2023 NMSU IR-4 STANDARD OPERATING PROCEDURES

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SOPs reviewed & submitted by: William Man (Field Research Director)

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Date: <u>17 April 2023</u> Date: <u>4/12/2023</u>

SOPs approved by: (Assistant Field Research Coordinator Western Region IR-4 Center, UCD)

Mika Tolson

Personnel Records and the Organizational Chart

SOP Number: 1101 Revision Number: 06

I. Subject: Maintaining Personnel Records

A. This SOP contains information on documenting and maintaining individual personnel records and organizational charts. Individuals engaged in the conduct of a study need to document relevant education, training, and experience.

B. This SOP applies to all GLP trials conducted by NMSU IR-4

II. Procedure

A. Keep the following signed and dated documents, or certified copies, on file.

1. A Résumé, Curriculum Vitae (CV) or similar documentation that lists education, experience, and training for each individual

2. A continuous training record for all personnel--record the training event and/or the applicable SOP number, the date of the instruction, and who conducted the training.

3. Current job descriptions

4. Current organizational charts showing all positions within the organization and their relation to each other--an organizational chart will be updated each time there is a change in personnel or position.

B. Review all personnel records and organizational charts approximately annually, and update as needed. Retain certified copies of outdated résumés/CVs, job descriptions, and organizational charts.

C. Retain certified copies of résumés /CVs, job descriptions, and training records of personnel who have left.

D. Temporary workers may occasionally be necessary for assistance with harvest, sample collection, or other aspects of a trial. No CV or personnel short form will be required for this work. However, documentation should be added to the field data notebook with the names of the workers, a short description of how they were trained and supervised, and the work they performed in the trial.

Standard Operating Procedure for SOPs

SOP Number: 1121

Revision Number: 08

I. Subject Standard Operating Procedures

This SOP contains information on the content, writing, revising, filing, and use of SOPs.

II. SOP Content and Format:

A. Maintain written standard operating procedures that adequately detail all study methods and ensure the quality and integrity of all data generated during the course of a study. Write SOPs in electronic format (MS Word) as an extended master file that should include the following:

- 1. All current individual SOPs
- 2. A table of contents which contains an area for approval of SOPs
- B. Individual SOPs should include the following:
 - 1. A descriptive title and a unique identification number

2. A two-digit revision number--the most current SOP should have the highest revision number. Use 00 for new SOPs.

3. A brief description of the subject and scope of the SOP

4. Adequate details of methods and procedures and the location where corresponding data is recorded.

III. Writing SOPs:

A. Write SOPs for all equipment and for any procedure that might require an SOP.

B. Via e-mail, submit an electronic copy of the SOPs to appropriate personnel in the Western Region IR-4 for review and correction.

C. When the review process is completed, the SOP Table of Contents is signed and dated by the Western Region IR-4 representative. SOPs are effective as of the approval date.

D. Keep a printed copy of the current approved SOPs with an original, signed Table of Contents as the official NMSU SOP set, and make all working copies from this copy.

IV. Reviewing and revising SOPs

A. Review SOPs approximately biennially.

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1. Make electronic revisions or additions to the current SOP file. A "revision" provides a substantive change in the meaning of the SOP. Correcting spelling and formatting errors along with making minor changes that clarify the intended meaning of the SOP do not constitute a revision.

2. If an SOP is retired, remove it from the SOPs and Table of Contents and add it to the Retired and Recalled SOP list. It should remain on this list for at least one year following retirement, but may be removed in future years.

3. Submit an electronic copy of the revised file to Western Region IR-4 personnel for review, correction, and approval process.

B. Discard the old copies of SOP files in the applicable SOP books and replace with copies of the newest revision.

C. After a QA inspection, the QA auditor and NMSU IR-4 personnel will discuss the SOPs used, make any recommended revisions, and/or write additional SOPs.

D. Retain copies of original and historic SOPs in the NMSU IR-4 Retention File.

V. Using SOPs

A. Use only SOPs with the highest revision number. Keep current versions in the SOP books, in electronic format, and in the NMSU file. Individual SOPs may be placed in pertinent logbooks to provide quick reference.

B. Keep a copy of SOPs readily available to all personnel for reference.

C. Employees should familiarize themselves with all SOPs.

D. Follow all applicable, current SOPs for equipment and procedures used during a study.

E. NMSU SOPs or forms do not need to be followed when a study protocol specifies a different procedure from that contained in an SOP.

Making Certified Copies

SOP Number: 1142 Revision Number: 04

I. Subject: Making Certified Copies of Raw Data

This SOP contains information on the procedure for making certified true copies of raw data, study documents, or other pertinent information.

II. Procedure

A. All copies of documents containing raw data must be stamped with a certified true copy stamp.

1. Make a copy of the raw data/study documents and place the stamp on the page so as not to obscure any information.

2. If the context of the document does not indicate where original is located, provide the location of the original document.

3. Initial and date in the space provided.

B. Documents that are bound together (i.e., binders, binder clips, etc.) and contain more than one page may be stamped with the certified true copy stamp on the first page only. If more than one page is copied, include the number of pages pertaining to the document.

Equipment Maintenance

SOP Number: 1203 Revision Number: 06

I. Subject: Documenting Equipment Maintenance.

A. Equipment used in field studies is to be adequately inspected, cleaned and maintained, and adequately tested, calibrated or standardized.

B. This SOP contains information for keeping equipment maintenance logs and for documenting non-routine maintenance.

C. This SOP does not apply to equipment used for field maintenance operations (tractors, irrigation equipment, discs, hoes etc.)

D. The Field Research Director is responsible for the performance, use, and maintenance of all study-related equipment.

II. Procedure:

A. If the equipment has an SOP, follow the SOP. Specific SOPs cover maintenance, cleaning and calibration/verification records for equipment used in GLP critical phases. This equipment includes, but is not limited to:

- 1. Balances used for weighing test material
- 2. Spray equipment used for applying test material
- 3. Sample storage freezers
- 4. Thermometers and other temperature recording equipment

B. Fill out equipment logs according to III and IV below. Logging the <u>use</u> of a piece of equipment is not required, but may be entered in a log in order to facilitate record keeping.

C. If equipment is leased or borrowed, refer to SOP 2201, Using Borrowed Equipment.

III. Routine maintenance

A. Routine maintenance is conducted due to wear attributable to normal use. Examples include checking assembly and operation, calibrating, cleaning, replacing hoses, seals etc.

B. Document routine maintenance in a maintenance log. Include the following information: name or description of equipment, date of activity, maintenance conducted, whether the maintenance was routine or non-routine, whether or not the SOP was followed, initials, and date of entry.

IV. Non-routine maintenance

A. Non-routine maintenance is conducted if a problem is encountered which might affect the integrity of collected data, or if equipment malfunctions and requires major repair or replacement.

B. Staff needs to document non-routine maintenance in a maintenance log, either directly or by using a non-routine maintenance form. Include the following information: date of occurrence, name or description of the equipment, nature of defect or problem, how and when the problem was discovered, repairs conducted or remedial action taken, and by whom, and initials/date of entry.

Collecting Raw Data and Rounding Numerical Data

SOP Number: 1302 Revision Number: 04

- I. Subject: Recording Raw Data and Correcting Errors
 - A. Recording raw data and correcting errors to the raw data.
 - B. Rounding numerical data entries and calculations.
- II. Procedure for recording raw data

A. Record all data in ink. All entries should be clear, understandable, and legible. Make entries as soon as possible after the event has occurred.

B. When an error is discovered or has occurred, draw a single line through the incorrect entry, and enter the correct data as near as possible. Initial and date the correction and classify it with one or more of the error codes listed in the front of the IR-4 Field Data Book.

C. If error codes are not provided or if other error codes are used, the codes must be entered or noted in the Field Data Book. (The following list may be used.)

AW = Accidental Write over	CA = Change or added wording for greater clarity.
CE = Calculation Error	EE = Entry Error
IC = Incorrect Comment	IE = Illegible Entry
IW = Inappropriate Word	LE = Late Entry
LLASC = Los Lunas Ag	ME = Measurement Error
Science Center	NA = Not Applicable
PE = Pagination Error	SE = Spelling Error
TE = Transcription Error	UE = Unnecessary Entry
WE = Wrong Entry	

If the codes inadequately describe the area or if more detail is needed, annotate, add footnotes, or otherwise write a reason for the correction.

IV. Procedure for rounding numerical data entries and calculations

A. For measurements, record to the degree of accuracy of the device used for the measurement (E.g. if reading from a balance that records to 0.1 g., record 12.3 g., not 12.30 g.)

B. Where applicable, round decimal numbers to the nearest hundredth (second number to the right of the decimal).

C. An exception is that temperature data may be rounded to the nearest whole degree.

D. Do not round any numbers within a calculation, round only the final result. Look at the digit following the digit that is to be last.

If less than 5, drop this digit and all digits to the right (1.2345 = 1.23)If equal to or greater than 5, increase the rounded digit by 1 (12.345 = 12.35)

Significant figures of measurements used in the calculation can be used for guidance on where to round the final result.

E. Conversion factors and other constants (e.g., sq. ft./acre, lbs a.i./gal) are not measurements and do not need to be rounded.

Taking Environmental and Crop Data, Verifying a Weather Meter and Collecting Phytotoxicity Data

SOP Number: 1303 Revision Number: 09

I. Subject: Taking environmental and crop data during test substance application for inclusion in the Field Data Book, and verifying weather meters.

A. This SOP describes the following procedures:

1. Taking temperatures (air and soil), relative humidity, and wind speed during a critical phase of a study.

- 2. Verifying weather meters using the Weather Meter Verification Form
- 3. Collecting phytotoxicity data.

III. Collecting environmental data and verifying weather meters

A. The soil temperature, air temperature, relative humidity, and wind speed will be recorded from an area as close to the test plots as possible. Record all information prior to, during, or immediately following an application.

B. Soil Temperature

1. Insert the soil thermometer approximately 2 - 4 inches into the soil within or near the nearest test plot.

2. Allow the thermometer to remain in the ground for at least 1 minute before reading it.

3. Remove the soil thermometer, clean off any soil, and put the thermometer away.

C. Wind Speed, Air Temperature and Relative Humidity – record the wind speed, relative humidity and air temperature using the KestrelPocket Weather Meter or other suitable instruments.

1. Turn the unit on and select the operating mode. (For more information see the operating instructions.)

2. Wind Speed: Direct the anemometer into the airflow you wish to measure. Read average wind speed.

3. Air Temperature and Humidity: Wave the unit rapidly back and forth, or hold it into an airflow of at least 2 MPH and read the display immediately. (The airflow ensures that the temperature sensor measures the temperature of the air and not the case.)

D. Verifying the weather meter:

1. Approximately yearly, and before the year's first trial verify the wind speed and relative humidity readings of the weather meter against another weather meter or similar instrument. Any general purpose fan may be utilized.

2. Record results on the Weather Meter Verification form or similar

3. Acceptable average limits are: low wind speed, all Kestrels average should be within 1 mph with fan setting on low; high wind speed, all Kestrels average should be within 4 mph with fan setting on high; relative humidity, $\pm 10\%$

E. Storage of the KestrelPocket Weather Meter

1. Avoid storing where it will be exposed to temperatures below $-4^{\circ}F$ (-20°C) or above 176°F (80°C) for extended periods of time. Doing so may permanently damage the LCD, electronics, battery, or enclosure. If the temperature of the actual LCD of the unit exceeds 158°F (70°C), it will temporarily become solid black until it cools down to below this temperature.

- 2. See the operating instructions for additional information.
- F. If a weather meter is not operating correctly, repair or replace it
- III. Collecting phytotoxicity data

Refer to the protocol to determine if phytotoxicity data are required and how data are to be collected. If in doubt, consult the Study Director. If data is not required, data does not need to be recorded, but the crop should be checked periodically for stunting, chlorosis, and other evidence of phytotoxicity.

A. Review the protocol to determine the method and timing of collecting phytotoxicity data. If no method is cited, follow the procedure below:

1. When possible, record phytotoxicity data at an appropriate time after the application

2. Observe all plots and rate the phytotoxicity on a scale of 0 to 100%. Zero percent = no phytotoxicity and 100% = completely dead. The rating between 0 and 100% indicates the degree of injury expressed as stunting, necrosis, chlorosis, leaf deformation, etc.

3. Document the use of other rating scales.

Collecting a Soil Sample

SOP Number: 1304 Revision Number: 04

I. Subject: Collecting a Soil Sample

This SOP describes the procedure for collecting, storing, and shipping a soil sample for soil characterization

II. Procedure:

A. Take 6-8 inch deep soil core samples using a core sampler. Take 5 - 10 (more if necessary) samples from each field or test plot. Walk in a zigzag pattern across the area, taking samples such that all parts of the area are represented.

B. Combine and thoroughly mix all individual soil cores in a clean container. Take a composite sample from this mixture and place it into a soil sample bag (from the desired analysis lab) or any other container provided. Close the sample container.

C. Label the sample with the information requested. If sampling is conducted for a specific trial, also include the study number, date, and the collector's initials.

D. Store the sample in a clean, dry location.

E. Take the sample to a local testing laboratory to conduct a 'Standard Soil Test', plus any other testing if required by protocol. Alternatively, ship the sample to an analysis lab for required testing.

Crop Sampling, Storing and Shipping, and Freezers

SOP Number: 1309 Revision Number: 18

I. Subject:

A. This SOP describes the procedures for sampling, storing, and shipping crop samples as required by the study protocol and Field Data Book guidelines.

B. Sampling comprises all sample collection procedures, from preparing and cleaning sampling equipment to shipping samples to the analytical laboratory. Document sampling procedures in the Field Data Book.

II. Sampling

A. Before each sampling critical phase, decontaminate all tools, including ice chests, bins, and buckets, knives, cutting boards etc., by washing with soap and water or by wiping down with an appropriate solvent.

B. Do not wear contaminated clothing.

C. When hand-sampling plots, wear a clean pair of protective gloves (nitrile or latex) while collecting treated samples.

D. Use new sample bags that have been stored in clean containers away from any chemicals or application equipment.

E. Sample untreated control plots first, then treated plot(s). When sampling multiple treated plots, minimize possible cross-contamination among plots (e.g., change gloves, decontaminate tools, sample in order of increasing potential for residues etc.)

F. Collect samples at an appropriate distance from the ends and sides of the plot. Collect each sample by a separate run through the plot. Samples should be representative of the entire plot. Please refer to protocol in FDB for specific requirements. Usually plot ends should be avoided from being sampled, approximately 5 feet into plot and outside rows should usually not be harvested.

G. If required by the study protocol, or if needed to clarify how sampling was conducted, complete a sampling diagram in the Field Data Book showing the location where samples were collected within the plot.

H. Handle samples gently to avoid removing any residues. If needed and allowed by the protocol, gently clean samples, and place in sample bags. Place TRT and UTC separately into plastic bags, labeled with IDs of contents.

I. Sample weighing is conducted by transporting a mechanical portion scale to the plot site. If scale cannot be transported or is inadequate, samples can be transported to the chem. lab on site to be weighed with a larger digital scale or mechanical portion scale. Samples are collected and placed into IR-4 sample bags and weighed

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or collected in buckets and transported to be reduced in size and then placed into IR-4 sample bags and weighed.

J. If transfer of samples to freezer may exceed protocol time constraints, place bagged samples into clean ice chests. Put ice or substitute ice (blue ice) in the cooler with the samples to keep them cool. Include an appropriate temperature-monitoring device in each ice chest.

K. In general, do not put treated samples in the same ice chest as untreated samples. If this must be done, physically separate treated and untreated samples with additional plastic bags (minimum double bagged) or similar barriers to prevent contamination.

III. Sample storage

A. Consider all samples perishable. Freeze the samples as soon as possible after collection.

B. Maintain a freezer log for each freezer in order to keep a record of freezer maintenance (reference: SOP 2401) and temp. monitoring equipment maintenance (reference SOP 2221), as well as sample inventory and min/max temperatures.

C. In general, do not put treated and untreated samples in the same freezer. If necessary, samples may be stored in the same freezer if TRT and UTC sample bags are contained in separate, doubled plastic garbage bags as previously described.

D. In general, maintain sample freezer temperatures at less than 0° F. Temperatures in freezers typically should not exceed ~10-15°F. However, on days when freezers are opened, such as when samples are added or removed, air temperatures in freezers may temporarily spike. These spikes don't compromise sample integrity.

E. Maintain a sample inventory record for all samples that are in a freezer. Record the following information in inventory record: 1) Date/time of activity, 2) Trial ID number 3) Sample ID, 4) Sample description, 5) whether the sample is being entered or removed, 6) initials.

IV. Freezer monitor/alarm

A. Equip freezers with an alarm system that alerts at least two responders (e.g., FRD and assistant/technician) when temperature in a freezer rises above a critical temperature (>15 F)

B. While samples are in the freezer and the alarm system is turned off, malfunctioning or otherwise inoperable, record min/max temps in the freezer log until alarm is operable.

C. Record alarm events and how events were resolved in the freezer log.

D. Record malfunctions or maintenance of alarm system in the freezer log.

E. Test alarm system for proper operation at start of season prior to adding samples, and record alarm test in freezer log.

1. The alarm should be tested in case of freezer malfunction and for power outages.

2. Freezer malfunction will be tested by removing the temperature probe from the freezer and allowing it to warm up until it reaches the alarm threshold.

3. Backup battery for the freezer alarm system will be checked approximately annually when freezers are on. Backup up battery is located in the panel box of the alarm system in room WT 148 Communications on the first floor of Skeen Hall, and is managed by NMSU Facility Services (FS). The battery is tested by NMSU FSs and should read above 4.55 Amp Hrs. Battery should be scheduled for replacement every 4-5 years or when Amp Hrs dropped below 4.55 Amp Hrs.

4. Documentation should include the date and time of the test, temperature at which the alarm engaged, time(s) messages were received, and personnel contacted.

5. If alarm did not work properly in the test, complete repairs as soon as possible, document corrective actions, and conduct a subsequent test to ensure the system is working. Contact NMSU FS at 575-646-7070 for further assistance. Place work order through Admin at Extension Plant Sciences offices.

V. Data Loggers

A. While samples are in freezers, deploy a data logger in each freezer to continuously log storage temperatures. Additional loggers may be used if needed.

B. Launch loggers so that they record temperatures at least every 4 hours.

C. Suspend logger probes to capture temperatures at the top and bottom 1/3 of the freezer box.

D. Temperature records may be downloaded and printed via Traceable® platform for the deployment period.

E. Record malfunctions or maintenance of deployed loggers in freezer log.

VI. Minimum/maximum digital thermometers

A. While samples are in freezers, deploy a min/max thermometer in each freezer. Suspend probes to record mid 1/3 of the freezer box. Record the min/max temps at least once a week and/or when accessing the freezers. This will be the primary temperature record and the data loggers will serve as the backup. B. Record malfunction or maintenance of thermometers in freezer log

VII. Remedial action in event of freezer malfunction

A. If a freezer malfunctions while holding samples and cannot be immediately repaired or replaced, or if there is an electrical outage which lasts long enough to possibly compromise integrity of samples, maintain integrity of frozen samples. Move samples to the adjacent freezer or other functioning freezer.

B. If samples are temporarily stored in another sample freezer. Physically separate treated and untreated samples. Temperature monitoring of samples must be maintained in other freezers using a min/max thermometer and/or a data logger.

C. If all freezers are inoperable, or if there is insufficient storage space in other freezers, maintain integrity of frozen samples.

1. <u>Transfer samples to another suitable freezer</u>: At minimum, place samples in doubled garbage bags or otherwise physically separate treated from untreated samples. Place samples and temperature-recording equipment into appropriate transfer containers, and transfer to a suitable backup freezer. <u>If a non-GLP freezer is used, fill out a **Using Borrowed Equipment form**</u>

2. <u>Optional: Add dry ice to freezer:</u> Protect sample bags from direct contact with dry ice by covering them with cardboard, layers of newspaper etc. Add sufficient dry ice to maintain freezer box temperatures below freezing. Add additional dry ice as needed.

3. After the freezer malfunction has been corrected, put samples and temperature recording equipment back into designated freezer(s).

D. During a freezer malfunction, document times, temperatures and all procedures followed to ensure sample integrity.

VIII. Shipping

A. General shipping procedures

1. Ship samples in an appropriate container, weighing no more than 70lbs.

2. Log out samples from the sample storage freezers and place them in the sample shipping containers. If there is sufficient room, both treated and untreated samples may be placed in the same container. Separate samples by sealing treated and untreated samples separately in plastic garbage bags (minimum double bagged) or other suitable barriers to prevent contamination.

3. Place the sample shipping and handling form and the chain of custody form in a sealable plastic bag and put inside the container.

4. Seal all box seams with packing tape.

5. Add labeling showing where the samples are to be shipped, the study number, and a box number, if needed (box 1 of 2, of 3, etc.). Use permanent ink or else cover labeling with clear packing tape to prevent smearing.

6. Phone or email the analysis laboratory before and/or shortly after shipping to inform them of the shipment, following the instructions in the protocol

- B. If shipping via ACDS freezer truck:
 - 1. Contact ACDS personnel to arrange pick up date and time.
 - 2. Ship samples in heavy-duty cardboard boxes.
- C. If shipping via FedEx or other overnight courier service:
 - 1. Contact the receiving lab before shipping for specific instructions.
 - 2. Ship samples in insulated shipping boxes or ice chests

3. Pack the samples with and adequate amount of dry ice per box. Separate samples from dry ice with suitable packing material.

4. Ship samples Monday – Wednesday and avoid shipping just before any major holidays. Please note ACDS scheduling needs to be taken into account.

Retention File and Archives

SOP Number: 1401 Revision Number: 11

I. Subject: Maintaining the Retention File and archiving records

A. This SOP contains guidance for maintaining records at the NMSU IR-4 Field Research Center, and for sending original documents to the archive.

B. IR-4 Project Headquarters will archive NMSU facility and study-related records.

II. Procedures for maintaining facility and study-related records at NMSU are as follows:

A. NMSU will retain original study-related raw data and other facility records for active (current crop year) studies, and copies of past records for 2 years.

B. Store original records in an organized and secure manner (e.g., in a file cabinet in a locked room). Access to records will be limited to NMSU IR-4 personnel.

C. NMSU Document Retention and Disposal

1. Copies of all study-specific documents are retained for 2 years

2. Copies of completed FDBs are retained until the current FDB is scanned and available on the WR IR-4 Website. Changed pages from QC reviews are printed out and kept with the copies of the FDBs until the current FDB is rescanned and re-posted on the WR IR-4 Website.

3. Documents older than 2 years may be shredded with an appropriate secured document shredding service.

III. Procedures for archiving original documents at IR-4 HQ

A. The archiving schedule and content of items to be archived will be determined by the Field Research Director.

B. Fill out an *IR-4 Raw Data and Documents Transfer Form*, or similar form, to include the following: An inventory of all documents to be shipped to HQ, name of originator and date of shipment, the shipping service and tracking number of the shipment, prompts for recipient to verify inventory, sign and date

C. Prior to shipment, make certified copies of all documents (including transfer form) for retention in NMSU File.

D. Staff must ship original documents, inventory, and chain of custody to IR-4 Headquarters. Send a copy of the archive documents chain of custody to the Western Region IR-4 office at UC Davis.

Maintaining a Facility Floor Plan

SOP Number: 1501 Revision Number: 06

I. Subject: Maintaining a Facility Floor Plan

This SOP contains information on maintaining a facility floor plan.

II. Procedure:

- A. Maintain a current facility floor plan. Include, at a minimum, the location of:
 - 1. Test substance storage areas.
 - 2. Location of Retention Files and other data storage cabinets
 - 3. Freezers
 - 4. Equipment storage areas
- B. Sign and date the Floor Plan form.

C. Prepare new floor plans whenever necessary. Review floor plans at approximately yearly intervals. If changes are required, make changes, then sign and date the new document. Retain copies of current and historic forms.

Contingency for Discontinuing the NMSU IR-4 Research Center

SOP Number: 1502 Revision Number: 02

I. Subject: Contingency for discontinuing or closing the NMSU IR-4 Research Center.

A. This SOP contains information for the disposition of study specific and facility records in the event that the NMSU IR-4 Research Center ceases operation.

II. Procedure

A. The IR-4 Study Director will be contacted and the disposition of study specific records (copies of field data books) will be determined by the Study Director.

B. All facility records will be permanently archived at IR-4 Headquarters.

Trial Site Information and GPS Use and Maintenance

SOP Number: 1511 Revision Number: 10

I. Subject: Trial Site Information and GPS Use

This SOP contains information for plot layout, recording trial location, plot location, and plot design.

II. Procedure

A. Provide directions to and/or maps of trial site and test plot area, and a plot plan as required in the FDB.

B. Establish test plots within the test system according to the protocol. Be sure to do the following:

- Ensure that the plot location is free of conflicting chemical residues from past applications. This may be done by utilizing historical data.
- Lay out plots to meet protocol requirements.
- Mark all corners of plots with survey flags or equivalent. Test systems consisting of single rows (e.g., orchards, vineyards etc.) may be marked by flagging the ends of the selected row areas. Use a plot identifier for each plot (or row) that clearly identifies the treatment number/type, trial ID#, and any other necessary information.
- Establish the location of the nearest permanent marker using geographic coordinates following the World Geodetic System (GoogleMaps) and measure distances from this marker to two corners of each plot using a tape measure.
- Establish adequate buffer zones between plots. If possible, locate the control plot upslope and upwind from the treated plot.
- If GPS will be used to identify the plot locations in the Field Data Notebook, verification will occur approximately annually and be recorded in logbook before trial plots are marked.

Test System Preparation and Care

SOP Number: 1513 Revision Number: 05

I. Subject: Test System Preparation and Care

A. This SOP contains a summarization of the necessary tasks that should be performed for test site preparation as well as suggestions on test system care and maintenance.

II. Procedure

A. Conduct field preparation and establish the test system using practices commonly used within the growing region or as stated in the study protocol.

B. Perform the necessary fertilization, irrigation, pest control, and care to a test system to ensure that disease, insects, weeds, or other conditions do not interfere with the purpose or conduct of the study. Conduct maintenance operations in the untreated plot first.

C. If a test system develops conditions that could interfere with a study, then:

1. The Field Research Director is responsible for diagnosing the problem and determining treatment options, or having the problem diagnosed by a specialist.

2. The Field Research Director will arrange the application/treatment. The Field Research Director will communicate with the Study Director to verify a treatment will not interfere with the study.

D. Record field operations, fertilization, pesticide applications etc. in an appropriate log.

III. Destruction of treated crops

A. Crops treated with the test substance will be destroyed in accordance with regulatory requirements by disking under or for permanent crops will be removed from the test site and composted/destroyed to render the crop unusable. In cases where the compound is already registered for the commodity, the current PHI must be followed.

Greenhouse Facilities

SOP Number: 1514 Revision Number: 00

I. Subject: Greenhouse facilities

- A. To ensure that greenhouse facilities are sufficient to meet research needs
- B. Applies to all greenhouse facilities used to conduct magnitude of residue studies

II. Procedure

A. Each greenhouse should be large enough to contain an entire trial or portion of a trial with enough space between treatments to prevent contamination.

B. If more than one trial is conducted simultaneously, there should be enough room between trials to prevent contamination between or among the trials.

C. Environmental parameters (light, temperature, humidity etc.) should be sufficiently uniform within the greenhouse or among multiple greenhouses to assure nearly uniform plant growth.

D. Walls, floors, ceilings should be in good conditions, and floors, benches, walkways and workspaces should be kept clean and free of debris.

E. Greenhouses should be equipped to maintain temperature, moisture, lighting etc. in a way that simulates commercial greenhouse conditions or as required by protocol.

F. Environmental monitoring devices should be installed and maintained as needed to ensure proper environmental conditions are maintained during the course of the study.

G. Document cultural practices used in the greenhouse and treatment locations in the Field Data Book.

Test Substance Receipt, Storage and Disposition

SOP Number: 1601 Revision Number: 09

I. Subject: Test Substance Receipt, Storage, and Disposition

A. This SOP contains instructions for receiving, storing, and disposing of test substances and containers.

II. Receipt

A. Assign each container of test substance (TS) a unique NMSU tracking number.

B. The container label should contain, at minimum: 1) chemical name, trade name or code name, 2) batch or lot number, 3) storage requirements 4) expiration date and 5) assigned NMSU tracking number. If any of this information is missing, add it to the test substance container and initial/date the entry.

C. Record receipt of each container of test substance in an inventory log. This record should include clear identification of the container, the amount received and date of receipt.

D. Enter required TS receipt data and insert original or certified copies of documents received with TS into appropriate FDBs.

III. Storage

A. Store test substances away from the test system in a ventilated, secure room or building.

B. Storage facility should be clearly marked as pesticide storage and provide limited access with a locked entry.

C. During the time from first receipt of test substance until applications are completed, monitor temperatures in the pesticide storage facility with a NIST-verified min/max thermometer and/or data logger(s). The min/max will serve as the primary data source.

D. Maintain a written temperature log approximately weekly, while chemicals are stored and up to their last application, and document special circumstances related to chemical storage.

E. If test substances are to be taken off-site during conduct of a trial, place them in a clean, insulated container such as an ice chest. Monitor the temperature in the ice chest with a NIST-verified min/max thermometer or logger to ensure that temperature extremes are not exceeded.

F. If a test substance is exposed to temperatures outside the manufacturer's

recommended storage range for a significant amount of time, contact the Study Director.

IV. Disposition of TS and containers

A. After completion of trial applications, it is permissible to use remaining test substance in accordance with the label (e.g., for maintenance applications).

B. Empty test substance containers must be retained until study is completed or canceled, or else returned to registrant.

C. If required, return TS containers as instructed by registrant. If possible, use shipping containers originally used with TS

D. If registrant does not require return, retain test substance containers until determined that containers can be disposed of. Information on container disposition is available at https://ir4app.cals.ncsu.edu/Ir4FoodPub/SubstanceDispoSch

E. Document container disposition in the inventory log.

Calculating Pesticide Dosages

SOP Number: 1602

Revision Number: 05

I. Subject: Calculating dosages

A. This SOP contains suggested calculations for required applications.

NOTE: These formulas are SUGGESTIONS ONLY. Document all used formulas in databooks.

II. Target output and speed

A. Determine plot size in **acres**:
$$\frac{length (ft)*width (ft) \left(\frac{ft^2}{plot}\right)}{43560 \frac{ft^2}{acre}} = \frac{acres}{plot}$$

- B. Find desired output in **mL plot**⁻¹: $\frac{acres}{plot}$ (A) * $\frac{gallons}{acre}$ (GPA) * $\frac{3785 \, mL}{gallon} = \frac{mL}{plot}$
- C. Find average boom discharge rate **mL sec**⁻¹: $\frac{total \ catchment \ volume \ (mL)}{total \ catchment \ time \ (sec)} = \frac{mL}{sec}$
- D. Determine required **pass time plot**⁻¹: $\frac{\frac{mL}{plot}(B)}{\frac{mL}{sec}(C)} = \frac{sec}{plot}$

E. Determine # of passes:
$$\frac{field \ width \ (in/cm)}{n \ nozzles \ * \ 20'' \ spacing \ (in/cm)} = \# \ of \ passes$$

F. Find time pass⁻¹:
$$\frac{\frac{sec}{plot}(D)}{\frac{\# of \ passes}{plot}(E)}$$
 = $\frac{sec}{pass}$

III. Amount of Liquid Test Substance

- A. Find target volume **mL plot**⁻¹: $\frac{acres}{plot}$ (A) * target rate $\left(\frac{form.,mL}{acre}\right) = \frac{mL}{plot}$
- B. Calculate overage factor and required volume: $\frac{total + excess tank volume (mL)}{desired output (II.B) \left(\frac{mL}{plot}\right)} = overage factor$

overage factor * target volume (III.A) $\left(\frac{mL}{plot}\right) = required volume (mL)$

IV. Amount of Solid Test Substance

A. If given the **grams test substance** (**product**) / **Acre** use the following calculation: <u>grams product</u> = <u>given grams product</u> x $\frac{1 \text{ Acre}}{43560 \text{ ft}^2}$ x <u>[Plot area (ft²) x overage]</u> Treatment Acre

B. Convert the desired rate into grams a.i. / acre using the following formula:

Rate (grams a.i./acre) = $\frac{\text{Rate (lb a.i.)}}{\text{Acre}}$ x $\frac{454 \text{ grams}}{1 \text{ lb}}$

C. Find grams test substance / gal carrier using the following formula:

 $\begin{array}{c} \underline{\text{grams test substance}} \\ \underline{\text{gal carrier}} \end{array} = \frac{\text{Rate (grams a.i.) x}}{\text{Acre}} \times \frac{1}{\% a.i.*} \times \frac{\text{Acre}}{\text{gal carrier}} \end{array}$

* % a.i. expressed as a decimal

D. Find grams test substance / treatment using the following formula:

grams test substancegrams test substancexMix size (gal carrier)Treatmentgal carrierTreatment

V. Amount of Adjuvant

A. Determine mean recommended rate of adjuvant \mathbf{v}/\mathbf{v} %: $\frac{pints}{gallons*\frac{8 pints}{gallon}} = \mathbf{v} / \mathbf{v}\%$

B. Determine required adjuvant volume (mL) for mix:

$$v_v \ll (V.A) * total + excess tank volume (mL) = mL adjuvant$$

VI. Amount of Water:

total + excess tank volume (mL) - required TS volume (mL) - <u>adjuvant volume (mL)</u> <u>=amount of water needed (mL)</u>

- VII. Determining actual applied rates
 - A. Applied **mL plot**⁻¹:

total pass time (sec $plot^{-1}$) * average boom discharge rate (mL $plot^{-1}$) = applied volume $\left(\frac{mL}{plot}\right)$

B. Applied substance **mL**: applied volume (VII.A) $*\frac{\text{test substance in mix (mL)}}{\text{tank mix (mL)}} = applied substance (mL)$

C. Applied rate **mL acre**⁻¹:*applied substance(VII.B)* * $\frac{43560 ft^2}{plot area ft^2}$ = **rate** $\left(\frac{mL}{acre}\right)$

D. Determine **GPA rate:**
$$\frac{applied \ volume \ (mL)}{3785 \frac{mL}{gal}} * \frac{43560 \ ft^2}{plot \ area \ ft^2} = GPA$$

E. Determine % accuracy:
$$\frac{applied \ rate\left(\frac{mL}{acre}\right)}{target \ rate\left(\frac{mL}{acre}\right)} - 1 * 100 = \pm \% \ accuracy$$

Measuring, Weighing and Mixing Test Substances and Adjuvants, and Use of pH Indicator Strips

SOP Number: 1603 Revision Number: 07

I. Subject: Measuring, weighing, and mixing the amount of test substances and/or adjuvants to be used. Use pH strips for determining alkalinity/acidity of carrier.

This SOP contains information for measuring both liquid and solid test substance to be used in an application, and use of pH indicator strips

II. Procedure

When mixing test substance or additives with carrier:

Some herbicide labels list a specific mixing sequence. In absence of specific directions, the recommended sequence for adding pesticide formulations to a tank partially filled with water is the **W-A-L-E-S method**.

Wettable powders and water dispersible granules Agitate tank mix thoroughly Liquid flowables and suspensions Emulsifiable concentrate formulations Surfactants/Solutions

Each ingredient must be uniformly mixed before adding the next component. For example, a soluble powder must be completely dissolved before adding the next component. Adjuvants are added in the same sequence as pesticides: ammonium sulfate is a soluble powder, oil adjuvants are emulsifiable concentrates, and most surfactants are solutions. Within each group, usually add the pesticide before the adjuvant. For example, add a soluble-powder pesticide before ammonium sulfate.

A. When mixing test substance or additives with carrier:

- 1. Put a portion of carrier in tank
- 2. Add test substance/additives to tank and gently agitate mixture.
- 3. Add remaining carrier.

B. When using a TC (to contain) type graduated cylinder or pipette to add liquid formulations:

- 1. Fill with desired amount of test substance.
- 2. Empty the solution into the spray tank or appropriate container.

3. Rinse at least 3 times with mix water into the spray tank or appropriate container.

C. When using a TD (to deliver) type graduated cylinder, pipette, or syringe to add liquid formulations:

1. Fill with the desired amount of test substance.

2. Empty the solution into the spray tank or appropriate container.

3. When measuring non-viscous substances, it is not necessary to rinse a TD device into the spray tank or the container being used.

4. When measuring viscous substances (incompletely drained by gravity) with TD graduated cylinders or pipettes, rinse at least 3 times with mix water into the spray tank or appropriate container.

- D. When adding solid formulations:
 - 1. Verify the balance according to the appropriate balance SOP.
 - 2. Weigh out the required amount of test substance.

3. Slurry the formulation in a clean container with some of the mix water. Add the slurry to the tank and rinse the jar 3-5 times into the tank to ensure all the pesticide is added to the tank.

4. Clean balance, if needed.

E. Use pH indicator strips following label instructions for use.

Storing and Maintaining Adjuvants (Spray Additives)

SOP Number: 1604 Revision Number: 03

I. Subject: This SOP contains instructions for storing, using and maintaining liquid adjuvants (spray additives) for use in IR-4 field residue studies

II. Labeling

A. The primary container label should contain, at minimum: 1) purchase date or date received at the field facility and initials 2) name of the additive 3) concentration 4) storage requirements and 5) expiration date. If any of this information is missing, add it to the adjuvant container and initial/date the entry. If the expiration date is not given, then use an expiration date that is 3 years from purchase date (unless information from the manufacturer supports a longer expiration), initial and date.

B. If material is transferred to a secondary container (e.g, from 2.5 gal. jug to 1 pt. bottle), label the secondary container with all information as previously described. These requirements do not apply to temporary containers used for measuring, but they should be adequately labeled to uniquely identify the product.

III. Storage

A. Store adjuvants in a location that has limited access and is temperature monitored.

B. Ensure adjuvants are in good condition prior to use. Dispose of any adjuvant which has undergone physical change (color, precipitation, viscosity etc.) or is beyond the expiration date.

IV. Use

A. Transfer adjuvant using a method that prevents a measuring device from entering the primary or secondary container more than once. Following are suggested methods. Other methods may be used.

1. Dispense a small amount of material into a temporary container (cup, beaker etc.) for measurement into mix. After adding to mix, discard any remaining material; do not use in another trial or return to adjuvant container.

2. Use a sealed, disposable syringe or pipette to transfer required amount of adjuvant from primary or secondary container. Discard syringe or pipette after single use; device should not enter container again.

B. Any previously opened container of adjuvant that does not have a known history of use as described cannot be used in a GLP trial.

QA Inspections and Audits

SOP Number: 1703 Revision Number: 02

I. Subject: QA Inspections and Audits

A. This SOP contains instructions for activities in response to EPA or contracted QAU inspections and/or audits. Inspectors may at any reasonable time and manner inspect all applicable study and facility records. EPA inspectors may not inspect or copy QAU reports.

- II. Procedure
 - A. Prior to an inspection or audit, the Field Research Director will:
 - 1. Notify the IR-4 Western Regional Coordinator and NMSU IR-4 employees of the pending inspection.
 - 2. Assess, collect, and organize all records pertinent to the inspection.
 - 3. Provide the inspector with facility records and any documents requested.

Operation and Maintenance of a CO₂ Backpack or Tractor Boom Sprayer

SOP Number: 2101 Revision Number: 13

I. Subject: Operation and Maintenance of a CO₂ Backpack or CO₂ Tractor Boom Sprayer

This SOP describes the procedure for operating and maintaining any of the NMSU IR-4 backpack and tractor boom sprayers. The sprayers are used for applications of test substances and maintenance chemicals.

II. Description of NMSU CO₂ sprayers

A. A CO_2 spray system is uniquely based on an individual pressure regulator, and comprises a CO_2 tank, the regulator, tank pressure gauge, line pressure gauge, air hose, spray container and delivery hose. Each sprayer is adaptable to many configurations using various connectors, spray containers, wands, and booms for meeting a broad array of application requirements. Sprayers may either be hand carried (backpack or belt) or mounted on application equipment.

A tractor boom spray system comprises the same general components as the backpack sprayer, but has an integral, mounted boom and is attached to a tractor via 3-point hitch used for applications over large areas or in tall crops.

III. To make a sprayer application

A. Before Use

1. Inspect the sprayer for proper operation. Make sure all nozzle tips and screens are the same size and are clean. Check hoses and quick couplers for leaks, holes, or cracks.

2. Check the CO₂ pressure and refill tank if necessary.

3. Prior to applying test substance, calibrate the sprayer as described in SOP 2102.

B. Operating a CO₂ Backpack Sprayer

1. Prepare pesticide mix in spray container as described in SOP 1603.

2. Prepare sprayer: assemble boom, downpipe, and delivery hose, and connect air hose to CO_2 tank. Check connections to ensure they are tight.

3. Make application: turn the screw valve on the CO₂ tank to pressurize regulator, open shut-off valve to pressurize spray container and boom, adjust boom to ensure proper height and spray pattern, charge boom by depressing trigger for a short time until appropriate spray pattern is delivered from all nozzles, then begin spray application.

C. Operating CO2 Tractor Boom Sprayer

1. Prepare pesticide mix in spray container as described in SOP 1603

2. Attach sprayer to three-point hitch on tractor and raise sprayer before removing leg stands.

3. Prepare sprayer: attach the booms, connect hoses from CO₂ tank to spray container and from the spray container to boom, check connections to ensure they are tight, adjust pressure regulator and boom height.

4. Prior to application: Make sure the valve on the CO₂ tank is open and that pressure is still set to the calibration pressure, agitate spray container to ensure sufficient mixing.

5. To start the flow of solution, turn the in-line valve on. To stop the flow of solution, turn the in-line valve off.

IV. Procedures for making multiple treatment applications

A. For multiple applications using the same test substance

1. If applications use the same chemical at the same rate, air-purge boom with CO₂ between applications.

2. If applications use the same chemical at different rates, apply in order of increasing concentration, and air-purge boom with CO₂ between applications.

B. For multiple applications using different test substances

1. Use separate spray tanks for each application or triple-rinse spray tank between applications.

2. Flush boom with clean water for ~ 30 seconds and air-purge boom with CO₂ between applications.

V. After Use

A. Spray out leftover solution in a suitable area, turn off in-line valve and CO_2 tank, if spray container has pop-off valve, vent tank with pop off, disconnect air hose, and then disconnect spray delivery hose.

B. Clean up sprayer: 1) triple rinse the tank or rinse until it is clean using either soap or an ammonia solution, 2) Run clean water through the system for a minimum of 1 minute to clean the lines and boom, 3) rinse off outside of sprayer 4) remove nozzle tips and screens and wash with soap or ammonia solution and then rinse with water 5) place tips, screens and nozzles back in identified sorted compartment or back on sprayer.

C. Store sprayer in the appropriate storage area.

VI. Remedial action

A. If problems arise with sprayer operation, repair or replace sprayer.

B. If the sprayer malfunctions or if the spray solution runs out prior to the end of spray application, mark the location in the plot where the event occurred with a flag. Make a note of the event in the FDB. Do not sample from the misapplied area. If the misapplication could affect the integrity of a study, contact the Study Director.

VII. Maintenance

A. No scheduled maintenance is required. Normal maintenance due to normal wear includes rebuilding malfunctioning regulators and replacing pressure gauges, triggers, hoses etc. on an as needed basis. It does not include changing sprayer boom configuration, nozzle tips, pressure setting, or other common adjustments.

B. Non-routine maintenance is for a malfunction that requires major repair or replacement of the equipment.

C. Record all use and maintenance in a log. Include the following information: 1) date of event, 2) event (trial ID number, or other), 3) maintenance conducted, 4) whether or not the SOP was followed: checking the SOP prompt certifies that, unless otherwise noted, calibration, use and cleanup of sprayer was conducted as per this SOP, 5) whether or not the maintenance is routine or non-routine: if maintenance is non-routine, fill out a *Non-Routine Maintenance* form and retain this form with the log, 6) initials/date of entry.

VIII. Responsible Personnel

A. Equipment inspection, verification, cleaning, and maintenance (routine and non-routine) shall be performed by trained personnel or supervised by the Field Research Director.

Discharge Calibration of a CO₂ or Tractor Boom Sprayer

SOP Number: 2102 Revision Number: 06

I. Subject: Calibrating a CO₂ or Tractor Boom Sprayer

A. This SOP contains instructions and suggested formulas for calibrating CO₂ backpack or tractor boom sprayers prior to use.

B. Follow procedures for all GLP trials.

II. Full calibration

A. A full calibration is always required in the following cases:

1. Prior to the first application in a trial; must be conducted no earlier than one day previous to the application.

2. Any time critical sprayer settings (nozzle size, type, number or boom spacing, or sprayer pressure settings) have been changed prior to a use, even if reconfigured to original settings. Normal procedures, such as charging CO₂ tank, disconnecting/reconnecting booms, cleaning nozzle tips etc. are not considered critical changes.

B. Add sufficient water to spray container to conduct the calibration

C. Check sprayer for proper operation, charge boom and adjust pressure as needed,

D. Run sprayer and catch discharge from each nozzle for a specific time (e.g., 30 sec.), then measure and record the amount of water delivered from each nozzle on the Sprayer Calibration form. Nozzles are numbered 1 through n from left to right when facing the direction of travel.), repeat for a total of three discharge runs.

E. Calculate the average discharge rate for each nozzle and for each run, and the overall average of all nozzles and all runs. If variation of average for any nozzle or run varies more than 5% of overall average, make changes to sprayer setup and restart the calibration procedure.

F. Air purge sprayer and boom to prepare for test substance application.

III. Recheck calibration

A. If critical sprayer settings haven't been changed, the most recent full calibration on a sprayer setup may be used for subsequent applications by conducting a discharge recheck. If settings have been changed, then a full calibration is required, even if sprayer has been reconfigured to the original settings.

B. A calibration recheck is performed by making a single calibration run as previously described. Record results on a Sprayer Calibration form. If the nozzle and run output in the recheck is within $\pm 5\%$ of the average output for the complete

calibration, then use the data from the full calibration. If the recheck is not within acceptable limits, conduct a full calibration.

C. If the full calibration is used for rechecks in another trial, insert an exact copy of the original full calibration data sheet into the secondary Field Data Book.

IV. Calibrating application speed

A. Target pass time method

1. Calculate the target pass time.

2. Conduct speed calibration within or adjacent to plot. Alternatively, measure off and mark a track that is the plot length on terrain similar to the plot area.

3. Carry the same equipment and wear the same PPE that will be used during the actual application if walking an application on. Travel the known pass distance, adjusting pace until the target pass time (\pm 5%) is achieved. A metronome is useful for setting pace.

4. Make three consecutive runs, each \pm 5% of target pass time. Record the results from each run on the calibration form.

B. Where a speed recheck is appropriate, a speed calibration can be verified with one run that is within \pm 5% of the target pass time.

V. Responsible Personnel

A. Equipment inspection, verification, cleaning, and maintenance (routine and non-routine) shall be performed by trained personnel or supervised by the Field Research Director.

Operation and Maintenance of a Portable Drip Applicator

SOP Number: 2104 Revision Number: 04

I. Subject: Use of a portable drip applicator for GLP trials.

The applicator consists of a mix tank and pressure pump connected to an inline pressure gauge assembly by hoses and valves. A main line (main) is placed with lateral drip lines on bed tops of the plot length. Laterals contain equally spaced emitters that discharge approximately equal rates over extended range pressures.

II. Setup

A. Connect laterals to main. If treating a single-row crop, lay laterals next to base of plants or over seed line, if multi-row crop, center laterals on bed tops.

B. Connect mix tank to pump inlet, pump outlet to pressure gauge assembly, and pressure gauge assembly to main.

III. Operation

A. Shut all in-line flow valves prior to startup.

B. Turn start lever and choke to "on," open priming cap on pump, open tank discharge valve to prime pump, close priming cap, start pump, and immediately open all down-line valves to allow flow to emitters.

C. To shut down, turn off pump motor, immediately close all valves.

IV. Verifying emitter discharge (required only prior to the first application in a trial)

A. Add sufficient water to tank to complete three verification runs and start pump, run system to ensure all emitters are flowing, check for leaks, repair as needed.

B. Place catch basins under single emitters spaced approximately equidistantly in the near, middle and far thirds of each lateral. Run applicator for a set time period (e.g., 3 minutes), then measure and record discharge from each catch basin. Calculate average discharge per emitter by line and location.

C. Compare average discharge by line and by location. Average discharge per emitter per run should be within $\pm 5\%$ of the overall average. There is variability in individual emitters due to manufacturing procedures or other, uncontrollable factors. It is not essential that every emitter be within 5%, as long as the overall distribution within the plot appears relatively consistent. If in doubt, contact Study Director.

V. Apply t.s. mix

A. To ensure more uniform distribution when adding TS to the irrigation tank, form a concentrated mix in an appropriate container of TS and water (especially important with dry TS). Retain some mix water for rinsing the container.

B. Add calculated volume of carrier/irrigation water to mix tank, filling to exact gallonage mark (if applicable) or to the next lowest mark on tank. If needed, add additional mix water in 5-gallon increments to approximate calculated total required. Add concentrated TS mix while agitating or stirring resultant tank mix. Rinse concentrate container into tank, using with small amount of additional water.

C. Start pump, run entire volume of mix through applicator, stirring tank mix occasionally to ensure uniform distribution of TS. within mix. (Due to variation in manufacture of mix tanks, there may be a small amount of mix remaining in tank.)

D. Apply additional measured volume of irrigation water.

VI. Clean up

A. Additional application of clean irrigation water cleans the system.

B. If no irrigation is applied, wash the inner surface of tank and by pumping clean water for a minimum of 30 sec. Ensure that discharge doesn't affect trial integrity.

VII. Remedial action

If drip applicator (uptake, distribution system, pump etc.) is not operating properly, repair or replace it. If the portable drip applicator has a significant leak, shut off pump and line valves and repair the leak, document activity in the Field Data Book.

VIII. Maintenance

A. No scheduled maintenance is required. Normal maintenance due to normal wear includes repairing and replacing lines, hoses, valves etc.as needed, and preventive maintenance of pump (oil change, tuneup etc).

B. Non-routine maintenance is for a malfunction that requires major repair or replacement of the equipment.

C. Record all use and maintenance in a log, and include: 1) date of application, 2) reason for use (trial ID number, or other, 3) maintenance conducted, 4) which SOP was followed 5) whether or not the maintenance is routine or non-routine: if maintenance is non-routine, fill out a *Non-Routine Maintenance* form and retain this form with the log, 6) initials/date of entry.

IX. Responsible Personnel

A. Equipment inspection, verification, cleaning, and maintenance (routine and non-routine) shall be performed by trained personnel or by the Field Research Director.

Using Borrowed Equipment

SOP Number: 2201 Revision Number: 07

I. Subject: Using Borrowed Equipment

A. This SOP contains information for using borrowed or leased equipment used for critical phase and for non-critical phase procedures.

B. The SOP applies to any such equipment that is used in a field study and is not covered by SOPs or logs. It does not apply to farm field equipment (tractors, irrigation equipment, discs, hoes etc.) used for field operations.

II. Procedure

A. If a piece of equipment is not working properly or is not adequate for a procedure, a similar piece of equipment or one that is adequate may be borrowed or leased from another source.

B. If the borrowed equipment is used for a GLP Critical Phase procedure and while the equipment is in the hands of IR-4 personnel, fill out a *Borrowed GLP Equipment Form*, or similar form, to include the following information: 1) applicable Trial ID #, 2) description of equipment, 3) testing to determine suitability for use, 4) cleaning procedures used to minimize possible contamination of test system, 5) any maintenance conducted on equipment, 6) any calibration/verification conducted, and where results are recorded, 7) initial and date.

III. Responsible Personnel

A. Equipment inspection, verification, cleaning, and maintenance (routine and non-routine) shall be performed by trained personnel or supervised by the Field Research Director.

Thermometer and Temperature Logger Verification and Maintenance

SOP Number: 2221 Revision Number: 09

I. Subject: Verification and maintenance of thermometers and temperature loggers, use of the Thermometer Verification Log, and use of a NIST Certified (NIST Traceable) thermometer

A. Purpose: to provide GLP-compliant equipment to keep a record of temperatures for a specific area, use, or piece of equipment.

B. This SOP contains instructions for verification and maintenance procedures for all thermometers used to generate raw data, and instructions for use of a NIST, or NIST Certified/Traceable thermometer.

C. For the purposes of verification, the term "thermometer" includes temperature data loggers

D. Assign each thermometer and data logger a unique identification number or name.

II. The NIST thermometer/data logger

A. NIST Certified temperature points should approximate the intended temperature range limits.

B. Have a digital thermometer or data logger professionally calibrated (NIST Certified or NIST Traceable) at approximately two-year intervals.

C. Use the NIST-Certified device to verify accuracy of temperature monitoring equipment.

III. Verification procedure

D. Keep a record of verification activities in an equipment log.

E. A newly purchased device that is NIST Traceable does not need to be verified for the year of purchase.

F. If a non-traceable thermometer is purchased during the year, it can be verified either by the NIST Certified device or a NIST verified device prior to GLP deployment.

G. Replace batteries, as needed, on devices requiring batteries or that have battery backup.

H. During verification, allow all thermometers/probes/loggers to rest in close proximity, and allow sufficient time for thermometers to equilibrate in each test environment.

I. With "direct read" devices, such as digital and analog thermometers and loggers with LCD displays, record temperatures after thermometers reach equilibrium.

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J. To verify temperature loggers that do not have LCD temperature displays, follow these steps:

- 1. Launch loggers and wait at least 10 minutes).
- 2. Compare readings from NIST logger to non LCD display temperatures.

K. Record the following information on a verification form or similar: 1) date of verification, 2) test environment (e.g., freezer), 3) test unit ID, 4) test unit temp. reading, 5) NIST unit ID, 6) NIST unit temp. reading, 7) result (difference in readings), 8) initials

L. Temperature readings for each unit/test environment combination should not vary from the NIST thermometer reading by more than 2°C. If temperature variation is outside this range, repeat verification, request calibration, or re-order.

IV. Maintenance

- A. Thermometers
 - 1. No routine maintenance is needed.
 - 2. No non-routine maintenance is needed.

3. If a thermometer malfunctions or fails, discard it and replace with another unit.

- B. Temperature data loggers
 - 1. No routine maintenance is needed.

2. For non-routine maintenance due to malfunction/failure of a temperature data logger, repair or replace the logger and document activity in an equipment log. If needed, include a completed *Non-routine Maintenance Form* or similar.

V. Responsible Personnel

A. Equipment inspection, verification, cleaning and maintenance (routine and non-routine) shall be performed or supervised by the Field Research Director, except as otherwise indicated in this SOP.

Sample Storage Freezers

I. Subject: Use and Maintenance of Sample Storage Freezers

A. This SOP contains information for the maintenance and use of the sample storage freezers and associated temperature-monitoring equipment.

B. NMSU IR-4 personnel are responsible for proper use and maintenance of freezers and temperature monitoring equipment.

II. Sample storage freezers

A. Keep freezers in a limited-access, locked room.

- B. Equip freezers with locks. Freezers should remain locked while holding samples.
- C. Set thermostat to maintain temperatures generally at or below 0° F.

D. Inspect freezers some weeks prior to storing samples. Clean inside of freezers and adjust thermostats, if needed. Verify temperatures by removing the alarm probe from the freezers to test alarm system. Record in freezer maintenance logbook.

E. While freezers contain samples, monitor temperatures with appropriate equipment to ensure integrity of samples. If freezers are shut down, freezers must be defrosted and cleaned. Clean with ammonia or bleach and let air dry. Leave door to freezer partially opened when not in use. When turning back on freezers freezer alarm will alert you to indicate freezers are working properly. Record alarm notification in freezer maintenance log. Reset Hobos to verify temperatures.

III. Maintenance

A. There is no regular, scheduled maintenance on freezers.

B. If a freezer malfunctions, requiring major repair or replacement, repair or replace it. If the freezer is holding samples, ensure sample integrity (reference SOP 1309). Thoroughly document the malfunction and how it was resolved in an equipment log, and fill out and include a completed *Non-Routine Maintenance Form* or similar.

IV. Responsible Personnel

A. Equipment inspection, verification, cleaning, and maintenance (routine and non-routine) shall be performed or supervised by the Field Research Director.

Calibration, Operation, and Maintenance of Balances

I. Subject: Calibration, Operation, and Maintenance of Electronic Balances

This SOP contains information for the calibration, verification, operation, and maintenance of balances used for GLP procedures.

II. Calibration

A. Have either the scale or the calibration weights certified at least once every two years by the New Mexico Department of Agriculture Weights and Measures department. Handle weights carefully in order to keep them clean.

B. Verify the balance prior to use with certified weights. If readings vary more than $\pm 2.5\%$ from the certified weights, calibrate the balance as directed in the manual, or have it professionally calibrated.

C. Record the calibration verification results in an equipment log. Include the following information: 1) balance identification 2) calibration weight nominal mass, 3) balance reading for each weight, 4) whether reading is within $\pm 2.5\%$, 5) comments, 6) initials/date.

III. Balance Use

A. Level the balance and verify the balance is within $\pm 2.5\%$ of two certified weights.

IV. Maintenance

Record all maintenance activities in a log. Include: 1) date, 2) use or activity; if used for weighing TS, enter trial ID number; if for other use enter "other", 3) if weighing TS, enter verification weights used and weights recorded, 4) which SOP was followed, 5) whether maintenance is routine or non-routine; if non-routine, requiring major repair or replacement, fill out a *Non-Routine Maintenance form*, and retain this form with the log, 6) initials/date of log entry.

V. Remedial Action

A. If a balance will not work properly, repair or replace it with another balance.

B. If a non GLP-compliant balance is used for a GLP critical phase, follow NMSU IR-4 SOP 2201, Using Borrowed Equipment.

VI. Responsible Personnel

A. Equipment inspection, verification, cleaning and maintenance (routine and non-routine) shall be performed by trained personnel or supervised by the Field Research Director, except as otherwise indicated in this SOP.