WHAT TO KNOW BEFORE YOUR NEXT REGULATORY AUDIT

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EXECUTIVE SUMMARY

One of the more terrifying moments a PSM Coordinator may experience in their career is receiving a letter that the facility is being audited by a regulator. However, with a little knowledge, some forethought, and adequate preparation, the regulatory audit can be a smooth, stress-free process. Regulatory audits are perceived to be more complicated and intense than a Triennial Compliance Audit, but in fact they are nearly identical. Proper preparation and perception are key to a successful regulatory audit.

The objective of the paper is to provide the information necessary to properly prepare for a regulatory audit (US EPA, OSHA, state, or local) and have the knowledge necessary to anticipate the needs of the regulator to successfully complete the audit. This topic is significant because many facilities do not understand the regulatory perspective and are not properly prepared when a regulatory audit is conducted. A secondary objective of the paper is to reaffirm confidence for the PSM Coordinator in their management of the regulatory audit session and to provide the necessary tools for success.

INTRODUCTION

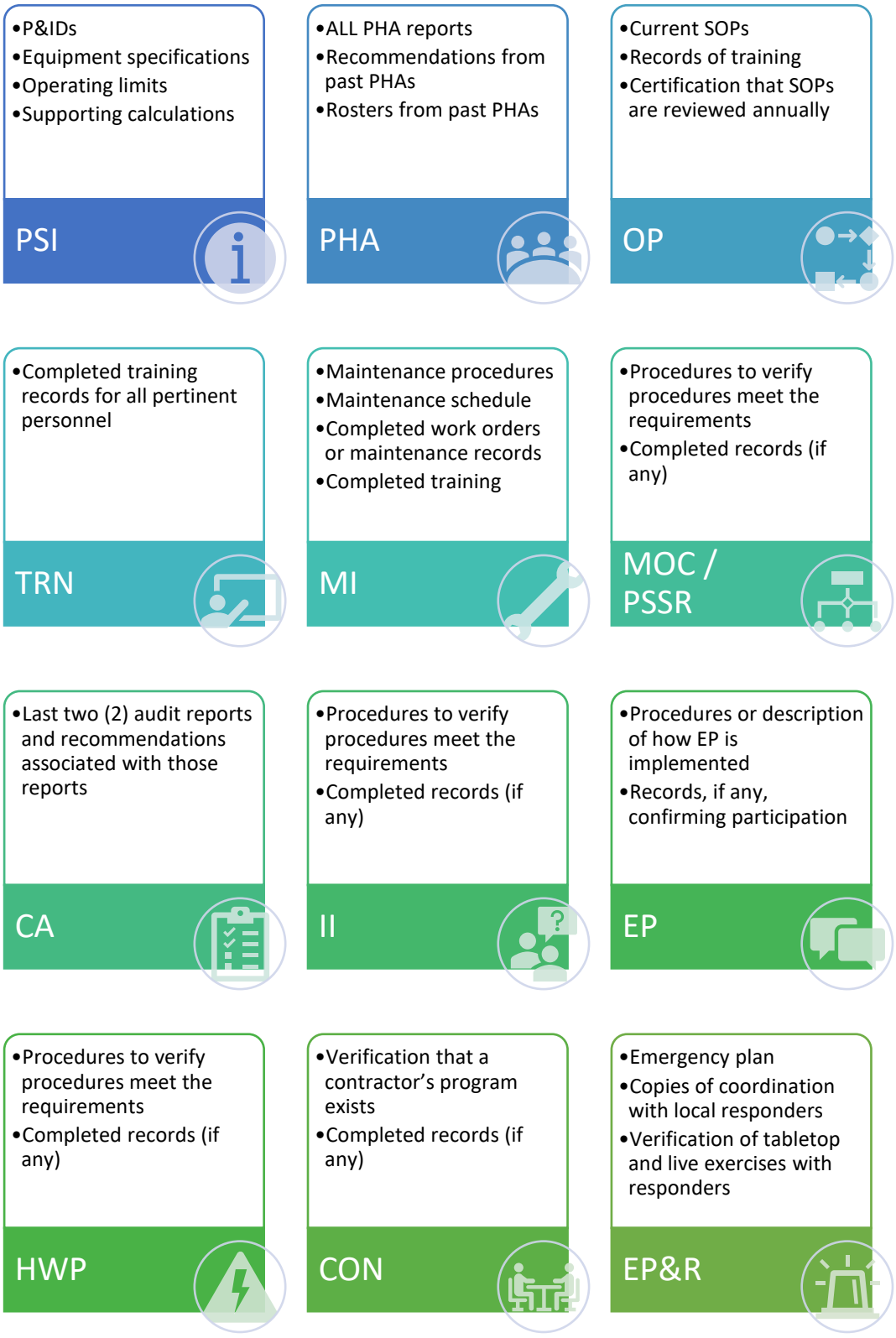
The intent of this paper is to identify the typical lifecycle of a regulatory audit. This includes the pre-audit notifications and tasks, to day-of audit considerations, and post-audit follow-up activities. Additionally, it will focus primarily on Federal regulatory agencies' requirements but will also provide some specifics for state and local agencies.

The paper will also review what the auditor is looking for during the audit and how to properly prepare for the auditor's presence on-site. Knowing what an auditor may be looking for and where typical deficiencies arise can assist in a productive preparatory effort for the audit.

Typical Audit Process

The typical audit process begins with a notification letter from a regulator including a request for information, a list of documentation (if different from the information request), and an audit schedule. The information request usually consists of a list of the program elements applicable to the facility with additional documents listed as necessary. Additional documentation could include specific operating procedures and/or maintenance records, records for past recommendations being closed, an Injury and Illness Prevention Plan (IIPP), and more. Typical requested documentation is listed below by Program Level 3 Program Element.

Figure 1: Program Support Documents



Proposed schedules vary. It is very possible that an auditor will just show up on-site and request an immediate audit, although this is rarer than a scheduled audit. Scheduled audits vary. Some auditors allow facilities time (possibly weeks) to prepare. Audits also vary in time on-site. Local regulators, such as in California, may spend a day on-site with a follow-up report. Others, such as OSHA or EPA, may spend several days on-site pouring over documentation and interviewing personnel. If the schedule is not clear, the PSM Coordinator should be asking in order to properly plan, prepare, and schedule personnel.

In rare cases, audits may go on for months. This is typically because proper documentation or interview personnel were not available for the audit originally scheduled and a second site visit is needed. With more documentation being electronic, this may also extend the length of audits to give regulators more time to review documentation off-site.

Every audit should have follow-up documentation from the regulator, usually in the form of a letter or report, documenting the findings and deficiencies, if any. This report is documentation of the results of the audit and should be kept with other regulatory documentation. If follow-up is requested, perhaps due to deficiencies, a response is usually needed to provide corrective action follow-ups and/or recommendation closures.

Preparation

Once the request letter is received with a schedule, it is time to get to work. The first step is to start gathering the documentation requested. At this time, it is a good idea to at least conduct a cursory review of the documentation for obvious deficiencies. Regulators will see the dates and know it may have been done last minute, but the result is more likely to be a verbal reminder that a better system should be in-place rather than a formal violation. A “fix-at-failure” mentality should not be present when maintaining these programs.

- Is documentation in order and easy to navigate through?
- Are there any hand-written changes that should be updated in electronic files?
- When was the last time recurring activities were done? Do they need to be done again?
- If documentation is missing, is there time to fix the issues before the audit?
- Does anything need to be updated?

Electronic documentation is widely accepted by regulators, but that does not mean every regulator will be satisfied with seeing only electronic documentation. Be prepared to print out certain documentation (like work orders for maintenance or training records). It is possible an auditor may want to see hard copies of certain documentation. A good rule is that documentation should be easily accessible in a minute or less. Any less organized is usually an indicator for a deficiency. In addition, only provide an auditor with the documentation requested. There is no obligation to provide additional or unrequested documentation. In fact,

providing extraneous documentation could lead to further investigation and, ultimately, an unexpected violation.

In addition, review the facility's recommendation list(s) from past PHAs, Compliance Audits, Management of Change / Pre-Startup Safety Reviews (MOC/PSSRs), and/or Incident Investigation. Recommendation lists are one of the easiest places to spot deficiencies. It may even be the first document a regulator requests to audit. PSM Coordinators should check recommendations in the preparation phase and make sure they spend time verifying closure or closing recommendation prior to the audit session.

While the PSM Coordinator is gathering documentation, it is also a good idea to request an audit space for the auditor. A conference room or private office serves as good space where a meeting can take place, documentation can be spread out, and interviews can be conducted. The requested space is also a great place to set aside documents needed for the audit during the preparatory phase.

Does the facility have a consultant that helps with regulatory programs? If so, call them! A consultant that knows how to navigate the audit process, or that can just be available for questions or missing documentation needs, can be a huge asset for the audit. This also applies for on-site personnel who may be helpful during the audit session. Every PSM Coordinator should have a well-established team of supporters for the facility's best interests.

Pertinent personnel who will be interviewed should also be notified and scheduled to be available for interviews the day of the audit. This schedule is not necessarily being available all day or for multiple days, but operations, maintenance, and management personnel should be prepared for at least part of their day to be interviewed by an auditor.

Figure 2: Efficient Preparation for a Regulator Audit

Lastly, be prepared for a facility tour with the auditor. Part of a regulatory audit, typically, is to tour the facility to inspect implementation measures of the regulatory programs. The regulator may inspect equipment

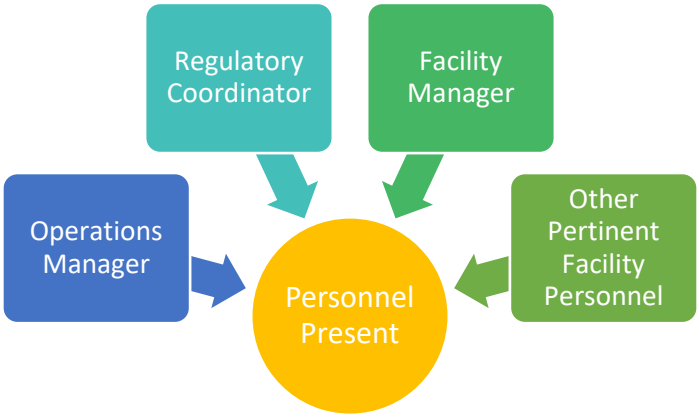
/ piping labeling, valve tagging, operations, equipment function, and general housekeeping. By walking the facility, the regulator can also assess the facility's efforts to implement the program through conversation and observation.

The most efficient preparation includes delegation. There is an opportunity for personnel involvement by delegating tasks for the audit preparation to assess the safety / regulatory culture at the facility. This also enables the PSM Coordinator to focus on the bigger picture, rather than the smaller tasks to prepare. Reviewing and/or updating documentation can be a great opportunity for a new hire to become more familiar with the program documentation content and/or what it takes to maintain the program, if there's an opportunity for their involvement in this process.

Audit Session

Audits can start with a facility tour. It is a good opportunity for an auditor to get a general view of the facility, take notes, ask questions, and take photos, as necessary. It is a nice ice breaker for the day. A rule-of-thumb is to take the most direct route to the areas the regulator requests to see. Giving an auditor "the grand tour" is not always in the best interest of the facility. It is especially important not to point out deficiencies for the regulator, even if unrelated to the audit focus or regulations. Auditors do have the latitude to notify other departments for inspections and/or write up violations related to other programs. Be cognizant of additional complications or issues when guiding an auditor through the facility.

Figure 3: Who Needs to be Present During the Audit?



The documentation review is typically next and will take most of the time in the audit session. Auditors sometimes focus on areas where they have seen the most deficiencies or where they are receiving instructions to spend more time. These areas of focus vary, but if a PSM Coordinator has spent the proper preparatory time, then there is little to be nervous about.

Interviews and/or questions may be mixed in with the documentation review or they may be scheduled during the day. Be prepared for a little of both. Interviews are usually informal, but somewhat thorough. Auditors want to assess the understanding the programs with operations, maintenance, and management individuals. It is also a good opportunity to assess the employee participation at the facility in the regulatory programs.

One very important step is to make sure a closure meeting occurs with the regulator. The closure meeting should review the events of the day, the findings of the audit, and potential violations or deficiencies. This is an opportunity for the PSM Coordinator to review the day with the auditor and correct any items that may have been missed or deficient before the auditor leaves the facility. It also serves as an advantage to know what the results are immediately, rather than waiting for a follow-up letter and/or report of findings.

What is the Auditor Looking For?

The biggest question on the PSM Coordinator's mind during an audit is "What is the auditor looking for?" Other questions may include: What does the auditor see that may have been missed in the preparation phase? What could someone say or do to reflect negatively on the audit? Was all the documentation correct and implemented?

During the facility tour, it is very likely that the auditor is looking for the following.

- Housekeeping issues that may reflect negatively on a facility's ability to implement the program or that may be in direct violation of the requirements.
- Equipment and/or piping labels that may be inaccurate, illegible, mismatch other documentation, and/or misleading or confusing to an operator.
- Equipment that appears to be ill-maintained or managed, by their best knowledge of the particular type of facility and industry best practice.
- Properly operating equipment that does not have obvious signs of wear-and-tear outside of normal or looks in need of repair.
- Standard operating procedures and/or maintenance procedures that do not reflect the current operations and/or maintenance practices on-site.

Of all the listed items above, correcting procedure implementation is probably the easiest potential deficiency to correct during the preparation phase of an audit, if time is in short supply. The return-on-investment of an operator (or multiple operators) reviewing the procedures during the preparation for the audit and editing / updating the necessary procedures is significant.

During the documentation review, an auditor will identify two (2) things: 1) that the documentation has been reviewed and/or updated within a reasonable timeframe and according to regulation, and 2) records of completion of these reviews have been saved and are in the documentation. Deficiencies associated with these documentation items are easily addressed in a well-managed program.

One of the easiest areas to find deficiencies is to look at a list of recommendations and if they are all closed within the required timeframe. From an audit perspective, this is a very good indicator of the level of importance a facility places on the program requirements and safe operation of the facility.

While interviewing personnel, regulators may be looking for the following.

- Consistent on-site practices between interviewees. Are all personnel saying the same things or sound like they are trained consistently?
- Do managers understand what training each employee needs, based on their position and job responsibilities?
- Do procedures being implemented match the documentation written in the program?
- Do personnel have a consistent, general understanding of the program requirements and where to find documentation or how to request it?
- Do personnel understand the program elements directly related to their job responsibilities? Do they appear or give the impression that they can conduct their job in a safe manner and according to program requirements?
- Are there are "red flags" to follow-up with?

The key to the interview process is to provide the most direct answer possible. Do not add "flourish" or details that are unnecessary. Think of an audit interview as a job interview. Being direct is ideal and questions should be answered thoroughly and thoughtfully, but also know that the auditor will be judging responses against the compliance of the program and providing notice of violations as needed.

Follow-up

After the audit is complete, the auditor will likely be sending a follow-up letter / report to the facility. The notes that support this report should have already been reviewed during the post-audit meeting with the regulator, so there should be no surprises. The letter / report serves as the official documentation of the audit.

In this letter / report, there should be findings from the audit, deficiencies, if any, and deadlines for deficiency correction, if needed. In addition, there may be requests to follow-up on regarding records of corrected actions, when completed, and additional documentation, if it were missed during the audit or the facility did not have it available. This is also the opportunity for the facility to respond in writing if representatives disagree with any of the findings. Facilities should provide formal responses to audits if they feel it is necessary to clarify findings and/or correct violations that should not be recorded.

REFERENCES

Code of Federal Regulations, Title 40, Chapter 1, Subchapter C, Part 68, Subpart D, Section 68.79, “Compliance Audits”; December19, 2019.