SOP Log Sheet

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FRD/LRD: Darrell Thomas & Michael Long & Peter Dittmar
Submitter

Effective Date: 3/18/19

Description of Material (s): 2019 SOPs

Reviewed By: Juliet Thompson
Sign/Date

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Archive Location:

Sign:

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S: Facility Files- SOP Cover Sheet

9/13/16 JT

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March 18, 2019

Darrell Thomas,Michael Long
University of Florida
Plant Science Research and Education Unit
2556 W. Hwy. 318
Citra, FL 32113

Dear Darrell and Michael,

Thank you for submitting the complete set of Standard Operating Procedures (SOPs) for the North Florida IR-4 Field Research Center for review. As requested, I have reviewed the documents and approved them with an effective date of 3/18/19.

Regards,

Janine Spies, Ph.D.

IR-4 Southern Region Field Coordinator

UF | UNIVERSITY of FLORIDA

Institute of Food and Agricultural Sciences
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March 14, 2019

Dear Janine,

Attached are the 2019 Standard Operating Procedures for the North Florida IR-4 Field Research Center.

The following has changed:

1) The revision number for SOP 1.4 was corrected to 9 instead of 8 and revision date updated to 2-26-18 on the contents page.

2) Updated SOP 2.2 Organizational chart. Revision number changed on contents page.

3) On Table of Contents pages changed Revision: 8 to Table of Contents Revision: 9 at bottom of pages.

4) Corrected spelling errors under procedures in SOP#2.3 and SOP # 3.2.

Sincerely,

Darrell Thomas
Field Research Director
University of Florida

Michael Long
Field Research Director
University of Florida

STANDARD OPERATING PROCEDURES

FOR

MAGNITUDE OF THE RESIDUE-FIELD STUDIES

North Florida IR-4 Field Research Center
University of Florida, Plant Science Research and Education Unit
2556 W. Hwy. 318, Citra, Florida 32113-2132

Dr. Peter Dittmar Field Research Center Director	(Signature)	(Initials)	3-14-19 (Date)
Darrell Thomas Field Research Director	(Signature)	D.T. (Initials)	3-14-19 (Date)
Michael Long Field Research Director	(Signature)	MZ (Initials)	3-14-19 (Date)
Janine Spies Regional Field Coordinator	(Signature)	JS (Initials)	3-18-19 (Date)

Table of Contents Revision: 9
Effective date: 3-18-19

North Florida IR-4 Field Research Center
University of Florida, Plant Science Research and Education Unit
2556 W. Hwy. 318, Citra, Florida 32113-2132

Contents- Standard Operating Procedures
Version 8

Table of Contents Revision: 9
Effective date: 3-18-19

North Florida IR-4 Field Research Center
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SOP NUMBER	TITLE	REVISION NUMBER	REVISION DATE
7.4	Method for collecting phytotoxicity data	9	2/26/18
7.5	Experimental design and data analysis	8	5/3/17
7.6	Data storage during the active life of the project	8	5/3/17
8.1	Sample collection, identification, and records	8	5/3/17
8.2	Sample packing and storage procedures	8	5/3/17
8.3	Sample shipping procedures	9	2/26/18
9.1	Raw data forms	8	5/3/17
9.2	Handling completed report forms that transcend two or more trial(s)	8	5/3/17
9.3	Disposition of raw data from trial(s)	8	5/3/17
9.4	Retention of data	8	5/3/17
9.5	General procedures-Archives	9	2/26/18
10.1	Disposal of pesticides	8	5/3/17
11.1	Safety and health procedures in handling pesticides	8	5/3/17
12.1	Procedures to follow prior to an announced EPA inspection	8	5/3/17
12.2	Procedures to follow during an EPA inspection	8	5/3/17
12.3	Procedures to follow after the EPA inspection	8	5/3/17

*All SOP's have been reviewed prior to signing:

_____ Date: 3-14-19

_____ Date: 3-14-19

_____ Date: 3-14-19

Table of Contents Revision: 9
Effective date: 3-18-19

North Florida IR-4 Field Research Center
University of Florida, Plant Science Research and Education Unit
2556 W. Hwy. 318, Citra, Florida 32113-2132

Revision Number: 8 SOP#: 1.1

Title: General requirements for the development and use of Standard Operating Procedures.

Purpose: To provide guidance to NFIFRC personnel in the development and use of standard Operating Procedures for field research.

Scope: All SOP's developed and used at the NFIFRC.

Procedures:

1. Each facility where trial(s) are conducted in support of the registration of pesticides will develop SOP's for all phases of the research.

2. Generic SOP's may be provided to each facility and these SOP's will be revised to accurately reflect that facilities policies, procedures and methods. Where generic SOP's are not available, the Field Research Director will see that the required SOP's are developed and approved prior to the initiation of any GLP studies.

3. The SOP's will be approved by the IR-4 Regional Field Coordinator or other appropriate approving official and this will become the effective date. The title page will show the signature of the approving official and the date signed by the approving official.

4. Each SOP will be reviewed annually and revised as needed. The effective date and revision number must be changed to reflect the revision, or if not revised the review documented by the reviewer signing the SOP "Reviewed by" and dating. The revision number will begin with 1 and increase sequentially with each revision. [All original SOPs will be retained by the Field Research Director and copies will be sent to IR-4 headquarters].

5. Any deviations from the SOP's must be documented in the raw data.

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Revision Number: 8 SOP#: 1.2

Title: Numbering system for SOP's.

Purpose: To provide a general outline for SOP's via a numbering system.

Scope: All SOP's will follow the numbering system to provide uniformity in the system.

Procedures: The numbering system for SOP's is as follows:

1. General
2. Personnel
3. Facilities
4. Equipment
5. Test System Establishment & Maintenance
6. Test Substance
7. Data Handling
8. Residue Sample Handling
9. Reporting and Retention of Data
10. Disposal of Pesticides
11. Safety and Health Procedures
12. Procedures to Handle an EPA Audit or Inspection

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Revision Number: 8 SOP#: 1.3

Title: Format for use in developing SOP's.

Purpose: To assure a uniform format in the development of SOP's.

Scope: All SOP's developed by NFIFRC scientists for use in the conduct of trial(s) under GLP.

Procedures: The following is the format to be used for each Standard Operating Procedure (SOP):

Name of Test Facility (centered)
Address (centered)
1 space

Effective Date (if not included on the "Contents" page):
1 space

Revision Number: (sequentially beginning with 1 for first use); SOP number: (SOP section number as a decimal)
1 space

Title: (title)
1 space

Purpose: (Brief description of the purpose of the SOP).
1 space

Scope: (Determines where and when the SOP is applicable).
1 space

Procedures: (Describe the operating procedures in numerical order from beginning to end so that an intelligent person with some knowledge of the process can carry out the procedures without any verbal input from other sources.) Each SOP will be numbered page __ of __.

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Revision Number: 9 SOP#: 1.4

Title: Designation of Field Research Director and responsibilities.

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

Scope: All trials performed at the NFIFRC.

Procedures:

1. The Field Research Director is designated by the Study Director based on the recommendation of the Regional Field Coordinator to conduct the trial(s). The Field Research Director shall be a scientist with appropriate training and experience to conduct the trial(s).

2. The Field Research Director will ensure that:
   a. The trial is carried out in accordance to an approved protocol and the GLP regulations
   b. Utilize personnel, resources, facilities, equipment, materials, and methods as necessary for the conduct of the trial.
   c. All personnel conducting the trial understand the protocol, SOP's for the project, and GLP regulations.
   d. All deviations reported by the Quality Assurance Officer are responded to in writing.
   e. All raw data, summaries and other items connected with the trial that need to be retained are transferred to the archives at IR-4 Headquarters or are archived at the NFIFRC.
   f. Maintain a current copy of a master schedule for all GLP projects under his/her direction.

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Revision Number: 8 SOP#: 2.1

Title: Personnel.

Purpose: Provide information to NFIFRC personnel about personnel requirements under Good Laboratory Practices.

Scope: All personnel involved in GLP trials at the NFIFRC.

Procedures:

1. The field facility will have on file current copies of a professional biography or CV, a position description, and training records for each person engaged in or supervising the trial(s).

2. The field facility will have a sufficient number of persons to carry out the trial(s) to its completion and the Field Research Director or designee will utilize trained personnel to conduct their portion of the trial(s).

3. The field facility will have a supply of safety equipment in working order and sufficiently clean to protect the health and safety of the personnel connected with the project as required by the Health and Safety SOP's, regulation, other institution regulations, pesticide labels or the trial(s) protocol.

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

5. Personnel handling pesticides will be trained in accordance with the current policies and guidelines of their institution.

6. Personnel documentation will be reviewed annually and revised as needed.

7. In the event that person's employment with the organization ends, their personnel records will be archived.

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Revision Number: 10 SOP#: 2.2

Title: Organizational chart.

Purpose: To show the organizational web of the NFIFRC and IR-4.

Scope: Organizational structure of the NFIFRC in relation to the University of Florida, IFAS, and IR-4.

Procedures:

1. The organizational chart describes the management structure of the NFIFRC/ IR-4. It also documents the reporting lines for personnel engaged in GLP studies both to the NFIFRC's management and to IR-4 Testing Facility Management.

2. Each block in the chart shows the title, and a brief description of the duties of each person.

3. The Horticultural Science Department Chair is included in the chart. This person approves the appointment of the Field Research Directors at the NFIFRC.

4. The chart then shows how the Field Research Director and the Quality Assurance Unit (QAU) independently report to the IR-4 Testing Facility Management.

5. Personnel engaged in the conduct of the trial(s) are shown on the cart with lines of supervision, communication, and cooperation indicated.

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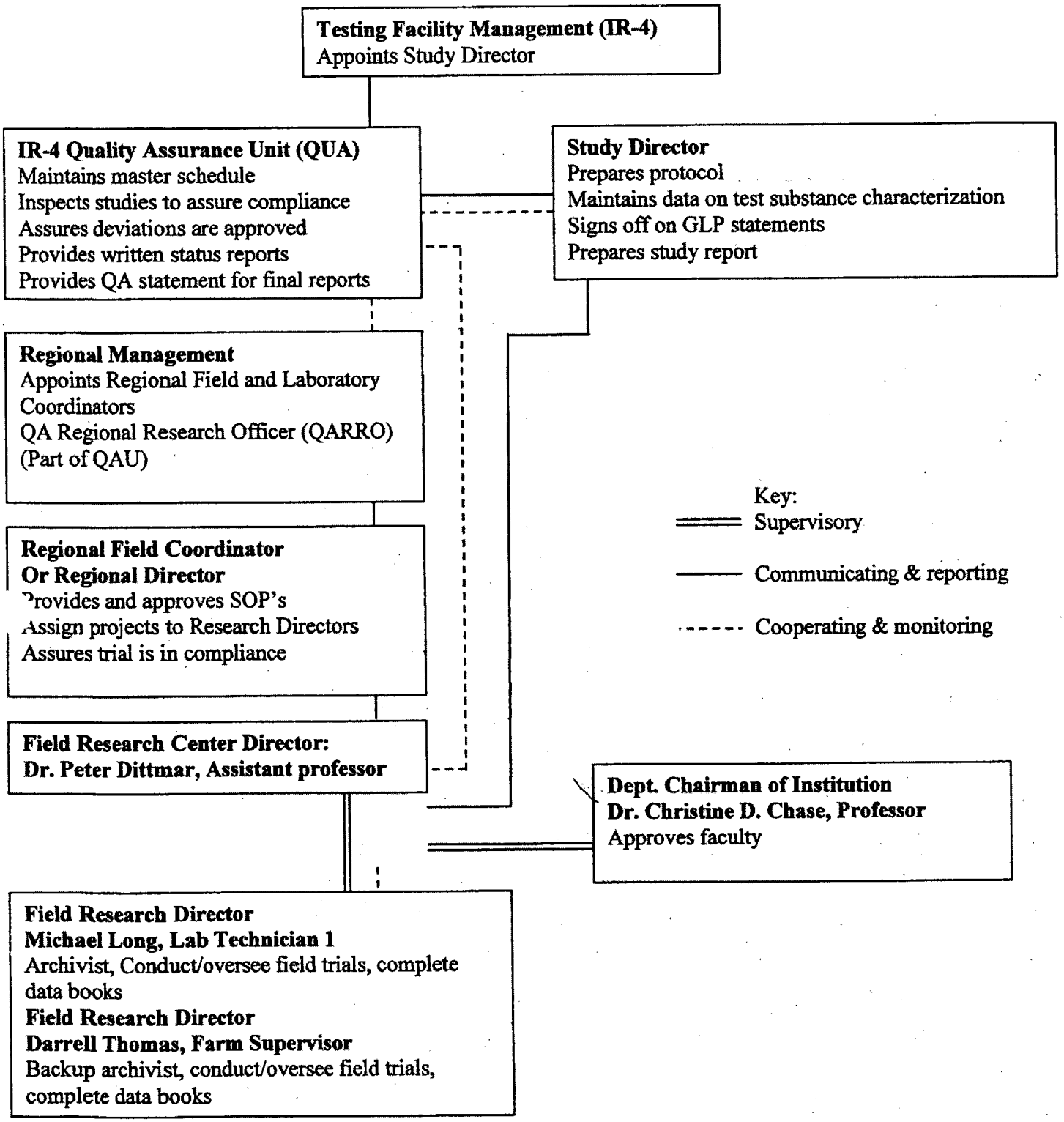

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Revision Number: 8 SOP#: 2.3

Title: Documentation of training.

Purpose: To assure that training for NFIFRC personnel is properly documented.

Scope: Training of all NFIFRC personnel involved in GLP trials.

Procedures:

1. All training of personnel engaged in GLP trials will be documented in a training record. All training records will be kept in the personnel file of the NFIFRC Archives.

2. Training received from any source, will be noted as to the name of the event, date(s) of attendance, instructor's name, and subjects covered. A copy of any type of certificates issued will be retained in the personnel files at the location.

3. Training on specific procedures and/or SOP's will also be documented. Record the name of the person giving the instruction, the name of the person receiving the instruction, the date given and a concise statement of the instruction, or SOP (e.g. Dr. X explained to Mr. Y how to label the sample bags as per SOP xx on 6/2/93).

4. Each person engaged in the conduct of the study will have read and understood those sections of the protocol and the standard operating procedures that pertain to their responsibilities.

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Revision Number: 8 SOP#: 3.1

Title: Guidelines for test substance storage.

Purpose: To assure that all test substances are stored in a manner consistent with GLP requirements

Scope: All test substance storage at the NFIFRC.

Procedures:

1. Test substances will be stored in a dry, well-ventilated building which is separate from offices, laboratories, and sample storage areas. The test substance area will be sufficient to allow storage of the test substances according to their label directions. Test substance will be stored in accordance with current policies and guidelines of IFAS, University of Florida.

2. The temperature within the storage facility will be monitored by a data logger and the data logger chart will be printed off monthly and entered into the appropriate log book. [See SOP 4.7 for specifics on data loggers]

3. The original containers for all GLP test substances must be retained until completion of the study and permission is given by the study director to dispose of the containers.

4. The storage facility will have limited access by utilization of a lock and key so that only authorized persons may have access to GLP test substances.

5. Highly visible, waterproof identification signs will be on doors, gates, buildings, and fences to advise of the hazardous nature of the storage facility's contents.

6. The telephone numbers and names of personnel responsible for and knowledgeable of the contents of the storage facility will be posted.

7. Materials such as adsorptive clay, granulated activated charcoal, hydrated lime, and sodium hypochlorite will be on hand for emergency treatment or detoxification of spill or leaks.

8. Containers of test substances that could be damaged by moisture or water, will be stored off the floor.

9. A current inventory log of all test substances will be kept in the IR-4 office on site, which is in close proximity to the storage room.

10. Test substances used under GLP will be stored in a separately labeled area in the storage facility.

11. The receipt and storage, and mixing areas for the test substance are separate to prevent contamination or mix-up.

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Revision Number: 9 SOP#: 3.2

Title: Site selection for field trial(s).

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

Scope: All GLP trials performed at the NFIFRC.

Procedures:

1. Site selection will be made in accordance with the horticultural practices acceptable for the commodity and the requirements.

2. Site will be large enough to accommodate the required number of replicates, buffer zones, and treatments in accordance with an approved study protocol and for the commodity to be grown under simulated commercial conditions yielding samples of sufficient size to comply with protocol sample size requirements.

3. Site will be located with sufficient isolation to prevent contamination of the test plots by spray drift sources such as commercial operations or other research trial(s).

4. Where samples for residue trial(s) are required, locate untreated plots within the same area [preferably upwind and up slope of the treated plots(s)] but with enough isolation to produce untreated, uncontaminated samples.

5. If the commodity is not required to be newly established, a site will be selected that meets commercial standards for production.

6. A plot map will be prepared showing the location and dimensions of each plot on the site, the slope, and the North azimuth. The plot map will contain distances to permanent reference points so that the plots can be re-located after the trial(s) is terminated.

7. Each trial site will be labeled with the field ID number and treatment as a minimum. If statistical analysis is to be performed on the data, assign the replicates and treatments to the plot map using a commonly accepted statistical design with sufficient information to identify the replicate and treatment assigned to each plot.

8. Each Plot will be located on the site using a suitable measuring device to accurately locate the plots on the site.

9. Both ends of each plot will be labeled with a marker of sufficient visibility to be seen easily throughout the duration of the trial(s).

10. The plot map (item 6) will be included in the raw data notebook.

11. Each treatment row will be identified as to plot # and row # in such a manner so that it will be visual throughout the life of the trial(s).

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Revision Number: 8 SOP#: 3.3

Title: Greenhouse/shade house facilities.

Purpose: To assure that greenhouse/shade house facilities are properly maintained and in sufficient working order throughout the trial(s) to obtain data useful in the registration of pesticides in the GLP program.

Scope: All NFIFRC trials performed in a greenhouse/shade house.

Procedures:

1. Each greenhouse/shade house will be sufficiently large enough to contain the entire trial(s) or a complete replicate of the trial(s) with sufficient space between plots to prevent contamination. Identify plots as described in SOP 3.2.

2. Where more than one trial(s) is conducted in a greenhouse/shade house, there will be sufficient isolation between the trial(s) to prevent contamination or interference between trial(s).

3. Environmental conditions will be sufficiently uniform at the trial(s) sites in the greenhouse/shade house to provide nearly uniform plant growth throughout the trial(s) sites.

4. The walls, floors, and ceilings of the greenhouse/shade house will be maintained in good condition. Floors, benches, and isles will be free of debris, weeds, and superfluous equipment and well-drained to prevent the buildup of excess moisture.

5. Greenhouses will be equipped so as to maintain temperature, lighting, and moisture conditions to simulate commercial greenhouse production techniques or as required by the study protocol.

6. Cultural practices used in the greenhouse and treatment locations will be document in the raw data notebook.

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Revision Number: 8 SOP#: 4.1

Title: Calibration and use of balances.

Purpose: To assure an accurate weighing of dry test substances.

Scope: Any trials performed at the NFIFRC which require use of a balance.

Procedures: The methods, materials, and schedules for routine inspection and cleaning and calibration will be:

1. Follow manufacturers recommendations for frequency of balance calibrations and for proper calibration methodology, and routine maintenance. Follow instructions in manufacturer's manual for routine maintenance and calibration and calibration checks. Manual is located in balance log book. Calibrations will be recorded in a balance log.

    a. Denver Instrument model XE-410D, serial number 0072905.

        1. Press the "cal" key and the word "calibrate" will display.

        2. Place the 40 g calibration weight on the plan.

        3. The display will show CAL 40. Then it will show CAL OK.

        4. When calibration is complete the balance will show 40.00 g, the weight used.

        5. Remove the weight. The display will show 0.00 g.

        6. Record calibration data in calibration log.

        7. Unsuccessful calibration routine: the display shows NOCAL. Repeat steps 1-5. If this does not work call Denver Instrument at 1-800-321-1125.

        8. Service on this scale will be performed by Denver Instrument Co.

    b. Berkel model RS-150, serial number 15S890027.

        1. Level scale using bubble level indicator.

2. Turn on scale.

3. Select units (pounds or kilograms). Select pounds.

4. Press zero to zero scale.

5. Put 2 lb weight on scale and read.

6. Record calibration data in calibration log.

7. If weight reading is incorrect remove weight and repeat steps 1 through 5. If this does not work call Berkel, Inc. at 1-219-326-7000.

8. Service on this instrument will be performed by Berkel, Inc.

2. Routine maintenance of balances also includes annual inspection and (re)certification by professional service person. A label with the service date, name of the service person, and the next service date is affixed to each balance. Standard weights are standardized against the service person's certified standard weights when the balances are re-certified. The readout should be with 1% for weights less than or equal to 100 mg or 0.1% for weights equal to or larger than 10 g. If not, the defective weights will be replaced. Results are documented in the balance logbook.

3. Prior to each use, the user will visually inspect the balance for cleanliness. Any dirt or chemicals within the chamber or on the pan must be cleaned immediately.

4. Weights must always be handled using tongs. Never touch weights with bare hands. Weights must always be stored in appropriate weight cases.

5. Balance accuracy checks will be performed, before weighing chemicals for residue tests, using two standard weights that bracket the amount to be weighted. Record declared weights and actual weights of standards as raw data.

   a. If the measured weights of both standard weights are within $\pm$2% from the standard weight, proceed with weighing.

   b. If the measured weight of either standard weight differs by more than $\pm$2% from the standard weight, recalibrate the balance.

c. If, after recalibration, the measured weights of both standard weights are within ±2% of the standard weights, proceed with weighing and record the measured weights.

d. If, after recalibration, the measured weight of either stand weight still differs more than ±2%, replace the defective weight. If it is determined that the problem is the balance, then service the balance before further use.

6. Appropriate safety equipment will be used while handling the test substance.

7. Select an appropriate container to hold the desired amount of test substance and tare it on the scale following the manufacturer's directions in the appropriate technical manual.

8. If taring the container is not practical, then record the weight of the container, add the weight of the desired amount of test substance to it and weigh out this amount.

9. Transfer the weighed material into an appropriate container for mixing with carrier.

10. Label the container to identify it as to the field trial PR#, treatment #, rate, and test material.

11. Remedial actions to be taken in case of failure or malfunction (non-routine maintenance) include:

    a. Any problem should be immediately reported to the NFIFRC field research coordinator, documented, and place in the balance records for non-routine procedures.

    b. If the problem cannot be corrected by instructions from the manufacturer's manual, the service representative will be notified. All corrective actions taken shall be documented in the balance logbook as non-routine maintenance.

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

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Revision Number: 8 SOP#: 4.2

Title: Measuring liquid formulations.

Purpose: To assure an accurate measurement of liquid test substances.

Scope: Any trials performed at the NFIFRC which require liquid measurement.

Procedures: 1. Obtain a clean cylinder or measuring device large enough to hold the volume of liquid needed, graduated in increments small enough to read to an accuracy within +/- 2% of the total volume required (i.e. if 50 mil is needed the smallest division on the cylinder should be 1 ml. or less). The following devices will be used to measure the designated volumes:

Volume to be Measured	Device to Use
0.5 to 1 ml.	1 ml. pipet
1 to 5 ml.	5 ml. pipet
5 to 10 ml.	10 ml. pipet or cylinder
10 to 25 ml.	25 ml. cylinder or 20ml/30ml. syringe
25 to 50 ml.	50 ml. cylinder or 30ml/60 ml. syringe
50 to 100 ml.	100 ml. cylinder
100 to 250 ml.	250 ml. cylinder
250 to 500 ml.	500 ml. cylinder
500 to 1,000 ml.	1,000 ml. cylinder

2. If the opening of the cylinder/device is too restricted to allow filling without danger of spillage, then do one of the following:

   a. Use a clean container with a pour lip as an intermediate and fill the cylinder/device from it.

   OR

   b. Use a clean funnel that is large enough to allow filling the cylinder with a minimum of spillage.

3. Select and wear or use appropriate safety equipment while measuring liquids.

4. Measure the liquid in the cylinder/device. Place the cylinder/device on a level surface and take the reading of the liquid in the cylinder/device at the bottom of the meniscus with the eye being level with the bottom of the meniscus. Document the amount of test substance measured in the raw data book.

5. Pour the liquid into an appropriate container, fit with leak proof lid and label as to contents and amount.

6. Cylinders/devices used to measure or transfer the test substance concentrate will be triple rinsed into the mixing container and then thoroughly washed with soap and water and triple rinsed with clean water after use to ensure that they are clean and cross-contamination of pesticides will not occur in future use.

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Revision Number: 8 SOP#: 4.3

Title: Calibration of a Liquid Sprayer.

Purpose: To determine the delivery rate of a liquid sprayer and make adjustments as necessary to ensure an accurate application of the test substance or a maintenance substance.

Scope: Any trials performed at the NFIFRC which require the use of a liquid sprayer.

Procedures: The methods, materials, and schedules for routine inspection and calibration will include.

1. Always calibrate before each test substance application or other use of a liquid sprayer.

2. Visually inspect pumps, hoses, pipes, fittings, regulators, gauges, and tanks for obvious wear or potential leaks. Repair or replace parts as necessary and document actions in Equipment Maintenance log.

3. Refer to the protocol for any specified application requirements. Select the appropriate type of nozzle, which is based on the pesticide formulation, the application method, the operating speed, the pressure setting and the dilution volume (e.g., gal/acre).

4. Use a calibration method suitable to the application and the equipment used.

5. Establish volume per acre. Standard operating procedures and/or protocols dictate pre-determined volume per acre in most cases. The standard volume per acre for the NFIFRC is 30 GPA @ 3 mph. Calibrate to the NFIFRC standard settings, unless different settings are specified or selected from the trial protocol.

   Example:
   Protocol calls for material to be applied in 30 gallons of water per acre. (Use 1.0 gallon = 3785 ml., 1 acre = 43560 ft.^{2})
   $\frac{30 \text{ gal.}}{1 \text{ acre}} = \frac{113550 \text{ ml.}}{1 \text{ acre}} = \frac{113550 \text{ ml.}}{43560 \text{ ft.}^2}$
   *If gal/acre not specified can determine existing delivery rate in gal/acre and base mix dilution upon delivery rate in calculations. Collect for 60 seconds output of sprayer in ml. divide by 3785 ml./Gal to obtain Gallons per Minute (GPM) and utilize the following equation to determine G/A: G/A=5940 x GPM (per nozzle)/MPH x W(inches).

6. Determine length of time to measure output. Normally this will be 15 seconds. Record nozzle output that is measured for this time in field data notebook.

7. Measure or establish travel speed of application. Usually this will be 3.0 mph = 4.8 km/hr = 4.4 ft./sec. Check speed of application and adjust to conform to established rate. When using backpack sprayers use a metronome to ensure correct pace to maintain speed. Walking speed is measured and recorded in field data books from a digital stopwatch measurement.

8. Measure and/or establish course width (width between nozzles) or width of band application. In most instances this will be 12, 16, or 24 inches.

9. Using time, speed, and width established in steps 5, 6, and 7 calculate square feet treated in 15 seconds @ X mph using:
time (in sec) x speed (in ft./sec.) x width (in ft.) = treated $ft.^2$

   Example:
   time= 15 sec.
   speed = 3 mph = 4.4 ft./sec.
   course width = 20 in = 1.666666 ft.

   15 sec. X 4.4 ft./sec X 1.6666666 ft. = 109.99999 $ft.^2$

10. Using figure obtained from step 7 above set up a simple proportion to determine needed output for established gallons per acre.

    Example:
    Need to spray at volume of 30 G/A

$$\frac{30 \text{ gal.}}{1 \text{ A}} = \frac{113550 \text{ ml.}}{43560 \text{ ft.}^2} = \frac{X \text{ ml.}}{109.99999 \text{ ft.}^2}$$

    Solve for X to determine correct target output from each nozzle for established gallons per acre.
    For existing delivery rate determination can use above equation except fill in the ml. in 15 seconds and reverse solution to solve for G/A or GPA.

11. Place the sprayer on level ground. Adjust the boom height and nozzle spacing from the correct application pattern. Determine whether all nozzles are discharging uniformly by spraying clean water only through them at a uniform pressure. Catch and record the discharge from each nozzle separately into a graduated cylinder over a timed interval (15 seconds) beginning after the nozzles are discharging. If the discharge varies widely, check, clean and replace screens and/or nozzle tips. Variation among nozzle tips should be less than 5%. Repeat the above procedure until average nozzle discharge is within 5 % of target output for trial.

    If the average nozzle output is within 5% of the target output for the desired gal/acre, as specified in the protocol and or SOP, then the sprayer is calibrated and the same settings will be used in actual application. When the measured gal/acre must be changed alter one or all of the following: nozzles, pressure, or speed. Minor flow-rate changes can be made with a slight pressure change. Major flow-rate changes require selection of new nozzle sizes or changes in ground speed.

12. Applicators must carefully operate under the same conditions as during calibration. Besides checking the nozzles for their proper flow rate, the spray pattern should also be

examined for it's complete and symmetrical arrangement. Ensure that solution is thoroughly mixed before application and continue to agitate during application if possible. The test substance must be applied uniformly to the entire test area.

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Revision Number: 8 SOP#: 4.4

Title: Calibration and use of granular applicators.

Purpose: To determine the delivery rate of the granular applicator and make adjustments as necessary to ensure an accurate application of the pesticide.

Scope: Any trials performed at the NFIFRC which require the use a granular applicator.

Procedures: The methods, materials, and schedules for routine inspection and calibration will include:

1. Determine that the applicator is in good working order and mechanical condition. Make sure that the openings to release the granular material are not clogged and free of debris.

2. It is important to understand that travel speed may or may not alter calibration. For ground driven applicators slight changes in travel speed should not alter calibration but large changes in speed may. For non-ground driven applicators (driven by hydraulics or electrical motors) travel speed will directly influence calibration. Humidity or other environmental factors may also affect calibration. It is imperative to calibrate before each use.

3. Refer to the operator's manual for the calibration method. If no manual or method is available then proceed as follows:

   Ground Driven Applicators

   A. Following protocol requirements, perform calculations to determine actual pounds (or appropriate measures) of material per acre (or appropriate measure). Follow this:

   $$\frac{\text{Rate (units a.i.)}}{\text{Acre}} \times \frac{1 \text{ unit material}}{\text{units a.i.}} = \frac{\text{Units of material}}{\text{Acre}}$$

   Example:
   Protocol requires 10 lb. a.i./A of a 15G material.

   $$\frac{\text{10 lb. a.i.}}{\text{Acre}} \times \frac{\text{1 lb. material}}{\text{0.15 lb. a.i.}} = \frac{\text{66.666666 lb. material}}{\text{Acre}}$$

   This will also be expressed as lb. material/43560 $ft.^2$

4. Measure the course width of the applicator. (This is the actual width of an application pass.) After course width is determined, measure, and flag 50 ft. for course length.

5. Using course width and course length calculate treated square feet.

   Course width X course length = treated square feet

Example:
Course width = 4 ft.
Course length = 50 ft.

4 ft. X 50 ft. = 200 ft.^{2}

6. Using treated square feet figure obtained from step 5 and actual pounds of material per acre obtained from step 3 above set up a simple proportion and solve for X.

$$\frac{\text{Y lb. material}}{43560 \text{ ft.}^2} = \frac{\text{X lb. material}}{\text{treated ft.}^2}$$

Example: (from steps 3 and 5)

$$\frac{66.666666 \text{ lb. material}}{43560 \text{ ft.}^2} = \frac{\text{X lb. material}}{200 \text{ ft.}^2}$$

(43560) (X) = (66.666666) X (200)
(43560) (X) = 13333.333
X = 0.3060912 lb. material

The solution will usually be converted to grams for accuracy in weighing. Use 453.6 grams/pound for conversion.

7. Wear protective clothing as necessary and fill the spreader with enough material to ensure proper operation. Attach a calibration pan under the spreader to catch the material as it is released.

8. Operate the applicator over the desired course (from step 4 above) and weigh the material caught in the calibration pan. Adjust the applicator as needed until it is applying the correct amount per acre (with ±5%). Document each setting and weight.

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Revision Number: 8 SOP#: 4.5

Title: Operation and maintenance of farm equipment.

Purpose: To assure that the crop or commodity under study is grown under simulated commercial conditions, in a quantity sufficient for the trial(s) and in a good state of health.

Scope: All farming operations performed for GLP studies at the NFIFRC.

Procedures:

1. Just prior to the initiation of the use of the equipment (tractor, plow, disk, harrow, planters, harvester, etc.), the Field Research Director or his designated representative will visually inspect the equipment to see that it is in good working order, properly lubricated, and in good mechanical condition.

2. Routine maintenance includes all inspection, cleaning, testing, and calibrations. Non-routine maintenance are actions taken in response to failure or malfunction of equipment. Any necessary repairs or adjustments will be made prior to the use of the equipment in the trial(s) and documented in the equipment maintenance log.

3. The operator of the equipment will be familiar with its operation and safety precautions.

4. Manuals (if available) on the operation and maintenance of the equipment and the name, address, and telephone number of a parts supply company should be kept in a place accessible to the operator and the Field Research Director.

5. Written records will be maintained for equipment used for the generation, measurement, or assessment of data in a GLP trial. The Equipment Maintenance log will contain maintenance service dates and what was done and repair dates and type of repair. When Equipment is shared and used on an occasional basis, a notation will be placed in the field data book indicating that the equipment was adequately inspected and in good working order prior to use in the study.

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

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Revision Number: 8 SOP#: 4.6

Title: Calibration of field and lab instruments.

Purpose: To assure that all field and lab instruments used in a GLP trial(s) are accurate and in good working order.

Scope: All field and lab instruments at the NFIFRC.

Procedures:

1. Each instrument used in a GLP trial (e.g. bimetal thermometers, hygrometers, anemometers, pH meter, etc.) will be calibrated or standardized to determine that it is accurate and in good working order. As part of routine maintenance, all instruments will be calibrated/standardized at least annually to assure their continued accuracy. Some instruments may need more frequent testing/calibration

2. A written record will be kept in the corresponding logbook of the dates of routine maintenance (inspection, cleaning, testing, calibration/standardization). Only non-routine maintenance records of Application Equipment (equipment used to apply the test substance to the test crop in the manner specified by the protocol) will be kept in its respective maintenance log. Routine maintenance of application equipment will written within the Field Data Book in section 6C and 6H at or prior to the application timing for the application equipment used in performing the application of the test substance.

3. Those instruments that give inconsistent results or are not accurate to within desired tolerances will be repaired or replace and a record of these non-routine maintenance actions will be kept.

4. The pH meter will be calibrated with at least 2 standard solutions on each day that it will be used. Standardization procedures for the pH meter are outlined below and in the operator's manual. This manual is stored in the pH meter log.

    a. Press on/off key to turn meter on. If pH indicator in main display area is not on, press pH key to place meter in pH mode.

    b. Clear current standardization points by pressing "Stdz" key. Then within four seconds, press "clear" key. Current standardization points will be removed form instrument memory.

    c. Immerse electrode in standard pH 4 buffer solution. Press "Stdz" key to begin standardization. When buffer value stops flashing, go to next step.

    d. Rinse electrode and repeat step c for each additional standard buffer solution.

    e. Rinse electrode and record standardization data in the pH meter log.

5. Calibration for all thermometers will be by the ice point method. Procedures for the ice point method are outlined below:

    a. Use crockery vessel with brass hose bibb in the bottom and the laboratory blender.

    b. Obtain a quantity of ice (approx. 3 gal.) and fill the blend 1/3 to ½ full of ice. Add enough water to float the ice.

    c. Turn on the blender and run until a slurry of ice and water is formed.

    d. Pour this slurry into the crockery vessel.

    e. Repeat steps B thru D until the crockery vessel is filled to about 1 inch from the top.

    f. Add water until the top of the ice is covered and stir with a clean plastic rod.

    g. Pack the slurry firmly with the bottom of a clean plastic beaker, open the brass hose bibb and drain enough water off until the top of the ice just turn white.

    h. Allow the slurry to stand for 10 minutes to equilibrate then insert thermometers into the ice slurry.

    i. Allow thermometers to stand in the ice slurry for 10 minutes to compensate for the thermometric lag, then read thermometers. The temperature of the ice slurry will be 32.

    j. Adjust thermometers if necessary and/or possible and record calibration data in the appropriate log books.

6. Standardization procedures for anemometers are outlined below.

    a. Obtain one or more hand held anemometers from another IFAS research group.

    b. Use each anemometer to measure wind speed.

    c. Record the values obtained in the instrument log book. If values differ greater than 5%, repeat the procedure with a third anemometer. Service and/or replace anemometer if readings differ more than 5% from check anemometer.

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

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Revision Number: 8 SOP#: 4.7

Title: Operation, calibration, and maintenance of data loggers.

Purpose: To assure that all data loggers used in GLP trials are accurate and in good working order.

Scope: All data loggers at the NFIFRC.

Procedures:

1. Activate the power supply to the data logger and choose recording chart type (if appropriate).

2. Identify the chart with date on, initial, and data logger ID.

3. When data recording period is over download chart period from computer, identify with date and initials. Place chart in appropriate logbook. Charts are raw data and will be handled as such.

4. Data loggers will be properly maintained and calibrated. Any routine and non-routine maintenance and calibration will be recorded in the appropriate log books. Routine maintenance includes cleaning, testing, calibrating, or standardizing data loggers. Any non-routine maintenance, prompted by failure or malfunction of equipment, will be handled by the data logger manufacturer. In case of failure, a backup data logger is running independently, but simultaneously with the primary unit. Manufacture's name and address is in the appropriate log book.

5. Log book contents (maintenance and calibration records, etc.) will be archived annually in the NFIFRC archives. When data logger chart overlaps year-end, the chart will be filed under the removal date.

6. Each data logger used for collection of raw data will be calibrated to determine that it is accurate and in good working order. All data logger will be calibrated at least annually to assure their continued accuracy.

7. A written record will be kept in the appropriate log book of the dates and results of the calibration.

8. Data loggers that give inconsistent results or are not accurate to within desired tolerances will be repaired or replaced.

9. Freezer temperature is monitored with a Remote Temperature/RKTC 2 data logger (see UTC-1 log or TRT-1 log). Calibration procedures for this data logger is outlined in the operator's manual in the appropriate freezer log book and below:

    a. The data logger does not have to be returned to Dickson Co. for recalibration. A newly calibrated Replaceable Sensor can be purchased with a 3-point calibration from the Dickson Co.

b. To replace, remove the existing sensor and plug in the new one.

c. If this procedure is unsuccessful, call Dickson Co. at 1-800-323-2448. Service for these data loggers will be performed by the Dickson Co.

10. Temperature in the NFIFRC pesticide storage room is monitored with a RKTC 2 data logger (see Pesticide storage-1 log). Calibration procedures for this data logger is in the operator's manual in the pesticide storage -1 log book and below:

    a. The data logger does not have to be returned to Dickson Co. for recalibration. A newly calibrated Replaceable Sensor can be purchased with a 3-point calibration from the Dickson Co.

    b. To replace, remove the existing sensor and plug in the new one.

    c. If this procedure is unsuccessful, call the Dickson Co. At 1-800-323-2446. Service for this data logger will be performed by the Dickson Co.

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

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Revision Number: 8 SOP#: 4.8

Title: Procedure to use for performing speed calibrations.

Purpose: To define techniques and proper procedures used for walking speed calibration and tractor speed calibration.

Scope: All GLP trials conducted under the management of the NFIFRC.

Procedures: 1. Walking speed calibration:

a. Determine what speed the applicator will walk when making an application. In most cases this will be 3.0 mph or 4.4 ft./sec.

b. Determine calibration course length. In most cases this will be 66 ft. At 3 mph, it will take 15 seconds to walk 66 ft.

c. Measure the course with an accurate measuring device such as a tape measure or a measuring wheel. Mark the course with easily visible markers.

d. Use of a metronome may help maintain a consistent stride. Establish beats per minute by counting number of steps needed to complete the 66 ft. course in 15 seconds.

e. Once a metronome setting and pace have been established for the applicator, the applicator will be calibrated by walking the course length at least 3 passes. Another person will time the applicator's passes with a stopwatch. The timer will record each pass time in Part 6C: SPEED CALIBRATION of the IR-4 Field Data Book.

2. Tractor speed calibration.

a. Determine what speed is correct for the type of application to be made. In most cases this will be 3.0 mph, or 4.4 ft./sec.

b. Determine calibration course length. In most cases this will be 66 ft. At 3 mph, it will take 15 seconds to drive 66 ft.

c. Measure the course with an accurate measuring device such as a tape measure or measuring wheel. Mark the course with easily visible markers.

d. Use the gear/speed selection chart on the tractor or in the operator's manual to select the proper gear, range, and engine rpm for the speed needed. In most cases this chart will only give you a good idea of the gear range and rpm selection to make. Under no circumstances are these charts to be used as exact speed indicators. Use these only as a rough guide.

e. Start the tractor and drive to within 20 ft. of the course. Select the proper gear, range and speed and put the tractor in motion. Use a stopwatch to begin timing when you cross the first course marker and stop the stopwatch when you cross the last course marker. This will take some trial and error to arrive at the correct combination of gear, range, and engine rpm for the target speed.

f. Once the correct combination of tractor gear, range, and engine rpm for the target speed have been established, run the tractor at these settings through the course at least 3 times with another person timing the passes with a stopwatch. Record all of these pass times in Part 6C: Speed Calibration of the IR-4 Field Data Book.

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Revision Number: 8 SOP#: 4.9

Title: Calibration of a handgun sprayer.

Purpose: To establish procedures used for calibrating handgun sprayers.

Scope: The SOP is to be followed by NFIFRC personnel when calibrating handgun sprayers.

Procedures:

1. Handgun sprayer calibrations will be calculated based on square footage of a single tree or bush. Example: Persimmon trees are planted on rows 20 ft. wide and trees are spaced 15 ft. apart in the row. Each tree occupies 300 $ft.^2$ (15 ft. X 20 ft. = 300 $ft.^2$).

2. Determine volume per acre of solution to apply or volume per tree to apply. Example: Protocol requires pesticide to be applied in 10 0gallons of water per acre. Use 3785 ml. = 1 gal, 43560 $ft.^2$ = 1 acre, 100 gal per acre = 378500 m./43560 $ft.^2$
Set up a simple proportion to determine ml. per tree.
3785 ml./43560 $ft.^2$ = X ml./300 $ft.^2$ X ml. = 2607 ml. per tree.

3. Determine the time required to deliver the calculated volume from the handgun. This will require some trial and error. Use a stopwatch and operate the handgun over an easily measured time interval (e.g. 10 seconds). Collect the output from the handgun into a suitable container and measure it with a graduated cylinder. Repeat this process varying pump speed, engine rpm or pressure until the correct output is achieved in an easily measured time interval.

4. Fill the sprayer with clean water and operate the handgun to purge all air from the lines.

5. Once the time required to deliver the necessary volume has been established, then calibrate the handgun. Calibrate the handgun by collecting the discharge over an easily measured time, such as 10 seconds. Collect the handgun discharge into a bucket and transfer into graduated cylinders. Time with a stopwatch. Repeat this procedure at least 3 times. Record the output for each time interval in Part 6: DISCHARGE UNIFORMITY of the IR-4 Field Data Notebook.

6. Apply the pesticide solution to the trees using the same setting of engine rpm and/or pressure and the same time interval. Pass times will be measured with a stopwatch.

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Revision Number: 8 SOP#: 4.10

Title: Calibration and use of Nikon Monarch® Laser 800 optical range-finder.

Purpose: To establish guidelines for the calibration and use of Nikon Monarch® Laser 800 in order to accurately measure distance related to the establishment of IR-4 magnitude-of residue trials at the NFIFRC IR-4 Field Research Center.

Scope: All facilities where trial(s) are conducted.

Procedures: Calibration:

Calibration of the Nikon Monarch® Laser 800 optical range-finder shall be done annually to determine if it is within the desired tolerance.

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

2. Check and replace batter, if necessary.

3. Establish a known distance that measures in whole yards (i.e., 10.0 yd.) and establish a known distance that measures in 0.5 yards (i.e., 3.5 yd.). Place an object, large enough for optical display to find in its crosshairs, at the determined distances above. Ensure that the object has a flat surface that will reflect the laser directly back to the optical range-finder.

4. Make sure the display is reading in yards. If meters are displayed, hold the MODE button down for more than 1.5 seconds. This will switch the units.

5. Record distance values from the range-finder.

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

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

Use:

1. To determine the distance to an object, do the following:

    a. Press the POWER button to turn on the unit.

    b. Make sure the object is large enough for the range-finder to detect and display a reading. If this is not the case, place an object that is large enough to be detected at/on the initial object. Be sure not created angles of deflection when placing the second object (see calibration, Step 3, above).

    c. While viewing the object through the range-finder, press the POWER button to create a displayed distance. Repeat at least once for consistency and accuracy. The value in yards will be converted into feet (1 yd. = 3 ft.) and record in the appropriate place.

Safety Precautions

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

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Revision Number: 8 SOP#: 4.11

Title: Calibration and Cleaning of Sideswipe Pro®.

Purpose: To establish guidelines for the calibration and use of a Sideswipe Pro® in order for the establishment of IR-4 magnitude-of-residue trials at the NFIFRC IR-4 Field Research Center.

Scope: All facilities where trial(s) are conducted.

Procedures: Calibration:

Calibration of the Sideswipe Pro® shall be done to determine the amount of water that it takes to saturate the wiper pad to the point of dripping.

1. Make sure that the roller is completely dry and that it is free of any debris or soil.
2. Fill a graduated cylinder with water to the 100 ml. mark and then pour the water into the Sideswipe Pro® to calibrate. Using a slow swaying motion, allow a few moments to wet the bottom area of the pad.
3. Once the pad starts to drip, pour the remaining water back into the graduated cylinder and measure the amount of water in a graduated cylinder and record the amount in the proper place in the Field Data Book (FDB).
4. Allow the wiper pad to completely dry and repeat the process two more times and record the amount of water it took to wet the pad each time in the FDB. Once the Sideswipe Pro® is calibrated it is ready for use.

Cleaning:

1. Once the Sideswipe Pro® has been used, using clean gloves remove the wiper pad and add soapy water to begin the cleaning process.
2. With gloved hands gently rub the wiper pad to aid in the cleaning process.
3. Pour out soapy water and rinse the wiper pad with clean water repeatedly until the pad is clean and free of soapy water.
4. Once the wiper pad is clean, allow the pad to dry completely before it is sored away for future use.

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Revision Number: 9 SOP#: 4.12

Title: Borrowed or seldom used equipment.

Purpose: To assure that borrowed or seldom-used equipment is in satisfactory working order for accurate application in GLP studies.

Scope: All GLP field studies under the IR-4 projects.

Procedures:

1. Inspect equipment for obvious problems, i.e. loose conditions, cracked hoses, etc.
2. Ascertain, if possible, last known use and document.
3. If equipment is spray equipment, clean it according to SOP 6.3.
4. If to be used in spray application, calibrate and adjust or replace those parts not functioning properly. Record all actions.
5. Enter date equipment was returned to original source.

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Revision Number: 8 SOP#: 4.13

Title: Operation, maintenance, and standardization of global positioning system (GPS).

Purpose: To ensure that global positioning satellite devices are operated and maintained properly so that they will give an accurate location reading. GPS units are used to mark permanent positions of plots.

Scope: All facilities where global positioning systems are used.

Procedures:

1. The GPS unit should be placed on a stable, relatively level surface with as much access to clear sky as possible.
2. Power up the GPS unit by pressing the power button and positioning unit with full view of sky. As soon as unit has tracked enough satellites to get a location reading, the satellite page appears on the screen of the GPS unit.
3. Place GPS unit in the spot that you want to take the readings and read the location given in degrees and decimal minutes.
4. Readings will be done for at least two plot corners of each plot. The north and south coordinates which are displayed on the screen should be recorded on the plot map.
5. If the batteries become weak or dead, replace them per operating instructions. If the device becomes damage or stops, replace it with another system if possible.
6. The GPS unit should be checked annually or as needed. To standardize, the GPS unit will be compared with Google Earth or another GPS unit. If the two devices differ from each other by over 0.020 minutes for the same spot, then the unit should be repaired or replaced.
7. All standardization and repair actions should be documented in the Maintenance and repair log.

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Revision Number: 8 SOP#: 4.14

Title: Calibration of the North Star® Liquid Sprayer.

Purpose: To determine the delivery rate of the North Star® liquid sprayer and make adjustments as necessary to ensure an accurate application of the test substance or a maintenance substance.

Scope: Any trials performed at the NFIFRC which require the use the North Star® liquid sprayer.

Procedures: The methods, materials, and schedules for routine inspection and calibration will include:

1. Always calibrate before each test substance application or other use of the North Star® liquid sprayer.

2. Visually inspect pumps, hoses, pipes, fittings, regulator, gauges, and tank for obvious wear or potential leaks. Repair or replace parts as necessary and document actions in Equipment Maintenance log.

3. Refer to the protocol for any specified application requirements. Select the appropriate type of nozzle, which is based on the pesticide formulation, the application method, the pressure setting and the dilution volume (e.g., gal/acre).

4. Use of calibration method suitable to the application and the equipment used.

5. Establish volume per acre. Standard operating procedures and/or protocols dictate pre-determined volume per acre in most cases. The standard volume per acre for the NFIFRC is 30 G/A at 3 mph. Calibrate to the NFIFRC standard settings, unless different settings are specified or selected form the trial protocol.

   Example:
   Protocol calls for material to be applied in 30 gallons of water per acre.
   (Use 1.0 gallon = 3785 ml., 1 acre = 43560 $ft.^2$)

$$\frac{30\ gal}{1\ acre} = \frac{113550\ ml.}{1\ acre} = \frac{1113550\ ml.}{43560\ ft.^2}$$

   *If Gal/Acre not specified can determine existing delivery rate in Gal/Acre and base mix dilution upon delivery rate in calculations. Collect for 60 seconds output of sprayer in ml. divide by 3785 ml./Gal to obtain Gallons per minute (GPM) and utilize the following equation to determine G/A: G/A = 5940 X GPM (per nozzle) / MPH X W (inches).

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Revision Number: 8 SOP#: 5.1

Title: Commodity production and maintenance.

Purpose: Assure that commodities are grown under best management practices.

Scope: All GLP trials grown under the management of the NFIFRC.

Procedures:

1. NFIFRC personnel will have on hand or know where to obtain up-to-date information on the production of the commodity under study. If no published material is available consult with a Cooperative Extension Specialist familiar with the commodity.

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

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

4. Determine the correct species and variety to use as specified by the study protocol. If the variety is not specified, determine the variety most commonly used in the area by commercial producers and use it for the trial(s). If a commercial producer is providing the plants, try to select plants as uniform in growth and color as possible.

5. Determine within and between row spacing and seed depth as specified in cooperative extension services recommendations.

6. Apply appropriate maintenance pesticides (preplant herbicide, soil insecticide, fungicide drench, soil-incorporate nematicide etc.) as required. Document maintenance chemicals in the field data notebook.

7. If pesticides are applied to the commodity to prevent losses due to pests not under trial(s), they will be applied according to the label directions. If this is a residue trial(s), no pesticide will be applied that would interfere with the chemical analysis of the pesticide under trial(s). If in doubt, consult the Study Director or analytical laboratory identified in the protocol to determine if a maintenance chemical may be used.

8. Perform other agricultural cultural practices as necessary to establish and maintain the commodity started.

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Revision Number: 8 SOP#: 5.2

Title: Determining yield or quality.

Purpose: To assure that a measurement of yield or quality of the various treatments is taken if required to evaluate the effects of the treatments.

Scope: All trials conducted by the NFIFRC which require yield and/or quality data.

Procedures:

1. Where possible, obtain an up-to-date copy of the United States standards for grades of the commodity under trial(s) from the Agricultural Marketing Service or other sources. If U.S. grade standards do not exist, then consult other sources and document the plant stage, fruit ripeness, or other characteristics needed to determine quality in the field data notebook.

2. Check the protocol for information on time of harvest. If none, then follow commercial practices in the area for the time of harvest of the commodity. These practices will be documented in the field data notebook.

3. Where grading standards are known or exist, the commodity should be graded accordingly at harvest to segregate the harvest to measure quality.

4. Each portion of the commodity, divided as to its quality standard, should be weighed or measured to determine yield. Written records should be kept of each measurement for each plot.

5. Various methods are utilized by various researchers to harvest a commodity. The method used if not specified in the protocol, will be recorded in the field data notebook.

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Revision Number: 9 SOP#: 6.1

Title: Adding a test substance concentrate to a carrier in the spray tank of a sprayer.

Purpose: To obtain the proper dilution and mixing of the concentrate in a liquid sprayer conducted by the NFIFRC.

Scope: All trials requiring dilution and mixing of a concentrate in a liquid sprayer conducted by the NFIFRC.

Procedures:

1. After the sprayer has been inspected and calibrated, empty the water from the tank.
2. Measure the amount of water needed to dilute the measured amount of concentrate into a separate container. Make sure the spray mix will be enough to cover at least one treatment plot (preferably all plots in one treatment). Make sure the spray tank will hold this amount and the concentrate. For tractor mounted sprayers or large tanks add ½ the water to the spray tank. Do not add water to backpack sprayers as the first step.
3. If needed (i.e. wettable powder formulation) make a slurry mix first by adding the concentrate to a small volume of water in a separate, clean container. Add the pesticide concentrate or slurry to the water in the spray tank. Triple rinse the container holding the pesticide concentrate (and slurry) using the other ½ of the water not in the spray tank and add the rinse water to the spray tank.
4. Add the remaining water to the spray tank. Close and tighten the lid.
5. Agitate the spray mix before and during application to insure an even mix of the pesticide and water.

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Revision Number: 8 SOP#: 6.2

Title: Procedures for the application of the trial(s) pesticide(s) in the field and greenhouse.

Purpose: To assure that the trial(s) pesticide(s) are applied uniformly to the plots.

Scope: All trials conducted by the NFIFRC.

Procedures:

1. Ensure all settings of pressure, speed, granular flow etc. are set according to specification from the calibration as previously performed.
2. In preparation for application, prime application equipment to ensure no air is in the equipment lines.
3. Just before entering each plot agitate tank mix, and begin application. Maintain the correct speed through the plot.
4. Apply the material according to the directions in the protocol or as specified on the label. If fumigants or mist blowers are used, follow instructions of the manufacturer of the equipment. If a fumigant is used, two people are required, one doing the actual application and one who can observe from a safe place to provide rescue assistance if necessary.
5. Calculations should be made to minimize the amount of spray material left in the spray equipment. This residue should be sprayed onto a similar crop or fallow land or disposed of according to current policies and guidelines of the research testing facility.

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Revision Number: 8 SOP#: 6.3

Title: Cleanup of application equipment.

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

Scope: All application equipment used by the NFIFRC.

Procedures:

1. For granules- Remove any excess granules and dispose of the excess by using appropriate methods for handling hazardous wastes. Note in the field data book the amount of granular material used in the trial(s).

2. Unused spray material should be applied to a labeled crop or fallow land at a distance adequate to prevent contamination of plots in the trial by drift or downslope movement of water.

3. In a suitable area away from aquatic areas or danger of aquatic contamination, hose down the granular applicator to remove pesticide dust from the inside and outside. Soapy water will be added to the spray container and then sprayed out on the labeled crop or fallow land. Then, triple wash sprayers and apply each wash to a crop on the pesticide label or to fallow land.

4. If an appropriate crop or fallow land is not available, then follow the disposal procedures for pesticide rinse water in accordance with the product label.

5. Dispose of expendable protective clothing according to the product label. Clean non-disposable items following the manufacturer's instructions or with soap and water if instructions are not provided.

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

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Revision Number: 8 SOP#: 6.4

Title: Handling the test substance and adjuvants.

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

Scope: All test substances used by the NFIFRC.

Procedures:

1. When the test substance is received, fill out PART 4. TEST SUBSTANCE RECORDS in the IR-4 FIELD DATA BOOK. Also enter the material in the NFIFRC GLP Materials Logbook.

2. The test substance will be stored in the pesticide storage facility until it is needed for use in the trial(s). When a test substance is used, the date, amount used, purpose of use, and initials of the user will be recorded in the IR-4 FIELD DATA BOOK, PART 4. TEST SUBSTANCE RECORDS.

3. The temperature within the storage facility will be monitored by a temperature monitoring device (such as a data logger) which allows recording of the minimum and maximum temperature range within the facility.

    a. If using a data logger to monitor temperature, units will be downloaded every first working day of the month, except on holidays or if field personnel are on leave , in which case the data will be downloaded upon field personnel's return to the office or shortly thereafter.
    b. Two data loggers [e.g. Dickson data logger, primary system] and a back up data logger [e.g. Dickson data logger] will be set to record the prevailing temperature in the pesticide storage area. Should the Dickson unit (primary) fail to record information, the backup unit (Dickson data logger) data will be used in place. The back-up Dickson unit should be reset each time the primary temperature monitoring device is downloaded.
    c. A min/max thermometer will also be set up in the cabinet as a tertiary backup. The temperatures reported from the min/max thermometer will be recorded at a maximum interval of two weeks.

4. The field center has two Dickson Remote Temperature data loggers. Both units run simultaneously one serving as the primary and one as the backup. The Dickson Remote Data logger services the general pesticide storage bay and a mini refrigerator that is located inside the storage bay. The Dickson Remote Data logger has a 2- probe system where the logger can monitor both the general area and the mini-refrigerator independently, but simultaneously. In case of failure, the backup Dickson Data logger is available to pull temperature data from.

5. If a test substance is removed or transferred to a different location for a period of time, record in all appropriate field data books and the NFIFRC GLP Materials logbook the date and purpose for which it is removed and the date when it is returned to the NFIFRC Pesticide Storage Facility.

6. All test substance containers must be stored until notification by the Study Director or Regional Field Coordinator that the containers may be discarded, unless the containers were returned to the registrant or sponsor.

7. Adjuvants will be handled in similar manner as test substances

    a. Adjuvants must be labeled with the name, concentration, storage conditions, and expiration date. If an expiration date is not given then a date 5 years after purchasing the adjuvant can be assigned as an expiration date. If storage conditions are not provided then recipient may assign conditions as "store ambient."

    b. Adjuvants will be stored in the secured area, but in a different location of the storage bay to prevent cross contamination with test substances. The storage area must be secure and all adjuvants will be temperature monitored utilizing the system described for test substances.

    c. Spray adjuvants will be in good condition prior to use- the physical characteristics of the additive should not have changed from purchase or be compromised (i.e. different color, consistency [cloudy, darkened] or smell or appear rancid).

    d. Spray additives will be dispensed into a temporary container (such as a beaker) prior to being used in a GLP residue trial. The spray additive once dispensed will not be used for a different trial or returned to the original or secondary container; it will be discarded. Spray additives will be dispensed from the original or secondary spray additive container using a factory sealed newly opened pipette or syringe. After this pipette or syringe is used it is discarded and never used again. This pipette or syringe never returns to the spray additive container. The Test substance is also dispensed by a different newly opened pipette or syringe, discarded after use.

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Revision Number: 8 SOP#: 6.5

Title: Procedures to follow when a problem occurs in the application of the test substance.

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

Scope: All trials performed by the NFIFRC.

Procedures:

1. During application, the operator will observe the process to assure that the test substance is being evenly distributed to the crop.

2. If something goes wrong, for example, a nozzle is plugged or a hose breaks, then the operator will take immediate action to correct the situation. This is considered non-routine maintenance.

3. The affected portion of the plot will be carefully marked off to indicate the area affected. This portion will not be used for obtaining samples of the commodity for residue analysis. If the unaffected area is too small to obtain the samples required for analysis, the Study Director will be contacted to determine the impact on the trial and whether the trial must be terminated.

4. Appropriate individuals (e.g., the Regional Field Coordinator, and the Study Director) will be notified of the incident, details recorded in the field data notebook, and appropriate non-routine maintenance records will be entered in the corresponding logbooks.

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Revision Number: 8 SOP#: 7.1

Title: Electronic collection of raw data.

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

Scope: All trials performed at the NFIFRC.

Procedures:
1. Due to usage of Electronic Field Data Books in limited trials, Data will be recorded upon the pages using an electronic pen in much of the same manner as is done with current Non-electronic Field Data Books.

2. Training will be provided and instruction on how to utilize this notebook in the field and procedures of handling the books.

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Revision Number: 8 SOP#: 7.2

Title: Recording of raw data.

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

Scope: All raw data pertaining to GLP trials at the NFIFRC.

Procedures:

1. All raw data will be recorded in indelible ink, preferably blue.

2. Changes to the raw data can only be made by drawing a single line through the original entry so as not to obscure it. The date, signature (or initials) and reasons for change (brief description or error code) must accompany any change. Acceptable error codes include:

ME = Measurement Error	CE = Calculation Error
SP = Spelling Error	EE = Entry Error
WE = Wrong Entry	IC = Incorrect Comment
IE = Illegible Entry	IW = Inappropriate Word
TE = Transcription Error	AW = Accidental Write over
UE = Unnecessary Entry	PE = Pagination Error

   Other error codes can be used, however, the codes must be noted in the IR-4 Field Data Book.

3. Pages containing raw data will not be discarded.

4. Cross-reference instrument or statistical printouts when such data are retained in a separate location.

5. All data entries will be dated on the day of entry and signed or initialed by the person entering the data.

6. Make sure that all data required by the study protocol or by the forms provided in the field data book are collected and recorded.

7. Run-on emails will be copied at the conclusion of the string of communication insuring all communication has been captured. Additionally, all questions will be answered during the coarse of email correspondence.

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Revision Number: 8 SOP#: 7.3

Title: Calculations for Data Presentation.

Purpose: To establish guidelines for computation and presentation of data.

Scope: All trials conducted at the NFIFRC.

Procedures:

1. Results must be reported to the correct number of significant figures to reflect an appropriate level of certainty.

2. In carrying measured quantities through calculations, the following rules are used:

    a. Multiplication and division: the result must be rounded off as having no more significant figures than the measurement with the fewest significant figures.

    b. Addition and subtraction: the result is rounded off to the same number of decimal places as that of the term with the least number of decimal places.

3. Round-off rules:

    a. If the first digit to be dropped is less than 5, round down.

    b. If the first digit to be dropped is great than or equal to 5, round up.

4. When a manual calculation involves two or more steps, retain at least one additional digit (insignificant figure) for intermediate answers. Round off at the end of the calculation.

5. In using computer and/or calculator, calculation round off is usually done at the display and serial calculations are done with unrounded numbers. Round off the final results.

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Revision Number: 9 SOP#: 7.4

Title: Method for collecting phytotoxicity data.

Purpose: To describe the procedure used for taking pesticide phytotoxicity data.

Scope: All magnitude of residue trials conducted at the NFIFRC.

Procedures:

1. Consult the protocol to determine the method of the phytotoxicity data. If no method is cited, then define a method and record the method in the field data notebook or proceed as follows.

2. Take phytotoxicity data after the first application of the test substance. Observe treated plots after each subsequent application. If no phytotoxicity symptoms are apparent, then 1 written record of phytotoxicity ratings is sufficient. If symptoms are apparent, then record ratings after each application of the test substance or periodically during crop growth.

3. Phytotoxicity ratings will be recorded in the IR-4 Field Data Book Part 3 as raw data.

4. Record phytotoxicity data on a scale of 0 to 100 where 0 = no phytotoxicity, and 100 = dead plants. Ratings are based on percentage of phytotoxicity per plot.

5. Record the symptom(s) observed and the rating value for each symptom in each plot.

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Revision Number: 8 SOP#: 7.5

Title: Experimental Design and Data Analysis.

Purpose: To assure that all data developed are statistically valid for studies designed for statistical evaluation of field data as specified in trial protocol.

Scope: All GLP trials conducted by the NFIFRC that are designed for statistical evaluation of field data.

Procedures:

1. The experimental design as specified by the protocol will be used. If none is designate, then the researcher should use a commonly accepted experimental design such as a complete randomized block design. The experimental design used will be documented in the field data notebook.

2. A minimum of 3 replicates should be used (4 is preferred). No replicates or statistical analysis are required where the trial(s) is for magnitude of the residue only.

3. Draw a plot map showing the location of each plot in the site selected for testing as described under SOP 3.2.

4. Randomly assign the treatments to the plots using a random number table or random number generator. Note the location of the treatments on the plot map. Retain the plot map in the field data notebook.

5. Determine the level of significance for the trial(s).

6. Select an appropriate statistical package for data analysis and record sufficient information to identify the statistical package (i.e. Data, Revision no., Title, Authors, Source etc.).

7. When the raw data are available for analysis, utilize the statistical package and follow instructions contained therein to conduct an analysis of variance and mean separation of the data.

8. Record the data as required on the appropriate forms and identify statistically significant differences in the data in the raw data note book.

9. Retain all data, analysis, notes etc. in the trial(s) folder with sufficient information to recalculate the data summaries and statistical analysis by another person without verbal input.

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Revision Number: 8 SOP#: 7.6

Title: Data storage during the active life of the project.

Purpose: To assure that all data resulting from the trial(s) is retained and usable.

Scope: All trials conducted by the NFIFRC.

Procedures:

1. It is the responsibility of the Field Research Director to see that all raw data, and other items connected with the trial(s) are properly retained.

2. The Field Research Director will see that a separate Field Data Book is maintained during the active life of each project for which he/she is responsible. The Field Data Book will contain all raw data specific to that trial and certified copies of raw data specific to the facility that is pertinent to the trial.

3. All pertinent raw data will be placed in the field data book as soon as possible after the information is generated.

4. All raw data will be clearly marked with the protocol number and field id number, the date generated, and any other information that may be needed to understand the data and its source.

5. Computer software or on-line programs such as SAS used in the trial(s) should be noted in the raw data notebook and software application information including the title, source, revision or other identifying information should be recorded. The data generated from these programs should be maintained in the field data book.

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Revision Number: 8 SOP#: 8.1

Title: Sample collection, identification, and records.

Purpose: To assure proper collection and identification of residue samples.

Scope: All residue trials conducted by the NFIFRC.

Procedures:

1. Consult the study protocol to establish specific dates and method for the collection of samples. If these dates are based on uncontrolled events (fruit size, spray application etc.) then tentative dates will be established in the NFIFRC master schedule and refined as necessary.

2. Samples should not be taken during periods of inclement weather.

3. Representative samples of the crop in each plot must be taken by a recognized procedure. Follow the protocol or record in the field data book the procedure used to ensure a representative sample.

4. Consult the study protocol to determine sample size and special instructions for the commodity.

5. Consult the study protocol for the sample inventory. Sample each replicate individually beginning with the untreated plots and working up the highest dosage. Treatments from each replicate will be individually packaged and labeled.

6. Take special care to do the following in the sample collection process:

    a. Avoid contamination of the field samples with the test substance during the sampling, labeling, storage, and shipping processes.

    b. Avoid taking diseased or undersized crop parts.

    c. Take care not to remove surface residues during handling, packing, or preparation.

    d. Be certain that harvesting tools are clean.

    e. Do not remove any soil or plant parts or trim the commodity unless it is so specified in the study protocol (leave stem in cherry, outer leaves of lettuce on etc. unless specified otherwise in the protocol.) Note any cleaning or trimming in the field data notebook.

7. Plastic-lined cloth sampling bags with an identification tag sewn into the bottom stitching are usually provided to GLP cooperators for sample collection. If these bags have not been provided, a sampling bag suitable to protect the integrity of the sample

should be used. Sample bags should be burst proof. Cloth laminated plastic bags are preferred.

8. Prior to sample collection, prepare a sufficient number of sample bags to collect all the samples required in the sample inventory. Use a paint pen or permanent marker to label each sample bag with the study ID number, sample number/letter, test substance and rate applied, crop and date of harvest. Include a bag number on the tag if more than one bag is used for the plot sample.

9. Included the same information as on the sample identification tag on a separate piece of paper. Place this duplicate identification tag in separate piece of paper. Place this duplicate identification tag in a moisture-proof container (e.g. plastic zip-lock bag) and place it inside the sample bag. This is an important step since the label on the outside of the bag may get lost during handling and transport.

10. After sampling is complete, record harvest and sampling information in the Field Data Book PART 7. SAMPLE COLLECTION AND STORAGE. The forms will be signed and dated by the Field Research Director or person entering the data.

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Revision Number: 8 SOP#: 8.2

Title: Sample packing and storage procedures.

Purpose: To assure the integrity of the samples after collection

Scope: All residue trials conducted by the NFIFRC.

Procedures:

1. Containers will be of sufficient size and burst proof strength to hold the samples. Separate containers will be used to hold samples from treated and control plots. Containers will be labeled "Treated" or "Untreated" to indicate which samples they will contain. If samples require refrigeration or freezing prior to shipment to the residue laboratory, then ice, blue ice, or dry ice in sufficient quantity to preserve the samples prior to storage will be taken to the field site in the containers.

2. Carefully place the sample as it is collected in the sample bag marked for the sample. Make sure that the extra labeling in the bag is enclosed with the sample.

3. Close the sample bag so as to prevent loss of the sample under reasonable storage, handling, and transportation conditions. Excess air should be expelled from the bag.

4. Place the sample bag in the appropriate container as determined in #1 above. Physically separate treated and untreated samples.

5. When sample collection is completed, the samples will be returned from the field to be placed in storage.

6. Consult the study protocol for the method, temperature, and maximum length of time for storage. If specification is not given in the protocol use the following as a rule of thumb for maximum temperature and storage times: -20°C. for frozen commodities, 4°C. and 14 days for refrigerated commodities and 25°C. And 2 days for commodities held at room temperature.

7. Samples identified for post-harvest processing will be process or shipped to the processor as soon after collection as possible.

8. Samples which are to be frozen before shipping will be place in the appropriate freezers at the NFIFRC offices. There are two freezers at the NFIFRC office building #7507, on ("Untreated-1") for samples from untreated control plots and on ("Treated-1") for samples from treated plots.

9. When samples are placed in the NFIRC freezers they will be logged into the appropriate freezer logbook.

10. The storage temperature of the samples will be constantly monitored by a temperature monitoring device (such as a data logger) which allows recording of the minimum and maximum temperature range within the freezers.

    a. If using a data logger to monitor temperature, units will be downloaded every first working day of the month, except on holidays or if field personnel are on leave , in which case the data will be downloaded upon field personnel's return to the office or shortly thereafter.
    b. Two data loggers [e.g. Dickson data logger, primary system] and a back up data logger [e.g. Dickson data logger] will be set to record the prevailing temperature in the pesticide storage area. Should the Dickson unit (primary) fail to record information, the backup unit (Dickson data logger) data will be used in place. The back-up Dickson unit should be reset each time the primary temperature monitoring device is downloaded.
    c. A min/max thermometer will also be set up in the cabinet as a tertiary backup. The temperatures reported from the min/max thermometer will be recorded at a maximum interval of two weeks.

    The field center has two Dickson Remote Temperature data loggers. Both units run simultaneously one serving as the primary and one as the backup. The Dickson Remote Data logger services both the untreated and treated freezers. The Dickson Remote data loggers have a 2- probe system where the logger can monitor both the treated and untreated freezers independently, but simultaneously. In case of failure, the backup Dickson Data logger is available to pull temperature data from. The date, initials, and data logger ID will be written on the charts when they are inserted into the log books. Data logger calibration and maintenance information is in SOP 4.7.

11. The freezers where the samples are stored are under lock and key with limited access. These freezers are only used for IR-4 trials.

12. A freezer logbook is maintained for each freezer. The logbook includes the freezer contents log, maintenance and repair logs for the freezer and calibration and maintenance logs for the associated data logger. Data logger charts are maintained in the freezer logbook until filed at the end of the year in the NFIFRC Archives. The freezer contents log lists the items inside the freezer indicating the Study ID No., date the sample was added and removed from the freezer, and the sample destination (disposition). As routine maintenance, the freezers are defrosted and cleaned annually. Any non-routine maintenance, prompted by failure or malfunction of the freezers or Data loggers is also recorded.

13. When no residue samples are stored in the freezer, the freezer temperature does not have to be recorded.

14. In case if an emergency with the freezers, NFIFRC personnel will be contacted by the data logger when temperatures have exceeded acceptable temperatures. A back up alarm system using the Sensaphone Model 1104 is set up to contact NFIFRC personnel. If the

back-up power is insufficient, the freezer contents integrity will be maintained by either loading freezers with dry ice in a 3:1 ratio of dry ice to contents weight or transported in ice chests to the IR-4 Freezers at the IFAS Food and Environmental Toxicology Lab on the University of Florida campus. In such an event, theses samples will be transported in ice chests with dry ice in a 3:1 ratio of dry ice to sample weight if possible.

15. The Sensaphone Model 1104 will be tested once every 2-3 months to ensure that the performing properly. The information will be logged into the Sensaphone Alarm logbook. Additionally, Min/Max thermometers will be placed in the NFIFRC freezers and will be read once a month and recorded into the Equipment Maintenance logbook.

16. An automatic generator will power the NFIFRC freezers when the power goes out at the NFIFRC facility. This generator will be check by "farm staff" as needed and "farm staff" will write in activities performed directly into Equipment Maintenance logbook.

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Revision Number: 9 SOP#: 8.3

Title: Sample shipping procedures.

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

Scope: All residue trials conducted by the NFIFRC.

Procedures:

1. Follow study protocol directions, noting any requirements on duration from harvest to shipping. If required in the study protocol, contact the residue laboratory person designated for specific shipping instructions. Air freight shipments should be made on Monday or Tuesday to avoid potential weekend layovers, and shipment during holidays should be avoided.

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

3. Obtain insulated containers, if necessary, of sufficient size and quantity to hold the residue samples and dry ice (where required) in a 4:1 weight ratio of dry ice to commodity per 24hrs of travel. Pack the samples and dry ice in the containers just prior to shipment. The containers should have sufficient bursting strength so as to withstand normal handling in shipping and storage.

4. Complete the Field Data Book Part 8: Residue Sample Shipping form(s). Place a copy of the residue sample shipping forms 8B and 8C in a waterproof container (e.g. sealed plastic bag) and place it in each of the sample shipping containers. Send a copy of the Residue Sample Shipping form(s) to the Regional Field Coordinator.

5. Label each container with the following information:
   a. Study Identification Number, Pesticide, and Commodity.
   b. Return Name and Address of the sender.
   c. Name and Address of the residue laboratory receiving the samples.
   d. Number of the container if more than one is used, label as Box ___ of ___.
   e. Where used, note "Dry Ice" on two sides of the container.

6. Tie or tape lids of each container firmly in place.

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

8. Provide the carrier with the samples for shipment.

9. Call the designated person at the Residue Analytical Laboratory or disposition site to inform them of the date of shipment of the samples. Provide the study ID number, the test substance, commodity, and shipping carrier.

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Revision Number: 8 SOP#: 9.1

Title: Raw data report forms.

Purpose: To review the forms used to report raw data.

Scope: All trials performed by the NFIFRC.

Procedures:

1. IR-4 Headquarters provides a field data book to each of the cooperators for each trial undertaken. Detailed instructions are provided in the book.
2. All forms will be filled out legibly and mistakes will be crossed with a single line, initial, dated, and the reason for change given.
3. Blank forms may be photocopied as needed.
4. The reporting forms as provided in the field data book will be filled out as completely as possible at the time the data is collected. Transcribing data is not acceptable.
5. The NFIFRC will use the forms provided or develop new forms where needed. Any new forms will be placed in the field data book.
6. If a particular form or section of the form does not require a response, make a slashed line (diagonal line from the top of the page or field to the bottom). Initial and date on the slashed line or sign and date at the bottom of the page.
7. Number each form (Part __ page __) within each part of the raw data book.
8. If data are recorded elsewhere, other than the raw-data book, date and sign data entries, and include true copies in the data book.

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Revision Number: 8 SOP#: 9.2

Title: Handling completed report forms that transcend two or more trial(s).

Purpose: To explain how report forms can be completed for one trial(s) and serve as raw data for other trial(s).

Scope: All trials conducted by the NFIFRC.

Background: Where a Field Research Director is conducting multiple trial(s) during the year, there may be an opportunity to utilize one form for data that pertains to more than one trial(s). Examples may be logs of various types, weather data, and sprayer calibration/pesticide application where the same test substance is used at the same time at the same rates on two or more crops (i.e. preplant herbicide, foliar insecticide). There are provisions within the GLPs for substitution of verified copies for original records. However, the retention of all original raw data is also a requirement. The following procedures are designed to meet the GLP and FIFRA requirements where copies of data are used.

Procedures:

1. Each form that is to be used for data common to more than one trial(s) should contain a notation at the bottom of the form as to the location of the original, raw data. This statement should read: "The original is in _____". Note the Field Data Book number or other site where the original raw data is maintained at the time of completing the form.

2. When the form is completed it will be photocopied. Each copy will contain a notation that this is a true or exact copy. The copy will be signed, dated, and placed in the field data books for the other trial(s) that utilize the same data.

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Revision Number: 8 SOP#: 9.3

Title: Disposition of raw data from the trial(s).

Purpose: To assure that raw data is properly archived.

Scope: All raw data generated by the NFIFRC.

Procedures:

1. The Field Research Director should make an exact copy of the original raw data in the completed Field Data books. This data should include correspondence, protocol deviation forms, logs, and any accompanying documentation such as weather charts etc. The original raw data and true copies of site-specific documents from the trial(s) will be forwarded in the Field Data books by the Field Research Director to the Regional Field Coordinator.

2. The Regional Field Coordinator or person designated by him/her will review the documents received for completeness and accuracy of reporting. The Regional Field Coordinator or person designated by him/her will follow up to obtain any missing data. The Field Data books will be forwarded to the Quality Assurance Unit. After Quality Assurance review, the Field Data books will be sent to the Study Director.

3. The Field Research Director will place a true copy of each Field Data book and the original raw data of site-specific documents in the appropriate section of the NFIFRC Archives. The Archives are maintained under lock and key at the NFIFRC offices, 2556 W. Hwy. 318 Citra, Florida 32113-2132.

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Revision Number: 8 SOP#: 9.4

Title: Retention of data.

Purpose: To assure all data and documents connected with the trial(s) are properly retained for the life of the registration and the Study Director indicates that all data has been archived at national headquarters.

Scope: All raw data generated by the NFIFRC.

Procedures:

1. The Field Research Director will see that the Field Data Book(s) for each trial is submitted to the Regional Field Coordinator for review and archiving. The Field Research Director will also retain a true copy of each Field Data book and archive original site-specific documents at the field facility to assure that raw data are not lost.

2. The Field Research Director should maintain a file and items placed in the files should be identified as to the trial(s) they pertain to or the dates when the items were in use. The following is a list of information that should be retained:

   a. Raw data or true copies of raw data including weather records, logs of instrument calibration and test substance receipt, distribution, etc.

   b. Copies of summaries including calculations and copies of information used form reference sources.

   c. Copies of reports and correspondence related to the conduct of the trial(s).

   d. Copies of completed forms used during the trial(s) and for summaries of the trial(s) data.

   e. Historical Standard Operating Procedures.

   f. Master schedule of all GLP trial(s) conducted by the facility personnel.

   g. Organizational charts, training records, job descriptions, and CV's (current, out of date, and former employees).

   h. Copies of computer software and/or information sufficient to identify outdated computer software or programs that were used in trial(s) so that the data developed from these programs can be repeated if necessary in re-construction of the trial(s).

   i. Any samples as required by the study protocol or the Study Director.

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Revision Number: 9 SOP#: 9.5

Title: General procedures- Archives.

Purpose: To assure the NFIFRC establishes and maintains an archives facility for retention of all data and documents connected with the program.

Scope: All raw data generated by the NFIFRC.

Procedures:

1. NFIFRC archives are located within the NFIFRC in fire-proof cabinets at the University of Florida, Plant Science Research and Education Unit, 2556 W. Hwy. 318, Citra, Florida 32113-2132.

2. The NFIFRC Research Center Director is responsible for the archives and will designate and Archives Librarian and backup archivist.

3. Each Field Research Director will be responsible for seeing that the field data notebook containing the raw data, copies of reports, logs, etc. are submitted for archiving and a true copy place in the NFIFRC archives.

4. The archives may be used only by those persons so authorized by the Field Research Director. The names of authorized users will be on file with the Archives Librarian.

5. For certain information, (e.g. computer printouts, personnel training certificates, weather records, maintenance pesticide records) NFIFRC defines the copies filed on NFIFRC archives as original raw data.

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Revision Number: 8 SOP#: 10.1

Title: Disposal of pesticides

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

Scope: All pesticides used by the NFIFRC.

Procedures:

1. Where institutional policies and guidelines do not exist, the following procedures should be followed.

2. Disposal of pesticide concentrate and/or containers.

   a. Follow procedures in the trial protocol. Generally, containers cannot be disposed of under GLP until the study is completed. If it is necessary to dispose of the container prior to the end of the trial(s), the Study Director will be consulted.

   b. Where possible, the pesticide concentrate and containers should be returned to the registrant or manufacturer. Transportation must be according to all Federal, State, and local laws and regulations.

   c. Follow label directions for use or disposal of the pesticide if option 2.b is not available. If no label directions exist for disposal, arrangements should be made with the University of Florida Hazardous Materials Management office or a licensed waste disposal firm for pickup and disposal of the pesticide and/or the empty containers.

3. Disposal of pesticide rinse water, unused spray solutions and other dilute pesticide waste.
   a. Check State and local laws and regulations to determine any procedures that may exist for proper disposal of pesticide solutions.

   b. Dispose of the dilute pesticide waste in the field by adding to the spray tank and spraying on a labeled crop or fallow land where this procedure does not violate any laws or regulations. All pesticide solutions should be mixed with the intent of limiting excess solutions.

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Revision Number: 8 SOP#: 11.1

Title: Safety and health procedures in handling pesticides.

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

Scope: All pesticide use by NFIFRC personnel.

Procedures:

1. Where institutional policies and guidelines do not exist, the following procedures should be followed.

2. A supply of soap/detergent and water will be readily accessible for cleanup in the case of an emergency.

3. All personal protective equipment (PPE) and clothing as required by the label or facility SOPs will be worn in the handling of pesticides for storage, mixing and application. Emergency personal protective equipment must be available when handling hazardous pesticides such as restricted use pesticides.

4. Appropriate weather conditions for the application of the pesticide should prevail otherwise the pesticide applications should be delayed.

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

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

7. All pesticides should be mixed in quantities which are adequate for the job to avoid excess dilute solutions. Cleanup procedures are established whereby excess sprays can be safely discarded preferably by spraying the material on a labeled crop or fallow land. The equipment will be washed off both inside and outside and all pesticide containers will be returned to a storage area immediately after use.

8. At the end of the working day it is recommended that employees who have applied or mixed pesticides should take a shower and change and wash clothes.

9. A pesticide-treated area, greenhouse, or field will not be entered until adequate time, as specified on the label of the pesticide, has passed for re-entry to the treated area. Follow label requirements for personal protective equipment when a treated area must be

entered prior to the re-entry interval (REI). For persons who regularly handle organophosphates and/or large quantities of carbamates, a cholinesterase level should be determined biannually.

10. a. Pesticide storage room is kept under lock and key with limited access.

    b. Unauthorized persons are not allowed in the pesticide storage area.

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

12. Do not drink, eat food, smoke, apply cosmetics, or use tobacco in area where pesticides are stored.

13. Wear unlined protective gloves while handling containers and mixing or measuring pesticides.

14. Do not put fingers in mouth or rub eyes while working with pesticides. Wash hand thoroughly with soap and water immediately after handling pesticides and, especially before eating, smoking, or using the toilet.

15. The local fire department has been provided with the location of the pesticide storage area. The home telephone of the persons responsible for the pesticide storage facility are posted inside the storage area door.

16. Treated fields will be posted with warning signs.

17. Pesticide storage areas will be properly ventilated.

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Revision Number: 8 SOP#: 12.1

Title: Procedures to follow prior to an EPA inspection.

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

Scope: All personnel at the NFIFRC.

Procedures:

1. Notify the study director, Quality Assurance Officer, and other interested personnel of the pending audit or review as soon as possible.

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

3. Make sure the Field Research Director or other personnel authorized to accept the Notice of Inspection will be present at the start and finish of the inspection.

4. Prepare trial(s) and/or facilities personnel for the inspection.

    a. Review position descriptions with technical personnel so they understand and can explain their role in the trail(s).

    b. Discuss possible questions that may likely come up about the trial(s) or facility and make sure every on understands what to expect.

    c. Request personnel to answer the questions only to the extent needed and not to provide extraneous information. Do not volunteer information; keep answers direct and to the point.

    d. Make certain that technical personnel know the safety precautions needed for the work area.

    e. Be certain that all documents pertaining to the trial(s)/facilities inspection are available. This would include:

        1) Master schedules for both the Field Research Director, Quality Assurance Officer and possibly the Regional Field Coordinator and IR-4 headquarters.

        2) Study Protocol and Standard Operating Procedures.

        3) Raw data, correspondence, and logs.

        4) Training records, CVs, job descriptions, etc. of personnel assigned to the trial(s).

5) Appropriate chain of custody documents for Field Data books.

6) Freezer logs including contents and temperature documentation.

7) Documentation of the test substance characterization (if available), receipt, handling, and storage records.

8) Calibration logs on equipment such as balances and application equipment.

9) Archives or storage of records and logs indicating removal and replacement of documents.

5. Have organization charts accessible, and a map of the facility and any information specific to the facility or area that will make the inspection go smoother.

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Revision Number: 8 SOP#: 12.2

Title: Procedures to follow during an EPA inspection.

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

Scope: All personnel at the NFIFRC.

Procedures:

1. Greet the inspection team and follow any institutional procedures for signing in. Provide name tags and escort the entire group to a conference or meeting room.
2. At the opening of the conference ask the lead inspector for his credentials and for any opening statements.
3. Introduce the facility personnel present and state their function in the facility of trial(s). Identify the person responsible who will accept the Notice of Inspection.
4. Distribute the organizational chart, map of the facility, and any other information previously prepared to make the inspection go smoother.
5. Ask the lead inspector for his/her agenda for the inspection as well as a list, if possible, of personnel conducting interviews during the inspection.
6. Explain any housekeeping rules such as the use of safety equipment in work area etc. to avoid any possible misunderstandings.
7. Proceed with the inspection.
    a. Provide documents requested and provide explanations needed.
    b. Keep notes of observations and of all interviews.
    c. Keep IR-4 management informed of the progress of the inspection and the findings.

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Revision Number: 8 SOP#: 12.3

Title: Procedures to follow after the EPA inspection.

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

Scope: All personnel at the NFIFRC.

Procedures:

1. Make sure that all personnel involved in the inspection are present for the closeout conference.
2. Clarify any discrepancies brought up during the exit interview and offer supporting documentation for clarification.
3. If you have corrected any problems during the inspection make sure the corrections are so noted in the inspector's logbook.
4. Have someone present take accurate notes during the close-out.
5. Be sure you obtain a copy of the list of documents or other materials that are taken as exhibits by the inspectors.
6. Debrief management, staff, and the Study Director with an explanation of any problems found.
7. Assign responsibility for preparation of possible solutions to problems and obtain time estimates for implementation.
8. Prepare any replies to the regulatory agency as necessary within a timely basis and keep interested parties such as the Study Director informed.