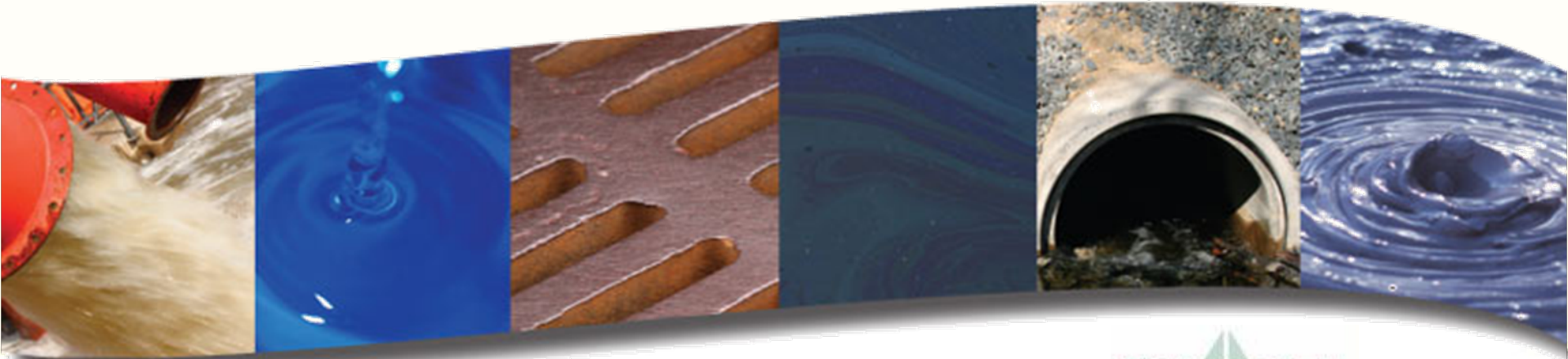


Conducting Internal Audits and Preparing for EPA/MDE Inspections

Triumvirate Environmental

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Audit - Why now?

- Increase in state and federal inspections and enforcement actions (increase state/federal revenue)
- There has been an increased focus on Pharmaceutical Waste Collection, Universal Waste
- Take advantage of the Self Disclosure Requirements

Audits:

Your Options – Your Risks

➤ Fire-fighting approach (Reactive)

- Address issues as they come up



➤ Compliance assessment/audit (Proactive)

- Comprehensive evaluation of issues



Benefits: Why conduct an audit?

➤Efficiencies

- Time
- Resources

➤Minimize potential for violations

➤Prevent fines/penalties

➤Stay out of the newspapers!



Multi-Media Audits

- Clean Water Act (CWA)
- Clean Air Act (CAA)
- Resource Conservation & Recovery Act (RCRA):
Hazardous Waste
- Department of Transportation (DOT)
- Emergency Planning & Community Right-to-Know
(EPCRA)
- Fungicide Insecticide and Rodenticide Act (FIFRA)

Preparing for an EPA/MDE Inspection

➤ Perform a Self-Assessment

- Internal
- Third-Party Assistance

➤ Conduct a Formal Audit

- Audit Policy
- Self Disclosure

EPA/MDE Inspections: Preparation is Key!



Form a Committee

- EH&S
- Facilities Dept.
- Maintenance
- Environmental Services
- Clinical Lab
- Researcher Admin.
- Radiology
- Pharmacy



EPA/MDE Inspections - Tips

➤ Be Prepared!

- Maintain up-to-date plans and records
- Know where documents are; be able to produce them in a timely manner
- Have a Preparedness Plan

➤ Records and Documentation Review

- Assemble materials requested by EPA/MDE
- Identify conference room (do not use offices) for records review
 - ◆ Offer only requested documents for specific locations
 - ◆ Make duplicate copies of records that they copy

Permits/Reports - Be Ready!

↘ Wastewater discharge permits
(*Local Authority permit*)

↘ Storm water permit (*for construction*)

↘ Documentation of sampling/ lab reports (*mercury analysis*)

↘ Air emissions reports/permits
(*Recordkeeping*)

↘ Copies of waste manifests (*and profile forms*)

↘ Biennial Hazardous Waste Reports (*LQGs*)

↘ DOT HazMat Shipper Registration

↘ Employee Training Records
(*OSHA Lab Safety, HAZCOM, RCRA/DOT*)

↘ Oil SPCC Plan (*tank inspection records, spill reports*)

↘ Hazardous Waste Contingency Plan

↘ DOT HazMat Security Plan

Organize Internal Resources

- Preparedness Coordinating Committee
- Facility Program Managers/Experts (CWA, CAA, RCRA, etc.)
- Facility Inspector Escorts
- Logistics and Planning
- Roles & Responsibilities
- Communications

Inspection Preparedness Coordinating Committee

- **Organizes and facilitates the Opening Conference**
- **Works out schedule with the inspectors**
- **Coordinates inspections with department/program managers**
- **Conducts daily debriefings**
- **Organizes and facilitates the Closing Conference**

Facility Program Managers/ Experts

- Serves as primary contacts for specific compliance categories (Air, Water, Haz Waste, etc.)
- Provides documents and records
- Accompanies escorts and inspectors as necessary
- Accessible to answer questions regarding regulations and your facility programs

Facility Inspector Escorts

- Introduces the inspector and convey seriousness of the interview.
- Intercedes when leading questions are asked during an interview
- Tactfully restates misunderstood questions to interviewee.
- Doesn't allow unqualified people to respond to questions

The Inspection



Inspections: Logistics and Planning

➤ Internal Notification
("The British are
Coming")

➤ Enacting the
Preparedness Plan

- Opening Conference
- Coordinating a schedule with EPA / MDE
- Debriefings with parties inspected



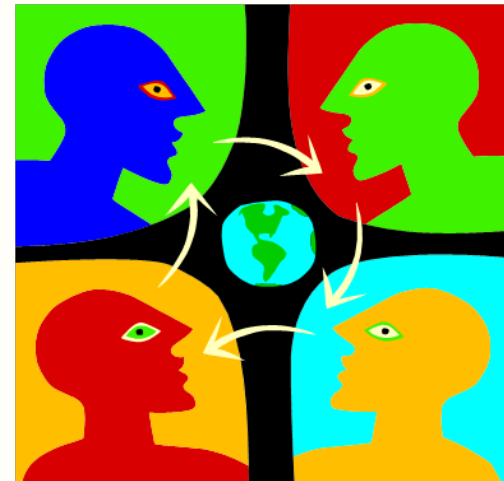
Effective Communication During the Inspection

➤ Internal communications

- Initial notification
- Opening conference
- During the audit
- Closing conference
- Debriefing

➤ Communications with inspectors

- Guidelines



Opening Conference

- ◆ State that the group has been assembled to help facilitate the inspectors' review & provide an open communication channel w/ key facility officials
- ◆ Outline positive working relationship with EPA/MDE inspectors
- ◆ Discuss how important compliance is to your facility
- ◆ Who in upper management is involved and how often your department meets with them
- ◆ Obtain an understanding of inspection scope

Guidelines: Site Inspection

- ◆ Identify nature and scope of inspection
- ◆ Accompany each inspector at all times
- ◆ Cooperate, but do not offer information not requested
- ◆ Duplicate all records copied
- ◆ Take good notes, photographs, split samples
- ◆ Monitor employee interviews
- ◆ Conduct an exit interview for each area to get an idea of what they found

Facility Escort Guidelines

➤ Restate unclear answers from the interviewee to the EPA/MDE inspector.

➤ Stay by the inspectors side

➤ Take notes

- During and shortly after the interview
- Of issues that the inspector notes during the inspection
- Of questions that could not be answered

Taking care of business

➤ Fixing Potential Violations

- As issues are found
- Prior to EPA entry
- Before EPA finishes for the day

➤ Behind the Scenes During the Inspection

- EPA Location during the day
- Fielding questions

Closing Conference



- Consider having VP level representative and attorney present
- Present documentation of correction actions taken during the inspection
- Have answers to questions that couldn't be answered in the field

Before they leave

- Ask for copies of their notes / pictures
- Ask what is the next step in the process
- Ask if there is anything that needs to be corrected



Guidelines for Communications During an Audit/Inspection

Attitudes & Behaviors

Goal: Stay in Control

- Be courteous and respectful
- Be positive, professional and confident
- Be honest

Communications

During an Audit/Inspection

➤Inspector Questions

- Be an “Expert” on your programs
- Answer questions; ask for clarification as needed

➤Understand the question - ask for clarification or repeat it back to them

➤Don't volunteer additional, unnecessary information

➤Keep answers simple and direct

➤If you don't know the answer, write it down and contact someone who does

More guidelines

- Take notes
- Don't attempt to deal with hypothetical situations
- "Fix" simple deficiencies along the way
- Make a copy of anything given to the inspectors
- Seek approval for all photos requested by the inspectors; take duplicate photos
- Likewise, take duplicate samples

Guidelines continued...

- Don't offer an opinion or agree/disagree with the inspectors
- Do talk about sports, music, general topics
- Don't be their "buddy" or confidant
- Don't sign anything
- Keep them from harm's way (no confined space entry or near high hazard areas)

Guidelines continued...

- Don't offer information unless specifically asked
- Don't argue with the inspectors
- Don't complain about the regulations
- Don't be pushed into giving an answer if you don't know...say that you don't know
- Don't be evasive. Answer directly and succinctly
- Don't lie to the inspectors or misrepresent what really happens in your area
- Don't engage in speculation

Thank You!

➤ **Rick Foote, CHEM – Senior Environmental Compliance Advisor**

- 617-686-6184
- rfoote@triumvirate.com

Questions?

Shane Zuffante
Account Manager

443-977-7293

stodisco@triumvirate.com

Rick Foote
**Senior Environmental
Compliance Advisor**

617.686.6184

rfoote@triumvirate.com