Inspection of Medical Device Manufacturers: Part VI References and Program Contacts

A. Applicable References

1. Guide to Inspections of Quality Systems, August 1999
2. Code of Federal Regulations, Title 21, Part 7, Subpart C, **Recalls**.
   Code of Federal Regulations, Title 21, Part 11, **Electronic Records and Electronic Signatures**.
   Code of Federal Regulations, Title 21, Parts 16 and 17, **Hearing Procedures**.
   Code of Federal Regulations, Title 21, Part 800, Subpart C, **Administrative Detention**.
   Code of Federal Regulations, Title 21, Part 803, **Medical Device Reporting**.
   Code of Federal Regulations, Title 21, Part 806, **Reports of Corrections and Removals**.
   Code of Federal Regulations, Title 21, Part 807, **Establishment Registration and Device Listing**.
   Code of Federal Regulations, Title 21, Part 809.10, **Labeling For In Vitro Diagnostic Devices**.
   Code of Federal Regulations, Title 21, Part 810, **Medical Device Recall Authority**.
   Code of Federal Regulations, Title 21, Part 820, **Current Good Manufacturing Practices/Quality System Regulation**.
   Code of Federal Regulations, Title 21, Part 821, **Tracking Requirements**.
   Code of Federal Regulations, Title 21, Parts 1000-1050, **Radiation Regulations and Standards**.
3. Federal Food, Drug, and Cosmetic Act, As Amended
4. Investigations Operations Manual (IOM) - Chapter 5, Subchapter 5.6, Devices
5. Biotechnology Inspection Guide, Reference Materials and Training Aids, November 1991
6. Medical Device Quality Systems Manual: A Small Entity Compliance Guide, HHS Pub. No. FDA 97-4179, December 1996
7. Calibration and Related Measurement Services of the National Institute of Standards & Technology, NIST Special Publication 250, National Institute of Standards & Technology, U.S. Department of Commerce, Washington, D.C. 20234.
8. Quality Management Systems - Process Validation Guidance, GHTF/SG3/N99-10:2004 Edition 2
9. Implementation of Risk Management Principles and Activities Within a Quality Management System, GHTF/SG3/N15R8/2005
10. Intercenter Agreement Between the Center for Biologics Evaluation and Research and the Center for Devices and Radiological Health, October 31, 1991
11. Glossary of Computerized System and Software Development Terminology, August 1995
12. Juran's Quality Handbook, Joseph Dufeo and J.M. Juran, 6th edition, McGraw-Hill, 2010.
13. AQL Inspector's Rule and Manual. This special purpose plastic slide rule that rigidly adheres to ANSI/ASQ Z1.4 can be obtained from INFO P.O. Box 58, Stillriver, MA. 01467. Phone (978) 456-3848. Cost is approximately $25 plus shipping cost for rule and manual.
14. Medical Device Reporting for Manufacturers, March 1997

15. Do It By Design: An Introduction to Human Factors in Medical Devices, December 1996
16. The FDA and Worldwide Quality System Requirements Guidebook for Medical Devices, 2nd Edition, Daniel Amiram and Edward Kimmelman, ASQ Quality Press, Milwaukee, Wisconsin, 2008.
17. Design Control Guidance for Medical Device Manufacturers, March 1997
18. Compliance Guide for Laser Products, June 1992
19. Guide to Inspections of Electromagnetic Compatibility Aspects of Medical Device Quality Systems, December 1997
20. Medical Glove Guidance Manual, January 22, 2008
21. Guidance for Industry and for FDA Staff: Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals, August 14, 2000

Copies of CDRH QS publications and FDA guidance documents are available from the Division of Industry and Consumer Education (DICE).
Telephone: 800-638-2041
FAX 301-847-8149
Email at: dice@fda.hhs.gov
Many of these publications are also available in the CDRH Good Guidance Practices (GGP) Database.

Sources to obtain copies free of charge:
Internet: FDA, CDRH, and ORA maintain web sites for easy access to information.

Good Guidance Practices (GGP) Database: This is a searchable database that contains all current CDRH guidance documents and provides links to the documents.

Applicable References - Specific To Sterilization

The following sources may be referenced for further guidance regarding sterilization processes

Food and Drug Administration:

Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices, December 1987 (document retired)

Updated 510(k) Sterility Review Guidance K90-1; Guidance for Industry and FDA, August 30, 2002

A searchable database of FDA-recognized standards

A list of FDA-recognized standards related to sterilization of medical devices can be obtained by searching on the category “Sterility.”

United States Pharmacopeia (USP)/National Formulary (NF), current edition:

U.S. Pharmacopeial Convention, Inc.
12601 Twinbrook Parkway
Rockville, Maryland 20852
http://www.usp.org
http://www.uspnf.com (USP/NF Online)

- <61> Microbial Limit Tests
- <71> Sterility Tests
- <85> Bacterial Endotoxins Test (LAL)
- <151> Pyrogen Test (USP Rabbit Test)

- <161> Transfusion and Infusion Assemblies and Similar Medical Devices
- <1211> Sterilization and Sterility Assurance of Compendial Articles
- <1035> Biological Indicators for Sterilization
- <55> Biological Indicator - Resistance Performance Tests
- Biological Indicator for Dry-heat Sterilization, Paper Carrier
- Biological Indicator for Ethylene Oxide Sterilization, Paper Carrier
- Biological Indicator for Steam Sterilization, Paper Carrier
- Biological Indicator for Steam Sterilization, Self-Contained

B. Program Contacts

ORA Contacts

Topic	ORA Contact
Questions regarding inspectional requirements and/or technical assistance	Division of Domestic Field Investigations Medical Device Group Telephone: (301) 827-5638
Questions about accessing or connecting to the CDRH Center Information Retrieval System (CIRS)	Employee Resource & Information Center (ERIC) Telephone: (301) 827-ERIC (3742) The current procedure for ORA is to request access to enhanced CIRS via ERIC. OITCDRH will: 1) create an Oracle account, 2) enter user's name to a table that is used by the single sign-on, and 3) install the Jinitiator. After these three things are completed, user can access enhanced CIRS through the enhanced CIRS link in the CenterNet.
Questions regarding sampling of devices and laboratory capabilities	Lawrence D Hoostelaere Division of Field Science (DFS), HFC-141 Telephone: (301) 827-1032 WEAC contacts for testing medical devices: Joseph Matrisciano, Jr. Engineering Branch Chief, HFR-NE480 Telephone: (781) 756-9705 Pamela Mackill Analytical Branch Chief, HFR-NE460 Telephone: (781) 756-9704 Brian Baker WEAC Center Director, HFR-NE400 Telephone: (781) 756-9701

Questions regarding COMSTAT	GWQAP@fda.hhs.gov Contact GWQAP Team Leader in Office of Enforcement

CDRH Contacts

NOTE: Refer to the CDRH/OC and OIVD Organizational Charts Attachment A and B respectively, to identify the unit within OC or OIVD that is responsible for the type of device for which you have a question or need guidance.

Topic	**CDRH Contact**
MDR Regulation Interpretation and Policy Questions	MDR Policy Branch Division of Postmarket Surveillance Office of Surveillance and Biometrics (OSB) Email: Telephone: (301) 796-6670 Fax: (301) 847-8135 (call or send email alert if sending a fax)
Data retrieval of MDR reports	Information and Analysis Branch Division of Postmarket Surveillance, OSB Email:MDR.Requests@cdrh.fda.gov
Questions regarding sampling and/or testing of general medical devices	Kevin Milne Office of Science and Engineering Laboratories Telephone: (301) 796-2516 Email: kevin.milne@fda.hhs.gov
Express Mail Address for All Regulatory Action Recommendations	Field Operations Branch Office of Compliance Center for Devices and Radiological Health 10903 New Hampshire Avenue Silver Spring, Maryland 20993-0002
Questions regarding the interpretation and applicability of the device Quality System regulation and GMP exemptions	Deputy Director for Regulatory Affairs Office of Compliance Telephone: (301) 796-5500 Jan Welch Quality System/IVD Expert Telephone: (301) 796-5776 Email: jan.welch@fda.hhs.gov
Questions regarding the reprocessing of single-use devices	Deputy Director for Regulatory Affairs Office of Compliance Telephone: (301) 796-5500
Questions regarding compliance of medical device software, quality system software, or production/manufacturing equipment software	John F. Murray, Jr. Software Compliance Expert Telephone: (301) 796-5543

Questions regarding Electronic Records and Electronic Signatures	Email: john.murray@fda.hhs.gov
Questions regarding sterilization	Check CDRH web site for current list of experts.
Questions regarding potential or proposed regulatory actions should be directed to the CDRH/OC Field Liaison	David Kalins Office of Compliance Telephone: (301) 796-6612 Email: david.kalins@fda.hhs.gov
Questions regarding compliance issues concerning in vitro diagnostic devices	James Woods Deputy Director, Patient Safety and Product Quality Office of In Vitro Diagnostic Devices Telephone: (301) 796-6225 Email:james.woods@fda.hhs.gov

FDA Websites

- **FDA Homepage**
- **About the Office of Regulatory Affairs**
- **About the Center for Devices and Radiological Health**
- **Mandatory Reporting Requirements: Manufacturers, Importers and Device User Facilities**
- **MedWatch: The FDA Safety Information and Adverse Event Reporting Program** Find clinically important safety information and report serious problems with human medical products.
- **QSIT Guide**
- **FDA Recognized Standards**
  NOTE: A list of FDA-recognized standards related to sterilization of medical devices can be obtained by searching on the category "Sterility."
- **Intercenter Agreement Between the Center for Biologics Evaluation and Research and the Center for Devices and Radiological Health**
- **Part 11, Electronic Records; Electronic Signatures — Scope and Application**
- **Medical Device Tracking - Guidance for Industry and Food and Drug Administration Staff**169
- **Registration and Listing Database**
- **Establishment Registration Database**
- **Device Listing Database**

- **Electronic Product Radiation Control Program** Getting a Product to Market, Regulations, Guidance
- **Reprocessing of Single-Use Devices**
- **Guidance for Industry and for FDA Staff. Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals**
- **Product Code Classification Database**
- **Good Guidance Practices Database**