SUBJECT:	IMPLEMENTATION DATE
INSPECTION OF MEDICAL DEVICE MANUFACTURERS	Upon Receipt
	COMPLETION DATE
	September 30, 2000

DATA REPORTING

PRODUCT CODES	PRODUCT/ASSIGNMENT CODES
73-91	82830L 42830L -- All Routine Inspections 82830C 42830C -- All F/U Inspections 82011 -- Report Time Spent on Assessment of Firm's MDR Practices

Field Reporting Requirements

Send to CDRH, HFZ-306, the EIR with the Design Control Inspectional Strategy Report for **each** inspection conducted under this program, regardless of the District decision.

A copy of all Warning Letters should be sent to HFZ-306.

If the district wishes to obtain comment from CDRH for other EIRs you must attach a cover memo outlining the issues to be considered by OC. This policy does not relieve the district from COMSTAT reporting requirements.

All EIRs and administrative/regulatory action recommendations shall be sent to HFZ-306.

PART I

BACKGROUND

- **This compliance program provides guidance to the FDA field and Center staffs for the phased-in implementation of the new design control requirements of the Quality System Regulation (FR/Vol 61, No. 195/Monday, October 7, 1996). It also provides guidance for continuing enforcement of those requirements that have either been carried over unchanged, or modified in some way from the 1978 GMP regulation (21 CFR Part 820). The revised GMP regulation is effective June 1, 1997. In addition, this compliance program provides guidance on the MDR regulation (21 CFR Part 803), and the Medical Device Tracking Regulation (21 CFR Part 821).**

A. THE GMP REGULATION

The new Quality System Regulation encompasses, for the first time, design control requirements for all Class III and II and certain Class I devices. These requirements will require major changes in the processes establishments use to develop and design devices. Because both the manufacturers and the field staff will require formal training and experience with the application of the design control requirements, FDA committed to a phase-in period of one year following June 1, 1997, the effective date of the regulation. During this period investigators will not include on the FDA Form 483, observations concerning design controls, nor will FDA initiate a regulatory action for failure to comply with the design control requirements. Investigators will, however, note their observations in the Design Control Inspectional Strategy Report and leave a copy of the report with the establishment. The strategy, outlined in the program, continues to place emphasis on manufacturers' responsibility to monitor their compliance with the requirements of the GMP regulation, and to make appropriate and timely corrections of problems in their manufacturing and quality assurance systems.

B. THE MDR REGULATION

The original Medical Device Reporting (MDR) regulation for manufacturers has been superseded by a revised regulation, effective on June 1, 1996. Significant changes have been made in time frames requirements for reporting both death and serious injuries. In addition, the regulation now includes requirements for establishing written MDR procedures. Distributors and users are also subject to certain reporting requirements. Inspections of distributors and users will be upon assignment only.

Every time a GMP inspection is conducted under this Compliance Program, an MDR inspection will also be conducted.

C. THE MEDICAL DEVICE TRACKING REGULATION

The Medical Device Tracking Regulation (21 CFR Part 821) requires manufacturers to implement a method of tracking permanently implanted or life sustaining/supporting devices used outside a device user facility, the failure of which would be reasonably likely to have serious adverse health consequences. This regulation is intended to ensure that a tracked device can be traced from the

manufacturing facility to the patient in the event that the device experiences a problem.

PART II

IMPLEMENTATION

A. OBJECTIVES

QUALITY SYSTEM REGULATION

1. MANUFACTURING QUALITY SYSTEMS

To identify domestic and foreign manufacturers who are not operating in a state-of-control. To bring such manufacturers into a state-of-control through voluntary, administrative or regulatory means, as appropriate.

2. DESIGN CONTROL REQUIREMENTS

During the one-year phase-in period,

a. develop an understanding of how the device industry implements design controls,

b. work with manufacturers that are experiencing problems implementing the design control requirements, and,

c. provide feedback, via the Design Control Report, as required.

After June 1, 1998, bring such manufacturers into a state-of-control through voluntary, administrative or regulatory means, as appropriate.

MDR

1. THE NEW MDR REQUIREMENTS

To identify manufacturers and importers who are not in compliance with the Medical Device Reporting Regulation. To bring such establishments into compliance through voluntary, administrative or regulatory means, as appropriate.

MEDICAL DEVICE TRACKING

2. To determine if manufacturers are making good faith efforts to comply with the Medical Device Tracking Regulation. To assure industry awareness of this requirement and encourage compliance as a prerequisite to a phased enforcement policy assuring compliance.

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 Compliance Status Information System (COMSTAT) inspections of devices when directed by HFC-240. This is in

accordance with the current COMSTAT Manual and to obtain data for COMSTAT profiles and/or updates during regularly scheduled GMP inspections.

b. As agreed to by the Office of Management and Budget (OMB) and FDA, the Agency will provide a transition period between June 1, 1997 and May 31, 1998 for implementation of the design control requirements of the Quality System Regulation (21 CFR Part 820.30). Additional time should be planned for each inspection to allow Investigators sufficient time to gain experience with different approaches manufacturers may use to implement the design control requirements. Investigators are being instructed to use the Design Control Inspectional Strategy for guidance, and for reporting their findings for each establishment that undergoes a GMP inspection. GMP inspections must include a completed Design Control Inspectional Strategy Report attached to the EIR. A copy of the Design Control Inspectional Strategy Report must be given to the establishment's management at the close-out meeting. Finally, remind investigators that they should not include observations related to design controls or changes in device or software design on the FDA Form 483 until June 1, 1998. If an establishment has not developed a new device or changed an existing device, the procedures required for design controls should be reviewed, especially procedures for design changes and procedures for design history files.

21 CFR 820.180 requires that establishments must make all records required by the Quality System Regulation available during an inspection. When the district provides advance notice of the inspection, remind the establishment's management that it is responsible for making design control documentation available to the investigator. At times, Districts may wish to inspect product development/design departments, located at other sites, to follow-up on issues with employees or managers.

When the development/research department is located in another district and you believe an inspection is necessary, issue an assignment for inspection of the design process. Many large companies have product development/design departments located in sites that were previously not required to register. Such establishments must be advised of their registration obligation. This does not preclude the District from assigning a Central File Number to the establishment. All documentation required by the design control requirements may not be maintained at one location. When the inspection is set up, the investigator should request that the firm request copies of all documentation for review.

The instructions for the Design Control Inspectional Strategy advises investigators that "the normal collection of documentation to establish a nonconformance will not be required." If the investigator inadvertently collects design control records related specifically to the development of a product or products (as opposed to generic design control procedures), return the original and all copies of the records to the manufacturer via certified mail. This will prevent accidental FOI release of trade secret information pertaining to the establishment's new product development.

If, during the progress of a Class III 510(k) inspection (7383.003) or PMA inspection (7383.001) the investigator collects design control records pertaining to the subject device, the district should forward the records with the EIR to HFZ-306.

c. If the device is labeled as sterile, also use Compliance Program Circular 7382.830A to inspect the sterilization process.

d. If the establishment is a contract sterilizer, (see 7382.830A for the definition of a contract sterilizer), it is subject to applicable requirements of the Quality System regulation and should be covered using this compliance program as well as 7382.830A.

Note: Contract sterilizers were inadvertently exempted from the requirement for registration (see 21 CFR 807.20). CDRH continues to advise such establishments that a proposal for revocation of the exemption will be published during CY 1997, and that they continue to be subject to the requirements of the Quality System Regulation.

e. Some manufacturers produce their own devices labeled as sterile and act as a contract sterilizer for other manufacturers. Such manufacturers should be covered under 7382.830A as well as this compliance program.

NOTE: A device which is subjected to a process designed to reduce its microbial load, but which is NOT labeled as sterile, is to be covered under this compliance program, not under 7382.830A.

f. Medical Devices related to AIDS diagnosis, blood banking and/or human blood processing will be inspected under this compliance program. For guidance, see Working Relationships Agreement Among the Bureaus of Medical Devices (BMD), Radiological Health (BRH), and Biologics (BOB), April 1, 1982.

2. Intensified Review of the Complaint File

Part III of this compliance program, as well as the GUIDE TO INSPECTION OF MEDICAL DEVICE MANUFACTURERS, contain special guidance for reviewing manufacturers' product experience reports to determine compliance with the GMP and MDR requirements for handling complaints.

The new Quality System regulation permits establishments to maintain complaint files at one corporate location, provided that copies of complaints pertaining to devices manufactured at a particular facility can be transmitted to that facility for review during an inspection. In the event that establishments do not comply with this requirement in a timely manner, district management should notify the Office of Compliance at CDRH immediately (see Part VI for contacts).

When a location other than the manufacturing facility or importer is responsible for investigating complaints and submitting MDR reports, the home district should forward a copy of the EIR to the district office where the complaints are handled, with a request for additional follow-up. The district office should send an "FYI" copy of its complaint file review to the home district. (Both districts should also follow the reporting requirements shown on the cover page of this program).

3. Scheduling Biennial Inspections of Medical Device Manufacturers

a. Priorities for GMP Inspections

In order to assure the best use of resources, and to assure that manufacturers of devices which present a greater risk to the public are inspected before those which pose a lesser risk, the following manufacturers should, for scheduling purposes, be given top priority:

(1) Manufacturers whose last GMP inspection was violative and there is no compelling evidence of correction.

(2) Manufacturers who received a 510(K) approval decision for a critical/significant risk device within the past year, and have not been inspected within the last two years for processes similar to those used to manufacture the 510(K) device.

(3) Manufacturers of all other Class II or III devices that have never received a GMP inspection.

(4) Manufacturers of all other devices listed in Attachment B. Within this group assign the highest inspectional priority to those establishments which have gone the longest without a GMP inspection.

Note: Inspections of manufacturers of devices with a pending PMA approval will be assigned under the PMA Compliance Program (7383.001).

Inspections of manufacturers that have submitted 510(K)s for preamendment Class III devices will be assigned under Compliance Program 7383.003.

All other manufacturers should be inspected as resources permit. The primary goal of emphasizing inspection of the above device manufacturers is to change the scheduling of inspections from one that is purely based on the interval since the last inspection to one that also considers the health-hazard significance of the device. Conducting the inspection shortly after a 510(k) has received approval will also allow an evaluation of manufacturers of significant devices at the most critical stage of production. Because most manufacturing and design problems develop or become apparent within the first year of the device's life cycle, inspecting at this time should provide a better opportunity for identifying manufacturing and design problems. GMP inspectional coverage will be focused on that segment of the industry that is actively bringing devices to market and thus presenting the most risk to the public. Those firms that may not receive a biennial inspection should be those producing lower risk products.

b. GMP Pre-Clearance Inspection Program for Class III 510(k) Pre-amendments Devices (CP 7383.003)

When top-priority inspectional assignments that support this program cover all profile classes (except those associated exclusively with certain Class I devices) the district may count the inspection as a qualifying GMP inspection.

c. Initial Inspections

Newly registered and listed firms should receive a **directed inspection** per the Guide to Inspection of Medical Device Manufacturers as soon as possible after manufacturing operations commence. Generally, firms that manufacture Class III devices and devices listed in Attachment B should be inspected within 6 months and firms that manufacture all other Class II devices within 12 months. If the device(s) classification is not known in advance and cannot be determined otherwise, i.e., phone contact, catalog review, etc., schedule the inspection and determine the appropriate inspectional approach after identifying the device(s). For guidance in determining if an establishment should be subject to the GMP regulation refer to page 50 of Medical Device GMP Guidance for FDA Investigators.

If it cannot be determined that at least one device is Class II, III, or Non-GMP exempt Class I, as discussed in section B.3.f. below, review the firm's complaint handling practices; then terminate the inspection. Report the time against PAC 82R800 (District Initiated Assignment).

d. Routine Reinspections

All manufacturers of Class II or III devices should receive a **directed GMP/MDR inspection** as resources permit after the previous "qualifying inspection". See part II, B.3.a [Priorities for GMP Inspections.]

e. Statutory Coverage List (formerly the Alert List)

Any registered firm that manufactures Class II or III devices and has not had a "qualifying inspection" during the 24 months since they registered will appear on the district's Statutory Coverage List (formerly the alert list).

- The Statutory Coverage List (formerly the Alert List) will be based on the date of the last "qualifying inspection" (i.e., the last GMP/MDR inspection under PAC's 82830 C, L, or F, 83001, 83003, or 42830 C, L, or F).

f. Class I Device Manufacturers

NOTE: All Class I devices, including those exempted from most of the Quality System Regulation requirements, must comply with the complaint file requirements as well as the reporting requirements of the MDR regulation. Class I manufacturers should receive lowest inspectional priority unless addressed by a special assignment or a health hazard is apparent. See Attachment C for those

Class I devices which are exempt from most GMP requirements.

g. Follow-up Inspections

Part III of this program instructs investigators to discontinue the inspection when they encounter conditions that meet the criteria for Situation I in Part V.A.1.. The Warning Letter to the manufacturer warns the manufacturer of its responsibility for reviewing all manufacturing and quality assurance systems. Because other problems may have existed which the manufacturer should have identified and corrected, **the follow-up inspection should be a comprehensive inspection**.

Follow-up inspections conducted to determine if violations have been corrected may be counted as qualifying inspections and should be reported against PAC 82830C. All other follow-up inspections, including washouts, are to be reported against PAC 82R800.

4. The Medical Device Initiative Pilot Program

While the pilot phase of the Medical Device Initiatives (MDI) ended in early 1997, the field should continue following the instructions issued by ORO for the MDI until notified to the contrary.

5. Resource Instructions

When possible, Electro-Optical Specialists should be used for inspection of laser devices.

Experienced and knowledgeable investigators should conduct inspections of establishments that are manufacturing high-risk devices. Contact DEIO (HFC-133) should the need for expertise, not available in the Region, become apparent (Refer to FMD No. 142).

PART III

INSPECTIONAL

BACKGROUND

This program includes guidance for determining compliance with the Quality System Regulation, Medical Device Reporting (MDR), and Medical Device Tracking regulations.

A. OPERATIONS

1. Inspectional Strategy

A "qualifying inspection" is a GMP inspection conducted under this program as per the inspectional strategy presented below.

This compliance program, introduced in FY'94, initiated a major change in inspectional strategy. Investigators will conduct a comprehensive inspection only when conducting a follow-up inspection following enforcement action. All other inspections will be **directed inspections** as directed in the Guide to Inspection of Medical Device Manufacturers.

The device industry and CDRH worked closely together to develop the design control requirements of the Quality System Regulation so that the requirements would be harmonized with ISO 13485, the standards for device design and manufacturing required by the European Economic Union. To allow the domestic industry sufficient time to implement the design control requirements, the Office of Management and Budget (OMB) and FDA agreed to the following **mandatory** policy regarding the reporting of inspectional observations related to design controls:

Beginning on June 1, 1997, when the new Quality System Regulation becomes effective, FDA investigators will cover the implementation of design controls by establishments on devices currently in the design phase. Any deficiencies identified will not be recorded on the FDA Form 483, but will be reported on the Design Control Inspectional Strategy Report. At the close out of the inspection, the establishment's management should be given one copy of the Design Control Inspectional Strategy Report with the observations noted, and discuss the observations. Also attach a copy of the completed Design Control Inspectional Strategy Report to the EIR.

After June 1, 1998, all observations concerning design controls will be reported on the FDA Form 483.

When conducting all routine GMP inspections you are required to start the inspection with a review of: (1) complaints and MDR reports (see Attachment A, Section I (B), (2) changes which the manufacturer has made in the design or manufacturing process, and (3) records of production lots which failed in-process or finished device testing. Any indications of problems that your review identifies will provide a focus for your

inspection. If you do not find indications of problems after reviewing the above records, complete the inspection as directed in the Guide to Inspection of Medical Device Manufacturers and the Design Control Inspectional Strategy, and issue an FDA Form 483, listing any objectionable conditions that you have observed.

WHEN THE INSPECTION IDENTIFIES SYSTEM WIDE DEFICIENCIES WHICH, IN TOTAL, MEET THE CRITERIA FOR SITUATION I IN PART V,A,1. OF THIS PROGRAM, DOCUMENT THE CONDITIONS THAT CONTRIBUTED TO THE PROBLEM(S), AND CLOSEOUT THE INSPECTION.

The FDA Form 483 should contain the following statement:

THE OBSERVATIONS NOTED IN THIS FDA FORM 483 ARE NOT AN EXHAUSTIVE LISTING OF OBJECTIONABLE CONDITIONS. UNDER THE LAW, YOUR FIRM IS RESPONSIBLE FOR CONDUCTING INTERNAL SELF-AUDITS TO IDENTIFY AND CORRECT ANY AND ALL VIOLATIONS OF THE GMP REGULATION.

2. Special Instructions Concerning Design Controls

The inspectional authority for review of design control records is derived from Section 704(e) of the Act. Counsel has determined that such authority applies only after the establishment has taken an action that demonstrates that it intends to actually market a prototype device (including free standing software, such as blood banking software) for which the design has been under development. Such action includes: (1) submitting to an IRB plans for clinical investigation of the device, (2) submitting to FDA a Product Development Protocol (PDP), or (3) submitting to FDA an IDE, 510(k), or PMA.

The above limitation does not apply to authority to review all design control procedures.

Review of design controls should cover any design processes after June 1, 1997. The establishment is not required to retrospectively apply design controls to all stages in the design process, if it had completed part of the design process. Certain requirements, however, such as formal design reviews, are essential to assuring that a device will meet the output requirements. Any design reviews conducted after June 1, 1997 should include a retrospective review up to the current stage of the device's development. Guidance for covering the new design control requirements of the Quality System Regulation is contained in the Design Control Inspectional Strategy and Design Control for Medical Devices Manufacturers' Guidance.

If an establishment normally designs its own devices, but has not initiated a design project, any design changes to current devices, or have a design project in process, limit your coverage to a review of the design control procedures that the establishment has established.

All documentation required by the design control requirements may not be maintained at one location. When the inspection is set up in advance, the investigator should request that the firm request copies of all documentation for review.

The observations that you place on the Design Control Inspectional Strategy Report should be limited to the adequacy of the procedures and/or controls established by the establishment. **It is not appropriate to place observations on the Design Control Inspectional Strategy Report that concern the adequacy, safety, or efficacy of a particular design.** Any such concerns should be noted in the EIR and the EIR flagged for review by the Office of Device Evaluation.

3. Special Instructions for Sterilization Processes

A device subjected to a process designed to reduce its microbial load, but which is NOT labeled as sterile, is to be covered only under this program.

If the device is labeled as sterile, inspectional coverage indicated in 7382.830A, where appropriate, is to occur.

4. Special Instructions for Inspecting Small Manufacturers

Refer to Section ??? of the *Guide to Inspection of Medical Device Manufacturers*.

5. Inspection of Radiation Emitting Devices

When conducting GMP inspections of radiation emitting devices, also cover the requirements of the applicable standard promulgated under PL90-602.

Device manufacturers subject to existing FDA performance standards should include in their device master and history records those procedures and records demonstrating compliance with the applicable standard.

6. Recalls

Under the provisions of the Safe Medical Device Act, manufacturers must now report to FDA any recalls/notifications that will reduce health risks or remedy violations that may pose a health risk. An implementing regulation, Medical Device Corrections and Removals (21 CFR, Part 806) is awaiting publication. Confirm that all subject recalls conducted by the establishment since the last inspection have, in fact, been reported to the district office. Also review files to determine if all events filed by the establishment as Class III recalls have been properly classified, i.e., should be Class I or II recalls.

7. Remanufacturers of Used Devices

Remanufacturers are persons who process, condition, renovate, repackage, restore or do any other act to a finished device that significantly changes the finished device's performance or safety specifications or intended use. Remanufacturers are considered to be manufacturers, and are subject to all applicable requirements of the Quality System Regulation, MDR requirements, Device Tracking requirements, registration and listing, and premarket clearance. If an establishment disputes its regulatory status, refer the EIR

to HFZ-305 (Attn. Wes Morgenstern) for assistance in interpreting the definition of a remanufacturer.

8. Refurbishers/Reconditioners of Used Devices

Refurbishers, reconditioners and "as is" resellers of used devices are not subject to the requirements of the Quality System Regulation. In 1997, FDA published an Advanced Notice of Proposed Rulemaking (ANPR) requesting public comments/proposals on regulation of refurbishers, reconditioners and "as is" remarketers of used devices. If you receive an assignment to inspect such an establishment please contact Wes Morgenstern (HFZ-305) at 301-594-4699 to determine the current regulatory status of such establishments.

9. Reprocessors of Single Use Devices

Third party reprocessors of single use devices are subject to those requirements of the Quality System Regulation that apply to the operations they perform. Because contractual arrangements with hospitals and questions of ownership may sometimes make the responsibilities of the third party unclear, please contact Larry Spears (HFZ-340) at 301-594-4646 for guidance before conducting an inspection of an establishment believed to be a third party reprocessor. Hospitals that reprocess/reuse single use devices for their own use are not subject to registration and listing requirements or routine inspections.

10. Selection of Device(s) for Inspection

See Part II, B. 4. for information on GMP inspection priorities.

The selection of establishments for inspection will be based first on whether an establishment manufactures a high risk device (as identified in Attachment B). If more than one high risk device is manufactured at the establishment, your selection of the device or devices to be covered should be based on evidence of defective and/or nonconforming devices identified by your review of the complaint files, change control records, in process testing records, and finished device testing records. The selection also will depend on the total number of appropriate profile classes [except those associated exclusively with GMP exempt Class I devices (see Part II, B.4.f.)] by examining the manufacturing of as few device lines representative of those classes as possible.

A Implantable and Life Sustaining Devices (Formerly Critical Devices)

Under 21 CFR 820.65, the requirements for devices and component traceability applies to implantable devices and life sustaining devices. See Attachment B for a list of such devices.

12. Comparison of Requirements Between the 1978 Regulation and the New Quality System Regulation

While the GMP requirements that apply to manufacturing are similar in both regulations, some of the requirements were reworded or otherwise modified to better harmonize with ISO 9001. See the The FDA and Worldwide Quality System Requirements Guidebook

for Medical Devices, page 5 for a chart comparing the requirements in the old and new regulations.

Some requirements have been added such as: 1) evaluation of supplies (820.50(a)); 2) statistical methods for sampling extended beyond just finished device testing (820.250); and, 3) handling, storage, and preservation of calibrated equipment so accuracy and fitness for use are maintained (820.72 (a)). Other requirements have been eliminated, such as requirements specific to critical devices.

13. FDA Compliance Status Information Systems (COMSTAT)

a. When selecting specific devices to represent profile classes, give preference to high risk devices and devices that have had problems. Where possible, select those devices which represent multiple, mutually exclusive profile classes. A list of the device related profile classes appears in the current FDA COMSTAT Manual.

b. Inspections conducted under a COMSTAT assignment should include:

(1) coverage of the device(s) specified in the assignment, or devices representing all the same profile classes as the assigned device; and

(2) other devices as required to provide coverage of any remaining profile classes, except GMP exempt Class I devices.

14. Complaint File Review

a. FDA surveys of establishments' complaint files have shown that some establishments were deficient in the their complaint handling practices. These deficiencies were caused by an establishment's failure to:

(1) follow its own procedures for processing product experience reports; or,

(2) develop procedures which meet the requirements of 21 CFR 820.198 or,

(3) do not take timely corrective actions after identifying problems.

The Quality System Regulation requires that all complaints be reviewed, evaluated and maintained by a formally designated unit. This unit could be one appropriately trained individual, or a department which is staffed with appropriately trained individuals. This unit must decide whether an investigation of the complaint needs to be performed. Under the Quality System Regulation there continues to be no requirement that all complaints must be maintained in one file. Now, however, establishments are required to have written procedures for processing complaints. It will be necessary to review the complaint processing procedures and to assess the adequacy of the procedures and their implementation by reviewing complaints received after June 1, 1997.

The review of complaints and failure investigations to determine which devices the inspection should be focused on should not be limited to only those complaints received after June 1, 1997. Typically, manufacturers will keep

complaints and related investigations in a customer file, product returns/credits file, warranty file, medical file, or legal file. The inspection should ascertain what files are maintained that meet the definition of a complaint, as found in 21 CFR 820.198.

[Note: If GMP defined complaints are not maintained by the formally designated unit, or written procedures are not in place, or not being followed, it should be noted on the FDA FORM 483.]

By placing complaints in different files, manufacturers have not noted instances of repeated component/device failure with a common cause. Ask the establishment if it analyzed complaints to identify recurring quality problems. If no trending or problem identification is done, then the inspection should begin with the investigation conducting an analysis of the complaints and/or failure investigations.

Note: The actual complaints or deficiencies in complaint handling practices may provide leads in identifying product defects, and possibly quality system problems, which have not been adequately corrected by the establishment. Possible corrective actions may include recall, and/or change in the design of the device, and/or change in the manufacturing process or quality system.

Reference No. 4 in Part VI explains how the GMP complaint files relate to reports required under MDR.

15. Medical Device Reporting

Operational Procedures for Determining Compliance with the MDR Regulation

New guidance for evaluating manufacturers compliance with the requirements of the revised MDR regulation are in Attachment C. A review of an establishment's adherence to its own MDR procedures as well as the MDR requirements must be conducted concomitant with each GMP inspection.

16. Medical Device Tracking

Determine if the establishment makes any medical device(s) subject to the Medical Device Tracking Regulation. See Attachment D for a list of subject medical devices. If so, follow the guidance in the Guide to Inspection of Medical Device Manufacturers, Section ?????, to determine if the establishment has device tracking procedures in place and, if it does, to assess their adequacy.

If there is a complete absence of a tracking system, you must cite this observation on the FDA FORM 483. Other observations should be addressed verbally and reported in the EIR. Please include a short paragraph in your EIR summarizing the establishment's tracking system, even though no problems were identified.

17. Sample Collection

For GMP or MDR violations, documentary samples will be collected as necessary.

Physical samples are not required to support GMP violations, and should not be routinely collected for GMP cases. If the district should reference violative documentary or physical samples as evidence to support GMP deviations, the condition of the sample should be tied to the GMP deviation to show a cause/effect relationship.

If you are uncertain as to whether a sample should be collected, the district should consult with the CDRH Headquarters Laboratory Liaison or the Division of Field Science in ORA on the laboratory capability to conduct the analysis. (See Part VI, C. for program contacts).

18. Imports

No import wharf examinations or sample collections are scheduled under this program.

19. Exports

The FDA Export Reform and Enhancement Act of 1996 includes a provision in Section 802 allowing an establishments to export an unapproved device without first obtaining FDA authorization, provided that the device has received marketing authorization from one of 27 countries listed in Section 802(b)(i). Section 802 also requires that any such device must be manufactured in "substantial" conformance with the GMP regulation.

During the inspection, ask the establishment if it has exported any unapproved devices under Section 802, and confirm that the establishment has subjected the device(s) to the same quality system used for devices sold domestically. In the event that Situation I conditions are identified, contact HFZ-305, Attn: Wes Morgenstern.

Otherwise, devices that are manufactured in the U.S., but not marketed in the U.S., are not subject to the GMP requirements, provided that the manufacturer has documented proof that its devices are offered for sale only in foreign countries.

20. Follow-up Inspections

The Situation I violations that were identified during the previous inspection may have been part of more widespread system problems that the investigator did not have an opportunity to evaluate. After receiving the Warning Letter the manufacturer should have investigated its manufacturing and quality assurance system and initiated appropriate corrections. To assure that the manufacturer has fulfilled its responsibility, the follow-up inspection should be conducted as a comprehensive inspection as directed by the Guide to Inspection of Medical Device Manufacturers. If problems similar to those originally identified, or new problems that meet the criteria for Situation I are identified, complete the comprehensive inspection and document all observations.

If it appears that the establishment did not make an adequate assessment of the extent of its problems, the follow-up inspection should place special emphasis on the establishment's self auditing procedures, especially as they address the problem areas. In addition, it is possible to assess the adequacy of the self audits by examining the history of problem areas. If the particular problem area was addressed in the auditing procedures, but was not corrected after an audit, either: (1) the audit was inadequately conducted, or (2) the problem area was identified by the audit, but management failed to

review the results, or (3) the problem area was identified by the audit, but management failed to take adequate corrective action.

21. Foreign Inspections

All foreign inspections should be conducted as comprehensive inspections per the Guide to Inspection of Foreign Medical Device Manufacturers.

B. REPORTING

1. General Reporting requirements are listed on the cover page. As a general rule the time used for preparing the EIR should not exceed the time spent conducting the inspection.

2. MDR Observations--If the establishment failed to comply with any of the MDR requirements of the revised regulation 21 CFR, Part 803. Note the observation on the FDA Form 483. Each EIR must include a summary of observations relating to each section of Part 803 identified in Attachment C.

3. GMP Observations--If you observe any violations of the GMP requirements, you should place them on the FDA Form 483, with the exception of observations concerning design controls during the period between June 1, 1997 and May 31, 1997. Observations concerning design controls under 21 CFR 820.30 should be noted on the Design Control Inspectional Strategy Report at the close out of the inspection and leave a copy with the establishment. Also attach a copy to the EIR.

   The most serious violations (e.g., those that could potentially result in production of defective devices, or identification of production problems) should be noted on the FDA Form 483 first. Your FDA Form 483 comment, however, should differentiate between problems that are indicative of a systems failure and rare isolated situations.

4. 510(k) Observations--If the establishment failed to have a 510(k), or made significant changes which requires a new 510(k), do not place the observations on the FDA FORM 483 unless you obtain concurrence from CDRH/OC.

5. Medical Device Tracking Requirements--The EIR must indicate whether or not the establishment inspected makes any device subject to the device tracking requirements (21 CFR Part 821) and, if so, whether the establishment is meeting its tracking obligations. These requirements had an implementation date of August 29, 1993. See Attachment D for questions and answers about the Medical Device Tracking Regulation.

   If the establishment manufactures a device subject to the tracking requirements, and there is a complete absence of a tracking system, you should cite this violation on the FDA FORM 483. Other violations should be verbally discussed with the establishment's management and reported on the EIR.

PART IV

ANALYTICAL

A. ANALYZING LABORATORIES

The district will make all the necessary arrangements for proper handling of samples with the following designated testing facilities:

TYPES OF DEVICES	ANALYZING LABORATORIES
All General Medical Devices	W E A C
Radioimmunoassay	W E A C
All Other In Vitro Diagnostic Devices	Micro—WEAC Chem—BLT
Sterility Analysis	Refer to CP 7382.830A

See PART VI regarding those persons designated as contacts for designated laboratories and specific products.

B. ANALYSES TO BE CONDUCTED

Sample collection and analysis will be determined on a case-by-case basis through consideration of inspectional findings, compliance and scientific capabilities and expertise. Full collaboration between investigations and analytical personnel is essential at this phase. See Part III A. 9. for additional information.

PART V

REGULATORY/ADMINISTRATIVE FOLLOW-UP

A. GMP REGULATORY/ADMINISTRATIVE FOLLOW-UP

1. Situation I

The district has evidence indicting that the manufacturing process and/or (after June 1, 1998, the design control process) is contributing or causing the production of nonconforming and/or defective finished devices. Such evidence would include information from sample analyses, complaint files, the establishment's failure analyses, MDR/PRP reports, or quality system observations made during the inspection.

OR

The inspection documents quality system deviations of a significant type or quantity to conclude that there is a reasonable probability -- in light of the relationship between quality system deviations observed, and the particular product and manufacturing process involved -- that the establishment will likely produce nonconforming and/or defective finished devices. Such deviations include one or more of the following:

- failure to establish and document a formal quality assurance program;
- failure to document, review, approve, implement and validate changes to components, finished devices, labeling, packaging or manufacturing process specifications (see 21 CFR 820.70) for changes related to software, see below;
- failure to establish, maintain, and implement procedures for implementing corrective and preventative action;
- failure to establish and implement an adequate complaint handling program;
- failure to establish and implement an adequate failure investigation program;
- failure to ensure that finished devices meet all specifications prior to distribution;
- failure to establish and implement adequate recordkeeping procedures (e.g., device history record, device master record, quality system records); and,
- when the follow-up to a violative inspection demonstrates that the establishment either failed to establish an adequate internal audit system, or failed to follow the established system with the result that additional deviations were identified by the investigator but not identified and corrected by the establishment.

Because software design validation and software change are closely related, districts should not initiate regulatory/administrative follow-up when an establishment's software change controls are deficient until June 1, 1998.

After June 1, 1998, Situation I deviations related to the design control requirements of the Quality System Regulation will include:

Because software design validation and software change are closely related, districts should not initiate regulatory/administrative follow-up when an establishment's software change controls are deficient until June 1, 1998.

After June 1, 1998, Situation I deviations related to the design control requirements of the Quality System Regulation will include:

- failure to establish written design control procedures and a design history file;
- complete failure to adhere to the established design control procedures, when the design process for a new device was initiated after June 1, 1997;
- failure to validate significant manufacturing processes and quality assurance tests (refer to Section 820.75, Process Validation in the Quality System Regulation, and the document titled "Guidelines on the General Principles of Process Validation for the Validation Requirements);
- failure to establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation for each design or design change after June 1, 1997;
- failure to establish and document design inputs and outputs, and any changes to the original inputs and expected outputs made during the design process, for each design change after June 1, 1997;
- failure to conduct documented design reviews at the stages specified by the design plan, for each device or device change after June 1, 1997;
- failure to validate the design of a device or device change, using the first devices manufactured by the established manufacturing process, or their equivalents, when the design process for the device, or device change was after June 1, 1997.
- failure to document, review, approve, implement and validate changes to either device operating software or process control software.

If any of these deviations exist, the significance of the deviation and the device warrants it, the district should consider administrative and/or regulatory action, e.g., warning letter, injunction, detention, seizure, civil penalty, and/or prosecution. The district is expected to classify the EIR as OAI.

See the Guide to Inspection of Medical Device Manufacturers for additional guidance on Situation I conditions.

If any of these deviations exist for foreign manufacturers, and the device warrants it, a Warning Letter and/or Warning Letter with Automatic Detention will be considered by CDRH/OC.

If a serious health hazard is identified, an FDA initiated recall or injunction should be considered as the initial action to bring the situation under prompt control.

2. Situation II

The inspection documents GMP deviations of a quantity and/or type to conclude that there is minimal probability -- in light of the relationship between quality system deviations observed and the particular product and manufacturing processes involved -- that the establishment will produce nonconforming and/or defective finished devices. The FDA Form 483, Inspectional Observations, will serve to inform the establishment of any objectionable findings.

The presence of quality systems deviations which have a low probability of leading to an unsafe or ineffective device will not usually warrant recommendation of an administrative and/or regulatory action.

3. Violative Devices Sold to Government Agencies

Agency policy requires that products sold to the federal government should be treated in the same manner as products sold to commercial accounts. Consequently, when FDA recommends against acceptance of a device by a government agency because that device, or its manufacturer, is in violation of the FD&C Act, FDA must also include appropriate regulatory/administrative action against the same or similar device sold to commercial accounts.

If an establishment has shipped a violative product to a Government agency, regulatory action consistent with the nature of the violation(s) may be taken even though there have been no shipments to commercial customers. Formal regulatory action in connection with a violative shipment may not be necessary in some cases. For example, the establishment promptly corrects the violative condition, and existing Agency policy would not require further action if the matter involved a product shipped to a non-government customer. However, where corrections are not or cannot be made promptly, the main concern is preventing the subsequent shipment of the product to another customer. When the product has been shipped solely to a Government agency and is under control of that agency and there is no threat to the public, the ORA/Medical Products Quality Assurance (MPQA) staff should ascertain the intention of the agency holding the goods (e.g., will they return or destroy the goods; will they request FDA to initiate seizure, etc.). If the procuring agency requests FDA action, the ORA/MPQA staff will refer the matter to the home district for their consideration of an appropriate recommendation.

4. Regulatory Actions

Actions which may be considered are FDA requested recall, FDA mandated recall, Warning Letter, seizure, injunction, and prosecution.

Corrective action proposals should be submitted by a responsible official of the establishment in writing, detailing the action(s) to be taken to bring the violative process or product into compliance within a specified time frame. Voluntary correction does not preclude the initiation of administrative and/or regulatory action.

In determining whether quality systems deviations are sufficient to support legal action, consideration should be given to the significance of the device, the establishment's quality history, and whether the problem is widespread or continuing.

When CDRH does not agree with a district's recommendation for a regulatory action, the district will be notified of the reasons for disapproval in writing.

a. Warning Letters

Districts must obtain CDRH concurrence before issuing Warning Letters related to refurbishing/reconditioning of used devices, or reprocessing of single use devices .

In addition, Districts must obtain CDRH concurrence before issuing Warning Letters concerning design controls other than those identified by A. 1. of this Part.

Issuance of all other Warning Letters should be in accordance with Chapter 4 of the Regulatory Procedures Manual (RPM) (see Attachment F) (see Attachment E for model Warning Letters).

If the District determines that issuance of the Warning Letter has resulted in corrective action by the establishment, the District shall, within five (5) working days after confirmation, update the establishment's Profile Data Sheet.

b. Violative Follow-Up Inspections

With the exception of comprehensive inspections of high risk devices, investigators are instructed to close out directed inspections as soon as they have documented conditions that have met the criteria of Situation I, and have completed coverage of the establishment's design controls. The model Warning Letters (Attachment E) advises manufacturers that the conditions identified by the investigator may be symptomatic of systems' problems, and that the manufacturer is responsible for investigating, identifying, and correcting systems' problems.

The model Warning Letters further direct the establishment to discuss in its response how it will address the systems problems related to the conditions identified by the investigator.

To assure that the manufacturer did, in fact, review all manufacturing and quality assurance systems, investigators are instructed to conduct a comprehensive follow-up inspection to all violative directed inspections. When investigators identify the same or additional conditions that meet the criteria for Situation I (note: deficiencies in the performance of self-auditing are considered a criteria for Situation I at the follow-up inspection stage), the District should consider seizure or injunction.

c. Enforcement Strategy For Establishments With Repeated Violative Inspections -- The Recidivist Policy

(1) Some establishments have a high rate of recidivism. They have developed a pattern of correcting violative conditions in response to Warning Letters or other administrative/regulatory actions, and usually maintain those corrections long enough to pass the follow-up inspection. When FDA next inspects the establishment (sometimes, as a follow-up to a recall), the investigator identifies similar conditions that again meet the criteria for Situation I. This tendency toward recidivism is often due to the failure of the establishment to have a strong quality policy and basic manufacturing and quality assurance systems which meet the requirements of the Quality System Regulation.

(2) When dealing with another violative inspection for such an establishment, the District should consider using the following strategy:

(a) Issue a Warning Letter that follows the model Warning Letter in Attachment E. This Warning Letter requests the manufacturer to submit to the District (for up to 2 years if the District believes that it is necessary) an annual certification by an outside expert consultant stating that it has conducted a complete audit of the establishment's manufacturing, quality assurance (and if applicable, design control) systems relative to the requirements of the Quality System Regulation. The establishment should submit a copy of the consultant's report[1], and certification by the establishment's CEO that he or she personally has received and reviewed the consultant's report and that the establishment has made all corrections called for in the report.

[1] Establishments may be asked to release consultant's reports as part of their voluntary agreement with FDA. Because of its voluntary nature, the request is not in conflict with 21 CFR 820.180C.

(b) You have the option of limiting your review of the certification only to the extent necessary to confirm that the consultant and the establishment have met the requirements set forth in the Warning Letter. You may also request a technical evaluation of the consultant's report by the appropriate branch within the Office of Compliance (OC). You have no obligations, however, to send to the establishment comments regarding the adequacy of the consultant's report or the establishment's corrections.

(c) It will not be necessary to schedule a follow-up inspection for at least 6-months after the establishment certifies that it has completed all corrections.

The District may remove the establishment from COMSTAT as soon as the establishment has certified that it has completed all corrections recommended by the consultant.

(d) If the follow-up inspection indicates that the corrections are satisfactory, notify the establishment that you have no objections to the corrections. Remind the establishment that it must continue to submit to the District, on the schedule specified in the Warning Letter, certification by an outside expert consultant that it has conducted an updated audit, certification by the establishment's CEO that any corrections noted to be necessary by the consultant have been made, and that it remains in compliance with the requirements of the Quality System Regulation. The establishment should continue to submit copies of the audit results.

(3) If conditions identified by the follow-up inspection meet the criteria for Situation I, consider action per 3.b. above.

(4) If the evidence indicates that the consultant's or establishment's certifications are fraudulent, the District may wish to request participation by the Office of Criminal Investigations. When there is clear evidence that the establishment falsified its status report to the District, initiate appropriate charges under 18 USC, 1001.

d. Recalls

If the District believes that prompt removal of a violative product from channels of commerce is necessary, it shall proceed in accordance with established recall procedures in Chapter 7 of the RPM and 21 CFR, Part 7 (Enforcement Policy), Subpart C (Recalls). In the event there exist serious adverse health consequences or a death, CDRH may order discontinuation of distribution and recall of a device to the user level in accordance with Section 518(e) of the Act.

e. Administrative Detention/Seizure

Prior to approving an administrative detention, the District Director must have reason to believe the device is misbranded or adulterated and the establishment holding the device is likely to quickly distribute or otherwise dispose of the device, or detention is necessary to prevent use of the device by the public until appropriate regulatory action may be taken by the Agency. District Directors must consult with CDRH by telephone. Contact the appropriate Division and/or Branch in OC for the subject device by consulting the CDRH/OC organization chart in Part VI, C. Concurrence must be given by the Director, OC, CDRH, based on a recommendation by the OC staff.

The District must immediately recommend a seizure.

A seizure action can be recommended without administrative detention to remove violative devices from commercial distribution, either at the manufacturer, distributor, repacker or a device user location.

f. Injunction

If an establishment has a continuing pattern of significant deviations in spite of past warnings, or its operations constitute a serious health hazard, injunction shall be the recommended action of choice. If a serious health hazard exists, the recommendation should include a request for a temporary restraining order (TRO) to prevent the distribution of devices which have been manufactured under the violative conditions documented by the inspection report (see RPM Chapter 6). The recommendation shall be accompanied by copies of all necessary documents, e.g., complete inspection reports, Warning Letters issued, sample analyses reports, establishment's response(s) to Warning Letters and/or forms FDA 483. In the absence of samples, the inspectional evidence must clearly show that the establishment has substantially deviated from the requirements of the Quality System Regulation. These deviations must be well documented.

g. Citation

A citation shall be recommended if appropriate as stated in Chapter 5 of the RPM.

h. Prosecution

The criteria stated in Chapter 6 of the RPM shall be the criteria for consideration of prosecution of individuals in violation of the requirements of the Quality System Regulation.

i. PMA Disapproval/Withdrawal

Refer to Compliance Program 7383.001, Part V.

j. Automatic Detention

In general, detention will be recommended by the Office of Compliance whenever there is clear documented evidence to suggest that the foreign manufacturer is producing or is likely to produce nonconforming and/or defective devices and the device presents a hazard to health.

k. Civil Money Penalties

Section 303(g)(1)(B)(i) of the Act states that civil money penalties shall not apply to GMP violations "unless such violation constitutes (I) a significant or knowing departure from such requirements, or (II) a risk to public health." Section 303(g)(1)(B)(iii) further stipulates that civil penalties shall not apply to "section 501(a)(2)(A) which involve one or more devices which are not defective." However, if it can be shown that the establishment has received appropriate warning (e.g., FDA Form 483, Warning Letter, etc.) and that the same, or similar, GMP violations are subsequently encountered, civil money penalties may be considered in situations where seizure or injunction is not feasible. Policy is being developed for use of civil penalties in violative GMP situations.

4. Facilitating Review of Regulatory Recommendations

a. The district is expected to consult with OC both prior to, and especially during the inspection, once it is determined that regulatory action is being considered. Contact the appropriate Division/Branch in OC for the subject device by consulting the CDRH/OC organization chart in PART VI, C.

b. When the district knows a regulatory action will be forthcoming as a result of the inspection, FAX a copy of the issued FDA Form 483 to the appropriate division in OC. The review process can begin within CDRH while the EIR and recommendation are being written by the district. A copy of the FDA Form 483 annotated with exhibit numbers, and EIR page numbers, helps the reviewers.

c. It is the responsibility of district management to ensure that the documentation and evidence presented with each legal action recommendation is sufficient to justify each charge. The volume of material submitted must be minimized, and should include only the basic documentation needed to support each GMP charge/example.

d. All necessary samples and other supporting documentation must be tabbed and their location cross referenced in the recommendation in order to assist in a timely review. It is highly recommended that you provide a table which cross references

the violation with the FDA Form 483 item number, the inspection report page number and the exhibit number.

e. It is essential that all significant questions, problems, or other weaknesses in the evidence regarding the recommended action be stated, along with pertinent district comments. Otherwise, reviewers may miss a problem entirely until litigation is commenced.

f. The recommendation must begin with the most serious violation of the regulations with reference to the EIR pages, exhibits and sample results which document the violation. Each charge must be parenthetically referenced in the recommendation memorandum and the page location of the supporting evidence given. Violations must be listed in decreasing order of importance. Each violation should be related to its effect on device quality in light of overall controls, and should be separated according to the type of manufacturing activity.

g. Physical samples are not required to support GMP violations, and should not be routinely collected for GMP cases. If the district should reference violative documentary or physical samples as evidence to support GMP deviations, the condition of the sample should be tied to the GMP deviation to show a cause/effect relationship.

h. Evidence of previous warning and other regulatory actions should be referenced along with a description of corrective actions. If the recommendation or current EIR references a previous report, either copy the cited EIR pages, or summarize the information.

i. All legal action recommendations shall be sent to CDRH/HFZ-306 for processing.

B. MDR REGULATORY/ADMINISTRATIVE FOLLOW-UP

1. General Information

MDR violations must be fully documented in any of the situations described in item "2" and "3" below.

Recommendations for regulatory/administrative actions, based upon suspected violations of the revised MDR regulation, shall be sent to HFZ 306 for review and concurrence. If other means are used to advise an establishment that they are in violation of the MDR regulation, inform HFZ-306 by forwarding copies of the FDA Form 483, memorandum of meeting, or other pertinent information.

2. Situation I

NATURE OF VIOLATION	ACTION TO CONSIDER

The establishment has received prior notice and still fails to comply with the MDR Regulation.	Recommend Warning Letter, seizure, injunction and/or Civil Money Penalties.
The establishment fails to submit an MDR reportable death or serious injury report.	Recommend Warning Letter.
The establishment fails to investigate an MDR reportable event per 21 CFR Parts 803.50(a)(2), 820.100 and 820.198.	Recommend Warning Letter.
The establishment fails to submit a five-day report.	Recommend Warning Letter.

3. Situation II

NATURE OF VIOLATION	ACTION
The establishment fails to submit an MDR malfunction report.	Cite on FDA Form 483.
The establishment has not established an MDR complaint file and/or written procedures.	Cite on FDA Form 483.
The establishment fails to obtain information necessary to file a complete death, or serious injury malfunction report.	Cite on FDA Form 483.
The establishment fails to submit or provide complete baseline report information.	Cite on FDA Form 483.

NATURE OF VIOLATION	ACTION
The establishment fails to submit a supplemental report when appropriate.	Cite on FDA Form 483.

All failures should be listed on the FDA Form 483. The District should follow the guidance in the Regulatory Procedures Manual (particularly where continuing violations have been documented) when determining whether to utilize additional means of notification beyond the FDA Form 483, such as issuing a Warning Letter or setting up a conference between the establishment and the District.

4. Guidance on Citations Used in and Content of Warning Letters

If reinspection reveals continuing problems with compliance with 21 CFR Part 803, particularly where a potential risk to health exists, the district should consider taking additional regulatory action (seizure, injunction, 518(e), etc.).

Cite Formats for Draft Warning Letters

a. When cite involves failure to report a reportable death or serious injury, use one of the following paragraphs:

502(t)(2) The devices are misbranded in that information required to be submitted to the Food and Drug Administration (FDA) by the Medical Device Reporting (MDR) Regulation specified in 21 CFR Part 803 was not submitted as follows:

b. In addition to the cite, include all of the following paragraphs that apply to your situation:

USE WHEN THE ESTABLISHMENT HAS NOT FILED ANY REPORTS

Failure to submit reports to FDA after receiving information which reasonably suggested that one of your marketed devices [IDENTIFY THE DEVICE(S) THAT APPLY TO THE CHANGE] has caused or contributed to a death or serious injury, as required by 21 CFR 803.50 (a)(i).

and/or

Failure to submit reports to FDA within five (5) calendar days when the establishment has initiated a remedial action as a result of an MDR reportable event, and the action was taken to prevent an unreasonable risk of substantial harm to the public health, as required by 21 CFR Part 803.53(a).

and/or

Failure to submit reports to FDA within five (5) calendar days concerning an event for which FDA has made a written request for submission of a Five (5) Day Report.

Note: Days are counted starting the day after an establishment learns of an incident.

C. MEDICAL DEVICE TRACKING

CDRH is still in the policy formulation phase relative to enforcement of the Medical Device Tracking Regulation. Districts should send Warning Letters only when establishments that manufacture the devices listed in Attachment E have failed to establish any form of tracking system. When districts wish to include in the Warning Letter other charges related to the requirements of the Device Tracking Regulation, the draft Warning Letter must be first approved by CDRH.

PART VI

REFERENCES, ATTACHMENTS AND PROGRAM CONTACTS

A. APPLICABLE REFERENCES OR AIDS

1. Code of Federal Regulations, Title 21, Part 820 Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation.

2. Federal Food, Drug, and Cosmetic Act, As Amended.

3. Investigations Operations Manual - Chapter 5, Subchapter 550.

4. GMP Complaint Files: How They Relate to Reports Required Under MDR, Originally published in Medical Device & Diagnostic Industry, Volume 7, Number 5, May 1985, Revised version (4/10/85) distributed to all district offices.

5. Medical Device Reporting for User Facilities – guidance document based on the final MDR regulation as it applies to user facilities. [Sources: A., B., C.]

6. Medical Device Reporting for Manufacturers – guidance document based on the final MDR regulation as it applies to manufacturers. [Sources: A., B., C.]

7. Medical Device Reporting for Distributors – guidance document based on the final MDR regulation as it applies to distributors. [Sources: A., B., C.]

8. Medical Device Reporting: An Overview – summary of the MDR regulation as it applies to user facilities and manufacturers. [Sources: A., B., C.]

9. 7/16/96 Variances 1-4 from manufacturer Report Number Format [Sources: C., D.]

10. 8/12/96 Variance 5 from manufacturer Report Number Format [Sources: C., D.]

11. 7/31/96 Medical Device Reporting - Interim Compliance Program 7382.830, Attachment E [Sources: C., D.]

12. 7/30/96 MDR Guidance Document: Remedial Action Exemption - E1996001 [Sources: C., D.]

13. 8/7/96 MDR Guidance Document: Breast Implant - E1996002 [Sources: C., D.]

14. 8/9/96 MDR Guidance Document: Needlesticks and Blood Exposure - E1996003 [Sources: C., D.]

15. 8/7/96 MDR Guidance Document: IOL - E1996004 [Sources: C., D.]

16. STERILIZATION - QUESTIONS AND ANSWERS, MARCH 1985

17. Medical Device Quality Systems Manual: A Small Entity Compliance Guide (HHS Pub. No. FDA 94-4179, Dec. 1996)

18. NBS special Publication 250 - May 1984 (or update) Calibration and Related Measurement Services, U.S. Dept. of Commerce NBS, Washington, D.C. 20234.

19. Sterile Medical Devices. A GMP Workshop Manual. fourth Edition November 1984. Prepared by Division of Small Manufacturers Assistance, Office of Training and Assistance, HHS Publication FDA 84-4174.

20. Guideline on General Principles of Process Validation: Notice of Availability published in the Federal Register on May 1987.

21. Working Relationships Agreement Among the Bureaus of Medical Devices (BMD), Radiological Health (BRH), and Biologics (BOB), published April 01, 1982, Refer to District Reference File for copies.

22. Plastic Medical Devices: A Study of Quality in The Making. September 1980. A copy of this film has been supplied to each FDA District office. This film is intended for use with the Medical Device Reference Files on plastics (see reference #17 below).

23. Medical Device Reference Files on syringes, catheters, tubes and airways, IOL and contact lenses, IUDs and filters. September 1980. One hard copy and one microfiche copy of each of these reference files has been supplied to each FDA District office.

24. Quality Control Handbook, Juran, J.M., 3rd edition, McGraw-Hill, 1974.

25. ANSI/ASQC Z1.4 (Replaces MIL-STD 105E), ANSI/ASQC Z1.9 (Replaces MIL-STD 414) Sampling Procedures and Tables for Inspection by Attribute.

26. GWQAP Manual

27. Classification Names for Medical Devices and In Vitro Diagnostic Products, HHS Publication No. (FDA) 91-4246, August 1995. This directory is organized by "keywords" in alphabetical order. The classification number (5 digit product code), class, and CFR regulation number is given for each entry listed.

28. Code of Federal Regulations, Title 21, Part 809.10, Labeling for In Vitro Diagnostic Products.

29. Advisory List of Critical Devices - 1988; Notice Published in the Federal Register on March 17, 1988.

30. Overview of Metallic Orthopedic Implants; Technical report, reference material and training aid for investigators prepared by the Division Emergency and Investigation Operations (HFC-132), Office of Regional Operations, Office of Regulatory Affairs, HHS, Public Health Service, FDA, June, 1988.

31. AQL Inspector's Rule and Manual. This special purpose plastic slide rule that rigidly adheres to MIL-STD-105E can be obtained from Infor. Inc., P.O. Box 606, Ayer, MA. 01432. Phone (508) 772-0713. Cost is approximately $20 each excluding shipping and packaging.

32. Guide to Inspections of Foreign Medical Device Manufacturers, prepared by the Division Emergency and Investigation Operations (HFC-132), Office of Regional Operations, Office of Regulatory Affairs, HHS, Public Health Service, FDA, June, 1988.

33. Code of Federal Regulations, Title 21, Part 821, Medical Device Tracking Requirements.

34. Medical Device Tracking - Questions and Answers Based on the Final Rule, HHS Publication No. (FDA) 93-4259, August 26, 1993.

35. Do It By Design: Design Control Guidance

36. The FDA and Worlwide Quality Systems Requirements Guidebook for Medical Devices, Compiled by Kimberly Trautman, ASQC Quality Press, Milwaukee, Wisconsin.

Copies of CDRH GMP publications are available from the Division of Small Manufacturers Assistance (DSMA),
Telephone: 800-638-2041 or FAX 301-443-8818.

Sources to purchase these documents:

☒ **A. National Technical Information Service (NTIS)** - For information on the NTIS system please CDRH F-O-D (see ☒ **D.** below) and request Shelf number 3799.

☒ **B. Health Care & Industry Organizations** - For a list of organizations that have agreed to assist in the distribution of this information please call CDRH F-O-D (see ☒ **D.** below) and request Shelf number 4799.

Sources to obtain copies free of charge:

✉ **C. World Wide Web (Internet)** - FDA/CDRH maintains a World Wide Web (WWW) site for easy access to information. The home page may be accessed via FDA's home page at **http://www.fda.gov**. For additional information on the WWW site please call CDRH F-O-D (see ✉ **D.** below) and request Shelf number 1799.

✉ **D. CDRH Facts-On-Demand (F-O-D)** - This automated fax system allows anyone to obtain CDRH information, 24 hours a day, 7 days a week by calling **800-899-0381** or **301-827-0111** from a touch-tone telephone. For additional information on obatining MDR documents from the CDRH F-O-D system please call CDRH F-O-D and request Shelf number 5799 from DSMA Facts (1 at first voice prompt [VP], 2 at second VP, then follow subsequent VPs).

Sources of MDR related documents:

The documents related to the new Medical Device Report (MDR) regulation are listed below followed by their Facts-On-Demand number)s), (FOD #:).

- 12/11/95 Federal Register, Final Rule: & 04/11/96 Federal Register, Final Rule: Medical Devices; Medical Device user Facility and Manufacturer Reporting, Certification and Registration (Docket 91N-0295). **[FOD #: 336, 1336]**.
- 07/23/96 Federal Register, Final Rule: Medical Devices; Stay of Effective Date; Revocation of Final Rule **[FOD #: 1074]**.
- 07/23/96 Federal Register, Proposed Rule: Medical Devices; Reporting; Certification and U.S. Designated Agents **[FOD #: 1075]**.
- 07/31/96 Federal Register, Final Rule: Medical Devices; Baseline Reports; Stafy of Effective Date **[FOD #: 1096]**.
- Medical Device Reporting for User Facilities – guidance document based on the final MDR regulation as it applies to user facilities. **[FOD #: 989]**.
- Medical Device Reporting for Manufacturers – guidance document based on the final MDR regulation as it applies to manufacturers. **[FOD #: 987]**.
- Medical Device Reporting for Distributors – guidance document based on the final MDR regulation as it applies to distributors. **[FOD #: 988]**.
- Medical Device Reporting: An overview – summary of the MDR regulation as it applies to user facilities and manufacturers. **[FOD #: 509]**.
- Instructions for Completing Form 3500A (specific to Mecical Device reporting) with Coding Manual for Form 3500A. **[FOD #: 853]**.

- Form 3500A, used by user facilities, manufacturers, and distributors. **[FOD #: 854]**.
- Abbreviated instructions for mandatory MedWatch Form 3500A. **[FOD #: 973]**.
- Baseline Report, Form FDA 3417. **[FOD #: 407]**.
- 07/01/96 Instructions for Completing Form 3417 Medical Device Reporting Baseline Report. **[FOD #: 1061]**.
- Semi-Annual User Facility Report, FDA Form 3419. **[FOD #: 409]**.
- 0924/96 Instructions for Completing Semi-Annual User Facility Report, FDA Form 3419. **[FOD #: 1409]**.
- 07/16/96 Variances 1-4 from manufacturer Report Number Format. **[FOD #: 1059]**.
- 08/12/96 Variance 5 from manufacturer Report Number Format. **[FOD #: 1060]**.
- 07/31/96 Medical Device Reporting - Interim Compliance Program 7382.830, Attachment E. **[FOD #: 1098]**.
- 07/30/96 MDR Guidance Document: Remedial Action Exemption - E1996001. **[FOD #: 188]**.
- 08/07/96 MDR Guidance Document: Breast Implant - E1996002. **[FOD #: 452]**.
- 08/09/96 MDR Guidance Document: Needlesticks and Blood Exposure - E1996003. **[FOD #: 250]**.
- 08/07/96 MDR Guidance Document: Intraocular Lenses (IOL) - E1996004. **[FOD #: 216]**.
- MDR Policy Listserv - Information on how to subscribe. **[FOD #: 1094]**.

B. ATTACHMENTS

ATTACHMENT A -	CLASS I DEVICES EXEMPT FROM MOST OF THE GMP REQUIREMENTS BY CLASSIFICATION REGULATIONS
ATTACHMENT B -	ADVISORY LIST OF DEVICES THAT ARE INTENDED FOR SURGICAL IMPLANT OR SUSTAINING LIFE
ATTACHMENT C -	INSPECTIONAL GUIDANCE FOR PERFORMING A REVIEW OF THE FIRM'S COMPLIANCE WITH .THE MDR REGULATION.
ATTACHMENT D -	MEDICAL DEVICE TRACKING, QUESTIONS AND ANSWERS BASED ON THE FINAL RULE, AUGUST 26, 1993
ATTACHMENT E -	MODEL WARNING LETTERS **(Revised)**

ATTACHEMENT F - DESIGN CONTROL INSPECTIONAL STRATEGY, MARCH 1997

C. PROGRAM CONTACTS

1. ORA Contacts

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

Division of Emergency & Investigational Operations
Medical Device Group
301-827-

b. Questions about accessing or connecting to the Parklawn Computer Center and Model 204

Leo Bauman
Division of Information Systems, ORA
(301) 443-1314

An easy method for Field Users to access the system is to log on to the regional VAX, then type:

TELNET PCCSNA.FDA.GOV <return>

Field Users should set up their communication program to emulate a VT100 or other option before logging on to the Regional VAX.

c. Questions regarding sampling of devices and laboratory capabilities:

Division of Field Science (DFS), HFC-140
Telephone: (301) 443-3320

d. The WEAC contact point for testing medical devices is:

Director
WEAC Engineering Branch, HFR-NE480
Telephone: (617) 729-5700

e. Questions regarding COMSTAT

Gillie Kovalsky

Division of Medical Products Quality Assurance (DMPQA), HFC-240
Telephone: (301) 827-0385

2. District Office Contacts For Industry Management Concerns About Their GMP Compliance Status.

Atlanta	Ballard Graham
Baltimore	Gary Pierce
New England	James Rahdo
Buffalo	E. Pitt Smith
Chicago	Ray Mlecko
Cincinnati	Guy Cartwright
Dallas	Austin Templer
Denver	William Sherer
Detroit	John Dempster
Kansas	Robert Wilson
Los Angeles	Elaine Messa
Minneapolis	John Feldman
Nashville	Ray Hedblad
New Orleans	James Green
New Jersey	
New York	Rick Trainor
Florida	Timothy Couzins
Philadelphia	Diana Kolaitis
San Francisco	Andrea Scott
San Juan	Sam Jones
Seattle	David Pettenski
St. Louis	Charles Bringman
Foreign Firms	Joy Lazaroff/Marje Hoban

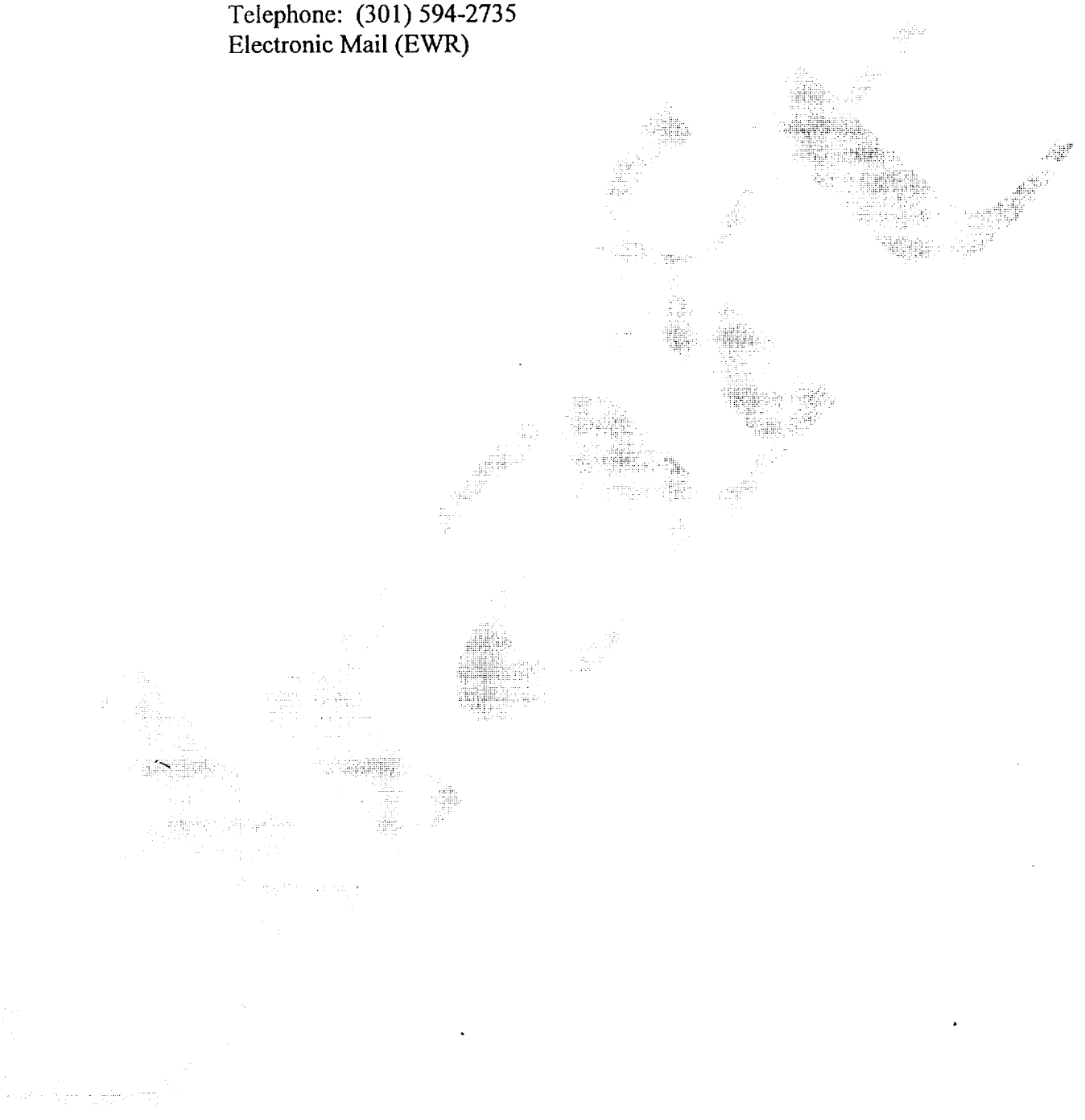
3. CDRH Contacts

See the New CDRH/OC Organizational Chart at the end of of Part VI to identify which unit within OC is responsible for answering your question or giving you guidance, depending on the type of device.

a. Questions regarding the interpretation and applicability of the MDR regulation:

Wayne Robinson
Division of Surveillance Systems, OSB
Reporting Systems Monitoring Branch, HFZ-533

Telephone: (301) 594-2735
Electronic Mail (EWR)



b. MDR Report and Data Summaries:

Arlene Underdonk
Division of Surveillance Systems, OSB
Information and Analysis Branch, HFZ-531
Telephone: (301) 594-2731

c. Industry MDR Report: (301) 427-7500. Do not call this phone number to make inquiries.

d. Questions about using **MDRAPSY** (MDR/PRP database).

Del Futrell
Division of Surveillance Systems, OSB
Information and Analysis Branch, HFZ-531
Telephone: (301) 594-2731

e. Questions regarding sampling and/or testing of **general medical** devices.

Edward Mueller or Donald Marlowe
Division of Mechanics and Material Sciences, HFZ-150
Telephone: (301) 443-7003

f. Express Mail Address for All Regulatory Action Recommendations:

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

g. Questions regarding the interpretation and applicability of the device GMP regulation and GMP exemptions:

Contact the appropriate Division/Branch in OC for the subject device by consulting the CDRH/OC organization chart at the end of Part VI.

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

Wes Morgenstern
Division of Program Operations, HFZ-305
Telephone: (301) 594-4699 ext. 102

i. Questions regarding the reprocessing of single use devices:

Larry Spears
Division of Enforcement III, HFZ-340
Telephone: (301) 594-4646 ext. 153

j. Questions regarding this Compliance Program:

Linda Godfrey
Field Programs Branch, HFZ-306
Telephone: (301) 594-4695 ext. 143
Fax: (301) 594-4715

ATTACHMENT A

CLASS I DEVICES EXEMPT FROM MOST OF THE GMP REQUIREMENTS BY CLASSIFICATION REGULATIONS

THE FOLLOWING LIST OF EXEMPTED CLASS I DEVICES IS ARRANGED IN PRODUCT CODE SEQUENCE.

TO USE THIS LIST CONSULT THE KEY WORD LIST FOR DEVICES TO DETERMINE THE PRODUCT CODE. THE KEY WORD LIST WAS FORMERLY INCLUDED IN THE EDRO DATA CODES MANUAL (TN-84-1) AND WILL BE ON FILE IN THE DISTRICT'S REFERENCE FILE.

ANESTHESIOLOGY DEVICES

(Final Regulation Published in July 16, 1982 FEDERAL REGISTER; EFFECTIVE DATE: 8/16/82)

			REGULATION
73	BTB	HOOK, ETHER	868.5420
73	BXJ	CLIP, NOSE	868.6225
73	BXL	ALGESIMETER, MANUAL	868.1030
73	BYN	CHAIR, POSTURE, FOR CARDIAC	868.5365
73	BYO	BOTTLE, BLOW	868.5220
73	BYW	REBREATHING DEVICE	868.5675
73	BZN	CART, EMERGENCY, CARDIOPULMONARY	868.6175
73	CBG	SPREADER, CUFF	868.5760
77	EPE	BRUSH, CLEANING, TRACHEAL TUBE	868.5795
73	JFE	VALVE, SWITCHING (PLOSS)	868.1965

CARDIOVASCULAR

74	---	(No devices have been exempted)	

CLINICAL CHEMISTRY DEVICES

(Final Regulation Published in May 1, 1987 FEDERAL REGISTER; EFFECTIVE DATE: 7/30/87)

75	JBS	TIMER, GENERAL LABORATORY	862.2050
75	JJP	ION SELECTIVE ELECTRODES (NON-SPECIFIED)	862.2050
75	JQO	ANALYTICAL BALANCE	862.2050
75	JQQ	DIALYZER	862.2050
75	JQY	PH METER	862.2050
75	JQZ	POLARIMETER	862.2050
75	JRB	MICRO MIXER	862.2050
75	JRG	HEATING BLOCK	862.2050
75	JRJ	DRYING UNIT	862.2050

75	JRK	EVAPORATOR	862.2050
75	JRL	MEMBRANE FILTER UNIT	862.2050
75	JRM	FREEZER	862.2050
75	JRO	BLENDER/MIXER	862.2050
75	JRQ	SHAKER/STIRRER	862.2050
75	JRR	TEMPERATURE REGULATOR	862.2050

DENTAL DEVICES
(Final Regulation Published in August 12, 1987 FEDERAL REGISTER;
EFFECTIVE DATE: 9/11/87)

76	EBH	MATERIAL IMPRESSION TRAY RESIN	872.3670
76	EEA	BASE PLATE SHELLAC	872.6200
76	EEJ	GUARD, DISK	872.6010
76	EFH	PAPER, ARTICULATION	872.6140
76	EFW	TOOTH BRUSH, MANUAL	872.6855
76	EFX	PROTECTOR, SILICATE	872.6670
76	EGD	INTRAORAL DENTAL WAX	872.6890
76	EGZ	FILM, X-RAY HOLDER	872.1905
76	EHJ	DISK, ABRASIVE	872.6010
76	EHK	PROPHYLAXIS CUP	872.6290
76	EHL	POINT, ABRASIVE	872.6010
76	EHM	STRIP, POLISHING AGENT	872.6010
76	EHY	TRAY, IMPRESSION, PREFORMED	872.6880
76	EIE	DAM, RUBBER AND ACCESSORIES	872.6300
76	EJP	ARTICULATOR	872.3150
76	EJQ	WHEEL, POLISHING AGENT	872.6010
76	JET	PICK, MASSAGING	872.6650
76	KCO	TUBE IMPRESSION AND MATRIX	872.5220
76	KCR	FACE BOW	872.3220
76	KCS	PANTOGRAPH	872.3730
76	KHR	SALIVA ABSORBER PAPER	872.6050
76	KMT	DISPOSABLE FLUORIDE TRAY	872.6870
76	KXR	RESIN APPLICATOR	872.4565

EAR, NOSE, AND THROAT DEVICES
(Final Regulation Published in November 6, 1986 FEDERAL REGISTER;
EFFECTIVE DATE: 12/8/86)

77	ESE	LARYNX, ARTIFICIAL (BATTERY-POWERED)	874.3375
77	ETM	GUSTOMETER	874.1500
77	JPN	MANUAL NEBULIZER PUMP	874.5220

77	JXS	BLOCK, CUTTING, ENT	874.3540
77	JXT	CRIMPER, WIRE, ENT	874.3540
77	JXW	DIE, WIRE BENDING, ENT	874.3540
77	JXX	FORCEPS WIRE CLOSURE, ENT	874.3540
77	JXY	JIG, PISTON CUTTING, ENT	874.3540
77	JXZ	PUNCH, GELFOAM	874.3540
77	JYA	SCISSORS, WIRE CUTTING, ENT	874.3540
77	JYB	VISE, OSSICULAR FINGER	874.3540
77	KCL	BLOWER, POWDER, ENT	874.5220
77	KCM	DROPPER, ENT	874.5220
77	KCN	EAR WICK	874.5220
77	KCO	INHALER, NASAL	874.5220

GASTROENTEROLOGY-UROLOGY DEVICES

(Final Regulation Published in November 23, 1983 Federal Register; EFFECTIVE DATE: 12/23/83)

78	EXI	PASTE-ON DEVICE FOR INCONTINENCE	876.5250
78	EXJ	DEVICE, INCONTINENCE, UROSHEATH TYPE	876.5250
78	EXN	HERNIA SUPPORT	876.5970
78	EYQ	PROTECTIVE GARMENT FOR INCONTINENCE	876.5920
78	EYT	SHEATH, CORRUGATED RUBBER	876.5250
78	FAQ	BAG, LEG (FOR EXTERNAL USE)	876.5250
78	FCE	ENEMA KIT	876.5210
78	FFH	COLLECTOR, URINE, PEDIATRIC	876.5250
78	KNX	Urine collector and accessories (not intended to be connected to an indwelling catheter:	876.5250

GENERAL AND PLASTIC SURGERY DEVICES

79	KCZ	PROSTHESIS, BREAST, EXTERNAL	878.3800

GENERAL HOSPITAL AND PERSONAL USE DEVICES

(Final Regulation Published in October 21, 1980 Federal Register: EFFECTIVE DATE: 11/20/80)

80	FLH	SANITIZER, MECHANICAL	880.6800
80	FMA	DEPRESSOR, TONGUE	880.6230
80	FME	GOWN, EXAMINATION	880.6265
80	FMF	NON-STERILE IRRIGATING SYRINGE (SYRINGE)	880.5860
80	FMH	CONTAINER, SPECIMEN	880.6175

80	FML	CHAIR, BLOOD DONOR (NON-WHEELED)	880.6140
80	FMP	PROTECTOR, SKIN PRESSURE	880.6450
80	FMQ	RESTRAINT PROTECTIVE	880.6760
80	FMR	TRANSFER DEVICE, PATIENT, MANUAL	880.6785
80	FMW	MATTRESS COVER (FOR MEDICAL PURPOSE)	880.6190
80	FNJ	BED, MANUAL	880.5120
80	FNN	NIPPLE, LAMBS FEEDING	880.5640
80	FNP	URINAL	880.6730
80	FNS	RING CUTTER	880.6200
80	FNY	BASIN, EMESIS	880.6730
80	FOA	BOARD, CARDIOPULMONARY	880.6080
80	FOB	BEDPAN	880.6730
80	FOK	PAD, NEONATAL EYE	880.6025
80	FOR	NON-STERILE ABSORBENT TIPPED APPLICATOR	880.5270
80	FPF	BOTTLE, HOT/COLD WATER	880.6085
80	FPP	STRETCHER, HAND CARRIED	880.6900
80	FPS	BOARD, BED	880.6070
80	FQA	SCALE, SURGICAL SPONGE	880.2740
80	FQJ	THERAPEUTIC SCROTAL SUPPORT	880.5820
80	FQK	BINDER, PERINEAL	880.5160
80	FQL	STOCKING, MEDICAL SUPPORT	880.5780
80	FQM	BANDAGE, ELASTIC	880.5075
80	FRI	SCALE, STAND-ON, PATIENT	880.2700
80	FRJ	CHAIR, GERIATRIC (NON-WHEELED, NON-POWERED)	880.6140
80	FRK	CHAIR, EXAMINATION, AND TREATMENT	880.6140
80	FRL	MEDICAL ABSORBENT FIBER	880.5300
80	FRP	PEDIATRIC POSITION HOLDER	880.5680
80	FSD	BINDER, ABDOMINAL	880.5160
80	FSL	STRETCHER, HAND CARRIED	880.6900
80	IKY	NON-POWERED FLOTATION THERAPY MATTRESS	880.5150
80	KIA	COVER, CAST	880.6185
80	KME	MEDICAL DISPOSABLE BEDDING	880.6060
80	KMO	BINDER, ELASTIC	880.5160
80	KYR	BAG, ICE	880.6050
80	KYT	BATTERY POWERED EXAM LIGHT	880.6350
80	KYW	GRADUATED LIQUID MEDICATION	880.6430
80	KYX	LIQUID MEDICATION DISPENSER	880.6430
80	LBJ	VEIN STABILIZATION DEVICE	880.6980

IMMUNOLOGY DEVICES

82	---	(No devices have been exempted)

MICROBIOLOGY DEVICES

(Final Regulation Published in November 9, 1982 FEDERAL REGISTER; EFFECTIVE DATE: 12/9/82)

83	GMB	LIGHT, WOOD'S FLUORESCENCE	866.2600
83	JTB	MEDIA DISPENSING/STACKING DEVICES	866.2440
83	JTM	ANAEROBIC GLOVE BOX	866.2120
83	JTQ	INCUBATORS/WATER BATHS, ALL	866.2540
83	KZC	MANUAL COLONY COUNTER	866.2180

NEUROLOGY DEVICES

(Final Regulation Published in September 4, 1979 FEDERAL REGISTER; EFFECTIVE DATE: 10/4/79)

84	GWI	TWO POINT DISCRIMINATOR	882.1200
84	GWX	TUNING FORK	882.1525
84	GWZ	PERCUSSOR	882.1700
84	GXB	ESTHESIOMETER	882.1500

OBSTETRICAL/GYNECOLOGICAL

85	---	(No devices have been exempted)

OPHTHALMIC DEVICES

(Final Regulation Published in September 2, 1987 FEDERAL REGISTER; EFFECTIVE DATE: 10/2/87)

86	HIT	TESTER, COLOR VISION	886.1170
86	HJC	OCULAR ESTHESIOMETER	886.1040
86	HJF	MAGNIFIER, HAND-HELD, LOW-VISION	886.5540
86	HJH	BINOCULAR LOUPE, LOW POWER	886.5120
86	HJI	LENS, FUNDUS, HRUBY, DIAGNOSTIC	886.1395
86	HJJ	LENS, FRESNEL, FLEXIBLE, DIAGNOSTIC	886.1390
86	HJL	LENS, CONDENSING, DIAGNOSTIC	886.1380
86	HKB	TELESCOPE, HAND-HELD, LOW-VISION	8886.5870
86	HKC	SPECTACLE MICROSCOPE, LOW-VISION	886.5540
86	HKD	TAPE, NYSTAGMUS	886.1905
86	HKF	MIRROR, HEADBAND, OPHTHALMIC	886.1500
86	HKG	FORNISXCOPE	886.1320
86	HKK	TELESCOPE, SPECTACLE, LOW-VISION	886.5870
86	HKM	RETINOSCOPE, BATTERY-POWERED	886.1780
86	HKN	REFRACTOR, MANUAL, NON-POWERED,	886.1770

86	HKQ	PRISM, ROTARY, OPHTHALMIC	886.1665
86	HKR	LENS, MADDOX	886.1400
86	HKT	PRISM, FRESNEL, OPHTHALMIC	886.1655
86	HKW	PRISM, BAR, OPHTHALMIC	886.1650
86	HLC	INSTRUMENT, MEASURING, STEREOPSIS	886.1460
86	HLE	RULER, NEAR POINT (PUNCTOMETER)	886.1790
86	HLH	PUPILLOMETER, MANUAL	886.1700
86	HLJ	OPHTHALMOSCOPE BATTERY-POWERED	886.1570
86	HLK	SCREEN, TANGENT, TARGET BATTERY-POWERED	886.1810
86	HLN	GAUGE, LENS, OPHTHALMIC	886.1420
86	HLO	TEST, SPECTACLE DISSOCIATION, BATTERY-POWERED	886.1910
86	HLP	TARGET, FUSION AND STEREOSCOPIC	886.1880
86	HLR	KERATOSCOPE, BATTERY-POWERED	886.1350
86	HMD	CHAIR, OPHTHALMIC, MANUAL	886.1140
86	HMG	STAND, INSTRUMENT, OPHTHALMIC	886.1860
86	HMJ	SCREEN, TANGENT, PROJECTION BATTERY-POWERED	886.1810
86	HMM	DISTOMETER	886.1190
86	HMQ	MARKER, SCLERA	886.4570
86	HMR	MARKER, OCULAR	886.4570
86	HMS	DRUM, OPTHALMIC KNIFE TEST	886.4230
86	HMX	CANNULA, OPHTHALMIC	886.4350
86	HMZ	TRABECULOTOME	886.4350
86	HNA	SPUD, OPHTHALMIC	886.4350
86	HNB	SPOON, OPHTHALMIC	886.4350
86	HNC	SPECULA, OPHTHALMIC	886.4350
86	HND	SPATULA, OPHTHALMIC	886.4350
86	HNE	SNARE, ENUCLEATING	886.4350
86	HNF	SCISSORS, OPHTHALMIC	886.4350
86	HNG	RONGEUR, LACHRYMAL SAC	886.4350
86	HNH	RING, OPHTHALMIC (FLIERINGA)	886.4350
86	HNI	RETRACTOR, OPHTHALMIC	886.4350
86	HNJ	PUNCH, CORNEO-SCLERAL	886.4350
86	HNK	PROBE, TRABECULOTOMY	886.4350
86	HNL	PROBE, LACHRYMAL	886.4350
86	HNM	NEEDLE, OPHTHALMIC SUTURING	886.4350
86	HNN	KNIFE, OPHTHALMIC	886.4350
86	HNP	INTRODUCER, SPHERE	886.4350
86	HNQ	HOOK, OPHTHALMIC	886.4350
86	HNR	FORCEPS, OPHTHALMIC	886.4350
86	HNS	EXPRESSOR	886.4350
86	HNT	ERISOPHAKE	886.4350
86	HNW	DILATOR, LACHRYMAL	886.4350

86	HNX	DEPRESSOR, ORBITAL	886.4350
86	HNY	CYSTOTOME	886.4350
86	HNZ	CURETTE, OPHTHALMIC	886.4350
86	HOA	COMPRESSOR, ORBITAL	886.4350
86	HOB	CLAMP, MUSCLE, OPHTHALMIC	886.4350
86	HOC	CLIP, IRIS RETRACTOR	886.4350
86	HOD	CLAMP, EYELID, OPHTHALMIC	886.4350
86	HOE	CALIPER, OPHTHALMIC	886.4350
86	HOF	BURR, CORNEAL, MANUAL	886.4350
86	HOH	SPECTACLE, OPERATING (LOUPE), OPHTHALMIC	886.4770
86	HOI	SPECTACLE, MAGNIFYING	886.5840
86	HOJ	SCREEN, TANGENT, TARGET	886.1810
86	HOL	SCREEN, TANGENT, FELT (CAMPIMETER)	886.1810
86	HON	PERIMETER, MANUAL	886.1605
86	HOP	CAMPIMETER, STEREO, BATTERY-POWERED	886.1810
86	HOQ	GRID, AMSLER	886.1330
86	HOR	SIMULITAN (INCLUDING CROSSED CYLINDER)	886.1840
86	HOT	AID, VISION, IMAGE-INTENSIFICATION, BATTERY-POWERED	886.5910
86	HOW	DRUM, OPTOKINETIC	886.1200
86	HOX	CHART, VISUAL ACUITY	886.1150
86	HOY	SHIELD, EYE, OPHTHALMIC	886.4750
86	HPA	FRAME, TRIAL, OPHTHALMIC	886.1415
86	HPB	CLIP, LENS, TRIAL, OPHTHALMIC	886.1410
86	HPD	LENS, BAGOLINI	886.1375
86	HPE	AID, VISION, OPTICAL, BATTERY-POWERED	886.5915
86	HPN	MAGNET, PERMANENT	886.4445
86	HRH	TREPHINE, MANUAL, OPHTHALMIC	886.4350
86	HRK	TABLE, INSTRUMENT, MANUAL, OPHTHALMIC	886.4855

ORTHOPEDIC DEVICES

(Final Regulation Published in September 4, 1987 FEDERAL REGISTER; EFFECTIVE DATE: 10/5/87)

87	HST	APPARATUS, TRACTION, NON-POWERED ORTHOPEDIC	888.5850
87	JQZ	TRACTION COMPONENT, NON-INVASIVE	862.2050
87	LGF	CAST COMPONENT	888.5940
87	LGG	MANUAL CAST APPLICATION AND REMOVAL INSTRUMENT	888.5980

HEMATOLOGY AND PATHOLOGY DEVICES

(Final Regulation Published in September 12, 1980 FEDERAL REGISTER;
EFFECTIVE DATE: 10/14/80)

88	GFL	PONCEAU STAIN	864.1850
88	GFR	NEW METHYLENE BLUE STAIN	864.1850
88	GGD	CRYSTAL VIOLET FOR HEMATOLOGY	864.1850
88	GGH	IRON STAINS	864.1850
88	GGI	PERIODIC ACID SCHIFF STAIN	864.1850
88	GHP	BRILLIANT CRESYL BLUE	864.1850
88	GIX	TOLUIDINE BLUE	864.1850
88	GJH	RETICULOCYTE STAIN	864.1850
88	GJJ	HEINZ BODY STAINS	864.1850
88	GJL	ROMANOWSKY STAINS	864.1850
88	GJO	SLIDES AND COVERSLIPS	864.3010
88	GJY	MICROSCOPE	864.3600
88	GLP	GIEMSA STAIN	864.1850
88	HYB	EOSIN Y	864.1850
88	HYC	FAST GREEN	864.1850
88	HYD	FAST RED SALT B	864.1850
88	HYE	FONTANNA SILVER SOLUTION	864.1850
88	HYH	GOLD CHLORIDE	864.1850
88	HYI	GRAMS IODINE	864.1850
88	HYJ	HEMATOXYLIN	864.1850
88	HYK	HEMATOXYLIN HARRIS'S	864.1850
88	HYL	HEMATOXYLIN MAYER'S	864.1850
88	HYO	HEMATOXYLIN WEIGERT'S	864.1850
88	HYQ	IRON CHLORIDE-WEIGERT	864.1850
88	HYR	LEUCO-PATENT BLUE	864.1850
88	HYS	LIGHT GREEN	864.1850
88	HYW	MALLORY'S TRICHROME STAIN	864.1850
88	HYY	METANIL YELLOW	864.1850
88	HYZ	METHENAMINE SILVER	864.1850
88	HZA	METHYL GREEN	864.1850
88	HZC	MUCICARMINE	864.1850
88	HZD	MULLER'S COLLOIDAL IRON	864.1850
88	HZE	NILE BLUE	864.1850
88	HZF	NUCLEAR FAST RED	864.1850
88	HZG	OIL RED O	864.1850
88	HZH	ORANGE G	864.1850
88	HZJ	PAPANICOLAOU STAIN	864.1850
88	HZL	PHLOXINE B	864.1850
88	HZM	PHOSPHOTUNGSTIC ACID HEMATOXYLIN	864.1850
88	HZN	PICRO METHYL BLUE	864.1850
88	HZO	PONCEAU STAIN	864.1850
88	HZP	PYRONIN	864.1850

88	HZQ	RED VIOLET - LB	864.1850
88	HZR	RESORCIN FUCHSIN	864.1850
88	HZS	SAFRANIN	864.1850
88	HZT	SCHIFF REAGENT	864.1850
88	HZX	SILVER NITRATE	864.1850
88	HZY	SIRIUS RED	864.1850
88	HZZ	SUDAN BLACK B	864.1850
88	IAA	TITAN YELLOW	864.1850
88	IAB	TOLUIDINE BLUE	864.1850
88	IAC	VAN GIESON'S STAIN	864.1850
88	IAD	VAN GIESON'S PICRO-FUCHSIN	864.1850
88	IAE	WEIGERT'S IRON HEMATOXYLIN	864.1850
88	IAF	WRIGHT'S STAIN	864.1850
88	IAM	LUGOL'S SOLUTION	864.4010
88	IAT	APATHY'S GUM SYRUP	864.4010
88	IAW	COLLODION	864.4010
88	IBJ	ICROSCOPE, LIGHT	864.3600
88	IBK	MICROSCOPE, FLUORESCENCE/UV	864.3600
88	IBL	MICROSCOPE, INVERTED STAGE, TISSUE CULTURE	864.3600
88	IBM	MICROSCOPE, PHASE CONTRAST	864.3600
88	ICC	EOSIN B	864.1850
88	ICD	DARROW RED	864.1850
88	ICF	CRYSTAL VIOLET FOR HISTOLOGY	864.1850
88	ICG	CRESYL VIOLET ACETATE	864.1850
88	ICH	CONGO RED	864.1850
88	ICI	CHROME ALUM HEMATOXYLIN	864.1850
88	ICL	CARBOL FUCHSIN	864.1850
88	ICM	BRILLIANT YELLOW	864.1850
88	ICN	BIEBRICH SCARLET	864.1850
88	ICO	BEST'S CARMINE	864.1850
88	ICQ	AZURE A	864.1850
88	ICR	AZOCARMINE B	864.1850
88	ICS	AZOCARMINE G	864.1850
88	ICT	AZAN COUNTERSTAIN	864.1850
88	ICX	ANILINE	864.1850
88	ICY	ANILINE ACID FUCHSIN	864.1850
88	ICZ	AMMONIACAL SILVER HYDROXIDE SILVER NITRATE	864.1850
88	IDA	ALCIAN BLUE	864.1850
88	IDB	ALDEHYDE FUCHSIN	864.1850
88	IDC	ACRIDINE ORANGE	864.1850
88	IDD	ALIZARIN RED	864.1850
88	IDE	ACID HEMATEIN	864.1850
88	IDF	ACID FUCHSIN	864.1850

88	IDL	MICROTOME, ACCESSORIES	864.3010
88	IDM	MICROTOME, ULTRA	864.3010
88	IDN	MICROTOME, FREEZING ATTACHMENT	864.3010
88	IDO	MICROTOME, ROTARY	864.3010
88	IDP	MICROTOME, CRYOSTAT	864.3010
88	IDQ	INFILTRATOR	864.3010
88	IDR	OVENS, PARAFFIN	864.3010
88	IDS	MELTING POT, PARAFFIN	864.3010
88	IDT	MELTING POINT APPARATUS, PARAFFIN	864.3010
88	IDW	DISPENSERS, PARAFFIN	864.3010
88	IDX	SIEVES, TISSUE	864.3010
88	IDY	FLOTATION BATHS, TISSUE	864.3010
88	IDZ	CASSETTES, TISSUE	864.3010
88	IEG	TABLE, SLIDE WARMING	864.3010
88	IEH	LAMPS, SLIDE WARMING	864.3010
88	IER	OLYETHYLENE GLYCOL (CARBOWAX)	864.4010
88	IEX	GELATIN	864.4010
88	IEZ	CELLOIDIN	864.4010
88	IFF	DECALCIFIER SOLUTION, ELECTROLYTIC	864.4010
88	IFH	ZENKER'S SOLUTION	864.4010
88	IFI	SPRAYS, SYNTHETIC, SMEAR	864.4010
88	IFJ	RICHARDSON GLYCOL FIXATIVE	864.4010
88	IFL	POLETHYLENE GLYCOL PRESERVATIVE	864.4010
88	IFN	ORTH'S SOLUTION	864.4010
88	IFO	NEWCOMER'S SOLUTION	864.4010
88	IFP	FORMALIN, NEUTRAL BUFFERED	864.4010
88	IFQ	MERCURIC CHLORIDE FORMULATIONS	864.4010
88	IFS	HELLY SOLUTION	864.4010
88	IFZ	GELATIN FOR SPECIMEN ADHESION	864.4010
88	IGB	FORMALIN-SODIUM ACETATE SOLUTION	864.4010
88	IGC	FORMALIN-SALINE	864.4010
88	IGD	FORMOL CALCIUM SOLUTION	864.4010
88	IGE	FORMALIN AMMONIUM BROMIDE	864.4010
88	IGF	FORMALIN-ALCOHOL-ACETIC ACID	864.4010
88	IGG	FORMALDHYDE (FORMALIN, FORMOL)	864.4010
88	IGK	CLARKE'S SOLUTION	864.4010
88	IGM	CARNOY'S SOLUTION	864.4010
88	IGN	BOUIN'S FLUID	864.4010
88	IHJ	BLENDORS FOR SPUTUM	864.3010
88	IJZ	CLEARING OIL	864.4010
88	JCC	PH BUFFERS	864.4010
88	JCE	ISOTONIC SOLUTION	864.4010
88	JCH	ESTERASE	864.1850
88	JCI	ACID PHOSPHATASE, CYTOCHEMICAL	864.1850
88	JTS	STAINS, MICROBIOLOGIC, ALL	864.1850

88	KDX	DECALCIFIER SOLUTION, ACID CONTAINING	864.4010
88	KDY	CHELATING AGENTS FOR DECALIFICATION	864.4010
88	KDZ	DEALCIFIER DEVICES, ELECTROLYTIC	864.3010
88	KEE	OSMIUM TETROXIDE	864.4010
88	KEF	PARAFORMALDEHYDE	864.4010
88	KEG	LAMPS, MICROSCOPE	864.4010
88	KEH	MICROMETERS, MICROSCOPE	864.3600
88	KEI	CONDENSERS, MICROSCOPE	864.3600
88	KEJ	STAGES, MICROSCOPE	864.3600
88	KEL	ALBUMIN-BASED ADHESIVES	864.4010
88	KEM	CLEARING AGENTS	864.4010
88	KEO	PARAFFIN, ALL FORMULATIONS	864.4010
88	KEP	OIL SOLUBLE MOUNTING MEDIA	864.4010
88	KEQ	WATER SOLUBLE MOUNTING MEDIA	864.4010
88	KER	EMBEDDING CONTAINER	864.3010
88	KES	COVERSLIPS, MICROSCOPE SLIDE	864.3010
88	KET	FILTER, CELL COLLECTION, TISSUE	864.3010
88	KEW	SLIDES, MICROSCOPE	864.3010
88	KFC	METHYLENE BLUE, TISSUE STAIN	864.1850
88	KFD	ANILINE BLUE	864.1850
88	KFE	NEUTRAL RED	864.1850
88	KFL	MICROTOME, SLIDING	864.3010
88	KIY	CHAMBER, SLIDE CULTURE	864.2240
88	KIZ	DISH, TISSUE CULTURE	864.2240
88	KJA	FLASK, TISSUE CULTURE	864.2240
88	KJB	ROLLER APPARATUS	864.2240
88	KJC	ROLLER BOTTLE, TISSUE CULTURE	864.2240
88	KJD	SPINNER FLASK	864.2240
88	KJE	SPINNER SYSTEM, CELL CULTURE	864.2240
88	KJF	SUSPENSION SYSTEM, CELL CULTURE	864.2240
88	KJG	TUBE, TISSUE CULTURE	864.3010
88	KJH	PERFUSION APPARATUS	864.2240
88	KJK	AURAMINE O	864.1850
88	KJL	AZURE C	864.1850
88	KJM	BISMARCK BROWN Y	864.1850
88	KJN	BRILLIANT CRESYL BLUE	864.1850
88	KJO	BRILLIANT GREEN	864.1850
88	KJP	CARMINE	864.1850
88	KJQ	CHLORAZOL BLACK E	864.1850
88	KJR	ERYTHROSIN B	864.1850
88	KJS	ETHYL EOSIN	864.1850
88	KJT	INDIGOCARMINE	864.1850
88	KJW	JANUS GREEN B	864.1850
88	KJX	JENNER STAIN	864.1850
88	KJY	MALACHITE GREEN	864.1850

88	KJZ	MARTIUS YELLOW	864.1850
88	KKA	METHYL ORANGE	864.1850
88	KKB	METHYL VIOLET 2B	864.1850
88	KKC	METHYLENE VIOLET	864.1850
88	KKD	NIGROSIN	864.1850
88	KKE	ORANGE II	864.1850
88	KKF	ORCEIN	864.1850
88	KKG	PROTARGOL S	864.1850
88	KKH	RESAUZRIN TABLET	864.1850
88	KKI	ROSE BENGAL	864.1850
88	KKJ	SUDAN III	864.1850
88	KKK	SUDAN IV	864.1850
88	KKL	THIONIN	864.1850
88	KKM	METHYLENE BLUE THIOCYANATE	864.1850
88	KKP	SILVER CARBONATE SOLUTION	864.1850
88	KKQ	SODIUM PERIODATE	864.1850
88	KKR	POTASSIUM PERIODATE	864.1850
88	KKS	PERIODIC ACID	864.1850
88	KKT	HEMATOXYLIN EHRLICH'S	864.1850
88	KKW	BASIC FUCHSIN	864.1850
88	KQD	HEMATOLOGY STAINS	864.4010

PHYSICAL MEDICINE DEVICES

(Final Regulation Published in November 23, 1983 Federal Register;
EFFECTIVE DATE: 12/23/83)

89	IKW	UTENSIL, HOMEMAKING	890.5050
89	IKX	AID, TRANSFER	890.5050
89	ILC	UTENSIL, EATING	890.5050
89	ILD	ADAPTOR, DRESSING	890.5050
89	ILE	SLING, ARM, OVERHEAD SUPPORTED	890.3475
89	ILG	STOCKING, ELASTIC	890.3475
89	ILH	SPLINT, HAND, AND COMPONENTS	890.3475
89	ILI	SLING, ARM	890.3640
89	ILP	SYSTEM, COMMUNICATION, NON-POWERED	890.3700
89	ILS	ADAPTOR, HYGIENE	890.5050
89	ILT	ADAPTOR, RECREATIONAL	890.5050
89	ILW	ADAPTOR, GROOMING	890.5050
89	ILZ	ACCESSORIES, TRACTION	890.5925
89	IMA	HEAT PACK, MOIST	890.5730
89	IME	PACK, HOT OR COLD, REUSABLE	890.5700
89	IMS	SUPPORT, HEAD AND TRUNK, WHEELCHAIR	890.3910
89	IMX	BOARD, LAP, WHEELCHAIR	890.3910
89	IMY	ARMBOARD, WHEELCHAIR	890.3910

89	IMZ	HOLDER, CRUTCH AND CANE, WHEELCHAIR	890.3910
89	INC	CUFF, PUSHER, WHEELCHAIR	890.3910
89	INE	SLING, OVERHEAD SUSPENSION, WHEELCHAIR	890.3910
89	INF	SCALE, PLATFORM, WHEELCHAIR	890.3940
89	INP	TIPS AND PADS, CANE, CRUTCH AND WALKER	890.3790
89	INT	PLINTH	890.3520
89	IOD	COMPONENTS, EXERCISE	890.5350
89	IOE	BARS, PARALLEL, EXERCISE	890.5370
89	IOG	TREADMILL, MECHANICAL	890.5370
89	ION	EXERCISER, NON-MEASURING	890.5370
89	IOY	SUPPORT, ARM	890.3475
89	IOZ	SPLINT, ABDUCTION, CONGENITAL HIP DISLOCATION	890.3665
89	IPG	SHOE, CAST	890.3025
89	IPM	COVER, LIMB	890.3025
89	IPR	CRUTCH	890.3150
89	IPS	CANE	890.3075
89	IPT	ORTHOSIS, THORACIC	890.3490
89	IPW	ORTHOSIS, SACROILIAC, SOFT	890.3490
89	IPX	ORTHOSIS, RIB FRACTURE, SOFT	890.3490
89	IPY	ORTHOSIS, LUMBO-SACRAL	890.3490
89	IQE	ORTHOSIS, LUMBAR	890.3490
89	IQF	ORTHOSIS, CERVICAL-THORACIC, RIGID	890.3490
89	IQG	ADAPTOR, HOLDER, SYRINGE	890.5050
89	IQI	ORTHOSIS, LIMB BRACE	890.3475
89	IQJ	SPLINT, CLAVICLE	890.3490
89	IQK	ORTHOSIS, CERVICLE	890.3490
89	IQM	SPLINT, TEMPORARY, TRAINING	890.3025
89	IQO	DEVICE, PROSTHESIS ALIGNMENT	890.3025
89	IQP	ROTATOR, TRANSVERSE	890.3025
89	IQQ	JOINT, SHOULDER, EXTERNAL LIMB COMPONENT	890.3420
89	IQW	HOOK, EXTERNAL LIMB COMPONENT, POWERED	890.3420
89	IQX	HOOK, EXTERNAL LIMB COMPONENT, MECHANICAL	890.3420
89	IQZ	HAND, EXTERNAL LIMB COMPONENT, POWERED	890.3420
89	IRA	HAND, EXTERNAL LIMB COMPONENT, MECHANICAL	890.3420
89	IRD	JOINT, ELBOW, EXTERNAL LIMB COMPONENT, MECHANICAL	890.3420
89	IRE	JOINT, ELBOW, EXTERNAL LIMB COMPONENT, POWERED	890.3420
89	ISH	ANKLE/FOOT, EXTERNAL LIMB COMPONENT	890.3420
89	ISL	JOINT, HIP, EXTERNAL LIMB COMPONENT	890.3420
89	ISM	PYLON, POST SURGICAL	890.3025
89	ISN	CABLE	890.3420
89	ISP	VALVE, PROSTHESIS	890.3420
89	ISR	BAND OR BELT, PELVIC SUPPORT	890.3425

89	ISS	PROSTHESIS, THIGH SOCKET, EXTERNAL COMPONENT	890.3420
89	ISY	JOINT, KNEE, EXTERNAL LIMB COMPONENT	890.3420
89	ISZ	UNIT, WRIST, EXTERNAL LIMB COMPONENT, MECHANICAL	890.3420
89	ITC	STIRRUP, EXTERNAL BRACE COMPONENT	890.3410
89	ITG	BANDAGE, CAST	890.3025
89	ITJ	WALKER, MECHANICAL	890.3825
89	ITM	CAGE, KNEE	890.3475
89	ITN	SPLINT, DENIS BROWN	890.3675
89	ITO	TWISTER, BRACE SETTING	890.3410
89	ITQ	JOINT, KNEE, EXTERNAL BRACE	890.3475
89	ITS	JOINT, HIP, EXTERNAL BRACE	890.3475
89	ITW	JOINT, ANKLE, EXTERNAL BRACE	890.3475
89	KGH	UNIT, WRIST, EXTERNAL LIMB COMPONENT, POWERED	890.3420
89	KHY	CANE, SAFETY WALK	890.3075
89	KND	ACCESSORIES, WHEELCHAIR	884.5390
89	KNL	BOARD, SCOOTER, PRONE	890.5370
89	KNP	ORTHOSIS, CORRECTIVE SHOE	890.3475
89	KTZ	BATH, SITZ, NON-POWERED	888.4150

RADIOLOGICAL DEVICES
(Final Regulation Published in January 20, 1988 FEDERAL REGISTER; EFFECTIVE DATE: 2/19/88)

90	IWY	HOLDER, HEAD, RADIOGRAPHIC	892.1920
90	IXF	TEST PATTERN, RADIOGRAPHIC	892.1940
90	IXG	PHANTOM, ANTHROPOMORPHIC, RADIOGRAPHIC	892.1950

CLINICAL TOXICOLOGY DEVICES
(Final Regulation Published in May 1, 1987 FEDERAL REGISTER; EFFECTIVE DATE: 7/30/87)

91	DJS	UV LIGHT, TLC	862.2270
91	DKK	DEVELOPING TANKS, TLC	862.2270
91	DLC	ATOMIZER, TLC	862.2270
91	DPA	THIN LAYER CHROMATOGRAPHY, APPARATUS, GENERAL USE	862.2270

ATTACHMENT B

ADVISORY LIST OF DEVICES

THAT ARE INTENDED FOR SURGICAL IMPLANT OR SUSTAINING LIFE

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION
(Docket No. 86N-0499)
ADVISORY LIST OF CRITICAL DEVICES-1988

AGENCY: Food and Drug Administration

ACTION: Notice

SUMMARY: The Food and Drug Administration (FDA) is publishing its updated and expanded "Advisory List of Critical Devices-1988" prepared by FDA's Center for Devices and Radiological Health (CDRH). In the preamble to FDA's final rule establishing good manufacturing practice (GMP) regulations for medical devices that FDA promulgated in 1978, FDA provided an illustrative list of devices that would be subject to the "critical device" requirements in that final rule. FDA's revisions to that list reflect current classification names for devices, changes resulting from petitions for exemption, and FDA decisions based upon recommendations of the Device Good Manufacturing Practices (GMP) Advisory Committee (the Committee). FDA is taking this action under the Medical Device Amendments of 1976.

EFFECTIVE DATE: September 14, 1988

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

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2094 Gaither Road
Rockville, MD 20850
Commercial (301) 594-4613, ext 139*

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of July 21, 1978 (43 FR 31508), FDA published the Good Manufacturing Practices (GMP) regulation for medical devices. The preamble to the GMP regulation provided a Guideline List of Critical Devices (43 FR 31511). This was an illustrative list of 75 devices provided to give examples of devices that FDA concluded met the definition of critical device as found in the final GMP regulation (21 CFR 820.3(f)). The definition reads as follows, "a device that is intended for surgical implant into the body or to support or sustain life and whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user." In developing this list, FDA used the recommendations received from the Committee (21 CFR 14.100(d)(2)) and the device advisory panels (21 CFR 14.100(d)(1)). The agency announced that the list was not exhaustive and that it was based on the most current information available to FDA. The agency also stated that the list would be updated periodically as additional information became available and after consultation with the Committee (43 FR 31511).

Since publication of the original list of 75 critical devices, 6 devices have been removed from the list. In the FEDERAL REGISTER of November 14, 1978 (43 FR 52701), FDA published a correction to the original "Guideline List of Critical Devices" to remove 2 of the 75 devices: catheter, embolectomy (No. 16); and catheter, septostomy (No. 18). These 2 devices were erroneously listed as critical devices.

On July 3, 1980, in response to a petition (79P-0460), FDA removed three devices from the critical device list: airway, bi-nasopharyngeal (No. 1); airway, nasopharyngeal (No. 3); and airway, oropharyngeal (No. 4). After examining manufacturing inspection reports, performance data, and the manufacturing technology used to fabricate these devices, the agency determined that noncritical GHP requirements are sufficient to provide reasonable assurance of the safety and effectiveness of these three devices.

On September 9, 1982, in response to a petition (81P-0362), FDA clarified its intent to require critical controls only for the life supporting or life sustaining gas machine for anesthesia (21 CFR 868.5160(a)) (No. 42). Previously, in the FEDERAL REGISTER of July 16, 1982 (47 FR 31130), FDA had identified separately the gas machine for analgesia intended for dental conscious sedation (21 CFR 868.5160(b)). In response to the petition, FDA determined that the gas machine for analgesia was neither life sustaining nor life supporting and did not meet the definition of a critical device in 21 CFR 820.3(f).

The Committee has held several meetings to discuss additions and changes to the original "Guideline List of Critical Devices." The meeting transcripts and summary minutes for June 29, 1979, November 8 and 9, 1979, July 22, 1980, March 29, 1984, October 23 and 24, 1985, and March 20 and 21, 1986, are available from the Dockets Management Branch (86N-0499). Data used by the Committee to for prepare for the October 1985 and March 1986 meetings are also available from the Dockets Management Branch. The information available includes the Committee's vote in 1979, the identified risks to health attributed to the use of each device, the additional GMP requirements that apply only to critical devices, and the rationale for these additional requirements.

Although the Committee discussed critical device issues at the June 1979 meeting, no voting took place. At the November 1979 meeting, the Committee recommended that 88 of 107 proposed additions be considered critical devices. The Committee reconsidered 20 of these devices at the July 1980 meeting, and as a result of presentations made by interested parties, again voted to add 19 of the 20 devices to the critical device list.

In October 1985, and in March 1986, the Committee again considered the devices that had previously been recommended for the critical device list as well as newly proposed additions to the list. Based upon information and recommendations from the classification panels and the appropriate divisions within CDRH, and based upon the recommendations of the Committee, the list of critical devices was again expanded and is now comprised of 182 devices.

To accommodate all of these changes, the FDA is making available its revised and expanded "Advisory List of Critical Devices -- 1988." The list identifies devices by Code of Federal Regulations (CFR) part and Section numbers, and by the classification names of the devices established in FDA's classification regulations (21 CFR Parts 862 through 892). For each device on the current critical device list that was also on the original list, FDA is cross-referencing the number (1 through 75) of that device on the former list.

The term "classification name" of a device is defined at 21 CFR 807.3(j) to mean "***" the term used by the Food and Drug Administration and its classification panels to describe device or class of devices "for purposes of classifying devices under section 513 of the act." For those few devices whose classification has been proposed but is not yet final, FDA is identifying the devices by the names used in their proposed classification regulations. In its list, FDA also is cross-referencing the former names for those devices on the list that were used before the classification regulations were promulgated.

Devices which are not the subject of proposed or final classification regulations are identified by a suitable description of their regulatory status. In those situations where not all devices identified in a section of a classification regulation are considered to be critical devices, the list describes which of the devices covered by the section are considered to be critical devices.

Periodically, FDA will revise its list after consulting with the Committee. Any revisions of the list will be published in the FEDERAL REGISTER and *will be available from the Dockets Management Branch and from CDRH's Division of Small Manufacturers Assistance (DSMA), Rockville, Maryland 20850.* As stated in the preamble to the GMP regulations, FDA emphasis is that this list of devices only illustrative and is not intended to be binding or exhaustive (43 FR 31511). Each manufacturer should continue to refer to the definition of a critical device (21 CFR 820.3(f)) in determining whether the critical device requirements apply to that manufacturer's device.

In order to allow manufacturers sufficient time to comply with critical device requirements, FDA advises that it does not intend to apply those requirements to newly added devices for a period of 180 days from the date of this notice.

A person seeking some form of administrative action with respect to the list of critical devices may file a citizen petition pursuant to 21 CFR 10-30. FDA requests that each petition address the scope of the action of relief sought, such as whether it would apply to a particular manufacturer or to all manufacturers of the subject device or devices. Guidance on how to file a petition is available from the Division of Small Manufacturers Assistance (DSMA). DSMA can be contacted at: 800-638-2041 or (301)443-6597. FAX number is (301)443-8818.

For the convenience of the reader, the agency is publishing its "Advisory List of Critical Devices-1988" in its entirety:

PART 868 -- ANESTHESIOLOGY DEVICES

	CFR or FR Cite	Classification Name of Device	Device No. on Original List	Former device name, or Additional Information
1.	868.1200	Indwelling blood oxygen partial pressure (P_{02}) analyzer.	5	Analyzer, oxygen, Neonatal Invasive
2.	868.2375	Breathing frequency monitor.	--	Apnea monitor.
3.	868.5090	Emergency airway needle.	43	Needle, emergency airway.
4.	868.5160(a)	Gas machine for anesthesia	42	Machine, gas anesthesia/ analgesia, complete systems. Section 868. 5160(b) Gas machine for analgesia is exempt from critical device requirements.
5.	868.5240	Anesthesia breathing circuit.	19	Circuit, breathing (w/ connector, adaptor y-piece).
6.	868.5400	Electroanesthesia apparatus.	6,62	Apparatus, electro-anesthesia; and stimulator, electro-anesthesia.
7.	**868.5440**	**Portable oxygen generator.**	**32**	**Generator, oxygen, portable.#See Pg 25**
8.	868.5470	Hyperbaric chamber. (Monoplace)	--	---

9.	868.5610	Membrane lung for long-term pulmonary support.	41	Lung, membrane (for long-term pulmonary support).
10.	868.5650	Esophageal obturator.	2	Airway, esophageal (obturator).
11.	868.5720	Bronchial tube.	66	Tube, bronchial (w/wo connector).
12.	868.5730	Tracheal tube.	67	Tube, tracheal (w/wo connector
13.	868.5740	Tracheal/bronchial differential ventilation tube.	68	Tube, tracheal/bronchial, differential/ventilation (w/wo connector).
14.	868.5750	Inflatable tracheal tube cuff.	27	Cuff, tracheal tube, inflatable.
15.	868.5800	Tracheostomy tube and tube cuff.	69	Tube, tracheostomy (w/wo connector).
16.	868.5810	Airway connector.	25	Connector, airway (extension).
17.	868.5830	Autotransfusion apparatus.	9	Autotransfusion apparatus.
18.	868.5895	Continuous ventilator.	73,56	Ventilator, continuous (respirator) and respirator, neonatal ventilator
19.	868.5905	Noncontinuous ventilator (IPPB).	75	Ventilator, noncontinuous (respirator).
20.	868.5915	Manual emergency ventilator.	58,70	Manual emergency ventilator; and resuscitator, pulmonary, manual.
21.	868.5925	Powered emergency ventilator.	70	Unit emergency oxygen and resuscitation.

22.	868.5935	External negative pressure ventilator.	74	Ventilator, external body negative pressure, adult (cuirass).

PART 870 - CARDIOVASCULAR DEVICES

23.	870.1025	Arrhythmia detector and alarm.	29	Detector and alarm, arrhythmia.
24.	870.1330	Catheter guide wire.	--	For use with percutaneous transluminal coronary angioplasty catheters. (See #56.)
25.	870.1360	Trace microsphere.	--	---
26.	870.1750	External programmable pacemaker pulse generator.	34	Generator, pulse, pacemaker, external, programmable.
27.	870.1800	Withdrawal-infusion PUMP.	54	Pump, withdrawal/ infusion.
28.	870.3250	Vascular clip.	22	Clip, vascular.
29.	870.3260	Vena cava clip.	23	Clip, vena cava.
30.	870.3300	Arterial embolization device.	--	---
31.	870.3375	Cardiovascular intravascular filter.	31	Filter, intravascular, cardiovascular
32.	870.3450	Vascular graft prosthesis of less than 6-millimeters diameter.	47,52	Prosthesis, arterial graft synthetic, and prosthesis vascular graft.
33.	870.3460	Vascular graft prosthesis of 6 millimeters and greater diameter.	47,52	Prosthesis, arterial graft synthetic, and prosthesis, vascular graft.
34.	870.3470	Intracardiac patch or pledget made of poly-	--	---

		propylene. polyethylene polyethylene tere-phthalate, or polytetra-fluoroethylene.		
35.	870.3535	Intra-aortic balloon and control system.	10	Balloon, intra-aortic, and control system.
36.	870.3545	Ventricular bypass (assist) device.	15	Bypass, ventricular (assist).
37.	870.3600	External pacemaker Pulse generator.	33	Generator, pulse, pacemaker, external.
38.	870.3610	Implantable pacemaker pulse generator.	35	Generator, pulse, pace-maker, implantable.
39.	870.3620	Pacemaker lead adaptor.	--	---
40.	870.3650	Pacemaker polymeric mesh bag.	--	---
41.	870.3670	Pacemaker charger.	--	---
42.	870.3680	Cardiovascular permanent or temporary pacemaker, electrode.	30	Electrode, pacemaker, permanent and tempor-ary.
43.	87O.3700	Pacemaker programmers.	--	---
44.	870.3710	Pacemaker repair or replacement material.	--	---
45.	870.3800	Annuloplasty ring.	--	---
46.	870.3850	Carotid sinus nerve stimulator.	--	---
47.	870.3925	Replacement heart valve.	71	Valve, heart replacement.
48.	870.4320	Cardiopulmonary bypass pulsatile flow generator.	--	---

49.	870.4350	Cardiopulmonary bypass oxygenator.	44	Oxygenator, cardiopul-- monary.
50.	870.4360	Nonroller-type cardiopulmonary bypass blood pump.	13	Blood pump, cardiopul-monary bypass, non-roller.
51.	870.4370	Roller-type cardiopulmonary bypass blood pump.	14	Blood pump, cardiopulmonary bypass roller type.
52.	870.5200	External cardiac compressor.	24,57	Compressor, external, cardiac powered, and resuscitator, cardiac mechanical.
53.	870.5225	External counter-pulsating device.	26	Counter-pulsating device, external.
54.	870.5300	DC-defibrillator (including paddles).	28	Defibrillator, DC-powered (including paddles).
55.	870.5550	External transcutaneous cardiac pacemaker (noninvasive).	45	Pacemaker, cardiac, external transcutan-eous.
56.	---	Percutaneous trausluminal coronary angiooiasty (PTCA) balloon dilation catheter.	--	Premarket approval device.
57.	---	Automatic Implanted Cardioverter Defibril-lator System.	--	Premarket approval device.
		PART 872 -- DENTAL DEVICES		
58.	872.3640	Endosseous implant.	--	---
		PART 874 -- EAR, NOSE, AND THROAT DEVICES		
59.	874.3620	Ear, nose and throat synthetic polymer material.	--	---

60.	874.3695	Mandibular implant facial prosthesis.	--	---
61.	874.3730	Laryngeal prosthesis (Taub design).	49	Prosthesis, Laryngeal
62.	874.3820	Endolymphatic shunt	--	---
63.	874.3850	Endolymphatic shunt tube with valve.	--	---
64.	874.3930	Tympanostomy tube with semipermeable membrane	--	---
65.	---	Ear, nose, throat natural polymer - collagen material.	--	Pre-Amendments Device; not classified.

PART 876 -- GASTROENTEROLOGY-UROLOGY DEVICES

66.	876.3350	Penile inflatable implant.	--	---
66a	876.3630	Penile rigidity implant	--	---
67.	876.5270	Implanted electrical urinary continence device.	--	---
68.	876.5540	A-V shunt cannula.	--	Included in blood access device and accessories.
69.	876.5630 #	Peritoneal dialysis system and accessories.	46	Peritoneal dialysis system, automatic delivery
70.	876.5820 #	Hemodialysis system and and accessories. Dialysate concentrate Hollow fiber capillary dialyzers Disposable dialyzers High permeability dialyzers Parallel flow dialyzers Single needle dialysis set Dialysate delivery system	36	Dialysate concentrate added.

 # See charts showing the critical/noncritical breakdown of peritoneal and hemodialysis systems on

pages 21 and 22 of Attachment D.

70A	876.5860 #	High permeability hemodialysis system. 36		Dialysate concentrate added.
71.	876.5870	Sorbent hemoperfusion system.	7	Apparatus, hemoperfusion, sorbent.
72.	876.5880	Isolated kidney perfusion and transport system and accessories.	--	---
73.	876.5955	Peritoneo-venous shunt.	--	---
74.	46 FR 7566 (1/23-/81)	Urethral sphincter prosthesis.	51	Prosthesis, urethra sphincter; device-not known to be in commercial distribution.
75.	46 FR 7566 (1/23/81)	Urethral replacement	55	Replacement, urethral. Device not known to be in commercial distri bution.

PART 878 -- GENERAL AND PLASTIC SURGERY DEVICES

(The following are class III devices. See 21 U.S.C. 360j(l).)

76.	42 FR 63474 (12/16/77)	Absorbable surgical sutures.	--	Class III transitional device.
77.	42 FR 63474 (12/16/77)	Nonabsorbable surgical sutures.	--	Class III transitional device.
78.	879.4520	Polytetrafluoroethylene (Teflon) injectable.	--	Class III transitional device.
79.	878.3300	Surgical mesh.	--	---
80.	878.3500	Polytetrafluoroethylene with carbon fibers	--	---

		composite implant material.		
81.	878.3530	Inflatable breast prosthesis	--	---
82.	878.3540	Silicone gel-filled breast prosthesis.	--	---
83.	---	Implanted mammary prosthesis of composite saline and gel-filled design.	510(k) device.	
84.	878.3610	Esophageal prosthesis.	48	Prosthesis, esophagus.
85.	878.3720	Tracheal prosthesis.	50	Prosthesis, trachea.
86.	878.4300	Implantable clip.	--	---
87.	878.4750	Implantable staple.	--	---
88.	---	Maxillofacial prosthesis.	--	ENT facial prosthesis. maxillofacial.
		PART 880 - GENERAL HOSPITAL AND PERSONAL USE DEVICES		
89.	880.5130	Infant radiant warmer.	12	Bed, radiant heat.
90.	880.5400	Neonatal incubator.	37	Incubator, neonatal ventilator.
91.	880.5410	Neonatal transport incubator.	--	---
92.	880.5725	Infusion pump.	53	Term "cardiovascular" dropped since not used in classification regulation and devices not marketed as "cardiovascular infusion pumps."
93.	--	Implanted infusion pump.	--	Premarket approval device.
		PART 882 - NEUROLOGICAL DEVICES		

94.	882.5030	Methyl methacrylate for aneurysmorrhaphy.	--	---
95.	882.5150	Intravascular occluding catheter.	17	Catheter, intravascular occluding.
96.	882.5200	Aneurysm clip.	20	Clip, aneurysm.
97.	882.5225	Implanted malleable clip.	--	---
98.	882.5250	Burr hole cover.	--	---
99.	882.5300	Methyl methacrylate for cranioplasty	--	---
100.	882.5320	Preformed alterable cranioplasty plate.	--	---
101.	882.5330	Preformed nonalterable cranioplasty plate.	--	---
102.	882.5360	Cranioplasty plate fastener.	--	---
103.	882.5550	Central nervous system fluid shunt and components.	59	Shunt, central nervous system fluid and components.
104.	882.5820	Implanted cerebellar stimulator.	60	Stimulator, cerebella, implanted.
105.	882.5830	Implanted diaphragmatic/ phrenic nerve stimulator.	61	Stimulator, diaphragmatic/ phrenic nerve, implanted.
106.	882.5840	Implanted intracerebral/ subcortical stimulator for pain relief.	63	Stimulator, intracerebral/ subcortical, implanted (pain relief).
107.	882.5850	Implanted spinal cord stimulator for bladder evacuation.	--	---
108.	882.5860	Implanted neuromuscular stimulator.	--	---
109.	882.5870	Implanted peripheral nerve	--	---

		stimulator for pain relief.		
110.	882.5880	Implanted spinal cord stimulator for pain relief.	--	---
111.	882.5880	Epidural spinal electrode.	--	Component of Implanted spinal cord stimulator for pain relief (#110).
112.	882.5900	Preformed craniosynostosis strip.	--	---
113.	882.5910	Dura substitute.	--	---
114.	882.5950	Artificial embolization device.	65	Thromboemboli, intravascular (artificial embolization device).
115.	---	Lyophilized human (cadaver) dura mater.	--	Pre-Amendments device; not classified.
116.	---	Stabilized epidural spinal electrode.	--	Premarket approval device.
117.	---	Implanted intracranial pressure monitor.	--	Premarket approval device.
118.	---	Totally implanted spinal cord stimulator for pain relief.	--	Premarket approval device.

PART 884 - OBSTETRICAL AND GYNECOLOGICAL DEVICES

119.	884.5360	Contraceptive intrauterine device (IUD) and introducer.	38	Intrauterine contraceptive device (IUD) and introducer.
120.	884.5380	Contraceptive tubal occlusion device (TOD) and introducer.	11 21 72	Band, tubal occlusion; Clip, tubal Occlusion; Valve, tubal occlusion.

PART 886 - OPHTHALMIC DEVICES

121.	886.3300	Absorbable implant (scleral buckling method)	--	---
122.	886.3400	Keratoprosthesis	39	Keratoprosthesis, non-custom
123.	886.3600	Intraocular lens	40	Lens, intraocular, ophthalmic; Class III transitional device.
124.	886.3920	Eye valve Implant	--	---

PART 888 ORTHOPEDIC DEVICES

125.	888.3000	Bone Cap.	--	---
126.	888.3010	Bone fixation cerclage.	--	---
127.	888.3020	Intramedullary fixation rod.	--	---
128.	888.3025	Passive tendon prosthesis.	--	---
129.	888.3027	Polymethylmethacrylate (PMMA) bone cement.	--	Class III transitional device.
130.	888.3030	Single/multiple component metallic bone fixation appliances and accessories.	--	---
131.	888.3040	Smooth or threaded metallic bone fixation fastener.	--	---
132.	888.3050	Spinal interlaminal fixation orthosis.	--	---
133.	888.3060	Spinal intervertebral body fixation orthosis	--	---
134.	888.3100	Ankle joint metal/composite semi-constrained cemented prosthesis.	--	---

135.	888.3110	Ankle joint metal/polymer semi-constrained cemented prosthesis.	--	---
136.	888.3120	Ankle joint metal/polymer non-constrained cemented prosthesis.	--	---
137.	888.3150	Elbow joint metal/metal or metal/polymer constrained cemented prosthesis.	--	---
138.	888.3160	Elbow joint metal/polymer semi-constrained cemented prosthesis.	--	---
139.	888.3170	Elbow joint radial (hemi-elbow) polymer prosthesis.	--	---
140.	888.3180	Elbow joint humeral (hemi-elbow) metallic uncemented prosthesis.	--	---
141.	888.3200	Finger joint metal/metal constrained uncemented prosthesis.	--	---
142.	888.3210	Finger joint metal/metal constrained cemented prosthesis.	--	---
143.	888.3220	Finger joint metal/polymer constrained cemented prosthesis.	--	---
144.	888.3230	Finger joint polymer constrained prosthesis.	--	---
145.	888.3300	Hip joint metal constrained cemented or uncemented prosthesis.	--	---
146.	888.3310	Hip joint metal/polymer constrained cemented or uncemented prosthesis.	--	---

147.	888.3320	Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis.	--	---
148.	888.3330	Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis.	--	---
149.	888.3340	Hip joint metal/composite semi-constrained cemented prosthesis.	--	---
150.	888.3350	Hip joint metal/polymer semi-constrained cemented prosthesis.	--	---
151.	888.3360	Hip Joint femoral (hemi-hip) metallic cemented or uncemented prosthesis.	--	---
152.	888.3370	Hip joint (hemi-hip) acetabular metal cemented prosthesis.	--	---
153.	888.3380	Hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis.	--	---
154.	888.3390	Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis.	--	---
155.	888.3400	Hip joint femoral (hemi-hip) metallic resurfacing prosthesis.	--	---
156.	888.3410	Hip joint metal/polymer semi-constrained resurfacing cemented prosthesis.	--	---

157.	888.3480	Knee joint femorotibial metallic constrained cemented prosthesis.	--	---
158.	888.3490	Knee joint femorotibial metal/composite non-constrained cemented prosthesis.	--	---
159.	888.3500	Knee joint femorotibial metal/composite semi-constrained cemented prosthesis.	--	---
160.	888.3510	Knee joint femorotibial metal/polymer constrained cemented prosthesis.	--	---
161.	888.3520	Knee joint femorotibial metal/polymer non-constrained cemented prosthesis.	--	---
162.	888.3530	Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis.	--	---
163.	888.3540	Knee Joint patellofemoral polymer/metal semi-constrained cemented prosthesis.	--	---
164.	888.3550	Knee joint patellofemoro-tibial polymer/metal/ metal constrained cemented prosthesis.	--	---
165.	888.3560	Knee joint patellofemoro-tibial polymer/metal/ polymer semi-constrained cemented prosthesis.	--	---

166.	888.3570	Knee joint femoral (hemi-knee) metallic uncemented prosthesis.	--	---
167.	888.3580	Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis.	--	---
168.	888.3590	Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis.	--	---
169.	888.3640	Shoulder joint metal/metal or metal/polymer constrained cemented prosthesis.	--	---
170.	888.3650	Shoulder joint metal/ polymer non-constrained cemented prosthesis.	--	---
171.	888.3660	Shoulder joint metal/ polymer semi-constrained cemented prosthesis.	--	---
172.	888.3680	Shoulder Joint glenoid (hemi-shoulder) metallic cemented prosthesis.	--	---
173.	888.3690	Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.	--	---
174.	888.3720	Toe Joint polymer constrained prosthesis.	--	---
175.	888.3730	Toe Joint phalangeal (hemi-toe) polymer prosthesis.	--	---
176.	888.3750	Wrist joint carpal lunate polymer prosthesis.	--	---
177.	888.3760	Wrist joint carpal scaphoid	--	---

		Polymer prosthesis.		
178.	888.3770	Wrist Joint carpal trapezium polymer prosthesis.	--	---
179.	888.3780	Wrist joint polymer constrained prosthesis.	--	---
180.	888.3790	Wrist joint metal constrained cemented prosthesis.	--	---
181.	888.3800	Wrist Joint metal/polymer semi-constrained cemented prosthesis.	--	---
182.	888.3810	Wrist joint ulnar (hemi-wrist) polymer prosthesis.	--	---

PERITONEAL DIALYSIS SYSTEMS AND ACCESSORIES

INDIVIDUAL DEVICE	COMPONENT	ACCESSORY	CRITICAL	
			YES	NO
Semi-auto Peritoneal Dialysis System			X	
Auto. Peritoneal Dialysis System			X	
Single Use Peritoneal Catheter			X	
Long Term Peritoneal Catheter			X	
		Stylet		X
		Trocar		X
		Obturator		X
		Disposable Administration Set	X	
		Peritoneal Dialysate Fileter		X

As of this time, the following peritoneal dialysate products are considered drugs and are registered by the CDER: sterile prepackaged dialysate and dialysate solutions for peritoneal dialysis.

HEMODIALYSIS SYSTEMS AND ACCESSORIES

INDIVIDUAL DEVICE	COMPONENT	ACCESSORY	CRITICAL	
			YES	NO
Conventional Dialyzer			X	
Dialysate Delivery			X	
	Water Purification System		X	
	Monitor & Control Mechanisms		X	
	Alarms		X	
		Unpowered HD Chair w/o Scale		X
		Powered HD Chair w/o Scale		X
		Dialyzer Holder Set		X
		Dialysis Tie Gun & Ties		X
		Hemodialysis Start/Stop Tray		X
		Hemodialysis Concentrate	X	
Extracorporeal Blood System			X	
	Tubing		X	
	Pumps		X	
	Pressure Monitors		X	
	Air Foam or Bubble Detectors		X	
	Alarms		X	

* Water purification systems when part of the dialysis delivery system.

ATTACHMENT B-1

"SIGNIFICANT RISK DEVICES" *

ANESTHESIOLOGY

Gas Machines for analgesia

CARDIOVASCULAR

Artificial Heart, permanent implant and short term use
Coronary Artery Retroperfusion System
Laser Coronary Angioplasty Device
Percutaneous Conduction Tissue Ablation Electrode

DENTAL

Total Temporomandibular Joint (TMJ) Prosthesis
TMJ Implants
Glenoid Fossa Prosthesis
Mandibular Condyle Prosthesis
Interarticular Disc Prosthesis
Collagen for any dental use
Bone filling and augmentation materials
Absorbable materials
Subperiosteal implants

EAR, NOSE AND THROAT

Total Ossicular Prosthesis Replacement

GASTROENTEROLOGY AND UROLOGY

Endoscope and/or Accessories
Extracorporeal Hyperthermia System
Extracorporeal Photophersis System
Extracorporeal Shock-Wave Lithotriptor
Mechanical/Hydraulic Incontinence Devices

* Defined according to 21 CFR 812.3 (m), Definitions for Investigational Device Exemptions. Significant risk devices that are also critical devices are included in the preceding advisory list of devices that are intended for surgical implant or sustaining life in Attachment B.

GENERAL MEDICAL USE

Catheters: Cardiology - diagnostic and treatment types
Gastroenterology and Urology - biliary and urologic
General Hospital - long-term percutaneous, implanted, subcutaneous and intravascular

Collagen Implant Material for use in orthopedics and plastic surgery
Lasers for use in Ob/Gyn, cardiology, gastroenterology, urology, pulmonary, ophthalmology and neurology. Tissue Adhesives for use in neurology, gastroenterology, ophthalmology, general and plastic surgery, and cardiology

GENERAL AND PLASTIC SURGERY

Absorbable Hemostatic Agents
Artificial Skin
Injectable Silicone
Silicon gel filled Angelchik Reflux Valve
Silicon gel filled Chin Prosthesis

OBSTETRICS AND GYNECOLOGY

Cervical Dilator
Chorionic Villus Sampling Catheter, phase II (pregnancy continued to term)
Contraceptive Devices: cervical cap, diaphragm, and sponge
Silicone gel filled Testicular Prosthesis

OPHTHALMICS

Extended Wear Contact Lens
Retinal Reattachment Systems: sulfur hexafluoride, silicone oil, tacks, perfluropropane

ORTHOPEDICS

Implantable ligament Prostheses:
Bone Growth Stimulator
Calcium Tri-Phosphate/Hydroxyapatite Ceramics
Xenografts

RADIOLOGY

Hyperthermia Systems and Applicators

SUPPLEMENTAL INFORMATION

* With regard to portable oxygen generators, the molecular sieve, or oxygen concentrator device, is not considered a critical device for purposes of applying the GMP, when it is intended for home respiratory therapy use.*

ATTACHMENT C

BACKGROUND

This attachment provides guidance for determining manufacturer compliance with the MDR regulation, 21 CFR Part 803. This audit must be accomplished for each inspection conducted under this compliance program. This is an interim program and will be evaluated after six months.

SPECIAL INSTRUCTIONS

A. The effective dates for two provisions of the MDR regulation have been stayed:

1. U.S. Designated Agent requirements, 21 CFR Parts 803.58, 807.3, 807.20 and 807.40, and the

2. Baseline Reports, only sections 21 CFR Parts 803.55(b) (9) and (10), which correlate to items 15 and 16 on the Baseline Report, FDA Form 3517.

B. Recommendations for all regulatory/administrative actions involving MDR violations will be forwarded to CDRH for 12 months after the effective date of MDR (July 31, 1996). This temporary suspension of direct reference authority will provide CDRH with sufficient time to identify and resolve MDR policy issues and to develop guidance.

NOTE: The aforementioned changes do not affect the field's authority to identify and cite, on FDA Form 483, any failure to comply with the remaining provisions of MDR. Manufacturers are required to report device related deaths, serious injuries, malfunctions, to develop written MDR procedures, investigate device related events, maintain MDR event files, etc. All MDR requirements not affected by the stay will be enforced.

SECTION I

INSPECTION OF MANUFACTURER

A. WRITTEN PROCEDURES

The following section of MDR are pertinent to this audit:

803.17 - Written MDR Procedures

803.18 - Files

803.50 - Individual Adverse Event Reports

803.53 - Five-Day Reports

803.55 - Baseline Reports - **MODIFIED BY STAY**

803.56 - Supplemental Reports

B. GENERAL

Attachment C-1 to this program provides general guidance regarding the submission of MDR reports. Attachment C-2 lists sources of information that may be helpful to an establishment who may not be aware of MDR. Additional MDR reference information has been forwarded to the field including copies of all MDR forms, the guidance document for Device Manufacturers as well as an overview of the MDR Regulation. These documents should be available from your Public Affairs Specialist or Small Business Representative. If not, refer to Attachment C-2 for information on how to obtain copies.

If you have questions about this Compliance Program, contact Chet Reynolds, 301-594-4618, ext. 114 or FAX at 301-594-4610. For questions regarding MDR interpretation, contact 301-594-2735 or FAX 301-827-0038.

C. INSPECTION PROCEDURES

This interim program was designed to be tutorial and reduce the need to constantly refer to the MDR regulation for guidance. Each section begins with an outline of the relevant requirements (Items 1, 3, and 5). The establishment's compliance with each of the items in these sections should be ascertained. Each section is followed by an audit section (Items, 2, 4, and 6) that further directs the scope of the inspection.

1. Written Procedures - 803.17

Manufacturers are required to develop, maintain and implement written MDR procedures

for the following areas:

- ❑ Internal Systems that provide for:
  - ♦ The timely and effective identification, communication and evaluation of events that may be subject to medical device reporting.
- ❑ A standard review process/procedure for:
  - ♦ Determining when an event meets the criteria for reporting an MDR event,
  - ♦ Timely transmission of complete medical device reports to FDA.
- ❑ Documentation and record keeping for:
  - ♦ Information evaluated to determine if an event is reportable,
  - ♦ All MDR reports and other information submitted to FDA,
  - ♦ Systems that ensure access to information that facilitates timely follow-up and inspection by FDA.

2. Audit Written Procedures

- ❑ Deficiencies in any of the preceding or following items should be noted on an FDA Form 483:
  - ♦ Does the establishment have written MDR procedures,
  - ♦ Are the procedures complete in all three areas,
  - ♦ Does the establishment follow its procedures.

3. Files - 803.18

- ❑ General Filing Requirements:
  - ♦ Manufacturers must establish and maintain MDR event files,
  - ♦ MDR files must be prominently identified as such and filed in a manner that facilitates access by an FDA investigator,
  - ♦ MDR files may be maintained as part of 820.198 complaint files IF they comply

with the aforementioned two criteria,

- ♦ MDR files may be hard copy or electronic.

❑ Content of Files:

- ♦ Information, from any source, that describes a device related death, serious injury or malfunction. In many instances this will be MedWatch FDA Forms 3500A/3500, but events not received from a User Facility may be on any form,
- ♦ Documentation of the establishment's deliberations/decision-making process that determined if an event was reportable,
- ♦ Copies of all MDR forms and other MDR related information submitted to FDA by the establishment, i.e., MedWatch FDA Form 3500A, Baseline Report FDA Form 3417, any Supplemental Reports or responses to FDA requests for information, etc.

4. Audit Files

Deficiencies in any of the preceding or following items should be noted on the FDA Form 483:

a. Does the establishment have an MDR event file.

b. Is the file easy to identify/access.

c. Does the file contain copies of:

- ♦ Death, Serious Injury and /or Malfunction Reports, FDA Form 3500A;
- ♦ Baseline Reports, FDA Form 3417;
- ♦ Supplemental Reports, FDA Form 3500A;
- ♦ Five-Day Reports, FDA Form 3500A;
- ♦ Other MDR correspondence with FDA and/or reporters.

d. Documentation concerning each decision to file/not file an MDR report for a device-related events.

e. Events involving a device related death, serious injury, and/or malfunction not reported to FDA must have written documentation from qualified medical staff explaining and/or justifying the decision. Document the credentials of the qualified medical staff making

decisions not to report a device related event.

f. Copies of any failure analysis, evaluation, or other cause and effect determination and any other relevant MDR information.

g. If MDR event files are contained within GMP files, the records must be readily identifiable as MDR records.

5. Individual Adverse Reaction Reports - 803.50

❑ General Requirements:

- ♦ Manufacturers must submit death, serious injury, and malfunction reports within 30 days after they become aware of a reportable event.
- ♦ The information can come from any source.
- ♦ Devices that "may have caused or contributed" to a death or serious injury; or a malfunction that would be likely to cause or contribute to a death or serious injury must be reported.

❑ Reasonably Known:

Establishments must provide all information that is reasonably known to them. FDA considers the following to meet this standard, i.e., any information:

- ♦ that can be obtained by contacting a user facility, distributor, and/or other initial reporter,
- ♦ in the manufacturer's possession,
- ♦ that can be obtained by analysis, testing or other evaluation of the device.

❑ Information required to be reported:

- ♦ The FDA Form 3500A is the primary reporting form for death, serious injury and malfunction events. With the exception of drug or biologic related items, all the fields must be completed or have an entry (NA, NI or UNK) indicating why the information could not be obtained.

❑ Missing Information:

- ♦ Manufacturers are responsible for obtaining and providing FDA with any information that is missing from reports that are received from user facilities,

distributors, and other initial reporters.

- If an establishment cannot provide complete information, it must provide a statement explaining why such information was incomplete and the steps taken to obtain the information.

- Any required information that is not available at the time of the report, obtained at a later date, must be forwarded to FDA in a supplemental report within 30 days.

❑ Investigation:

- manufacturers are responsible for investigating EACH event and evaluating the cause of each event.

- These investigations must follow the requirements in 820.198 and 820.162, and provide the information required on FDA Form 3500A, Block H.6, H.7, and H.9.

❑ Five-Day Reports - 803.53:

- Manufacturers must submit a five-day report on FDA Form 3500A within five days under the following two conditions:

  ✧ They become aware that an MDR reportable event, from any source, requires remedial action to prevent an unreasonable risk of substantial harm to the public health.

  ✧ They receive an FDA written request for the submission of five-day reports.

❑ Baseline Reports - 803.55:

- Manufacturers are required to submit a baseline report on FDA Form 3417 when the device model is first reported under 803.50.

- Baseline Reports must be updated annually (if information changes) on the scheduled registration date for the establishment, per Part 807.21.

❑ Supplemental Reports - 803.56:

- Manufacturers are required to submit, within one month after receipt, any required information that was not available to them during the initial 30 day reporting requirement of deaths, serious injuries, or malfunction. This also includes five-day reports.

6. MDR Certification - 803.57

Device manufacturers, both domestic and foreign, as well as domestic distributors, are required to submit an annual certification statement to FDA on an annual basis using FDA Form 3381.

- The Domestic/Foreign Device Manufacturer, or domestic device distributor, has submitted an annual Certification, FDA Form 3381, in accordance with Part 803.57 and Part 807.21.

- The individual who signed the Certification statement on FDA Form 3381 is qualified as specified in 803.57 (b) i.e., they have oversight responsibilities for, and knowledge of, the firm's MDR reporting system.

  NOTE: An establishment may designate more than one certifying official when it determines that one individual cannot oversee or have complete knowledge of the establishment's reporting system or manufacturing sites.

  NOTE: You have already determined if the establishment has: an MDR reporting system, written MDR procedures and is following its MDR procedures. These elements are part of the requirements in the certification statement.

- All Certification reports submitted to FDA are filed as required by 803.19,

- If a certification statement indicates that no MDR reports were received during the period specified on FDA 3381 review MDR, and any other appropriate files, to verify that no reportable events were received by the establishment.

7. Auditing Individual Adverse Reaction Reports

Most of the deficiencies in this section should be deleted/noted during the examination of files, 803.18. Also, check the establishment file to determine if there are any computer generated "deficiency" letters from CDRH. If yes, discuss these letters with the establishment to determine if the problems have been resolved.

ATTACHMENT C-1

GENERAL MDR GUIDANCE

This document provides general guidance regarding the reporting of adverse events required by the Medical Device Reporting Regulation. MDR reporting has been in effect since 1984 and it must be noted that all prior guidance, policies, etc., are null and void after July 31, 1996. Some of the guidance documents will be reinstated with appropriate updating but, as a general rule, the logic used for the last 11 years is being replaced by both a new regulation and policy.

The following guidance will be appended as more experience is obtained with the new regulation:

A. PER SE RULE

This requirement no longer exists. Therefore, the submission of an event by a health care professional does not require the manufacturer to report the event based solely on the statements of a health care professional. The event must meet the reporting criteria in MDR to qualify as a reportable event.

B. REPORTING TIME FRAMES

Establishments now have up to 30 CALENDAR days after they become aware of a device related death, serious injury or malfunction before they are required to submit a report to FDA.

C. FIVE-DAY REPORTS

If an establishment has initiated a remedial action, as a result of an MDR reportable event, and the action is being taken to prevent an unreasonable risk of substantial harm to the public health, a five-day report is required. NOTE: five-day reports are not required for all or any remedial action, the action must be taken to prevent an unreasonable risk of substantial harm to the public health.

D. NON-REPORTABLE EVENTS

Device establishments have the discretion to determine if an event is reportable based upon the evaluation by qualified medical personnel, (e.g., a physician, nurse, risk manager, or biomedical engineer) and a subsequent determination that the event is not a reportable death, serious injury or malfunction. In lieu of in-house or on-site qualified medical personnel, the establishment may use consultants. When reviewing non-reportable events, validate/document the qualifying credentials of the individuals making these decisions.

E. INVESTIGATION

Establishments are required to investigate EVERY device related death, serious injury and malfunction in accordance with the GMP regulation, 820.198 and 820.162. Failure to comply with this provision is a violation of BOTH the GMO regulation and MDR. Manufacturers are also required to VERIFY information on each FDA Form 3500A as well as make a good faith effort to obtain information that is missing/not provided by the reporter.

If the establishment cannot obtain the missing information, then the MDR complaint files shall contain an explanation of why the information could not be obtained as well as documentation of the establishment's error to obtain the information.

F. RESONABLY KNOWN INFORMATION

FDA considers information that can be obtained by contacting a reporter, is in the possession of an establishment, and can be obtained by analysis, testing, or other evaluation of a device to be information that an establishment is expected to REASONABLY know, obtain and report.

G. RESONABLY KNOWN/GOOD FAITH EFFORT

An establishment must demonstrate that it exercised "good faith" in any failed attempts to obtain required data that was missing, incorrect, or that FDA considers to be reasonably known. While the concept of good faith is generally considered to be an "honest/diligent attempt," CDRH has not developed a standard. However, the establishment's procedures for obtaining missing information should appear under the "Internal Systems" section of its written MDR procedures. In addition, the Center believes that the parameters of good faith effort must, at a minimum, comport with the level of risk/nature of the device associated with the event being investigated.

H. SERIOUS INJURY

The interpretation of what constitutes a serious injury can be subjective and complicate the enforcement of MDR. The "unanticipated temporary impairment" part of the former serious injury definition has been rescinded, thus alleviating a source of subjectivity. In addition, the requirements that intervention be "immediate" and the concept of "probability" have also been removed from the serious injury definition.

The current MDR regulation states that a serious injury is an "injury or illness." This literally means that there has to be an injury (including a temporary one) in order for an even to be reportable as a serious injury. If there is no injury, then there is no serious injury report. However, this type of event may qualify as an MDR reportable malfunction depending upon the circumstances.

The Center may decide to clarify the definition of serious injury. These categories will be provided to the field and the industry through MDR guidance documents and/or letters, as necessary.

I. MALFUNCTIONS

These reports have been the subject of concern by both industry and the FDA in regard to clarifying what is reportable. Basically, a malfunction is an event that is likely to cause or contribute to either a death or serious injury; however, circumstance prevented the injury or death.

These events are very important since they represent "potential" deaths or serious injuries and permit the Agency to be proactive in reducing risks. Not all malfunctions are MDR reportable events.

If a malfunction has never led to a death or a serious injury, and an establishment can document this conclusion, it is not reportable. This rule applies UNLESS there is a compelling clinical evaluation to indicate that the event would be likely to cause or contribute, even though a previous death/serious injury had not occurred.

If a malfunction is not MDR reportable it may be a complaint and thus subject to the GMP

complaint handling requirements.

Determining if an event is a reportable malfunction involves a series of challenges:

1. Is the event device related;

2. Has it failed to perform its intended function/meet its performance specifications; and,

3. Is this failure likely to cause or contribute to a death or serious injury if the event were to happen again.

There is a presumption in MDR that if the event happened once, it can happen again. The determination of whether to submit a report should be based on the potential outcome, i.e., if this malfunction were to occur, how would it affect the patient: If the answer is, "it's likely to cause or contribute to death or serious injury," then the event is reportable. The preamble offers the following guidance, i.e., a malfunction report is required when:

1. The chance of a death or serious injury occurring as a result of the recurrence of the malfunction is note remote;

2. The consequences of the malfunction affect the device in a catastrophic manner that may lead to a death or serious injury;

3. The malfunction results in the failure of the device to perform its intended function and compromises the device's therapeutic, monitoring or diagnostic effectiveness, which would cause or contribute to a death or serious injury.

   NOTE: The essential function of a device refers, not only to the device's labeled use, but for any use widely prescribed within the practice of medicine.

4. The malfunction involves a long-term implant or a device that is considered to be life-supporting or life-sustaining and thus is essential to maintaining human life. Malfunctions of long-term implants are not routinely or "automatically" reportable unless the malfunction is likely to cause or contribute to a death or serious injury if it recurs.

5. The manufacturer takes or would be required to take an action under sections 518 or 510(f) of the Act as a result of the malfunction of the device or other similar devices.

Conversely, malfunctions ARE NOT REPORTABLE if they are not likely to result in a death, serious injury, or another malfunction.

ATTACHMENT C-2

SOURCES OF INFORMATION

WHERE TO OBTAIN FORMS

1. Consolidated Forms and Publications Office
   Washington Commerce Center
   3222 Hubbard Road
   Landover, MD 20785
   NOTE: FDA Form 3500A ONLY

2. Division of Small Manufacturers Assistance
   Office of Health and Industry Programs
   Center for Devices and Radiological Health
   1350 Piccard Drive (HFZ-220)
   Rockville, MD 20850
   NOTE: AVAILABLE ONLY THROUGH FACTS-ON-DEMAND SYSTEM

3. Food and Drug Administration
   MEDWATCH (HF-2)
   5600 Fishers Lane
   Room 9-57
   Rockville, MD 20850
   301-443-0117
   NOTE: FDA FORMS 3500 AND 3500A ONLY

WHERE TO SUBMIT ALL MDR REPORTS

Food and Drug Administration
Center for Devices and Radiological Health
P.O. Box 3002
Rockville, MD 20874-3002

NOTE: Envelopes shall be specifically identified with the type of report encolsed, e.g., User Facility Report, Semiannual Report, Five-Day Report, etc.

WHERE TO OBTAIN MDR GUIDANCE DOCUMENTS/OTHER MDR INFORMATION

1. CDRH Facts-On-Demand, telephone number 1-800-899-0381 or 301-827-0111. After connecting, follow the recorded instructions. The system allows for one request per call. Enter the shelf number of choice from the list below followed by the # (pound) sign and continue with the programmed prompts.

MDR DOCUMENTS FROM FACTS-ON-DEMAND SYSTEM

SHELF NO.	TITLE
336 #	Final MDR Regulation, 77 pages
799 #	List of and Sources for all MDR Documents
1336 #	Amendment to final rule, Federal Register, 04/11/96
1074 #	Stay of Certification and U.S. Designated Agent requirements, Federal Register,

07/23/96.

1075 # Reproposal of Certification requirement, Federal Register, 07/23/96.

2. FDA Internet Home Page (HP)

a. http://www.fca.gov. - once connected select the CDRH icon.

b. The CDRH home page can be contacted directly using the address http://www.fca.gov/cdrh/.

ATTACHMENT D

DEVICE TRACKING

Questions and Answers
Based on the Final Rule

August 26, 1993

TABLE OF CONTENTS

USEFUL DEFINITIONS

The following terms are used in the tracking regulation:

Act. The Act refers to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 et seq., as amended.

Device failure (21 CFR 821.3(d)). A device failure is the failure of a device to perform or function as intended, including any deviations from the device's performance specifications or intended use.

Distributor (21 CFR 821.3(h)). A distributor is a person who furthers the distribution of a device from the original place of manufacture to the person who makes delivery or sale to the ultimate user, i.e., the final or multiple distributor, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package.

Distributor, final (21 CFR 821.3(i)). A final distributor is a person who distributes to the patient a tracked device intended for use by a single patient over the useful life of the device. The term includes licensed practitioners, retail pharmacies, hospitals, and other types of device user facilities.

Distributor, multiple (21 CFR 821.3(k)). A multiple distributor is a device user facility, rental company, or any other entity such as a home health care agency that distributes a tracked device intended for use by more than one patient over the useful life of the device.

Importer (21 CFR 821.3(b)). An importer is the initial distributor of an imported device who is required to register under section 510 of the Act (21 USC 360), and 21 CFR 807.20 of FDA's regulations. An importer does not include anyone who only performs a service for the person who furthers the marketing, i.e., a broker, jobber, or warehouser.

Life-supporting or life-sustaining device used outside a device user facility (21 CFR 821.3(y)). A life-supporting or life-sustaining device is a device that is essential, or yields information that is essential, to the restoration or continuation of a bodily function. Such a device is being "used outside a device user facility" when it is used outside of a hospital, nursing home, ambulatory surgical facility, or diagnostic or outpatient treatment facility. For example, a device used in a home or a doctor's office is being used outside a device user facility.

Manufacturer (21 CFR 821.3(c)). A manufacturer is any person, including any importer (i.e., an initial distributor of an imported device), repacker, relabeler, or specifications developer, who manufactures, prepares, propagates, compounds, assembles, or processes a device or engages in any of the activities described in 21 CFR 807.3(d).

Permanently implantable device (21 CFR 821.3(f)). A permanently implantable device is a device that is intended to be placed into a surgically or naturally formed cavity of the human body

to continuously assist, restore, or replace the function of an organ system or structure of the human body throughout the useful life of the device. The term does not include any device which is intended and used only for temporary purposes or which is intended for explanation.

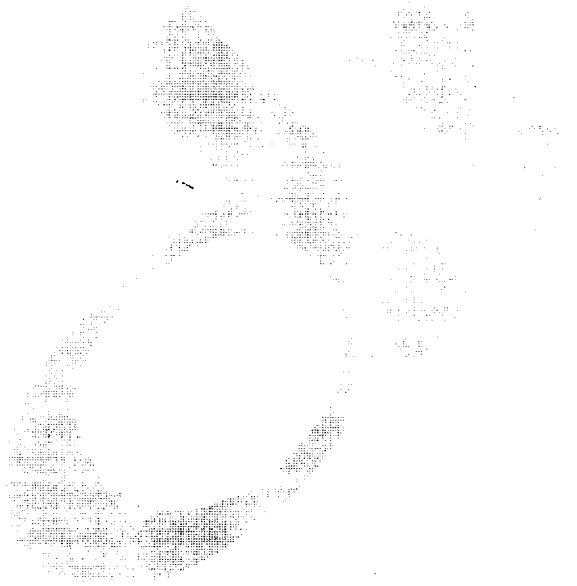
Prescribing physician. A prescribing physician is the physician who implants a device or orders the use of a life-supporting or life-sustaining device for use outside a device user facility.

Physician regularly following a patient. A physician regularly following a patient is a physician who routinely sees the patient in conjunction with the use of the tracked device.

Reasonably likely. Reasonably likely means probable. For purposes of tracking, "reasonably likely" does not relate to the probability of a device failure occurring. Rather, the term relates to whether, if a device failure occurs, serious adverse health consequences are more likely than not to occur.

Serious adverse health consequence (21 CFR 821.3(e)). A serious adverse health consequence is any significant adverse experience related to a device, including events which are life-threatening or which involve permanent or long-term injury or illness.

Useful life (21 CFR 821.60). The useful life of a device is the time that a device is in use and in distribution for use.



GENERAL QUESTIONS AND ANSWERS ABOUT THE DEVICE TRACKING REGULATION

1. Why did Congress require device tracking?

The tracking provision of section 519(e) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 USC 360i(e), added in 1990 by the Safe Medical Devices Act (SMDA), is intended to ensure that the Food and Drug Administration (FDA) can require manufacturers to expeditiously remove potentially dangerous or defective devices from the market and/or notify patients of significant device problems.

Tracking augments FDA's authority under section 518(e) of the Act, 21 USC 360h(e), to order the mandatory recall of a device and under section 518(a), 21 USC 360h(a), of the Act to require notification of health professionals and patients regarding unreasonable risk of substantial harm associated with a device.

2. When does the tracking regulation become effective?

The tracking regulation becomes effective on August 29, 1993.

3. What devices must be tracked?

Under section 519(e), three categories of devices are subject to tracking.

Section 519(e)(1) identifies two categories of devices that are subject to mandatory tracking. These are:

- permanent implants whose failure would be reasonably likely to have serious adverse health consequences; and
- life-supporting or life-sustaining devices used outside of a device user facility whose failure would be reasonably likely to have serious adverse health consequences.

Under section 519(e)(2) of the Act, FDA also can designate other devices which must be tracked. The term "designated device" is used to distinguish those devices from the devices that meet the statutory requirement for mandatory tracking under section 519(e)(1) of the Act. FDA anticipates that it may need to designate a device for tracking if a device:

- poses a significant risk to health; or
- demonstrates (or may demonstrate) recurrent, unexpected, unpredictable, or widespread failures that are hazardous, i.e., presents risks of injury, death, or other adverse effects.

The following is an illustrative list of devices that FDA believes meet the criteria for mandatory tracking:

Permanently implantable devices whose failure would be reasonably likely to have serious adverse health consequences (21 CFR 821.20(b)(1)).

Vascular graft prosthesis of less than 6 millimeters diameter
Vascular graft prosthesis of 6 millimeters and greater diameter
Total temporomandibular joint prosthesis
Glenoid fossa prosthesis
Mandibular condyle prosthesis
Interarticular disc prosthesis (interpositional implant)
Ventricular bypass (assist) device
Implantable pacemaker pulse generator
Cardiovascular permanent pacemaker electrode
Annuloplasty ring
Replacement heart valve
Automatic implantable cardioverter/defibrillator
Tracheal prosthesis
Implanted cerebellar stimulator
Implanted diaphragmatic/phrenic nerve stimulator
Implantable infusion pumps

Life-sustaining or life-supporting devices used outside device user facilities whose failure would be reasonably likely to have serious adverse health consequences (21 CFR 821.20(b)(2)).

Breathing frequency monitor (apnea monitor) including ventilatory efforts monitor
Continuous ventilator
DC-defibrillator and paddles

The following is a list of devices that have been designated by FDA for tracking:

Designated Devices (21 CFR 821.20(c)).

Penile inflatable implant
Silicone inflatable breast prosthesis
Silicone gel-filled breast prosthesis
Silicone gel-filled testicular prosthesis
Silicone gel-filled chin prosthesis
Silicone gel-filled Angelchik reflux valve
Infusion pumps (electromechanical only)

All devices subject to tracking by statutory requirement under section 519(e)(1) of the Act or by FDA designation under section 519(e)(2) of the Act are referred to as "tracked devices" in the tracking regulation.

4. **Are these lists of tracked devices subject to change?**

Yes. As FDA determines that new devices meet the statutory criteria for mandatory tracking, it will add these devices to the illustrative list (21 CFR 821.20(b)(1) and (2)). Similarly, if FDA determines that a device no longer meets the statutory criteria, FDA will remove it from the list. FDA will handle changes to the list of designated devices the same way (21 CFR 821.20(c)).

5. **How will FDA notify manufacturers, others involved in the distribution of devices, health professionals, and the public of any changes to the lists of tracked devices?**

If FDA learns of a new device through the premarket clearance process, FDA will notify the sponsor of the submission when clearing or approving the product. FDA will also publish a notice in the **Federal Register** announcing that there is a new generic type of device subject to tracking.

If FDA determines that a device should no longer be tracked, it will notify manufacturers by letter and publish a notice in the **Federal Register.**

6. **Will FDA routinely notify manufacturers that their devices are subject to tracking?**

Yes. When clearing a premarket notification submission (510(k)) or premarket approval (PMA) application, FDA intends to notify the sponsor that FDA believes the device is subject to mandatory tracking or has been designated for tracking. FDA intends to give this notification both when the device is already on the list and when it is a new generic device. This notification will be given in writing, but will not be a part of the 510(k) order or the PMA approval order.

7. **Are all vascular grafts subject to tracking?**

Yes. All vascular grafts are subject to tracking unless, under 21 CFR 821.2, individual manufacturers petition the agency for an exemption or variance from the tracking requirements for certain uses of these devices and FDA agrees that the individual manufacturer's tracking protocols identify and track only those grafts that fall within the tracking criteria.

FDA agrees that vascular grafts used to replace or assist peripheral vasculature or used solely for vascular access do not meet the statutory requirements. However, FDA believes that the vascular grafts used for cardiac repair or for replacement of aorto-coronary, aortic renal, or carotid artery function do require tracking under section 519(e)(1) of the Act.

FDA is willing to consider tracking protocols that exclude vascular grafts used in peripheral locations or for vascular access, if the manufacturer can ensure that those graft uses subject to tracking are reliably and consistently identified and tracked. FDA believes that these protocols would need to identify how the labeling would distinguish among the various uses of the device.

QUESTIONS SPECIFIC TO MANUFACTURERS

8. When must the manufacturer of a tracked device begin tracking that device?

The manufacturer of a tracked device must begin tracking devices that are distributed on or after August 29, 1993.

9. What does tracking require?

Tracking requires manufacturers to adopt a method of tracking (21 CFR 821.25(a)) that is capable of providing certain critical information about the location of tracked devices within a short time frame so that mandatory recalls or notifications can be carried out expeditiously and effectively.

For example, for devices that have not yet been distributed to a patient, within 3 working days of a request by FDA, the manufacturer must be able to tell FDA where the device is in the distribution chain (21 CFR 821.25(a)(1)). After a tracked device is distributed to a patient, the manufacturer must provide the identity and current location of the patient (and other information described in more detail below) within 10 working days of a request by FDA (21 CFR 821.25(a)(2) and (3)).

10. Who has primary responsibility for the tracking of a medical device?

The manufacturer of a tracked device bears the primary responsibility for tracking the device from the manufacturer throughout distribution to the end user of the device (patient) (21 CFR 821.1(b) and (d)).

Although the regulation does not preclude a manufacturer from involving an outside organization in its device tracking effort, the manufacturer is responsible for ensuring that its agents and contractors comply. The manufacturer's tracking responsibility cannot be altered, modified, or in any way abrogated by contracts or other agreements, unless the contract or agreement is sanctioned by the FDA through approval of an exemption or variance.

11. Does the regulation require a specific method of tracking?

No. The regulations require manufacturers to develop written standard operating procedures (SOPs) for a method of tracking that can generate the required information in the required time period (21 CFR 821.25(a)(1), (2) and (3)). FDA envisions that different manufacturers will have different tracking systems.

12. What does a tracking SOP have to contain?

To ensure that tracking methods are effective, the regulation (21 CFR 821.25) specifies certain items that each SOP must contain. The SOPs must include data collection and recording

procedures for all required information, methods for data modifications, and quality assurance procedures (21 CFR 821.25(c)).

To ensure that the SOP is working effectively, the regulation requires that the quality assurance program provides for audits of the tracking system (21 CFR 821.25(c)(3)). For the first three years of tracking a device, the manufacturer must perform the audits at 6-month intervals. After three years, the tracking system must be audited annually. These audits should check both the functioning of the tracking system and the accuracy of the data in that system.

13. What information about a tracked device must a manufacturer collect and maintain?

The information that a manufacturer is required to collect and maintain depends on the kind of device and where the device is in the chain of distribution.

- For all tracked devices, prior to the distribution of a tracked device to a patient (21 CFR 821.25(a)(1)):
  - name,
  - address, and
  - telephone number of the distributor, final distributor, or multiple distributor holding the device for distribution and the location of the device.

  The manufacturer must be able to provides this information, in writing, within 3 days of a request from FDA.

- For single use tracked devices (devices that are only for use by one patient), the manufacturer must obtain and keep current (in accordance with its SOP) the following (21 CFR 821.25(a)(2)):
  - lot, batch, model, or serial number of the device or other identifier necessary to track the device;
  - date the device was shipped by the manufacturer;
  - name, address, telephone number, and social security number (if available) of the patient receiving the device;
  - date that the device was provided to the patient;
  - name, mailing address, and telephone number of the prescribing physician;
  - name, mailing address, and telephone number of the physician following the patient if different than the prescribing physician; and

- if and when applicable, the date that the device was explanted and the name, mailing address, and telephone number of the explanting physician, the date of the patient's death, or the date that the device was returned to the manufacturer, permanently retired from use, or otherwise disposed of permanently.

- For multiple-use tracked devices (devices that can be used by more than one patient over the useful life of the device), the manufacturer is not required to obtain and maintain the identity of each patient that uses the tracked device. Rather, the manufacturer must have a current record relating to the multiple distributor possessing the device and must be capable of providing, within 10 working days of a request by FDA, the following (21 CFR 821.25(a)(3)):

  - lot, batch, model, or serial number of the device or other identifier necessary to provide for effective tracking of the device;
  - date the device was shipped by the manufacturer;
  - name, address, and telephone number of the multiple distributor;
  - name, address, telephone number, and social security number (if available) of the patient using the device;
  - location of the device;
  - date the device was provided to the patient using the device;
  - name, address, and telephone number of the prescribing physician; and
  - if and when applicable, the date that the device was returned to the manufacturer, permanently retired from use, or otherwise disposed of permanently.

14. As referred to in question 12, can the "prescribing physician" and "physician regularly following the patient" be the same person?

Yes. The prescribing physician may also routinely see the patient in conjunction with the use of the tracked device. Over the useful life of a tracked device, the follow-up physician may change from a surgeon to a specialist to a family physician.

15. Is a separate tracking system required for each type of device that a manufacturer is required to track?

No. The manufacturer can use one general tracking system to track any number of devices. The system must be capable of capturing and producing all of the required information and of tracking the device to the patient level. However, if a manufacturer uses one system to track

several different products, it must have SOPs tailored to the tracking of each product; records should be kept in such a way that there is no likelihood of mixup; and it must audit each product separately.

16. **What does FDA mean by auditing a "statistically relevant sampling" of the manufacturer's tracking data (21 CFR 821.25(c)(3))?**

This means that when auditing records, a manufacturer should use a recognized sampling plan (such as MIL STD 105E) which includes a high level of confidence.

17. **Is a manufacturer entitled to review tracking records during an audit of a distributor, final distributor, and multiple distributor?**

Yes. The regulation (21 CFR 821.30(c)(3)) requires a distributor, final distributor, or multiple distributor, upon written request of the manufacturer, to make its tracking records available to the manufacturer of the device for audit purposes. The distributor is not required to show any other records to the manufacturer. Manufacturers need only be given access to those records that are necessary to verify the tracking information reported to the manufacturer by the distributor. If they wish, distributors can establish separate tracking files to keep this information separate from other sales and distribution records.

18. **Must a manufacturer visit distributors, hospitals, and patients as part of tracking or its auditing of tracking records?**

Not necessarily. A manufacturer is only required to develop an adequate tracking system which may or may not include actual visits to distributors, hospitals, and patients. A manufacturer's auditing of its tracking system should include either visiting or otherwise communicating with these groups.

19. **What should a manufacturer do if a distributor, final distributor, or multiple distributor is not reporting as required by the regulations?**

If a manufacturer determines that a distributor or subsequent final distributor or multiple distributor is not reporting the required information to it, the manufacturer (after a good faith effort to determine the information) should advise FDA so that the agency can take appropriate action against the nonreporting parties (21 CFR 821.25(d)).

20. **Is a manufacturer's tracking method subject to FDA inspection and audit?**

Yes. Routine Good Manufacturing Procedures (GMP) inspections will include a review and audit of tracking systems to ensure that a device can be tracked through the distribution chain to the end user (21 CFR 821.50(a)). In addition, FDA will inspect tracking systems at any other time that it feels necessary.

21. **What events would terminate the obligation to track a device?**

The obligation can be terminated with documentation of explanation of the device, death of a patient, return of a device to the manufacturer, or documentation that the device has been refurbished or remanufactured (and tracked by the refurbisher or remanufacturer).

22. If a patient dies, is the manufacturer required to keep their tracking records?

A tracking record may be retired (i.e., removed from that portion of the tracking system that periodically updates tracked devices) if it becomes known that the device is no longer in use, has been explanted, returned to the manufacturer for destruction, or the patient has died (21 CFR 821.60).

23. How long is a manufacturer required to keep tracking records? Does this apply to patients lost to follow-up?

A manufacturer is required to keep tracking records for the useful life of the device whether or not the patient is lost to follow-up.

24. What happens if a manufacturer or distributor discontinues the marketing of a tracked device?

A manufacturer or distributor which goes out of business is required to notify FDA at the time that it notifies any government agency, court, or supplier and provide FDA with a complete set of its tracking records and information (21 CFR 821.1(e)).

If a manufacturer or distributor goes out of business and other persons acquire the right to manufacture or distribute the tracked devices, then they are responsible for continuing the tracking responsibilities of the previous manufacturer or distributor.

If a manufacturer or distributor ceases distribution of a tracked device but continues to do other business, then it is still responsible for the tracking of devices that it previously distributed.

25. Is a manufacturer required to identify a tracked device in the labeling?

No. The tracking regulation does not require that a tracked device be identified in labeling. Nevertheless, FDA believes that some form of identification accompanying the device would be extremely useful in ensuring effective tracking because the recipient would be aware of the tracking requirements for the device.

26. If a tracked device is sold to the United States (U.S.) military or civilian government, must it be tracked?

Yes. A tracked device which is under the control of the U.S. military or civilian government is subject to the tracking regulation. The U.S. military or civilian government assumes the responsibilities of a distributor, final distributor, and multiple distributor.

27. **Do exported devices have to be tracked?**

A tracked device distributed outside the U.S. is not subject to tracking unless it is sold to the U.S. military or civilian government. However, manufacturers must track devices that are distributed outside the U.S. throughout the chain of distribution in the U.S. to the person or firm that exports or physically carries the device outside the country, e.g., to the physician who travels with pacemakers to another country for the implantation in patients there.

28. **Is a tracked device that is implanted or distributed in the U.S. to a non U.S. citizen subject to tracking when that person leaves the U.S.?**

Yes. Such a device is subject to all of the tracking requirements by the manufacturer and any distributors in the chain of distribution. A reasonable effort must be made to track the device to the foreign address of the recipient.

29. **Who is responsible for tracking if a device is imported into the U.S.?**

The importer that initially distributes a tracked device in the U.S, as an initial distributor and thus a manufacturer (21 CFR 821.3(c)), is required to track the device throughout its distribution in the U.S. If the foreign manufacturer acts as its own initial distributor, then the foreign manufacturer of the tracked device is responsible for tracking.

30. **What happens if an importer fails to comply with the tracking requirements?**

In addition to the sanctions available for noncompliance that would be available against a domestic company, if an importer (initial distributor) of a tracked device does not comply with the tracking requirements, the devices may be subject to detention at the port of entry.

QUESTIONS SPECIFIC TO DISTRIBUTORS, FINAL DISTRIBUTORS, AND MULTIPLE DISTRIBUTORS

GENERAL INFORMATION

31. Do persons other than the manufacturer of a tracked device have tracking responsibilities?

Yes. In addition to manufacturers, others in the chain of distribution, i.e., distributors, final distributors, and multiple distributors, have reporting and recordkeeping responsibilities, particularly multiple distributors (21 CFR 821.30). Although the tracking regulation does not specifically impose regulatory requirements on patients, for tracking to be successful, they must cooperate by providing information such as name, address, telephone number, and change of address.

32. When are distributors, final distributors, and multiple distributors responsible for complying with the tracking requirements?

On or after August 29, 1993, the distributors, final distributors, and multiple distributors are responsible for collecting, maintaining, and reporting back to the manufacturer the required information for tracked devices that they receive.

33. What should a distributor, final distributor, or multiple distributor do if it has a question about whether or not a device must be tracked?

Contact the manufacturer of that device.

34. Does the regulation require each distributor, final distributor, and multiple distributor to notify a manufacturer from whom it receives a tracked device?

Yes. Each distributor, final distributor, and multiple distributor must notify the manufacturer when and from whom it received a tracked device (21 CFR 821.30(a)(3) and (4)).

35. When a distributor, final distributor, or multiple distributor purchases or acquires any interest in a device, what information must be reported to the manufacturer?

Upon purchasing or acquiring any interest in a tracked device, a distributor, final distributor, or multiple distributor must promptly report to the manufacturer (21 CFR 821.30(a)):

- its name and address;
- lot, batch, model, serial number or other identifier of the device;
- date the device was received;

- person from whom the device was received; and
- if and when applicable, the date that the device was explanted, the date of the patient's death, or the date that the device was returned to the distributor, disposed of permanently, or permanently retired from use.

36. What is a "broker" and what are its tracking obligations?

For tracking purposes, FDA considers a broker to be someone who does not take ownership or acquire an interest in a device. A broker may take possession of the device to expedite or facilitate its transport to a customer, but acts as an agent for the manufacturer or the owner of the device. A broker does not have tracking responsibility under the regulation (21 CFR 821.3(b)).

FINAL DISTRIBUTOR INFORMATION

37. Does the regulation require a final distributor to notify the manufacturer to whom it distributes a tracked device?

Yes. The final distributor must also report to the manufacturer the name of the patient to whom it distributed the device and other required information (21 CFR 821.30(b)).

38. What tracking information must a final distributor report to the manufacturer of a tracked device when the device is sold or otherwise distributed for use in or by a patient?

The final distributor of a tracked device must promptly provide the manufacturer with the following information (21 CFR 821.30(b)(1) through (7)):

- name and address of the final distributor;
- lot, batch, model, or serial number of the device or other identifier necessary to track the device;
- name, address, telephone number, and social security number (if available) of the patient receiving the device;
- date that the device was provided to the patient;
- name, mailing address, and telephone number of the prescribing physician;
- name, mailing address, and telephone number of the physician regularly following the patient; and
- when applicable, the date that the device was explanted and the name, mailing address, and telephone number of the explanting physician, the date of the patient's death, or the

date the device was returned to the manufacturer, was permanently retired from use, or otherwise disposed of permanently.

39. In the case of permanently implanted tracked devices, is the hospital or the physician considered to be the final distributor?

It depends on exactly who "owns" the device. The person or institution purchasing the device would be considered to be the final distributor.

MULTIPLE DISTRIBUTOR INFORMATION

40. Does the regulation require a multiple distributor to notify the manufacturer to whom it distributes the tracked device?

Yes. The multiple distributor must keep tracking records each time that a tracked device is distributed to a patient for use outside device user facility. The multiple distributor does not have to advise the manufacturer of the patient using the device until requested to do so by the manufacturer. The patient's identity must then be reported to the manufacturer within 5 working days of a request from the manufacturer for this information (21 CFR 821.30(c)(2)).

41. What tracking records must a multiple distributor keep?

In addition to reporting to the manufacturer that it has received a tracked device (see question 34), a multiple distributor must keep the following written tracking records when it distributes a device to a patient or user (21 CFR 821.30(c)(1)(i) through (vii)):

- lot, batch, model, or serial number of the device or other identifier necessary to provide for effective tracking of the device;
- name, address, telephone number, and social security number (if available) of the patient using the device;
- location of the device;
- date the device was provided to the patient using the device;
- name, address, and telephone number of the prescribing physician;
- name, address, and telephone number of the physician regularly following the patient; and
- if and when applicable, the date that the device was returned to the manufacturer, permanently retired from use, or otherwise disposed of permanently.

The multiple distributor must provide this information to a manufacturer within 5 days of a

request from the manufacturer and to FDA within 10 days of a request from FDA (21 CFR 821.30(c)(2)).

42. If a multiple distributor rents a device to another multiple distributor who in turn rents the device to the patient, who is responsible for reporting and to whom?

In this instance(s), the first multiple distributor reports as a distributor (see question 34 and 21 CFR 821.30(a)). The second multiple distributor reports receipt of the tracked device to the manufacturer (21 CFR 821.30(a)) and becomes the multiple distributor that tracks the device to the patient (maintaining appropriate records; see question 43 and 21 CFR 821.30(c)(1)) and reports the required patient information to the manufacturer within 5 working days of receiving a request from the manufacturer (21 CFR 821.30(c)(2)).

QUESTIONS SPECIFIC TO DEVICE USER FACILITIES (HOSPITALS, NURSING HOMES, ETC.)

43. What are the responsibilities of a device user facility and when does the user facility become a final or multiple distributor?

A device user facility has the same responsibilities as a final distributor or a multiple distributor depending on whether the device is for single or multiple use. For example, a hospital engaged in the implantation of tracked devices is a final distributor of those devices; the hospital's outpatient clinic that rents, leases, or loans an apnea monitor or other tracked device to a series of patients is a multiple distributor of those devices.

44. Does the hospital have the obligation to report to a manufacturer on the manufacturer's form or using the manufacturer's format?

No. The regulation does not require hospitals (or anyone else) to use a manufacturer's form or format, but the required information must be provided to the manufacturer. However, to foster ease of tracking, whenever possible, hospitals should make every effort to report the required information in the format requested by the manufacturer.

45. What must be reported to the manufacturer when a hospital transfers or loans a tracked device to a different hospital?

If the hospital receiving the device will be using the tracked device outside the facility, the hospital is required to notify the manufacturer that it has received a tracked device and from whom it received the device (21 CFR 821.30(a)).

46. When a tracked device is explanted, must the explanting facility report to the manufacturer?

Yes. At the time of explanation, the explanting institution must notify the manufacturer identified on the device.

47. What should a hospital do when it explants a tracked device and it cannot identify the manufacturer?

If the institution knows that it is a tracked device, then the facility must make a good faith attempt to determine the manufacturer and to report the device's explanation. For example, it is likely that the patient or the patient's doctor will know the identity of the manufacturer. If the hospital cannot identify the manufacturer, then the hospital should maintain a record of the explanation in its tracking files containing its attempt to locate the manufacturer.

48. If a type of life-sustaining or life-supporting tracked device can be used both inside and outside of the hospital, must the hospital report to the manufacturer on both the devices used inside the hospital and outside the hospital?

If the devices are subject to mandatory tracking under section 519(e)(1) of the Act, then only those life-sustaining or life-supporting devices used outside the hospital must be tracked.

49. How is a device that is resterilized and repackaged by a hospital to be tracked?

The fact that a hospital sterilized, resterilized, or repackaged a tracked device does not make the hospital a manufacturer for tracking purposes; it remains a final or multiple distributor.

50. Must a hospital track infusion pumps used within the hospital?

No. In identifying infusion pumps as designated devices requiring tracking, FDA has established the level of tracking necessary for the device. Although infusion pumps can present a risk of serious adverse health consequences and that risk exists even if the pump is not being used to support or sustain life, FDA believes that those devices used within a device user facility can be located without the tracking requirements in case of a recall or notification. However, if the infusion pump is used by multiple patients outside the device user facility, then the hospital is a multiple distributor and must comply with the tracking requirements. Implantable infusion pumps are considered permanently implantable tracked devices which the hospital must track.

51. Are defibrillators used on ambulances required to be tracked?

Yes. Defibrillators are to be tracked to the ambulance or organization that purchased the device for the ambulance. However, defibrillators would not be required to be tracked to the patient on whom the defibrillator was being used.

52. Who bears tracking responsibility for a ventilator used by patients in a nursing home when the ventilator is prescribed by an in-house physician, supplied on a rental basis by a rental company, and set up for use by a nursing home therapist?

The rental company which is a multiple distributor.

53. After a hospital reports the name of the recipient of an implant, who is obligated to update the address of the patient?

The manufacturer has the responsibility to track the device through the chain of distribution to the end user, in this case, the patient, and to update the address as appropriate. How the manufacturer will update patient information should be specified in its tracking SOP.

54. Does a patient have the right to refuse to participate in tracking?

Yes. A patient may refuse to have their device(s) tracked. Such refusals should be documented and be provided to the manufacturer by the product, model, and serial number. The manufacturer must maintain these records for the useful life of the products.

55. Must a final distributor obtain written consent from a patient in order for the patient's tracking information to be released to the manufacturer?

No. The regulation does not require that a patient give written consent to have a device tracked or to release their identity to the manufacturer.

56. If a hospital has a policy to require written consent from its patients before releasing their names for tracking purposes and a patient refuses to sign that consent, does that relieve the manufacturer of its responsibilities to track the device?

No. The manufacturer must be capable of tracking the device to the hospital (final distributor). The patient's refusal should be documented and be provided to the manufacturer with the product, model, and serial number. The manufacturer must maintain this record for the useful life of the product. The hospital could be contacted by the manufacturer or FDA and, under section 518(a) and (e) of the Act, might have to assist in a patient notification or recall if later there were a problem with the device.

57. What is the hospital's responsibility when a patient refuses to have their device tracked?

By regulation, the hospital is considered the final distributor of a tracked device for use by one patient (21 CFR 821.3(i)) or a multiple distributor of a tracked device for use by multiple patients (21 CFR 821.3(k)). As such, it has the responsibility to report to the manufacturer the receipt of a tracked device and that a patient refuses to have their device tracked. The hospital should provide documentation of the refusal and the device, model, and serial number to the manufacturer. The hospital should maintain appropriate documentation of the refusal for the useful life of the device. The hospital could be contacted by the manufacturer or FDA and, under section 518(a) and (e) of the Act, might have to assist in a patient notification or recall if later there were a problem with the device.

58. Is patient confidentiality protected?

Section 821.55(b) of the tracking regulation requires that the names of patients or other

identifiers be provided to manufacturers or other persons subject to the tracking requirements or to a physician when the health or safety of a patient requires that such disclosure and pursuant to agreement that the information will not be further disclosed.

ATTACHMENT E

MODEL WARNING LETTER
(GMPs and MDR)

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

RESPONSIBLE INDIVIDUAL, TITLE
ESTABLISHMENT NAME
ESTABLISHMENT'S COMPLETE ADDRESS

Dear (Addressee):

During an inspection of your establishment located in (city, state), on (dates), our investigator(s) determined that your establishment manufactures (generic type of device). (Generic name of device) are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to conduct planned and periodic audits of the quality assurance program in accordance with written procedures. For example, no audits of the quality assurance program have been performed for at least 3 years.

2. Failure to investigate the failure of a device to meet performance specifications after a device has been released for distribution, and to make a written record of the investigation including conclusions and follow-up. For example, there are no records of failure investigations for Model ____, S/N ___, and Model __, S/N ___, which were returned because they did not operate properly.

3. Failure to maintain device history records for Model __ to demonstrate that the devices are manufactured in accordance with the device master record.

4. Failure to immediately review, evaluate and investigate any complaint pertaining to injury, death, or any hazard to safety. For example, there is no record of the investigation of a report that a child's death associated with the use of Model ___ at the Community Medical Center on/or about February 8, 1997.

Additionally, the above stated inspection revealed that your devices are misbranded within the meaning of Section 502(t)(2) of the Act, in that your establishment failed to submit information to the Food and Drug Administration as required by the Medical Device Reporting (MDR) Regulation, as specified in 21 CFR Part 803. Specifically, you failed to submit an MDR report to FDA after receiving information which reasonably suggested that one of your commercially distributed devices may have caused or contributed to a death. The February 8, 1997, incident report from the Community Medical Center in which a child standing in a crib fell over, caught his head in a "Y" formed by the crib rail and end post, and died, should have been reported as a death.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to (name), Compliance Officer, Food and Drug Administration, (street address), (city, state & zip code).

Sincerely yours,

District Director
_____ District

ATTACHMENT E

FOR USE WHEN FOLLOWING THE ENFORCEMENT STRATEGY FOR ESTABLISHMENTS WITH REPEATED VIOLATIVE INSPECTIONS (Part V, A.3.c.).

MODEL WARNING LETTER
(GMP's and MDR)

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

RESPONSIBLE INDIVIDUAL, TITLE
ESTABLISHMENT NAME
ESTABLISHMENT'S COMPLETE ADDRESS

Dear (Addressee):

During an inspection of your establishment located in (city, state), on (dates), our investigator(s) determined that your establishment manufactures (generic type of device). (Generic name of device) are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

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1. Failure to conduct planned and periodic audits of the quality assurance program in accordance with written procedures. For example, no audits of the quality assurance program have been performed for at least 3 years.

2. Failure to investigate the failure of a device to meet performance specifications after a device has been released for distribution, and to make a written record of the investigation including conclusions and follow-up. For example, there are no records of failure investigations for Model ____, S/N ___, and Model __, S/N ___, which were returned because they did not operate properly.

3. Failure to maintain device history records for Model __ to demonstrate that the devices are manufactured in accordance with the device master record.

4. Failure to immediately review, evaluate and investigate any complaint pertaining to injury, death, or any hazard to safety. For example, there is no record of the investigation of a report that a child's death associated with the use of Model ___ at the Community Medical Center on/or about February 8, 1997.

Additionally, the above stated inspection revealed that your devices are misbranded within the meaning of Section 502(t)(2) of the Act, in that your establishment failed to submit information to the Food and Drug Administration as required by the Medical Device Reporting (MDR) Regulation, as specified in 21 CFR Part 803. Specifically, you failed to submit an MDR report to FDA after receiving information which reasonably suggested that one of your commercially distributed devices may have caused or contributed to a death. The February 8, 1997, incident report from the Community Medical Center in which a child standing in a crib fell over, caught his head in a "Y" formed by the crib rail and end post, and died, should have been reported as a death.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

In order to facilitate FDA in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contracts, and to resume marketing clearance for Class III devices for which a 510(k) has been submitted, and Certificates to Foreign Governments for products manufactured at [x] facility, we are requesting that you submit to this office on the schedule below[1], certification by an outside expert consultant that he/she has conducted an audit of your establishment's manufacturing and quality assurance systems relative to the requirements of the device GMP regulation (21CFR, Part 820). You should also submit a copy of the consultant's report, and certification by your establishment's CEO (if other than yourself) that he or she has reviewed the consultant's report and that your establishment has initiated or completed all corrections called for in the report. The attached guidance may be helpful in selecting an appropriate consultant.

The initial certifications of audit and corrections and subsequent certifications of updated audits and corrections (if required) should be submitted to this office by the following dates:

- Initial certifications by consultant and establishment -Show actual date (allow approximately six months from issuance of Warning Letter).

- Subsequent certifications-Show actual date(s). You may ask for annual reports for two years after the follow-up inspection.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take

[1] This policy is intended to address situations where manufacturers have filed to maintain adequate quality assurance systems over a period of several years. Requesting certifications of compliance subsequent to initial certifications is intended to help manufacturers institutionalize an adequate quality assurance system. Districts have the option, however, of not asking for subsequent reports or varying the period over which subsequent reports may be requested.

this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office within 15 days of receipt of this letter, of the specific steps you will be taking to comply with our request.

Your response should be sent to (name), Compliance Officer, Food and Drug Administration, (street address), (city, state & zip code).

Sincerely yours,

District Director
_____ District

The following guidance was originally published in the CDRH, Office of Compliance Industry Letter No. 2, dated July 6, 1993.

SELECTING A CONSULTANT ?

As the number of consultants has increased in the past few years, so too has our concern about their qualifications and the quality of their work. While most consultants accurately and honestly promote their capabilities, we believe the device industry should exercise diligence in the selection of a consultant. It is very disappointing to see a company which is experiencing serious problems go to the expense of hiring a consultant who fails to constructively contribute to the restoration of the company's regulatory health.

Of course, FDA cannot recommend or endorse a particular consultant, but we can offer some criteria that should be considered when selecting one. You should first determine what type of consultant you need. There are basically three types of consultants: regulatory, quality, and technical. A regulatory consultant is one that will specialize in 510(k) and PMA issues, GMP's and/or device labeling. A quality consultant is adept at GMP auditing, and writing and revising procedures. The technical consultant basically knows how to find problems and fix them. In some cases a company may need the services of one or more of these consultants. The ideal consultant would be highly qualified in all three of these areas. Since we in compliance deal most with GMP issues, we have identified some factors that we recommend you consider when selecting a quality consultant, but these factors may have applicability for the other types of consultants also:

- How long has the consultant worked with the device (not drug) GMP regulation?
- Is his/her knowledge current?
- How does he/she know what CDRH's "current" policies and interpretations are for device GMP's?
- Does the consultant sponsor/participate in training courses?
- Is he/she frequently asked to give presentations at FDA/industry sponsored seminars? What have been the reactions to these presentations?
- One of the primary attributes of a good consultant is to be a "good communicator". He/she must be able to communicate problems and provide solutions in a clear, concise manner, and in such a way that the company knows how to perform corrections the "right" way, the first time.
- Has he/she been deposed and/or testified as an expert witness, either for the FDA or for industry?
- Obtain a listing of the consultant's clients over the last several years. Check these references!
- What types of certifications does the consultant have, i.e., Is the certification recognized by

professional societies, etc?

We believe that a little homework in identifying and selecting a consultant will have long term payoffs for any company.

ATTACHMENT F

FINAL - DESIGN CONTROL INSPECTIONAL STRATEGY

MARCH, 1997

Effective Date: June 1, 1997 through June 1, 1998

IMPORTANT NOTE: 21 CFR 820.30 DESIGN CONTROL REQUIREMENTS OF THE QUALITY SYSTEM REGULATION ARE BY LAW IN EFFECT AS OF JUNE 1, 1997.

Instructions

1. This is intended to be an information gathering document. Information that cannot be gathered indicates an item or area in need of improvement. This document should not be used from June 1, 1997 through June 1, 1998 as an enforcement tool but will be officially attached to the manufacturer's Establishment Inspection Report (EIR) for historical purposes.

2. Since this is an information gathering document, the normal collection of documentation to establish a nonconformance will not be required. However, the types of documents reviewed should be addressed in the responses to the questions.

3. A copy of this completed Design Control Inspectional Strategy will be known as the Design Control Inspectional Strategy Report (the report). The original report will officially become a part of the manufacturer's EIR. One copy of the report will be issued to the manufacturer at the time of the inspection close-out meeting. A second copy of the report will be submitted with the EIR to the Center for Devices and Radiological Health, HFZ-306.

4. Since this report will be a part of the manufacturer's EIR, it will be available to the public through the Freedom of Information Act (FOIA). Any trade secret or proprietary information that this report may contain should be specifically noted by the FDA investigator in cooperation with the manufacturer to aid in determining where redaction may be required for purposes of filling FOIA requests.

5. Most sections of the regulation have a clause requiring specific documentation of the person(s) involved, dates, identification of project, etc. that is not identified as a requirement in section 820.30(j) Design History File (DHF). Since these specific DHF requirements are only addressed in the individual sections, areas of improvement would be cited in those respective sections and not in section 820.30(j), Design History File.

820.30(a) General

Regulatory Requirements

1. Each manufacturer of any class III or class II device, and the class I devices listed in paragraph (a)(2) of this section, shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

2. The following class I devices are subject to design controls:

   i. Devices automated with computer software; and
   ii. The devices listed in the chart below.

Section	Device
868.6810	Catheter, Tracheobronchial Suction
878.4460	Glove, Surgeon's
880.6760	Restraint, Protective
892.5650	System, Applicator, Radionuclide, Manual
892.5740	Source, Radionuclide Teletherapy

Questions

1. Select and describe a device that was subject to design controls and indicate whether it was an original design or a modification to an existing design. (This includes any changes to an existing device that occurred after June 1, 1997.)

2. For the device selected, identify at what stage in the design and development effort design controls were applied. If the design and development effort has not been completed, identify the current status of the design and development effort. (Note, if the design and development effort was initiated prior to June 1, 1997, identify the date the design effort was initiated.)

820.30(b) Design and Development Planning

Regulatory Requirements

Each manufacturer shall establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation. The plans shall identify and describe the interfaces with different groups or activities that provide, or result in, input to the design and development process. The plans shall be reviewed, updated, and approved as design and development evolves.

Questions

1. Summarize the format and structure of the design and development planning process for the chosen device. (If the manufacturer has established a written procedure used to control or describe their overall design process, attach a copy. Note, this is not a specific requirement under the regulation but may be useful during the one year learning phase.)

2. Determine if the plan describes or references and assigns responsibility for the implementation of each of the following:

   - Risk Analysis
   - Design Input
   - Design Output
   - Design Review
   - Design Verification
   - Design Validation
   - Design Transfer
   - Design Changes
   - Interfaces

3. Determine whether the plan has been reviewed, updated, and approved as design and development evolves.

820.30(c) Design Input

Regulatory Requirements

Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient. The procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements. The design input requirements shall be documented and shall be reviewed and approved by a designated individual(s). The approval, including the date and signature of the individual(s) approving the requirements, shall be documented.

Questions

1. Summarize the manufacturer's written procedure(s) for identification and control of design input. From what sources are design inputs sought?

2. Do design input procedures cover the relevant aspects, such as: (Mark all that apply and list additional aspects.)

   - intended use
   - user/patient/clinical
   - performance characteristics
   - safety
   - limits and tolerances
   - risk analysis
   - toxicity and biocompatibility
   - electromagnetic compatibility (EMC)
   - compatibility with accessories/auxiliary devices
   - compatibility with the environment of intended use

- human factors
- physical/chemical characteristics
- labeling/packaging
- reliability
- statutory and regulatory requirements
- voluntary standards
- manufacturing processes
- sterility
- MDRs/complaints/failures and other historical data
- design history files (DHFs)

3. For the specific design covered, how were the design input requirements identified, reviewed for adequacy, and documented?

4. Summarize the process for resolving incomplete, ambiguous, or conflicting requirements. For the design reviewed, identify any incomplete, ambiguous, or conflicting requirements that were not resolved per the manufacturer's procedures.

5. Summarize how general input information and requirements are translated to specific requirements or specifications.

6. Summarize how the design input addresses the user interface: the hardware (and software, if applicable) features that define the interactions between users and equipment. For example, are exploratory studies (e.g., interviews), usability studies (e.g., user evaluation, task analysis, risk analysis, or workload analysis), or any combination thereof conducted? Describe the method(s) used.

7. Summarize the methods used for any risk analysis done at the design input stage.

8. For an electrically powered device, where electromagnetic compatibility (EMC) should have been considered in the design, determine the following:

   - How has EMC been addressed with regard to the device use environment? For example, the interface with other medical devices or the interference from other consumer products.

   - If complaint or failure data for similar devices distributed by the manufacturer indicated EMC problems, did the manufacturer use this information in establishing the design requirements for the new device?

   - Identify any relevant EMC standards used as a part of the design input process.

9. Who is responsible for review and approval of the design input requirements? Has approval been documented?

820.30(d) Design Output

Regulatory Requirements

Each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements. Design output procedures shall contain or make reference to acceptance criteria and shall ensure that those design outputs that are essential for the proper functioning of the device are identified. Design output shall be documented, reviewed, and approved before release. The approval, including the date and signature of the individual(s) approving the output, shall be documented.

Questions

1. How do the design and development procedures identify and define design output?

2. Explain how design outputs are expressed in terms that allow comparison to design inputs.

3. How are the characteristics essential to the proper functioning of the device identified in the design output?

4. Provide some examples of acceptance criteria for design output.

5. Who is responsible for review and approval of the design output prior to release? Has approval been documented?

820.30(e) Design Review

Regulatory Requirements

Each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development. The procedures shall ensure that participants at each design review include representatives of all functions concerned with the design stage being reviewed and an individual(s) who does not have direct responsibility for the design stage being reviewed, as well as any specialists needed. The results of a design review, including identification of the design, the date, and the individual(s) performing the review, shall be documented in the design history file (the DHF).

Questions

1. Summarize the manufacturer's procedure(s) that defines and controls formal design reviews. Discuss any alternative terminology for design review used by the manufacturer pertaining to design review activities.

2. What has the manufacturer identified as appropriate stages of design and development for formal design reviews.

3. What documentation exists to demonstrate that the manufacturer has conducted formal design reviews at the identified stages?

4. What mechanisms in the design review procedure exist to assure that formal design reviews are comprehensive and systematic? How are problems or action items identified during a design review handled?

5. Select a problem or action item that was identified during a formal design review and summarize its disposition if completed.

6. How does the design review procedure(s) assure identification of organizational functions which should be represented at formal design reviews?

7. Review the documentation from at least one formal design review and verify that the appropriate organizational functions participated, including at least one individual not having direct responsibility for the design stage being reviewed. If not, explain.

8. How does the design review procedure(s) assure that identified design inputs are addressed by design outputs? How is this documented?

820.30(f) Design Verification

Regulatory Requirements

Each manufacturer shall establish and maintain procedures for verifying the device design. Design verification shall confirm that the design output meets the design input requirements. The results of the design verification, including identification of the design, method(s), the date, and the individual(s) performing the verification, shall be documented in the DHF.

Questions

1. Briefly describe the manufacturer's procedure(s) for design verification.

2. Provide example(s) of significant point(s) during the design process where verifications were conducted. (Verification may occur at one point or multiple points.)

3. Choose one specific input requirement. Describe the verification methods and activities used to confirm that the input requirement has been fulfilled by the design output.

4. In terms of human factors or user interface, what verification methods have been employed to confirm that the input requirements are met (e.g., usability testing such as prototyping, simulations).

5. Does the verification data show that output meets input? If output does not meet input, provide

an example of how the manufacturer resolved the discrepancy.

6. Does the design history file identify the methods of design verification, dates, and individuals performing verification activities?

820.30(g) Design Validation

Regulatory Requirements

Each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions. Design validation shall include software validation and risk analysis, where appropriate. The results of the design validation, including identification of the design, method(s), the date, and the individual(s) performing the validation, shall be documented in the DHF.

Questions

1. Summarize the design validation procedure(s).

2. Briefly describe at least one design validation activity performed on production or equivalent devices.

3. If design validation activities were performed on non-production devices, then how were the devices shown to be equivalent to production devices?

4. What evaluations (clinical or other activities) were performed to assist in validating that the device design meets defined user need and intended uses? Design validation activities may include:

   - Clinical studies approved via Internal Review Boards (IRBs) and Investigational Device Exemptions (IDEs), or IRB alone for non-significant devices.
   - 510(k) historical database search.
   - Clinical evaluations in clinical or nonclinical settings.
   - Literature searches. •Review of labels and labeling, packaging, and other historical product information.

5. Describe the actual or simulated use conditions under which the finished device was evaluated to validate the design.

6. How did the manufacturer resolve discrepancies encountered during design validation activities? Provide an example of an unresolved discrepancy, if any, and the manufacturer's justification for leaving the discrepancy unresolved.

7. If the device contains software, explain the method(s) by which the software has been validated.

8. Give a few examples of how risks have been identified, analyzed, and reduced. Were tools such as Failure Mode Effects Analysis (FMEA), Failure Mode Effects and Criticality Analysis (FMECA), Fault Tree Analysis, etc. utilized? Provide examples of any risks that were not resolved.

9. Based upon the review of the design history file, does the documentation identify the design, methods of design validation, dates, and individuals performing design validation activities? Explain any discrepancies.

820.30(h) Design Transfer

Regulatory Requirements

Each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

Questions

1. Describe the procedure(s) for transferring the design output for the device from design to manufacturing.

2. Select at least one design feature and review the transfer process to confirm that procedures from design transfer were followed and design output was correctly translated into production specifications.

820.30(i) Design Changes

Regulatory Requirements

Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.

Questions

1. When in the design process does the firm begin to control design changes?

2. What criteria in the design change procedure(s) are used to control changes to approved elements of the design?

3. Does the design change procedure(s) address when verification of changes is sufficient in lieu of validation of changes?

4. For design changes that were verified but not validated, what was the justification that validation was unnecessary?

5. Who is authorized to review and approve design changes before they are implemented, and how is the approval documented?

820.30(j) Design History File

Regulatory Requirements

Each manufacturer shall establish and maintain a DHF for each type of device. The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part.

Questions

1. How does the manufacturer maintain and retain the contents of the design history file?

2. List the key elements in the manufacturer's design history file and explain how these elements support that the design was developed in accordance with the design plan and procedures.

3. If more than one device shares a common design history file, how does the firm identify each device within the family or group having common design characteristics?

AREAS OF NEEDED IMPROVEMENT

Investigator(s) Signature_____ Date _____