SUBJECT:	IMPLEMENTATION DATE
INSPECTION OF MEDICAL DEVICE MANUFACTURERS	June 15, 2006*
	COMPLETION DATE
	June 15, 2010

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 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.

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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) HFZ-306 and for human cells, tissues, and cellular and tissue-based products (HCT/Ps), 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.

Warning Letters: A copy of all Warning Letters related to all requirements covered in this compliance program should be sent to HFZ-306 and HFC-210**.**

Comment:

- 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

PROGRAM	**PACs**
Quality System	Level 1 (82845A)
	Level 2 (82845B)
	Level 3 (82845C)
For Cause	82845G
Joint FDA/Accredited Persons	82845P
Independent Accredited Person Inspection	82A800
MDR	81010 & 81011
Tracking	81845T

PROGRAM	PACs
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 by necessary for multi-jurisdictional products (i.e. tissue) and combination products. Please refer to the inspection assignment for guidance