5 Sure-Fire Methods

Complying with Standard QSA.02.11.01 for Laboratories

Inaccurate lab results can lead to misdiagnosis and unnecessary treatments. Joint Commission Quality System Assessment for Nonwaived Testing (QSA) Standard **QSA.02.01.11** requires that laboratories conduct surveillance of patient results and related records as part of their quality control programs (*see* "Related Requirements" on page 3 for the entire standard). During the first half of 2015, 19% of surveyed laboratories have been found to be noncompliant with this standard.

The well-being of many patients depends on the quality and accuracy of laboratory testing. Surveillance of patient results and related records is an essential component of quality control.

According to John Gibson, MA, MT(ASCP), DLM, associate director, Standards Interpretation Group, The Joint Commission, one of the major issues leading to noncompliance is failing to ensure that the lab reports go all the way through the system to the electronic medical record (EMR). "Electronic transfer to the EMR is very important," Gibson says. "Many laboratories don't do a complete review to make sure the reports make it all the way into the patient record. Instead, they stop at the lab."

Stacy Olea, MBA, MT(ASCP), FACHE, executive director for laboratory accreditation, The Joint Commission, says laboratories are also struggling with compliance with Element of Performance (EP) 5. "Many labs are not incorporating handwritten or manual screenings into their daily screening processes," she says.

Delegation of daily screenings with no direction can also lead to noncompliance. "We often find that daily reviews are being delegated without any criteria as to what the person doing the screening should be looking for," Gibson says. "You need to do more than just transfer numbers from one interface to another. You need to be looking for things like incongruent test results and unacceptable quality control results."

Olea says that some laboratories are also struggling with the monthly time

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Related Requirements

Standard QSA.02.11.01
The laboratory conducts surveillance of patient results and related records as part of its quality control program.

Elements of Performance for QSA.02.11.01

1. The laboratory has written policies and procedures for surveillance activities that include a coordinated review of the following:
   - Patient test results
   - Work records
   - Equipment performance testing records
   - Quality control results

   (*See also* QSA.02.02.01, EP 5)
2. The policies and procedures include criteria to determine acceptability of patient results before they are released. (*See also* QSA.02.02.01, EP 5)
3. The general supervisor performs or delegates to technical staff the daily supervisory review of patient results. The supervisory review is documented.
   Note: *Technical staff performing the review use specific criteria or computer algorithms to identify outlier results for manual review. Examples of criteria include the following:*
   - *Unacceptable quality control results*
   - *Test results that do not correlate with a patient's known condition, age, sex, diagnosis, or pertinent clinical data; distribution of patient test results; and relationship with other test parameters*
   - *Incongruent test results on one patient*
   - *Abnormal test results*
   - *Critical values*

   (See also *LD.04.05.01, EP 1; QSA.02.02.01, EP 5)*
4. For high-complexity testing performed by trained high school graduates qualified under 42 CFR 493.1489(b)(5), the laboratory director, general supervisor, or technical supervisor reviews all results within 24 hours of patient testing. (*See also* QSA.02.02.01, EP 5)
5. The laboratory performs daily screening for errors in patient test results due to handwritten or manual data entry (for example, clerical errors). The daily screening is documented. (*See also* QSA.02.02.01, EP 5)
   Note: *Screening a sample of data is acceptable for compliance with this element of performance.*
6. The laboratory performs screening for errors (for example, electronic transmission errors, formatting errors) in electronic and printed patient test results at a frequency defined by the laboratory. The screening is documented. (*See also* QSA.02.02.01, EP 5)
7. The laboratory performs review of other records (for example, work records, equipment records, quality control summaries) at a frequency defined by the laboratory, but at least monthly. The review is documented. (*See also* QSA.02.02.01, EP 5)

frame for performing review of other records, as outlined in EP 7 of the standard.

Gibson and Olea provide the following five strategies to help laboratories to better comply with Standard QSA.02.11.01:

1 **Develop a written policy for surveillance activities or review your current policy for gaps.** "A good policy should include time frames, the name of the person who should be conducting the daily reviews, criteria to identify outliers, a list of what needs to be reviewed, and what should be done if erroneous results are found," says Gibson.

"Labs should be auditing areas that are known to be problematic," Olea adds. "Also, ad hoc comments that are entered into the laboratory information system should be transferred to the patient chart."

2 **Make sure surveillance is being conducted.** "Reviews need to be conducted at the supervisory level," Gibson says. "Someone needs to be assigned to make sure they are happening, and there needs to be accountability. One way to do that is to include the results in the performance improvement report that goes to leaders."

3 **Have someone other than the individual who performs the test review the results.** "Many organizations have the second shift review the results for first shift, the third shift review the results for second shift, and the first shift review the results for third shift," says Gibson. "That way, there's no operator bias involved."

4 **Include tests that are conducted outside the lab.** "Make sure the lab is aware of all tests that are being done outside the lab and that they are incorporated into the supervisory review for those tests," Olea says.

5 **Assign the monthly review to a qualified individual.** "Have the monthly review assigned to somebody specific," says Olea. "That way, everyone knows whose responsibility it is. Put it on the calendar and the work schedule as a reminder that it has to be completed within the set time frame." TS

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