PART VI

REFERENCES AND PROGRAM CONTACTS

A. APPLICABLE REFERENCES

1. Guide to Inspections of Quality Systems, August 1999 (http://www.fda.gov/ora/inspect_ref/igs/qsit/qsitquide.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/fdcact/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/ora/inspect_ref/igs/biotech.html)

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/sg3/inventorysg3/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/sg3/inventorysg3/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/oc/ombudsman/bio-dev.htm)

11. Glossary of Computerized System and Software Development Terminology, August 1995 (http://www.fda.gov/ora/inspect_ref/igs/gloss.html)

12. Quality Control Handbook, Juran, J.M., 5th edition, McGraw-Hill, 1999.

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/cdrh/manual/mdrman.pdf)

15. Do It By Design: An Introduction to Human Factors in Medical Devices, December 1996 (http://www.fda.gov/cdrh/humfac/doitpdf.pdf)

16. The FDA and Worldwide Quality Systems Requirements Guidebook for Medical Devices, Compiled by Kimberly Trautman, ASQ Quality Press, Milwaukee, Wisconsin.

17. Design Control Guidance for Medical Device Manufacturers, March 1997 (http://www.fda.gov/cdrh/comp/designd.pdf)

18. Compliance Guide for Laser Products, September 1985, reprinted July 1989 (http://www.fda.gov/cdrh/radhlth/pdf/lasgde01.pdf)

19. Guide to Inspections of Electromagnetic Compatibility Aspects of Medical Device Quality Systems, December 1997 (http://www.fda.gov/ora/inspect_ref/igs/elec_med_dev/emc1.html)

20. Draft Medical Gloves Manual July 30, 1999 (http://www.fda.gov/cdrh/manual/glovmanl.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/cdrh/comp/guidance/1168.pdf).

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 301-443-8818. Many of these publications are also available in the CDRH Good Guidance Practices (GGP) Database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfggp/search.cfm).

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/cder/guidance/old005fn.pdf)

Updated 510(k) Sterility Review Guidance K90-1; Guidance for Industry and FDA, August 30, 2002 (http://www.fda.gov/cdrh/ode/guidance/361.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 Field Investigations
Medical Device Group
Telephone: (301) 827-5645

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://eric.fda.gov

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, 3) install the Jinitiator. After these three things completed, user can access enhanced CIRS through the enhanced CIRS link in the CenterNet.

c. Questions regarding sampling of devices and laboratory capabilities:

William Campanaro or Lydia Rosas-Marty
Division of Field Science (DFS), HFC-140
Telephone: (301) 827-7605

d. WEAC contacts for testing medical devices:

Laurence Coyne, Ph.D., Director
Engineering Branch, HFR-NE480
Telephone: (781) 729-5700, ext. 761

Pamela Mackill, Director
Analytical Branch, HFR-NE460
Telephone: (781) 729-5700, ext. 748

e. Questions regarding COMSTAT:

Gillie Kovalsky
Division of Compliance Information and Quality Assurance (DCIQA)
HFC-240
Telephone: (240) 632-6817

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:

Reporting Systems Monitoring Branch, HFZ-533
Division of Surveillance Systems, OSB
Telephone: (301) 594-2735

Data retrieval of MDR reports:

Information Analysis Branch, HFZ-531
Division of Surveillance Systems, OSB
Telephone: (301) 827-2983

b. Questions regarding sampling and/or testing of general medical devices:

Thomas R. Lee
Office of Science and Engineering Laboratories, HFZ-160
Telephone: (301) 827-4993
Email: thomas.lee@fda.hhs.gov

c. Express Mail Address for All Regulatory Action Recommendations:

Field Operations Branch, HFZ-306
Office of Compliance
Center for Devices and Radiological Health
2094 Gaither Road
Rockville, Maryland 20850

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

Kimberly A. Trautman
Quality Systems/GMP Expert, HFZ-340
Telephone: (240) 276-0296
Email: kimberly.trautman@fda.hhs.gov

Jan Welch
Quality System/IVD Expert, HFZ-320
Telephone: (240) 276-0354
Email: jan.welch@fda.hhs.gov

e. Questions regarding remanufacturing, refurbishing/reconditioning of used devices:

Casper Uldriks
Office of Compliance, HFZ-300
Telephone: (240) 276-0106
Email: casper.uldriks@fda.hhs.gov

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

Larry D. Spears
Office of Compliance, HFZ-300
Telephone: (240) 276-0100
Email: larry.spears@fda.hhs.gov

g. Questions regarding this Compliance Program:

Kimberly A. Trautman
Quality Systems/GMP Expert, HFZ-340
Telephone: (240) 276-0296
Email: kimberly.trautman@fda.hhs.gov

h. Questions regarding compliance of product software, stand alone software, or process equipment software:

John F. Murray
Office of Compliance Software Expert, HFZ-340
Telephone: (240) 276-0284
Email: john.murray@fda.hhs.gov

i. Questions regarding sterilization should be directed to:

Patrick Weixel
Division of Enforcement A, HFZ-333
Telephone: (240) 276-0355
Email: patrick.weixel@fda.hhs.gov

Candace McManus
Division of Enforcement A
HFZ-333
Telephone: (240) 276-0345
Email: candace.mcmanus@fda.hhs.gov

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

John F. Murray
Division of Enforcement B, HFZ-340
Telephone: (240) 276-0284
Email: john.murray@fda.hhs.gov

k. Questions regarding potential or proposed regulatory actions should be directed to the appropriate CDRH/OC Case Expert:

Louis J. Kaufman
Division of Enforcement A, HFZ-320
Telephone: (240) 276-0151
Email: louis.kaufman@fda.hhs.gov

Andrea P. Latish
Division of Enforcement B, HFZ-340
Telephone: (240) 276-0294
Email: andrea.latish@fda.hhs.gov

l. Questions regarding compliance issues concerning in vitro diagnostic devices:

James Woods
Deputy Director, Patient Safety
Office of In Vitro Diagnostic Devices, HFZ-440
Telephone:240-276-0443 ext. 177
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/cdrh/mdr

   e. MedWatch: http://www.fda.gov/medwatch

      http://www.fda.gov/medwatch/report/instruc.htm
      (Instructions for completing MedWatch Form 3500A)

   f. QSIT Guide: http://www.fda.gov/ora/inspect_ref/igs/qsit/qsitguide.htm

   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/oc/ombudsman/bio-dev.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://www.fda.gov/cdrh/comp/estregls.html

   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/cdrh/comp/eprc.html

p. Single-Use Device Reprocessing:
http://www.fda.gov/cdrh/reuse/index.html

q. Guidance for Industry and for FDA Staff. Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals:
http://www.fda.gov/cdrh/reuse/1168.html

r. Product Code Classification Database (searchable):
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/pcdsimplesearch.cfm

s. Good Guidance Practices Database (searchable):
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfggp/search.cfm