

IR-4 Advisory #2014-01 (7/10/14)

Title: Maintaining Freezer Storage Systems at IR-4 Field and Laboratory Research Sites

**Issue/
Question:** The IR-4 Education and Training Committee has been given a mandate by the IR-4 Project Management Committee (PMC) to develop an IR-4 Advisory to address project-wide maintenance of sample storage systems, particularly freezer storage. The intent of the PMC's mandate is to establish a policy that defines the expectations for maintaining the integrity of all frozen samples held as part of IR-4 GLP residue studies.

Background: IR-4 will not continue to suffer sample losses due to freezer issues that, with today's technology, can easily be avoided. Such losses have resulted in extensive financial and other resource losses, but more importantly damage to IR-4's reputation for being able to consistently carry out studies in a timely manner. It is critical that IR-4 make on-time submissions, thus delivering timely registrations of new pest management tools for specialty crop grower stakeholders.

In recent years, frozen samples in various IR-4 field and lab facilities have been lost when freezer temperatures have risen and remained above the freezing point for many hours without detection. The samples thawed, resulting in loss of crop substrate integrity and unquantifiable degradation of pesticide residues. Samples have had to be destroyed, and repeat trials conducted.

Some freezer systems have failed due to power outages from storms or other unexpected events without backup emergency electrical supply or a warning system to alert responsible persons that a freezer failure has occurred. Other freezer failures have happened even with emergency back-up systems/plans in place, but those systems or plans failed to activate properly when the situation developed due to lack of testing all aspects of the system on a regular basis, or due to inadequate repair of a system known to be deficient. Needless to say, these issues have cost IR-4 significant resources and time when effective, cost efficient monitoring systems should have been in place.

Resolution: Although IR-4 has experienced several freezer failures with loss of frozen samples in recent years for a variety of reasons, technology has existed that could have been in place in every situation, most certainly avoiding sample losses resulting in repeat field trials and submission timeline delays. In most of these situations, power interruptions could not have been avoided by any actions of IR-4 personnel, but lack of appropriate precautionary actions to have fully functional back-up/monitoring/warning systems in place has been the primary issue leading to unacceptable sample losses.

In order to eliminate the potential for future losses of frozen samples at every IR-4 field and laboratory facility, the processes listed below MUST be established for every freezer used to store samples of any type involved in IR-4 GLP studies. It is mandatory that every field and laboratory site maintain integrity of all samples for which they are responsible for the entire storage duration.

- 1) Samples should be moved out of frozen storage and shipped to the target laboratory as soon as possible per any specific protocol instructions and site SOP(s); don't keep freezers full of samples for long periods of time.
- 2) Back-up emergency plans/systems must be in place and functional for all storage equipment used for maintaining frozen samples in any GLP residue study. The appropriate SOPs must be in place, which describe the systems and their operation, maintenance, testing, etc. In the event that freezer functionality can't be restored quickly, procedures for maintaining the samples should be addressed (i.e., location to obtain dry ice, location of alternate freezers, etc.). Each site must define an appropriate back-up system which will allow detection of a freezer failure in time to take corrective actions before loss of samples occurs.
- 3) These back-up emergency plans/systems must be tested on a regular basis to confirm they are totally functional should a power loss or thermostat malfunction occur. The results of the testing must be documented. If testing demonstrates any kind of failure or malfunction, needed repairs and further system testing must be completed as soon as possible to provide assurance that sample integrity will not be compromised, in the event of a freezer failure.
- 4) During all IR-4 facility inspections by QA where sample storage exists, back-up emergency plans/systems must be examined for full functionality. Repair and maintenance documentation must be in order. Quality Assurance will also audit these plans/systems, as appropriate, during other regularly scheduled audits of various study phases. Any observations regarding issues with sample storage systems will be captured as findings in audits, thus requiring IR-4 personnel to immediately address the situation. Testing Facility Management review of such audit findings will result in sign-off when a detailed plan is presented for restoring system functionality, or when issues have been communicated as resolved.
- 5) When issues/concerns about functionality of back-up sample storage emergency plans/systems are discovered, the problems should be brought to the attention of local, regional and headquarters IR-4 personnel. All parties must be kept informed of progress in resolving the situation. If

needed, the situation will be presented to the IR-4 Project Management Committee for discussion and development of an action plan.

- 6) There are some sites where there will be no samples stored in freezers at certain times during the year (for instance, during winter in the northern part of the country). Facility SOP(s) should address procedures to follow in these situations.
- 7) In certain emergency situations it may be necessary to find off-site frozen storage solutions. Facility SOP(s) should address procedures for this situation, including at least one address of an off-site facility and means of temperature monitoring while samples are being held there. One option might be ACDS (Agricultural Chemicals Development Services, Inc., Phelps, NY) or other such frozen storage service to maintain integrity of these valuable frozen samples.

If you have any questions, please contact your Regional/ARS Field or Lab Coordinator, the appropriate Study Director or Headquarters Management for further guidance.