

Compliance Today - January 2021 The ABCs of an effective investigative process: Part 1

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Investigations are essential to running an effective compliance program. A well-defined investigation sets forth how individuals report potential compliance concerns and mentions any remedial measures once the investigation has concluded. These practices also create a culture of compliance within an organization by assuring employees and surrounding community members. The organization's commitment to corporate integrity and creating a thorough investigative process can be challenging and exhaust a number of limited resources. In order to create a strong investigative process, an organization should look internally to determine what processes they have in place and whether any new processes should be implemented.

The strength of an effective investigation is determined by breaking the process into two parts: (1) receiving/triaging a concern and conducting the investigation and (2) benchmarking and reporting.

In this two-part article, we will illustrate how to implement a well-defined investigative process. Our mission is to provide compliance departments looking to adopt their own processes with a road map of how to build a strong and reliable investigation system.

Receiving and triaging a concern

A compliance department may initiate an investigation once a concern has been raised. Anyone from within or outside an organization may raise a concern as long as it is presented in good faith. An effective investigative process involves well-defined policies and procedures to address these concerns.

Investigation policy and procedure

It is important for an organization to have a well-publicized and accessible reporting policy regarding potential good-faith compliance concerns. A well-defined policy should include the following:

- Types of issues to report,
- Where/how to report an issue,
- Good faith/nonretaliation, and
- Investigation process.

Investigation policies should outline rules and regulations (e.g., Health Insurance Portability and Accountability Act, Anti-Kickback Statute, Stark Law) related to potential concerns and provide examples of critical issues.

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After identifying the types of issues that should be raised, a comprehensive policy should outline how the issues should be reported. Typically, compliance concerns can be reported through a compliance hotline, directly to compliance (in person or by email or phone call), or through the chain of command (in person or by email or phone call).

It is also important to outline any additional ways the compliance program receives and manages these concerns. This involves publicizing all applicable avenues through which the program is able to receive a concern.

All investigation policies should include how issues are brought in good faith and the organization's commitment to nonretaliatory behavior—neither the government nor an organization will discipline or retaliate against any individual who raises an issue in good faith. Issues not brought in good faith leave the reporter open to disciplinary actions, which could include suspension and/or termination.

Those who report issues in good faith are protected against potential retaliatory action. It is imperative the investigation policy clearly outlines the reporter's right to nonretaliation and the importance of reporting any retaliatory behavior.

Aside from outlining the steps on reporting and a reporter's protections, a well-defined investigation policy will also include the investigative process, as well as any remedial measures taken if the concern is found to be valid. An investigation policy should outline how compliance will conduct the investigation and any follow-up measures once an investigation has been completed. This would likely allow a reporter to feel comfortable with raising a potential compliance issue. The policy should outline how concerns will be handled by the compliance department and the expected amount of time an investigation may take to complete. Additionally, it should direct the reporter on how to provide any additional information they may want to provide during the investigation, or establish guidelines regarding how compliance personnel may connect anonymously with a reporter for additional information.

The investigation policy should also set out the possible remedial measures the compliance department may take after an investigation has been completed, including closure, disciplinary actions, and any applicable reporter follow-up. The investigation policy should also outline an organization's stance on what information will be conveyed back to a reporter once an investigation has been completed and refer to the organization's confidentiality policy.

Finally, it is important that the compliance department handling the investigation educate its members. This education can be offered annually or ad hoc, depending on the organization's calendar. Training should emphasize the importance of reporting all identified compliance concerns, how to report, nonretaliation, the general policy, and any remedial measures that may occur.

Having a clear and organized investigative process is paramount to running an effective compliance program. It is also important to have a process in place to educate members about the types of eligible issues to raise and how to bring them forward.

Conducting the investigation

Once an investigation process has been established, the compliance department must follow up and appropriately investigate all concerns that have been introduced. To ensure effectiveness, the following steps should be taken:

1. Document all necessary/required information and attach any applicable documents within a central repository (e.g., an occurrence reporting system or Microsoft Excel).

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- 2. Alert all individual stakeholders related to the concern, including human resources, leadership (if necessary), and any other individuals with interest in the investigation.
- 3. Prepare and conduct the investigation.
- 4. Review all collective information and determine the next plan of action.

Documenting necessary information

To accurately track and complete an investigation, it is important to document all of the information under an occurrence reporting system or the organization's investigation tool. We have discussed the process of receiving a concern and documenting necessary information gathered during the intake process. Collecting all of the information received during the investigation and attaching the documents used is of equal importance. The objective is to have a central location for all information related to an investigation in the event there is need for an additional review or if a new concern is raised related to the reported issue. Also, it is best practice to document and attach all documents to prepare for a potential external review.

Alerting stakeholders

It is imperative to alert all individual stakeholders of any concerns. Stakeholders include the individual accused of the concern, human resources, applicable manager/director, and senior leadership, if applicable. Confidentiality must be communicated when all stakeholders are contacted to protect the integrity of the ongoing investigation.

In anticipation of a stakeholder meeting, it is important that compliance is prepared to ensure all issues are interpreted the same and that the most effective questions are presented. Moreover, not understanding the reported concern will often lead to an inadequate interview and prevent pertinent information from being shared. The objective of a structured outline is to generate questions to effectively communicate with the stakeholder.

Preparing and conducting the investigation

Normally, an investigation will include interviews with all interested parties or ones with knowledge of the concern. Additionally, compliance will review all applicable policies and procedures related to the concern. Below is an effective road map to conducting an interview:

- 1. Prepare prior to the interview,
- 2. Go over the concern reported and confidentiality policy,
- 3. Take thorough notes, and
- 4. Recap discussion and provide contact information for any follow-up.

Prior to a conversation with an interviewee, the investigator should outline the goals of the interview and prepare the interview questions. Increased preparation will help capture all related points to the concern and prevent any follow-up due to missed questions in an initial interview. Also, an investigator should review the organization's confidentiality policy. A lack of confidentiality during an investigation can lead to rumors within a department or cause stakeholders to collaborate on information that would likely compromise the integrity of the investigation. Also, providing a synopsis of the concern will help the interviewee understand the purpose of the interview and what information the interviewee shall provide.

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Next, it is important to record accurate and complete notes. During this process, the investigator must remain attentive of the interviewee and ensure the notetaking does not interfere with the flow of the conversation.

Finally, it is important to summarize your discussion at the end. Ensuring that all major points were addressed will keep the process on pace without the need for a second interview. Also, a recap may invite additional information from the interviewee and confirm all issues have been discussed. It is wise to exchange contact information at the end of the session.

Reviewing information and determining next steps

Once the investigation has been conducted, stakeholders have been interviewed, and documents have been reviewed, it must be determined whether there has been an actual violation and whether any additional steps need to be taken. If at the end of all of the interviews there is still no clarity surrounding the concern, it is wise to refer back to the outline to find what information is lacking and to collect it. Though at times an investigation may require more information at its completion, it is important to document what information was lacking to avoid future omissions.

If all pertinent information has been provided and is enough, ensure that all remedial measures follow your organization's policies and procedures. Best practice is to consult with human resources to ensure appropriate disciplinary steps are taken while documenting all those steps. For all concerns not resulting in disciplinary actions, the reporter must be contacted and informed of the status of the investigation and outcome, which may be in the form of a letter, email, or phone call. While compliance must be prepared to answer any questions, it is also important to communicate to all stakeholders the outcome of the investigation, including the individual accused and any leadership or manager/director.

As a final step, the case should be closed down after a summary of the outcome is composed for tracking purposes. It is important to document this information to effectively communicate within the organization and to detect consistency among any future concerns.

When a concern is raised, an organization must follow its unique investigation process. Abiding by your company's policies and procedures will aid in organizing the investigation while offering a guide on how to investigate accurately.

Part 2 of this article will be published in the February 2021 issue of Compliance Today.

Takeaways

- Compliance programs should have an updated investigation policy that outlines the program's process for conducting an investigation.
- Investigations should be carefully planned and well thought out prior to interviewing potential stakeholders.
- Investigators should document conversations and any applicable documentation related to potential concerns.
- Remediation and follow-up should be consistent with organizational policies to avoid potential issues.
- Outcomes, as well as identified educational opportunities within the organization, should be reported to stakeholders.

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