

February 15, 2012

Dr. Michelle Samuel-Foo
Food & Environmental Toxicology Laboratory
University of Florida
SW 23rd Drive, Bldg. 685
Gainesville, FL 32611

Dear Michelle,

For your review and approval is enclosed the original set of the 2012 SOP's for conducting trials for the IR-4 program at Texas AgriLife Research -Weslaco, TX.

Only SOP 8.1 and the organizational chart had a significant revision. SOP 8.1 - Section 10-making additional labeling of samples optional. Removed some names because personnel has changed.

If you approve the entire set of SOP's, you may sign the cover page to indicate this (SOP 1.1, Sect. 3) or sign each individual SOP. If you have any questions concerning an SOP, please notify me and we will discuss it.

After you complete your review, make copies as needed and please return the originals to me.

Thanks for your help.

Sincerely,



Lori Lynn Gregg
Texas AgriLife Research
2415 E. Bus. Hwy 83
Weslaco, TX 78596
Phone: 956-969-5655
lgregg@ag.tamu.edu

CHAIN OF CUSTODY for STANDARD OPERATING PROCEDURES

Effective Date: February 07, 2008

This is the Chain of Custody for this original set of Standard Operating Procedures (SOPs) affiliated with Texas AgriLife Research - Weslaco, TX. The Field Research Director shall start the custody log. When the SOPs original set is transferred to another individual, the sender must note to whom and when the set is sent. The recipient must sign the next block and date the form upon receipt.

Signature of Field Research Director: Lori Lynn Gregg Initials: LLG

Printed Name: LORI LYNN GREGG Date: Feb. 7, 2008

SOPs sent / given to: DR. CHARLES MEISTER Date Sent: FEB. 7, 2008

Signature of Recipient: Charles Meister Date Received: 2/10/08

Printed name of Recipient: Charles Meister Initials: CM

SOPs sent / given to: Lori Lynn Gregg Date Sent: 2-11-08

Signature of Recipient: Lori Lynn Gregg Date Received: 2-13-08

Printed name of Recipient: LORI LYNN GREGG Initials: LLG

SOPs sent / given to: Michelle Samuel-Foo Date Sent: 2-15-12

Signature of Recipient: Michelle Samuel-Foo Date Received: 2/20/12

Printed name of Recipient: Michelle Samuel-Foo Initials: MSF

SOPs sent / given to: Lori L. Gregg Date Sent: 2/20/12

Signature of Recipient: _____ Date Received: _____

Printed name of Recipient: _____ Initials: _____

SOPs sent / given to: _____ Date Sent: _____

Signature of Recipient: _____ Date Received: _____

Printed name of Recipient: _____ Initials: _____

SOPs sent / given to: _____ Date Sent: _____

Standard Operating Procedures
for
Magnitude of the Residue-Field Studies

Conducted by:

Texas AgriLife Research
2415 E. Bus. Hwy 83
Weslaco, TX 78596
(956) 969-5655 FAX# (956) 969-5655

Lori Lynn Gregg
Field Research Director


Signature

LLG
Initials

Feb. 15, 2012
Date

Reviewed and Approved by:

Dr. Michelle Samuel-Foo
Regional Field Coordinator


Signature

MSF
Initials

2/20/12
Date

Effective Date: February 15, 2012

Standard Operating Procedures Index for Texas AgriLife Research
 2415 E. Hwy 83 / Weslaco, Texas 78596
 Effective Date: February 07, 2008

SECTION	SOP#	REV#	TITLE
1. GENERAL	1.1	4	General requirements for the development and use of SOPs.
	1.2	3	Numbering system for SOPs.
	1.3	5	Format for use in developing SOPs.
	1.4	4	Format for use in revising SOPs.
	1.5	3	Designation of Field Research Director and responsibilities.
2. PERSONNEL	2.1	3	Personnel.
	2.2	3	Organizational chart.
	2.3	3	Documentation of training.
	2.4	1	Designation of personnel for duties.
3. FACILITIES	3.1	5	Test substance storage.
	3.2	3	Site Selection for field trial(s).
	3.3	3	Greenhouse / shadehouse facilities.
4. EQUIPMENT	4.1	3	Calibration and use of balance.
	4.2	2	Measuring liquid formulations.
	4.3	4	Calibration of liquid sprayers.
	4.4	3	Calibration and use of granular applicators.
	4.5	3	Operation and maintenance of farm equipment.
	4.6	3	Calibration of field instruments including GPS units.
	4.7	2	Calibration and use of temperature measuring devices.
	4.8	1	Calibration and use of hygrothermographs.
	4.9	2	Calibration and use of pH measuring devices.
	4.10	2	Calibration and use of wind measuring devices.
	4.11	1	Calibration and use of sling psychrometer.
	4.12	3	Calibration and use of temperature data logger devices.
	4.13	3	Operation and maintenance of refrigerator or freezer.
	4.14	1	Procedure used for collecting soil samples using ESP soil probe.
	4.15	1	Borrowed or rented equipment procedures and documentation.
5. TEST SYSTEMS ESTABLISHMENT AND MAINTENANCE	5.1	4	Commodity production and maintenance.
	5.2	2	Method for seeding or transplanting.
	5.3	2	Determining yield or quality.
	5.4	1	Method for collecting soil samples for analysis.
6. TEST SUBSTANCE APPLICATION AND HANDLING	6.1	2	Preparation of application mix.
	6.2	4	Procedure for application of test substance for trial(s).
	6.3	3	Cleanup of application equipment.
	6.4	4	Handling of test substance(s).
	6.5	3	Procedures to follow for misapplication of test substance.
	6.6	1	Disposal of pesticides.
	6.7	0	Procedure for dip, drench, and low volume application of test substance.
7. DATA COLLECTION, REPORTING, AND RETENTION.	7.1	3	Collection of raw data electronically.
	7.2	3	Recording of raw data.
	7.3	2	Calculations for data presentation.
	7.4	2	Method for collecting efficacy and phytotoxicity data.
	7.5	2	Experimental design and data analysis.
	7.6	3	Data storage during active life of project.
	7.7	1	Handling of raw data forms that transcends two or more trials.
	7.8	2	Disposal of raw data from the trial(s).
	7.9	1	Retention of data.
	7.10	1	Procedures for archiving.

SECTION	SOP#	REV#	TITLE
8. RESIDUE SAMPLE HANDLING	8.1	4	Sample collection, identification and records.
	8.2	4	Procedures for sample packing and storage.
	8.3	4	Procedures for sample shipping.
9. TRIAL CANCELLATION	9.1	1	Procedures to handle a failing or failed trial.
	9.2	2	Procedures to follow for a trial termination.
10. QUALITY ASSURANCE	10.1	1	Scope of quality assurance unit.
	10.2	1	Non-compliance with Good Laboratory Practices.
11. HEALTH AND PESITICIDE SAFETY	11.1	3	Guidelines for handling pesticides safely.
	11.2	2	Labeling and handling of reagents and/or solutions.
12. EPA AUDIT OR INSPECTION	12.1	4	Procedures to follow prior to an announced EPA inspection.
	12.2	2	Procedures to follow during an EPA inspection.
	12.3	2	Procedures to follow after an EPA inspection.
APPENDICES	A	- -	Organizational Chart (Updated Feb. 6, 2008)

Standard Operating Procedures Index for Texas AgriLife Research
 2415 E. Hwy 83 / Weslaco, Texas 78596
 Effective Date: February 15, 2012

SECTION	SOP#	REV#	TITLE
1. GENERAL	1.1	4	General requirements for the development and use of SOPs.
	1.2	3	Numbering system for SOPs.
	1.3	5	Format for use in developing SOPs.
	1.4	4	Format for use in revising SOPs.
	1.5	3	Designation of Field Research Director and responsibilities.
2. PERSONNEL	2.1	3	Personnel.
	2.2	3	Organizational chart.
	2.3	3	Documentation of training.
	2.4	1	Designation of personnel for duties.
3. FACILITIES	3.1	5	Test substance storage.
	3.2	3	Site Selection for field trial(s).
	3.3	3	Greenhouse / shadehouse facilities.
4. EQUIPMENT	4.1	3	Calibration and use of balance.
	4.2	2	Measuring liquid formulations.
	4.3	4	Calibration of liquid sprayers.
	4.4	3	Calibration and use of granular applicators.
	4.5	3	Operation and maintenance of farm equipment.
	4.6	3	Calibration of field instruments including GPS units.
	4.7	2	Calibration and use of temperature measuring devices.
	4.8	1	Calibration and use of hygrothermographs.
	4.9	2	Calibration and use of pH measuring devices.
	4.10	2	Calibration and use of wind measuring devices.
	4.11	1	Calibration and use of sling psychrometer.
	4.12	3	Calibration and use of temperature data logger devices.
	4.13	3	Operation and maintenance of refrigerator or freezer.
	4.14	1	Procedure used for collecting soil samples using ESP soil probe.
	4.15	1	Borrowed or rented equipment procedures and documentation.
5. TEST SYSTEMS ESTABLISHMENT AND MAINTENANCE	5.1	4	Commodity production and maintenance.
	5.2	2	Method for seeding or transplanting.
	5.3	2	Determining yield or quality.
	5.4	1	Method for collecting soil samples for analysis.
6. TEST SUBSTANCE APPLICATION AND HANDLING	6.1	2	Preparation of application mix.
	6.2	4	Procedure for application of test substance for trial(s).
	6.3	3	Cleanup of application equipment.
	6.4	4	Handling of test substance(s).
	6.5	3	Procedures to follow for misapplication of test substance.
	6.6	1	Disposal of pesticides.
	6.7	0	Procedure for dip, drench, and low volume application of test substance.
7. DATA COLLECTION, REPORTING, AND RETENTION.	7.1	3	Collection of raw data electronically.
	7.2	3	Recording of raw data.
	7.3	2	Calculations for data presentation.
	7.4	2	Method for collecting efficacy and phytotoxicity data.
	7.5	2	Experimental design and data analysis.
	7.6	3	Data storage during active life of project.
	7.7	1	Handling of raw data forms that transcends two or more trials.
	7.8	2	Disposal of raw data from the trial(s).
	7.9	1	Retention of data.
	7.10	1	Procedures for archiving.

SECTION	SOP#	REV#	TITLE
8. RESIDUE SAMPLE HANDLING	8.1	5	Sample collection, identification and records.
	8.2	4	Procedures for sample packing and storage.
	8.3	4	Procedures for sample shipping.
9. TRIAL CANCELLATION	9.1	1	Procedures to handle a failing or failed trial.
	9.2	2	Procedures to follow for a trial termination.
10. QUALITY ASSURANCE	10.1	1	Scope of quality assurance unit.
	10.2	1	Non-compliance with Good Laboratory Practices.
11. HEALTH AND PESITICIDE SAFETY	11.1	3	Guidelines for handling pesticides safely.
	11.2	2	Labeling and handling of reagents and/or solutions.
12. EPA AUDIT OR INSPECTION	12.1	4	Procedures to follow prior to an announced EPA inspection.
	12.2	2	Procedures to follow during an EPA inspection.
	12.3	2	Procedures to follow after an EPA inspection.
APPENDICES	A	--	Organizational Chart (Updated Feb. 14, 2012)

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 1.1 Rev: 4

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg ~~LLG~~ 2-6-08 (Init./Date)

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

Purpose: To provide guidance to scientists conducting field trial(s) in the development and use of Standard Operating Procedures for field research.

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- 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 SOPs 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 within a reasonable period of time.
 3. The SOP's will be reviewed by the Field Research Director and approved by the IR-4 Regional Field Coordinator or other appropriate approving official. The title page should show the signature of the approving official, and the date signed by the approving official. Approval may also be in the form of a dated signature on each SOP.
 4. Each SOP will be reviewed at a maximum interval of three years and revised as needed. Significant changes in the established SOPs shall be properly authorized in writing by the IR-4 regional field coordinator. The effective date and revision number must be changed to reflect the revision, or if not revised, the review documented by the reviewer signing or initialing the SOP "Reviewed by" and dating.
 5. For an SOP with no revisions, the revision number = "0". For each revision made to an SOP, the revision number for the revised SOP should begin with 1 and increase sequentially with each revision. Minor changes (i.e. grammatical, spelling, title change) that do not alter context or responsibility of the SOP do not require a revision number change.
 6. Revised SOPs that are relocated into another section or consolidated with another SOP must reference previous SOP number and revision number in parenthesis on the new SOP after the title. This reference is to be listed on the SOP until subsequent revision is made. The revision number of the relocated SOP is to begin with '0' and increase sequentially.
 7. Effective date will be assigned by Field Research Director and shall reflect the date reviewed.
 8. A historical life of the SOPs will be maintained at the facility. The Active file will contain the copy of the SOPs currently being used by the testing facility. The Historical file will contain a copy of all SOPs that have been used by the testing facility that are not active.
 9. Protocol requirements supersede SOP's. Deviations from the SOPs other than where the study protocol requirements differ, must be documented in the raw data and authorized by the Study Director.
 10. End of SOP will be identified by "Reviewed by" portion.

Reviewed by:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08						
LLG	2-13-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 1.2 Rev: 3

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG ²⁻⁶⁻⁰⁸ (Init./Date)

Title: Numbering system for SOPs.

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

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

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 Application & Handling
 7. Data Collection, Reporting & Retention
 8. Residue Sample Handling
 9. Trial Termination
 10. Quality Assurance
 11. Health and Pesticide Safety
 12. EPA Audit or Inspection
- Appendix

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
HJD	2/7/08						
LLG	2-13-12						

SOP: 1.3 Rev: 5

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg ~~LLG~~ 2-6-08 (Init./Date)

Title: Format for use in developing SOPs.

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

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

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

Name of Test Facility (centered)

Address (centered)

Space

SOP: (SOP section number as a decimal) Rev: (revision number sequentially beginning with 0 for first use) Effective Date:

Space

Submitted by: (Type name of person developing the SOP followed by a space for person to initial and date)

Space

Reviewed by: (Type name of person developing the SOP followed by a space for person to initial and date)

***If same person is submitting and reviewing SOP, these two lines can be combined.*

Space

Optional (Refer to SOP 1.4) Approved by: (Type name of person approving the SOP followed by a space for person to initial and date)

Space

Title: (title) *** If SOP has been relocated, need to indicate by writing "(Formerly SOP# Rev#)".*

Space

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

Space

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

Space

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

*** If SOP is more than 1 page, the top left corner of the subsequent page(s) label with SOP# Rev.# Page # of #.*

Space

Reviewed by: (Table with several lines for initial and date of review as indicated in SOP 1.1. This table denotes the end of the SOP.)

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08						
LLG	2-13-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 1.4 Rev: 4

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg ~~1/12-6~~⁰⁸ (Init./Date)

Title: Format for use in revising SOPs.

Purpose: To provide information on revising individual SOP's.

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. Authorized personnel with knowledge of the procedure will revise the SOP to accurately describe procedures being used. The revision of the SOP will be indicated by the revision number in the header of the SOP. Person revising the SOP will then sign (or initial) and date in the designated area (Submitted by:) in the header of the SOP.
 2. The revised SOP will then be reviewed by the Field Research Director or designee for the testing facility. If the revisions are not acceptable, the reviewer and the submitter will revise the document until it accurately reflects the procedures being utilized at the testing facility. When revisions are acceptable, the reviewer will sign (or initial) and date in the designated area in the header of the SOP and assign an effective date.
 3. After reviewing, the SOP(s) is sent to the Regional Field Coordinator for approval. If approval is denied, the SOP(s) will need to be re-revised. If approved, the approving official will sign (or initial) and date the title page of the SOPs or in the designated area in the header of an individual SOP.
 4. The approved, revised SOP will replace the 'old' SOP (un-revised).
 5. When the revised SOP comes into effect, the Field Research Director or designated personnel are responsible for the following:
 - a. Remove the original copy of the 'old' SOP from the active file and transferring it to the historical file.
 - b. Locate all other copies (than the above mentioned) of the 'old' SOP and replacing it with true copies of the revised version. The 'old' SOP copies will then be destroyed.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
HJD	2/7/08						
HJD	2-13-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 1.5 Rev: 3

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg ^{LLG} (Init./Date)

- 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:** Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.
- 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 study understand the protocol, SOPs 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 study that need to be retained are transferred to the archives at IR-4 Headquarters.
 - f. Maintain a current copy of a master schedule for all GLP projects under his/her direction.
 - g. Retain true copies of raw data from each trial for minimum of 5 years unless directed otherwise from the GLP study sponsor.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08						
LLG	2-13-12						

Texas AgriLife Research
2415 E. Bus.Hwy 83 / Weslaco, TX 78596

SOP: 2.1 Rev: 3

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

Title: Personnel.

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

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- 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, regulations, 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 must have completed the EPA Worker Protection Pesticide Handler course.
 6. Personnel documentation will be reviewed annually and revised as needed, or indicated by a dated signature that the document was reviewed.
 7. In the event that a person's employment with the organization ends, their personnel records will be archived.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08						
LLG	2-13-12						

Texas AgriLife Research
2415 E. Bus.Hwy 83 / Weslaco, TX 78596

SOP: 2.2 Rev: 3

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

Title: Organizational chart.

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

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:
1. An organizational chart should describe the management structure of the institution performing the work. It should also document the reporting lines for personnel engaged in GLP studies both to the institution's management and to IR-4 Testing Facility Management.
 2. Each block in the chart should show the title, and a brief description of the duties of each person.
 3. The head of the unit (i.e. Department Chair, Director, etc.) should be included in the chart. This person should be the one who appoints the Field Research Director at the institution.
 4. The chart should then show 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) should then be shown on the chart with lines of supervision, communication, and cooperation indicated.
* Facility organizational chart in Appendix.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08	LLG	2-13-12				
OM	2/10/08						

Texas AgriLife Research
2415 E. Bus.Hwy 83 / Weslaco, TX 78596

SOP: 2.3

Rev: 3

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg ~~HA~~ 2-6-08 (Init./Date)

Title: Documentation of training.

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

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. Formal training at institutions of personnel engaged in GLP trials should be documented in a training record, to be kept at the field facility. This may consist of a notation that the person received a degree and the discipline, year graduated and the institutions should be noted. If a degree was not awarded then the years of attendance and specialty should be noted.
 2. Training received from workshops, conferences, etc. should be noted as to the name of the event, date(s) of attendance. A copy of any type of certificates issued should be retained in the personnel files at the location.
 3. Training on specific procedures and/or SOPs should 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 should have read and understood those sections of the protocol and the standard operating procedures that pertain to their responsibilities. The Field Research Director or designee should record in their respective training records, the names of the personnel and dates that the SOPs were explained to them. This information should be placed in the personnel file.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
HL	2/7/08						
HA	2-13-12						

Texas AgriLife Research
2415 E. Bus.Hwy 83 / Weslaco, TX 78596

SOP: 2.4 Rev: 1

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

Title: Designation of personnel for duties

Purpose: To assure that personnel involved in the study are properly trained for the duty assigned.

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. Duties shall be assigned by the Field Research Director (FRD) or authorized personnel in the absence of the FRD. Authorized personnel include but are not limited to the on-site supervisor of the FRD, Regional Field Coordinator and Study Director.
 2. Personnel performing the duty should have been properly trained for the duty (SOP 2.3). Should personnel be unable to perform the duty assigned, he/she is responsible for notifying the FRD or authorized personnel assigning the duty.
 3. Personnel performing the duty is responsible for ensuring that the duty performed is documented accurately. (e.g. If Mr. X irrigated crop 0.5 inches, Mr. X is responsible for documenting the raw data of having the FRD record the raw data accurately.)

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08						
LLG	2-13-12						

SOP: 3.1 Rev: 5

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

Title: Guidelines for test substance storage.

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

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. Test substances will be stored in accordance with pesticide label directions. If none are supplied, they will be stored in a dry, well-ventilated room which is separate from offices and sample storage areas in a lock-able unit (i.e. cabinet). The test substance area should be sufficient to allow storage of the test substances according to their label directions.
 2. The temperature within the storage facility will be monitored by a temperature monitoring device which allows recording of the minimum and maximum temperature range within the facility.
 - a. If using a data logger to monitor temperature, should be set for a maximum time interval of one hour. Unit should be downloaded at a maximum interval of 90days (refer to SOP4.12).
 - i) In case of data logger failure, a secondary or back-up unit (i.e. min/max thermometer, second data logger) should also be placed within the area. If it is noted that the data logger failed to operate, the temperature reading of the back-up unit should then be recorded and used for the time duration for which the data logger failed to operate.
 - ii) The back-up unit should be re-set each time the data logger (primary temperature monitoring device) is downloaded and documented in a maintenance log.
 - b. If using a minimum/maximum thermometer unit as the primary temperature monitoring device, the temperatures should be recorded a minimum of every other day except on weekends or holidays.
 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 or testing facility management to dispose of the containers.
 4. The storage facility should have limited access by utilization of a lock and key so that only authorized persons may have access to GLP test substances.
 5. Place highly visible, waterproof identification signs on doors and/or building walls to advise of the hazardous nature of the storage facility's contents.
 6. Make available the telephone number(s) and name(s) of personnel responsible for and knowledgeable of the contents of the storage facility.
 7. Make accessible, materials such as adsorptive clay, granulated activated charcoal, hydrated lime, or sodium hypochlorite for emergency treatment or detoxification of spills or leaks.
 8. Store containers of test substances that could be damaged by moisture or water, off the floor.
 9. Check test substance containers within storage unit regularly for corrosion and leaks. If such is found, the contents should be transferred to a suitable clean container and be properly labeled. The original container should be properly stored (e.g. seal container in leak-proof plastic bag) to prevent contamination or accidental exposure.
 10. Post a current inventory of all test substances in the storage unit accessible to study personnel. This inventory will include yet not limited to the pesticide name, the EPA No., EPA Est. No., or CAS No. and amount of product received or being stored.

11. GLP test substances will be stored in a separate area (i.e. shelf, cabinet, etc.) from non-GLP substances.
12. The receipt, storage, and mixing areas for the test substance(s) should be separate to prevent contamination or mix-up.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
ADD	2/7/08	AA	2-13-12				
CM	2/10/08						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP#: 3.2 Revision Number: 3

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

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 re-located after the trial(s) is terminated.

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. Site selection will be made in accordance with the horticultural practices acceptable for the commodity and the requirements established by the protocol.
 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. Locate site with sufficient isolation to prevent contamination of the test plots by spray drift sources such as commercial operations or other research trial(s). Should contamination occur, document the incident in the raw data.
 4. Where samples for residue trial(s) are required, if possible, locate untreated plots within the same area (preferably upwind and upslope of the treated plot(s)) but with enough isolation to produce untreated, uncontaminated samples.
 5. If the commodity is not required to be newly established, select a site that has commercial standards for production.
 6. Prepare a plot map showing the location and dimensions of each plot on the site, the slope, and the North azimuth. The plot map should contain distances to permanent reference points or GPS (Global Positioning System) readings of plot ends (preferably opposite corners of plot) so that the plots can be re-located after the trial(s) is terminated.
 7. Label each plot with the field ID number and treatment number 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. Lay out each plot on the site using a suitable measuring device to accurately locate the plots on the site.
 9. Identify both ends of each plot with a marker of sufficient visibility to be seen easily throughout the duration of the trial(s).
 10. The plot map (item 6) should be included in the raw data notebook.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08						
LLG	2-13-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP#: 3.3 Revision Number: 3

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

Title: Greenhouse/shadehouse facilities.

Purpose: To assure that greenhouse/headhouse and/or shadehouse 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: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. Each greenhouse/shadehouse must 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 or shadehouse, there must be sufficient isolation between the treated plot(s) to prevent contamination or interference between trial(s).
 3. Lighting, temperature, humidity, and shade should be sufficiently uniform at the trial(s) sites in the greenhouse/shadehouse to provide nearly uniform plant growth throughout the trial(s) sites.
 4. The walls, floors, and ceilings of the greenhouse/shadehouse should be maintained in good condition. Floors, benches and aisles should be free of debris, weeds and superfluous equipment and well-drained to prevent the buildup of excess moisture.
 5. Greenhouses should 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. Temperature monitoring device should be installed. All calibrations or accuracy checks will be documented in the maintenance logs.
 7. Document cultural practices used in the greenhouse and treatment locations in the raw data notebook.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08						
LLG	2-13-12						

SOP: 4.1 Rev: 3

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG-6-08 (Init./Date)

Title: Calibration and use of balances.

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

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. Prior to and after each use, the user will visually inspect the balance set-up (level unit if needed) and for cleanliness. Any dirt or chemicals within the weighing chamber or on the pan must be cleaned immediately.
 2. The balance accuracy should be checked each day before use and after calibration to ensure accuracy. The accuracy check should be performed using two standard weights that bracket the amount to be weighed. The declared weights and the actual weights of the standards should be recorded as raw data.
 - a. If the measured weights of both standard weights are within $\pm 2\%$ of the standard weights, 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 are within $\pm 2\%$ of the standard weights, proceed with weighing and record the measured weights.
 - d. If, after recalibration, the measured weight of either standard weight still differs by more than $\pm 2\%$ of the standard weights, replace the defective weight. If it is determined that the problem is the balance, then it should be serviced before further use.
 3. Balance should be calibrated if accuracy check indicates that the unit needs to be calibrated. For the Satorius BP3100S, the following procedure may be used or document the procedure used if different.
 - a. Select the calibration function. (i.e. 191 for BP3100S)
 - b. When a zero readout is displayed begin calibration. For example, Satorius BP3100S, press the 'cal' key and this will start the calibration.
 - c. Center the calibration weight (i.e. 2kg for BP3100S) on the weighing pan. For example, the BP3100S balance then calibrates automatically and the end of calibration, the weight readout and the stability symbol 'g' are displayed. Other balance units may require adjusting the unit manually. Make adjustments to the balance until the readout is $\pm 1\%$ of the declared amount of the calibrated weight.
 - d. If display readout is accurate, then unit is calibrated and you may proceed with weighing. If display weight readout is incorrect ($> \pm 1\%$) or an error message is displayed, unit needs to be recalibrated. If after recalibration, the readout is still incorrect, the unit is not properly calibrated and further adjustments to unit is required by a appropriately trained technician prior to use.

4. Standard weights will be calibrated/standardized annually. To standardize weights, weigh each unit on two different calibrated balances or compare weight(s) against another standard weight(s) of equal stated weight. Document procedure used and record the declared weights and actual weights of weight units and weighing scale utilized as raw data.
 - a. If the measured weights of the weight unit are within $\pm 1\%$ of the declared weight, then weight unit is acceptable for use.
 - b. If the measured weights of the weight unit differs by more than $\pm 1\%$ of the declared weight, then weight unit may not be used as a standard weight for that declared weight. Weight unit must be re-standardized before future use.
5. When weighing a test substance, select an appropriate container to hold the desired amount of test substance. With the balance 'on', place the container on the weighing pan or hook (for hanging scale) and tare it on the scale.
6. 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.
7. Select and wear or use appropriate safety equipment while handling the test substance.
8. If test substance is not to be immediately added to a pre-labeled application mix container, label the test substance container to identify it as to the test material and the amount (minimum labeling required).
9. Between weighings, check scale for cleanliness and clean if necessary. When all weighing is completed, clean scale and surrounding area which may have become contaminated with test substances.
10. Remedial actions to be taken in case of failure or malfunction include:
 - a. Any problem should be immediately reported to the facility director or designated personnel, documented, and placed in the records for non-routine procedures.
 - b. Any repairs or replacements resulting from malfunction during use will be documented as non-routine maintenance in the appropriate log(s).
11. Personnel currently operating the equipment are responsible for the maintenance and remedial action taken in case of malfunction.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
HJD	2/7/08						
YAA	2-13-12						

SOP: 4.2 Rev: 2

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg ~~HA~~ 2-6-08 (Init./Date)

Title: Measuring liquid formulations.

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

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. Obtain a clean measuring device (i.e. graduated cylinder, syringe or micropipetter) large enough to hold the volume of liquid to be measured, graduated in increments small enough to read to an accuracy within +/- 5% of the volume to be measured (i.e. if 3 ml is needed, use a 5 ml syringe having 0.1 ml divisions or if 0.5 ml is needed, use a 1 ml syringe having 0.01 ml divisions).
 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. If measuring the liquid in the graduated cylinder, then 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. If using a syringe, take the measurement reading from the bottom of the plunger head. Document the amount of test substance measured in the raw data book.
 5. Pour the liquid into an appropriate container, fit with a leak proof lid and label as to contents and amount. If the measuring device has a "TC" designation, it must be triple rinsed into the intermediate or mixing container. If it has a "TD" designation, this is not necessary unless the test substance is viscous.
 6. Cylinders/devices used to measure or transfer the test substance concentrate should be triple rinsed into the mixing container and then thoroughly washed with cleanser (i.e. dish soap, ammonia cleaner) and water after use to ensure that they are clean and cross-contamination of pesticides will not occur in future use.
 7. If excess test material is withdrawn from the container, do not place it back into the original container to avoid possible contamination of the test substance. The excess material is labeled as 'waste' and the amount documented in the chemical use log. The waste material may be disposed of by following disposal procedure on the pesticide label or diluted following label or protocol instructions and applied on overplanting of a crop.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
HA	2/7/08						
HA	2-13-12						

SOP: 4.3 Rev: 4

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg ~~LLG~~ 2-6-08 (Init./Date)

Title: Calibration of a liquid application unit.

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

Scope: Sites where a liquid application unit is used in conducting studies under GLP guidelines.

Procedures: For liquid application equipment such as Solo Backpack sprayer, Lee Spider Spray Trac, CO2 propelled units, in-furrow applicator unit yet not limited to.

1. Prior to use visually inspect unit (i.e. hoses, fittings, nozzles, regulators, gauges, tanks and pumps if motorized unit) for cleanliness, obvious wear or potential leaks and repair, replace or clean as necessary as part of routine maintenance. Make sure that air/fuel level(s) are sufficient for application(s). Then turn unit on (i.e. start motor or open valve to CO2 tank) and inspect further for any malfunctions which may interfere with proper application of test substance (i.e. leaks in hose, poor seal at nozzle gasket). Record any maintenance performed in the routine log.
2. Calibrate unit before initial application. Same calibration may be used for multiple applications if applications are made using the same set-up and under the same field conditions. For multiple applications using the same set-up, recheck the calibration to confirm accuracy of delivery (e.g., $\pm 5\%$ of initial calibration or as specified by the protocol).
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 rate (e.g., gal/acre).
4. Use a calibration method suitable to the application and the equipment used. Use the following methods or document methods used in the field notebook.
5. **Calibrate speed.** Select an area that is similar to the conditions where the application is to be made. Record the time it takes to travel a measured distance for a minimum of two runs. Calculate the speed.

$$\text{ft/sec} = \frac{\text{Distance traveled (ft)}}{\text{Time to travel distance (sec)}} \quad \text{OR} \quad \text{MPH} = \frac{\text{Distance traveled (ft)} * 0.682}{\text{Time to travel distance (sec)}}$$

For example: $100\text{ft} \div 30.86 \text{ sec} = 3.24 \text{ ft/sec}$

Unit speed is calibrated when consecutive pass times are uniform ($\pm 5\%$).

6. **Establish output volume.** Standard operating procedures and/or protocols dictate pre-determined volume per acre in most cases. Record all details not described in an SOP in the field data book, and all calibration data and calculations should be recorded in the raw data. Use these formulas to calculate volume output needed for test application or document formula used.

$$\text{Treatment plot acreage} = \text{plot length (ft)} \times \text{plot width (ft)} / 43,560 \text{ ft}^2/\text{A}$$

$$\text{Gal/Acre (desired)} * 3785 \text{ ml/gal} = \text{ml/acre}$$

$$\text{ml/acre} * \text{acreage (treatment plot)} \div \text{number of nozzles} = \text{ml/nozzle}$$

$$\text{ml/nozzle} \div \text{seconds} = \text{ml/nozzle/sec}$$

For example: Desired application rate = 30 gal/acre ; 4 nozzles on spray boom
Treatment plot area: 100' * 6.67' / 43560sq.ft/acre=0.015312 acre

Time: 100 ft (plot length) ÷ 3.24 ft/sec (desired speed) = 30.86 sec

For 30gal/acre * 3785 ml/gal = 113,550 ml/acre

113,550 ml/acre * 0.015312 acre = 1738.7 ml (needed for TRT plot area)

1738.7 ml÷4 nozzles = 434.7 ml/nozzle for 30.86 sec (Round-off to 435 ml)

OR

434.7 ml/nozzle ÷ 30.86sec = 14.086 ml/nozzle/sec (Round-off to 14.1 ml)

7. **Calibrate Output.** Adjust the unit settings (boom height and nozzle placement, pressure) for the correct application pattern. Visually check whether all outlets are discharging accurately (spray pattern) by spraying clean water only through them at a uniform pressure. Then catch and measure the discharge from each outlet separately over a timed interval.
 - a. For horizontal booms, if the discharge from each nozzle varies widely (>5% of mean), inspect all nozzles (and filter screens if applicable) that give a much larger or much smaller discharge. Clean or replace tips or filters as needed. Repeat the above procedure until all nozzles are discharging uniformly ($\pm 5\%$). [For air-blast sprayers or vertical booms, the nozzle discharge because of sprayer design, may not be uniform (within 5%) and should be adjusted as needed to ensure an accurate application to the target site.]
 - b. Record catch time and nozzle discharge as raw data for a minimum total of three consecutive times. Output is considered calibrated when consecutive nozzle discharges are uniform ($\pm 5\%$) or accurate for the unit design.

$$\frac{\text{Average volume caught per nozzle (ml)} * \text{number of nozzles}}{\text{Time interval (sec)}} = \text{Total Discharge (ml/sec)}$$
8. **Calculate the actual gal/acre.** The following formulas can be used or record the procedure used.

$$\text{Actual Gal/Acre} = \frac{\text{Total Discharge(ml/sec)} * 43560 \text{ ft}^2/\text{A}}{\text{Speed(ft/sec)} * \text{Swath width(ft)} * 3785 \text{ ml/gal}}$$
 - a. If the measured gal/acre is within limit as specified in the protocol , then the unit is calibrated and the same settings should be used in actual application.
 - b. 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.
9. Applicators must carefully operate under the same conditions as during calibration. Ensure 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.
10. **Calibration re-check.** Check the output and/or speed for one catch and/or run. If the recorded measures are within 5% of the previous calibration, then proceed with application using the previous calibration (not re-check) values in calculations.
11. Thorough cleaning of the equipment is required after each period of use and when changing test substance.
12. Remedial action to be taken in case of failure or malfunction should include:
 - a. Any problem should be immediately reported to the Field Research Director or designated personnel, documented.
 - b. If problems occur during application, refer to SOP 6.5.
 - c. Any repairs or replacements resulting from a malfunction during application will be documented as non-routine maintenance in the appropriate maintenance log(s).

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

Example Summary of Liquid Sprayer Calibration Calculation Procedure:

I. Output calibration:

$$\frac{\text{Average Discharge caught per Nozzle(ml)} \times \# \text{ of nozzles}}{\text{Discharge Time (sec)}} = \text{TOTAL DISCHARGE (ml/sec)}$$

II. Speed calibration:

$$\frac{\text{Distance Traveled (ft)}}{\text{Time to Travel Distance (sec)}} = \text{SPEED (ft/sec)}$$

III. Delivery rate calculation:

$$\frac{\text{Total Discharge(ml/sec)} \times 43560 \text{ sq.ft./A}}{\text{Speed (ft/sec)} \times \text{Swath width(ft)} \times 3785 \text{ ml/gal}} = \text{GALLONS / ACRE}$$

(Verify within Protocol Range)

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
APP	2/7/08						
HA	2-13-12						

SOP#: 4.4 Rev: 3

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

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: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

Procedures: The methods, materials, and schedules for routine inspection and calibration should include the following. Record all details used for calibration not described in an SOP or protocol in the field data book.

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. **Ground Driven Applicators:**
Refer to the operator's manual for the calibration method. If no manual is available then proceed as follows or document procedure used:
 - a. Measure an area (for example: 0.01 acre or 435.6 ft²) that is similar to test plot if possible. Calculate distance.
Area(ft²) ÷ width of application (ft) = Distance to travel(ft)
 - b. Determine the approximate setting of the openings and the approximate speed to operate the applicator for the desired amount of test substance per acre.
 - c. Wear protective clothing as necessary and fill the spreader with enough material to ensure proper operation. If a 'blank' material is available, use it during calibration procedures. If a calibration pan is available, attach the pan under the spreader to catch the material as it is released. Operate the applicator over the measured distance and collect the output. If more than one outlet, check and ensure that all outlets are discharging uniformly (+/- 5%) by collecting the discharge from each outlet separately and weighing the material. Make appropriate adjustments to achieve a uniform discharge (+/- 5%) between outlets (i.e. adjust opening settings).
 - d. Weigh the collected material and determine the amount applied per acre. If desired application rate is achieved consistently (+/- 5%) then the applicator is calibrated and the same settings should be used in the actual application. When the measured rate must be changed, you may need to alter the outlet opening setting or speed. Adjust the applicator as needed until it is applying the correct amount per acre (within ± 5%, or as specified in the protocol). Document calibration data in the field data notebook.
3. **Non-Ground Driven Applicators.**
Following protocol requirements, perform calculations to determine actual pounds (or appropriate measures) of material per acre (or appropriate measure). Use the following procedure or document the procedure used.
 - a. Place the applicator on level ground or hold level to the ground. Determine whether all openings are discharging uniformly by turning on the applicator and observing output. Catch and weigh the discharge from each opening separately or from all at once for broadcast applicators in a calibration pan or other appropriate container over a timed interval (e.g., 15 seconds) beginning after the openings are discharging if practical.
 - b. If a minimum of two (preferably three) consecutive measures (for example, lb/acre) are within 5% of the desired amount, as specified in the protocol and/or SOP, then the applicator is calibrated and the same settings should be used in actual application. When the measured amount must be changed, alter one or all of the following; discharge opening size, applicator drive speed (if possible) or ground speed.

4. Applicators must carefully operate under the same conditions as during calibration. All discharge outlets should be unobstructed and flow from each should be uniform. The test substance should be applied uniformly to the entire target area.
5. Thorough cleaning of the applicator is required after each period of use and when changing chemicals.
6. Remedial action to be taken in case of failure or malfunction should include:
 - a. Any problem should be immediately reported to the facility director or designated personnel, documented, and placed in the records for non-routine procedures.
 - b. If problems occur during application, refer to SOP 6.5.
 - c. Any repairs or replacements resulting from malfunction during application will be documented as non-routine maintenance in the appropriate log(s).
7. Personnel currently operating the equipment are responsible for the maintenance and remedial action taken in case of malfunction.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
HJD	2/7/08						
AA	2-13-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP#: 4.5 Rev: 3

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg ~~LLG~~ 2-6-08 (Init./Date)

Title: Operation and maintenance of farm equipment.

Purpose: To assure that equipment used in the trial(s) are in good working order.

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. Just prior to the initiation of the use of the equipment (tractor, plow, disk, harrow, planters, harvester, application unit, etc.) the trained personnel operating the equipment will visually inspect the equipment to see that it is in good working order, properly lubricated, and in good mechanical condition.
 2. Any necessary repairs or adjustments should be made prior to the use of the equipment in the trial(s). If the equipment is GLP-maintained, any maintenance or repairs made need to be documented in routine maintenance log.
 3. The operator of the equipment should be familiar with its operation and safety precautions.
 4. If available, manuals 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 should be maintained for equipment used for the generation, measurement, or assessment of data in a GLP trial. The record should 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 should be placed in the raw data 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, documentation if GLP-maintained and remedial action taken in case of malfunction.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08						
LLA	2-13-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 4.6 Rev: 3

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg ~~2/7-6-08~~ (Init./Date)

Title: Calibration of field instruments including GPS units.

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

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. Each gauge or instrument used for deriving data in a GLP trial (e.g. temperature and humidity gauges, GPS unit, stopwatches, etc.) should be tested to determine that it is within the desired tolerance. If item is used continuously, it should be tested frequently enough to assure its continued accuracy (i.e. annually, every six months, monthly, after every 10 hrs. use etc.). If the item is used infrequently, it should be tested before it is first used each year in a GLP trial and as often thereafter as necessary to assure its accuracy.
 2. Each unit will be assigned a unique number, code or name for the purpose of identification. A written record should be kept of the maintenance (i.e. battery changes), accuracy testing, dates and results of the tests and of the acceptable tolerance for each instrument.
 3. Document method(s) used for accuracy check or re-calibration of unit in the relevant log or an SOP.
 4. In the case of GPS units for calibration check, coordinates should be within 20 ft of a reliable pre-determined point (i.e. government topographical map, aviation map, information service measurement).
 5. Those gauges or instruments that give inconsistent results or are not accurate to within desired tolerances (generally within +/- 5%), should be re-initialized (i.e. GPS unit), re-calibrated (i.e. scales), repaired or replaced.
 6. Personnel currently operating the equipment is responsible for the maintenance and remedial action taken in case of malfunction.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
HJD	2/7/08						
LA	2-13-12						

SOP: 4.7 Rev: 2

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg 2/12-6-08(Init./Date)

Title: Calibration and use of temperature measuring devices.

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

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. Prior to use visually inspect the measuring device for cleanliness and that it is in good working condition. Check the power supply (if applicable, batteries should be replaced when display area begins to dim). Record inspection and any maintenance performed in appropriate logs. Use the following methods or document the methods used as raw data .
 2. All temperature measuring devices used for GLP studies or equipment associated with studies will be checked for accuracy at least once a year against a reference thermometer, either directly or by a recorded traceable chain.
 3. Records of thermometer accuracy check will be maintained in a log.
 4. All mercury and min/max thermometers will be identified by a unique number or code. The identification number or code will be placed on the measuring device such that it can easily be cross-referenced to calibration log records.
 5. Measuring devices to be checked for accuracy and the reference thermometer will be read side by side under conditions appropriate to the intended use. For example: thermometers used to measure temperatures of liquids should be calibrated in water baths.
 6. **Water Bath Method.** At least two water baths will be used. Examples of temperature ranges to test may include:
 - a. Warm (approx. 40 to 55°C)
 - b. Room temperature (approx. 22°C)
 - c. Ice (approx. 0°C)
 - d. Dry ice in a suitable solventWater baths will be contained in a pan or beaker deep enough for adequate immersion of the instrument. The ice bath should be made with chopped ice in water to form a tightly packed slush, without floating ice.
 - Air Method.** At least two air temperature conditions will be used. Examples of temperature ranges to test may include:
 - a. Warm , i.e. 40 to 60 °C (drying oven may be used)
 - b. Room temperature (approx. 22 °C)
 - c. Cool, i.e. 5 to 10 °C (refrigerator may be used)
 - d. Cold, i.e. -5 to -20 °C (freezer may be used)
 7. The thermometer(s) and the reference thermometer will remain in the calibrating environment until a constant reading is reached. When the analyst feels confident that reading is constant, the values will be recorded in the log. The following information will be documented in the log:
 - a. date of accuracy check
 - b. initials of person doing check
 - c. reference temperature measuring device reading and ID.
 - d. temperature measuring device (being checked) reading and ID.

8. Temperature readings taken from the reference thermometer may be rounded to whole numbers (e.g.: If reference reads 38.2°C, the recorded value will be 38°C).
9. If possible, each measuring device will be labeled following calibration and will include:
 - a. ID or code number
 - b. if needed, temperature adjustment, date of accuracy check and initial of person doing check.
 - c. if no adjustment is required then no notation of adjustment required.
10. If the reading of the laboratory thermometer is $\pm 1^\circ\text{C}$ of the reference reading, no temperature adjustment will be made and unit or unit container labeled to indicate this (i.e. "OK" or "PASS" and temperature range that unit has been standardized for). If the reading is more than 1°C in relation to the reference thermometer, the proper adjustment will be made. For example: If the thermometer reads 20°C and the reference reads 22°C , the adjustment would be $+2^\circ\text{C}$ at 22°C . When this thermometer is used, the individual would add 2°C to the 20°C observed reading and 22°C would be recorded as the temperature reading.
11. When recording a thermometer reading, the following information should also be included in the entry:
 - a. Date
 - b. Initials of individual conducting the activity
 - c. Temperature measuring device ID or code number
12. Accuracy checked temperature measuring devices may be used to check other temperature recording devices as long as they can be traced back to a reference calibration. These devices may include continuous thermographs used for walk-in digital displays on up-right freezer/refrigerator units, etc.
13. Remedial action to be taken in case of failure or malfunction should include:
 - a. Any problem should be immediately reported to the facility director or designated personnel, documented, and placed in the records for non-routine procedures.
 - b. Any repairs or replacements resulting from malfunction during application will be documented as non-routine maintenance in the appropriate log(s).
14. Personnel currently operating the equipment are responsible for the maintenance and remedial action taken in case of malfunction.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
HAD	2/7/08						
HAD	2-13-12						

SOP: 4.8 Rev: 1

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG-6-08 (Init./Date)

Title: Calibration and use of hygrothermographs.

Purpose: This document is for use by IR-4 personnel to define techniques used for calibrating, operating, and maintaining thermographs and hygrothermographs.

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. To activate unit turn on the power switch or wind up unit with proper clock key. Some battery operated units do not need activating. Some units can be set for using daily, weekly, or monthly removable charts.
 2. Identify the chart with the unit ID number, location, time on and initial and date.
 3. When the reading period is over, remove chart and replace with a new one. Record time off and initial and date.
 4. Additional information may be added to the recording chart as necessary (i.e., location, weekly high, flow, etc.). These charts will be deemed raw data and handled as such at all times.
 5. Units will be appropriately maintained. If the unit fails, it will be serviced by a technician. The only exception is the changing of batteries and charts or the adjustment of sensor arms during calibration.
 6. All problems encountered, calibration, and maintenance will be documented in the appropriate log. In addition, completed charts will be kept on file and periodically archived.
 7. All units will be calibrated/standardized on a semiannual basis, using the following procedure:
 - a. Place a calibrated thermometer beside the unit to be calibrated.
 - b. Allow at least 15 minutes to assure thermometer equilibrium.
 - c. Observe and record the temperature values of the thermometer and the recording thermograph or hygrothermograph into the appropriate log.
 - d. The difference in temperature observed by these thermometers must not be greater than 1°C.
 - e. If the temperature difference is greater than 1°C, adjust the thermograph or hygrothermograph. If the unit is being monitored with a thermometer, replace it with one that is newly calibrated against a reference thermometer.
 - f. If the above correction fails, a serviceman will be called to service the unit. Another appropriate monitoring device will be used as a replacement until the unit is repaired.
 - g. Logbooks or true copies will be archived periodically at IR-4 Headquarters.
 - h. The relative humidity will be calibrated against a sling psychrometer. The wet and dry bulb readings will be documented in the appropriate log and the relative humidity determined by the use of a standard reference table.
 - i. If the difference in relative humidity is greater than 1% adjust the hygrothermograph. Document the adjustment in the appropriate log.

- 8. Remedial actions to be taken in case of failure or malfunction include:
 - a. Any problem should be immediately reported to the facility director or designated personnel, documented, and placed in the balance records for non-routine procedures.
 - b. Any repairs or replacements resulting from malfunction during use will be documented as non-routine maintenance in the appropriate log(s).
- 9. Personnel currently operating the equipment are responsible for the maintenance and remedial action taken in case of malfunction.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
<i>HJD</i>	<i>2/7/08</i>						
<i>HA</i>	<i>2-13-12</i>						

SOP: 4.9 Rev: 2

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg ~~2/2-08~~ (Init./Date)

Title: Calibration and use of pH measuring devices.

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

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. Prior to use visually inspect the pH measuring device for cleanliness and that it is in good working condition. Check the power supply (if applicable, batteries should be replaced when display area begins to dim or every two years). Check the standard pH solutions (i.e. expiration date, indicator color of solution). Record inspection and any maintenance performed in appropriate logs.
 2. The pH measuring device will be checked for accuracy in measuring the pH of solutions each day prior to use. Records of pH accuracy checks and calibrations will be maintained in a log. Use the following methods or document method used in the field data book.
 3. **Accuracy check.** Use two standard pH solutions that bracket the pH of the solution to be measured. The standards should be from a reliable source (i.e. Fisher Scientific, certified buffer solution) and used only before the expiration date on the label. Record the standard buffer pH and the measured reading from the pH measuring device as raw data.
 - a. If both of the measured pHs of the solutions are within ± 0.4 units of the declared pH values of the standards, then unit is reading accurately (OK) and is acceptable for use.
 - b. If either of the measured pH values of the solutions differ more than ± 0.4 units of the declared pH values of the standards, then unit will need to be calibrated before future use.
 - c. If using pH paper (i.e. pHydriion Brilliant Dip Stik 0-13) and either of the measured pH values (visual color change) does not match the corresponding pH color on the standard color card then that set of pH papers is determined to be inaccurate and may not be further used in GLP studies.
 4. **Calibration.** Select the pH buffer standards as required for the equipment calibration (refer to manual) and the pH range you intend to measure (for Oakton WD-00663-00 pH wand, pH 4 and 7 buffers for acid ranges and pH 7 and 10 for basic ranges).
 - a. With the unit on, place the probe into the first buffer (i.e. pH 7). Wait 15 to 30 sec until unit reading is consistent. Adjust the meter until the displayed reading is the same value as the pH buffer at the calibration temperature. Then thoroughly rinse this buffer from the electrode with water.
 - b. Place electrode in next buffer (i.e. pH 4 or 10). Wait 15 to 30 sec until unit reading is consistent. Adjust the meter until the displayed reading is the same value as the pH buffer at the calibration temperature. Then thoroughly rinse this buffer from the electrode with water. Calibration is complete.
 5. After calibration, repeat accuracy check. If unit fails accuracy check, re-calibrate. If after re-calibration, measured value differs from buffer value more than ± 0.4 units, then the pH measuring device should be serviced before future use.

6. Between pH measurements, the probe should be thoroughly rinsed with water. When all pH measurements are completed, turn the unit off, then thoroughly rinse and store probe.
7. Remedial actions to be taken in case of failure or malfunction include:
 - a. Any problem should be immediately reported to the facility director or designated personnel, documented, and placed in the maintenance log records for non-routine procedures.
 - b. Any repairs or replacements resulting from malfunction during application will be documented as non-routine maintenance in the appropriate log(s).
8. Personnel currently operating the equipment are responsible for the maintenance and remedial action taken in case of malfunction.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
HDD	2/7/08						
HA	2-13-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 4.10 Rev: 2

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

Title: Calibration and use of wind speed measuring devices.

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

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. Prior to use visually inspect the measuring device for cleanliness and that it is in good working condition. Check the power supply (if applicable, batteries should be replaced when display area begins to dim). Record inspection and any maintenance performed in appropriate logs. Use the following methods or document the methods used in the field data.
 2. **Use.** Just prior to application check the wind speed in the area to be treated. The measurement should be taken 2 to 3 ft above the nozzle height when using a boom sprayer. If using an air blast sprayer, measurement should be taken 5 to 6 ft above the soil surface. Record the wind speed as raw data.
 3. **Calibration check.** The wind speed meter will be checked for accuracy once a year. The measuring device to be checked and the reference device will be read side by side under conditions appropriate to intended use. Record the reference reading and the reading from the unit to be calibrated as raw data.
 - a. If the measured speed from the unit to be calibrated is within ± 0.5 mph of the reference meter reading, then unit is reading accurately (OK) and is acceptable for use.
 - b. If the measured speed from the unit to be calibrated differs more than ± 0.5 mph of the reference meter reading, then the unit needs to be serviced before future use.
 4. Remedial actions to be taken in case of failure or malfunction include:
 - a. Any problem should be immediately reported to the facility director or designated personnel, documented, and placed in the maintenance log records for non-routine procedures.
 - b. Any repairs or replacements resulting from malfunction during application will be documented as non-routine maintenance in the appropriate log(s).
 5. Personnel currently operating the equipment are responsible for the maintenance and remedial action taken in case of malfunction.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08						
LLG	2-13-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 4.11 Rev: 1

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

Title: Calibration and use of sling psychrometer.

Purpose: The purpose of this SOP is to establish procedures used when calibrating a sling hygrometer.

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. Prior to use visually inspect the measuring device for cleanliness and that it is in good working condition. Record any maintenance performed in appropriate logs. Use the following methods or document the methods used in the field data.
 2. **Use.** With the 'wet' bulb wick wetted, extend the thermometer unit out of the plastic casing thus allowing the thermometer frame to rotate while holding the outer case. 'Whirl' the instrument at about 2 to 3 revolutions per second for approximately 1 minute. After stopping read the temperatures on the 'wet' and 'dry' bulb. Close the instrument taking care to have both calculator scales on the same side. Align the 'dry' bulb reading on the 'dry' scale with the 'wet' bulb reading on the 'wet' scale. Record the reading on the % Relative Humidity scale indicated by the arrow on the 'dry' scale you were using.
 3. **Calibration check.** The sling hygrometer will be checked for accuracy once a year. The measuring device to be calibrated and the reference device will be read side by side under conditions appropriate to intended use. Record the reference reading and the reading from the unit to be calibrated as raw data.
 - a. If the measured humidity from the unit to be calibrated is within $\pm 5\%$ of the reference unit reading, then unit is reading accurately (OK) and is acceptable for use.
 - b. If the measured humidity from the unit to be calibrated differs more than $\pm 5\%$ of the reference unit reading, then the unit needs to be serviced before future use.
 4. Remedial actions to be taken in case of failure or malfunction include:
 - a. Any problem should be immediately reported to the facility director or designated personnel, documented, and placed in the maintenance log records for non-routine procedures.
 - b. Any repairs or replacements resulting from malfunction during application will be documented as non-routine maintenance in the appropriate log(s).
 5. Personnel currently operating the equipment are responsible for the maintenance and remedial action taken in case of malfunction.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08						
LLG	2-13-12						

SOP: 4.12 Rev: 3

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg ~~LA~~ 2-6-08 (Init./Date)

Title: Calibration and use of temperature datalogger devices.

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

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. Prior to use visually inspect the datalogger for cleanliness and that it is in good working condition. Check the power supply (if applicable, batteries should be replaced when the power indicator light does not blink while the unit is on). Record inspection and any maintenance performed in appropriate logs. Use the following methods or document the methods used as raw data.
 2. All temperature measuring devices used for GLP studies will be checked for accuracy at least once a year against a reference thermometer, either directly or by a recorded traceable chain or by comparing against a minimum of two similar units. Records of accuracy checks will be maintained in a log.
 3. All dataloggers will be identified by a unique number or code. The identification number or code will be placed on the measuring device such that it can easily be cross-referenced to log records.
 4. Datalogger(s) to be checked for accuracy and the reference thermometer (if applicable) will be read side by side under conditions appropriate to the intended use.
 5. **Air Method.** At least two air temperature conditions will be used. Examples of temperature ranges to test may include:
 - a. Warm, i.e. 40 to 60 °C (drying oven may be used)
 - b. Room temperature (approx. 22 °C)
 - c. Cool, i.e. 5 to 10 °C (refrigerator may be used)
 - d. Cold, i.e. -5 to -20 °C (freezer may be used)
 6. The datalogger(s) and the reference thermometer will remain in the calibrating environment until a constant reading is reached. When the analyst feels confident that reading is constant, the values will be recorded in the log. The following information will be documented in the log:
 - a. date of accuracy check
 - b. initials of person doing check
 - c. reference thermometer identification (ID) and reading (if applicable)
 - d. datalogger ID and reading
 7. Temperature readings taken from units involved in accuracy check may be rounded to whole numbers (e.g.: If reference reads 38.2°C, the recorded value will be 38°C).
 8. If the reading of the datalogger is $\pm 1^\circ\text{C}$ of the reference reading, no temperature adjustment will be made and the label will read "OK". If the reading is more than 1°C in relation to the reference thermometer, the proper adjustment will be made. For example: If the datalogger reads 20°C and the reference reads 22°C , the adjustment would be $+2^\circ\text{C}$ at 22°C . When this datalogger is used, the individual would indicate on the printout to add 2°C to the 20°C observed reading and 22°C would be recorded as the temperature reading.
 10. **Launch unit.** Select the duration of time which best suits the use (i.e. 30 days for chemical storage cabinet).

11. **Downloading unit.** At the end of the data collection period, the data should be transferred to a storage system (i.e. computer diskette labeled 'Datalogger' and year of entries) and the data immediately printed out (hard copy). This hard copy will be retained in a file as raw data. The following information should be included on the printout:
 - a. Date
 - b. Initials of individual conducting the activity
 - c. Datalogger ID or code number
 - d. Temperature sensor location at the time of reading(s)
 - e. Units of measurements
12. The hard copy of the data from the datalogger(s) should be legible to persons with normal vision.
13. Remedial action to be taken in case of failure or malfunction should include:
 - a. Any problem should be immediately reported to the facility director or designated personnel, documented, and placed in the records for non-routine procedures.
 - b. Any repairs or replacements resulting from malfunction during use will be documented as non-routine maintenance in the appropriate log(s).
13. Personnel currently operating the equipment are responsible for the maintenance and remedial action taken in case of malfunction.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
HDD	2/7/08						
HA	2-13-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 4.13 Rev: 3

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG-2-6-08 (Init./Date)

Title: Operation and maintenance of refrigerator or freezer.

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

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. Prior to use visually inspect the unit for cleanliness and that it is in good working condition. Document inspection(s) and any maintenance performed in appropriate logs.
 2. Temperature within the unit should be checked prior to sample storage. A temperature measuring device (i.e. datalogger, min/max thermometer) should be placed in the unit. The temperature range recorded by the device should be within the limits as required for storage of the sample.
 - a. If temperature measured is within the sample storage range, then unit is approved for use.
 - b. If temperature measured is not within the sample storage range, then adjust the temperature control until the unit maintains the correct temperature range.
 - c. If after adjustment, the unit cannot maintain a temperature range within the sample temperature storage range, then the unit must be serviced by a trained technician prior to use.
 3. When unit is being actively used for storage, the temperature should be monitored and recorded frequently enough (refer to SOP 8.2) to ensure that the unit is working properly (refer to SOP 8.2). If no samples are being stored in the unit, no records of the temperature need to be maintained.
 4. Unit should be cleaned approximately once a year or upon inspection it is determined that it needs cleaning and no samples are being stored in unit. To clean the unit, the following procedures should be used or document in routine maintenance log procedure used.
 - a. Turn power off or unplug unit. Open bottom drain if present.
 - b. Melt any ice crystals that had accumulated within unit. Using a clean cloth, wipe down the inside of unit with a dilute cleaning solution (i.e. 1% ammonia cleaner solution) and remove any debris.
 - c. Using a clean damp cloth, wipe down the inside of the unit and remove any standing water from bottom of unit that didn't drain out. Then use a clean dry cloth and dry the inside of unit.
 - d. Close drain, close lid, and turn power on or plug-in unit. Temperature should be checked prior to sample storage.
 5. Remedial actions to be taken in case of failure or malfunction include:
 - a. Any problem should be immediately reported to the Field Research Director or designated personnel, documented, and placed in the maintenance log records for non-routine procedures.
 - b. Any repairs or replacements resulting from malfunction during application will be documented as non-routine maintenance in the appropriate log(s).
 6. Personnel currently operating the equipment are responsible for the maintenance and remedial action taken in case of malfunction.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08						
LLA	2-13-12						

SOP: 4.14 Rev: 1

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg ~~11/26/08~~ (Init./Date)

Title: Procedure used for collecting soil samples using ESP soil probe unit.

Purpose: To establish procedures used when collecting soil samples using ESP soil probe unit.

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. Prior to use visually inspect the unit for cleanliness and that it is in good working condition. Record any maintenance performed in appropriate logs. Consult the protocol for soil sampling requirements. If method is not described, use the following methods or document the methods used in the raw data book.
 2. Equipment needed to collect soil samples should include but are not limited to the following.
 - a. ESP Soil Probe unit = JMC® Environmentalist's Subsoil Probe (ESP) unit which consists of a stand with an integral jack, slide hammer assembly and sampling tube (i.e. 36" length) with removable standard stainless steel tip.
 - b. Liner with caps similar to PETG copolyester 36-inch long liner with two vinyl end caps that are preferably each a different color (i.e. red cap for top or surface soil and a black cap for bottom)
 - c. Permanent marker
 - d. Measuring tape
 - e. Knife or a pair of cutters if necessary for reducing liner length.
 - f. Cardboard box or similar container large enough to place liners containing samples inside to shield from direct sunlight, if necessary.
 3. Using measuring tape and permanent marker, mark the length of the soil core needed on the slide hammer assembly and the liners, if necessary.
 4. At site selected for sampling, remove surface soil debris (e.g. leaf litter, weeds).
 5. Place soil probe stand over sampling site.
 6. Place liner into sampling tube. Screw steel tip onto sampling tube end, then place tube into soil probe stand.
 7. Place slide hammer assembly into soil probe stand on top of sampling tube and begin pounding the sampling tube into the ground using the slide hammer assembly. Continue pounding until you have reached the required sampling depth.
 8. Remove the slide hammer assembly. Then remove the sampling tube from the soil by using the jack or by removing the soil probe stand and pulling the tube up by hand. Care should be taken when handling the soil sampling tube to minimize soil loss. For example, excessive shaking or jarring of the sampling tube during removal from the ground could in crease amount of soil loss from the bottom end of the sample.
 9. Remove steel tip from sampling tube. Gently slide the end of the liner out of the sampling tube and place a cap on the liner end. Then completely remove the liner from the sample tube.
 10. Check you soil sample.
 - a. It should be of the required depth (length) and that there are no sizeable air gaps in the sample indicating that you it a hole.
 - b. If excessive amounts of soil sample was lost while removing sampling tube from ground or during handling of liner or found sizeable air gap(s) in sample, discard soil sample and liner.

11. Cut the liner tube to match the soil sample length. Place a cap on the end. Then final liner length should be as close as possible to the soil sample length inside liner so that there will be no air gaps at the ends of the liner tube to allow for the soil sample to shift within the tube during future handling.
12. Label the liner as required by protocol then if necessary, place liner inside a container to prevent further exposure to direct sunlight.
13. In between samples, clean the sample tube steel tip of any adhering soil. Inspect the inside of sample tube that it is free of debris (if a liner is used for sampling, there should be no debris in tube). If debris exists, clean it out by blowing air through tube or inverting and shaking the tube.
14. After sampling is complete, clean the ESP unit thoroughly using compressed air to remove the dust and debris. Steel tip may be washed and rinsed. Then thoroughly dry the tip as soon as possible to prevent corrosion.
15. Remedial actions to be taken in case of failure or malfunction include:
 - a. Any problem should be immediately reported to the Field Research Director or designated personnel, documented, and placed in the maintenance log records for non-routine procedures.
 - b. Any repairs or replacements resulting from malfunction during application will be documented as non-routine maintenance in the appropriate log(s).
16. Personnel currently operating the equipment are responsible for the maintenance and remedial action taken in case of malfunction.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
HJD	2/7/08						
SA	2-13-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 4.15 Rev: 1

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

Title: Borrowed or rented equipment procedures and documentation

Purpose: To establish procedures used when using borrowed or rented equipment.

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. Contact appropriate source for the equipment to be borrowed or rented.
 2. Determine whether there is an operational manual and or SOP available for the equipment. Request a copy if available.
 3. The following information should be documented for borrowed or rented equipment.
 - a. Source
 - b. Description of equipment (e.g. type, make, model, year)
 - c. Brief history of use, if available.
 4. Prior to use visually inspect the unit for cleanliness and that it is in good working condition. Document inspection(s) and any maintenance (e.g. decontamination procedures) or modifications performed in appropriate log(s).
 - a. Any problems should be reported to the Field Research Director or designated personnel, documented, and placed in the appropriate log(s).
 - b. Any repairs or replacements resulting from malfunction during application will be documented as non-routine maintenance in the appropriate log(s).
 5. Personnel currently operating the equipment is responsible for the maintenance and remedial action taken in case of malfunction.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08						
LLG	2-13-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 5.1 Rev: 4

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

Title: Commodity production and maintenance.

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

Scope: Sites conducting trial(s) to obtain registration of pesticides.

- Procedures:**
1. Refer to an up-to-date publication on the production of the commodity under trial(s). If no such publication exists, consult with cooperative agricultural specialist familiar with the production practices for the commodity under simulated commercial conditions.
 2. Determine pH, soil fertility, and soil characteristics requirements of the commodity. If possible, prior to beginning of field study, obtain a random composite sample of soil for testing from the trial(s) site and 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.) Soil test results for a field tract will remain valid for a maximum of five years. If a soil test is not performed for the field tract, provide soil information in the field data notebook from the USDA Soil Conservation Service soil survey of the area or document soil information source used.
 3. Lime, fertilize and/or condition the soil at the site as necessary to bring the soil within the requirements of the commodity.
 4. Apply appropriate maintenance pesticides (preplant herbicide, soil insecticide, fungicide drench, soil-incorporated nematicide etc.) as required. Document maintenance chemicals in the field raw data notebook.
 5. If pesticides are applied to the commodity to prevent losses due to pests not under trial(s), they should be applied according to the label directions. If this is a residue trial(s), no pesticide should be applied that would interfere with the chemical analysis of the pesticide under trial(s). If in doubt, consult the analytical chemist or analytical laboratory identified in the protocol to determine if a maintenance chemical may be used.
 6. Perform other agricultural cultural practices as necessary to establish and maintain the commodity to completion of the field trial.
 7. After receiving verification from the residue laboratory that all samples from the trial have been received, as soon as possible, destroy the treated crop so that it may not be used for human consumption or animal feed.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08						
LLG	2-13-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 5.2 Rev: 2

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

Title: Method for seeding or transplanting.

Purpose: Assure that commodities are grown under good agricultural practices and provide an acceptable crop for trial(s).

Scope: Sites conducting trial(s) to obtain registration of pesticides.

- Procedures:**
1. Determine the correct species and variety to use as specified by the study protocol. If the variety is not specified, determine the commercial variety most suitable for the protocol's objective and 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.
 2. Determine within and between row spacing and seed depth as specified in an up-to-date publication on the production of the commodity under trial(s) or from a cooperative agricultural specialist familiar with the production practices for the commodity under simulated commercial conditions.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08						
LLG	2-13-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 5.3 Rev: 2

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

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: Sites conducting studies where the protocol requires yield 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 raw 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. The practices used will be documented in the raw 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, should be recorded in the raw data notebook.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08						
LLG	2-13-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 5.4 Rev: 1

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg ~~LHG~~ LHG 2-6-08 (Init./Date)

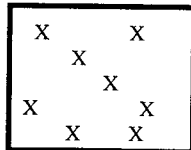
Title: Method for collecting soil samples for analysis.

Purpose: To assure that commodities are grown under good agricultural practices and provide acceptable crop for the study.

Scope: Sites conducting studies for the registration of pesticides for field or orchard use.

- Procedures:**
1. Soil samples should be collected as soon as study location(s) is determined.
 2. Take a composite soil sample from field tract to be used for trial(s). If test site is located in a grower's field/orchard, samples are to be collected from the entire plot area where the study(s) will be located.
 3. The composite sample should be taken from a minimum of 8 different sites representing the entire field or test area.

For Example:



Place these 8 (or more) samples in a clean container (e.g. plastic bucket or paper sack), mix thoroughly and take out approximately 1 pint for composite sample.

4. When taking soil samples, use a spade or soil sampling tube. Scrape the litter (dead plant material, weeds) from the surface. Make the core 8 to 10 inches in the soil. If using a spade, dig a V-shaped hole 8 to 10 inches deep and take 1-inch of soil from the smooth side of the hole. Then take approximately 1 x 1 inch core from the center of the shoved slice.
5. Place the composite sample in a clean container for shipping to soil laboratory (i.e. soil sample bag, sealable plastic container). Do not use metal or glass containers. Label container with unique area identifier or field tract number and name/address of personnel requesting soil information.
6. Determine specific analysis that need to be performed for trials being conducted at the site. For general field studies it is suggested to request the routine analysis (pH, NO₃, P, K, Ca, Mg, Na, S), micronutrients (Zn, Fe, Cu, Mn), texture analysis and organic matter.
7. Mail sample with requested analysis information to soil testing laboratory. For example: Soil, Water and Forage Testing Laboratory / 2474 TAMU / College Station, TX 77843-2474.
8. If procedure used for soil sampling or laboratory differs from written above, document procedure used in the raw data.
9. The original soil analysis report from the testing laboratory is to be treated as raw data.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE
LHG	2/7/08		
LHG	2-13-12		

SOP: 6.1 Rev: 2

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg ~~11-2-08~~ 11-2-08 (Init./Date)

Title: Preparation of application mix.

Purpose: To obtain the proper dilution and mixing of the concentrate into the spray tank.

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

Procedures: After the sprayer has been inspected and calibrated, empty the water from the tank. Use the following methods or document the methods used in the field data book for determining spray mix volume and adding the test concentration to the spray tank.

1. **Spray mix volume.**

- a. Determine the spray volume required to treat area to be sprayed.

For example: $\text{Acre(s)} * \text{GPA} = \text{gallons (spray volume required)}$
(Area to be sprayed)

**You may convert gallons to milliliters: $\text{gal} * 3785 \text{ ml/gal} = \text{ml}$

- b. Spray mix volume is the spray volume required to treat an area plus overage volume. The overage volume is the approximate amount of extra volume needed for priming the sprayer prior to application plus an approximate volume of spray mix (extra) added to avoid sprayer picking up air during the application within test plot due to low volume of spray mix.

For example: Desired delivery rate = 30 Gallons per Acre (GPA)

$0.0153 \text{ A} * 30 \text{ gal/A} = 0.459 \text{ gal(required)} * 3785 \text{ ml/gal} = 1737 \text{ ml required volume}$

For a CO2 backpack/hand boom sprayer with 3 L spray tank:

$75 \text{ ml/sec} * \sim 7 \text{ sec} = \sim 525 \text{ ml} + \sim 250 \text{ ml} = \sim 775 \text{ ml}$
Output rate * time to prime unit prime unit + Extra = Overage

Therefore, $1737 \text{ ml} + \sim 775 \text{ ml} = \sim 2512 \text{ ml}$

Required + Overage = Spray mix volume

2. **Calculate Amount of Test Substance.** If units of measurements used are not those shown in the following equations, then document units used and show conversion factor in raw data notebook.

- a. By Weight (Dry Formulation and % ai wt / wt):

$$\frac{\text{Grams of Test Substance}}{\text{GPA} * \% \text{ ai in Formulated Material (as decimal)}} = \frac{\text{Protocol Rate (lb ai/A)} * \text{Gals of Spray Mix Volume} * 454 \text{ g/lb}}$$

- b. By volume (Liquid Formulation or % ai wt/vol):

$$\frac{\text{mls of Test Substance}}{\text{GPA} * \text{lb ai/gal of Formulated Material}} = \frac{\text{Protocol Rate (lb ai/A)} * \text{mls of Spray Mix Volume}}$$

3. Measure the amount of water needed to dilute the measured amount of concentrate into a separate container. Make sure the spray tank will hold the spray mix volume and test substance amount for intended application.
- a. If adding a liquid concentrate to a 3 liter spray tank (or a similar size unit for which the solution within can be easily mixed) and using a syringe to measure the test substance, the full measured amount of carrier solution (water) can be added to the spray tank. Then add the measured test substance to the tank and rinse the syringe using contents within spray tank. Then seal tank to prevent spillage and thoroughly mix the solution by swirling and if possible, occasionally invert the spray tank during initial mixing.

- b. If test substance measuring devices require rinsing for complete transfer of substance to tank or adding a liquid concentrate to a larger tank which can not be easily shaken, add 1/2 to 3/4 of the water to the spray tank. Use remaining water to triple rinse the measuring device. Add the rinsate to the spray tank. Then add the remaining measured volume of water to the spray tank.
- c. If test substance requires dissolving (i.e. wettable powder formulation) or diluting before adding to tank, add 1/2 to 3/4 of water needed to the tank. Then make a slurry mix by adding the concentrate to a small volume of the measured water (not in the tank) in a separate, clean container. Add the test substance concentrate or slurry to the water in the spray tank. Triple rinse the container holding the test substance concentrate using the remaining water not in the spray tank and add the rinse water to the spray tank. Then add the remaining measured volume of water to the spray tank.
4. Close and tighten the lid of the spray mix container. If any spillage had occurred while adding the test substance to the spray tank, rinse the outside surface of the spray tank with clean water.
5. Agitate the spray mix before and if possible during application to insure an even mix of the test substance and carrier.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
HPD	2/7/08						
HA	2-13-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 6.2 Rev: 4

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

Title: Procedures for the application of test substance for trial(s).

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

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. Check plot. Read the plot marker and verify that the plot to which the application is to be made is the correct plot. Check that the plot boundary markers are clearly visible to the applicator.
 2. Check application equipment. Ensure all settings of pressure, speed, nozzle/outlet position etc. are set according to specification from the calibration as previously performed.
 3. Applicator(s) will wear proper protective clothing as specified on the pesticide label. If protective clothing is not specified on the label or in the protocol, then the applicator will wear a minimum of eye protection (i.e. goggles), breathing-air filtration device (i.e. half-mask respirator), clothing with long arm sleeves and long pant legs (i.e. coveralls), unlined gloves and shoes (i.e. rubber boots).
 4. Just before entering each plot make sure you are applying as protocol requires (i.e. spray applications require traveling at the correct speed and turn on the sprayer or release of granules at/or before entering plot and maintaining the correct speed through the plot; drench requires specific volume/area or plant; drip irrigation required amount of volume/area).
 5. 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 protocol and manufacturer of the equipment. If a hazardous material is applied, two people should be present, one doing the actual application and one who can observe from a safe place to provide rescue assistance if necessary.
 6. Calculations should be made to minimize the amount of application material remaining. This residual mixture should be applied to a suitable crop or disposed of according to current policies and guidelines of the research testing facility.
 7. Treated areas should be posted with warning signs which indicate that a pesticide has been applied. Re-entry will follow label directions or if none exists, re-entry interval will be 24 hours.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08						
LLG	2-13-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 6.3 Rev: 3

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

Title: Cleanup of application equipment.

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

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. Granules-Remove any excess granules and return them to the original container if this procedure does not affect the integrity of the contents or dispose of the excess by using appropriate methods for handling hazardous wastes. Note in the pesticide log for the chemical, the amount of granular material used in the trial(s).
 2. If possible, unused test substance application materials should be applied to an over-planting of the crop or another area with suitable plant material at a distance adequate to prevent contamination of the test plot by drift or downslope movement of water. If a suitable area is not available, then empty remaining pesticide into on-site pesticide disposal unit.
 3. In a suitable area away from danger field/greenhouse trial(s) or aquatic contamination, clean the application equipment. For granular application, document procedure used (if available refer to equipment manual for a procedure. Use the following procedure for liquid application units or document procedure used .
 - a. Wash equipment parts that have been exposed to application mix (i.e. mix container, hoses, booms, nozzles, filters) with either a minimum 1% v/v dish soap or ammonia cleaner solution.. Fill mix container a minimum of 1/4 full with cleaner solution. Using a brush or by shaking the container, expose the entire interior of the container to the solution.
 - b. Connect container containing cleaner solution to application unit and run cleaning solution through unit parts (i.e. hoses, nozzles, filters, booms) used for application of test substance mix.
 - c. Then rinse container and all application unit parts with water sufficient to remove all cleaner solution. Rinse a minimum of three times or run enough water through parts until rinsate coming out is no longer foamy.
 4. Dispose of expendable protective clothing by placing the items in a container for disposal in a landfill. If possible, wash the protective clothing prior to disposal. Clean non-disposable items separate from other clothing and wash appropriate as to remove pesticide residue.
 5. After the application equipment is dry, lubricate those parts requiring lubrication and return the equipment to storage.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08						
LLG	2-13-12						

SOP: 6.4 Rev: 4

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg ~~LL 2-6-08~~ (Init./Date)

Title: Handling of test substance(s).

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

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

Procedures:

1. Upon receipt of a test substance, name on container label, lot/batch number, quantity, date of receipt, condition of the material, and storage location should be recorded in the raw data notebook.
2. If a protocol requires that a test substance be characterized to meet GLP (Good Laboratory Practice) standards, the GLP characterization status should be verified prior to use. If verification can not be obtained, notify the Study Director. Verification can be documented in the raw data notebook by one of the following methods:
 - a. If "GLP" is on container label, document this in raw data notebook.
 - b. Paperwork for test substance which has a comment referring to the substance's "GLP" characterization status should be included in the raw data notebook.
 - c. Verbal verification from the Study Director or registrant representative documented in the raw data notebook.
3. All GLP test substance containers should be labeled as follows:
 - a. Chemical common or trade name
 - b. Formulation
 - c. Manufacturer
 - d. Batch and/or Lot number
 - e. GLP status
 - f. Expiration date - if not provided, contact Study Director or registrant representative
 - g. Storage conditions. If not available, assign storage condition of 45 to 95°F.
 - h. Field Study number - optional
4. If label does not contain this information, it can be properly documented by authorized personnel on label or on supplemental label which should be securely attached to the container where it does not camouflage the original labeling.
5. The test substance should be stored in the pesticide storage facility until it is needed for use in the trial(s). When a test substance is removed or transferred to a different location for a period of time except for a protocol application, record when it is removed, when it is returned and the purpose for which it was removed from the facility.
6. The storage temperatures of the test substance should be recorded in the raw data. If using a min/max thermometer, the minimum and maximum temperature will be recorded a minimum of three times a week except on weekends and holidays. If available, a continuous temperature recorder can be used recording continuous temperature.
7. When a test substance is used, the date, amount used, purpose of use, and initial/signature of the user should be recorded in the raw data.
8. If excess test material is removed from the container during handling and placing the material back into the test substance container may jeopardize the integrity of the test substance, the excess material should now be classified as waste and should be then handled accordingly.

- 9. All test substance containers must be stored until notification by the study director or testing facility management that the containers may be discarded or returned to the registrant or sponsor.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
HJD	2/7/08						
HA	2-13-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 6.5 Rev: 3

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

Title: Procedures to follow for misapplication of test substance.

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

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. During application, the operator should observe the process to make sure that the test substance is being evenly distributed to the commodity.
 2. If something goes wrong, for example, a nozzle is plugged or a hose breaks, then the operator should take immediate action to correct the situation.
 3. The affected portion of the plot should be carefully marked off and staked to indicate the area affected. This portion should not be used for obtaining samples of the commodity for residue analysis. The Study Director should be contacted to decide if adjusted plot size can be properly sampled.
 4. The Study Director and appropriate individuals should be notified of the incident and corrective actions taken.
 5. Document change in plot size on plot map.
 6. Document details of the incident in the raw data notebook in the appropriate logs (i.e. GLP compliance log, communication log, maintenance records, etc.).

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08						
LLG	2-13-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 6.6 Rev: 1

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG-6-08 (Init./Date)

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: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

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 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 should 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.
- d. If no label directions exist for disposal, arrangements should be made with 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 an overplanting of the crop (or similar crop) where this procedure does not violate any laws or regulations. All pesticide solutions should be mixed with the intent of limiting the problem of excess solutions.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08						
LLG	2-13-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 6.7 Rev: 0

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg ~~2-6-08~~ (Init./Date)

Title: Procedures for dip, drench and low volume application of test substance.

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

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. Select commodity as specified in protocol. For post harvest applications, if possible, use freshly harvested fruits or vegetables. Document source and history (if available).
 2. Wash fruit/vegetables, if needed, as specified in protocol to remove dirt and debris. If procedure is not specified in protocol, wash commodity using the following procedure or document procedure used.
 - a. Dip commodity in dilute soap solution (i.e. 0.5% v/v Dawn™ dish soap in water) for a recorded timed interval (i.e. 30 seconds) with agitation.
 - b. Thoroughly rinse with water to remove soap solution.
 - c. Dry fruit/vegetables prior to initiating treatments.
 - d. If chlorination is specified in protocol, fruit/vegetables should be in the chlorinated wash from one to ten minutes. Concentrations of wash generally range from 50 to 150ppm (0.8 - 2.4 pints of 5.25% NaOCl per 100 gallons).
 2. Check application equipment. Ensure that equipment is clean, working properly. If applicable, ensure all settings of pressure, speed, nozzle/outlet position etc. are set according to specification from the calibration as previously performed.
 3. Dip applications: Apply as specified in protocol. If procedure is not specified in protocol, use the following method or document method used.
 - a. Mix solution of test substance as stated in the protocol. Treatment should be applied within 2 hours of mixing.
 - b. Dip the commodity into the test solution. Record the time (i.e. dip for 30 seconds). A basket, net, or other container can be used to submerge/float the commodity into the larger container of test substance solution. If necessary gently agitate or submerge floating fruits or vegetable to ensure even exposure to the test substance solution.
 - c. Drain commodity over the test substance solution container. All treatments should have the same drain and drying times unless otherwise specified in protocol.
 - d. Roll dry to ensure even drying on the commodity. If a roller unit is not available, this can be accomplished by manually rolling the fruit at timed intervals (i.e. every 30 seconds for the first 3 minutes, then every 2 minutes for the following 10 minutes.) Document procedure used.
 4. Drench applications. Apply as specified in protocol. If procedure is not specified in protocol, use the following method or document method used.
 - a. Mix solution of test substance as stated in the protocol. Treatment should be applied within 2 hours of mixing.
 - b. Apply/pour test substance solution over commodity as specified in the protocol. If a timed interval is required, record the time for drenching. If a specified volume per area or per number/weight of fruit/vegetables is stated in protocol, record the volume of test substance solution applied.

- c. For post-harvest applications, roll dry commodity. (Drench applications to soil/media should not require a drying procedure.)
- 5. Controlled Droplet Applicators (CDA) or In-Line applications. Apply as specified in protocol. If procedure is not specified use the following method or document method used.
 - a. Mix solution of test substance as stated in the protocol. Treatment should be applied with 2 hours of mixing.
 - b. Prime application unit long enough to ensure that the test substance mixture will be properly applied (i.e. coat brushes in the system prior to introduction of commodity.)
 - c. Fruits/vegetables should have adequate application time such that commodity is uniformly coated with test substance solution after application.
 - d. Roll dry to ensure even drying of commodity. If heat is required prior to/during drying, document equipment and procedure used.
- 6. After applications, clean equipment and if appropriate, the area where the treatment was applied. Document in appropriate logs.
- 7. Treated areas should be posted with warning signs which indicate that a pesticide has been applied. Re-entry will follow label directions or if none exists, re-entry interval will be 24 hours.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
HYP	2/7/08						
HA	2-13-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 7.1 Rev: 3

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

Title: Collection of raw data electronically.

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

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. Check the power supply on portable units to see that it will be adequate during the data collection and data transfer period. All remote sensing and other automatic data collecting and/or recording devices should be inspected and calibration checked. If manual is available, refer to the manufacturer's recommendations.
 2. Make sure the correct program for data collection is ready and available for use for accurate collection of data.
 3. At the beginning of data collection, verification that the system is working should be performed. This can be accomplished by using the following method or document the method used. Collect a set of *sample* data from a plot electronically and also have someone record the data by hand. At the end of the data collection period, printout the electronically collected data. If both sets of data are in agreement a signed and dated statement to that effect should be written in the maintenance log.
 4. Prompts should be used as much as possible to avoid any confusion in collecting the data. Where feasible, the prompts should state the plot # from which the data is being collected, the current date, and the type of data being collected. Data should be taken in an orderly fashion so as to avoid any confusion.
 5. If possible, at the end of the data collection period, the data should be transferred to a storage system as soon as feasible. If applicable, a hard copy should be printed out with appropriate identification. This hard copy must be dated and signed then stored in the trial(s) file folder.
 6. Prints or plots of data from these devices must be legible to persons with normal vision.
 7. Each data sheet from a monitoring device should be marked in ink with the name of the study ID number, dates (day, month, year) of occurrence of the event measured, units of measurement and signed and dated by the person preparing the data sheet.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08						
LAA	2-14-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 7.2 Rev: 3

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

Title: Recording of raw data.

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

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. All raw data will be recorded in indelible ink and legibly so that a person with normal vision may read it.
 2. Each recording of raw data should be made as promptly as possible and accurate. Sufficient detail or appropriate reference should be provided as to the data collection methods so that it can be recreated without physically repeating.
 3. 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 but are not limited to the list below. Document other error codes used in the raw data book.

NA = Not Applicable	LE = Late Entry
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 Writeover
UE = Unnecessary Entry	PE = Pagination Error

4. Pages containing raw data shall not be discarded.
5. Cross-reference instrument or statistical printouts when such data are retained in a separate location.
6. All data entries shall be dated on the day of entry and signed or initialed by the person entering the data.
7. Make sure that all data required by the study protocol or by the forms provided (if applicable) in the field data book are collected and recorded. If a particular form or section of a form does not require a response, draw a diagonal line through the area and initial and date the line or sign and date the bottom of the page.
8. Blank forms may be copied or new forms can be developed by the FRD or designated personnel. The new forms should mimic the sponsor (e.g. IR-4) forms as close possible.
9. If data is transcribed, the data shall be noted as such and the original raw data location must be referenced. If possible, the original data or a true copy of the data should be included in the data book.
10. The Field ID number will be written on the top of each page within the raw data book.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE
LLG	2/7/08		
JAA	2-14-12		

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 7.3 Rev: 2

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg #A 2-6-08 (Init./Date)

Title: Calculations for data presentation.

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

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. Results must be reported to correct number of significant figures reflecting 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 round 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 greater 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.
 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.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
<i>AGD</i>	<i>2/7/08</i>						
<i>YJA</i>	<i>2-14-12</i>						

SOP: 7.4 Rev: 2

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG-6-08 (Init./Date)

Title: Method for collecting efficacy and phytotoxicity data.

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

Scope: Sites conducting studies for the registration of pesticides.

Procedures: A. Phytotoxicity data:

1. Consult the protocol to determine the method and timing of the phytotoxicity data. If no method is cited then reference your method or proceed as follows.
2. Where possible, take phytotoxicity data within 24 hours before the initial pesticide treatment and within 48 hours after the treatment, 1 week later and at the termination of the trial(s). If symptoms occur during this period that warrant a reading, then additional phytotoxicity data should be taken as necessary.
3. Randomly select 5 plants in the middle row of each plot and record a phytotoxicity rating of 0 to 5 for each plant. Zero= plant healthy. Five= Plant dead. One thru four= the percentage necrosis and/or yellowing of the plant. If there are less than five plants/row, record data from 5 plants/plot or all the plants in a plot.

B. Pest data:

1. Consult the protocol to determine the method and timing of the pest data. If no method is cited then reference your method(s) for each pest or proceed as follows.
2. Where possible, take pest data within 24 hours before the initial pesticide treatment and within 48 hours after the treatment and at various intervals thereafter depending on the pest life cycle and at the termination of the trial(s).
3. Disease data-Record the name of the disease(s) being observed. Record the symptom(s) for each disease. Randomly select 5 plants in the middle row of each plot and record the severity of each disease in a rating system of 0 to 10 for each plant. Zero= plant healthy. Ten= Plant dead. One thru nine= the percentage disease appearing on the plant. If there are less than five plants/row, record data from 5 plants/plot or all the plants in a plot.
4. Insect data-Record the name of the insect(s) being observed. Record the damage symptom(s) for each insect. For damage symptoms-randomly select 5 plants in the middle row of each plot and record the severity of damage for each insect in a rating system of 0 to 10 for each plant. Zero= plant healthy. Ten= Plant dead. One thru nine= the percentage damage appearing on the plant. If there are less than five plants/row, record data from 5 plants/plot or all the plants in a plot.

For insect pest population counts-take a random sample of the pest population (i.e. 5 leaves/plant of 5 plants/plot, 4 3-in diam. soil cores/plot, 100 apples/tree etc.) to insure an accurate reflection of the pest density/unit area.

5. Nematode data-Record the name of the nematode(s) being observed. Record the damage symptom(s) for each nematode. For damage symptoms-randomly select 10 plants in the middle row of each plot and record the severity of damage for each nematode on each plant using one of the rating systems described by the following:

Barker, K.R., J.L. Townshend, G.W. Bird, I.J. Thomason and D.W. Dickson. 1986. Determining nematode population responses to control agents. In Kickey, K.D. (ed.). Methods for evaluating pesticides for control of Plant Pathogens. Pages 283-296.

If there are less than 10 plants/row, record data from all the plants in a row.

For nematode population counts-take a random sample of the pest population (i.e. root system of 2 plants/plot, 4 3-in diam. soil cores/plot, etc.) to insure an accurate reflection of the pest density/unit area as described by Barker et.al. cited above. Use a method suitable to extract the nematodes from the soil or plant sample and cite the method here. Count and record the number of nematodes by the various life stages/unit of soil or root.

6. Weed data-Visually observe each plot and record the percentage (%) of the area (to the nearest 5%) covered by weeds. Record the names of the 5 most prominent weed species and the area they cover (to the nearest 5%) in each plot. Randomly place a grid covering an area of 0.1 M² and divided by quadrants in the plot. Where possible, count the number of weeds in the grid. If weeds are too numerous, then count the number of weeds in the lower left quadrant, multiply by 4 and record this value as the number of weeds in the grid.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
HYD	2/7/08						
JFA	2-14-12						

SOP: 7.5 Rev: 2

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

Title: Experimental design and data analysis.

Purpose: To assure that all efficacy, yield, and phytotoxicity data developed are statistically sound.

Scope: Sites conducting studies for the registration of pesticides.

- Procedures:**
1. The experimental design as specified by the protocol should be used. If none is designated, then the researcher should use a commonly accepted experimental design such as a complete randomized block design. The experimental design used should be documented in the raw 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.
 5. Retain the plot map in the trial(s) folder.
 6. Determine the level of significance for the trial(s).
 7. Select an appropriate statistical package for data analysis and record sufficient information to identify the statistical package (i.e. Date, Revision no., Title, Authors, Source etc.).
 8. 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.
 9. Record the data as required on the appropriate forms and identify statistically significant differences in the data in the raw data note book.
 10. Retain all data, analyses, notes etc. in the trial(s) folder with sufficient information to recalculate the data summaries and statistical analyses by another person without verbal input.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08						
LLG	2-14-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 7.6 Rev: 3

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

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: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. It is the responsibility of the Field Research Director to see that all raw data, summaries and other items connected with the trial(s) are properly retained prior to sending the data to the Study Director for archiving.
 2. The Field Research Director or designee will see that a separate file containing all raw data, summaries, data logs, etc. connected with the trial(s) is maintained during the active life of each project for which he/she is responsible.
 3. Dated and signed hard copies of electronic data, computerized summaries etc. should be placed in the file as soon as possible after the information is generated.
 4. Reports generated from a non-GLP source (i.e. soil analysis, weather) shall be initialed and dated upon receipt by individual responsible for receiving report(s). The original reports that transcend several studies may be filed in a Facility File for the current year for later archiving. True copies are to be placed in raw data books as it pertains to.
 5. All notebooks should be clearly marked with the name of the project, project identification number, dates generated, name of investigator and other information that may be needed to understand the data and its source.
 6. Data sheets should be marked with project identifier, data sheet identifier, and page number (i.e. Field ID#06868.06-TX68, Part6-A, Page 1).
 7. Computer software or on line programs such as SAS used in the trial(s) should be noted in the raw data notebook and information on the title, source, revision or other identifying information should be recorded and the data maintained and updated as needed and filed in the trial(s) folder.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2-7-08						
LLG	2-14-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 7.7 Rev: 1

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

Title: Handling of raw data forms that transcend two or more trials.

Purpose: To establish procedure for handling raw data forms which transcend two or more trials.

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

Background: Where a Field Research Director is conducting multiple trials during the year, there may be an opportunity to utilize one form for data that pertains to more than one trial. There are provisions within the GLPs for substitution of verified copies for original records. However, the retention for 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 or in a highly visible area as to the location (i.e. raw data book or facility file) that has been designated for containing the original raw data. This should read similar to: "The original is in IR-4 field data book . . .".
 2. When the form is completed, it should be photocopied. Each copy should contain a notation that it is a true copy. The copy(s) should be signed or initialed, dated and placed in the field data books for the other trial(s) that utilize the same data.
 3. Facility files may also be used to handle originals of pages that transcend 2 or more trials.
 - a. Originals may be placed in a facility file which is to be sent for archiving at IR-4 headquarters on an annual basis.
 - b. True copies of the originals shall be placed in the pertaining raw data books with a clearly visible notation that it is a true copy and the location of the original being in the facility file and the year. This should read similar to: "This is a true copy of the original in TALR Facility File '08", initialed and dated.
 - c. Examples of pages that may be included, but are not limited to, are:
 - i) Maintenance logs (i.e. freezer, application equipment, scale, data loggers)
 - ii) Field site information (i.e. map to field site, soil characterization)
 - iii) Qualification summaries
 - iv) Test substance storage temperature logs
 - v) Weather data

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08						
LLG	2-14-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 7.8 Rev: 2

Effective Date: February 07, 2006

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

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

Purpose: To assure that raw data are sent to the archives(s) is retained and usable.

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. The Field Research Director (FRD) or designee should make an exact copy of the original raw data including completed field data books, correspondence, protocol deviation forms, logs, and any accompanying documentation such as weather charts, etc.
 - a. The true copy of the raw data book will then be placed in a folder labeled with Field/Study ID#, crop and test substance and retained at the testing facility.
 - b. The original raw data and true copies of site specific documents from the trial(s) should be forwarded to the Regional Field Coordinator (RFC) or as indicated in protocol.
 2. The RFC or protocol designated person may review the document received in Sect. 1 for completeness and accuracy of reporting.
 - a. If needed, the reviewer will contact the FRD regarding any missing data or correct deficiencies. Responses will be made according to direction of RFC. Copies of corrective actions, if any, shall be filed in the Field folder at the testing facility.
 - b. After data book is approved by RFC, it will be forwarded to appropriate personnel for future archiving.
 3. The Quality Assurance (QA) personnel will review the raw data book (or original copy). A copy of the audit should be sent to the FRD for response to any finding as soon as possible. If corrective actions need to be made, if applicable, the FRD will make corrections or consult (i.e. phone or e-mail) with the Study Director. Copies of corrective actions, if any, should be filed in the Field folder at the testing facility.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08						
LLA	2-14-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 7.9 Rev: 1

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

Title: Retention of data.

Purpose: To assure that each location conducting trial(s) retains all data and documents connected with the trial(s) until the study is completed and the Study Director or Testing Facility Management (TFM) indicates that all data has been archived.

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. The Field Research Director (FRD) or designee will see that the trial(s) file containing the raw data, originals or true copies of reports, logs, etc. are submitted to the Study Director for archiving and a true copy and original site specific documents are retained at the field facility to assure that the raw data is not lost for a period of at least 10 years unless released by the Study Director or TFM.
 2. The Field Research Director or designee should maintain files pertaining to the GLP studies 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. True copies of raw data including pest counts, yield, phytotoxicity, weather records, logs of instrumentation calibration and test substance receipt, distribution, etc.
 - b. Copies of summaries including calculations and copies of information used from referenced 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 at the facility.
 - g. Organizational charts, training records, job descriptions and CVs (current, out-of-data, or 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 the re-construction of the trial(s).
 - i. Any samples as required by the study protocol or Study Director.
 3. Data may be removed and destroyed for those trials were the Study Director or TFM has indicated the study is completed (or canceled) and raw data have been archived.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08						
LLG	2-14-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 7.10 Rev: 1

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LAG 2-6-08 (Init./Date)

Title: Procedures for archiving..

Purpose: To assure that site conducting studies for registration of pesticides establishes and maintains an archive facility for retention of any raw data and documents connected with GLP studies that is retained at the research testing facility.

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:
1. Raw data that is likely to be retained at research testing facility, but not limited to:
 - a. Farm records, such as soil preparation and crop maintenance activities.
 - b. Irrigation records.
 - c. Monthly weather report summaries.
 - d. SOP's
 - e. Equipment manuals
 - f. Personnel training records
 2. Whenever possible raw data should be included with the raw data book that it pertains to upon completion, or as directed by Testing Facility Management or other qualified personnel.
 3. The Field Research Director is responsible for the archives and may designate an Archivist and Archivist backup. Lori Lynn Gregg will be designated as the Archivist and John Drawe as Archivist backup.
 4. The Archivist will establish and maintain a log of the contents of the archives. The log will contain, but not limited to, a content of the archived materials (i.e. historical SOP's, personnel files).
 5. Only the Archivist or Archivist backup will file or remove documents from the archive file cabinet. An In/Out placard will be used in place of any documents removed from the file cabinet. The placard will contain the specific name of the documents removed/returned, initials of person removing/returning and dates of activity.
 6. Archive files are located in a locked cabinet in Special Projects work area (Bldg. WE005) connected to the Special Projects main office. Only the Archivist and Archivist backup will have access to the key.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LAG	2/7/08						
LAG	2-14-12						

SOP: 8.1 Rev: 5

Effective Date: February 15, 2012

Submitted & Reviewed by: Lori Lynn Gregg LLG (Init./Date)

Title: Sample collection, identification, and records.

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

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- 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 applications etc.) then tentative dates should be established and refined as necessary.
 2. If possible, avoid sampling during periods of inclement weather.
 3. Representative samples of the crop in each plot must be taken according to trial protocol. Describe procedure used in detail in raw data notebook.
 4. Consult the study protocol to determine sample size and special instructions for the commodity.
 5. Sample each replicate individually beginning with the untreated plots and working up to the highest dosage. Treatments from each replicate should be individually packaged and labeled.
 6. Sampling for Residue analysis: If procedure is not specified in the protocol, use the following method or document method used in the field data book.
 - a. Avoid sampling from the area that is within 3 ft of the end plot markers.
 - b. Sample will be taken from the entire length of the individual treatment plot except for avoiding plot ends. Starting at one end of the plot, samples will be taken at random intervals while walking down the entire plot length. If a two row plot, samples will be taken from alternate rows while walking down the plot. This process will be repeated until required amount of sample is obtained.
 - c. Sample will be representative of the crop (i.e. for peppers, fruit will be harvested from high and low, inside and out, exposed or shielded in proportion to the fruit load on the plants).
 7. 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. Sample untreated first, then treated (1X, 2X, etc.)
 - c. Wear clean gloves or wash hands prior to beginning sampling. Change gloves or clean hands between treatment sampling.
 - d. Be certain tools are clean prior to sampling each treatment.
 - e. Avoid taking diseased or undersized crop parts.
 - f. Take care not to remove surface residues or damaging fruit surfaces during handling, packing or preparation.
 - g. 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.)

SOP#: 8.2 Revision Number: 4

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg ~~1/2-6-08~~ (Init./Date)

Title: Procedures for sample packing and storage.

Purpose: To assure the integrity of the samples after collection.

Scope: Sites conducting trial(s) under GLP guidelines to obtain residue samples.

- Procedures:**
1. If samples require refrigeration or freezing prior to shipping to the residue laboratory, and sampling site is over 30 minutes away from freezer area, then clean containers with ice, frozen ice packs or dry ice in sufficient quantity to preserve the samples prior to storage should be taken to the site. Otherwise clean containers of sufficient size and burst proof strength to hold the samples should be used. Avoid contamination of the field samples with the test substance or other foreign material which may jeopardize the integrity of the sample.
 2. Carefully place the sample as it is collected in the sample bag marked for that sample. Make sure that the 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. If required, time to freezer = time-bag-closed to time-bag-placed-in-freezer.
 4. Physically separate treated and untreated samples during transport and in freezer.
 5. When sample collection is completed, the samples should be returned from the sampling location to be placed in storage.
 6. Consult the study protocol for the method, temperature, and maximum length of time for storage. If specifications are not given in the protocol use as a rule of thumb for maximum temperature and storage times: -5°C for frozen commodities, 4°C and 14 days for refrigerated commodities and 25°C and 5 days for commodities held at room temperature.
 7. Samples identified for post-harvest processing should be processed or shipped to the processor as soon after collection as possible. Refer to protocol for storage and shipping temperature requirements.
 8. The storage temperature of the samples should be recorded frequently enough to ensure that the temperature is maintained within the limits as prescribed by the study protocol or within limits to preserve the commodity and the pesticide residues as close to the condition at harvest as is feasible. It is preferred that a continuous recorder be used to monitor the temperature of the stored samples. If a continuous temperature recorder is not available, the minimum and maximum temperature should be recorded from a min/max thermometer every other day except on weekends and holidays.
 9. The refrigerator, freezer, or room where the samples are stored should be under lock and key with limited access and, where possible, only be used to store GLP samples.
 10. Attached to the storage facility (i.e. freezer, refrigerator etc.) should be a log of the items inside indicating the Field ID No., Date samples placed in storage unit, and Number of sample bags for each project. Removal of the samples prior to shipment should be recorded on the log sheet as to the name of the person removing them, what sample bags or parts thereof were removed, date removed and date returned.
 11. Freezer temperature does not have to be recorded during time when no residue samples are being stored.

12. If freezer unit should malfunction the following steps should be taken,
 - a. Samples should be transferred to a properly working clean unit as soon as possible. A temperature monitoring device should be with the samples at all times. If a freezer unit is not available, then samples may be packed in a proper container (i.e. styrofoam or insulated plastic ice chest) with dry ice.
 - b. The temperature monitoring device in the malfunctioning freezer should be checked for temperatures out of the proper sample storage range during sample storage. If this has occurred, notify the Study Director.
 - c. The freezer should be inspected prior to placing samples in and if needed, serviced by a qualified technician.
 - d. Record all actions taken in the field data book.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
<i>HDD</i>	<i>2/7/08</i>						
<i>HA</i>	<i>2-14-12</i>						

SOP#: 8.3 Revision Number: 4

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

Title: Procedures for sample shipping.

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

Scope: Sites conducting trial(s) under GLP guidelines to obtain residue samples.

Procedures:

1. Prior to shipping samples, notify designated personnel at the residue laboratory. Notify him/her of the Pr. No., shipment dates and method of shipment. Verify shipping address and ask for any special instructions in shipping the samples. If possible, air freight shipments should be made on Monday, Tuesday or Wednesday to avoid potential weekend layovers, and shipment during holidays should be avoided.
2. Complete residue sample shipping form(s), make copies and send, fax or e-mail to the study director, regional coordinator and residue chemist.
3. Make arrangements with the carrier for shipment of the samples and determine any special packing instructions etc. that is required to preserve the sample integrity. Note any limits on quantity of dry ice, package size, weight, etc. that may be set by the carrier.
4. Obtain insulated containers, if necessary, of sufficient size and quantity to hold the residue samples and dry ice (where required) in sufficient quantity to keep samples frozen during shipping (i.e. 1:2 weight ratio to commodity). Pack samples in dry ice as soon as samples are removed from freezer. The containers should have sufficient bursting strength so as to withstand normal handling in shipping and storage.
5. Control and treated samples may be shipped within the same container as long as samples are physically separated, such as placing control in a closed plastic bag and/or by a divider between the samples, such as cardboard.
6. Place a true copy of the residue sample shipping form in a waterproof container (i.e. plastic bag) and place it in one of the shipping containers.
7. Label each container with the following information:
 - a. Return Name and Address of the sender
 - b. Name and Address of the residue laboratory receiving the samples
 - c. When appropriate, label as box ___ of ___
 - e. Affix a "Perishable" label on each carton
 - f. Where used, affix "Dry Ice" on one side of each container
8. Tie or tape lids of each container firmly in place.
9. Fill out carrier shipping form. If space is provided, indicate that shipment is perishable.
10. Provide carrier with shipment and the phone number of the residue laboratory receiving the samples and request the carrier to notify the laboratory when the samples arrive at a remote terminal for pickup.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08						
LLG	2-14-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 9.1 Rev: 1

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

Title: Procedures to follow for handling a failing or failed trial.

Purpose: To assure proper procedures are followed for handling a trial that is not within protocol standards.

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. The Field Research Director or authorized personnel must notify the Study Director in detail the cause for the trial not being within protocol standards. Examples of causes are as follows but are not limited to:
 - a. Misapplication (i.e. application of substance out of protocol range, equipment malfunction during application).
 - b. Severe crop damage or crop failure (i.e. insect or herbicide damage, extreme bad weather)
 - c. Unsuitable sample storage conditions (i.e. freezer malfunction, delay during shipping)
 - d. Contamination of trial site with same or similar pesticide.
 2. Consult with Study Director. If it is determined that a suitable sample(s) for residue analysis can not be obtained, the trial may be terminated.
 3. Document communications and remedial actions taken in appropriate logs.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08						
LLA	2-14-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 9.2 Rev: 2

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

Title: Procedures to follow for a trial termination.

Purpose: To assure proper procedures are followed for the termination of a field or greenhouse trial.

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. The Field Research Director (FRD) or authorized personnel must have verification from the Study Director that the trial has been terminated before terminating the field or greenhouse trial. Verification should be obtained in writing from the Study Director.
 2. If no applications of the test substance have been made, inform the Study Director of this either verbally or in writing.
 - a. Unless otherwise directed by the Study Director, no other documentation pertaining to the terminated trial is required.
 - b. The field data book pages are then placed in a folder labeled with Field ID#, crop and test substance with the word "Cancelled" visibly written and filed in the testing facility archives unless Study Director states otherwise.
 3. If an application of the test substance has been made, then consult with the Study Director on how to proceed.
 - a. Unless otherwise directed by the Study Director, the field data book, complete with the data generated up to the time of termination will be sent for archiving.
 - b. A true copy of the data book will be placed in a folder labeled with Field ID#, crop, test substance and the word "Terminated" or "Cancelled" visibly written and filed in the testing facility archives.
 - c. Destroy the treated crop as to prevent it from being used for human or animal consumption..
 4. Document communications and any actions taken in raw data book prior to terminating trial.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08						
LLG	2-14-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 10.1 Rev: 1

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

Title: Location and scope of the Quality Assurance Unit (QAU).

Purpose: To assure that data generated for the registration of pesticide(s) is conducted under Standard Operating Procedures (SOPs) and meet the requirements of Good Laboratory Practices (GLP).

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. The Testing Facility Management will assign the QAU.
 2. The QAU will be responsible for monitoring studies to assure management that the facilities, equipment, personnel, methods, practices, records and controls are in compliance with GLP.
 3. Shortly after a Study has been planned, but prior to initiation of the study a Quality Assurance Coordinator (QAC) will be assigned to each Study.
 4. The QAU will be responsible for conducting facility inspections at all locations involved in the Study and conduct critical phase inspections of each study at intervals adequate to ensure the integrity of the Study.
 - a. The QAU will develop a system to randomly monitor the studies to assure that they are in compliance with GLP.
 - b. The inspectors will provide the research facility with guidance on how to improve its GLP compliance.
 - c. A facility inspection of each test site will be conducted at a minimum of once every three years.
 - d. Critical phase inspections will be conducted on an "as needed basis".
 - e. All reports from facilities and critical phase inspections will be provided to the appropriate Study Director and the Testing Facility Management.
 5. The Quality Assurance (QA) report of the results of an inspection will be provided to the Field Research Director (FRD) for comment. The FRD will return the QA report with appropriate comments to findings and corrective actions taken if needed to the Study Director or personnel designated by the Test Facility Management.
 6. The QAU will review the final report to assure that it accurately reflects the raw data of the study and will prepare and sign a statement noting dates the inspections and findings were reported to management and the Study Director.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08						
LLG	2-14-12						

SOP: 10.2 Rev: 1

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

Title: Non-Compliance with Good Laboratory Practices Procedures.

Purpose: To provide information concerning QAU procedures for cases of non-compliance with GLPs.

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

Definitions of Non-Compliance: Non-Compliance will be considered if one or more of the following occurs:

1. Failure to have access to personnel records or make them available with a reasonable period of time.
2. Falsification of personnel records.
3. Failure to designate a Field or Laboratory Research Director.
4. Failure to assure the existence of a Quality Assurance Officer (QAO).
5. Failure of the QAO to conduct any inspection or maintain any records.
6. Failure to maintain Standard Operating Procedures (SOPs).
7. Failure to follow SOPs or have deviations from the SOPs approved and signed by the Study Director.
8. Failure to have evidence of a characterization of the test substance. This information may be held by the company or the Testing Facility Management but some documentation must be available to show possession.
9. Failure to have a field or laboratory phase protocol.
10. Deviation from the protocol without documentation and/or evidence of Study Director's sign-off/approval.
11. Failure to record raw data or falsification of raw data.
12. Failure to retain raw data and specimens (where required) in a designated archives facility.
13. Failure to maintain logs and other records as required.

- Procedures:**
1. The following are items which cannot be corrected and will result in termination of the trial or result in the data not to be considered acceptable for submission to EPA.
 - a. Completion of trial without an authorized protocol.
 - b. Failure to record raw data or falsification of raw data.
 - c. Failure of the QAU to conduct at least one inspection while a study is in progress.
 - d. Any deviation from the protocol or SOPs that would significantly affect the outcome of the trial and the Study Director recommends the termination of the trial.
 - e. Failure to retain original raw data associated with trial.
 2. Several additional items render a trial as not being in full compliance with GLP. When corrective actions are taken to bring the trial into GLP compliance without violating the integrity of the data, the trial can be considered in compliance. Otherwise, the trial shall be terminated.
 - a. SOPs exist but are not completely up-to-date and minor modifications will correct this deficiency.
 - b. Personnel records are not up-to-date.
 - c. Starting a trial without an authorized protocol.
 - d. Deviating from protocol and/or SOPs without Study Director's approval.
 - e. Failure to use test or reference substance that has not been properly characterized.

- 3. Where a location is consistently in non-compliance with GLP, the Testing Facility Management will designate personnel to work with management at the Research Testing Facility to take the corrective actions necessary to bring the facility into compliance or determine whether or not funds should continue at the location to support GLP studies.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
HJD	2/7/08						
JAP	2-14-12						

Texas AgriLife Research
2415 E. Bus.Hwy 83 / Weslaco, TX 78596

SOP: 11.1 Rev: 3

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

Title: Guidelines for handling pesticides safely.

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

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. A supply of soap/detergent and water should be readily accessible for cleanup in the case of an emergency.
 2. All personal protective equipment and clothing as required by the pesticide label, in the paperwork which was received with the test substance or written SOPs should be worn in the handling of pesticides for storage, mixing and application. Emergency personal protective equipment (e.g. coveralls, self-contained breathing apparatus) must be available when handling hazardous pesticides such as restricted use pesticides.
 3. Appropriate weather conditions for the application of the pesticide should prevail otherwise the pesticide applications should be delayed.
 4. All precautions should be taken to avoid applying pesticides to or near sensitive areas or where drift to these areas may occur.
 5. Prior to application, the equipment should 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 should have lids. Filling the spray tank should be done carefully so it does not run over. All machinery should be shut down if necessary to adjust or repair any moving parts. Never blow out nozzles, hoses, or clogged lines by mouth.
 6. 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 after the job is completed. Cleanup procedures should be established whereby excess sprays can be safely discarded preferably by spraying the material on an overplanting of the commodity. The equipment should be washed off both inside and outside and all pesticides and pesticide containers should be returned to a storage area immediately after use.
 8. At the end of the working day employees who have applied or mixed pesticides should wash exposed skin areas and change out of protective clothing (i.e. coveralls, aprons, boots, gloves, etc.) Protective clothing should be washed (or disposed of properly if clothing was disposable) after the end of the day. In no cases should the same clothing, including shoes, be worn on a second day after it has been worn during a pesticide application.
 9. A pesticide-treated area, greenhouse, or field should not be entered until an adequate time, as specified on the label of the pesticide (re-entry interval) has elapsed. For persons who regularly handle organophosphates and/or large quantities of carbamates, a cholinesterase level should be determined at least monthly throughout the pesticide application season.
 10. Do not permit unauthorized persons in the pesticide storage area.
 11. Do not store pesticides next to food, feed, seed, 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 present.

12. Do not drink, eat food, smoke, apply cosmetics, or use tobacco in areas where pesticides are present.
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.
15. Wash hands thoroughly with soap and water immediately after handling pesticides and, especially before eating, smoking, or using the toilet.
16. Treated field(s) should be posted with warning signs immediately after application and throughout the re-entry interval.
17. Pesticide storage areas should be properly ventilated.
18. The Field Research director or designated personnel is responsible for making sure that personnel working with pesticides have the needed protections (i.e. training, personal protective equipment, pesticide information) available as required by the pesticide label/MSDS or Worker Protection Standards if pesticide label/MSDS is not available.
19. In case of an incident (i.e. fire, flood), the Field Research Director will be responsible for providing a floor plan of the pesticide storage area indicating where different pesticide classifications are regularly stored and an inventory.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
HPD	2/7/08						
JJA	2-14-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 11.2 Rev: 2

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

Title: Labeling and handling of reagents and solutions.

Purpose: To assure that reagents and solutions are labeled and handled properly.

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. When reagents and solutions are received, containers are to be labeled with the following information, if the information is not provided on the manufacturer's label:
 - a. Name of reagent/solution.
 - b. Alternative name, if available.
 - c. Concentration.
 - d. Batch or Lot number, if available.
 - e. Storage requirements.
 - f. Date received.
 - g. Expiration date.
 2. Refer to MSDS sheet to obtain necessary information to compete label.
 3. If expiration date is not provided, reagents/solutions are to be evaluated annually. The storage conditions of the previous year are to be considered in re-evaluating the reagent/solution.
 4. All personal protective equipment and clothing as required by label or MSDS should be worn in the handling of the reagent/solution for storage and use.
 5. Container(s) of reagent/solutions which are to be used in GLP trials should be stored in an area with limited access (i.e. lock-able cabinet) to prevent possible contamination by unauthorized use and the storage conditions monitored.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08						
LLG	2-14-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 12.1 Rev: 4

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

Title: Procedures to follow prior to an EPA inspection.

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

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

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 available the personnel who may be associated with the trial(s) or facilities audit.
3. Make sure someone who is authorized to accept the Notice of Inspection is going to be present at the start and finish of the inspection such as the Field Research Director or location Resident Director. This person is responsible for the following:
 - a. Confirm that the documents and other preparations are in place for the inspection.
 - b. Coordinate with the Testing Facility Management such as Quality Assurance Officer and Study Director as necessary.
4. Prepare trial(s) and/or facilities personnel for the inspection.
 - a. Review position descriptions with technical personnel so they understand and can explain their role in the trial(s).
 - b. Discuss possible questions that may likely come up about the trial(s) or facility and make sure every one 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. Ensure that all documents pertaining to the trial(s)/facilities inspection are available. This would include:
 - i) Master schedule for the field research director.
 - ii) Study Protocol and Standard Operating Procedures.
 - iii) Raw data, correspondence and logs.
 - iv) Training records, CVs, job descriptions, etc. of personnel assigned to the trial(s).
 - v) Appropriate chain of custody documents for samples and freezer logs and storage temperature documentation.
 - vi) Documentation of the characterization of the test substance, receipt, handling, and storage records.
 - vii) Calibration and maintenance logs on equipment such as balances and application equipment.
 - viii) Archives or storage of records and logs indicating removal and replacement of documents.
5. Have accessible organizational charts, a map of the facility and any information specific to the facility or area that will make the inspection go smoother.

6. Make certain all working areas associated with conducting "GLP" trials are "clean", well-organized and that all documentation (maps, labeling maintenance logs, etc.) are in order and up-to-date.
 - a. Pesticide Storage Area - inventory up to date and readily available. "GLP" test substances properly labeled.
 - b. Chemical Mixing Area - all instrumentation clean and well-organized, manuals and maintenance logs for equipment up-to-date and readily available.
 - c. Field Testing Areas - properly marked and adequately maintained.
 - d. Sample Handling/Storage Area - Sampling equipment properly stored to avoid possible contamination. Freezer should be clean, in good working condition. Freezer temperature, maintenance and inventory logs readily available and up-to-date.
 - e. Application Equipment Storage - Equipment should be properly stored, well-organized and in good working condition. Maintenance logs should be up-to-date and if available Operation manuals readily available.
 - f. "Paperwork" area - All documentation is well-organized, properly identified and up-to-date.(i.e. maintenance logs, temperature logs, notebooks, archive logs, personnel logs, etc.).

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
<i>HJD</i>	<i>2/7/08</i>						
<i>ZFA</i>	<i>2-14-12</i>						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 12.2 Rev: 2

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

Title: Procedures to follow during an EPA inspection.

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

Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- Procedures:**
1. Greet the inspection team and follow any institutional procedures for signing in. Provide (if possible) 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 or trial(s). Identify the person responsible who will accept the Notice of Inspection.
 4. Distribute organizational charts, map(s) of the facility and any other information previously prepared to make the inspection go smoother.
 5. Ask the lead inspector for his/her agenda for the inspection as well as a list, if possible, of personnel for interview during the inspection.
 6. Explain any housekeeping rules such as the use of safety equipment in work areas etc. to avoid any possible 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 management informed of the progress of the inspection and the findings.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08						
LLG	2-14-12						

Texas AgriLife Research
2415 E. Bus. Hwy 83 / Weslaco, TX 78596

SOP: 12.3 Rev: 2

Effective Date: February 07, 2008

Submitted & Reviewed by: Lori Lynn Gregg LLG 2-6-08 (Init./Date)

Title: Procedures to follow after an EPA inspection.

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

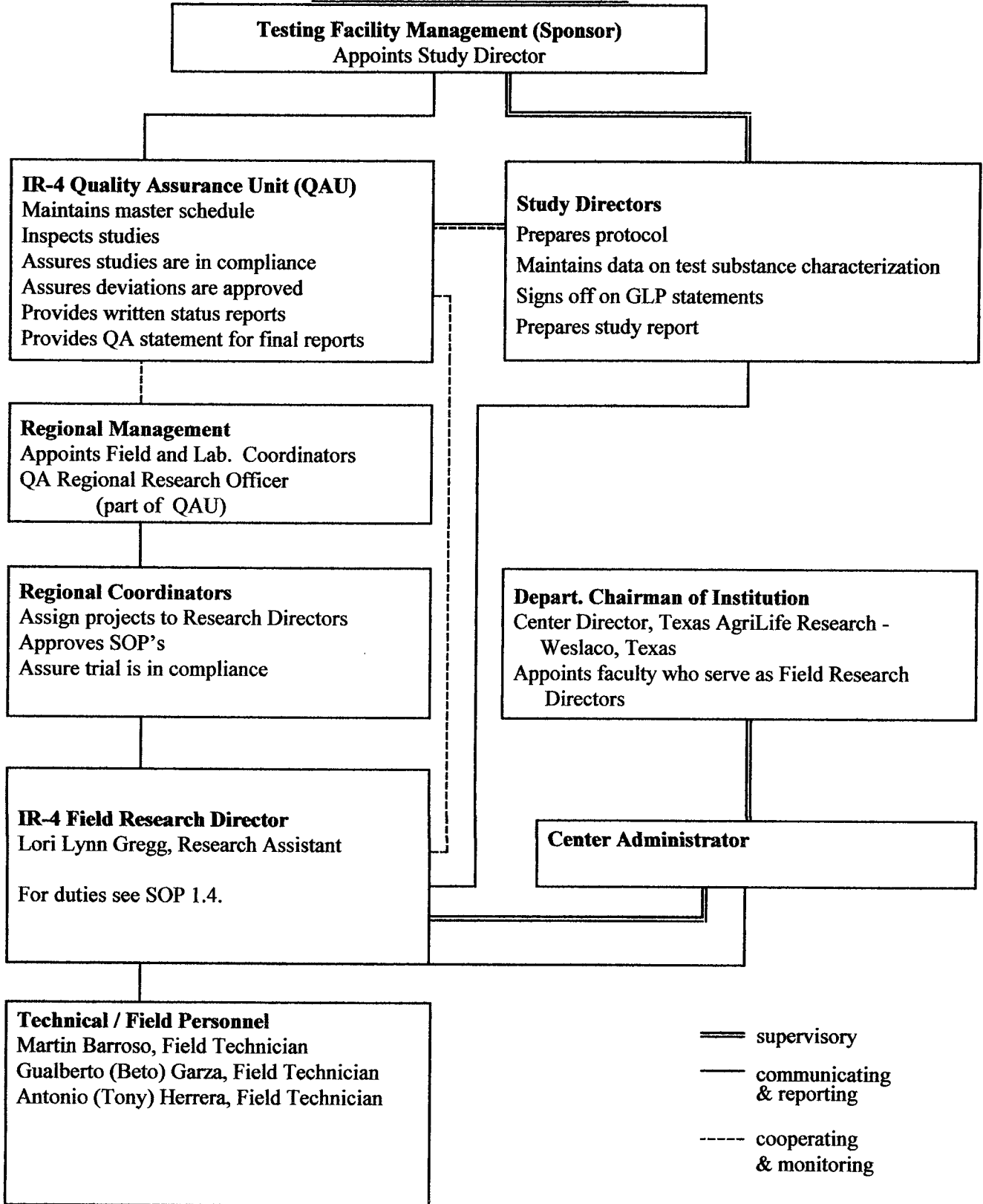
Scope: Sites conducting trial(s) to obtain registration of pesticides under GLP guidelines.

- 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 during the close-out to take accurate notes.
 5. Be sure you obtain a copy of the list of documents or other materials that may be taken as exhibits by the inspectors.
 6. Debrief management, staff, and the Field Study Director with an explanation of any problems found.
 7. Assign responsibility for preparation of possible solutions to problems and obtain time estimates for implementation.
 8. Prepare any replies to the regulatory agency as necessary within a timely basis and keep interested parties such as management and the Field Study Director informed.

REVIEWED BY:

INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE
LLG	2/7/08						
LLG	2-14-12						

ORGANIZATIONAL CHART



Updated Feb. 14, 2012 by Lori Lynn Gregg

LLG 2-14-12