

LDT Final Rule

Resources & Impacts for

Public Health Laboratories



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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:

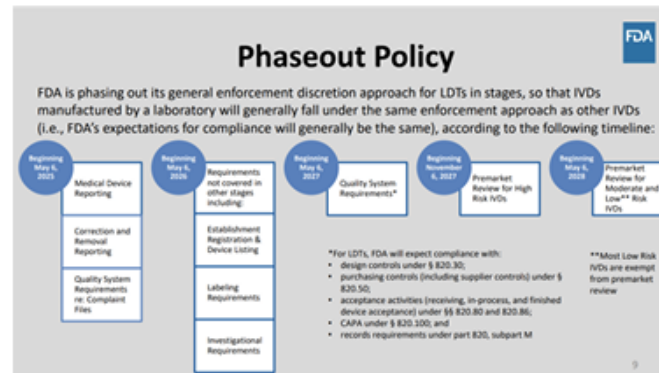
APHL Guide to the LDT Final Rule

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



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.



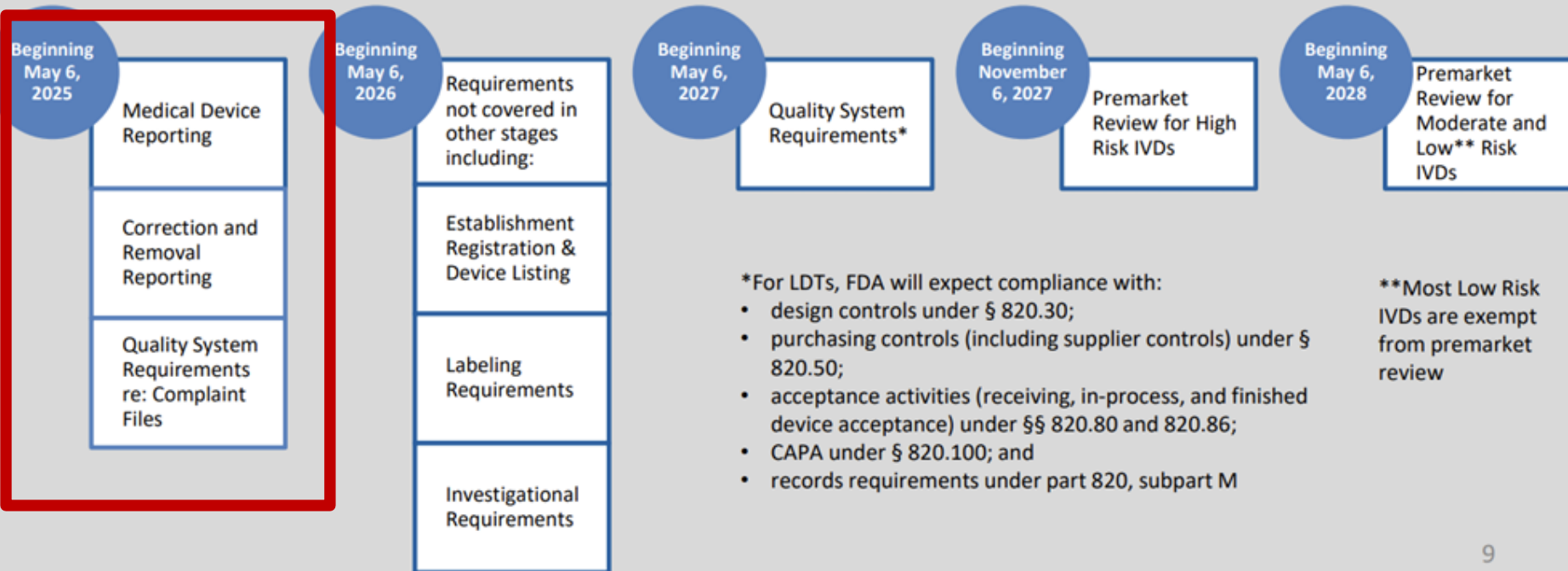
[Link to Guide](#)

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

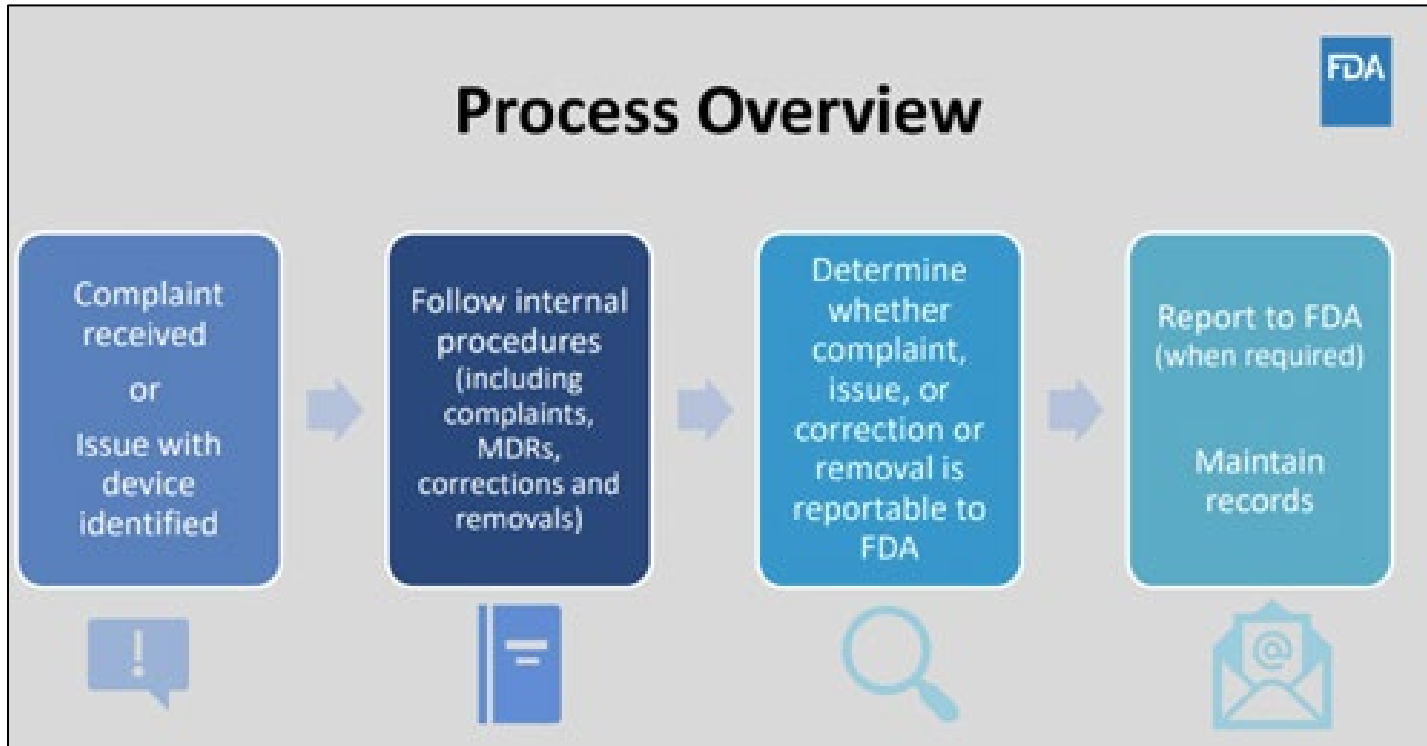


Phaseout Policy

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:



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



Focus on establishment of formal, consistent documentation and reporting practices

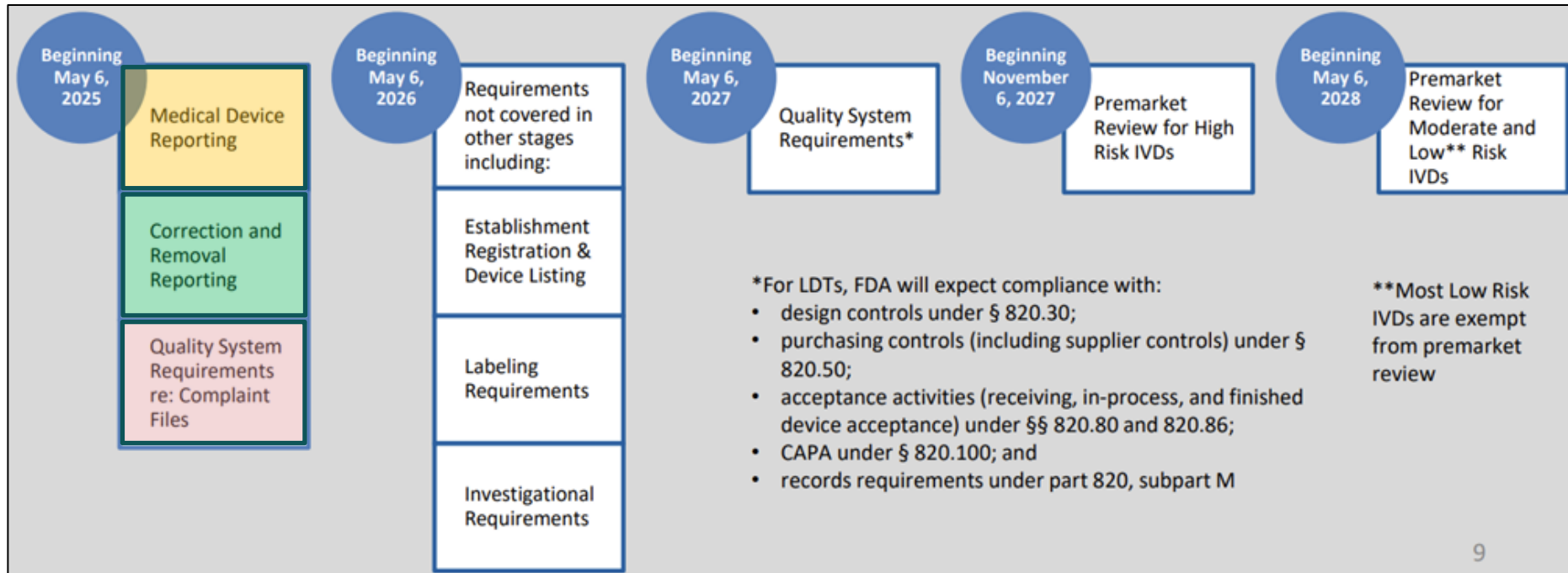
LDTs that must be compliant with Phase 1 reporting requirements

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

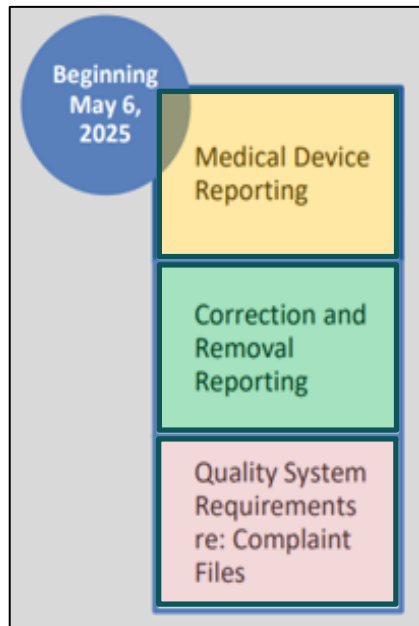
1. LDTs in use before May 6, 2024 that are not modified or are modified in limited ways (see Allowable Modifications under definitions).
2. FDA-authorized tests that become LDTs due to modifications of another manufacturer's 510(k) or De Novo authorized test.
3. New LDTs for emerging outbreaks (such 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



10 steps to meet the Phase 1 requirements



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



Complaint Investigation Records

Required documentation includes:

 The name of the device	 The nature and details of the complaint
 The date the complaint was received	 The dates and results of the investigation
 Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used	 Any corrective action taken
 The name, address, and phone number of the complainant	 Any reply to the complainant

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***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

What You Need in Order to Submit

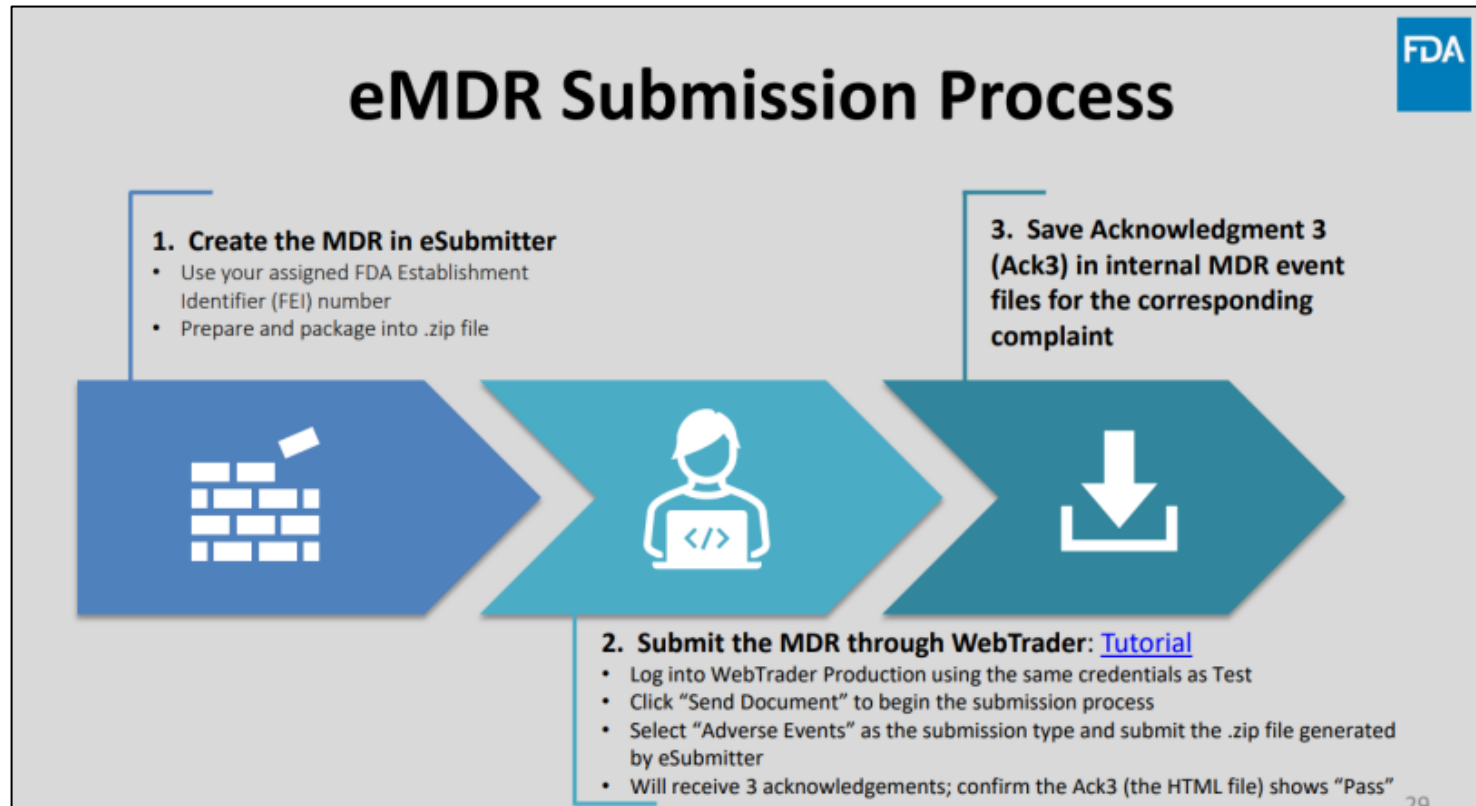


FEI Number	Device Product Code	Adverse Event Codes
 - The Facility FEI (FDA Establishment Identifier) Number data element is a number assigned by the FDA for tracking inspections - The FEI number can be requested at no cost from FDA at feiportal@fda.hhs.gov	 - Classification product codes are a method of classifying and tracking medical devices - Are used for internal tracking purposes, such as adverse event monitoring or compliance actions - Are assigned and maintained by the Agency	 7 Categories - Required to submit at least one code per category - Select the lowest level, most detailed code or codes necessary to describe the event How to Code an MDR Adverse Event Report FDA

✱✱ Lean on your document control system

APHL Guide:

5. Establish an account



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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

LDT Product Codes

FDA

SCH

LDT, approved by NYS CLEP

Laboratory developed tests (LDTs) that are approved by the New York State Department of Health Clinical Laboratory Evaluation Program (NYS CLEP) described in section V.B.2 of the preamble to the LDT Final Rule (89 FR 37286).

SCI

IVD offered as LDT, not an LDT or under a targeted enforcement discretion policy described in preamble to LDT Final Rule

In vitro diagnostic products (IVDs) offered as laboratory developed tests (LDTs) that are not designed, manufactured, and used within a single laboratory, are within the scope of the phaseout policy and are not subject to a targeted enforcement discretion policy described in the preamble to the LDT Final Rule (89 FR 37286).

SCJ

LDT, not under a targeted enforcement discretion policy described in preamble to LDT Final Rule

Laboratory developed tests (LDTs) within the scope of the phaseout policy and not subject to a targeted enforcement discretion policy described in section V.B of the preamble to the LDT Final Rule (89 FR 37286).

SCK

LDT, Non-molecular antisera for RBC antigens when there is no alternative IVD

Non-molecular antisera laboratory developed tests (LDTs) for rare red blood cell (RBC) antigens when manufactured and performed by blood establishments, including transfusion services and immunohematology laboratories, and when there is no alternative in vitro diagnostic product (IVD) available to meet the patient's need for a compatible blood transfusion within the scope described in Section V.B.3 of the preamble to the Final LDT Rule (89 FR 37286).

SCE

IVD offered as LDT, first marketed before May 6, 2024, not modified beyond scope described in preamble to LDT Final Rule

Currently marketed in vitro diagnostic products (IVDs) offered as laboratory developed tests (LDTs) that were first marketed prior to May 6, 2024, and not modified following that date or not modified beyond the scope described in section V.B.3 of the preamble to the LDT Final Rule (89 FR 37286).

SCF

LDT, unmet need within an integrated healthcare system

Laboratory developed tests (LDTs) manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system as described in section V.B.3 of the preamble to the LDT Final Rule (89 FR 37286).

SCG

Modified version of another manufacturer's FDA-authorized test within scope described in preamble to LDT Final Rule

When a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and meeting CLIA's regulatory requirements to perform high complexity testing modifies another manufacturer's 510(k) cleared or De Novo authorized test, and in compliance as described in section V.C.3 of the preamble to the LDT Final Rule, in a manner that could not significantly affect the safety or effectiveness of the test and does not constitute a major change or modification in intended use, and where the modified test is performed only in the laboratory making the modification as described in sections V.C.4 and V.C.5 of the preamble to the LDT Final Rule (89 FR 37286).

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

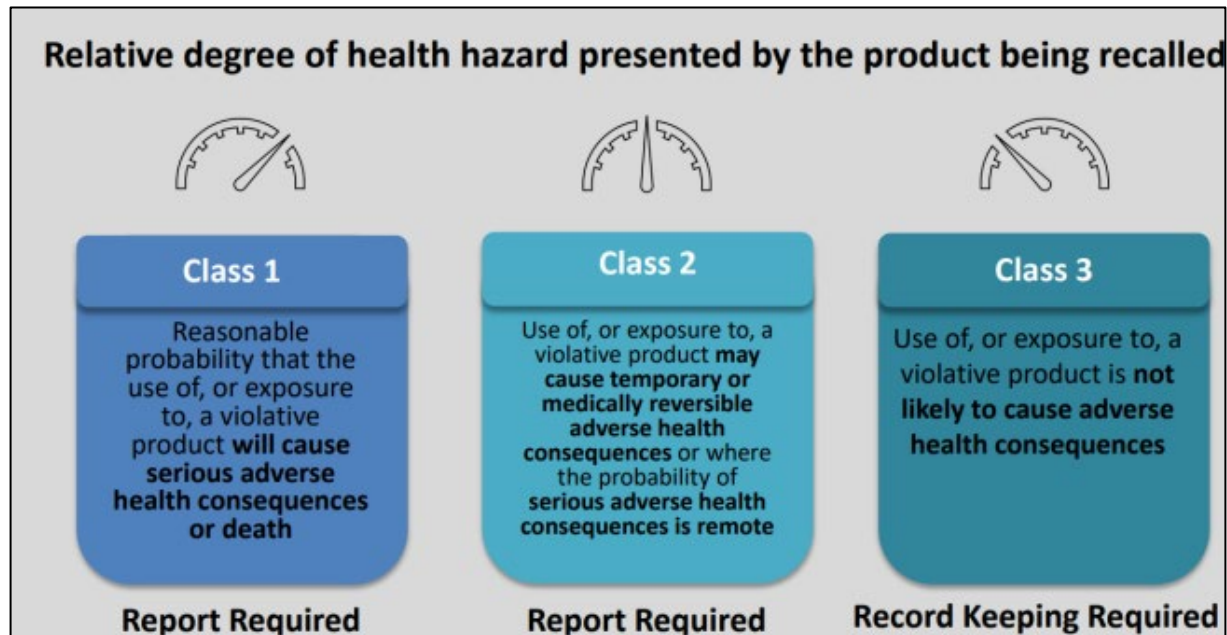
Has *malfunctioned* and that the device or a similar device marketed by the manufacturer would *be likely to cause or contribute to* a death or serious injury if the malfunction *were to recur*

?

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

