Sections included in this document

1. Purpose/Scope

To establish a procedure to be followed by ALL district offices, and the Office of Medical Products and Tobacco Operations (OMPTO)/Division of Medical Products and Tobacco Program Operations (DMPTPO) in updating District Use Codes (DUC) in FACTS using information received from the Center for Devices and Radiological Health (CDRH). This procedure summarizes field and headquarter responsibilities and ensures information that is in the Center files and the field's Official Establishment Inventory (OEI) and Registration files.

2. Responsibility

It is the responsibility of the District OEI Coordinator, District Medical Device Monitor, Medical Device Registration Coordinator or designee to manage assigning district use codes in accordance with this work instruction.

District includes both domestic and foreign areas.

Note: The document refers to District Registration Monitor throughout, but is referring to the above statement.

3. Background

Non-medical electronic products only require inspection under the Electronic Product Radiation Control (EPRC) requirements (laser, x-ray; 21 CFR Parts 1000-1050). Medical devices which do not emit radiation, or use radioactive materials are only inspected under the Medical Device Quality System

regulation (21 CFR 820). Electronic products which are medical devices are inspected under both EPRC and QS regulations (**Attachment 9.1**).

Previously, these firms were not identifiable in FACTS, and investigators were not clear which regulations to evaluate and apply during inspections. This procedure provides guidance for identifying these firms in FACTS.

4. Procedure

4.1 Dissemination of information

Step 1: CDRH/Office of In Vitro Diagnostics and Radiological Health (OIR)/Division of Radiological Health (DRH) sends an Excel Spreadsheet to the National OEI Coordinator annually (first quarter of the fiscal year) for the firms that need to be updated in FACTS.

Step 2: The Excel spreadsheet includes the FEI number, firm information, Listing Product Code, Device Class, Inspection Type, PAC Code, Device Generic or Common Name.

Step 3: The National OEI Coordinator sends the Excel spreadsheet to the Director of Investigations Branch (DIB) for each District, with a copy to the OEI Coordinator/ Registration Monitor.

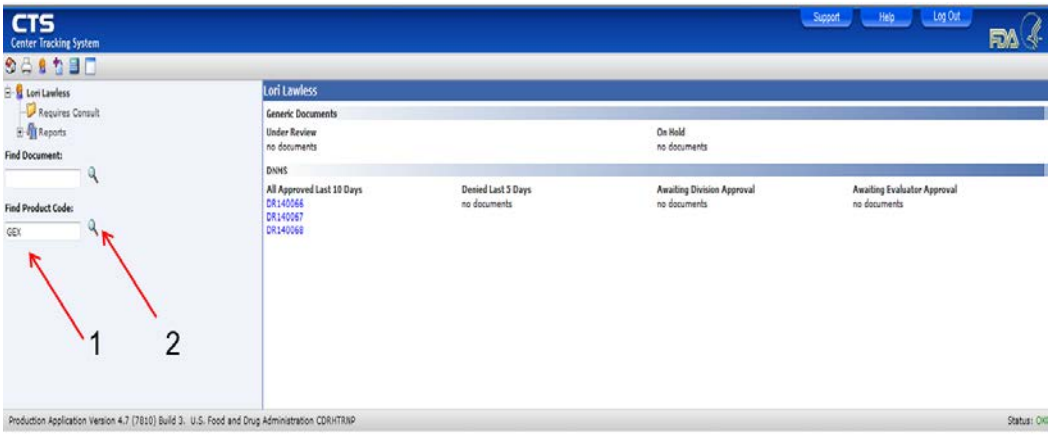
Step 4: If the list is extensive, the list may be divided and distributed into smaller sections and distributed each quarter (preferably in the first month of the quarter).

Step 5: The OEI coordinators/Registration Monitors update FACTS within one month of receiving the spreadsheet.

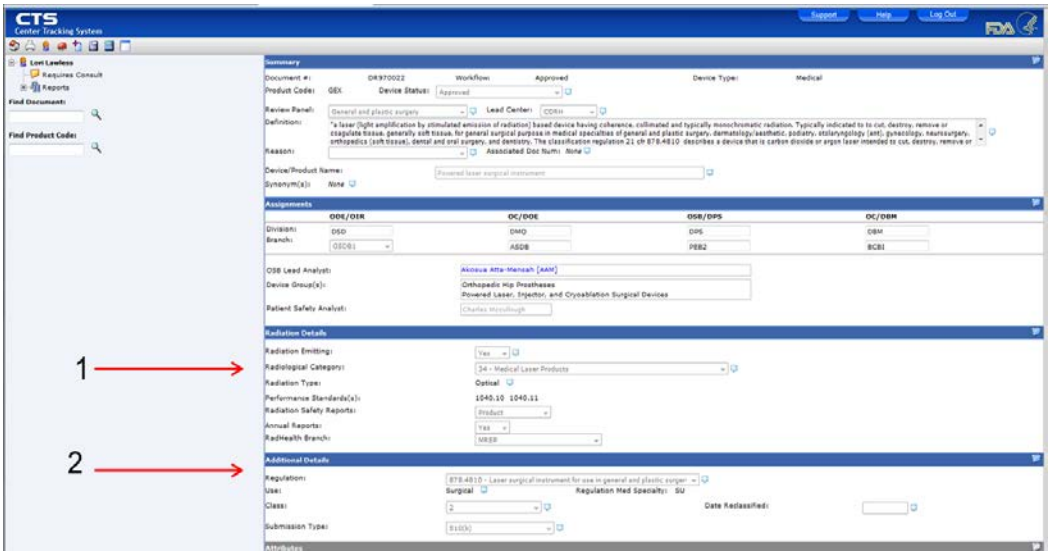
Step 6: The National OEI Coordinator, on a quarterly basis, spot-checks to assure that the information is being updated as requested. If not, the National OEI Coordinator will reach out to the OEI Coordinator/ Registration Monitor and District management to discuss the process.

4.2 Updating FACTS

Step 1: The Registration Monitor/OEI Coordinator/designee accesses the Center Tracking System (CTS) and enters the Product Code from the Excel Spreadsheet into the box “Find Product Code” (1), and clicks the magnifying glass (2).



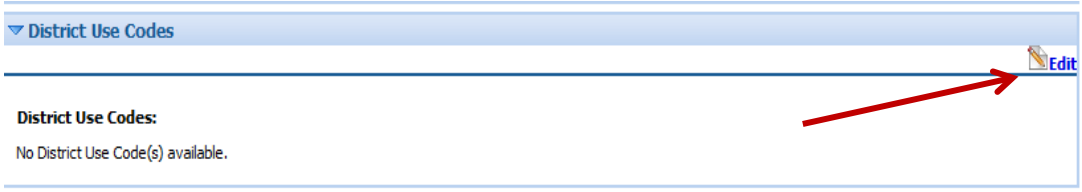
Step 2: Radiological category (1) is identified in the “Radiation Details” section. This information will help identify whether, and if so, what type of electronic product regulations apply for the product code entered. If there is information under additional details section, this product is also regulated as a medical device.



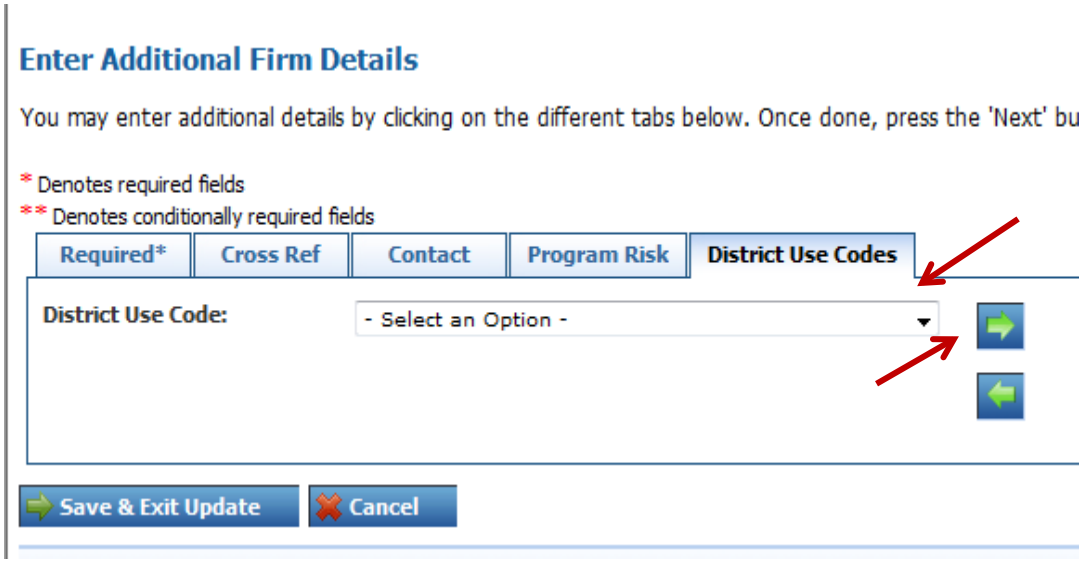
Step 3: Find the “Radiological Category” in Attachment 9.2 to identify the district use code (DUC).

Step 4: Go to Firm Maintenance Services (FMS) in FACTS and search for the firm being updated.

Step 5: Under “Firm Details”, scroll to the bottom of the page and click “Edit” next to “District Use Codes”.



Step 6: Using the drop down menu, identify the appropriate District Use Codes. Use the "Right" Green Arrow to add the District Use Code.



4.3 Communications with CDRH

Step 1: Questions regarding the data in the spreadsheet should be communicated to the National OEI Coordinator.

Step 2: The National OEI Coordinator is the point of contact (POC) between CDRH and ORA, and will route all communications.

5. Glossary/Definitions

A. CDRH: Center for Devices and Radiological Health
B. CFN: Central File Number
C. CTS: Center Tracking System
D. EPRC: Electronic Product Radiation Control
E. FEI: Field Establishment identifier
F. FACTS: Field Accomplishment Tracking System
G. FMS: Facility Management Service
H. OEI: Official Establishment Inventory
I. QS: 21 CFR 820 Quality System Regulations

6. Supporting Documents

A. 21 CFR 820
B. 21 CFR Parts 1000-1050
C. CPGM 7382.845 “Inspection of Medical Device Manufacturers”
D. CPGM 7386.001 “Inspection and Field Testing of Radiation-Emitting Electronic Products”
E. CPGM 7386.003a “Field Compliance Testing of Diagnostic (Medical) X-Ray Equipment”
F. Quality Inspectional Technique

7. Document History

Version #	Status* (D,I, R, C)	Date	Author Name and Title	Approving Official Name and Title
1.0	I	7/2/15	LORI LAWLESS, NATIONAL OEI COORDINATOR	Kate Bent, Director OPRM

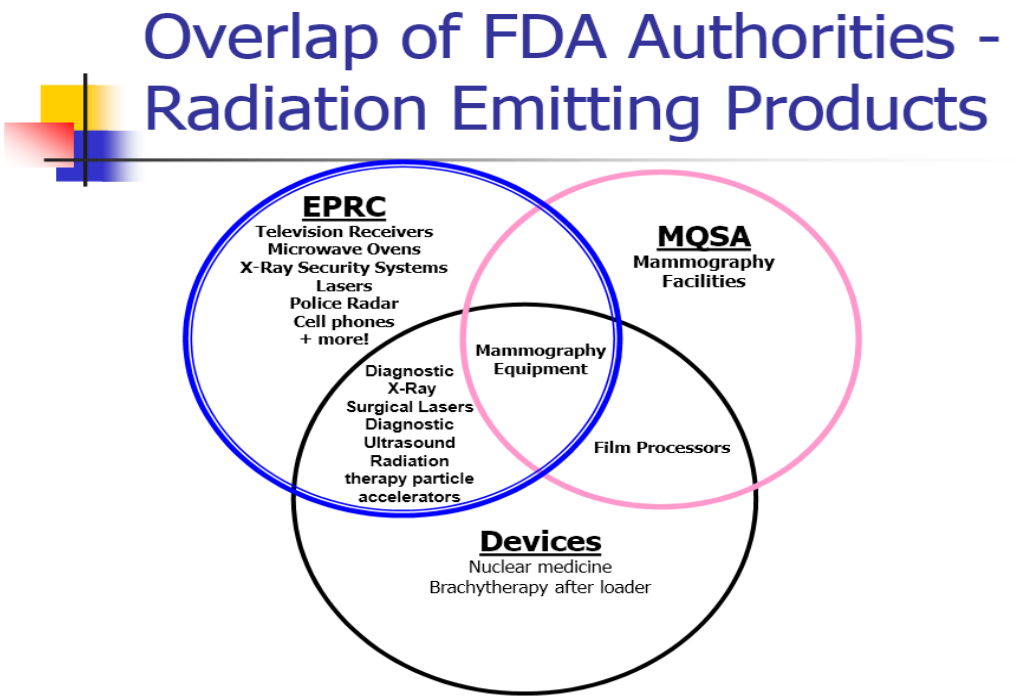
* - D: Draft, I: Initial, R: Revision, C: Cancel

8. Change History

Version	Change
1.0	Initial

9. Attachments

9.1 Overlap of FDA Authorities- Radiation Emitting Products



9.2 Radiological category

LS: Laser Facilities (medical), QS and EPRC requirements apply, including laser performance standard
NL: Non-medical Laser, EPRC requirements only apply, including laser performance standard
XR: X-rays (medical), QS and EPRC requirements apply, performance standard for diagnostic systems only
NX: X-rays (non-medical), EPRC requirements only (performance standard for cabinet systems only) apply
EC: Electronic Product and Radiation Control facility, EPRC requirements only apply, no performance standards applicable