Surviving Regulatory Inspections

Allison Treloar, MS, CBA(ASQ), MB(ASCP)^{CM}, SLS^{CM}

Topics Covered

Why do we need inspections?
Inspection types.
Preparation & Timeline
Hallmarks of an Efficient Inspection
What Could Go Wrong?
Dealing with Deficiencies.

WE WORK ‘IN *THE BOX*’!

If we work in the box, why are we inspected?

1. The lab willingly agreed to get into the box when it sought to be regulated /accredited, *and*
2. It agreed to the terms of accreditation or to be bound by the regulations surrounding testing.
3. Regulatory / accreditation inspections provide external validation of laboratory function.

RESEARCH vs REGULATED LABORATORIES

RESEARCH: Innovative, Risk-taking

REGULATED: Consistent, Accurate, Reliable

TYPES OF INSPECTIONS/AUDITS

- **Internal**
  - In-house, between regulatory inspections
- **Regulatory**
  - Government agency, audits against regulations.
- **Accreditation**
  - (3rd party) Independent organization approved to perform audits which meet or exceed the regulatory standard.
- **ISO**
  - Not regulatory
  - Each country forms accrediting body which authorizes certification organizations
  - International Standard

TYPES OF INSPECTIONS/AUDITS

- **On-site**
  - Inspectors are in your lab!
- **Document**
  - Off-site review of requested documentation.
- **Virtual** (including hybrid)
  - Answer to the 2020 pandemic!

TYPES OF INSPECTIONS/AUDITS

- **Scheduled** *or* **Announced**
  - Date or window is known in advance.
  - CAP (reaccreditation), EPA, FDA, etc.
- **Unscheduled** *or* **Unannounced**
  - Surprise!?
  - FSAP (interim), any agency.
- **Federal Inspectors**
  - MUST be allowed into your facility by law.

INSPECTION PREPARATION

- **Review Checklists / Regulatory Guidelines**
  - **Fill in checklists with evidence of compliance** (*not just yes/no*) **such as records, file locations, storage areas, binder names, electronic file locations, etc.**
  - **When referencing SOPs or manuals, give the page number or section for relevant policies or information.**

INSPECTION PREPARATION

- Review Checklists / Regulatory Guidelines
- **Perform mock inspections**
  - **Ensure documents, records, and logs can be easily found and laboratory areas are in compliance.**
  - **Don't be a push-over!**
  - **Can be used to train staff.**

INSPECTION PREPARATION

- Review Checklists / Regulatory Guidelines
- Perform mock inspections
- **Review available records & documents for closure** (signed/dated)
  - **Find, Fix, and Document problems and their corrective actions before inspectors do!**

INSPECTION PREPARATION

- Review Checklists / Regulatory Guidelines
- Perform mock inspections
- Review available records & documents for closure (signed/dated)
- **Select typical cases for inspector review.**

INSPECTION PREPARATION

- Review Checklists / Regulatory Guidelines
- Perform mock inspections
- Review available records & documents for closure (signed/dated)
- Select typical cases for inspector review.
- **Don't forget SAFETY, SECURITY, FACILITIES, and IT.**

‘If you stay prepared, you don’t have to get prepared.’

Coach Brown. *Last Chance U**

* *(Netflix series)*

Set up a schedule of internal inspections that keep tabs on all aspects of laboratory operations.

Have an SOP with procedures for conducting internal audits and procedures for handling external inspections.

INSPECTION PREP TIMELINE

-6 MONTHS

- Review Checklist
- Mock Audit

-5 MONTHS

- Fix any 'big' problems.
- Initiate Document Revisions
- Review Safety, Maint., & IT

-3 MONTHS

- Fix 'little' problems.
- Close deficiencies.
- Select typical case files.

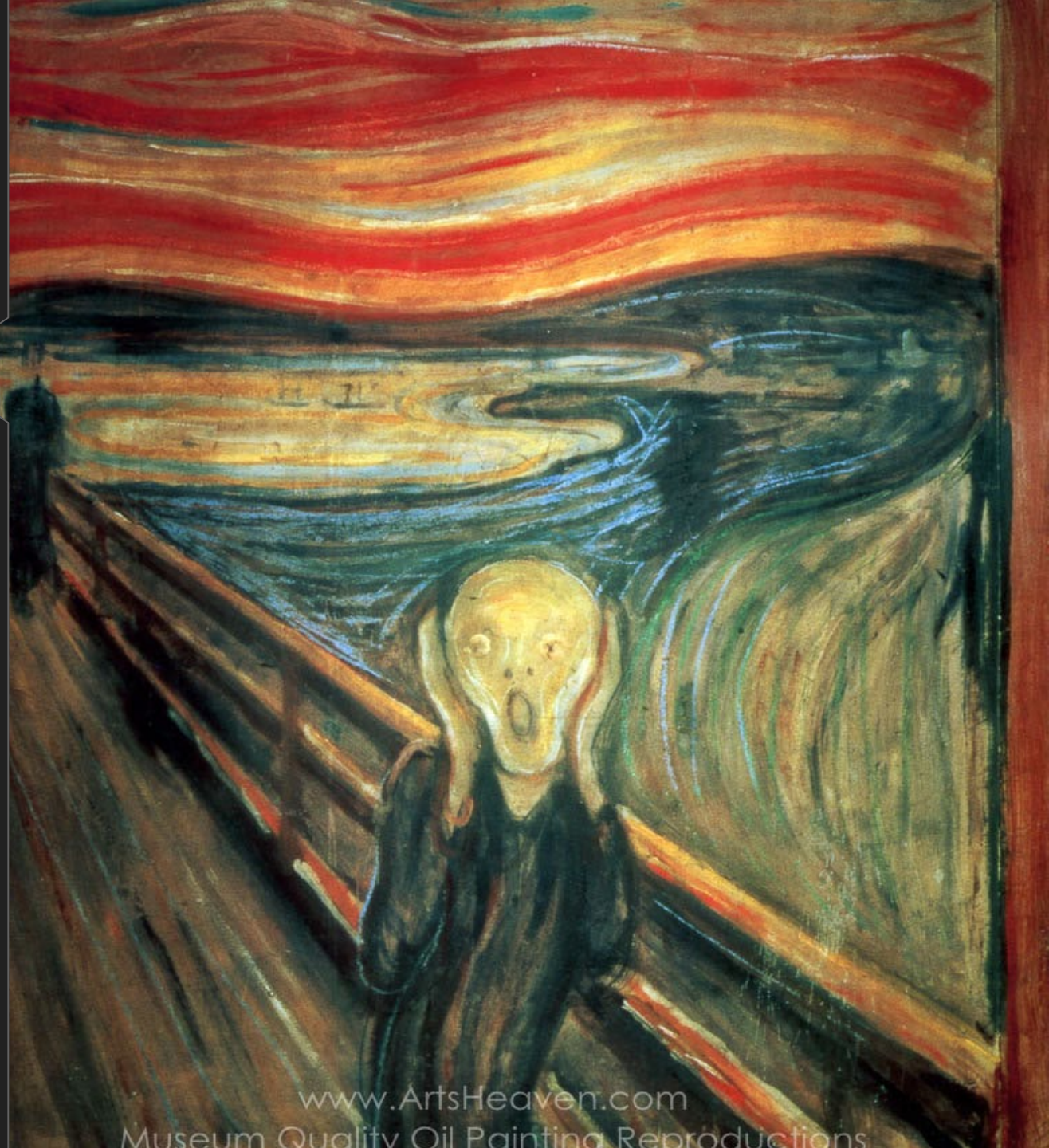
-2 MONTHS

- Clean & Organize.
- Review logs.
- Review training records.

-1 MONTH

- Authorize document changes.
- Review inspection etiquette.
- Logistics check.

'THE INSPECTORS ARE HERE!!'



DON'T PANIC.

- **COMMUNICATE !**

  As the inspection team is checking in with security, let your laboratory management know that inspectors have arrived.

- **CONFIRM !**

  Inspectors must show identification and provide the laboratory with a letter which describes their authority to perform an inspection.

- **ADAPT !**

  Reserve a conference room or closed area where the team can work.

  Make sure that your work areas are free of sensitive information.

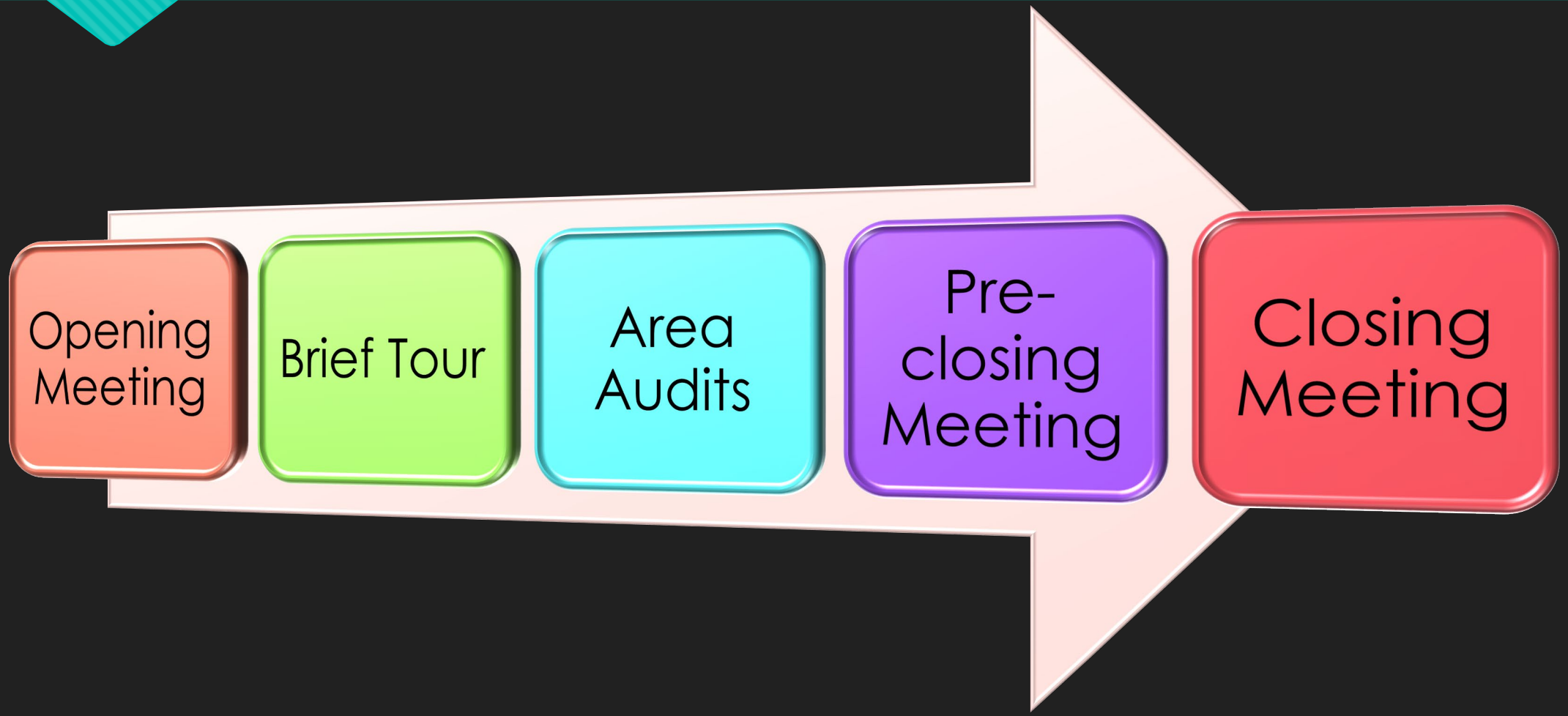
  Assign a facilitator.

KEY PERSONNEL

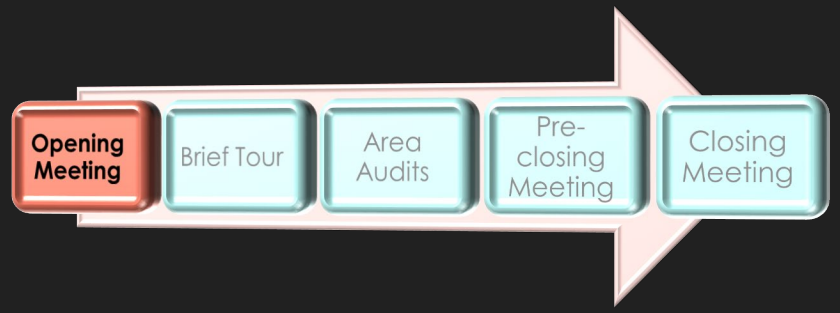
Who MUST *and* SHOULD be included in an audit?

- **MUST INCLUDE**
  - The Laboratory Director
  - The Quality Manager / Supervisor
  - Supervisors + 1 analyst from the inspected departments
- **SHOULD INCLUDE**
  - QA Team
  - Maintenance Supervisor
  - IT personnel
  - Safety Officer

INSPECTION SCHEDULE OVERVIEW



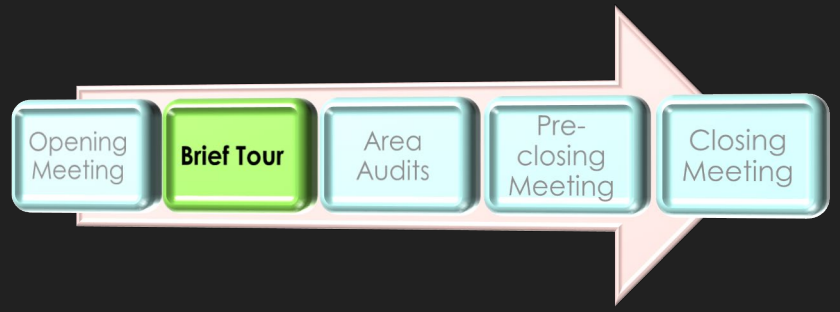
THE INSPECTION PLAN



❑ Opening Meeting

- Defines the scope of inspection, the proposed schedule, and the documents needed for review.
- There will be a sign-in sheet for attendees of the opening meeting. COPY IT!
- There will be a letter for management to sign agreeing to the inspection. COPY IT!
- Facility safety briefing, housekeeping, lunch plan.

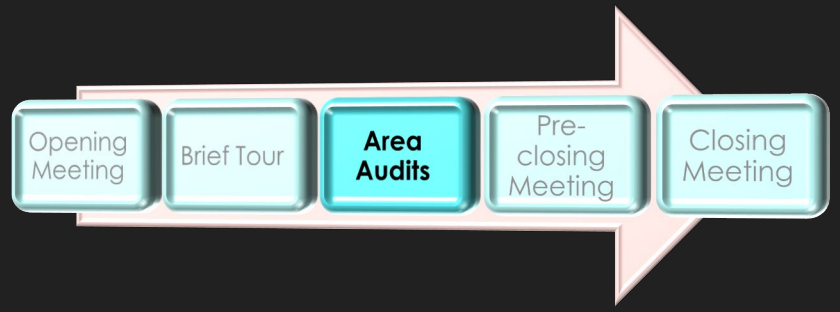
THE INSPECTION PLAN



❑ Tour

- Conduct a ***BRIEF*** tour of the facilities to familiarize team with the layout.
- Cover areas relevant to the scope of the inspection.
- Defer any questions during the tour.

THE INSPECTION PLAN



❑ Area Audits

- Review documents (or may have reviewed in advance). SOPs/proficiencies/competencies/records/logs
- Federal inspectors may make copies of documents, but accreditors may not.
- Interview staff about methods, instruments, safety, etc. Common to have analyst take them through a method from receipt to reporting.

GENERAL INSPECTION TIPS

- ❑ DON'T GIVE INSPECTORS UNESCORTED ACCESS TO THE LABORATORY

Inspectors are visitors to your laboratory. It is best to make sure that they are escorted within the laboratory so that questions can be answered, and assumptions do not show up on deficiency reports.

GENERAL INSPECTION TIPS

❑ BE FRIENDLY, BUT BE PROFESSIONAL.

Inspectors are fellow professionals, but also human beings. There is no need to be overly formal or treat them as the 'enemy' during your audit.

Follow your employer's guidelines for professional behavior.

Report any unprofessional behavior on the part of the inspectors to their parent agency.

GENERAL INSPECTION TIPS

- **NEVER SAY ‘I DON’T KNOW’.**

  If you honestly don’t know the answer to a question, acceptable responses are:

  LET ME ASK MY SUPERVISOR

  LET ME CHECK THE SOP

  Never make up an answer.

INSPECTOR TACTICS

The friendly inspector.

- **Technique**
  - The inspector wants to get you talking, so they will be friendly and sympathetic.
- **How to manage**
  - Remember that this is an audit!
  - Stick to answering the inspector's questions.
  - Once you have answered the question, resist offering explanations, past history, or personal opinions.

INSPECTOR TACTICS

The silent inspector.

- Technique
  - Uses long pauses and silence to keep you talking.
- How to manage
  - Do not feel the need to fill the silence!
  - Stick to answering the inspector's questions.
  - Once you have answered the question, wait until there is another request.

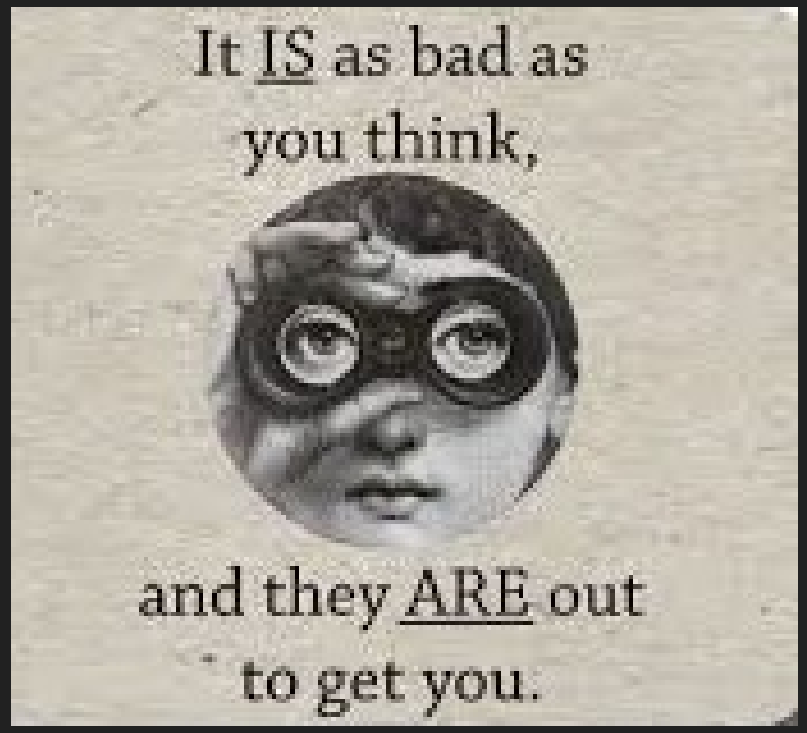
WHAT COULD GO WRONG?

The disorganized inspector.

- How to spot
  - Asks for every document, and when offered, then asks for different documents.
- How to manage
  - Bring them the documents as requested!
  - Feel free to ask them questions and guide them through the requested items.
  - Provide a pre-filled checklist.
  - Keep a log of what was provided and when.

WHAT COULD GO WRONG?

Inspector on a mission!



- How to spot
  - Looks for that 'GOTCHA' moment.
- How to manage
  - Know your regulations!
  - If you are in the right, you can explain how you are in compliance.
  - Avoid open argument with the inspector.
  - Prepare to provide evidence to the reviewing body to annul findings that are incorrect.

WHAT COULD GO WRONG?

That's not how we do it in my lab.

- How to spot
  - Compares your clinical lab to theirs.
- How to manage
  - Maintain your composure!
  - Nicely point out that there are many ways to comply with the regulations.
  - If they do have a good idea, thank them for the suggestion.
  - If cited, dispute the finding with evidence.

DON'T SABOTAGE YOUR OWN INSPECTION by…

Wasting time talking about yourself or your program,
Stopping normal operations during the inspection,
Failing to check documents prior to handing them over,
Failing to prepare your staff for what to expect,
Allowing inspectors to overhear break room/lunchroom gossip,
Being argumentative or acting superior.

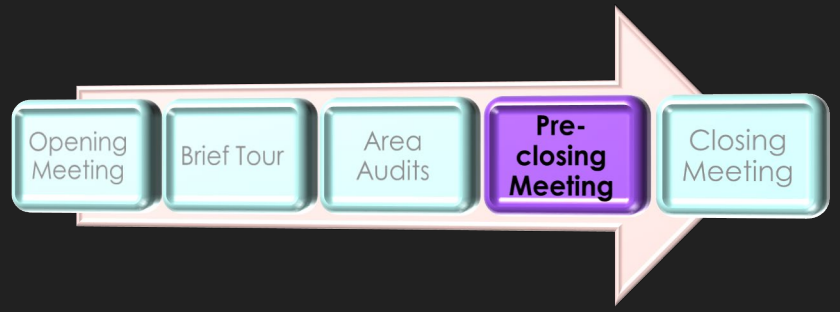
WHAT COULD GO WRONG?

THE GOOD INSPECTORS

Doing it Right!

- How to spot
  - Starts with a plan, stays within scope, uses time efficiently, offers helpful suggestions, communicates deficiencies early, and wants to help you improve.
- How to manage
  - Be professional and honest!

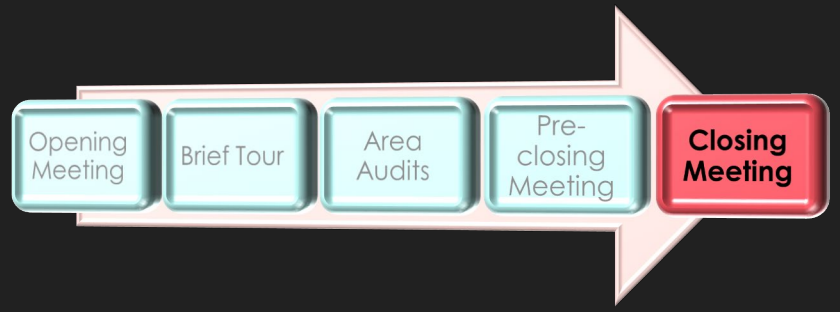
THE INSPECTION PLAN



❑ Pre-closing Meeting

- Optional courtesy meeting.
- Findings/Deficiencies are discussed with the Lab Director privately.
- Specific to a staff member or actionable by human resources.

THE INSPECTION PLAN



❑ Closing Meeting

- All staff should attend but not a requirement.
- Inspectors discuss the results of the audit, any findings, and recommendations.
- Findings should always reference the specific regulation or checklist item. No ‘general’ opinions.

The Audit Report:

Response

- Received within a specific timeframe (30-60 days)
- Final report may not include all the inspection findings.
- May have upgraded a recommendation to a finding.
- Require response usually within 30 days of report receipt.

The Audit Report:

Recommendations

vs

Findings

- Recommendations do not require responses or changes in your procedures.
- Findings require ACTION!
  - Plan the change.
  - Implement the change
  - Document the change
- Timeline is short, but you knew about deficiencies at the time of inspection. Start changes then!

The Audit Report:

It is *OK* to appeal a finding!

- Inspectors are human and make mistakes, *but your facility doesn't have to live with them.*

- Dispute with clear evidence of compliance.
  - Use logs, photos, documents, records.
  - Evidence must have been in place at the time of the audit – no time travel!
  - Evidence must clearly demonstrate compliance.

SHARE INSPECTION RESULTS

- Let laboratory staff know the results of the inspection.
- Share notice of re-accreditation / certification with the Department and clients.
- Review the good and the bad and plan Quality Improvement ideas for the next audit experience.

You WILL Survive!

Resources

Checklists

College of American Pathologists *(must be member to obtain checklists)*

CLIA - https://www.dph.illinois.gov/sites/default/files/forms/survey-checklist-041216.pdf

CLIA for LRN-C/Rad/Biomonitoring: https://www.aphl.org/AboutAPHL/publications/Documents/EH_2013December_CLIA-Inspection-Checklist.pdf

FDA - Evaluation of Milk Laboratories / Important Documents: https://ncims.org/

Inspection Guides: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspection-guides

EPA – https://nepis.epa.gov

ISO *(must belong to an accrediting organization)*

FSAP - https://www.cdc.gov/selectagent/checklists.html

Resources

Regulatory Interpretations

EPA Guidance Portal - https://www.epa.gov/guidance

FDA Guidance Documents - https://www.fda.gov/regulatory-information/search-fda-guidance-documents

FSAP - https://www.cdc.gov/selectagent/compliance.html

CLIA - https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories