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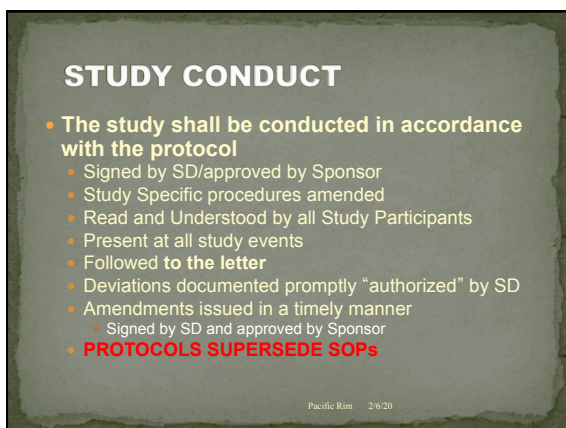
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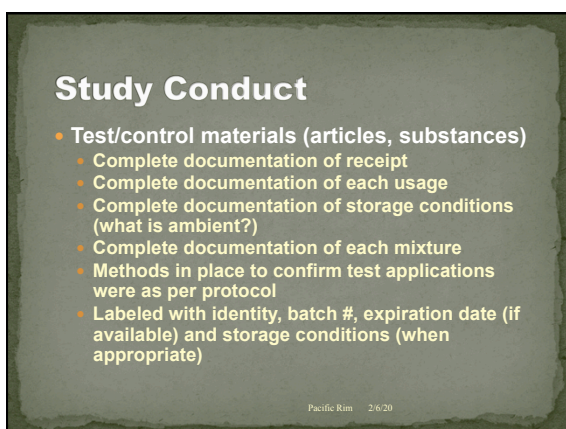
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## STUDY CONDUCT

- **The test system shall be monitored in conformity with the protocol**
  - Periodic checks - documented
  - Pay attention to adverse weather conditions
  - Monitor for pests/disease
  - Communicate with growers
  - Appropriately identified – stakes, flags, markers
  - Any other test system requirements as specified in the protocol
  - Complete "cradle to grave" documentation



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## STUDY CONDUCT SOPs

- Immediately available
- Referenced in data
- Key elements documented
- **Followed to the letter**
- Deviations "authorized" by SD
- Accurately reflects current procedures
- **Provide sufficient detail**



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## STUDY CONDUCT

- **In-life conduct**
  - If it's not recorded, it wasn't done
  - If it's not documented, it's a rumor
  - Don't allow for assumptions
  - Are the data/study reconstructable?
  - Is there enough narrative/detail when needed?
  - Are data corrections well documented?
  - If you died or were seriously injured tomorrow – will the study be lost?

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## STUDY CONDUCT

- Routine Observations/Documentation
  - Support protocol/SOP requirements
  - Unusual responses recorded
  - Unforeseen circumstances documented and corrective actions taken
  - Routine observations taken; consistent between technicians
  - Periodic review by SD/Investigator

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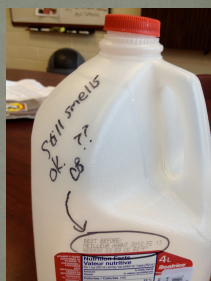
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## REAGENT AND SOLUTION LABELING REQUIREMENTS

- Identity
- Titer or Concentration
- Storage requirements
- Expiration date
  - Deteriorated or outdated reagents and solutions shall not be used
  - Manufacturers expiration dates may not be extended
- Additional recommendations
  - Date prepared
  - Who prepared



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## Reagents and Solutions

- Guidelines for expiration dates – when the Manufacture has not provided one
  - Dry reagents - 5 years
  - Solvents - 1 yr from date opened or 2 yrs from date received
  - Solutions/mixtures
    - No later than earliest expiring component
    - Keep volatility in mind
    - Use good science
  - May be extended upon reevaluation with SOP
- Use Common sense – have an SOP

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## STUDY CONDUCT

- **Specimen Collection**
  - Done according to protocol/SOP
  - Areas of plot/trees as per protocol
  - Crop stage as per protocol
  - Commodity as per protocol
  - Specimens required, collected
  - Integrity preserved (dry ice, ice packs, CO2)
  - Complete chain of custody
    - Who, what, when, how (transfers complete)

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## SPECIMEN LABELING REQUIREMENTS

- **Test system** (soil, water, corn,.)
- **Study** (usually study number)
- **Nature** (grain, hay, DAT, PHI, etc.)
- **Date of collection**
- Information shall be located on the container or shall accompany specimen in a manner that precludes error in the recording and storage of data



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## Sample Handling

- Complete C of C from the time samples are taken until final values reported
- Documentation of storage at field site
- Documentation of shipping
- Documentation of receipt and logging in
- Documentation of every step of processing and analysis

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## Sample Handling

- Storage conditions documented at lab
- Reference standards characterized
- Any repeat or reanalysis documented
- Electronically captured data in compliance with GLP/Part 11
- Personnel adequately identified
- QC procedures in place – for the run and for the data and analysis
- Stability data available covering samples from collection to last data

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## STUDY CONDUCT Reporting Results

- All data reported
- Rejected data "mentioned" in report
- Circumstances affecting data quality reported
- Analytical
  - Raw values reported
  - Corrected values
  - Formulas present
- No picking and choosing data
- Rejection or reanalysis of data points
  - Accompanied by scientifically valid reasons
- Outlier tests conducted
- Reported but excluded from analysis
- Values averaged or otherwise identified

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## QUESTIONS?????



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