# STANDARD OPERATING PROCEDURE

EFFECTIVE DATE: 3/31/18

SOP 1.02 Business Structure

APPROVAL: Blaine D DATE: 3/31/18

## 1.0 PURPOSE & SCOPE

1.1. This Standard Operating Procedure (SOP) introduces Turner Ag Research and provides information relating to its structure, responsibility, and guidance in case of company closure.

## 2.0 INTRODUCTION

2.1. Turner Ag Research was established in 2013 to provide independent agricultural research and consulting to its clients. The staff is highly trained and experienced with basic and applied research.

2.2. Turner Ag Research's goal is to provide high quality contract research. The company has a wide range of services from GLP research to environmental testing services.

## 3.0 ORGANIZATION

3.1. Turner Ag Research's facility is located in Woodland, California.

## 4.0 RESPONSIBILITIES

4.1. Principal Field Investigator provides test site facility management and oversees all aspects of the study. Principal Field Investigators have primary responsibility for the conduct of trials in accordance with GLP standards (where applicable), sponsor protocols and guidelines, as well as sound science and Turner Ag Research SOPs.

4.2. The Research Assistant provides assistance to the Principal Field Investigator. Under the guidance and supervision of the Principal Field Investigator, the Research Assistant carries out specified tasks in equipment care and maintenance, irrigation care, test substance application, study sampling, data recording and organization, and pest control.

4.3. Technicians maintain research plots and the facility. They provide assistance under direct supervision of a Research Assistant or the Principal Field Investigator for sampling and other study related activities.

4.4. Archivist has primary responsibility for the condition, maintenance, and control of Turner Ag Research's archives. The Backup Archivist has the same responsibilities.

4.5 Quality Assurance will be responsible for monitoring each study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with the regulations in this part. For any given study, the quality assurance unit shall be entirely separate from and independent of the personnel engaged in the direction and conduct of that study. The quality assurance unit shall conduct inspections and maintain records appropriate to the study.

4.6. Test Site Manager has primary responsibility for the training of employees and the organization of the test site facility to comply with GLP standards (where applicable), sponsor protocols and guidelines, as well as sound science and Turner Ag Research SOPs.

4.7. Each employee of Turner Ag Research is responsible for the: quality; promptness of completion; necessary reporting; and appropriate follow-up, for specific responsibilities to which they have been assigned by their supervisor. Individual assignments will be made according to the individual's qualifications.

## 5.0 COMPANY CLOSURE

5.1. In the case where Turner Ag Research should close or it is decided to discontinue business for whatever reason, the following procedure will be implemented by the company management.

5.1.1. All sponsor companies that have conducted business with Turner Ag Research will be notified promptly in writing of the closure.

5.1.2. Compliant with 40 CFR Part 160.195(g) Retention of Records:
"If a facility conducting testing or an archive contracting facility goes out of business, all raw data, documentation and other material specified in this section, shall be transferred to the archives of the sponsor of the study. The EPA shall be notified in writing of such a transfer."

5.1.3. Copies of Completed GLP Studies:
Copies of all studies will be sorted by Turner Ag Research. Each company will be notified in writing listing the studies. Companies may choose whether to have the copy of each study sent to them or destroyed.

5.1.4. Facility Raw Data for GLP Studies:
All study sponsors will be contacted in writing regarding whether they would like to archive Turner Ag Research facility raw data. Each sponsor will be notified that a single company will be chosen to archive the original facility data. When the company to archive the facility data has been chosen, each sponsor company will be notified. Certified copies of all facility data will be sent to sponsors not archiving the original raw data and informed where the original raw data is being archived.

5.1.5. GLP Test Substances
All test substances remaining with Turner Ag Research will be returned to the relevant study sponsor.

5.1.6. GLP Field Residue Trial Notebooks
All GLP field residue trial notebooks that are continuing will be closed out and any remaining chemicals will be returned as per Section 5.1.5.

## 6.0 HISTORY OF CHANGE

| REVISION | DATE | DESCRIPTION |
|---|---|---|
| 1.01 | 3/9/2016 | Changed job titles to match the org chart and updated job descriptions. |
| 1.02 | 3/31/2018 | Added Backup Archivist description |

**STANDARD OPERATING PROCEDURE**

EFFECTIVE DATE: 3/10/16

SOP 2.01 PERSONNEL

APPROVAL: Blaine Turner DATE: 3/10/16

## 1.0 PURPOSE & SCOPE

1.1. This SOP details the procedure for the maintenance and disposition of Turner Ag Research employee training records, curricula vitae (summary of education or specialized training), and job descriptions for individuals engaged in the conduct of GLP regulatory studies.

## 2.0 INTRODUCTION

2.1. The GLP Personnel File for: Principal Field Investigator, Research Assistant and Research Technician will contain the current job description, curricula vitae and training records. Each individual will update, sign and date their curricula vitae annually. Each individual will sign her/his job description at the time of hire or when their job description changes. Training records will be updated annually. These documents shall be kept in the records section of the facility.

2.2. All positions actively engaged in regulatory trials shall use the Personnel Training Record.

2.3. Personnel will review and document review of the SOPs using the Personnel SOP Review Record on an annual basis.

2.4. Employees acquiring new responsibilities or new employees, who conduct regulatory studies shall participate in GLP training and submit a CV, job description and training record before starting new position or responsibilities for a regulatory study.

## 3.0 EXCEPTIONS

3.1. Individuals utilized to assist with miscellaneous tasks will be personally supervised by qualified field personnel and training records are not required.

3.2. General GLP training will be offered once a year. The Principal Field Investigator shall conduct GLP training.

3.3. Specialized training shall be provided to new personnel by the Principal Field Investigator. This specialized training shall be documented in the training record.

3.4. All training shall be documented on the Personnel Training Record.

## 4.0 HISTORY OF CHANGE

| REVISION | DATE | DESCRIPTION OF CHANGE |
|---|---|---|
| SOP 2.01 | 3/10/16 | Formatting Header and corrected personnel titles for consistency |

**STANDARD OPERATING PROCEDURE**

EFFECTIVE DATE: 3/9/16

SOP 3.01 WRITING STANDARD OPERATING PROCEDURES

APPROVAL: Blaine D DATE: 3/9/16

## 1.0 PURPOSE & SCOPE

1.1. This Standard Operating Procedure defines a SOP, the format and guidelines used when writing a SOP for Turner Ag Research.

## 2.0 DEFINITION

2.1. A Standard Operating Procedure is the written instructions for performing a common procedure. A SOP provides instruction for a procedure which is repeated without variations in the normal course of operations or when the procedure must be defined for compliance purposes.

## 3.0 FORMAT

3.1. The Standard Operating Procedure manual contains SOPs that are enumerated with decimal format and title. If necessary, lower case letters can be used to emphasize additional points under subsections.

3.2. SOPs will be identified by the number preceding the decimal and revisions will be noted after the decimal with a two digit number.

3.3. Management shall hand write the effective date of an SOP.

3.4. SOPs shall be written in an outline format. All SOPs shall start with a purpose and scope, which shall explain the objective and contents of the SOP. The rest of the SOP shall be presented in a logical and concise manner with each section titled and numbered.

3.5. Operational SOPs shall contain a list of materials used.

3.6. Equipment SOPs are required by EPA and FDA GLPs to contain a section for routine and non-routine maintenance. This section shall come directly before the Reference Section and History Section.

3.7. All SOPs shall conclude with a History Section. which shall describe all changes made in each revision.

3.8. SOPs will address how documentation shall be recorded. Any attachments to SOPs will be clearly labeled and referenced in the text of SOP. These attachments shall be

considered part of the SOP and will have page numbers that will be included in the total number of pages.

## 4.0 GUIDELINES

4.1. All procedures that are common and repetitive shall have a SOP. Complex procedures with specialized steps may need to separate steps into individual SOPs.

4.2. SOPs should be able to stand alone. The procedure should able to be completed by following only the SOP.

4.3. SOPs shall be written so experienced and inexperienced employees can understand and use the SOPs to complete the relevant tasks.

## 5.0 REFERENCES

5.1. All applicable references shall be listed in a separate section within the SOP. All References must be readily available for personnel review.

## 6.0 HISTORY OF CHANGE

| REVISION | DATE | DESCRIPTION OF CHANGE |
|---|---|---|
| SOP 3.01 | 3/9/16 | Reformat headers, corrected grammatical errors |

**STANDARD OPERATING PROCEDURE**

EFFECTIVE DATE: 3/10/16

SOP 4.01 SOP PREPARATION, APPROVAL AND MAINTENANCE

APPROVAL: _____ DATE: 3/10/16

## 1.0 PURPOSE & SCOPE

1.1. This Standard Operating Procedure provides guidelines for the preparation, approval, revision, distribution and maintenance of all SOPs.

## 2.0 RESPONSIBILITY

2.1. The Test Site Manager will be the responsible employee for all aspects of Turner Ag Research SOP maintenance and storage.

## 3.0 INTRODUCTION

3.1. The contents of all SOPs shall be enough to insure the continuity of operations. All SOPs shall provide sufficient detail to accurately describe procedures and methods. Management is responsible for reviewing and approving SOPs. Personnel who have been provided a SOP Manual shall be responsible for its maintenance. SOP copies assigned to personnel shall be approved by the Test Site Manager.

## 4.0 PREPARATION AND REVIEW

4.1. Any employee may author or initiate a needed SOP. An employee may and submit a draft to management or may notify management of a needed SOP. Management may write the SOP or assign a qualified employee to write the needed SOP.

4.2. All new SOPs shall be forwarded to the Test Site Manager for SOP classification, regulatory compliance, and incorporation into SOP Manual.

4.3 The author of the SOP shall make revisions upon the request of the Test Site Manager, before final SOP is incorporated with other SOPs.

## 5.0 APPROVAL

5.1. Each SOP shall be signed and dated by the Test Site Manager once SOP is approved. The signature and date indicate that the Test Site Manager read and approved the SOP.

5.2. All SOPs shall become effective upon approval unless otherwise stated.

## 6.0 REVISION AND RETIREMENT

6.1. The SOP Manual shall be reviewed and revised if needed on an annual basis. Revisions may also be done at other times if needed.

6.2. The last page of written text is the History of Change. The History of Change consists of the version number, effective date and a description of the revisions made to each version. All attachments shall follow the History of Change.

6.3. After SOP revision is reviewed, a SOP revision number shall be assigned.

6.4 When a SOP is revised, the previous original signature version shall be archived in the Turner Ag Research historical SOP file. All SOP manuals shall be updated with the revision. All copies of the previous revision shall be destroyed.

6.5. Should a SOP become obsolete, employees shall be notified of SOP retirement. The original signature version of the SOP shall be archived.

## 7.0 DISTRIBUTION OF SOPS AND SOP MANUALS

7.1. Approved sets of all SOPs or individual SOPs shall be available to Turner Ag Research personnel as approved by management. The Test Site Manager shall maintain a record of SOP Manual distribution. Each person assigned a manual or individual SOP shall be listed on a SOP Distribution Log. The Test Site Manager shall be responsible for providing new or revised SOPS to all personnel in possession of a SOP Manual.

7.2. The original signature version of each approved SOP shall be archived in a current SOP file.

## 8.0 RETENTION

8.1 All original signature copies of individual SOPS shall be kept in current or historical SOP files.

## 9.0 HISTORY OF CHANGE

| REVISION | DATE | DESCRIPTION OF CHANGE |
|---|---|---|
| SOP 4.01 | 3/10/16 | Made titles consistent with other SOP's |

**STANDARD OPERATING PROCEDURE**

EFFECTIVE DATE: 3/10/16

SOP 5.01: SOP DEVIATIONS

APPROVAL: Blain D DATE: 3/10/16

## 1.0 PURPOSE & SCOPE

1.1. This SOP describes the procedures followed by Turner Ag Research during facility inspections. During a facility inspection, review is made to assess the facility's compliance with regulations and guidelines.

1.2. Turner Ag Research designated quality assurance shall perform inspections.

## 2.0 DEFINITION

2.1. A SOP deviation occurs when:

2.1.1. A partial or entire procedure governed by a SOP is not followed due to error.

2.1.2. There is a planned change from a SOP requirement.

## 3.0 PROCEDURE

3.1. A deviation shall occur if SOPs are not followed. When a deviation occurs, a SOP Deviation Form must be filled out and submitted for approval to the Test Site Manager. A SOP Deviation Form shall make known the deviation and the reason for deviating from the SOP procedure.

3.2. Deviations that are evaluated by the Test Site Manager to be more effective than the current SOP procedure shall replace the current procedure. Revision of the SOP shall commence immediately.

## 4.0 HISTORY OF CHANGE

| REVISION | DATE | DESCRIPTION OF CHANGE |
|---|---|---|
| SOP 5.01 | 3/10/16 | Changed titles to be consistent with other SOP's |

Turner Ag Research

# STANDARD OPERATING PROCEDURE

EFFECTIVE DATE: 3/26/2013

SOP 6.00 Study Number Assignment

APPROVAL : Blair D DATE: 3/26/2013

## 1.0. PURPOSE AND SCOPE

1.1. This Standard Operating Procedure (SOP) describes how Turner Ag Research study numbers are assigned.

## 2.0. RESPONSIBILITY

2.1. Study numbers shall be assigned when Turner Ag Research receives an accepted bid and the responsibility for a study.

2.2. The assignment of study numbers will be the function of Turner Ag Research management.

## 3.0. PROCEDURE

3.1 The study number for each study is comprised of a two digit number indicating the year of the study initiation, followed by a two digit sponsor code, followed by a consecutive number to identify the study in series of that year for that sponsor. The numbers will be assigned as follows (for example):

3.1.1. A two digit year (2013): 13
A two digit sponsor code: 01
The study numbers begin at -1 and increase by 1 for each new study for that sponsor.
The study number would be: 13-01-01

## 4.0 HISTORY OF CHANGE

| REVISION | DATE | DESCRIPTION OF CHANGE |
|---|---|---|

STANDARD OPERATION PROCEDURE

EFFECTIVE DATE: 3/10/16

SOP 7.01 VERIFICATION OF THERMOMETERS

APPROVAL: _____ DATE: 3/10/16

---

1.0 PURPOSE AND SCOPE

1.1 Thermometers, which include electronic data loggers, are used to record temperatures of storage facilities containing test substances, storage facilities containing frozen residue samples, and other environmental areas such as soil dissipation studies, must be verified annually against a certified thermometer. The principal field investigator (PFI) is responsible for ensuring that the following procedures have been conducted annually.

2.0 INITIATION

2.1 The PFI should complete the Thermometer Verification Log which should be used to document the verification of the thermometers. A unique identifier ID for the standard thermometer, and/or min/max thermometers shall be entered on the log forms. Thermometers with data loggers should have the printout of the temperature verification readings placed with the Thermometer Verification Log.

3.0 VERIFICATION

3.1. The certified thermometer will be verified first by placing into ice water and verifying the reading is at 0 °C. Then record on the Thermometer Verification Log the readings at two temperatures of the standard thermometer being verified and the certified thermometer. The unique ID for the certified thermometer and its location shall be recorded. A reading variance of ± 2 °C (± 4°F) between the certified thermometer and the thermometer being verified is allowed. If the thermometer does not meet the above criteria, a new verifiable thermometer will be purchased and verified. The certified thermometer will be securely stored and used only for verifying other thermometers.

4.0 IDENTIFICATION

4.1 Each thermometer must have a unique identification (ID) which may consist of the manufacturer's serial number or an ID indelibly marked (engraved, painted, etc.) on the thermometer/thermograph. The certified thermometer ID will be indicated on the manufacturer's calibration report. This ID should be referred to in all calibration/verification logs.

## 5.0 RECORDS

5.1 The PFI is responsible for ensuring that the Thermometer Verification Logs are completed correctly. These will be provided to the archivist for archiving by April 30 of the following year as applicable.

5.2 Applicable records of the test substance and freezer storage temperature logs will be included as part of the field data package submitted to the Sponsor and/or Study Director whenever required.

## 6.0 HISTORY AND CHANGE

| REVISION | DATE | DESCRIPTION OF CHANGE |
|---|---|---|
| SOP 7.01 | 3/10/16 | Added certified thermometer verification. |

STANDARD OPERATING PROCEDURE

SOP 8.01 ELECTRONIC BALANCES

EFFECTIVE DATE: 3/10/16

APPROVAL: Blaine L DATE: 3/10/16

## 1.0 PURPOSE AND SCOPE

1.1 The Electronic balance is routinely used to accurately weigh dry formulations of test substances and samples. Electronic balances may be powered by batteries or an AC adapter. To insure accuracy of the measurement, the principal field investigator is responsible for conducting the following procedures:

## 2.0 CALIBRATION / VERIFICATION

### 2.1 STANDARD WEIGHTS

Standard weights used for balance calibration will be verified annually using a balance that has been recently calibrated, cleaned and/or certified within manufacturer's specifications by a professional service technician as applicable or available. Each weight reading must be within ± 1% of the expected weight or be discarded and replaced. Record verification results and the Balance ID on the Weight Verification Log.

### 2.2 ELECTRONIC BALANCES

2.2.1 The balance will be verified each time it is used. Place the balance on a flat, level surface. Minimize any wind currents, which may affect verification. Place a verified standard weight similar to the amount of the desired test substance, on a balance pan. Read and record on the Balance Log. It is desirable to run two verification checks, one weight below and one weight above that of the desired weight. The balance reading must be within± 2% of the verified standard weight.

2.2.2 The verification results are to be recorded on the Balance Log indicating the verification date, standard weight ID, standard weight amount, the balance reading and the individual doing the balance verification.

## 3.0 OPERATION

3.1 For specific operation of the electronic balance, the operator should refer to the instruction manual. Some of the balances can be selected for various weight units (grams, troy ounces, etc.) and, where necessary, this should be done as a first step. If necessary, press the on/re-zero switch to zero the balance. Place any containers or weight boats used to hold the test substance on the balance plate and tare the balance. Add the test substance until the desired weight is displayed. If the test substance is weighed out incrementally (i.e. the total amount of the test substance exceeds balance capacity), record the incremental weight measurements to reach the desired total test substance weight.

3.2 For sample weights tare the sample container or bag then collect the sample and weigh the sample. Record the sample weight.

## 4.0 IDENTIFICATION

4.1 Each balance and standard weights or standard weight set must have a permanent identification (ID). For balances, the manufacturer's serial number or an ID assigned by the employee and indelibly marked (engraved, painted, etc.) on the balance will suffice. The ID for the weights/weight set will be marked on the weight's container. The ID of the balance will be recorded on the Balance Log.

## 5.0 MAINTENANCE, REPAIRS, SERVICE

5.1 To keep the balance operating properly, the cover, housing, and platform must be kept clean and protected from foreign materials at each use. Before each use, balance will be inspected to assure it is clean and free of any visible possible contamination.

5.2 Routine maintenance will be a certification of the balance performed by a certified service technician annually as applicable or available. If equipped with electronic balance batteries should be replaced with new batteries annually. The service technician will provide written documentation of the service(s) performed.

5.3 In the event of an equipment malfunction, the principle field investigator will add a notation on the balance (e.g. Out of Service) so it will not be used until repaired. The balance will be repaired by a professional service technician contacted by the principal field investigator or designate in the event of a malfunction. The balance will be discarded and replaced if not repairable. All non-routine maintenance and repairs to the balance are to be recorded on the NON-ROUTINE MAINTENANCE RECORD. Service invoices must be retained with the balance records

## 6.0 RECORDS

6.1 Balance records (calibration, verification maintenance, repair and service records) will be maintained. The PFI is responsible for ensuring that logs are completed correctly. These will be provided to the archivist for archiving by April 30 of the following year as applicable.

6.2 Applicable copies of the balance log records will be included as part of the field data package submitted to the Sponsor and/or Study Director as required and /or

requested.

## 7.0 HISTORY OF CHANGES

| REVISION | DATE | DESCRIPTION OF CHANGE |
|---|---|---|
| SOP 8.01 | 3/10/16 | Reformat headers |

STANDARD OPERATING PROCEDURE

Effective Date: 3/10/16

SOP 9.01 MONITORING OF FREEZERS AND REFRIGERATORS CONTAINING TRIAL/ STUDY SAMPLES

APPROVAL: Blair D DATE: 3/10/16

---

1.1 PURPOSE AND SCOPE

1.2 This Standard Operating Procedure (SOP) provides a description of Turner Ag Research's method to insure the proper function, use, maintenance, and documentation of monitoring of freezers and refrigerators used to store GLP test material such as test substance or samples.

2.1 GENERAL

2.2 Freezers are commonly utilized to preserve regulatory samples when immediate shipment is not practical.

2.3 As a guideline, freezers containing samples should operate within a temperature range of -23 °C to -18 °C (-10 °F to 0 °F). The temperature normally fluctuates with changes in the ambient temperature, the addition of samples, and the opening of the door.

2.4 Where practical, freezers should be equipped with an electronic temperature data logger to provide a continuous measurement of freezer temperatures by utilizing Method A outlined below. Alternatively, freezer temperature can be monitored by recording the temperature from a min/max thermometer on at least a weekly schedule (Method B). Method A is the preferred procedure. However, Method B may be used as described below. The recording device should be placed in an area of the freezer not influenced by opening/closing of the door.

2.5 Refrigerators may be used for storage of certain samples if specified in the protocol. All refrigerators should operate at a temperature of 2 °C to 7 °C (35 °F to 45 °F). They can be monitored using the same types of equipment and procedures specified below for freezers.

3.0 CALIBRATION/VERIFICATION

3.1 Recording electronic temperature dataloggers or min/max thermometers shall be calibrated/verified annually at two temperatures using a certified thermometer, or a standard thermometer, which has been verified annually against a certified thermometer. This procedure will be documented in the freezer and refrigerator temperature verification logs.

3.2 Method A: Electronic Temperature Dataloggers:

Place an electronic temperature datalogger in the same proximity as the stored samples. Calibrate/verify the datalogger against a standard/certified thermometer annually using SOP 7.01. Approximately monthly, download the datalogger information into a laptop computer taken to the site. Each time the datalogger is downloaded, print out a chart of the data list of recorded and/or the temperatures that include the recorder ID, the date the datalogger was launched and the date of the download and labeled with the appropriate freezer or refrigerator ID. The individual doing the download must initial the chart. Use a calibrated/verified min/max thermometer or another datalogger as a backup in case of malfunction of the main datalogger.

3.3 Method B: Min/Max Thermometer:
A min/max thermometer may be used to monitor the freezer or refrigerator used to store frozen sample when an electronic temperature datalogger is not available. The min/max thermometer must be verified against a certified standard thermometer. The temperature readings will be recorded on at least a weekly schedule while the samples are in storage. Readings will be recorded in the freezer and refrigerator temperature logs. Entries must be initialed and dated.

## 4.0 IDENTIFICATION

4.1 Each freezer or refrigerator used to store regulatory samples and thermometers and dataloggers used to monitor frozen storage temperatures must have permanent unique identification (ID) which must be permanently marked (engraved, painted, etc.). The ID of all utilized equipment must be recorded on the freezer and refrigerator temperature logs.

## 5.0 SCHEDULES FOR MAINTENANCE AND REPAIR

5.1 There is no standard schedule for maintenance required. All routine maintenance (e.g. defrosting, cleaning) will be described and recorded , see Section 7. In the event of a freezer or refrigerator malfunction, a service technician will be contacted by the PFI. A NONROUTINE MAINTENANCE RECORD (See example) will be prepared. Copies of service invoices will be retained with the facility records. The appropriate Study Director will be notified immediately if the integrity of the residue samples are negatively affected by the equipment malfunction.

5.2 If the frozen or refrigerator storage conditions are compromised due to power outage or freezer/refrigerator failure, one of the following procedures will be followed to preserve the integrity of the samples if feasible:

5.2.1. A power generator will be purchased, rented, or borrowed to restore electricity to the freezer.

5.2.2 Alternate frozen storage will be located and the samples will be transferred temporarily until the power supply is restored or the freezer is repaired or replaced . Sample transfer (location to location, and why) must be documented in the transfer of the samples from one storage unit to another.

5.2.3 Dry ice will be purchased and placed into the freezer to maintain frozen storage conditions.

5.2.4 Block ice will be purchased and placed into the refrigerator to maintain refrigerated conditions.

5.3 Whatever method is used, the procedure must be documented and included with the site facility records. If the frozen or refrigerator storage location is changed, the address of the new storage area must be documented . Continuous temperature monitoring of the frozen or refrigerated samples should be maintained as outlined under Calibration/Verification above.

5.4 A spare freezer or refrigerator may be held in reserve in case of a freezer or refrigerator mechanical failure or malfunction if no other alternatives are available.

## 6.0 DOCUMENTATION

6.1 When using Method B, Sample Storage (Frozen) Temperature Verification Log and Sample Storage Temperature Log is the primary method of documenting frozen storage conditions, including thermometer calibration/verification, storage temperatures, freezer maintenance/repairs, and frozen storage record gaps. Sample Storage (Refrigerated) Temperature Verification Log and Sample Storage (Refrigerated) Temperature Log is the primary method of documenting refrigerator storage conditions, including thermometer calibration/verification, storage temperatures, refrigerator maintenance/repairs, and refrigerator storage record gaps. The Temperature Verification Log may be used to document the calibration/verification of min/max thermometer or electronic temperature datalogger against a certified thermometer.

6.2 The principal field investigator should initiate the process by completing the upper portion of the log: the freezer/refrigerator ID, storage location, and the identity of the thermometers and/or devices used. The thermometers will be verified against a certified thermometer and the entries on the verification log dated and initialed.

6.3 Freezer and refrigerator records, e.g. datalogger charts or freezer/refrigerator temperature logs will be kept in a secured centrally located fire resistant cabinet during the current year.

## 7.0 CLEANING/DEFROSTING

7.1. Refrigerators and freezers containing regulatory samples must be properly cleaned and/or defrosted prior to and during use to minimize potential contamination and efficient operation. Cleaning and defrosting will be the responsibility of the principal field investigator unless specific measures are designated or prohibited by the study protocol.

## 8.0 RECORDS

8.1 Freezer and refrigerator records (calibration, maintenance, repair and service records) will be maintained. The PFI is responsible for ensuring that the temperature logs are completed correctly. These will be provided to the archivist for archiving by April 30 of the following year as applicable.

8.2 Applicable copies of the freezer/refrigerator log records will be included as part of the field data package submitted to the Sponsor and/or Study Director as required and/or requested.

## 9.0 ALARM EQUIPMENT

9.1 Freezer Storage should be equipped with a Hobo alarm system. When the freezer temperature exceeds a maximum temperature of 20 °F it will trigger the Hobo data logger to send an email alert to a minimum of two Turner Ag Research employees. The employees will have their smart phones configured to have the emails from the Hobo Data loggers set as a favorite or other similar function depending on the phone and operating system to pop up immediately as a notification. This is the same as receiving a text or phone call alert.

9.2 Temperature alarm tests will be done once per year to verify the alarm notification system. The notification system test is done by taking the temperature probe out of the freezer and triggering the notification system to send an email. The emails will send to a minimum of 2 employees of Turner Ag Research. The notification email will be printed out and entered into the temperature log book.

## 10.0 HISTORY OF CHANGE

| REVISION | DATE | DESCRIPTION OF CHANGE |
|---|---|---|
| SOP 9.01 | 3/10/16 | Added Alarm equipment and test procedure. Removed attachments. |

STANDARD OPERATING PROCEDURE

EFFECTIVE DATE: 6/11/17

SOP 10.01 APPLICATION EQUIPMENT CALIBRATION, VERIFICATION, MAINTENANCE AND EQUIPMENT USE LOG

APPROVAL: Blair D DATE: 6/11/17

## 1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) provides a description of Turner Ag Research's method to insure the proper function, use, maintenance, and documentation of application equipment used to test pesticide chemicals in a test system, if the sponsor does not provide other instructions in the study protocols, notebooks, or electronic data collection system.

## 2.1 GENERAL INFORMATION

2.2 The principal field investigator (PFI) or designate is responsible to ensure that, where appropriate, this SOP is followed. This SOP covers the following application equipment. Tractor mounted and backpack boom sprayers, granular applicators, chemigation, wiper applicators, spot applications and hooded sprayer applications.

2.2 If the sponsor does not provide their own forms for recording application methods and data, the application methods and calibration/verification may be recorded on facility worksheets. Procedures not covered in this SOP can be used to calibrate application equipment as long as the procedure meets the calibration/verification requirements of this SOP and is documented on worksheets. The Trial Notes form can be used to document miscellaneous comments.

2.3 Balances used to weigh granular or dry powder formulation of test substances and adjuvants must be verified prior to weighing test substances to ensure accuracy. Test substances should be weighed immediately before application, but no longer than 72 hours prior to application. However, the storage conditions of the weighed test substance will be monitored continuously until application.

2.4 Balance verification readings must be recorded on the BALANCE LOG.

2.5 SAFETY. It is the responsibility of the PFI to ensure that assigned trials are conducted in accordance with company, Country/ Province, state and federal safety regulations as applicable. As a part of this safety responsibility, applicators and handlers must wear the minimal personal protective equipment specified in the SDS or product label when applying test substances and maintenance pesticide products.

2.6 EXCESS SPRAY SOLUTION DISPOSAL. PFI will ensure that mix sizes result in minimal excess spray solution. Excess spray solution and rinses will be disposed of in accordance with local regulations. Excess spray solution will be disposed of at a safe distance from the plot areas to prevent possible contamination of the plots.

## 3.0 CALIBRATION AND VERIFICATION

3.1 Calibration of the application equipment should occur within one calendar day prior to application of a test substance(s) to ensure the correct amount of test substance(s) is applied to the target.

3.2 When required by the protocol, verification of the application equipment is needed before using it the day after calibration. Verification is normally one output and one speed check within +/- *5%* of the calibration value.

3.3 Equipment used to apply test substance must be used within the manufacturer's recommended guidelines, i.e., effective spray swath, boom height, pressure, speed, output, gauge settings, or other specific instructions/recommendations. For broadcast applications, an effective spray swath is normally the number of nozzles multiplied by the nozzle spacing (6 nozzles x 20 inch spacing= 120 inches/ 12 inches per foot= 10-foot effective spray swath). For single pass applications, the effective spray swath should be the same width as or larger than the plot width.

3.4 Where a study protocol indicates an application output range (e.g., 10-30 GPA 15- 46 liters per hectare [LPH]), applicator output must be within this specified application range. Where a study protocol indicates a specific application output (i.e., 3 GPA or *5* LPH), applicator output must be within +/- 5% of the specified output.

3.5 Prior to applying test chemical in a regulatory study, application equipment output calibration must be performed and recorded a minimum of three (3) times at the same settings. The same size spray solution container with the same fittings used for calibration should be used for the actual test substance application.

3.6 If the output of an individual nozzle or outlet is not within +/- 5% of the average, repair or replace it and conduct additional calibration catch runs until you have three runs within specification.

3.7 Application equipment speed calibration is recorded a minimum of three (3) times.

3.8 If an application equipment speed run is not within +/- 5% of the mean, additional application equipment speed calibration runs are required until you have three runs within specifications.

## 4.0 THE EQUIPMENT USE LOG

4.1 The Equipment Use Log will be used to record the calibration, verification, routine maintenance, non-routine repair and cleaning of field equipment used in regulatory trials. Entries must indicate if the SOP was followed for the activity recorded by placing a checkmark in the "SOP" column.

## 5.0 EQUIPMENT IDENTIFICATION

5.1 Application equipment used in regulatory studies must have permanent, unique identification (ID), even though the user may have only one piece of that kind of equipment. The manufacturer's serial number will serve this purpose or, alternatively, the PFI may give the sprayer an ID, which must be indelibly marked (engraved, painted, etc.) on any component of the equipment which is not subject to frequent routine replacement. The ID should be referred to in measurements, calibrations, service records and logs. For assistance when assigning a unique new equipment ID, consult the current list of GLP equipment.

5.2 Application equipment description s and unique identification will be recorded on the appropriate forms at the time of use.

## 6.0 ROUTINE EQUIPMENT MAINTENANCE

6.1 Routine maintenance includes modifications to equipment done to keep the equipment in working order. For a pesticide applicator, this includes, but is not limited to, inspections, cleaning, washing, rinsing, nozzle and screen replacement, pressure adjustments, configuration changes, gauge setting changes and lubrication. For associated equipment (soil sampler, shakers, soil sieves, buckets, shovels, etc.), these include washing with soap solution, thorough rinsing with clean water, and drying.

6.1.1 Record the date of maintenance on the Equipment Use Log

6.1.2 Give a brief description of the maintenance in the column headed "other".

6.1.3 Circle "R" under the "Non-routine or Routine Maintenance" column.

6.1.4 The person completing the form must initial and date the log.

6.2 PRE-CALIBRATION ROUTINE- The spray system is checked for leaks or malfunctions. Spray lines are flushed with tap water. Nozzle tips and mesh screens are washed with detergent solutions then rinsed thoroughly with tap water.

6.3 POST- SPRAY ROUTINE- Left over spray solution sprayed out in an open, unused section of the field. The spray line is flushed with soap solution followed by flushing with clean tap water to rinse. The spray container is washed with detergent solution and triple-rinsed. Nozzles and screens are washed with soap solution and rinsed. Tractor and sprayer are thoroughly hosed down with clean tap water.

## 7.1 NON-ROUTINE EQUIPMENT MAINTENANCE

7.2 Non-routine repairs include any repair or part replaced because of failure or malfunction of the equipment.

7.2.1 Record the date of the equipment malfunction/failure or the date the equipment

failure was noticed on the Equipment Use Log.

7.2.2 In the column headed "other", record "see NON-ROUTINE MAINTENANCE RECORD".

7.2.3 Circle "N" under the "Non-Routine or Routine Maintenance" column.

7.2.4 The person completing the form must initial and date the record as needed.

7.2.5 If repairs were contracted to an outside vendor, attach an invoice copy to the Non-Routine Maintenance Record.

## 8.0 MALFUNCTION PROCEDURES

8.1 If a malfunction occurs while actually applying the test substance to the test plot, record the nature of the malfunction on the Trial Notes form and the Equipment Use Log and check the "Non-Routine Repair" box as described for non-routine equipment repairs above.

8.2 If the severity of the malfunction constitutes a deviation from the SOP or study protocol, immediately notify the appropriate Study Director. A study protocol or a SOP deviation must be completed by the PFI and sent immediately to the Study Director for his/her signature and comments.

## 9.0 EQUIPMENT CLEANING

9.1 All equipment utilized in regulatory studies must be properly cleaned (washing with an appropriate cleaning solution and rinsing with water three times as required) prior to and after use to minimize potential contamination. The decision as to which measures need to be taken will be the responsibility of the PFI or designate, unless specific measures are preferred or prohibited by the study protocol. Cleaning will be documented by checking the "Clean" column on the Equipment Use Log.

## 10.0 BORROWED OR SINGLE-APPLICATION EQUIPMENT

10.1 Single use application equipment is equipment that is built to apply a test substance(s) to a regulatory trial(s) and then dismantled for other uses. Indicate on the Equipment Use Log that the equipment is "borrowed" or "single use". In the applicator ID entry area of the Equipment Use Log assign the equipment an ID number.

10.2 Conduct and document on the Equipment Use Log equipment inspection, washing, cleaning, rinsing, calibration and maintenance prior to application. Initial and date all entries.

10.3 Calibrate the equipment as described in this SOP.

10.4 Record and date any subsequent maintenance during the course of the trial as needed.

## 11.0 RECORDS

11.1 Application records (calibration, maintenance, repair and service records) will be maintained. The PFI is responsible for ensuring that the Equipment Use Log is

completed correctly. These will be provided to the archivist for archiving by April 30 of the following years as applicable.

11.2 Applicable copies of the application records will be included as part of the field data package submitted to the Sponsor and/or Study Director as required and/or requested.

12.1 BOOM SPRAYERS

12.2 Purpose of Equipment

12.2.1 Boom sprayers are used to apply liquid spray solution containing test substance to regulatory studies plots.

12.3 Description of Equipment

12.3.1 Tractor-mounted boom sprayers may include straight boom, drop nozzle, or other configurations from which test substance is emitted in solution under pressure through hoses and nozzles. The sprayer is mounted on a tractor or similar self-propelled vehicle capable of speeds up to approximately 15 mph. The sprayer is supplied with pressure from either an air compressor, C02 tank or a mechanical pump. Spray boom pressures generally are regulated at approximately 15-60 psi using a pressure regulator. Spray solutions are mixed in spray containers which are carried on the sprayer. The containers typically in use range in size from 0.5 - 10 gallons with some equipment having several hundred gallons capacity. The sprayer is activated by manual, electrical, or pneumatic controlled valves.

12.3.2 Back-pack or other hand-held sprayers generally consist of a 0.25- to 5-gallon spray container pressurized by a compressed air or C02 tank which is carried by the applicator. The spray boom is hand-held. Operating pressure is adjusted with a pressure regulator mounted on the C02 or compressed air tank and the on/off valve is manually operated.

12.4 Calibration

12.4.1 Prior to calibration, test the spray system to check for leaks, cracked, broken or loose nozzles, hoses and fittings. Ensure that switching devices operate properly and that the system {tanks, lines, screens, nozzles) is free of particles or debris. Each spray nozzle will be calibrated within pressure and flow rate recommendations in the manufacturer's specifications.

12.4.2 Adjust the spray boom height for correct spray pattern overlap as described by the manufacturer for the spray nozzle selected. Determine the width of the effective spray swath. For band applications, determine from the protocol whether the application rate is based on only the band sprayed area, or if it is based on the total overall area sprayed.

12.4.3 Determine required application volume in gallons/acre (GPA or liter/hectare [LPH]) from study protocol.

12.4.4 Check nozzles for accurate volumetric output. Total volume output is determined

by adding the output of the individual nozzles. Individual nozzle output should be within +/- 5% of the mean nozzle output for the boom.

12.4.5 Determine the target sprayer speed (e.g., mph, ft/sec, sec./100ft, or m/sec, etc.) based upon the total sprayer output, spray width, and the target application volume (GPA or LPH) required in the study protocol. Trial runs will be within +/- 5% of the target speed. A minimum of three measurements will be averaged for a final sprayer calibration speed.

12.4.6 The speed calibration should be done in an area similar to the area to be treated and which has been under the same irrigation and tillage regime as the plot(s) to be treated. Where required, cultivation/incorporation equipment should be attached and set to proper depth to simulate actual application.

12.4.7 Time actual application pass time(s) through the plot and if collected, record on the appropriate worksheet.

12.4.8 A description of the spray equipment along with raw data and calculations for speed and volume determinations must be recorded on a worksheet. On the Equipment Use Log, record the date the spray calibration or verification was performed, the trial(s) the calibration or verification was performed for, and the person performing the calibration or verification procedure.

## 13.1 GRANULAR TEST SUBSTANCE APPLICATORS

### 13.2 General

13.2.1 Prior to calibration, read the operator's manual (if applicable) to become familiar with the basic operations and adjustments available. Inspect the applicator unit to ensure the unit (hopper and outlets) is clean and free of dirt, debris, etc. Clean if necessary.

13.2.2 Make all hydraulic and/or electric connections, if necessary. Operate the unit (empty) according to manufacturer's instructions and inspect for proper operation. Make adjustments or repair. All cleaning and/or repairs should be entered in the appropriate logs (Equipment Use Log and/or Non-routine Maintenance Record).

### 13.3 Blank Granules

13.3.1 Do not use the test substance or blank granules more than twice for calibrating. Do not use granules used for calibration for trial applications. Each time the granules flow through an applicator, a physical change may occur that could cause them to flow differently. Test substance or blank granules used for calibration should not be returned to the original container. Blank granules may be discarded. Test substance granules may be used for maintenance applications, combined with a non-GLP container of the same product or stored for proper disposal at a later date. If test substance granules were used for calibration, the amount used should be properly recorded on the appropriate Test Substance Use log.

13.3.2 Balances used to weigh granular test substances must be verified prior to weighing test substances to ensure accuracy. Test substances should be weighed immediately before application, but no longer than 72 hours prior to application. However, the storage conditions of the weighed test substance will be monitored continuously until application. The test substance should be stored in an airtight container if not used within 24 hours.

13.3.3 Balance verification readings must be recorded on the Balance Log.

13.2.4 Record calibration or verification on a worksheet including equipment description. Record on the Equipment Use Log the date the calibration/verification was performed, the trial(s) the calibration/verification was applied, and the person performing the calibration/verification procedure.

13.3 Nobel and Gandy -Type Planter-Mounted Applicators

13.3.1 The planter-mounted granular applicator is used to apply granular test substances to test plots. Placement of the test substance using granular mounted applicators is usually "in-Furrow", "T-Banded" or "Banded". Granular applicators can be mounted on a toolbar to apply test substance chemicals "Over-The-Row".

13.3.2 Method 1-Moving Calibration for Ground-Driven Band Applicators: Select and calibrate/verify applicator speed for application on soil similar to the plot. Individual runs should be within +/- 5% of the mean. Measure a set distance (typically 50-500ft) and set each applicator outlet adjustment for the approximate desired flow rate. Calculate amount of test substance product needed for the measured distance. Unhook flow tubes from the bottom of each applicator outlet, add enough calibration granules to the hopper boxes to cover the openings during calibration and attach the granule collection containers to each applicator outlet. Drive the unit with the applicator(s) engaged through the measured area. Compare the weight of granules collected to the calculated amount. The collected output should be within +/- 5% of the product rate specified in the study protocol. Individual outlet should be within +/- 5% of the mean. Reattach the flow tubes to the bottom of each applicator outlet.

13.3.3 Method 2 - Stationary Calibration for Ground-Driven Banded Applicators: Determine the number of revolutions the planter drive wheel or granular applicator drive wheel will make in a set distance. Select applicator equipment speed for application. Calculate amount of test substance product needed for the measured distance. Unhook flow tubes from the bottom of each granular applicator outlet; add enough calibration granules to the hopper boxes to cover the outlets during calibration. Set each applicator outlet for the approximate flow rate desired and attach granule collection containers to each outlet. Turn each planter drive wheel or granular applicator drive wheel by hand at the same speed (+/- 5%) it will turn during application. This should be done for the calculated number of revolutions in the calculated number of seconds to equal the feet per second the unit will be traveling during application. The drive wheel must be turned at an even speed throughout the calculated time period. The calculated number of revolutions must be

completed in the calculated time and the drive wheel immediately stopped. Compare the weight of granules collected to the calculated amount. The collected output should be within +/- 5% of the product rate specified in the study protocol. Individual applicator outlet should be within +/- 5% of the mean. Reattach the flow tubes to the bottom of each applicator outlet.

13.3.4 Method 3 - Stationary Calibration Using an Electric Motor to Calibrate Ground-Driven Band Granular Applicators: Determine applicator equipment speed (mph) for application . Application speed should be the speed simulated by the electric motor. Select length of time to run the electric motor for application. This may be determined from the chart supplied by the calibrator motor manufacturer. For a chosen speed, the chart lists the time (seconds) to run the motor and the simulated distance covered. Calculate the amount of product required for the time and speed selected for calibration. Unhook flow tubes from the bottom of each applicator outlet, set each applicator outlet for the approximate desired flow rate, add enough calibration granules to the hopper boxes to cover the openings during calibration and attach granule collection containers to each outlet. Attach electric motor to the planter. Run calibrator motor for the exact length of time selected in Method 2. Compare the weight of granules collected to the calculated amount. The measured output should be within +/- 5% of the product rate specified in the study protocol. Individual applicator outlet output should be within +/- 5% of the mean. Reattach the flow tubes to the bottom of each applicator outlet. Calibrate applicator speed (ft/sec) in the field.
Applicator speed should be the same as determined above. Individual runs should be within +/- 5% of each other.

13.3.5 Method 4- Calibration of Electric-Driven Gandy-Type Band Applicators: Determine amount of test substance needed for plot. Determine amount of product (gram) for each applicator outlet for calibration for the selected speed and time for calibration. Unhook tubes from each applicator outlet, fill the hopper with enough calibration granules to cover the outlet opening during calibration and attach collection containers for each applicator outlet. Operate the unit for the time selected above and collect granules from each outlet. Adjustments to output should be made according to manufacturer's instructions until output collection is within the specified rate. The measured output should be within +/- 5% of the rate specified in the study protocol. Individual applicator outlet should be within +/- 5% of the mean. Calibrate/verify applicator equipment speed in the field on ground similar to the test plot.

13.4 Broadcast Granular Applicators

13.4.1 Purpose of Equipment: Granular broadcast applicators are used to broadcast granular test substances to test plots.

13.4.2 General: The accuracy of the test substance application may be influenced by wind, granular particle size and shape, application rate, ground slope, ground speed and local terrain. Application of granular test substance should be done

when the wind velocity is less than 10 miles per hour (mph). Alternately, wind screens that allow accurate placement of granules may be used. For Gandy-type pneumatic applicators, check hoses (clean and tighten connections), boom height, distance between applicator outlets, air-flow (900-1200 cubic feet per minute (cfm), operation of electrical or ground drive units and proper metering wheels.

13.4.3 Method 1- Moving Calibration for Centrifugal (Spinner)-Type Applicators: Calibration course and collection trays should be set as per the diagram following this section. The width of each collection tray used for collection and calibration of test substance should not exceed 10% of the anticipated swath width. The length of the collection tray should be equal to or greater than the width with a minimum length of 1.0 feet. A collection tray measuring 1.5 to 2.9 ft x 1.5 to 2.0 ft is usually adequate. Trays should be placed a minimum of 25% wider than the anticipated effective swath width. All passes should be made in the same direction at a constant ground speed and spinner speed. Prior to making any calibration passes, fill the applicator hopper with a sufficient quantity of test substance or blank granules, if available, to ensure that the outlet holes are completely covered throughout the calibration process and application of the test substance. First make a trial application(s) to determine the effective application swath width. Apply sufficient product (approximately 100 pounds product/acre) so that differences in swath pattern may be determined. The trial applications should be made using a ground speed and a gate opening for the applicator near the settings used for application to the test plot. After the trial application(s), weigh the granules from each collection tray. The effective swath pattern width (ft) is the distance between the points on either side of a single swath where the rate of deposit equals one-half of the effective application. Example: The center collection tray has 20 grams (g) of material. The effective swath width would be the sum of distances in each direction from the center tray to a point where 10 g of material was collected. If the trays that collected 10 g of the material were each 10 ft. from the center, then the effective swath width is 20 ft. A plot of the amount of material collected from each tray will provide the application pattern. The plot may be made using graph paper. An example is provided following this section to assist the applicator in constructing a spread pattern test graph. The applicator may then determine whether the swath pattern is acceptable by comparing to those swath patterns detailed in a diagram following this section. Data collected and graphs made by the PFI to determine effective swath width and to confirm an acceptable distribution pattern of granules need not be submitted as part of the data package. However, these records (appropriately identified, signed and dated) should be maintained with the PFI's copy of the trial data. If necessary, adjustments to the swath pattern may be made by: 1) adjustment of the spinner or gate opening; 2) change of spinner speed; 3) change of travel speed and; 4) general applicator orientation {spinner should be parallel to the application surface).

13.4.4 Calibration Verification: Determine effective swath width as above. Measure a specified distance to be traveled. Place a measured and recorded amount of test substance or blank material in the hopper. In some instances, the amount of material to be applied to the test area is so small that a uniform application cannot be achieved. In these instances, the applicator may uniformly mix measured and

recorded amounts of the test substance and blank material to achieve a uniform application to the plot area. Travel the measured distance at a constant spinner and travel speed while applying the test substance or blank material. The time (seconds) taken to travel the calibration distance should be recorded on the appropriate worksheet form for each application pass. The mean speed of application should be calculated. Each individual time application (seconds) is to be within +/- 5% of those obtained for calibration. If not, re-calibration is required. Measure and record the weight of material left and determine the application rate. The mean output should be calculated. Each individual output measurement should be within +/- 5% of the mean. The measured output for the applicator should be within +/- 5% of the rate specified in the protocol.

13.4.5 Method 2- Stationary Calibration for Gandy-Type (Pneumatic) Applicators and for Centrifugal (Spinner)-Type Applicators: Determine effective swath width and test substance output needed per plot for broadcast application. Select speed (mph) for application and time for calibration. Determine amount of product needed for each applicator outlet for calibration. Fill hopper with calibration granules, operate the unit and collect granules from each individual outlet for the period of time selected. The collected output should be within +/- 5% of the rate specified in the study protocol. If not within +/- 5%, make necessary adjustments according to manufacturer's instructions and recalibrate. Calibrate/verify applicator equipment speed in the field on soil similar to the plot. Applicator speed should be within +/- 5% of the mean. Note: If using an electric motor to calibrate the Gandy-Type Pneumatic Applicator, follow the procedures for "Stationary Calibration Using an Electric Motor to Calibrate for Ground-Driven Band Granular Applicators". The Gandy Type Pneumatic Applicator can be calibrated in a stationary position with the airflow off.

## 14.0 TREE AND VINE SPRAYERS

### 14.1 Purpose and Description of Equipment

14.1.1 Sprayers designed to make application of test substances to trees and vines may use an air stream to transport and distribute spray droplets to the target, as in the case of an orchard air-blast sprayer or a backpack mist blower (hand-held air-blast sprayer). These sprayers have fans that create a current of air that passes by spray nozzle(s) and propels the spray material into the tree or vine canopy.

14.1.2 Alternatively, applications may also be made using appropriate pressure through single nozzle "hand gun" type sprayers.

14.1.3 The hand gun applicators or orchard blast applicators may be a PTO driven unit or a self-powered unit pulled behind a tractor. Solo backpack mist blowers are hand-held applicators.

### 14.2 Operation

14.2.1 Proper operation of tree and vine sprayers depends on the type of sprayer, the crop being sprayed, the size and density of trees or vines, weather conditions and other factors. The manufacturer's manual should be consulted concerning safe and efficient operating procedures. If the application equipment has been custom-manufactured, then operation should be similar to commercially

available equipment.

14.3 Calibration

14.3.1 For most applications to vigorously growing vines and fruit or nut trees, it is desirable to apply 67% of the spray material in the upper half of the canopy and 33% of the material in the lower half of the canopy. Consult the manufacturer's manual for proper nozzle selection and arrangement on the sprayer manifold or boom. Select nozzles for air-blast sprayers that provide 67% of nozzle output to the top half of tree or vine (usually top half of manifold) and nozzles that deliver 33% nozzle output to lower half of the tree or vine (usually lower half of manifold). If a single nozzle handgun or mist blowers are used the percent distribution to the tree canopy (upper and lower) does not apply.

14.3.2 For orchard blast sprayers or hand gun applicators, the following calibration methods may be used.

14.4 Method A

14.4.1 Calibrate just like a regular straight boom sprayer described, i.e. discharge measurement for the individual nozzle for a set time and taking the speed at a set distance three times, then calculating the gallons per minute (GPM or liters [LPM]). Individual nozzle output should be within whatever the protocol specifies.

14.4.2 When the nozzles are not on a horizontal boom, calculate the actual swath width based on row spacing or 1/2 row spacing, as appropriate.

14.5 Method B

14.5.1 Determine the appropriate rate of travel for the application. Speeds of 1 - 2 mph or 1.6-3.2 kph are most common. Slower speeds may be used to provide better coverage of large areas and vines, especially when dense foliage is present. Faster speeds may be used for smaller, easier to cover trees and vines or when foliage is not present to impede spray penetration.

14.5.2 Determine speed in mph. Drive the tractor a measured distance over a surface comparable to the orchard or vineyard floor. Use the tractor gear setting and operating RPM that will be used during spraying. Measure and record the time (seconds) required to travel the distance three (3) times and then average the three pass times for a mean time. (Miles per hour (MPH) equals 60 divided by the number of seconds to go 88 ft.)

14.5.3 Determine gallons per acre (GPA or liters per hectare [LPH]) from the protocol.

14.5.4 Determine discharge in gallons per minute (GPM) from the following formula:

$$GPM = \frac{GPA \times MPH \times Row\ Spacing\ (ft)}{495}$$

Note: The Constant (495) is derived from 43,560 ft2/A ÷88ft.

14.5.5 Example calibration:

1. Determine speed in MPH (2).
2. Determine GPM. For example, for 200 GPA,

2 MPH and tree or vine row spacing of 20 ft.

$$GPM = \frac{200 \times 2 \times 20}{495} = 16.16 \text{ GPM}$$

3. The spray manifold or boom should be set up with a nozzle combination that will deliver 16.16 GPM. For air-blast sprayers operated using one side of the manifold (for application to a single row of trees or vines), make sure the true swath width is taken into consideration (rows spacing/2).

14.5.6 Discharge rate in LPM can also be determined using comparable equations using LPH, KPH, row spacing in (m) and 10,000 m /hectare

14.5.7 Calibrate/verify sprayer output.

1. Fill the sprayer with water to a known level (preferably full to overflowing) with the engine and pump running at operating RPM.
2. With the tractor stationary, operate the sprayer for a minimum of 15 seconds at the tractor RPM and operating pressure to be used during application. Low GPA's may require longer run time for accuracy.
3. With the engine and pump still running at operating RPM, measure the volume needed to refill the sprayer to the known level.
4. Divide the volume used to refill the tank by the number of seconds the sprayer ran to determine sprayer output.

14.5.8 Total sprayer output in GPM for the initial application will be determined three (3) times and then averaged for total sprayer output.

14.5.9 Record on the appropriate worksheet a description of the spray equipment along with raw data and calculations used to determine applicator speed and total output (GPA). Record in the Equipment Use Log the date the sprayer calibration or verification was performed, the trial(s) the calibration/ verification was performed for and the person performing the calibration or verification procedure

14.6 Back-pack mist blowers

14.6.1 Calibration Method A:

1. Place a known volume of water into the applicator.
2. Measure the amount of time required for the applicator to discharge the water.
3. Repeat Steps I and 2 a minimum of three times to determine the average rate of discharge. (Record this information on a worksheet).
4. After determining the rate of discharge, calculate the application time required per plot to apply the targeted application rate (GPA).
5. Practice and adjust walking speed to meet the desired rate of speed.
6. Repeat Step 5 until three consecutive walking passes are within +/- 5% of the calculated speed. (Record this information on a worksheet) .
7. Record on the appropriate worksheet a description of the spray equipment along with raw data and calculations used to determine applicator speed and total output (GPA). Record in the Equipment Use Log the date the

sprayer calibration or verification was performed, the trial(s) the calibration/ verification was performed for and the person performing the calibration or verification procedure .

14.6.2 Calibration Method B:

1. Place a known excess volume of water into the applicator (start volume)
2. Run the applicator for a pre-set time (i.e. 30 seconds)
3. Disconnect and measure the remaining volume in the applicator (end volume)
4. Calculate the discharge volume.
5. Repeat steps 1 through 4 a minimum of three times to determine coverage rate of discharge.(Record this information in a worksheet)
6. After determining the rate of discharge, calculate the application time required per plot to apply the targeted rate (GPA or LPH)
7. Practice and adjust walking speed to meet the desired rate of speed.
8. Repeat step 7 until three consecutive walking passes are within +/- 5% of calculated speed. (Record this information in a worksheet)
9. Record on the appropriate worksheet a description used to determine applicator speed and total output (GPA or LPH) Record in the Equipment Use Log the date the sprayer calibration or verification was performed, the trial(s) the calibration/ verification was performed for and the person performing the calibration or verification procedure.

## 15.1 CHEMIGATION (APPLYING CHEMICALS IN IRRIGATION)

15.2 Purpose of Equipment

15.2.1 Chemigation equipment is used to uniformly apply test substance to test plots via open or closed irrigation systems. Open systems include flood, furrow, border, or basin systems. Closed systems include sprinkler, micro-sprinkler, trickle, and drip systems.

15.3 Description of Equipment

15.3.1 Uniform application of irrigation water is prerequisite to uniform application of test substance. Equipment requirements are dependent upon the type of irrigation system utilized at the test site. Equipment chosen for application of test substance must be described on the appropriate form.

15.4 Open Irrigation Systems

15.4.1 Application of test substance via an open irrigation system requires the use of a gravity flow pesticide dispensing system, also known as a constant head siphon device, using TeeJet 4916 series orifices. Test substance flow rate is determined by the orifice size. This device may be threaded into a 5-gallon or larger container to allow gravity flow of test substance into irrigation water. An example of such device is shown at the end of this section. Alternatively, other pesticide dispensing systems using orifices or regulating valves may be utilized to uniformly meter concentrated or dilute test substance into irrigation water.

15.5 Closed Irrigation Systems

15.5.1 Closed irrigation systems require that test substance be injected into pressurized irrigation lines. There are several types of injection equipment. The preferred method is a Mazei injector. It is placed inline before the irrigation equipment and the pressure differential created with an inline valve system controls the rate of injection.

15.6 Calibration

15.6.1 Calibration is made to ensure that the correct amount of test substance is applied to the target site. It is recognized that small amounts of undiluted test substance are difficult to apply via chemigation. For ease of application, as well as increased accuracy, test substance may be diluted with a known, and recorded, volume of diluent or may be mixed undiluted.

15.6.2 Determine flow rate for closed or open irrigation system.

1. Determine the amount of test substance to be applied to the treated plot.
2. Determine the time required to irrigate the treated plot.
3. Determine desired flow rate or injection rate by dividing the amount determined in Step 1 by the time determined in Step 2.
4. Example 1: Calibration to apply 3.1 lb *ai*/A of undiluted EPTAM 7E in irrigation. Plot size is 20ft x 100ft= 0.046 acre. Amount of test substance required= 0.046 acre x 3.1 lb *ai*/A= 0.1426lb ai = 77.1 mi.
   Expected time required to irrigate treated plot = 30 minutes. Desired flow rate or injection rate = 77.1 ml / 30 minutes = 2.57 ml / minute.
5. Example 2: Calibration to apply 3.1 lb *ai*/A of diluted EPTAM 7E in irrigation. Plot size is 20ft x 100ft= 0.046 acre. Amount of test substance required= 0.046 acre x 3.1 lb ai/ acre = 0.1426 lb ai = 77.1 ml Test substance is diluted with 3709.9 ml water to produce 3785 ml of solution to be applied. Expected time required to irrigate treated plot= 30 minutes. Desired flow rate or injection rate= 3785 ml/ 30 minutes = 126.2 ml/ minute.

15.6.3 Calibrate flow rate.

1. Open Irrigation Systems. If using a system requiring TeeJet 4916 series orifices, choose the proper size orifice for the desired flow rate or injection rate using the chemical manufacturer's guidelines for gravity flow systems or TeeJet guidelines for pressurized systems. Flow rates are affected by temperature and viscosity of the solution. It may be necessary to change orifices several times before obtaining the desired flow rate. If using other metering devices, follow manufacturer's instructions for adjusting flow rate. Measure and record flow rate three (3) times and take the average for a final volume output.
2. Closed Irrigation Systems. Determine the pressure on the irrigation line before and after the Mazei injector (typically 22 before and 12 after). It may be necessary to change pressure difference to obtain the desired chemigation time. Less differential equals slower injection rate. Also increasing the outflow by increasing the number of drip lines or micro sprinklers can increase the injection flow. The calibration of the flow is only used to approximate the time to inject the diluted test substance. The entire diluted test substance should be injected and the container rinsed and injected three times to insure 100% of the test substance was delivered to the plot area.

3. Record on the Trial Notes form the length of time required for irrigation of each plot and the length of time application of test substance occurred.

15.5.4 Record on a worksheet form a description of the application equipment along with raw data and calculations used to determine flow rate. Record on the Equipment Use Log the date the calibration or verification was performed, the trial(s) the calibration or verification was performed for, and the person performing the calibration or verification procedure.

## 16.0 WIPER APPLICATORS

### 16.1 Description of Equipment

16.1.1 Wiper applicators are devices that physically wipe appropriate concentrations or amounts of spray solution directly onto the target without contacting the crop. They may be either tractor-mounted or hand held units. Wiper applicators generally consist of a hollow plastic holding tube with rope or sponge applicators running on the outside of the tube.

16.1.2 The spray solution, which is contained within the holding tube, flows from the tube into the rope or sponge applicators. Small hand-held units may or may not have a small bottle reservoir with an adjustment valve to allow the appropriate amount of solution to wet the rope wick or sponge applicators. The wiper applicator should allow the solution to flow at sufficient pace to saturate the sponge or rope applicators without excessive dripping.

### 16.2 Calibration and Application

16.2.1 Carefully check the wicking material to be sure that it is in good condition and clean. Replace the wicking material if it is in poor condition, dirty or contaminated.

### 16.3 Wiper Applicators With Reservoirs

16.3.1 Calculate the amount of test substance solution required to fill the wiper reservoir and record on a worksheet. Prepare the test substance solution as recorded on the worksheet. Record on a form the total test substance, total adjuvant and total diluent used in the test substance solution. Fill the water reservoir to prime the system. Check the rope wicks or sponges to determine whether the solution is flowing freely through the applicator with minimal dripping.

16.3.2 After the applicator is primed, empty the reservoir and record the amount recovered on the worksheet. Add this solution back to the reservoir as the starting amount for the application.

16.3.3 Drive or walk the wiper applicator through the plot area. After application, empty the reservoir, measure the amount recovered and record on a worksheet. Subtract the amount recovered after application from the starting amount and record the difference as the amount applied.

### 16.4 Wiper Applicators Without Reservoirs

16.4.1 Calculate the amount of test substance solution required to saturate the wiper applicator and cover the plot area. Record calculations on a worksheet. Prepare the test substance solution as recorded on a worksheet. Record the total substance, total adjuvant and total diluent used to make the test

substance solution. Saturate the wiper applicator to prime the system. Check the wicks or sponges to determine whether the solution is flowing freely through the applicator with minimal dripping.

16.4.2 After the applicator is primed/saturated, record the amount of test substance solution remaining and record on a worksheet form as the starting amount for the application.

16.4.3 Walk the wiper applicator through the plot area re-saturating the applicator as needed to ensure adequate coverage.

16.4.4 After application, re-saturate the wiper applicator, measure the amount of test substance solution remaining and record on a worksheet. Subtract the amount of test substance solution remaining after re-saturating after application from the starting amount and record the difference as the amount applied.

16.5 Application Pass Time(s)

16.5.1 The application rate for wick applicators is based on the amount of contact the applicator has with the weed target. Application speed, whether applied by hand or by tractor, has no direct effect on application. However, a slower speed may promote a more even application. For the purpose of calibration, application pass times are not required. The rate applied will be based upon spray solution concentration and total amount of material applied.

16.5.2 Record a description of the equipment along with the raw data and calculations used to determine the concentration of the spray solution applied to the plot on a worksheet. Record on the Equipment Use Log the date the equipment calibration/verification was performed, the trial(s) the calibration/verification was performed for, and the person performing the calibration/verification procedure.

## 17.0 SPOT APPLICATION

17.1 Purpose of the Equipment

17.1.1 Spot applications are performed to control pests in small localized areas of a field. An applicator will walk or ride a specialized cart through a field looking for pests and then apply varying volumes of spray solution containing a recommended concentration of the test substance to control the pest. To control pests in larger areas of a field, the applicator may calibrate a large commercial sprayer and turn the sprayer on/off as it passes over the pest. Equipment used in spot applications must deliver a specified concentration of test substance to a defined portion of the plot area. The protocol instructions will specify the total area of the spot application (usually 10% of the plot area) and concentration of the spray solution (usually 5% v/v). Volume of spray solution to apply the "spot" area of the plot may vary depending on the application method used.

17.1.2 The spray concentration, volume, and area to be treated specified in the study protocol must be delivered within +/- 5%. These parameters must be met to provide spot application data that will support label recommendations.

17.2 Description of Equipment

17.2.1 Spot application to small localized areas may be applied with single nozzle hand-held sprayers of various types.

17.2.2 A back-pack or side-pack sprayer consisting of a 0.25- to 3-gallon spray

container pressurized by a C02 tank which is carried by a person may be used. Operating pressure for the back-pack sprayer is adjusted with a regulator mounted on the C02 tank and the on/off valve is manually operated on the hand-held portion of the boom.

17.2.3 Single nozzle sprayers that are readily available from garden supply stores that use air pressurized by a hand pump may be used. Unless fitted with a pressure regulator, these units do not allow the operator to control the pressure. The on/off valve is manually operated on the hand-held portion of the boom.

17.2.4 An even fan nozzle will generally give a defined uniform spray pattern. However, other nozzles can be used as long as the spray pattern is confined to the defined area of the spot area(s) in the plot.

17.2.5 Spot applications may be made with tractor-mounted sprayers. The applicator will calibrate the sprayer to deliver a volume of spray solution at the specified concentration to the specific area by turning the spray unit on/off as it is driven across the plot.

17.3 Calibration/Application

17.3.1 Hand-Held Units: Carefully check the sprayer to ensure that it is clean and in good working conditions. Be sure the spray lines as well as the spray solution are clean. Replace any worn or broken parts. It is best to test the operation of the sprayer with the calculated amount of water in an area of the same size as the spot area before trying to apply the test substance to ensure the correct amount of solution will be delivered to the target area. Document the sprayer equipment used on the appropriate worksheet form. Document calibration/verification, application, cleaning and any maintenance on the Equipment Use Log.

1. Mark the areas in the plot area to receive the spot application. Record the size and location(s) of the spot application on the Plot Plan. For a protocol that requires application to 10% of the plot area, a 500 ft2 plot requires that 50 ft2 of the plot be identified for the application. The application should try to mimic coverage typical of an actual field application. Spray narrow strips or randomly scattered spots (as long as the areas can be measured and identified for sampling) through the plot rather than treating one large area. For the 10 ft x 50 ft plot, five 2 ft x 5 ft strips or five 1 ft x 10 ft strips applied with an even fan nozzle would provide the required area.
2. Determine the amount of solution to mix for the application. Record the calculations on a worksheet. If the recommended application rate is 13 gal/A (1.3 gallons solution on 10% of an acre) and the spot area is 10% of the plot, a plot size of 10 ft x 50 ft would require that 56 ml be applied in an area totaling 50 square ft.

   50 ft2 /43560 ft2 /acre = 0.0011 acre

   1.11 e x 13 gal/acre x 3785 ml gal =56 ml

3. Calculate the amount of test substance needed for the spray solution. Record the calculations on a worksheet. For a 5% solution with an adjuvant at 1%, the spray solution would be 2.8 ml test substance (56 x 0.05) + 0.6 ml adjuvant (56 x 0.01) + 52.6 ml water (56.0- 2.8- 0.6). The total solution = 56.0 ml.

4. Apply the spray solution to the identified plot area(s). Record on a worksheet the amount of solution applied and the total area covered. If the exact amount of solution was mixed and part of the spray solution is left over after spraying the spot area, the remaining solution can be applied to the area already sprayed because a spot application area does not require a uniform application of test substance over the sprayed area. If more solution is mixed than is needed to cover the spot areas, collect and measure the remaining solution so the total amount of test substance applied to the plot can be determined and recorded on a worksheet.
5. Record a description of the equipment and applicator along with the raw data and calculations used to determine the total amount of the spray solution applied to the plot on a worksheet. Record on the Equipment Use Log the date the equipment calibration/verification was performed, the trial(s) the calibration/verification was performed for, and the person performing the calibration/verification procedure.

17.3.2 Tractor-Mounted Sprayer and Hand-Held Sprayers Using Set GPA

Prior to calibration, test the spray system and check for leaks, cracked, broken or loose nozzles, hoses, and fittings. Ensure that switching devices operate properly and that the system (tank, lines, screens, and nozzles) is free of particles or debris. Each spray nozzle will be calibrated within pressure and flow rate recommendations in the manufacturer's specifications. Adjust the spray boom for correct spray pattern overlap as described by the manufacturer for the spray nozzle selected. Determine the width (ft) of the effective spray swath.

1. Mark the areas in the plot area to receive the spot application. Record the size and location(s) of the spot application on the plot map.
2. Determine required application volume in gallons/acre (GPA) from the study protocol.
3. Check nozzles for accurate volumetric output by measuring output three times. Individual nozzle output should be within +/- 5% (+/- 7% for flood jet nozzles) of the mean nozzle output. Total volume output is determined by taking the sum of the individual nozzle output. Each of the three volume output measurements should be within +/- 5% (+/- 7% for flood jet nozzles) of the average of the three measurements.
4. Determine the target sprayer speed (e.g., MPH, ft/sec, sec/100ft) based upon the total sprayer output, spray width, and the target application rate (GPA) required in the study protocol. Two trial runs will be within +/- 5% of the target speed. The mean of the two measurements will be taken as the finale sprayer calibration speed.
   The speed calibration should be done in the field in an area adjacent to or near the plot(s) to be treated and which has been under the same irrigation and tillage regimes as the plots to be treated.
5. Mix the spray solution as described for the hand-held units.
6. Time application pass(es) through the plot.
7. Record actual pass time(s) on a worksheet form.

8. Apply the spray solution to the identified plot area(s). Spray solution remaining in the tank does not have to be measured because the known output and tractor speed can determine the amount of test substance applied.
9. Record on appropriate worksheet a description of the spray equipment along with raw data and calculations for speed and volume determinations. Record on the Equipment Use Log the date sprayer calibration or verification was performed, the trial(s) the calibration or verification was performed for, and the person performing the calibration or verification procedure.

## 18.0 HOODED SPRAYER APPLICATORS

### 18.1 Description of Equipment

18.1.1 Hooded applicators are used to apply non-selective chemicals to vegetation between the rows of susceptible crops. They are usually tractor-mounted half cylinders, U-shaped plastic devices with flexible plastic flaps on the ends with one to three nozzles mounted in the forward, top part of the enclosure. The plastic hood confines the spray droplets to the weeds between the rows.

### 18.2 Calibration and Application

18.2.1 Check to ensure the hooded applicator is assembled and plumbed according to the manufacturer's instructions. The unit usually comes with TeeJet even flat fan spray tips (e.g. 95015VS). Other even flat fan spray tips can be used to obtain the desired gallons per acre application rate. It is recommended that the lowest pressure with the largest nozzle(s) providing the required gallons per acre be used to reduce crop injury from small particle drift.

18.2.2 Prior to calibration, test the spray system and check for leaks, cracked, broken or loose nozzles, hoses and fittings. Ensure that switching devices are operating properly and that the system (tank, lines, screens and nozzles) is free of particles or debris.

18.2.3 Determine effective spray swath (inside width to the nearest inch at the bottom of the hood).

1. Determine required application volume in gallons/acre (GPA) from the study protocol and calculate nozzle output and application speed.
2. Nozzles should be checked for similar output. Collect and record a volume catch for each nozzle with a hooded applicator or collect and record a total catch for all nozzles for each hooded applicator.
3. Total volume output is determined by taking the sum of the output from individual nozzle for a hooded applicator or a single catch from all nozzles from a hooded applicator. The total volume output for each hooded applicator must be within +/- 5% of the overall mean for all hooded applicators.
4. Determine the target application speed (e.g., MPH, ft/sec, sec/100ft). Trial runs will be within +/- 5% of the target speed. A minimum of three measurements will be averaged for a final sprayer calibration speed.
5. The speed calibration should be done in the field in an area adjacent to or near the plot(s) to be treated and which has been under the same irrigation and

tillage regimes as the plots to be treated. Where required, cultivation and/or incorporation equipment should be attached and set to proper depth to simulate actual application.

6. Record applications pass time(s) through the plot.
7. Record a description of the spray equipment along with the raw data and calculations for speed and volume determination on a worksheet or Trial Notes form. On the Equipment Use Log, record the date the sprayer calibration or verification was performed, the trial(s) the calibration or verification was performed for, and the person performing the calibration or verification procedure.
8. The band application rate under the hood is determined by dividing the effective swath by the row width and multiplying the answer by the application rate.

19.0 HISTORY OF CHANGE

| REVISION | DATE | DESCRIPTION |
|---|---|---|
| SOP 10.01 | 3/10/16 | Fixed general equipment description section and headers. |
| SOP 10.02 | 6/11/17 | Updated chemigation procedure.. |

STANDARD OPERATING PROCEDURE

EFFECTIVE DATE: 3/10/16

SOP 11.01 WATER METER CALIBRATION, MAINTENANCE AND USE

APPROVAL: _____ DATE: 3/10/16

## 1.0 PURPOSE AND SCOPE

1.1. The purpose of this Standard Operating Procedure (SOP) is to provide guidelines of the maintenance and validation of the water meter when used for GLP trials.

## 2.1 VALIDATION

2.2 The water meter will be calibrated once a month. If it has been more than thirty days since it was calibrated, it will be calibrated before using it for trials.

2.3 The water meter will be calibrated from 1000 ml to five gallons.

2.4 A container will be used to collect water from the water meter. The actual meter reading (in gallons) can be converted to ml if desired then recorded on the Water Meter Verification Log.

2.5 The water in the container will be poured into a graduated cylinder(s) to verify the volume measured or measured by weight by pouring the water into a tared container and placing on the scale. This value (in ml,g,kg,lb) will also be recorded on the Water Meter Verification Log.

2.6 If the actual measurement differs by more than ± 5% from the meter reading then an adjustment will be made to the meter so that the difference is less than ± 5%.

2.7 Steps 2.2, 2.3and 2.4 will be repeated a total of three times and the data recorded on the Water Meter Verification Log for the calibration.

2.8 It is the Principal Field Investigator's responsibility to be sure that the water meter is validated and in good working order before he/she makes the tank mix using the water meter.

## 3.0 MAINTENANCE AND USAGE

3.1. Batteries will be replaced in the water meter as necessary.

3.2. The water meter will be cleaned before and after each use to prevent possible contamination.

3.3. The water meter will have water run through it to clean it if it is used to measure anything but water.

3.4. Any routine maintenance will be recorded in the Equipment Use Log.

3.5. Any non-routine maintenance (equipment malfunction, etc.) will be recorded in the NON-ROUTINE MAINTENANCE RECORD.

## 4.0 HISTORY OF CHANGE

| REVISION | DATE | DESCRIPTION OF CHANGE |
|---|---|---|
| SOP 11.01 | 3/10/16 | Changed procedure to more accurately reflect use. |

STANDARD OPERATING PROCEDURES

EFFECTIVE DATE: 3/10/16

SOP 12.01 FINAL REPORT PREPARATION

APPROVAL: [signature] DATE: 3/10/16

## 1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes what information will be contained in a Turner Ag Research final report prepared for submission to the US EPA or US FDA or OECD Country on behalf of a study sponsor.

## 2.0 FINAL REPORTS

2.1 A draft final report will be issued prior to the final report. This copy will serve as a means for reviewing the content and accuracy of the final report. The draft final report is not signed by any study personnel.

2.2 A copy of the draft final report and supporting raw data will be provided to QA for audit.

2.3 A copy of the draft final report will be provided to the sponsor for review, before, during, or after the QAU audit.

## 3.0 REPORT FORMAT

3.1 A general outline of a final report format is as follows:

a. Study Title Page.
b. Statement of (No) Data Confidentiality Claims.
c. Good Laboratory Practice Compliance Statement.
d. Quality Assurance Statement.
e. Certification of Authenticity or report approval page.
f. Table of Contents.
g. Text, beginning with a stand-alone Abstract, and typically including, Introduction, Objectives, Materials and Methods, Results, Discussion, and Conclusion.
h. Tables.
i. Figures.
j. Appendices.

3.2 Specifically, the following format will be followed which incorporates the GLP requirements (noted with an *) and PR Notice 86-5 (not report requirements, but submission requirements):

a. Page 1, Title Page, showing:
- The study title,
- A reference to the registration requirement (such as code of federal regulation, or OPPTS test guideline),
- The name of the report author(s),
- The date the study was completed (date the report was signed), terminated or discontinued,
- The name and addresses of all performing laboratories and the laboratory's internal project number (if too many to list, the testing facility and a reference of the page where the list is presented),
- The name and address of the sponsor,
- And the total number of pages.

b. Page 2, A Statement of (No) Data Confidentiality, identifying confidential data, if any, included in the report, and signed by the company agent, or a blank page with the statement "page reserved for country-specific requirements".

c. Page 3, A GLP compliance statement*, certifying the GLP compliance status of the study, and identifying exceptions (if any) to the GLPs that occurred during the study, and signed by the study director, applicant and sponsor.

d. Page 4, A Quality Assurance Statement*, listing all inspections conducted by the QAU during the course of the study, showing the phase inspected, the date the inspections were performed, and the dates they were reported to the study director and management, and signed by a responsible individual of the QAU. Inspections conducted by any contract facilities may be listed on the same statement, or a reference to the contract facility's own QA statement showing the page where it can be found in the report.

e. Page 5, Certification of Authenticity or report approval page, identifying:
- Study title,
- The name of the study director,
- The name and address of the testing facility* and all performing laboratories,
- The names of the principal investigators and all scientific personnel involved in the study*,
- The name and address of the sponsor,
- Dates on which the study was initiated and completed, terminated, or discontinued*,
- The locations where all specimens, samples, raw data and the final report are archived*,
- Certificate of authenticity (or report approval) signed and dated by the study director. This signature completes the study, and must be separate from the signature appearing in the GLP compliance statement.

f. Table of Contents, showing at a minimum the first level of sorting.

g. Body of Report, including

- A standalone Abstract/Summary page,
- Objectives and procedures stated in the approved study protocol, including any changes in the original protocol*. (A copy of the study Protocol and its changes may be referenced to an appendix.)
- The test, control, and reference substances identified by name, chemical abstracts service (CAS) number or code number, strength, purity and composition, or other appropriate characteristics of each batch *.
- Stability and, when relevant to the conduct of the study, the solubility of the test, control, and reference substances under the conditions of administration*.
- A description of the methods used*. (A copy of the methods may be referenced to an appendix.)
- A description of the test system used. Where applicable, the final report shall include the number of animals used, sex, body weight range, source of supply, species, strain and sub-strain (including variety for plants), age, and procedure for identification *(e.g.,* labeling of each animal or plot)*.
- A description of the dosages, dosage regime, route of administration, and duration*.
- A description of the transformations, calculations, or operations performed on the data*. (Include an example using actual data of the study.) A summary and analysis of the data, including tabulated results, and a statement of the conclusions drawn from the analysis*.
- Statistical methods employed in analyzing the data*. These should be presented in sufficient detail for a person not associated with the study to be able to verify the same statistics independently.
- A description of all circumstances that may have affected the quality or integrity of the data *(e.g.,* protocol or SOP deviations)*.

h. Tables,

I. Figures,

J. Appendices, including:

- Protocol and amendments, if not addressed in the text.
- Copies of all methods used in the study, if not described in detail in the text.
- The signed and dated reports of each of the individual scientists or other professionals involved in the study, including each person who, at the request or direction of the testing facility or sponsor, conducted an analysis or evaluation of data or specimens from the study after data generation was completed*.

o A copy of the certificate of analysis of each batch of test, control and reference substance used in the study.

## 4.0 FINAL REPORT CORRECTIONS OR ADDITIONS

4.1 Once the final report of a study is issued, any changes must be issued in the form of an "Amended Final Report" (preferred procedure) or an "Amendment to the Final Report".

4.2 If the entire report is re-issued as an "Amended Final Report", a page (or pages) is inserted into the re-issued final report (placed in front of the QA Final Report Statement) that clearly identifies each part of the final report being changed, stating the changes made, and giving the justification for the changes. This list must be exhaustive, and include changes to the Title Page, GLP Statement, QAU Statement, Table of Contents, etc.

4.3 The amended report receives:

- A new title page stating "Amended Final Report",
- A new Statement of (No) Data Confidentiality,
- A revised Good Laboratory Practice Statement,
- A revised QA Final Report Statement that includes the date(s) the amended changes were reviewed,
- A revised table of contents (to include the page(s) with the amended changes),

4.4 Each page of the report that was amended should state "amended page" as a page footer or header.

4.5 The amended report is signed and dated by the study director, sponsor and QAU.

4.6 Since the GLP compliance statement is solely a submission document, and not a GLP final report requirement, a change to the GLP compliance statement before the study is submitted to EPA is not a change to the final report. The new GLP compliance statement is simply inserted to replace the old compliance statement. Any GLP exceptions that may have occurred during the amendment period may be added at this time.

4.7 If changes are presented only as an "Amendment to the Final Report", this document will include the following:

- A title page stating "Amendment to the Final Report",
- A Statement of (No) Data Confidentiality,
- A Good Laboratory Practice Compliance Statement only applicable to the amendment,
- A QA Final Report Statement only applicable to the amendment,
- A table of contents,
- A page clearly describing the parts of the final

report being changed, stating the changes made, and giving the justification for the changes.

4.8 Typically, an amendment to the final report may be considered when additional data are presented, that were not included in the initial final report.

## 5.0 HISTORY OF CHANGE

| REVISION | DATE | DESCRIPTION OF CHANGE |
|---|---|---|
| SOP 12.01 | 3/10/16 | Fixed grammatical errors. |

STANDARD OPERATING PROCEDURES

SOP 13.00 DATA PRESENTATION EFFECTIVE DATE: 3/26/2013

APPROVAL: Blair D DATE: 3/26/2013

## 1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes how numerical data will be presented and which statistical analyses will be performed when Turner Ag Research generates a study protocol and its final report. Methods of presenting data may be specified in the study protocol; otherwise, the following formats are routinely used in reports.

## 2.0 NUMERICAL DATA

2.1 Numerical data are presented in individual tables or summary tables. Both summary and individual data tables should include (as applicable) the table title, study number, interval of data collection, treatment identification, parameters measured and units of measurement, mean and standard deviation (or CV) values, and the results of intergroup statistical analyses. Numbers are rounded to the correct number of significant figures, as established in SOP 20.00.

## 3.0 STATISTICS

3.1 Statistical tests deemed necessary and appropriate by the sponsor or study director for understanding and interpreting the statistical significance of the data should be specified in the protocol. Statistical methods may include regression analysis; t, F, chi-square tests; analysis of variance; multiple range tests; and factor analysis.

3.2 Other statistical analysis may be conducted in addition to that proposed by the protocol. An amendment to the protocol is not necessary, unless the proposed statistics are replaced with analysis using a different principle of study interpretation.

## 4.0 HISTORY OF CHANGE

| REVISION | DATE | DESCRIPTION OF CHANGE |
|---|---|---|

STANDARD OPERATING PROCEDURES

EFFECTIVE DATE: 3/18/19

SOP 14.03 ARCHIVE DESCRIPTION

APPROVAL: Blaine D DATE: 3/18/2019

## 1.0 PURPOSE AND SCOPE

1.1 The purpose of this SOP is to describe the area assigned as the designated archive at Turner Ag Research and the procedures for storage of documents within this area.

1.2 The archives at Turner Ag Research are considered permanent. All original facility-related documents for each calendar year are prepared for archiving purposes by April 30 of the following calendar year (i.e. 2013 facility data will be archived by April 30, 2014). All facility-related documents will be retained in the archives as long as Turner Ag Research is conducting regular business.

1.3 All original study-related documents are sent to the Sponsor for archiving purposes before the study is completed (signed by the study director). However, at the discretion of Turner Ag Research personnel, copies of selected study-related documents maybe retained in the archives for an unspecified period.

1.4 Chemical or biological test, control and reference substance retain samples are not archived by Turner Ag Research. They are either archived at the sponsor or at a site designated by the Sponsor to maintain these archived samples.

1.5 Specimens from studies conducted by Turner Ag Research are typically soil, water, or plant material. All specimens are either sent to the sponsor or to a soil/water characterization laboratory as requested by the sponsor.

1.6 On occasion Turner Ag Research conducts studies or trials at locations other than the Yuba City facility. If those locations generate facility records, they will be archived at the Yuba City facility.

## 2.0 ARCHIVING PROCEDURES

2.1 The archives area consists of designated locked fire-proof cabinets for paper raw data. Electronic copies of field trial notebooks and other raw data sent as a data package to the clients may be kept on a google drive in a folder designated for Archiving.

2.2 A designated Archivist will assume responsibility for the condition, maintenance, and control of Turner Ag Research's archives. A back-up archivist(s) will also be designated. The designated archivist and back-up will be documented in the appropriate personnel file.

2.3 The designated archivist and back-up archivist retain the keys to the archives cabinets.

2.4 Current conditions of storage are under ambient indoor conditions. Fire protection is provided by the fire-proof cabinet and/or sprinkler system. General insect control will be performed if insect activity is observed by the archivist.

2.5 Upon receipt of documents for archives, the documents will be inspected by the archivist. If there are any discrepancies, the originator of the materials will be notified.

2.6 An Archive Index Log will be computer-generated for all materials of the previous calendar year placed into the archive by April 30 of the following calendar year. Facility-related data should be indexed in alphabetical order by type of data (i.e., cultural practices, equipment use logs, test substance receipt logs, weather data). GLP Personnel Records will be archived at the time the employee leaves Turner Ag Research service. CV's and job descriptions will be archived when new CV's and job descriptions are signed. Copies of any study-related data will be indexed by Study No. and/or Trial No. The trial data may be archived electronic copies on google drive. The location will be designated by the archivist.

2.7 Any materials archived after April 30 concerning facility-related and/or study- related documents from the previous calendar year will be recorded manually on the Archival Index Log.

2.8 Each file of documents will be appropriately labeled as described above.

## 3.0 HISTORY OF CHANGE

| REVISION | DATE | DESCRIPTION OF CHANGE |
|---|---|---|
| 14.01 | 10/17/13 | Typographical correction |
| 14.02 | 3/10/16 | Format Heading |
| 14.03 | 3/18/19 | Updated Facility location/added electronic archive option |

STANDARD OPERATING PROCEDURE

EFFECTIVE DATE: 3/10/16

SOP 15.01 REQUESTING ARCHIVED MATERIALS

APPROVAL: _____ DATE: 3/10/16

## 1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) describes how documents and other materials may be accessed for review or transferred after being placed in the archive at Turner Ag Research.

## 2.0 PROCEDURE

2.1 Only designated Turner Ag Research archive personnel may retrieve materials from the archive area. Only Turner Ag Research archive personnel may have access to documents in the archive. Personnel designated by a Sponsor may accompany the archive personnel to the archive area. The material must only be signed out by the archive personnel in order to maintain a record of access.

2.2 When personnel access material, a sign-out log, which is maintained by the archivist, is used, and notes what material was removed, when it was removed and returned, and the responsible person. The personnel accepting the signed out archived material assumes full responsibility, and will be held accountable for all material until they are returned to the archive personnel. No original archived documents will leave the offices of Turner Ag Research without approval of the Archivist.

2.3 The Archivist or back-up may make a copy of documents removed, if necessary.

2.4 Documents (not copied) or other materials removed by Turner Ag Research archive personnel must be returned to the archives the same day in which they were signed out. Examples for removal are:

- 2.4.1 Removed to fax or image documents for a client.
- 2.4.2 Removed to inventory materials.
- 2.4.3 Removed for a regulatory or client inspector, etc.

2.5 Turner Ag Research personnel may not retain the signed out materials for extended periods or over weekends, unless authorized by the Archivist. The Archivist or back up will notify the responsible personnel to return the materials immediately to prevent this from occurring.

2.6 When the client requests material to be returned, or when transferring materials to another facility, a chain of custody will be used. This Chain of Custody is signed by both the archivist and the recipient.

3.0 HISTORY OF CHANGE

| REVISION | DATE | DESCRIPTION OF CHANGE |
|---|---|---|
| SOP 15.01 | 3/10/2016 | Deleted Attachments and corrected spelling and grammar errors. |

STANDARD OPERATING PROCEDURE

EFFECTIVE DATE: 3/10/16

SOP 16.01 ELECTRONIC NOTEBOOKS

APPROVAL: _____ DATE: 3/10/16

## 1.0 PURPOSE AND SCOPE

1.1. The purpose of this Standard Operating Procedure (SOP) is to establish guidelines for Turner Ag Research to follow when receiving, using and transmitting Electronic Notebook files provided by the Sponsor for use with the Sponsor's Field Trials.

## 2.0 INTRODUCTION

2.1. Turner Ag Research will use electronic notebooks provided by the Sponsor to record their trial data. This data will be transmitted to Sponsor at the end of the trial and at other times designated by the Sponsor and/or protocol.

## 3.0 RECEIPT OF ELECTRONIC NOTEBOOK AND UPDATES

3.1. The Principal Field Investigator (PFI) will be responsible for uploading the electronic notebook file into a computer upon receipt of Electronic Notebook or updates.

3.2. When the Electronic Notebook is initially installed on a computer the verification process and/ or (SOP's) required by the Sponsor will be followed. The results of the verification will be checked against the script provided by the sponsor and kept in the data records for that computer.

3.3. When there are significant updates of the Electronic Notebook the verification process will be followed as required by the Sponsor. The results of the verification will be checked against the script provided by the sponsor and kept in the data records for that computer.

## 4.0 AUTHORIZED PERSONNEL

4.1. Only authorized Turner Ag Research personnel will be allowed to enter data. Authorization may come from the Sponsor System Administrator. The Sponsor System Administrator will decide the level of access the individual will have to the electronic notebook.

## 5.0 DATA ENTRY

5.1. Data will be entered at the time of the event or as soon as possible after the event if the computer is not available to be taken to the field trial site.

5.2. If the computer is not available to be taken to the field trial site, then the data will be recorded on either Turner Ag Research forms and/or forms provided by the Sponsor specifically designed for the electronic notebook being used. The recorded data will be transcribed into the electronic notebook as soon as possible after the event. The raw data will then be added to the Field Data Notebook that will be submitted at the end of the study.

## 6.0 TRANSMISSION OF UPDATES AND FINAL TRANSMISSIONS

6.1. Updates will be transmitted as per Protocol or Sponsor requirements.

6.2. Final update will be transmitted timely manner or according to Protocol or Sponsor requirements.

6.3. The PFI or other authorized individual may transmit updates. However, PFI will do final update.

## 7.0 HISTORY OF CHANGE

| REVISION | DATE | DESCRIPTION OF CHANGE |
|---|---|---|
| SOP 16.01 | 3/10/16 | Reformat header |

STANDARD OPERATING PROCEDURE

EFFECTIVE DATE: 3/10/16

SOP: 17.01 COMPUTER AND DATA MANAGEMENT

APPROVAL: Blair C DATE: 3/10/16

## 1.0 PURPOSE AND SCOPE

1.1. The purpose of this Standard Operating Procedure (SOP) is to establish Turner Ag Research guidelines for maintenance of computers hardware and software. It will give guidelines on the records that should be kept on both the computers and the software for those computers used for data entry into the electronic notebook(s) being used.

## 2.0 INTRODUCTION

2.1. Turner Ag Research will maintain computers in good working order and update and backup the hardware and software as needed.

## 3.0 FIELD UNIT FAILURE

3.1. If there is a computer malfunction the Principle Field Investigator or other authorized user will consult the Troubleshooting section of the Computer User's Manual to try to correct the problem. If the user cannot resolve the problem then the hardware support organization will be consulted.

3.2. If the computer is not available for use due to malfunction, the field data must be recorded on Turner Ag Research forms and/or forms provided by the Sponsor specifically designed for the electronic notebook being used. The information will then be transcribed into the electronic notebook with appropriate statement that the information is transcribed.

3.3. There will be a log maintained for all non-routine maintenance of the computer. The log will indicate what the problem was and how it was solved. An invoice from the hardware support organization will be attached to the log if applicable.

## 4.0 ADDITION OF NEW SOFTWARE

4.1 There will be a log of all software programs on each computer used for data entry into the electronic notebooks (desk and laptop).

4.2 This log will be updated whenever a new program is added or an old program is deleted or updated. The operating system (i.e. Windows XP) will be exempt of that log as updates are automatically initialized by the provider (i.e. Microsoft).

4.3 Only software approved by the Management will be authorized.

## 5.0 DATA BACKUP

5.1 Data will be backed up regularly to an external hard drive or other suitable device as need to prevent loss of data due to computer malfunction.

5.2 USB storage Drives, Flash Drives and Memory sticks are for temporary data storage and the data should be transferred to the computer and external hard drive as soon as possible for long term storage

## 6.0 HISTORY OF CHANGE

| REVISION | DATE | DESCRIPTION OF CHANGE |
|---|---|---|
| SOP 17.01 | 3/10/16 | Reformat header |

STANDARD OPERATING PROCEDURE

EFFECTIVE DATE: 3/18/19

SOP: 18.04 CONDUCT OF TRIAL

APPROVAL: Blaine D DATE: 3/18/2019

---

## 1.0 PURPOSE AND SCOPE

1.1 This document establishes a common standard and provides a guide for conducting regulatory field studies compatible with current U.S. Environmental Protection Agency (EPA) and Organization for Economic Co-operation and Development (OECD) guidelines and registration objectives. Where conflicts between the study protocol and these procedures arise, the protocol must be followed.

## 2.0 GOOD LABORATORY PRACTICES (GLP)

2.1 Regulatory field trials must be conducted and documented according to accepted Good Laboratory Practices. A detailed protocol approved by sponsor management is required. Each protocol must include a list of data requirement for that study. The trials must be conducted as instructed in the protocol or have a written explanation of protocol or SOP deviations. Documentation of the details of each trial is imperative. Such documentation should allow verification of the quality and quantity of the test substance applied, the personnel that did the work, details of how the samples were collected, preserved and shipped, and if necessary, the weather data or any supportive information that may be needed to fully understand the conduct of the study.

## 3.0 SAFETY

3.1 Trial personnel must at all times observe precautionary measures described in the label, material safety data sheet (MSDS), or technical information sheet of each test substance. It is important that the field personnel are fully informed of precautionary measures that may be required for applying test substances or sampling of crops and soils. The MSDS sheet usually provides a toll-free number in case of emergency.

## 4.0 STUDY/ TRIAL MANGEMENT

4.1 Every person involved in the conduct of regulatory trials is expected to adhere to the highest possible professional standards.

4.2 The Principal Field Investigator (PFI) is ultimately responsible for the proper conduct of an individual trial in the field and the completion and submission of all the required

raw data. The PFI is obligated to use appropriate SOPs to conduct the studies as detailed by the protocol. The PFI must be familiar with the trial objectives and submit reports on the conduct of the study as required by the protocol.

4.3 The Research Assistant and the Research Technicians will serve as field support staff performing or supervising field operations as applicable. The Research Technicians are responsible for the cleaning, maintenance and service of all the farm implements, as well as keeping up to date records of each operation. He/she is responsible for the procurement of supplies and field labor necessary for the conduct of a regulatory trial.

4.4 The services of an external GLP Quality Assurance person will be retained to monitor the site and to ensure that the facilities, equipment, personnel, methods, records and controls are in compliance with the GLP regulations. The QA person will, upon request, inspect the facility and/or field operations and will report the findings to the Test Site Manager.

4.5 All data generated during the conduct of a study, except data that are entered directly into an electronic data system, shall be recorded directly, promptly and legibly in ink on appropriate forms. All data entries shall be dated on the day of entry and signed or initialed by the person entering the data.

## 5.0 TRIAL PLOT DESIGN

5.1 The site/location for the trial should be representative of a growing area and must be suitable for growing the test crop. Avoid locating plots where flooding is a risk or in heavily trafficked areas to minimize the potential for a trial failure.

5.2 Site history for as many years as required by the protocol must be known before conducting any regulatory trial. This is to ensure that the test compound has not been recently used and chemicals previously used will not interfere with the analysis. In addition, the PFI should be aware of any previous treatments or practices which could be detrimental to the crop.

5.3 To ensure proper crop development, the plot area should be adequately prepared according to commercial practices or per protocol prior to trial initiation. This may include sub-soiling, disking and cross-disking, plowing, fertilizing, fertilizer incorporation, rototilling, furrowing and bed preparation. The crop should be established, maintained, and cultured according to agronomic practices typical to the growing area. Protocol directions regarding maintenance chemicals or cultural practices for the study, if specified, must be followed.

5.4 The plot must be sufficiently large to obtain representative samples on each sampling event, to eliminate sampling at the edges of the plot, to allow random sampling and avoid "oversampling" when multiple samples are collected, and to accommodate application equipment.

5.5 The plot size may be larger than the minimum prescribed by the protocol depending on the ground equipment to be used for application or trial

maintenance, and to the irrigation system used.

5.6 Adequate separation between treated plots and control plots is required to avoid plot-to-plot contamination. When multiple treated plots are required by the protocol, adequate separation is also required to prevent contamination between those plots. The minimum distance between the treated and control plots should be properly identified on the plot plan or any other documentation. If the protocol does not specify a minimum buffer distance between control and treated plots, or buffer distance between multiple treated plots then there should be a minimum distance of 10ft for row crops and at least one guard row for tree or vine crops.

5.7 The control plots should be located upwind and/or upslope from treated plots. Plots with lower rates should likewise be located upwind and/or upslope from those plots with higher application rates. Every effort should be exerted to minimize contamination due to drift, e.g., spray when winds are at a minimum, maintain adequate buffer zones between plots, and use drift retarding measures.

5.8 Once the crop is established, the crop should be maintained to ensure normal crop development during the growing season. Crop care methods are dependent on the crop, environmental parameters, and pest pressures. Crop development should be monitored to insure proper measures are taken in a timely manner and to assure the minimum protocol quantities of the required raw agricultural commodities can be collected at specified timings. Cultural practices will be recorded.

5.9 Plot boundaries should be readily identified with markers located at or near the corners of the plot. These markers should be located in such a way as not to interfere with the necessary operation of farm equipment. Borders may be mowed or cultivated to clearly define plot boundaries.

5.10 Each plot should have at least one marker labeled with an indelible pen or other permanent form of labeling to indicate the trial number. Each plot must also be labeled with the corresponding plot identifier. Each plot must be delineated using wooden markers or surveyor flags at or near the comers. At least one plot comer should be measured to two identifiable permanent markers (fence posts, irrigation valves, trees, etc.). If no identifiable permanent markers are available to help locate the plot(s) then at least two GPS coordinates must be determined. Measurements between all the plots are required as needed to enable future reconstruction of the trial layout after its completion.

5.1 1 For broadcast applications, boundaries of a treated plot are defined by the area treated with the test substance. For banded applications or treatments on trees and vines, the boundaries are defined by the row middles and length.

5.12 Samples collected for analysis are to properly represent crop samples harvested and distributed through normal commercial channels. If crop development is somehow compromised by environmental conditions or other parameters such as pests and diseases, these factors should be documented.

5.13 Atypical situations arising during the study that may affect the trial should also be

documented. If these atypical situations could jeopardize the integrity of the study, the Study Director must be notified.

5.14 Plots will be observed at least monthly after the first critical event for the trial has occurred. Observations will be done at each critical event as well.

## 6.0 TEST SUBSTANCE USAGE

6.1 Test substance use (Test Substance Receipt, Use and Transfer Logs) must be completed for the amount of test substance removed for each application, even when the sponsor provides an electronic data collection system.

## 7.0 SPRAY SOLUTION PREPARATION

7.1 Ingredient s for the spray solutions will be used and added as outlined in the study protocol and documented in the study records. The PFI will ensure that sufficient tank mix is prepared to conduct the application as well as have extra solution to charge the apparatus, etc.

7.2 No adjuvants, surfactants, stickers, oils, etc. are to be added to the spray solution unless specifically stated in the protocol.

7.3 Adjuvants, surfactants, stickers, oils, etc. will be measured or weighed as appropriate using GLP standards.

## 8.0 APPLICATION

8.1 Equipment calibration and verification should be conducted as described in SOP 10 Application and Equipment Calibration, Verification, Maintenance and Equipment Use Log.

8.2 Application pass times must be recorded. The overall application rate using application pass times should be within +/- 5 % of the protocol rate, or as specified by the protocol. The Study Director must be notified promptly and a Study Protocol and/or SOP Deviation must be completed and submitted if the calculated rate using pass times are outside the range allowed in this SOP or the protocol.

8.3 In the event an application pass time was inadvertently not recorded, the PFI should record an additional timed speed run at the end of the normal application under the same conditions. The PFI must document the reason for the problem and notify the Study Director regarding the deviation and to discuss how to proceed with calculating the application rate.

8.4 Any discharge problem, e.g. section of the treated plot unsprayed because of insufficient bulking of spray solution, must be recorded. The problematic section of the plot must be marked, discarded or destroyed to eliminate it for sampling.

8.5 At the time of application or immediately after application the environmental

conditions should be recorded in the field trial notebook. Refer to the trial protocol for required data. Usually the required data includes wind speed and direction (do not spray if wind exceeds 10mph, some protocols require wind to be less than 5mph and not in the direction of the control plot), air temperature, relative humidity, soil temperature (refer to protocol for depth of measurement), soil moisture, foliage conditions (dry/moist/wet) and cloud cover in percentage. Wind speed, air temperature and humidity can be measured using a hand held device such as a Kestrel 3000. Soil temperature should be taken with a soil thermometer.

## 9.0 CROP SAMPLING METHODS

9.1 Avoid contamination of the field sample with the pesticide under study or pesticides prohibited in the study during sampling, packaging, storage, and shipping. Sources of possible contamination may include:

- 9.1.1. Sample containers that have been stored or transported in close proximity to the test substance
- 9.1.2. Application and sampling equipment
- 9.1.3. Hands and clothes that have been in contact with pesticides or treated samples
- 9.1.4. Spray drift
- 9.1.5. Vehicles which have previously transported chemicals

9.2 Unless otherwise indicated by the protocol, samples should be frozen (ideally within 4 hours of sampling) after removal from the field to preserve the pesticide residue. The samples and the pesticide residue are perishable. If the sample is allowed to stand in heat, the residue may be lost due to volatility or chemical process, or the sample may deteriorate or spoil, which could alter or decompose the residue. The storage or shipping conditions and location of the samples from sampling to final delivery to the analytical or crop processing laboratory should be documented.

9.3 Control samples should always be collected first before treated samples to avoid potential contamination from handling. When treated samples must be collected shortly after application, e.g., 1 to 2 hours or after the spray has dried, collect the control samples prior to application to minimize the chance of contamination, if allowed by the protocol. If weather or other factors necessitate an application of the same substance used in the trial just prior to sampling the control, use precautions to keep control samples separate from application activities.

9.4 Treated and untreated samples should be placed in separate coolers with ice or blue ice to minimize sample deterioration on the way to frozen storage. If necessary and allowed by the protocol untreated samples may be double bagged and placed in the same freezer as the treated sample.

9.5 Unless the protocol indicates otherwise, within four hours after collection samples should be placed in a freezer maintained below 32 °F/ 0 °C. If this proves impractical, they should be placed in a cooler with ice, blue ice, or dry ice while awaiting permanent frozen storage. The freezer storage temperature will be monitored and recorded. The equipment identification and location of the freezer must be indicated.

9.6 Samples should not be allowed to thaw. If freezer storage temperatures exceed the allowable limits set in the protocol or applicable SOP(s), or if the samples thaw, the Study Director must be notified immediately.

9.7 Plastic-lined cloth sample bags bearing the appropriate label information are generally used to store and ship all Regulatory Studies samples, unless other containers are specified in the protocol. Always use new bags. Never reuse a sample bag. If the sample containers are stored before use, store them in a dust-protected area isolated from test products and application equipment.

9.8 Sampling tools (e.g., pruning shears, knives, soil corers, etc.) must be thoroughly decontaminated before each use. Washing with warm soapy water generally will suffice. Separate sampling tools for each plot is preferred otherwise clean the sampling tools between plots when sampling from more than one treated plot within a trial. Ensure adequate separation of sampling equipment from chemical storage, chemical weighing/preparation areas or application equipment to prevent contamination of residue samples during sampling.

9.9 Care must be taken to minimize contamination of sampling supplies during transport to the field for sampling. They may be placed in closed, clean boxes, the cab of the transport vehicle, or other appropriate secure location.

9.10 When samples need to be dried (straw/hay) they will be left in the plot until sampled. If rain is eminent the harvested plants will be placed on clean plastic in a covered area. The samples from each plot will be kept separate and identification of the study, trial, and plot ID will be placed by each sample. Harvest and sampling dates will be recorded.

## 10.0 SAMPLE COLLECTION AND STORAGE

10.1 Collect the raw agricultural commodities (RAC) that are specified in the protocol. These crop parts normally constitute the commercial commodity as it leaves the field to enter interstate commerce. In some specific trials, parts other than the normal products of commerce may be sampled, e.g., immature fruits or plants. Always follow sampling methods specified or allowed by the protocol.

10.2 Avoid sampling severely diseased or senescent crop parts, frost-damaged crops, loose heads, unfilled pods, undersize fruit, or other abnormal produce.

10.3 Collect samples in a manner that is reasonably representative of typical harvesting practice. Crops may be harvested by hand or by mechanical means. Hand and sometimes mechanically harvested samples, e.g., roots, tubers, etc., may require removal of adhering particles such as soil. Additionally, the protocol may require specific field trimming, e.g., removal of base or outside wrapper leaves from cabbage or lettuce heads. Regardless of the method of physical harvesting, cleaning and trimming the samples, sampling must be conducted according to the protocol unless otherwise approved by the Study Director. All sampling specifics must be accurately reported.

10.4 Avoid removal of surface residues during sampling and handling, e.g. friction or rough handling. Place samples directly into sample bag unless additional steps are required by the protocol.

10.5 Avoid sampling from plot edges.

10.6 For adequate plot representation of row crops, collect sufficient sample quantity from at least 12 random locations within the plot area. Amounts specified in the protocol are minimum weights or numbers of raw agricultural commodities. Larger sample size is acceptable where it is believed that a more representative sample will result.

10.7 RAC samples should not be subdivided unless specifically allowed in the study protocol or where discussed and agreed in advance with the Study Director. The following guidelines for sampling will apply when not specified in the study protocol.

10.7.1. When raw agricultural commodities are bulky such as straw, forage, fodder, silage, hay, and the like, or where samples need to be segmented and inspected for quarantine purposes, a small shredder or a knife cleaver may be used to shred or chop the sample. Sub-sample after thoroughly mixing the shredded sample.

10.7.2. Similarly, sub-sampling with a clean knife may be performed for bulky commodities such as cabbage, cauliflower and head lettuce. In such cases, the raw agricultural commodities should be quartered longitudinally with a clean knife, taking quarter samples from whole plants, head or fruit. The number of sampling points in the plot should always represent at least the number of points indicated in the protocol.

10.7.3. In the case of corn forage, sections may be taken as follows: Collect a minimum of 12 plants from at least 12 random spots of the plot. Divide each stem with leaves attached into three equal lengths. Take top, middle, and bottom sections, respectively, from each of three groups of four stems ensuring that the three parts of the 12 plants are included in the sample.

10.7.4. When sampling vine crops, such as grapes, collect a minimum of 12 bunches from at least 12 separate areas in the plot (high, low, inside, outside, etc.). Any diseased or senescent grapes will be removed from each bunch before placing in the appropriate labeled sample bag.

10.7.5. When sampling bush fruit (e.g. raspberries) collect a minimum of 1 kg per sample from at least 12 separate areas in the plot (high, low, inside, outside, etc.).Any diseased or senescent fruit will not be sampled. The picked fruit will be placed in an appropriately labeled sample log.

10.7.6. When sampling tree fruits (e.g. stone fruit and citrus) collect a minimum of 24 fruit pieces per sample. Typically treated plots contain 6 trees of which samples are taken from the inner 4 trees. Control plots may be smaller than 6 trees and so samples can be collected from all trees. Each tree is divided into quadrants and fruit are removed from each quadrant as per fruit load (sampling high, low, inside

and outside, etc.) directly into labeled sample bag.

10.7.7. When sampling small tree fruit (e.g. cherries), collect a minimum of 1 kg per sample. As described above, the fruit are removed from each tree quadrant as appropriate per fruit load and picked into a clean container. The picked fruit are then transferred in to the appropriate labeled sample bag.

10.7.8. When sampling tree nuts (e.g. almonds), collect a minimum of 2 kg of whole nuts (hulls, nutmeat and shells) to obtain approximately 1 kg of nuts (nutmeat with shells). Specific samples and sample weight requirements are usually outlined in the study protocol. The tree nuts are collected from each quadrant of each tree by shaking appropriate branches with a pole or other appropriate device. Typically, treated plots contain 6 trees with samples collected from the 4 inner trees. The whole nuts are either allowed to fall onto the ground or on to a clean tarp as directed by the study protocol. The whole nuts from each quadrant of each tree (16 sampling locations) are gathered into piles and sampled into appropriate containers. The whole nuts in the containers are removed from the field site and taken to a separate location at the facility for processing as outlined in the study protocol.

10.7.9. When sampling specialized tropical fruit (e.g. bananas) collect four fingers from the bunch from a minimum of 6 trees (24 fruit/sample) . The fingers will be from the inner and outer portion of the bunch. The picked fruit will be placed on absorbent towels, before, placing in plastic bags and an appropriate labeled sample bag.

10.8 Residue samples collected from plots receiving spot applications should represent the commodity that would be removed by commercial harvest procedures. Collect a proportionate sample of spot treated and non-spot treated plants that represent the entire plot area. If plant material from spot treated areas would not be removed by commercial harvest, plant material from spot treated areas should not be included in the residue sample.

10.9 When sub-sampling is required, it should follow the same sequence as sampling. Sub-sampling of the control sample should occur before sub-sampling of the treated sample. Reasonable care must be exercised to prevent contamination.

10.10 The crop commodity supplied should be "clean" and not contaminated by large amount of other materials such as chaff in grain samples.

10.11 All crop samples should be placed directly into properly labeled sample bags. Readily perishable samples should be cooled immediately upon collection by placing them into a cooler filled with ice, blue ice, or dry ice.

10.12 When replicated samples are required, they must be sampled separately. Do not collect one large composite sample and split into two samples.

10.13 After sample collection is completed (either individually, control samples and/or treated samples), the samples are weighed on an appropriate non-GLP maintained scale. The sample weights are recorded as specified in the protocol before placing them in a freezer.

10.14 Always ensure that soil or crop samples will not intermix with spray solution samples by storing them in separate freezer or in a separate location in the same freezer. Likewise, the control and the treated samples must also be stored either in separate section of the same freezer (separated by physical barriers) or in different freezers. Always see to it that samples are isolated from contact with pesticides or contaminated equipment at all stages of storage and shipment. Ensure adequate separation of frozen samples from chemical storage, chemical weighing/preparation areas, or application equipment. It is preferable to locate the freezer in a separate room or building.

## 11.0 SAMPLE IDENTIFICATION

11.1 Individual samples will be placed into one or more containers at the time of sampling. Container refers to sample bag, vial, or other enclosure into which the sample is placed. Label sample bags using waterproof ink or attach a pre-printed label and cover the entire label with clear shipping tape, ensuring the label is fully secured to the bag on all sides.

11.2 Label the sample container (per Section 9.1) clearly to assure cross-reference and agreement with the raw data. Include the following data on the label:
- 11.2.1. Trial number
- 11.2.2. Sample number
- 11.2.3. Sampling date
- 11.2.4. Container number, if more than one container is used per sample

11.3 When multiple containers are used for large samples, label each container with the same sample number, trial number, sampling date and indicate the container number as "1 of 2", "2 of 2", etc. Indicate the number of containers for a single sample on the appropriate form.

11.4 Each soil sample core is to be identified with a label bearing at least the following information:
- 11.4.1. Study number
- 11.4.2. Trial number
- 11.4.3. Sample number
- 11.4.4. Core number
- 11.4.5. Sampling depth
- 11.4.6. Plot and sub-plot identification
- 11.4.7. Sampling date
- 11.4.8. Occasion

11.5 The Study Director/Study Coordinator may be able to provide computer

generated self-adhesive labels or assist in making labels for the study.

11.6 Label the sample container containing the soil core samples clearly to assure cross-reference and agreement with the raw data. Include the following data on the label:

11.6.1. Trial number
11.6.2. Sample number
11.6.3. Sampling date
11.6.4. Container number

11.7 When multiple containers are used for large samples, label each container with the same sample number and trial number and indicate the container number is "1 of 2", "2 of 2", etc. Indicate the number of containers used for a single sample on the appropriate form.

12.0 SHIPPING

12.1 All shipments containing dry ice and transported using commercial air carriers (with the exception of alternative vendors detailed below), will be made in accordance with regulations defined by the International Air Transport Association (IATA) and detailed in the Dangerous Goods Regulations. These regulations are usually available from the shipper like Federal Express.

12.2 General Instructions

12.2.1. Samples from the field will be shipped by the PFI according to protocol directions. This could be directly to the Sponsor's analytical laboratory of choice or directly to its own facility.
12.2.2. Samples should be shipped as soon after collection as is reasonable. Refer to the protocol or contact the Study Director/ Study Coordinator for additional instructions if questions arise or problems are encountered regarding sample shipping.
12.2.3. When shipping samples with dry ice, the samples should be deep frozen prior to packaging for shipping when it is practical to do so. This will conserve the dry ice and help ensure the samples will arrive frozen. If rapid shipment following sample collection is required, it will be specified in the study protocol. In such cases, a sufficient amount of dry ice is required in the shipping container to freeze and ship the samples.
12.2.4. Spray mixture solution samples must never be shipped in the same container as crop or soil samples.
12.2.5. A copy of the appropriate form(s) indicated by the protocol should be sent with sample shipments.
12.2.6. When several boxes of samples are shipped together, all boxes should be numbered as follows using an indelible marker: "1 of 3", "2 of 3", etc.; or alternately, the number on the bill of lading may be used. Place all appropriate residue trial sample information forms, such as a chain of custody, into a plastic zip-lock bag and place the bag inside the box on top of the samples. Indicate on the outside of the box which box contains the paperwork. It is helpful to indicate the sample numbers on the outside of each box. This may be done in any number of ways - hand written, computer printout, etc.

12.2.7. Shipping boxes, bags, styrene box inserts, labels and other shipping supplies may be provided by the sponsor company or purchased from a third party.

12.3 Refer to the study protocol to determine if samples are to be shipped frozen. For samples shipped frozen, the samples are to be chilled or preferably frozen before they are packaged for shipment. Pack the frozen samples securely. Insulating styrene box inserts may be used to protect the samples from thawing and to reduce the formation of condensation on the outside of the boxes. Condensation may subsequently weaken and damage the box, resulting in failure of the shipping company to deliver those boxes.

12.4 Where the samples are frozen before packaging and styrene inserts are used with the inner and outer shipping boxes, place approximately 6 kg (12 lb) or more of dry ice on the top and bottom of the samples for shipping.

12.5 During warm seasons, or if the samples are not frozen prior to shipping, approximately 14 kg (30 lb) of dry ice (15 lb top and bottom) is recommended. In a test of the effectiveness of the styrene inserts conducted at an ambient air temperature of approximately 75 °F., 30 pounds of dry ice kept samples frozen approximately five days.

12.6 Where styrene inserts are not used, place approximately 11.3 kg (25 lb) of dry ice in the bottom of the box. Place the samples in the box and place an additional 11.3 kg (25 lb) of dry ice on top of the samples. If possible, wrap the dry ice in paper before placing it in the box. The 23 kg (50 lbs) of dry ice placed in the box as described should keep the samples frozen for approximately 48 hours. During warm seasons it is advisable to use more than 23 kg (50 lb) of dry ice, or use the styrene inserts to keep the samples frozen.

12.7 Both the inner and outer boxes should be taped shut, taking care to seal all edges. Appropriate residue forms placed into a sealed plastic bag may be placed inside the box or between the top flaps of the inner and outer boxes. Generally, the cardboard boxes used for shipping are not airtight. IATA regulations require that the packaging is to be designed and constructed to permit the release of carbon dioxide gas and to prevent the build-up of pressure that could rupture the packaging. Dry ice must not be shipped in airtight containers which could potentially rupture.

12.8 The shipper is responsible for all necessary marking and labeling of each package, in compliance with appropriate regulations. The following instructions apply to consignments shipped via air carrier and containing dry ice.

12.9 Apply the following labels or markings:

12.9.1. Airbill with address
12.9.2. One black and white hazard label for class 9, miscellaneous dangerous goods:
1 UN 1845 Carbon Dioxide, solid [dry ice]
2 The weight of the carbon dioxide [dry ice] in kilograms (kg) in the container
3 The shipper's and addressee's addresses
4 The contents, e.g., soil or plant material (for possible quarantine purposes)
5 Indicate which box contains residue forms
6 Indicate box ___ of____

For consolidated consignments shipped via overland carrier, e.g., ACDS, the following marking and labeling instructions may be followed:

12.9.3. Address label
12.9.4. The contents, e.g., soil or plant material (for quarantine purposes)
12.9.5. Indicate which box contains residue forms.
12.9.6. Indicate box_ of_ or bill of lading number

12.10 Large size AGF (Aspirated Grain Fraction) and processing samples (greater than three boxes per sample) can be packaged and labeled as described above or by using the following modified procedure.

12.11 One address label and a computer generated label with the box number (usually bill of lading number}, study number, trial number, sample number, sample date, and designated box of the total number of boxes can be placed on the top of the outer box to identify the sample. Other labeling conventions can also be used. A large plastic bag instead of the white polyethylene-lined cloth bag may be used and may be placed inside the inner box or between the inner and outer box of the double box container.

12.12 Carbon dioxide solid (dry ice) is classified in the lATA Dangerous Goods Regulations. Appropriate documentation is required for all packages containing dry ice and may be completed according to the following procedure. The following procedures for shipping dry ice are based on information current as of the issue date of this SOP. The PFI will need to keep abreast of procedural changes arising from lATA regulations or FEDERAL EXPRESS policies.

12.13 A Shipper's Certification of Restricted Articles/Dangerous Goods is not required for shipping dry ice (lATA packaging instruction 904) providing the following information is included on the Waybill exactly as it appears below. Air Waybills for various vendors may differ in appearance. However, the information detailed below must be provided. FEDERAL EXPRESS Air Waybills styles change on occasion. A FEDERAL EXPRESS Air Waybill for a shipment containing both dry ice and agricultural samples should be completed as follows.

12.13.1. Section 1 -Senders address, telephone number, etc.
12.13.2. Section 3- Destination address, telephone number, etc.
12.13.3. Section 4- Check box "FedEx Priority Overnight"
12.13.4. Section 5-Check box "Other Packaging"
12.13.5. Section 6-Check box "Dry Ice" and fill in total containers x total kg

Dispatch the shipment on Monday, Tuesday or Wednesday of a non-holiday weekday so samples will arrive on a workday.

12.14 Only vendors approved by the sponsor company may be used for overland transport of Regulatory Study samples. Authorization from the Study Director/Coordinator may be required prior to consigning shipments to vendors other than the specialized delivery service of ACDS Trucking, Inc. which is normally used for shipping.

12.15 For safety reasons, ACDS prefers that boxes may not exceed 34 kg (75 lb.) gross weight.

12.16 Samples consigned to ACDS are shipped in refrigerated/freezer trailers and may therefore be packed into boxes without dry ice.

12.17 The study protocol will specify if samples are to be shipped non-frozen. In such cases the Sample Preparation Unit of the consignee must be notified of the impending shipment. Quarantine restrictions might be in effect. Quarantine regulations, if any, must be met.

12.18 International Shipments

12.18.1. Due to the varied regulations of each Country and if shipping fresh or frozen row agricultural commodities to the USA, it is highly recommended to consult with the Study Sponsor and/or the Country's local shipper (i.e. DHL) on the appropriate procedure to follow in order to ship the samples to his/her facility or designated analytical laboratory in the USA.

## 13.0 HISTORY OF CHANGE

| REVISION | DATE | DESCRIPTION OF CHANGE |
|---|---|---|
| 18.01 | 10/17/13 | Typographical corrections |
| 18.02 | 4/7/14 | Added section 8.5 to define data collected at application |
| 18.03 | 3/10/16 | Reformat header |
| 18.04 | 3/18/19 | Corrected personnel titles |

STANDARD OPERATING PROCEDURE

EFFECTIVE DATE: 3/10/16

SOP: 19.01 Completion of Notebook Forms

APPROVAL: Blaine D DATE: 3/10/16

## 1.0 PURPOSE AND SCOPE

1.1 The purpose of the document is to provide instructions for entering data onto the forms provided by the Sponsor or in the absence of equivalent forms Turner Ag Research Trial Notebook Forms will be completed. As appropriate and permissible, an original or true copy of these forms will be included as part of the field data package for the relevant trials.

## 2.0 TRIAL REPORT FORMS

2.1 The Trial Reporting Forms have been designed to provide the documentation required by the EPA as set forth in the Data Reporting Guidelines in accordance with the EPA Good Laboratory Practice Standards. The forms are designed to enable entry of specific data as well as general information needed to document the conduct of the trial.

2.2 Descriptions and instructions for each form are given in the following text. Each form is discussed in a separate section. The completed forms, if any, that are included in this SOP are examples.

2.3 All information concerning the trial will be entered on the Field Trial Notebook Forms. Substitute forms are permitted as appropriate.

## 3.0 GENERAL GUIDELINES FOR RAW DATA DOCUMENTATION

3.1 All notes and comments that are not entered elsewhere on the Field Trial Notebook and Sponsor forms should be entered on the Trial Notes form or Sponsor trial notes forms. If information is related to data presented on other forms, entry should reference the appropriate forms.

3.2 The principal field investigator (PFI) must follow the following guidelines in completing the Field Trial forms and Sponsor forms:

- 3.2.1 The information documented on all forms is GLP raw data.
- 3.2.2 All GLP raw data should be recorded directly on the forms.
- 3.2.3 Transcribed data must be identified as such on the Field Trial forms. The original raw data must be submitted or indicate where the original data will be filed and archived.
- 3.2.4 Retention of raw data, regardless of the medium used for recording, e.g., napkins, tissue paper, etc., is a GLP requirement. In general, you should keep all Field Trial and Sponsor forms with other original data and trial information in order to prevent loss until trial completion.
- 3.2.5 Make entries with an indelible ball point pen, preferably black or blue ink.

Entries must be distinct and legible.

3.2.6 Signatures or initials are required of those performing the task and entering the data. If the signature or initials of the person (individual) performing a task cannot be obtained, enter his/her name in block letter print.

3.2.7 The "Completed by" section on all forms will be signed or initialed by the person entering the data.

3.2.8 Always enter the trial number and/or study number on each form and any substituted forms, attachments to the forms and/or supporting data.

3.2.9 All dates entered on the Field Trial forms are formatted on the Month/Day/Year convention. For Sponsor forms dates should be formatted per Sponsor requests.

3.2.10 The use of NA on any of the forms will mean non-applicable unless otherwise indicated.

3.2.11 Units of measure can either be metric or English.

## 4.0 DOCUMENTING RAW DATA CORRECTIONS

4.1 If an error is made, draw a single line through the error without obscuring the original entry and write in the correct entry. You must initial, date and provide a brief explanation for each correction. You may use the error code listed below for an explanation of errors in data entry. Write the code next to your initials and circle the code.

| | |
|---|---|
| MS | Misspelled |
| ME | Mathematical Error |
| WE | Wrong Entry |
| WO | Write Over |
| TSE | Transposition or Sequencing Error |
| TE | Transcription Error |
| FC | Form Change |
| WC | Wrong Conclusion |
| IE | Illegible Entry |
| UE | Unnecessary Entry |
| LE | Late Entry |
| EE | Entry Error |
| RE | Recording Error |

## 5.0 PROTOCOL DEVIATONS

5.1 Whenever a deviation occurs, the PFI must notify the Study Director/Study Coordinator as soon as possible. In cases where a deviation is anticipated, consult with the Study Director/Study Coordinator on possible options before proceeding. For example, weather conditions could prevent application at specified timing. Fill out Protocol/SOP Deviation form or Sponsor form and send it to the Study Director for his/her signature.

5.2 A copy of the Protocol/SOP Deviation form or Sponsor form may be faxed/emailed to the Study Director/Study Coordinator. The Protocol/SOP Deviation form or Sponsor Form should be sent to the Study Director/Study Coordinator as soon as possible after it has been written. Do not wait to send the form with the data package.

5.3 The signed Protocol/SOP Deviation Form or Sponsor form will remain in the study file to document the deviation from the original study protocol and will be included with the filed and archived data at the conclusion of the study.

## 6.0 PHOTOCOPIES

6.1 Photocopies of the Field Trial forms or Sponsor forms with raw data should not be substituted for the original forms. If photocopying is unavoidable, the copy must be verified as an authentic copy, initialed, and dated.

6.2 If photocopies of maps or worksheets are used, the guidelines below may be followed:

- 6.2.1 Anticipate you will be making copies prior to placing the study and trial number on the original form.
- 6.2.2 Copy the form and verify the copy.
- 6.2.3 On the verified copy, indicate the new study number and trial number.
- 6.2.4 On the verified copy, indicate where the original data is. For example, state that the original calibration was done for Study 13-01-01.
- 6.2.5 Initial or sign and date the form.
- 6.2.6 Be aware that photocopying may be more time-consuming than just writing the same information twice. It is acceptable to use the same calibration data for more than one study if all the parameters are the same.

## 7.0 SHIPPING

7.1 When shipping samples a Chain of Custody form must accompany each shipment. Sponsor forms will be used when provided.

## 8.0 TRIAL COMPLETION

8.1 At trial completion, or at times indicated in the study protocol, retain copies of the forms for your file and send the completed data package consisting of the original forms to the address indicated in the study protocol. The responsible PFI will sign and complete the Chain of Custody form for the Field Trial Notebook and forward the data package to the address indicated in the study protocol, if appropriate.

## FORM DESCRIPTIONS

## 9.0 TRIAL INITIATION

9.1 Purpose: To inform the Study Director that the first application or planting was done.

9.2 General Instructions

- 9.2.1 The trial initiation form should be completed and faxed to the Study Director/Study Coordinator immediately after planting or the first application of test product to a trial. Trial initiation information is needed to maintain a study schedule of the trial. This form does not need to be sent to the Study

Director/Study Coordinator if they have been notified of trial initiation by other means of communication. The original form will remain with the study trial records.

9.3 Trial Data

9.3.1 Trial Location: Record the city/town nearest to the trial site and the country, state and/or province where the trial is located as applicable.

9.3.2 Date of Planting of First Application: Enter the date of planting or the first application of test product for this trial.

9.3.3 Date of Approximate First Sampling Date: Enter the estimated date of the first sampling occasion for this trial.

9.3.4 Principal Field Investigator Signature/Date: Sign the form and enter the date. The form should be signed by the person conducting the trial.

## 10.0 TRIAL PERSONNEL

10.1 Purpose: To identify GLP personnel active in conducting, documenting, and monitoring the study.

10.1.1 Trial Personnel: Each individual who enters data on any of the forms must sign, initial and date this form. Each person should print his/her full name, and then give his/her signature, initials and date the form. After an individual has signed the Trial Personnel form, only his/her initials are needed at any other place in the forms requesting a signature in a "Completed By" section.

## 11.0 STATEMENT OF GLP COMPLIANCE

11.1 Purpose: To provide statement of GLP compliance and list all GLP exceptions.

11.2 The PFI should check the box next to specific exceptions and list all other exceptions to GLP compliance on this form. The PFI should sign this form and submit with the data package at the end of the trial to verify that the trial was completed per GLP requirements with the listed exceptions. The PFI should not line out the other exceptions space as the Study Director may choose to add to this list after the Field Trial Notebook has been submitted.

## 12.0 PROTOCOL/SOP DEVIATION FORM

12.1 Purpose: To describe any deviations from the protocol or SOP's.

12.2 Enter the trial information and describe the deviation. Sign and date the form and send to the Study Director.

12.3 Effect on the study should be entered by the Study Director or may be entered by the PFI per the Study Director's instructions.

## 13.0 TRIAL NOTES

13.1 Purpose: Document general trial activity and correspondence throughout the trial. Also to provide a place to document any data that is not recorded elsewhere in the Field Trial Notebook.

13.2 Entries: Initial and date all entries. Record any phone conversations and print any emails and include in this section. All emails should be initialed and dated when inserted into the Field Trial Notebook.

14.0 PESTICIDE/CROP HISTORY FORM

14.1 Purpose: To document the pesticide and crop history for a trial location.

14.2 Entries: List the year, crop and pesticide applied for the time period required by the protocol.

15.0 TRIAL PLOT DATA

15.1 Purpose: To provide general descriptive information on the plots used in the trial as well as specific information that may be required for environmental trials. Optional box on the form need not be completed but may be required for studies such as soil dissipation, groundwater, and aquatic soil dissipation.

15.2 Trial Location: Enter the address or direction from closest street intersection for the trial location.

15.3 County: Enter the county where the trial is located.

15.4 Crop/Variety: Enter the crop and the variety.

15.5 Planting Details: Enter the date planted or the age of the crop if an established crop, row spacing, plant spacing, row direction and slope of the field.

15.6 Soil Characterization Data: Enter the soil data and document where the information was obtained from.

16.0 TRIAL LOCATION

16.1 Purpose: Provide a map to the trial location.

16.2 Entry: Insert a map showing the location of the test site, general roads and the closest city with enough details for a person unfamiliar with the location to find the trial site.

17.0 PLOT MAP

17.1 Purpose: To show plot dimensions, site details, and permanent marker locations for locating plots and treatments.

17.2 Entries: Sketch the plots showing: treatment/plot#, distance between plots, length and width of plots, row direction, fixed irrigation point if applicable, GPS coordinates for two points or distance to two permanent markers if available, prevailing wind direction, estimated % of slope and down direction, location of soil characterization sampling if applicable.

18.0 TRIAL CULTURAL PRACTICES

18.1 Purpose: Document cultural practices during the trial period.

18.2 Entries: Record the cultural practice performed, performed by, and date.

19.0 TRIAL MAINTENANCE CHEMICALS

19.1 Purpose: Document maintenance pesticide and fertilizer applications during the trial period.

19.2 Entries: Enter the date, product, rate and purpose of the maintenance product. Be sure to not apply any products restricted by the protocol.

20.0 APPLICATION EQUIPMENT

20.1 Purpose: Describe the application equipment.

20.2 Entries: Provide the equipment ID and describe the equipment used. Draw or insert a diagram of the equipment and the spray pattern relative to the crop.

21.0 CALIBRATION WORKSHEET

21.1 Purpose: Record output/speed calibration and GPA calculations.

21.2 Entries: Record at least three output volumes and three pass times. Record the setting for the sprayer or applicator including psi, hopper setting. Record the rpm, gear setting for tractor mounted applicators. Make sure all individual values are within +/- 5% of the mean or adjust/clean and recalibrate.

22.0 TEST SUBSTANCE CALCULATIONS

22.1 Purpose: Provide space to calculate test substance, carrier and adjuvant for the application.

22.2 Entries: Calculation method should be well documented using a method preferred by the PFI. If available have someone qualified double check the calculations.

23.0 APPLICATION PASS TIMES

23.1 Purpose: Calculate target pass time and record actual pass times and direction.

23.2 Entries: Calculate a target pass time based on the calibration pass time per length and the actual plot length. Record a verification pass time in the field prior to application. The verification pass time should be within +/- 5% of the target pass time. Record the actual pass times and direction for the application.

24.0 ACTUAL APPLICATION RATES

24.1 Purpose: Calculate actual application rate.

24.2 Entries: Enter the total actual pass time and divide it by the target total pass time. Times

that by a hundred to get the percent of target rate applied. Refer to the protocol for acceptable variability and notify the Study Director immediately if out of range.

25.0 APPLICATION SUMMARY

25.1 Purpose: Record the conditions at application, summarize application details and document disposal of remaining spray mixture.

25.2 Entries: Enter weather data and the equipment/method used to collect the data. Record the crop details at the time of application. Record the time to first irrigation after application. This usually requires entry at a future date. Initial/date that entry at time of entry. Document the method of disposal of the remaining spray mixture.

26.0 SAMPLING DESCRIPTION

26.1 Purpose: Use this form to describe the crop growth stage at sampling, sampling equipment and methods used to collect samples.

26.2 Entries: Use the BBCH codes or Sponsor required growth stage codes to describe the crop at sampling. Check the appropriate boxes or describe the sampling equipment and methods. Describe the method of field storage and transportation to the permanent freezer storage if applicable.

27.0 SAMPLE STORAGE LOG

27.1 Purpose: Track sampling times and sample storage/transfer.

27.2 Entries: Enter the date, sample number, number of fruit, time of sampling, time into field storage, time into permanent storage, freezer ID and date shipped.

28.0 CHAIN OF CUSTODY

28.1 Purpose: Document the transfer of samples or the Field Trial Notebook.

28.2 Entries: Enter the person shipping and the shipping address. The protocol should describe the method of shipment to use and the location to ship samples or raw data. Record the number of boxes shipped and the material shipped. Record the method of shipping and include any tracking numbers with original shipping documents entered behind this form. Make sure to notify the receiver of shipment per protocol instructions.

29.0 STORAGE TEMPERATURES

29.1 Purpose: Section for entering required temperature logs.

29.2 Entries: Insert required authentic copies of GLP Test Substance Storage Temperatures from the time of test substance receipt to the last application, samples storage temperatures.

30.0 ENVIRONMENTAL DATA

30.1 Purpose: Document daily and historical weather data.

30.2 Entries: Provide a description or name for the weather station and the location and distance in reference to the trial site. Note that some protocols may require rainfall during the trial period to be collected on site.

31.0 IRRIGATION/RAINFALL RECORD

31.1 Purpose: Document irrigation and on-site rainfall.

31.2 Entries: Include all rainfall and irrigation events including the method of irrigation from the time of application until the last sampling.

32.0 ADDITIONAL RECORDS

32.1 Purpose: Provide additional documentation as required by the protocol and requested by the sponsor.

32.2 Entries: Inert into this section copies of Table of Contents for facility SOPs with SOP's used marked, personnel CV's, facility equipment logs, freezer storage logs and any additional information requested by the protocol or study director.

33.0 HISTORY OF CHANGE

| REVISION | DATE | DESCRIPTION OF CHANGE |
|---|---|---|
| SOP 19.01 | 3/10/16 | Error code "WO" added |

STANDARD OPERATING PROCEDURE

EFFECTIVE DATE: 3/10/16

SOP: 20.01 SIGNIFICANT FIGURES

APPROVAL: Blair D DATE: 3/10/16

---

## 1.0 PURPOSE AND SCOPE

1.1 This Standard Operation Procedure (SOP) describes the principles behind significant figures and how arithmetic calculations are handled when performed as part of testing conducted by Turner Ag Research.

## 2.0 SIGNIFICANT FIGURES

2.1 Reported analytical values should contain only significant figures. The number of reportable significant digits is affected by the accuracy of measurement instruments and analytical equipment used in the analysis. For example, if a value is reported as 21 .8, the 21 must be firm while the 0.8 is somewhat uncertain, but presumably better than the values 0.7 or 0.9.

2.2 Significant figures are numbers reflecting a measurement that is believe to be correct within a specified or implied limit of error.

a. Whole numbers (digits 1 through 9) area always considered significant.
b. Zeros between digits 1 through 9 are considered significant.
c. Zeros with no digits 1 through 9 to their left locate the decimal point and therefore are not significant.
d. Zeros to the right of any digit may or may not be significant. If the zero only locates the decimal point, it is not significant. If the zero results from a reasonably precise measurement, it is significant.
e. Examples - the significant figures are underlined:

| VALUE | NO. OF SIGNIFICANT FIGURES |
|---|---|
| 126.5 cm | 4 |
| 126.50 cm | 5 |
| 0.013 m | 2 |
| 0.0130 m | 3 |
| 1.0034 g | 5 |
| $1.50 \times 10^4$ g | 3 |
| 15,000 g | 2* |

*Significance of the zeros is not clear without further information regarding the accuracy of the measurement.

2.3 When conducting arithmetic operation, the procedure is to carry all digits through the calculations and then to round the final answer to the proper number of significant figures. The final figure should be rounded to the number of significant digits of the least accurate instrument/device.

2.4 The number of significant figures reported in hand recorded or transformed data is to be internally consistent. The number of significant figures reported is dependent on the value of the calculation with the fewest number of significant figures

Example: [4.5 x 123.503] ÷ 12.3 = 570 or 5.7 E2,
*i.e.,* only the two significant figures based in 4.5

## 3.0 ROUNDING OF NUMBERS

3.1 If the figure following those to be retained is less than 5, the figure is dropped and the remaining figures are kept unchanged.

Example: 1.14 rounded to two digits is 1.1

3.2 If the figure following those to be retained is 5 or greater than 5, the figure is dropped, and the last figure remaining is raised by 1.

Example: 3.36 rounded to 2 digits= 3.4

## 4.0 HISTORY OF CHANGE

| REVISION | DATE | DESCRIPTION OF CHANGE |
|---|---|---|
| SOP 20.01 | 3/10/16 | Reformat Header |

STANDARD OPERATING PROCEDURE

EFFECTIVE DATE: 3/10/16

SOP 21.02 TEST SUBSTANCE RECEIPT STORAGE, USE AND TRANSFER

APPROVAL: _____ DATE: 3/10/16

---

## 1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedures (SOP) describes the test substance receipt, storage, use, and transfer during the field phase of GLP studies. The principal field investigator is responsible for ensuring this SOP is followed for GLP trials.

## 2.0 TEST SUBSTANCE RECEIPT

2.1 Prior to GLP trial initiation, the principal field investigator (PFI) estimates and requests the amount of test substance needed for each trial. Upon receiving the test substance, the PFI must record the receipt of the material on a Test Substance Receipt, Use, and Transfer Log even if an equivalent form or electronic data collection file is provided by the client company. The test substance containers must be labeled with the following:

A. Identity
B. Date of receipt
C. Lot #
D. Expiration date
E. Storage Conditions

2.2 If multiple containers are received on the same day with the same name and batch number, these containers may all be listed in the CONTAINER NUMBER section of the log.

2.3 All Test Substances after receipt documentation is completed should be placed in an appropriately labeled cabinet or containers in the chemical storage area. This building or area is locked when not in use.

## 3.0 TEST SUBSTANCE USE

3.1 Each time a test substance is used, the DATE of removal, the AMOUNT REMOVED from the container, the TRIAL NUMBER for which it was used, and the USER INITIALS must be recorded on the Test Substance Receipt, Use and Transfer Log.

3.2 If multiple containers are used, list the container number in the CONTAINER NUMBER column in addition to the information required above.

3.3 After a test substance has no further use for regulatory trials, remaining contents can be used for maintenance spraying where labeled. Indicate the use of the test substance in the "Disposition of the Remaining Test Substance" section. Date and initial the entry.

## 4.0 BLANK MATERIAL

4.1 Blank (inert) granules may be utilized to calibrate and verify application equipment. Because blank granules are not considered test substances, records for receipt, use and transfer are not required unless specifically requested by protocol. Blank granular containers do not have to be retained. The use of blank granules for calibration should be documented on the Trial Notes form or Worksheet form for purposes of trial reconstruction.

## 5.0 CONTAINER RETENTION AND DISPOSAL

5.1 GLP requires that all test substance containers be retained until the final study report is completed. The PFI will retain all test substance containers until notified by the Study Director or Study Coordinator. Following notification, the PFI can dispose of test substance containers in accordance with proper disposal Procedures. The PFI will complete the "Disposition of the Remaining Test Substance" section on the bottom of the Test Substance Receipt, Use, and Transfer Log. Archive the original Test Substance Receipt, Use, and Transfer Log as described in the records section of this SOP. Note: The Sponsor is responsible for the retention of a sample of the test substance.

5.2 The original Test Substance Receipt, Use, and Transfer Log must be retained as well as the test substance container until notification by the Study Director or Study Coordinator that the study has been completed and the test substance container can be disposed.

5.3 If the test substance container is received and logged on a Test Substance Receipt, Use, and Transfer Log and none of the test substance in the container is used for regulatory trials, the container and test substance can be disposed of without notification from the Study Director or Study Coordinator. If the container is the only container listed on the log for this container can be discarded. If the container is one of several containers date and initial an entry such as "Container XXX not used for regulatory trials and disposed of in the "Disposition of Remaining Test Substance" section of the log and dispose of the container. GLP markings should be removed and the container labels and markings should be defaced to indicate the container is no longer a GLP container.

5.4 GLP containers may be retained in one of the following types of storage, depending on the status of the trial.

5.4.1 GLP storage area. This must have temperature monitoring.

5.4.2 Long-term storage for GLP containers for which all applications have been completed and the sponsor has requested to retain the container until notification. Temperature monitoring is not required.

5.4.3 General chemical storage for containers no longer required to be stored.

## 6.0 TEST SUBSTANCE TRANSFER

6.1 The Test Substance Transfer section must be completed when a change of custody takes place. Per Sponsor request on protocol requirements. In the "Transfer of Test Container and/or Substance" section, the From Address, the To Address (destination), Date Shipped, and Signature of the individual shipping the container must be completed on the Test Substance Receipt, Use, and Transfer Log prior to shipment. Upon receiving the shipment, the recipient must record the Date Received and Signature of the person receiving the test substance on the Test Substance Receipt, Use, and Transfer Log. Arrangements should be made with the recipient prior to shipment.

6.2 In the event of additional transfers, the information in the "Transfer of Test Container and/or Test Substance" can be entered on the bottom of the form. Alternately, the top section (Test Substance Receipt) and "Transfer of Test Container and/or Substance" section of a new Test Substance Receipt, Use, and Transfer Log can be completed. Change the page number(s) on the forms to reflect the added page. Date, initial and error code the page changes. The original copy of the log is maintained with the container until final disposal of the container.

6.3 When the Test Substance Receipt, Use and Transfer Log is not being used because the sponsor provides an alternate method of documentation, follow their instructions as to container return or storage.

## 7.0 MONITORING TEMPERATURES OF STORAGE FACILITIES CONTAINING TEST SUBSTANCE

7.1 Test substances must be stored under acceptable environmental conditions to ensure stability of the material until use in the designated trial. To ensure the material is stored within acceptable temperature ranges, the test substance storage area must be monitored to establish the maximum/minimum temperature range of storage conditions. The temperature range must be monitored from the time of receipt of the test substance until the final use of the test substance for each regulatory trial. This will ensure that a complete temperature record is obtained for each test substance received.

7.2 Use one of the following methods to monitor test substance storage facility temperatures:

7.2.1 Method A: Place a verified Min/Max thermometer close to the test substances. Calibrate/verify the Min/Max thermometer annually prior to use with a standard thermometer. At least weekly, record the minimum and maximum temperatures on the Test Substance Storage Temperature Log. Entries required include DATE of entry, MIN and MAX temperature readings of the min/max thermometer, INITIALS of the individual making the reading, and circle whether the temperatures are in Fahrenheit or Centigrade. The min/max thermometer must be reset after each reading.

7.2.2 Method B: Place an electronic temperature datalogger in the same proximity as the stored test substance. Calibrate/verify the datalogger against a standard/certified thermometer annually. Approximately monthly, download the datalogger information into a laptop computer taken to the site. Each time the datalogger is downloaded, print out a chart of the data that includes the recorder ID, the date the datalogger was launched, the date of the download

and labeled (i.e. "chemical storage"). The individual doing the download must initial the chart. Use a calibrated/verified min/max thermometer or an additional datalogger as a backup in case of malfunction of the main datalogger.

## 8.0 RECORDS

8.1 The original Test Substance Receipt, Use, and Transfer Log must be retained as well as the test substance container until notified by the Study Director or Study Coordinator that the study has been completed and the container can be disposed of.

8.2 The PFI is responsible for ensuring that the Test Substance Receipt, Use and Transfer Log is completed correctly for each test substance. These will be provided to the archivist for archiving by April 30 of the following year as applicable.

8.3 Applicable records of the test substance logs will be included as part of the field data package submitted to the Sponsor and/or Study Director as required.

## 9.0 HISTORY OF CHANGE

| REVISION | DATE | DESCRIPTION OF CHANGE |
|---|---|---|
| SOP 21.01 | 2/22/2015 | Added the labeling requirements for the test substance container and deleted the attached forms. |
| SOP 21.02 | 3/10/16 | Reformat Header |

Turner Ag Research

STANDARD OPERATING PROCEDURE

EFFECTIVE DATE: 10/17/13

SOP: 22.01 Adjuvant Labeling

APPROVAL: _____ DATE: 10/17/2013

---

## 1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedures (SOP) describes how adjuvants will be assigned expiration dates appropriately labeled.

## 2.0 ASSIGNING EXPIRATION DATES

2.1 When an adjuvant is received at the facility it will be checked to verify if an expiration date has been recorded on the bottle by the manufacturer. An expiration date will be assigned if no date is provided.

2.2 The expiration date assigned will be no more than three years from the date of receipt at the facility.

2.3 If there is an expiration date on the container that expiration date will be used.

## 3.0 ADJUVANT LABELING

3.1 After verification of an expiration date, the adjuvant container should be affixed with a label containing the following information:

- 3.1.1. Identity (Name as on container)
- 3.1.2. Date of receipt
- 3.1.3. Lot # (If available)
- 3.1.4. Expiration date
- 3.1.5. Storage Conditions

3.2 The adjuvant should be placed in general chemical storage.

## 4.0 STORAGE OF THE ADJUVANT

4.1 When the adjuvant has expired, it will not be used for GLP trial tank mixes. The remaining adjuvant may be used for maintenance applications.

4.2 The adjuvant will be stored in general chemical storage for the site. It does not need to be temperature monitored.

## 5.0 HISTORY OF CHANGE

| REVISION | DATE | DESCRIPTION OF CHANGE |
|---|---|---|
| 22.01 | 10/17/13 | Added storage conditions labeling requirement |

STANDARD OPERATING PROCEDURES

EFFECTIVE DATE: 5/14/2013

SOP 23.00 Quality Assurance

APPROVAL: _____ DATE: 5/14/2013

## 1.0 PURPOSE AND SCOPE

1.1 The purpose of this SOP is to describe the quality assurance role and responsibilities.

1.2 This SOP will apply to all internal and contracted quality assurance (QA) agents responsible for monitoring each study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with the regulations in 40 CFR, part 160 Good Laboratory Practices. For any given study, the quality assurance unit shall be entirely separate from and independent of the personnel engaged in the direction and conduct of that study.

## 2.0 MASTER SCHEDULE

2.1 A designated QA will maintain a copy of the master schedule sheet of all studies conducted at the testing facility indexed by test substance, and containing the test system, nature of study, date study was initiated, current status of each study, identity of the sponsor, and name of the study director.

2.2 The master schedule will be updated on a monthly basis by the PFI or Test Site Manager during the active field season typically April through October and sent via email for review by the designated QA. After approval by the QA the QA will initial and date the master schedule and it will be added to the facility records.

## 3.0 PROTOCOLS

3.1 Maintain copies of all protocols pertaining to all studies for which the unit is responsible.

## 4.0 INSPECTION AND REPORTING INTERVAL

4.1 Inspect each study at intervals adequate to ensure the integrity of the study and maintain written and properly signed records of each periodic inspection showing the date of the inspection, the study inspected, the phase or segment of the study inspected, the person performing the inspection, findings and problems, action recommended and taken to resolve existing problems, and any scheduled date for reinspection. Any problems which are likely to affect study integrity found during the course of an inspection shall be brought to the attention of the study director and management immediately.

4.2 Periodically submit to management and the study director written status reports on each study, noting any problems and the corrective actions taken.

4.3 Determine that no deviations from approved protocols or standard operating procedures were made without proper authorization and documentation.

4.4 Review the final study report to assure that such report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study.

4.5 Prepare and sign a statement to be included with the final study report which shall specify the dates inspections were made and findings reported to management and to the study director.

4.6 Facility inspections will be completed at a minimum of once per year. The inspection should include all facility records, equipment and SOP's for compliance with GLP.

4.7 Inspection reports will be submitted within 15 days of inspection.

5.0 Report Routing

5.1 For facility audits the inspection will be sent to the test site manager.

5.2 For critical phase inspections the original reports will be sent to the PFI, to make initial comments. The PFI will then send the report to the Study Director. The Study Director will then forward to the study director management for final review. The report may be emailed in a pdf* format if approved by the study director and the reports printed and signed on different copies of the report as long as the original signatures are all included in the final report.

5.3 Final report audits will be sent to the study director for review and comments.

6.0 RECORD KEEPING

6.1 The records required to be kept by the quality assurance unit include inspection dates, the study inspected, the phase or segment of the study inspected, and the name of the individual performing the inspection and shall be indexed by year and the testing facility trial number. This information is suggested to be kept on the same form as the master schedule but it will not be included on the printout for the facility records. It will be maintained by the quality assurance unit.

6.2 These records will be made available for inspection to authorized employees or duly designated representatives of EPA or FDA.

7.0 HISTORY OF CHANGE

| REVISION | DATE | DESCRIPTION OF CHANGE |
|---|---|---|

STANDARD OPERATING PROCEDURES

SOP 24.00 Nut Sheller

EFFECTIVE DATE: 8/15/13

APPROVAL: Blair D DATE: 8/15/13

## 1.0 PURPOSE AND SCOPE

1.1 The purpose of this SOP is to describe the use and cleaning of the drill nut sheller for almonds and other hard shell nuts.

1.2 This SOP will apply to all sample processing conducted using the drill nut sheller.

## 2.0 CLEANING

2.1 Before each use and in between samples, all parts of the nut cracker will be thoroughly cleaned with a 50% IPA solution.

2.2 A clean 5 gallon bucket shall be used to collect each sample.

## 3.0 USE

3.1 The nut cracker is to be used only for its intended purpose and should not be used to process any type of samples other than nuts.

3.2 Untreated samples should be processed first to avoid any cross contamination between plots.

3.3 Drill nut sheller will be placed on top of a clean 5 gallon bucket. Electric drill should be secured with Velcro strap prior to use. A single almond will be dropped into hopper and choke should be adjusted to the smallest passage necessary to allow the nut to pass through. After the nut drops into the bucket, turn the choke 6 half turns.

3.4 Engage the drill trigger lock and start the drill at a low speed setting. Begin dropping the nuts to be cracked into the hopper. Nut sheller will crack the nuts and all nuts will be collected in the 5 gallon bucket. If necessary, collect largest uncracked nuts, turn the choke 6 more half turns and pass uncracked nuts through nut sheller once more. Once all nuts from the sample have been cracked, sort nutmeats into appropriate pre-labeled sample bags and discard shells. Before cracking nuts from subsequent samples or treatments, run excess nuts from untreated crop samples through the nut sheller to ensure all bits of treated nuts are removed from the nut sheller. Begin processing next sample with a clean bucket.

## 4.0 MAINTENANCE

4.1 The nut sheller will be inspected prior to each use and undergo routine maintenance as needed.

5.0 HISTORY OF CHANGE

| REVISION | DATE | DESCRIPTION OF CHANGE |
|---|---|---|

STANDARD OPERATING PROCEDURES

EFFECTIVE DATE: 10/17/13

SOP 25.00 Outside Inspections

APPROVAL: Blaine D DATE: 10/17/2013

## 1.0 PURPOSE AND SCOPE

1.1 The purpose of this SOP is to describe the procedure to be followed in case of an outside inspection, for example, by the EPA.

1.2 This SOP will apply to all outside agencies that wish to conduct an audit or inspection of the facility or field sites.

## 2.0 CREDENTIALS AND NOTIFICATION

2.1 Sponsors will be notified immediately upon notification of intent of inspection. This should be done to provide the sponsor enough time to provide any data or records necessary for the inspection.

2.2 A checklist detailing the scope of the inspection and also a list of specific trials to be inspected should be requested from the auditor to prepare for the inspection.

2.3 Upon entering the facility, badge of EPA inspector or auditor will be verified and business card will be collected.

## 3.0 PHOTOGRAPHS

3.1 If inspector takes any photos during the inspection, an associate of TAR will take photos from the same location.

## 4.0 COMMUNICATION

4.1 Client, auditor, or inspector must be accompanied at all times while in restricted areas.

4.2 TAR associates are to answer only the questions that are asked. Do not volunteer information or speculate if you are not sure of the answer. Refer those questions to management or the Sponsor if necessary. Be polite and courteous.

## 5.0 Auditor Exit

5.1 At the end of the audit the auditor should review any findings or suggestions.

5.2 TAR should request a copy of the findings or suggestions from the agency inspector.

5.3 TAR management should respond to findings or suggestions in a timely manner.

## 5.0 HISTORY OF CHANGE

| REVISION | DATE | DESCRIPTION OF CHANGE |
|---|---|---|

STANDARD OPERATING PROCEDURE

EFFECTIVE DATE: 3/10/16

SOP: 26.01 SOIL SAMPLING EQUIPMENT OPERATION AND MAINTENANCE

APPROVAL: Blaine D DATE: 3/10/16

---

## 1.0 PURPOSE AND SCOPE

1.1 This Standard Operating Procedure (SOP) outlines procedures for all Turner Ag Research (TAR) personnel to follow when operating and maintaining a hydraulic soil sampler.

## 2.0 USE

2.1 A typical hydraulic soil core sampler (e.g.: Giddings) is mounted on a tractor, with hydraulic pump being run off the tractor's PTO. Tractor RPM will be set for optimal hydraulic pump function.

## 3.0 CLEANING

3.1 After a sampling event, the tractor and soil sampler will be cleaned with water. The soil probes will be cleaned with IPA + H2O 50% solution.

## 4.0 MAINTENANCE

4.1 Routine maintenance is performed in the first quarter of each calendar year and consists of the following:

a. Check for worn or broken parts and replace as needed
b. Lubricate as needed.
c. Change oil filter.
d. Check oil level.

4.2 The person responsible for seeing that routine maintenance is performed is specified on the master equipment log.

4.3 Non-routine maintenance is performed as needed.

## 5.0 DOCUMENTATION

5.1 All maintenance operations are documented in the equipment logbook and are specified as routine or non-routine.

5.2 When routine maintenance is performed, it is documented in the maintenance log that this

SOP was followed.

5.3 When non-routine maintenance is performed, the nature of defect, how and when it was discovered, and the remedial action taken are documented in the equipment log.

5.4 Use and cleaning according to SOP 10.01

5.5 Documentation of maintenance is archived annually.

## 6.0 HISTORY OF CHANGE

| REVISION | DATE | DESCRIPTION OF CHANGE |
|---|---|---|
| SOP 26.01 | 3/10/16 | Changed heading. |

STANDARD OPERATING PROCEDURE

EFFECTIVE DATE: 2/14/2014

SOP: 27.00 SOIL SAMPLING PROCEDURES

APPROVAL: Blaine D DATE: 2/14/2014

---

## 1.0 PURPOSE AND SCOPE

1.1 This document establishes a common standard and provides a guide for conducting soil sampling pertaining to soil dissipation studies. Where conflicts between the study protocol and these procedures arise, the protocol must be followed.

## 2.0 SAMPLE COLLECTION, LABELING, AND STORAGE

2.1 Untreated plots are to be sampled prior to the treated plots if scheduled for that sampling event. Personnel are to wear disposable gloves and shoe covers which will be changed between plots. When collecting samples immediately after an application it is also recommended to wear coveralls for as many days as recommended by the label or MSDS to comply with early re-entry intervals.

2.2 Soil sampling begins with a first stage probe with a larger diameter than the second stage probe. Typical protocols will require a 0-3 inch depth section and/or a 3-6 inch depth section to be taken prior to a longer soil core of 6-36 inch or 6-48 inch depth core. This first section can be taken using the Giddings Hydraulic probe with an acetate liner inside or by using a PVC/metal pipe and hammering it down into the soil. If using the Giddings hydraulic probe, connect the first stage probe using the pins and insert an acetate liner. Position the probe directly over the sampling location, avoiding the edges and borders of the subplot or any wheel tracks where sprayer or tractor may have driven. Lower the probe until it pushes in to the desired depth, which is usually flush with the base of the outer sleeve of the probe. Extract the probe after removing the pin that holds the bottom base by reversing the hydraulic handle direction until the core has cleared the remaining base. Hold onto the probe, keeping it upright until the top of it has been capped or placed directly into the sample bag. Pull the acetate liner from the top using needle nose pliers or push the core from the bottom to remove the soil core in the acetate liner. Place a red cap on the top of the core and a black cap on the bottom. Take the core outside of the plot to a sectioning area or place in a cooler for sectioning at a later time. If sectioning immediately in the field, cut the core with a saw or loppers and place into the labeled sample bag. The acetate liner should be labeled with

trial#, treatment and rep if samples will be stored and processed at a later date. It is important that the first stage section have a sleeve or be left in the ground when sampling the next stage to prevent contamination of lower sections from top soil.

2.3 The second stage soil sample will be taken using a smaller diameter probe than the first stage probe. For example a 48 inch long Giddings Hydraulic stainless steel soil probe could be used with an internal diameter of 3.8 cm to sample through the retaining sheath from the first stage probe. An Acetate liner is inserted into the probe. The probe is attached to the Giddings Hydraulic ram using a pin. The probe is driven down using the hydraulic to the required depth which is usually 36 inches or greater. The probe is then pulled up using the hydraulics and the pin is removed from the top of the soil probe that connects it to the hydraulic ram. The soil probe is then carefully removed and tilted slightly making sure that no top soil is lost from the top of the soil probe. Needle nose pliers are then used to pull the acetate liner slightly out of the top of the soil probe approximately 3 inches. A red cap will be placed on the top of the soil core, then, the probe is inverted and tapped slightly to loosen the soil at the tip or bottom of the probe and then the acetate liner is removed by lifting the soil probe straight up letting the acetate liner slide down. Keeping the acetate liner inverted with the red cap down, a black cap is placed on the soil core indicating the lowest depth end of the core. The core is to be labeled with a sharpie with the treatment and rep. The core will then be removed from the subplot to a processing area outside of the treated plot area. If the cores will be stored and processed at a later time, the cores should be labeled with study number and stored in a cooler in the field containing artificial ice or dry ice. Before removing the retaining sheath from the first stage probe the hole should be filled with untreated soil and the subplot marked with a flag to prevent resampling at future sampling events. Repeat this process as necessary to collect the desired number of replicate cores per subplot.

2.4 After collecting the cores from a subplot the cores are sectioned using a clean table. Large loppers are used to section the cores. A measuring tape and permanent marker can be used to mark the acetate liners with the correct depth sections. The cores are to be cut starting from the lowest depth. All the cores for a rep are cut at the lowest depth and the soil is composited into a pre-labeled sample bag. The next lowest depth section is to be cut and composited up to the last section. The sample bags are then placed into a cooler with artificial ice, dry ice or directly into freezer storage. The loppers and table should be cleaned in between processing each subplot.

## 3.0 GRASS CLIPPINGS

3.1 In the event that a study requires grass clippings, grass shears will be used to

cut the forage off, down to the thatch layer, inside of a 1 $ft^2$ template made out of ¾ inch PVC pipe. Separate shears and templates are to be used between the untreated and treated plots. The grass will be removed by hand and placed into a labeled plastic ziplock bag.

## 4.0 CLEANING

4.1 All sampling equipment including probe, retaining sheaths, loppers, processing surface should be cleaned with a suitable solution such as IPA/H20 at 50%/50% before sampling, between reps and treatments.

## 5.0 HISTORY OF CHANGE

| REVISION | DATE | DESCRIPTION OF CHANGE |
|---|---|---|

STANDARD OPERATING PROCEDURES

EFFECTIVE DATE: 4/7/14

SOP 28.00 Kestrel Weather Meter

APPROVAL: Blaine D DATE: 4/7/14

## 1.0 PURPOSE AND SCOPE

1.1 The purpose of this SOP is to describe the use, maintenance and cleaning of the Kestrel Weather Meter.

1.2 This SOP will apply to all Kestrel Weather Meters.

## 2.0 CLEANING

2.1 Before each use, the weather meter should be inspected to make sure the wind speed impeller, temperature sensor and relative humidity coil are clean and operating correctly. If necessary, clean the outside of the weather meter with a paper towel that is moist with a 50% IPA solution.

## 3.0 USE

3.1 Slide the cover off.

3.2 Turn on by pressing the power button (round button with the half circle).

3.3 Select operating mode by pressing the right or left arrow button to scroll through the different measurements.

3.4 Select the units of measurement by pressing the right arrow button while holding down the half circle button to scroll through the units of measure.

3.5 When taking the wind speed hold the display facing you and face directly into the direction that the wind is coming from. This will have the wind entering the back of the weather meter. Try to have the weather meter close to the same height as the spray application as wind speed can vary with height. For example if you are making a ground application at 18 inches above the ground the wind should be measured close to 18 inches from the ground.

3.6 When taking the temperature, make sure the weather meter has adjusted to the ambient temperature. This is especially important if the holding case has been sitting out in the sun. The air temperature should be taken in the shade and the weather meter will adjust faster to ambient temperature if it is waved from side to side or held into the wind. For water temperature or snow temperature, submerge the temperature sensor in the water or snow.

3.7 After the weather meter has adjusted to the ambient temperature the relative humidity can be taken. The relative humidity should also be taken in the shade.

3.8 To turn off hold the power button for 2 seconds.

3.9 Clean the weather meter if necessary with a paper towel moist with a 50% solution of IPA and distilled water.

3.10 Return the weather meter to its cover.

## 4.0 MAINTENANCE

4.1 The weather meter is waterproof and will float if dropped in water. Store the weather meter in temperatures above -22°F and below 176°F.

4.2 If the display starts to dim or disappears, replace the battery. Use a large coin to open the battery compartment. Replace the battery with a CR2032 coin cell battery. When replacing the battery door, make sure to keep the black rubber o-ring seated in the groove on the case back.

4.3 The manufacturer recommends sending the weather meter to the factory to replace the impeller and re-certify the temperature and humidity sensors every two years or a home calibration kit may be purchased and the calibration can be completed at the Turner Ag Research station. Either way, this should be done every two years by April 1st and the certificate or recalibration records maintained with the equipment log.

4.4 Each weather meter is used for collecting GLP data and should be assigned a unique identifier. The use of the meter will be recorded on the Equipment Log forms and routine and non-routine maintenance will be documented.

## 5.0 HISTORY OF CHANGE

| REVISION | DATE | DESCRIPTION OF CHANGE |
|---|---|---|

**STANDARD OPERATING PROCEDURE**

EFFECTIVE DATE: 9/5/2017

SOP 29.00 TTR Sampling

APPROVAL: _____ DATE: 9/5/2017

## 1.0 PURPOSE & SCOPE

1.1. This Standard Operating Procedure (SOP) provides the steps to sample pesticide transferable turf residues efficiently from residential or commercial lawns. This SOP also describes the fabrication and assembly from specific materials and equipment

## 2.0 Equipment Required

- Construction with equivalent materials is possible, provided the dimensions and weight are those described below. Items that are **bolded** should **not** be modified. The following equipment is needed to fabricate the MCR and sampling media:

    - **4 in. (outside diameter) x 24 in.** schedule 40 PVC pipe.

    - 4 in. expandable pipe plugs (two, one for each end).

    - Sufficient filler material (approximately 25 lb for the inside of the roller (e.g., lead sheet, steel pipe, sand, or concrete and steel rebar, etc.) to produce a **32 lb** roller. NOTE: filler material that does not fill the internal volume should not be used for the weight as it may shift.

    - 10 ft. of 1/2 in. or 3/4 in. diameter **thin-walled electrical conduit** (EMT pipe) for fabricating a handle. The finished handle should be approximately 4 ft. in length or long enough to traverse the length of the sample plot without having to step into the plot.

    - 3/8 in. x 3 in. carriage head bolts (2), 3/8 in. lock nuts (2), 3/8 in. nuts (4), 3/8 in. flat washers (4) for roller axle assembly.

- **1/2 in. thick** polyurethane foam sheet or pipe insulation (e.g., 4 in. x 24 in. Imacolock pipe insulation tubes) with moderate rigidity, approximately 1.4 ft. x 2 ft. to wrap around the roller for traction and cushioning.

- Appropriate adhesive to attach the foam to the roller and duct tape to secure the seam.

- **1/4 in.** thick PVC sheet, cut to 30 in. by 42 in. with a center cut out measuring **24 1/2 in. by 36 in.** This is the basis of the media sampling frame.

- Six toggle clamps (at minimum) for locking pressure.

- Two 1/2 in. x 1/2 in. L-shaped metal bars approximately 28 in. to 30 in. in length.

- 24 No. 8 sheet metal screws.

- **100% white cotton sheeting (200 thread count)** cut to 27 in. by 39 in Prepare one sheet for each sample to be collected. Cloth may be cut to 27.5 in. by 39.5 in., if desired.

- 4 mil thick **clear plastic sheeting** cut to 28 in. by 40 in. Prepare one for each sample to be collected.

- Spikes (or similar) to secure the media frame to the sample area; e.g., 6 in. long 1/4 in. spikes - one in each corner.

- The following tools are helpful in assembling this equipment: 9/16 in. wrench, conduit bender, 3/8 in. drill bit, 1/8 in. drill bit, electric drill, screw driver, jig saw, bench vise, caulking gun, and a razor blade or utility knife.

## 3.0 Equipment Assembly

- Modified California Roller (MCR):

  - Prepare the PVC pipe by smoothing the ends and installing one end cap. Add the filler material to the inside of the roller. The filler material must be evenly distributed across the length of the roller and should not shift during transport. Be sure to leave space for the second end cap. The total weight of the finished roller (including the end caps and filler material, but excluding the handle assembly) must

be **32 lb ± 1 lb** variation. The weight of the roller as specified is essential to apply the appropriate pressure to the sampling media.

- After adding the appropriate weight of filler material, cap and secure the open end. The end caps, with two 3/8 in. x 3 in. carriage bolts for the axle, are used to secure the handle to the roller. The standard bolts that come with the locking end caps must be replaced with these longer bolts.

- Attach the foam pipe insulation or polyurethane foam sheet to the roller assembly with glue and/or tape. The covering should not interfere with the roller operation. This covering will provide the necessary traction across the plastic and help maintain contact between the sheet and the turf during sampling.

- Prepare the roller handle by bending the conduit tubing into a simple U-shaped handle (single length of tubing). The length of the handle should be at least 4 ft. to allow the sampling of the test plot without having to step in the plot while rolling. For example, bend the conduit 90° 4 ft. in from each end of the tubing. This will result in a handle with a 4 ft. length and a 2 ft. width. Slightly flatten the ends of the tubing and drill holes to attach to the roller. Secure the handle to the roller with the appropriate bolts, nuts, and washers. An alternate handle design, such as a T-shaped handle (two equal lengths of tubing) may be used.

- Ensure that the roller turns freely. Make any necessary adjustments.

- Rollers may be reused for sample collection as often as necessary.

- Frame and Sampling Media:

  - Cut **1/4 in. thick** PVC sheeting (Plexiglas) to a rectangle measuring 30 in. x 42 in.

  - Locate the positions for the pressure clamps along the PVC sheet and pre-drill the mounting holes. Two clamps are located on the ends of the frame (short side) near the corners of the inner hole. The metal bar will be attached to each pair of end clamps. One clamp will be located in the middle of the long sides. Secure each clamp to the frame with No. 8 sheet metal screws. If additional locking pressure is needed, more clamps may be used.

  - Drill a 3/8 in. hole in each corner of the frame to secure the frame to the ground with the spikes. Locate each hole at least 1/2 in. from the outer edge of the frame.

- Cut an opening in the center of the sheet that measures **24 1/2 x 36 in.** The long sides of the frame should be 2 3/4 in. wide while the short sides of the frame are 3 in. wide. This provides a small gap which allows the roller to turn freely inside the frame.

- Cut the **cotton sheet** to 27 in. x 39 in. (24 in. x 36 in. sampling area with 1 1/2 in. overlap on each side) for each sample to be collected. Cloth may be cut to 27.5 in. by 39.5 in., if desired.

- Cut the plastic sheeting to 28 in. x 40 in. for each sample to be collected.

- Lay the assembled frame on a clean surface. Lay the **cotton sheet** over the inner opening, centering it within the frame. Lay the plastic sheeting over the cloth on the frame. The plastic must completely cover the **cotton sheet.**

- Close the clamps, securing the cloth and plastic sheets to the frame. The sheets should not be stretched taut across the frame.

- Transport the frame to the appropriate sampling area.

4.0 Transferable Turf Residue Sample Collection

- Make the appropriate application to the turf (liquid, granular, etc.). Ensure the spray on the turf has dried before sampling.

- Wear clean gloves when handling the sampling media. Always change gloves between replicates and after handling contaminated equipment.

- Place the sampling frame with clean sampling media attached on the designated sampling plot. Secure the frame to the plot with spikes (or suitable means) in each corner of the sampling frame. Do not place the spikes such that they penetrate the sheet. **Do not move or adjust the position of the sampling frame once it has been placed on the treated plot.**

- Carry the roller to the sampling plot and place it carefully on top of the plastic sheet in the sampling frame at the edge closest to you. This is the starting point. Do not allow the roller to come in contact with treated turf or the **cotton sheet.**

- Using the frame sides as a guide, slowly and evenly push the roller to the inside far end of the frame and then pull it to the original starting point. **Repeat four more times, for a total of five traverses across the sampling media.** Ensure that the roller is freely turning during the sampling event and not merely sliding across the plastic sheet and sampling media. Do not

exert any extra downward pressure on the roller handle while rolling across the sheet. Do not step into the sampling area or on the media frame.

- Remove the MCR to a clean area. Remove the spikes from the sampling frame and lift the frame from the turf, being careful not to drag the sampling media on the turf or dislodge residues. Carefully examine the **cotton sheet** and remove any visible debris (grass, thatch, granules from granular applications, etc.).

- Remove the **cotton sheet** from the frame by releasing the clamps; fold the **cotton sheet** with the exposed sides together, and place in a container. Discard the plastic sheet.

- Clean off the sampling frame with a suitable solvent or cleaner. Dry and reassemble, if necessary.

- Repeat for each residue sample to be collected.

## 5.0 HISTORY OF CHANGE

| REVISION | DATE | DESCRIPTION OF CHANGE |
|---|---|---|