

# Public Benefit of Filling the Gap

## From Bottleneck to Pipeline



Bruce Beurlington



98W-339R

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# Stakeholders Meeting

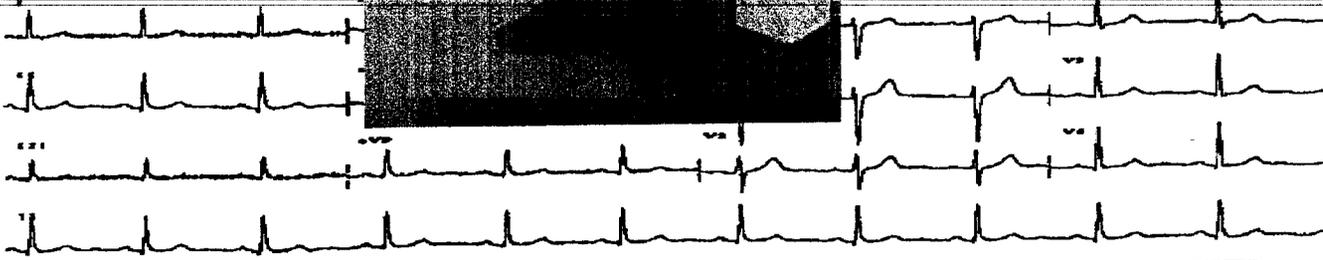
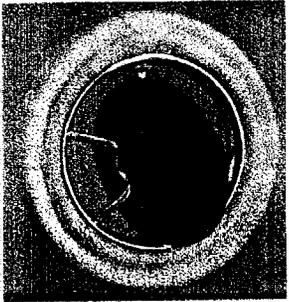
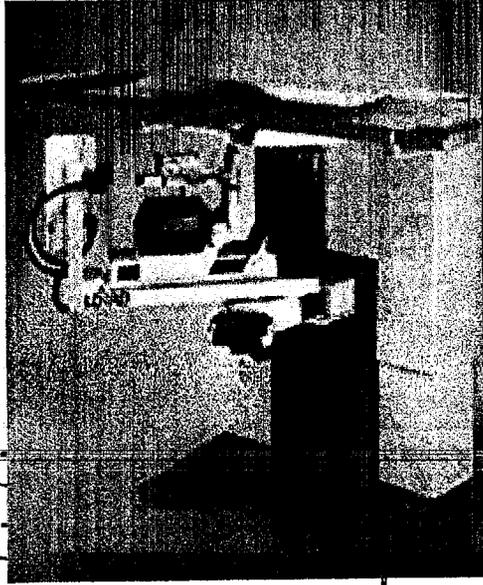
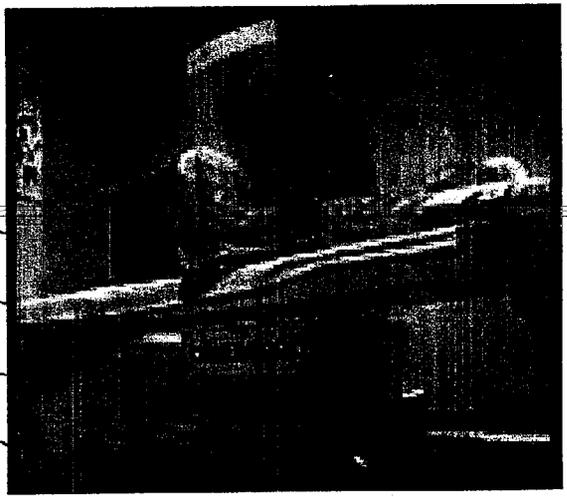
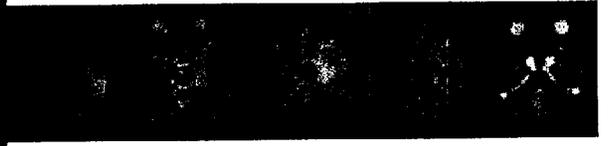
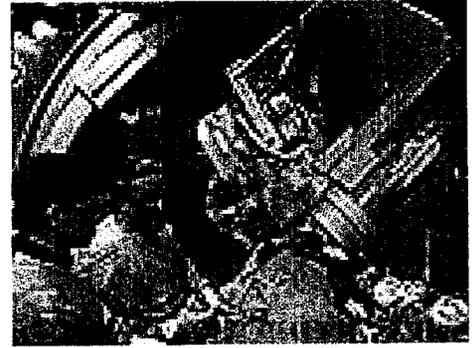
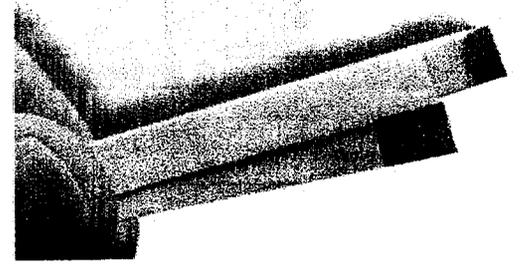
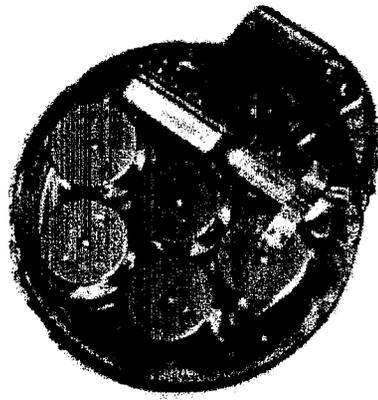
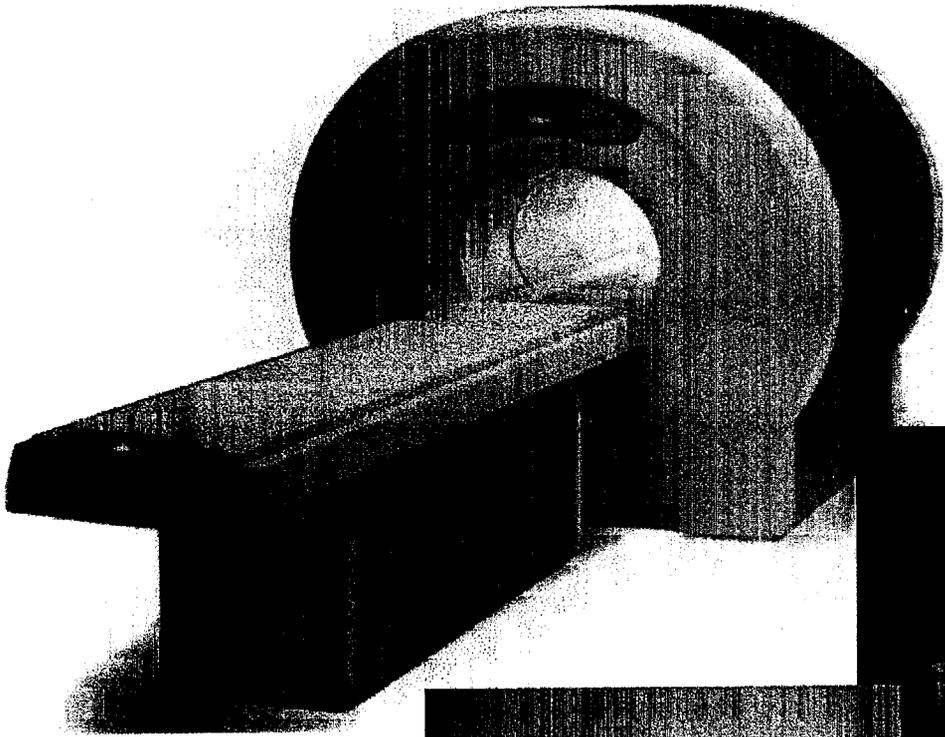
August 18, 1998



TS 1

# **Today's Presentation**

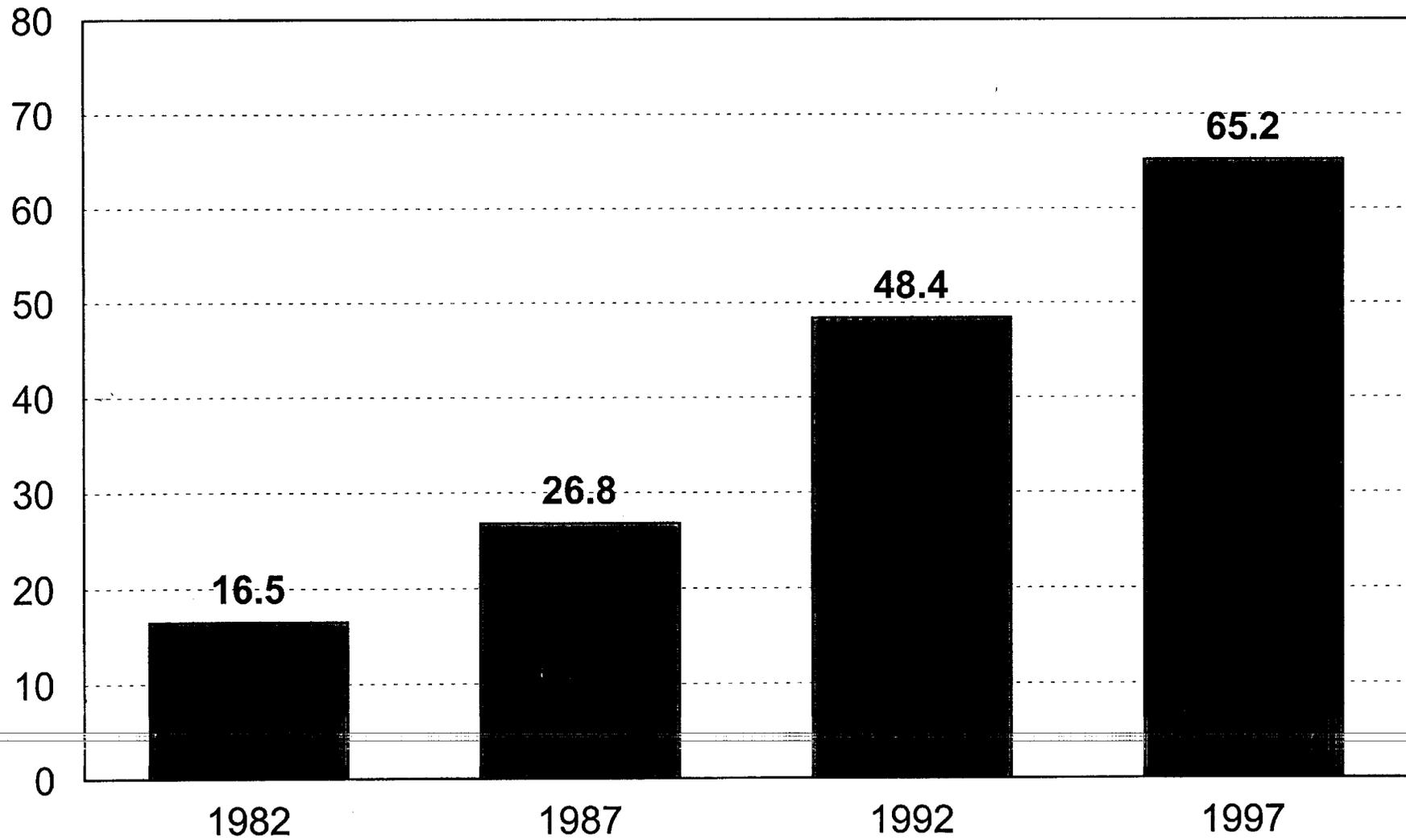
- **Growing Responsibilities**
- **Diminishing Resources**
- **Reengineering Improves Program  
But Leaves Performance Gaps**
- **Need Public Advice on Meeting  
FD&C Act Requirements**



100 2500-0000 SPEED 25 mm/sec ALPHABET 1 25 CHARACTERS 25 mm/sec

2500 25-10-100 100

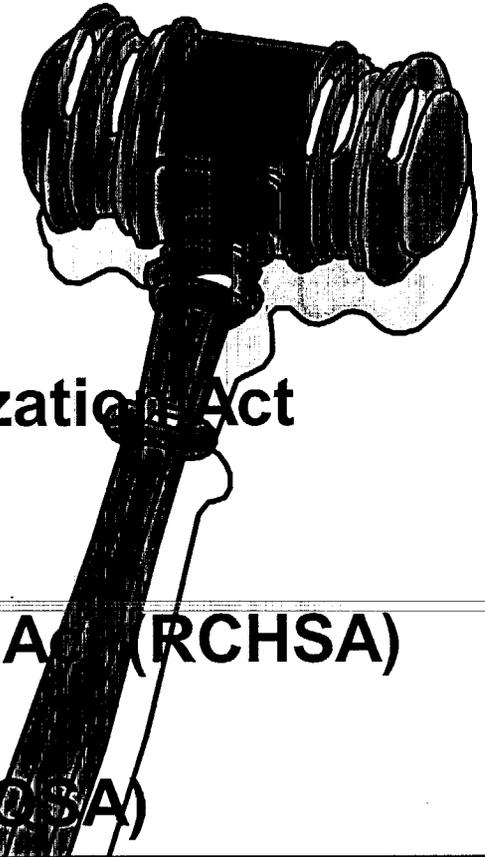
## Medical Device Industry Value of Shipments (\$ Billions)



Source: HIMA

# Legislative Mandates

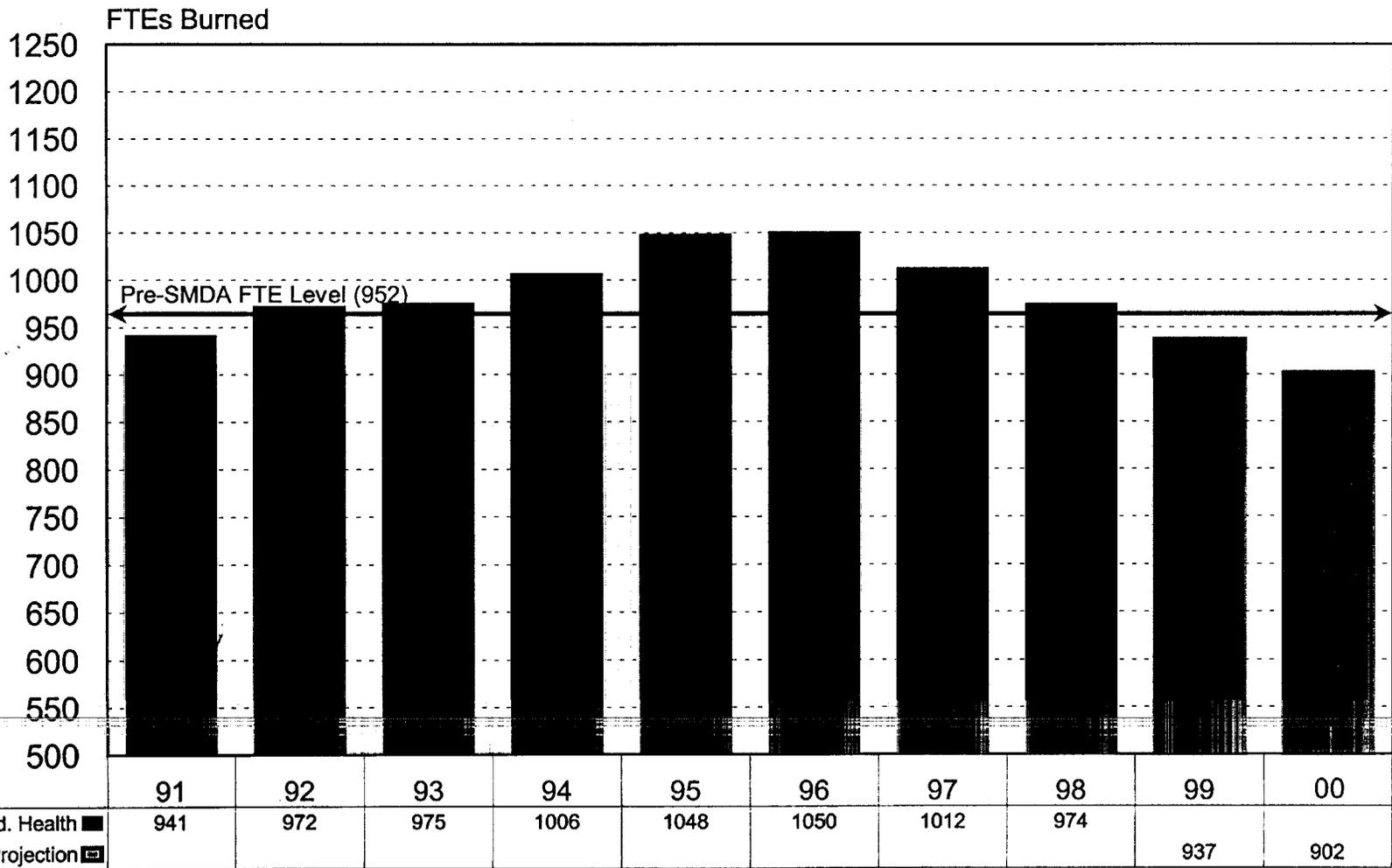
- **Food, Drug and Cosmetic Act (FD&C)**
  - ✓ **Medical Device Amendments**
  - ✓ **Safe Medical Devices Act (SMDA)**
  - ✓ **Food & Drug Administration Modernization Act (FDAMA)**
  - ✓ **Radiation Control for Health & Safety Act (RCHSA)**
- **Mammography Quality Standards Act (MQSA)**



# **FDAMA Themes**

- **Interactive Development**
- **Decisive Timely Action**
- **Patient Access**
- **Codifies Reengineering**
- **Accountability**
- **Discretion vs. Criteria**
- **International Harmonization**

# Center for Devices and Radiological Health FTE History

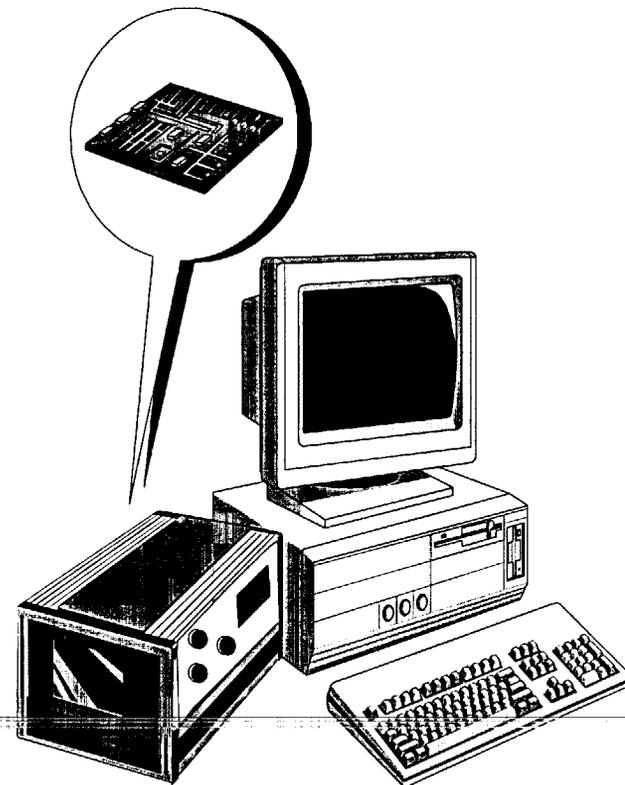


Fiscal Year

Note: MQSA resources are excluded

# Increase in Product Complexity

## Pap Smear Reader

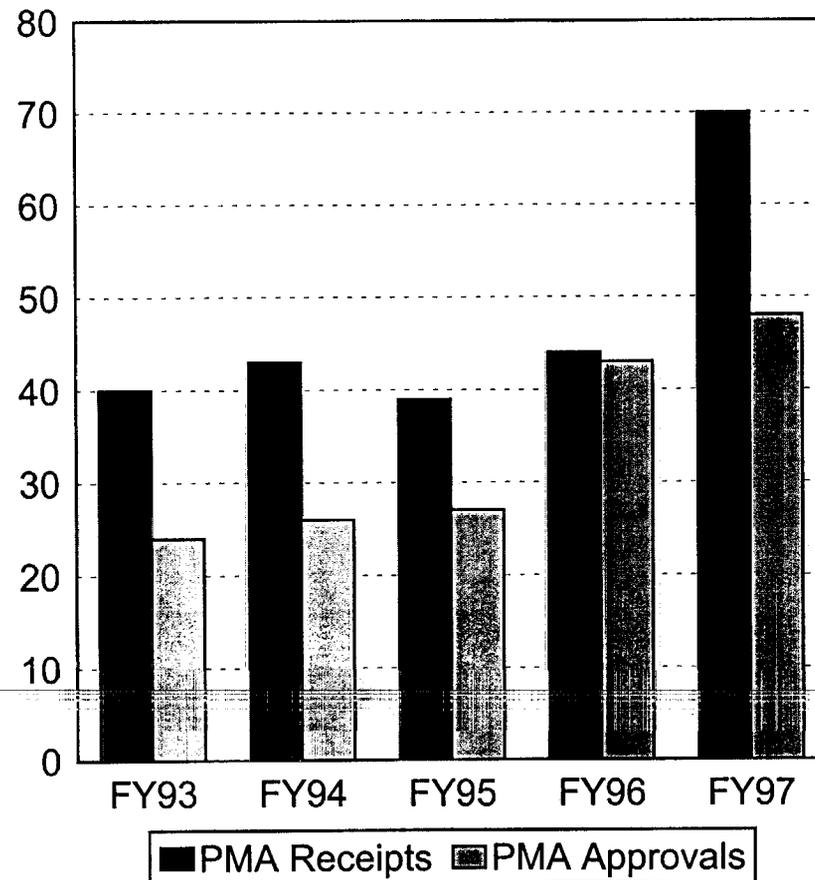


- Miniaturization
- Artificial Intelligence
- Microprocessing
- Remote Operation
- Combinations

# PMA Workload is Growing in Number and Complexity

## Examples of Medical Device Breakthroughs FY97

1. GenESA System Closed-Loop Infusion System for automated cardiac stress testing
2. NeuroCybernetic Prosthesis System to help quadriplegics use their arms
3. Fetal Bladder Stent for congenital urinary tract abnormalities
4. Sacral Nerve Stimulator for intractable incontinence
5. Autonomic Nerve Stimulator for epilepsy
6. Deep Brain Stimulator Lead for Essential tremor and Parkinsonism



# Medical Device Reporting Workload

## Obstacles

Paper-intensive

Lack of good data on high risks

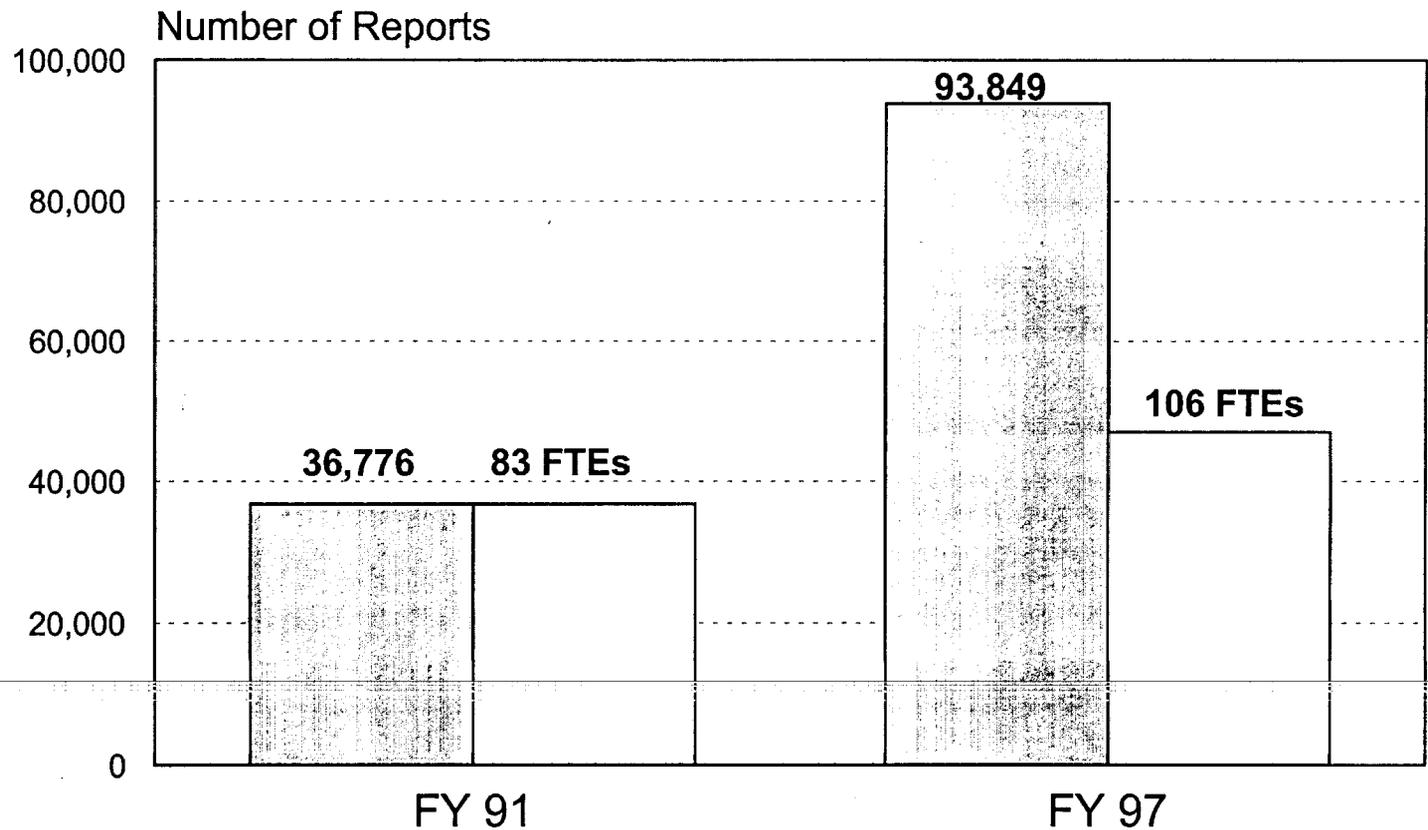
Resources absorbed by data entry

## Proposed Changes:

Expand summary reporting

Develop strong Sentinel system

Strengthen voluntary reporting

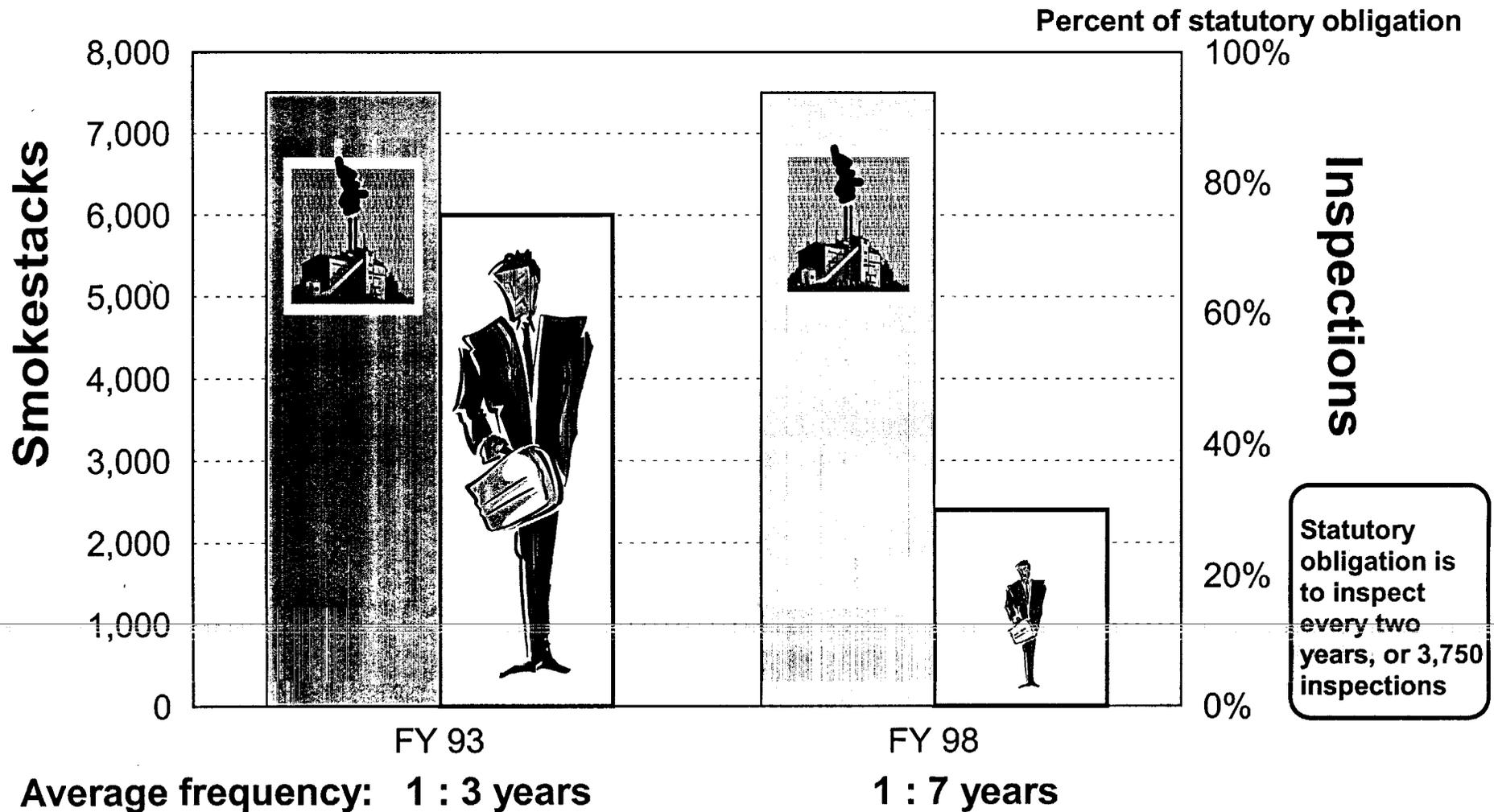


Ratio of FTEs to reports: 1 : 443

1 : 885

# Device GMP Inspections

FY 93 vs FY 98

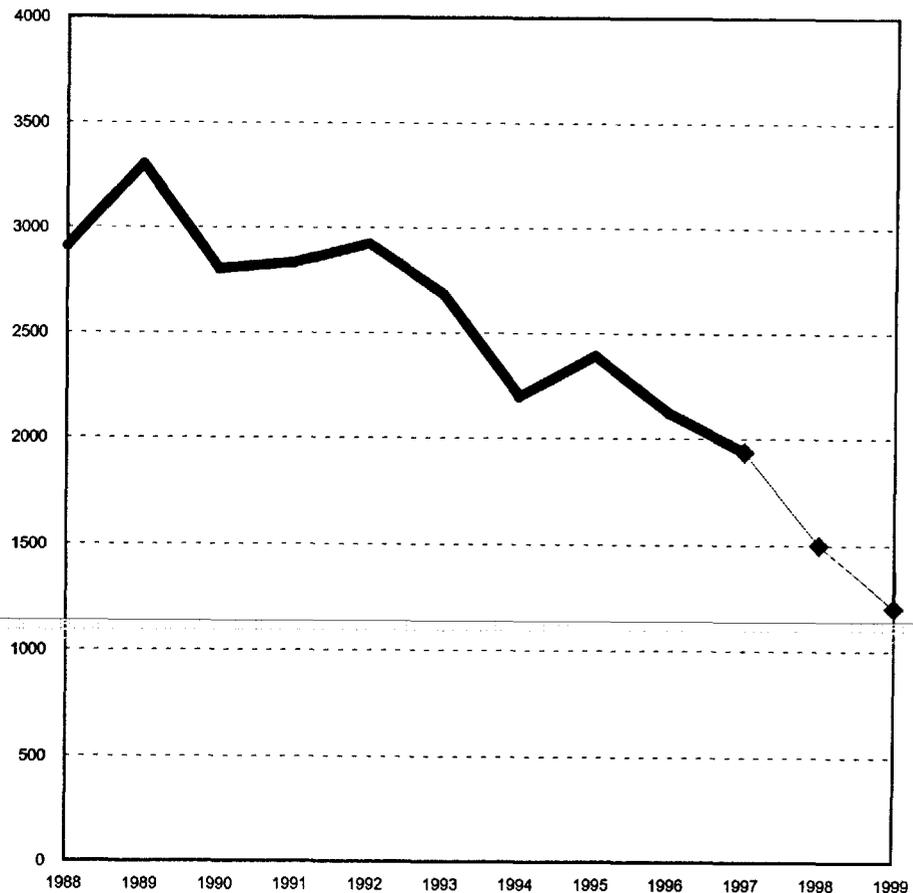


# Radiological Health Workload and Current Issues

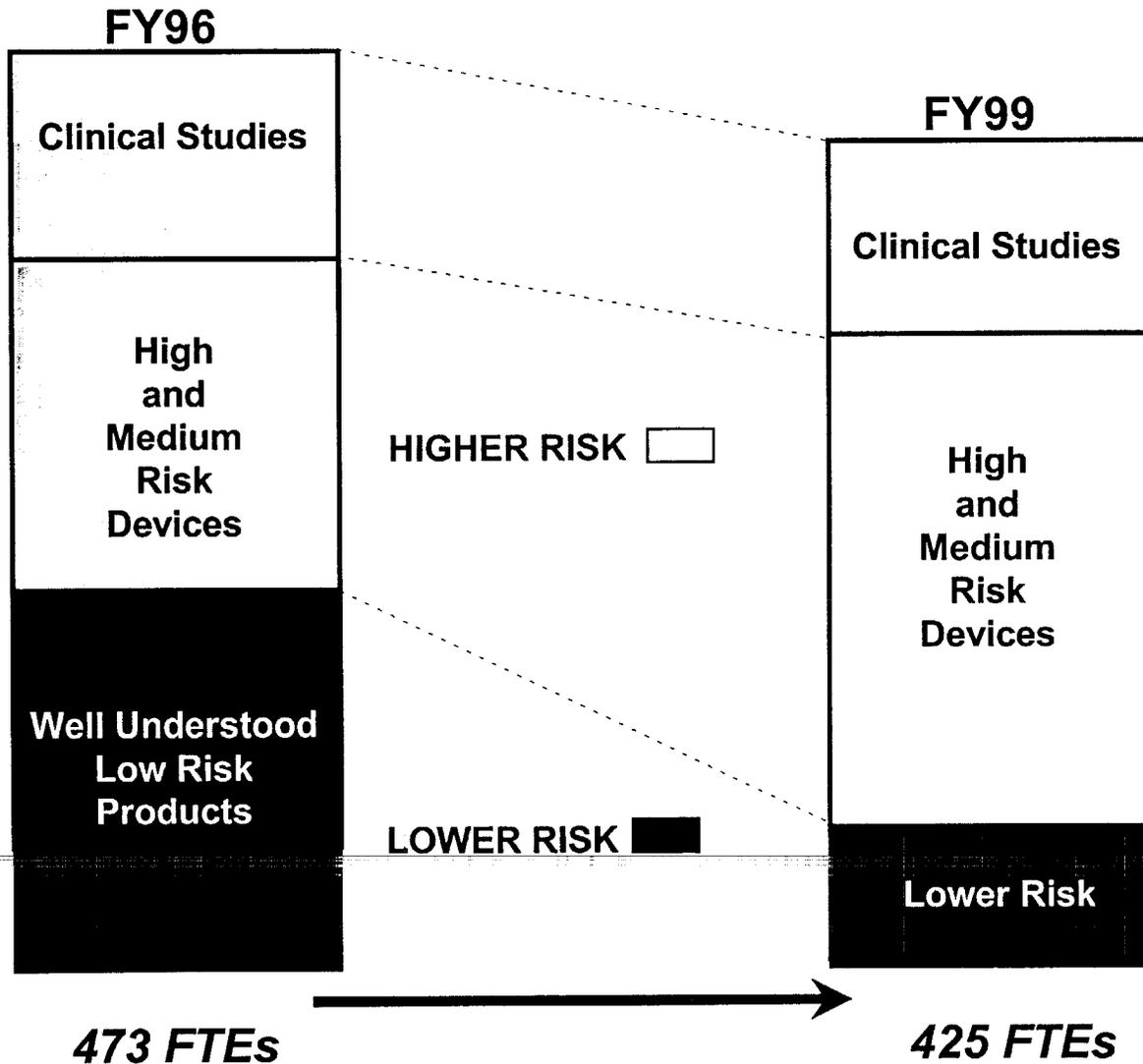
## Examples of Radiological Health Issues in FY 98

1. EAS device Interactions
2. Digital Broadcast Device Interactions
3. Fluoroscopy Burns

Number of X-Ray Systems Tested by Year  
Excludes MQSA



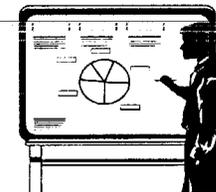
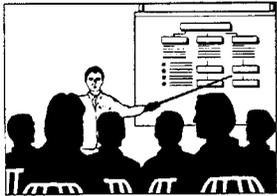
# Re-Focusing Premarket Resources



# Reengineering



- **Consult Stakeholders**
- **Map Process**
- **Model New Process**
- **Pilot/Evaluate**
- **Implement**



# Premarket Notice: 510(k)

## **OLD**

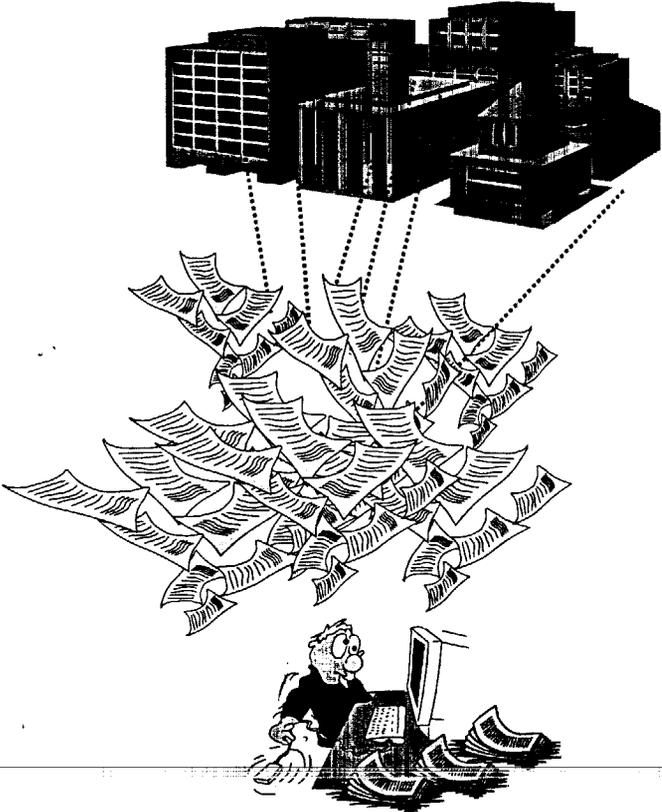
- Complete Data Set
- Modified Product  
New 510(k)

## **NEW**

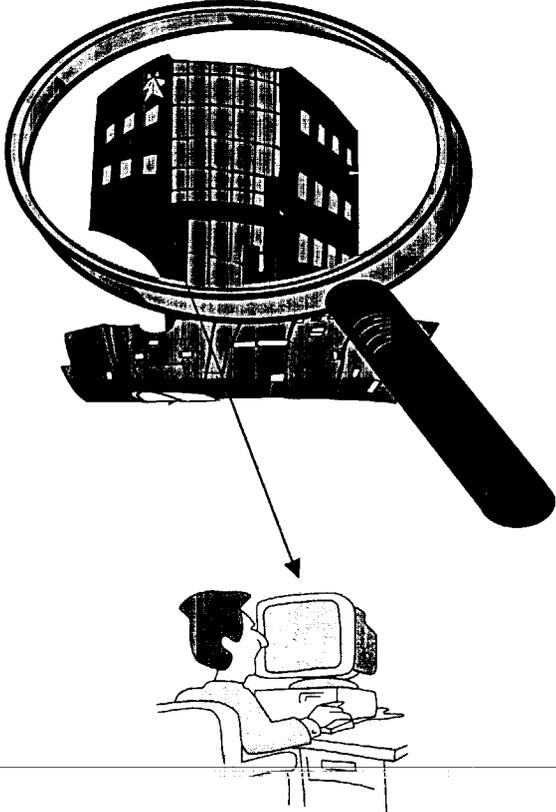
- Exemptions
- Abbreviated 510(k)  
Standards
- Modified Product 510(k)  
Standards  
Design Control (ISO 9001)
- Full Data Set 510(k)

# Medical Device Reports

## Current System

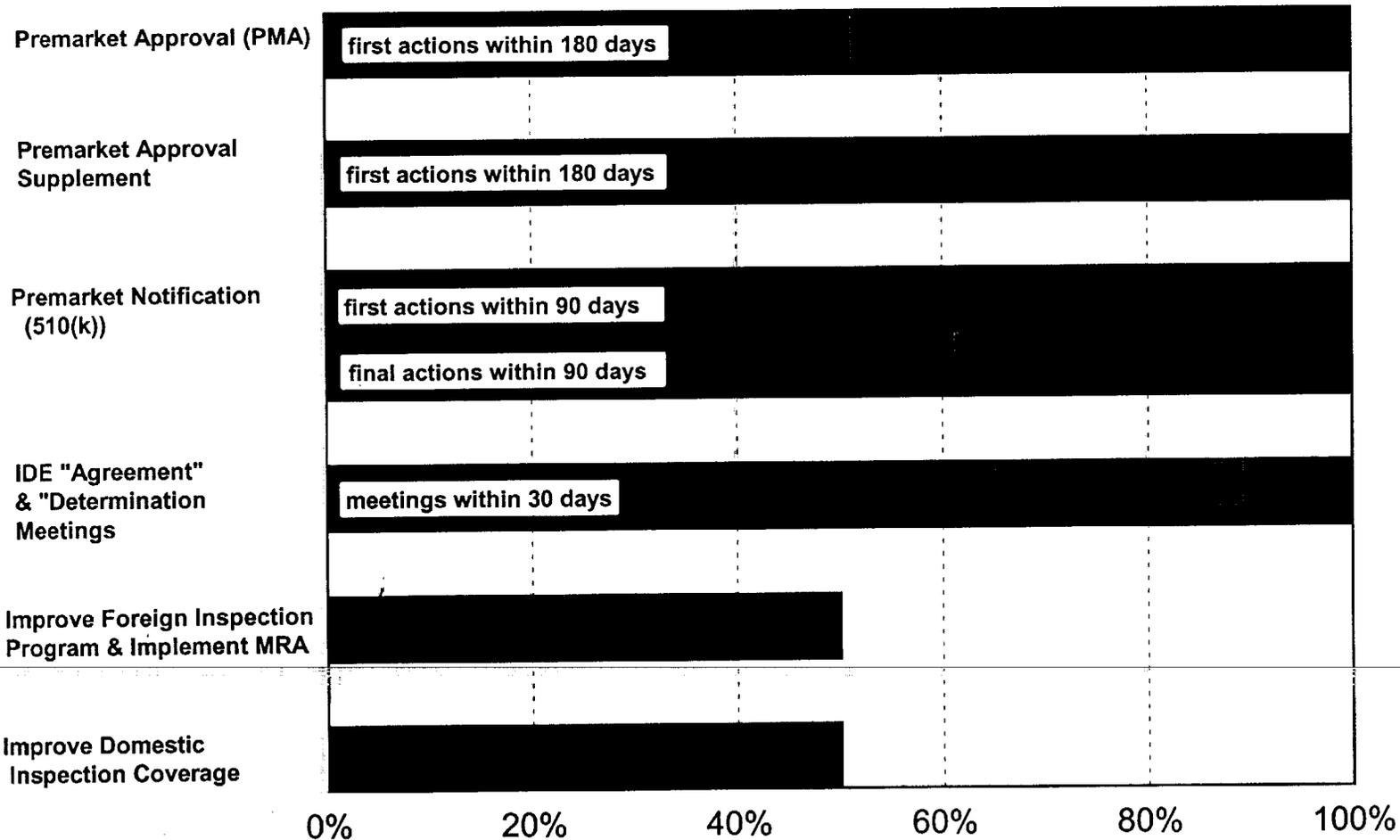


## Sentinel System





# Statutory Requirements vs Current Status



- - - - - METS - - - - - WITH STATUTORY TIME FRAMES