Experience Laboratory Accreditation That Evolves and Elevates Quality to a Different Standard

Dr. Jeremy Hart, MD, MBA, FCAP
Patricia Nortmann, MBA, MT (ASCP)

Wednesday, April 13, 2022
12:00–1:00 PM CST
Webinar Housekeeping

Today’s webinar is being recorded

A link will be provided so you can revisit the content and share it with colleagues

We invite you to interact with the speakers by submitting questions in the Ask a Question box

Tell us how we did in the survey immediately following the webinar
Experience Laboratory Accreditation That Evolves and Elevates Quality to a Different Standard

Dr. Jeremy Hart, MD, MBA, FCAP
Medical Director of Clinical Laboratories
St. Elizabeth Healthcare

Patricia Nortmann, MBA, MT (ASCP)
AVP Laboratory Services
St. Elizabeth Healthcare
St. Elizabeth Healthcare

MISSION

As a Catholic healthcare ministry, we provide comprehensive and compassionate care that improves the health of the people we serve.

VISION

St. Elizabeth will lead the communities we serve to become the healthiest in America.
About St. Elizabeth Healthcare

Six facilities throughout Northern Kentucky & Southeastern Indiana

- Covington
- Dearborn
- Edgewood
- Florence
- Ft. Thomas
- Grant

165 St. Elizabeth Physicians specialty and primary care offices located throughout

- Kentucky
- Ohio
- Indiana
Laboratories at St. Elizabeth Healthcare

- 10 CLIA certified laboratories
- “System” CAP accreditation
- Joint venture “core” laboratory
- ~$70 million annual operating budget
- 400+ FTEs and 10 pathologists
- 6.6 million+ annual billable tests
- 19 outpatient draw sites
Operating a High-Quality Laboratory Service at St. Elizabeth Healthcare

Today’s Laboratory Needs

- Maintain continuous quality improvements to strengthen quality management
- Focus on competency, learning, and development
- Adapt to an evolving environment while upholding safety for patients and staff

CAP Laboratory Accreditation Program

- Customized discipline-specific checklists combined with peer inspections
- Access to complimentary learning opportunities, tools, and resources
- Annual checklist updates incorporate input from 33 scientific resource committees
The College of American Pathologists

The Preferred Partner for Laboratory Excellence
Focused on Collaboration from Our Founding

• Largest member association of board-certified pathologists
  • ~ 18,000 global members

• Exclusive laboratory focus

• Trusted partner of CMS, FDA, CDC, ASCO, NMDP, UNOS, and many others
Leading in Laboratory Quality Solutions

• Accrediting nearly 8,000 laboratories worldwide with >500 abroad in 50+ countries

• Providing 23,000 laboratories worldwide with proficiency testing

• Offering cancer protocols for complete and accurate diagnostic reports
CAP Leadership in the Pandemic

• **Pathologists and laboratorians**
  - Delivered in-depth guidance and tools on implementing SARS-CoV-2 testing in a rapidly evolving environment

• **Laboratory**
  - Launched SARS-CoV-2 proficiency testing for viral and serology tests
  - Successfully petitioned CMS to delay inspections
  - Provided safety precautions for anatomic pathology procedures and autopsies plus recommendations for protecting the blood supply via our resource committees

• **Community**
  - Gave input to the AMA for development of new CPT codes and advocated for increased reimbursement
Accreditation That Goes Beyond Compliance

**COMPLY**
with CLIA, FDA, and OSHA standards

**EXCEED**
>40% of our standards exceed minimum requirements consequently bolstering patient care and safety

**STAY CURRENT**
with advances in laboratory medicine, technology, regulations

**PURSUE**
laboratory excellence with industry best practices
Accreditation to Elevate Quality and Mitigate Risk

CAP Laboratory Accreditation Program

- Discipline-specific Checklists
- Collaborative Peer Inspections
- Educational Resources

© College of American Pathologists.
A Blueprint for Running a High-Quality Laboratory

- Simplify compliance
- Provide best-in-class standards
- Guided by expertise from all laboratory participants
- Incorporate best practices
- Written in straightforward language
- Updated annually
- Suitable for all staff

CAP Accreditation Checklists
## Discipline-Specific Checklists

For guidance across the laboratory *and* at the bench level

<table>
<thead>
<tr>
<th>Director Assessment</th>
<th>Laboratory General</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>All Common</strong></td>
<td></td>
</tr>
<tr>
<td>Hematology &amp; Coagulation</td>
<td>Anatomic Pathology</td>
</tr>
<tr>
<td>Chemistry &amp; Toxicology</td>
<td>Cytopathology</td>
</tr>
<tr>
<td>Urinalysis</td>
<td>Cytogenetics</td>
</tr>
<tr>
<td>Microbiology</td>
<td>Forensic Drug Testing</td>
</tr>
<tr>
<td>Transfusion Medicine</td>
<td>Histocompatibility</td>
</tr>
<tr>
<td>Immunology</td>
<td>Molecular Pathology</td>
</tr>
</tbody>
</table>
Customized Checklists Based on Testing Menu

**NO SURPRISES**

Customized checklists ensure you know what will be inspected before the inspection based on your exact testing menu.
## Incorporating ISO Concepts to Strengthen Quality

### Laboratory General Checklist

**Expanding & Enhancing Quality Management Requirements**

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Description</th>
<th>Resource</th>
</tr>
</thead>
<tbody>
<tr>
<td>GEN.203010</td>
<td>Investigation of non-conforming events</td>
<td>Root Cause Analysis–Focus on Compliance webinar &amp; toolbox*</td>
</tr>
<tr>
<td>GEN.20318</td>
<td>Corrective and preventative action</td>
<td></td>
</tr>
<tr>
<td>GEN.20316</td>
<td>QM indicators of quality</td>
<td>Test utilization modules for CAP members</td>
</tr>
<tr>
<td>GEN.13806</td>
<td>Quality Management System</td>
<td>QMS–Focus on Compliance webinar*, QMS examples*, and QMEd course (QMS Implementation Roadmap*)</td>
</tr>
<tr>
<td>GEN.20326</td>
<td>Assess QMS for effectiveness</td>
<td></td>
</tr>
</tbody>
</table>

*Resources available in e-LAB Solution Suite*
Clarification and Compliance Guidance

Experienced Technical Specialist (Medical Technologist) available via phone (800-323-4040) or email (accred@cap.org)

- Clarify checklist requirements
- Provide guidance on compliance
- Educate on best practice
Peer Inspections Reduce Risk

Team inspections cover **all aspects of the laboratory** reducing risk

Teams match to **size, scope, expertise, and specialty** with laboratory services

Pathologist-led teams bring **real world experiences**

A collegial environment facilitates **peer-to-peer exchange** for mentoring opportunities

Peer inspections reduce risk by encompassing the entire laboratory

Other accreditors use a “tracer” methodology, narrowing the focus of the inspection
A Unique Perspective Through Reciprocal Inspections

• >10,000 laboratory professionals participate annually
• Gain fresh insights and share best practices
• Identify gaps in your own compliance
• Learn multiple ways to meet requirements
• ~18 months after your anniversary date
Thorough Inspection Team Training

Online Training
Coursework and tools for a successful inspection
Role specific training for Team Leader/Team Member

Earn CME/CE and SAM credit

Fast Focus on Compliance
Mini-vignettes providing supplemental training
Practical approaches for handling new and perplexing topics
Real-world scenarios

Live Inspector Training
In-person events held annually
Opportunities to engage and interact with other trainees
What Program Participants Are Saying

“Being a CAP inspector has helped me become a better medical technologist and supervisor ... I know how to apply this knowledge to improve quality and enhance patient care.”

Kristin Neel, Technical Supervisor
TriCore Reference Laboratories

“CAP inspections provide a unique opportunity to speak with peers who are facing the same challenges you are.”

Owatha Tatum, PhD, MBA, HLD/CC(ABB)
Medical Director, MicroGen Dx

“When members of our staff serve on inspection teams, it can actually help us meet our own compliance requirements.”

Sheelagh Lindberg, MHA, BSMT(ASCP)
Administrative Director, Laboratory, Banner Baywood Medical Center, Banner Heart Hospital/Laboratory Sciences of Arizona
Peer Inspection Options to Accommodate Your Needs

In-Person Inspection
- Designated inspection team visits facility on site
- Defined day and time for routine inspection
- Inspection typically completed in one day

Virtual Inspection
- Provides safety for both inspectors and the laboratory
- Uses technology to facilitate peer exchange like digital file transfer and live video stream
- Results in an accreditation decision

Advance Document Review
- Available for both in-person and virtual inspections
- Share select documents before the inspection with the inspection team

To learn more visit https://www.cap.org/laboratory-improvement/accreditation/inspector-tools-and-training
Affiliated Inspection Options

Coordinated Inspection
- Affiliated laboratories sharing the same anniversary dates
- Located within 15 miles/30 minutes of each other
- Same inspection team

Staff Inspection
- Small laboratories not offering AP or cytopathology
- Conducted by in-house laboratory scientists
- Diverse range of expertise
- Representing all laboratory disciplines

System Inspection
- All laboratories on the same inspection cycle
- Two or more full-service laboratories
- Common administration and ownership
- Located within a 3-hour drive from a central site
- Meet eligibility
A Journey Toward Standardization

An Integrated Network of Clinical Laboratories at St. Elizabeth Healthcare

- Evolve and elevate quality
- Mitigate risk
- Multiple sites of varying size
- Grow and adapt over time
Complementary Education for Continuous Compliance

**Focus on Compliance webinars**
- Topics to navigate the ever-changing rules of compliance
- Get expert knowledge on best practices
- Suitable for laboratory directors, managers, and technologists

**Fast Focus on Compliance vignettes**
- Specialized content to supplement inspector training
- Practical approaches to handle new and perplexing topics
- Real-world scenarios for a clear understanding of requirements

**e-LAB Solutions Suite online portal**
- Obtain FAQ for >75 common deficiencies
- Access customized compliance checklists
- Download templates such as Competency, Analytical Validation & Verification
- Use toolboxes like IQCP, PT/EQA, Root Cause Analysis, Self & Post Inspection

---

© College of American Pathologists.
Mitigate Risk Using Real-Time Performance Data

- **Accreditation**
  - Manage your risk and compliance
  - Prepare for accreditation inspections

- **Proficiency testing**
  - Perform data analysis to mitigate risk by patterns & trends
  - Access evaluations, result forms, and participant summary reports
  - Benchmark your laboratory against your peers and CAP-wide performance

- **Reporting**
  - Focus on relevant details with in-depth analysis
CAP Laboratory Accreditation Programs

Optional Assessment to Help You Attain Accreditation
Know Where You Stand Before You Start

CAP Accreditation Readiness-Assessment (CARA)
Gain reassurance by preparing with an on-site evaluation

- Tailored assessment for key laboratory policies and processes
- Conducted by experienced CAP inspectors
- Better understand CAP accreditation requirements
- Identify areas that meet standards or need improvement

Develop an action plan using tools from the CAP
# Specialty Accreditation Programs

<table>
<thead>
<tr>
<th>Program</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproductive Laboratory Accreditation Program</td>
<td>Designed for laboratories that perform at least one embryology-related procedure or perform semen analysis and at least one additional high-complexity test.</td>
</tr>
<tr>
<td>Forensic Drug Testing Accreditation Program</td>
<td>Designed for the unique needs of forensic drug testing laboratories and intent for laboratories that perform confirmatory testing.</td>
</tr>
<tr>
<td>Biorepository Accreditation Program</td>
<td>Designed for biorepositories that collect, process, store, and distribute biospecimens for research.</td>
</tr>
<tr>
<td>CAP 15189 Accreditation Program</td>
<td>Accreditation to the ISO standard strengthens the quality management system throughout the laboratory and all parts of the organization that interact with the laboratory, enabling process improvement, risk reduction, and improved operational efficiencies. Accreditation from the CAP’s Laboratory Accreditation program is a prerequisite.</td>
</tr>
</tbody>
</table>
Begin Your Path to Laboratory Excellence!

Let Us Help Start Your Journey Today

Email Us
accred@cap.org

Get Started
cap.org/laboratory-improvement/accreditation

Learn More
cap.org

Become CAP Accredited
CAP Laboratory Accreditation Program

Experience
*Operational Excellence*
held at the highest standard
of quality to ensure the best
patient care

- *Discipline-specific Checklists*
- *Collaborative Peer Inspections*
- *Educational Resources*
Interactive Session

We invite you to engage with our speakers by submitting a question

Questions?

Learn more about laboratory accreditation
https://www.cap.org/laboratory-improvement/accreditation