

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## NUCLEAR REGULATORY COMMISSION

### 10 CFR Part 40

[NRC–2009–0079 and NRC–2011–0080]

RIN 3150–A150

### Domestic Licensing of Source Material—Amendments/Integrated Safety Analysis; Correction

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Extension of public comment period and public meeting; correction.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is correcting a notice appearing in the **Federal Register** on July 27, 2011 (76 FR 44865), that extended the public comment period and provided a date for a public meeting for the proposed rule, “Domestic Licensing of Source Material—Amendments/Integrated Safety Analysis.” This action is necessary to correct the date of the public meeting in the **DATES** section, and to correct the Docket ID information for accessing publicly available documents related to the proposed rule and draft guidance document in the **ADDRESSES** section.

**FOR FURTHER INFORMATION CONTACT:** Cindy Bladey, Chief, Rules, Announcements and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–492–3667 or e-mail: [Cindy.Bladey@nrc.gov](mailto:Cindy.Bladey@nrc.gov).

**SUPPLEMENTARY INFORMATION:** On page 44865 of **Federal Register** document 2011–14060, published July 27, 2011 (76 FR 44865), in the third column, under the section titled **DATES**, second paragraph, “August 7, 2011” is corrected to read “August 17, 2011.” Also, on page 44866 of the same document, in the first column, the last bulleted item before the section titled **FOR FURTHER INFORMATION CONTACT** is removed and the following bulleted item is added in its place:

- *Federal Rulemaking Web site:* Public comments and supporting

materials related to the proposed rule and proposed draft guidance document can be found at <http://www.regulations.gov> by searching on Docket ID NRC–2009–0079 for the proposed rule and Docket ID NRC–2011–0080 for the proposed draft guidance document.

Dated at Rockville, Maryland, this 29th day of July 2011.

For the Nuclear Regulatory Commission,  
**Cindy Bladey,**

*Chief, Rules, Announcements and Directives Branch, Division of Administrative Services, Office of Administration.*

[FR Doc. 2011–19726 Filed 8–3–11; 8:45 am]

**BILLING CODE 7590–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 870

[Docket No. FDA–2011–N–0526]

### Effective Date of Requirement for Premarket Approval for a Pacemaker Programmer

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the class III preamendments device pacemaker programmers. The agency is also summarizing its proposed findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring this device to meet the statute’s approval requirements and the benefits to the public from the use of the devices. In addition, FDA is announcing the opportunity for interested persons to request that the agency change the classification of the aforementioned device based on new information. This action implements certain statutory requirements.

**DATES:** Submit either electronic or written comments by November 2, 2011. Submit requests for a change in classification by August 19, 2011. FDA intends that, if a final rule based on this proposed rule is issued, anyone who

wishes to continue to market the device will need to submit a PMA within 90 days of the effective date of the final rule. Please see section XII of this document for the effective date of any final rule that may publish based on this proposal.

**ADDRESSES:** You may submit comments, identified by [Docket No. FDA–2011–N–0526], by any of the following methods:

#### Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

#### Written Submissions

Submit written submissions in the following ways:

- *Fax:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

*Instructions:* All submissions received must include the agency name and Docket Number and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the Comments heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number(s), found in brackets in the heading of this document, into the Search box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Elias Mallis, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 1538, Silver Spring, MD 20993, 301–796–6216.

**SUPPLEMENTARY INFORMATION:**