Recall Communication: Medical Device Model Recall Notification Letter
Ron Brown

SLIDE 1
Welcome to CDRH Learn. CDRH Learn is a training program developed by FDA's Center for Devices and Radiological Health, and is designed to bring you training on a wide range of topics that involve the regulation of and policies related to medical devices and radiation products.

I am Ron Brown, the Acting Recall Branch Chief, for the Division of Risk Management Operations. Today, I am going to discuss the Medical Device Model Recall Notification Letter

SLIDE 2
What are some of the Recall notification requirements for a company?
The recalling company is responsible for Promptly notifying each of its affected direct accounts that is, distributors, contractors, and customers, about a recall.

A recall communication can be in the form of a press release, telephone call, telegram, mailgram, or a first class letter. It is highly recommended that the recalling firm discuss a recall letter with their FDA district recall coordinator before issuing the notification.

The web addresses at the bottom of this slide are references for you to obtain further information.

SLIDE 3
What are some of the reasons for a company's notification?

-- To provide details regarding the product recall,

-- To supply information to help users identify the product, and

-- To minimize health consequences by providing instructions on what action or actions need to be taken.

SLIDE 4
-- Mark a First Class Letter and envelope, preferably in bold red type, with the words -- "URGENT Medical Device Recall."
Mark "Urgent" for all Class I and Class II recalls and, when appropriate, for Class III recalls.

-- Document all communication related to the notification.

SLIDE 5

Note that the Notification template is divided into sections. The sections are numbered for reference, but the numbers are not part of the notification.
The letter template, as shown here, has been broken into sections to make it easier to quickly get the information needed.

The section headers should be in bold text to provide an easier visual reference and consistency.

SLIDE 6

The Recall notification title must include:
-- the company Name
-- the date the notice is released
-- the words "URGENT Medical Device Recall" typed in capital letters,
-- and the product name, which must be prominently displayed.

SLIDE 7

Now let's discuss the Recall Notification Letter.

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SLIDE 8

Please follow the arrows as we go along. The Greeting to Customers is fairly straight forward and contains the basic information about the user. Also included in this section are details of who the company is and what device they are voluntarily recalling. This section should also include the identification information for the product in question, as well as details of any serious adverse events associated with the product. This information should be in bold text and include the number of injuries that have been reported to date.

The next section, indicated by the arrow, shows the Reason for the Voluntary Recall. This should provide as much detail regarding the issue as possible, including:

-- frequency of the failure occurrences,

-- the number of complaints received to date,

-- and any Adverse Events including what types of injuries have been seen as a result.

SLIDE 9

The next section references the footnotes located at the bottom of the slide to the left.

SLIDE 10

On this slide we would like to point out that recall notifications are recommended for Class I and II recalls. "Urgent" should be noted on both the letter and envelope as per 21 CFR 7.49(4)(b).

Please also note that for radiation emitting devices, the recall action is regulated under 21 CFR 1004, which requires manufacturers to bring the affected product to conformance at no charge to the user. This varies from the requirements of 21 CFR 806 for Medical Device recalls.

SLIDE 11

The next section is the Risk to Health and Actions to be taken by the Customer or User.

SLIDE 12

Risk to Health. The firm should provide a detailed description of what risk the device failure will pose to the user.

For example, what hazard is the likely outcome of the device failure? Is it an injury, a delay in therapy, inappropriate therapy, etc?

If the failure is detectable, be sure to highlight that in bold text for the user. Please provide the information in lay terms. Anything that helps the user recognize the failure early is good!

Our next Section -
"Actions to be taken by the Customer or User" should detail the steps the user or customer should take. For example: discontinue use of the product, discard it, or correct it.

At a bare minimum, these instructions should include treatment or actions to minimize risks, action to take pending corrective action, list of alternative products, instructions for any associated recalls, and the instructions for acknowledgement of the recall.

SLIDE 13

Next we have the Product Distribution and Actions taken by the Company section.

SLIDE 14

Our "Product Distribution" section contains the product identification information provided by the manufacturer.
This includes the Product Name, the manufacturer's product number, the lot or serial number, the manufactured or distribution dates, the quantity, and expiration date, if applicable.

The "Type of Action by the Company" section provides any actions that the manufacturer is taking to correct this issue. This includes actions such as providing a system update, market removal, or change in labeling. Also, provide details on when these actions will be taken and whether these are long term or short term corrections, any findings from the Failure Investigation should be provided here.

SLIDE 15
Our next section is reserved for other important information that has not been provided.

SLIDE 16
This section should include contact information for the user or customer. It should also list details for acknowledging receipt of the recall notification and provide information for reporting adverse events to the FDA.

SLIDE 17
Please remember that the format, content, and extent of the notification should correspond with the recall hazard and strategy.

SLIDE 18
A Notification letter should include a Return Response form that the customer can use to acknowledge receipt of the communication. It's key that customer or user have a means of responding and acknowledging that they received the notice and have taken appropriate action.

SLIDE 19
This slide provides examples of Inappropriate Information in a Recall Notification, such as:

-- Qualification data

-- Promotional materials, or

-- Any other statement that may detract from the message.

SLIDE 20
Notification Follow-up. Whenever necessary, additional communication should be sent to customers who fail to acknowledge receiving the initial notice.

SLIDE 21
This slide shows Consignee and Distributor Responsibilities.

Upon receipt of a recall notification, Consignees and Distributors should follow the instructions set forth by the recalling firm, and when necessary, extend the recall to its customers in accordance with the instructions provided by the firm.

SLIDE 22
In conclusion, notification letters must provide clear details regarding the issue and the health risk to users.

Information identifying affected products must be easy to find.

Actions to be taken by the users should be bulleted or numbered to clearly articulate the requirements needed to minimize the risk or impact of the affected product. And the notification should be sectioned to allow the user to quickly see the information needed.

SLIDE 23
If you have further questions regarding reporting requirements, contact your local FDA District Recall Coordinator or refer to the other sources listed on this slide.

Thank you.