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Creating and maximizing your audit and monitoring program

By Jessenia Cornejo and Brittani Summers

For those of you who have experienced building compliance programs from the ground up, you may have realized the importance of creating and implementing your organization's audit and monitoring program. For those who have not, this article may help explain the significance. After establishing the hotline, compliance manual, code of conduct, etc., your audit and monitoring program will ensure your organization's processes are in compliance.

First, it's essential to have a good understanding of auditing versus monitoring. Audits are customarily larger in scope, can occur monthly, quarterly, and/or annually and are performed by individuals independent of the process.^[1] If possible, you want individuals not directly involved in the process to remove any conflicts of interest when performing the audit. Audits can be performed on a statistical sampling of a certain population or can be completely random. In the laboratory space, certain volumes of samples are tested regularly. One audit could take 10% of the sample volume for auditing purposes. Whereas, in another audit, how much to audit could be based on the number of resources available at the time. Monitoring assesses the controls that are in place regularly and is more reflective of your daily business operations. This allows you to consistently check in on the mechanisms you've put into place for compliance adherence.

Some examples of monitoring are survey results and compliance training. Employee exit interviews and compliance program surveys may identify potential issues within your program or organization, such as retaliation, a poor compliance culture, the effectiveness of your reporting tools, etc. A compliance training review ensures your employees actively review your company's compliance manual and code of conduct and attend compliance training. This is important as it allows employees to have visibility into the program and better understand compliance. The most effective monitoring is completely dependent on your organization or industry.

Why is it important to audit and monitor?

1. **Measures the effectiveness of your program.** In the United States Department of Justice's (DOJ) *Evaluation of Corporate Compliance Programs*, prosecutors consider this question: "Does the corporation's compliance program work in practice?"^[2] Auditing and monitoring allows you to check what is or isn't working.
2. **Identifies criminal or malicious conduct.** This is extremely important, as criminal conduct may need to be

reported to external agencies, and malicious conduct may identify the employees within the organization whose employment may require re-evaluation.

3. **Highlights risk areas.** Risk areas can vary across specialties and industries. Once your risk areas are identified, your organization can modify accordingly. After identification, you might want to change employee training and/or policies and procedures, implement mitigation steps to various processes to decrease risk, or implement other measures for mitigation.
4. **Accountability.** Allows all participants in the audit process to be on the same page about who is responsible for each audit or monitoring process. This also allows for transparency between compliance and other departments within the organization.
5. **Continuous improvement.** You don't want your program to stagnate; you want to improve and contribute to the business objectives. Additionally, government agencies, like the DOJ or Office of Inspector General, want to see organizations consistently improve their compliance programs.
6. **Promotes collaboration.** This helps other departments see compliance as partners as opposed to adversaries. Additionally, it can create compliance champions in other departments. This is incredibly valuable if there is a one-or-two-person compliance team.
7. **Efforts are rewarded.** If a regulatory agency comes knocking on your door, you want to show them that you have been auditing and monitoring; provide examples of how you have improved your program based on your organization's findings. DOJ prosecutors may reward efforts to promote improvement and sustainability.^[3]

Where to start?

One can perform various types of audits: internal, external, concurrent, or retrospective. All these audits will identify issues and create steps to take corrective and preventive action (CAPA).

Once you have an idea of the types of audits you want to perform, you can create an action plan. An annual audit work plan or annual compliance work plan will allow you to manage your goals and objectives for the year, including scheduling and tracking your audits. Additionally, work plans can be reviewed with your compliance committee, board, and senior leadership—which will give them insight into compliance's responsibilities for the year. This may highlight constraints, which the committee or board can help with identified constraints. The Health Care Compliance Association's *Complete Healthcare Compliance Manual* is a good reference tool when creating your work plan.

You also want to identify your risk areas by asking the following questions: What are your industry/organization's risk areas? What are your requirements? A lab has Clinical Laboratory Improvement Amendments (CLIA) and College of American Pathologists or Commission on Office Laboratory Accreditation requirements; hospitals have CLIA and Joint Commission on Accreditation of Healthcare Organizations requirements. Some say you do your risk assessment prior to developing your audit and monitoring plan. It's what works best for your organization.

Furthermore, you want to define the scope of your audit, such as sample size and/or date range. Identifying the audit scope allows you to determine the resources and time required to complete the audit.

Lastly, create an audit report template that includes purpose, scope, findings, and responses to the deficiencies, which includes your CAPA. Having this before the start of the audit allows you to think about your CAPA as you identify the deficiencies. The audit report is essential, as this is what may be shown to an inspector/investigator

when questioned on your audit program. Documentation is key!

Available resources to streamline your program

Now that you have the background, you're ready to dive into the process. We want to focus on streamlining auditing and monitoring activities wherever possible.

Automation allows you to refine and streamline existing processes and take out some of the unnecessary manual steps that may exist. When considering automation, where do you even start? Think about your organization's audit process, and ask yourself these types of questions:

- Are there any tasks that take a long time to complete? Which tasks feel especially time-consuming?
- Are any of those tasks redundant? Unnecessarily redundant?
- Are these tedious tasks mostly manual?
- Can any portion of that be automated?

Next, consider what steps you can take to address redundancy and manual tasks. Are there any manual steps that can be done electronically to save you some time or effort? Are there any external systems or vendors, for instance, audit software? Or are there perhaps vendors/consultants that help in streamlining processes?

Let's look at an actual example of automation. Do you have an employee handbook or code of conduct? As you know, a code of conduct needs to be reviewed and acknowledged by employees. If you are still collecting paper signatures, then an easy adjustment is the creation of electronic acknowledgment (e.g., Google Form, Microsoft Forms, DocuSign, or Adobe Sign).

Analytics gives access and visibility to trends and scores, and can be used to mitigate risk. For example, you can use analytics dashboards showing audit results that can serve as an executive summary of compliance activities and trends. Analytics can also be used to optimize and improve the customer experience through insights. For example, what is your customer interested in? Do they want to see real-time data and trends? Let's discuss a couple of examples. In the lab industry, it's common to monitor test utilization. This is done by analyzing testing data yearly and looking at billing codes for the top tests performed.^[4] One can create their own dashboard by incorporating the relevant information. This can be shared with the provider, giving them access and the ability to see their own data while the lab reviews it. Putting this information back into the provider's hands gives real-time information they, in turn, use to view trends and make decisions. I've also seen dashboards that reflect billing and other errors in real-time. How is this useful? By showing errors on a dashboard, one can drill down to see the cause (i.e., missing or incorrect insurance information) of the mistakes, and, as a result, take the necessary action to address and reduce that error rate moving forward. Essentially, this type of dashboard can be used to identify gaps and act appropriately.

As you establish and refine your auditing and monitoring plan, you likely have activities that take place at different frequencies. Create calendar invites/reminders when those are scheduled and due. This will help you track audits and not lose track of them.

Partner with leadership and make them aware of your auditing and monitoring efforts. Not only does this make them aware of what you're working on, but it can prove beneficial if you run into any roadblocks or need additional assistance, and leadership can support those efforts.

If you have a team, there are some things you can do to maximize their output. First, challenge them to find

better, more efficient ways of doing things. This will lend to continuous improvement and streamlined processes, as they regularly think outside the box and share ideas and suggestions to eliminate manual and duplicative efforts. You might also consider rotating assignments to ensure the entire team is familiar with each audit. This leads to a well-rounded team, and if someone goes on vacation, nothing gets put on hold while that person is out. Rotating assignments may also prove beneficial for some of the redundant processes, as a fresh set of eyes may find an inefficiency with the current process. On the flip side to having the entire team exposed to all aspects of each audit, it may also be valuable to have subject matter experts within the compliance team who focus on specific compliance items. Another thing to consider is what each team member enjoys doing and where their strengths lie. The benefit is that the team members enjoy and are good at their work.

There really is no right or wrong answer with your approach—it all depends on what works best with your team and your organization.

You also want to hold your team accountable, which will require setting expectations up front. Who is responsible for the audit? Is it clear who is doing what, and what the expectation is? What if there is a deficiency? What is the timeline for completion? Who owns the process from start to finish? Are there any roadblocks that may be preventing them from completing their tasks? Have regular check-ins with the team to check progress and assist with any roadblocks they may be running into.

For those of you that are a department of one, you are small but mighty! You likely have limited bandwidth, so where do you start? Identify your highest risks and prioritize them. Performing a gap assessment can help. This will identify existing gaps in your program. Based on the gaps identified, you know what needs work and can prioritize those efforts accordingly.

Other departments may also prove a valuable resource in compliance audits. For organizations with small teams, this helps complete the audit where bandwidth may be an issue. Regardless of organization size, there are other benefits to involving others in compliance audits and processes. It brings awareness to the audit process, provides insight into risk areas and safeguards that are in place, and promotes collaboration amongst departments. Plus, we want everyone to be compliance champions!

How might one go about engaging other departments? To initiate the conversation, reach out to department managers ahead of time and ask if their team has the bandwidth and would be willing to assist. It helps to outline the purpose of the request—the end goal—and of course, the benefits. Put your sales cap on and hype up the auditing process to get teams on board to participate! Once auditors have committed, train each of them on the section(s) they'll be auditing and give a due date. Be sure to assign a reasonable due date since this is not their primary role/duty.

Presenting your findings

Now you've completed your audit, and it's time to present your findings. Presenting the information can be done several ways: a formal report, a summary of findings, an audit score, or a report focused solely on identified deficiencies. The presentation will really depend on your audience. What information do they *need* to receive, and what do they *want* to know about?

Compliance committee members may want a summary of the score or the findings. The board may only want a high-level report on identified deficiencies, whereas other departments may want to dive deeper as the results may impact them. Investors such as private equity firms, institutional investors, or other organizations in your industry may want a formal report.

An analytics dashboard can be used when you're displaying audit or survey results, trends, etc. Here are a few

ideas.

- Present your audit findings with a visual representation of pass rates or deficiencies
- Highlight any identified gaps and bring attention to your risk areas
- Display survey results
- View and monitor trends

Whichever format you choose, you want to clearly convey your audit findings, including any CAPA or compliance recommendations if applicable. Typically, the audience wants to know exactly what deficiencies were identified and what is being done to correct them.

Once you've presented your findings to stakeholders, were there any objections to the proposed CAPA or disagreements with compliance recommendations? If so, additional discussions may be warranted. In your final audit report, be sure to document any final CAPA (new recommendations from stakeholders, or changes to your proposed CAPA).

Why is it important to present your findings? As a compliance professional, you want to make sure that leadership is aware of any risk areas (financial or otherwise) that may affect the compliance program or the organization overall. Or you can look at it from a lens of revenue retainment—help the organization keep the money they make!

Takeaways

- Auditing and monitoring are both important to measure compliance program effectiveness, maintain compliance, and demonstrate ongoing compliance.
- Identify and prioritize your highest risks. Perform a gap assessment to identify what needs work and prioritize your efforts accordingly.
- Continuously look for inefficiencies and ways to improve processes and challenge your team to do the same. Automation and analytics can streamline processes, giving you time to focus on other things.
- Partner with other departments and leadership throughout the auditing process. This may help with bandwidth and also gives others insight into compliance processes.
- Convey your audit findings clearly, including any corrective and preventive action and compliance recommendations if applicable. Highlight any deficiencies identified and what is being done to fix them.

1 Mark P. Ruppert, "Defining the Meaning of 'Auditing' and 'Monitoring' & Clarifying the Appropriate Use of the Terms," Health Care Compliance Association and Association of Healthcare Internal Auditors focus group, last accessed August 31, 2022,

<https://ahia.org/assets/Uploads/pdfUpload/WhitePapers/DefiningAuditingAndMonitoring.pdf>.

2 U.S. Department of Justice, Criminal Division, *Evaluation of Corporate Compliance Programs*, June 2020,

<https://www.justice.gov/criminal-fraud/page/file/937501/download>.

3 U.S. Department of Justice, *Evaluation of Corporate Compliance Programs*.

4 Department of Health & Human Services, Office of Inspector General, *Publication of OIG Compliance Program Guidance for Clinical Laboratories* (August 24, 1998), <https://oig.hhs.gov/authorities/docs/cpglab.pdf>.

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