COLLEGE of AMERICAN PATHOLOGISTS

What's New in Laboratory Accreditation

A few things have changed….

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March 17, 2022

Objectives

- Learn what the constraints are for accreditation and the best tactics to get your inspection completed
- Understand the types of inspections and how they differ
- Review the significant changes to the current checklists
- Discover some CAP resources available to facilitate your journey

Accreditation Backlog – some history

- Inspections halted in March 2020 due to the COVID pandemic
- A slow ramp up of inspections began in June 2020
- What the CAP did to help get your laboratories inspected:
  - Created hybrid (document pre-review) and virtual inspection models
  - Developed and implemented online inspector training for the virtual model
  - Implemented a SharePoint site for document sharing
  - Updated Organization Profile to upload documents for review
  - Communicated updates to customers
  - Hired additional temporary support

How do you get your inspections done?

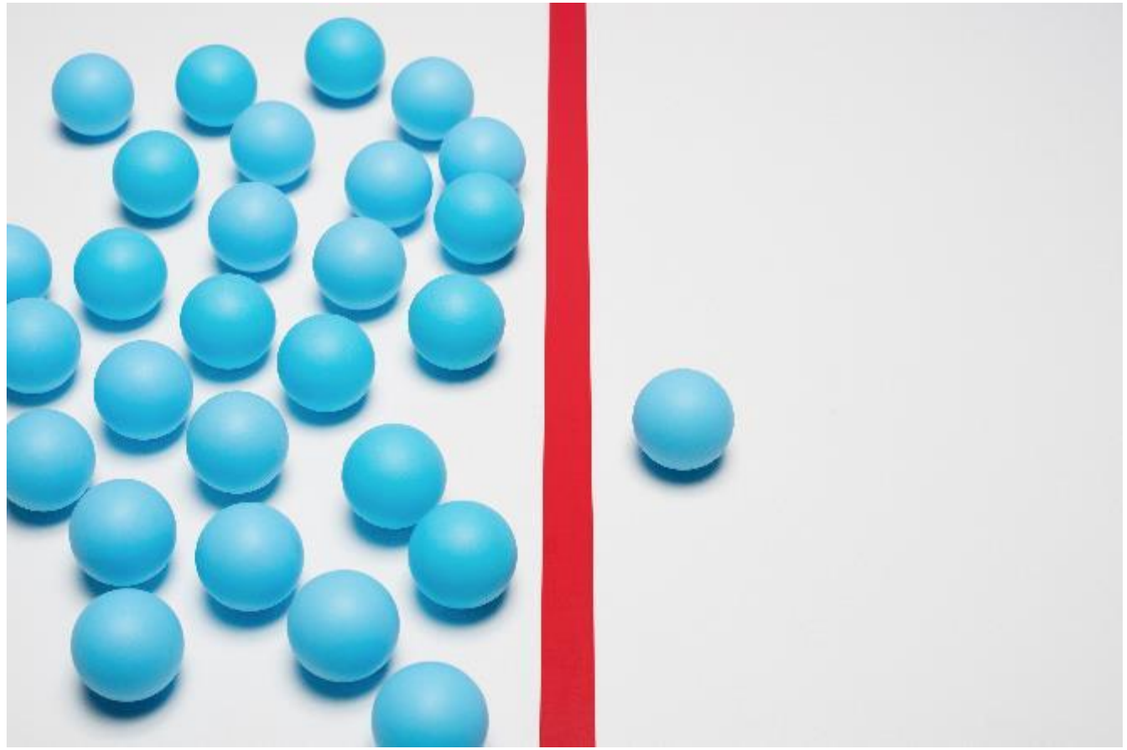
What are the constraints?

What tactics should you use?

CAP Strategy

INSPECT THE PREPARED AND THE WILLING

Constraints



- COVID – multiple surges
- COVID – additional testing volume
- Staffing – techs leaving the field
- Corporate policies
- Travel restrictions
- You name it!

Tactics to win!

- Eat the elephant one bite at a time!
- Stay educated
- Don’t overthink it
- If it applies, apply it!
- Divide and conquer
- Support each other
- **Know your capabilities**

What methods are we going to use to do your inspections?

"A crisis is a terrible thing to waste. It should give people, institutions and politicians the necessary courage to implement change."

Patrick Anderson

New inspection models for a changing world…

Inspection Models

- In-Person (Traditional)
- In-Person with advance document review
- Virtual
- Virtual with advance document reveiw

What is a Virtual Inspection?

UTILIZES LIVE STREAMING TECHNOLOGY TO “PERFORM” THE INSPECTION

SET UP AN INSPECTION SCHEDULE

ORGANIZE ELECTRONIC MEETINGS FOR DOCUMENT SHARING AND PROCESS REVIEW

IT TAKES WORK!

Required Technology

Secure audio/visual collaboration applications

- Zoom or Microsoft teams or Webex or whatever…

Webcam access with ability to transmit video from all laboratory locations

- Need software installed ahead of time on mobile phones…and make sure the phone is charged!
  - Cell phones work well but setup differs with phone/software brands so practice ahead of time
- “Good enough” wi-fi signal throughout lab needed
- Operator needs to have a steady hand and be able to follow directions

Live Video Streaming: Definitions and Warnings

- **Live video streaming:**
  - **Audio/video is broadcast live over the internet in real time.**
    - **Not totally secure**

- **Recording:**
  - **Use of desktop capture tools or software to take screenshots**
  - **The CAP does not permit recording of any part of the inspection including taking screen shots of any files displayed!**
  - **Filming of patients is not permitted (consent issues)**
  - **No transmitting of protected health information**

Virtually Stepping Outside the Laboratory

Point-of-care, respiratory, and blood administration must be managed very carefully in a virtual environment.

Patient protection is paramount.

The internet never forgets.

- Patients must not be streamed, and no PHI should be visible to the inspector (if it's visible to you that means it's visible to the internet)
- Alert non-laboratory areas in your institution that the virtual inspection will be taking place

What is an In-Person Inspection?

- Assumes travel/visit laboratory
- Utilizes face-to-face inspection
- Performed by a full onsite team
- Preparation is “as usual”

Either of those “With Advance Document Review”

ACCESS TO DOCUMENTS AND SOPS PRIOR TO INSPECTION INTERACTION

DOCUMENTS REVIEWED AND QUESTIONS “COLLECTED”

ONSITE OR VIRTUAL INSPECTION THROUGH INTERACTIONS WITH LABORATORY STAFF

Now…that's HOW we are doing the inspection…

What's changed in the requirements?

Summary of Changes in 2021

Checklist	Requirements	New	Significant Changes	Deleted	Moved/Merged
ANP	187	2	16	0	2
BAP	178	0	4	0	2
CBG	73	0	2	0	0
CHM	160	1	2	0	1
COM	85	3	29	0	0
CYG	68	0	6	0	1
CYP	86	6	12	0	1
DRA	20	0	8	0	0
FDT	108	0	4	0	10
FLO	49	1	3	0	1
GEN	252	8	38	1	0
HEM	181	2	8	0	1
HSC	147	0	9	0	0
IMM	66	3	7	0	3
LSV	281	6	24	1	6
MIC	242	3	28	0	27
MOL	161	0	35	0	9
POC	64	2	10	0	0
RLM	118	2	7	0	0
TRM	259	2	25	0	5
URN	27	0	5	0	0
TOTAL		41	282	2	69

Laboratory General Checklist

Quality Management Systems (QMS)

- **GEN.13806 Quality Management System (QMS)**

The laboratory has a document that describes the overall QMS.

  - **Expanded concept of a quality management program to a QMS**

Access the November 17, 2021, Focus on Compliance webinar: Building a Quality Management System (QMS) for Your Laboratory: Moving on Up to the QMS Side (in Accreditation Resources)

- **GEN.13820 Scope of Service**

There is a document that describes the patient care and client services offered by the laboratory (eg, tests offered, hours of operation, turnaround times).

  - **New Phase I requirement**

Refer to webinar toolkit for QMS resources.

Competency Assessment Elements

- **GEN.55500 Competency Assessment Elements – Nonwaived Testing**

The competency of personnel performing nonwaived testing is assessed using all six elements (as applicable) on each test system.

- **Revised to focus on assessing all six elements for each test system**
  - **You can ensure compliance by:**
    - ✓ **Identifying the test systems that testing personnel use to generate test results**
    - ✓ **Including primary and back-up methods used for testing**
    - ✓ **Outlining practices and processes used to evaluate competency in a written procedure**
    - ✓ **Recording and tracking each element assessed and maintaining the supporting records**

A test system is the process that includes preanalytic, analytic, and postanalytic steps used to produce a test result or set of results.

Competency Assessment Frequency

- **GEN.55505 Competency Assessment Frequency – Nonwaived Testing**

The competency of personnel performing nonwaived testing is assessed at the required frequency at each laboratory (CAP/CLIA) number where testing is performed.

- **New Phase II requirement (split out of GEN.55500)**

Competency Assessment Frequency – Nonwaived Testing
At least semiannually (**first assessment within seven months from initiation of testing and second assessment no later than 12 months from the start of testing)** during the first year an individual tests patient specimens (new employees)
At least annually after an individual has performed assigned duties for one year *
When problems are identified with an individual's performance

**** The annual competency assessment may be performed throughout the entire year to minimize the impact on workload.***

Competency Assessment: Assessor Qualifications

- **GEN.55510 (POC.06920) Competency Assessment – Assessor Qualifications**

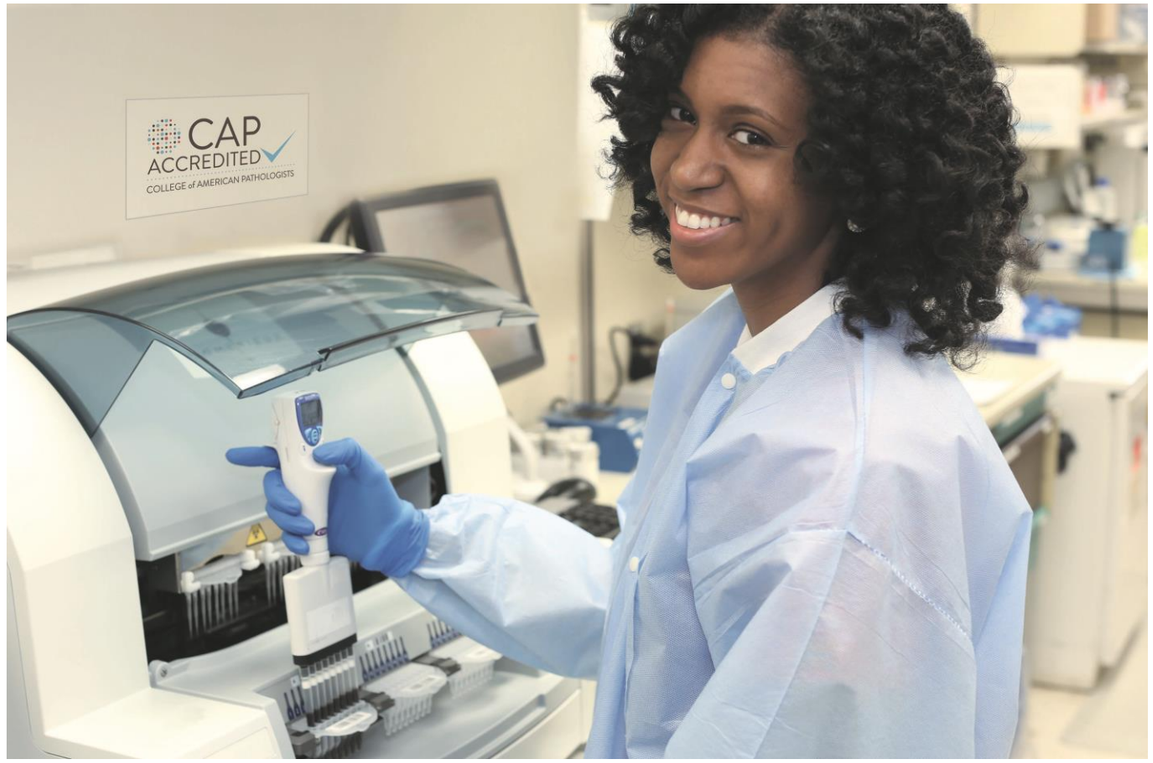
Individuals responsible for competency assessments have the education and experience to evaluate the complexity of the testing being assessed.

  - **Meet minimum qualifications and be knowledgeable about the test system**
  - **Follow more stringent state or local regulations (including state licensure requirements)**

Complexity	Qualifications
High Complexity	Section director (technical supervisor) or individual meeting general supervisor qualifications (GEN.53400, GEN.53600)
Moderate Complexity *	Technical consultant or individual meeting those qualifications (GEN.53625)
Waived Testing	May be determined by the laboratory director

**** A technical consultant must have a bachelors degree in a chemical, physical, biological, clinical laboratory science, or medical technology and have at least two years of training/experience in nonwaived testing in the designated specialty/subspecialty supervised.***

All Common Checklist



Proficiency Testing: COM.01100

- **COM.01100 Ungraded PT Challenges**

The laboratory director or designee assesses its performance on PT challenges that are ungraded.

  - **Requires the laboratory director or designee to assess performance on ungraded PT challenges**
  - **Includes educational PT challenges (added in the 2020 edition)**
  - **Defines minimum records of assessment to include notation of acceptability of the ungraded result and investigation and corrective action for unacceptable results**

  - **You can ensure compliance by:**
    - ✓ **Defining the policy on how to record assessment of ungraded PT challenges**
    - ✓ **Maintaining records of the assessment**

Specimen Aliquoting

- **COM.06250 Specimen Aliquoting**

The laboratory follows a written procedure for aliquoting of specimens to prevent cross-contamination and mix-up of specimens and aliquots.

  - **New Phase II requirement**
  - **Prohibits returning specimens into the original container for certain types of testing (eg, molecular-based testing, forensic drug testing, and biorepository storage)**
  - **Cautions laboratories to consider contamination and potential for mix-up when defining procedures**
  - **Replaces similar requirements from other checklists (CHM.12133, LSV.39875, MIC.63322, MOL.32385, FDT.05080, BAP.01723)**

Test Method Validation/Verification: EUA

- **Emergency use authorization (EUA)**
  - **Must verify the test performance specifications based on the test's FDA-designated authorized setting (found in the EUA letter of authorization)**

Authorized Setting	Requirement	Actions
Authorized for use in a patient care setting	**COM.30980**	• Deemed by FDA to be CLIA waived • Follow manufacturer's instructions for introduction • Have records of laboratory director/qualified designee approval of test prior to use
Authorized for use in moderate or high-complexity testing laboratories	**COM.40300**	• Verify analytical accuracy, precision, reportable range, and reference intervals

CAP Resource: Frequently asked questions on www.cap.org/covid-19

Point of Care Checklist

New POC.06915

Competency Assessment Frequency – Nonwaived Testing

Phase II

The competency of personnel performing nonwaived testing is assessed at the required frequency at the laboratory (CAP/CLIA number) where testing is performed.

NOTE: Competency assessment evaluates an individual's ongoing ability to apply knowledge and skills to achieve intended results. Competency must be assessed at the following frequency:

- **At least semiannually (first assessment within seven months from initiation of testing and second assessment no later than 12 months from the start of testing) during the first year an individual tests patient specimens (new employee)**
- **At least annually after an individual has performed assigned duties for one year***
- **When problems are identified with an individual's performance.**

New POC.09625

Competency Assessment Frequency – PPM Phase II

The competency of physicians and mid -level practitioners performing provider-performed microscopy is assessed at the required frequency at the laboratory (CAP/CLIA number) where testing is performed.

NOTE: This requirement does not apply to waived testing. The laboratory director may determine how competency of waived testing is determined. Competency assessment evaluates an individual's ongoing ability to apply knowledge and skills to achieve intended results. Competency must be assessed at the following frequency:

- **At least semiannually (first assessment within seven months from initiation of testing and second assessment no longer than 12 months from the start of testing) during the first year an individual tests patient specimens (new employees)**
- **At least annually after an individual has performed assigned duties for one year***
- **When problems are identified with an individual's performance.**

Top 10 Deficiencies - 2021

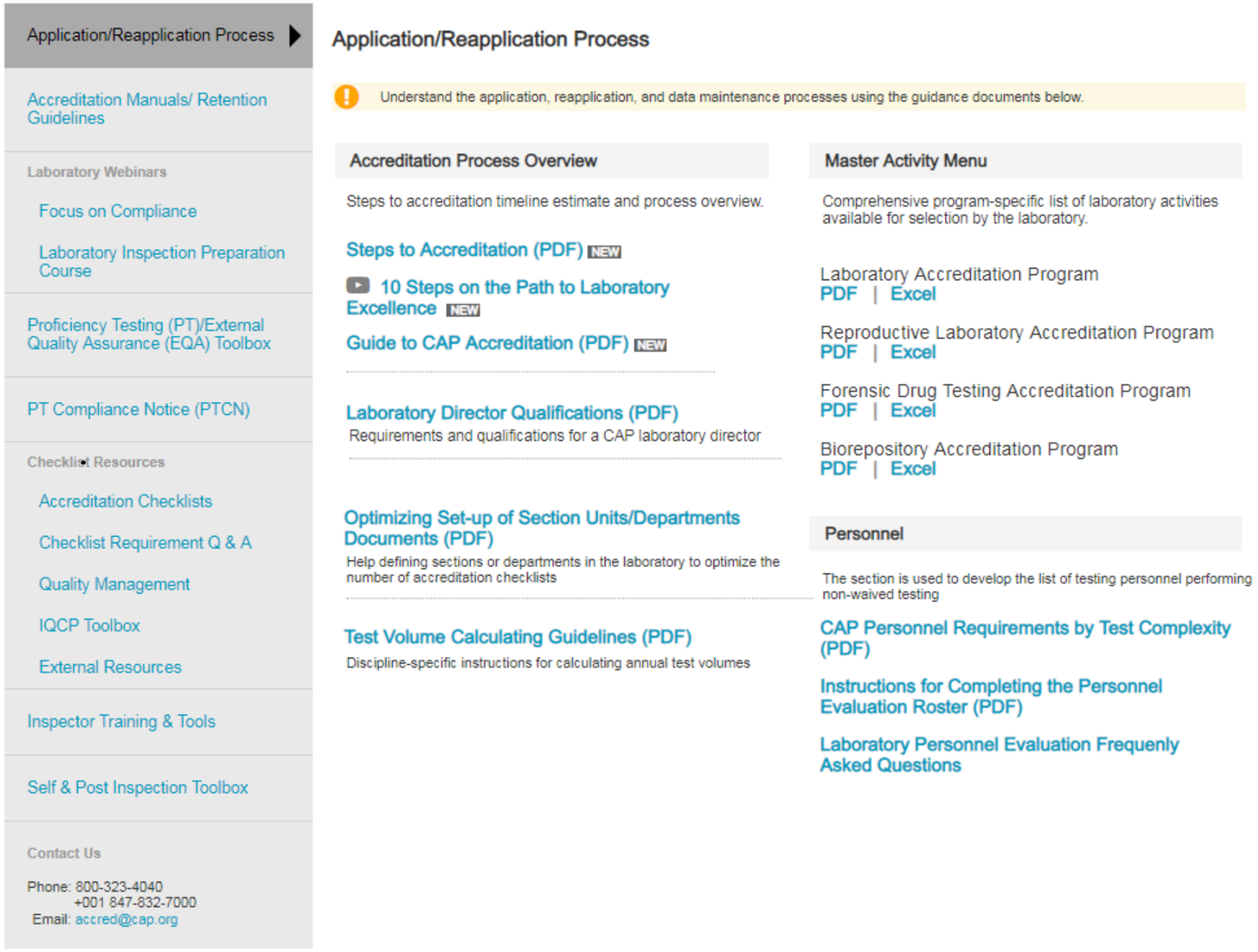
CHECKLIST REQUIREMENT	CAP-WIDE
COM.01200 Activity Menu	**1**
GEN.55500 Competency Assessment	**2**
COM.10000 Procedure Manual	**3**
COM.04250 Comparability of Instruments and Methods – Nonwaived Testing	**4**
COM.04200 Instrument/Equipment Record Review	**5**
COM.30600 Maintenance/Function Checks	**6**
COM.01700 PT and Alternative Assessment Result Evaluation	**7**
COM.30750 Temperature Checks	**8**
COM.01400 PT Attestation Statement	**9**
COM.30450 New Lot/Shipment Confirmation of Acceptability	**10**

Fewer staff, COVID, changes to the inspection, more requirements….

Can this be more difficult???

The CAP is working hard to make it easier!

Accreditation Resources



Organization Profile

Demographics

Basic Details >>

Addresses and Phones >>

Account List >>

Hours of Operation >>

Travel and Lodging >>

Security Access >>

General Information

General Questionnaire >>

FTEs and Annual Test Volumes >>

Information Systems >>

Relationships

Licensure and Certification >>

Inspection Unit >>

Roles/Personnel

Staff List >>

Roles

- Organizational and Institutional Roles >>
- CAP Program Roles >>
- Section/Department Roles >>

Personnel Evaluation Roster

Sections/Departments

Section/Department List >>

Family Fertility Center >>

- Section Details
- Section Activities

Inspections

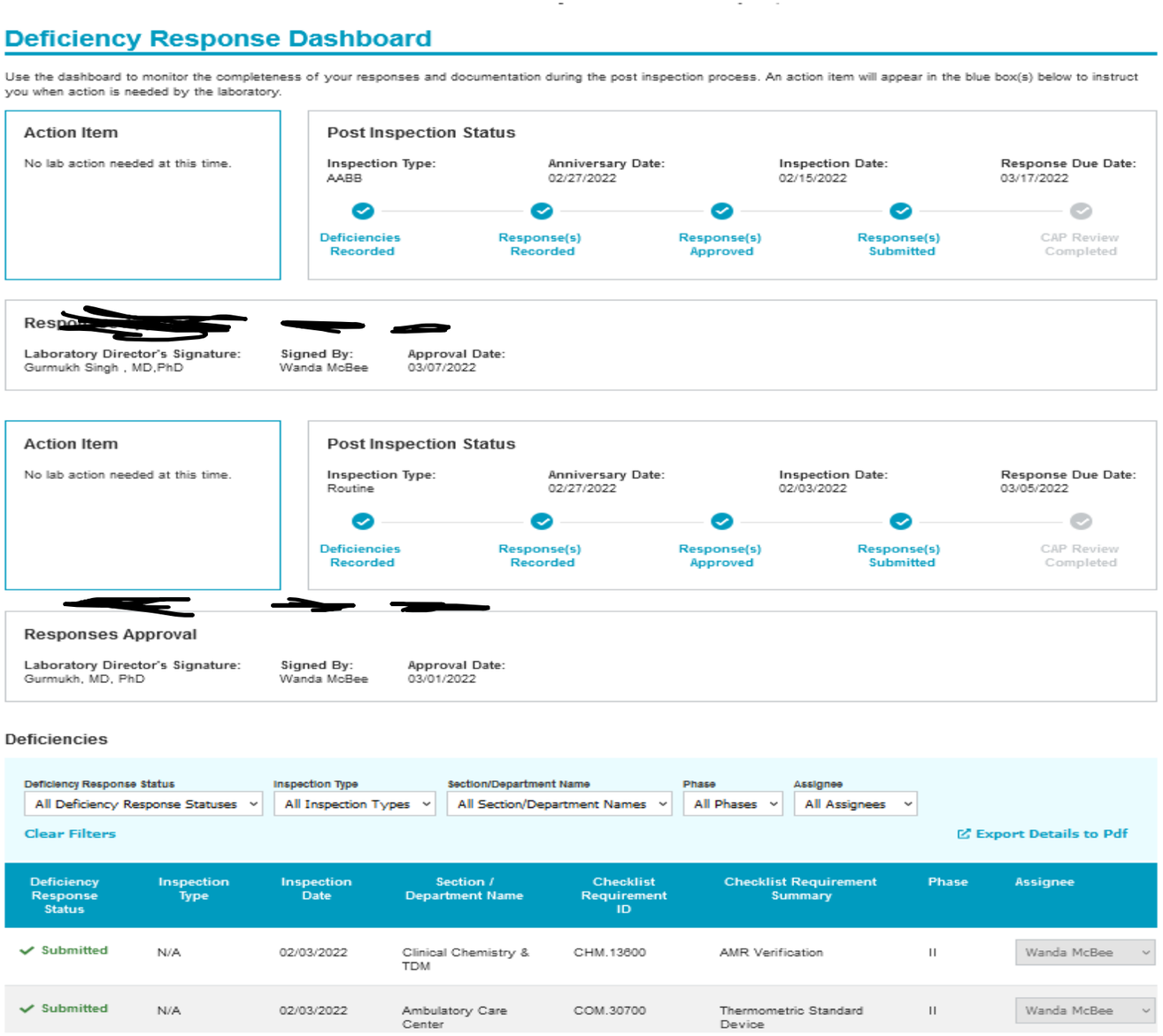
Terms of Accreditation >>

Documents for Review

- Document Review Options >>

Performance Analytics Dashboard

Online Deficiency Response



Deficiency Response Dashboard

Use the dashboard to monitor the completeness of your responses and documentation during the post inspection process. An action item will appear in the blue box(s) below to instruct you when action is needed by the laboratory.

Action Item

No lab action needed at this time.

Post Inspection Status

Inspection Type:	Anniversary Date:	Inspection Date:	Response Due Date:
AABB	02/27/2022	02/15/2022	03/17/2022

Deficiencies Recorded ✓ — Response(s) Recorded ✓ — Response(s) Approved ✓ — Response(s) Submitted ✓ — CAP Review Completed

[redacted]

Laboratory Director's Signature: Gurmukh Singh , MD,PhD
Signed By: Wanda McBee
Approval Date: 03/07/2022

Action Item

No lab action needed at this time.

Post Inspection Status

Inspection Type:	Anniversary Date:	Inspection Date:	Response Due Date:
Routine	02/27/2022	02/03/2022	03/05/2022

Deficiencies Recorded ✓ — Response(s) Recorded ✓ — Response(s) Approved ✓ — Response(s) Submitted ✓ — CAP Review Completed

[redacted]

Responses Approval

Laboratory Director's Signature: Gurmukh, MD, PhD
Signed By: Wanda McBee
Approval Date: 03/01/2022

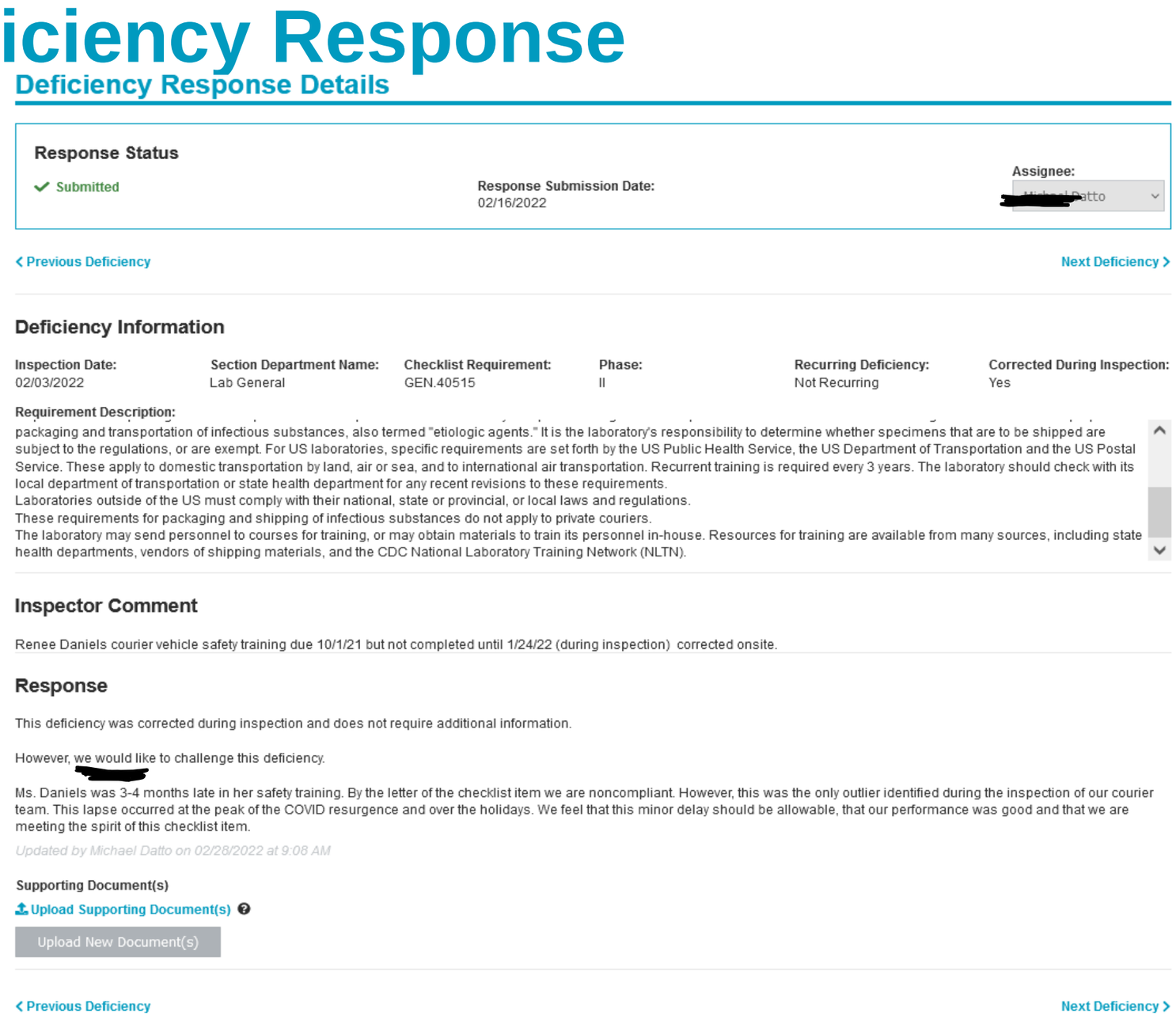
Deficiencies

Deficiency Response Status: All Deficiency Response Statuses | Inspection Type: All Inspection Types | Section/Department Name: All Section/Department Names | Phase: All Phases | Assignee: All Assignees

Clear Filters — Export Details to Pdf

Deficiency Response Status	Inspection Type	Inspection Date	Section / Department Name	Checklist Requirement ID	Checklist Requirement Summary	Phase	Assignee
✓ Submitted	N/A	02/03/2022	Clinical Chemistry & TDM	CHM.13600	AMR Verification	II	Wanda McBee
✓ Submitted	N/A	02/03/2022	Ambulatory Care Center	COM.30700	Thermometric Standard Device	II	Wanda McBee

Online Deficiency Response



Deficiency Response Details

Response Status

Submitted

Response Submission Date:
02/16/2022

Assignee:
[redacted]atto

< Previous Deficiency Next Deficiency >

Deficiency Information

Inspection Date:	Section Department Name:	Checklist Requirement:	Phase:	Recurring Deficiency:	Corrected During Inspection:
02/03/2022	Lab General	GEN.40515	II	Not Recurring	Yes

Requirement Description:

packaging and transportation of infectious substances, also termed "etiologic agents." It is the laboratory's responsibility to determine whether specimens that are to be shipped are subject to the regulations, or are exempt. For US laboratories, specific requirements are set forth by the US Public Health Service, the US Department of Transportation and the US Postal Service. These apply to domestic transportation by land, air or sea, and to international air transportation. Recurrent training is required every 3 years. The laboratory should check with its local department of transportation or state health department for any recent revisions to these requirements.
Laboratories outside of the US must comply with their national, state or provincial, or local laws and regulations.
These requirements for packaging and shipping of infectious substances do not apply to private couriers.
The laboratory may send personnel to courses for training, or may obtain materials to train its personnel in-house. Resources for training are available from many sources, including state health departments, vendors of shipping materials, and the CDC National Laboratory Training Network (NLTN).

Inspector Comment

Renee Daniels courier vehicle safety training due 10/1/21 but not completed until 1/24/22 (during inspection) corrected onsite.

Response

This deficiency was corrected during inspection and does not require additional information.

However, we would like to challenge this deficiency.

Ms. Daniels was 3-4 months late in her safety training. By the letter of the checklist item we are noncompliant. However, this was the only outlier identified during the inspection of our courier team. This lapse occurred at the peak of the COVID resurgence and over the holidays. We feel that this minor delay should be allowable, that our performance was good and that we are meeting the spirit of this checklist item.

Updated by Michael Datto on 02/28/2022 at 9:08 AM

Supporting Document(s)

Upload Supporting Document(s)

Upload New Document(s)

< Previous Deficiency Next Deficiency >

Direct Transmission of Proficiency Testing

Lots of change over the last two years…

The goal of exceptional patient care is still the same!

Good Luck!

- Questions?
- Thank you!!!

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