

Self-Assessing Your Quality Assurance Program

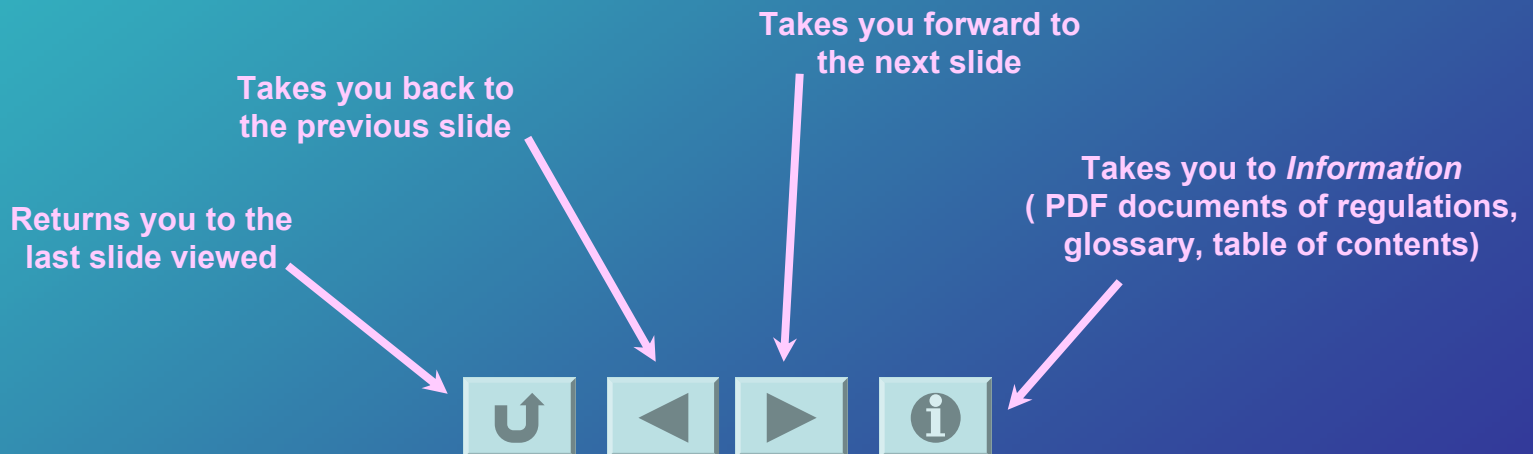


Course Navigation

You will navigate through the course using the buttons at the bottom of the screen. You may also right-click your mouse to open a menu of navigation options.

The “i” button will take you the “Information” page, which has links to PDF files included with this course. Clicking on a link will open the file in Adobe Acrobat[®]. To return to the course, close or minimize Acrobat when you are finished reading or printing.

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General Information



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Independent Evaluation

If for some reason you would prefer to fulfill your annual assessment requirement by utilizing an independent evaluator, we are available to assist you for an additional fee. Please recognize that when we are serving as an independent evaluator, we pull no punches and will provide an honest, complete assessment, and the final assessment report will include all findings and observations, whether they are good or bad.



Introduction



Quality is a Journey

Quality is not something that you just write down in your Quality Management Plan (QMP) and then forget about. The initial development of your program and the implementation of it is just the beginning. Quality is a journey!

One of the primary benefits of a good quality assurance program is that it provides for continuous improvement. The basic reason for self-assessment is to allow you to evaluate your program and look for ways to improve work processes. An added benefit is that better quality usually results in less rework, fewer problems, and creates efficiencies that improve your profitability. Making sure that your quality activities and quality control are performing well greatly adds to your credibility and reduces liability should you be involved in litigation over your work.

The correct response to the identification of a problem or deficiency is to investigate the problem, determine the cause, then identify and implement a corrective action which will solve that problem and prevent similar ones from recurring. Over the course of time, this one facet of quality assurance alone will improve your operations substantially. Your quality assurance program should specifically address the concept of continuous improvement.



Chapter 1

Program Self-Assessment Requirements



A self-assessment (audit) is a formal, structured, and comprehensive review. They are the responsibility of the licensee and are in addition to any audits conducted by the Department.

Self-assessments may be conducted by:

- The licensee
- An employee
- An outside auditor



A self-assessment should include:

- A written report of findings and results
- A written assessment of whether or not the quality assurance program is achieving its goals
- Suggestions for improving the program due to changes in technology, quality concepts, regulations, or environmental conditions



It is possible to condense most quality system assessments into four simple questions:

1. Are you doing “it”? (All the things that you agreed to do in your quality assurance program documentation, specifically your Quality Management Plan.)
2. Is it documented? (Did you document how things are supposed to be done, using procedures and other instructions?)
3. Are you doing it the way you said you would? (Are you following your own procedures and instructions?)
4. Is it working and effective? (Does your quality system meet the objectives you established?)



Self-Assessment

One fact that most people don't realize is this: when an auditor evaluates a quality assurance program, most problems occur because people do not meet the commitments which they established when they set up their program. For example, say that there is a requirement that instruments be calibrated on an annual basis, but you put in your QMP that you will calibrate monthly. If a Department auditor comes in and your records indicate that you have been calibrating every other month, you will probably receive a finding. You met and exceeded the Department requirement, but you failed to meet your own QMP commitment.



This is why it is extremely important to periodically review your program to ensure that you are both doing everything required by the Department as well as everything you promised in your QMP. A self-assessment also helps you to identify changes which need to be made to your QMP. During the course of a year, you may change vendors for detection equipment, hire additional employees, or start offering additional services. Each of these changes should initiate a revision to your program.

Another little-known fact about auditors is that if you identify a problem yourself, and establish a plan of action to correct it, most of the time the auditor will not be concerned about it, and may not even mention it in his or her audit report, except to positively note your responsiveness. However, if the auditor discovers that you were aware of a problem and haven't addressed it, you may get a finding for both the original problem and another one for your failure to fix it.



The Department has been reasonably satisfied with the licensee application process, and their audits indicate that licensees are doing a fairly good job of complying with the regulations. The intent of the focus on self-assessment is to encourage licensees to take their Quality Assurance Programs to “the next level.” This includes making improvements to the program, ensuring that changes in operations/equipment, are properly reflected in the QMP, and ensuring that the QMP is a working document which is kept up to date.



Chapter 2

Objective Evidence



One of the most important concepts to remember about quality assurance is “objective evidence.” “Objective evidence” is usually defined as something which can be substantiated by information which is factual and can be verified. In other words, if there is no evidence, then it didn’t happen!

An auditor typically has three ways of obtaining objective evidence:

- 1) Examining documents or records that are maintained, such as calibration records, quality control charts, and measurement reports.
- 2) Observing how a particular activity is performed and comparing it to how the procedure or the QMP states that it should be done.
- 3) Asking questions. When you are asked to describe how you perform an activity, the auditor can use your responses of how it is supposed to be done and how well you understand the requirements.

For self assessments, Item (1) is the one we should concentrate on. You need to evaluate your program and the quality of your documentation. It is important that you are able to locate all of the records of the objective evidence that are referenced in your Quality Management Plan and procedures and any others which demonstrate your performance.



Examples of objective evidence might include:

- Quality control charts for accuracy, precision, etc.
- Copies of radon measurement reports
- Procedures
- Calibration logs showing the time/date/results
- Training certificates



(continued) Examples of objective evidence might include:

- Licenses
- Receipts/bills/correspondence for spiking services, etc.
- Photographs of mitigation systems showing required features, labels, etc.
- Drawings, sketches, etc.
- Field Log Book entries
- Copies of signed tampering agreements
- Copies of building, electrical permits, etc.



Since the Department is usually unable to witness the performance of your work and seldom even gets a chance to see a completed mitigation installation, they must rely on the objective evidence you maintain in order to evaluate your compliance and performance. The more objective evidence you have, the better off you are.

Another important reason for good recordkeeping is that it decreases your reliance on your memory. If a question comes up concerning a mitigation system that you installed three years ago, it would certainly be reassuring if you could quickly locate the file for that job and point to documentation to answer the questions, rather than having to depend on your memory. Adequate records include all of those which are specified by Department rules. You should have enough records to provide clear proof that you have met all requirements. Records should be organized so that you can readily locate them upon request. However, it is not a requirement that your files be so organized that an auditor could find everything by themselves.

It is important that you maintain objective evidence to prove that you are in compliance with requirements. Like all records, they must be controlled, protected, and retrievable with minimum effort.



Chapter 2 Activity

Review your QMP and SOPs and find at least 20 examples of objective evidence. List each of these and note which document they were located in.

