



Providing Safe and Effective Pest
Management Solutions for
Specialty Crop Growers

IR-4 Field Data Book Guidance

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IR-4 FIELD DATA BOOK GUIDANCE

(Authored by E. Lurvey, with revision assistance from K. Samoil, T. White, V. Starner)

The collection of all data in IR-4 GLP residue studies is governed by the Good Laboratory Practice Standards (GLP's). These standards were set forth by the U.S. Environmental Protection Agency in a final rule in the Federal Register (Vol. 54, No. 158) on August 17, 1989, and can be found in their entirety in 40 CFR Part 160.1 to 160.195 (<http://www.gpoaccess.gov/cfr/index.html>) Some actual text of GLP regulations is included in this guidance document for extra emphasis. If you do not have a copy of the GLP regulations, please contact your Regional Field Coordinator for a copy or find it on the EPA website.

I. Introduction

Field Data Books (FDBs) are used in all trials conducted by IR-4 cooperators in support of requests to establish a pesticide tolerance, or to expand or maintain a registration. These trials must be conducted under Good Laboratory Practices (GLP). Any data recording or procedure that is not conducted in adherence with GLP must be noted in the compliance statement.

This document is meant to serve as guidance for Field Research Directors (FRD) on how to fill out FDBs. It does not illustrate the only acceptable way to complete a FDB, nor does it cover all the possible permutations within IR-4 studies. It is all right to handle things in a different manner, as long as all GLP issues are addressed, and the data are presented in a manner that can be efficiently reviewed by Regional Field Coordinators (RFC), Quality Control (QC), Quality Assurance (QA) personnel, and Study Directors (SD).

Completed Field Data Books should be forwarded to the Regional Field Coordinator (RFC) as soon as possible after residue sample shipment, preferably within two months, unless a different chain of custody is requested. Timely submission of the FDB is essential to maintaining the 30-month timeline for IR-4 studies. On occasion, the SD may request special handling of a given FDB. Such a request must be submitted in writing to the person who has the FDB (FRD, RFC, or QA), with proper IR-4 approvals. FDBs should not be handled differently without this authorization. If a trial is dropped or terminated, or if a study is canceled, data entry into the FDB(s) should stop immediately and the partially completed FDB(s) should be forwarded to IR-4 headquarters (HQ) per established routing procedures, unless other instructions are provided. Such FDBs will not be subjected to QA audit, but must be filed and eventually archived with the study data at HQ.

II. General points, common to the entire Field Data Book

GOOD LABORATORY PRACTICE STANDARDS, 40 CFR Part 160 - Environmental Protection Agency Section 160.130 Conduct of a study: (e) All data generated during the conduct of a study, except those that are generated by automated data collection systems, shall be recorded directly, promptly, and legibly in ink. All data entries shall be dated on the day of entry and signed or initialed by the person entering the data. Any change in entries shall be made so as not to obscure the original

entry, shall indicate the reason for such change, and shall be dated and signed or identified at the time of the change. In automated data collection systems, the individual responsible for direct data input shall be identified at the time of data input. Any change in automated data entries shall be made so as not to obscure the original entry, shall indicate the reason for change, shall be dated, and the responsible individual shall be identified.

Please note that although the look of some pages has changed (i.e., table format instead of text), the information requested remains similar to previous years.

1. Data should be entered in real time; that is, entry dates should reflect the dates when actions were taken. For example, the dates when Test Substance Use Log entries were initialed and dated should correspond to the dates test substance was weighed.
2. When data is entered on a page on more than one date, each entry must be initialed and dated. For example: 4B, Test Substance Use Log, or 8A Residue Sample Shipping Information.
3. When more than one person enters data on a page, clearly indicate who made each entry with initials and date
 - A. In some cases, the FDB prompts for the individual making the entries within the page (4B).
 - B. In other cases, a signature and date at the bottom of the page (8A) indicate the data entry person. In this case, if another person enters data on the page, they must initial and date their entries. For example, if more than one person collects weather and field condition data and enters it on 6H, the person not signing the bottom of the page should initial and date each entry he/she made.
4. All entries should be clear and legible. Any change or correction to the raw data must be made by drawing a single line through the entry so as not to obliterate the original entry. The change must include the reason for the change, either as a written explanation or as an acceptable error code, as well as the initials of the person making the change and the date. If codes or abbreviations are used in the FDB that are not defined in the General Instructions at the front of the book, they must be defined somewhere in the FDB such as in Part 3.
5. Data electronically generated should be initialed and dated when printed. This includes, but is not limited to: e-mail, electronic temperature monitoring device data, and weather station data. This initialed and dated data printout then becomes the original raw data.
6. All pages must be identified with at least a complete Field ID number, as provided in the protocol, including both sides of any double-sided pages. The field ID number is an assigned specific number in the format ZZZZZ.XX-YYNNN, where ZZZZZ is the study number [a four digit number based on the Project Clearance Request number (abbreviated as PR#) preceded by a zero (0) or a letter (A, B, C, etc.)], XX are the last two digits of the year, YY is the state or province, and NNN is a two or three digit trial number for the given state. Examples are 09999.01-NY19 or A8899.01-CA*109 (an "*" after the YY for state or province indicates it is an ARS trial).

7. The order of the pages within each Part of the original Field Data Book should be maintained (e. g. 1A, 1B, 1C), with supporting data pages placed behind the pages to which they pertain; for example copies of weather data print outs should be behind 9A, followed by 9B. Other supporting data should be included where necessary and logical. In Part 6 Application, it is preferable that pages be arranged by application for multiple application trials. For example, application 1: 6A, 6B, 6C, 6D, 6E, etc.; application 2 (using the same sprayer, no changes): 6C, 6D, 6E, etc. (include 6A and 6B if different equipment is used).

8. All pages in each Part of the FDB must be numbered including those pages not originally part of the FDB (i.e. supporting data). The pages should be numbered consecutively within each Part, starting with Page 1, along with the total number of pages in that section (for example, Part 1, page 5 of 25). If a page is added after the Part/FDB has been paginated, number the page with the previous page number and a letter, for example Part 1, page 5A of 25. In each part of the FDB, all the pages in the entire part should be numbered consecutively, not taking into account sections (A, B, C, etc.).

9. All forms must be completed and all data prompts (lined areas and tables) must have a response. If a particular form or section of a form does not apply to the trial, some indication, such as NA, not applicable, none, etc., should appear. An acceptable exception is a data prompt starting with the conditional clause 'If'. In this case, based on Standard English usage, the conditional clause does not require a response, if the condition is not met. For example on 6H, when crop vigor is good, no response is needed to "If crop vigor is poor . . . "

10. The absence of data must be explained (e.g. not available, NR = not recorded, etc.). The error code NA is only for not applicable.

11. Information may be submitted using customized forms or other supplementary data sheets, but extensive use of customized forms is not encouraged. Where other forms are used, its equivalent FDB form must precede the new form. In this case the FDB form or section of the form must be properly annotated (e.g. see next page), lined out, initialed and dated. The customized form should be arranged in such a way that a person unfamiliar with the form can easily understand the information on that form. **DO NOT REMOVE** unused FDB pages – cross them out.

12. Lining out should be done using a diagonal line from the top of the page or section to the bottom. If the form or section of the form is simply not needed, an initial and date are sufficient. Unused portions of tables or lined areas should also be lined out, initialed and dated, if, for example, three or more rows/lines or entire columns are not used. Blank areas after written descriptions, calculations, etc., should also be lined out, initialed and dated.

13. All copies included in the FDB must be certified copies, and the location of the original specified on the copy. Copies should be made from the original to assure readability. In the case of application calibrations used for more than one application in a given day, the original will be placed in one FDB, and certified copies (see bottom of IR-4 form 6C and D) in other affected FDBs, citing the location of the original. If raw data belongs to two or more trials, such as weather information, the original should be placed in one FDB, in facility files, or in a

Common Data Book (these are allowed in some cases; contact your RFC for more information.), with true copies in all the other affected FDBs, citing the location of the original.

14. Additional pages may be added anywhere the FDB form does not provide enough space for a complete description or explanation. These additional pages should be inserted behind the pages to which the information pertains. Examples: application narrative (6H); description of sample collecting and storage (7A); etc.

15. When adding pages to a FDB, be careful that holes are not punched through data. If this happens, write in the lost data as though it were an I.E. (Illegible Entry). Note: After FDBs leave the FRD, they are not kept in ring binders, so holes are not necessary.

III. Review for completeness, general: During review of the introductory pages of the FDB, be certain that:

1. The Title Page is present. This is not a requirement, but the page is included with the protocol and is helpful to subsequent reviewers.
2. The **General Instructions for the Completion of the IR-4 Field Data Book** have been retained. These pages must be present as they contain the correction codes.
3. The Chain of Custody Form has been completed by all personnel that have had custody of the book. The blank areas of these pages should not be crossed out.

IV. Review for completeness, specific review, by Part:

1. PART 1 – GOOD LABORATORY PRACTICE COMPLIANCE INFORMATION

- 1A: Standard Operating Procedures: Should be completed or crossed out, initialed and dated with a reference to attachments. Copies of SOP Index and Title Page, where appropriate, should be inserted. If certain SOPs need to be added to the FDB, insert them here. The SOPs must cover the time from the first application through the shipment of the residue samples. That is, the approval signature must be dated before any data are collected for the trial.
- 1B: Deviation Form: Copies of field site deviations (prior to SD signature) should be included or the unused page crossed out, initialed and dated. In some cases, copies of deviations that have been signed by the Study Director can be placed with the protocol in Part 10. A suggested guideline would be to include deviations from your field site in Part 1, as they refer directly to the FDB being reviewed. **Please note that the original of a deviation you prepare should be sent to the SD, even though the notification was made by phone, e-mail or FAX.**

1C: Good Laboratory Practice Statement: The GLP Compliance Form (1C) should be completed and signed by the FRD. Any procedure that is not in compliance with GLP must be listed, or the common examples which are listed can be checked. If the GLP compliance statement provided by the FRD does not accurately reflect the trial, the FRD must approve inclusion of additional items or procedures. This page **MUST** always be an original for each FDB, even if the non-compliance issues are always the same.

2. PART 2 – PERSONNEL INVOLVED IN TRIAL

2A: Identification of Individuals: This page should be completed with the names of all personnel involved in the trial, including all individuals who entered data and/or worked on the trial (general field workers, QC, QA, SD, and RFC do not need to be included). This may be a certified copy of an original, but the location of the original must be cited as either another Field Data Book, the facility files, etc. It is preferable to have an original of this Part 2A in each FDB. This page has a “true copy” prompt at the bottom, but FRD are encouraged to provide originals, thus confirming the listed people did work on this trial, not everyone associated with the test site.

2B: Qualifications Summary: A qualifications summary or CV and training records are to be included here for each person listed in 2A. The original CV should be initialed and dated. CVs and training records must be certified copies, citing where the originals are located. An additional sheet may be added for personnel who were involved in critical parts of the trial, such as timing pass times or harvesting, but who did not record data and are not listed on 2A. This sheet should name the person and the portion of the trial in which they took part, along with the training they received and who did the training.

3. PART 3 - NOTES AND COMMUNICATION LOG

This part should contain documentation (written logs, phone logs, emails, faxes, etc.) of any communication directly involving conduct of the trial that is not documented elsewhere. The types of events the communication log may include, but are not limited to:

- a. notification/discussion of protocol or SOP deviations
- b. discussions of GLP confirmation of the test substance
- c. discussion/questions concerning the test substance application, sampling or shipping
- d. any unusual events that may affect the integrity of the trial
- e. email printouts that are initialed and dated
- f. discussions with farm manager or maintenance farm crew

Although the instructions on this FDB page state “for continued entries or explanations to other sections,” a preferable location for that type of additional pages might be behind the page to which the continuation or explanation pertains.

4. PART 4 - TEST SUBSTANCE RECORDS

4A: Receipt, Storage and Disposition of Test Substance: All information requested should be entered, and the page signed and dated at the time of Test Substance Receipt.

Please remember to include packing slips and any other GLP-relevant documentation. **Note:** MSDS sheets are not required, but Part 4 of the FDB is a good place to include them for handy reference. A separate form is needed for the same test substance (t.s.) if the lot/batch numbers are different, or if there is more than one receipt date. The name of the t.s. should be entered as it appears on the container label. Be sure it agrees with the protocol and it, along with the lot/batch number, can be traced through the packing slips and certificate of analysis. If not, contact the SD.

- 4B: Use Log: One log per container should be filled in. The dates and amounts entered here reflect the dates and amounts recorded in Part 6 application. These entries should be made at the time of the measurement. Unused cells should be crossed out, with initials and date. If the same t.s. container is used in more than one trial, one log should be filled in for all uses and placed in one FDB, with a certified copy placed in FDBs for other trials.
- 4C: Disposition of Test Substance Containers: The pertinent part of the page should be filled in and the other parts crossed out, with initials and dates on the lines, or the signature and date at the bottom of the page. Please do not return containers to the registrant without the permission of the SD and the agreement of the registrant. Please remember that retention of the t.s. container is a requirement.
- 4D: Identification and Receipt of Spray Additives: This page should be crossed out if it does not apply, or the pertinent part filled in, with the rest of the page filled in or crossed out, initialed and dated.
- 4E: Chemical Storage Building Temperature Log: This table should be filled in or crossed out, initialed and dated, with a reference to attached data, if appropriate. Please note that prompts for min/max storage temperatures have been added for a second t.s. at the bottom of the page. Fill in if more than one t.s. was used, otherwise cross out. The minimum and maximum storage temperatures between receipt and the last application should be entered for each test substance. Attached copies must be certified, with the location of the original data cited. SOP's should define the frequency at which temperature data are recorded. If the t.s. was stored in a temporary location (such as in an office) before transfer to the long-term t.s. storage location, dates and location should be known and recorded, as well as actual or estimated (e.g. approx. 68-72°F) temperatures in the temporary storage and an explanation of why this short-term storage was needed. The temperature recording device must have a unique identifier, and that identifier must be included on all temperature log pages or temperature recording charts, and on device calibration documentation. T.s. must be stored under conditions provided on the container label and/or associated documents. If this is not possible, contact the SD immediately.
- 4F: Balance Calibration Check: This page should be filled in if the test substance is a dry formulation. Otherwise, it should be properly crossed out. The standard weights used for a calibration check should bracket the amount of test substance being weighed. If

using a scale/balance, a certificate of service and standardization of the weights should be included.

The test substance temperature monitoring device logs and its calibration/verification data should be included at the end of Part 4, or in Part 3.

5. PART 5 - TRIAL SITE INFORMATION

If the spaces for maps and plot plans are not used, they should be crossed out and the attached map or diagram referenced.

- 5A: Directions to Test Site: Please remember the name and location of the test site. Photocopies of the appropriate section of state or county maps, as well as computer generated maps or diagrams may be used. The rest of the page should be filled in.
- 5B: Directions to Test Plot Area: The distance from the farm entrance to the plot should be given on 5B or 5C, along with the irrigation source and meteorological station. If copies are used, an original should be found in the facility file. All pages should be signed and dated. If the scale of the farm map is such that some of the finer detail, such as the irrigation source would be hard to distinguish, feel free to include two maps.
- 5C: Plot Plan: Once again, the plot plan can be drawn on a separate sheet, and included. The plot plan must include:
- Location and dimensions of the treated and untreated plots (length, width, row/bed spacing, etc.) and distances to permanent marker(s) from at least two plot corners. GPS readings for permanent markers are acceptable (an SOP should be in place, including how accuracy is verified). Dimensions of buffer areas are also needed.
 - Number of rows/beds - for established plantings of trees and bushes, the number of plants in the row and the distance between rows is useful here.
 - Direction and % of slope - an arrow should be used to point down the slope. Please note that the slope can go more than one direction, esp. on crown of knoll.
 - Direction of the rows
 - North direction

Please complete this plan before making the first application. Relative positions and buffers of adjacent trials can sometimes be useful information.

- 5D: Site and Soil information Characteristics: The site and soil information should be filled in with supporting soil analysis or soil maps attached. Soil characterizations should be no more than 15 years old. Preferably, soil fertility and pH should be analyzed in the year in which the trial is conducted. Attached copies should be certified, with the location of the original data cited.
- 5E: Test Site History Form: Three years of pesticide/fertilizer history is requested. The information may be attached, if properly referenced. Attached copies must be certified, with the location of the original data cited. If information was copied from

another source, it must be clearly marked as transcribed. It is recommended that a second person verify the accuracy of transcriptions. The person verifying the data does not have to be GLP trained, listed in Part 2A or sign their name in the FDB. For example, if the data is being verified by a farmer, the FRD may enter the farmer's name in the blank provided. If information was received verbally from a grower, this communication should be documented in Part 3 of the FDB.

- 5F: Test Crop Records: The trial site information must be completely filled in and agree with data in 5C. Please note slight changes to this form concerning rows vs. beds vs. trees. As the row/bed choices are conditional, the section that does not apply could be left blank, but NA is recommended in this situation.
- a. If the seed lot is not available, indicate this.
 - b. Remember to include plot dimensions, as laid-out. Treated area is captured on Part 6A.
 - c. Additional Treated Plot: indicate NONE if there is no plot other than TRT 01 and TRT 02.

5G and H: Cultural Practices Log and Maintenance Fertilizers and Pesticides: These pages should be filled in or crossed out, referencing attached sheets. Attached sheets, if copies, must be certified, with the location of the original data cited. Please note that transcription and verification guidance covered in Part 5E apply here also.

6. PART 6 - APPLICATION: NOTE there are different forms for airblast sprayers 6A & B: Equipment and Diagram of Application Equipment: Both forms should be completely filled in.

- a. They only need to be included once for multiple applications, if the sprayer and application types do not change. If the crop matures significantly during the conduct of the trial, more than one illustration of sprayer position relative to crop may be useful. Type of application – when in doubt, contact the Study Director.
- b. Treated area – the area that is considered treated for rate calculation purposes, paying special attention to banded and directed applications (see FDB directions for 6A).
- c. If pertinent, explain why the treated area is not the same as the laid out area.

6C through 6J must be provided for every application (group these pages by application). Enter the application number in the prompt at the top of each page. This helps subsequent reviewers keep track of applications. Please remember there is a difference between treatment and application: treatments are defined in the protocol and consist of t.s rate per acre, application type and spray volume; an application is a single spraying event (spraying t.s. onto the test system). In studies with more than two treatments (e.g. TRT01, TRT02, TRT03), it is useful to enter both the treatment and application number at the top of each page, as long as they are clearly distinguished (e.g. Appl. 2 for TRT03, etc.).

6C: Discharge Calibration:

- a. The entire page should be filled in, initialed and dated.
- b. The calibration or recheck should be the day of or the day before the application.

- c. If it is the first application, a full calibration must be conducted.
- d. The calculations for the calibration must be shown. Remember units.
- e. If it is a recheck, the calculations showing that it is within 5% of the original calibration must be provided.
- f. If the same calibration was used for more than one trial, the original should be placed in one FDB and certified copies, with the location of the original indicated, in all other pertinent FDBs (see the area at the bottom of the FDB page).
- g. Cells not used in the Discharge table should be lined out. If you use a single run recheck, runs 2 and 3 should also be lined out.
- h. REMEMBER to fill in totals and averages.

6D: Speed Calibration:

- a. The entire page should be filled in, initialed and dated.
- b. The calibration or recheck should be the day of or the day before the application, and should be conducted on terrain similar to the plots.
- c. If it is the first application, a full calibration is needed.
- d. The calculations for the calibration must be shown.
- e. If it is a recheck, the calculations showing that it is within 5% of the original calibration should be provided.
- f. If the same calibration is used for more than one trial, the original should be placed in one FDB, and certified copies, with the location of the original indicated, in all other pertinent FDBs (see the area at the bottom of the FDB page).
- g. Cells not used in the Speed table, such as gear, should be lined out. If you use a single run recheck, runs 2 and 3 should also be lined out.

6E & 6F: Delivery Rate Calibration, and Volume, Mixing and Dilution Calculations:

- a. The application number should be provided.
- b. The formula and information used in the calculations must be provided.
- c. The calculations, including units, must be clear and correct.
- d. The page should be signed and dated, and the date should correspond to the application date.
- e. Remember these calculations are based on the results of full calibrations, not on single run rechecks.
- f. In Part 6F fill in a brief description of holding and transport of the t.s. from storage location to area of tank mixing.

6G, 6H and 6I must be original raw data – no copies.

6G: Application Information (original raw data - no copies):

- a. All cells should be filled in. If a data prompt does not apply, use “NA.”
- b. The treatment (TRT) number should be entered at the top of the column.
- c. Unused columns should be lined out, initialed and dated.
- d. The technique used to measure pH should be given, and if this data is not generated according to GLP, indicate this on the Compliance page in Part 1.
- e. The signature and date should be the same as the application date, to verify the data was entered on the day of the application.

- f. In some complex studies, although applications of more than one treatment may be made on the same day, the application numbers may not be the same for each treatment (e.g. on 6/30/05 Appl. 2 of TRT02 and Appl. 1 of TRT03). In this case, care needs to be taken to clearly indicate which application was made of which treatment. In some cases, it might be best to use separate Part 6G pages for each treatment/application combination.

6H: Additional Information (original raw data - no copies):

- a. The entire page should be filled in, signed and dated on the same day as the application.
- b. The brief description portions of the page should provide sufficient information so that subsequent reviewers can reconstruct what was done. For the application summary include such things as number of passes, placement of boom (nozzles) in relationship to crop (angled, etc.), band widths and distance from plants, when applicable. Pay particular attention to anything that might be out of the ordinary. In the cleaning section include a statement such as: “the excess spray mixture was sprayed on the designated non-crop area,” “the sprayer was rinsed once with water, then washed with detergent and triple rinsed,” etc.
- c. Once again, for complex studies, clearly indicate treatment/application combinations.

6I: Post Application Rate Confirmation (original raw data - no copies):

- a. Pass times should be recorded and units (sec., min.) provided. The number of pass times recorded should equal the number of passes, unless an explanation is given.
- b. Pass number rows and treatment columns not used in the table should be lined out.
- c. The discharge rate to be used in the rate confirmation calculations should be from the most recent full calibration, not from a single catch recheck. This may mean using the full calibration from the first application.
- d. Fill in the prompt for the “actual plot area treated.” This might be different from 6A if there were problems during the application. If so, explain.
- e. The back calculation must show the formula and units used. The calculation must go back to the amount of product or lb ai per acre **specified in the protocol** for comparison. It is required that the % deviation from the protocol target rate be calculated here (see 6J for example formulae).
- f. The volume of liquid product should be included in the total volume of spray mix.
- g. Confirm that the entry date corresponds to the application date.
- h. If you have to contact the SD for applications outside the protocol rate, remember to document the communication in the appropriate locations.

6J: Post Treatment Records should be complete:

- a. Rainfall and irrigation must be entered, even if the event occurred after the next application.
- b. If no irrigation was used, state this clearly to avoid questions. For example, in the space for date of first irrigation, indicate “None used in this trial,” or “None used after this application.” If no rain or irrigation occurs between applications and harvest, state that also.

6K: Application Equipment Maintenance and Repair Log: This information only needs to be included once (at the end of Part 6 in the FDB), if the same equipment was used for the entire trial. An attached equipment log for the entire season is preferred. Clearly indicate routine and non-routine maintenance. Entries for all calibrations and cleanings are suggested.

7. PART 7. SAMPLE COLLECTION AND STORAGE

7A: General Harvesting Information (original raw data - no copies):

This section consists of two pages to provide enough space for detailed descriptions. Provide enough detail so that subsequent reviewers can reconstruct exactly how the sampling was done. If more than one crop fraction, such as roots and tops, are being sampled on the same date, separate forms may be needed for each fraction to make the sampling procedures clearly understood.

- a. The harvest date is the day the samples were cut, dug, or picked. The PHI is based on the harvest date. If sampling is at a 0-day PHI, the number of hours after application is needed, or a statement that the plants were dry.
- b. If there is drying or other procedures where the sample is not bagged and frozen on the day it is harvested, then the date that the sample is bagged and frozen is the sampling date.
- c. If the crop is a tree or bush crop, the number of trees/bushes from which the commodity was sampled should be indicated. If the number of trees/bushes is less than specified in the protocol, contact the SD.
- d. If the protocol requires a minimum number of fruit, heads, roots, etc., clearly state the number that were collected per sample, and if more than the minimum # are needed to meet a weight requirement, an approximate # is sufficient. Close approximation is preferable, e.g. if you are harvesting 50 jalapeños for a pepper trial, ~48 is preferable to >24.
- e. If knives, rakes, scopes, shears, shovels, buckets, machinery, etc., were used, there must be a description of how the equipment was cleaned.
- f. Provide a brief, but detailed, description of how the samples were collected to address the protocol requirement for representative samples.
 1. To harvest, were plants cut, dug, pulled, combined, etc.?
 2. How was a representative sample obtained? A plant/fruit taken from every other plant, every x feet? For multiple rows was a zig-zag pattern used? Diagonal? 5 fruit from each row? For example, a beet plant was pulled every three steps down the row, starting 5 ft. in from the beginning of the row.
- g. If the commodity was not harvested directly into sample bags, the explanation needs to state into what they were harvested, e.g., plastic lined baskets, buckets that had been cleaned with soap and water, etc.
- h. Description of modifications – How did you:
 1. cut off roots or remove dead/senescent leaves (document what was used); how did you do it; e.g. cut onion leaves 1 inch above bulb?
 2. dry crop (document where, length of time, temperatures, how contamination was avoided, what was cleaned and how)?

3. shell beans, pit cherries, etc. (document how the process was done; if mechanical sheller, combine or other device used, include model numbers and/or unique identifiers)?
4. cut crop to reduce bulk weight or remove pits (what did you do; where did you do it; how did you insure no contamination of samples; e.g. starting with the untreated peaches first, the fruit were cut in half, the pit removed, one half of peach was placed in residue sample bag, the other discarded; the peaches were cut on the plastic covered tailgate of the project vehicle, using a separate cutting board and knife for the untreated and treated samples; the entire untreated sample was completed and bagged prior to starting on the treated samples; new gloves and plastic were used between samples and the cutting boards and knives were washed with soap and water before use)?
 - i. Describe sample cleaning (where cleaning is necessary):
 1. Generally it is sufficient to state that loose dirt and debris were brushed off by hand or with a clean brush.
 2. If rinsing or other, more drastic cleaning is absolutely necessary, and allowed in the protocol, a detailed description is needed (document where it was done, how much water, running or in separate buckets, dried by patting with paper towel, etc.)
 - j. Describe sample transport in enough detail that reviewers can reconstruct what was done. For example, “each sample, as bagged, was placed in a separate cooler for treated and untreated samples, with blue ice and driven to the freezers in a pickup after all samples were collected.”

7B: Specific Sample Information and Inventory, and Treated Crop Destruction (original raw data - no copies):

- a. An entry must be made for each sample.
- b. The time of completion of sample collection should be based in reality. If one or two people are harvesting, the completion time can't be exactly the same for all samples – it takes a fair amount of time to harvest 2-4 lbs of snap beans by hand.
- c. Elapsed time to freezer should reflect reality, as above. If all the samples go to the freezer at same time, there should be differences in elapsed time for each sample unless using 4 different harvesters.
- d. You must indicate how the crop was destroyed or kept out of the food chain. This is a FIFRA requirement. Where remaining commodity is allowed to drop to the ground and rot, there should be some indication that the researcher has control over that, e.g. on an experimental research station.

7C: Freezer Temperature Log:

- a. Must be filled in or attached sheets referenced, with temperature units (°F or °C) noted. The temperature recording device unique identifier must be provided on all temperature log pages or temperature recording charts, and on device calibration documentation (inclusion of temperature recording device calibration data is suggested).
- b. Sheets must contain dates of record, for example start and end dates.
- c. Sheets must be initialed and dated at the time of data collection.

- d. If copies, they must be certified with location of the original cited. The originals must be sent to IR-4 HQ, preferably in a FDB or maintained in facility files.
- e. Cells not used in any table must be lined out with initials and date.

7D: Freezer Contents Log:

- a. Must be filled in or attached sheets referenced.
- b. Arrows or brackets to mark what entries belong to trial are helpful.

7E: Freezer Maintenance and Repair Log:

- a. Must be filled in or attached sheet properly referenced.
- b. Copies must be certified and the location of the original cited.

The calibration/verification of the temperature-monitoring device should be included in this Part, or in Part 3, with unique identifier indicated.

8. PART 8. RESIDUE SAMPLE SHIPPING

8A: Residue Sample Shipping Information: Sample-shipping form must be completed.

- a. Much of the form can be filled in prior to shipping, but date and time given to carrier must be entered in real time when pickup occurs. It would be preferable to make an exact copy of what can be filled in, leaving times and dates and final signature until actual shipping.
- b. You should indicate that the lab was contacted about shipping and provide documentation (phone log, email, etc.) here or in Part 3.
- c. You should indicate how much dry ice was used for overnight shipment.
- d. Bill of lading or other documentation should be attached behind this page. Be sure to put Field ID number on ACDS sheets.

8B: Residue Sample Chain of Custody Form

- a. Trial location should be listed as was done on Part 5A (name and location for test site)
- b. Complete this page and cross out unused portions of table, with initials and date.
- c. Some notification of sample receipt at the lab should be attached behind this page.

8C: Sample Arrival Check Sheet: For shipment of all samples, fill in Part 1 of this form, and place a copy in each sample box from the same trial.

9. PART 9: WEATHER AND IRRIGATION RECORDS

9A. Daily Field Trial Weather Records

- a. Bottom of page with weather station information should be filled in.
- b. Weather data table should be completed for each month or weather inserted behind. Copies must be certified with the location of the original. Original should be in another FDB or in facility files. At some sites the weather data is kept by another entity and the FRD will not have the original in his/her possession; if this is the case, indicate so in this Part.
- c. Cross out unused portions of the table.

9B: Additional Meteorological Information:

- a. Respond to the questions on this page as appropriate.
- b. Irrigation information should be completed, if pertinent.
- c. Information on unusual weather conditions and its potential impact on the crop is essential as the local situation may differ from official weather sites. Note that historical averages are no longer required.

PROTOCOL & PROTOCOL CHANGES

- a. This is where the protocol and protocol changes should be attached. Pages in this section must also be identified with the Field ID number, like the other sections (all pages of the protocol and changes should already have the Field ID number on them).
- b. Additional information should be placed in the related part of the FDB or in Part 3 (if it does not fit anywhere else).