6.1	2-28-24
1.3	6.1	1-8-21	6.4	6.1	2-15-24	9.7	6.1	2-28-24
1.4	6.1	1-8-21	6.5	6.0	1-5-18	9.8	6.0	1-5-18
1.5	6.2	1-5-22	6.6	6.2	2-15-24	9.9	6.0	1-5-18
2.1	6.1	4-6-23	6.7	6.0	1-7-19	10.1	6.0	1-5-18
2.2	6.0	1-5-18	6.8	6.1	1-5-22	10.2	6.0	1-5-18
2.3	6.1	2-15-24	7.1	6.0	1-5-18	10.3	6.1	4-6-23
2.4	6.2	2-15-24	7.2	6.2	2-15-24	10.4	6.4	6-15-23
2.5	6.0	1-5-18	7.3	6.0	1-5-18	10.5	6.2	2-28-24
2.6	6.0	1-5-18	7.4	6.3	2-15-24	10.6	6.3	6-15-23
3.1	6.2	2-15-24	7.5	6.1	2-15-24	11.1	6.2	2-28-24
3.2	6.0	1-5-18	7.6	6.0	1-5-18	11.2	6.2	2-28-24
3.3	6.1	2-15-24	7.7	6.2	2-15-24	11.3	6.1	2-28-24
4.1	6.0	1-5-18	7.8	6.1	4-6-23	12.1	6.1	1-5-22
4.2	6.3	2-15-24	7.9	6.1	2-15-24	12.2	6.0	1-5-18
5.1	6.0	1-5-18	8.1	6.0	1-5-18	13.1	6.0	1-5-18
5.2	6.0	1-5-18	9.1	6.0	1-5-18	14.1	6.0	1-5-18
5.3	6.0	1-5-18	9.2	6.1	2-15-24	14.2	6.0	1-5-18
5.4	6.0	1-5-18	9.3	6.0	1-5-18	14.3	6.0	1-5-18
6.1	6.1	2-15-24	9.4	6.0	1-5-18			

IR-4 North Central Region Field Coordinator's Office

Department of Entomology

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Department of Horticulture
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Effective Date: March 1, 2024
Revision Number: 6.7

Index of Standard Operating Procedures Page 1 of 2

Department of Horticulture
Michigan State University
East Lansing, MI 48824-1325

Effective Date: March 1, 2024
Revision Number: 6.7

Submitted by Field Research Director: Nicole Soldan DATE: 2-28-24
Nicole Soldan

Approved by Regional Director: Mary Hausbeck DATE: 3-1-24
Mary Hausbeck

Department of Horticulture
Michigan State University
East Lansing, MI 48824-1325

Revised: 1-5-18
Revision Number: 6.0

SOP 1.1

TITLE: General requirements for Standard Operating Procedures (SOPs).

PURPOSE: To provide guidance in development and use of sops for field research studies.

SCOPE: Field pesticide residue studies in the Department of Horticulture at Michigan State University.

PROCEDURES:

1. The IR-4 Field Research Director (FRD) will develop standard operating procedures (sops) for all phases of research conducted in support of pesticide registration. Adherence to the sops will assure compliance with EPA requirements for Good Laboratory Practices (GLP).

2. The individual sops together with a directory and SOP Approval Log will constitute THE SOP for IR-4 pesticide residue studies at the Department of Horticulture, Michigan State University.

3. THE SOP will be reviewed annually and revised as needed. The revision number and date of revision will be recorded in the SOP index, which will be maintained as part of THE SOP. All earlier versions of THE SOP will be archived at headquarters.

4. Any deviations from the sops that would affect the results of a study must be documented in writing and signed by the Study Director.

5. The FRD is responsible for annually distributing the current version of THE SOP to the RFC. Other study personnel will receive copies of THE SOP upon request.

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Revised: 1-7-19
Revision Number: 6.1

SOP 1.2

TITLE: Annual review and revision.

PURPOSE: Record annual review and revisions

SCOPE: All sops

PROCEDURES:

1. The "Standard Operating Procedures for pesticide residue trials on fruits, vegetables, and ornamental crops" (THE SOP) will be reviewed annually by the Field Research Director and revised as needed. The date of the review and the numbers of the sops revised will be recorded in the SOP index.

2. Major revisions of THE SOP will be designated by whole numbers (e.g., 1.0, 2.0, 3.0).

3. Revisions of individual sops will be designated by decimal numbers (e.g., 2.0, 2.1, 2.2, 2.3).

4. A revision provides a substantive change in the meaning of the SOP. Correcting spelling and formatting errors along with making minor changes that clarify the intended meaning of the SOP do not constitute a revision.

5. When many individual sops have been revised, a major revision of THE SOP will be instituted and designated as the succeeding whole number.

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Revised: 1-8-21
Revision Number: 6.1

SOP 1.3

TITLE: Definitions for THE SOP.

PURPOSE: To define the terms used in this SOP.

SCOPE: All SOPs.

PROCEDURES:

1. In all sops developed under THE SOP, the following terms will have the meanings specified.
   a. BATCH - a specific quantity or lot of a test substance that has been adequately characterized.
   b. EXPERIMENTAL START DATE - the first date the test substance is applied to the test system (crop).
   c. EXPERIMENTAL TERMINATION DATE - the last date on which data are collected directly from a study.
   d. GOOD LABORATORY PRACTICES (GLP) - a set of guidelines mandated by Congress to which researchers must adhere to assure the integrity of research data. All IR-4 studies are conducted under GLP guidelines.
   e. MASTER TIMETABLE - a list of trials which is maintained by the Field Research Director. It must be indexed by test chemical and crop, and contain type of trial, approximate experimental start dates, and termination dates.
   f. MASTER SCHEDULE - a list, maintained by the quality assurance unit, of all studies conducted at the testing facility indexed by test substance, and containing the test system, nature of study, date study was initiated, current status of each study, identity of the sponsor, and name of the study director.
   g. PROTOCOL - a specific document, provided by the sponsor that contains details for accurate completion of a trial.
   h. QUALITY ASSURANCE UNIT (QAU) - any person or organizational element, EXCEPT THE STUDY DIRECTOR OR FIELD RESEARCH DIRECTOR, who is designated to perform the monitoring duties to assure that the research is conducted according to Standard Operating Procedures and GLP. Regional IR-4 representatives will designate the Quality Assurance Officer (QAO) for IR-4 trials.
   i. RAW DATA - worksheets, records, memoranda, notes, etc., that are the results of original observations and activities of a study. This includes photographs and computer printouts.
   j. RESEARCH - the collection of information about a particular subject.
   k. SPONSOR - the individual, corporation, association, scientific or academic establishment, government agency or other organizational unit who initiates and supports, by provision of financial or other resources, a study.
   l. STANDARD OPERATING PROCEDURES (SOP) - written documentation of routine activities utilized in research studies.
   m. TRIAL - an experiment in which a test substance (pesticide) is applied under field conditions to determine or help predict its effect, metabolism, environmental and chemical fate, or other characteristics.
   n. FREQUENTLY USED ACRONYMS -
      Michigan State University (MSU)
      Plant and Soil Sciences Building (PSSB)
      Horticulture Teaching and Research Center (HTRC)

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Revised: 1-8-21
Revision Number: 6.1

SOP 1.4

TITLE: Numbering system for SOPs.

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

SCOPE: All SOPs.

PROCEDURES:

1. SOPs will be organized using these major headings:

    1. General rules and requirements for Standard Operating Procedures (SOPs)
    2. Personnel
    3. Study protocol and experimental design
    4. Site selection and plot establishment
    5. Agronomic practices for field experiments
    6. Application equipment calibration, maintenance and use
    7. Test chemical receipt, storage, handling and disposal
    8. Safe handling of pesticides and use of safety equipment
    9. Collection of pesticide data, weather data, and other information
    10. Residue sample collection, storage, and shipping
    11. Trial reports
    12. Archives and record storage
    13. Quality Assurance
    14. EPA inspection

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Revised: 1-5-22
Revision Number: 6.2

SOP 1.5

TITLE: Format for sops.

PURPOSE: To assure a uniform format in the development of sops.

SCOPE: All SOPs.

PROCEDURES:

1. The following is the format to be used for each standard operating procedure:

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Revised:
Revision Number:

SOP #: (Category number followed by sop number in numerical order [1 to n]).

TITLE: (Sop title).

PURPOSE: (Brief description of the purpose of the sop)

SCOPE: (Determines where and when the sop is applicable)

PROCEDURES:

(Describe the operating procedures from beginning to end so that regulatory personnel can understand what was done.)

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Revised: 4-6-23
Revision Number: 6.1

SOP 2.1

TITLE: Personnel.

PURPOSE: To describe personnel involved in pesticide registration trials and their responsibilities under GLP.

SCOPE: All personnel directly involved in the trials.

PROCEDURES:

1. Each individual engaged in the conduct of or responsible for the supervision of a trial shall have education, training, and experience to enable that person to perform the assigned functions.

2. Personnel involved in pesticide registration research will be designated as Study Director, Field Research Director, GLP Coordinator, or other personnel.

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Revised: 1-5-18
Revision Number: 6.0

SOP 2.2

TITLE: Study Director.

PURPOSE: To describe responsibilities of the Study Director.

SCOPE: All IR-4 field research studies.

PROCEDURES:

1. The Study Director for each IR-4 study will be appointed by the IR-4 Headquarters. The Study Director has overall responsibility for the technical conduct of the study, as well as for the interpretation, analysis, documentation, and reporting of results, and represents the single point of study control.

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Revised: 2-15-24
Revision Number: 6.1

SOP 2.3

TITLE: Field Research Director

PURPOSE: To describe responsibilities of the Field Research Director.

SCOPE: All IR-4 field research trials.

PROCEDURES:

1. The Regional Field Coordinator will designate a Field Research Director for each trial. The Field Research Director has immediate and personal responsibility for conduct of a trial, including supervision of all other personnel involved in the trial.

2. The Field Research Director will:

   a. Assure that the trial is carried out according to the protocol and good laboratory practices.

   b. Assure that personnel, resources, facilities, equipment, materials and methods are available as scheduled for the conduct of the trial.

   c. Assure that all personnel conducting the trial understand the protocol and sops for the trial.

   d. Maintain a Master Timetable for all IR-4 field research trials under their control.

   e. Submit a copy of the Master Timetable to the QAO within a timely manner of receiving all trial assignments.

   f. Complete all report forms and transfer all reports and raw data (except as noted in sop 12.1: Archives and Record Storage) to the RFC upon completion of the trial.

3. Either the Field Research Director or the GLP Coordinator will:

   a. Report deviations from protocol or sops to Study Director.

   b. Respond to all deviations reported by the Quality Assurance Unit (QAU) in writing.

   c. Prepare responses to eQA Audits and Field In-Life Inspections.

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Revised: 2-15-24
Revision Number: 6.2

SOP 2.4

TITLE: Other Personnel.

PURPOSE: To provide information concerning requirements under GLP for other personnel involved in pesticide trials.

SCOPE: All IR-4 field research trials.

PROCEDURES:

1. The Field Research Director will have on file a current summary of training and experience and a job description for all personnel actively engaged in the conduct of a trial.

2. GLP Coordinator is a title that may be given to a Field Research Director's assistant that assists, coordinates and manages IR-4 trials.

3. Temporary field workers involved in critical phases of a trial but NOT entering data in the FDB do NOT require CV or training record. However, a separate page should be included in the FDB that provides their names, describes the impromptu training that was given and identifies the actions performed in the trial.

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Revised: 1-5-18
Revision Number: 6.0

SOP 2.5

TITLE: Organizational Chart.

PURPOSE: To describe requirements for an organizational chart.

SCOPE: All IR-4 field research trials.

PROCEDURES:

1. An organizational chart which reflects the management of the facility and the reporting lines of the personnel engaged in IR-4 trials will be developed and kept on file by the Field Research Director.

2. Each entry in the chart should show the name and title of the person filling that position.

3. The chart must show how the Field Research Director reports to the Study Director and the National Director, and the relationship between the QAU and the other parts of the organization.

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Revised: 1-5-18
Revision Number: 6.0

SOP 2.6

TITLE: Documentation of training.

PURPOSE: To assure that training for personnel involved in IR-4 trials is properly documented.

SCOPE: All personnel actively involved in IR-4 field trials.

PROCEDURES:

1. All formal education beyond secondary school should be included in each person's vita.

2. Relevant training received at workshops, conferences, etc. should be recorded. A copy of training certificates issued should be retained in the personnel files.

3. The Field Research Director will document any other training provided for personnel involved in the trials.

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Revised: 2-15-24
Revision Number: 6.2

SOP 3.1

TITLE: Study protocol and experimental design.

PURPOSE: To describe the normal methodology for obtaining a study protocol and planning an IR-4 field research trial.

SCOPE: All pesticide registration trials.

PROCEDURES:

1. The protocol is an official document and must be followed completely to assure that the data generated will be useful in the registration process.

2. The Field Research Director is responsible for meeting all requirements of the protocol.

4. The Field Research Director will prepare a Master Timetable including all major functions of all trials to be conducted at his location in a given year. The Field Research Director will submit the Master Timetable to the Quality Assurance Officer and the Regional Field Coordinator as early as possible. The Field Research Director will maintain a file of annual Master Timetables.

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Revised: 1-5-18
Revision Number: 6.0

SOP 3.2

TITLE: Deviations from protocol.

PURPOSE: To provide methodology for dealing with unforeseen changes in protocols or field conditions that preclude complete compliance with the protocol.

SCOPE: Changes or deviations initiated by Sponsor, Study Director, or Field Research Director.

PROCEDURES:

1. For changes in protocols initiated by the Sponsor or Study Director, the Study Director will send a copy of the protocol change form listing specific changes in the protocol to the Field Research Director. The protocol change form should be sent to the Field Research Director before the experimental start date when practical. A copy of the protocol change form will be attached to the protocol and a copy will be filed with the trial report.

2. For deviations from protocol initiated by the Field Research Director, the Field Research Director or the GLP Coordinator will prepare a study deviation form and submit it to the Study Director and notify the Study Director by email or phone as soon as possible. The Study Director will determine appropriate action for deviations. Minor deviations that do not significantly change the results of a trial may be accepted.

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Revised: 2-15-24
Revision Number: 6.1

SOP 3.3

TITLE: Experimental design

PURPOSE: To assure that all efficacy, yield, and phytotoxicity data developed is statistically sound.

SCOPE: All IR-4 field research trials to support pesticide registration.

PROCEDURES:

1. The experimental design as specified by the protocol should be used. Residue trials are normally not randomized. Efficacy and phytotoxicity trials may be randomized. The experimental design used should be documented in the Field Data Book.

2. IR-4 does not normally require Field Research Director to analyze data.

3. Create a plot map showing the location of each plot. Retain the plot map in the Field Data Book.

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Revised: 1-5-18
Revision Number: 6.0

SOP 4.1

TITLE: Site selection, plot establishment and use of GPS

PURPOSE: To assure that plots will provide the required data and samples with sufficient uniformity to meet EPA requirements.

SCOPE: All IR-4 field research trials to support pesticide registration.

PROCEDURES:

1. Sites will be selected that are representative of normal production areas for the commodity.

2. Sites will be large enough to accommodate the number of treatments, required buffer zones and the sample sizes required by the protocol.

3. Where possible establish site so that treated plots are downwind of the untreated plot or downslope of the untreated plot.

4. Locate the site with sufficient isolation to minimize contamination from external sources such as commercial operations or other research studies.

5. Obtain a soil test for the site as per sop 4.2.

6. If the trial is to be conducted on perennial fruit crops on a commercial farm, select a reliable grower with a planting in good health, managed by accepted horticultural practices and with a previous pesticide history that meets protocol requirements.

7. If the site is on a commercial farm, arrangements should be made with the grower for crop destruction and remuneration if a non-registered pesticide is used on his crop.

8. If the commodity is already established, select a site that has a uniform stand.

9. Prepare a plot map showing the location of each plot on the site, the North azimuth and any significant slope. The plot map should contain permanent reference points so that the plots can be relocated after the trial is terminated. Alternatively, the site may be identified by and permanent landmark reference points determined by a hand-held GPS unit.

10. Place a stake at the first plot identifying the trial number. Assign each treatment and subplot a number. Number stakes with sufficient information to identify the replicate and treatment assigned to each plot.

11. Identify both ends of each plot with a marker of sufficient visibility to be seen easily throughout the duration of the trial.

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Revised: 2-15-24
Revision Number: 6.3

SOP 4.2

TITLE: Soil sampling and characterization.

PURPOSE: To describe procedures for taking soil samples for field trial sites.

SCOPE: All IR-4 field trials.

PROCEDURES:

1. If the site has had a soil test within the last 5 years, these results may be used for soil characterization. It is also acceptable to take a new soil test.

2. If no current soil test is available, take a soil sample during the experimental period using the following methods:

   a. Using a clean soil probe and clean bucket or plastic bag take 5-15 random soil samples at a 6 to 8 inch depth in the field and place samples in the clean bucket or plastic bag.

   b. Once all samples are taken, mix the soil thoroughly in the bucket or plastic bag. Fill a soil container with soil from the bucket or plastic bag. Label the container with an identification number and send it to a soil testing laboratory for analysis (ex. A&L Great Lakes Soil, Plant and Agricultural Analysis).

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Revised: 1-5-18
Revision Number: 6.0

SOP 5.1

TITLE: Agronomic practices for field experiments.

PURPOSE: To assure that crops grown for pesticide trials are produced following good agronomic practices.

SCOPE: All IR-4 pesticide trials to support registration.

PROCEDURES:

1. Determine good horticultural practices for the commodity to be grown.

2. Perform and record all cultural practices (e.g. plowing, disking, dragging, cultivating) carried out before and after planting. Fertilize as needed to produce the crop.

3. Apply pesticides that will not interfere with the outcome of the trial, as needed, to grow the crop. Record all pesticides applied in the Field Data Notebook.

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Revised: 1-5-18
Revision Number: 6.0

SOP 5.2

TITLE: Greenhouse, shadehouse and testing facilities.

PURPOSE: To assure that greenhouse and shadehouse facilities are adequate for growing transplants for IR-4 field trials.

SCOPE: All IR-4 field trials in which greenhouse or shadehouse facilities are used for growing transplants.

PROCEDURES:

1. Each greenhouse or shadehouse must be sufficiently large enough to contain the plants for a trial. All flats will be labeled for identification and action dates. Appropriate observations will be entered in the Field Data Notebooks.

2. Plants should be grown under good horticulture procedures to provide acceptable plants for the trials. Plants exhibiting disease or pest problems will be removed from the open greenhouse area and examined to determine the cause of the problem. Observations will be reported to the Field Research Director.

3. In projects that require transplants to be treated during greenhouse production, the test substance will be applied to the flats or plants on the grassy area adjacent to the greenhouse. Transplants will be returned to greenhouse within 15 minutes after application.

4. Greenhouse temperature will be monitored by a portable thermographic device for projects that require transplants to be treated during greenhouse production. The thermographic device will be maintained in accordance with SOP 9.5 and 9.6.

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Revised: 1-5-18
Revision Number: 6.0

SOP 5.3

TITLE: Seeding and transplanting.

PURPOSE: To assure that commodities are established following good agricultural practices.

SCOPE: All IR-4 trials.

PROCEDURES:

1. Follow good horticultural practices for the crop.

2. Select a suitable cultivar for the trial. Note cultivar and source in Field Data Notebook. If the information is available, also note the date that seed or transplants were received, and lot number.

3. Seed or transplant to establish the crop according to accepted horticultural practices.

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Revised: 1-5-18
Revision Number: 6.0

SOP 5.4

TITLE: Crop maintenance.

PURPOSE: To assure that commodities are grown under good horticultural practices and to provide a uniform crop for observation and harvest.

SCOPE: All IR-4 field trials.

PROCEDURES:

1. The Field Research Director will:

   a. Maintain the crop as well as possible throughout the duration of the trial.

   b. Approve the application of labeled pesticides as needed to prevent losses due to pests and will not apply pesticides that may interfere with the chemical analysis of the pesticide under study. If in doubt call the Study Director.

   c. Provide all records of pesticide applications including product, active ingredient and rate.

   d. Compile all irrigation and rainfall records.

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Revised: 2-15-24
Revision Number: 6.1

SOP 6.1

TITLE: Application equipment calibration, maintenance and use.

PURPOSE: To describe the calibration, maintenance, and use of pesticide application equipment used in IR-4 research trials.

SCOPE: All application equipment used in experiments to support pesticide registration.

PROCEDURES:

1. All application equipment used for conducting GLP studies should be inspected, cleaned, and maintained prior to the beginning of the field season. The written records from this maintenance and inspection will be recorded on the Equipment Maintenance and Calibration form. Pre-season equipment maintenance is described as inspecting all lines, hoses, and connections, removing and cleaning all nozzles and screens and performing an initial calibration.

2. Records noted on the Pesticide Application Equipment Maintenance and Calibration form will designate activities as routine or non-routine.

    a. Pre-season inspection, cleaning, maintenance, testing and calibration are routine procedures.
    b. Any repair as a result of malfunction is non-routine.

3. In the case of equipment failure, malfunction or damage, the remedial action plan will be followed, and alternate equipment will be obtained to complete trial requirements. A written description the equipment failure or malfunction will be recorded on the Equipment Maintenance and Calibration form.

4. Application equipment will be cleaned after each use (unless spraying more than one trial with the same chemical at the same rate immediately after) to ensure integrity of succeeding applications.

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Revised: 1-5-18
Revision Number: 6.0

TITLE: Calibration of a hand carried CO2 pressurized boom sprayer.

PURPOSE: To set the delivery rate of the sprayer to ensure accurate application of the pesticide.

SCOPE: All IR-4 sponsored trials where a hand carried CO2 pressurized sprayer is used in the application of pesticides.

PROCEDURES:

1. Sprayers should be calibrated daily before use, or as required by trial protocols, and results recorded in the appropriate Field Data Book.

2. Visually inspect equipment for obvious wear or potential leaks and repair or replace as necessary.

3. Choose the appropriate nozzle tips to deliver the volume, pressure, and spray pattern required.

4. Pressurize the spray tank with sufficient CO2 to maintain the desired pressure throughout the application. Set the pressure regulator on the CO2 tank to deliver the desired volume and pressure at the nozzle.

5. To determine whether all nozzles are discharging uniformly, place each nozzle in a graduated cylinder and open the trigger valve for a given length of time. Replace nozzle tips that vary more than 5% from the average. Repeat the above procedure until all nozzles are discharging relatively uniformly.

6. When spraying with a single nozzle boom, use even spray nozzles and measure the desired band width before spraying the treatment plots.

7. When spraying with a multiple nozzle boom, hold boom at desired height over target to obtain an approximate 30% overlap on each side of each nozzle.

8. Calibrate the boom as follows:

a. Calibration calculations are based on information provided in the Spraying Systems Co. Catalog. All fluid delivery calculations are based on the assumption that any XX02 nozzle delivers 0.2000 gallons of water a minute at 40 psi, any XX04 nozzle delivers 0.4000 gallons of water a minute at 40 psi and XX10 nozzle delivers 1 gallon of water a minute at 40 psi. To extrapolate to 30 psi, the following formula is used:

$$\frac{GPM\ 1}{GPM\ 2} = \frac{\sqrt{PSI\ 1}}{\sqrt{PSI\ 2}}$$

Thus, for our applications with 8002 and 11002 nozzles the GPM at 30 psi (GPM) calculation is as follows:

$$\frac{GPM30}{.2000} = \frac{\sqrt{30}}{\sqrt{40}} \rightarrow \frac{GPM30}{.2000} = \frac{5.48}{6.32} \rightarrow GPM\ @\ 30\ psi = 0.1734\ gpm$$

3785.3 ml/gal x 0.1734 gpm = 656.4 ml/min = 10.94 ml/sec per nozzle @ 30 psi. The delivery of an XX04 nozzle is double the delivery of an XX02 and the delivery of XX10 is five times the delivery of XX02. Therefore, in this formula, an XX04 nozzle would deliver 21.88 ml/sec and an XX10 would deliver 54.70 ml/sec.

b. To calibrate the boom and CO2 pressure regulator, the tank is filled with water and pressurized. The nozzles are placed into graduated cylinders and the trigger valve is opened for 15 or 30 seconds(depending on nozzles selected). 8002 and 11002 nozzles should deliver 328 ml in 30 seconds. 8004 nozzles should deliver 328 ml in 15 seconds. 8006 nozzles should deliver 482 ml in 15 seconds. 8010 nozzles should deliver 820.5 ml in 15 seconds. If delivered volume is not correct, the CO2 regulator is adjusted and the process repeated until the delivery is within 3% of the desired amount. The pressure readings on the CO2 regulator and spray boom are recorded for each test. When the correct amount has been delivered three times, the boom is considered calibrated. Calibration results (pressure readings and nozzle discharge volumes) are recorded in the Field Data Book. The first calibration of the season, or those calibrations requiring maintenance and/or repair of sprayer equipment will be recorded on the Equipment Maintenance and Calibration Form.

9. Calculate walking speed as follows:

a. Walking speed is calibrated by marking out a 50 foot strip and walking it with a full sprayer and timing each trip with a stopwatch until the correct time for 50 feet is achieved. Time for 50 ft is calculated by the following formula:

$$\frac{a \times 50\ ft}{43{,}560\ ft^2/acre} \times b\ gpa \times \frac{3785.3\ ml/gal}{c\ ml/sec} = \text{time in sec for 50 ft}$$

a = effective band width in feet, *or plot width for directed applications*
b = desired volume per acre in gallons
c = volume of boom in ml/sec at desired pressure

b. Our four nozzle boom consists of four nozzles mounted 16 inches apart with a band width of 64 inches. With 8002 nozzles it delivers 43.76 ml/sec (four 8002 nozzles x 10.94 ml/sec). Thus:

$$\frac{5.33 \times 50 \text{ ft}}{43{,}560 \text{ ft}^2/\text{acre}} \times 20 \text{ gpa} \times \frac{3785.3 \text{ ml/gal}}{43.76 \text{ ml/sec}} = \underline{\textbf{10.6 sec for 50 ft}}$$

c. Our four nozzle boom with XX04 nozzles (8004, 9504, 11004, or OC04) delivers 87.52 ml/sec (four XX04 nozzles x 21.88 ml/sec). Thus:

$$\frac{5.33 \times 50 \text{ ft}}{43{,}560 \text{ ft}^2/\text{acre}} \times 40 \text{ gpa} \times \frac{3785.3 \text{ ml/gal}}{87.52 \text{ ml/sec}} = \underline{\textbf{10.6 sec for 50 ft}}$$

This boom may be adjusted so that the outside nozzles spray the sides of the plants while the center nozzles spray the top of the plants. This boom is used for small to moderate sized fruit trees and plants.

d. Wider or narrower bands can be obtained by adding or deleting nozzles from a boom and recalibrating as above.

e. Our two nozzle boom consists of two nozzles mounted 16 inches apart with a band width of 32 inches. It delivers 21.88 ml/sec (2 nozzles x 10.94 ml/sec). Thus:

$$\frac{2.67 \times 50 \text{ ft}}{43{,}560 \text{ ft}^2/\text{acre}} \times 20 \text{ gpa} \times \frac{3785.3 \text{ ml/gal}}{21.88 \text{ ml/sec}} = \underline{\textbf{10.6 sec for 50 ft}}$$

f. Our two nozzle tandem boom consists of two nozzles (8010) mounted 12 inches apart in tandem. (The second nozzle is behind the first nozzle.) It delivers 109.4 ml/sec from two nozzles and has a band width of 16 inches. Thus:

$$\frac{1.33 \times 50 \text{ ft}}{43{,}560 \text{ ft}^2/\text{acre}} \times 200 \text{ gpa} \times \frac{3785.3 \text{ ml/gal}}{109.4 \text{ ml/sec}} = \underline{\textbf{10.6 sec for 50 ft}}$$

g. Speed in miles per hour is calculated as follows:

$$\frac{5{,}280 \text{ ft/mile}}{50 \text{ feet}} = 105.6 \times 10.6 \text{ sec} = 1119.36 \text{ sec/mile}$$

$$\frac{1119.36 \text{ sec/mile}}{3600 \text{ sec/hour}} = 0.311 \text{ hr/mile}$$

$$\frac{1}{0.311 \text{ hr/mile}} = 3.2 \text{ mile/hr}$$

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Revision Number: 6.0

SOP 6.3

TITLE: Calibration and use of a tractor-mounted CO2 pressurized boom sprayer.

PURPOSE: To set the delivery rate of the sprayer to ensure accurate application of the pesticide.

SCOPE: All IR-4 sponsored trials where a tractor-mounted CO2 pressurized sprayer is used for pesticide application.

PROCEDURES:

1. Visually inspect equipment for obvious wear or potential leaks and repair or replace as necessary.

2. Choose the appropriate nozzle tips to deliver the volume, pressure, and spray pattern required.

3. Pressurize the spray tank with sufficient CO2 to maintain the desired pressure throughout the application. Set the pressure regulator on the CO2 tank to deliver the desired volume and pressure at the nozzle.

4. To determine whether all nozzles are discharging uniformly, place a container under each nozzle to catch output. Open the valve for a given length of time and measure the output. Do this at least three times. Replace nozzle tips that vary more than 5% from the target delivery rate. Repeat the above procedure until all nozzles are discharging relatively uniformly.

5. Adjust boom height over target to obtain an approximate 30% overlap on each side of each nozzle.

6. Calibrate the boom as per SOP 6.2.

7. Calibrate the tractor ground speed using the formula from SOP 6.2 section 8, using a 100 ft strip instead of a 50 ft strip. The time to travel 100 ft is 21.2 sec.

8. Check the speed of the tractor by operating the tractor over a measured distance of 100 ft at the calculated speed and record the time it takes to travel the distance. Calculate the actual miles per hour (mph) from the following formula:

$$MPH = \frac{\text{Feet traveled} \times 0.682}{\text{Time in sec to travel}}$$

   Record transmission gear and range and engine RPM at which the desired ground speed is obtained. Use these settings for future calibration.

9. Record the time required to travel the length of the plot in the Field Data Book.

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Revision Number: 6.1

SOP 6.4

TITLE: Calibration and use of a granular applicator.

PURPOSE: To set the delivery rate of the granular applicator to ensure accurate application of the pesticide.

SCOPE: All IR-4 sponsored trials where a granular applicator is used in the application of pesticides in field research.

PROCEDURES:

1. Inspect the spreader to determine that it is clean and in good mechanical condition.

2. Fill the spreader at least half full of the material to be applied. Attach a pan under the spreader to catch the material as it is released.

3. Measure an area of approximately 0.01 acre or 435.6 square feet (e.g., 43.5 ft long x 10 ft wide).

4. Determine the approximate setting of the openings and the approximate speed to walk for the desired amount of product/acre.

5. Operate the applicator over the measured distance and collect the output in the pan attached to the spreader.

6. Weigh the material from the pan and multiply by 100 to give the amount applied per acre.

7. Continue with steps 4 through 6 until the desired rate is achieved within 5% of the desired amount per acre.

8. Example: You want to apply 10 lbs product per acre. Spreader band width is 10 ft.

$$\frac{435.6\ ft^2}{10\ ft\ wide} = 43.5\ ft\ (distance\ to\ walk)$$

You should apply 1/100 of the amount per acre in this area, or 0.1 lb (45.4g)

9. An alternative method of granular application is to weigh out the amount of product needed per plot, and apply it uniformly with a shaker.

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SOP 6.5

TITLE: Cleanup of application equipment.

PURPOSE: To ensure that pesticide application equipment is clean to avoid contamination of succeeding trials.

SCOPE: All IR-4 field research trials.

PROCEDURES:

1. Apply any excess pesticide mix or granules to an approved area.

2. Rinse tank with clean water. Place approximately 1 tsp of tank cleaner in rinsed tank. Add approximately 1 liter of water and mix solution by shaking tank. Spray out soapy water through boom. Rinse tank at least 2 times with water. Fill tank approximately half way with water and spray out contents through boom.

3. Store portable equipment at HTRC in Bldg 407H, Room 104.

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Revised: 2-15-24
Revision Number: 6.2

SOP 6.6

TITLE: Remedial action in case of equipment failure.

PURPOSE: To ensure that a prescribed course of action is followed in case of equipment failure.

SCOPE: All IR-4 field research trials.

PROCEDURES:

1. Equipment is identified as all instruments, apparatus and implements used to complete measurement, application and assessment for IR-4 field trials. Equipment includes, but is not limited to, sprayers, applicators and nozzles, tanks and pressure regulators, temperature monitoring systems, weather monitoring equipment and meters, hand held GPS unit, soil probes and samplers, stop watch, pH strips, freezer, balance used for weighing test substance and sample weights, graduated cylinders, tape measure, wheel, and electronic Field Data Book mobile device (i.e. laptop or tablet).

2. In the case of equipment failure, malfunction or damage, equipment will be repaired, alternate equipment will be secured, or service personnel will be contacted to perform non-routine maintenance to return equipment to working order and complete trial requirements.

3. At a minimum, documentation of these actions should include the nature of the failure, date of first notice, remedial actions taken and an assessment of potential impacts on trial.

4. If a trial is not affected or impacted in any way, it does not need to be noted in the Field Data Book. If a residue trial is impacted by equipment failure, SD should be notified in a timely manner and it should be noted in the Field Data Books of all affected trials.

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Submitted: 1-7-19
Revision Number: 6.0

TITLE: Calibration, Use and Maintenance of New and Borrowed Equipment.

PURPOSE: To ensure proper calibration and accurate measurements with the use of borrowed equipment or newly acquired equipment for which SOPs have not yet been written and approved.

SCOPE: All IR-4 field research trials.

PROCEDURES:

1. Be familiar with any available manuals pertaining to the use, calibration, and maintenance of borrowed equipment.

2. Calibration:

    a. Calibrate all borrowed equipment before use if appropriate for its intended use.

    b. Follow the calibration instructions in the specific equipment manual, if available.

    c. If no calibration instructions are available, follow the industry standards for calibrating a specific type of equipment.

    d. Record the calibration method followed in the equipment log.

3. Use:

    a. Prior to using any borrowed equipment, visually inspect the equipment to determine that it is working properly and its condition is appropriate for its intended use.

    b. Make any necessary repairs or adjustments prior to using borrowed equipment in the study.

    c. Be sure equipment is clean prior to use.

    d. Be thoroughly familiar with the operation of the equipment.

    e. Only use borrowed equipment when personal safety can be assured.

4. Maintenance:

    a. If possible, check with the owner of the equipment if any major maintenance or repairs are required.

    b. Check borrowed equipment at the time of use for any necessary maintenance (e.g. oil, gas, tire pressure, etc.) or repair.

    c. If assistance is required because of failure or malfunction, consult the manual and/or the manufacturer or service personnel regarding repair or maintenance to borrowed equipment.

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5. Documentation:

   a. Designate the person responsible for each operation in the equipment log.

   b. Record in the equipment log the maintenance and calibration operations. Include dates of maintenance and calibration and describe whether the maintenance operations were routine and followed the written standard operating procedures above.

   c. Record any non routine repairs performed on borrowed equipment as a result of failure and malfunction. Document the nature of the defect, how and when the defect was discovered and any remedial action taken in response to the defect.

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Submitted: 1-5-22
Revision Number: 6.1

TITLE: Chemigation

PURPOSE: To ensure that equipment utilized for the generation, measurement, or assessment of GLP data is properly operated and maintained.

SCOPE: Applies to research trials conducted through the Michigan State University - Dept. Horticulture - IR-4 Field Research Center.

Operation:

1. Prior to calibration, a general inspection will be made of the irrigation system for visual damage or potential problems. The irrigation system will then be operated to verify that the emitters or nozzles provide the desired pattern and that the pressure gauge, if present, is operating properly.

2. Injection of the test substance may be done through overhead irrigation sprinklers, micro- sprinklers, and drip tape or drip line. The test substance may be injected into the watering system using a Mazzei injector or other suitable injection system that is accurate and reproducible. Prior to injecting, operate the system to ensure that there is no off-target leakage in the irrigation system. Regardless of the type of irrigation system used, there should be a backflow valve present to prevent the test substance from flowing into the main water source.

3. The injector system is made up of the Mazzei injector, 2 flow valves, metering valve, and plastic tube with end filter.

4. Typically, the protocol will dictate the amount of irrigation water to be applied with the test substance and the amount of irrigation water to apply to test plots after application of test material.

5. Monitor the pressure gauge during the calibration and application and readjust to the target pressure as needed.

Calibration

1. Prior to use, the irrigation system output will be timed and recorded to obtain the actual output using an inline flowmeter or by catching the output of a minimum of one emitter/sprinkler at the beginning of the drip line or irrigation line and one emitter/sprinkler at the end of the drip line or irrigation line (2 per line) for a minimum of three times, or other method that is accurate and reproducible.

2. After obtaining the system output, calculations can be done to obtain how long to operate the system during and after application to obtain the correct amount of test substance/water and post application irrigation water stated in the protocol. If the amount of water to apply after application is not stated in the protocol, generally apply 0.5 acre inches of water to the test plot for row crops, which includes the

amount of water needed to inject the test substance. For permanent crops, generally apply test substance in approximately 0.5 acre inches of water followed by additional irrigation to move the test product into the root zone.

3. Calibration of the Mazzei injection system will occur prior to each use by a method which is accurate and reproducible. This method will be documented and may include, but not necessarily be limited to, the following:

   A known amount of water will be measured into a graduated cylinder (i.e. 4000 ml). The injection system will be operated and will draw down a known volume from the graduated cylinder (i.e. 1,000 mls). The time required to draw down the known volume will be measured with a stopwatch. This will produce the flow rate of the injector. The calibration will be done a minimum of three times total. After obtaining the average flow rate the amount of water needed to mix with the test substance can be calculated to obtain the desire acre inches of water to apply the test substance in.

Cleaning and Maintenance

1. After completion of injecting the test substance into the irrigation system, water will be run for a minimum of 10 minutes through the irrigation system to ensure that all test substance has been purged from the irrigation lines.

2. No scheduled routine maintenance is required.

3. Maintenance required as a result of equipment malfunction, not normal wear, defines non- routine maintenance. In the event of non-routine repair, a record will be kept which will describe the nature of the defect, how and when the defect was discovered, and remedial action, if any, taken.

Records

1. A record of the dates of equipment inspection, calibration, and cleaning will be kept in an equipment logbook. Calibration results can be accessed by reference of the study number recorded in the Equipment Log at the time of these operations. Historical records will be retained in the archives.

Contingency Procedures

1. If during the generation, measurement or assessment of data, an equipment malfunction occurs, the supervising personnel and Study Director shall be advised of the malfunction. The equipment will be replaced or repaired and, if possible, the study will continue. Documentation of the malfunction shall be described in the study raw data and an appropriate entry made in the equipment log describing the repair.

RESPONSIBLE PERSONNEL

1. Equipment inspection, calibration, cleaning, maintenance (routine and non- routine), and use shall be performed or supervised by the Field Research Director or GLP Coordinator.

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Revision Number: 6.0

SOP 7.1

TITLE: Test substance storage handling, and records.

PURPOSE: To describe the procedures for handling pesticides and documenting all uses.

SCOPE: All IR-4 field research trials.

PROCEDURES:

1. All personnel involved in the handling of pesticides should be properly trained in their use and wear appropriate protective equipment as described on the pesticide label.

2. All test substance receipt, application and disposal must be recorded in the respective IR-4 Field Data Books and receipt, transfer and/or disposal in the facility Pesticide Log Book.

4. Test substances and additives will be stored in a manner to ensure their integrity and temperatures will be monitored.

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Revised: 2-15-24
Revision Number: 6.2

SOP 7.2

TITLE: Test chemical request, receipt, use, and disposal.

PURPOSE: To ensure that chemicals used in residue tests are properly received, logged, stored, and disposed of upon completion of the trial.

SCOPE: All pesticides used in IR-4 field research trials.

PROCEDURES:

1. The FRD will receive a sufficient quantity of pesticide to complete the trial. If the test substance is not received or the quantity does not meet the needs of the trial, the FRD must notify the Study Director. Pesticide samples used in residue trials should be obtained in the year in which the trial is performed.

2. Upon receipt of test chemicals, record the following information from the container label or product documentation in the respective IR-4 Field Data Books; Test Substance Records: date of receipt, name of individual receiving test substance, carrier and tracking number, name of substance, batch or lot number, expiration date and source, amount received, container description and condition upon arrival, GLP status and storage location. Examine the accompanying literature for any pertinent information regarding storage conditions, such as temperature requirements. Upon completion of the trial a copy of each Test Substance Record will be added to the facility IR-4 Pesticide Log Book.

3. Label test substance container with Field ID #, date received, batch or lot number, expiration date, storage requirement conditions and initials. If there is more than one container for a single trial or more than one location using the same test substance, each container should be labeled with a unique number such as 1 of X, 2 of X, etc. An additional label may be attached to container to document this information.

4. If a test substance arrives without an expiration date or evidence of GLP status, contact Study Director immediately.

5. Upon use of a pesticide, record in the respective IR-4 Field Data Book the date used, amount used, purpose, and initials of person using the product.

6. Test chemical containers must be stored until indicated by the Food Request Database - Test Substance Container Disposal Approval list from Headquarters found on the IR-4 website. The disposition and/or disposal of containers will be recorded in the facility IR-4 Pesticide Log Book.

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Revision Number: 6.0

SOP 7.3

TITLE: Test chemical storage.

PURPOSE: To describe acceptable storage facilities and procedures for test chemicals.

SCOPE: Storage facilities for test pesticides used in IR-4 field research trials.

PROCEDURES:

1. The chemical storage facility should have limited access and a sign on the door indicating the hazardous nature of the contents.

2. All test chemicals should be stored in a locked cabinet in the chemical storage facility. Store test substance containers until a disposal date is indicated on the Food Request Database - Test Substance Container Disposal Approval list which is available on the IR-4 website. Keep pesticides from freezing. Maintain chemical storage temperature records in a permanent file.

3. Monitor room temperature with a data logger/recorder (primary devise marked "A", back-up system marked "B"). Recorders will be replaced or serviced before lifetime of batteries is reached. Annual verification of temperatures from recording devices is performed and recorded in the permanent file. Acceptable deviation from standard is less than 5%. Data loggers are set to record temperature readings every 30 minutes.

4. Have a spill kit accessible in the pesticide storage facility.

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Revised: 2-15-24
Revision Number: 6.3

SOP 7.4

TITLE: Calculating and measuring liquid pesticides.

PURPOSE: To ensure an accurate dosage of liquid pesticides in IR-4 field research trials.

SCOPE: All IR-4 field trials using liquid formulations of pesticides.

PROCEDURES:

1. Apply all applications in 20 gpa or as appropriate to meet the needs of the protocol. Mix a minimum of 1 gallon of spray mix for each treatment when possible.

2. Calculate the amount of liquid pesticide needed per volume of spray mix by the following formula:

$$\frac{\text{rate lbs ai/acre}}{\text{lbs ai/gal}} \times \frac{3785.3 \text{ ml/gal}}{\text{gal. spray volume/acre}} = \text{ml pesticide/gal. of spray mix}$$

ml. pesticide/gal. of spray mix x gallons needed = total ml. of pesticide required

3. Obtain a clean graduated cylinder or syringe that is of a volume appropriate to the quantity of pesticide required. Measure to the limit of the measuring device units.

4. For test substance volumes less than 10 ml, measure to the nearest 0.2 ml gradation*. For volumes between 10 and 25 ml, measure at to nearest 0.5 ml gradation*. For volumes between 25 ml and 50 ml, measure at to the nearest 1.0 ml*. For volumes over 50 ml, measure to the nearest 1 ml*. Read the level of the liquid in the cylinder at the bottom of the meniscus. Record the amount actually measured. After dispensing the test substance from the original container, excess material will not be returned to the original container.

5. After the carrier water has been measured into the spray tank, add the liquid pesticide to the spray tank. If using a graduated cylinder, hold back a sufficient quantity of carrier water to adequately rinse the test substance from the cylinder. Rinse the cylinder at least three times or until all pesticide has been visibly removed. Pour the rinsate into the spray tank and add the remainder of the carrier water.

6. Record the amount of pesticide removed from the container and the purpose of use in the Test Substance Records Use Log of the FDB. Record the amount of test substance, carrier and adjuvant in the Application Record of the FDB.

7. Wash all measuring devices with soap and water after each use. Syringes can be disposed of.

*It is acceptable to record to a greater accuracy if the measuring equipment allows for this.

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SOP 7.5

TITLE: Calculating and measuring dry pesticides.

PURPOSE: To ensure an accurate dosage in the application of dry pesticides in IR-4 field research.

SCOPE: All IR-4 field trials using dry formulations of pesticides.

PROCEDURES:

1. Apply all applications in 20 gpa or as appropriate to meet the needs of the protocol. Mix a minimum of 1 gallon of spray mix for each treatment when possible.

2. Calculate the amount of dry pesticide needed per volume of spray mix by the following formula:

$$\frac{\text{rate lbs ai/acre}}{\text{\% ai (as a decimal)}} \times \frac{453.6 \text{ g/lb}}{\text{gal. of spray volume/acre}} = \text{grams of pesticide/gal of spray mix}$$

   grams of pesticide/gal. of spray mix x gallons needed = total grams of pesticide required.

3. Calibrate the balance according to SOP 7.6.

4. Unless the protocol specifies otherwise, place a clean weigh boat/transfer container on the balance and tare it. Remove the dry pesticide from its original container to the transfer container with a clean spatula, spoon, or other appropriate device. Measure the pesticide as accurately as possible to the nearest 0.01 gram. Transfer the pesticide to a marked, sealable portable container. After dispensing test substance from primary container, excess material will not be returned to the original container.

5. Mark the portable container with the name of the chemical, amount, date and FID#.

6. Wash transfer devices and reusable containers with soap and water after each use.

7. Record in the Test Substance Records Use Log of the IR-4 Field Data Book the amount of pesticide removed from the container, the purpose, initial and date and any other data required in the FDB.

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SOP 7.6

TITLE: Calibration of an electronic balance for dry pesticide measurement.

PURPOSE: To ensure an accurate dosage in the application of dry pesticides.

SCOPE: IR-4 trials where a dry material is weighed for use in field research.

PROCEDURES:

1. Prior to use visually inspect electronic balance for cleanliness. Wipe with clean moist cloth as needed.

2. Prior to weighing the pesticide for use in a trial, calibrate the balance by first establishing zero followed by weighing standard weights that bracket the amount of test substance needed. Record in the Field Data Book the date, standard weights used and recorded weights and initials of person performing this task. If the balance does not weigh within one percent of the standard weight, service will be called and another balance used. Tare balance with weighing receptacle in place and weigh test substance. Record amount of test substance removed in Field Data Book.

3. The Field Research Director or designate is responsible for inspection, maintenance and calibration of the electronic balance.

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Revision Number: 6.2

SOP 7.7

TITLE: Application of pesticides in the field.

PURPOSE: To apply pesticides accurately in the field to meet requirements for GLP.

SCOPE: All IR-4 field research trials.

PROCEDURES:

1. Water will be used as a carrier for all applications.

2. Make a minimum of 1 gallon of spray mix for each treatment. Increase the amount mixed as needed in increments of 1 gallon if possible.

3. Measure the gallon of water using a clean graduated cylinder or other measuring device. If using a liquid pesticide, discard an amount of water equal to the volume of the test chemical to be added.

4. The pH of the mix water will be determined with pH test strips and recorded in the Field Data Book.

5. If using a graduated cylinder to measure test substance, pour about half the water into the spray tank. Add the test chemical to the tank. Rinse the graduated cylinder or other measuring device at least three times with water and pour the rinsate into the tank. Then add the rest of the water to the tank. If using a syringe, it is not necessary to rinse.

6. Mix dry chemicals in a clean container that holds at least one half gallon of water. Pour mixture into spray tank and add additional water to obtain desired volume. Rinse container until all test substance is visibly removed and pour rinsate in spray tank.

7. Apply the material beginning with the lowest concentration and continuing with higher concentrations up to the highest concentration.

8. Proceed at the correct speed toward the plot and turn on the sprayer upon entering the plot or slightly before. Maintain the correct speed throughout the plot.

9. Turn off the sprayer at the end of the plot.

10. Record pass times in the Field Data Book.

11. Spray out excess pesticide mix on an approved location, preferably approximately 50 ft from experimental area.

12. Record weather data at time of application, including air temperature, soil temperature, wind direction and velocity, relative humidity, sky conditions, soil surface moisture, and plant surface moisture. Keep a record of all precipitation, irrigation, and air temperatures for the duration of the trial.

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SOP 7.8

TITLE: Procedures for problems during application of test chemicals.

PURPOSE: To explain the procedures to handle problems that may occur during the application of the test chemical that could effect the integrity of the trial.

SCOPE: All IR-4 field research trials.

PROCEDURES:

1. The applicator should observe all aspects of the application to make sure that the test chemical is distributed accurately.

2. If there is a problem, the operator should take immediate action to correct the situation. See SOP 6.6 procedure 2.

3. If a portion of the plot has been compromised, clearly mark off affected area and promptly contact the Study Director. Along with the Study Director, a plan can be formulated to determine the most appropriate way to proceed.

4. The Regional Field Coordinator and the Study Director should be notified by phone or e-mail and in writing of the incident and details should be recorded in the IR-4 Field Data Book.

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Revision Number: 6.1

SOP 7.9

TITLE: Adjuvant (Spray Additive) storage and maintenance

PURPOSE: To describe the procedures for labeling, handling, and storage of adjuvants (spray additives).

SCOPE: All IR-4 field residue trials.

PROCEDURES:

1. Adjuvant containers will be marked with the date of receipt, initials of the person who received the containers, date that container was opened, adjuvant name, concentration, storage conditions, and expiration date. If an expiration date is not provided, an expiration date of 5 years plus the date of receipt will be assigned.

2. A secondary container may be used for storage for ease of use and transport to remote sites. This secondary container must be properly labeled per the original container and will take on all the requirements and properties of an "original container".

3. All adjuvants used for IR-4 research trials will be stored in a locked cabinet within a limited access facility. The cabinet temperature will be monitored with primary ("A") and back-up ("B") loggers.

4. Before use in an application, adjuvants will be inspected for quality. If there appears to be any changes (different color, consistency, smell) or if there is any suspicion of contamination, the adjuvant will be discarded.

5. Adjuvants will be handled in a manner to prevent cross contamination with test substances and other spray additives.
    a. Liquid spray additives will be dispensed into a clean graduated cylinder or syringe for measuring. After dispensing from the original or secondary container excess spray additive will not be returned to the original or secondary container.
    b. Dry spray additives will be dispensed into a clean plastic measuring boat, using a clean plastic spoon if necessary, and weighed on a certified balance.

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SOP 8.1

TITLE: Safe handling of pesticides and use of safety equipment.

PURPOSE: To ensure that pesticides are handled safely and that personnel are protected by adequate safety equipment.

SCOPE: All IR-4 field pesticide trials.

PROCEDURES:

1. All personnel involved in field pesticide experiments will be properly trained in the safe use of spray equipment and pesticides.

2. When applying or mixing pesticides wear protective equipment as described and required on the pesticide label. This equipment may include rubber gloves, boots, coverall, goggles, hat, and respirator.

3. Do not apply pesticides when winds exceed 10 MPH. Apply pesticides with the wind to your back or side whenever possible.

4. Always have clean water available while handling pesticides to wash off pesticides that contact exposed skin or eyes.

5. Upon completion of the application wash all exposed skin with soap and water.

6. Clean safety equipment and let it dry before placing it into storage.

8. Clothing worn during pesticide application should be washed at the end of the day.

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Revision Number: 6.0

SOP 9.1

TITLE: Collection of pesticide data, weather data, and other information.

PURPOSE: To obtain accurate and complete data for pesticide registration.

SCOPE: All IR-4 field trials for pesticide registration.

PROCEDURES:

1. Collect and record all data in accordance with good scientific practices.

2. Follow all guidelines in this SOP and the respective protocols to meet the requirements for GLP.

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Revision Number: 6.1

SOP 9.2

TITLE: Recording, handling and storage of raw data

PURPOSE: To assure that raw data is recorded, handled and stored properly

SCOPE: All IR-4 field research trials.

PROCEDURES:

1. Data is defined as values obtained from measuring, counting or rating.

2. It is the responsibility of the Field Research Director or GLP Coordinator to ensure that all raw data, summaries, and other items connected with the study are properly entered and stored in the Field Data Book.

3. A hard copy of electronic data and charts from monitoring devices may be placed in the file after the information is generated. The first printing of data from monitoring devices is considered the original document from which exact copies may be made. Documents that have been uploaded to the electronic Field Data Book (eFDB) are considered electronic raw data and must not be deleted from the eFDB.

4. All paper raw data will be recorded in an IR-4 Field Data Book in indelible ink. Blue ink is preferred to distinguish original documents from copies. All entries must be dated and initialed.

5. Corrections to paper documents will be made by crossing through the item with one line, initialing and dating it, and writing a short explanation for the change. Error codes in the IR-4 Field Data Book should be used whenever possible to explain the change.

6. Pages containing data should not be removed from the Field Data Book. Copies of blank forms may be added to the book as needed. Verified copies of data from other trials may be added following requirements on the form.

7. Give the location of the original data if true copies are included in the Field Data Book.

8. Make sure that all data required by the study protocol or by the forms provided is collected and recorded. Carefully review the forms provided with the protocol to make sure that all the required data is being collected.

9. The Field Research Director will maintain all raw data for the current season in a secure location.

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SOP 9.3

TITLE: Collecting efficacy and phytotoxicity data.

PURPOSE: To describe the procedure used for taking biological field data.

SCOPE: All IR-4 field research trials.

PROCEDURES:

1. Consult the protocol to determine the method and timing of the phytotoxicity data. If no method is cited proceed as directed in this SOP.

2. For preemergence applications, rate crop phytotoxicity 20 to 40 days after application. Wait until most of the crop plants have emerged.

3. For postemergence applications, record crop stand, size, and vigor data the day of the initial herbicide treatment. Rate plots 7 to 14 days after treatments. If symptoms occur after this period, rate the plots again as needed.

4. Rate all the crop plants in the treatment at one time. Record phytotoxicity on a 1-10 scale: 1 = no injury; 10 = complete kill.

5. Consult the protocol to determine the method and timing of obtaining weed control data. If no method is cited, record the height, number of leaves, and density of the various weed species present the day of the initial treatment. Rate the plots 20 to 40 days after preemergence application and 7 to 14 days after postemergence treatments and again as needed.

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SOP 9.4

TITLE: Determining yield and quality.

PURPOSE: To accurately assess yield and quality, if required by the protocol.

SCOPE: All IR-4 trials in which the protocol requires or encourages yield data.

PROCEDURES:

1. Check the protocol for information on time of harvest. Note the number of days between treatment and harvest (Pre harvest interval - PHI). If none, follow commercial practices in the area for the time of harvest of the commodity.

2. Harvest a sufficient area of the plot to give a good estimation of the effects of the treatments. Harvest by hand or machine using accepted harvest procedures for the commodity. Weigh and record the yield.

3. If quality grading is required by the protocol, grade according to USDA or other accepted grading standards and record weight of each portion. Record the grading standard.

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Revision Number: 6.2

SOP 9.5

TITLE: Collection and recording of data from monitoring devices.

PURPOSE: To describe methods for handling data from temperature and weather collection and recording devices.

SCOPE: All IR-4 field research trials.

PROCEDURES:

1. All automatic data collecting and/or recording devices (except the Automated Weather Station) should be inspected and calibrated as described in SOP 9.6.

2. Printouts, charts, or uploads from these devices must be legible to persons with normal vision. If the downloaded data is printed, the original print-out from a device is the original document. Reproductions of these documents must be marked as copied.

3. Hard copies of computerized data and/or other written, typed, or plotted data sheets must be retained in the file folder of the trial or if applicable to more than one trial, in a common data logbook.

4. Printed charts or data sheets from a monitoring device should be marked in ink with location, dates (month, day, year) of the period measured, and initialed by the individual who removes the chart from the device. Units should be indicated on the charts.

5. Automated weather monitoring equipment is preferred when available. Electronic or hard copies of weather data from automated monitoring equipment should be included in trial reports.

6. If automated equipment is not available, weather data should be recorded manually in an experiment station log book and maintained on file at the station. The data can be transferred from there to the final report.

7. The Field Research Director is responsible for inspection, maintenance, and calibration of this equipment.

8. Since the Field Research Director does not control weather monitoring devices, weather data may not meet requirements for GLP.

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Revision Number: 6.1

SOP 9.6

TITLE: Maintenance of monitoring, data generating devices and GPS unit.

PURPOSE: To assure that monitoring and data generating devices under the control of the Field Research Director are reasonably accurate and in good working order.

SCOPE: All IR-4 field research trials.

PROCEDURES:

1. All temperature monitoring devices (not including the Automated Weather Station) under the Field Research Director's control used to gather data in field or storage should be periodically tested to determine that they are accurate. Temperature monitoring devices should be tested annually by comparison to a high quality thermometer.

2. Batteries will be changed annually, or more frequently if necessary, in monitoring and data generating devices.

3. A hand held GPS unit may be used to determine the coordinates of the plot corners (or plot centers for perennials) and the distance to permanent landmarks. At the beginning of the field season the GPS unit readings will be verified for accuracy and precision against a permanent known reference point. The reference point, Beaumont AZ MK NF1309, was established in 1997 by the National Geodesic Service and is located on the east side of Farm Lane at the MSU Pavillion. Three readings will be taken and reported to establish accuracy. Readings within 2 meter of the NGS Benchmark will be considered accurate. The results of the annual verification of the benchmark site, the date of the annual battery change and any maintenance of the unit will be noted on the annual GPS Log Form.

4. Monitoring devices that give inconsistent results or are not accurate to within ten percent should be repaired or replaced.

5. A record, the Equipment Maintenance and Calibration Form, will record the dates and results of the annual testing.

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SOP 9.7

TITLE: Data archiving and retention

PURPOSE: To assure that data collected from a field trial is archived at IR-4 Headquarters and updated data is maintained at Michigan State University Plant and Soil Science Building Rm A440.

SCOPE: All IR-4 field research trials.

PROCEDURES:

1. The official archive for original raw data will be located at IR-4 headquarters.

2. The Field Research Director or GLP Coordinator will make an exact copy of the original raw data including completed Field Data Books, logs, weather data, personnel forms, etc. These copies will be retained in a secure location at Michigan State University Plant and Soil Science Building in room A440 or A448.

3. All information in the Field Research Director's file should be clearly identified.

4. All original raw data not included in a Field Data Book (e.g. logs, weather data, personnel forms, etc.) will be sent directly to IR-4 Headquarters with a chain of custody from including name of courier, tracking number and inventory of items sent.

5. All completed Field Data Books will be submitted to the Regional Field Coordinator to review for completeness and accuracy. The Regional Field Coordinator or designee will follow up to obtain any missing data or correct deficiencies.

6. The Field Research Director or GLP Coordinator will add any additional or changed pages to the Field Data Book copy on file and these updated pages will be used for all subsequent quality control or quality assurance reviews or audits.

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SOP 9.8

TITLE: Equipment not requiring SOPs.

PURPOSE: To identify what type of equipment will not require an SOP.

SCOPE: Equipment used in IR-4 Research Trials.

PROCEDURES:

1. The equipment used in trials that require a SOP are:

    a. Application Equipment (i.e. boom sprayers and granular applicators): SOPs 6.2, 6.3, and 6.4.

    b. Electronic Balance: SOP 7.6.

    c. Automated Data Collection/Recording Devices (except the weather station): SOP 9.6.

    d. GPS unit: SOP 9.6.

2. All other equipment used to conduct an IR-4 field trial will not require a SOP.

3. As new equipment is acquired, the Field Research Director will determine whether it requires a SOP.

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SOP 9.9

TITLE: Significant figures and rounding numbers

PURPOSE: To describe a procedure for determining significant figures and rounding numbers

SCOPE: All IR-4 field research trials.

PROCEDURES:

1. Retain sufficient decimal places to accurately express the measurements and measuring equipment. Consider the calibration of the equipment used to measure. All measurement numbers will be maintained at the level of accuracy produced by the measurement equipment.

2. All numbers derived from instruments and the digits generated from subsequent calculations using these numbers will be carried through the calculations and rounded after a final value is determined.

3. If the last digit is <5 the number will be rounded down. If the last digit is 5 or greater, it will be rounded up.

4. Report the final value or mean value with the same number of significant figures as the data was taken.

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SOP 10.1

TITLE: Residue sample collection, storage, and shipping.

PURPOSE: To describe procedures for harvesting, handling, storing, and shipping residue samples.

SCOPE: All IR-4 field trials from which residue samples are required.

PROCEDURES:

1. All residue samples will be handled according to the SOP and the study protocol.

2. Residue samples will be handled and stored in such a way as to ensure their integrity upon arrival at the analysis laboratory.

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SOP 10.2

TITLE: Collecting residue samples.

PURPOSE: To assure that representative residue samples are collected and that their integrity is maintained.

SCOPE: All IR-4 field trials from which residue samples are required.

PROCEDURES:

1. At the beginning of each growing season, the Field Research Director will prepare a Master Timetable for all projects. The Master Timetable will include projected planting, treatment, and sample collection dates. Depending on the protocol, samples may be required at a specific number of days after treatment, at the earliest commercial harvest, or at some other predetermined time. Sample collection dates may be adjusted as the season progresses, and the projected dates modified on the Master Timetable. The Quality Assurance Officer (QAO) will be kept informed of changes in projected sampling dates.

2. Avoid collecting samples during rain, unless it is necessary to do so to meet a time requirement in the protocol (e.g., specified days after treatment).

3. Collect samples from untreated plots first, then proceed to the lowest and sequentially higher dosages. Collect all samples from each subplot of a treatment before proceeding to the next treatment.

4. Consult the protocol to determine sample size and sampling method. If no instructions are given, collect 2 to 4 lb of good quality product from each subplot.

5. If 2 lb of product is not available collect as much as possible, and describe in the IR-4 Field Data Book any reasons for the small sample size.

6. Do not wash or clean sample product unless directed to do so by the protocol.

7. Avoid cross-contamination of samples during harvesting and handling by wearing clean gloves and changing the gloves between samples.

8. The pre-harvest interval (PHI), prompted in Part 7A of the Field Data Book, is calculated by counting the day after the last application up to and including the day of harvest.

9. After harvest, treated rows of annual crops will be mowed, disked, or otherwise destroyed. Date of this action will be noted in the Field Data Book.

10. Treated rows or trees of perennial crops will be marked with a sign which will indicate that fruit should not be picked and/or eaten and plot should not be entered.

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Revision Number: 6.1

SOP 10.3

TITLE: Sample containers and identification.

PURPOSE: To specify how samples are to be identified.

SCOPE: All IR-4 field trials requiring residue samples.

PROCEDURES:

1. Prior to sample collection, obtain from the IR-4 Regional Field Coordinator a sufficient number of IR-4 plastic lined cloth bags for the trial.

2. Before sampling, label each IR-4 plastic lined cloth bag with waterproof ink with the following information:

a. Field trial identification number
b. Commodity (crop)
c. Chemical (common name) and application rate (lb ai/a)
d. Treatment number
e. Sample number
f. Sampling date
g. Investigator: Name/Address/Phone

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Revised 6-15-23
Revision Number: 6.4

TITLE: Sample packing and storage.

PURPOSE: To assure the integrity of the samples after collection in the field.

SCOPE: All IR-4 field research trials where residue samples are collected.

PROCEDURES:

1. Collect samples directly into labelled, cloth IR-4 residue sample bags.

2. If necessary (to reduce leaking, etc.), place the sample as it is collected into a plastic sample bag marked for that sample. Place the Sample Identification Card into the bag. If the protocol does not specify approval of plastic bags, get SD approval.

   Expel excess air and close the plastic sample bag with a twist tie. Place plastic sample bag into marked IR-4 cloth sample bag. Tie the bag securely closed.

3. Place filled sample bags into cooler(s) or other appropriate containers containing blue ice and transport to freezer (A450 PSSB or CIPS) or lab (A447 or A498-F PSSB) if additional sample preparation is required. Place sample bags from same treatment group into large plastic bags and put into shipping carton(s) before placing samples in freezer. Treated and untreated samples may be shipped in the same carton unless specified differently in the protocol. Samples will remain in the freezer until shipped.

4. A freezer log of IR-4 samples will be maintained indicating for each harvest the following:

   a. Study I.D. number
   b. Time and date samples were placed in freezer
   c. Time and date of removal from freezer

   Each entry should be dated and initialed by the individual making the entry.

5. Store the residue samples in a freezer. Maintain a record of storage temperature and submit the record with the IR-4 Field Data Book upon completion of the trial.

6. a. In order to maintain integrity of IR-4 GLP residue samples for the entire storage duration, an alarm system has been installed to monitor freezer functions. In the event of temperature spikes above freezing, an alarm will sound and emails or text messages will be sent to GLP coordinator, application specialist and/or Field Research Director.

   b. In the event of an alarm, at least one of the notified personnel will promptly address the issue and take measures to restore freezer functionality.

   c. If the freezer cannot be repaired in a timely manner, IR-4 samples must be moved to a back-up freezer location (i.e. B36 PSSB or A450 PSSB).

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d. At the beginning of each field season, the freezer alarm system will be tested. If there are any issues or concerns during the alarm test or at any other time during the storage of IR-4 samples in the freezer, needed repairs and further system testing will be completed as soon as possible. The date of alarm test along with any other maintenance or repairs to freezer or monitoring system must be documented in the appropriate equipment maintenance log.

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SOP 10.5

TITLE: Sample shipping procedures.

PURPOSE: To assure that residue samples are shipped to the residue laboratory with no loss of integrity.

SCOPE: All residue samples from IR-4 field trials.

PROCEDURES:

1. Place the original completed IR-4 Residue Sample Chain of Custody Form (8B) and a copy of the Sample Arrival Check Sheet (8C) into a sealed plastic bag and into each shipping container. If there is more than one shipping container, the original will go in one and copies in the remaining containers.

2. Pack the boxes securely so that they can withstand stacking in the truck. Tape the lids shut. No dry ice is needed for shipping by freezer truck. If shipped by airfreight add dry ice in a 3:1 ratio to sample weight (3# dry ice to 1# of sample) or 40# dry ice regardless of sample weight.

3. Label each shipping carton with the following information:

    a. Name and address of the sender
    b. Name, address, of the residue lab receiving the samples.
    c. Number of the container if more than one is used (e.g., 1 of 2, 2 of 2).
    d. Where used, affix "Dry Ice" on two sides of the container.
    e. Field ID number.
    f. Commodity and pesticide.

4. Ship samples by freezer truck if possible. After harvest, contact freezer truck company regarding the next sample pick-up date. They will schedule a pick-up date and contact the Field Research Director. The Field Research Director will notify the receiving laboratory as soon as possible after the pick-up date and time are confirmed. When the truck arrives, deliver the samples directly to the truck.

5. If it is not possible to ship by freezer truck, ship by airfreight with next day delivery. Ship airfreight on Monday or Tuesday to avoid weekend arrivals.

6. After samples have been shipped, send a copy of the Residue Sample Chain of Custody Form (8B) to the Regional Field Coordinator and Study Director.

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SOP 10.6

TITLE: Maintaining Freezer Storage Systems.

PURPOSE: To maintain the integrity of all frozen samples held as part of IR-4 GLP residue studies.

SCOPE: All IR-4 field research trials where residue samples are collected.

PROCEDURES:

1. In order to maintain integrity of IR-4 GLP residue samples for the entire storage duration, a Temp Stick WiFi Temperature and Humidity Sensor was set up and installed to monitor freezer functions in chest freezer located in PSSB 498-F. If the freezer temperature spikes above freezing, an alarm will sound and emails or text messages will be sent to GLP coordinator, application specialist and/or Field Research Director.

2. In the event of an alarm, at least one of the notified personnel will promptly address the issue and take measures to restore freezer functionality.

3. If the freezer cannot be repaired in a timely manner, IR-4 samples must be moved to a back-up freezer location (i.e. PSSB A450, B36 PSSB).

4. At the beginning of each field season, the freezer alarm system will be tested in the Temp Stick app by going to Alerts > Create New Alert > Send Test Alert. If there are any issues or concerns during the alarm test or at any other time during the storage of IR-4 samples in the freezer, needed repairs and further system testing will be completed as soon as possible. The date of alarm test along with any other maintenance or repairs to freezer or monitoring system must be documented in the appropriate equipment maintenance log.

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SOP 11.1

TITLE: Trial reports.

PURPOSE: To describe the format for reporting trial activities and results.

SCOPE: All IR-4 field trials.

PROCEDURES:

1. Upon completion of a trial, the FRD will notify the RFC and Study Director of completion by email. The FRD will retain any hard copies or original data pertaining to the trial. After the RFC office conducts a Quality Control Review, the FRD will make any necessary changes and send original paper data to HQ.

2. Additional forms, data, or information that may be needed to comply with standard operating procedures and GLP include:

    a. Organizational chart
    b. Current vita and position descriptions
    c. Pesticide log book
    d. Chemical storage recorder
    e. Freezer storage recorder printout
    f. Equipment maintenance and calibration form
    g. Balance weights verification
    h. Master timetable
    i. Freezer inventory log
    j. Study deviation forms
    k. Protocol change forms
    l. Correspondence concerning the trial or project
    m. Pesticide application equipment maintenance and calibration form
    n. Global positioning system (GPS) report
    o. Soil analysis report
    p. Weather records
    q. Maps
    r. Shipping bill of lading

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SOP 11.2

TITLE: Completion of the IR-4 Field Data Book.

PURPOSE: To explain the use of report forms contained in the IR-4 Field Data Book.

SCOPE: All IR-4 field trials.

PROCEDURES:

1. All paper forms should be filled out legibly in indelible ink or typewritten. Mistakes should be crossed out with one line, initialed, and dated. Include the reason for the change. Use error codes where appropriate.

2. The date format for entries in the Field Data Book will follow month/day/year.

3. Use forms provided in the IR-4 Field Data Book. Blank forms may be photocopied or printed from website or eFDB attachments as needed.

4. The appropriate forms should be filled out as completely as possible within a reasonable period of time after the information is available. Data should be recorded directly into the IR-4 Field Data Book or transcribed into the eFDB promptly.

5. If a paper form or section of a form does not require a response, draw a diagonal line from the top of the page or section to the bottom. Initial and date on the diagonal line or sign and date at the bottom of the page. If the requested data are not applicable, give an explanation. For electronic Field Data Book, marking a page as completed indicates that any spaces left blank were done so intentionally and this is the equivalent to lining out.

6. Number each paper form (e.g., Part x Page x) within each section of the IR-4 Field Data Book. Include the total number of pages in each section on the first page of each section.

7. If raw data applies to more than one trial (e.g., weather data, field history, or personnel information), the original will be kept in the common data logbook by the Field Research Director until the end of the field season. Copies placed in the Field Data Books will be marked as a "True Copy of the Original", signed and dated, and the location of the original noted. At the end of the field season the original documents will be transferred to Headquarters to the archives.

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SOP 11.3

TITLE: Disposition of IR-4 Field Data Books and other documentation.

PURPOSE: To assure that completed IR-4 Field Data Books reach the Study Director as soon as possible.

SCOPE: All IR-4 field trials.

PROCEDURES:

1. Upon completion of the Field Data Book, the FRD will notify the RFC and Study Director by email. The FRD will retain any paper raw data pertaining to the trial. After the RFC office conducts the QC review, the FRD will make any necessary changes to the electronic documents and paper documents. The original paper data will be sent to HQ.

2. The IR-4 Regional Field Coordinator will review the IR-4 Field Data Books for completeness and accuracy. Incomplete IR-4 Field Data Books will be corrected by the Field Research Director with comments on deficiencies and suggestions for completion.

3. The Field Research Director will upload an QC related documents and ensure completeness of report. The FRD will scan any paper documents prior to shipping to HQ.

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SOP 12.1

TITLE: Record storage.

PURPOSE: To assure the integrity of information and data under the control of the Field Research Director.

SCOPE: All IR-4 field trials.

PROCEDURES:

1. A limited access facility (e.g., a locked room or cabinet) of sufficient size to contain all records should be available at or in close proximity to the location of the Field Research Director responsible for the conduct of the trials. An index of records and materials contained in the archives should be available.

2. The facility should be in a building with adequate fire protection.

3. The archives for all completed IR-4 trials will be maintained at IR-4 headquarters. Raw data and Field Data Books will be sent to IR-4 headquarters through the IR-4 Regional Field Coordinator upon completion of the trials.

4. At the end of the field season the Field Research Director will transfer all original GLP data and other GLP records from the test site to IR-4 HQ for archival. Data and records will include: equipment maintenance/calibration forms, freezer content log, freezer logger temperature data, GPS calibration log, personnel forms, pesticide storage temperature monitoring data, weather , other original data forms that were used for more than one trial and original SOPs. An IR-4 Raw Data/Documents Transfer Form will show the inventory of all items being transferred and document the chain of custody information. The Field Research Director will hold a copy of all materials.

5. The Field Research Director will maintain the following in their record storage area:

   a) Photocopies or scanned copies of completed IR-4 Field Data Books including the protocols, audits and other relevant information.
   b) Photocopies or scanned copies of all original records transferred to Headquarters' archives.
   c) Organizational charts, training records, job descriptions and CVs for current and former employees.
   d) Any correspondence pertaining to IR-4 trials.
   e) Service reports for equipment.
   f) Soil test reports.
   g) GPS plot location data.
   h) Other relevant information.

6. The Field Research Director is the designated archivist for the facility and the GLP coordinator is the back-up archivist.

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SOP 12.2

TITLE: Retention times for documents in archives.

PURPOSE: To assure that data and documents are retained as long as required.

SCOPE: All IR-4 field trials.

PROCEDURES:

1. All original data will be sent to headquarters for archiving.

2. Copies of the original data and all Field Data Books will be maintained at MSU PSSB A440. However, these copies will not be provided for EPA field site inspection. Original raw data provided from HQ archives should be the only FDBs presented for an EPA auditor to review.

3. FDBs can be retained indefinitely. However, disposal of copies is permitted after the Study Director has signed the final report for the study. Determining when FDB disposal is acceptable can be done in the same way as IR-4 Advisories #2003-02 and #2005-01 provide resolution for disposal of test substance containers. When test substance container disposal is acceptable for a study, disposal of FDB copies is also acceptable for all trials in that study.

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SOP 13.1

TITLE: Quality Assurance.

PURPOSE: To meet IR-4 requirements for Quality Assurance.

SCOPE: All IR-4 field trials.

PROCEDURES:

1. A Quality Assurance Unit (QAU) will monitor research trials to assure that good scientific methods are being employed and that the Field Research Director is complying with his SOP and with study protocols. Quality Assurance Unit sop's are maintained by IR-4 Headquarters and all QAU activities are coordinated by the IR-4 QAU.

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SOP 14.1

TITLE: Procedures to follow prior to an EPA inspection.

PURPOSE: To provide guidance to MSU personnel in responding to a request for an EPA audit, inspection or review.

SCOPE: All IR-4 research trials in the Department of Horticulture at Michigan State University.

PROCEDURES:

1. Notify the Study Director and Regional Field Coordinator of the pending audit or review as soon as possible.

2. Have available as much as possible all personnel directly involved in IR-4 trials in Horticulture, MSU.

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

4. Prepare trial and/or facility 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. Instruct personnel to respond specifically to the questions asked and not to provide extraneous information. Do not provide any information unless asked.

   d. Be certain that all documents relevant to the trial and facilities are available, including:

      1) Master schedule for the field research director.

      2) Study Protocol and current and historical Standard Operating Procedures.

      3) Raw data, correspondence and logs.

      4) Training records and CVs of personnel involved in the audited trial.

      5) Documentation of test substance characterization, receipt and handling.

      6) Maintenance/Calibration logs on equipment.

5. Have available the organizational charts and a map of the facility.

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Revised: 1-5-18
Revision Number: 6.0

SOP 14.2

TITLE: Procedures to follow during an EPA inspection.

PURPOSE: To provide guidance to trial personnel in responding to a request for an EPA audit/inspection or review.

SCOPE: All IR-4 research trials in the Department of Horticulture at Michigan State University.

PROCEDURES:

1. Greet the inspection team and follow any institutional procedures for signing in. Escort the entire group to the 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 who will accept the Notice of Inspection.

4 Ask the lead inspector for his/her agenda for the inspection.

5. Proceed with the inspection.

   a. Provide documents requested and provide explanations as needed.

   b. Keep notes of observations and of all interviews.

   c. Keep IR-4 management informed of the progress of the inspection and the findings.

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SOP 14.3

TITLE: Procedures to follow after the EPA inspection.

PURPOSE: To provide guidance to trial personnel in responding to a request for an EPA audit/inspection or review.

SCOPE: All IR-4 research trials in the Department of Horticulture at Michigan State University.

PROCEDURES:

1. The Field Research Director or designated representative must be present for the close-out conference.

2. If the inspector's comments are in error, call this to the inspector's attention.

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

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

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

6. Inform site personnel, Regional Field Coordinator, and the Study Director(s) of any problems found.

7. Respond to deficiencies as required.

8. Keep Study Director(s) informed of any activity related to the inspection.