COLLEGE of AMERICAN PATHOLOGISTS

FDA LDT Rule: Quality System Complaint Processes

College of American Pathologists

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Today’s Presenters

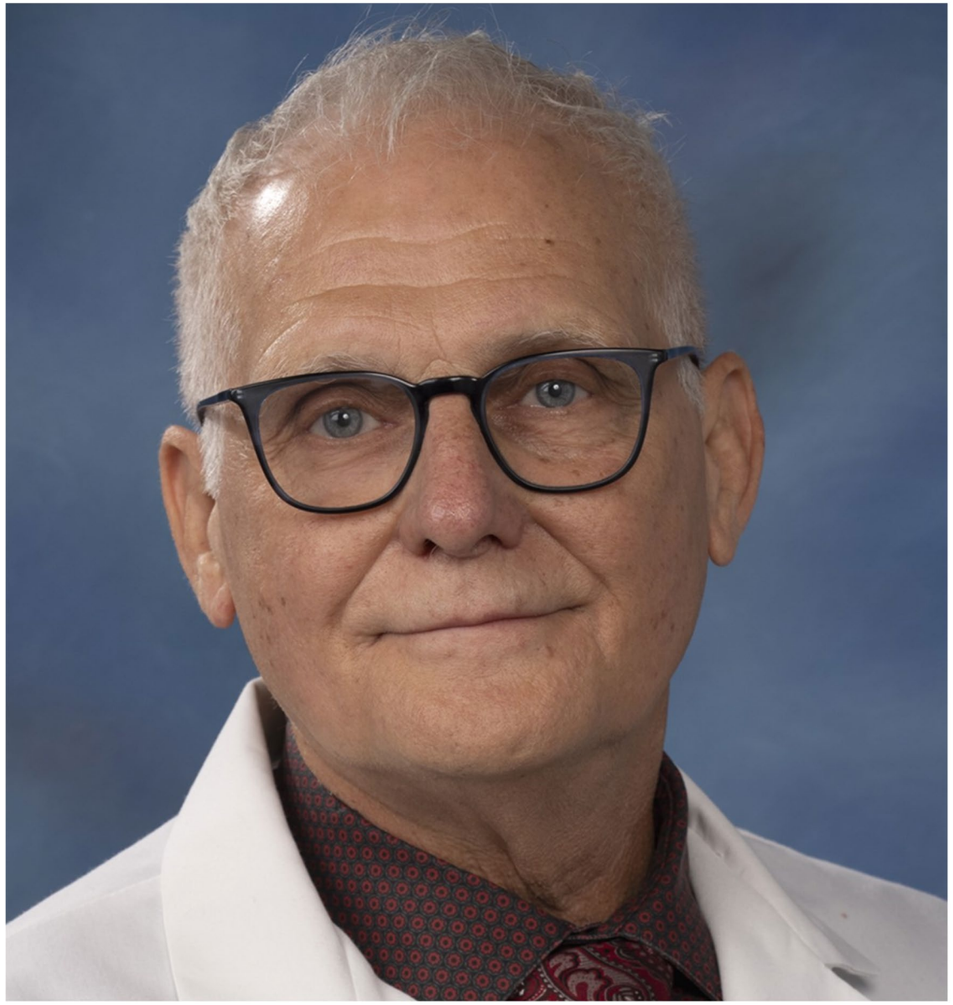
Bobbi S. Pritt, MD, FCAP

- Board-certified in anatomic, clinical pathology and microbiology
- Professor of laboratory medicine and pathology at Mayo Clinic, Rochester, MN; Chair of the clinical microbiology division
- Earned her medical degree at the University of Vermont Larner College of Medicine; residency at UVMC; fellowship in clinical microbiology at Mayo Clinic College of Medicine
- Producer of the podcast “Answers from the Lab.”
- Awarded Mayo Clinic's 2018 Distinguished Educator Award, CAP Excellence in Teaching award, and CAP Distinguished Patient Care award
- Chair of CAP’s Council on Scientific Affairs

Today’s Presenters

Earle S. Collum, MD, FCAP

- Board-certified in anatomic and clinical pathology
- Serves as medical director for LabCorp's Center for Esoteric Testing West and its Phoenix and Denver regional laboratories
- Earned his medical degree from the Medical University of South Carolina and completed his residency at Yale-New Haven Medical Center
- Former medical director of pathology and laboratory medicine at St. Joseph’s Hospital and Medical Center in Phoenix, Arizona
- Performed over 300 laboratory inspections and facilitated 20 Inspector Training Seminars
- Chair, CAP's Council on Accreditation
- CAP Lifetime Achievement Award recipient



Today's Presenters

Deeona Gaskin, JD, MPH

- Partner at the law firm of Sidley Austin LLP in Food, Drug, and Medical Device Group
- Former Associate Chief Counsel at FDA
- Earned her law degree at the Harvard Law School and her Master in Public Health at the Harvard T.H. Chan School of Public Health
- Advises medical device and in vitro diagnostic (IVD) manufacturers regarding various regulatory and compliance issues, including complaints, medical device reporting (MDRs), corrections and removals (recalls)
- Provides strategic guidance regarding FDA's new LDT rule

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Stage 1

- **May 6, 2025**
- Compliance with medical device reporting, correction and removal reporting, and quality system requirements for complaints

Reminder!

Step 1 should be an analysis of whether and how the new LDT rule applies to your LDT(s)

Applicability differs based on:

- Intended uses (e.g., compliance not expected for public health surveillance tests, forensic tests, or “1976 type LDTs”)
- Intended users (e.g., for “direct-to-consumer” tests, donor screening tests, and blood typing tests, compliance expected now)

The list of LDTs used to comply with COM.40830 can be used to help the lab register their LDTs, although it’s not required until May 6, 2026

CLIA Regulations vs. FDA Regulations

CLIA regulations	FDA regulations
Quality Management System	Quality System Regulation
GEN.13806	**21 C.F.R. § 820.198**
Identification of non-confirming events	
GEN.20208	
Investigation of non-conforming events	
GEN.20310	

Key Terms and Concepts

Key Terms and Concepts

Laboratory Developed Test

“[A]n IVD that is intended for clinical use and that is designed, manufactured, and used within a single laboratory that is certified under CLIA and meets the regulatory requirements under CLIA to perform high complexity testing”

89 Fed. Reg. 37286, 37289

Key Terms and Concepts

Quality System

"[O]rganizational structure, responsibilities, procedures, processes, and resources for implementing quality management." 21 C.F.R. § 820.3(v).

Key Terms and Concepts

Manufacturer

"[A]ny person who designs, manufactures, fabricates, assembles, or processes a finished device." 21 C.F.R. § 820.3(o).

Key Terms and Concepts

Complaint

Any written, electronic, or oral communication alleging deficiencies in a device's (test's):

- Identity
- Quality
- Durability
- Reliability
- Safety
- Effectiveness
- Performance

21 C.F.R. § 820.3(v).

Key Terms and Concepts

Complaint definition centers around **allegations**, not conclusions.

Complaint Systems

Complaint System – Goals

1. Enable laboratories to identify issues and trends requiring further investigation and corrective actions
2. Allow FDA to assess product performance in the market
3. Protect patients

Complaint System Requirements

Requirements include, but are not limited to:

- Establishing a formally designated unit (21 C.F.R. § 820.198 (a))
- Establishing complaint procedures (21 C.F.R. § 820.198 (a))
- Promptly evaluating complaints for MDR reportability and clearly identifying reported complaints (21 C.F.R. § 820.198 (a)(3), (d))
- Determining whether an investigation is necessary (21 C.F.R. § 820.198 (b))
- Maintaining complaint files (21 C.F.R. § 820.198 (a))

Establish Formal Complaint Procedures

Laboratories should create written procedures that address:

- Scope and definitions that include both oral and written complaints
- Complaint handling process (initial receipt through resolution)
- Clear criteria for assessing complaints
- Specific documentation requirements
- Defined workflow

Document Complaints Thoroughly

For example, documentation should include:

- Test name and identification
- Date complaint received
- Complainant’s name and contact information
- Nature and details of the complaint (the allegations)
- Investigation details (including whether complaint confirmed or not confirmed)
- Corrective actions, if any
- Any reply to complainant

21 C.F.R. § 820.198(e)

Reminder! Quality Management System Regulation

- FDA issued a final rule in 2024 to amend the quality system regulation, including related to complaint requirements, to better align with international standards, specifically ISO 13485.
- The compliance date for this new rule is February 2, 2026.
- The requirements for complaints under the current regulations at 21 C.F.R. § 820.198 and under the new rule are similar.
- As FDA explained in the preamble to its LDT rule:

> " 21 CFR 820.198 generally requires that a manufacturer maintain complaint files and establish and maintain procedures for receiving, reviewing, and evaluating complaints, including requiring that certain complaints which are required to be reported to FDA under part 803 be promptly reviewed, evaluated, and investigated. When the final rule to amend part 820 takes effect in February 2026, the comparable requirements can be found in International Organization for Standardization (ISO) 13485 subclause 8.2.2 as modified by part 820. Under these provisions, manufacturers will generally be required to document procedures for timely complaint handling, including minimum requirements and responsibilities for receiving and recording information, evaluating whether the information constitutes a complaint, investigating complaints, determining the need to report information to appropriate regulatory authorities, handling of complaint-related product, and determining the need to initiate corrective action. Additionally, new § 820.35 will require, among other things, that manufacturers maintain records of such review and report to FDA complaints that are required under part 803 [the MDR requirement]."

Complaint Investigations

Key Questions with Complaint Handling and Investigations

1. What happened?
2. Do I need more information?
3. Does this complaint need to be reported to FDA as an MDR?
4. Is this complaint confirmed?
5. What caused this to happen (*i.e.,* root cause)?
6. Who has been impacted?
7. How can I limit the impact?
8. How can I prevent the problem from recurring?

Complaint Elements

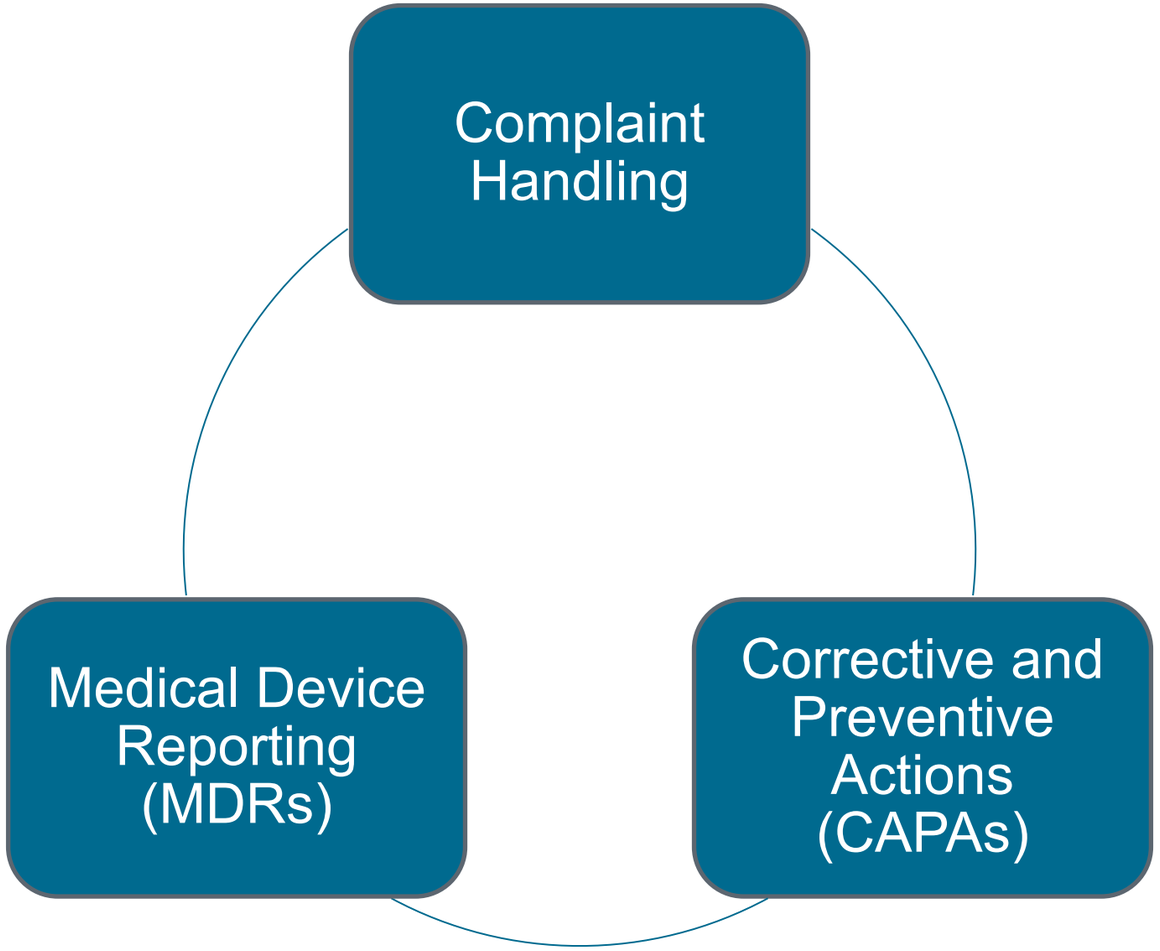
Reminder! All Medical Device Reports Are Complaints

- Manufacturers need to submit reports within 30 calendar days:
  - Of becoming aware of an event that "reasonably suggests" a marketed device:
    - "(i) May have caused or contributed to a death or serious injury, or
    - (ii) Has malfunctioned and that the device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur."

  21 C.F.R.§ 803.3(o)(2)
- Manufactures need to submit reports within 5 work days:
  - Of becoming aware of:
    - "(i) A reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health or
    - (ii) A reportable event for which we [FDA] made a written request."

  21 C.F.R.§ 803.10(c)(2)
- **All MDRs are complaints!**

How These Systems Work Together



Case Discussion

Example 1

A specimen collection kit for a test includes a tube for sample collection.

The customer reports that the tube broke.

Discussion

Would this be a complaint?
Should this be investigated?
Should it be reported to the FDA?

Example 2

In analyzing an immunohistochemistry stain sample, a pathologist observes an unusual staining pattern. The pathologist contacts the lab and raises this issue.

Discussion

Would this be a complaint?
Should this be investigated?
Should it be reported to the FDA?

Example 3

A customer requests a duplicate test report because the customer believes that the report was never received.

Discussion

Would this be a complaint?
Should this be investigated?
Should it be reported to the FDA?

Example 4

A physician requests an expedited test, but the results do not come within the requested timeframe.

Discussion

Would this be a complaint?
Should this be investigated?
Should it be reported to the FDA?

Example 5

A physician questions whether a result is a potential false negative given other clinical symptoms.

Discussion

Would this be a complaint?
Should this be investigated?
Should it be reported to the FDA?

Top 6 Takeaways

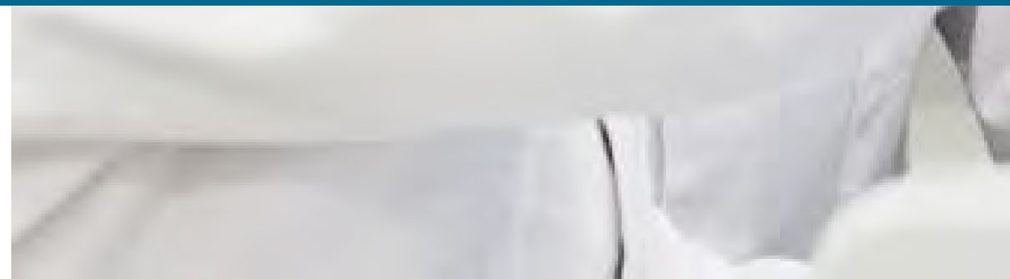
What should laboratories be doing to prepare?

- Familiarize yourself with FDA terminology and requirements
- Identify tests that are in scope of the LDT rule
- Identify individuals and departments that will be responsible for complaints (complaint handling unit)
- Train relevant individuals
- Update policies and procedures to account for the new regulations
- Prepare databases / record storage systems
- Consult with legal counsel / consultants for additional guidance

Resources

- CAP LDT Oversight web page: https://www.cap.org/advocacy/laboratory-oversight-and-regulation/laboratory-developed-test-oversight
- FDA final rule on LDTs: https://www.federalregister.gov/documents/2024/05/06/2024-08935/medical-devices-laboratory-developed-tests
- Quality System Regulation, Complaints: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820

Questions and Answers



Six-Part Webinar Series on LDTs

- Register for our other webinar programs:

  Understand and Prepare for the Impact of the FDA's LDT Final Rule

  - How Enforcement Discretion Categories & Modification Rules Apply to Your LDTs (May 8, 2025)
  - Navigating FDA LDT Oversight Requirements During Public Health Emergencies (July 10, 2025)

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