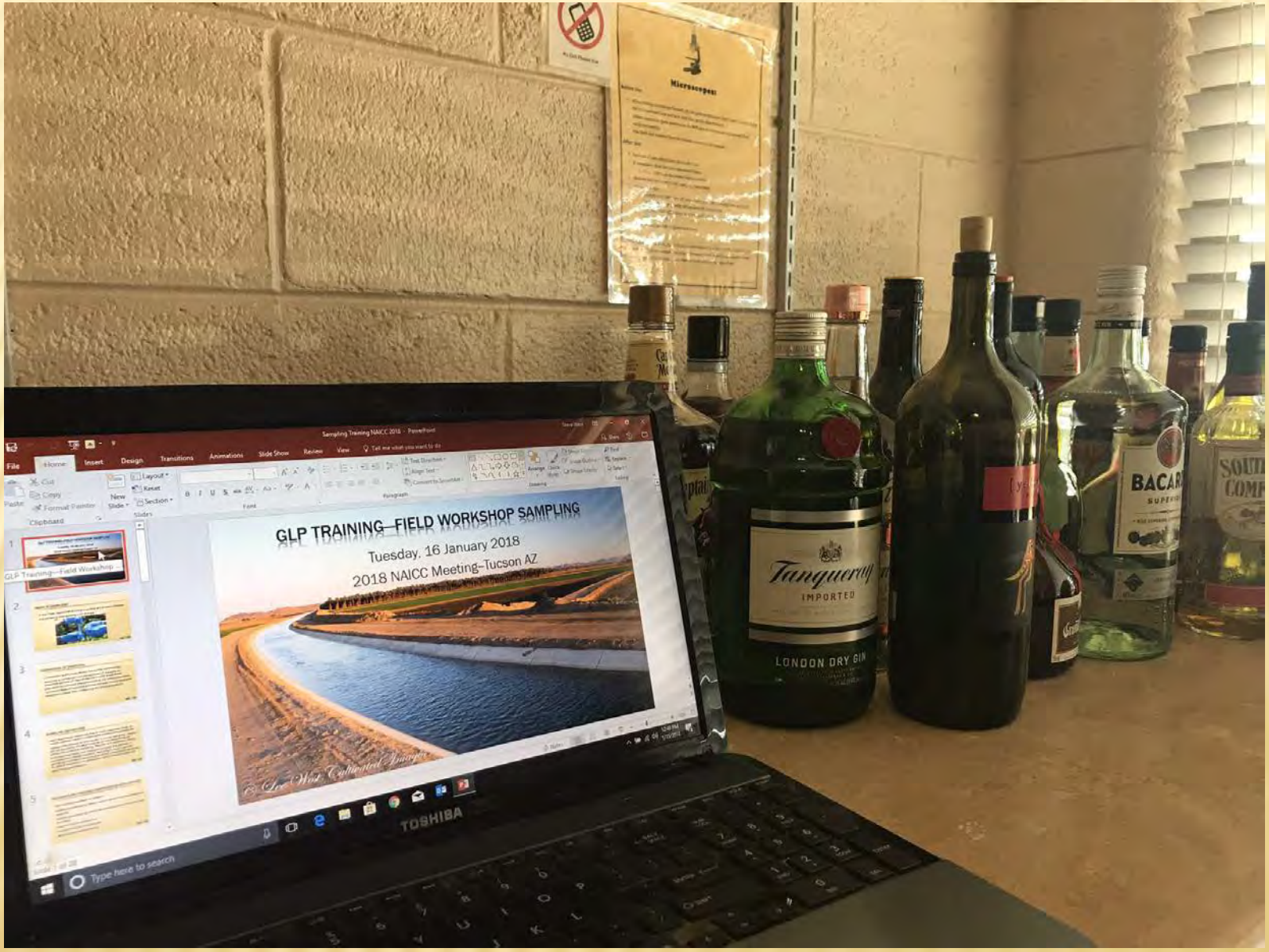
GLP TRAINING—FIELD WORKSHOP SAMPLING

Tuesday, 16 January 2018

2018 NAICC Meeting--Tucson AZ

A PICTURE SPEAKS A THOUSAND WORDS



THE DICTIONARY SAYS AS A NOUN

1. a representative part or a single item from a larger whole or group especially when presented for inspection or shown as evidence of quality: specimen
2. a finite part of a statistical population whose properties are studied to gain information about the whole

AND AS A VERB

- to take a sample of or from; especially: to judge the quality of by a sample

DEFINITIONS OF SAMPLING

- In statistics, quality assurance, and survey methodology, sampling is concerned with the selection of a subset (a statistical sample) of individuals from within a statistical population to estimate characteristics of the whole population. Two advantages of sampling are that the cost is lower and data collection is faster than measuring the entire population.

SAMPLING DEFINITIONS

- Each observation measures one or more properties (such as weight, location, color) of observable bodies distinguished as independent objects or individuals. In survey sampling, weights can be applied to the data to adjust for the sample design, particularly stratified sampling. Results from probability theory and statistical theory are employed to guide the practice. In business and medical research, sampling is widely used for gathering information about a population. Acceptance sampling is used to determine if a production lot of material meets the governing specifications.

THE SAMPLING PROCESS COMPRISES SEVERAL STAGES:

- Defining the population of concern
- Specifying a sampling frame, a set of items or events possible to measure
- Specifying a sampling method for selecting items or events from the frame
- Determining the sample size
- Implementing the sampling plan
- Sampling and data collecting

WHAT IS SAMPLING?

- In the Field, Traditional thinking is putting dirt or plant material in a container and sending it off to a lab.

NOT THE SAME TODAY

- These days as often as not we are sampling growth stages of Crops under GLP requirements
- What procedure are we using to do this sampling?
- A Protocol with some instructions?
- Literature from the Internet?
- Long term experience?

HOW OFTEN ARE WE DOING THIS?

- More than once a century?
- If not yet, soon, we need an SOP for this.
  - Writing an SOP for proper growth staging of plants, agronomic evaluations, determining first pollen dates, silking dates, flower dates fruit set dates, pod fill dates, pod maturity dates maturity, lettuce rosette dates and so forth is virtually impossible.
- The first one with a actually USEABLE SOP on Vigor wins the prize

GLP FOR NOVEL TRAIT TRIALS, AND POSSIBLY EFFICACY

- European Union required that any data submitted to them and be done under some kind of an ISO 9000 (Quality Management) type of the system.
- ANY legitimate QMS program is sufficient.
  - GLP
  - Excellence Through Stewardship, ETC
- However since most of the major companies are used to doing things for FIFRA or r OECD GLP they decided to utilize that program rather than a QMS

TRIANGLE HOLE—HOLOGRAPHIC PEG

- This is unfortunate because of course GLP is Triangular hole, and agronomic trials with transgenics or other types of Novel Traits, regulated organisms such as biostimulants are a Holographic peg.
  - They don’t even begin to fit.
- And so it is impossible at the current time to do a full program FIFRA GLP.

WHAT IS GLP REALLY?

- Let's take a look back at the basic reason why we have GLP's.
  - I'm not going to go into the old discussion about the pesticide work that was being done on rats that was shoddily accomplished
- Intent is that we have good science, and
- The Bigger intent is that we find a way to document a Study so that it is re-creatable.
  - This means that if it's right you know how it was done
  - If there's something incongruous you know how it was done.

THAT IS GLP

- So Lets Head OUTSIDE and enjoy the day
- Or not…. Sadly…

WHAT DOES IT TAKE TO HAVE A RE-CREATABLE TRIAL?

- Certainly good trial notebooks of sorts is important.
  - That of course rules out the majority of the electronic notebooks.
- Agronomic evaluations really require a whole bunch of pages where you can write down a list notes and then go back through and re-think it…
  - I have never had an agronomic evaluation where I don't halfway through the first Rep and rethink everything that I've done
  - And what is your GLP reason for correction a dozen entries that are subjective anyway?
  - While that may be GLP with a whole bunch of corrections I can assure you that your competence will be called into question

RD4AG

SO WE WILL TACKLE THE EASY PART FIRST

- The traditional part you thought you were getting
  - But Really– If you can't follow a protocol and SOP which says
    - Sample mature potatoes by digging at least 24 tubers from a minimum of 12 different locations
    - Knock off (do not wash) loose soil
    - Bag in pre-labeled bag, and put in a -20c or colder freezer within 4 hours
  - You really don't belong in this line of work

STEVE'S KEYS TO NOT LOOKING INCOMPETENT

- First—Have a sample list, which is accurate, double checked and appropriate labels able to be made.
- Two—RTFP today as you get ready to start…
  - Read the Fabulous Protocol
  - Not last week and hope you remember what Child Maiming Chemical Company requested
  - Not based on what you did earlier today for Mutant Plant Genetics…
- For this trial at hand… RIGHT NOW!
  - Everyone has a better mouse trap, be SURE you understand this clients requirements.

KEEPING INCOMPETENCE AT BAY PAGE 2

- Make sure you are following the Sample Order
  - UTC to treated,
  - Low to High rates
  - Comparators to traited
- Handle the Samples as required in the Protocol
  - Washed or not
  - Frozen or not
  - Bag type
  - and and and and and and and

THE BIGGEST INCOMPETENCE OF ALL

- I have Never, In my life seen a sample over labeled…
- I have seen too many shoddily labeled
- Redundancy is king.
- They give you this wimpy little tag to put on a bag and hope that it holds up in the dry ice. If you didn't write on the bag or put an additional tag inside the bag you screwed up
- Mark my words, sooner or later that hokey tag will fall off and you will end up losing samples if you don't have a redundancy.
- I don't care what QA tells you I don't care what the study director tells you
- Write a deviation or whatever you need redundantly label the bags

STEVE'S PET PEEVE ON SAMPLE LABELS

- Sign or initial the label
- Date is GLP required--Signing is not
- If the protocol asks and you forget,
  - it is a protocol deviation,
  - It is NOT a GLP deviation since a label is not raw data
- RAW DATA must be archived.
- Sample labels or sample bags are not archived.
  - Hence not raw data.

SO IN SUMMARY

- Sample List
- RTFP
- Sample Order
- Follow the Handling Instructions

OVER LABEL IT

OFF FROM THE EASY STUFF

- Where are we likely to have to do GLP Agronomic, Biotic, Abiotic, Phenotypic, Plant Response, Phytotoxic Response, Vigor, Growth Stage, etc. ad nausea evaluations?
- The Reality?
  - I suspect it will be a very LARGE part of our work in the future

THE TWO SYSTEM DELIMA

- We do traditional FIFRA work GLP
- We are supposed to do most USDA Regulated Article work GLP
- We regularly do Stewarded trials with Novel Traits or not yet fully approved TG traits GLP or under a QMS
- Often we are doing a European Efficacy study under a quasi-QMS requirement
- Our daily product performance work is NOT a formal QMS system

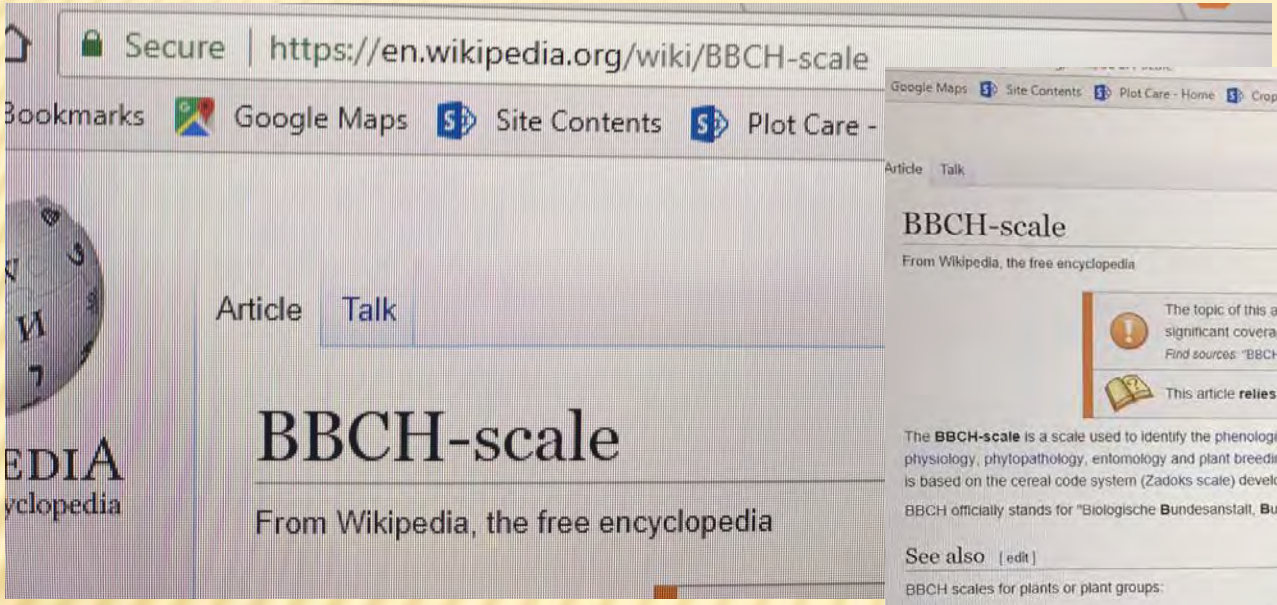
THE OBVIOUS DANGERS

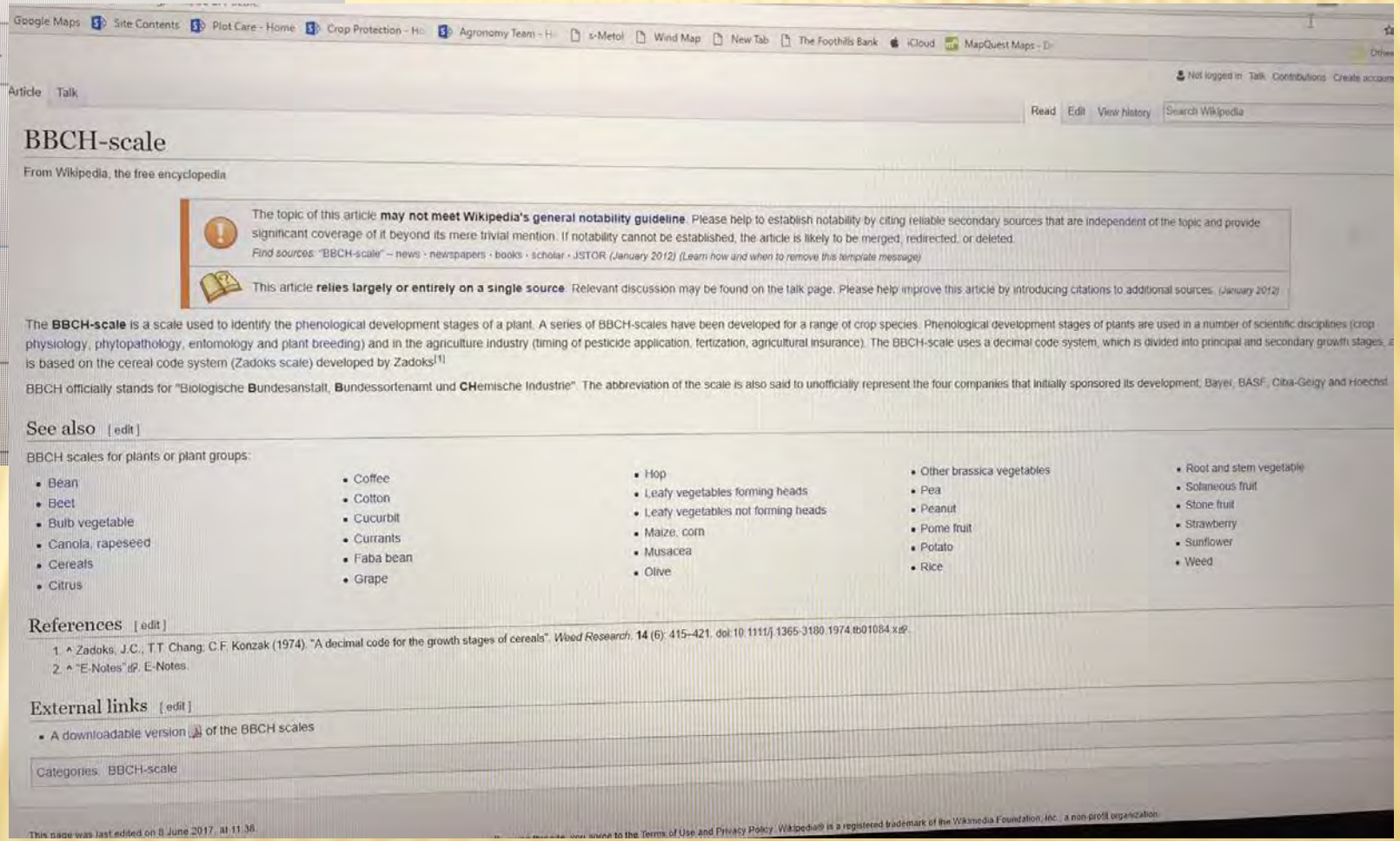
- So having multiple systems in the same facility is problematic
- Us old dogs remember the nuances
- The new folks struggle to understand when they need to have a detailed cleaning log of the planter with devitilization or just blow it off and go situation
- The more hands involved, the more hands are involved…

BUT!!!!

- Writing GOOD Sops for everything is very time consuming
- It is something which takes a very experienced person to do
- It will never be great in all cases
- And if you write it loose, the supporting documentation is tough
- And if you do it differently each time based on a method you found in researching it, then it is not Standard, is it?

GROWTH STAGES





Wikipedia is a good place to get the BBCH lists

Following slides show things to consider

GROWTH STAGES!

Notes– Be sure you understand the growth stage lingo for a crop… In Head Lettuce we count Leaves

PLANTING DATE AND PERSON WHO PLANTED

And how will you list the person who planted this one?

KEEPING THINGS STRAIGHT FOR WITH INNOCULANT TRIALS

Organization, color coding, being meticulous yield HUGE benefits in appearance and trackability

SEED TREATMENT DOCUMENTATION

And will you need to clean the planter between entries? Do you have a way to keep track of what goes where that is fool proof?

STAND COUNTS

32 Line spinach on a 60 inch bed… better count early!!!

Which part of the field are you going to count???

PLANT RESPONSE

One person deciding what the stage is typically works better than multiple people.

ABIOTIC AND BIOTIC STRESS

What scale will you use for the corn fill on the left?

What lengths do you need to go to for Pest ID? You know what it is? Smithsonian ID confirmation?

VARIABLE FERTILIZER AND IRRIGATION TRIALS

How will you decide what is 100%? How will you measure 100% and the reduced areas? What data and sampling do you need to do to verify? Tensiometers? Tissue tests? GLP?

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ECOTOX STUDIES AMPLIFY THE CHALLENGES

ISOLATION MAKES EVALUATIONS CHALLENGING

How are you going to eval abiotic and biotic stressors, or growth stage in these tents for pollen isolation?

PLOT LABELING, FIELD NOTES AND STAYING ORIENTED!

APPLICATION TECHNOLOGY IS EVER CHANGING

Do you need to do tank mix samples?

ELECTRONIC EVALUATIONS

The New Frontier of sampling… GLP Calibration? SOP's, Training Logs? And and and….

DATES FOR SELFING OR CROSSING

MATURITY

Nope

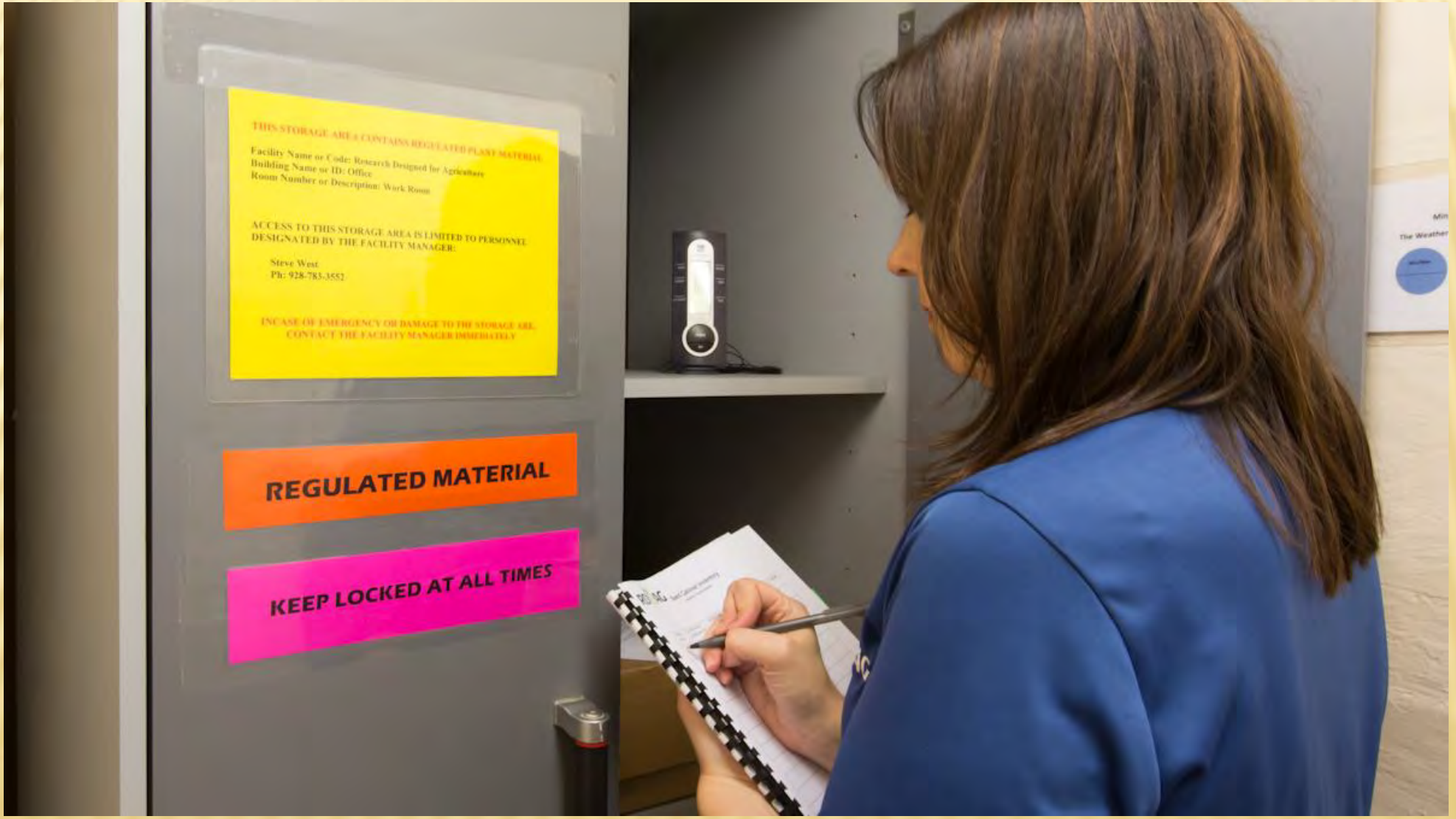
Yep

Too Late

EQUIPMENT CLEAN OUTS

Will your sample be contaminated?

STORAGE INVENTORY AND MONITORING




Merci - Thank You
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