

## Basics of Auditing for Regulators

### Introduction

Three regulators were faced with an ever-expanding workload of inspections and very scarce resources available to conduct those inspections. They concluded that they could not perform enough inspections to protect the public unless they got other regulators to help them. But they needed to make sure that those other regulators would perform inspections that were equivalent to the ones that they themselves would have performed.

Performance audits function as an important part of FDA's quality control system.

They agreed that their problem was not too much different from that of a coach trying to select the best players for a basketball team. So, each of the regulators set off in a different direction to seek advice from basketball coaches.

The first regulator met a coach who told him that the best way to determine how well someone could play was to look at their record. The coach said that he spent hours pouring over the prospective player's qualifications and statistics. For example, the coach said he looked at the player's physical characteristics (e.g., height, weight, sprint speed, etc.) and game stats (e.g., minutes played, points scored, penalties, shooting percentage, assists, etc.). Then, he selected the players whose qualifications and statistics indicated they could perform well.

The second regulator encountered a coach with a different approach. This coach said that she believed that the best way to tell if a player was good was to put that player through a variety of performance tests. So, the coach would set up a series of simulations to see how high the player could jump, how fast the player could run, and how well the player could dribble the ball and make lay-ups, jump shots, 3-point shots, and free throws. Then, she selected the players whose performance in these simulations indicated they could play well.

The third regulator came upon a coach with yet another idea about how to identify the best players. This coach's method was to observe the player's performance during an actual game. The coach would take notes on what the player did in various game situations and compare that performance to established criteria for how the game was supposed to be played. The coach would then select the players who could perform best under actual game conditions.

The performance audit is not unlike the method the third coach chose to ensure the best players were selected for the basketball team.

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One of the best ways of examining and understanding what is actually going on is by direct observation. Performance audits involve comparison of direct observations to established criteria and provide concrete evidence on how well a given activity is being performed. Performance audits function as an important part of FDA's quality control system.

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## Overview

### Objectives

1. Recognize why performance oversight of the regulatory process/function is important.
2. Recognize the differences between assessing individuals and programs.
3. Identify the skills required of performance auditors.

### Why performance audits?

Although there are several other ways to assess the quality of inspections performed by an FDA investigator or state, local or tribal regulators, they tend to be less reliable and/or more costly than performance audits. For example, we could conduct an independent re-inspection. However, we would not necessarily know whether any objectionable conditions we found existed when the previous inspection was made.

Another approach might be to review past inspections conducted by the individual. However, it would be hard to tell from such a retrospective review of paperwork how well the work was actually done or whether the results represented the work of the individual inspector or others who may have been involved.

Another option would be to conduct a simulation exercise. But, it is difficult and costly to set up a realistic simulation, and it may not be indicative of what the candidate would actually do if the candidate were actually dealing with a “real” situation.

The option that appears to provide the best measure of capability is the direct observation of a real-life inspection while it is actually being performed.

### FDA's performance audit programs

FDA's Performance Audit Programs (including in-house certification programs, state contract inspection programs, and third-party inspection programs) contribute to maintaining the quality of regulatory inspections in a variety of programs:

- **Level 1 certification audits.** FDA assesses the capabilities of first-year investigators and analysts through the use of a performance audit. The intent of this program is to ensure that those completing the basic investigator/analyst curriculum are competent to perform as FDA investigators or analysts.
- **Level II certification audits.** In the mid-1990s, FDA began certifying experienced investigators in several commodity areas, including medical devices, seafood, blood banks and plasma centers, and drugs. This voluntary certification program was aimed at enhancing the professionalism of FDA investigators and increasing industry and public confidence in the effectiveness and consistency of FDA inspectional activities. The Level II certification program also provided a focused training plan for the ongoing professional development of agency investigators. Although Level II certification audits are no longer conducted, most of the commodity-specific program areas have evolved (due to industry changes and ORA program alignment). Certification exams are now being developed and used to assess the competency of FDA investigators' knowledge and skills participating in the voluntary certification program.
- **Audits of inspections conducted by others.** The mission to protect the public health is not FDA's alone. Resources from other organizations that have shared interests in

protecting the public health contribute significantly to FDA's ability to accomplish its mission. However, FDA has an obligation to maintain adequate oversight of the inspectional activities conducted on its behalf in order to continue to meet its legal and regulatory responsibilities.

For example, FDA relies heavily on state contract inspections of food and feed establishments. Audits play a key role in ensuring that inspections conducted by others under contract are equivalent to those conducted by FDA.

- **Program audits.** FDA has a role in establishing exemplary criteria for the implementation and administration of various health safety regulatory programs. FDA also performs a role in auditing programs against those established criteria. While individual performance auditing and program auditing differ, some of the same concepts can be applied. Therefore, this course is appropriate for those auditing regulatory programs as well as those auditing the performance of individual inspectors or investigators.

### Auditing persons vs. auditing programs

There are a couple of differences between auditing a person and auditing a program. The main difference is that an individual performer comprises only one part of a program. For example, the results of a performance audit of a single state inspector conducting a contract inspection for FDA provides only a partial picture of the extent to which that state is conducting contract inspections that are equivalent to those that FDA would conduct. The direct interaction with the person and the potential impact that the results of the audit may have on that person can increase the stress and discomfort that the auditor feels. Auditing a program tends to be more impersonal than auditing an individual inspector.

In program auditing, aspects of a program other than inspector performance are often compared against established criteria (i.e., FDA's Voluntary National Retail Food Program Standards). Program elements (e.g., laws and regulations, training programs, and enforcement procedures) may be examined against agreed-upon criteria. However, certain ideas and concepts presented here can be applied equally well to the program auditing situation. Concepts for improving your assessment, understanding the obstacles to assessment, recognizing expectations, preconceptions and common assessment errors, and systematically observing and recording observations can greatly improve the quality of a program audit.

### Why train regulators in performance auditing?

In the performance audit program, the auditor is the measurement instrument. The performance auditor will be making judgments about whether an inspector is conducting the inspection in accordance with established performance standards. But judgments are subjective and can vary between auditors. The goal of performance auditor training is to reduce subjectivity and variability through a form of calibration. That is, the training aims to "calibrate" auditors as a group, so that their judgments will be as consistent as possible across all auditors and the programs they audit.

Even if an FDA investigator or State inspector is not involved in any of the performance audit programs, the kinds of skills included in this training can be very useful in other contexts (e.g., supervisory oversight of assigned staff and in program evaluations) and also during inspections.

The goal of performance auditor training is to reduce subjectivity and variability through a form of calibration.

### Performance auditor skill areas

Performance auditors need a variety of competencies to perform their role effectively. The following three areas of competencies are particularly important: technical, assessment, and communication and feedback.

#### **Technical**

In the technical area, performance auditors need to possess knowledge of:

- How to conduct inspections and investigations in their particular program area
- Objectives and procedures of the specific performance audit process
- Scope of the particular inspection or investigation
- Audit criteria

#### **Assessment**

In the assessment area, performance auditors must be able to make accurate assessments. This entails the following competencies:

- Ability to distinguish between observation and inference
- Knowledge of common sources of assessment error
- Ability to observe performance systematically
- Skill at recording observations systematically
- Discipline to defer judgment until all information is in

#### **Communication and feedback**

With regard to communication and feedback, performance auditors need to know how to:

- Set an appropriate climate for the audit
- Maintain the role of observer and avoid influencing the inspection
- Provide feedback to the inspector on the results of the audit
- Deal with the inspector's reaction to the audit results

The technical competencies (e.g., knowledge of the audit process and audit criteria in each program area) are specific to those areas and will not be addressed in this course. Rather, this course will focus on the skills of assessment, communication, and feedback roles of the auditor.

## Knowledge Check - Overview

**Reflect on these questions about the material you have just read.**

1. What is the most effective way of assessing a person's capability to conduct an effective inspection?
2. What is the primary purpose behind FDA's Performance Audit Programs?
3. What is the measurement instrument in the performance audit?
4. What competencies are important for a performance auditor to possess?
5. What is the main difference between auditing a person's performance and auditing a program?

**Directions for taking the online exam are at the end of this document.**

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## Improving Assessments

### Objectives

1. Recognize obstacles to an accurate assessment
2. Identify ways to improve an assessment

Auditors need a number of competencies in the assessment area in order to effectively conduct the audit. First of all, they must be able to overcome the uncomfortable aspects of the auditor's role. Assessing the performance of another person is not an easy task and people are often uncomfortable in that role. Some of the reasons for this discomfort are concerns about:

- Hurting the person's feelings
- Potentially damaging the person's career
- Audit criteria not being well defined
- Displaying subjectivity rather than objectivity in judging the individual's performance

While no one wants to hurt someone's feelings, it is important to recognize that this may not always be avoidable. In order to maintain standards and ensure the quality of inspections, FDA investigators and State inspectors need to be made aware of things they may be doing or not doing that have a negative impact on the effectiveness of their inspection.

It is unlikely that if an investigator or inspector does not perform well on a single audit that it would have a major impact on their career. In fact, feedback from the audit can help to improve the individual's skills.

### Apply the audit criteria

The auditor needs to learn the policy and procedures relevant to the specific performance audit program they are involved in. The auditor also needs to know the kinds of evidence that demonstrates acceptable and unacceptable inspectional techniques and performance. The same holds true for program evaluations. Each of the programs to be evaluated has established, written criteria to be used as the benchmark for performance, and the auditor must learn the measures of acceptability for the program to be evaluated.

Fortunately, there are a number of things that performance auditors can do to minimize these concerns:

- Stay in the role of auditor and avoid influencing the inspection.
- Become aware of the obstacles to accurate observation and the kinds of errors and biases that can creep into assessments.
- Make systematic observations.
- Record observations systematically.
- Defer judgment until all information is in.
- Discuss questions that may arise with other auditors or Performance Audit Program points-of-contact.

Concentrate on objective, non-evaluative observation.

### Maintain the role of auditor

An important part of your role as auditor involves minimizing your impact on the inspection. It is NOT your inspection. Maintain a low profile to avoid influencing the inspection.

### **Minimize the observer effect**

When you observe the inspection, you change the dynamics of the situation. When people are aware they are being observed, they act differently than they would if they were not being observed. The problem is not unique to this program. It has sometimes been referred to as the experimenter effect, Hawthorne effect, restaurant manners effect, and job interview effect.

Your role as an observer can affect the way the inspector or investigator conducts the inspection. Your presence can both distract and cause stress. Ultimately, anything you do or do not do can have some effect on what you are observing. There is no complete protection against this. The inspector or investigator being audited will constantly be looking for your reactions to what they have done, cues on how they are doing or what they should be doing.

What can you do to minimize your impact? To minimize the observer effect, you need to be as invisible as possible. The goal is to have the inspector or investigator perform as if you were not there. So, you need to be as unobtrusive as you can.

To do this, you should avoid asking questions or making statements or comments unless it is absolutely necessary. If an inspector or investigator asks you a question, you should attempt to deflect it. One way to do this is to have the inspector or investigator consider what they would do if you were not there. Then, remind the individual that your function during the inspection is only as an auditor.

You also need to be conscious of your body language and facial expressions. The inspector or investigator may read something into your expression that causes them to worry about what they are doing during the inspection.

As an auditor, you also need to avoid interactions with the firm. Again, it's not your inspection. It could undercut the actual inspector and it could confuse the firm. If a firm representative asks you a question, re-direct them to the inspector or the investigator either verbally or by eye contact, indicating that you are not being evasive, but you are not leading the inspection.

## Overcoming obstacles to accurate assessments

Accuracy is also an important aspect of auditing performance, and it can be affected by a number of obstacles. The primary way to overcome such obstacles is by being aware of what the typical obstacles are and the impact they can have on making accurate assessments.

### **1. Avoid confusion between observations and inferences**

The role of the performance auditor entails the making of judgments. Sound judgment requires careful distinction between two kinds of ideas we have about the world around us—those based on observations and those based on inferences.

Observations are products of personal experience. To observe something, we must see, hear, feel, smell, or taste it. Observations are experienced directly.

Inferences are conclusions that we draw about the meanings of our observations, the way they fit together, or how they are related. So, inferences are indirect conclusions intended to explain or understand our observations.

Both kinds of ideas are indispensable to our reasoning ability, but mistaking inferences for observations can be problematic to making fair and accurate assessments. For example, if we observe that a particular step in a process has not been performed, there are a variety of inferences we could draw. The performer:

- forgot to perform the step.
- does not know that the step should be performed.
- knows about the step, but does not believe it needs to be performed in this instance.
- intends to do that step later.

At the time the observation is made, the observer does not know which inference is correct.

We are usually not interested in our observations for their own sake. Rather, we are interested in our observations because they tell us something about the situation. Therefore, it is fairly natural to slip past our actual observations and draw inferences prematurely. It is quite easy to mistake inferences for observations, but awareness should help us avoid this obstacle to make an accurate assessment.

### **2. Avoid Expectations and Preconceptions**

One way to improve the accuracy of our assessment is to actively avoid forming expectations. Expectations can have a strong effect on an auditor's observations. People have a tendency to "see" what they expect to see. If an auditor expects an inspector or investigator to do well, the auditor may tend to focus on indicators of effective performance and overlook indicators of less effective performance. On the other hand, if an auditor expects an inspector or investigator to do poorly, the auditor may tend to focus on indicators of less effective performance and overlook indicators of effective performance. This phenomenon is sometimes referred to as a "self-fulfilling prophesy".

### **3. Minimize Contextual Distractions**

Our observations are not made in a vacuum. What we see is affected by the context in which we see it. To enhance the accuracy of your observations, you need to be aware of the potential impact that contextual factors may have and try to keep them from distorting the accuracy of your observations.

What we see or think we see can be affected by several contextual factors:

- Intensity--More emotionally intense behavior attracts more attention. For example, if someone is angry or yelling it will tend to attract greater attention.
- Novelty/Familiarity--The unique or unexpected in a familiar setting will stand out, as will the familiar in an incongruous setting.
- Repetition--The frequency of a behavior increases the likelihood of its being accurately observed.
- Order--Greater attention tends to be paid to early performance (first impressions) and more recent performance (last impression) than to performance in the middle the period.
- Expressive behavior--Body language, eye contact, facial expressions, tone, pitch, and other forms of expressive behavior can reinforce or divert attention from making accurate observations.

### **4. Avoid Common Sources of Assessment Errors**

Another thing we can do to improve our assessments, is to become aware of and consciously avoid the following common sources of assessment errors:

- Halo Effect: Assessing a person who is exceptionally good on one element, high on all other elements
- Horns Effect: Assessing a person who is poor on one element, low on all other elements
- Leniency: Not holding person to the appropriately strict standard
- Strictness: Holding a person to too strict a standard
- Contrast Effect: Assessing persons relative to each other rather than against standards
- Similarity Effect: Assessing persons who are similar to our self, higher than those who differ from us
- Reputation Effect: Assessing a person based on their reputation, rather than their current observed performance
- Recency Effect: Basing an assessment inordinately on more recent performance
- Primacy Effect: Basing an assessment inordinately on early performance

Some of these same effects can apply to programs or organizations as well as to individuals, since programs can have good or poor reputations, can conduct business in the same or different ways than those with which you are familiar, can do things poorly in some areas and better in others, and can have risk being compared to each other rather than to the criteria. Being aware of these common assessment errors can help you to avoid them.

The keys to avoiding these common sources of assessment errors are to:

- Assess the FDA investigator, State inspector or program on each element of the criteria independently
- Use the audit criteria to make your assessment, rather than your own internal standard or comparing the inspector or programs to others
- Base your assessment on the entire inspection or evaluation

### Improving your observations

An important task for performance auditors is to stay involved and observant. There will appear to be a lot of “dead time” for you when the inspector or investigator is engaged in mental activities. You need to remain focused on what the inspector or investigator is doing so that you will not miss anything that may be important in assessing the way in which the inspection was conducted.

### **Make systematic observations**

Observe every aspect of the inspection and continue observing in order to get representative information. The audit criteria were designed to cover the full range of activities that should be performed to conduct an effective inspection. Therefore, you need to observe on all major tasks, activities, and meetings.

Note typical as well as extraordinary actions and incidents. It tends to be easier to recall the extraordinary events, because they attract more of our attention. But you need to be alert to noticing the individual’s more-typical activities.

Throughout the inspection, try to concentrate on objective, non-evaluative observation. By focusing on specifically observed facts, you will be collecting the evidence that you will need to support your conclusions. For example, you should note the specifics of what was done and what was said, and save your evaluation of your observations against the criteria until all information is in.

### **Deal with “unobservables”**

As noted earlier, a great deal of what an inspector or investigator does during an inspection takes place inside their head, and is therefore, beyond our ability to directly observe. This raises the question regarding what an auditor can do to assess this unobservable dimension of the inspection.

One way of getting at the “unobservables” is to ask the investigator or inspector to talk you through what they are doing. For example, if the inspector or investigator is examining a set of records or a log, the inspector or investigator could tell you what they are looking for and why. This should be arranged with the inspector or investigator before entering the firm, when you get together to discuss the inspection.

### To ask or not to ask

Another way of getting at the “unobservables” is to ask questions. However, in asking questions there is some risk that you will be interfering with the inspection process. That is, your questions could prompt the inspector or investigator to do something that they would not have done in the absence of your question. Also, your question may interrupt

the inspector's or investigator's train of thought. If you have a question, you need to consider whether your question can be asked without interfering and whether it can wait until later to be asked. In most cases, the audit will be better served if you note your question and ask it later.

### **How to ask questions**

When you do ask questions, you should ask them in a neutral manner. That is, your question should not be phrased in such a way as to make the inspector or investigator think that they have done something wrong. For example, instead of asking "Why did you not look at the complaints filed last year?" you might ask "How did you decide on what records to review?" This gives the individual a chance to provide their rationale without creating the impression that the decision was flawed in some way.

In asking questions, you should use open-ended questions rather than closed-end questions. Closed-end questions are typically questions that can be answered by a simple "yes" or "no." Open-ended questions require the person to phrase an answer in a more detailed way. For example, rather than ask "Are you going to include the open delivery bay doors as an objectionable condition?" you could ask "What issues, if any, do you plan to cite as objectionable conditions?"

You should also avoid using leading questions. A leading question is one that suggests what the appropriate response is. For example, you should not ask an inspector or investigator a question like "You are not going to use the firm's thermometer to take that temperature reading are you?"

### **Record observations systematically**

Making accurate observations is only part of what an auditor needs to do. The auditor also needs to record those observations, as they are made, in order to provide the specific details that will be used to support the auditor's conclusions. Many performance audit programs provide worksheets to be used by the auditor to systematically record observations.

Note taking should be a fairly constant activity. For one thing, it will keep you involved in what is going on. Also, if you are continuously taking notes, your note taking will be less likely to attract the attention of the inspector/investigator or distract them.

Focus on actual observations and describe details. You are more likely to get agreement that a given act occurred (or did not occur when it should have), while conclusions are much more subject to disagreement. The more details you have, the easier it will be to support your assessment. For example, you will have more support for your assessment if you record that the inspector/investigator "reviewed sanitation monitoring records only and did not accompany the firm during their sanitation monitoring" than if you merely record your conclusion as "the inspector/investigator did not appropriately assess sanitation monitoring."

You should separate your evaluation from your observations, and the recording of those observations. Evaluation should be left until the inspection has been completed and all information is in. At that time, you can better compare your observations to the criteria

to develop a fair and accurate assessment. This helps avoid the situation where expectations begin to form and you inadvertently start looking to confirm those expectations.

### Defer final judgment

No two individuals will conduct an inspection in exactly the same way or perform all the steps in exactly the same order. If you notice that a step in an inspection process has not been performed, at that point in time, you cannot know for certain that it will not be done later. This is why you should take notes as you observe actions or as you observe that expected actions have not been performed, and defer your conclusions until all information is in. Resist the urge to instantly evaluate what you see. Disciplining yourself to defer your judgment until the inspection is over can help you avoid the problem of prematurely reaching a conclusion before all the information is in.

### Knowledge Check – Improving Assessments

**Reflect on these questions about the material you have just read.**

1. As a performance auditor, what should you do if you find that an inspector/investigator is not conducting the inspection in accordance with the established criteria?
2. What is something that auditors can do to minimize the discomfort of the auditor role?
3. What is the difference between an observation and inference?
4. During the inspection if you observe that the inspector/investigator has omitted a step in an inspectional process, what should you do?
5. What are 3 keys to avoiding the common sources of assessment errors?
6. What is an effective way of dealing with “unobservables”?
7. What are some effective techniques to recording observations systematically?

**Directions for taking the online exam are at the end of this document.**

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## Communication and Feedback

### Objectives

1. Identify how to give constructive feedback
2. Recognize what *not* to do during a feedback session

The third set of competencies that performance auditors need to possess involve communication and feedback. Performance auditors need to be able to:

- Set an appropriate working climate with the inspector/investigator.
- Provide constructive feedback at the end of the audit.
- Deal effectively with the individual's reaction.

### Setting the climate

Part of the responsibility of the performance auditor is to:

- Establish and maintain good rapport with the inspector or investigator
- Be diplomatic and professional in dealing with facilities, investigators, inspectors, and program managers
- Be objective and non-judgmental in your communications and interactions
- Offer your feedback as guidance and suggestions rather than criticisms after the inspection is complete

To accomplish these responsibilities, you will need to set a climate that is conducive to a good working relationship between you and the inspector or investigator. Research and experience have shown that creating a non-defensive communications climate is important to fostering good working relationships.

- Be descriptive rather than evaluative. For example, rather than say “Your technique is ineffective,” say something like “When checking the sanitary condition of labelers and equipment feeding cans to the labeler, the IOM calls for determining whether any old product is present on any equipment that touches the can end seams.”
- Treat the investigator or inspector as an equal.
- After the inspection and related paperwork has been completed, present your findings as provisional rather than absolute and certain. For example, rather than stating that “You did not document the interstate movement of the product or ingredients,” say something like “I did not notice any documentation of interstate movement of the products or ingredients.” This provides the individual with an opportunity to make the auditor aware of something the auditor may have missed. It also affords the investigator or inspector an opportunity to explain their rationale for performing or not performing some action.

Feedback from the audit can help to improve the individual's skills, which may improve or enhance their career potential.

### Providing feedback to the investigator/inspector

Another part of your role as auditor involves relating your observations to the inspector or investigator when the audit has been completed. As stated earlier, feedback from the audit can help to improve the individual's skills, which may improve or enhance their career potential. Depending on the program, this feedback may occur shortly after leaving the firm or some time later after all paperwork is completed.

If the inspection has gone well, providing feedback will not be a particularly difficult task. However, if some aspects of the inspection were not done well and there are areas where the inspector or investigator needs improvement, this can be both difficult and stressful—for you and the inspector or investigator.

Here are some guidelines for this part of your role:

- Give the feedback in a private place away from the firm. This will allow the inspector or investigator to receive the information without fear that others may overhear.
- Focus on observed behavior. Your objective is to get the inspector or investigator to “buy into” your assessment. The more you can support your assessment by citing specific observations, the more likely the inspector or investigator is to accept your assessment. For example, if you are able to describe in detail what the inspector or investigator did and did not do while collecting a sample, you will be in a much better position when it comes to convincing the inspector or investigator what they need to improve.
- Be as specific as possible. Provide both the context and details about your observations. You should also provide positive feedback as well as feedback on areas that need improvement. It is important to use a constructive tone in delivering feedback. Finally, maintain control of your emotions.

### Dealing with the inspector's reaction to the feedback

The feedback session should NOT be a one-way conversation. You need to be open to the inspector's or investigator's response. Listen carefully to what the inspector or investigator has to say. Make sure you understand their perspective. Ask for specifics.

Sometimes the inspector or investigator might respond by criticizing your audit, such as you made them nervous, you do not know how things are done in the field, and so on. When this happens, you will be tempted to defend your performance as an auditor. But you need to remain non-defensive and keep your focus on the performance of the

inspector or investigator. Tell the inspector or investigator that you are willing to discuss what you did or did not do, that may have affected the inspection or the results of the audit, but only after you have finished providing your feedback.

No matter how careful you are to follow these guidelines, you may still encounter difficult situations from time to time. If you come across a difficult feedback situation, there are certain things that you should try to do. You should be empathetic and respectful, but clear in terms of the message. You need to make sure that the inspector or investigator understands where they need to improve.

You should also allow for the expression of feelings. Communicate your awareness of the inspector's or investigator's emotional state. There is probably nothing that conveys a lack of empathy more than if someone is falling apart in front of you, and you appear not to even notice. Let the person know that you understand how difficult it is to receive unfavorable feedback. However, you need to remain objective and focus on your observations.

When faced with a difficult feedback situation, there are also some things you should NOT do:

- Do not become defensive or counterattack if the inspector or investigator questions your expertise or the way you performed the audit.
- Do not be pressured into saying something appeasing in an attempt to avoid the difficult situation. Throwing out a “positive” comment may cause the individual to be confused regarding whether they performed well or need improvement.
- Do not accuse the person of being overly emotional. How people deal with disappointment and criticism is part of their personality. If you criticize the person's emotional control, you will have moved from criticizing their performance in a particular inspection to criticizing them as a person.
- Do not back away from your observations unless you are convinced that you were not aware of some information that should have been taken into account.

### Knowledge Check – Communication and Feedback

**Reflect on these questions about the material you have just read.**

1. What are the responsibilities of a performance auditor?
2. What are some attributes of an effective working climate as it relates to the auditor and the inspector or investigator?
3. How should the auditor give feedback to the inspector or investigator?
4. What should you do as an auditor if you encounter a difficult feedback situation where the inspector or investigator gets very emotional?
5. How may the performance of the auditor affect the inspector's performance?
6. Are there any circumstances under which an auditor should change an original assessment? Explain.

**Directions for taking the online exam are below.**

If you are required to complete this course and must have an official record of completion, you must log on to ORAU's [ComplianceWire](#), complete the exam and electronically sign that you completed the course.

After logging in, select **Knowledge Finder > Multiple program**

Search for **Basics of Auditing for Regulators – Exam**

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