

PART VI

REFERENCES AND PROGRAM CONTACTS

A. APPLICABLE REFERENCES

1. Guide to Inspections of Quality Systems, August 1999
(<http://www.fda.gov/downloads/ICECI/Inspections/UCM142981.pdf>)
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
(<http://www.fda.gov/opacom/laws/fdact/fdctoc.htm>)
4. Investigations Operations Manual (IOM) - Chapter 5, Subchapter 5.6, Devices
(http://www.fda.gov/ora/inspect_ref/iom/)
5. Biotechnology Inspection Guide, Reference Materials and Training Aids, November 1991
(<http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074181.htm>)
6. Medical Device Quality Systems Manual: A Small Entity Compliance Guide, HHS Pub. No. FDA 97-4179, December 1996 (<http://www.fda.gov/cdrh/dsma/gmpman.html>)
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
(http://www.ghtf.org/documents/sg3/sg3_fd_n99-10_edition2.pdf)
 9. Implementation of Risk Management Principles and Activities Within a Quality Management System, GHTF/SG3/N15R8/2005
(<http://www.ghtf.org/documents/sg3/sg3n15r82005.pdf>)
 10. Intercenter Agreement Between the Center for Biologics Evaluation and Research and the Center for Devices and Radiological Health, October 31, 1991
(<http://www.fda.gov/CombinationProducts/JurisdictionalInformation/ucm121175.htm>)
 11. Glossary of Computerized System and Software Development Terminology, August 1995
(<http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074875.htm>)
 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. Information regarding the AQL Inspector's Rule and Manual can be found at the following web site: <http://www.aqlinspectorsrule.com>
 14. Medical Device Reporting for Manufacturers, March 1997
(<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094529.htm>)
 15. Do It By Design: An Introduction to Human Factors in Medical Devices, December 1996
(<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm095061.pdf>)
 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

- (<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070642.pdf>)
18. Compliance Guide for Laser Products, June 1992
(<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095304.pdf>)
 19. Guide to Inspections of Electromagnetic Compatibility Aspects of Medical Device Quality Systems, December 1997
(<http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074885.htm>)
 20. Medical Glove Guidance Manual, January 22, 2008
(<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073359.pdf>)
 21. Guidance for Industry and for FDA Staff: Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals, August 14, 2000
(<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm107164.htm>)

Copies of CDRH QS publications and FDA guidance documents are available from the Division of Small Manufacturers International and Consumer Assistance (DSMICA), Telephone: 800-638-2041 or FAX 301-847-8149 or Email at: dsmica@fda.hhs.gov. Many of these publications are also available in the CDRH Good Guidance Practices (GGP) Database (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>).

Sources to obtain copies free of charge:

Internet (World Wide Web): FDA, CDRH, and ORA maintain web sites for easy access to information. The FDA home page is <http://www.fda.gov>; the CDRH home page is <http://www.fda.gov/cdrh/>; and the ORA home page is <http://www.fda.gov/ora/>.

Good Guidance Practices (GGP) Database: This is a searchable database that contains all current CDRH guidance documents and provides links to the documents. (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfggp/search.cfm>)

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

(<http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM080966.pdf>)

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

(<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM072790.pdf>)

A searchable database of FDA-recognized standards is available at:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/search.cfm>

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

1. ORA Contacts

- a. Questions regarding inspectional requirements and/or technical assistance:

Division of Domestic Field Investigations
Medical Device Group
Telephone: (301) 827-5638

- b. Questions about accessing or connecting to the CDRH Center Information Retrieval System (CIRS):

Employee Resource & Information Center (ERIC)
Telephone: (301) 827-ERIC (3742)
<http://inside.fda.gov:9003/EmployeeResources/AboutEmployeeResourceInformationCenter/AboutERIC/default.htm>

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.

- c. Questions regarding sampling of devices and laboratory capabilities:

Lawrence D Hoostelaere
Division of Field Science (DFS), HFC-141
Telephone: (301) 827-1032

- d. 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

- e. Questions regarding COMSTAT:

GWQAP@fda.hhs.gov

Contact GWQAP Team Leader in Office of Enforcement

3. 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.

- a. MDR Regulation Interpretation and Policy Questions:

MDR Policy Branch
Division of Postmarket Surveillance
Office of Surveillance and Biometrics (OSB)
Email: rsmb@fda.hhs.gov
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

- b. 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

- c. 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

- d. Questions regarding the interpretation and applicability of the device Quality System regulation and GMP exemptions:

Kimberly A. Trautman
Quality Systems/GMP Expert
Telephone: (301) 796-5515
Email: kimberly.trautman@fda.hhs.gov

Jan Welch
Quality System/IVD Expert
Telephone: (301) 796-5776
Email: jan.welch@fda.hhs.gov

- e. Questions regarding the reprocessing of single-use devices:

Larry D. Spears
Office of Compliance
Telephone: (301) 796-5517
Email: larry.spears@fda.hhs.gov

- f. 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
Email: john.murray@fda.hhs.gov

- g. Questions regarding sterilization:

Check CDRH web site for current list of experts:

<http://inside.fda.gov:9003/PolicyProcedures/SOPsbyProgram/PeerReview/ucm011680.htm>

- h. Questions regarding Electronic Records and Electronic Signatures should be directed to:

John F. Murray, Jr.
Software Compliance Expert
Telephone: (301) 796-5543
Email: john.murray@fda.hhs.gov

- i. 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

 - j. 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
4. FDA Web Sites:
- a. FDA home page: <http://www.fda.gov>
 - b. ORA home page: <http://www.fda.gov/ora/>
 - c. CDRH home page: <http://www.fda.gov/cdrh/>
 - d. MDR:
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm>
 - e. MedWatch: <http://www.fda.gov/medwatch>

<http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/ucm149238.htm>
(Instructions for completing MedWatch Form 3500A)
 - f. QSIT Guide: <http://www.fda.gov/downloads/ICECI/Inspections/UCM142981.pdf>
 - g. FDA Recognized Standards:
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/search.cfm>
- NOTE: A list of FDA-recognized standards related to sterilization of medical devices can be obtained by searching on the category “Sterility.”

- h. The Biologics and Devices Intercenter Agreement:
<http://www.fda.gov/CombinationProducts/JurisdictionalInformation/ucm121175.htm>
- i. Electronic Records and Electronic Signatures:
http://www.fda.gov/ora/compliance_ref/part11/
- j. Field Accomplishments and Compliance Tracking System (FACTS):
<http://web.ora.fda.gov/factsite/default.htm>
- k. Medical Device Tracking:
<http://www.fda.gov/cdrh/comp/guidance/169.html>
- l. Registration and Listing Database (files to be downloaded):
<http://drsm-sun2.cdrh.fda.gov:7784/cirs/cirs.do>
- m. Establishment Registration Database (searchable):
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrl/registration.cfm>
- n. Device Listing Database (searchable):
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrl/listing.cfm>
- o. Electronic Product Radiation Requirements:
<http://www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/default.htm>
- p. Single-Use Device Reprocessing:
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/default.htm>
- q. Guidance for Industry and for FDA Staff. Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals:
<http://www.fda.gov/OHRMS/DOCKETS/98fr/000053gd.pdf>
- r. Product Code Classification Database (searchable):
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/pcdsimplesearch.cfm>
- s. Good Guidance Practices Database (searchable):
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfggp/search.cfm>