"Phoenix Proceedings"

2006 IR-4 National Education Conference

(Phoenix, AZ, February 28-March 2, 2006)

The 2006 IR-4 National Education Conference was opened with introductions by conference co-chairs Dan Kunkel and Van Starner, followed by greetings from Western Region Director Marion Miller and PMC Chair and Southern Region Director Marty Marshall. Western Region Field Coordinator Rebecca Sisco introduced a special welcoming address by the Director of the AZ Dept. of Agriculture, Donald Butler. Don welcomed conference attendees and talked about the current status of agriculture there. Agriculture is the third largest industry in the state, with an abundance of winter specialty crops grown in the Yuma area. One major challenge facing AZ growers is labor, which could be alleviated with a guest worker program with Mexico.

Over 170 participants registered for the two and a half day conference, including IR-4 Field Research Directors, field technicians, Laboratory Research Directors, lab analysts/technicians, Regional Field Coordinators, Quality Control reviewers, Quality Assurance officers, Study Directors, Project Management Committee members, and Canadian colleagues involved in NAFTA collaborative field trials. This was the first national training event since the 2001 training in San Antonio, TX, and was organized by members of the IR-4 Training Committee (TC).

What follows herein is a brief summary of presentations, with highlights of some talks (and links to some of them), questions/answers and other pertinent items to be documented from the conference.

Feb. 28 (afternoon):

1. Robert Holm started the conference with a presentation entitled "The State of the IR-4 Project" in which he highlighted recent IR-4 successes, current initiatives, and future challenges.
2. Rocky Lundy, Chair of the IR-4 Commodity Liaison Committee and of the Mint Industry Research Council, discussed the status of current and future funding for IR-4.
3. Dan Kunkel gave a review of 2005 IR-4 approvals at EPA, previewed the 2006 field research program, and commented on the significant impact of PRIA (Pesticide Registration Improvement Act) on coordination of IR-4 submissions to EPA.
4. Laurie Richards of Laurie Richards and Associates, Washington, D.C., provided a well-received Keynote Address as she enthusiastically encouraged participants to "Strive to do things better, don't just get the job done!"

On the second day of the conference, for most of the day, lab and field participants attended separate sessions geared specifically to either lab or field issues.

Mar. 1 (lab sessions):

1. Daniel Myers, EPA Office of Compliance, started the lab session with a presentation/discussion about "Formatting and Writing SOPs." To view his slides, go to: Myers presentation, and for the mock SOP he used, go to: Myers SOP example.

2. Dustin Yaworski, Agilent Technologies, followed with a presentation titled "New Analytical Instrumentation."
3. Charles Stafford (EPA Analytical Branch) discussed analytical method modification and trends in enforcement methodology from registrants.

Mar. 1 (field sessions – morning):

1. Andrew Landers, Cornell University, began the field session with a multi-media presentation about optimizing application technology
2. John Wise, Michigan State Univ., continued the focus on application technology as he discussed various application parameters of IR-4 study protocols. From results of a spray deposition study on grapes in MI, John also addressed the potential effect on crop residues and product efficacy of sprayer type, spray volume and performance characteristics of the pesticide. To access John's presentation, go to: Wise presentation. The spray deposition study with 3 types of airblast sprayers and three different spray volumes (gallons per acre [GPA]), showed a couple key results pertinent to conducting GLP residue trials. a) A Proptec sprayer (designed for low volume spraying) gave the best spray deposition characteristics at 5 GPA vs 10 and 20 GPA; b) With a regular airblast machine, the best spray characteristics were seen at 50 GPA vs 20 and 100 GPA – this was an unexpected result; c) With the lower rate new products being developed today, the ideal GPA is more critical. John also asked that the descriptive word for coverage in Section 14 of the protocol be carefully chosen, as "adequate," "maximum," "complete" and "optimal" can mean different things to different people.
3. Small Group discussions: field participants were organized into groups of 6-10, with one person designated as moderator and another as scribe at each individual table. Each table was asked to consider a series of questions as a group, and to capture relevant comments, questions, and recommendations to be compiled with input from all other tables.

At each table a considerable amount of time was spent discussing the IR-4 protocol. The Questions (**Q**) or requests which follow were posed by participants, and where appropriate IR-4 answers (**A**) or responses are provided.

Question 1A: An effort to revise the IR-4 protocol has been initiated. How can the IR-4 protocol be improved? What changes would make the IR-4 protocol easier to follow? Responses:

Q1. Add specific Field ID # (trial project number) to the protocol.

A: Field ID #, as defined in the IR-4 FDB Guidance document: All pages must be identified with at least a complete Field ID number, as provided in the protocol. 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#) proceeded 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 number trial number for the given state. Examples are 09999.01-NY19 or A8899.01-CA*109 (an "*" after the Y for state or province indicates it is an ARS trial).

Adding the complete, individual Field ID # on each page of each protocol would put an undue burden on IR-4 HQ, as the protocol would have to be printed separately for each trial (as many as 16/study).

Q2. Add specific Field ID # (trial project number) to the field data book (FDB) cover page.

A: For IR-4 to generate a special cover page for each FDB would be difficult. FRD are encouraged to add the Field ID # themselves.

Q3. Make changes from draft protocol clearly evident in the final protocol.

Q4. The FRD and RFC should have say in final draft protocol due to special requirements needed in different regions and to possibly catch errors that may exist

A: Suggestions from the field on the draft protocols are taken seriously. Site specific suggestions are usually not added to final protocols, as they are written to reflect the worst case scenario at the national level. If something (such as application rates) really will not work at your site, please contact the SD. Some site specific needs can best be handled as a protocol change.

Q5. Separate and send FRD field protocols only - no need for lab section; separate the field and lab protocol changes.

A: A number of years ago, protocols were separated into field and lab phases. The US EPA GLPs require a single protocol for a study. If only a portion of the protocol is sent, we are not in compliance with GLPs. By IR-4 headquarters SOP, SD copy protocol changes to QA and to others in the study as necessary. Typically most all changes go to the lab, and FRD receive only changes pertinent to their trials.

REMINDER: Protocols and all protocol changes can be viewed/printed from the IR-4 website – just enter the food crops database and search on the PR#, click on the protocol icon, and PDFs of the protocol and all changes can be opened. Protocols and changes are typically posted to the website within a day or so of being signed by the SD and Sponsor.

Q6. In Section 11, base the buffer zone on application method and crop.

A: Section 11 usually requires a minimum of a 15 foot buffer between plots. This leaves the actual buffer size to the discretion and expertise of the field researcher, based on the crop and other conditions (for example, 15 feet is never an adequate buffer for airblast applications). If in doubt, please consult with your RFC or the SD. In some cases the SD indicates a more specific buffer size that must be followed. The revised protocol may change this wording, or take into account different types of crops and applications. If possible a physical means of "drift control" can be planted between plots.

Q7. Expand Section 15 to clarify who is doing which trial (for example, sweet vs tart cherries, pickling vs slicing cucumber, etc).
Provide a table of FRD names and contact info

A: Hopefully the 2006 protocol revisions helped address these issues. If the treatment list is not the same for each trial, Section 15 is typically divided into tables 15A, 15B, etc., with trial numbers specified in the heading of each table. Trial numbers can be compared with those in Section 24, where all FRD names appear with trial numbers. In 2006 protocols, Section 24 included a table with FRD names/contact info, and as appropriate, identified which FRD were doing sweet vs tart cherry, pickling vs slicing cucumber, etc.

Q8. Return unused product back to registrant.

Q9. Train FRDs to be authorized and legally allowed to ship haz-mats

A: We can not force registrants to take back unused product. Please remember that the container must be kept until the final report for the trials in which the test substance was used is signed by the SD (see Advisories #2003-02 and 2005-01 for Test Substance Container disposal advice). Please do not return product with out first getting permission from the SD and company representative listed in the protocol. Remember to obtain a formal, signed chain of custody with the storage location given, for inclusion in your FDB. A copy of the signed shipping form, printed from the FedEx, UPS, etc., website is probably not adequate as a receipt.

The rules governing the shipping of hazardous materials are federally mandated, and training is required. Fines can be steep ($30,000), if the shipper is not trained. Most university systems also have their own rules and offer courses on the subject. This is a good place to start looking for training. NAICC and possibly other professional groups also provide training. IR-4 will try to identify training possibilities and add them to our website under "GLP Training Opportunities."

Q10. Include more details on shipping samples to Canada – value claims, etc.

A: An excellent suggestion for an IR-4 Advisory - the Training Committee is considering this. We may want to consider if it may be more appropriate for such details to just be provided in protocols when the lab is in Canada. We also could both develop an Advisory, and include more details in the protocol. The Advisory could be included with the protocol or sited in the protocol.

Q11. Provide examples of different application types.

A: See IR-4 Advisory # 2004-02, titled "IR-4 Application Type Definitions" on the IR-4 website.

Q12. FRD would like the option to change application type.

A: If a specific application type is required by protocol, contact the SD regarding any proposed changes. Note that "foliar application" does allow some leeway to choose "foliar-directed" or "foliar-broadcast."

Q13. Expand Section 18 to include forms and shipping addresses.

A: The shipping address is in Section 19, and the shipping forms (8B and 8C) are in the FDB. One of the recommendations for the protocol format revision is make the shipping address more visible by making it a stand-alone paragraph/bullet.

Q14. Section 13: test substance label data requirements need to be clarified.

A: See IR-4 Advisory # 2003-04, titled "Test/Reference Substance Container Labels – Required Information" on the IR-4 website.

Q15. Section 17: make sample bag data requirements the same as on the bag labels; need bigger labels on the sample bags so there is enough room to write important information

A: The Section 17 sample bag requirements and bag labels are the same on newer bags. There may still be some older bags out there where the tags do not correspond to the requirements. In that case, please follow the protocol; IR-4 will look into the possibility of buying bags with larger labels to facilitate writing all the information required.

Q16. Section 14: allow target sprayer outputs.

A: Target sprayer outputs are allowed in some very specific cases. Otherwise the practice is not encouraged, as it is a less accurate way to calculate product application.

Q17. Section 15 should have a statement like, "the application is considered acceptable if the accuracy is within –5% - +10% of the spray volume range."

A: Protocols always provide a spray volume range, and to make acceptable accuracy within -5 to +10% of that **range** just makes the range bigger. The FRD should use a sprayer output that is not at the extremes of the range, to avoid deviations. The actual application rate must be compared back to protocol requirements (protocol values are pounds active ingredient and/or grams/mls of product).

Q18. Section 12: the word "will" implies one must provide site history, and some growers don't have that.

A: We really do want 3 years of history on a site – one year is a bare minimum. If the information is not going to be available, the SD should be consulted before the trial is initiated. There are very few crops where this information is not needed.

Q19. An explanation is needed when no PHI is specified.

A: The SD needs to be sure that some guidance, such as crop maturity, is given about when to harvest. In some cases, where crop maturity is not a given, a minimum PHI, such as no less then 45 days, would help, while not proving problematic for varietal differences.

Protocol format suggestions - were forwarded to B. Barney, chair of the protocol revision team:

- Any unique parameters should be **bold** to stand out (this is being done on occasion. There is a concern that putting much more of the information in bold could become excessive, and obscure the important points).
- Current font size and spacing is hard to read
- Simplify - put together critical info to reduce errors
- Table of contents in the beginning - ~50% of survey agreed
- Trial summary in the beginning – ~50% of survey agreed (at the moment, FRD are encouraged to make their own summaries. A headquarters-generated summary would not be able to capture specifics for individual trial sites. There is also some concern that the summary might be used in lieu of a thorough reading of the protocol.
- Include surfactants in the table in Section 15 not as a footnote; also specify the type (COS, NIS), but not brand (this is being done in more recent protocols)
- Add a line to separate sections
- In section 19, separate line of where samples are to be shipped
- Eliminate page breaks in the middle of the text; conclude a section before starting a new page (this may not be possible for some of the larger sections; will try not to split bullet points between two pages)
- Avoid ambiguous terms and have consistent definitions among protocols (some of this may be taken care of in the revision; once again, when in doubt, contact the Study Director)
- Wording: representative vs random samples: representative should be used

The small-group discussion committee was unsure of the meaning of the following comments:

- Ensure that all personnel in trial receive the draft and final protocols not just the RFC and the FRDs (Which personnel? Please remember that the draft and final protocols, and all protocol changes are available on the IR-4 web site)
- Footnote 5 in section 20, and FDB section 5D are conflicting (What is the inconsistency?)
- Make phyto information/changes upfront (upfront as in Section 15?)
- Include examples of plot map in the instructions (What are you looking for here?)
- Crop phenology, table 10 (?) sample size (Is this about the size of the samples? Please remember that the sampling requirements come directly from the EPA, per "OPPTS 860.1500 Attachment 8. Codex Guidelines on Minimum Sample Sizes for Agricultural Commodities from Supervised Field Trials for Residue Analysis." Even with cutting, some samples are huge.)

Question 1B: Did any of you have time to look over the document with suggested formats? If so, do you have any questions or comments? Responses:

- Numbered and bulleted format, easy to reference and read - most discussion groups agreed, as did 63% of survey respondents. 37% were in favor of numerical format. The end result may be a hybrid of the two.
- Indented format was better (1 group) – *not included in survey*
- Write out sections 1-9 in 1 page (if possible) then bullet the rest of the info and bold unique or changed information
- Larger font, but not necessary for whole protocol

Question 2: How do you organize yourself to prepare for your field trials?" or "Getting ready for application day." Do you have any secrets or tips that make things easier? Responses:

- Organize planting, application and harvesting dates on a calendar, dry erase board or computer software such as MS project or Excel
- Color code application dates in red, green for planting/harvesting
- Checklists to keep in line with the protocol and atypical use patterns
- Customize calibration section for your application to be user friendly
- Separate control and treated crops in different fields
- Sunflowers as buffer zones
- Send a copy of calendar to farm manager, regional field person and Q&A
- Be sure to have equipment calibrated and functioning properly before application day
- Check the weather the day before a spray in case you need to delay or move up an application date
- Bring a form with you that shows required rates, GPA, psi
- Do the math beforehand or have excel sheet to confirm calculations
- Check nozzles and replace (buy new) when needed
- Gather information and general practices concerning the commodity
- Keep plot size consistent to aid in calculations
- Do the applications in the morning to avoid stronger winds and heat, also allows for more time if something goes wrong
- Be sure that the field crew understands the sampling techniques
- If trial is at a different location, remind the grower the day before and have everything you will need ready to go
- Separate location for IR-4 GLP equipment
- Always clean any equipment after use - make it a habit

General Topics – Some groups were unable to respond to the following questions due to time constraints.

Question 3: Plot lay out. Permanent markers? GPS? Other issues? Responses:

- There really are no "permanent" markers
- GPS is probably questionable, uses permanent markers for reference
- One group wanted to know what is considered a permanent marker. Oak tree, cyclone fence, irrigation riser; is an irrigation riser that is 500 ft away or a cyclone fence 40 ft away better? Is GPS accurate within a meter ok? Are you within 1 meter if you pull a tape wheel out 700-800 ft?

Question 4: Plot size vs. treated area. Why aren't they the same (especially for broadcast applications)?

- Plot size - easier to keep them the same, what is relevant? Tree volume can change during the season; a broadcast application will cover the soil oftentimes when the target is the foliage; be more specific on what we should calculate on.

Question 5: Discuss equipment logs. What equipment needs logs? What needs to be documented? Documentation of equipment calibration, cleaning, maintenance, etc. Discuss ways to identify these activities as "routine" or "non-routine." Define maintenance. Responses:

- Equipment logs: are they really needed if they are calibrated every spray they make? Yes - see 160.63(a) below. For our purposes, equipment logs are needed, at a minimum, for:
  1) The balance/scale used to measure dry test substance and/or any automated devices (pipettes) used for liquid test substance measurements
  2) Spray equipment:
     - Tractors pulling spray equipment do not necessarily need logs, as there is generally a pressure gauge at the interface with the spray equipment, but keeping records for your own use is not a bad practice.
     - Based on 160.63 (b) and (c), both calibration and cleaning do need to be listed in the equipment logs as routine. A single line, citing SOPs followed would probably be enough. Other routine activities might include routine inspections prior to applications and changing nozzles between applications.
     - Non-routine activities should cover unexpected events, be marked as non-routine and be completely described in the log.
  3) Equipment (thermometers, psychrometers, wind gauges, etc.) used to take weather conditions at time of application;
     - Although we do have a blanket statement for non-GLP compliance for seasonal weather data, this does not include the climatic conditions data (Part 6H) collected at the time of the application. The thermometers, psychrometers, wind and humidity gauges, etc., used to gather this data must be calibrated or verified, with SOPs describing the activity and logs capturing the information. Please note that this log should also indicate what happens to the equipment when it is removed from service (broken, replace, etc.).
  4) Residue sample freezers
     - IR-4 has generally accepted yearly logs for the freezers, beginning when the freezer is cleaned and turned on for the season. Please note that any service on the freezers should be documented.

(NOTE: The training committee is proposing that Equipment Logs be addressed in a future training session.)

- Maintenance log: have a check list of typical maintenance activities and check them off each time it's checked (one way of dealing with equipment logs)

§ **160.63 Maintenance and calibration of equipment**.

(a) Equipment shall be adequately inspected, cleaned, and maintained. Equipment used for the generation, measurement, or assessment of data shall be adequately tested, calibrated, and/or standardized.

(b) The written standard operating procedures required under section 160.81(b)(11) shall set forth in sufficient detail the methods, materials, and schedules to be used in the routine inspection, cleaning, maintenance, testing, calibration, and/or standardization of equipment, and shall specify, when appropriate, remedial action to be taken in the event of failure or malfunction of equipment. The written standard operating procedures shall designate the person responsible for the performance of each operation.

(c) Written records shall be maintained of all inspection, maintenance, testing, calibrating, and/or standardizing operations. These records, containing the dates of the operations, shall describe whether the maintenance operations were routine and followed the written standard operating procedures. Written records shall be kept of nonroutine repairs performed on equipment as a result of failure and malfunction. Such records shall document the nature of the defect, how and when the defect was discovered, and any remedial action taken in response to the defect. This information is available on line at:
http://www.biotechnicalservices.com/downloads/CFR_160%20and%20792.pdf.

Question 6: How to handle exact copies, copies of exact copies, copies of electronically generated data/information (hobo logs, email correspondence, shipping documents etc.)?
Responses: None from participants.

The IR-4 Field Data Book guidance document (available on the website) provides the following advice:

II. General Points.

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.

#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.

In addition, if you receive what is clearly a copy of an original, and you don't know where the original actually is (might be with the registrant or elsewhere), you should indicate exactly that on the copy you receive. If you make copies of this copy, you should indicate that.

Question 7: What supplementary data needs to be provided with the FDB? What does not need to be included in the raw data? Responses (what must be provided):

- Is study dependent; prefer three years of site history especially herbicides
- Any raw data that supports the actual data generated in conjunction with a specific trial
- Equipments logs, including maintenance and calibration/verification data
- Communications between the FRD and SD or RFC concerning such things as the status of test substance, application questions or problems, and harvest questions or problems
- Communications on draft protocols, other general questions that do not relate directly to signed protocol or actual trial, and QA communications should not be included in the FDB
- All requirements as listed in the Protocol Section 20 (see below), unless they do not pertain to the trials; perhaps multiple templates of this section are needed to more closely reflect the differences in data from some studies, such as postharvest and seed treatment

From Protocol Section 20: At a minimum, collect and maintain the following raw data:

- Names of all personnel conducting specific research functions
- Amendments and deviations from protocol and standard operating procedures
- Test site information
- Plot maps
- Test substance receipt, use and container/substance disposition records
- Test substance storage conditions (including temperatures)
- Data regarding calibration and use of application equipment
- Treatment application data
- Crop maintenance pesticides and cultural practices
- Residue sample identification, collection, storage conditions and handling
- Residue sample shipping information
- Description of crop destruction, or explanation for lack of destruction
- Meteorological/Irrigation records
- Pass times (if applicable) and other data to confirm amount of material applied to plots
- Equipment maintenance records with indication of routine vs. non-routine nature of maintenance
- Other applicable data requested in the IR-4 Field Data Book that is needed to confirm that the study was conducted in accordance with the protocol.

Question 8: Documentation of data in trials that don't fit neatly into the FDB, such as processing, postharvest, seed treatment, etc. How to record data for which specific prompts are not provided in the FDB? Responses:

- Idiot proof sheets to add information
- Send out sheet asking for specific additional information
- Customized sheet/form specifically for commodity
- Do we need additional specialized FDB pages, similar to the two different Part 6's for conventional and airblast sprayer applications? If so, what parts/pages?
- Perhaps the protocol can be more specifically written to reflect at a minimum the different application techniques and data needed for postharvest, and special production systems such as Belgium endive and mushrooms.

Question 9: Discuss test substance issues- i.e. batch/lot #s vs. other numbers on the COA/label/shipping papers. Responses:

- Need to emphasize to registrants the importance of including all relevant information about the test substance with the shipment; avoid having to track down information

- Registrants should be required to take excess test substances back; they often ship too much
- Would like to receive the test substance in a timely manner, not to early, not to late
- Print off shipping papers from fed-ex site or UPS site instead of copying box; leave original on box and reference that.
- Are signed-off shipping papers from shipping website ok for proving registrant has received test substance for return? **Only if there is documentation about where the substance is stored**.

Question 10: Is irrigation calibration necessary? Why? What detail needs to be recorded in the FDB? Responses:

- It is unreasonable to demand irrigation calibration especially when grower's fields are used. Does it matter in most trials? What is the relevance? **A**. Details about irrigation can be very relevant for most studies. For example, for a foliar-applied insecticide or fungicide where irrigation is by drip tape, details are less important (for interpreting analytical results) than if irrigation was via over-head sprinkler where the irrigation water directly impinges leaf surfaces where the test substance was applied – but in both these cases, details about the irrigation are still needed.
- If it is to be recorded, estimate volume, duration, date and possible time of irrigation.

Other Participants' Issues/Questions and IR-4 comments:

- Post photos of spray equipment on the website
  - Actually not a bad idea – some FRD find it helpful to see the equipment others are using, and get great ideas for their own equipment.
- Website message board so F.R.D. can communicate with each other
  Would this really be used? Would the telephone or email be more efficient?
- Save paper: is there any way to cut down on protocol and FDB pages keeping in line with the legal requirements?
  - Probably not, without customizing the books for each trial. Do the best you can.
- IR-4 should consider providing a program (and training) like MS Project software or something similar to the FRDs to help track key events for the duration of the trial.
  - IR-4 would rather allow each FRD to choose their own system for organizing their trials.

Mar. 1 (field sessions – afternoon):

1. In the afternoon participants took two 1-hour mini-courses, chosen from a selection of a total of four courses (two of which were given each hour, due to popular demand). The two courses available each hour were: a) Daniel Myers teaching about "Writing/Reviewing SOPs" (to view his slides, go to: Myers presentation, and for his mock SOP he used, go to: Myers SOP example); and b) Andrew Landers teaching "Application Technology" (if you didn't pick up handouts he provided, contact the IR-4 Training Committee Chairperson). A third course on the do's and don'ts of "Conducting Performance Trials" was team taught by entomologist and IR-4 AZ state liaison John Palumbo and plant pathologist Mike Matheron, both from the Univ. of AZ (to view their slides, go to: Palumbo presentation, Matheron presentation). Finally, another interactive course titled "Perspectives on QA Audits and Responses" was team-taught by Martin Beran (Western Region QA), John Roncoroni (FRD at U.C. Davis), and Van Starner (Study Director) – to view this presentation, go to: Beran Roncoroni Starner presentation.
2. The remainder of the afternoon consisted of a general Q & A session for all conference participants. Two brief presentations were provided by Ken Samoil highlighting 2006 changes in the IR-4 FDB and protocols, and Van Starner reviewing the IR-4 Advisory process and the nine Advisories that have been approved and published to-date (all are accessible on the IR-4 website by clicking "IR-4 Advisories/Training" on the home page bottom toolbar).

3. General questions and discussions ensued following these formal talks. A request was raised by a field researcher that in QA audit findings, the auditor should not simply refer to the A, B, 1, 2, etc., of the QA audit checklist, but to actual page number in the FDB, etc. It is not always clear what the topic of the finding is without leafing back to the checklist to determine.

Mar. 2 (morning):

1. Edith Lurvey and Van Starner led off the Thur. morning sessions for all conference participants with an interactive presentation/discussion on "Capturing Sample Collection Descriptions in the IR-4 FDB," in which they discussed the need for very detailed crop sampling descriptions in FDB Part 7A, and provided actual FDB examples that encouraged lively discussion. To view this presentation, go to: Lurvey Starner presentation. The following are a couple questions/comments from this session.

- Based on EPA guidelines, we should add wording to our protocols, Section 17, about "making two separate runs" through each plot to obtain two representative and independent samples.
- We should provide examples of the kind of description desired for sample collection as one "proceeds through the plots."
- Don't place sample bags on the ground within the plot as sampling proceeds, to avoid potential contamination.

2. Emy Pfeil led a lab/field/QA panel discussion with the following panelists: Berry Tanner, Univ. of FL FRD; Mike Dunlap, Ohio State Univ. field; Michelle Mitchell, Coastal Research Services, CA, field; Bronson Hung, U.C. Davis lab; Robert Kon, Mich. State Univ. lab; Jane DeCann, Cornell Univ. lab; and Martin Beran, U.C. Davis, QA. To view this presentation, go to: Pfeil panel presentation. The following are highlights of questions/comments during this session.

- 1) Sample cleanliness – does it matter? Yes, it does!
  - Whatever is on or harvested with the crop can get into the raw and purified extracts and into the analytical instrumentation.
  - Problems: interfering substances, higher than actual residues (extracted from the soil or extraneous plant materials, i.e.: residues in the pods of dry beans), reduction in instrument performance; while this represents a worst case scenario it can make or break a tolerance acceptance particularly for highly filled risk cup chemistries
  - The lab cannot rinse frozen commodities: they either have to analyze what they receive from the field, or separate out contaminants as best they can - this is not easy when dealing with frozen commodities.
  - Registrant labs require samples to be as clean as they are in a grocery store.

♦Recommendations:

- Best scenario: at the draft protocol draft, if an FRD knows there is a high likelihood that their samples will be harvested with significant soil residues, contact the study director who will decide whether it is acceptable to add language to the protocol allowing light rinsing and drying.
- At harvest time if you are in a region where it is likely that a weather event will likely result in very dirty samples, again contact the SD for advisement on light rinsing/drying or harvest delay.
- A suggestion was made to check the CODEX Guidelines on harvest/removal of soil and other potential contaminants, i.e. what is acceptable?
- A request was made that the labs inform FRD if there is a problem with samples so they know what constitutes a 'dirty' sample in the future.

- 2) FDB Part 8C (Sample Arrival Check Sheet)
  - Problem: Field dislikes form 8C: which is the original – it gets confusing. HQ indicated this has not been a problem. Both the 'sent out from FRD' 8C and the 'returned to FRD from lab' 8C are placed into the FDB. Several field researchers noted that they will often put a line through the lab section of the 'sent out' 8C and make a notation to see the 'returned' 8C form.
  - Problem: Labs dislike form 8C: the form is too compact for easy recording of information since one form is being used by both the FRD and the lab; the form doesn't provide sufficient space for multiple log-in and true copy stampings; there also is concern that the tight spacing and small font could result in poor quality reproduction when the form is scanned for emailing.
  - Issue: Labs have their own Sample Arrival Check Form and it's easier for them to use the forms they've created; lab-designed forms contain not only the data requested on 8C, but also lab-specific information, so labs often use both their form and 8C, resulting in lots of duplication.

♦ Recommendations:

- If the lack of return confirmation from the lab about sample receipt is primarily a contract and registrant lab issue, can the FDB language and/or protocols be strengthened to impress on these "non-IR-4" labs the importance of generating and returning these forms?
- A majority of conference attendees "voted" in favor of elimination or modification of the Part 8C form. However, the FRDs stressed that they need sample receipt confirmation, and that if form 8C is the way to get it, then they want to keep it. Even with 8C receipt notification is still problematic with some contract/registrant labs!
- The Protocol Section 25 does not specifically request that FDB Part 8C must be returned by the lab to the FRD, but only that the lab must notify the FRD and RFC. If a return receipt form (8C or lab's own form) is required, addition of such a requirement to Section 25 was recommended, as well as requirement to also notify the SD at the same time.

POST-MEETING NOTE: The form 8C is to be included in the FDB for 2007, but with instructions that will allow the lab to return it OR their own Sample Arrival Check Sheet back to FRDs.

- 3) FDB Part 8B (Residue Sample Chain of Custody Form)
  - The EPA views the use of dittos, arrows, asterisks', etc. in the completion of these columns as 'speed data'. They discourage/disallow this use. A suggestion was made to pre-enter this data (placing an asterisk by each typewritten entry and adding a 'pre-entered data' notation to the sheet, see below) or to use a diagonal line across several fields with the appropriate annotation written on the line.

    '* This typewritten data was pre-entered by *Name of Operator* on *Date of Entry*. It has in fact occurred and is accurate for this application. *Initial of Operator* (*initials*) *Date of Execution* (*Date*).'
  - A question was asked if it mattered to the laboratories if the 8b form was filled out and initialed by someone other than the FRD; and that if only an initial was used, did it matter if the laboratory didn't know who the person was. The consensus was that it did not matter and that so long as the FDB/field raw data identified the individual, an initial was acceptable.
  - It was stressed by the Sample Control Officers on the panel that it is important that the 8b form be placed in each shipping box (as instructed in the 2006 protocols and in the 2006 FDB). This is necessary for instances (albeit rare) where a box is destroyed, damaged or lost. If the 'lost' box was the one with the sample forms then custody could be compromised or the lab might not know what samples were expected in the shipment.

- 4) Sampling Issues
  - Sample Size: The audience consensus was that labs notify SDs/FRDs/RFCs if samples seem to be too small or too large so that they know there is a problem to watch for in future trials. It was also recommended that RFCs/FRDs contact SDs as early in the process as possible (i.e.: protocol draft stage or at least prior to harvest) if there is a good likelihood that the samples will be large (i.e.: outside the protocol specified range). The SD may be able to authorize a reduction in volume technique (i.e.: 'slicing/dicing') of the sample. So long as the sample is representative of the field trial treatment, it works to everyone's advantage if reasonable sample weights are shipped to the labs.

    Another problem mentioned was that of wide disparity in the ripeness of samples from various field trials. It was noted that often the sugar content of the sample can result in wide ranging laboratory extraction efficiencies (40% versus 85%). It was hoped that language relating to sample ripeness could be added to future protocols or that if sampling allows, harvest a representation of the level of crop ripeness across the field plot. No acceptability comments were received aside from 'market-sized' which doesn't necessarily mean fully ripe.

- 5) Sample Shipping Issues
  - It was noted that block dry ice lasts longer than pelleted. When considering how much dry ice to add, remember the amount of time, effort and money that has gone into the sample to bring it to that point. Erring on the side of excess (at least 2 day's worth) is advised. In the past, protocols specified a 3:1 (w:w) ratio of dry ice to sample. This ratio may be used as a guide but doesn't necessarily have to be the rule.
  - Separate tracking #'s – if a box of a set gets lost/waylaid, it may not be directly traceable.
  - Return of coolers is still a problem. The recommendation was that FRDs let LRDs know if they must have them shipped back. Labs don't want to spend $25-45 to send back a $30-40 cooler chest. This is still problematic, and we're looking for a solution. POST-MEETING NOTE: In conjunction with their A.C.D.S. freezer truck residue sample pick-up/delivery service, Trammel Farms, Inc., in Phelps, NY sells insulated boxes that may provide a solution if the price is nearly the same as the cost of returning coolers to field researchers (contact them for prices, etc., at phone 315-548-8612, fax 315-548-8868).
  - Use outer plastic bags for untreated samples shipped with treated samples; or for treated samples shipped with other ai level or PHI treated samples.
  - Bags – labs need to be able to reuse the bags, so one good knot is sufficient!
  - Notifications – Labs have no preference – they just want them! Email, phone, fax, mail – all are acceptable to LRDs - FRDs can choose.

3. Kathryn Hackett-Fields gave a presentation on "GLP, EPA and IR-4 Information Sources: Current and Future." To view this presentation, go to: Hackett-Fields presentation.

4. Dan Kunkel summarized IR-4's involvement in electronic data submissions to EPA, and looked ahead at the future of electronic data capture of all IR-4 data.

5. Karen Briggs of 3C Company concluded the conference with an overview of IR-4's 2005 "JustWrite" 3C Pharma Pen Pilot Project and a preview of the 2nd-year plans for 2006. This served as a transition for the 2006 JustWrite participants (FRD, RFC, QA, SD) who met Thur. for training.