New England District

Medical Device Update

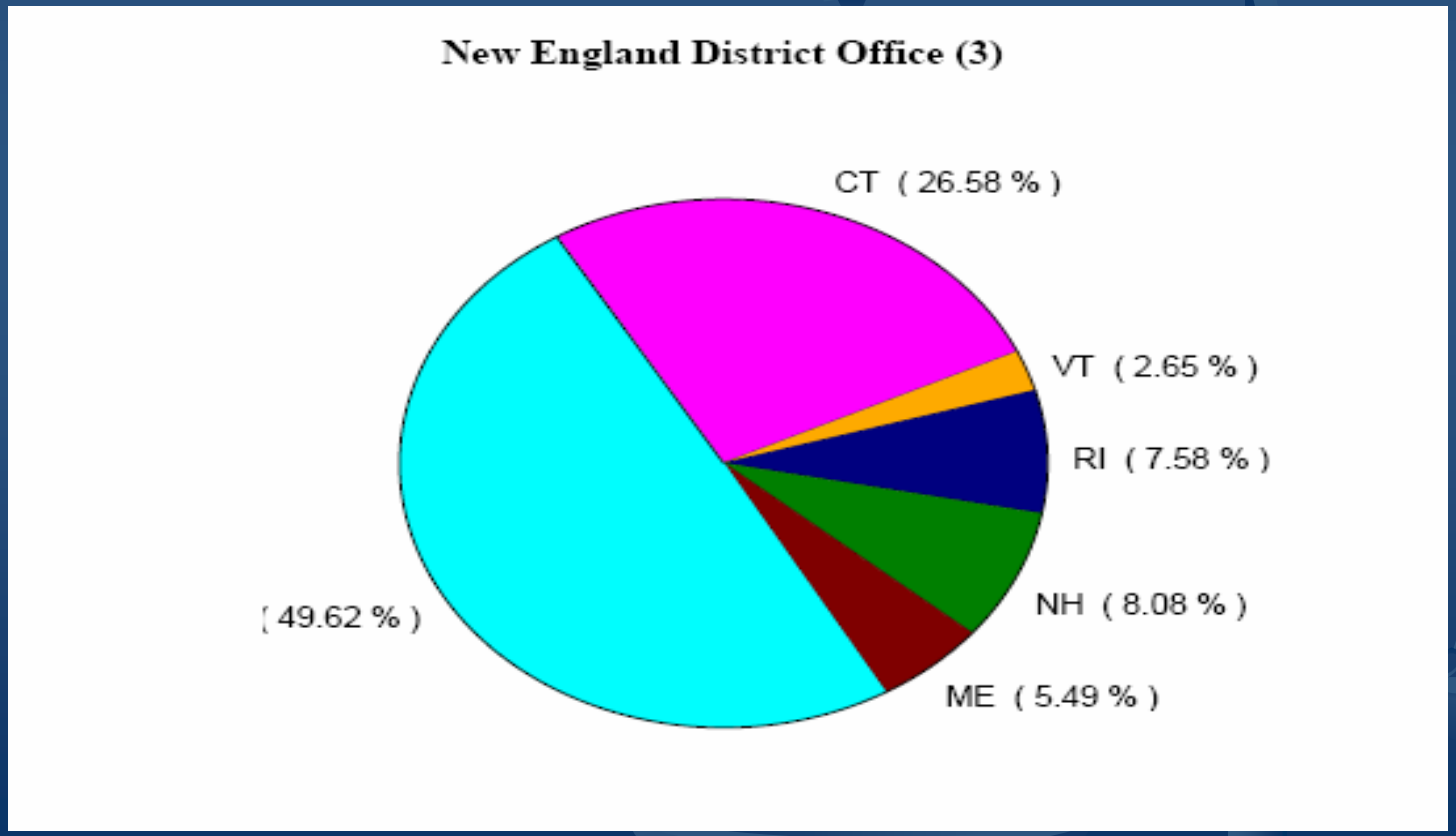
July 27, 2011

UMASS - Dartmouth


Houlton R.P.
Calais R.P.
Augusta R.P.
Highgate R.P.
Concord R.P.
New England District Office
WEAC
Boston R.P.
Worcester R.P.
Providence R.P.
Hartford R.P.
Bridgeport R.P.
Clayton Lake
Presque Isle
MAINE
Dover-Foxcroft
Bangor
Bar Harbor
Augusta
Lewiston
Berlin
Burlington
Montpelier
VERMONT
Rutland
Lebanon
Concord
NEW HAMPSHIRE
Manchester
Keene
Lowell
Worcester
Providence
Hartford
New Haven
Norwich

Inventory

- 8745 establishments
  - 3021 device firms



Accomplishments FY10

- 1355 Inspections
  - 264 Device inspections
    - 20 Foreign inspections

NWE-DO Structure

- Investigations Branch
  - 102 Investigators
  - 11 Supervisors
- Compliance Branch
  - 9 Compliance Officers
- Administrative Branch

Compliance Actions

- FY10
  - 22 Warning Letters
    - 9 Device QSRs
  - 2 Permanent Injunctions
- FY11
  - 24 Warning Letters
    - 7 Device QSR's (inc 510(k) & MDR)

Commissioner's Enforcement Initiatives August 6 2009

- Implement a formal Warning Letter "close-out" process
  - After FDA determines violations have been corrected notice will be posted on FDA website
  - For WL issued after 9/1/09
- Warning Letter "close-out" process
  - Since 09/01/09 18 close out letters sent, 4 of which were device related

Transparency Initiative

- An agency-wide effort to open the doors of the agency and promote innovation, in a manner compatible with the agency goal of appropriately protecting confidential information.
- http://www.fda.gov/AboutFDA/Transparency/TransparencyInitiative/ucm254426.htm

FY10 Device Cites

- Lack of Written MDR Procedures
- Lack of or inadequate CAPA procedures
- CAPA Documentation
- Lack of or inadequate process validation
- Complaint handling procedures

FY10 Device Cites

- Lack of purchasing or inadequate controls
- Lack of or inadequate complaint procedures
- Lack of investigation of device failures
- Lack of or inadequate quality audits
- Lack of or inadequate design change procedures

In My Experience

- Prepare
- FDCA, CFR, IOM, RPM, CPGM, CPG, QSIT
- Inspection expectations
- Open, honest discussion
- Clear, concise response