Distinguishing Medical Device Recalls from Medical Device Enhancements

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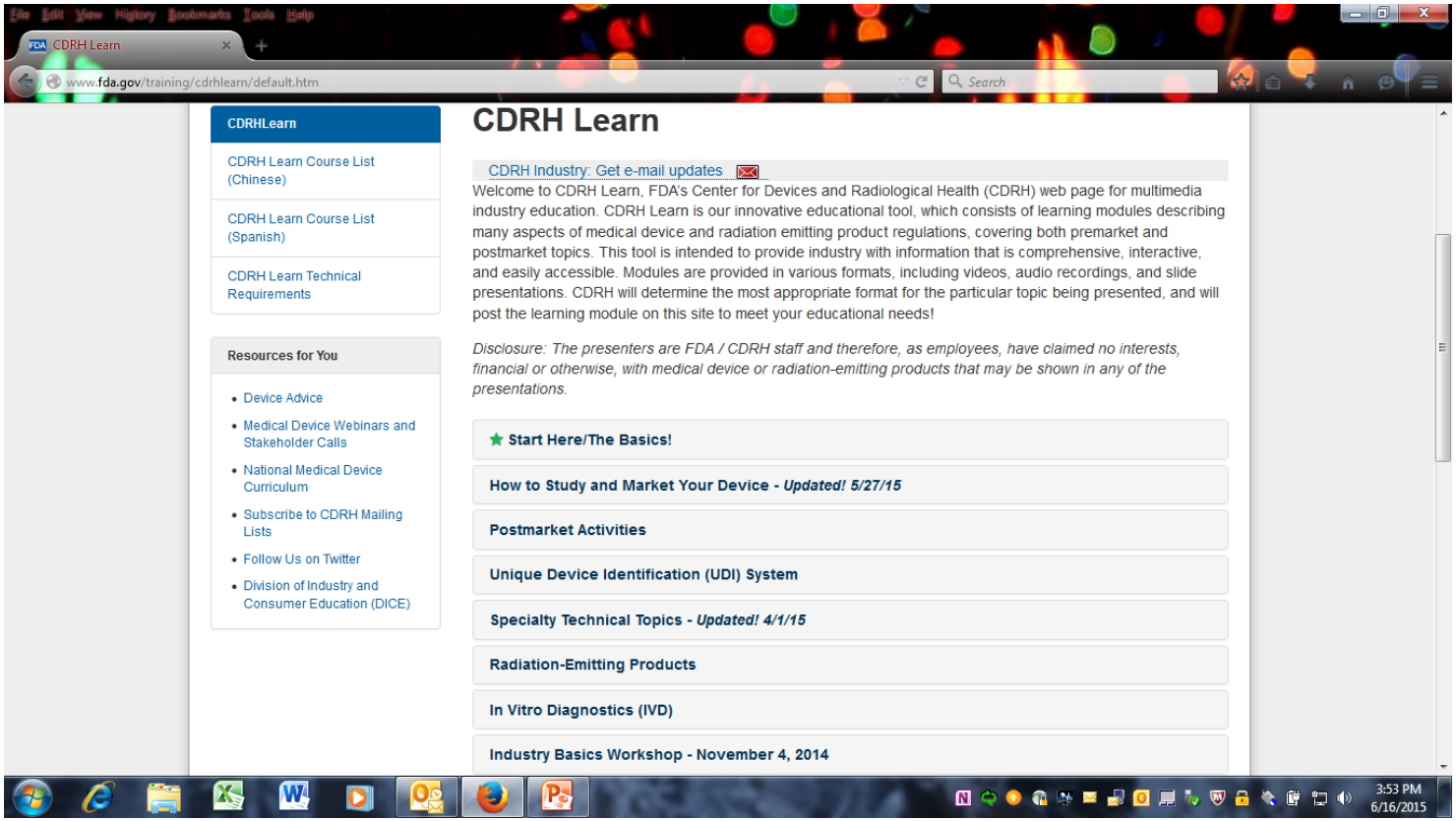
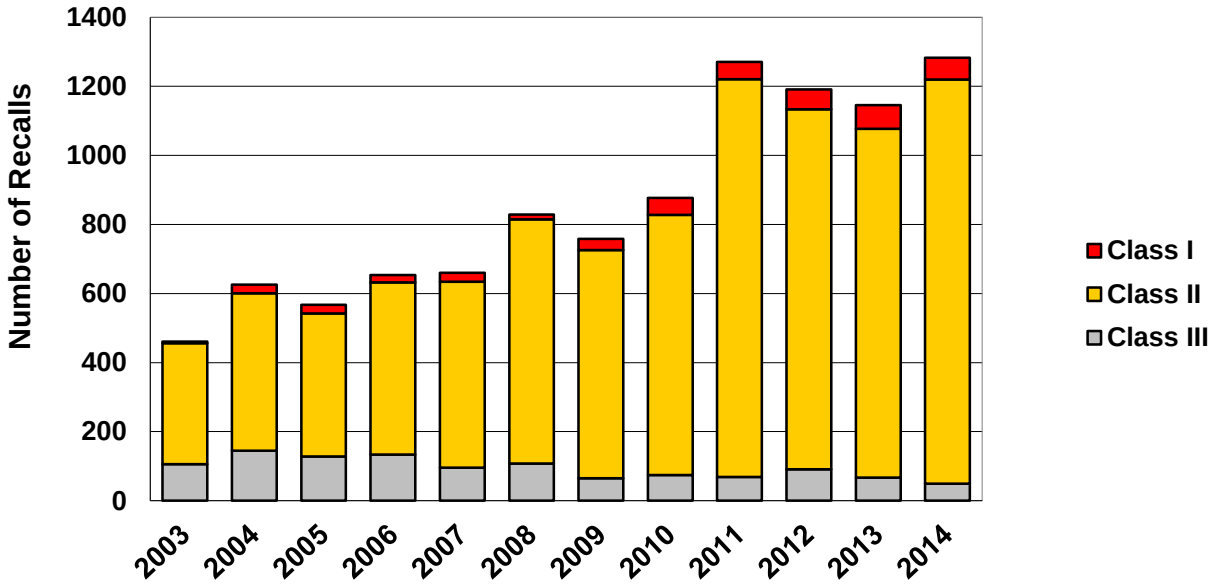
Objectives

- CDRH Recall Classifications and Trends
- Distinguishing Medical Device Recalls from Medical Device Enhancements

A gift from your government





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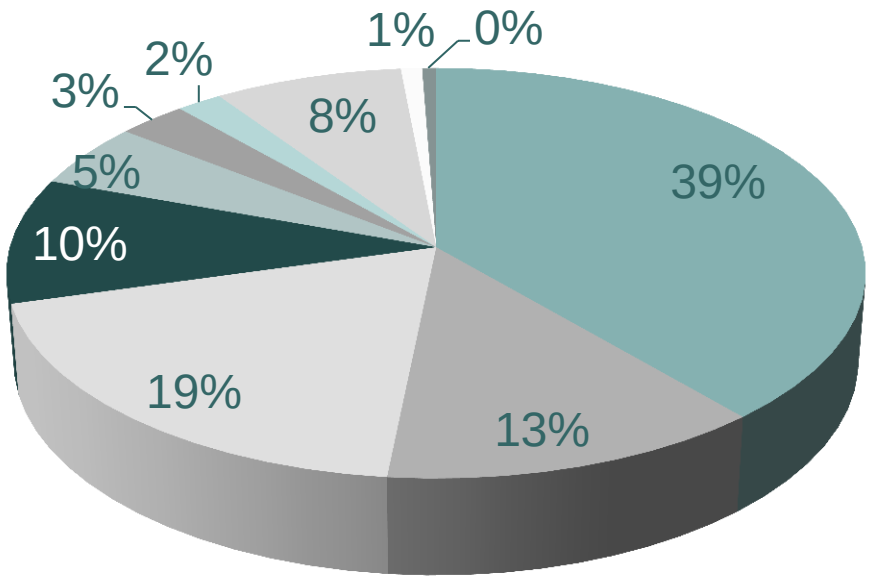
Class I	5	25	25	22	26	14	32	49	50	57	69	63
Class II	350	456	414	498	538	707	661	754	1152	1043	1010	1171
Class III	106	145	128	134	96	108	65	74	69	91	67	49
Total	**461**	**626**	**567**	**654**	**660**	**829**	**758**	**877**	**1271**	**1191**	**1146**	**1283**

Recall Regulatory Violations: 2014



Top Recall Regulatory Violations: 2014

Number	Regulation Subpart Title	Class I	Class II	Class III
820.30	Design controls	703	1,759	36
820.80	Receiving, in-process, and finished device acceptance	204	1,068	61
820.70	Production and process controls	119	830	58
820.90	Nonconforming product	17	415	28
820.75	Process Validation	16	390	30
820.50	Purchasing controls	19	366	29
820.130	Device packaging	0	377	5
820.120	Device labeling	2	271	29
820.25	Personnel	0	159	2
820.100	Corrective and preventive action	0	122	7

Distinguishing Medical Device Recalls from Enhancements

The guidance is intended to:

- Clarify when a change to a device constitutes a medical device recall
- Distinguish those instances from device enhancements
- Clarify reporting requirements under 21 CFR Part 806

Factors that do not apply

This guidance does not address nor apply to:

- whether a new premarket submission is required
- radiation-emitting electronic product defects or failures to comply with radiation safety performance standards contained in 21 CFR Parts 1020 to 1050
- methodologies for risk management or risk assessment

Recall Definition

- As defined at 21 CFR 7.3(g), “recall means a firm's **removal** or **correction** of a **marketed** device that the Food and Drug Administration considers to be in **violation** of the laws it administers and against which the agency would initiate legal action, e.g., seizure. Recall does not include a market withdrawal or a stock recovery.”
- Recall does not include routine servicing.
- Recall also does not include an enhancement, as defined by this guidance.

Enhancement Definition

A device enhancement is

- (1) a change to improve the performance or quality of a device; that is
- (2) *not* a change to remedy a violation of the FD&C Act.

Device enhancements include, but are not limited to, changes designed to better meet the needs of the user, changes to make the device easier to manufacture, changes to improve the device's safety or performance, and changes to the appearance of the device that do not affect its use.

What is the Violation?

- The key factor in distinguishing a medical device recall from an enhancement is the existence of a violation of the FD&C Act.

Differentiating Violative Devices from Non-Violative Devices

- Are the changes intended to resolve a failure to meet specifications or failure of the device to perform as intended?
- Is the labeling for the device to which you are considering making changes false or misleading, does it fail to have adequate directions for use, or does it include indications for use that are not cleared?
- Are you otherwise out of compliance with the FD&C Act or FDA regulations?

Comparison Example

- An in vitro diagnostics (IVD) device firm markets a test to detect the level of a specific antigen in blood.
- The device represents 95% sensitivity to the specific antigen.

Comparison Example (Recall)

- Two years after initial marketing, the firm determines that the device **sensitivity** to the specific antigen, as manufactured, **has decreased to 90%**; thus, not meeting performance specifications and making the device violative.
- As a result, the firm modifies the product in the field to “improve” the sensitivity from 90% to 95%.
- Because the firm’s actions are returning the product to the quality it was represented to possess, FDA would generally consider these actions a recall.

Comparison Example

- An in vitro diagnostics (IVD) device firm markets a test to detect the level of a specific antigen in blood.
- The device represents 95% sensitivity to the specific antigen.

Comparison Example (Enhancement)

- Two years after initial marketing, the firm **modifies the product to improve the sensitivity to the antigen from 95% to 98%.**
- This modification is determined to be an improvement to the safety and effectiveness of the device, and is determined to be unrelated to any known device violation.
- FDA would generally regard this action as a device enhancement, although it may require a regulatory submission.

806 Reporting Requirements

- Medical device enhancements do not require the submission of an 806 report.

Other Regulatory Considerations

- Once a determination has been made, whether the change represents a medical device recall or enhancement, additional regulatory obligations should be considered.

Important Factors

Reiterate: The guidance is not introducing anything new and only providing more clarity of FDA expectations. Note that this guidance…

- seeks to address concerns that firms may have about making enhancements
- applies to medical devices regulated by CDRH, whether or not they require or are exempt from premarket review
- does not alter current expectations regarding medical device recalls

Summary

- CDRH encourages firms to apply continuous process improvement
  - Enable product improvements for non-violative products
  - Reduce unnecessary paperwork and administrative workload
- The final guidance provides clarity to regulatory terms and definitions specific to medical device recalls and enhancements

Summary

- Correctly categorizing medical device recalls and medical device enhancements
  - Amplifies the likelihood that firms will appropriately determine when to report a recall
  - Fosters the likelihood that FDA would concur with industry decisions regarding device enhancements.

Summary

- Non-Violative devices may be enhanced
- Violative device may result in recalls
- No changes or impact to existing compliance program, CFRs, performance standards, or 510(k) requirements.
- Investigators should request to see any records for device enhancements, correction and removals, field notifications, etc.
- Please contact CDRH if you are unsure about whether something is reportable.

References and Websites

- 21 CFR Parts 7, 806, 810, and 820
- www.fda.gov
  - CDRH Learn: Recalls video and slide shows
  - Enforcement Report http://www.fda.gov/opacom/Enforce.html
  - Recalls & Safety Alerts – contains industry guidance
  - http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/default.htm (CDRH recalls site)
- Federal Register - June 16, 1978 - Part 7
- FDA Regulatory Procedures Manual, Chapter 7

Questions?

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