Competency assessment continues to top challenging standards list for laboratories

Human Resources (HR) standard HR.01.06.01: *Staff are competent to perform their responsibilities*, leads the list of 10 requirements identified most frequently as “not compliant” during laboratory surveys from Jan. 1, 2017, through Dec. 31, 2017.

Joint Commission surveyors assess these six elements of HR.01.06.01 for competency:

- Direct observations of routine patient test performance.
- Monitoring, recording and reporting of test results.
- Review of intermediate test results or worksheets, quality control, proficiency testing, and preventive maintenance performance.
- Direct observation of performance of instrument maintenance function checks and calibration.
- Test performance as defined by laboratory policy.
- Problem-solving skills.

Also, remember the following:

- For new hires, competency must be assessed after orientation/training (HR.01.04.01 EP 10), after six months (HR.01.06.01 EP 19) and after one year (HR.01.06.01 EP 20).
- Staff competency is determined by test complexity.
  - Nonwaived tests are classified into complexity – either high complexity or moderate complexity — as designated by the U.S. Food and Drug Administration.
  - For high complexity testing, a technical supervisor or general supervisor can assess competency, and the general supervisor responsibility must be delegated in writing from the technical supervisor.
  - For moderate complexity testing, a technical consultant must assess competency, and responsibility cannot be delegated.
  - Information about the education and experience requirements for technical supervisors, technical consultants or general supervisors can be found in the Clinical Laboratory Improvement Amendments (CLIA) of 1988 regulations.
- Provider-provided microscopy procedures are nonwaived and require all six elements.
- Problem-solving skills are the most commonly missed elements.

Proficiency testing is another area identified as most challenging for laboratories. Three of the Top 10 were requirements in the Quality System Assessment for Nonwaived Testing (QSA) chapter:

- QSA.01.03.01: *The laboratory has a process for handling and testing proficiency testing samples.*
- QSA.01.01.01: *The laboratory participates in Centers for Medicare & Medicaid Services (CMS)-approved proficiency testing programs for all regulated analytes.*
- QSA.01.02.01: *The laboratory maintains records of its participation in a proficiency testing program.*

Some tips for ensuring compliance with these requirements include ensuring that:

- Proficiency testing is performed for each regulated analyte.
- One instrument is designated as primary and used to analyze proficiency testing samples.
• Unsatisfactory and failed proficiency testing results are reviewed and explained.
• Proficiency testing samples are run the same as patient samples.
• Proficiency testing samples are never sent out to another laboratory.
• Proficiency testing results are never shared or discussed until after the submission date.
• Staff performing proficiency testing are rotated.

The Joint Commission collects data on organizations’ compliance with standards; National Patient Safety Goals (NPSGs); the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™; and Accreditation and Certification Participation Requirements, to identify trends and focus education on challenging requirements. View the full list below. For more information about the Top 10 challenging requirements, see the April issue of Perspectives or the Standards Frequently Asked Questions. (Contact: Standards Interpretation Group, 630-792-5900 or online question form)

<table>
<thead>
<tr>
<th>Noncompliance percentage</th>
<th>Standard Label</th>
<th>Standard Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 %</td>
<td>HR.01.06.01</td>
<td>Staff are competent to perform their responsibilities.</td>
</tr>
<tr>
<td>39 %</td>
<td>QSA.02.10.01</td>
<td>The laboratory performs quality control testing to monitor the accuracy and precision of the analytic process.</td>
</tr>
<tr>
<td>37 %</td>
<td>DC.02.03.01</td>
<td>The laboratory report is complete and is in the patient’s clinical record.</td>
</tr>
<tr>
<td>33 %</td>
<td>QSA.02.08.01</td>
<td>The laboratory performs correlations to evaluate the results of the same test performed with different methodologies or instruments or at different locations.</td>
</tr>
<tr>
<td>32 %</td>
<td>QSA.01.03.01</td>
<td>The laboratory has a process for handling and testing proficiency testing samples.</td>
</tr>
<tr>
<td>31 %</td>
<td>EC.02.04.03</td>
<td>The laboratory inspects, tests, and maintains laboratory equipment.</td>
</tr>
<tr>
<td>28 %</td>
<td>QSA.01.01.01</td>
<td>The laboratory participates in Centers for Medicare &amp; Medicaid Services (CMS)-approved proficiency testing programs for all regulated analytes.</td>
</tr>
<tr>
<td>28 %</td>
<td>QSA.02.04.01</td>
<td>The laboratory develops and implements an individualized quality control plan (IQCP) in an eligible specialty or subspecialty.</td>
</tr>
<tr>
<td>25 %</td>
<td>LD.04.05.07</td>
<td>The laboratory director, technical consultant, and/or technical supervisor are responsible for maintaining laboratory performance.</td>
</tr>
<tr>
<td>25 %</td>
<td>QSA.01.02.01</td>
<td>The laboratory maintains records of its participation in a proficiency testing program.</td>
</tr>
</tbody>
</table>

On-site survey insight from a surveyor: Part 1
Dr. John Russell (Russ) Forney, PhD, recently sat down with Lab Focus to discuss some of the greatest challenges facing laboratory organizations and strategies for getting into compliance. Dr. Forney has surveyed laboratories for The Joint Commission for three years.

Prior to joining The Joint Commission, Dr. Forney was a Centers for Medicare & Medicaid Services-trained surveyor in South Dakota and Wyoming, covering care settings such as acute care and critical access hospitals, ambulatory surgery centers, long-term care, and clinical laboratories. Dr. Forney’s career also has spanned laboratory management, infection prevention, academic appointments, and strategic leadership. His education focus is in clinical parasitology, with post-doctoral experience in tropical medicine and regulatory affairs.

In Part 1 of the interview (Part 2 will be featured in Issue 3 of Lab Focus), Dr. Forney spoke about what he’s asked most while on survey, what he sees as the biggest issues facing organizations, and why competency requirements continue to challenge laboratories.

Lab Focus: What are you asked most about while on survey?

Dr. Forney: Common questions include:
• How can we stay current with changes to the accreditation standards?
• What resources are available to help us improve performance and quality?
• How do we get help to better understand Individualized Quality Control Plan (IQCP)
requirements and be compliant?

- Can you please involve my supervisors and technical leads during the survey? They want (and need) to learn about the survey process and their role in our overall compliance.
- Does The Joint Commission provide training or webinars to assist laboratories in understanding standards and processes that can help us succeed?

**Lab Focus: What are laboratories’ expectations of the survey?**

**Dr. Forney:** Laboratories want to better understand what is required to be compliant, and they are looking for tools to help them be successful. They also look to the surveyor and the survey process as an educational opportunity for the laboratory and the parent organization. Laboratories are enthusiastic and successful and want those characteristics to be recognized.

They uniformly state that they want their successes to be affirmed, a thorough review (survey) to identify previously unrecognized gaps and risks, and to be informed from the surveyor’s experiences in organizations.

**Lab Focus: What are the biggest challenges you see laboratories/organizations facing while on survey?**

**Dr. Forney:** There are three big challenges for laboratories and/or the organizations that house them. In general, resources are scarce for laboratories. The pool of trained technologists is decreasing through retirement and a lack of new talent entering the field. It is not uncommon to survey laboratories that have 20-30 percent of their bench-level positions vacant and a crippling rate of turnover among phlebotomists. This presents a challenge for any organization, but it is particularly difficult for rural critical access hospitals and small community hospitals that often have additional hurdles when recruiting and retaining technical staff.

Organizations also may be experiencing fiscal realities that don’t favor capital investments in new equipment, laboratory environment upgrades, robust outreach activities or expanding test menus. A growing number of laboratories are keeping instrumentation until it becomes obsolete, which often means reduced capacity and slower turnaround times. Not only is this a frustrating situation for the laboratory, the provider staff also expresses their dissatisfaction with services from aging analytic systems.

Point-of-Care (POC) testing is another challenging environment for hospital-based laboratories. A successful POC environment is based on a strong partnership between the laboratory and direct care staff. Both parties must expand their perspectives, learn a hybrid nurse-lab language, and adopt an empathy for their collective demands — all to the benefit of patient safety. When it works, it is an amazing process.

**Lab Focus: In terms of compliance, why does competency continue to be among the most challenging of requirements for laboratories?**

**Dr. Forney:** Successfully achieving accreditation standards is a complex challenge. The standards are rigorous and — in some cases — novel to the traditional concept of a clinical laboratory. Process-focused standards are inclusive and compelling, they foster a better understanding of risks, error reduction and cooperative engagement. I’ll offer two examples that illustrate how the Joint Commission laboratory standards are process-focused and trace care delivery across department boundaries.

1) Consider transfusion services: The associated standards require not just a high level of technical proficiency and analytic quality in the blood bank, but also the survey follows the transfusion event to the patient’s bedside and assesses the roles and responsibilities of the transfusionist and direct care staff. So, we now have a unit of blood accepted into inventory, a patient specimen submitted for compatibility testing, and a transfusion event — three separate threads that must be woven into a singularly successful process.

2) Similarly, a successful POC environment requires an extraordinary level of communication and cooperation between the clinical laboratory and direct care staff. POC testing is a complex and
problem-prone area in some organizations. It requires laboratorians and nurses to explore perspectives on accuracy, critical thinking and the impact of nontraditional roles for both partners in the POC process.

Check out Lab Focus Issue 3 for Part 2 of this interview with Dr. Forney. Also, for up-to-date laboratory standards information, check out issues of Joint Commission Perspectives, Joint Commission Online or Lab Focus.

**CMS reapproves Joint Commission for deeming authority of accredited laboratories**

The Joint Commission has been reapproved by the Centers for Medicare & Medicaid Services (CMS) as an accreditation organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program for all specialty and subspecialty areas.

CMS announced the reapproval and granting of deeming authority to The Joint Commission for a period of six years — from May 25, 2018, through May 28, 2024 — in a notice published in the Federal Register.

This means that any laboratory accredited by The Joint Commission will be deemed to meet the CLIA requirements for subspecialties and specialties and will generally not be subject to routine inspections by a state survey agency to determine its compliance with CLIA requirements. The notice does state, however, that accredited laboratories are subject to validation and complaint investigation surveys performed by CMS, or its agent.

**QUALITY AND SAFETY**

**Improve laboratory biosafety practices by participating in national initiatives**

The U.S. Centers for Disease Control and Prevention (CDC) considers the matter of biosafety in clinical laboratories as an urgent, unmet national need. Recent outbreaks, such as those of the Ebola and Zika viruses, heightened the need for a comprehensive review on the status of biosafety practices and training in Clinical Laboratory Improvement Amendments-certified laboratories.

Because of The Joint Commission’s leading role in advancing quality and patient safety beyond laboratory accreditation, it is taking an active role to better assess health care organizations’ preparedness in addressing biosafety needs.

Through its Laboratory Accreditation program, The Joint Commission has been a member of the Association of Public Health Laboratories (APHL) Biosafety and Biosecurity Partners Forum since 2016. The purpose of the APHL Partners Forum is to establish better partnership among public health laboratories and clinical laboratories nationwide. Forum members discuss policies, practices, gaps and improvements — with the overall goal of sharing timely information to improve biosafety and biosecurity in the nation’s public health and clinical laboratories.

While The Joint Commission continues to review its requirements to incorporate up-to-date recommendations on addressing biosafety threats, it encourages the health care community to participate with various national initiatives to improve awareness and strengthen biosafety practices.

Through APHL, a free platform for biosafety professionals/officers to communicate with each other and share resources is available via Laboratory Biosafety CoLLABorate platform. This new community is an online mailing list that engages both public health professionals and non-public health clinical laboratory representatives in biosafety and biosecurity discussions, providing resources and best practices. The goal of this platform is to connect and facilitate the sharing of ideas, biosafety tools and other resources, as well as assist with answering biosafety-related questions.

Learn more.
**Refreshed Speak Up™ has ready-to-use patient safety resources**

Speak Up™ – The Joint Commission’s award-winning patient safety program – is back with a new look following national market research that was conducted last year with patients and their family caregivers. The refreshed Speak Up™ program kicked off with **Speak Up™ About Your Care**, describing different ways patients and their advocates can be active in their own health care decisions.

Speak Up™ provides patient education materials used for public service announcements, websites, community newsletters, health fairs, closed circuit patient education television and more. Speak Up™ materials are available in simplified, easy-to-read format and are available at no cost to all health care organizations as downloadable, ready-to-use patient safety resources.

Starting with Speak Up™ About Your Care, all future Speak Up™ campaigns will feature four components:

- Animated video
- Infographics (in English and Spanish) in three sizes:
  - 8.5x11
  - 11x17
  - 24x36
- Podcast
- User’s guide on how and to whom organizations can distribute materials

While Speak Up™ is copyrighted, no reprinting permissions are required for Speak Up™ infographics, brochures or videos — the materials may be copied and distributed. Their use, however, does not indicate that an organization is accredited by The Joint Commission.

Since its launch in 2002, Speak Up™ has expanded to more than 70 countries.

**Download** Speak Up™ About Your Care, or **sign up** for email delivery of future campaigns. (Contact: Caron Wong, cwong@jointcommission.org)