

SUBJECT:  INSPECTION OF MEDICAL DEVICE MANUFACTURERS		IMPLEMENTATION DATE  February 2, 2011
		COMPLETION DATE  February 2, 2015
DATA REPORTING		
PRODUCT CODES	PRODUCT/ASSIGNMENT CODES	
73-91	82845A; 42845A	All Level 1 (Abbreviated) Inspections
	82845B; 42845B	All Level 2 (Comprehensive) Inspections
	82845C; 42845C	All Level 3 (Compliance Follow-up) Inspections
	82845G	All For Cause Inspections
	82845H	Risk Based Work Plan Inspections
	82845P	Joint FDA/Accredited Person Inspections
	82845S	Report Time spent on Assessment of Firm's Sterilization processes
	81010	Report Time spent on MDR Follow-up
	81011	Report Time spent on Assessment of Firm's MDR Practices
	81845T	Report Time spent on Assessment of Firm's Tracking Practices
	81845R	Report Time spent on Assessment of Firm's Corrections and Removals Practices
	82A800	Independent Accredited Person Inspections

\* Previous editions obsolete.

**Index for Compliance Program 7382.845**

**Coversheet**

**Field Reporting Requirements**

**Part I**

**Background**

- A. The Quality System (QS) Regulation
- B. The MDR Regulation
- C. The Medical Device Tracking Regulation
- D. The Corrections and Removals Regulation
- E. The Registration and Listing Regulation

**Part II**

**Implementation**

- A. Objectives
- B. Program Management Instructions

**Part III**

**Inspectional**

- A. Operations
  - 1. Inspectional Strategy
    - a. QS inspections
    - b. Level 1 Inspections
    - c. Level 2 Inspections
    - d. Level 3 Inspections
    - e. For Cause Inspections
    - f. Risk Based Work Plan Inspections
    - g. Foreign Inspections
  - 2. Inspectional Instructions
  - 3. Special Instructions Concerning Design Controls
  - 4. Special Instructions for Sterilization Processes
  - 5. Inspection of Radiation Emitting Devices
  - 6. Sample Collection
- B. Additional Considerations
  - 1. Registration and Listing
  - 2. Imports
  - 3. Exports
  - 4. Electronic Records and Electronic Signatures
- C. Remarketed Devices
- D. Reporting

**Part IV**

**Analytical**

- A. Analyzing Laboratories
- B. Analyses to be Conducted
- C. Methodology

**Part V**

**Regulatory/Administrative Follow-up**

- A. Quality System/GMP Regulatory/Administrative Follow-up
  - 1. Compliance Decision
  - 2. Contract Sterilizers, Contract Device Manufacturers and Finished Device Manufacturers – Deciding Responsibility When Taking Regulatory Action
  - 3. Violative Devices Sold to Government Agencies
  - 4. Administrative and Judicial Actions
  - 5. Facilitating Review of Regulatory Recommendations
- B. MDR Regulatory/Administrative Follow-up
- C. Tracking Regulatory/Administrative Follow-up
- D. Corrections and Removals Regulatory/Administrative Follow-up
- E. Registration and Listing Regulatory/Administrative Follow-up
- F. Radiation Emitting Device Regulatory/Administrative Follow-up
- G. Exports Regulatory/Administrative Follow-up

**Part VI**

**References and Program Contacts**

**Attachments**

- Attachment A** CDRH Office of Compliance Organizational Chart
- Attachment B** CDRH Office of In Vitro Diagnostic Devices Organizational Chart
- Attachment C** Summary of MDR Reporting Requirements
- Attachment D** Summary of Tracking Requirements
- Attachment E** Summary of Corrections and Removals Requirements

Field Reporting Requirements

**EIRs:** All recommendations for administrative/regulatory action should include the EIR, FDA-483 and exhibits. The recommendations should be sent to the Center for Devices and Radiological Health (CDRH) and for tissue or combination products the recommendations should also be sent to the Center for Biologics Evaluation and Research (CBER) and/or the Center for Drug Evaluation and Research (CDER) as appropriate.

Note: If the district wishes to obtain comment from CDRH for any EIR, the district should attach a cover memorandum to the EIR outlining the issues to be considered by the Office of Compliance (OC) or Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD).

This guidance document represents the agency’s current thinking on the enforcement of the Quality System (QS), Medical Device Reporting (MDR), Medical Device Tracking, Corrections and Removals, and the Registration and Listing regulations. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

**PAC Guidance**

<b>PROGRAM</b>	<b>PACs</b>
Quality System	Level 1 (82845A)
	Level 2 (82845B)
	Level 3 (82845C)
For Cause	82845G
Risk Based Work Plan	82845H
Joint FDA/Accredited Persons	82845P
Independent Accredited Person Inspection	82A800
MDR	81010 & 81011
Tracking	81845T
CAR	81845R
Sterilization Inspections	82845S

Note: When conducting sterilization review as part of the Production and Process Controls subsystem, report **only** the time spent reviewing the sterilization process during the Quality System inspection, if covered under PAC 82845S. Also, report PACs, 81010, 81011, 81845T and 81845R, as applicable.

The above PAC Guidance is provided for investigator reference only. Additional CBER and/or CDER PAC codes may also be necessary for multi-jurisdictional products (i.e. tissue and combination products). Please refer to the inspection assignment for guidance.