Year End Report
FY 2010

USDA, APHIS
Veterinary Services
Center for Veterinary Biologics
Inspection and Compliance

LSRTIS Background

- Custom modules developed around the functional components of the CVB
- Retired 1 non-supported application
- Provides flow processing for licensing and pre-licensing of over 124 veterinary biologics manufacturers and more than 2500 products
- Provides serial release processing, tracking, and authorization for over 73 Billion doses of vaccines, and related animal biologic products.
- Incorporates laboratory testing information of samples for the serial release process.

2010 LSRTIS Actions

- LSRTIS Phase II completed and placed into production
  - Provides logical process flow and checks for:
    - Biologics Material Processing - receiving/storing biologic samples for testing
    - Licensing
    - Pre-Licensing
    - Laboratory Testing
    - Serial release tracking for vaccines and other biologic materials.
- Phase III application development initiated
- Certification and Accreditation
  - Phase I C&A completed and approved.
  - Phase II initiated

2011 LSRTIS Actions

- LSRTIS Phase III initiated
  - Merge LSRTIS Phase I and LSRTIS Phase II developments into one application package.
  - Enhance application by adding:
    - Compliance Module – supporting compliance activities associated with veterinary biologics
    - Inspection Module – supporting inspections of veterinary biologics licensed establishments
    - Export Module – supporting certification of licensed veterinary biologics that are exported
- Certification and Accreditation
  - Phase II C&A to be completed and approved.

Pharmacovigalence (PV)

- Improve adverse event reporting and defect tracking of regulated biologics for USDA licensed products
- Improve common interface for veterinary adverse event reporting between USDA and FDA
- Provide CVB with a system that meets international regulatory requirements for pharmacovigilence

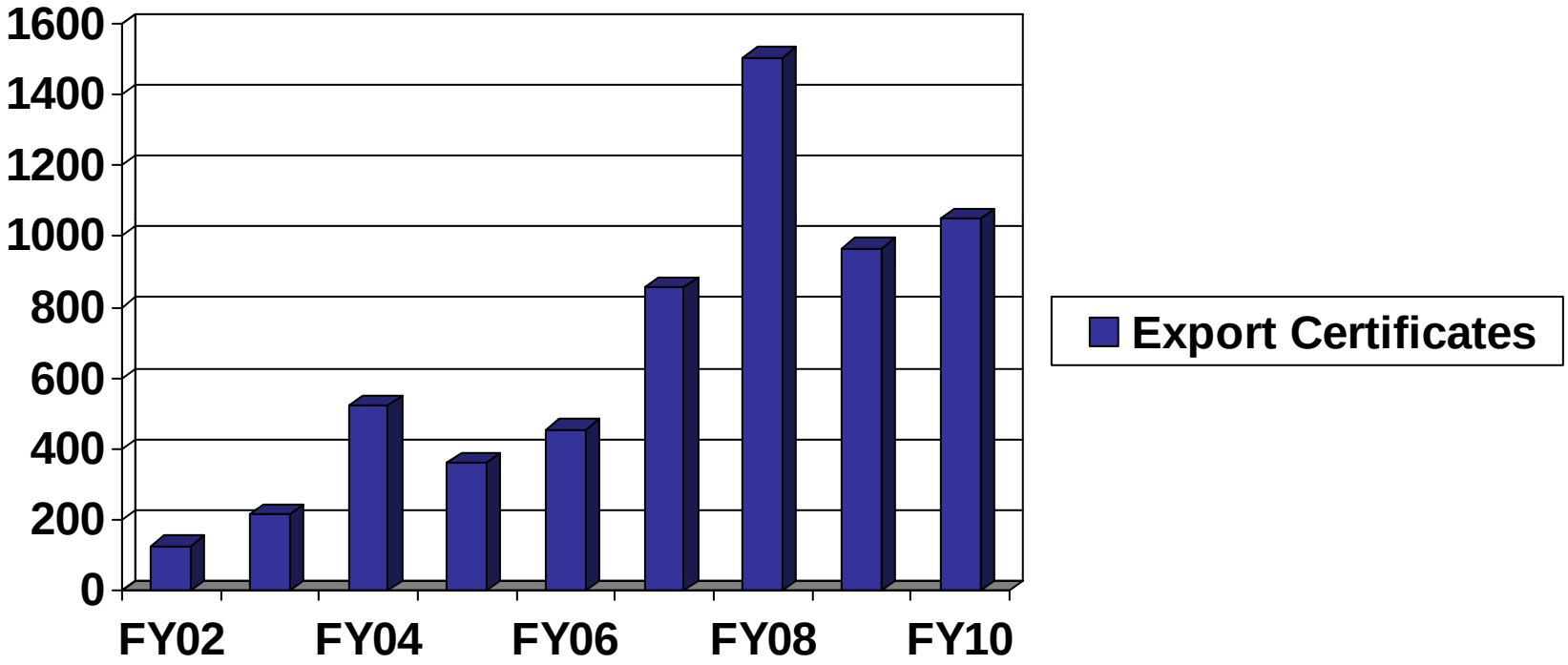
2011 PV Actions

- Commercial Off The Shelf (COTS) package purchased
  - PV Works (Vendor: Assured Information Systems)
  - Installation of COTS Package
  - User Acceptance Testing of Application
  - Development of Requirements for any added functionality
- Certification and Accreditation
  - Complete Phase I C&A
  - Initiate Phase II C&A
- Development
  - Initiate customization to prepare for interface with FDA and EPA.

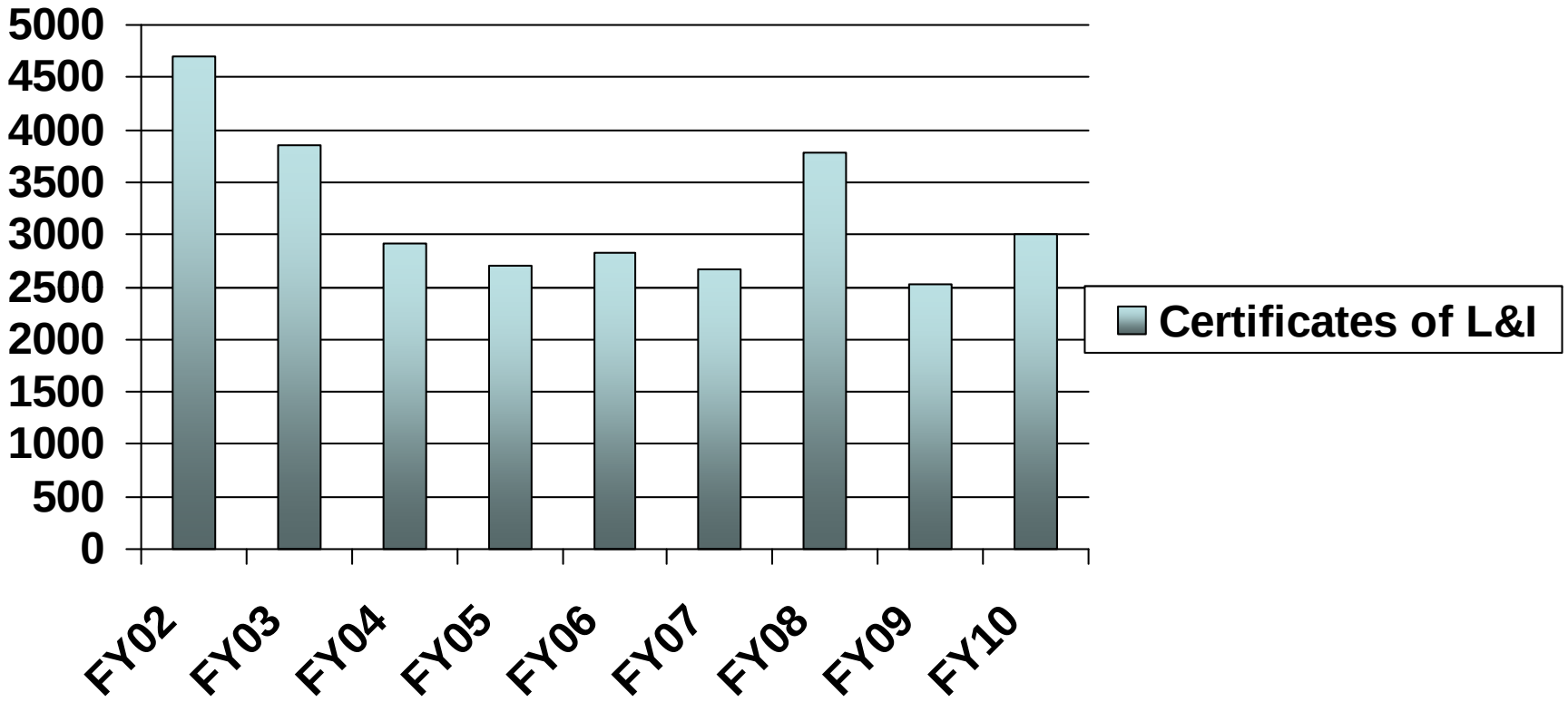
Other Pharmacovigalence Activities

- VICH Pharmacovigalence Expert Working Group
  - Completed work – June 2010. Additional guidance documents published for consultation (FR Vol 75, No 204, 65293-65294) Open for comment until 21 DEC 2010
- Rulemaking
  - Will be developing new proposed rule for adverse event reporting following VICH guidance (estimate late 2011 – early 2012)
  - Final rule to be developed following comments
  - Delayed implementation for firms to come into compliance (estimate 2016-2017) for mandatory reporting to CVB

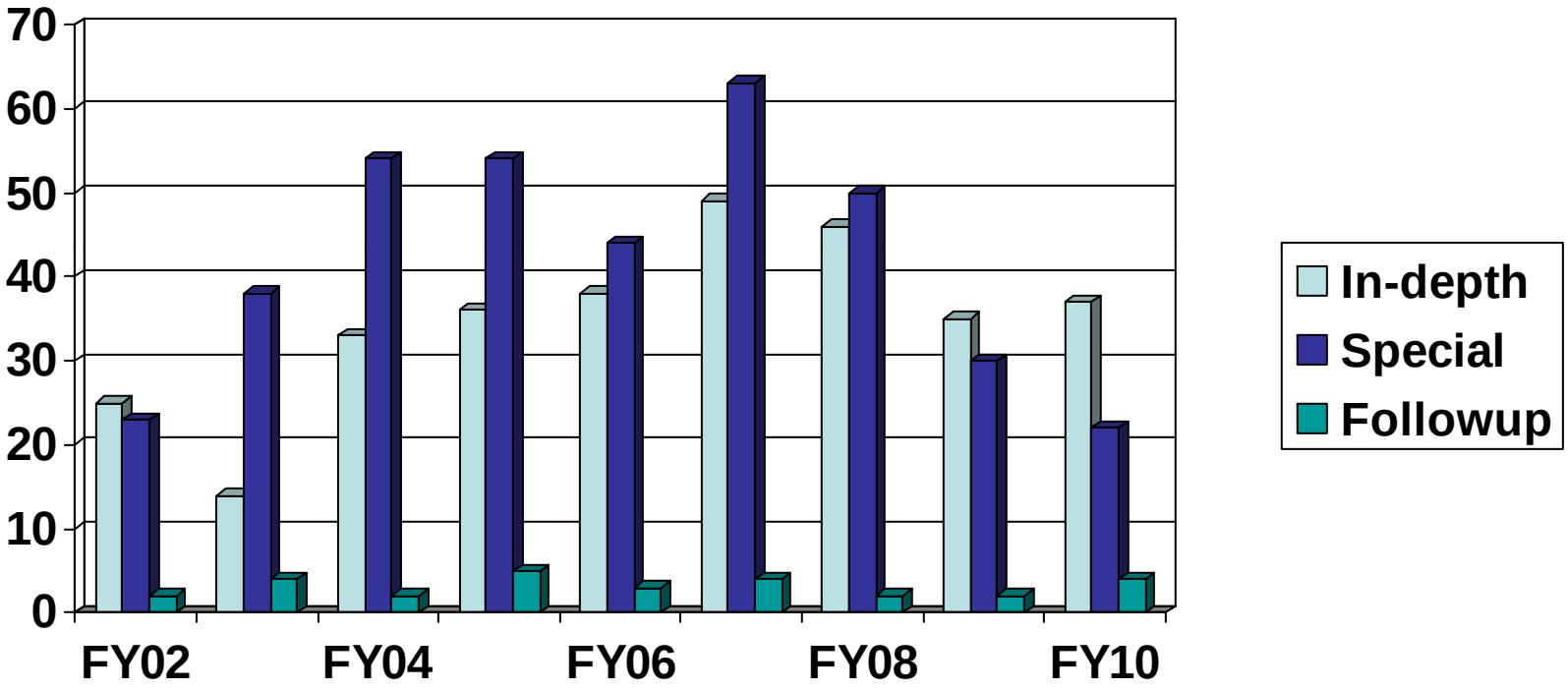
Export Activities by Serial



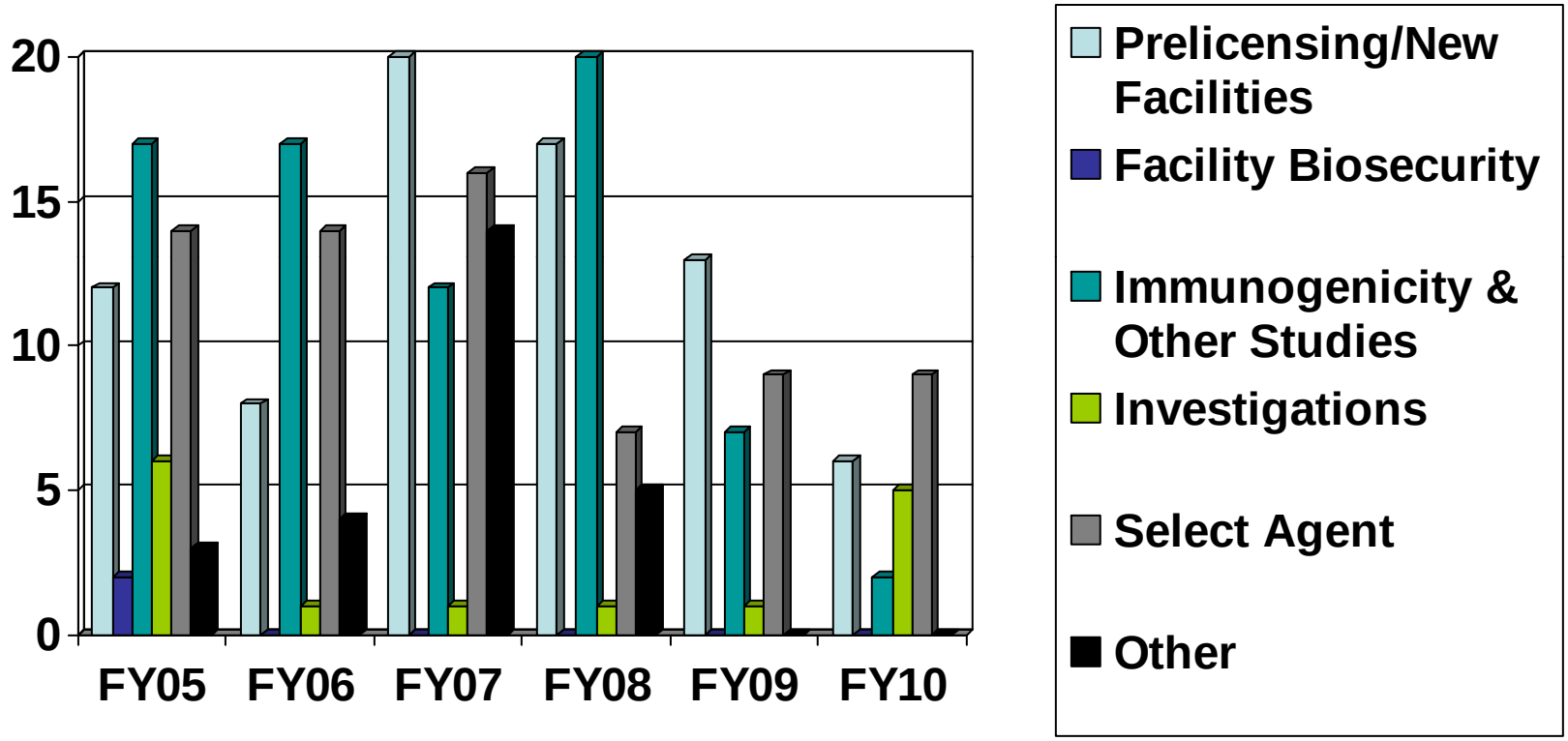
Export Activities by Product



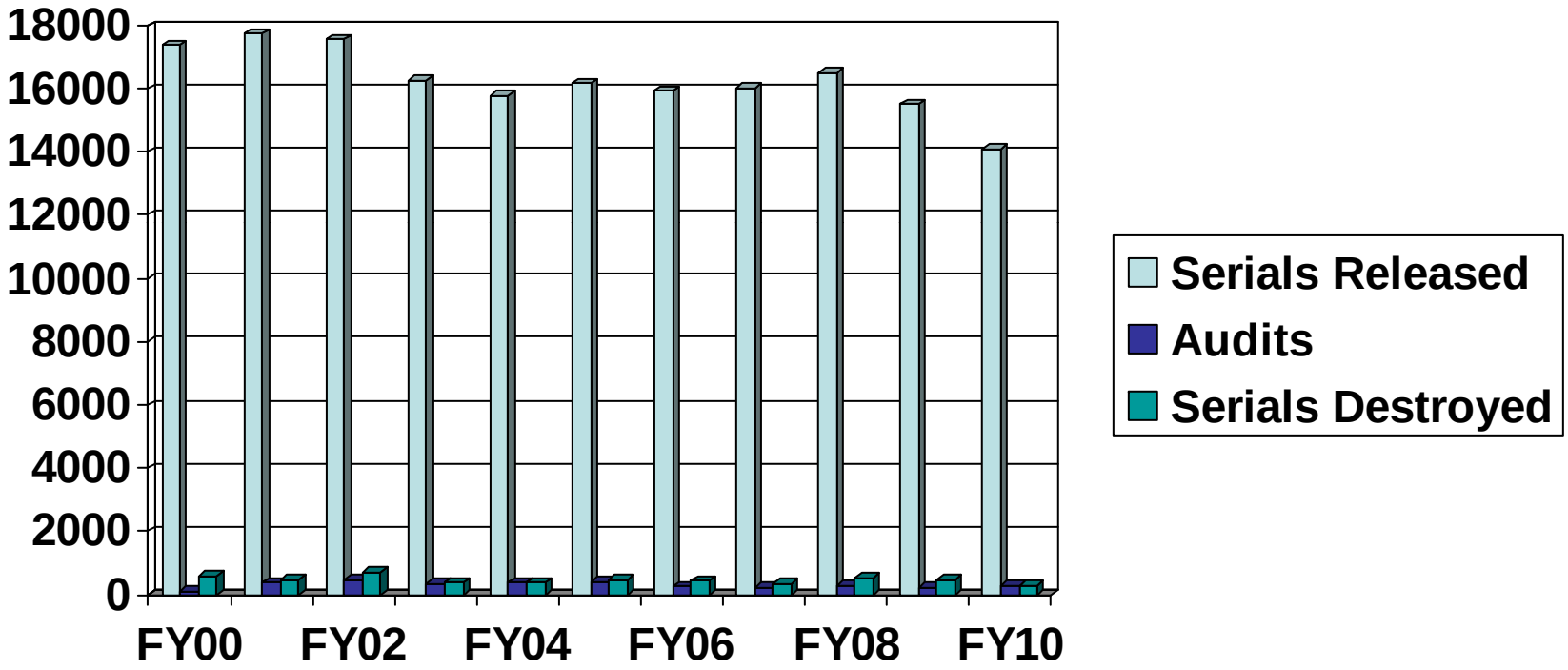
Inspections



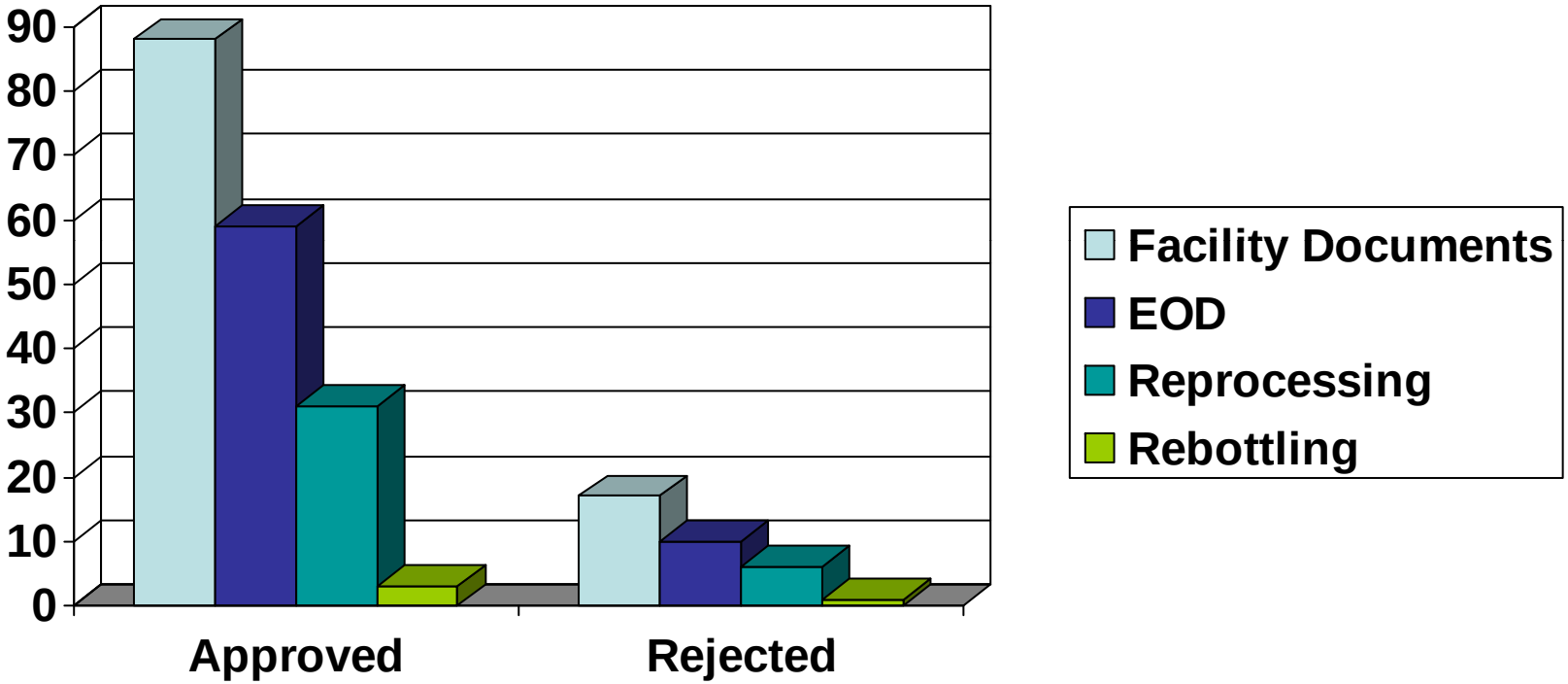
Special Inspections



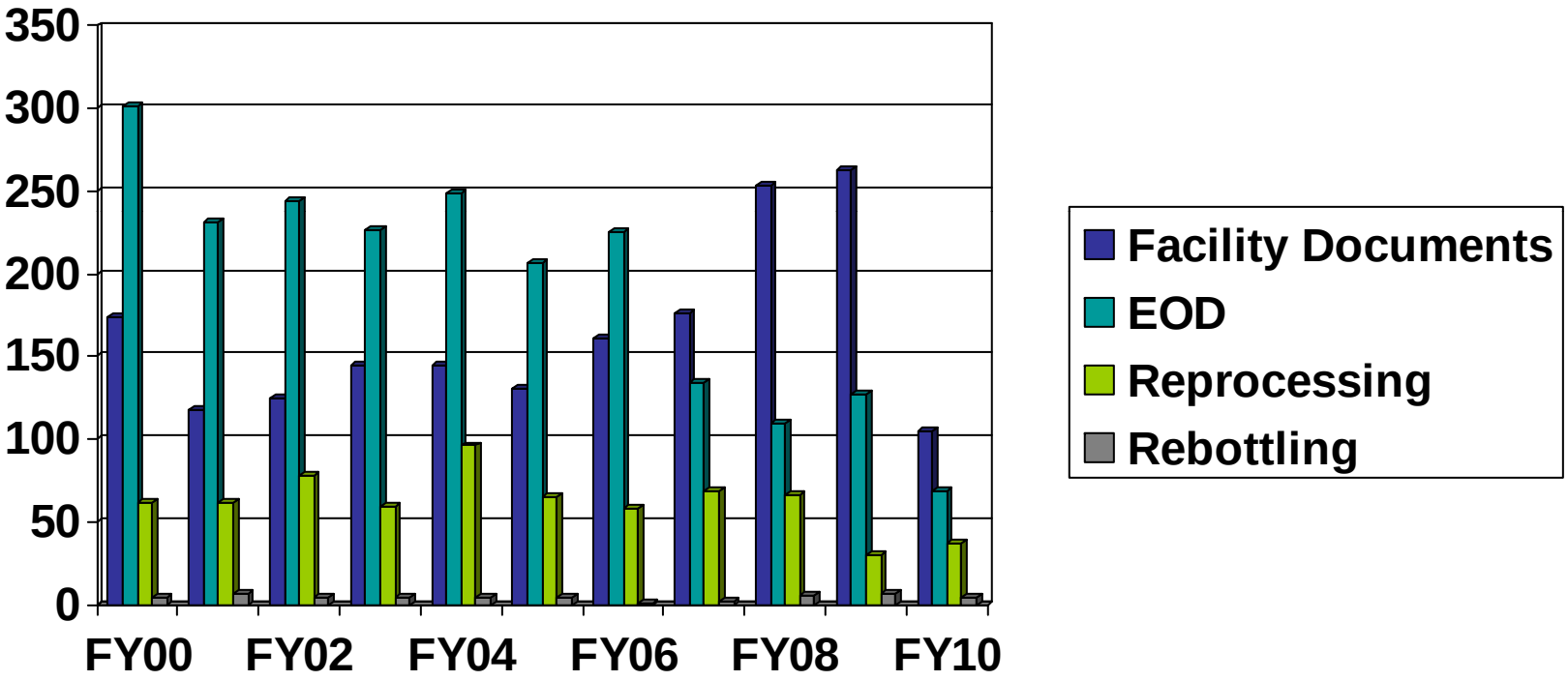
Serial Release Activities



Product Inspection Activities – FY 10

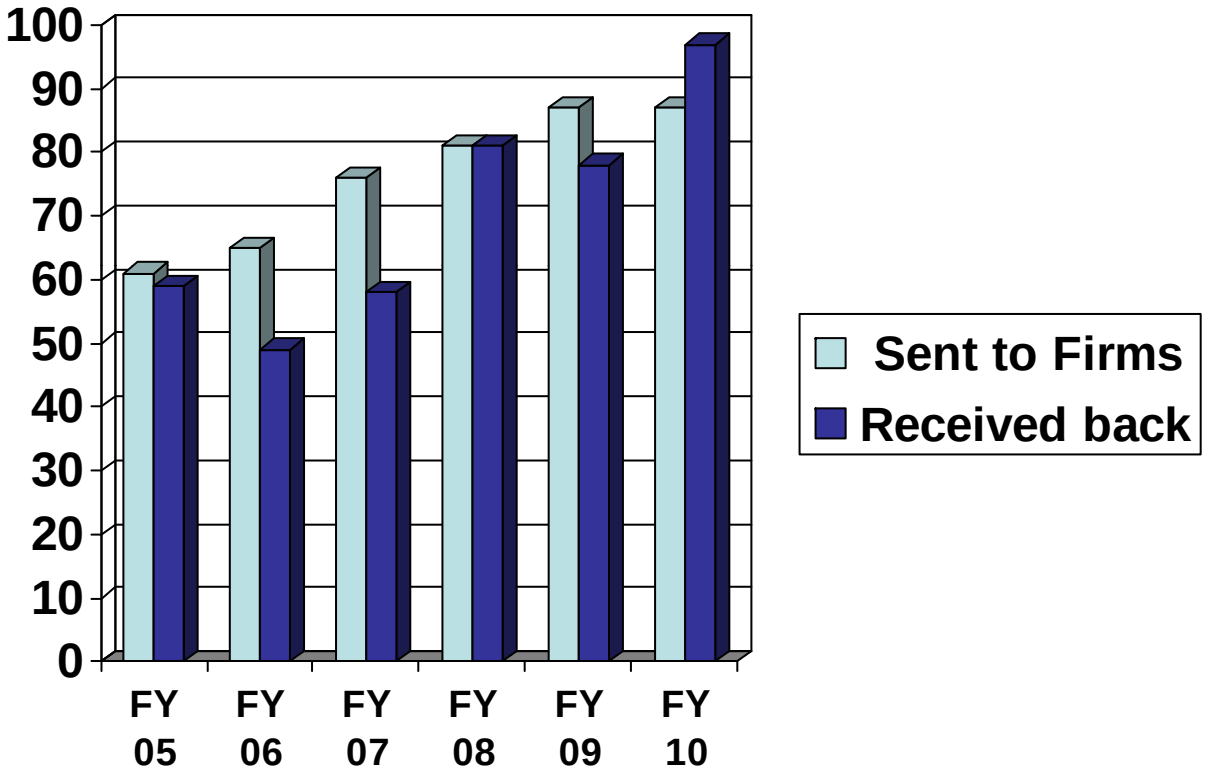


Product Inspection Activities

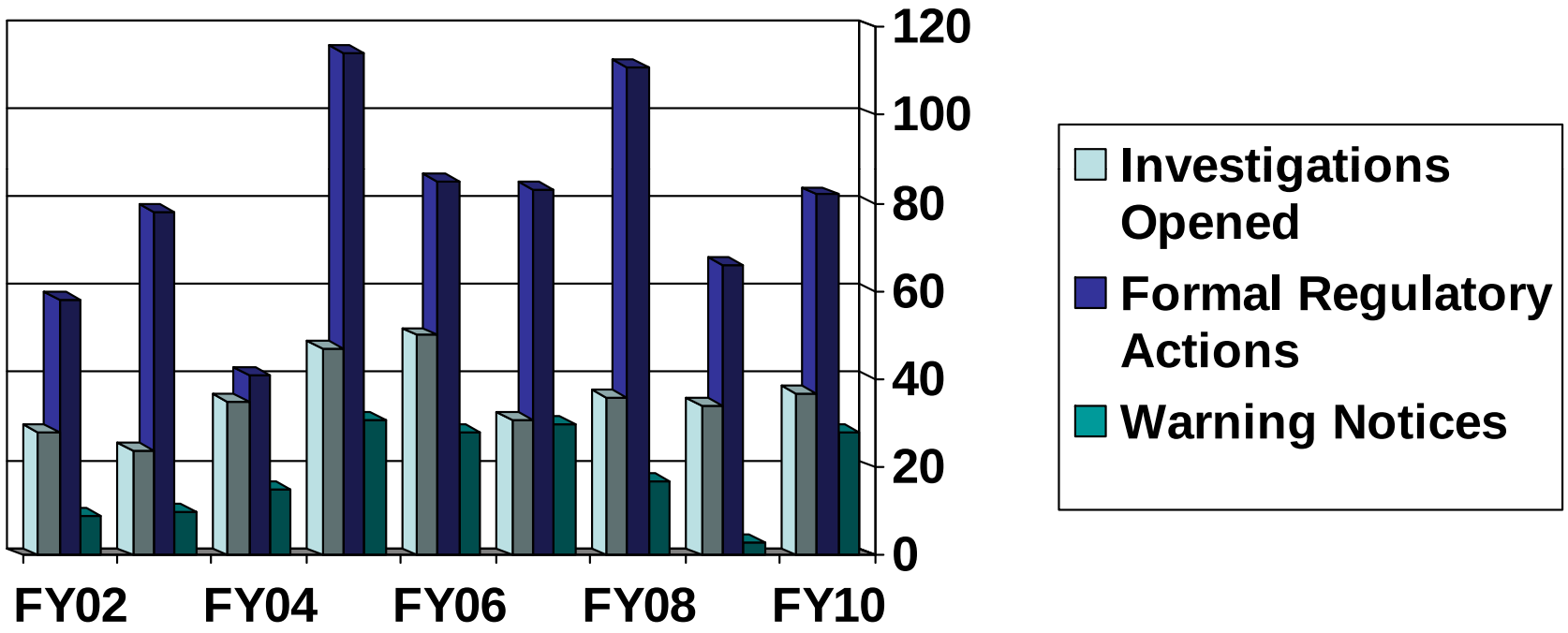


Administrative Inspection Review (AIR)

Activity per Year



Regulatory Actions



Investigations