Compass AgriTech
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SOP's approved by: 1/25/19

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Standard Operating Procedures

1.1 SOP Creation and Use

Revision number: 3

Purpose: To describe the purpose, creation, distribution, use, revision, and archival of Standard Operating Procedures used to guide research performed by Compass AgriTech (C.A.T.)

Scope: All Compass AgriTech personnel

Procedures:

1. A standard operating procedure, or SOP, is a written document that describes how routine activities are to be performed. Federal law requires research conducted in support of pesticide registration to be guided by SOPs "to insure the quality and integrity of the data generated in the course of a study."
2. The protocol always takes precedence over any SOP.
3. All deviations from the SOPs must be documented and approved by the Study Director. Significant changes to SOPs will be authorized in writing by Compass Agri-Tech management.
4. An SOP should exist for all routine procedures and regularly used equipment.
5. SOPs will be used to ensure consistent and proper performance of research activities by various personnel, serve as training materials for new personnel, reduce errors, and promote the use of sound scientific practices.
6. Individuals familiar with the process or equipment should write the SOP(s).
7. An SOP should include enough detail so that someone with the appropriate education, training, and experience can perform the procedure correctly.
8. SOPs will be submitted to the sponsor for review if requested. The effective date of the SOPs will be the date they are approved by C.A.T. management. The revision date is the date the SOP was revised and approved by C.A.T. management.
9. Current SOPs, equipment manuals, and other documents must be immediately available to research personnel. The Field Research Director will distribute copies of the current SOPs to the appropriate personnel. The original SOPs will be kept in a secure file in the Field Research Director's office.
10. The Field Research Director will review the SOPs annually and revise them as needed. Other research personnel should review the SOPs applicable to their work.
11. When an SOP is revised, the revision number and revision date will be changed to reflect the revision. The revision number will begin with 0 (to indicate the original version) and increase sequentially with each revision.

12. After revision, SOPs will be collected by the Field Research Director and replaced with the new versions.
13. Revised and retired SOPs will be archived.

1.2 Numbering System for SOPs

Revision number: 1

Purpose: To provide the numbering system used to index SOPs

Scope: All SOPs created and used by Compass AgriTech

Procedures:

1. A numbering system will be used for SOPs. Its format is as follows: A.B.C where A=section number, B=specific SOP number in the category, and C=revision number (e.g., 4.2.3 refers to the third revision of the second SOP issued in the Equipment section). When referring to an SOP, the A.B.C format will be used. On the SOPs themselves, the A.B and title will appear on the title line, with the revision number, or C, listed separately for ease of review.
2. The SOP category numbers are as follows:
    1. SOPs
    2. Personnel
    3. Facilities
    4. Equipment
    5. Data
    6. Test system
    7. Test substance
    8. Sample Procedures
    9. Audits and inspections
    10. Reference materials

1.3 SOP Format

Revision number: 2

Purpose: To describe the required components of an SOP

Scope: All SOPs created and used by Compass AgriTech.

Procedures:

1. SOPs should include the following:
    a. Facility name and address
    b. Identification on each page after the title page: SOP number (A.B) and title. See SOP 1.2.1 for explanation of numbering system.
    c. Revision number.
    d. Purpose. Provide an expansion of the title.
    e. Scope. Describe the people, equipment, locations, situations, etc. that the procedure specifically applies to.
    f. Procedures. Describe procedures in detail, but do not be overly restrictive. Describe what is done and then do what is written in the SOP.

2.1 Personnel

Revision number: 2

Purpose: Outlines personnel record keeping procedures and training requirements

Scope: Applies to all Compass AgriTech personnel

Procedures:

1. The Field Research Director will ensure that a sufficient number of personnel are available and properly trained to conduct trials.
2. Each individual working on the trials shall have sufficient education, training, and experience to perform their duties.
3. The facility will maintain a current summary (a resume, curriculum vitae, or similar document) of the education, training and experience of each person involved with trials.
4. Job descriptions for each individual in the program directly involved with trial activities will be kept as part of the facility files. Job descriptions for other program personnel will be made available as needed.
5. Individual personnel will maintain their own training records. See SOP 2.2 for specific requirements.
6. Personnel applying pesticides must be properly licensed.
7. Personnel records maintained in the facility files will be reviewed annually by the Field Research Director. Outdated records will be archived and replaced with updated/new records.

2.2 Training Records

Revision number: 2

Purpose: Describes how personnel training records are to be maintained

Scope: Applies to all Compass AgriTech personnel

Procedures:

1. Individuals are responsible for maintaining their own training records.
2. Training record entries should include the names and dates of classes, seminars, workshops, conferences, reading of SOPs, and verbal instruction received on a method, procedure, or equipment. If appropriate, include the names of the people involved in the training and a brief description of the training.
3. Sign and date all training record entries.
4. Individuals should annually review their training record, resume or curriculum vitae and position description and revise as needed. Sign and date the documents when they are reviewed and/or revised.
5. A current summary of training and experience in the form of a resume or CV, a job description, and a copy of training records for individuals involved in trial activities will be maintained in the facility files.
6. Personnel records for those people no longer employed at the facility will be archived.

2.3 Organizational Chart

Revision number: 5

Purpose: To outline the Compass AgriTech organization

Scope: All research activities performed by Compass AgriTech

Procedures:

1. A document (the organizational chart) will be maintained that lists the name and title of the individuals associated with Compass AgriTech as well as the lines of authority and responsibility within the company
2. The Principal Investigator (PI)/Field Research Director (FRD) will annually review the organizational chart and revise it as needed. Initial and date the newly revised chart. The outdated chart will be archived.
3. The following is a brief description of the duties and responsibilities of Compass AgriTech personnel:
    - PI/FRD-responsible for conducting trials according to protocol and SOPs, supervises trial personnel, reports deviations from protocol or SOPs to the sponsor, responds to Quality Control reviews and Quality Assurance audits/inspections, completes the trial notebook or similar document.
    - Research Technician-assists the Field Research Director in conducting the trials and completing the trial notebook or similar document.
    - Research Support Personnel-assists Field Research Director and Research Technicians in conducting trials and maintaining crops.

2.4 Field Research Director (Principal Investigator)

Revision number: 5

Purpose: Describes the designation, duties, and responsibilities of the Field Research Director (Principal Investigator)

Scope: Applies to all research performed by the Compass AgriTech

Procedures:

The Field Research Director's (FRD)/Principal Investigator's (PI) duties include, but are not limited to, the following:

- Conduct the trial according to protocol and GLP regulations. This includes maintaining the crop; applying the test substance; collecting, storing and shipping samples; completing the trial notebook or similar document; and responding to quality control reviews and quality assurance audits and inspections. The FRD/PI can designate capable personnel to fulfill this function. Note: Field Investigator is synonymous with Principal Investigator.
- Reporting all deviations from the protocol or SOPs to the study director and sponsor. The FRD/PI should also notify the study director and sponsor of any circumstances that may jeopardize the trial.
- Preparing and/or maintaining the resources needed for the trials including personnel, facilities, field or greenhouse sites, supplies, and equipment.
- Maintaining a Master Schedule of all active GLP trials under his/her direction.
- Ensuring personnel involved with trials understand the protocol and SOPs.
- Ensure that all data and documents associated with the trials are properly handled and archived.
- Retaining copies of raw data from each trial for a minimum of 5 years or until otherwise directed by Compass AgriTech management or the trial sponsor, as applicable.
- Maintaining facility files including current summaries of training and experience and job descriptions for each individual involved with trials.

3.1 Greenhouse Facilities

Revision number: 1

Purpose: Outlines requirements for research areas within greenhouses

Scope: Applies to all greenhouse facilities used to conduct magnitude of residue or efficacy and performance trials

Procedures:

1. Each greenhouse should be large enough to contain an entire trial or portion of a trial with enough space between plots to prevent contamination.
2. If more than one trial is conducted in a greenhouse, there should be enough room between the trials to prevent contamination or interference between the trials.
3. Environmental conditions (temperature and humidity) should be sufficiently uniform at the trial sites within the greenhouse to allow nearly uniform plant growth throughout the trial area. This is especially important if the trial is conducted in more than one greenhouse or rooms within one greenhouse.
4. The walls, floors, and ceilings of the greenhouse should be kept in good condition. Floors, benches, and aisles should be well drained and free of debris, weeds, and unessential equipment.
5. Greenhouses should be equipped to allow temperature, lighting, and moisture to be maintained in a way that simulates commercial greenhouse conditions or as required by the protocol.
6. Environmental monitoring devices should be installed and maintained as needed to ensure that proper temperature and humidity conditions are maintained during the course of the trial.
7. Record cultural practices performed at the trial site(s) within the greenhouse(s) in a trial notebook or similar document.

4.1 Balance Calibration and Use

Revision number: 3

Purpose: To describe the calibration and use of balances

Scope: All facilities/sites where Compass AgriTech conducts research

Procedures:

1. The balance should be placed on a stable, level surface that is free from vibration and away from direct sunlight and drafts. Keep the pan clean. Never weigh chemicals directly on the pan. Do not weigh items that exceed the capacity of the balance.
2. Before weighing a test substance, perform the following standardization procedure:
    a. Tare the balance.
    b. Weigh two standard weights that bracket the weight of the chemical sample(s) to be weighed. For example, if the test substance amounts to be measured are 1.5 g and 4.5 g, weigh the 1 g and 5 g standard weights.
    c. Make the needed entries in the balance log.
    d. If the measured weights of the two standard weights are within ±2% of the standard weights, proceed with weighing the chemical samples.
    e. If the measured weight of either standard weight differs by more than ±2% of the standard weight, calibrate the balance following instructions in the balance manual.
    f. After calibrating, weigh the standard weights again. If their measured weights are within the 2% range, proceed with weighing the chemical samples.
    g. If the measured weight(s) again fall outside the 2% range, weigh a third standard weight (one as close to the weight of the "problem" standard weight as possible) to determine if the problem is the weight rather than the balance. If the weight of the third standard weight and at least one of the original standard weights are within the 2% range, proceed with weighing the chemical samples. The problem weight should be discarded and a new standard weight obtained.
    h. If the measured weight of two of the three standard weights again falls outside the 2% range, the balance will be removed from service and tagged "do not use" until it has been professionally serviced.
3. Before weighing crop samples, standardize the balance to be used by weighing standard weights that bracket the weight of the samples to be weighed. Record this in the field data book or similar document.

4. Check the balance before and after each use and clean if necessary.
5. Balance(s) will be inspected, calibrated, and certified on an annual basis by a qualified outside balance service. Alternatively, balances can be inspected and an in-house verification of performance can be conducted using reference weights that cover a range of weights.
6. Standard weights should also be kept clean and certified on a regular basis; normally at the same time the balance certification occurs.

4.2 Sprayer Calibration and Use

Revision number: 2

Purpose: To describe the proper calibration and use of sprayers

Scope: Applies to any sprayer used to apply test substances for residue or efficacy trials (does not apply to maintenance chemical applications)

Procedures:

1. Calibrate the sprayer to ensure that the test substance will be properly applied to the plot and that the amount applied can be accurately determined.
2. Before using a sprayer, inspect pumps, hoses, pipes, fittings, regulators, gauges, tanks, and other parts for wear and leaks. Repair or replace parts as needed. Check for leaks by discharging clean water through the sprayer. This is normally done during discharge calibration.
3. Refer to the R & D Sprayers, Inc. Operation Manual or similar documents for guidelines for sprayer operation, safety precautions, and other technical information.
4. Use nozzles that will deliver the proper amount of spray volume at a given pressure and in an appropriate pattern. Consult the Spraying Systems catalog, R&D Sprayers catalog, or other documents to select nozzles.
5. **Discharge calibration**:
    a. Discharge the sprayer for at least 30 seconds (approximately, times slightly less than 30 seconds are acceptable), collecting the output from each nozzle in a separate container. Measure and record the amounts collected (See SOP 4.4).
    b. If the output from any nozzle differs by more than ±5% of the average of all the nozzles, clean or replace the nozzle and/or screen. Also check sprayer for leaks. Perform the calibration run again.
    c. Calibration is complete when three consecutive runs are performed with nozzle outputs in the ±5% range.
    d. Calibration should be done just before the application is to be made. If necessary, it may be done the day before the application is to be made in order to expedite the application in the early morning to avoid unfavorable conditions such as wind. If this is done, perform a re-check (a single run as described in 5.a.) of the nozzle outputs on the day of the application. The re-check output must be within ±5% of the original calibration.
    e. When spraying more than one trial on the same day, perform a calibration re-check between applications. This only applies to applications that are the same type and are to be made at the same spray volume without

changing equipment components or settings. Clean equipment between these applications by spraying out a sufficient amount of clean water to be sure all lines, booms, etc. are thoroughly flushed clean.

6. Calculate the delivery rate by dividing the average total discharge by the average run time.
7. Calculate the amount of spray to be applied to the test plot based on plot size and the desired spray volume.
8. Using the calculated sprayer delivery rate, calculate the target application time required to treat the plot with the required amount of spray.
9. **Speed calibration**:
    a. Measure and mark a calibration track in terrain similar to that of the test plot.
    b. Wearing the proper safety equipment and the sprayer (if a backpack, waist-belt, or similar sprayer is used), walk/drive the track until a pace/speed is set that will allow the treated plot to be sprayed within ±5% of the target time. If possible, use a metronome to set cadence.
    c. Perform a minimum of three consecutive, successful speed calibration runs.
10. Record all discharge and speed calibration data in enough detail to enable the procedure to be reproduced.
11. **Cleaning**:
    a. Clean the sprayer after each use. Some chemicals are corrosive and can damage sprayer parts if allowed to remain in the system even for a short time.
    b. Apply any remaining spray solution to an appropriate area, normally a waste area adjacent to the trial site. Rinse the tank at least three times with an appropriate solvent, e.g. water, detergent, or ammonia. Apply rinse water to waste area.
    c. Partially fill the tank with water and spray water out through the system to clean lines, booms, etc. Apply rinse water to waste area.
    d. Remove nozzle caps, nozzles, screens, and washers (as appropriate or possible) and clean in an appropriate solution, usually water and detergent.
12. A written record of inspection, maintenance, testing, and calibration will be maintained.

4.3 Air Blast Sprayer Calibration and Use

Revision number: 4

Purpose: Describes the proper maintenance, calibration, and operation of an air blast sprayer

Scope: Applies to all trials (typically tree fruit) requiring air blast applications

Procedures:

1. **Maintenance**
    a. Apply grease to the PTO joints and the agitator and pump pulley route, but do not over-grease.
    b. Check/maintain pump oil level. Keep above the halfway mark on the clear plastic fill tube. If low, add good quality non-detergent motor oil.
    c. Check hose fittings and connections for tightness.
    d. Make sure strainer is clean and fits tightly.
    e. Check for broken/worn/loose sprayer nozzles.
    f. Change pump oil after 200 hours of use or end of each season, whichever comes first. Check diaphragm for swelling/stretching/wear. Also check for valve seat wear and valve spring fatigue.
    g. Record inspection, maintenance (routine or non-routine), testing, and calibration in the appropriate log.
2. **Calibration-Method 1**
    a. Place a length of Tygon tubing, or similar material, over each nozzle to be used to make the application.
    b. At a standard operating pressure, usually 100 psi, charge sprayer system.
    c. After system has been charged, place each section of tubing in a container numbered to correspond to the nozzle.
    d. Discharge sprayer for a period of time, a minimum of 30 seconds (approximately), collecting the output from each nozzle in the numbered containers. Record outputs, tractor rpm, and sprayer pressure and repeat this procedure two times, for a total of three consecutive runs.
    e. Calculate the average total discharge and the delivery rate of the sprayer for the three consecutive runs.
    f. Perform necessary calculations to determine target pass time(s) for application.
    g. Speed calibration:

1. Drive tractor (at operating RPM and PSI) with sprayer tank filled with approximate amount of spray to be applied, along a test track (usually 100 feet) with terrain similar to that of the test plot.
2. Record the time taken to cover the length of the test track.
3. Perform a total of three consecutive runs. Calculate speed by dividing track length by the seconds taken to cover the track.

3. Calibration-Method 2

1. Fill the spray tank to a known level with clean water. Charge sprayer
2. Pressurize the system to the desired level and spray for a period of time, usually 3 minutes. Be sure the pump speed and pressure are the same that will be used when spraying.
3. Determine the amount of water needed to refill the tank to the original fill level.
4. Repeat this procedure two times, for a total of three consecutive runs.
5. Calculate average total discharge and delivery rate.
6. Perform necessary calculations to determine target pass time(s) for application.
7. Calibrate sprayer speed using same procedure described in Method 1.

4. Operation

a. With sprayer attached to tractor, fill tank with enough water to test sprayer.
b. Activate PTO and adjust RPM to bring sprayer to proper pressure. Review valve controls for boom operation.
c. Empty remaining water after testing sprayer.
d. Fill with proper amount of water and chemical with PTO engaged to ensure a homogenous mix.
e. Upon completion of spraying, thoroughly clean sprayer to prevent contamination of other crops with test substance.
f. Sprayer cleaning procedure: Drain remaining spray in a waste area, discharge sprayer to purge system, remove and clean filter, rinse interior of spray tank and drain, add clean water to tank, discharge sprayer again to purge system, drain tank and clean filter once more.
g. Make required entries in the sprayer log.

4.4 Measuring Devices

Revision number: 4

Purpose: To ensure that devices used to measure liquids, temperatures, humidity, wind speed, and other parameters are properly calibrated/standardized

Scope: All Compass AgriTech research facilities/sites

Procedures:

Environmental Measurement Devices: General Use

1. Temperature and humidity devices are rated for use in a specified range of temperatures. Use them accordingly.
2. Install new batteries as needed to ensure continued operation of the device. The date the batteries were changed should be noted in the equipment maintenance log.
3. Placement:
    a. The device should be placed on a stable, relatively level surface or held in place (using a magnet, Velcro, etc.) to ensure it does not fall and become damaged. When monitoring freezer temperature, avoid placing the device near the back wall, the defroster coils, or light bulb. Do not place the device in a door rack or near warm samples recently placed in the freezer.
    b. When monitoring test substance (pesticide) storage area temperature, do not place the device on chemical containers, near ventilation systems, or in areas that may not accurately reflect storage conditions.
4. Charts and printouts are critical raw data and should be handled as such. True copies of each chart or printout should be made and placed with the raw data for the study to which it applies. The original should be placed in facility records or in the trial data book.
5. Standardization
    a. Devices should be standardized, calibrated, and/or inspected by an independent entity (e.g. equipment service company) or on-site using a NIST traceable thermometer on an approximately annual basis.
    b. To standardize, place devices to be compared together, at a range of environmental conditions that covers their intended use. If a device differs from similar devices by ±5%, follow the instructions in the owner's manual for the device. If the device cannot be accurately calibrated, it should be discarded or returned to the manufacturer.

Because data loggers cannot be calibrated, they must be sent back to the manufacturer for calibration.

6. All calibration, standardization, inspection, testing, and maintenance should be documented in the appropriate log.
7. Min/Max thermometers will serve as backup temperature monitoring devices when using a data logger or other primary recording device.

Data Loggers

1. Using data loggers:
    a. Launch the data logger using the software program provided by the manufacturer. Be sure the parameters specified are appropriate for the necessary data and time period.
    b. Download the data from the logger using a portable data transfer device or directly using a computer. Re-launch the logger to start recording again.
    c. When applicable, download data from portable data transfer device using the software program previously mentioned.
    d. Save an electronic copy of the downloaded data on a disc or hard drive and print one copy of data. This printout is original raw data and should be handled as such.

Thermometers

1. Thermometers used to measure temperatures of pesticide storage units, freezers, coolers, soil, water, and air temperatures should be verified before the start of the season.
2. Thermometers should be standardized against a NIST certified reference thermometer in the area and under the conditions it will be used.
3. Allow at least 15 minutes for thermometers to equilibrate and record the temperatures from the reference thermometer and the thermometer being tested.
4. If the temperature on the thermometer being tested is within 5° F of the reference thermometer, the thermometer is considered acceptable for use.
5. If the tested thermometer's temperature is outside the 5° F range, it should not be used and should be replaced with a thermometer that meets the standard.
6. Measure soil temperatures in the plot itself, or as close as possible. Allow enough time for thermometer to stabilize.

Weather Monitoring Devices

1. Kestrel 3000 Pocket Weather Meter or similar device
    a. Refer to the manufacturer's instructions for operation, maintenance, troubleshooting, and other information.
    b. When measuring wind speed, avoid areas where eddies may form. Hold the anemometer long enough to measure an accurate average wind speed.
2. If other weather monitoring devices are used, ensure they are working properly and are designed for the environment they will be used in.

Pipette

1. Mount the capillary-piston according to manufacturer's instructions. Set the volume using the adjustable volumeter**.** To set a volume below the initial value shown on the volumeter, come slowly to the new value making sure not to pass the required volume. To set a volume above the initial value shown on the volumeter, pass the required value by a small amount and then come slowly back to the new volume, making sure not to pass the required volume.
2. To aspirate the liquid, press the push-button to the first stop, immerse the capillary into the liquid, and slowly release the push-button to draw up the liquid.
3. To dispense the liquid, depress the push-button slowly to the first stop.
4. Finally, eject the capillary-piston and dispose of it properly.
5. Troubleshooting: If the pipette leaks, change the capillary and piston. If the pipette does not work, check to see that the piston is seated correctly. If the capillary is difficult to fit, clean the capillary holder with water, ethanol, or another suitable solvent. If the amount of liquid measured appears inaccurate or imprecise, check to see if the capillary is correctly fitted and/or change the capillary and piston. If it is difficult to set the volume, the pipette may be damaged internally. In this case, the pipette should not be used and should be returned to the manufacturer for repair.

Flow Meter

1. With meter attached to hose, run water through system to fully charge it and to check for leaks. Turn off water.
2. Zero the flow meter.
3. Turn on water and collect the water discharged in container with a known volume, and marked with a graduated scale until a predetermined amount has been collected. Suggested amount is three to five gallons.
4. Determine if the amount collected and the readout on the electronic water flow meter are within allowable tolerances (±5% based on manufacturer's specifications).
5. Repeat the process for a total of three consecutive times.

4.5 Farm Equipment

Revision number: 0

Purpose: To ensure the proper and safe use of farm equipment

Scope: All Compass AgriTech research facilities/sites

Procedures:

1. When operating trucks, tractors, self-propelled sprayers, combines, roto-tillers, and other farm equipment or towing trailers be sure that all personnel involved are familiar with the safe operation of the equipment. Refer to user manuals.
2. When loading/unloading tractors or other equipment, another person should be present to guide the driver on or off the trailer and in the event emergency assistance is needed.
3. Properly secure all equipment before transporting on a trailer.
4. Fire extinguishers should be readily accessible and in good working order in work vehicles and at work sites.
5. The Field Research Director or other designated personnel is responsible for the performance of farm equipment.

4.6 Freezers

Revision number: 3

Purpose: To describe the proper operation, maintenance, and monitoring of freezers to maintain the integrity of residue samples.

Scope: All freezers used to store samples from residue trials

Procedures:

Location and Operation

1. Freezer(s) should be located in a secure area away from possible sources of contamination. If possible, locate freezers in an area separate from test substance storage areas or areas where equipment used to handle test substances are kept.
2. Be sure the electrical outlet used is grounded and the circuit is not overloaded. The outlet should not be connected to a wall switch that could be turned off accidentally. There should be unobstructed airflow around the coils and adequate space around the freezers to ensure their proper operation.
3. The freezer(s) should be capable of maintaining an average temperature that is within the range acceptable for sample storage. This should be ensured before sample storage by placing a recording thermometer, a minimum/maximum thermometer, or similar device inside the freezer for at least 7 days.
4. Freezer doors should be sealed tightly and locked when samples are being stored within the freezer. Freezer contents logs should be posted to indicate the presence of untreated/treated samples within freezer.

Maintenance

1. All freezers shall be defrosted and cleaned with an appropriate decontaminating solution when the absence of samples permits. Cleaning should be recorded in the appropriate log. This is considered routine maintenance.
2. Any unusual noises from the motor, failure of the freezer or any of its components or inability of the freezer to maintain required temperatures warrants the services of a qualified repairman. Any repairs performed must be documented in the appropriate log. This is considered non-routine maintenance.

Monitoring

1. Freezer shall be clearly posted with a designation number and the serial number and/or a unique identifier for the temperature recording devices assigned to the specific freezer. These identifiers shall be used on temperature records.
2. An automated data logger, min/max thermometer, or similar device shall be placed inside the freezer at all times samples are stored in the freezer. If a min/max thermometer is used as a primary device, the temperature ranges should be recorded at least weekly and the thermometer should then be reset. A thermometer that can be read without opening the freezer is preferable.
3. If the freezer is not equipped with an alarm designed to notify personnel of rising temperatures, then the temperatures must be checked regularly while samples are being stored (once in every 24-hour period if possible).
4. A min/max thermometer or data logger must be used as a backup monitoring system.

Equipment failure

1. In the event the freezer fails due to a power outage or malfunction, the following procedures should be implemented:
    a. To maintain a cold temperature in the freezer, limit the number of times the freezer door is opened.
    b. If the failure lasts longer than 24 hours or the temperature in the freezer exceeds 20° F, follow procedure c. and/or d. below.
    c. Put enough dry ice in the freezer to maintain samples in a frozen state. Keep freezer door open slightly.
    d. Arrange for samples to be moved to another freezer. Any samples transported should be kept with their temperature-recording device. If time does not allow for pre-use monitoring of the new freezer, check temperature recording device often enough to ensure that freezing temperatures are being maintained. Make note of the new sample storage location in the freezer temperature records and in the field data book, detailing the sample chain of custody.

4.7 Borrowed or Rented Equipment

Revision number: 1

Purpose: To describe the proper use and documentation of borrowed or rented equipment

Scope: All Compass AgriTech research facilities/sites

Procedures:

1. Make arrangements for pickup or delivery enough in advance that equipment can be thoroughly checked for proper operation and to become familiar with its operation.
2. Request copies of the operator's manual and/or an SOP if needed and available.
3. The following information should be recorded for the equipment:
    a. Equipment owner or source
    b. Description of equipment, e.g. type, make, and model
    c. Year manufactured (if available)
    d. Purpose (what the equipment will be used for)
    e. Trial identification number, crop, and chemical name for trial
    f. Condition upon receipt
    g. Maintenance performed (if applicable)
    h. Modifications required (if applicable)
    i. Cleaning/decontamination procedures performed before and after use
    j. Field Research Director statement of suitability for use
    k. Demonstration of proper operation prior to use
    l. Date of use
    m. Time procedure initiated and completed
4. The person recording the information should initial and date entries.
5. The information described above should be included in the trial notebook or similar document.

4.8 GPS Receivers

Revision number: 4

Purpose: To ensure proper use and maintenance of GPS receivers

Scope: Applies to use of GPS receivers for mapping plot locations and related features of trials conducted according to Good Laboratory Practice (GLP) Standards

Procedures:

1. Traditional GPS Receivers (stand-alone device)
    a. Verifying Accuracy:
        i. Check receiver accuracy prior to use for determining plot location reference points. Record accuracy check in maintenance log.
        ii. Select a location with known coordinates such as a USGS benchmark or other well surveyed location and record the coordinates for the location.
        iii. Turn receiver on and wait for position to be acquired. Once position is acquired, wait a minimum of 1 minute for reading to stabilize before recording first position coordinates.
        iv. Record the first position coordinates and then record position coordinates approximately every 3 minutes, for a total of 6-8 position readings over at least 20 minutes. Calculate the difference between the receiver reading and the location coordinates to determine the reliability of the receiver. There are a number of methods to do this. Refer to user guides or other reference material, and record calculations in the maintenance log.
        v. If the measured location varies from the known coordinates of the location by more than 15 meters, the GPS receiver should not be used.
    b. Use:
        i. When trying to receive satellite signals, hold the receiver so the top of the unit points toward the sky. If the unit is held with the top pointed toward the horizon, satellite reception will be severely degraded.
        ii. Follow users manual for proper use instructions
        iii. Check and replace batteries as needed. Remove batteries from the unit if it will not be used for several months.

    c. Maintenance

i. No routine maintenance is required for the GPS receiver.
ii. Store the receiver in a clean, safe location. Avoid storing the receiver where it will be exposed to very hot or very cold temperatures (e.g. in the cab of a truck).

d. Documentation
i. Record maintenance and accuracy verification procedures in the GPS receiver log. Note the SOP that was followed and if the operation was routine or non-routine. If the operation was non-routine, i.e. done due to a failure or malfunction, describe the nature of the defect, how and when it was discovered, and any corrective actions taken. Remember to initial and date all entries.

2. Smartphone GPS or GPS App
a. Because accuracy of GPS tools that are a built-in part of a smartphone or a specific GPS app for a smartphone has improved dramatically over the past few years, location readings from a smartphone or smartphone app can be used for research plot mapping. No maintenance or calibration is required for use of a smartphone GPS tool or app. The smartphone model and/or the app and version used should be noted in the field databook or similar document.

4.9 Backpack Mistblower Calibration and Use

Revision number: 1

Purpose: Describes the calibration, use, and maintenance of backpack mistblowers

Scope: All Compass AgriTech research facilities/sites – trials subject to GLP standards

Procedures:

1. Review the operator's manual and familiarize yourself with the sprayer before use.
2. Calibration
    a. Because sprayer output will vary due to nozzle type, position, angle, blower speed, etc., the sprayer must be calibrated using the same configuration that will be used in making the test substance application.
    b. Calibration may be done based on a specific area, number of crop units (trees, bushes, etc.), or by simply operating sprayer for a measured period of time.
    c. For example: Fill tank with a known amount of water. Set nozzle to desired setting. Start engine. Set throttle to desired position, usually full throttle. Engage sprayer to spray out water measuring time sprayed.
    d. Measure amount discharged by either refilling to pre-marked level on tank or draining sprayer to measure amount remaining in sprayer.
    e. Perform three consecutive discharge runs. Calculate average discharge rate.
    f. Next, determine a target application time based on discharge rate. This can be a walking pace, a time per crop unit (e.g. tree), or other measure that can be easily replicated and measured during the application of the test substance. Thoroughly explain the process, measurements, and calculations in the trial notebook.
    g. For the discharge rate and the speed calibrations, the three runs should be within a + or – 5% range of one another.
3. Test substance application:
    a. Ensure the spray nozzle/line is in the closed position. Carefully measure and add carrier to the tank. Measure and add test substance(s) and adjuvants. In some cases, a portion of the carrier should be used to premix the test substance in a container prior to adding it to the spray tank. This ensures the materials are evenly mixed to create a homogenous solution.
    b. After spray mixture is prepared and added to tank, seal tank, start engine, and check sprayer for any leaks or other problems.

    c. Wearing proper PPE, put sprayer on back and move to the plot. Set throttle to same level used during calibration and engage sprayer to make application. Measure application time(s) as needed.
    d. When the application is complete, turn sprayer off and move out of plot area. In most cases, it is best to conduct a check of the spray amount applied by draining the spray remaining in the sprayer, measuring it, and comparing it to the application amount calculated using discharge rate and application time. The two values should be close to one another.
4. Cleaning and maintenance: Following an application, the sprayer must be carefully cleaned by rinsing tank and spray lines/nozzles with clean water and/or an appropriate detergent solution. Check sprayer for damage and wear, repairing or replacing parts as needed.
5. Record keeping: Thorough documentation of use and maintenance should be recorded in a trial notebook or equipment logbook. For maintenance, note if it is routine or non-routine. If non-routine, explain the situation and corrective actions taken.

5.1 Recording Raw Data

Revision number: 2

Purpose: Describes proper data recording, storage, and archival

Scope: All Compass AgriTech research facilities/sites

Procedures:

1. **Read the protocol and other trial instructions**. Make sure all data required is collected and recorded.
2. Raw data is the first place data is recorded. This includes any worksheets, records, memoranda, notes, or exact copies that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. Raw data also includes bills of lading, shipping documents; any information or documents received with the test substance or received as a result of shipping samples, test substance and/or test substance containers; weather records; and equipment logs.
3. All data generated during the conduct of a study, except those that are generated by automated data collection systems, shall be recorded directly, promptly, and legibly in indelible (can't be erased) blue or black ink. Blue is preferred because originals can be distinguished from copies more easily. Do not use pencil.
4. Entries should be clear, understandable, and legible.
5. All raw data, regardless of what it is, must be retained. Do not destroy data. During the active life of a trial, raw data will be stored in a trial notebook or file. Additional notebooks, folders, or files may be used to store large volumes of data that do not fit in the original data notebook.
6. The amount of data transcribed from notes, scrap paper, etc. should be kept to a minimum. If it is necessary to transcribe data, the original must be retained and its location noted on the transcribed copy. If data is transcribed from another source, the transcription should be verified by another person.
7. If a page contains data that is applicable to two or more trials, make a verified true copy and place the copy in the proper field data book or similar document. To make a true copy, mark the copy with the statement "TRUE COPY OF ORIGINAL", or a similar statement, and note the location of the original and initial and date the copy.
8. When an error is made while recording data, do not obscure the original entry and make it unreadable. To correct an entry, draw a line through the original entry and make the necessary correction, then initial and date the correction. Note the reason for the change, e.g. spelling error or transcription error.

9. All entries must be initialed and dated by the person making the entry. If entries on a page are made on different days, each must be initialed and dated. If the date the data were generated is different than the date they were entered, this must be noted. If one person records the data and another reads the instrument, then both must sign and date the data. If a particular form or section of a form does not require an entry, make a slashed line (diagonal from the top of the page or section to the bottom), initial and date on the slashed line or at the bottom of the page. A brief note explaining why the space is not used is helpful.
10. The first printout of electronic data is considered raw data and should be handled as such.
11. All pages should be identified with a trial identification number or similar identifier. Paginate as required.
12. Enter calculations in a logical manner showing all steps and conversions so that they can be easily followed and reconstructed. Complete calculations promptly so any deviations from the protocol or SOPs can be documented and appropriate action taken.
13. Rounding numbers:
    a. Avoid rounding numbers in calculations until the final answer is figured.
    b. Round down (i.e., drop the last digit) if it is less than 5. Round up, if the last digit is 5 or greater.
    c. Show calculations and rounding in enough detail so that someone else checking your work can get the same answer.
14. Significant figures in data calculations:
    a. When rounding numbers, retain enough decimal places to accurately and meaningfully reflect the measurement and measuring equipment.
    b. Example: 13.3 ft x 100 ft ÷ 43,560 ft^2/acre = 0.0305326 acres (not 0.03 acres) x 2 lb ai/acre x 453.6 gram/lb=27.70 grams (not 27.699175)
    c. When comparing the actual rate applied to the target rate given in the protocol, use the same number of decimal places.
15. Upon trial completion, review the trial notebook, complete as needed, make a copy of the notebook, and transfer to the sponsor as instructed. Retain the copy of the trial notebook for a minimum of five years.

5.2 Data from Monitoring Devices

Revision number: 2

Purpose: To ensure data collected from monitoring devices is properly recorded

Scope: All Compass AgriTech facilities/sites

Procedures:

General Guidelines

1. Monitoring devices directly owned and operated by Compass AgriTech should be inspected and maintained as outlined in SOP 4.4.
2. Data printouts from monitoring devices should be clear and legible.
3. The first printout of electronically recorded or processed data is considered to be original raw data and should be handled as such.
4. Printouts from automated monitoring systems, such as the Colorado Agri-Meteorological Network (CoAgMet), data loggers, or similar systems should be initialed and dated by the person receiving/printing the report.
5. True copies will be placed in the appropriate trial notebook or similar document.
6. The original raw data will be kept in a facility file or trial notebook during the current season.
7. The original raw data will be archived at the end of the season or included as part of an original trial notebook transferred to the trial sponsor.

Weather Data

1. Consult the protocol to determine the weather data required.
2. For field trials, air temperature and rainfall are usually required to be monitored daily. This data can usually be obtained from the nearest CoAgMet, Colorado Climate Center, NOAA, or other weather station. For greenhouse trials, air temperature, humidity, and photoperiod are usually required to be monitored daily. This data can be obtained using a data logger or other device or from greenhouse facility records. Be sure the protocol does not require on-site data before using an outside station or source.
3. If the sponsor requires daily soil temperatures, a soil thermograph or similar device should be used.

5.3 Phytotoxicity and Efficacy Data

Revision number: 0

Purpose: To outline how crop injury and pesticide efficacy data are collected

Scope: All Compass AgriTech facilities/sites

Procedures:

Phytotoxicity

1. Consult the protocol for the method and timing for rating crop injury. If no specific direction is given, describe the procedure used or use the following procedure:
    a. Inspect the crop within 24 hours of the initial application and then at 1, 3, and 6 weeks after the application was made.
    b. Visually estimate injury on a scale from 0 (no injury) to 10 (crop death).

Efficacy

1. Consult the protocol for the method and timing for rating pesticide efficacy. If no specific direction is given, describe the procedure used or use the following guidelines:
    a. For weed control, inspect the plot within 24 hours of the first application and note the species present, their size, relative density, and/or other parameters that will aid in assessing efficacy.
    b. Rate control at 1, 3, and 6 weeks after application or at intervals deemed appropriate.
    c. Compare the treated plots to the untreated plots. Visually estimate control on a scale from 0 (no control) to 10 (complete control). Ratings can be converted to percentages for data analysis.
    d. For disease or insect control, follow commonly used and accepted rating systems and document the method used in the raw data.

5.4 Experimental Design and Data Analysis

Revision number: 0

Purpose: To ensure experiments are properly designed and the appropriate data analysis is performed

Scope: All Compass AgriTech facilities/sites

Procedures:

1. Follow the experimental design specified in the protocol. If no directions are given, then use a commonly accepted experimental design.
2. Residue trials typically consist of one untreated plot and one or more treated plots and are not replicated. Treatments are assigned to plots to ensure they are representative of the plot area and to prevent contamination of the untreated plot.
3. Record the experimental design used in the raw data.
4. If using a randomized complete block design, use at least three replicates; four is preferred.
5. Make a plot map that includes the location of each plot, treatment, north direction, and slope. Retain the plot map in the raw data.
6. Assign treatments to plots using a random number table or generator. This applies only to efficacy and performance trials, not to residue trials.
7. Conduct the appropriate analysis of the data using a commonly used software program.
8. Record the data as required on the forms provided by the sponsor or on similar documents.

5.5 Data Archival and Disposition

Revision number: 3

Purpose: Describes the storage and distribution of raw data

Scope: Applies to raw data generated during conduct of GLP trials

Procedures:

1. Definitions:
    a. Archive: a limited access facility (e.g. locked room or cabinet) used to store historical original raw data. The facility should provide environmental conditions necessary to preserve the data in good condition.
    b. Archivist: person responsible for placement of data in, or removal of data from, the archive. If no individual holds this title, the Field Research Director (FRD) will serve as archivist. The FRD can designate a backup archivist.
    c. Historical raw data: all raw data from a completed trial or study.
2. All raw data generated during the course of a study subject to GLP standards will be kept in trial notebook, trial file, or in facility files.
3. Upon completion of the field trial the completed trial notebook is sent to the sponsor as instructed. A reference copy of the completed trial notebook will be kept by the FRD.
4. Data for trials will be handled as requested by the sponsor.
5. Raw data not included in the trial notebook or similar document are considered historical raw data and will be archived. This includes, but is not limited to, equipment logs; temperature records; personnel documents (resumes, CVs, training records, job descriptions, etc.); facility documents (organizational charts, maps, field records, etc.); and any other GLP related data. A dedicated, locked cabinet or similar storage unit will be used at the C.A.T. facility archive.

6.1 Trial Site

Revision number: 1

Purpose: To ensure trial sites are properly chosen and identified

Scope: Applies to all Compass AgriTech research trial locations

Procedures:

1. The purpose of a field and greenhouse trials is to provide representative samples (plant, soil, water, or other material) that have been treated as described in the protocol. All activities associated with planning and designing the trial should be done with this goal in mind.
2. When conducting a trial to determine the magnitude of residue of a pesticide on a crop, the target pest need not be present.
3. Site selection will be made with regard to the common agricultural practices for the commodity.
4. The Field Research Director will normally choose the trial location. The site should be one where the crop could be, and preferably is, grown commercially.
5. Be sure that the pesticide history of the site is in accordance with protocol requirements.
6. The site will be large enough to provide room for the required number of replicates, buffer zones, and treatments outlined in the protocol. The site will allow the commodity to be grown under simulated commercial conditions in order to provide the needed yield and quality of the commodity.
7. Plot size:
    a. Consult the protocol for fixed dimensions or minimum/maximum plot sizes. The plot size depends on the sample size, the number of samples requested in the protocol, amount of test substance available for the trial, and the application method.
    b. Plots should be large enough to allow application of the pesticide accurately with the appropriate equipment.
    c. Using an average yield as a baseline, it is best to make the plot large enough to provide at least 2+ times the total quantity of sample requested. This can be an estimate at best because field situations are dynamic. No calculations need be provided for these estimates.
8. Arrangement:
    a. A buffer zone must be used between untreated and treated plots. The buffer zone must be large enough to prevent contamination of the untreated plot from the treated plot. Follow protocol guidelines for buffer zone.

b. Arrange the plots in a way that will minimize the risk of contamination of the untreated plot caused by drift, volatilization, leaching, or runoff. If possible, place the untreated plot upwind and away from the treated plot(s). If runoff or flooding is a concern, locate the untreated plot upslope from the treated plot(s). Similarly, plots treated with lower rates should be upwind and upslope of plots treated with higher rates.

9. Neighboring plots:
    a. When selecting a location for the trial plots, consider the types of chemical applications that are going to be made to nearby plots or fields.
    b. Nearby plots or fields may be treated with chemicals that could contaminate the trial plots and interfere with residue analysis. This applies to private farming activities in the area as well as research activities. Adequate precautions should be taken to prevent contamination from these sources.
10. Plot identification:
    a. Mark plots with a stake/flag/sign that shows the trial identification number the treatment (e.g. Untreated or Treatment 1). The stake/flag/sign should last for the length of the trial or be easily replaced if necessary. Flags should be placed at all four corners of the plots to prevent farm crews from entering accidentally. Posts with "NO ENTRANCE" signs may be used for additional marking purposes.
    b. Use flags that can be seen above the plant canopy (for field and row crops). Choose a flag color that will stand out against the plant's vegetative and reproductive structures.
    c. For tree and vine crops, tag each plant in the plot with surveying tape. In private orchards/vineyards, use a different color/pattern of tape than the grower is using. Set flags where they will not interfere with cultural practices (e.g. mowing, ditching).
    d. Post signs that indicate the flagged areas are agricultural research plots and trespassing or unauthorized harvest of the crop is dangerous and prohibited.
    e. To honor agreements of confidentiality, avoid identifying any research plots with the sponsor's name or test substance name, unless specifically requested.
11. Draw a plot map following the protocol and/or sponsor instructions given in the trial notebook. The plot map should be drawn before the first application of the test substance is made. Include the number and direction of rows, slope direction, and if pertinent, direction of prevailing winds. Measure and record the distance from two plot corners to two permanent landmarks or use a GPS unit to record the coordinates of at least two plot corners. The relation of the plot to the permanent markers should be drawn in sufficient detail so the plot can be located again without flags or other identification.

12. The ability to control as many factors as possible is a primary consideration when choosing a location for a study. The following order of preference should generally be followed:
    a. Colorado State University (CSU) research facilities
    b. Other agricultural research facilities
    c. Commercial farms on which successful studies have been performed
    d. Commercial farms willing to cooperate in the conduct of studies
13. If the commodity is an established crop, e.g., apples, cherries, or pears, select a site that has a uniform stand with healthy plants or trees.
14. Cultural practices (plowing, disking, planting, etc.) should be performed before the plot is laid out in the field, if possible.
15. If the trial requires statistical analysis, assign the treatments and replicates using an accepted statistical design and label the plot map with enough detail to clearly identify the treatment and replicate assigned to each plot.

6.2 Establishing and Maintaining the Crop

Revision number: 2

Purpose: To ensure the crop, also referred to as the test system, is established and maintained in a manner consistent with commercial practices while still allowing the protocol requirements to be met.

Scope: Applies to all Compass AgriTech research facilities/sites

Procedures:

Protocol requirements

1. Prior to establishing the crop, the Field Research Director should discuss the goals of the study with the farm manager. The discussion should cover crop timing, possible varieties, ground preparation, layouts for the planting of the crop (row width, plant spacing, plot size), desirable locations, etc.
2. Follow protocol or sponsor requirements for crop establishment. The Field Research Director should make every effort to ensure that the requirements of the protocol are met.
3. When the protocol specifies practices that are significantly different from the established commercial practices in the area, the study director and/or sponsor should be notified. Any time the specifications in the protocol are not followed, these deviations must be documented and reported to the sponsor immediately.
4. Establish and maintain the crop according to generally accepted commercial practices for the crop in the area. Consult with local growers, crop consultants, extension agents, and other agricultural professionals for information. Publications (books, pamphlets, bulletins, etc.) can be very useful in obtaining the needed information.
5. Useful crop information includes soil salinity tolerance, suitable varieties for the area, soil preparation, fertility, planting techniques including row spacing and plant populations, pest (disease, insect, weed) management, cultural practices, local pest pressures and accepted methods of control, irrigation (amount and timing), and harvest practices.
6. The crop seed source, variety, and planting date are required raw data and shall be documented. Any tags or labels, or copies thereof, included with seed shall be retained as raw data. A germination test may be necessary for a seed source that does not have such information furnished on the tag or label, or for seed that may have been compromised by time or environmental conditions.

Monitoring the crop

1. The Field Research Director will ensure that the crop is monitored prior to the application of a test substance and at regular intervals thereafter. If possible, check the crop within two days after an application and weekly thereafter until sample collection. Monitoring intervals should be set considering the type of crop and anticipated problems inherent to the area and time of year.
2. Always inspect untreated plots first, then treated plots in order from lowest to highest rate if more than one rate is applied. This will avoid accidental contamination of the untreated plot.
3. Books, pamphlets, bulletins or other reliable scientific sources should be consulted to identify pest species and establish proper management practices for crops grown in a particular location.
4. Document crop monitoring in the raw data. Take appropriate action to remedy problems and document this in the raw data.
5. Areas to monitor:
    a. Monitor soil conditions to minimize moisture stress and to ensure normal crop growth. Irrigation should be scheduled as needed.
    b. Check crops for signs of nutrient deficiencies. Crop tissue or soil samples may need to be taken and analyzed to determine fertility needs.
    c. Monitor weed presence to minimize competition. Specific attention should be given to the identification, size, and population of weed species and the best methods of control, e.g., chemical or mechanical control.
    d. Disease(s) present at a level that may affect the overall health of the crop and quality of the raw agricultural commodity to be sampled, should be identified, documented, and controlled if possible.
    e. Insect monitoring and control is important. Insects can vector diseases and heavy infestations can jeopardize the integrity of the trial. Specific attention should be given to the identification of harmful insects and to infestation levels.
    f. Damage from other pests, such as nematodes, rodents or other mammals should also be monitored.
    g. If it appears the number of dead/damaged plants will reach a level that could negatively affect the conduct/integrity of the trial, the sponsor should be notified immediately.

Maintenance pesticides and fertilizers

1. Use only registered pesticides for maintenance purposes. Apply according to label instructions.
2. Make identical applications to the untreated and treated plot(s). Spot sprays are exempt.
3. Do not use pesticides or other chemicals that are similar to the test substance and might interfere with the residue analysis. If in doubt, contact the Study Director.
4. Before any maintenance pesticides are applied, consider the impact they may have on nearby plots. Buffer zones should be used to protect nearby plots from drift.

6.3 Determining Yield and/or Quality

Revision number: 0

Purpose: To describe methods for determining crop yield and/or quality

Scope: Applies specifically to residue trials, but also is an important consideration for efficacy trials

Procedures:

1. Where possible, obtain a reasonably up-to-date copy of the United States standards for grades of the commodity under study from the Agricultural Marketing Service or other source.
2. If U.S. grade standards do not exist, consult other sources for information about plant growth stage, fruit ripeness, or other characteristics needed to determine quality.
3. Follow protocol instructions for time of harvest and sample collection and crop stage. If no directions are given then contact the sponsor and/or follow local commercial practices for the commodity. Document the practices followed in the raw data.
4. Use grading standards or other methods to ensure the samples collected are representative of the commodity and are of a marketable quality.

7.1 Test Substance Receipt, Use, and Disposition

Revision number: 3

Purpose: To describe proper test substance receipt, use, and disposal.

Scope: All Compass AgriTech facilities/sites

Procedures:

Test substance receipt

1. Upon receipt of a test substance, record the information required by the protocol or sponsor. If no directions are given, record the following:
    a. Date received and person who received the shipment
    b. Test substance name and formulation
    c. Lot/batch number
    d. Expiration date
    e. Number of containers and their condition on arrival
    f. Amount received (listed on container label)
    g. Evidence of GLP characterization
    h. Storage location and date placed in storage unit
    i. Courier and bill of lading or tracking number
2. Place all documents sent with the test substance in the trial notebook. If possible, make a photocopy of the shipping label attached to the package and place it with the raw data.
3. Each container must be labeled with the name, batch/lot number, expiration date, and storage conditions. If any of this information is not on the label, refer to SDS or other document for this information and then write it on the container label. Initial and date additions to the container label.
4. Multiple containers should be numbered and referenced separately in the logs.
5. If the container is leaking, the study director and/or sponsor should be notified immediately. A new shipment should be arranged if necessary. Appropriate steps should be taken to ensure that the leak has been contained and properly cleaned up. Dispose of waste and contaminated materials in a legal and safe manner.

Test substance storage

1. See SOP 7.2 Test Substance Storage for proper storage procedures.

Safety procedures

1. Personnel involved with pesticide handling, storage, measurement, transportation, mixing, application, and disposal should be familiar with the principles of safe and proper use of pesticides.
2. An emergency contact list, with phone numbers and addresses, should be readily available where pesticides are stored, handled, and transported. The list should be updated at least once a year.
3. Refer to the SDS, pesticide label, or other technical information to determine the personal protective equipment (PPE) needed to safely handle the pesticide. All clothing and equipment should be properly cleaned or discarded after use.
4. Inspect spray equipment prior to the start of the season and during the season for wear, leaks, or conditions that may cause potential problems. This is normally done during sprayer calibration.
5. First aid kits and eye flush kits should be available and accessible in work vehicles and at work sites.

Test substance measurement

1. Liquid test substances: see SOP 7.3.
2. Dry formulations: see SOP 4.1 Balance Calibration and Use. Always use a weighing pan or other container to avoid contamination of the balance and thoroughly clean the area after weighing. Remember to record the necessary information in the trial notebook.

Mixing test substances

1. After the sprayer has been inspected and calibrated, empty water from tank and lines. Open tank lid.
2. Measure and add the correct amount of carrier (e.g., water) to the tank.
3. Add the test substance to the tank.
4. Liquid formulations: If necessary, set aside a portion of the carrier to rinse the device used to measure the test substance. Include the volume of rinse solution in the total volume of spray solution.
5. Dry formulations may be pre-mixed in a plastic bag or other container and then added to the spray tank. Include the volume of the pre-mix solution in the total volume of the spray solution. Rinse bag or container. Include the volume of the rinse solution in the total volume of the spray solution.
6. Close and tighten the lid.
7. Agitate the spray solution sufficiently to ensure an even distribution and concentration of test substance throughout the spray tank.
8. Mix the spray solution as close as possible to the time of application. Record the information required by the protocol or sponsor. If no directions are given, record the mix time; mix order; application time; amount of test substance(s), adjuvant(s) and carrier in the solution; source, type (usually water), pH, and temperature of the carrier. Use measuring devices appropriate for the quantities being measured.

Test substance/empty container return

1) Upon conclusion of a trial, the remaining test substance or empty container(s) will be handled in one of the following ways (in order of preference):
   a) Remain in the possession of the Field Research Director
   b) Return to the registrant, sponsor, or other designated entity
   c) Handle in some other safe and legal manner

2) EPA regulations require that test substance container(s) must be retained until the final study report is completed.

3) Study completion can be confirmed by contacting the Study Director or a sponsor representative.

4) Record test substance container disposition. Refer to the protocol and/or shipping documents for instructions. Be sure to contact the recipient before shipping test substance or empty containers.
5) When documenting test substance/container disposition, include the following information:
   a. Study or trial number
   b. Address of recipient
   c. Date shipped
   d. Courier name
   e. Bill of lading or tracking number
   f. Person responsible for shipping
   g. Other information as requested by registrant, sponsor, or other party. This may include test substance name and formulation, batch/lot number, and approximate amount shipped.

1. Package the test substance containers in a way that is legal, safe, and meets DOT shipping requirements. Include a copy of the test substance SDS with the shipment. Secure bottle and jar lids with tape. If needed, include adequate absorbent in the package in case of a spill.
2. If the test substance is a labeled compound, it may be retained and used for labeled uses not related to the study. The Study Director, registrant, or other designated party must give approval. Document all use of the test substance and retain the container as required by GLP guidelines.
3. Shipping documents generated during test substance disposition are critical raw data and should be treated as such.

Test substance use

1. Test substance use must be documented. Record the information required by the protocol or sponsor. If no directions are given, record the following information:
   a. Date of removal and initials of person responsible for removal
   b. Name of test substance
   c. Lot/batch number
   d. Purpose of removal (e.g., apply treatments, retainer sample, return)

e. Amount used
f. The minimum and maximum temperatures if the chemical was removed from the storage area for more than 4 hours
g. Date container returned to storage unit, initials of person responsible

7.2 Test Substance Storage

Revision number: 4

Purpose: To ensure test substances are stored in conditions that will preserve their integrity and which meet requirements listed on the label or SDS

Scope: Applies to chemicals used for trials conducted according to GLP standards

Procedures:

1. Upon receipt of a test substance it shall be placed in an appropriate storage area. The area should be secure, dry, and well ventilated with adequate fire protection and should be separate from equipment and sample storage areas, offices and laboratories. It should provide environmental conditions that will preserve the integrity of the test substance and that meet the label or SDS specified storage conditions.
2. The primary storage area is the Compass AgriTech chemical storage cabinet located in Montrose, CO.
3. Signs indicating the nature of the contents being stored should be posted where needed (e.g. doors, gates, buildings, fences).
4. Check the label, SDS and/or protocol for special storage conditions. Document procedures taken to comply with these requirements. If special storage conditions are needed and are not indicated on the label, write them on label so they are readily available. Initial and date additions to the container label.
5. Pesticide containers must be retained until the final study report is completed. Follow directions given in shipping documents or protocol or contact the registrant for directions.
    a. If pesticide containers will be retained by Compass AgriTech, they will be stored in the chemical storage cabinet.
    b. Prior to transfer, complete document(s)/form(s) used to track the location of the product.
    c. Transport pesticide(s) to and from the trial site in a secure container (e.g. insulated cooler).
    d. Upon placement in the archival cabinet, log the pesticide into the inventory.
6. Test substances should be kept in their original, labeled containers. Check them regularly for corrosion and leaks. Damaged containers should be replaced. If this is not possible, the contents may be transferred to a suitable container. Label the container with the test substance name, batch/lot number, CAS or code number, storage condition requirements, and expiration date. If necessary, the container and its contents may be disposed of properly.

7. Personal protective equipment and supplies for the proper treatment of spills should be readily accessible. Personnel involved in handling test substances should be familiar with the principles of containing spills and decontamination.

Test substance monitoring

1. The temperature of the test substance storage area must be monitored and documented when test substances are present. A constant recording thermometer, data logger, thermograph, or similar device may be used. See SOP 4.4 for use of these devices. A minimum/maximum thermometer is acceptable. When using a min/max thermometer, record temperatures and reset the thermometer weekly ± 3 days. The Field Research Director will ensure that thermograph charts are replaced, min/max thermometers are read and reset, or data loggers are downloaded according to equipment specifications.
2. A primary and back-up temperature-monitoring device will be used.
3. If the temperature of the test substance storage area exceeds the stability range for any stored test substance, notify the Study Director or other designated contact immediately.
4. If there is any reason to suspect pests are adversely affecting the storage of test substances, appropriate control measures should be taken.

7.3 Measuring Liquid Test Substances

Revision number: 1

Purpose: Describes how to correctly measure liquid test substances using different devices

Scope: Applies specifically to chemicals used in residue trials

Procedures:

General guidelines

1. Always wear/use appropriate personal protective equipment (PPE) when measuring liquids.
2. Liquids should be measured in equipment that is accurate to the fractional increment required. For example, if 10.9 ml of a test substance is required, the device used should be marked in 1/10 ml increments or less.
3. Use equipment that is of a volume appropriate to the quantity required. For example, use a 50 ml graduated cylinder to measure a 20 ml volume, rather than a 500 ml beaker.
4. Read all volumes within the measuring device from the **bottom of the meniscus** at eye level. This applies to glass devices only; plastic devices have no meniscus.
5. Record the amount of test substance(s), carrier, and adjuvant(s) included in the mixture as well as the order they were added to the spray mixture. Actual amounts measured may differ from calculated target amounts. Be sure all data entries are consistent with values used in calculations.

Graduated cylinder/beaker

1. Use a graduated cylinder with a volume appropriate for the quantity being measured (see #3 above). For example, use a 50 ml graduated cylinder to measure a 20 ml volume, rather than a 500 ml beaker.
2. If the cylinder opening is small and there is a chance the pesticide may spill when poured from the original container into the graduated cylinder use either a clean glass container with a pour lip as an intermediate container or use a clean glass funnel.
3. Measure the liquid in the cylinder. If necessary, use a syringe or pipette to bring the volume to the desired amount. Read the volume of the liquid in the cylinder at the bottom of the meniscus at eye level. This applies to glass devices only; plastic devices have no meniscus.
4. Pour the liquid directly into the spray tank.

5. Rinse containers at least three times. Include the rinse solution volume in the total volume of the spray solution.

Air and positive displacement pipettes

1. Mount the capillary-piston according to manufacturer's instructions. Set the volume using the adjustable volumeter**.** To set a volume below the initial value shown on the volumeter, come slowly to the new value, making sure not to pass the required volume. To set a volume above the initial value shown on the volumeter, pass the required value by one-third of a turn and then come slowly back to the new volume, making sure not to pass the required volume.
2. To aspirate the liquid, press the push-button to the first stop, immerse the capillary into the liquid, and slowly release the push-button to draw up the liquid.
3. To dispense the liquid, depress the push-button slowly to the first stop.
4. Finally, eject the capillary-piston and dispose of it properly.
5. Troubleshooting: If the pipette leaks, change the capillary and piston. If the pipette has no stroke, check to see that the piston is seated correctly. If the capillary is difficult to fit, clean the capillary-holder with ethanol. If the amount of liquid measured appears inaccurate or imprecise, check to see if the capillary is correctly fitted and/or change the capillary and piston. If it is difficult to set the volume, the pipette may be damaged internally. In this case, the pipette should not be used and should be returned to manufacturer for repair.

Syringe

1. Using a clean, disposable positive displacement syringe, withdraw the required amount of pesticide concentrate from the container. If the syringe won't fit in the original container, transfer a portion of the test substance to a clean, unused disposable container or clean beaker. The remainder should then be transferred back to the original container.
2. Hold the syringe at the opening of the spray tank and discharge the pesticide concentrate from the syringe into the carrier (e.g., water) in the tank.
3. Disposable syringes do not need to be rinsed due to positive displacement.
4. Dispose of the syringe promptly and properly.

Other measuring devices

1. If devices not described in this SOP are used to measure liquids, detail their use in the trial records. Follow use instructions provided by the manufacturer.

Cleaning

1. Clean measuring devices using an appropriate solvent (e.g., water, soap, acetone). Do not use a solvent that will dissolve the measuring device.
2. If necessary, set aside a portion of the carrier to rinse the device used to measure the test substance. Rinse container at least three times. Include the volume of rinse solution in the total volume of spray solution.

7.4 Test Substance Application

Revision number: 2

Purpose: To ensure the proper application of test substances

Scope: All Compass AgriTech facilities/site

Procedures:

General guidelines

1. See SOPs 7.1, 7.2, and 7.3 for handling, storage, and measurement procedures.
2. Wear/use required personal protective equipment (PPE).
3. Spray equipment should be inspected and calibrated prior to use. See SOPs 4.2 and 4.3. Maintain the same speed and sprayer configuration (e.g., pressure, nozzle configuration, etc.) used in the successful calibration runs.
4. Follow protocol for maximum wind speed allowable for application. If no directions are given, do not spray when wind speed exceeds 10 MPH. When deciding whether or not to spray, consider the buffer area size, wind direction in relation to the untreated plot and other plots, the spray droplet size, etc.
5. Measure and record the environmental conditions required by the sponsor and/or protocol.

Methods of application

1. The following method may be used to apply the test substance to the test plot:
    a. Prepare more spray solution than needed to apply to the treated plot.
    b. When possible, start and stop spraying in buffer areas outside the test plot.
    c. Time the application between the plot markers with a stopwatch.
    d. Calculate the actual application rate.
    e. Excess spray should be applied to a crop or waste area well away (down-slope and downwind) from the plots or handled in another appropriate manner.
    f. Clean equipment. See SOPs 4.2 or 4.3.
2. When necessary, and if possible, apply test substances from the lowest concentration to the highest.
3. For greenhouse applications using fumigants or mist blowers, follow equipment manufacturer's use instructions.
4. The following formulas can be used to calculate the amount of test substance (TS) applied per acre:
    a. Total pass time × discharge rate per nozzle × the number of nozzles = amount of spray solution applied to plot

b. Amount of spray solution applied to plot × (amount of TS in tank mix ÷ total volume of tank mix) = amount of TS applied to plot
c. Amount of TS applied to plot × (43,560 sq. ft. ÷ plot area treated in sq. ft.) = amount of TS applied per acre

5. Other formulas may be used to calculate the actual application rate. Record all calculations, formulas, and results and define all units of measurement. Note: When calculating the amount of test substance to apply to the test plot, it is suggested, but not required, that the rate given in active ingredient and not actual product be used.
6. Record information in enough detail to reconstruct the procedure. Remember to make the appropriate entries in the sprayer log and the test substance use log.

Contingencies

1. If there is a problem with the sprayer during the application, stop immediately, turn off the boom, and stop the stopwatch. Safety of the applicator is the primary concern. If the equipment malfunction has resulted in exposure of the applicator to the test substance, immediate action should be taken to prevent further injury.
2. If the applicator is in no danger, note or flag the area where the application ended. If the malfunction did not affect the application to that point, corrective action should be taken and the application continued. Notify the study director as soon as possible after the application has been completed.
3. If a ruptured hose or plugged nozzle makes it is impossible to determine how much test substance was applied, note or flag that area and, if possible, exclude this area from sampling.
4. If the pressure drops during the application, measure the amount of spray mix remaining to determine the actual amount applied to the test plot. If the pressure increases, such that there is not enough mix to cover the plot, stop spraying when the sprayer begins to sputter. Measure the area sprayed to determine the actual amount applied.
5. If the wrong plot was sprayed and it is possible to re-flag and re-mark (i.e., switch plots) without affecting the integrity of the study, do so. Remember to make changes on the plot map.
6. If the actual amount(s) applied differ(s) from the protocol target rates, or the malfunction has affected the integrity of the trial, the study director and/or sponsor should be notified as soon as possible.
7. In all cases the data should accurately reflect what occurred and what course(s) of action was taken to preserve the integrity of the study.

8.1 Sample Collection and Storage

Revision number: 2

Purpose: To ensure samples are properly collected and handled to preserve their integrity.

Scope: Applies to all commodity samples collected for magnitude of residue trials

Procedures:

General guidelines

1. Refer to the protocol for instructions related to sample collection (days after last application, growth stage, plant part, sample size).
2. Collect the untreated samples first, then treated samples in order from lowest treated rate to highest.
3. Collect representative, impartial samples. Do not sample diseased, stressed or undersized crops at a stage that would not normally be harvested, unless specifically requested in the protocol.
4. Samples should be typical of the commercial commodity.
5. Record sampling procedures in detail.
6. Do not sub-sample the plants in the field (i.e., do not provide portions of plants unless specified in the protocol or otherwise allowed and documented).
7. Do not collect samples from the outside edges of the plot, or end trees, where there may not have been uniform coverage of the test substance at application.
8. Do not trim any samples in the field unless required by the protocol.
9. Do not wash any crop samples unless required by the protocol or sponsor. Follow protocol directions for removal of loose soil adhered to samples. Avoid removing surface residues during handling or packing.
10. If the samples cannot be placed in the freezers within four hours, or if ambient temperatures are high, samples should be immediately placed in an insulated container with block ice, cubed ice, blue ice, or dry ice. A minimum/maximum thermometer or other temperature-monitoring device should be placed in the container. If block ice or cubed ice is used, care should be exercised to keep the samples from getting wet. Plastic sample bags that have no fiber reinforcement should be protected from direct contact with dry ice because the extreme cold may cause the bags to crack. It is possible to actually freeze the samples in the field if enough dry ice is used. If this is the case, monitor the samples and record the time the samples were frozen. Record the time elapsed between sample collection and placement in the freezers.
11. See SOP 4.7 if borrowed or rented equipment is used for harvest and/or sample collection.

Sampling with commercial equipment

1. Some types of samples can be collected from small-scale or large-scale commercial harvesting equipment. Decontamination of this type of equipment is often best handled by running the harvester through a sufficient amount of the untreated crop to adequately clean it.
2. Avoid sampling from plot edges. Collect impartial, representative samples in a manner that will not require an excessive amount of commodity to be harvested. For example, small amounts of the requested commodity could be taken from the stream of the harvested commodity at numerous locations throughout the plot or the entire inner area of the plot may be harvested, thoroughly mixed, and samples collected from the mix. Remember to carefully follow the protocol and discuss methods to be used with study director as needed.
3. When moving from one plot to the next, be sure all of the commodity from the previous plot has been purged from the harvester before beginning to collect samples from the next plot.

Sampling with processing equipment

1. The guidelines outlined in the previous section also apply to processing equipment. Generally the equipment will need to be decontaminated by processing some untreated commodity through the system before collecting samples and when necessary between treatments.
2. As with all sampling methods, the untreated samples should be handled first, and then progress from the lowest treated rate to the highest. All of the commodity for each treatment must be purged from the equipment before a sample can be obtained from the next treatment. Particular care must be taken to ensure that the identity of each sample is maintained through all of the processing steps.

Preventing contamination

1. Physically separate untreated and treated samples, including those treated with different rates or formulations.
2. Use clean tools that have been appropriately decontaminated with a solution suitable for the chemistry involved. If necessary, work on a clean drop cloth to prevent the samples from coming in contact with the ground, truck bed, etc.
3. Collect samples from the untreated plots first, and then proceed from the lowest treated rate plots to the highest.
4. Do not contaminate samples with hands, clothes, or equipment that have been in contact with the test substance or other potential contaminants.
5. Use new storage bags only. Do not use torn or worn bags. Double bag samples that could be handled roughly or fruit samples with a high sugar content or liquid/juice.
6. Transport untreated and treated samples in separate coolers, or separate physically. Thoroughly clean coolers, inside and out, prior to each use, using soap and water or other cleaner.
7. Avoid transporting residue samples in vehicles carrying pesticides or contaminated equipment. If this is not possible, take appropriate action to ensure

samples will not be contaminated, e.g. physical separation, wash/clean area to be used, use plastic tarps or bags to isolate samples from contaminated areas/items.

8. Avoid packing, storing, or freezing residue samples in areas that may be contaminated with pesticides.
9. The method of decontamination for equipment and personnel should be noted in the raw data.

Sample identification

1. Label sample bags according to protocol.
2. Labels should be attached to the bags in a way that prevents their accidental removal or destruction.
3. If a code or sample number is used, provide a key to the codes in the raw data. Often the protocol will designate sample numbers in advance. If not, a system should be devised to ensure that the samples are positively identified both at the field site and at the laboratory.

Sample storage

1. Store samples in an area with limited access.
2. If possible, store untreated and treated samples in separate freezers. If they are to be stored in the same freezer, physically separate them.
3. Placing several samples in the freezer at once or removing several for transport may cause the temperature to rise significantly. These events should be noted on temperature records log or on the thermograph chart, particularly if the temperature exceeds 32° F.
4. Record movement of samples in and out of freezers in the appropriate freezer contents log. Include the date and time samples were placed in the freezer, the study number, initials of person placing samples in freezer, date and time removed from freezer, initials of person removing samples from freezer, and a description of the samples (identification number, sample identifier, and/or number of samples).

8.2 Sample Shipment

Revision number: 0

Purpose: To ensure residue samples are properly packaged and shipped

Scope: Applies to all magnitude of residue crop samples

Procedures:

Sample packaging

1. Follow sponsor or protocol instructions for packaging residue samples for shipment. If none are given, use the following procedure:
    a. Use the boxes provided by the sponsor or use clean, sturdy boxes if none are provided.
    b. Label boxes with the study or trial number, the treatment number, sample identification codes assigned to the samples within the box, type of sample (untreated or treated) and name of crop and/or crop part.
2. If boxes are packed with dry ice, they must be labeled with the appropriate warnings and codes required by law. The shipping company can provide this information. When shipping by airfreight, always write on boxes that there are important frozen samples within that must not be defrosted.
3. If more than one box is sent to a location, the boxes should be marked to indicate the number of boxes sent in that shipment (e.g., 1 of 3, 2 of 3, and 3 of 3).
4. Untreated samples and treated samples should be packaged in separate boxes. If this is not feasible then some kind of separation should be designed within the box to prevent contamination.
5. The appropriate paperwork should be included in each box shipped.
6. After placing samples in the boxes, close and tape all boxes securely shut to prevent accidental opening during shipment.
7. If possible, return samples to freezers after packaging. If this is not possible, monitor the sample temperatures while awaiting pickup. If the temperatures begin to rise above freezing, unpack the samples and return to the freezer or pack samples with dry ice. Record procedures taken to package and hold samples for shipment. Also record time of packaging, time of transfer to carrier, and storage temperature of samples while awaiting pickup by carrier.
8. Record the necessary information in the field data book or similar document.
9. The bill of lading or similar document from the shipping company is a critical piece of raw data for the study. The study ID number must be written on the bill of lading or similar document. It is recommended that the sample numbers contained in each box be indicated on the bill of lading or similar document.

10. Prior to shipment, notify the receiving party of the shipping date, carrier, and if possible, an estimated date of arrival. Remember, the integrity of the sample is our responsibility until the receiver at the shipping destination has signed the chain of custody document and taken custody of the samples. Document all communication between sender and receiver of samples in the raw data.

Sample shipment by airfreight

1. Follow specific protocol procedures for shipment by airfreight.
2. Ship samples by a pre-approved overnight airfreight carrier only, typically Fed Ex.
3. Use insulated boxes or coolers if required.
4. Use an adequate amount of dry ice to ensure that samples do not thaw during shipment. The amount of dry ice in the box must be written as "XX pounds dry ice" on the outside of each box.
5. When necessary, protect samples from direct contact with the dry ice by wrapping paper around the dry ice or sample bag(s). This will prevent sample bags from becoming brittle and breaking, and potentially spilling the sample inside the box. Poly-impregnated cloth bags do not usually require extra protection.
6. Notify the lab prior to shipment.
7. Record notification of sample shipment and receipt in the raw data.
8. Ship only on Monday, Tuesday, Wednesday, or Thursday of non-holiday weeks so that it can be assured that someone will be present at the lab to accept the samples and keep them frozen. If samples must be shipped on Friday or Saturday, make prior arrangements for receipt.

Sample shipment by freezer truck

1. Dry ice and insulated boxes are not needed for shipment of residue samples by freezer truck.
2. If possible, return samples to freezers after packaging. If this is not possible, package samples immediately prior to shipment. Monitor the sample temperatures while awaiting pickup. If the temperatures begin to rise above freezing, unpack the samples and return to the freezer or pack samples with dry ice. Record procedures taken to package and hold samples for shipment. Also record time of packaging, time of transfer to carrier, and storage temperature of samples while awaiting pickup by carrier.

8.3 Soil Sampling

Revision number: 0

Purpose: Describes proper methods for soil sample collection and analysis

Scope: Applies to all research conducted by Compass AgriTech

Procedures:

Residue analysis sampling

1. Specific instructions for collecting soil residue samples, including sampling times and depths, will be given in the protocols for individual residue trials. These instructions will be followed carefully and documented in the study data.
2. To avoid cross contamination, buffer areas should be established around each plot, especially in test areas with uneven topography. The untreated and treated plots should be separated by buffer zones.
3. Remove excess stubble or straw from the soil surface before sampling, unless otherwise indicated in the protocol.
4. Decontaminate all sampling tools prior to use by washing and scrubbing them with soap and water. Remove any adhered soil using a brush or tool. Based on prior use, tools may need to be cleaned using ammonia or other solvent and then rinsed with water. Record the type of equipment used for sampling and decontamination measures taken.
5. Samples should be collected first from the untreated plot, then from lowest treated rate plots to highest, for each compound or combination. If several compounds or combinations are sampled in the study, a different sampling device should be used for each compound or combination. If this is not possible, the sampling device should be properly decontaminated between each compound or combination.
6. Accurately measure and record the length of each sample collected. For example, if 0-3 inch and 3-6 inch samples are required, use a soil probe to collect a core to a depth of 7 inches. The two individual samples should then be carefully measured and cut to the appropriate lengths. Record all procedures in the study data.
7. To collect a representative sample from a 10 ft. by 30 ft. plot, a minimum of 10 cores should be taken per sampling time. The total sample weight should be at least two pounds. If necessary, collect more than 10 cores to meet the two-pound requirement. If the experiment requires the collection of more than a total of 100 cores per plot, the plot sizes should be greater than 10 ft. by 30 ft. In most cases, it is better to increase plot length rather than plot width.

Characterization analysis sampling

1. Sampling tools
    a. The preferred tool for collecting soil samples is a soil probe. In cases where very hard or stony soil is encountered and the use of a soil probe is not practical, a shovel or trowel should be used. Sampling tools should be free of soil and debris.
2. Number of sample sites and techniques
    a. If soil conditions in the experimental area appear uniform, then one composite sample from the area should be taken. If soil conditions do not appear uniform, then samples should be taken either by replication or by combining samples from similar areas to give a number of samples that will provide a representative analysis of the area.
    b. At least 10 cores from the test area or replicated block should be taken to obtain a representative composite sample. Before bagging the soil core, scrape off the top debris or surface residues. When sampling a field that has been in row crops, sample between the rows to avoid fertilizer band areas. However, if a pesticide in question has been applied as a band, then sample within the row and note this in the study data.
    c. The soil cores should be placed in a clean sample bag and labeled with a study ID number or other unique identifier.
3. For trials using a soilless growing media, no analysis needs to be conducted. Instead, record information that describes the media's manufacturer, components, pH, etc.

Shipping instructions and distribution of results

1. Ship or deliver the individual soil samples to the testing lab as soon as practical after collection. Soil samples do not have to be dried or sieved; however, wet soil samples should not be stored for a long time before being shipped or delivered to the testing lab. Do not oven dry soil samples. Be sure to include the appropriate information with the soil samples. Consult the protocol to ensure that the required analyses are performed. Request a separate analysis report for each sample.
2. File the original soil analysis report with the raw data and fill out the appropriate pages in the field data book. In addition to the soil analysis results, retain any copies of information related to the general soil description, chemical and physical properties of the soil, and location of the field studies as they appear on soil survey maps.

9.1 Quality Assurance Audits and Inspections

Revision number: 2

Purpose: To identify the quality assurance unit for trials conducted by Compass AgriTech

Scope: Applies to all research performed by the Compass AgriTech that is subject to Good Laboratory Practice standards

Procedures:

1. The sponsor will designate the Quality Assurance (QA) personnel responsible for audits and inspections.
2. A quality assurance audit is an inspection of a facility or operation performed by the study sponsor's Quality Assurance Unit or a contract QA auditor. There are two types of audits/inspections. The first, a facility inspection, is an inspection of equipment, facility records, and SOPs. The second, a critical phase audit, is an inspection of a particular trial procedure as it is being performed, e.g. test substance application, sample collection or sample shipping.
3. The Field Research Director/PI will provide the Quality Assurance personnel with the SOPs applicable to the audit/inspection being performed.
4. The Field Research Director/PI will respond, in writing, to the audit/inspection findings within 30 days of receipt of the audit/inspection report.

9.2 EPA Inspections

Revision number: 1

Purpose: To ensure that personnel and facilities are properly prepared for an EPA inspection

Scope: Applies to all Compass AgriTech personnel, facilities, and files

Procedures:

Before the Inspection

1. Notify the sponsor(s) and other interested personnel of the pending audit or review as soon as possible.
2. Arrange to have personnel available who are associated with the trial(s) or facilities to be inspected.
3. Make sure someone who is authorized to accept the Notice of Inspection is present at the start and finish of the inspection.
4. Prepare trial(s) and/or facilities and personnel for the inspection.
    a. Review position descriptions with technical personnel so they understand and can explain their role in the trial(s).
    b. Discuss possible questions about the trial(s) or facility and make sure everyone understands what to expect.
    c. Personnel should answer questions only to the extent needed and should not provide extraneous information. Do not volunteer information; keep answers direct and to the point.
    d. Make certain that technical personnel know the safety precautions needed for work areas.
    e. Make sure all documents related to the trial(s)/facilities being inspected are available. These include:
        1. Master schedules.
        2. Study Protocol and Standard Operating Procedures.
        3. Raw data, correspondence and logs.
        4. Current summary of training and experience (resume, CV, or professional biography) and a job description for each person involved with the trial(s), including supervisors.
        5. Appropriate chain of custody documents for samples. Freezer logs and storage temperature documentation.
        6. Documents related to test substance characterization, receipt, handling, and storage.
        7. Calibration/standardization records for equipment.

8. Archived records and logs used to record removal and replacement of documents.

5. Ensure that organizational charts, facility maps, and any information specific to the facility or work area(s) that will make the inspection go smoothly are accessible.

During the Inspection

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

After the Inspection

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