5 Sure-Fire Methods

Complying with QSA.01.03.01 for Laboratories

In addition to compromising patient safety, failure to comply with proficiency testing standards can lead to serious sanctions. Quality System Assessment for Nonwaived Testing (QSA) Standard **QSA.01.03.01** requires that laboratories have a process for handling and testing proficiency testing samples (*see* "Related Requirements" on page 3 for the entire standard). This was one of the most problematic standards for laboratories in 2012. Recent Joint Commission statistics show that 21% of laboratories were not in compliance with this standard in 2012.

According to John Gibson, MA, MT(ASCP), DLM, associate director, Standards Interpretations Group, The Joint Commission, one of the reasons laboratories are being cited for noncompliance is that organizations with multiple Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificates are not conducting proficiency testing within the confines of the separate labs. "If a single organization has multiple CLIA certificates, management may not draw the distinction that these are separate labs," he says. "Each lab must conduct its testing independently."

Another reason organizations are being cited for noncompliance with Standard QSA.01.03.01 is that they do not treat proficiency testing samples the same way they treat patient samples. "Labs sometimes think of the proficiency testing sample as a test, so they may run it twice to make sure they get the same result," says Jennifer Rhamy, MBA, MA, MT(ASCP)SBB, HP, executive director, Laboratory Accreditation, The Joint Commission. "They would never do that with a patient sample unless that particular sample met certain criteria that would require them to run it more than once." Gibson adds, "Proficiency testing is not a separate technical exercise. It has to be part of the regular workload and evenly distributed among staff. It is not acceptable to do extra quality control or calibrate instruments out of

The Source, August 2013, Volume 11, Issue 8

cycle for proficiency testing samples."

A third reason laboratories are being cited for noncompliance is a failure to sign attestations documenting that proficiency testing samples were tested in the same manner as patient specimens, as required in EP 7. "The people who are doing the testing must sign the attestation, then it has to be cosigned by the lab director or technical supervisor," Gibson says.

Gibson and Rhamy offer the following five strategies to help organizations to better comply with Standard QSA.01.03.01:

1 **Develop a written policy and procedure for testing of proficiency testing samples.** "The standard's EPs should be used as a foundation for the policy," says Gibson. "If an organization does not have a policy that includes all of the requirements, it is unlikely that they'll be able to follow through."

2 **Educate staff.** "A really good policy isn't going to be much use unless it's extremely well communicated," Gibson says. "Organizations need to develop good education programs so that staff know the rules." Each new staff member is required to have a thorough orientation to his or her responsibilities, according to Gibson. The organization should have a policy outlining all of the requirements for proficiency testing, and education on the requirements should be included in the orientation. "Consider requiring that each employee who is assigned to perform proficiency tests should be required to review that policy again before performing the tests to refresh his or her understanding of the requirements," Gibson added.

3 **Treat proficiency testing samples as you would patient samples.** "Proficiency testing samples should be treated exactly like patient samples up until you've done all you can within the confines of your lab," says Rhamy. "When you reach the limits of your lab, you have to stop." Gibson adds, "If you get to a point where you would normally refer a sample, document that's what you would do next. Don't actually refer."

4 **Develop a method for ensuring that attestations are signed.** "If your lab director is not on site, he or she may need to schedule time to come in and sign the attestations within the appropriate time frame unless a designee acceptable to your proficiency testing provider has been assigned through policy," Rhamy says. "Some proficiency testing companies will also allow online signatures, so you may want to set up a system to notify the lab director when an attestation needs a signature."

5 **Assign someone to thoroughly review documentation before it is submitted.** "The most frequent cause of unsatisfactory proficiency testing results involves clerical error," says Gibson. "It's important to have someone take a second look at the transcription and other documentation to make sure everything is complete before the technical supervisor signs off." Clerical entries can be reviewed by anyone assigned by laboratory management. The individual should be qualified to perform the testing being reported to ensure that he or she understands the testing process and is able to recognize an obvious clerical error. TS

Related Requirements

Standard QSA.01.03.01

The laboratory has a process for handling and testing proficiency testing samples.

Elements of Performance for QSA.01.03.01

1. The laboratory has written policies and procedures for testing proficiency testing samples.
2. The laboratory tests proficiency testing samples according to its policies and procedures.
3. The laboratory performs proficiency testing for each test method used as the primary method under each Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate for each regulated analyte.

   Note: *Proficiency testing for secondary analyzers is not required. (*See also *QSA.02.08.01, EP 1, for correlation study requirements between primary and secondary methods)*
4. Proficiency testing samples are tested along with the laboratory's regular patient testing workload by staff who perform the laboratory's testing.
5. The laboratory rotates proficiency testing samples among the staff who perform patient testing.
6. The laboratory's staff tests the proficiency testing samples the same number of times that they test patient samples.
7. The laboratory staff who performed the proficiency testing and the laboratory director or technical supervisor sign attestations documenting that proficiency testing samples were tested in the same manner as patient specimens.