SOP Log Sheet

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State: OH City: Wooster

Location: NCR Field OSU

FRD/LRD: Allison Robinson
Submitter

Effective Date: 6/8/21

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Reviewed By: Juliet Thompson 7/13/21
Sign/Date

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S: Facility Files- SOP Cover Sheet

9/13/16 JT

MICHIGAN STATE
UNIVERSITY

TO: Allison Robinson
Department of Horticulture and Crop Science, OARDC Weed Lab
The Ohio State University
Wooster, OH

FROM: Dr. Anthony VanWoerkom, IR-4 Regional Field Coordinator

SUBJECT: STANDARD OPERATING PROCEDURE (1.2) APPROVAL

DATE: June 8, 2021 (Effective Date)

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	1.1	2-19-18	6.2	1.1	2-16-18	9.7	1.2	2-12-20
1.2	1.1	2-16-18	6.3	1.1	2-16-18	9.8	1.1	2-16-18
1.3	1.1	2-16-18	6.4	1.1	2-16-18	9.9	1.1	2-16-18
1.4	1.1	2-16-18	6.5	1.1	2-16-18	10.1	1.1	2-16-18
1.5	1.1	2-16-18	6.6	1.1	2-16-18	10.2	1.1	2-16-18
2.1	1.1	2-16-18	7.1	1.1	2-16-18	10.3	1.1	2-16-18
2.2	1.1	2-16-18	7.2	1.1	2-16-18	10.4	1.1	2-16-18
2.3	1.2	2-12-20	7.3	1.1	2-16-18	10.5	1.3	5-18-20
2.4	1.1	2-16-18	7.4	1.1	2-16-18	10.6	1.1	2-16-18
2.5	1.1	2-16-18	7.5	1.2	2-20-19	11.1	1.1	2-16-18
2.6	1.1	2-16-18	7.6	1.2	2-20-19	11.2	1.1	2-16-18
3.1	1.1	2-16-18	7.7	1.2	2-12-20	11.3	1.1	2-16-18
3.2	1.1	2-16-18	7.8	1.3	2-12-20	12.1	1.1	2-16-18
3.3	1.1	2-16-18	7.9	1.2	2-12-20	12.2	1.1	2-16-18
4.1	1.1	2-16-18	8.1	1.1	2-16-18	13.1	1.1	2-16-18
4.2	1.2	2-12-20	9.1	1.1	2-16-18	14.1	1.1	2-16-18
5.1	1.1	2-16-18	9.2	1.1	2-16-18	14.2	1.1	2-16-18
5.2	1.1	2-16-18	9.3	1.1	2-16-18	14.3	1.1	2-16-18
5.3	1.1	2-16-18	9.4	1.1	2-16-18			
5.4	1.1	2-16-18	9.5	1.1	2-16-18			
6.1	1.1	2-16-18	9.6	1.1	2-16-18			

IR-4 NORTH CENTRAL REGION RESEARCH CENTER
Michigan State University
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STANDARD OPERATING PROCEDURES

IR-4 Pesticide Residue Trials

Fruit and Vegetable Crops

Revision: 1.3

OARDC Weed Lab

Department of Horticulture and Crop Science

The Ohio State University

Ohio Agricultural Research and Development Center

Wooster, Ohio, 44691

Allison Robinson Field Research Director	Allison Robinson (Signature)	AR (Initials)	5/10/2021 (Date)
Anthony VanWoerkom Regional Field Coordinator	(Signature)	AVW (Initials)	6/8/2021 (Date)

Approved by Field Research Director: Allison Robinson Date: 5/10/2021

Approved by Regional Field Coordinator: [signature] Date: 5/18/2021

No.	TITLE	Revision # & Date
1.1	General requirements for Standard Operating Procedures	1.1 (02/19/18)
1.2	Annual review and revision	1.1 (02/16/18)
1.3	Definitions for the SOP	1.1 (02/16/18)
1.4	Numbering system for SOPs	1.1 (02/16/18)
1.5	Format for SOPs	1.1 (02/16/18)
2.1	Personnel	1.1 (02/16/18)
2.2	Study Director	1.1 (02/16/18)
2.3	Field Research Director	1.2 (02/12/20)
2.4	Other Personnel	1.1 (02/16/18)
2.5	Organizational Chart	1.1 (02/16/18)
2.6	Documentation of training	1.1 (02/16/18)
3.1	Study protocol and experimental design	1.1 (02/16/18)
3.2	Deviations from protocol	1.1 (02/16/18)
3.3	Experimental design	1.1 (02/16/18)
4.1	Site selection, plot establishment and use of GPS unit	1.1 (02/16/18)
4.2	Soil sampling and characterization	1.2 (02/12/20)
5.1	Agronomic practices for field experiments	1.1 (02/16/18)
5.2	Greenhouse, shadehouse and testing facilities	1.1 (02/16/18)
5.3	Seeding and transplanting	1.1 (02/16/18)
5.4	Crop maintenance	1.1 (02/16/18)
6.1	Application equipment calibration, maintenance, and use	1.1 (02/16/18)
6.2	Calibration of hand-carried CO_2-pressurized boom sprayer	1.1 (02/16/18)
6.3	Calibration and use of tractor-mounted CO_2-pressurized boom sprayer	1.1 (02/16/18)
6.4	Calibration and use of a granular applicator	1.1 (02/16/18)
6.5	Cleanup of application equipment	1.1 (02/16/18)
6.6	Remedial action in case of equipment failure	1.1 (02/16/18)
7.1	Test substance storage, handling, and records	1.1 (02/16/18)
7.2	Test substance request, receipt, use, and disposal	1.1 (02/16/18)
7.3	Test substance storage	1.1 (02/16/18)
7.4	Adjuvant storage and maintenance	1.1 (02/16/18)
7.5	Calculating and measuring liquid pesticides	1.2 (02/20/19)
7.6	Calculating and measuring dry pesticides	1.2 (02/20/19)
7.7	Calibration of an electronic balance for dry pesticide measurement	1.2 (02/12/20)
7.8	Application of pesticides in the field	1.3 (02/12/20)
7.9	Procedures for problems during application of test chemicals	1.2 (02/12/20)
8.1	Safe handling of pesticides and use of safety equipment	1.1 (02/16/18)
9.1	Collection of pesticide data, weather data, and other information	1.1 (02/16/18)
9.2	Recording, handling and storage of raw data	1.1 (02/16/18)
9.3	Significant Figures and Rounding Numbers	1.1 (02/16/18)
9.4	Collecting efficacy and phytotoxicity data	1.1 (02/16/18)
9.5	Determining yield and quality	1.1 (02/16/18)
9.6	Collection and recording of data from monitoring devices	1.1 (02/16/18)
9.7	Maintenance of monitoring, data generating devices and GPS unit	1.2 (02/12/20)
9.8	Data archiving and retention	1.1 (02/16/18)
9.9	Equipment not requiring SOPs	1.1 (02/16/18)
10.1	Residue sample collection, storage, and shipping	1.1 (02/16/18)
10.2	Collecting residue samples	1.1 (02/16/18)
10.3	Sample containers and identification	1.1 (02/16/18)
10.4	Sample packing and storage	1.1 (02/16/18)
10.5	Maintaining freezer storage systems	1.3 (05/18/20)
10.6	Sample shipping procedures	1.1 (02/16/18)

No.	TITLE	Revision # & Date
11.1	Trial reports	1.1 (02/16/18)
11.2	Completion of IR-4 Field Data Book	1.1 (02/16/18)
11.3	Disposition of IR-4 Field Data Books and other documentation	1.1 (02/16/18)
12.1	Archive and record storage	1.1 (02/16/18)
12.2	Retention times for documents in archives	1.1 (02/16/18)
13.1	Quality Assurance	1.1 (02/16/18)
14.1	Procedures to follow prior to EPA inspection	1.1 (02/16/18)
14.2	Procedures to follow during an EPA inspection	1.1 (02/16/18)
14.3	Procedures to follow after the EPA inspection	1.1 (02/16/18)

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Wooster, OH 44691

Effective Date: See Approved RFC Date
Revision Number: 1.1
Revised: 02/19/18
Submitted by Douglas Doohan

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 and Crop Science at OSU / OARDC.

PROCEDURES:

1. The IR-4 Field Research Director (FRD) will develop standard operating procedures (SOPs) for all phases of the research conducted in support of pesticide registration. Adherence to the SOPs will assure compliance with EPA requirements and 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 and Crop Science at the Ohio State University/OARDC.

3. The SOP will be reviewed annually and revised as needed. The revisions and their effective dates will be recorded on the SOP approval log, which will be maintained as part of the SOP. The Field Research Director will retain all earlier versions of the SOP.

4. The cover page and index page will be approved and dated by the Field Research Director and Regional Field Coordinator (RFC).

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

6. 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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Submitted by Douglas Doohan

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 food/feed crops will be reviewed annually by the Field Research Director and revised as needed. The date of the revision and the number(s) of the SOP will be recorded on the SOP Approval Log.

2. Major revisions on the SOP will be designated by whole numbers.

3. Revisions of individual SOPs will be designated by decimal numbers.

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

SOP 1.3

TITLE:	Definitions for the SOP
PURPOSE:	To define the terms used in this SOP
SCOPE:	All SOPs developed by FRD

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 is collected from a study.
   d.) Good Laboratory Practices – (GLP) a set of guidelines mandated by Congress to which researchers must adhere to ensure the integrity of the research data.
   e.) Master Timetable – a list of trials, which is maintained by the Field Research Director. It must be indexed by test chemicals 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 test 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 results of original observations and activities of a study. Includes photographs and computer printouts.
   j.) Research – the collection of information about a particular subject.
   k.) Sponsor – the individual, corporation, association, academic or scientific establishment, government agency or other organizational unit who initiates and supports, by provision of financial or other resources, a study.
   l.) Standard Operating Procedure – (SOP) written documentation of routine activities and procedures 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 effects, metabolism, environmental and chemical fate, or other characteristics.
   n.) Frequently Used Acronyms –
      The Ohio State University (OSU)
      Ohio Agriculture Research and Development Center (OARDC)
      Department of Horticulture and Crop Science (HCS)

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Submitted by Douglas Doohan

SOP 1.4

TITLE:	Numbering Systems for SOPs
PURPOSE:	To provide a general outline for SOPs via numbering system
SCOPE:	SOPs developed by Field Research Director

PROCEDURES:

1. SOPs will be organized using these major headings:

    1. General requirements for Standard Operating Procedures
    2. Personnel
    3. Study Protocol and Experimental Design
    4. Site selection, plot establishment and use of GPS unit
    5. Agronomic practices for field experiments
    6. Application equipment calibration, maintenance, and use
    7. Test substance storage, handling, and records
    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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SOP 1.5	
TITLE:	Format for SOPs
PURPOSE:	To assure a uniform format in development of SOPs
SCOPE:	All SOPs developed by Field Research Director for use in the conduct of field research trials.

PROCEDURES:

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

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Wooster, Ohio 44691

Effective Date:
Revision Number:
Revised:
Submitted by

SOP# (Category number followed by SOP number in numerical order)	
TITLE:	(SOP title)
PURPOSE:	(Brief description of the purpose of the SOP)
SCOPE:	(Determines where and when the SOP is applicable)
PROCEDURES: (Describes the operating procedures done from beginning to end so that regulatory personnel can understand what is being done.)	

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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 tasks.

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

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Submitted by Douglas Doohan

SOP 2.2

TITLE:	Study Director
PURPOSE:	To describe the responsibilities of the Study Director
SCOPE:	All IR-4 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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Submitted by Douglas Doohan

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 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 under his control.
   e. Submit a copy of the Master Timetable to the QAO in a timely manner upon receiving all trial assignments.
   f. Approve all completed report forms and assure to transfer all raw data to the RFC upon completion.

3. With review and approval from the FRD, GLP coordinator will:
   a. Report deviations from protocol or SOPs to Study Director.
   b. Be responsible for conducting IR-4 field trials
   c. Respond to all deviations reported by the Quality Assurance Unit
   d. Develop responses to QA Audits and field live inspections

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SOP 2.4

TITLE:	Other Personnel
PURPOSE:	To provide information concerning requirements under GLP for other personnel involved in the 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. Temporary field workers involved in critical phases of a trial but NOT entering data in the Field Data Book (FDB) do not require a CV or training record. However, a separate page should be included on 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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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 management of the facility and the reporting lines of the personnel engaged in IR-4 will be developed and kept on file by the Field Research Director.

2. Each entry in the chart should show the name 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, the relationship between the QAU and the other parts of the organization.

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SOP 2.6

TITLE:	Documentation of Training
PURPOSE:	To assure that training for personnel for IR-4 trials is properly documented.
SCOPE:	All personnel actively involved in IR-4

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 personnel files.

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

SOP 3.1

TITLE:	Study Protocols 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 sponsor will provide the Study Director with a protocol to follow in doing a trial. The Study Director will provide a copy of the protocol to the Field Research Director.

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

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

4. The Study Director will sign the coversheet, indicating that he agrees with the protocol, and then send it to the Field Research Director.

5. The Field Research Director or GLP coordinator 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 or GLP coordinator will submit the Master Timetable to the Study Director, 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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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 protocol 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. The protocol change form will be attached to the protocol

2. For changes in protocol initiated by the Field Research Director, the Field Research Director or GLP Coordinator will prepare a study deviation form and submit it to the Study Director and notify the Study Director by emails 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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SOP 3.3

TITLE:	Experimental Design
PURPOSE:	To assure that all efficacy, yield, and phytotoxicity data 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. The experimental design used should be documented in the Field Data Book.

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

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

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SOP 4.1

TITLE:	Site Selections, Plot Establishment and Use of Global Positioning System (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 size required by the protocol.

3. Where possible, establish site so that treated plants are downwind of untreated plants or down slope from untreated pots

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

5. Follow SOP 4.2 to get soil test data

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

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

8. If the commodity is already established, select the 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 permanent reference points determined by hand held GPS.

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 easily seen throughout the duration of the trial.

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Effective Date: See Approved RFC Date
Revision Number: 1.2
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Submitted by Douglas Doohan

SOP 4.2

TITLE:	Soil Sampling and Characterization
PURPOSE:	To describe procedures for taking soil samples for field trial sites
SCOPE:	All IR-4 fields trials

PROCEDURES:

1. If the site has had a soil test within the last 5 years, use the results of that test for soil characterization information.

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 10-20 random soil samples at a 6-8 inches depth in the field and place samples in clean bucket or plastic bag.
   b. Once all samples are taken, mix the soil thoroughly in bucket or plastic bag. Fill a soil container with soil from the bucket or plastic bag. Label the container with date, test site and identification number and send it to a certified laboratory for analysis.

3. To determine soil type and series for the site, look up the field location in the appropriate county soil survey report.

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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 agricultural practices for the commodity to be grown.
2. Perform and record all cultural practices 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.

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 and 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 agricultural 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.

3. Apply labeled pesticides as needed to prevent losses due to pests/disease. Do not apply pesticides that may interfere with the chemical analysis of the pesticide under study. If in doubt call the Study Director.

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

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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 agricultural 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 agricultural practices.

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Department of Horticulture & Crop Science
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SOP 5.4	
TITLE:	Crop Maintenance
PURPOSE:	To assure that commodities are grown under good agricultural practices to provide a uniform crop for observation and harvest.
SCOPE:	All IR-4 field trials

PROCEDURES:

1. The Field Research Director or GLP coordinator will assure to;
   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/disease 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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Department of Horticulture & Crop Science
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SOP 6.1

TITLE:	Application Equipment Calibration, Maintenance, and Use.
PURPOSE:	To describe the calibration, maintenance, and use of pesticide application equipment used in experiments 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 initial calibration.

2. Written records noted on the Pesticide Application Equipment Maintenance and Calibration form will designate activities as routine or 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 of the equipment failure or malfunction will be written on the Equipment Maintenance and Calibration form.

4. Application equipment will be cleaned after each use to ensure integrity of succeeding applications.

OARDC Weed Lab
Department of Horticulture & Crop Science
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SOP 6.2

TITLE:	Calibration of Hand-carried CO_2-pressurized Boom Sprayers
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 CO_2 pressurized sprayer is used in 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 Book Data.

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 tanks with sufficient CO_2 to maintain the desired pressure throughout the application. Set up the pressure regulator on the CO_2 tank to deliver the desired volume and pressure at the nozzle.

5. To determine whether all nozzles are discharging uniformly, place each nozzle directly over a graduated cylinder or a container 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 bandwidth before spraying the treatment plot.

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 the 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 .2000 gallons of water in a minute at 40 psi, any XX04 nozzle delivers .4000 gallons of water in a minute at 40 psi. To extrapolate to 30 psi, the following formula is used:

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

SOP 6.2

b. To calibrate the boom and CO_2 pressure regulator, the tank is filled with water and pressurized. The nozzles are placed directly over graduated cylinders or containers and the trigger valve is opened for 15 to 30 seconds. The pressure readings on the CO_2 regulator and spray boom are recorded for each test. Test repeated three times and when the output of each test is within 5% of the mean, the boom is considered calibrated. Calibration results 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 Equipment Maintenance and Calibration form.

9. Calculate walking speed as follows:

a. Walking speed is calibrated by marking out a 100-foot strip and walking it with a full sprayer and timing each trip with a stopwatch until the correct time for 100 feet is achieved. Time for 100 feet is calculated by the following formula:

$$Time\ in\ second\ for\ 100\ ft = \frac{a \times 100\ ft}{43{,}560\ ft^2/acre} \times b\ gpa \times \frac{3785.3\ ml/gal}{c\ ml/sec}$$

a = effective band width in feet for one nozzle on a boom
b = desired volume per acre in gallons
c = flow rate of one nozzle in ml/sec at desired pressure

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

$$Speed\ in\ miles\ per\ hour = \frac{100\ ft}{x\ sec} \div 5280\ ft/mile \times 3600\ sec/hr$$

x = time in second for 100 ft

OARDC Weed Lab
Department of Horticulture & Crop Science
The Ohio State University
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SOP 6.3

TITLE:	Calibration and Use of Tractor-mounted CO_2-pressurized Boom Sprayers
PURPOSE:	To set the delivery rate of the sprayer to ensure accurate application of the pesticide.
SCOPE:	All IR-4 trials where a tractor-mounted CO_2-pressurized sprayer is used for pesticide applications.

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 CO_2 to maintain the desired pressure throughout the application. Set the pressure regulator on the CO_2 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 the output. Open the valves 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 average. 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 9, using a 100-foot strip.

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

$$Speed\ in\ miles\ per\ hour = \frac{y\ ft}{x\ sec} \div 5280\ ft/mile \times 3600\ sec/hr$$

x = time in second traveled
y = feet traveled

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 it takes to travel the length of the plot in the Field Data Book.

OARDC Weed Lab
Department of Horticulture & Crop Science
The Ohio State University
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SOP 6.4

TITLE:	Calibration and Use of Granular Applicator
PURPOSE:	To set the delivery rate of the granular applicator of the pesticides
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 if it is clean and in good mechanical condition.

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

3. Measure an area of .01 acre or 435.6 square feet.

4. Determine the approximate setting of the openings and the approximate speed to walk for the desired amount of product per 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 step 4 through 6 until 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.

$$Distance\ to\ walk = \frac{435.6\ ft^2}{10\ ft\ wide} = 43.5\ ft$$

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

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

OARDC Weed Lab
Department of Horticulture & Crop Science
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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 more times with water. Fill tank halfway with water and spray out contents through boom.

3. Store portable equipment at OARDC pesticide storage facility.

OARDC Weed Lab
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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, handheld GPS units, soil probes and samplers, stop watch, pH strips, freezer, balance used for weighing test substance and sample weights, graduated cylinders, tape measure, and wheel.

2. In the case of equipment failure, malfunctions, 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. 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, it should be noted in the Field Data Books in all affected trials. At a minimum, documentation of the actions should include the nature of the failure, date of first notice, remedial actions taken, and assessment of potential impact on the trial.

OARDC Weed Lab
Department of Horticulture & Crop Science
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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 research trials

PROCEDURES:

1. All personnel involved in handling 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 information must be recorded in the respective IR-4 Field Data Book and receipt, transfer, and/or disposal in the facility Pesticide Log Book.

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

OARDC Weed Lab
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SOP 7.2

TITLE:	Test Substance 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. Upon receiving study protocols for the current year, the Study Director will contact the manufacturers of the required pesticides to obtain characterized samples of the pesticides in sufficient quantity to complete the trial. If the pesticides were not ordered by the Study Director, the Field Research Director or GLP coordinator will contact the manufacturer to obtain characterized samples. Pesticide samples used in residue trials should be obtained in the year in which the trial is to be 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: date of receipt, name of individual receiving test substance, carrier and tracking number, batch or lot number, expiration date and source, amount received, container description and condition upon arrival, GLP status and storage conditions, such as temperature requirements.

3. Label test substance container with Field ID #, date received, batch or lot number, expiration date, storage requirements 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 the 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. Upon completion of a trial, extra test pesticide may be disposed of in a legal manner. Record all use or transfer in the IR-4 Field Data Book and/or IR-4 Pesticide Log Book.

7. 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's IR-4 Pesticide Log Book.

OARDC Weed Lab
Department of Horticulture & Crop Science
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SOP 7.3

TITLE:	Test Substance 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 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 temperatures readings every 30 minutes.

3. Monitor room temperature with a primary and back-up data logger/recorder. Recorders will be replaced or serviced before lifetime of batteries is reached. Annual verification of temperatures from recording devices is performed and recorded. Deviation from standard is acceptable within 2 °C. Data loggers are set to record temperature readings every 30 minutes. Have a spill kit accessible in the pesticide storage facility.

OARDC Weed Lab
Department of Horticulture & Crop Science
The Ohio State University
Wooster, OH 44691

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SOP 7.4

TITLE:	Adjuvant Storage and Maintenance
PURPOSE:	To describe the procedures for labeling, handling, and storage of adjuvants.
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, the date that the 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 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 and back-up loggers.

4. Before use in an application, adjuvants will be inspected for quality. If there appears to be any changes 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 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 weigh on a certified balance.

OARDC Weed Lab
Department of Horticulture & Crop Science
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SOP 7.5

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 unless directed differently by the protocol or as recommended by FRD. Make a minimum of 1 liter of spray mix for each treatment.

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

$$Total\ ml.of\ pesticide\ required = \frac{rate\ lbs\ ai/acre}{lbs\ ai/gal} \times \frac{3785.3\ ml/gal}{gal.spray\ volume/acre} \times gal.needed\ for\ spray$$

3. Obtain a clean graduated cylinder that is of a volume appropriate to the quantity of pesticide required.

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 to the nearest 0.5 ml gradation. For volumes between 25 ml and 50 ml, measure to the nearest 1.0 ml gradation. For volumes over 50 ml, measure to the nearest 1 ml or accuracy allowed by measuring device. Read the level of the liquid in the cylinder at the bottom of the meniscus. Record the amount actually measured. After dispensing the test from the original container, excess material will not be returned to the original container.

5. 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 Application Record of the FDB.

6. Wash all measuring devices with soap and water after each use.

OARDC Weed Lab
Department of Horticulture & Crop Science
The Ohio State University
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SOP 7.6

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 unless directed differently by the protocol or as recommended by FRD. Make a minimum of 1 liter of spray mix for each treatment.

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

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

3. Calibrate the balance according to SOP 7.7.

4. Unless the protocol specifies, otherwise, place a clean 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 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.

OARDC Weed Lab
Department of Horticulture & Crop Science
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SOP 7.7

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 each weighing event, visually inspect pesticide for use in a trial, calibrate the balance by first establishing zero followed by weighing standard weights that bracket to the nearest 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 GLP coordinator is responsible for inspection, maintenance and calibration of the electronic balance.

OARDC Weed Lab
Department of Horticulture & Crop Science
The Ohio State University
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SOP 7.8

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. Clean water will be used as a carrier for all applications.

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

3. Measure each liter of water using a clean graduated cylinder or other measuring devices. If using a liquid pesticide or adding a liquid adjuvant, discard an amount of water equal to the volume of the test chemical and adjuvant to be added.

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

5. Pour about half the water into the spray tank. Add the test chemical to the tank. Rinse the measuring device or container three times with water and pour the rinsate into the tank. Then add the rest of the water to the tank.

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

7. Proceed at the correct speed toward the plot and turn on the sprayer upon entering the plot. Maintain the correct speed throughout the plot.

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

9. Record pass times in the Field Data Book.

10. Spray out excess pesticides on an approved location, preferably near the experimental area.

11. 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.

OARDC Weed Lab
Department of Horticulture & Crop Science
The Ohio State University
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SOP 7.9

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 affect 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, fax, or email and in writing of the incident and details should be recorded in the IR-4 Field Data Book.

OARDC Weed Lab
Department of Horticulture & Crop Science
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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 pesticide 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 and 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.

7. Clothing worn during pesticide application should be washed or disposed at the end of the day.

OARDC Weed Lab
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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.

OARDC Weed Lab
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SOP 9.2

TITLE:	Recording, Handling, and Storage of Raw Data
PURPOSE:	To assure that 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 and 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 should 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 extra copies are made.

4. All 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 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 required data is being collected.

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

OARDC Weed Lab
Department of Horticulture & Crop Science
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SOP 9.3

TITLE:	Significant Figures and Rounding Numbers
PURPOSE:	To describe a procedure for determining significant figures and rounding numbers
SCOPE:	All IR-4 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 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 the final value is determined.

3. If the last digit is <5 the number will be rounded down. If the last digit is ≥5, 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.

OARDC Weed Lab
Department of Horticulture & Crop Science
The Ohio State University
Wooster, OH 44691

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Submitted by Douglas Doohan

SOP 9.4

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 pre-emergence applications, rate crop phytotoxicity 7 and 14 days after crop germination.

3. For post-emergence applications, record crop stand, size, and vigor data the day of the initial herbicide treatment. Rate plots 7 and 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 0-100 scale: 0 = no injury: 100 = 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 pre-emergence application and 7 to 14 days after post-emergence treatments again as needed.

OARDC Weed Lab
Department of Horticulture & Crop Science
The Ohio State University
Wooster, OH 44691

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SOP 9.5

TITLE:	Determining Yield and Quality
PURPOSE:	To accurately assess yield and quality, if required by the protocol.
SCOPE:	All IR-4 field research 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. 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 protocol, grade according to USDA or other accepted grading standards and record weight of each portion. Record the grading standard.

OARDC Weed Lab
Department of Horticulture & Crop Science
The Ohio State University
Wooster, OH 44691

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SOP 9.6

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 should be inspected and calibrated as described in SOP 9.7

2. Printouts or charts from these devices must be legible to persons with normal vision. The original printout of the downloaded data 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 separate file in the Field Research Director's archives.

4. Each chart or data sheet 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. The Field Research Director or GLP coordinator is responsible for inspection, maintenance, and calibration of the equipment.

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

7. Automated weather monitoring equipment is preferred when available. Hard copies of weather data from automated monitoring equipment should be included in trial reports.

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

OARDC Weed Lab
Department of Horticulture & Crop Science
The Ohio State University
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SOP 9.7

TITLE:	Maintenance of Monitoring, Data Generating Devices and GPS Unit.
PURPOSE:	To assure 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 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 comparison to high quality thermometer.

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

3. A handheld GPS unit may be used to determine the coordinates of the plot corners 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 permanent known locations. Three readings will be taken and reported to establish accuracy. Readings within 2 meters of the location are considered accurate. The GPS unit will be charged as often as needed. The results of the annual verification of the permanent site and any maintenance to the unit will be noted on the annual GPS Log Form.

4. Monitoring devices that give inconsistent results or that are not in between the following ranges should be replaced or repaired.
   a) Air temperature thermometer: ±5% °F
   b) Weather monitoring equipment: ±5%
   c) WatchDog Temperature logger: ±5% °F
   d) GPS unit: ±2 meters
   e) GLP Electronic Balance: ±1%

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

OARDC Weed Lab
Department of Horticulture & Crop Science
The Ohio State University
Wooster, OH 44691

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SOP 9.8

TITLE:	Data Archiving and Retention
PURPOSE:	Data archiving, retention and Quality Control review
SCOPE:	All IR-4 field research lab.

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 Book, including logs, weather data, personnel forms, etc. These copies will be retained in a secure location at OSU OARDC.

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

4. All original raw data not included in the Field Data Book, will be sent directly to IR-4 Headquarters with a chain of custody form 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 will follow up to obtain any missing data or correct deficiencies with the Field Research Director's consent.

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 and audits.

OARDC Weed Lab
Department of Horticulture & Crop Science
The Ohio State University
Wooster, OH 44691

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SOP 9.9

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 an SOP are:
   a. Application Equipment: SOP 6.2, 6.3, 6.4.
   b. Electronic balance: SOP 7.6
   c. Automated Data Collection/ Recording Devices: SOP 9.6.
   d. GPS unit: SOP 9.6.

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

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

OARDC Weed Lab
Department of Horticulture & Crop Science
The Ohio State University
Wooster, OH 44691

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SOP 10.1

TITLE:	Residue Sample Collection, Storage, and Shipping.
PURPOSE:	To describe procedures for harvesting, handling, storing, and shipping.
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.

OARDC Weed Lab
Department of Horticulture & Crop Science
The Ohio State University
Wooster, OH 44691

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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 or GLP coordinator will prepare a Master Timetable for all projects. The Master Timetable will include project 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 dates modified on the Master Timetable.

2. Avoid collecting samples during rain, unless it is necessary to do so to meet a time requirement in the protocol.

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 the 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 Field Data Book any reasons for the small sample size.

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

7. Avoid cross contamination of samples during harvesting and handling by wearing disposable surgical 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 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.

OARDC Weed Lab
Department of Horticulture & Crop Science
The Ohio State University
Wooster, OH 44691

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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. If these bags are not available, use any clean sampling bags suitable to preserving the integrity of the samples. Double plastic bags are usually sufficient. Plastic, food type bags may be used for sample collection. These are placed inside of cloth bags after sampling is completed.
2. Before sampling, label each IR-4 plastic lined cloth bag with waterproof ink with the following information:
    a. Field Trial Identification Number
    b. Crop fraction
    c. Test substance
    d. Treatment number
    e. Sample number
    f. Harvest date
    g. Sampling date
    h. Investigator: Name/ Phone
3. Each plastic, food type bag should be labeled with the following information:
    a. Field Trial Identification Number
    b. Crop fraction
    c. Test substance
    d. Treatment number
    e. Sample number
    f. Harvest date
    g. Sampling date
4. Fill out a Sample Identification Card for each sample bag. Sample I.D. cards should contain the following information:
    a. Field Trial Identification Number
    b. Crop fraction
    c. Test substance
    d. Treatment number
    e. Sample number
    f. Harvest date
    g. Sampling date
5. Place each card in a moisture proof container and place it inside the plastic food type bag with the harvested sample.
6. Place the plastic bag with the harvested sample in the IR-4 plastic lined cloth bag and tie bag closed securely.

OARDC Weed Lab
Department of Horticulture & Crop Science
The Ohio State University
Wooster, OH 44691

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SOP 10.4

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. Place the sample as it is collected into a plastic sample bag marked for that sample. Place the Sample Identification Card into the bag.

2. 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 bag securely closed.

3. Place a filled sample bag into cooler or other appropriate container containing blue ice and transport to freezer or lab if additional sample preparation is required. 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 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.

OARDC Weed Lab
Department of Horticulture & Crop Science
The Ohio State University
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SOP 10.5

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. A walk-in freezer (typically Freezer 47, Selby Hall) will be maintained by Leona Horst, USDA, ARS, Wooster following her approved SOP 4.5 Revision number 10 for use as sample storage for residue samples. The freezer is capable of achieving and maintaining temperatures consistent with those requested in trial protocols. All original data of temperature records will be in Leona Horst's facility files and true copies will be inserted in the OARDC Weed Lab Field Data Books. Leona Horst's procedures from SOP 4.5 Revision number 10 are duplicated below in items 10.5.2 – 10.5.15 in this SOP.

2. If samples are not to be frozen, they must be kept in a suitable location, with monitored temperature and limited access.

3. Maintenance records, including routine and non-routine maintenance, will be kept for the freezer storage facility.

   a. Routine maintenance is the result of normal wear.
   b. Non-routine maintenance is the result of equipment malfunction.

4. Prior to the first harvest of each season, the freezer will be inspected and the temperature range confirmed.

5. While GLP samples are present in the freezer, access to those samples will be restricted.

6. All GLP samples will be designated as such to separate them from non-GLP samples. All samples will be stored in such as way as to prevent contamination.

7. Temperature conditions in the freezer will be monitored continually using a data logger (or data loggers) from the time of the first harvest of the season to the time of shipment of the last set of samples. Temporary spikes resulting form addition or packing of samples are acceptable.

8. A freezer contents log, documenting the movement of samples to and from the freezer, will be maintained. This log, or a copy, will be placed in the appropriate FDBs.

9. The freezer is connected to an alarm system in the event that the freezer temperature goes below -40 or above 20F. This system is not maintained under GLP guidelines and is intended only to monitor freezer conditions.

10. If the alarm is activated, record the time and temperature on the freezer temperature log. Once the temperature is restored to the freezer unit, record the freezer temperature and time in the freezer temperature log.

SOP 10.5

11. The temperature of the Sensaphone system will be checked monthly against a NIST thermometer and recorded in a maintenance log along with the date. Note in the Sensaphone log whether the operation is routine or non-routine.

12. The Sensaphone will be unplugged and allowed to go through a power outage alarm/temperature alarm cycle at the beginning of the field season. Date and time of testing will be noted as a routine operation in the log for the Sensaphone.

13. In the event of a malfunction with the primary freezer, samples may be placed in another freezer capable of sustaining temperatures at or below 0oF (see Freezer in Rm130, Selby Hall or Freezer in Horticulture Insects Laboratory). A data logger will be placed in this temporary facility for as long as samples remain there.

14. If the malfunction results in a deviation from a study protocol, the deviation will be documented and the Study Director will be notified.

15. Appropriate measures will be taken to prevent contamination during temporary storage.

OARDC Weed Lab
Department of Horticulture & Crop Science
The Ohio State University
Wooster, OH 44691

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SOP 10.6

TITLE:	Sample Shipping Procedures
PURPOSE:	To assure that the 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 a copy of completed IR-4 Residue Sample Chain of Custody Form (8B) and a copy of the Sample Arrival Check Sheet (8c) into each shipping container.

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 or 40 lb dry ice regardless of sample weight.

3. Label each shipping carton with the following information:
   a. Name and Address of sender.
   b. Name, address, of the residue lab receiving samples
   c. Number of container if more than one is used
   d. Where used, affix "Dry Ice" on two sides of the container.
   e. Field ID number
   f. Commodity and Pesticide

4. Ship samples by ACDS freezer truck (ACDS Trucking Inc, Phelps, NY) if possible. After harvest, contact ACDS regarding the next sample pick up date. ACDS will schedule a pick-up date and contact the Field Research Director. The Field Research Director or GLP coordinator 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 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.

OARDC Weed Lab
Department of Horticulture & Crop Science
The Ohio State University
Wooster, OH 44691

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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. All data and information from a trial will be included in the IR-4 Field Data Book, which will be returned to the Regional Field Coordinator by the Field Research Director upon completion of the field portion of the trial.

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 or thermograph records
   e. Freezer inventory log
   f. Equipment maintenance and calibration form
   g. Balance weights verification
   h. Master timetable
   i. Freezer inventory log
   j. Freezer thermograph charts
   k. Study deviation forms
   l. Protocol change forms
   m. Correspondence concerning the trial or project
   n. Pesticide application equipment maintenance and calibration form
   o. Global Positioning System (GPS) report
   p. Soil analysis report
   q. Weather records
   r. Maps
   s. Shipping bill of lading

OARDC Weed Lab
Department of Horticulture & Crop Science
The Ohio State University
Wooster, OH 44691

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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 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 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.

5. If a 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.

6. Number each 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 in the first page of that section.

7. If raw data applies to more than one trial, the original will be kept in temporary storage by the Field Research Director or GLP coordinator 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. The original may also reside in the permanent archive/ record storage facility and "True Copies", signed, dated, and indicating this location may be used in the Field Data Book. At the end of the field season the original documents will be transferred to Headquarters to the archives.

OARDC Weed Lab
Department of Horticulture & Crop Science
The Ohio State University
Wooster, OH 44691

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SOP 11.3	
TITLE:	Disposition of Completed IR-4 Field Data Books and Other Documentation.
PURPOSE:	To assure completed IR-4 Field Data Books reach the Field Research Coordinator as soon as possible.
SCOPE:	All IR-4 field trials.

PROCEDURES:

1. The original of the completed IR-4 Field Data Books and any accompanying documentation should be forwarded to the IR-4 Field Research Coordinator within a reasonable period of time after the trial is completed.

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 returned to the Field Research Director with comments on deficiencies and suggestions for completion.

3. The Field Research Director or GLP coordinator will place a copy of the completed reports and related correspondence in his trial folder to be used for subsequent QA audits.

OARDC Weed Lab
Department of Horticulture & Crop Science
The Ohio State University
Wooster, OH 44691

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SOP 12.1

TITLE:	Archive and 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 of sufficient size to contain all records/archival material 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 archive 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 or GLP coordinator 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: the equipment maintenance/ calibration forms, freezer content log, freezer logger temperature data, GPS calibration log, personnel forms, pesticide storage temperature monitoring data, weather and other original data forms that were used for more than one trial. 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 copies of the following in his archive/ record storage area:
   a. Completed IR-4 Field Data Books including the protocols, audits, and other relevant information.
   b. All original records transferred to Headquarters' archives.
   c. Current and previous editions of Standard Operating Procedures (SOP).
   d. Organizational charts, training records, job descriptions and CVs for current and former employees.
   e. Original thermograph charts from temperature monitoring devices.
   f. Any correspondence pertaining to IR-4 trials.
   g. Service records for equipment.
   h. Soil test reports.
   i. GPS plot location data.
   j. Other relevant information.

SOP 12.1

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

OARDC Weed Lab
Department of Horticulture & Crop Science
The Ohio State University
Wooster, OH 44691

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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. Data supporting the registration of a pesticide use pattern should be retained for the life of registration.

2. Data that is not used in support of the registration of a pesticide use pattern should be held for 2 years following the date of the completion of the study. It may only be discarded with written approval of the Study Director.

OARDC Weed Lab
Department of Horticulture & Crop Science
The Ohio State University
Wooster, OH 44691

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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.

SOP 14.1

TITLE:	Procedures to Follow prior to an EPA Inspection.
PURPOSE:	To provide guidance to OSU personnel in responding to a request for an EPA audit, inspection or review.
SCOPE:	All IR-4 research trials in the Department of Horticulture and Crop Science at the Ohio 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 HCS, OSU/OARDC.

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.

SOP 14.2

TITLE:	Procedures to Follow during EPA Inspection.
PURPOSE:	To provide the 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 and Crop Science at the Ohio 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 or 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.

OARDC Weed Lab
Department of Horticulture & Crop Science
The Ohio State University
Wooster, OH 44691

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SOP 14.3

TITLE:	Procedures to Follow after the EPA Inspection.
PURPOSE:	To provide guidance to personnel in responding to a request for an EPA audit/inspection or review.
SCOPE:	All IR-4 research trials in the Department of Horticulture and Crop Science at the Ohio State University.

PROCEDURES:

1. The Field Research Director or GLP coordinator must be present for the closeout 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 closeout 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 of any problems found.

7. Respond to deficiencies as required.

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