Device Recalls 101 – Recall Classification

FDA classifies medical device recalls into three categories, representing the potential risk to public health: Class I, Class II, and Class III. This classification process usually takes place after the company has issued its recall.

- Class I - High Risk
- Class II - Less-Serious Risk
- Class III - Low Risk

FDA’s classification determines the number of checks the company has to make and the number of audits FDA will conduct to ensure the effectiveness of the recall action. It is intended to make sure that the company has followed through on its decision to implement the recall action.

The responsibility for an adequate recall belongs to the manufacturer. The decision and timing of FDA’s recall classification does not change or delay the company’s obligation to take appropriate action.

Class I Recall

A Class I recall is the most serious type of recall. In a Class I recall, there is a reasonable chance that the product will cause serious health problems or death.

In a Class I recall, the company:

- Notifies their customers (i.e. distributors or vendors), and directs them to notify the intended recipients of the device (i.e. other vendors, hospitals, nursing homes, outpatient treatment facilities, doctors, or individual patients). The notification usually contains the name of the device being recalled, identifying lot or serial numbers, the reason for the
recall, and instructions about how to correct, avoid, or minimize the problem. It should also provide a telephone number for questions related to the recall.

- Issues a press release to notify the public, if appropriate to minimize health consequences.

FDA may also issue its own press release or public health notice.

**Class I Recall Example - Zoll Medical**

<table>
<thead>
<tr>
<th>Date Recall Initiated</th>
<th>February 12, 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Posted</td>
<td>April 01, 2009</td>
</tr>
<tr>
<td>Recall Number</td>
<td>Z-1206-2009</td>
</tr>
<tr>
<td>Product</td>
<td>Zoll AED Plus Defibrillator</td>
</tr>
<tr>
<td>Code Information</td>
<td>Serial numbers below X_ _ _200000</td>
</tr>
<tr>
<td>Recalling Firm/Manufacturer</td>
<td>ZOLL Medical Corporation</td>
</tr>
<tr>
<td></td>
<td>World Wide Headquarters</td>
</tr>
<tr>
<td></td>
<td>269 Mill Rd</td>
</tr>
<tr>
<td></td>
<td>Chelmsford, Massachusetts 01824</td>
</tr>
<tr>
<td>Reason For Recall</td>
<td>Device fails to discharge the defibrillation energy.</td>
</tr>
<tr>
<td>Action</td>
<td>On 3/31/09, the firm revised their recall strategy and required all users to perform a &quot;Mandatory Upgrade&quot; software The software upgrade allows all potentially affected devices to monitor battery charging performance through periodic self-testing. If defective batteries are detected at any time prior to the recommended maximum of five years, users are prompted by the device to install fresh batteries. Firm issued Press Release on April 2,</td>
</tr>
</tbody>
</table>
2009.

In the first notification Zoll notified customers by letter on 2/12/09 via certified mail. Customers instructed to replace device batteries every three years. In lieu of replacing batteries every three years, customers will also have the choice to update their devices with software that will monitor batteries for the identified defect.

ZOLL will be send email notification to all consignees who have provided an email address as part of their contact information. ZOLL will also be publishing information of the notification on industry magazines.

- Quantity in Commerce 183,535 units
- Distribution Worldwide distribution

**Class II Recall**

A Class II recall usually represents a less-serious risk than a Class I recall. In a Class II recall, there is either a possibility that the device will cause temporary or reversible health problems, or there is a remote chance that the device will cause serious health problems.

In a Class II recall, the company notifies their customers (i.e. distributors or vendors) and sometimes asks them to notify the intended recipients of the device. FDA generally does not issue a press release or expect the company to issue a press release for Class II recalls, unless there is a specific need to do so (for example, if the device could affect the health of a large number of people, if patients need more information, or if the recalling company could not reach every intended recipient).
Class II Recall Example - Boston Scientific

- **Date Recall Initiated**: March 04, 2009
- **Date Posted**: July 17, 2009
- **Recall Number**: Z-1620-2009
- **Product**: Guidant Contak Renewal 3 CRT-D Model H170; 3CRT-D, Model H175; 3HE CRT-D, Model H177; 3HE CRT-D, Model H179; 4CRT-D REF H190; 4CRT-D REF H195; 4HE CRT-D REF H197; 4HE CRT-D REF H199; 4AVT CRT-D, REF M177; 4AVT HE CRT-D REF 179. Cardiac Resynchronization Therapy Defibrillator, Sterile EO, Guidant Corporation, 4100 Hamline Avenue North, St Paul, MN 55112-5798.

Indicated for patients who are at risk for sudden cardiac death due to ventricular arrhythmias and may require pacing support.

- **Code Information**: SERIAL NUMBERS FOR MODEL #H170 : 361904, 363420, 363895, 364293, 364294, 364349, 364350, 364470, 364480, 364485, 364494, 364510, 364539, 364617 and 364621; and ...

- **Recalling Firm/Manufacturer**: Boston Scientific CRM Corp
  4100 Hamline Ave N
  Saint Paul, Minnesota 55112-5700

- **Reason For Recall**: In April 2007, Boston Scientific CRM communicated with physicians regarding the potential for reduced Elective Replacement Indicator (ERI) to Battery End of Life (EOL) time in a subset of implantable defibrillators due to degradation of a low-voltage capacitor. Since that time, the April 2007 advisory population has not experienced any clinically significant
changes to either the rate of occurrence

- **Action**

  A Boston Scientific "Product Advisory" letter dated March 4, 2009, was also made available to physicians to distribute to patients. The letter informed the patient that their defibrillator was included in a group of devices that might experience a performance issue.

  For further questions, Contact Boston Scientific CRM at 1-800-227-3422.

- **Quantity in Commerce**
  112

- **Distribution**
  Worldwide Distribution

**Class III Recall**

A Class III recall represents a less-serious risk than a Class II recall. In a Class III recall, there is little chance that using or being exposed to the device will cause health problems. However, because the product violates FDA law, there is still a need to take an action to address the problem.

In a Class III recall, the company notifies their customers (i.e. distributors or vendors). FDA would not issue a press release, and it would not expect the company to issue a press release.
Class III Recall Example – St Jude Medical

- **Date Recall Initiated**: March 23, 2009
- **Date Posted**: June 12, 2009
- **Recall Number**: Z-1422-2009
- **Recalling Firm/Manufacturer**: St. Jude Medical 575 Route 73 North, Bldg D Cooper Run Executive Park West Berlin, New Jersey 08091
- **Consumer Instructions**: Contact the recalling firm for information
- **For Addition Information**: Contact Angela Craig 856-753-8533
- **Reason For Recall**: Non-compliance with IEC Standard 60601-1 Clause 57.6 relative to fusing of AC input line. The neutral line is not fused. The hot line in fused. Clause 57.6 calls for both lines to be fused.
- **Action**: All foreign customers were sent Urgent Product
Safety Information letters on March 23, 2009. Letters described units affected, the reason for action, and the actions to take to eliminate risk. It is recommended that the information in the letter be circulated to all users, risk managers and the biomedical engineering department responsible for maintaining and inspecting electrical equipment located within their institution. The letter also stated that a SJM representative will be in touch to perform the EP-4 Stimulator fuse modification. Customers are to complete and return the attachment.

- **Quantity in Commerce**
  694 total (US, Canada, and OUS)

- **Distribution**
  Worldwide distribution