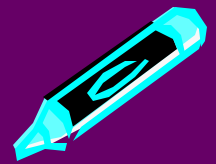


FIELDNOTES DATA ISSUES

NAI CC Presentation

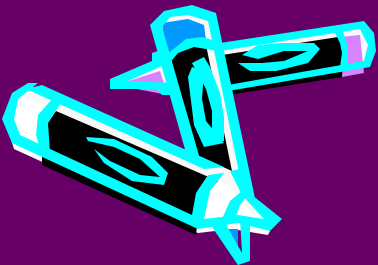
Renee Daniel

January 16, 2003



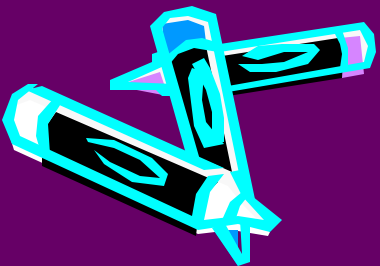
BACKGROUND

- FieldNotes data audits since program came out.
- Comments are combination of common issues based on audits of Bayer reports done last year (trials primarily conducted between 2000 and 2001) and comments from Bayer QA.



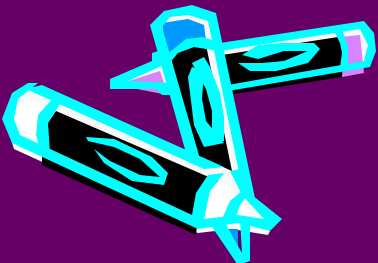
PROTOCOLS

- Protocols are in 2 parts - assure that generic as well as specific sections are read thoroughly.
- Some requirements are not where you expect them to be.
- Protocols require field QA to audit the data.



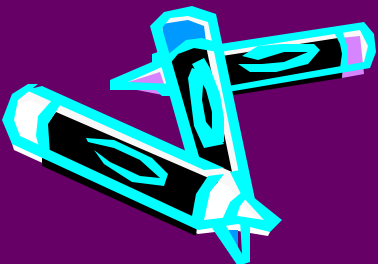
DATA TRANSFERS

- Transfers were required within 48 hours of applications, sampling and shipment (now 1 week).
- Final transfers typically required within 30 days of final sample shipment and need to be marked as a final transfer.
- READ section on frequency of reporting.



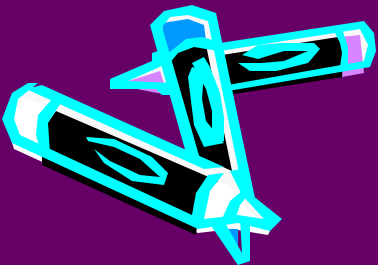
TRANSCRIBED DATA

- Must indicate which data is transcribed. One note listing all transcribed data is sufficient.
- Late entries (e.g., substance receipt, planting info, irrigation, cultural practices, crop conditions, sample storage) must be noted as transcribed.
- For study-specific transcribed data, assure that original data is sent to sponsor for archiving.



INCOMPLETE DATA

- All areas not grayed-out need to be completed.
- Many final notebooks have incomplete sections especially for
 - Application conditions (lack of comments, not checking a rainfall after app. box)
 - Chemical storage
 - Weather data.



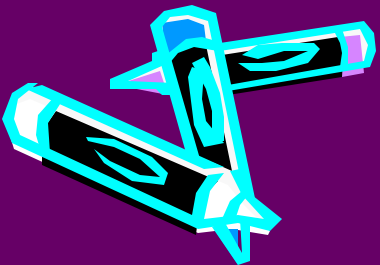
DATA REQUIRED FOR REPORT

- Test substance storage temperatures from receipt to last application.
- Name and location of nearest government weather station.
- Whether application equipment was cleaned after each use.



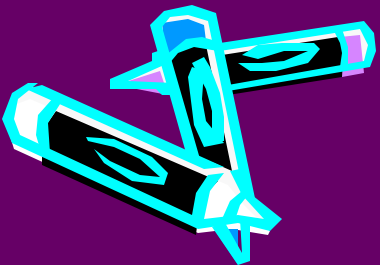
DATA REQUIRED FOR REPORT

- Check “none applied” box on irrigation and maintenance pages if applicable.
- Do not use N/A as an abbreviation for none applied for fertilizer and maintenance pesticides.



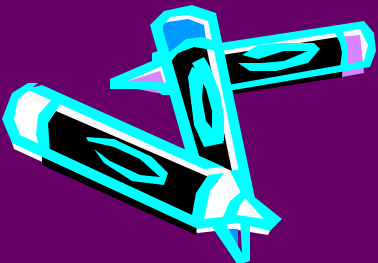
DATA REQUIRED FOR REPORT

- Rainfall from first application to last sampling.
- I identify which data is used for rainfall since there are sometimes 3 different sets of weather data in electronic file (e.g., on-site, off-site, winter).



MAPS

- Assure site map not default (Valdosta).
- Clearly explain plot diagram changes
 - Attach note (i.e. old data, what was changed)
 - Audit trail will indicate old image to new image and not any specifics.
 - Alternative is to print old plot diagram before changing and include printout in raw data.



OTHER

- Assure that all appropriate boxes are checked for GLP Compliance (e.g., pesticide history, maintenance and cultural practices).
- Assure that there are not conflicting entries for pesticide history.
- Assure that quantity or weight of samples is entered into FieldNotes.



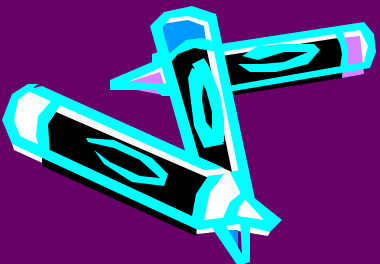
OTHER

- If test substance not logged into storage immediately when received assure that there are records of interim storage location and temperatures.
- Some protocols require that plot be tilled just prior to planting (e.g., crop rotation studies).



OTHER

- Some protocols require samples to be shipped within 30 days of last sampling.
- All amendments should be summarized in appropriate section in FieldNotes.
- Deviations need to be written up in FieldNotes and sent to sponsor (now within 2 days of occurrence).



HAY SAMPLES

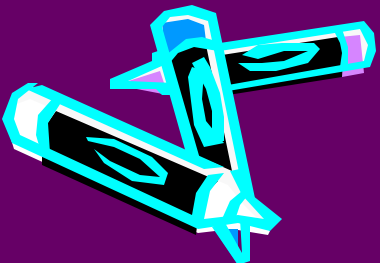
- Date cut needs to be entered in FieldNotes (typically same day forage is cut/sampled).
- Date sampled for hay is date hay is collected and put in bags not day it is cut.



HAY SAMPLES



- Time to freezer calculated from time they became hay samples (i.e., when they are ready to put in bags) not from time they were cut and put out to dry.
- Sample event sheet should include date cut, date dried and date sampled.



CONTACT INFO

- Paul Toll - Supervisor, Quality Assurance
Bayer CropScience
Phone: (913) 433-5131
email: paul.toll@bayercropscience.com
- Renee Daniel
Perspective Consulting
Phone: (941) 371-0371
email: reneedaniel@mindspring.com

