Most common deficiencies – CAP Accreditation

CLINICAL LABORATORY IMPROVEMENT ADVISORY COMMITTEE

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Agenda

- Top 10 Deficiencies: Overview
- Themes:
  - Regulatory
  - Workforce
  - Technology
- Recommendations

Top 10 Deficiencies: Overview*

- GEN.55500 Competency Assessment Elements - Nonwaived Testing

- COM.04250 Comparability of Instruments and Methods - Nonwaived Testing

- COM.01200 Activity Menu

- COM.10000 Policy and Procedure Manual

- COM.01700 PT and Alternative Performance Assessment Result Evaluation

- COM.30600 Maintenance/Function Checks

- COM.04200 Instrument/Equipment Record Review

- COM.01400 PT Attestation Statement

- COM.30750 Temperature Checks

- GEN.20450 Correction of Laboratory Records

*Please see addendum "Accreditation 2022 Top 10 Deficiencies" for more information

Top 10 Deficiencies: Root Causes*

Common reasons for citations across top 10 deficiencies:

- o Missing records for activities to be performed at defined frequencies (eg, daily, weekly, monthly, twice a year, annually)
- o Not following (equipment) manufacturer's defined frequency for maintenance /verification or written procedures
- o Inadequate records of supervisory oversight (eg, competency, PT, maintenance)
- o Lack of understanding of complex requirements

Root Causes

- o Regulatory Documentation Requirements Are Complex
- o Workforce Shortages and Inexperienced Staff (Staff turnover)
- o Manual Processes (Lack of Technology Solutions)

Regulatory

Regulatory Documentation Requirements demand a significant amount of laboratory employee time.

- **Documentation and recordkeeping must be done by laboratory personnel often pulling them away from 'the bench'**

- **Regulations are complex and can be difficult to comply with all required aspects**

  o **Competency assessment is a prime example.**

Regulatory (remake)

At least Semiannually during the first year and yearly thereafter (unless methodologies change), each employee must be evaluated for competency.

(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedure and report test results promptly, accurately and proficiently. The procedure for evaluation of the competency of the staff must include, but are not limited to –

(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;

(ii) Monitoring the recording and reporting of test results;

(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and performance maintenance records;

(iv) Direct observation of performance of instrument maintenance and function checks;

(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and

(vi) Assessment of problems solving skills; and

https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493

Workforce

Limited laboratory workforce means that personnel and supervisors must focus their time on patient-facing work at the expense of record-keeping and administration

- In 2022 there were only 342,900 Clinical Laboratory Technologists and Technicians in the US (typically Bachelors, average $27.59/hour).

- In 2014 there were 335,721 (1.5% growth over 8 yea

- Currently there are about 24,000 unfilled positions

Clinical Laboratory Technologists and Technicians

Percent change in employment, projected 2022-32

Health technologists and technicians	7%
Clinical laboratory technologists and technicians	5%
Total, all occupations	3%

https://www.bls.gov/ooh/healthcare/clinical-laboratory-technologists-and-technicians.htm
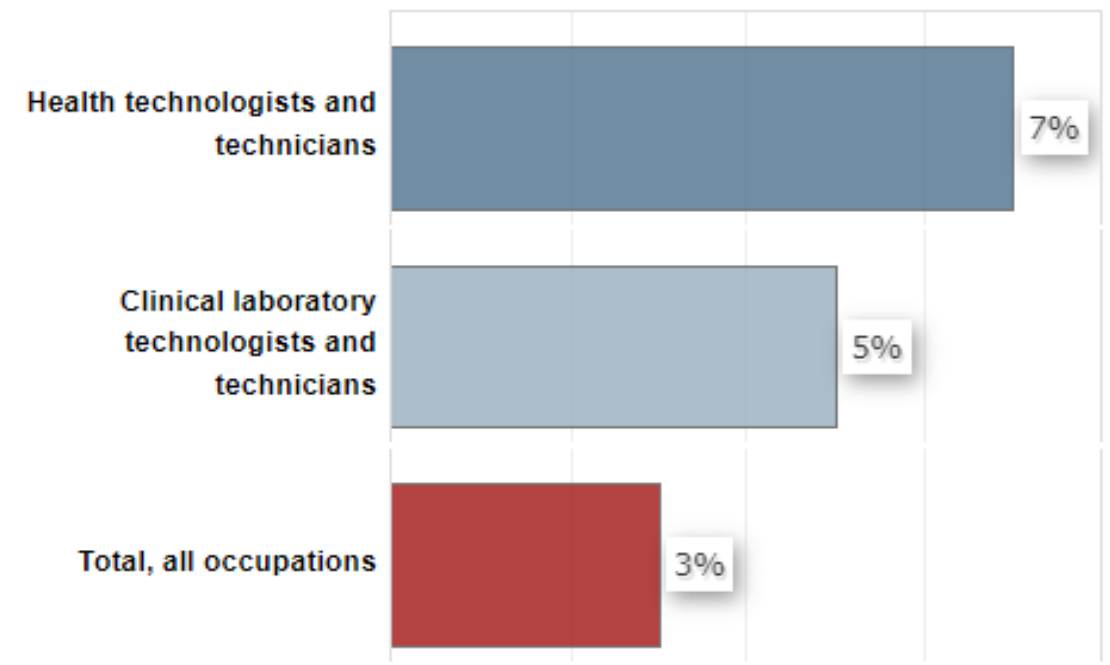
Technology

Technology, including In-Vitro Diagnostic (IVD) and Health Information Technology (HIT) can be used to save laboratory workers' time.

- Paper documentation and paper-based workflows for reporting, inventory management, sample tracking, training, competency, etc. remain a common practice in many laboratories.

- CMS requires paper-based submission in certain settings.

- Transitions from paper documentation to electronic systems carries significant up-front costs with hard to realize longer term savings.

Initiatives and Recommendations

- **Regulatory:**
  - CAP continues to make tools available to laboratories to standardize documentation for things like competency assessments, new test validations, personnel requirements. By standardizing the way labs document, we can standardize the practice itself.
  - We recommend that CLIA/CMS do the same
    - Simplify and provide clarification, examples, and FAQs for compliance with complex regulatory requirements including those listed as common deficiencies in this presentation.
    - Support the development of tools that can automate or standardize documentation and record keeping for common deficiencies including competency assessments, personnel records.
    - Evaluate the impact of how we define a laboratory on compliance with current regulations.
      - Allow competency assessment to be transferable
      - PT for the distributive testing model (NGS)

Recommendations

- **Workforce:**
  - **CAP:**
    - Serves as a resource for CAP laboratories to evaluate personnel qualifications
    - Advocates for policies and programs at federal level to make medical technologist an attractive career: e.g., loan forgiveness, creation of community college pipelines
  - **We recommend that CMS/CLIA:**
    - Continue to allow flexibility in remote work for the review of images and data.
    - Clearly define 'testing', the components of work that go into producing a test result, and qualifications required to perform these components. This may broaden the scope of those able to work in laboratory medicine, e.g.: Is loading a highly complex instrument high complexity testing?
    - Allow general supervisors to perform competency assessments of moderate- and high-complexity personnel
    - Create clear qualification algorithms for testing personnel based on their education instead of specific degrees

Recommendations

- **Technology:**
  - CAP has created templates and processes to streamline laboratory information exchange
    - Direct Transmission of Proficiency Testing (PT) results
    - Online systems for deficiency response and proficiency testing compliance follow-up
    - Electronic cancer protocols
  - We recommend that CMS/CLIA
    - Develop automated electronic reporting processes whenever compliance documentation is required to remove burden from staff.
    - Convene a tri-agency group (CMS, FDA, ONC) to identify technology-driven solutions to streamline documentation and automate reporting within regulated devices and HIT systems

Questions?

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