SOP Log Sheet

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IR-4 National Standard Operating Procedures

SOP N-01.1
Rev # 0
Title: Guidelines for IR-4 National Standard Operating Procedures

PURPOSE: To provide general guidelines for development, revising, reviewing, maintaining and archiving IR-4 National Standard Operating Procedures (SOPs).

SCOPE: Applies to all GLP (Good Laboratory Practice) research conducted through the National IR-4 Program.

PROCEDURES:

1. **National SOP Format and General Guidelines:**
   A. All National SOPs will be uniquely identified by SOP number (and the revision numbers). Each SOP number will begin with the prefix 'N', followed by SOP category, and sequential SOP number.

      a. Header Format: SOP N-(SOP category).(sequential number); next line (revision number); next line (Title)

      Example: SOP N-01.1
      Rev# 0
      Title: Guidelines for IR-4 National Standard Operating Procedures

      b. Body Format: (PURPOSE); next line (SCOPE); next line (PROCEDURES); next line (APPENDICES)

      Example: **PURPOSE** (Brief description of the purpose of the SOP)
      SCOPE (Determines where and when the SOP is applicable)
      PROCEDURES (Describes the operating procedures in numerical order from beginning to end so that a person with proper training can carry out the procedures without any verbal input from other sources. Describes exactly how each activity addressed by the SOP will be conducted. As appropriate, number each section (such as 1, 2, 3, etc.) and specific instructions (such as A, B, C, etc.))
      APPENDICES (if necessary, provides additional clarification, such as an illustration, an example, or a list of specific items pertaining to that SOP. If more than one appendix per SOP number, letters will be used to differentiate, i.e. Appendix A, Appendix B, Appendix C, etc.)

   B. Example National SOP Categories are as follows:

      01 Administrative
      02 Electronic Field Data Book (eFDB)

   C. National SOPs will be located in eQA/eDOCs from TMS, which is the IR-4 electronic system for Quality Assurance Unit audit packets and the repository for electronic documents.

a. A list of the current National SOPs can be found in eDOCs within the eQA system by doing a document search for National Standard Operating Procedures as the document type.

D. **National SOP Training:**

a. Those who have access to eQA must train on assigned National SOPs using the training module within 4 weeks of the SOP effective date, using the eQA training module. New hires must be trained on assigned SOPs within 8 weeks of hire date.

b. For those who do not have access to eQA, it is the responsibility of each site Field Research Director (FRD)/Laboratory Research Director (LRD) to ensure persons who collect data for IR-4 studies at their sites are trained and that the training is documented in the training records.

E. **Deviations from National SOPs:**

a. Study-specific deviations must be signed and dated by the person preparing the deviation and by the Study Director (SD), and filed in the appropriate study file(s).

b. Any other deviations must be signed and dated by the person preparing the deviation, discussed with the appropriate Study Director(s), signed and dated by Testing Facility Management (TFM), and filed in the IR-4 National SOP archive file.

F. The study protocol will supersede the National SOPs in case of conflicting information.

2. Development and Revision:

A. Requests for a new National SOP, or changes to existing National SOPs, may be made to the National SOP Committee at any time. The chairperson will acknowledge requests and circulate to the National SOP Committee for review. The committee will determine the appropriate timing for addressing any changes.

a. Requests should include an explanation of why the request is being made and an attachment of the draft SOP or a list of the specific suggested changes for an existing SOP. Committee members may be consulted to determine the effects on GLP and broader program compliance.

b. The committee will review draft SOPs for applicability to the IR-4 Project, but it is the responsibility of individual sites to ensure there are no conflicts between site SOPs and National SOPs. National SOPs will supersede site SOPs where there is a conflict. Any conflicts should be brought to the committee's attention and the committee will recommend an appropriate resolution.

c. Acceptance of the SOP by the committee should be decided by a majority principle. If a committee member strongly disagrees with the new or revised SOP, they may ask TFM to review the situation. The decision of the TFM will be final.

B. Once the National SOP Committee accepts the proposed draft (and/or changes), the SOP will be sent to the Education & Training Committee (E&TC) for a two-week review/comment period. The National SOP Committee will incorporate revisions (if deemed necessary) and then distribute the revised draft to Regional Field Coordinators (RFCs), SDs, Quality Assurance (QA), LRDs, and the E&TC for another two-week review/comment period. The committee will incorporate any new suggested revisions (if deemed necessary) and then distribute for a final two-week review/comment period by the IR-4 Project Management Committee (PMC). The committee will incorporate any suggested revisions, if deemed necessary. For this review process, the chairperson may request expedited review times, when necessary.

C. The National SOP is approved when signed by wet or electronic signature and dated by the IR-4 Executive Director. When a National SOP is issued or revised, the National SOP eQA administrator will assign it to the relevant IR-4 personnel for training. Refer to Section 1 of this SOP for additional training information.

3. Review:

A. National SOPs will be reviewed by the National SOP Committee at a minimum of once approximately every 2 years to determine if revisions are needed. Revisions will follow the procedures described in Section 2 of this SOP.

a. If no revisions are deemed necessary, the National SOP eQA administrator will assign IR-4 personnel to train on the SOP. See Section 1 of this SOP for additional training information.

b. If revisions are deemed necessary, the review process in Section 2 of this SOP will be followed. After the revisions are approved, the training process in Section 1 of this SOP will be followed.

B. The National SOP Committee, with approval from the Executive Director and/or PMC, will determine if a National SOP should be retired. When a National SOP is retired:

a. The National SOP eQA administrator will change the SOP to inactive in eQA. See Section 5 for archival information.

b. The committee will notify IR-4 Headquarters (HQ) to inform all IR-4 personnel.

c. Retired National SOP numbers will not be re-assigned.

C. A complete list of National SOPs and their effective dates can be produced using the eDOCs report creation ability. Using report "Document Listing by Location & Document Type", select the document type "National Standard Operating Procedures" and the Active field "yes" to generate a report containing the Doc ID, Revision #, Title and Effective date for all active National SOPs in the system. Using the same report but with "no" in the Active field will generate a report containing the same information as listed above for all inactive National SOPs in the system.

4. Maintenance:

A. **National SOP Committee:**
It is the responsibility of the National SOP Committee to ensure National SOPs are developed, reviewed and revised (when needed) to meet the IR-4 Project needs. The committee will include at a minimum one member each of: RFC (or designee), HQ, and QA, with others as needed to represent different aspects of the IR-4 Project. The chairperson is ultimately responsible for ensuring the new or revised SOPs are suitable for all users. Members are required to be active participants on the committee and may be removed if that cannot be accomplished.

B. **IR-4 Project Personnel:**
It is the responsibility of all IR-4 personnel to ensure that the National SOPs meet the needs of the IR-4 Project. If a new SOP is required, or an existing one does not meet the needs of a Test Site, Test Facility, or the program as a whole, IR-4 personnel should contact the National SOP Committee.

5. Archiving:

A. National SOPs with original wet signatures, or verified copies of electronically signed SOPs, will be filed at the IR-4 Headquarters archive and copy(s) accessible through the eQA system. The archive SOP file shall be maintained by the National QA Unit Manager.

B. Retired National SOPs will be permanently archived at the IR-4 Headquarters archive.

Signatures

Jerry Baron

Document ID: SOP N-01.1
Revision: 0
Electronically signed by Jerry Baron
Title: Testing Facility Management
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IR-4 National Standard Operating Procedures

SOP N-02.1
Rev # 0
Title: iAdvantage Electronic Field Data Book Use

PURPOSE: This document outlines the data recording and submission procedures when using the electronic field data book (eFDB) in GLP field residue studies.

SCOPE: This SOP shall be used by all IR-4 personnel when using the eFDB for data entry, submission of the electronic data and accompanying paper documentation, during the review and revisions processes, and at archiving. This SOP replaces the IR-4 HQ SOP 5.8. References to HQ SOP 5.8 in test site SOPs and study protocols are considered to be referring to this SOP.

PROCEDURES:

1. Hardware and Software Compatible and Mobile Editions

A. The eFDB operates as a web-based, cloud hosted, software service maintained by iAdvantage Software Inc. (1135 Kildaire Farm Rd #327, Cary, NC 27511). If operating with an internet connection, no software download or storage of data on a user's device is required to utilize the eFDB,

   a. If using the eFDB in an internet browser, use the program according to the current version of the *eNotebook Guide for Online Browsers from iAdvantage*.

B. The eFDB can also be used offline with the Windows Mobile Edition and iPad Mobile Edition. The minimum system requirements are provided in the table below.

	Operating System	Internet Connection	RAM	Diskspace
On-Line	Windows Vista/7+, OS X, Chrome	required	4 GB	N/A
Windows Mobile	Windows Vista/7+	required for download/upload	4 GB	500 MB+
iPad Mobile	iOS 10+	required for download/upload	N/A	500 MB+

   a. The Windows Mobile Edition or iPad Mobile Edition is downloaded directly onto a Windows operating system device or iPad, respectively. This allows the user to "check out" forms from the online eFDB, enter the data into the forms while offline, and "check-in" the forms when back with an internet connection.
   b. If using the Windows Mobile Edition, install the software and use the program according to the current version of the *Guide for Windows Mobile Edition* from iAdvantage.
   c. If using the iPad Mobile Edition, install the software and use the program according to the current version of the *Guide for iPad Mobile Edition* from iAdvantage.
   d. If using a Mobile Edition when collecting raw data, the forms should be uploaded back into the online eFDB in a timely manner after each critical event.
   e. The Field Research Director is responsible for a timely upload of offline (checked out) eFDB forms.

2. **Device Verification:**
   A. The electronic notebook mobile edition software must be verified on the electronic device(s) that are used for offline data entry prior to entering any field trial data onto offline forms.
      a. Every test site will have at least one electronic device that is verified for offline use.
      b. Verification is not required if the device is only used for read-only access or if data entry is only made via the website https://www.estudy.org/ir4/elm.
      c. Subsequent verification(s) will be required only if the eNotebook or eStudy software is updated or if major changes have occurred to the computer on which the software resides (e.g., change of operating system, integral hardware changes or repairs). Adding or removing external devices, routine software updates or installations, or other common usages of a computer do not qualify as major changes. Changes to internal components of a computer, or other forms of hardware/software repair would be considered major.
      d. Verification of the software should occur as soon as possible following major changes or significant updates to software or hardware.

   B. Device verification is performed according to the following procedures:
      a. Open the Windows or iPad Mobile Edition and Login to the user account.
      b. Refresh the notebook list after selecting to check the Verification Study Notebook for the name of the FRD. An eStudy Administrator will provide the Verification Study Notebook.
      c. Select to Move Off Line the verification form provided in the notebook.
      d. Enter your name, initials, and username to the form and save the entries in the mobile edition. If needed, add an additional row for making a subsequent verification entry.
      e. Select Move On Line to return the verification form online.
      f. Open the eFDB website and login to access the online eFDB for the Verification Study Notebook.
      g. Open the verification form within the notebook.
      h. Use a screen shot, snipping tool, or print screen to generate a file showing that the offline entries were populated in the online form.
      i. Print or otherwise retain this file, with initial and date, and place it in Facility Records.
      j. Make an entry into the eFDB Device maintenance log denoting that verification was performed, when performed, by whom, using what SOP or process, and where the location of the screen shot raw data is retained.

3. **Maintenance and Repair Log:**
   A. Record all pertinent information in an equipment maintenance log for any device that enters or changes data online and in the mobile edition. Devices on which

electronic notebook mobile edition software is installed must also have a verification performed. Information should include, at least, the following:

a. Computer Make and Model. Computer ID or Serial No
b. Operating System (e.g., Windows 10, Windows 11, etc.)
c. Electronic notebook mobile edition software version number (found on the sign-in screen of the program)
d. Type of procedure performed (e.g., software verification, installation of updates, any type of service or maintenance, etc.)
e. Indication as to whether the procedure performed was Routine or Non-Routine and which standard operating procedures it followed. If non-routine, describe the nature of it, how and when it was discovered and the remediation taken. See 40 CFR 160.63(c) Subpart D-Equipment for details.
f. Date verification procedures performed and evidence from the verification test (if used with mobile edition)
g. Initials or signature and date of person performing the procedure

B. Upload a PDF of the Maintenance and Repair Log to the eFDB for each trial prior to trial completion. Retain the Maintenance and Repair Log according to test site SOPs for equipment files.

C. The Field Research Director is responsible for maintaining an equipment maintenance log.

D. Cleaning of the device should be performed by user(s) as needed and is not required to be documented on the equipment maintenance log.

4. Raw Data Recording and Audit Trail:

A. Raw data is defined by its first point of entry. It is strongly suggested that the eFDB be the first point of entry for critical data (e.g., application equipment calibration, test substance mixing, test substance application, environmental data, etc.). However, if data is first recorded outside of the eFDB, follow the instructions for transcribed data below.

B. Each user at a field site that enters data into a notebook will have and use their own username and password. The username and password entered when saving is the equivalent of a signature for designating the user who entered the data.

C. The Audit Trail component of the eFDB records all saved entries and changes and serves as the electronic signature for these entries/changes.
   a. The Audit Trail can be generated within the eFDB system when needed as an Excel file format or a PDF file format.
   b. The PDF file format version does not contain the entries for "Transcribed?", "yes" or "no".

c. The Audit Trail provides the timestamp for when data is saved. This is presented as a conversion from the local time zone when the data was saved to the time zone for GMT (Greenwich Mean Time). GMT is a world standard time zone.

D. When saving entries, the program requires the user to designate the data as being transcribed or not, which is recorded in the Audit Trail. Data entered and saved directly into the electronic notebook (i.e., data not first recorded elsewhere) will be designated as raw data in the Audit Trail.
   a. Data that is first recorded on paper or electronically by individuals at the test site, then entered into the eFDB form(s) will be marked as transcribed.
   b. Data that is entered for the first time in the eFDB form but was read from another location is not considered transcribed (e.g. test substance information read from the bottle or Certificate of Analysis; minimum and maximum storage temperatures read from a data logger output file; first rainfall after application read from a weather station record).
   c. All data that is entered at one time and saved, including automatically generated calculations, will have only one prompt for providing the response to "transcribed?", "yes" or "no". The user can enter and save data with separate clicks of the save button to only ascribe transcribed? "yes" or "no" to those data point for which this is an accurate statement. Then complete the remaining data entries and save for the opposite answer to transcribed? "yes" or "no". The user cannot change the entry for transcribed "yes" or "no" in the audit trial after it is saved. If an inaccurate Audit Trial entry of transcribed "yes" or "no" is provided a note should be added to document this discrepancy.
   d. The Audit Trail designates system calculated values with the description "custom formula". System calculated values are determined based on the specific formula and are not able to be directly entered or changed by users. Audit Trail designation of transcribed "yes" or "no" should be disregarded, because these entries are system generated and were not recorded by the user. (i.e. it is not possible to have system calculated entries be transcribed. If "yes" is recorded in the Audit Trial for calculated values, it is because the other non-calculated values that were saved at the same time were transcribed.).

E. Recording raw data on IR-4 Headquarters provided or approved electronic or paper pages is acceptable. Contact the Study Director or Regional Field Coordinator to determine whether a custom form is acceptable.
   a. The eFDB Attachments section contains a PDF file with blank notebook forms, called the eFDB Paper Raw Data Notebook. Follow the instructions provided in that notebook. Unused pages of the notebook should be removed prior to uploading and submitting the raw data.
   b. Additional notes, images, and descriptions may be provided that are not on approved forms.

c. The Print Utility function may be used to generate a PDF version of the eFDB forms. These may be printed on paper to serve as a backup option during critical phases or for other uses.
d. Trial data that is recorded outside of the eFDB should be transcribed as needed into eFDB forms, in a timely manner. A true copy scan of the original data page must be uploaded to the eFDB. Original paper trial specific data pages must be maintained in the paper raw data notebook for the trial.
e. All trial-specific handwritten or printed raw data must be signed (or initialed) and dated at the time it was recorded or printed. The raw data pages must be scanned and added as a document to the eFDB, and must be submitted with the trial raw data package.

F. Document uploads must visibly contain the necessary information to properly attribute the file. The attribution elements may be present on the file or added prior to upload with a text box, via a file editor.
a. The attribution elements are Field ID number, the initials (or signature) and date, and the source of the file. Each must be provided. The Field ID number is not required for these files: their CV/ Resume, SOP index, and map of the location of the research station and nearest city/ highways.
b. The source should clearly denote where the file was derived from or who generated it (e.g. the name of the weather station or name of the data logger).
c. If the file is a scan of a piece of paper, the source is provided as a true copy stamp, which describes this electronic file as a true copy, provides the location of the original paper, and the initials and date of the individual who made the true copy mark.
d. Documents, when uploaded, are given a name within the eFDB system. The name should be (but is not required by this SOP) in the format of "eFDB Part number", "description of the file", and if necessary appended with the statement describing the file as a "revision number" or "version number". *E.g.* " Part 1 SOP Index"
e. Files that are uploaded cannot be deleted. Any changes necessary to the file are made in the form of a subsequent document upload, with the appropriate file name describing the iteration of revision. *E.g.* "Part 1 SOP Index version 2"

G. Additional descriptions, unusual circumstances, notes, communications, or other data may be entered using the "Notes" button, which is present on each eFDB form. The "Notes" button should be (but is not required by this SOP to be) selected on the appropriate form, which pertains to the note, in order to attribute the note to that section of the raw data. Document upload files should be used for descriptions longer than a few sentences.

5. Raw Data Submission

A. After trial raw data has been entered into an eFDB form by the Field Research Director or other field trial personnel, the form should be marked as completed, via the Form Data button.
   a. The Form Data button is used to provide the initials of the person marking the form as complete and the date the form is being marked complete.
   b. The Form Data button is also used to mark the form as being *Transcribed*, "yes", "no", or "n/a".
      i. "Yes" is selected when all or a portion of the data in that eFDB form was first recorded on paper or electronically by individuals at the test site, then entered into the eFDB form(s) via transcription.
      ii. "No" is selected when the entire eFDB form was entered directly without a transcription.
      iii. "N/A" is selected when the form is left blank and not used for the trial.
   c. The Form Data button contains prompts for Date Reviewed and Date QCd, which are not used.
   d. Data prompts within an eFDB form that are left blank when the form completion is marked are acceptable and considered intentionally left blank. Many data prompts require a specific type of data input such that a "NA" response is not always possible. There is no ability to "cross-out" unused portions of form.

B. The FRD will notify the appropriate individuals (e.g. their RFC, the Study Director and the eFDB administrator(s)) via e-mail when they have completed their eFDB for a given trial.
   a. After notification of completion, a Quality Control (QC) step may be performed. If performed, the following steps are followed during the QC process.
   b. The QC reviewer will notify the FRD of any suggested changes, questions, or comments.
   c. After being provided an e-mail of QC findings, the FRD should make all necessary changes in the eFDB system or to the paper raw data and upload the revised version(s) of any changed document uploads.
   d. Questions or comments with the QC reviewer should be discussed via e-mail or otherwise documented appropriately.
   e. After completing necessary revisions, the FRD will notify the QC reviewer, their RFC, and Study Director that all changes have been complete and provide an appropriate response to the QC findings.
   f. The QC reviewer will confirm via e-mail that the responses and/or changes are acceptable. The FRD will include this QC correspondence, with the QC findings and FRD responses, in the eFDB document uploads.

C. The FRD will prepare their raw data paper pages for shipment to IR-4 Headquarters.
   a. Paper pages that were collected during the trial will be paginated by FDB part number, and the first seven pages of the eFDB paper raw data file are placed in front of the raw data pages.

b. The first seven pages will contain the title page, instructions, a completed chain of custody, a completed checklist of document uploads, and a page for logging additional pages added after initial pagination.
c. The FRD will scan or copy the paper raw data and introduction pages prior to shipping, as a backup for possible loss during transit and notify IR-4 Headquarters (the Study Director, eFDB Administrators, and/or appropriate individuals at HQ responsible for receiving raw data) and their RFC that the paper raw data file has been shipped or is being shipped.
d. The paper raw data file is then shipped to IR-4 Headquarters (addressed to James Byrtus or appropriate individuals at HQ responsible for receiving raw data). Once received the file for the trial will be retained in the file room until archiving.

D. The paper raw data file (paper or scanned true copy) will be provided or made available to the Quality Assurance Unit (QAU) for field data book auditing.
a. After shipping the paper raw data file to IR-4 Headquarters, there must be no changes made to the electronic raw data or the paper raw data file, until QA audit findings are provided.
b. QAU will audit the eFDB and paper raw data and provide findings to the FRD via the eQA system.
c. Once notified of findings, the FRD should make the needed revisions to the eFDB, and transmit any corrected or additional raw data paper pages to IR-4 Headquarters QAU. The additional or corrected raw data pages should be scanned and uploaded by the FRD to the eQA audit responses and to the eFDB documents.

6. Archiving

A. The paper raw data and eFDB data is reviewed and changes may be made by the Study Director or other HQ personnel according to IR-4 HQ SOP 5.4.

B. The paper raw data will be stored in the file room and, prior to Final Report signing, it will be archived according to the current version of IR-4 HQ SOP 7.7 (See also HQ SOP 6.0).

C. To archive the eFDB electronic data, the writing and notebook access permissions are removed for all users (except the eStudy Administrators). iAdvantage Software controls the access to the raw data server archives.

D. The Study Director or other HQ personnel will create a read-only PDF as a backup copy of the eFDB forms and all electronic raw data using the Print Utility function. An Audit Trail Report is also generated and saved as a read-only PDF as a backup copy that provides all entries and changes made to the eFDB forms during the study. A true copy stamp is added to each electronic file, which describes this electronic file

as a true copy, provides the location of the original data, and the initials and date of the individual who made the true copy mark. These PDF copies of the iAdvantage server data are archived for the study in the Protected Drive in the IR-4 Shared Folder.

7. Additional eFDB Requirements

A. The eFDB program has been validated by IR-4 HQ and iAdvantage, which has demonstrated acceptable installation, performance, and operation for online and offline GLP raw data use. Validation of the system is performed according to the HQ SOP 5.6.

B. The Field Research Director(s) and other trial personnel who enter electronic raw data will have documented eFDB training from an IR-4 eStudy Administrator prior to entering electronic raw data. Documentation of eFDB training must be included in the personnel training log for each eFDB user.

C. The Field Research Director is responsible for ensuring that eFDB device(s) are adequately functioning, suitably located for use and safe storage, and that there is adequate control of access to the device, particularly when forms are checked out on the device in the Mobile Edition.

D. Any error, problem, concern, question, or comment regarding the eFDB should be provided to one of the eStudy Administrators. If they are not available, contact the appropriate RFC provided in the study protocol. The protocol also provides the contact information for who to contact at IR-4 Headquarters, if the RFC is not available.

a. eStudy Administrator: Philip Moore, IR-4 Project Headquarters, North Carolina State University, 1730 Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606, (615) 426-6175, E-mail: pmoore@ncsu.edu
b. eStudy Administrator: James Byrtus, IR-4 Project Headquarters, North Carolina State University, 1730 Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606, (919) 515-3017, E-mail: jpbyrtus@ncsu.edu

8. Limitations of the System

A. The Website eFDB and the Mobile Edition display and recording of the eFDB entries have built in data field settings for certain numbers in the iAdvantage Fixed Forms 11,12, and 14. These user entered or calculated values are required to contain a specific number of digits displayed after the decimal point. The actual values entered by the user are changed by the system to append trailing zeros after the decimal or to truncate a value to a fewer number of digits after the decimal. E.g. an entry of 100 seconds is changed to 100.00 seconds. This does not change the absolute value of

the entry, but attributes an artificial level of precision for the entry, which should be considered superficial. This setting is meant to provide a consistent display of values and for the program to conduct calculations in the background on those values.

B. The iAdvantage Fixed Forms 11,12, and 14 contain data fields that allow only specific data input formats. This format requirement allows for calculations to be performed using the user input, which is a specific format of number. In the circumstance where the data input is not possible to be provided in the required format, the FRDs and those who use the forms are instructed to use a "default" number, such as a "1", even if that is not the most appropriate literal response to the data prompt. E.g. the prompt for nozzle spacing, when the application is using an airblast sprayer, will be entered as "1" because the form will not accept an entry of "nozzles 1 through 3 are 3 inches apart and nozzles 4 through 6 are 4 inches apart".

C. The iAdvantage Fixed Forms 11, 12, and 14 can be used for any application that occurs with a calibrated output and time of output applied to a given area. Certain applications require a "work around" to use these forms to generate the application result. The FRDs and those who use the forms are provided with specific instructions to use when a "work around" is needed due to an application where the equipment is not a standard boom or the data prompts are not entirely appropriate. Applications with irrigation injection and airblast have instructions in the Attachments section of the eFDB for how to enter certain data fields in the Forms 11, 12 and 14.

D. The iAdvantage Fixed Forms 12 and 14 require a protocol adjuvant rate. IR-4 protocols often do not provide a specific adjuvant rate and instead require that the FRD determine which adjuvant is appropriate for the specific application scenario and to utilize a recommended rate based on that adjuvant's label.

   a. A calculated amount of adjuvant to measure in a tank mix is provided based on the protocol rate, equipment output rate, adjuvant concentration, and treated area. FRDs and those who use the forms are advised that if the protocol does not provide a required numerical adjuvant rate, the forms will display a default adjuvant rate of 0.5 % v/v. The user will see a calculated amount of adjuvant to use in their tank mix based on that default rate and will determine the actual amount that should be used, based on the adjuvant's label recommended rate.
   b. An application result is provided based on the actual adjuvant rate compared to the protocol adjuvant rate. FRDs and those who use the forms are advised that if the protocol does not provide a required numerical adjuvant rate, the forms will display an arbitrary comparison of the actual adjuvant rate and the protocol rate. The user will determine whether the adjuvant was applied appropriately according to the protocol, by comparing the actual adjuvant rate provided relative to the adjuvant's label recommended rate.

c. If the adjuvant provides multiple rates for different application scenarios, it is recommended that a note or emphasis is added to ensure reviewers can identify the adjuvant rate that was intended for the application.

Signatures

Jerry Baron

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Revision: 0
Electronically signed by Jerry Baron
Title: Testing Facility Management
Date: 6/28/2024 7:45:39 AM
Reason: Approval of Document

Valid for 5 days from: 07/22/2024