LDT Final Rule
Resources & Impacts for Public Health Laboratories

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Tennessee Public Health Lab Director

Phaseout Policy

FDA is phasing out its general enforcement discretion approach for LDTs in stages, so that IVDs manufactured by a laboratory will generally fall under the same enforcement approach as other IVDs (i.e., FDA's expectations for compliance will generally be the same), according to the following timeline:

Beginning May 6, 2025

- Medical Device Reporting
- Correction and Removal Reporting
- Quality System Requirements re: Complaint Files

Beginning May 6, 2026

- Requirements not covered in other stages including:
- Establishment Registration & Device Listing
- Labeling Requirements
- Investigational Requirements

Beginning May 6, 2027

- Quality System Requirements*

Beginning November 6, 2027

- Premarket Review for High Risk IVDs

Beginning May 6, 2028

- Premarket Review for Moderate and Low** Risk IVDs

*For LDTs, FDA will expect compliance with:

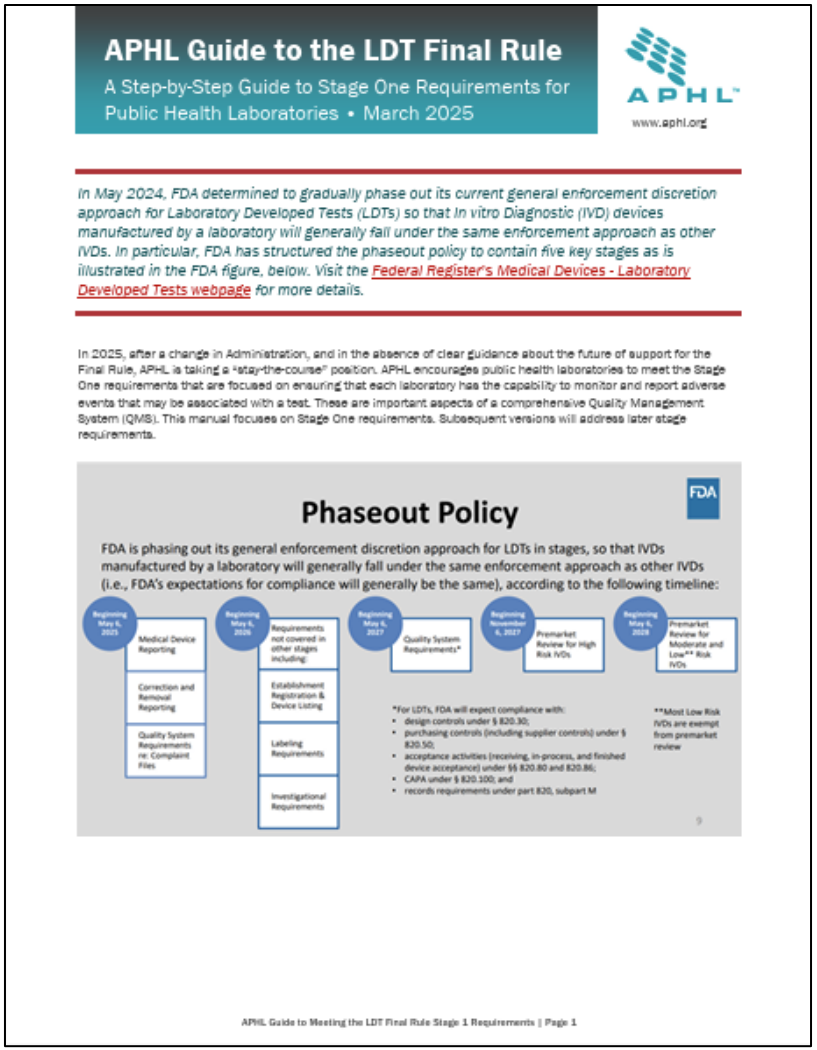
- design controls under § 820.30;
- purchasing controls (including supplier controls) under § 820.50;
- acceptance activities (receiving, in-process, and finished device acceptance) under §§ 820.80 and 820.86;
- CAPA under § 820.100; and
- records requirements under part 820, subpart M

**Most Low Risk IVDs are exempt from premarket review

Impact on PHLs:

- Shouldn't stop implementation of LDTs but changes approach
- Puts focus on diagnostic vs. surveillance testing
- Phases will require increasing changes to PHL structure & processes

APHL Guide:



APHL Guide to the LDT Final Rule

A Step-by-Step Guide to Stage One Requirements for Public Health Laboratories • March 2025

APHL
www.aphl.org

In May 2024, FDA determined to gradually phase out its current general enforcement discretion approach for Laboratory Developed Tests (LDTs) so that In vitro Diagnostic (IVD) devices manufactured by a laboratory will generally fall under the same enforcement approach as other IVDs. In particular, FDA has structured the phaseout policy to contain five key stages as is illustrated in the FDA figure, below. Visit the Federal Register's Medical Devices - Laboratory Developed Tests webpage for more details.

In 2025, after a change in Administration, and in the absence of clear guidance about the future of support for the Final Rule, APHL is taking a "stay-the-course" position. APHL encourages public health laboratories to meet the Stage One requirements that are focused on ensuring that each laboratory has the capability to monitor and report adverse events that may be associated with a test. These are important aspects of a comprehensive Quality Management System (QMS). This manual focuses on Stage One requirements. Subsequent versions will address later stage requirements.

Phaseout Policy

FDA

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APHL Guide to Meeting the LDT Final Rule Stage 1 Requirements | Page 1

Link to Guide

Phase 1: Ensuring labs monitor & report adverse events that may be associated with a test

Phaseout Policy

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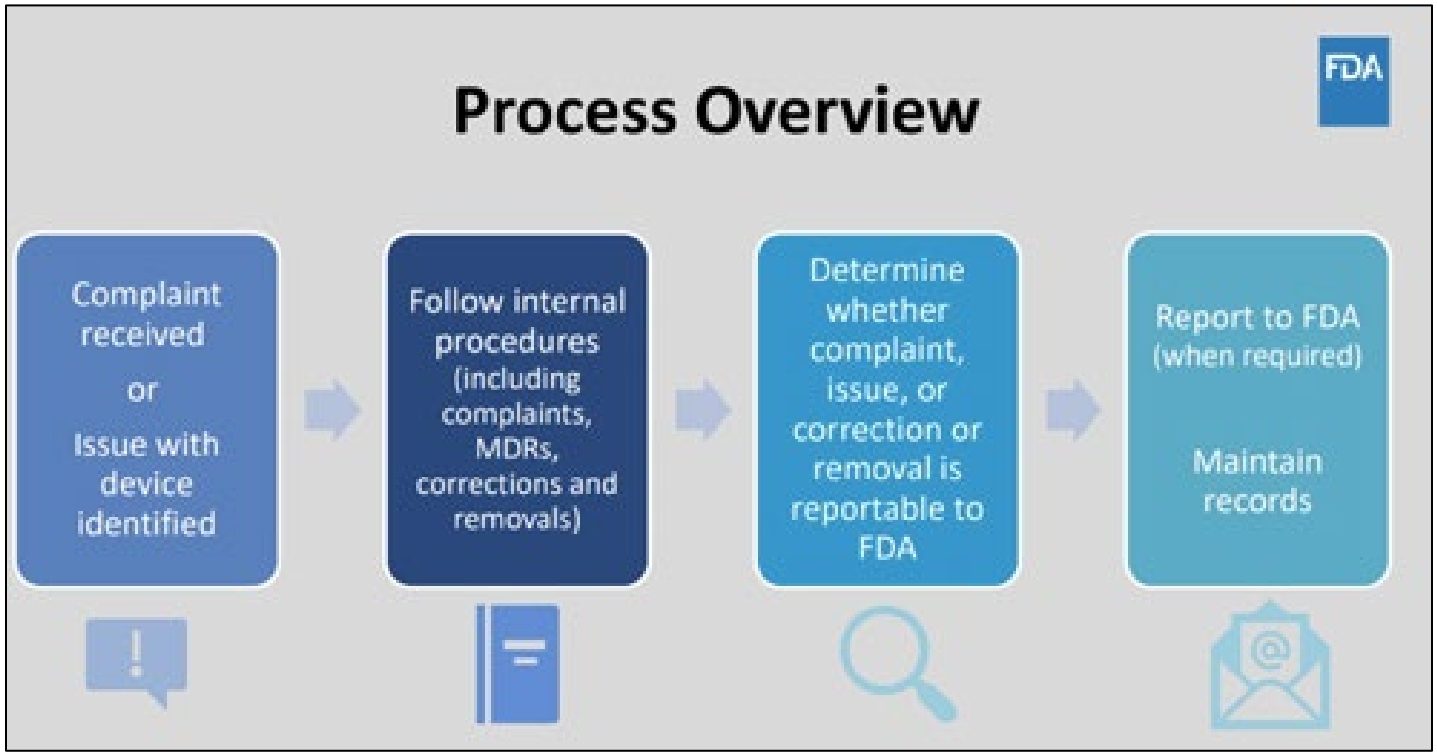
Phase 1: Build on QMS, but don't reinvent the wheel



Focus on establishment of formal, consistent documentation and reporting practices

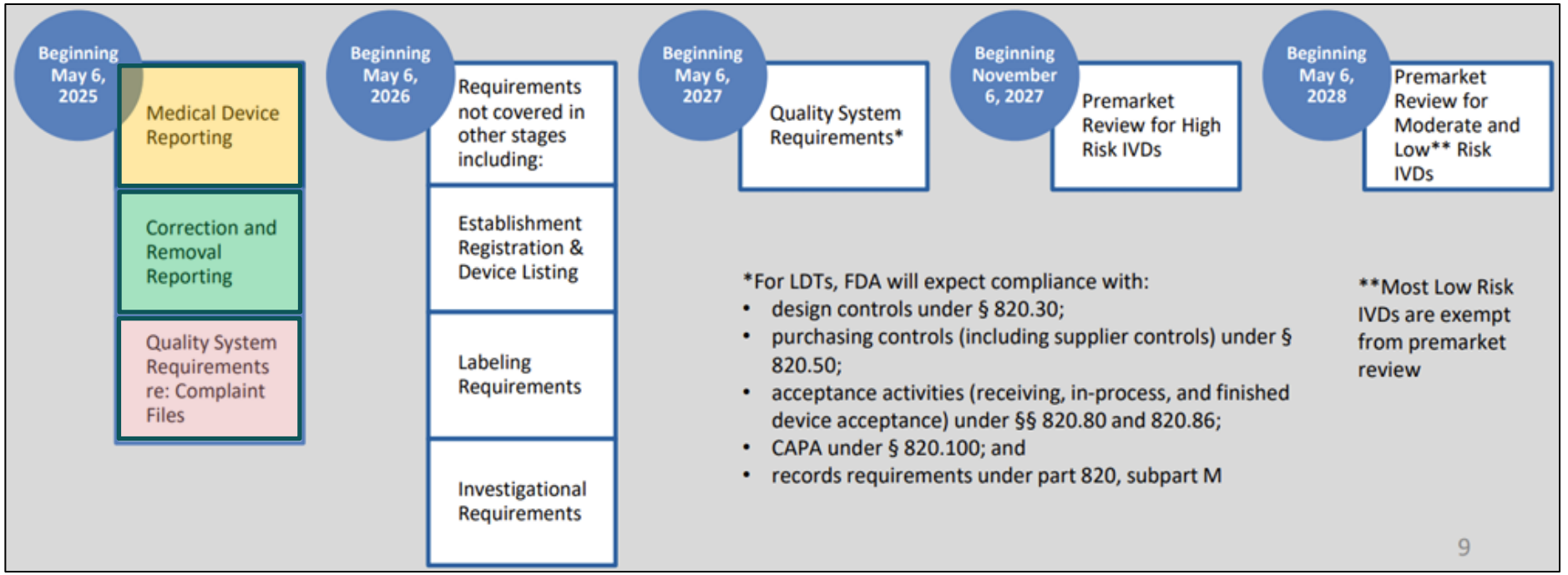
LDTs that must be compliant with Phase 1 reporting requirements

The following PHL LDTs must be compliant with the Stage 1 reporting requirements by May 6, 2025.

1. LDTs in use before May 6, 2024 that are not modified or are modified in limited ways (see Allowable Modifications under definitions).
2. FDA-authorized tests that become LDTs due to modifications of another manufacturer's 510(k) or De Novo authorized test.
3. New LDTs for emerging outbreaks (such as for Oropouche virus and highly pathogenic avian influenza).
4. LDTs approved by the New York State Clinical Laboratory Evaluation Program (NYS CLEP).
5. LDTs for unmet needs that are manufactured and performed by labs integrated within the healthcare system treating the patient.
6. New LDTs developed/marketed after May 6, 2024.

Note that FDA does generally not intend enforce premarket review and QMS requirements on LDTs that were first marketed, i.e. in use in the PHL, prior to the date of issuance of this rule, May 6, 2024, and that are not modified, or that are modified in certain limited ways.

10 steps to meet the Phase 1 requirements



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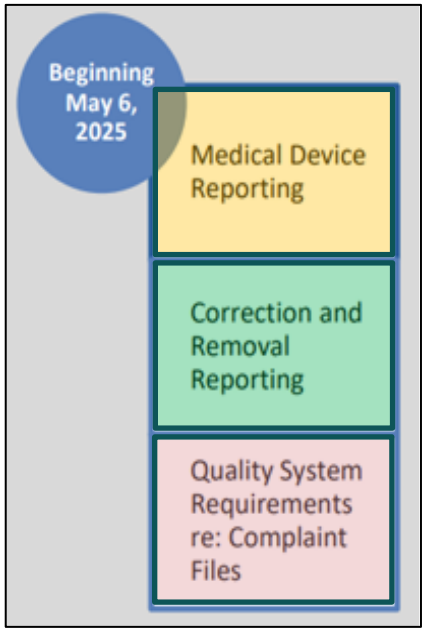


1. Set up LDT management team
2. Compile list of LDTs
3. Develop process to receive complaints
4. Implement FDA system for submitting reports
5. Establish an account
6. Establish an FEI number
7. Establish device product codes for your LDTs
8. Identify adverse event codes for reporting
9. Determine what needs to be reported to FDA
10. Notify FDA about test corrections/removals

Who needs to be involved

1. Set up LDT management team

- Lead scientist
- Informatics
- Quality
- CLIA director

Take stock of LDTs in your lab

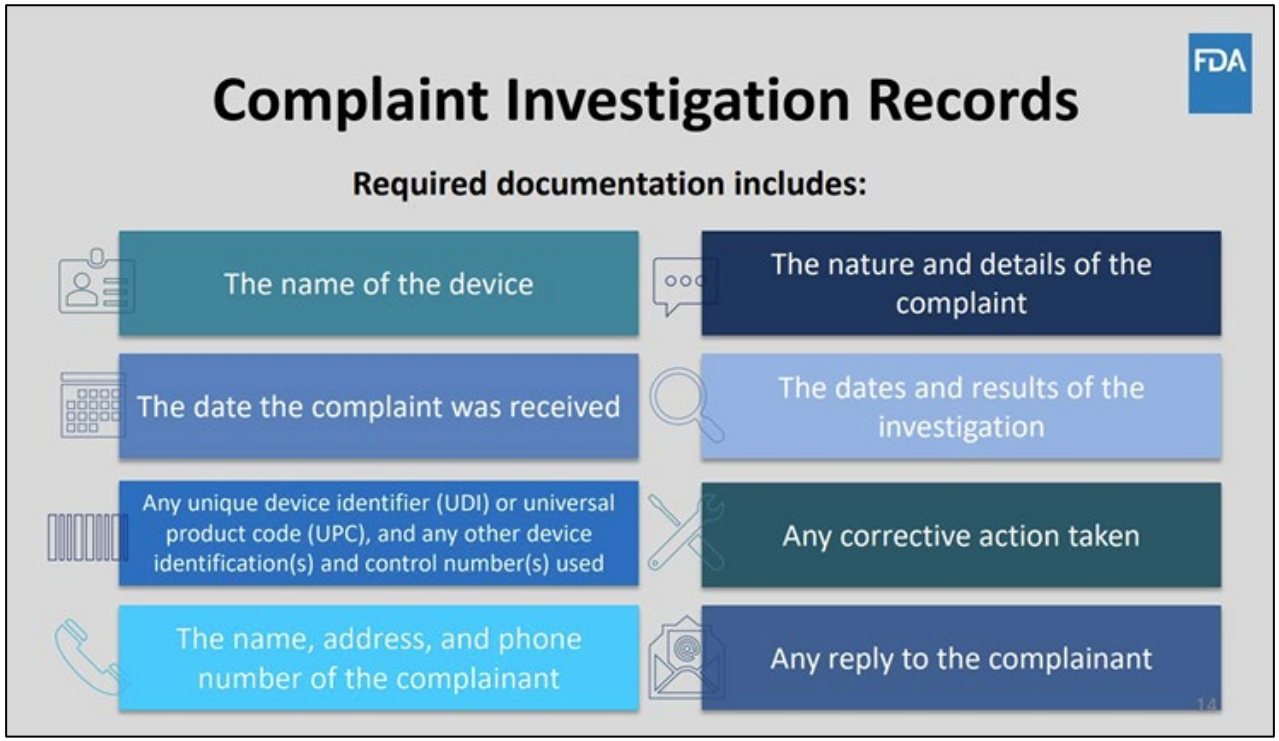
2. Compile list of LDTs

Template linked in guide

- Test name, method, section
- IVD/RUO marking, FDA cleared/approved
- Type of LDT, any modifications, test components
- Estimated annual test volume
- Validated prior to May 6, 2024, date
- Priority
- Possibility of discontinuation, alternatives

Need defined process to receive complaints

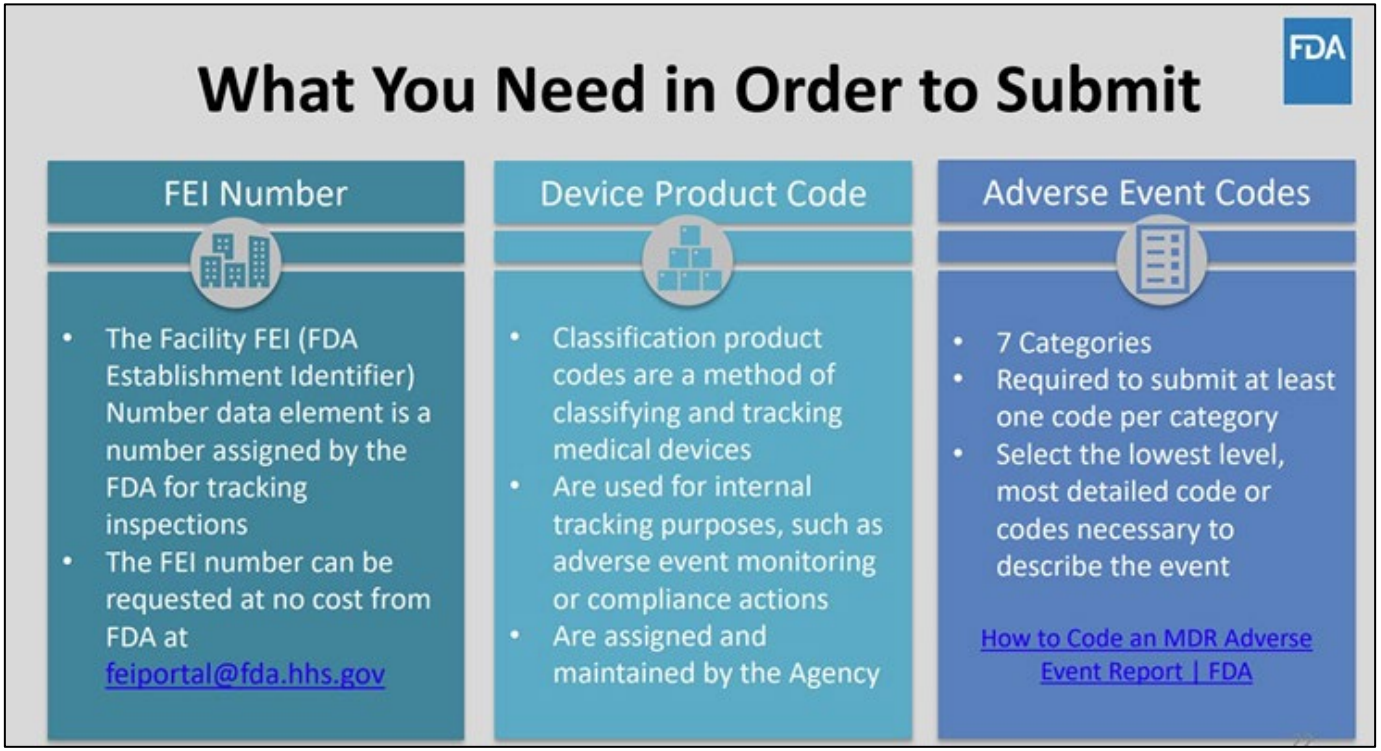
3. Develop process to receive complaints



**PHLs may not have all the info/data, can put N/A on those fields in the forms

Medical device reporting biggest lift for Phase 1

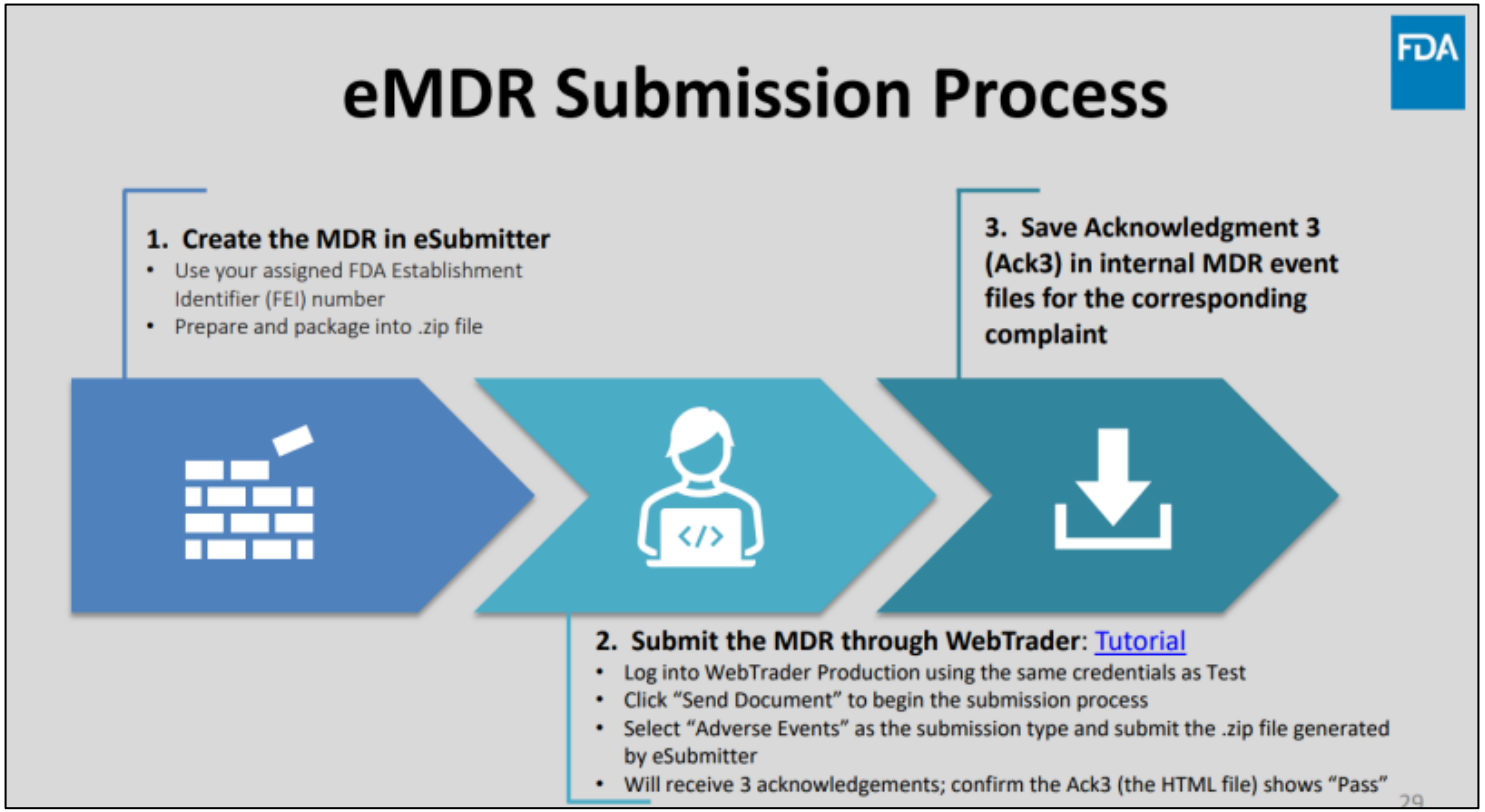
4. Implement FDA system for submitting reports



** Lean on your document control system

APHL Guide:

5. Establish an account



Limited cost impact on PHLs for now

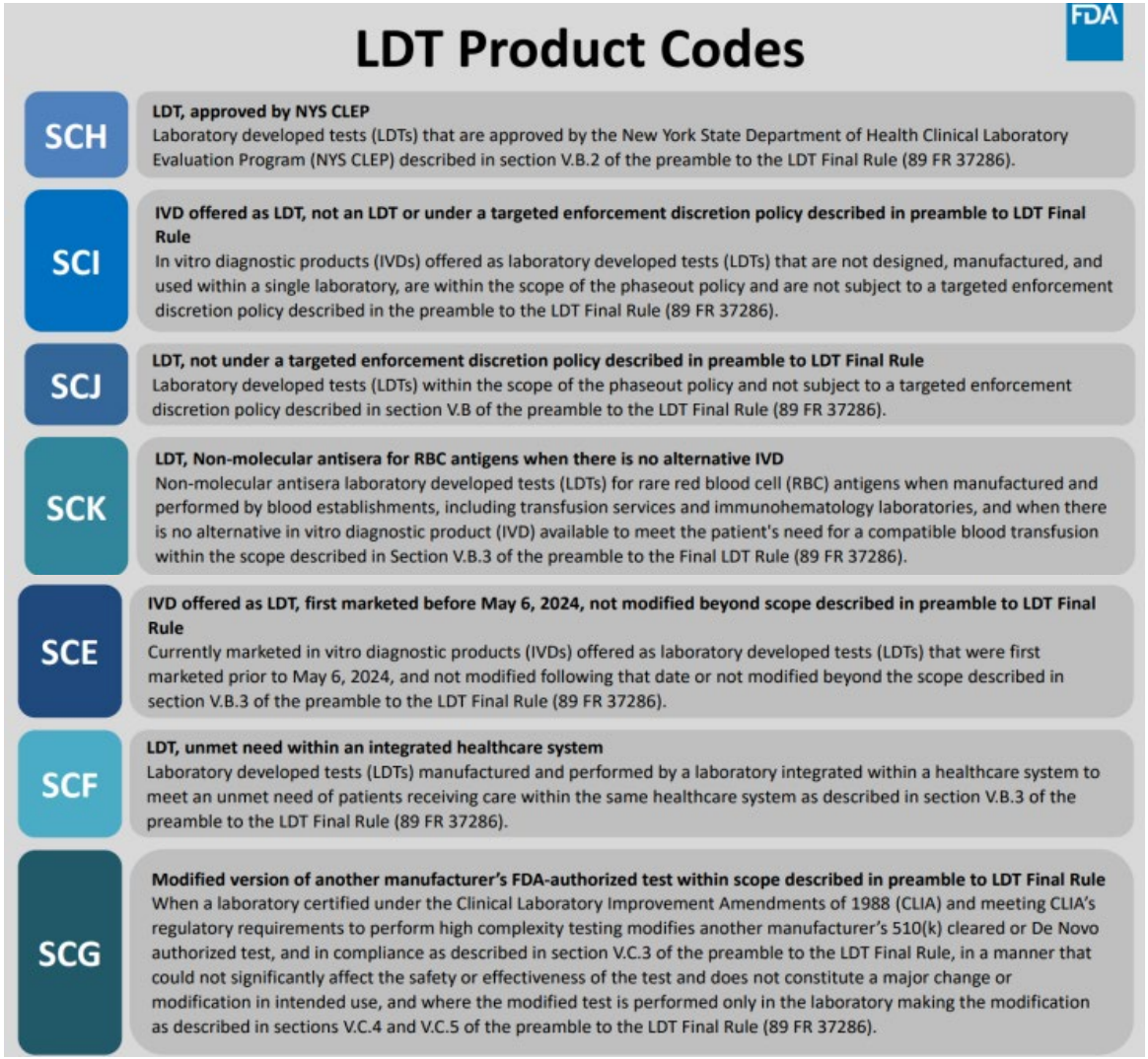
6. Establish an FEI number

Most state and federal PHLS will **not** need to pay registration/submission fees (see linked table in Guide)

Food, Drug, and Cosmetic Act (738(a)(3)(B)(i)):
State or Federal Government sponsors: No fee shall be required under subparagraph (A) for a premarket application, premarket report, supplement, premarket notification submission, or de novo classification request submitted by a State or Federal Government entity unless the device involved is to be distributed commercially.

No LDT-specific codes, find best fit

7. Establish device product codes for your LDTs



Adverse events ≈ non-conforming events but not all NCEs are reportable adverse events

8. Identify adverse event codes for reporting

Adverse Event Codes

Device Codes	**Medical Device Problem:** Annex A	Problems (malfunction, deterioration of function, failure) of medical devices
	Medical Device Component: Annex G	The parts and components which were involved in, or affected by, the medical device adverse event/incident.
Evaluation Codes	**Cause Investigation - Type of Investigation:** Annex B	What was investigated and what kind of investigation was conducted to specify the root cause of the adverse event.
	Cause Investigation - Investigation Findings: Annex C	The findings in the specific investigation that are the keys to identify the root cause of the event.
	Cause Investigation - Investigation Conclusion: Annex D	The conclusion regarding the root cause of the reported event.
Patient Codes	**Health Effects - Clinical Signs and Symptoms or Conditions:** Annex E	The clinical signs and symptoms or conditions of the affected person appearing as a result of the medical device adverse event/incident.
	Health Effects - Health Impact: Annex F	The consequences of the medical device adverse event/incident on the person affected.

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Investigation & decision-making must be documented

9. Determine what needs to be reported to FDA

Starts with complaint investigation

Uses defined decision-making processes

What is an MDR Reportable Event?

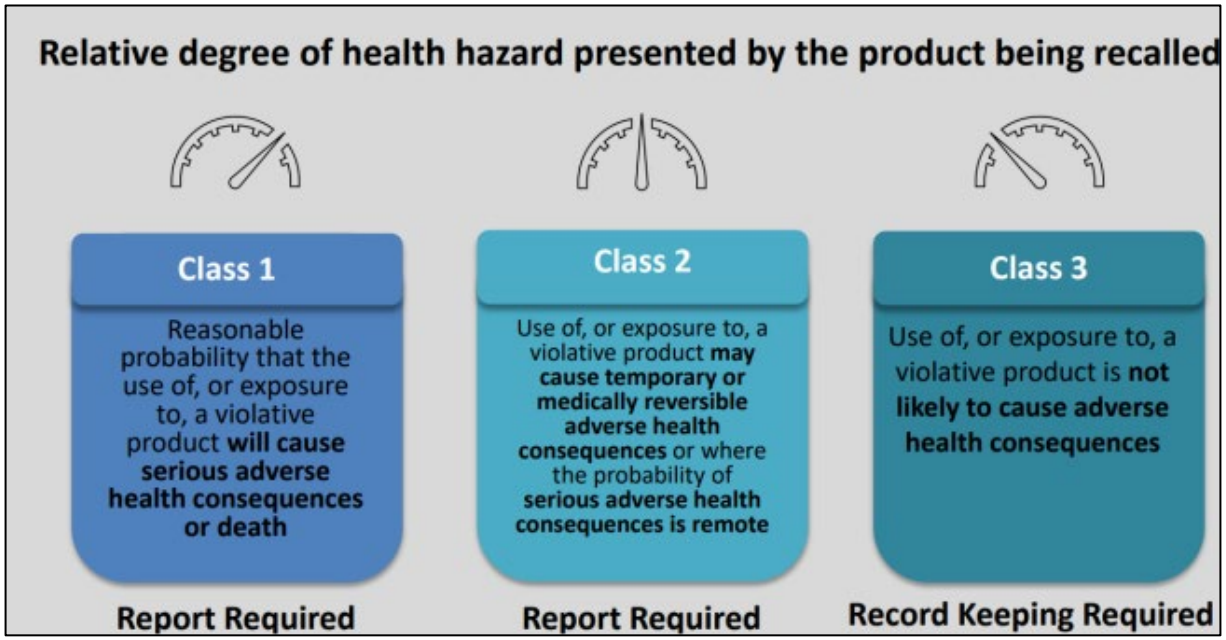
An event that manufacturers become aware of ***that reasonably suggests*** that one of their marketed devices:

- May have ***caused or contributed*** to a death or ***serious injury***, OR
- Has ***malfunctioned*** and that the device or a similar device marketed by the manufacturer would ***be likely to cause or contribute to*** a death or serious injury if the malfunction ***were to recur***

PHL must notify FDA of changes to a test

10. Notify FDA about test corrections/removals

- Removal=physical change in device (test) location
- Correction=modification/adjustment of device



Additional resources

- FDA webinar
  - "*IVDs-MDR Requirements, Correction and Removal Reporting Requirements, and Quality System Complaint Requirements*" webinar link, slides link
- APHL LDT website
- ARUP webinar (minutes 4:00-23:30 for Phase 1)
- Questions? LDTquestions@aphl.org

Takeaway

- We all want the same thing, timely and accurate tests
- Phase 1 is an opportunity to take existing QMS and make it more robust