

Item No.	Title of Standard	Reference No. and Date
30	Medical Electrical Equipment—Part 1–2: General Requirements for Safety—Collateral Standard: Electromagnetic Compatibility—Requirements and Tests.	ANSI/AAMI/IEC 60601–1–2:2001
31	Symbols to be used with medical device labels, labeling and information to be supplied.	ISO 15223:2000
32	Graphical symbols for use in the labeling of medical devices.	EN 980:1996+A1:1999+A2:2001
55	Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging.	ASTM F2182–02

D. Tissue Engineering

Item No.	Title of Standard	Reference No. and Date
1	Standard Guide for Characterization and Testing of Alginates as Starting Materials Intended for Use in Biomedical and Tissue-Engineered Medical Products Application.	ASTM F2064:2000
2	Standard Guide for Characterization and Testing of Chitosan Salts as Starting Materials Intended for Use in Biomedical and Tissue-Engineered Medical Product Applications.	ASTM F2103:2001

IV. List of Recognized Standards

FDA maintains the agency's current list of "FDA Recognized Consensus Standards" in a searchable database that may be accessed directly at FDA's Internet site at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>. FDA will incorporate the modifications and minor revisions described in this notice into the database and, upon publication in the **Federal Register**, this recognition of consensus standards will be effective. FDA will announce additional modifications and minor revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often, if necessary.

V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under the new provision of section 514 of the act by submitting such recommendations, with reasons for the recommendation, to the contact person (see **FOR FURTHER INFORMATION CONTACT**). To be properly considered, such recommendations should contain, at a minimum, the following information: (1) Title of the standard, (2) any reference number and date, (3) name and address of the national or international standards development organization, (4) a proposed list of devices for which a declaration of

conformity to this standard should routinely apply, and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

VI. Electronic Access

In order to receive "Guidance on the Recognition and Use of Consensus Standards" via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number 321 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

You may obtain a copy of "Guidance on the Recognition and Use of Consensus Standards" by using the Internet. CDRH maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes this guidance as well as the current list of recognized standards and other standards related documents. After publication in the **Federal Register**, this notice announcing "Modifications to the List of Recognized Standards, Recognition List Number: 008" will be available on the CDRH home page. You may access the CDRH home page at <http://www.fda.gov/cdrh>.

www.fda.gov/cdrh. You may access "Guidance on the Recognition and Use of Consensus Standards," and the searchable data base for "FDA Recognized Consensus Standards," through hyperlinks at <http://www.fda.gov/cdrh/stdsprog.html>. This **Federal Register** notice of modifications in FDA's recognition of consensus standards will be available, upon publication, at <http://www.fda.gov/cdrh/fedregin.html>.

VII. Submission of Comments and Effective Date

Interested persons may submit to the contact person (see **FOR FURTHER INFORMATION CONTACT**) written or electronic comments regarding this document. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Identify comments with the docket number found in brackets in the heading of this document. FDA will consider any comments received in determining whether to amend the current listing of "Modifications to the List of Recognized Standards, Recognition List Number: 008." These modifications to the list of recognized standards are effective upon publication of this notice.