

Performance Based Inspection

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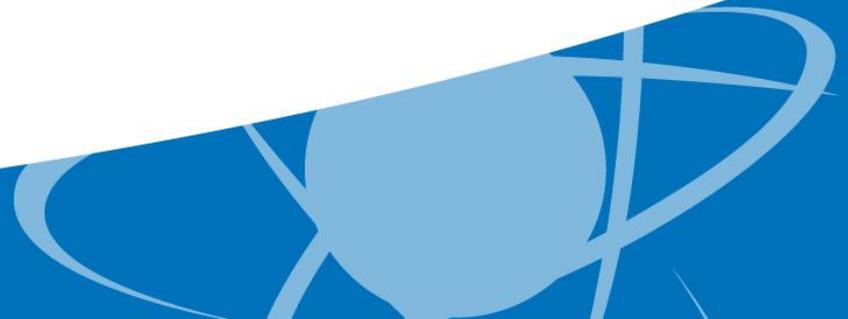


Objectives

- Discuss performance based inspection techniques
- Discuss common misconceptions regarding performance based inspections
- Describe the inspection process
- Discuss examples of performance based inspections
- Discuss documentation of inspection results

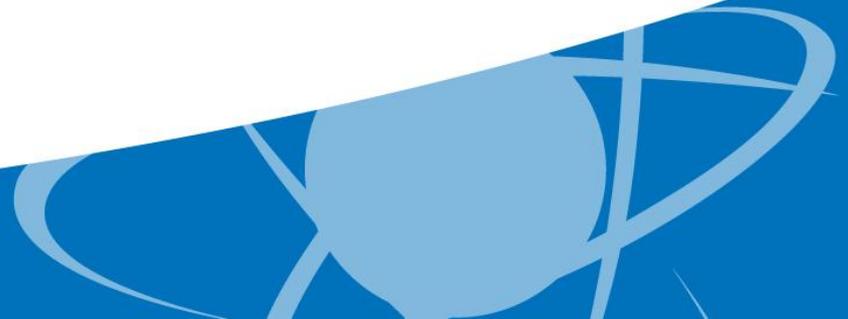


What is Performance Based Inspection?

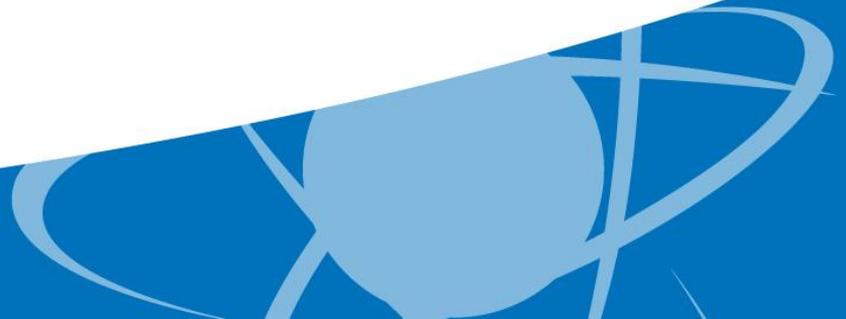


Performance Based Inspection:

- Is an observation of a licensee's program and activities to determine if regulatory and technical objectives are being met
- Examines results or outcomes rather than a prescriptive process, technique, or procedure
- Can be used for any type of licensed activity

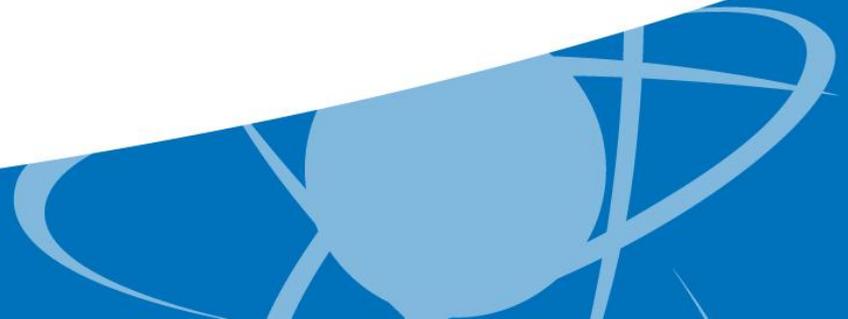


Misconceptions Regarding Performance Based Inspections



Performance Based Inspection Misconceptions:

- Myth: Doing Performance Based inspections is a new concept
- Fact: Inspectors have been using Performance Based inspection techniques for many years



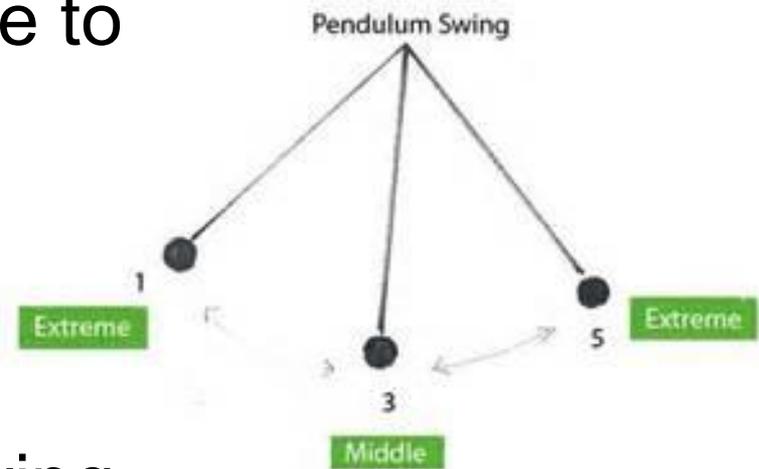
Performance Based Inspection Misconceptions:

- **Myth:** Performance Based inspection takes less time than Compliance Based inspection
- **Fact:** Performance based inspection involves actual observation of activities in progress, which usually takes more time than simply reviewing a record related to that activity



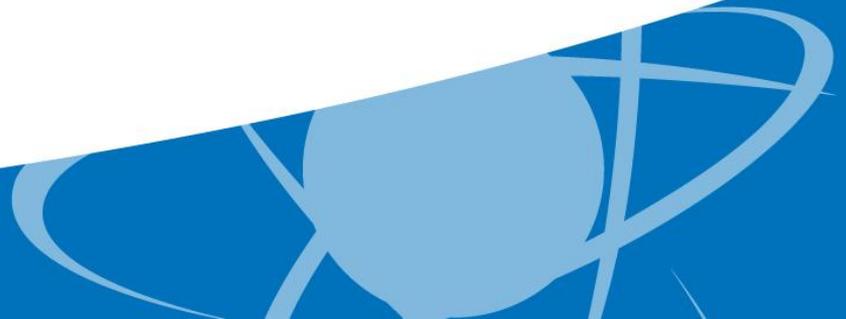
Performance Based Inspection Misconceptions:

- **Myth:** Performance Based inspection means I don't have to look at any records or documents.
- **Fact:** A balance must be achieved between observing licensed activities and reviewing licensee records. Record reviews may be necessary to further inspect and support your observations.



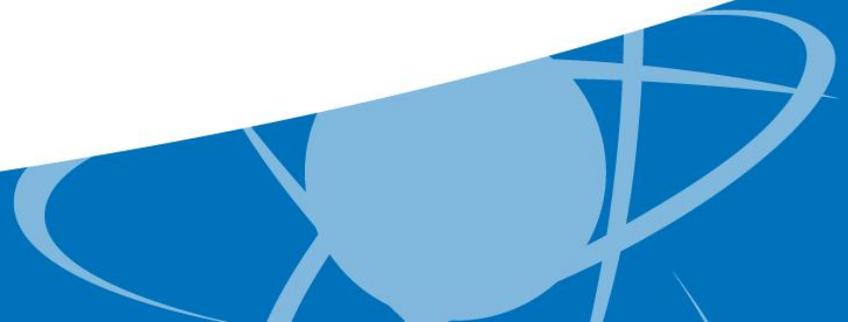
Performance Based Inspection Misconceptions:

- **Myth:** If the licensee isn't performing licensed activities the day of my inspection, I can't do a performance based inspection.
- **Fact:** Performance based inspection techniques are not just observation of activities in progress but also includes interviews with workers and demonstrations.



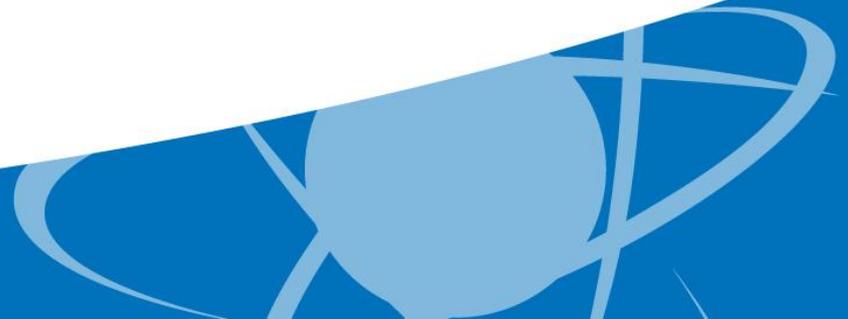
Performance Based Inspection Misconceptions:

- **Myth:** Performance based inspecting means that I ignore violations of low safety significance.
- **Fact:** Not true; although you should spend your time observing safety-significant licensed activities, if you happen to identify any violation, it should be handled through the normal enforcement process.



Why use Performance Based Inspection Techniques?

- Compliance does not always equal Safety
- Inspection results are more clearly linked to safety and risk significance
- Obtain real-time facts to support conclusions
- Enhances licensee corrective actions by encouraging them to continuously improve performance

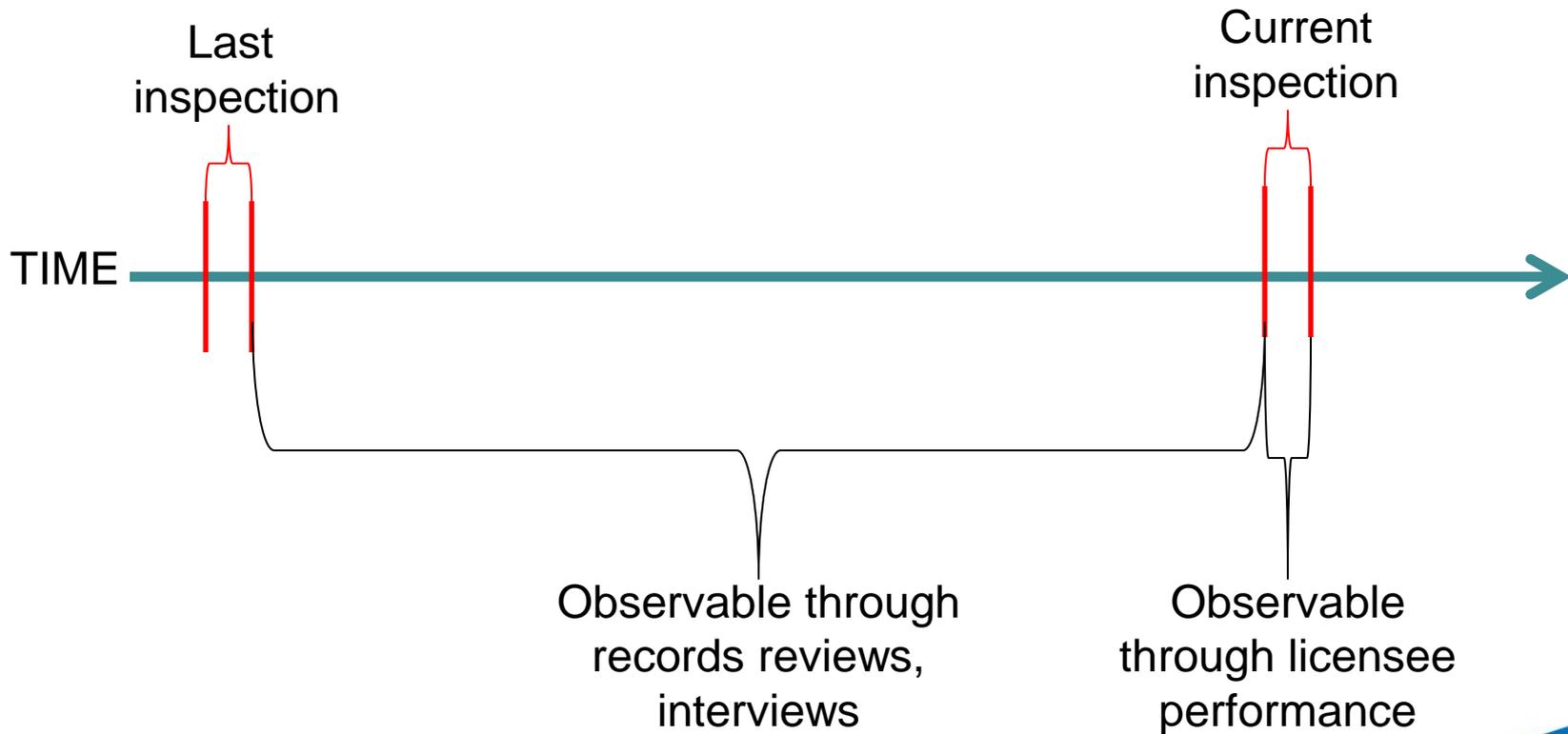


What is Risk?

- Risk is the relationship between consequence and probability
- Highest risk licensees are inspected more frequently and typically more thoroughly (e.g. inspection priority codes)
- Similarly, when performing an inspection, we should focus on the higher risk-significant activities

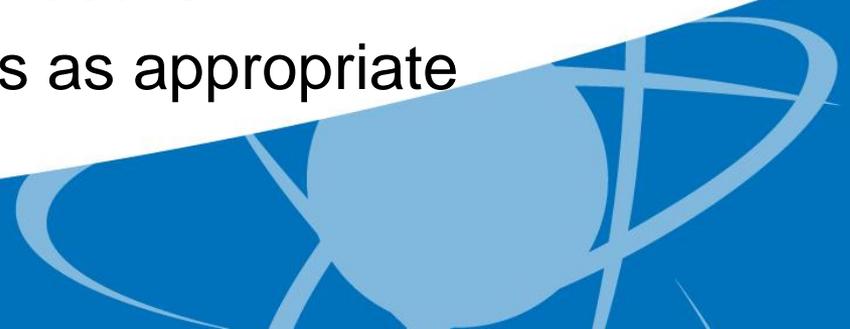


Each Inspection is a Snapshot in Time



Inspection Process

- Prepare for the inspection
- Plan the inspection
- Perform the inspection
 - Make Observations
 - Evaluate Observations
- Conclude the inspection
 - Overall judgment of licensee performance
 - Make findings as appropriate
 - Document the inspection results
 - Take enforcement actions as appropriate



Prepare for the Inspection



- Don't underestimate the value of proper preparation
- Be familiar with the applicable regulations/requirements
- Review the appropriate inspection procedure(s)
- Be familiar with relevant guidance documents or other generic communications



Prepare for the Inspection



- Review the license
 - Note any higher risk-significance activities
 - Note any uncommon license conditions or unusual license tie-downs
 - Has the license been amended or renewed since the last inspection? Does this warrant additional onsite review or follow-up?



Prepare for the Inspection

- Review the previous inspection results.
 - Is there anything that warrants follow-up?
 - Are there things that were not reviewed during the last inspection?
- Has the licensee reported any events since the last inspection? Have events or generic issues been identified at similar licensees?
- Based on the above, as well as input from your management, select the elements for inspection

Plan the Inspection

- Inspection Timing

- Perform the inspection when the likelihood is highest that licensed activities, especially high risk licensed activities, will occur
- Consider any site-specific training or security clearances that may be necessary for access to the licensee's facility

- Performing inspections on the backshift or off-normal hours?



Plan the Inspection

- Assemble resources
 - Your knowledge is the best resource
 - Select a proper instrument for the inspection type and know how to use it
 - Bring or have access to any documents you might need (e.g. copy of the license, regulations, previous inspection record, etc.)
 - Have the necessary and appropriate gear and equipment to observe the licensed activities



Perform the Inspection

- At the beginning of the Inspection:
 - If possible, go to the location/area you want to inspect first
 - Make any “immediate” observations (e.g. there is a package containing radioactive material sitting unattended in the hallway)
 - Ask questions
 - **What activities are ongoing today?**
 - **What can I observe today?**
 - Identify the areas you want to focus on and set a tentative schedule
 - Be flexible! Modify your inspection plan to adjust for the opportunity to observe activities



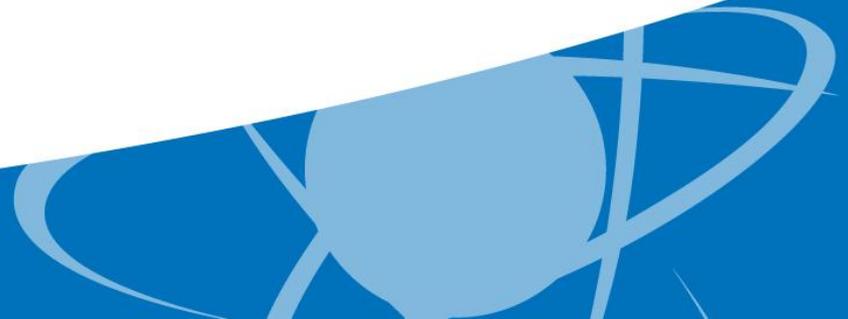
Perform the Inspection

- During the Inspection:
 - Observe
 - Direct observation of licensed activities is best
 - No activities in progress or planned? Indirect observation
 - Conduct interviews
 - Ask for demonstrations and walk-throughs
 - Review selected documents
 - Maintain constant awareness of what is going on around you, look for inspection opportunities



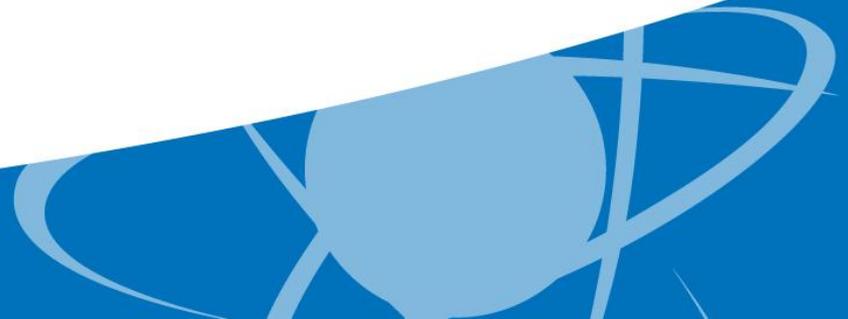
Perform the Inspection

- During the Inspection:
 - Perform independent measurements, and when appropriate collect samples
 - Set the performance example (e.g. frisking when leaving an area of use for unsealed material)



Perform the Inspection

- During the Inspection:
 - Engage/Interface at all levels of licensee personnel (e.g. RSO, materials users, housekeeping, administrative staff, security personnel, etc.)



Perform the Inspection

- During the Inspection:
 - It's your inspection, not the licensee's
 - Keep your focus
 - Take the high road
 - Be reasonable
 - You are the regulator



Perform the Inspection

- Find your own inspection opportunities
 - How to locate temporary job sites **prior to** the office inspection
 - Look online or in the phone book for fabrication shops, refineries, etc.
 - Know where licensed activities are being performed from previous inspection records
 - Using your survey meter to triangulate work locations
 - Looking for radiography trucks and well logging trucks at gas stations, hotels, and work locations

Perform the Inspection

- Find your own inspection opportunities
 - How to locate temporary job sites **during** the office inspection
 - Review utilization logs if you are inspecting well loggers, radiographers, portable gauges
 - Interview workers that routinely use licensed material in the field
 - Ask management
 - You can take a lunch break and look for workers at temporary job sites, then report results to management upon your return

Interview Skills

- Be approachable
- Have a questioning attitude
- Do not ask “yes or no” questions
- Do not ask leading questions
- Ask open-ended questions
- It is not your time to impress with your knowledge
- Listen to the answer, even if you think you know what the answer is (jump to conclusions)
- Watch body language and “non-verbal communication”
- Don’t confront person because of a “wrong answer”
- Repeat the question or ask it a different way
- Try to interview staff away from their supervisors; they may be reluctant to talk to you with their management listening in

Pull the String

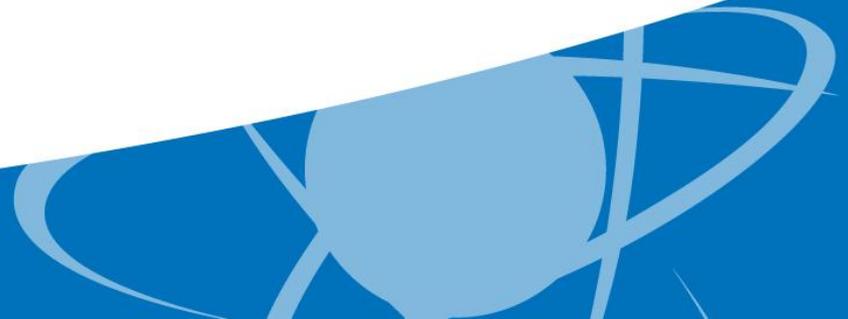


Evaluate your Observations



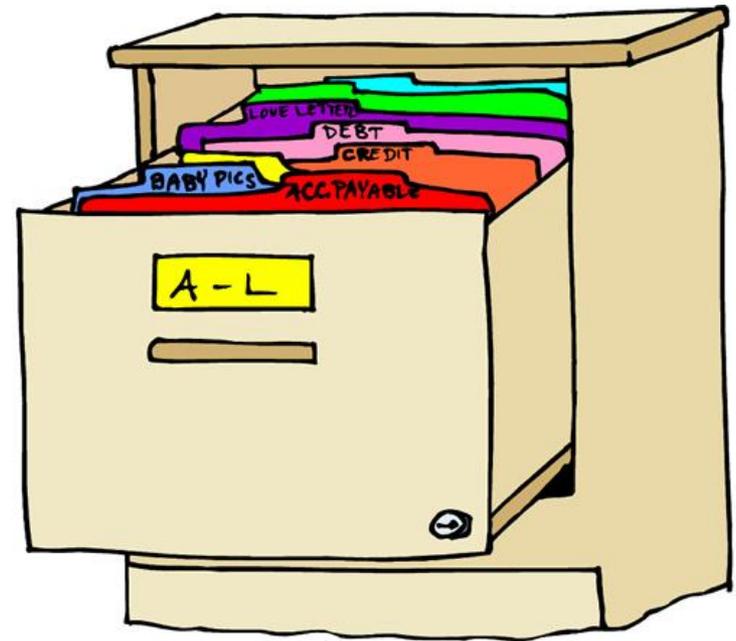
- Trust that the licensee has provided you with accurate information; then verify the accuracy of selected information you obtained from the licensee
 - Cross-check some selected records against your observations and licensee statements
- Based on what you have observed/heard, are there any issues that warrant further inspection effort? Potential violations? Safety Issues? Security issues?
 - If yes: gather more information
 - Is it isolated or is it programmatic?
 - Do you understand the cause?
 - If no: move on

**Examples of
Compliance Based
Vs.
Performance Based Inspection
Techniques**



Leak Tests:

- Compliance Based Technique:
 - “Show me your last 5 years of leak test records for these gauges.”
 - Then spend 1 hr looking at all of them and documenting the results in your inspection record.



Leak Tests:

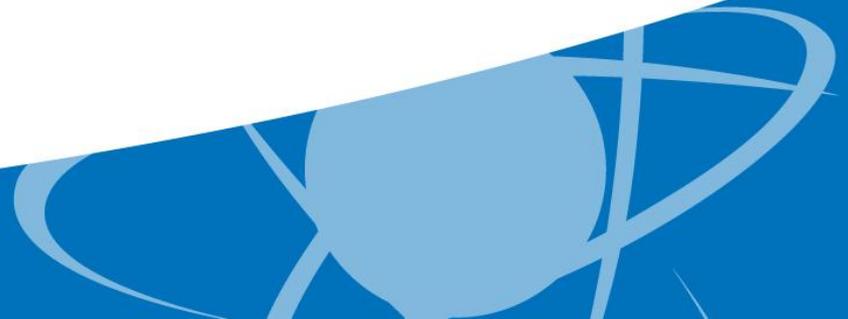
- Performance Based Technique:
 - “Can you tell me how often you leak test this gauge?”



- “Can you explain to me or demonstrate how you would leak test this gauge?”
- “Do you know what results would indicate there is potentially a problem?”
- “What would you do if it was found to be leaking?”

Leak Tests:

- If the answers to the above make sense, you may wish to review a small sample of representative records, and move on.
- If the answers to the above do not make sense, or there may be a potential violation, dig deeper.
 - Ask to see copies of records, procedures, interview other workers, etc.



Written Directives

- Compliance Based Technique:
 - Look at file with written directives and check to make sure required blocks are filled out
 - e.g. patient name, radionuclide, treatment site, dose per fraction, number of fractions, total dose
- Performance Based Technique:
 - Ask the Medical Physicist to walk through a sample of case files and explain how they verify that the administration is in accordance with the written directive

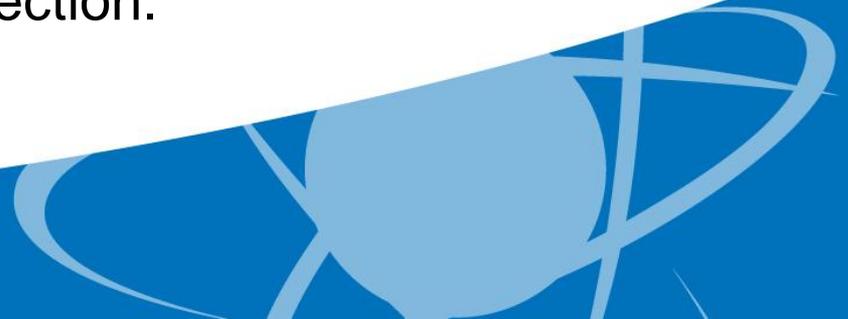


Identified Violations

- What is the potential significance of the finding?
- Inform licensee management in a timely manner, but commensurate with the significance of the potential violation
- Gather supporting information:
 - What requirement was violated?
 - How did this violation occur?
 - When did the violation first occur? How long did it exist? Does it still exist?
 - Who identified the violation?
 - What are the actual or potential safety/security consequences?
 - What causal factors that led to this violation?
 - Is the violation isolated or programmatic? Extent of condition?
 - What are the licensee's corrective actions to address the violation?

What if I Observe Unsafe Conditions?

- Take prompt action if the unsafe condition or violation, if not immediately corrected, could result in an licensee employee or member of the public being harmed or could cause harm to the environment
 - Example: Radiography being performed without performing a survey after source retraction
- Tactfully intervene
- Inform the licensee personnel engaged in the activity that the activity that is ongoing or is about to be performed is contrary to safety or regulatory requirements
- Request corrective actions
- Immediately notify licensee management and your supervisor
- Licensee pushback? Seek out licensee senior management and consult your management for direction.



Corrective Actions

- Try to “prioritize” violations with respect to safety or security significance
 - e.g. missing posting on a door vs. unsecured licensed material
- Short Term Corrective Actions:
 - Immediate
 - Compensatory
 - Stops the violation right now but may not be long lasting
- Long Term Corrective Actions:
 - Corrects the issue with greater permanence
 - Addresses programmatic weaknesses
 - Prevents the violation from recurring

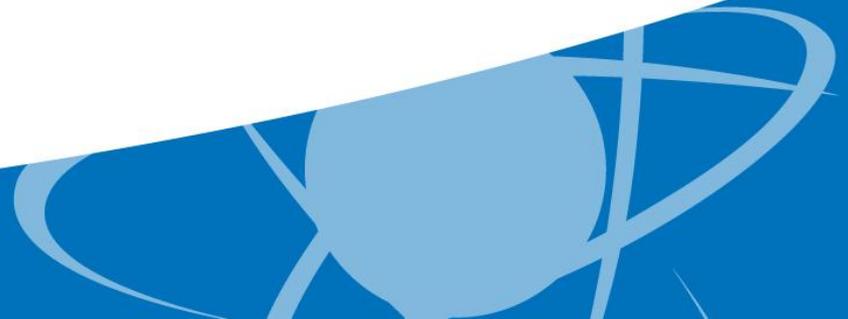


You Can't Inspect 100% of Everything Since the Last Inspection

- Time constraints
 - It takes time to fully develop inspection findings
- Don't panic!
 - You or another inspector can come back later if necessary to look at other areas, or inspect them during the next inspection, or ask your management for inspection assistance, etc.

Things to Avoid When Conducting Performance Based Inspections

- Allowing an unsafe or unsecure condition to continue without saying something immediately/promptly
- Compromising your personal safety or that of licensee personnel
- Doing something or asking the licensee to do something that will put licensee into non-compliance or be unsafe
- Unnecessary radiation exposure
- Unnecessary security risks



Things to Avoid When Conducting Performance Based Inspections

- Interrupting patient care
- Unnecessarily delaying scheduled licensee work activities
- Making unreasonable demands and impositions on the licensee/licensee staff
- “Bossing” licensee staff around
- Damaging licensee equipment



Conclude the inspection

- Make an overall judgment of licensee performance
- Before leaving the licensee facility
 - Explain any findings or preliminary findings
 - Cite the specific requirement and how it does not appear they are meeting it
 - listen to the licensee's perspective
 - Understand what licensee intends to do to correct any identified findings
- After leaving the licensee facility
 - Discuss with your management
 - Gather any additional or follow-up information
 - Document the inspection results
 - Take enforcement actions as appropriate

Document the Inspection

- Documentation to the licensee
 - Should be clear
 - Should document the basis for any findings and enforcement actions
- Documentation for the file
 - Program scope, inspection scope
 - Performance observations
 - Follow-up on any previous violations and events
 - Sufficient information to support any identified findings
 - Conclusions



Summary

- Performance-based inspections are used to determine whether or not a licensee's program activities are executed in a manner that ensures safety
- Prepare-Plan-Perform-Evaluate-Document



Questions?

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