PART II

IMPLEMENTATION

A. OBJECTIVES

QUALITY SYSTEM REGULATION

1. To identify domestic and foreign manufacturers who are not in compliance with the Quality System regulation. To bring such manufacturers into compliance through voluntary, administrative and/or regulatory means, as appropriate.

MEDICAL DEVICE REPORTING REGULATION

2. To identify manufacturers and importers who are not reporting information to FDA in compliance with the Medical Device Reporting (MDR) regulation. To bring such firms into compliance through voluntary, administrative and/or regulatory means, as appropriate.

MEDICAL DEVICE TRACKING REGULATION

3. To identify manufacturers and importers who are not in compliance with the Medical Device Tracking regulation. To bring such firms into compliance through voluntary, administrative and/or regulatory means, as appropriate.

CORRECTIONS AND REMOVALS REGULATION

4. To identify manufacturers and distributors who are not in compliance with the Corrections and Removals (CAR) regulation. To bring such firms into compliance through voluntary, administrative and/or regulatory means, as appropriate.

REGISTRATION AND LISTING REGULATION

5. To identify firms who are not in compliance with the Registration and Listing regulation. To bring such firms into compliance through voluntary, administrative and/or regulatory means, as appropriate.

B. PROGRAM MANAGEMENT INSTRUCTIONS

1. The following guidelines are suggested for implementing this compliance program:

   a. This compliance program is to be used to conduct Quality System inspections of devices. The profile information should be updated in FACTS for QS inspections.

Instructions for updating firm profiles in FACTS are referenced in the IOM Exhibit 5-13, and on the Office of Enforcement's intranet.

b. Many large firms have several manufacturing facilities located in more than one district. These firms often have a research and development (R&D) center or corporate design facility, which services several manufacturing facilities.

- Upon completing an inspection of an R&D center or corporate design facility, districts should send copies of the inspection report to the home districts of the firm's manufacturing facilities.

- Unless additional information must be obtained from the manufacturing facility, the home district of the manufacturing facility during the next inspection need only verify the coordination aspects of the design control activities as long as the inspection of the R&D center or corporate design facility was conducted within the previous two years. Examples of design control coordination activities are:

  - How design change information is shared, verified, and, where appropriate, validated as full scale manufacturing;
  - How design transfer activities at the manufacturing facility are verified;
  - How the risk analysis is performed with respect to manufacturing controls; and,
  - How the risk analysis is continually being updated as manufacturing changes occur.

- Likewise, if an inspection of the R&D center or corporate design facility has not been conducted within the previous two years, the home district of the manufacturing facility should issue an assignment to the home district of the R&D center or corporate design facility requesting a design control inspection. The above guidance is NOT applicable to Pre-Approval inspections.

c. Sterilization of medical devices is covered as a part of the QSIT inspection under this compliance program. Guidance provided in the QSIT Guide is to be followed when inspecting sterilization processes for the following types of facilities:

- device manufacturers that sterilize their own product;
- device manufacturers that use contract sterilizers; and,
- contract sterilizers.

Medical Devices related to AIDS diagnosis and screening, blood banking, blood screening and/or human blood processing will be inspected under this compliance program and CBER's compliance program 7342.008, "Inspection of Licensed Viral Marker Test Kits." For guidance, see the Intercenter Agreement between the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health, dated October 31, 1991.

The Biologics and Devices Intercenter Agreement can be found at the following web site: http://www.fda.gov/oc/ombudsman/bio-dev.htm

2. Scheduling Inspections of Medical Device Manufacturers

a. Priorities for QS Inspections

Districts should target coverage of manufacturers of Class II and Class III devices, utilizing a risk based methodology. Resources must be directed towards accomplishing performance goals.

Selection of firms to accomplish the performance goals and then remaining work plan obligations should be focused using the risk based model below:

1) Pre-Market and Pre-Clearance inspections under MDUFMA (Inspections of manufacturers of devices with a pending PMA approval will be assigned under the PMA Compliance Program 7383.001.)

2) Manufacturers of Class III devices that have never been inspected.

3) Compliance Follow Up/For Cause Inspections (See Part III B for further discussion.)

4) Manufacturers of high risk devices which can be identified by:

A. Special Assignment from CDRH;

B. Devices with a higher frequency of recalls and MDRs;

C. Devices that are driven by software and those with rapidly evolving technological changes. Both of these types of devices are subject to rapid and potentially poorly controlled modifications that could affect their continued safety and efficacy; or,

D. New devices that have not been manufactured and distributed for very long.

5) Single Use Device Reprocessors: Hospital reprocessors and third party reprocessors. See Part III of this program for further instructions related to reprocessors.

Highest priority should be given to MDUFMA assignments and those Class III device manufacturers that have not been previously inspected. The high risk device category noted in 4) above, lists suggestions to the field on how to identify firms for surveillance inspections based on a risk model.

b. Class I Device Manufacturers

All Class I devices, including those exempted from most of the Quality System regulation requirements, must comply with record keeping requirements and complaint file requirements, as well as reporting requirements under the MDR regulation. Class I manufacturers should not be routinely scheduled for inspection but should receive lowest inspectional priority unless addressed by a special, "For Cause" assignment or when a health hazard is apparent. Use the following link to determine if a device is Class I exempt from QS requirements. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm

If inspecting a manufacturer that was originally planned as a Class I QS non-exempt, Class II or III device firm, and the inspection finds that the firm no longer makes Class I QS non-exempt, Class II or Class III devices, the investigator should review the firm's complaint handling system and MDR practices, then terminate the inspection. The District should report the time against PAC 82845A.

3. Pre-Announcement of Inspections

Refer to Guide to Inspections of Quality Systems, August 1999, and IOM 5.2.1, Pre-Inspectional Activities.

4. Annotation of the FDA 483

Annotation of the FDA 483 should occur for all medical device inspections unless the manufacturer declines. Refer to IOM 5.2.3.4.

5. Resource Instructions

Only QSIT trained individuals should perform these inspections. Contact DFI (HFC-130) should the need for expertise, not otherwise available in the Region, become apparent (Refer to FMD No. 142). When possible, Electro-Optical Specialists (EOS) should be used for inspection of laser devices, whose time is reported under PAC 86001. If QSIT trained, EOS's should also conduct the QS portion of this program.