

Inspection Observations and Follow-up Actions

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September 26-27, 2005

Objectives

- Inspection Results
- Follow-Up Actions

Recent Inspection Results

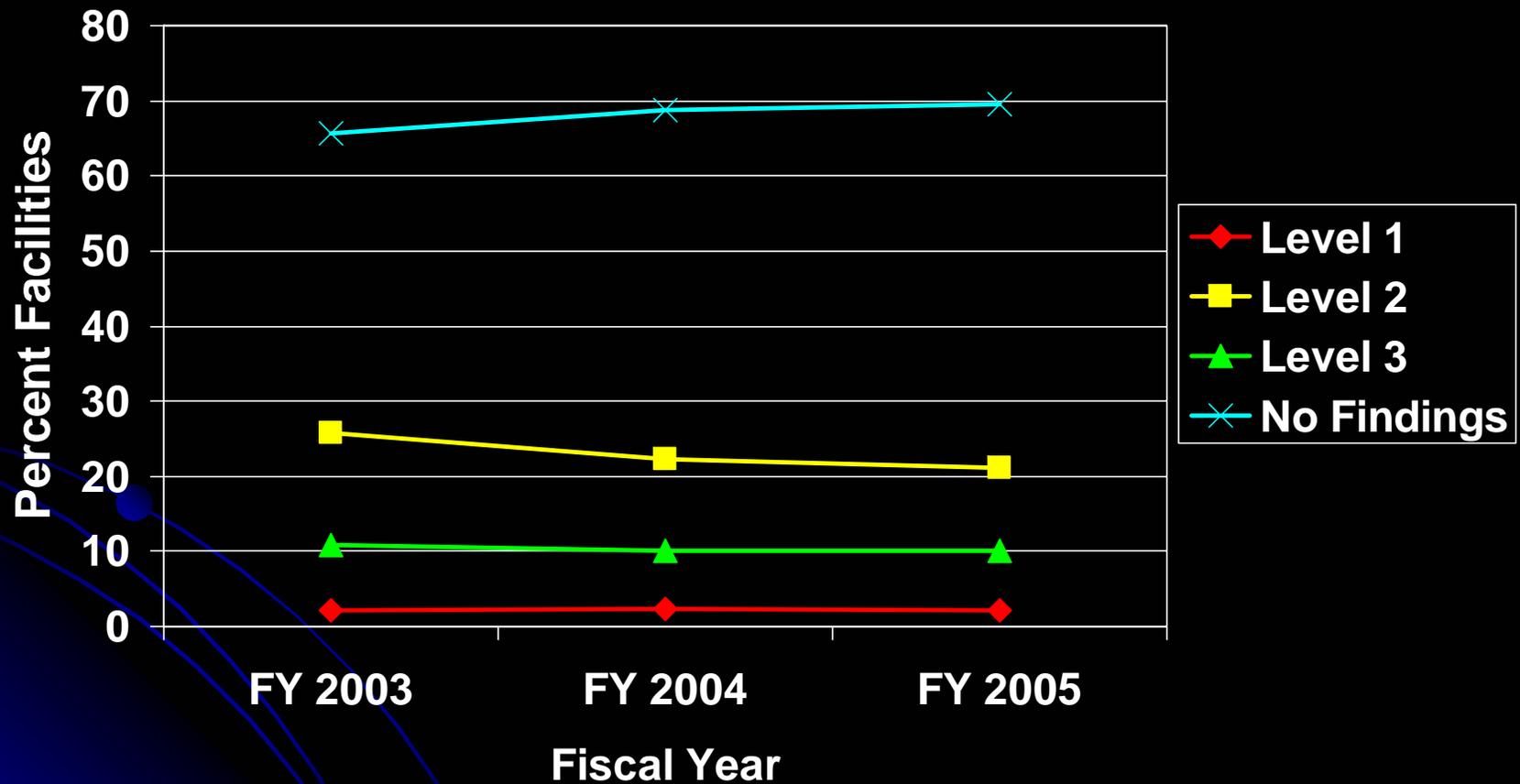
Fiscal Years 2003 to 2005*

*10/1/2004 to 8/26/2005

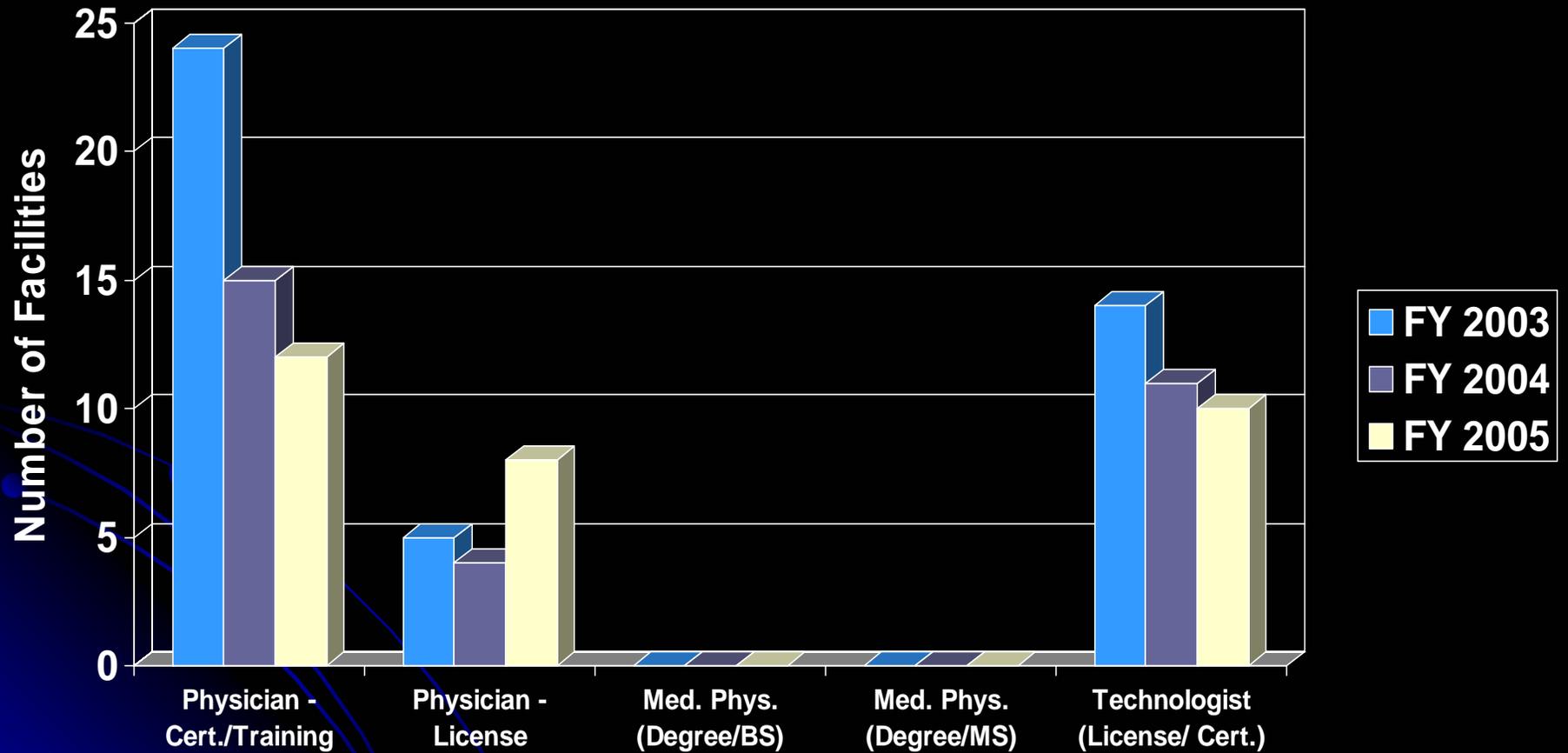
Inspection Finding Levels

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

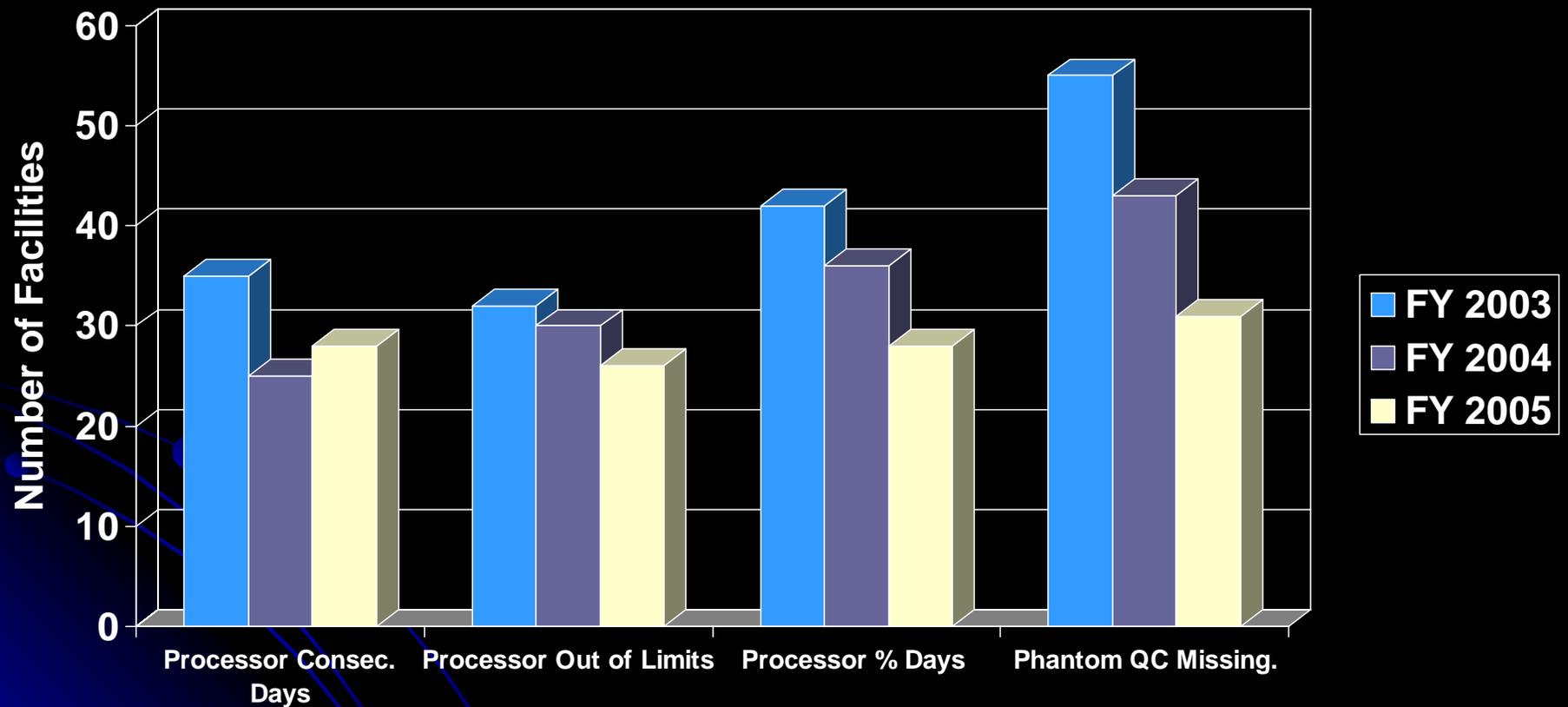
Violations by Level Change by Year



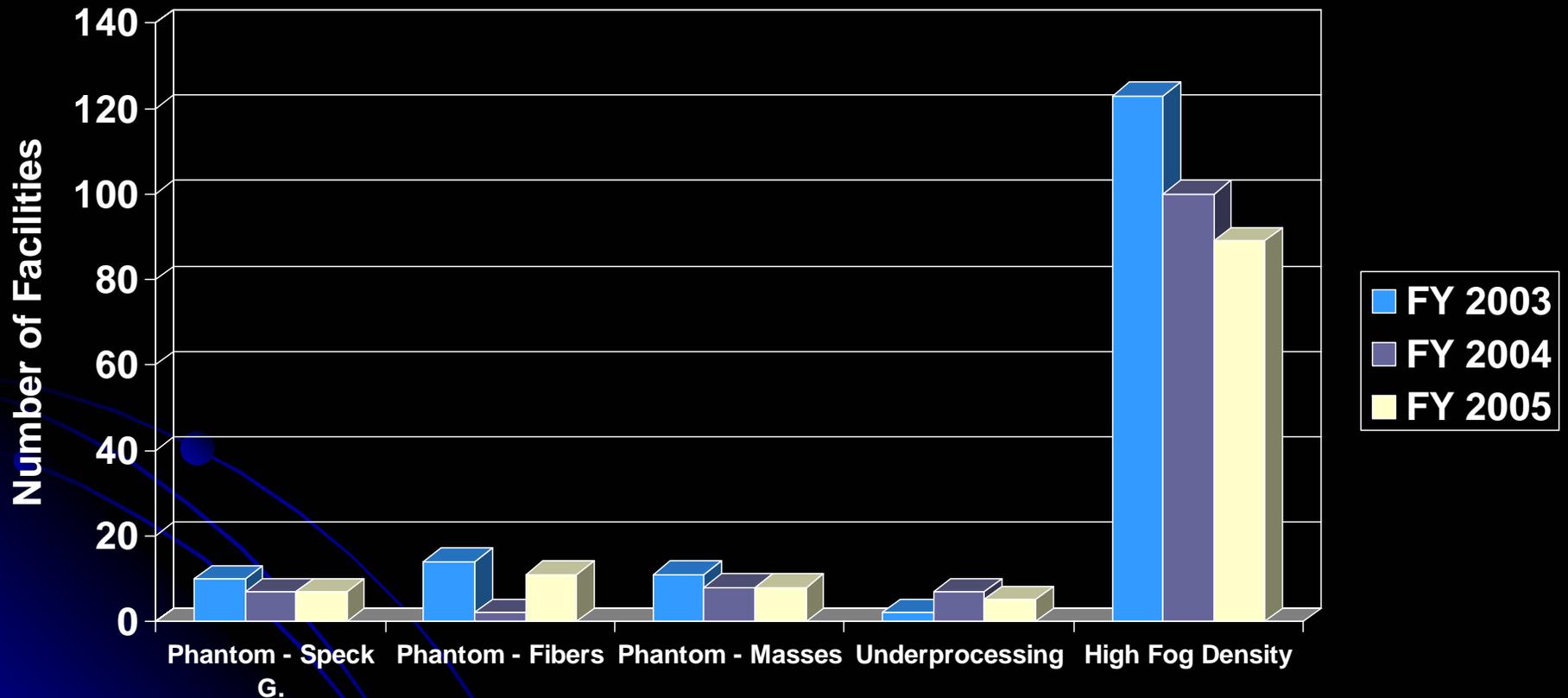
Level 1 Initial Qualifications



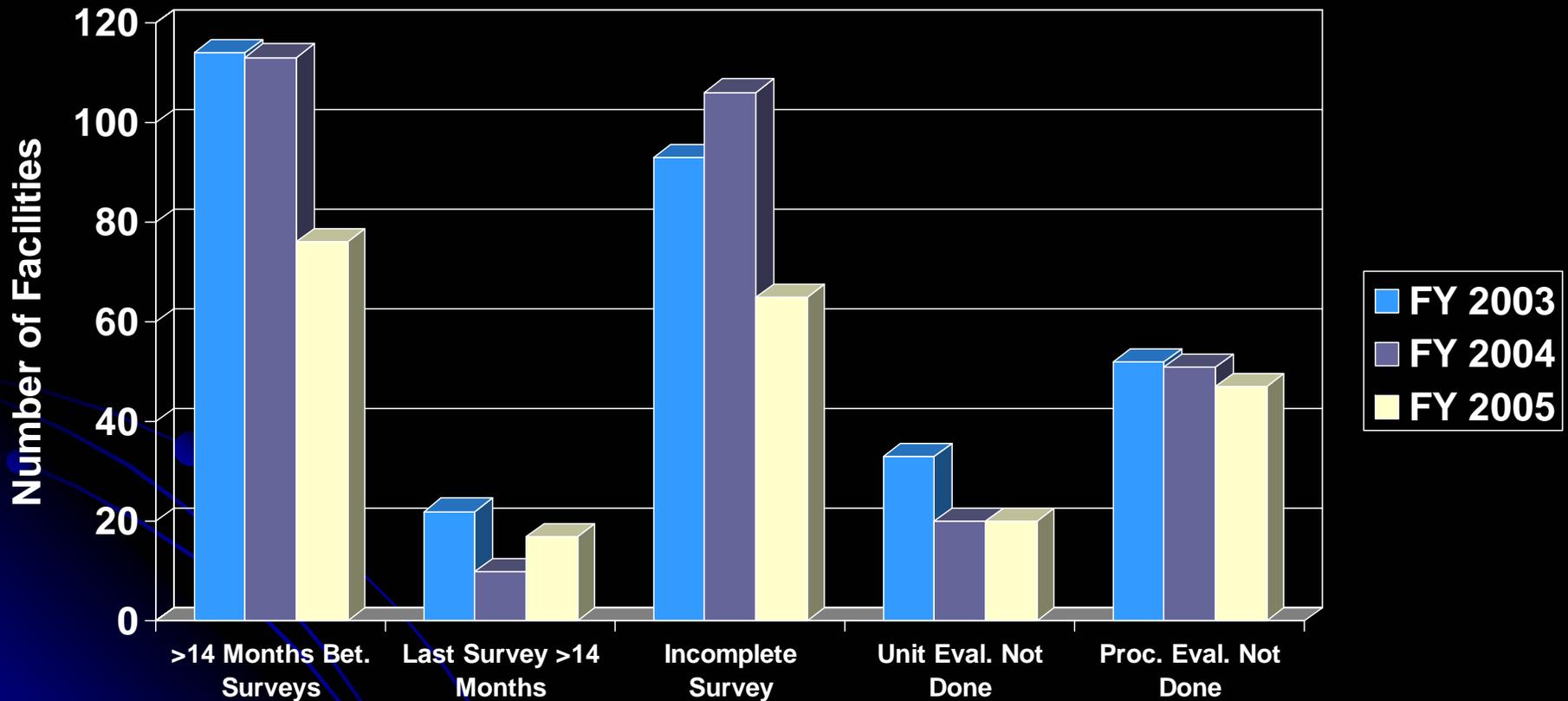
Level 1 - Processor and Phantom Quality Control



Level 2 - Phantom Score & Processing Conditions

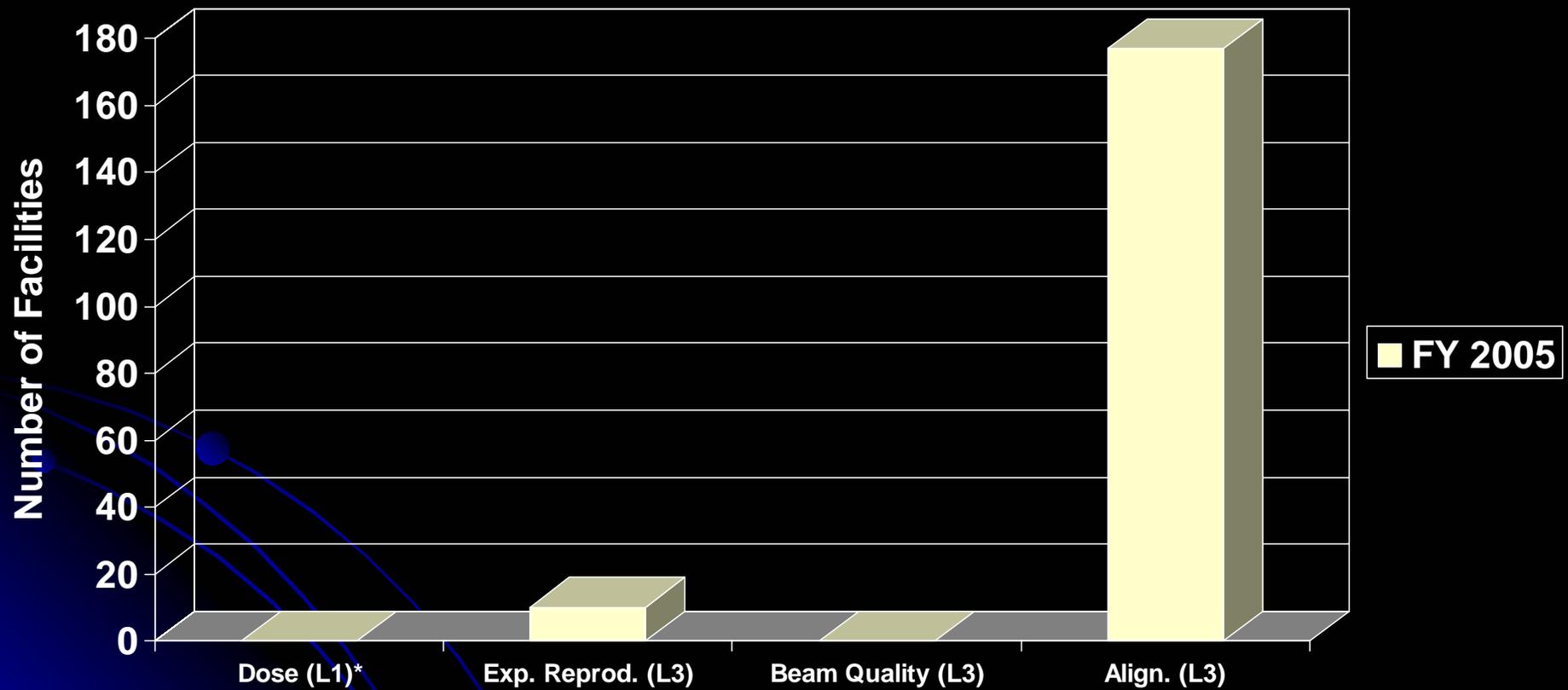


Level 2 - Annual Survey & Equipment Evaluation



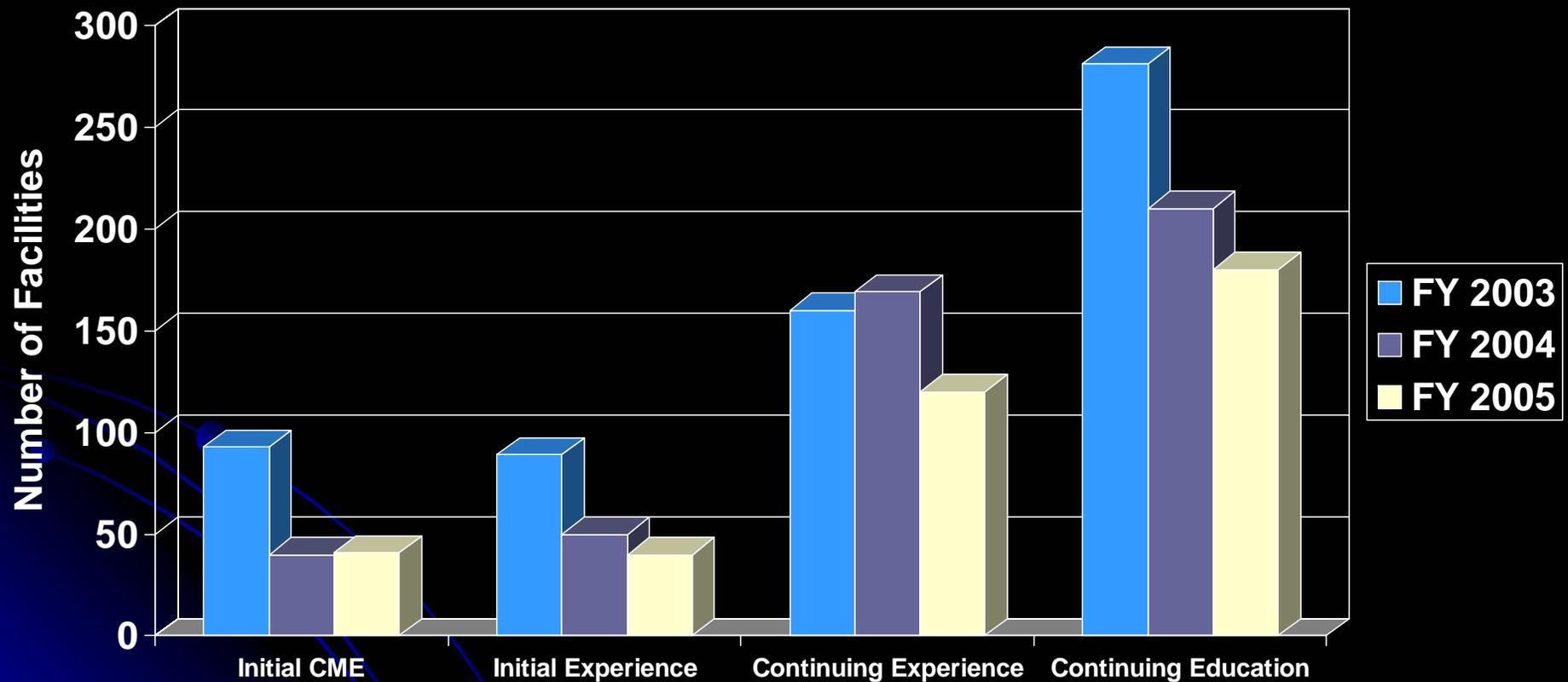
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Testing by Inspectors

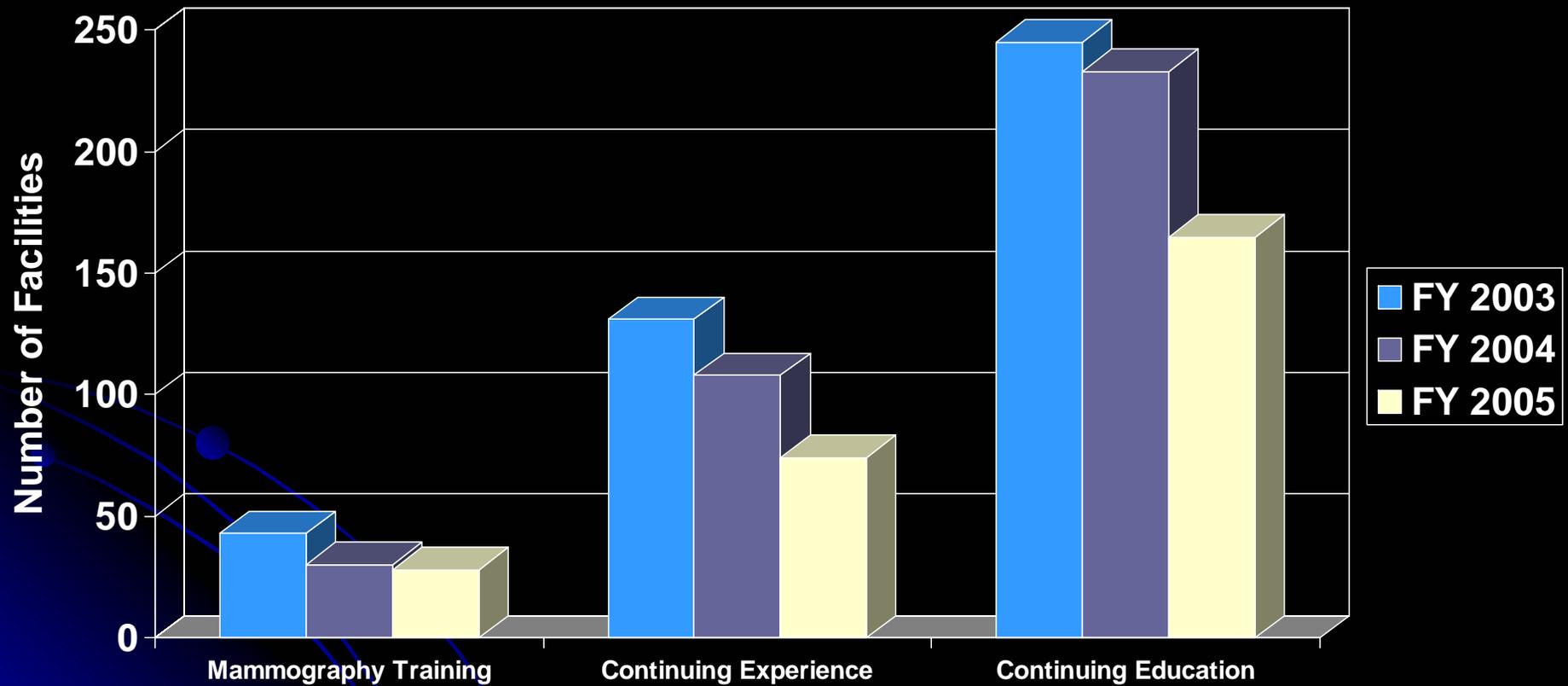


*Last noncompliance in 1997

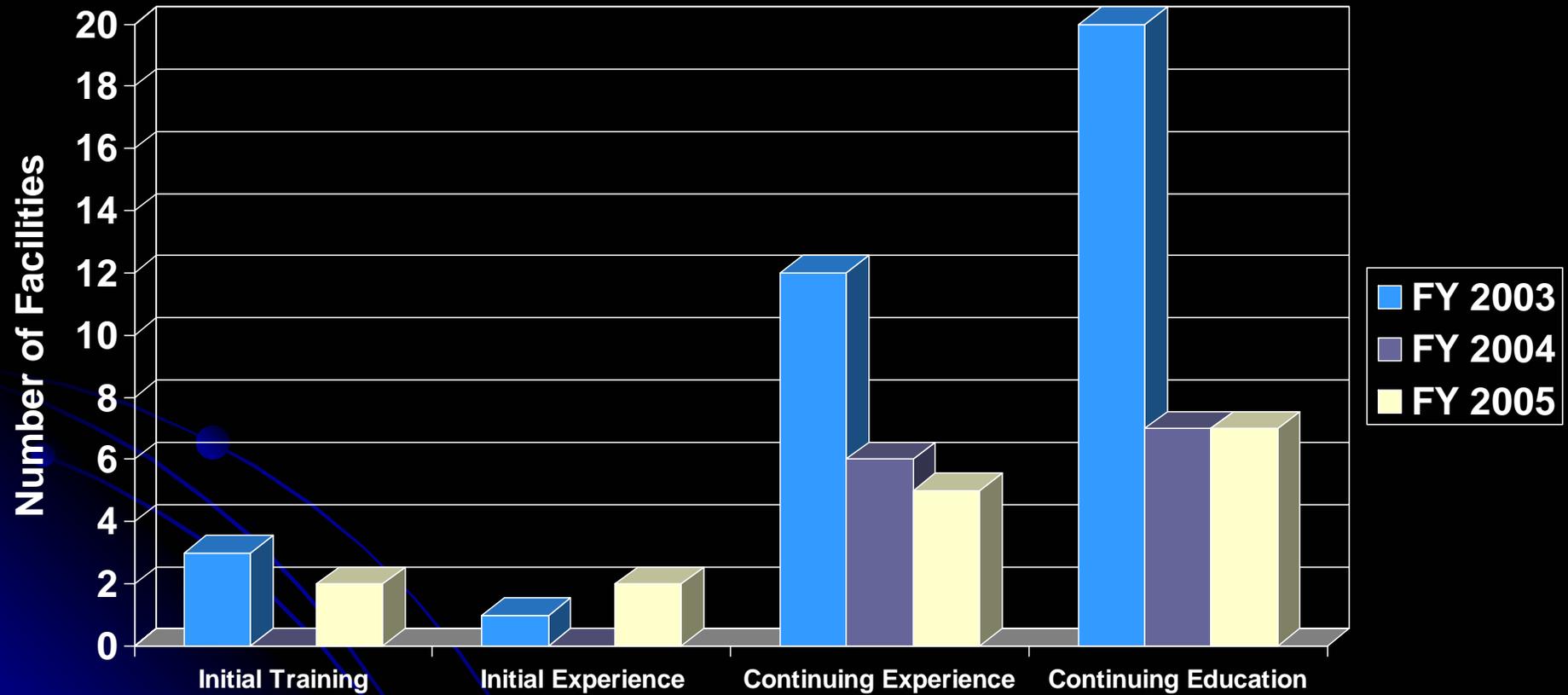
Level 2 - Interpreting Physician Qualifications



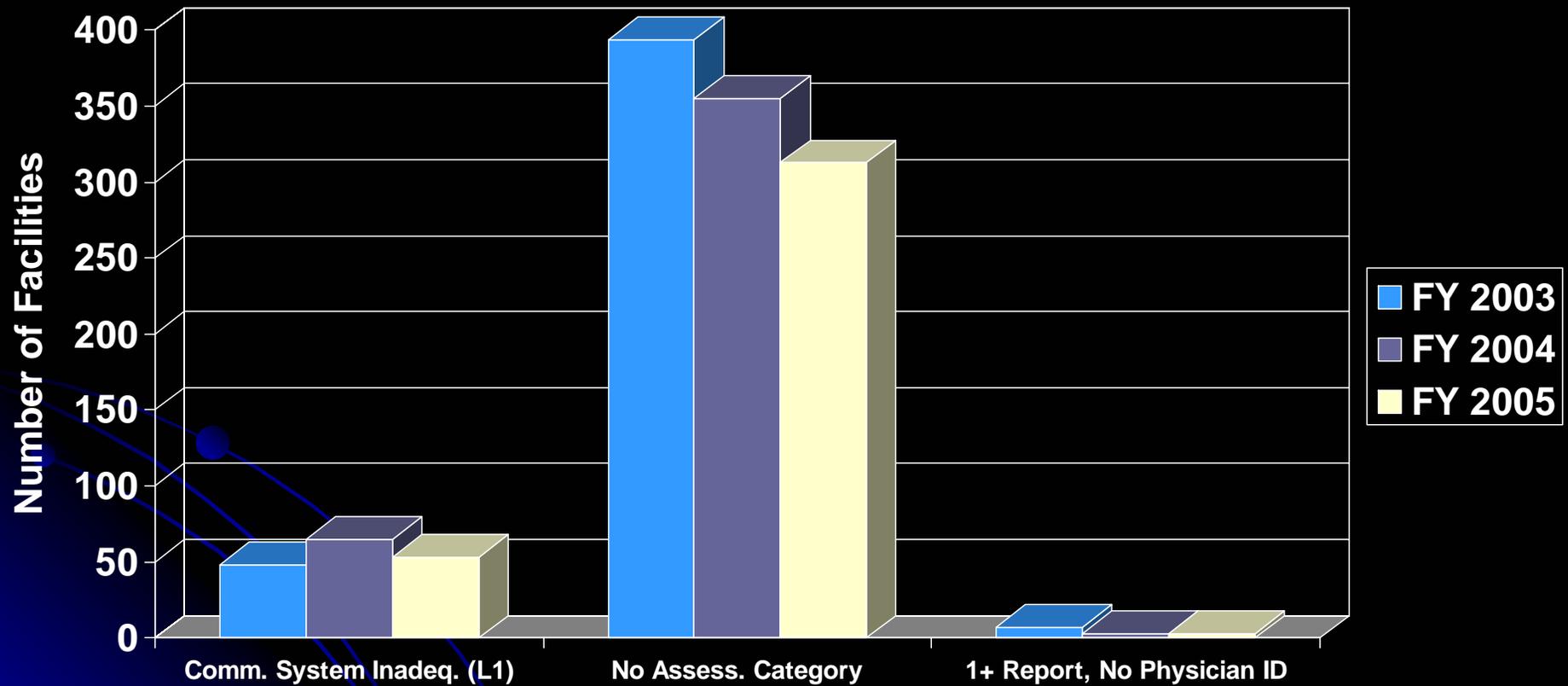
Level 2 - Technologist Qualifications



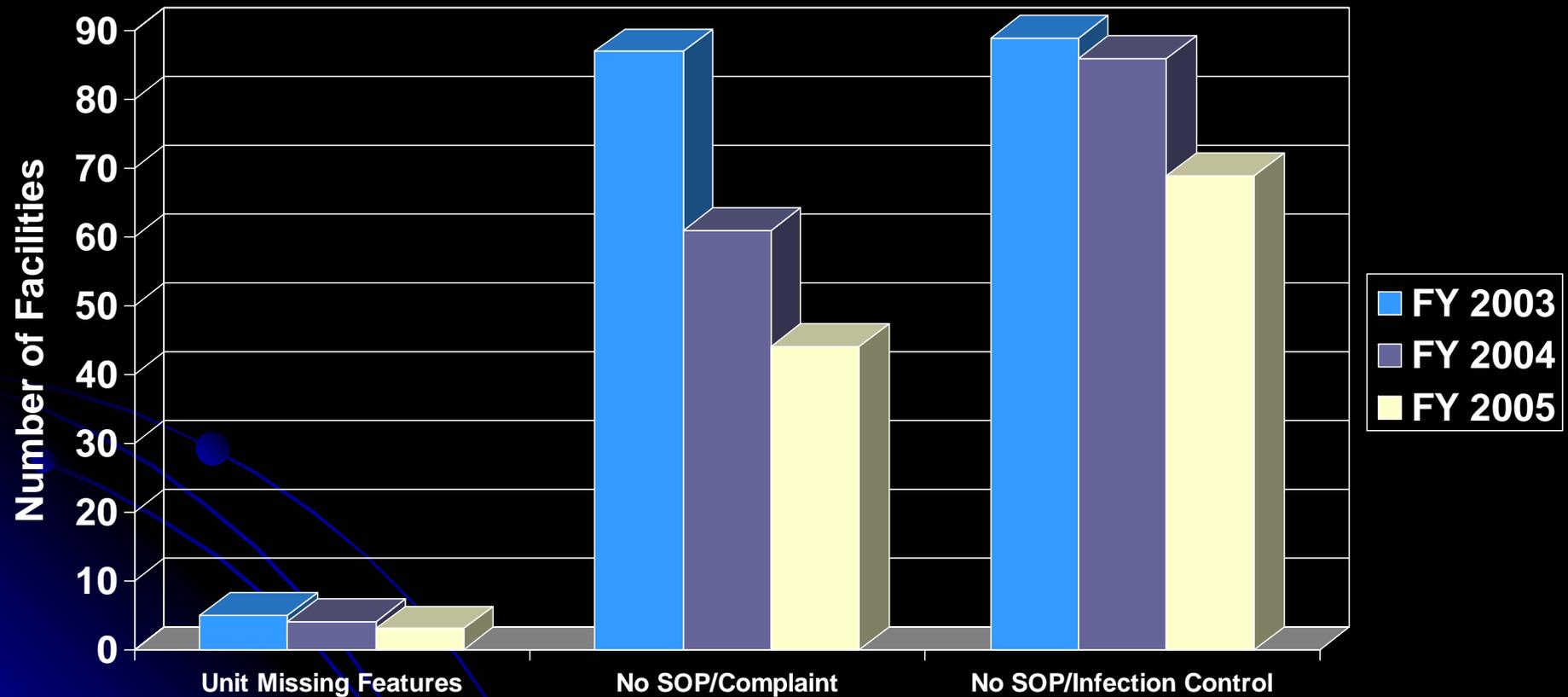
Level 2 - Medical Physicist Qualifications



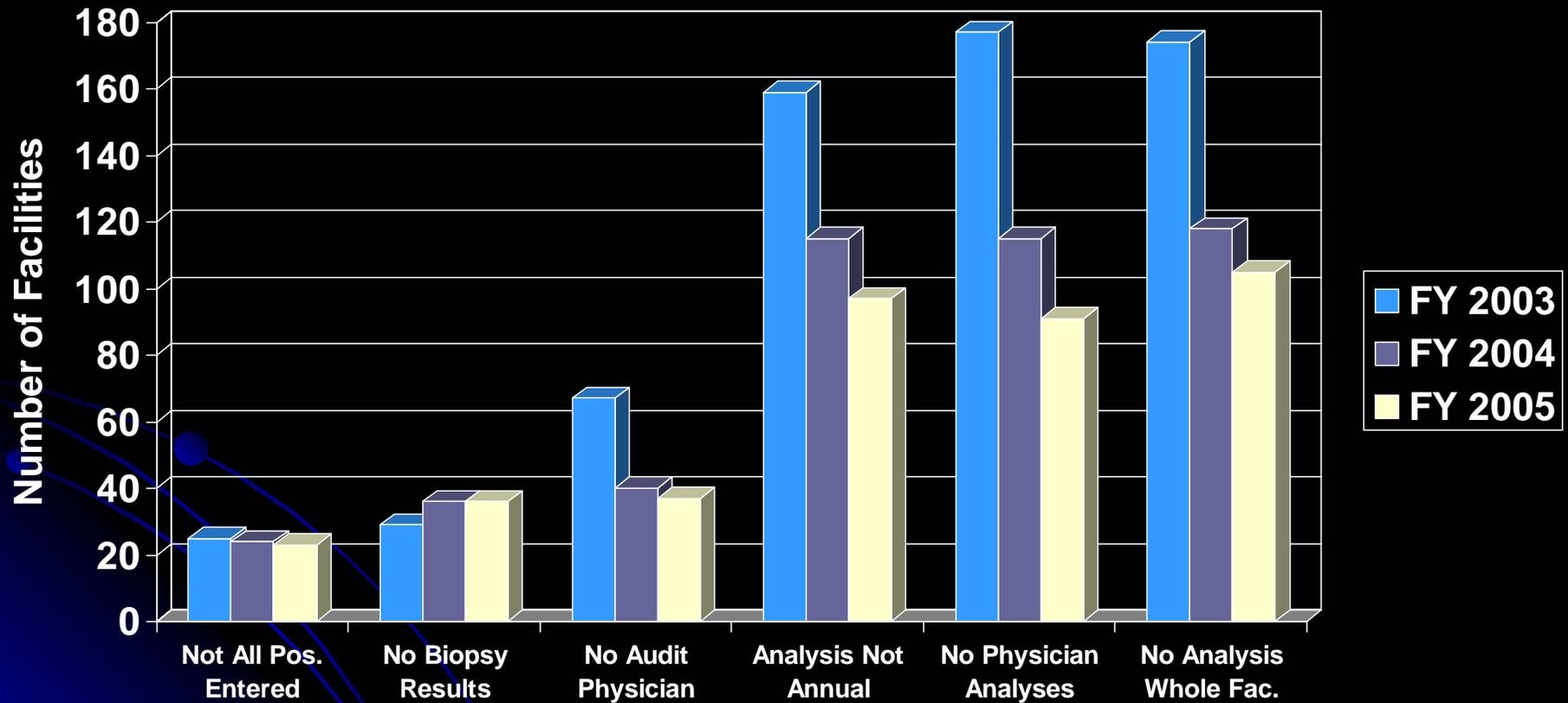
Medical Records Issues Levels 1 and 2



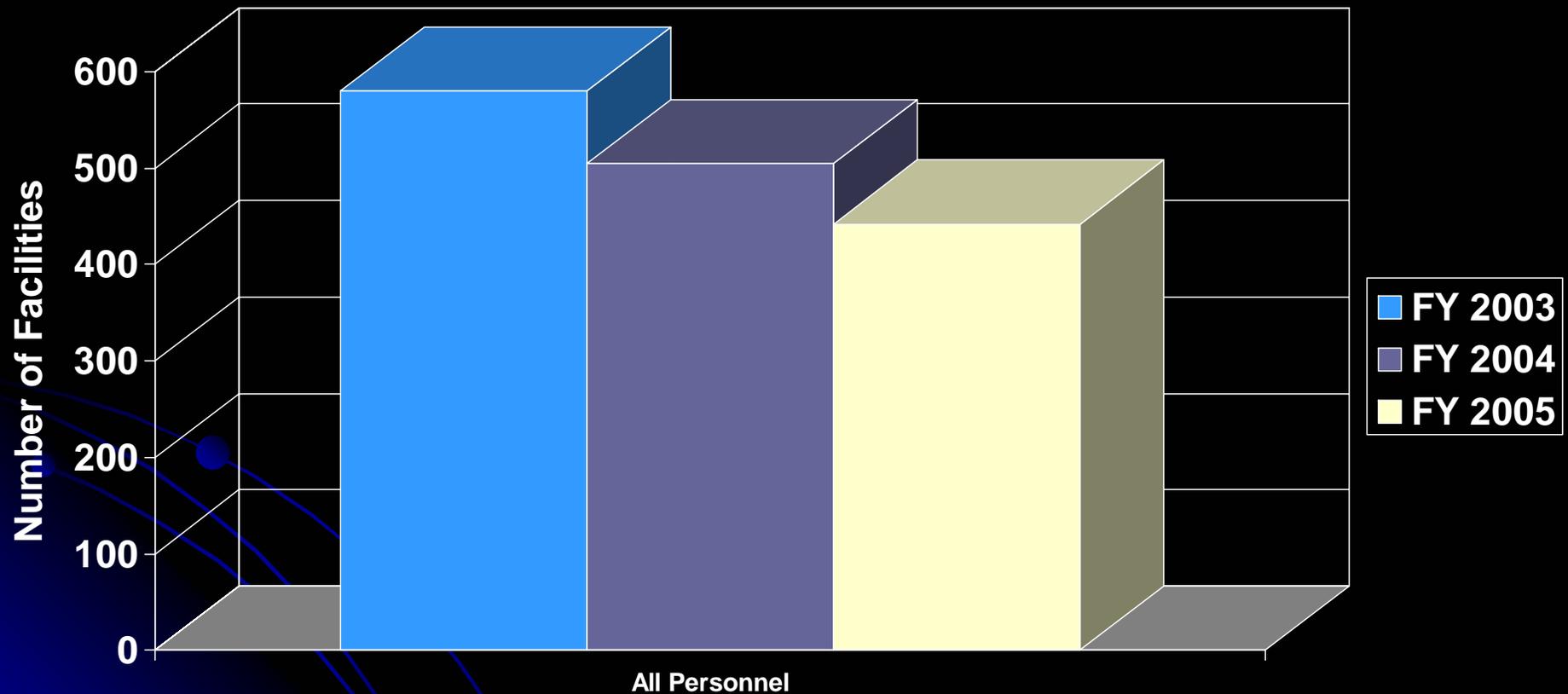
Level 2 - Unit Requirements and QA Issues



Level 2 - Audit System



Level 3 - Failure to Maintain Personnel Documents



Follow-Up Actions

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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	64
Patient and Physician Notifications	17
Directed Plans of Correction	4
Civil Money Penalties	3
Suspensions*	6
Revocations, Injunctions	0