Food and Drug Administration, HHS

§ 898.13

Paragraph prevents a manufacturer, distributor, or retailer from sponsoring or causing to be sponsored any athletic, musical, artistic, or other social or cultural event, or team or entry, in the name of the corporation which manufactures the tobacco product, provided that both the corporate name and the corporation were registered and in use in the United States prior to January 1, 1995, and that the corporate name does not include any brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.

PART 898—PERFORMANCE STANDARD FOR ELECTRODE LEAD WIRES AND PATIENT CABLES

§ 898.11 Applicability.

Electrode lead wires and patient cables intended for use with a medical device shall be subject to the performance standard set forth in §898.12.

§ 898.12 Performance standard.

(a) Any connector in a cable or electrode lead wire having a conductive connection to a patient shall be constructed in such a manner as to comply with subclause 56.3(c) of the following standard:

International Electrotechnical Commission (IEC)

601-1: Medical Electrical Equipment


Amendment No. 1 (1991)

Amendment No. 2 (1995).

(b) Compliance with the standard shall be determined by inspection and by applying the test requirements and test methods of subclause 56.3(c) of the standard set forth in paragraph (a) of this section.

§ 898.13 Compliance dates.

The dates for compliance with the standard set forth in §898.12(a) shall be as follows:

(a) For electrode lead wires and patient cables used with, or intended for use with, the following devices, the date for which compliance is required is May 11, 1998:

<table>
<thead>
<tr>
<th>Phase</th>
<th>Product code</th>
<th>21 CFR section</th>
<th>Class</th>
<th>Device name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>73 BZQ</td>
<td>868.2375</td>
<td>II</td>
<td>Monitor, Breathing Frequency.</td>
</tr>
<tr>
<td>1</td>
<td>73 FLS</td>
<td>868.2375</td>
<td>II</td>
<td>Monitor (Apnea Detector), Ventilatory Effort.</td>
</tr>
<tr>
<td>1</td>
<td>74 DPS</td>
<td>870.2340</td>
<td>II</td>
<td>Electrocardiograph.</td>
</tr>
<tr>
<td>1</td>
<td>74 DRG</td>
<td>870.2910</td>
<td>II</td>
<td>Transmitters and Receivers, Physiological Signal, Radio Frequency.</td>
</tr>
<tr>
<td>1</td>
<td>74 DRT</td>
<td>870.2300</td>
<td>II</td>
<td>Monitor, Cardiac (including Cardiotachometer and Rate Alarm).</td>
</tr>
<tr>
<td>1</td>
<td>74 DRX</td>
<td>870.2360</td>
<td>II</td>
<td>Electrode, Electrocardiograph.</td>
</tr>
<tr>
<td>1</td>
<td>74 DSA</td>
<td>870.2900</td>
<td>II</td>
<td>Cable, Transducer and Electrode, Patient (including Connector).</td>
</tr>
<tr>
<td>1</td>
<td>74 DSH</td>
<td>870.2800</td>
<td>II</td>
<td>Recorder, Magnetic Tape, Medical.</td>
</tr>
<tr>
<td>1</td>
<td>74 DSI</td>
<td>870.1025</td>
<td>III</td>
<td>Detector and Alarm, Arrhythmia.</td>
</tr>
<tr>
<td>1</td>
<td>74 DXH</td>
<td>870.2920</td>
<td>II</td>
<td>Transmitters and Receivers, Electrocardiograph, Telephone.</td>
</tr>
</tbody>
</table>

(b) For electrode lead wires and patient cables used with, or intended for use with, any other device, the date for which compliance is required is May 9, 2000.
§ 898.14 Exemptions and variances.

(a) A request for an exemption or variance shall be submitted in the form of a petition under § 10.30 of this chapter and shall comply with the requirements set out therein. The petition shall also contain the following:

(1) The name of the device, the class in which the device has been classified, and representative labeling showing the intended uses(s) of the device;

(2) The reasons why compliance with the performance standard is unnecessary or unfeasible;

(3) A complete description of alternative steps that are available, or that the petitioner has already taken, to ensure that a patient will not be inadvertently connected to hazardous voltages via an unprotected patient cable or electrode lead wire for intended use with the device; and

(4) Other information justifying the exemption or variance.

(b) An exemption or variance is not effective until the agency approves the request under § 10.30(e)(2)(i) of this chapter.

Effective Date Note: At 62 FR 25477, May 9, 1997, § 898.14 was stayed pending Office of Management and Budget clearance for information collection.
SUBCHAPTER I—MAMMOGRAPHY QUALITY STANDARDS ACT

PART 900—MAMMOGRAPHY

Subpart A—Accreditation

§ 900.1 Scope.
The regulations set forth in this part implement the Mammography Quality Standards Act (MQSA) (42 U.S.C. 263b). Subpart A of this part establishes procedures whereby an entity can apply to become a Food and Drug Administration (FDA)-approved accreditation body to accredit facilities to be eligible to perform screening or diagnostic mammography services. Subpart A further establishes requirements and standards for accreditation bodies to ensure that all mammography facilities under the jurisdiction of the United States are adequately and consistently evaluated for compliance with national quality standards for mammography. Subpart B of this part establishes minimum national quality standards for mammography facilities to ensure safe, reliable, and accurate mammography. The regulations set forth in this part do not apply to facilities of the Department of Veterans Affairs.

§ 900.2 Definitions.
(a) Accreditation body or body means an entity that has been approved by FDA under § 900.3(d) to accredit mammography facilities.
(b) Action limits or action levels means the minimum and maximum values of a quality assurance measurement that can be interpreted as representing acceptable performance with respect to the parameter being tested. Values less than the minimum or greater than the maximum action limit or level indicate that corrective action must be taken by the facility. Action limits or levels are also sometimes called control limits or levels.
(c) Adverse event means an undesirable experience associated with mammography activities within the scope of 42 U.S.C. 263b. Adverse events include but are not limited to:
(1) Poor image quality;
(2) Failure to send mammography reports within 30 days to the referring physician or in a timely manner to the self-referred patient; and
(3) Use of personnel that do not meet the applicable requirements of § 900.12(a).
(d) Air kerma means kerma in a given mass of air. The unit used to measure the quantity of air kerma is the Gray (Gy). For X-rays with energies less than 300 kiloelectron volts (keV), 1 Gy