

# Inspection Observations and Follow-up Actions

**Michael P. Divine, M.S.**

Division of Mammography Quality and Radiation Programs  
Office of Health and Industry Programs  
Center for Devices and Radiological Health  
Food and Drug Administration  
Department of Health and Human Services

# Objectives

- Inspection Results
- Follow-Up Actions

# Recent Inspection Results

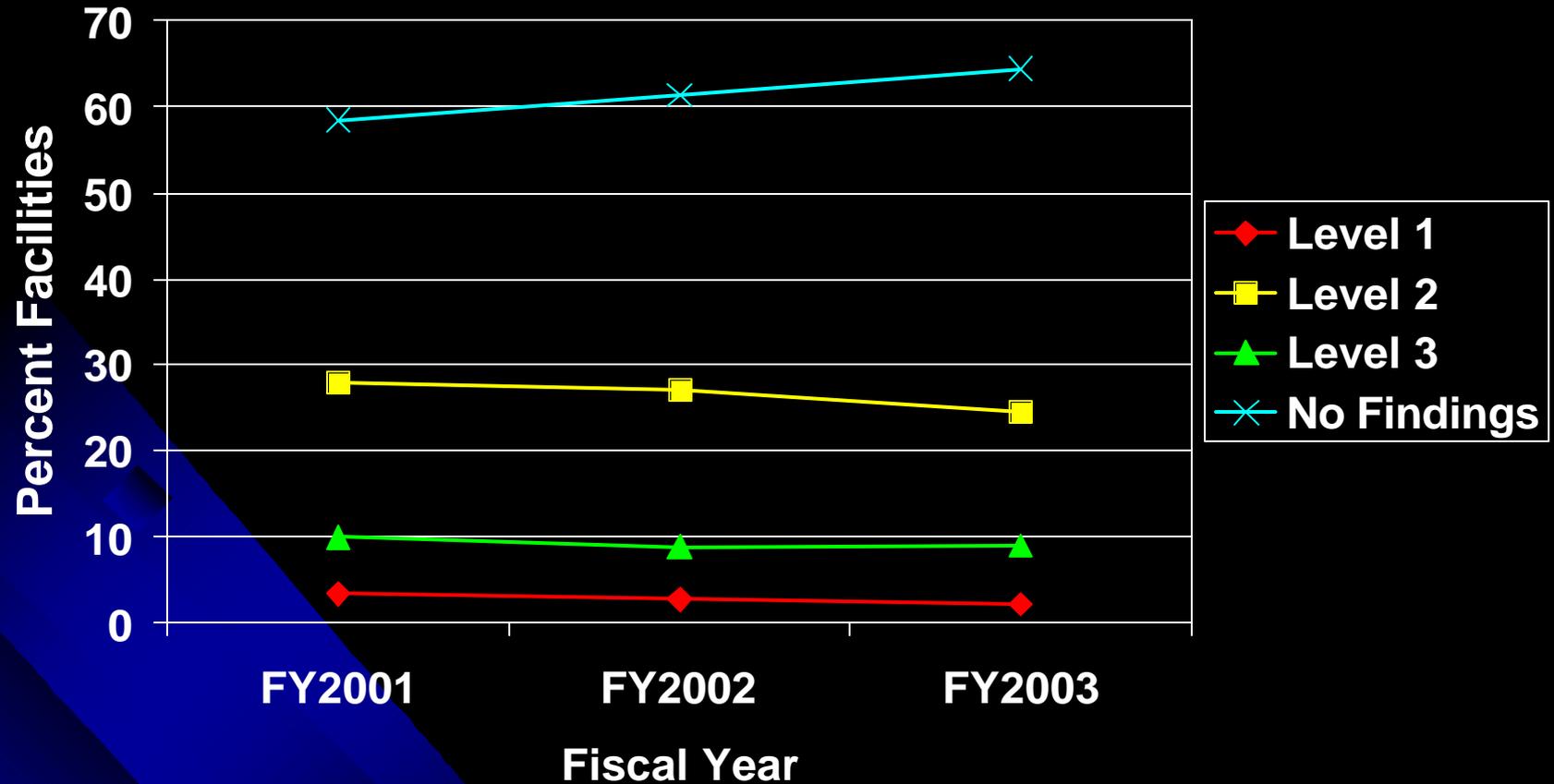
Fiscal Years 2001 to 2003\*

\*10/1/2002 to present

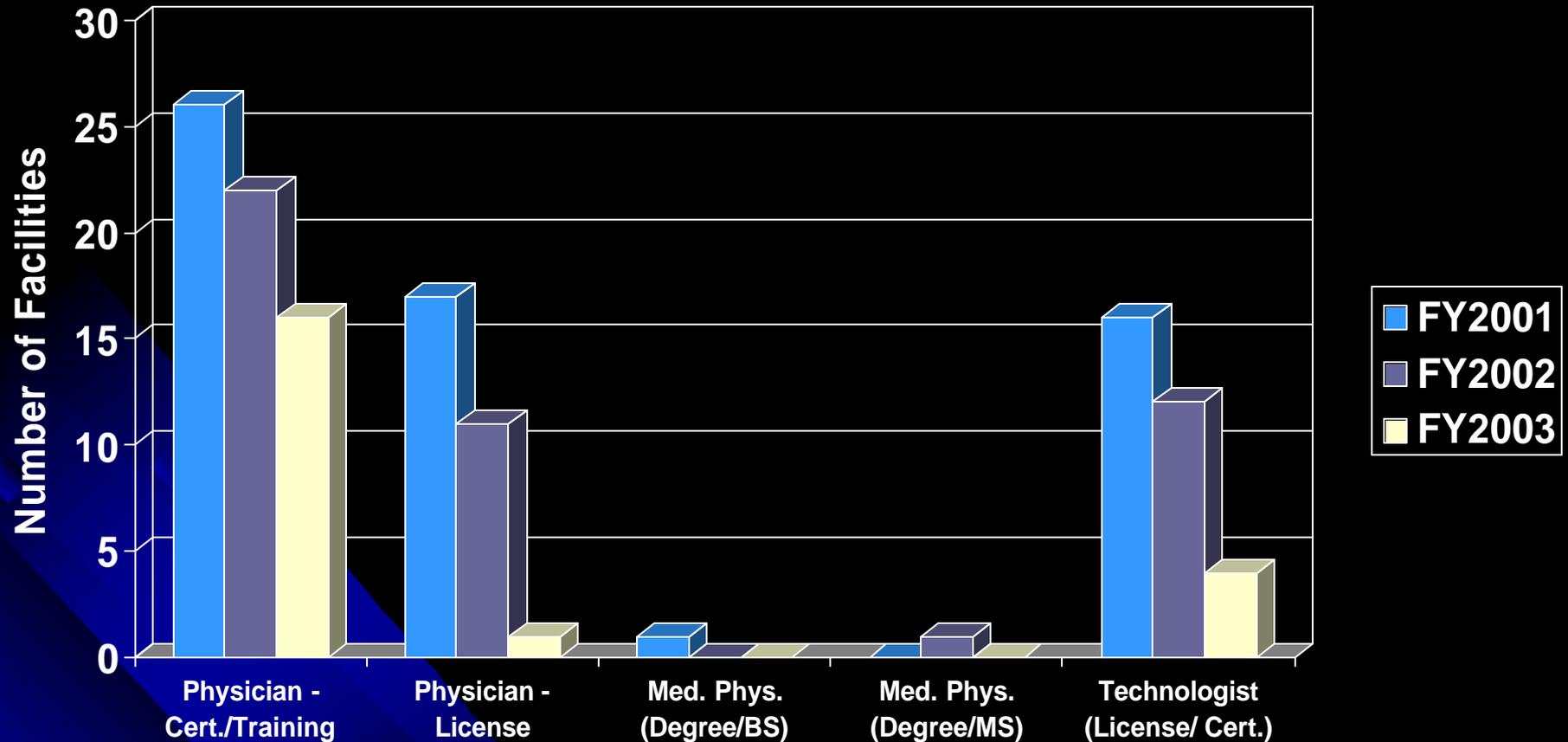
# Inspection Finding Levels

- Level 1 - Serious
- Level 2 - Moderate
- Level 3 - Minor

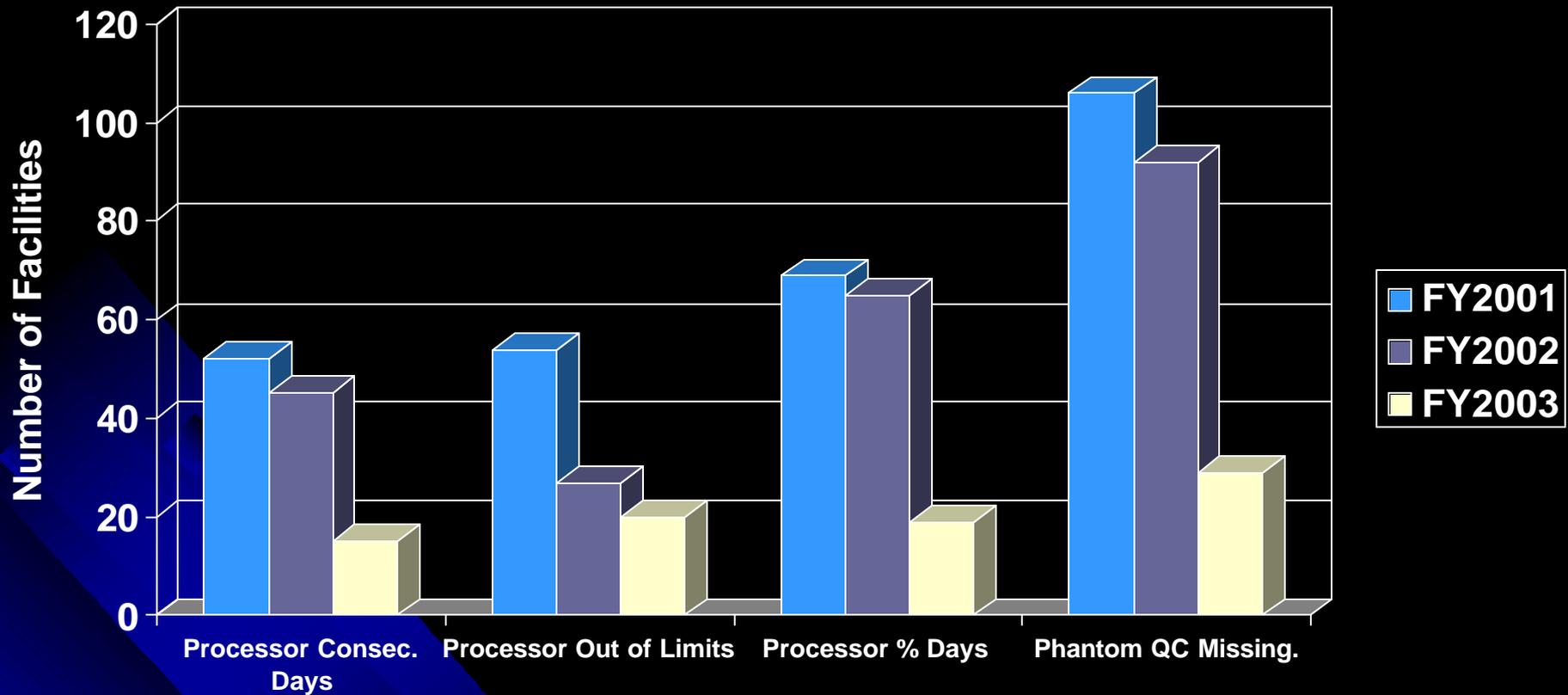
# Violations by Level Change by Year



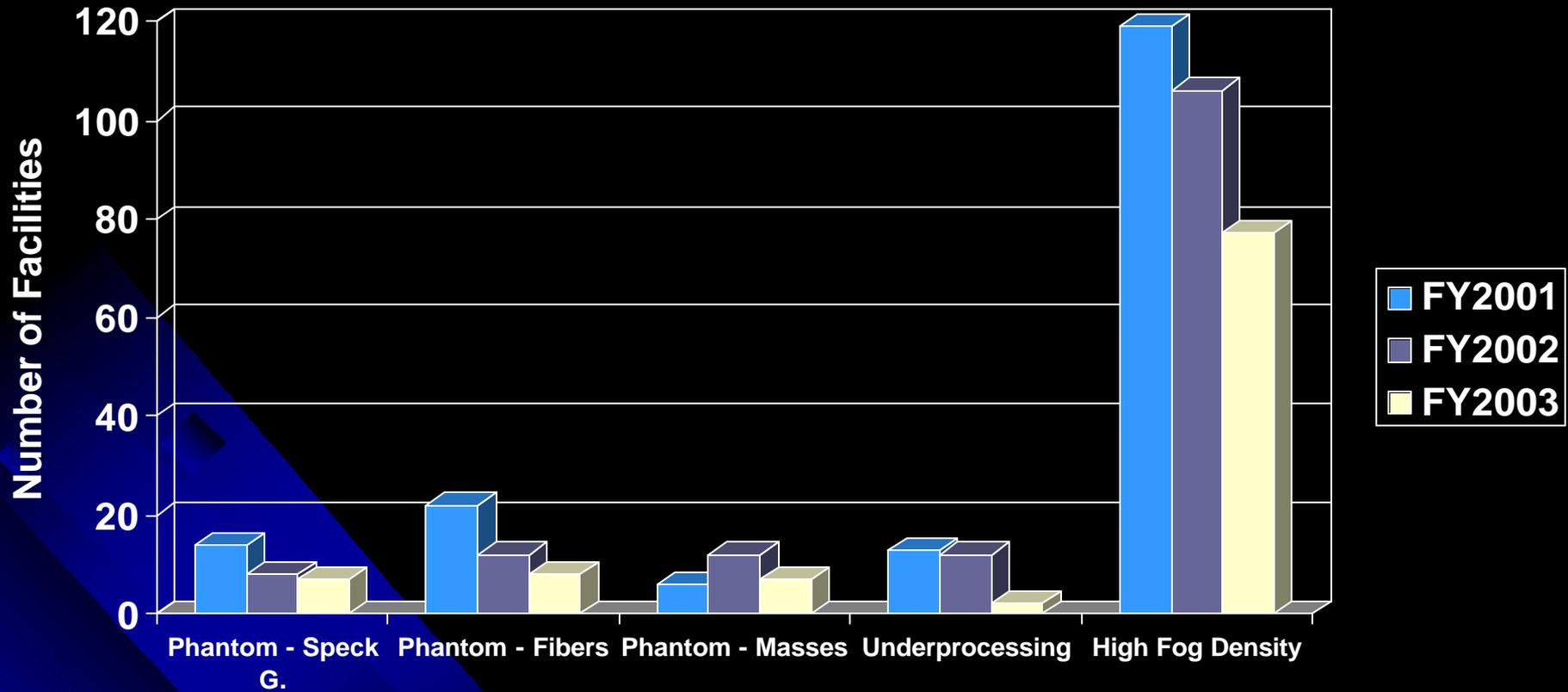
# Level 1 Initial Qualifications



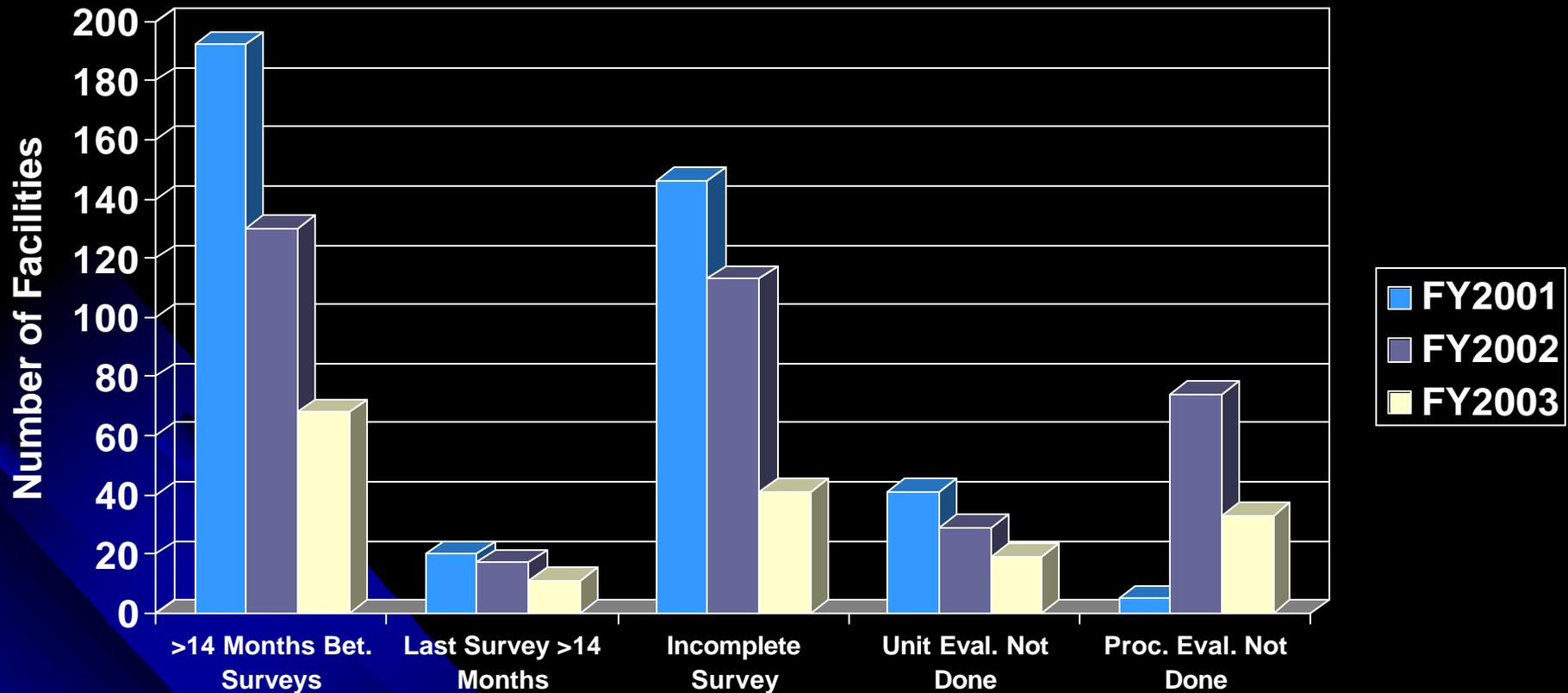
# Level 1 - Processor and Phantom Quality Control



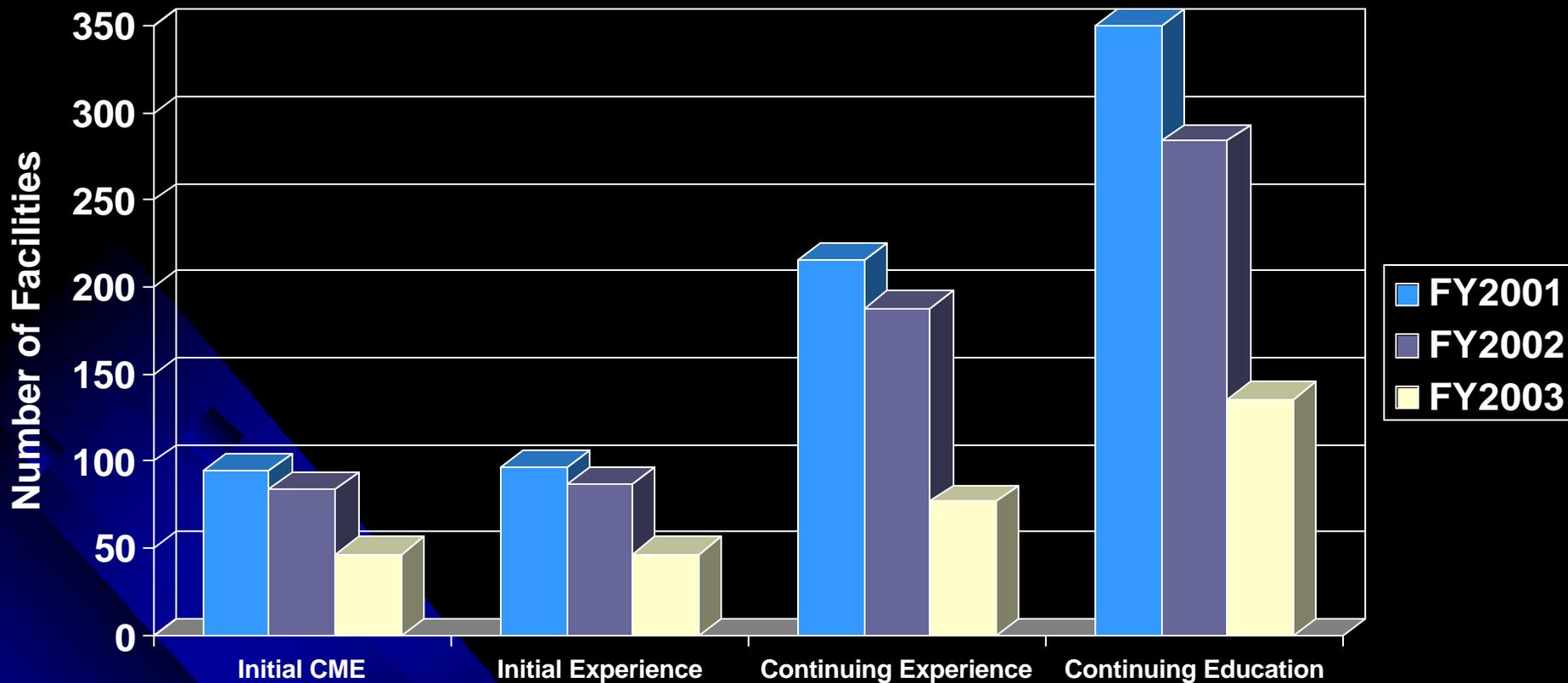
# Level 2 - Phantom Score & Processing Conditions



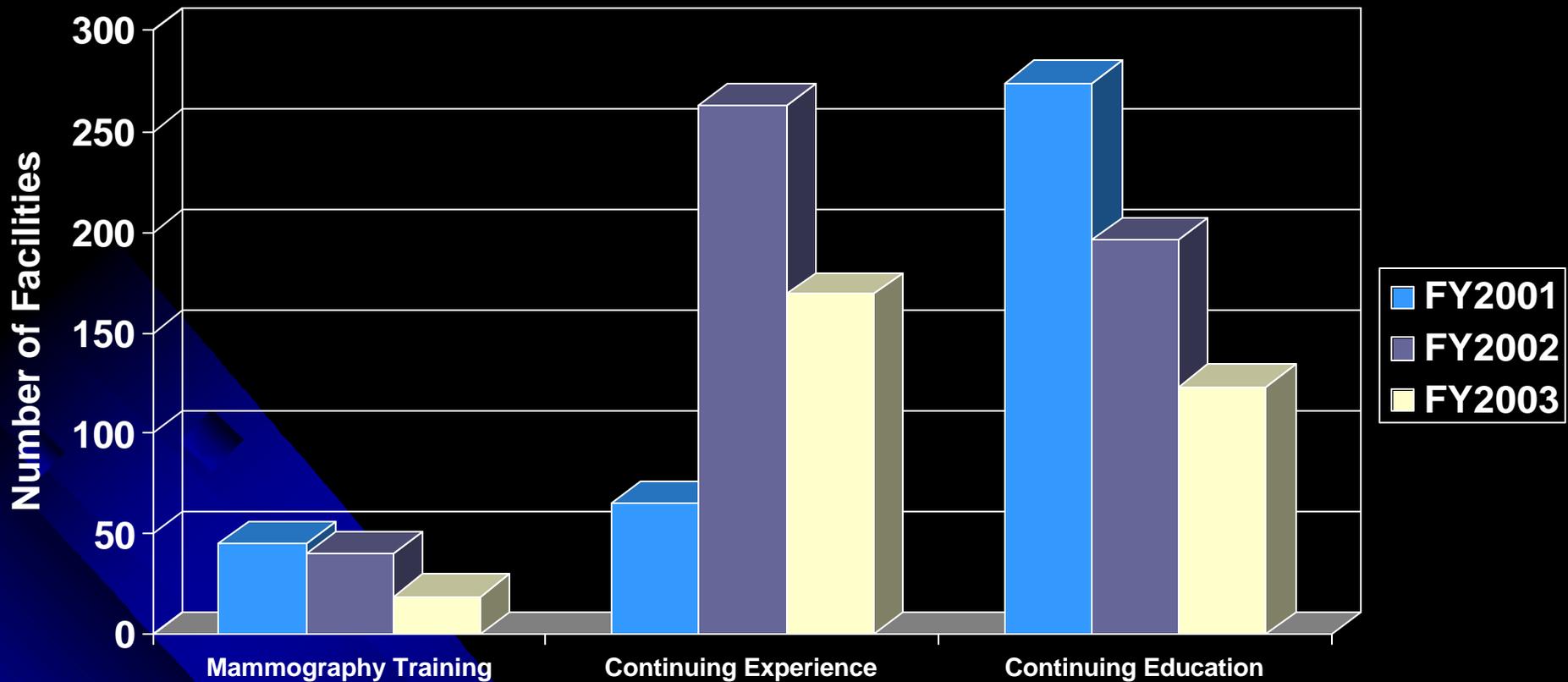
# Level 2 - Annual Survey & Equipment Evaluation



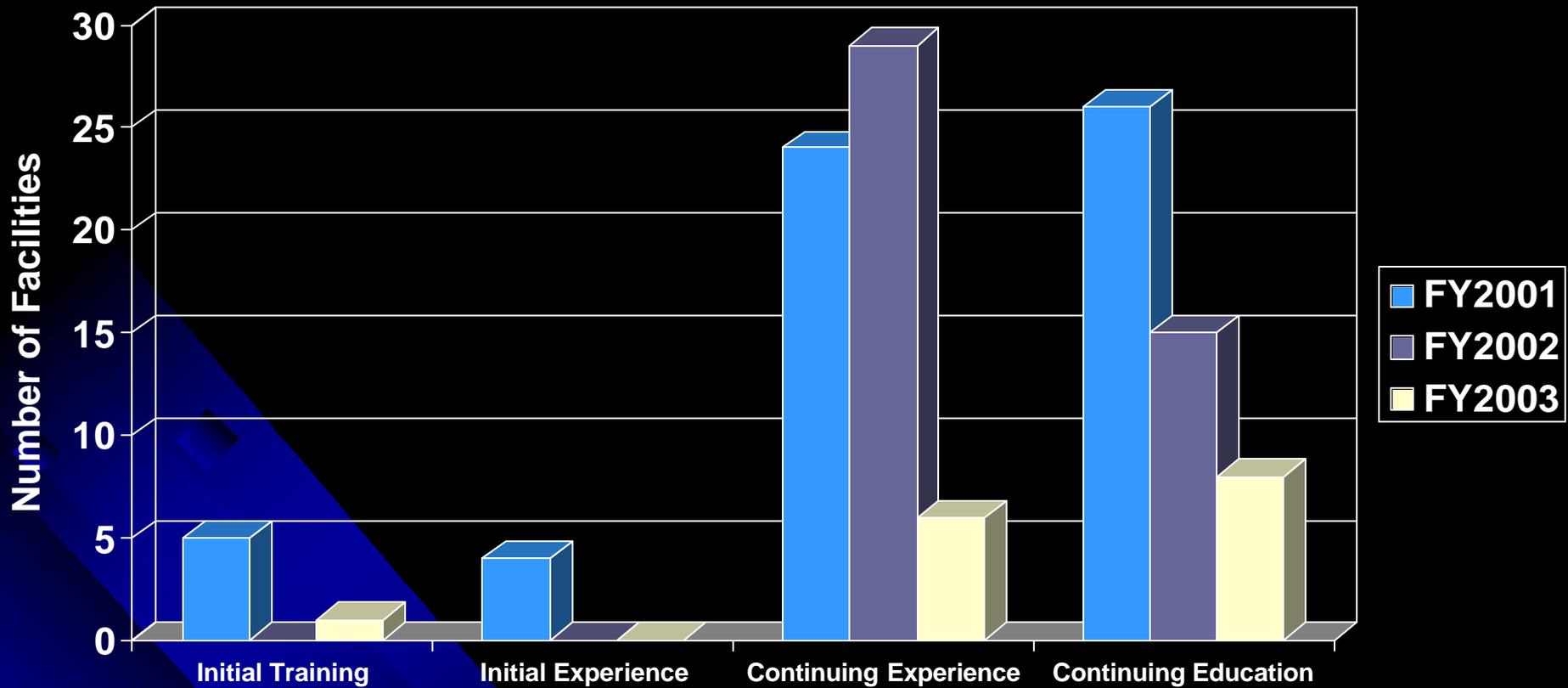
# Level 2 - Interpreting Physician Qualifications



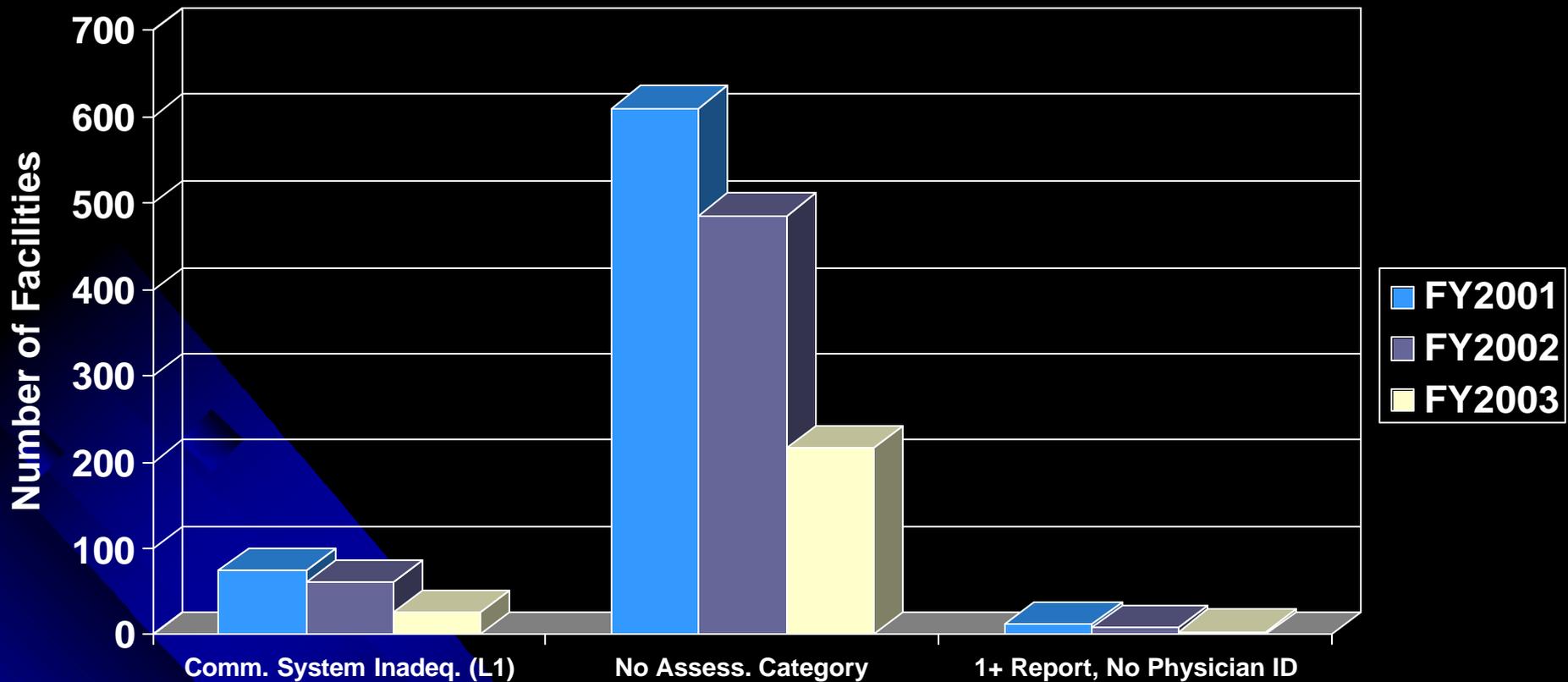
# Level 2 - Technologist Qualifications



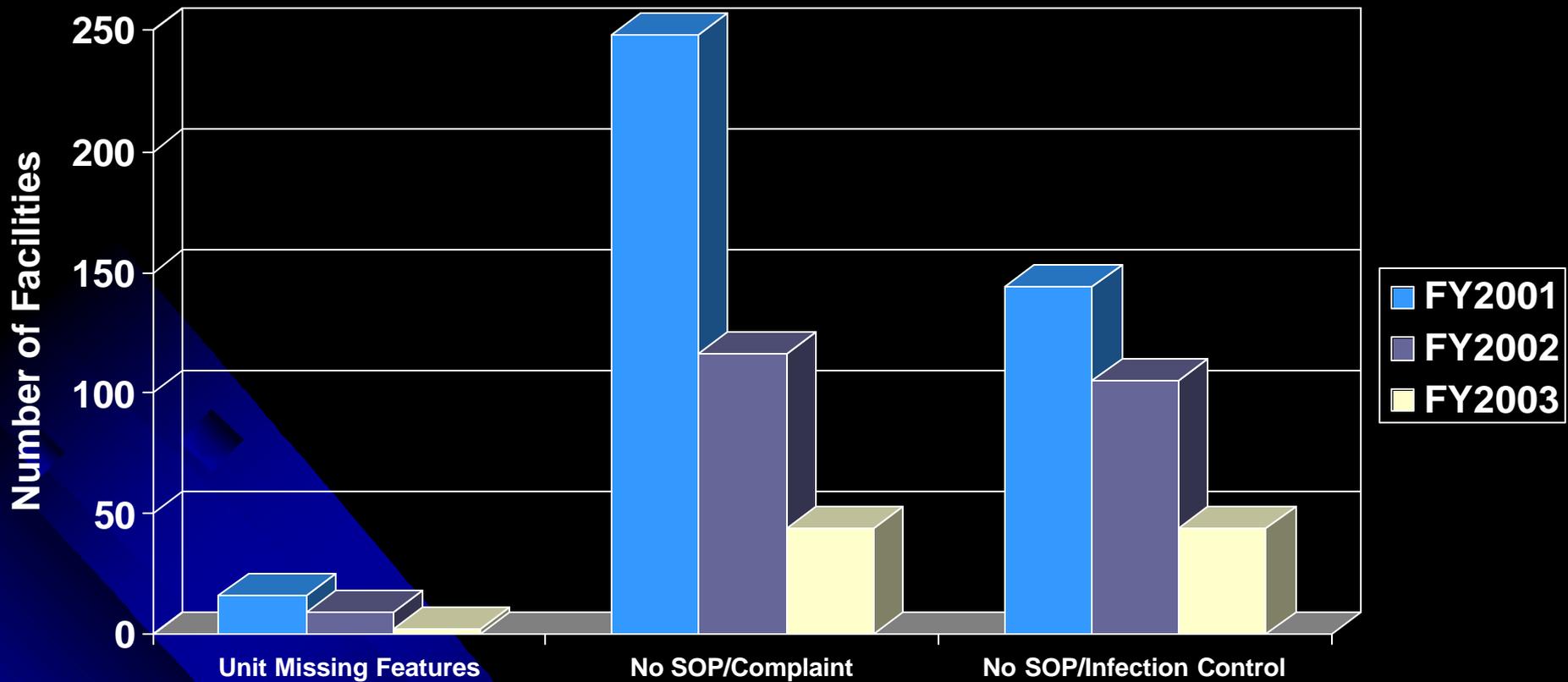
# Level 2 - Medical Physicist Qualifications



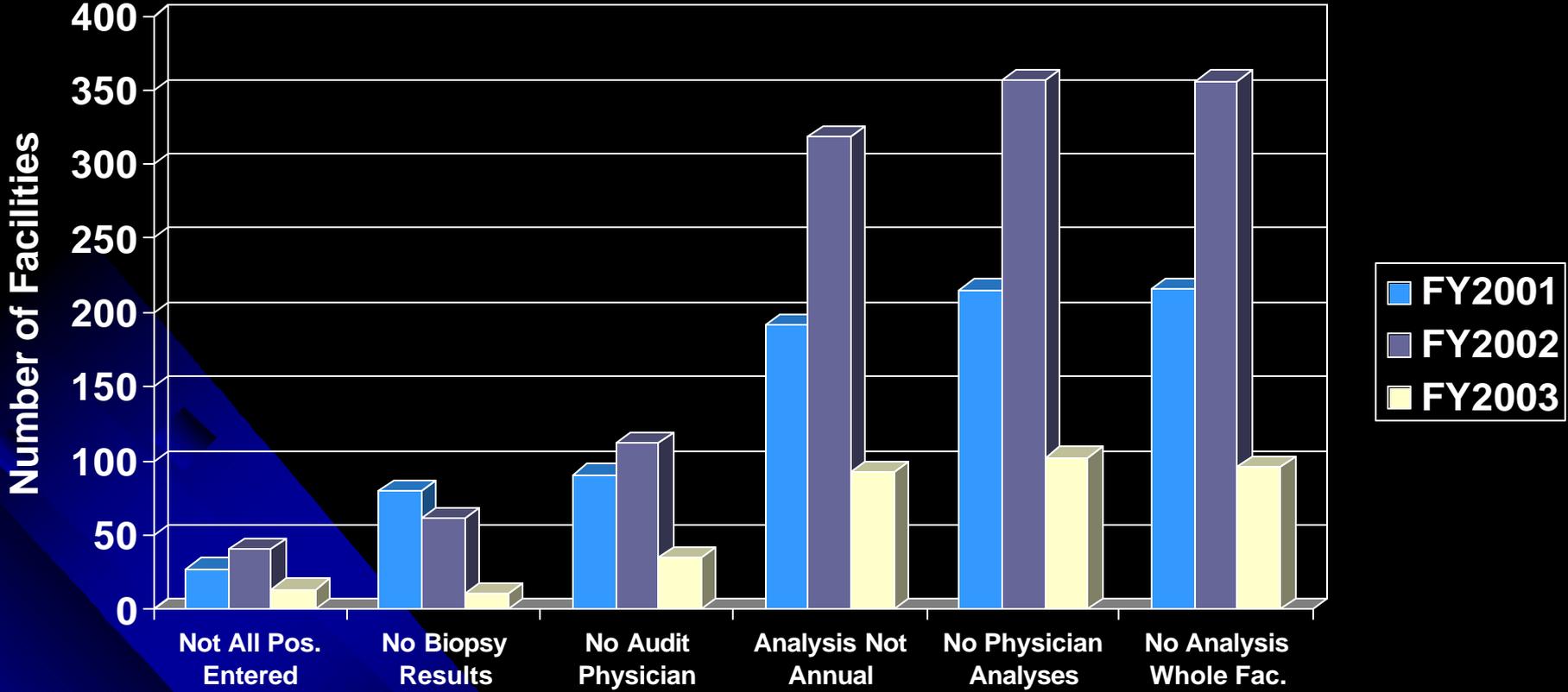
# Medical Records Issues Levels 1 and 2



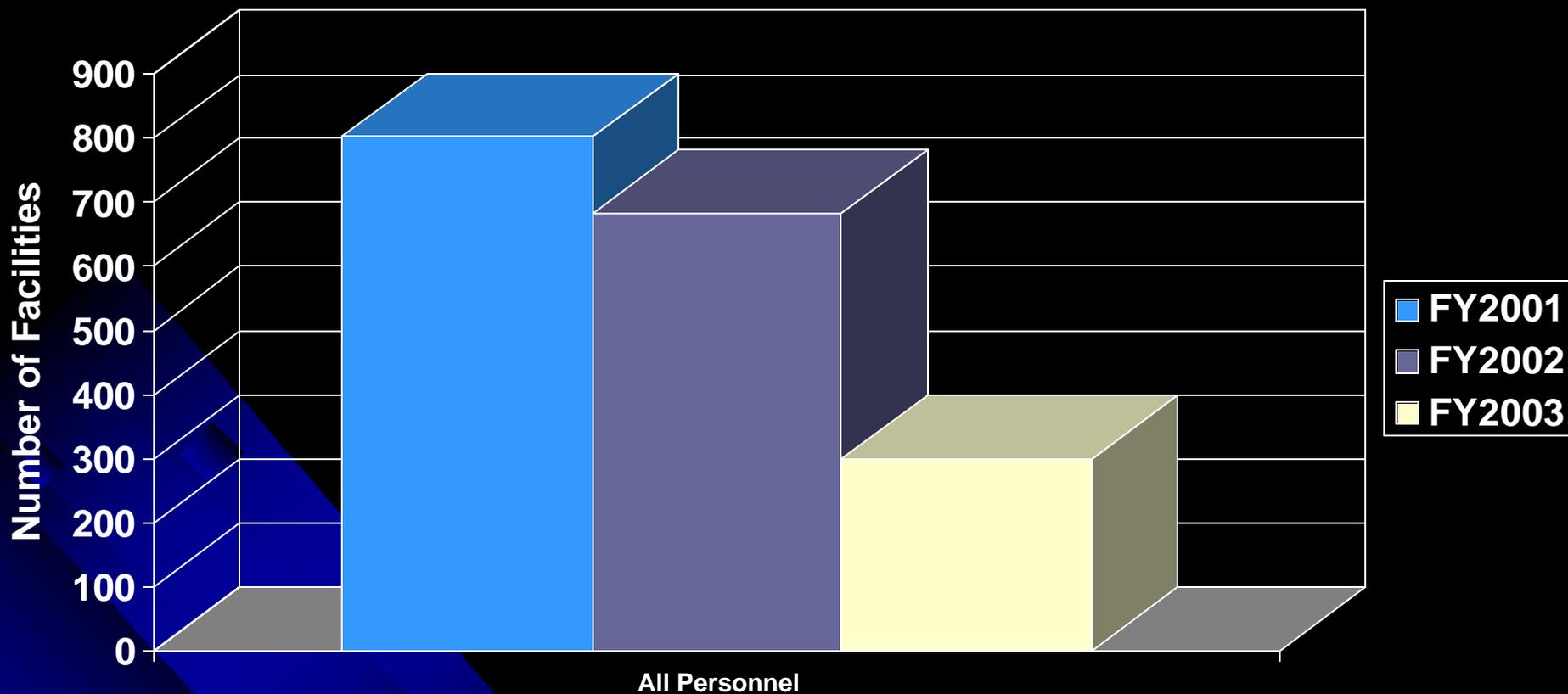
# Level 2 - Unit Requirements and QA Issues



# Level 2 - Audit System



# Level 3 - Failure to Maintain Personnel Documents



# Follow-Up Actions

# Types of Actions

- Follow-Up Inspections
- Additional Mammography Review
- Patient and Physician Notification
- Directed Plans of Correction
- Civil Money Penalties
- Suspension or Revocation (of certificate)
- Injunction

# Follow-Up Inspections

- **Check on corrective actions for serious problems (Level 1)**
- **Usually limited to specific problems**

# **Additional Mammography Review**

- **Review by Accreditation Body or other party**
- **Possible patient and physician notification (serious risk)**

# **Additional Mammography Review**

- **Level 1 phantom image (inspection)**
- **Level 1 interpreting physician**
- **Clinical image quality problems**
- **Overall quality assurance failures**
- **Fraudulent recordkeeping**

# Patient and Physician Notification

- **AMR shows serious risk to health**
- **Provides patients and physicians with follow-up options**
- **Plain language used**

# Directed Plans of Correction

- **Imposes additional requirements on facility**
- **Monitoring of quality assurance program**
- **Additional inspections**

# Suspension

- **Serious violations**
- **Voluntary corrections  
ineffective**
- **Health Hazard – no prior  
hearing**

# Action

# Number

Additional Mammography  
Reviews

38

Patient and Physician  
Notifications

11

Directed Plans of  
Correction

4

Civil Money Penalties

1

Suspensions

1

Revocations, Injunctions

0