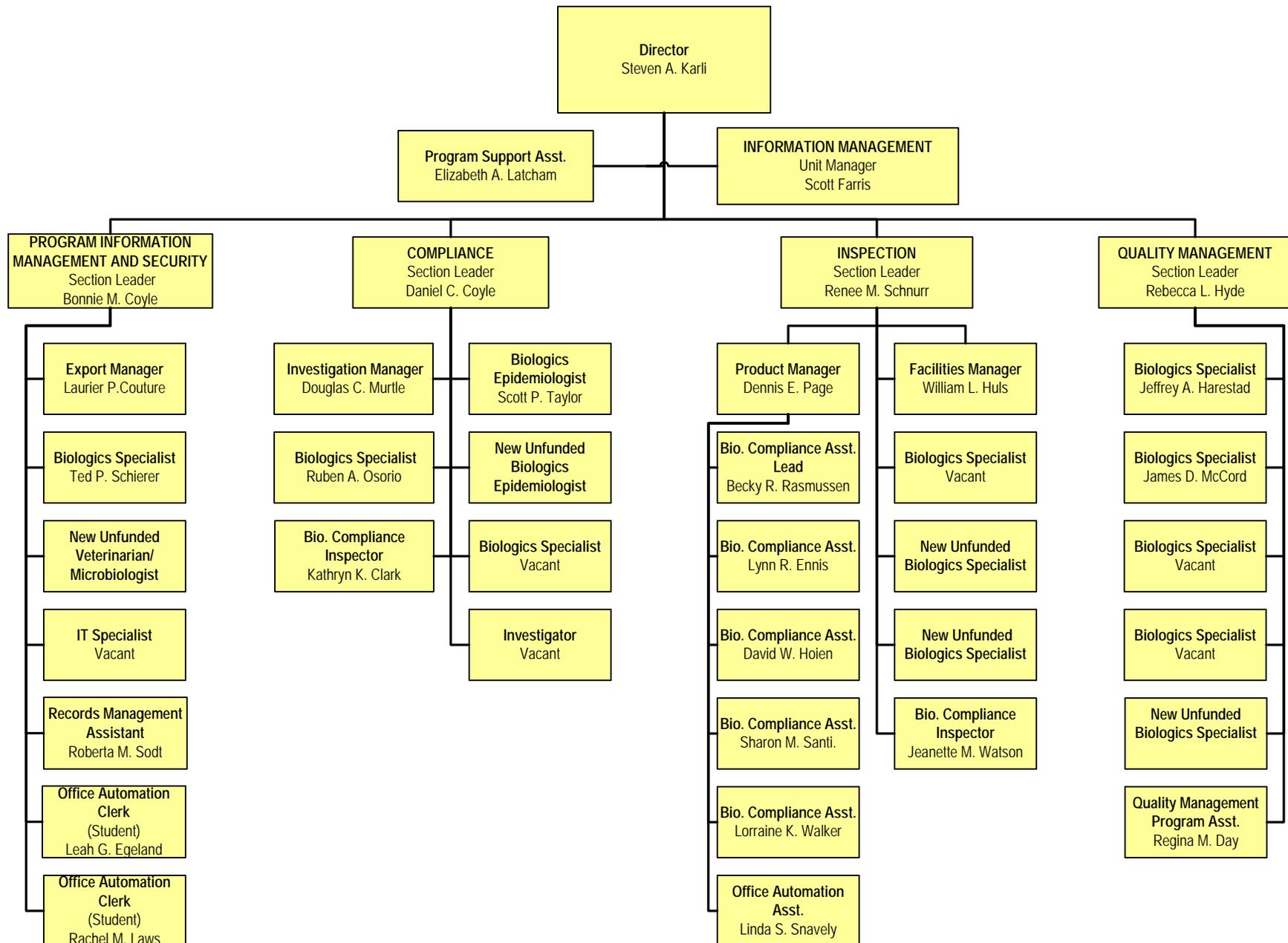


# **Year End Report FY 2009**

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



## Certification to ISO 9001:2000 standards

Effective business management system to ensure:

- Quality product
- Customer satisfaction

Emphasizing:

- Individual accountability
- Process improvement based on measurable objectives

Registered since 04Sep07 to ISO 9001:2000 standards  
by Quality Systems Registrars, Inc.

1

The ISO 9001:2000 standards focus on effective business practices to ensure quality product and customer satisfaction by emphasizing individual accountability and process improvement based on measurable objectives.

## Scope of the CVB ISO 9001:2000 Certification

- Review of prelicensing data
- Issuance of establishment and product permits and licenses
- Inspection of facilities
- Production of testing aids (Supplemental Assay Methods, References, & Reagents)
- Evaluation of product
- Writing of standards and procedures for product release
- Providing compliance oversight for firms producing or distributing Veterinary Biologics in the United States

## ISO 17025:2005 Accreditation

Formal accreditation to ISO 17025:2005 standards is a goal of the CVB as it provides independent 3<sup>rd</sup> party verification of laboratory competency for testing.

The CVB Laboratory is nearing conformance to all the requirements for ISO 17025 accreditation. However, the process of formal 3<sup>rd</sup> party accreditation has been placed on hold pending budgetary considerations.

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The total number of Export Certificates received by CVB (APHIS Form 2017; these are **serial specific**) has been increasing over the years.

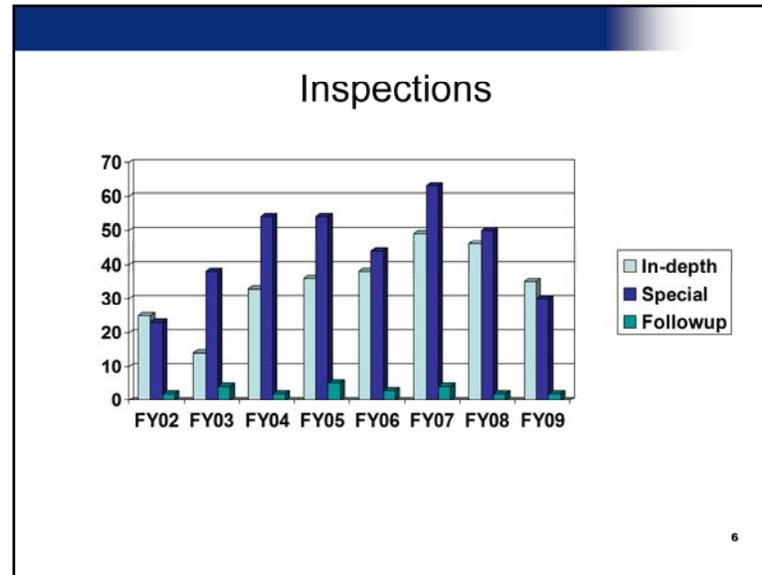
|                          |               |                           |                                      |
|--------------------------|---------------|---------------------------|--------------------------------------|
| FY 02                    | 124 approved  | 4 returned (128 total)    |                                      |
| FY 03                    | 196 approved  | 21 returned (217 total)   |                                      |
| FY 04                    | 431 approved  | 93 returned (524 total)   | Greater than 100% increase from FY03 |
| FY 05                    | 309 approved  | 54 returned (363 total)   |                                      |
| FY06 (AY)                | 356 Approved  | 100 returned (456 total)  |                                      |
| FY07 (AY)                | 659 Approved  | 196 returned (855 total)  |                                      |
| FY08 <sup>1</sup> (13 m) | 1504 Approved | 344 returned (1848 total) |                                      |
| FY09                     | 797 Approved  | 170 returned (967 total)  |                                      |

<sup>1</sup> More than doubled from previous year and the percent returned went from 23% in 07 to 19% in 08, a 5 % improvement in certificates received, showing our education has a positive effect – also all processed w/in 2 days.



#### Certificates of L&I

|             |               |   |
|-------------|---------------|---|
| FY 02       | 4385 approved | 316 returned (4701 total) – 7% return rate    |
| FY 03       | 3523 approved | 337 returned (3860 total) – 9% return rate    |
| FY 04       | 2636 approved | 281 returned (2917 total) – 9.5% return rate  |
| FY 05       | 2400 approved | 295 returned (2695 total) – 11% return rate   |
| FY 06 (AY)  | 2138 approved | 696 returned (2834 total) – 25% return rate   |
| FY07 (AY)   | 2180 approved | 485 returned (2662 total) – 18% return rate   |
| FY08 (13 m) | 3018 approved | 769 returned (3787 total) – 20% return rate   |
| FY09        | 2073 approved | 445 returned (2518 total) – 17.7% return rate |



|          | FY02 | FY03 | FY04 | FY05 | FY06 | FY07 | FY08 | FY09 |
|----------|------|------|------|------|------|------|------|------|
| In-depth | 25   | 14   | 33   | 36   | 38   | 49   | 46   | 35   |
| Special  | 23   | 38   | 54   | 54   | 44   | 63   | 50   | 30   |
| Followup | 2    | 4    | 2    | 5    | 3    | 4    | 2    | 2    |

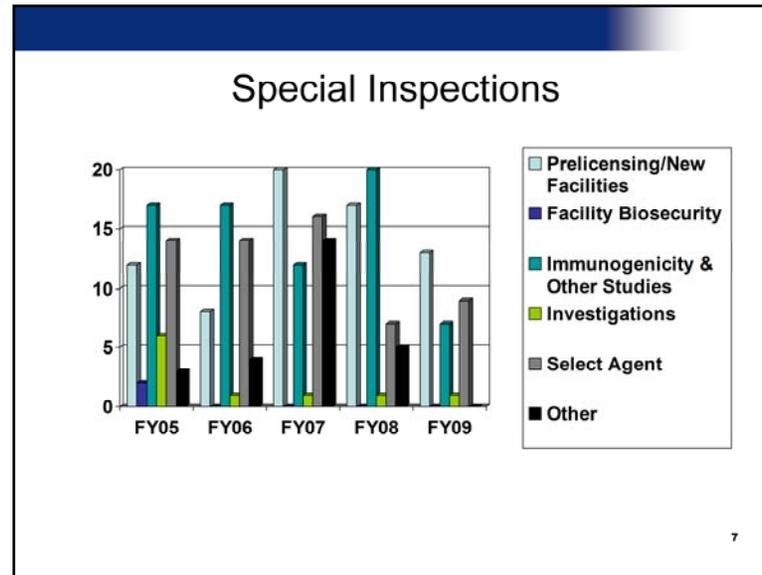
#### FY 2009

35 In-depth Inspections (24% decrease)

30 Special Inspections (including 9 Select Agent Inspections) (60% decrease)

2 Follow-up Inspections (same)

Four Biologics Specialist positions were vacant in 09. Using a new risk system, the inspection matrix, IC was able to inspect the sites most at risk based on product prepared, regulatory actions, and last time inspected.



|                                | FY05 | FY06 | FY07 | FY08 | FY09 |
|--------------------------------|------|------|------|------|------|
| Prelicensing/New Facilities    | 12   | 8    | 20   | 17   | 13   |
| Facility Biosecurity           | 2    | 0    | 0    | 0    | 0    |
| Immunogenicity & Other Studies | 17   | 17   | 12   | 20   | 7    |
| Investigations                 | 6    | 1    | 1    | 1    | 1    |
| Select Agent                   | 14   | 14   | 16   | 7    | 9    |
| Other                          | 3    | 4    | 14   | 5    | 0    |

#### AY 2009

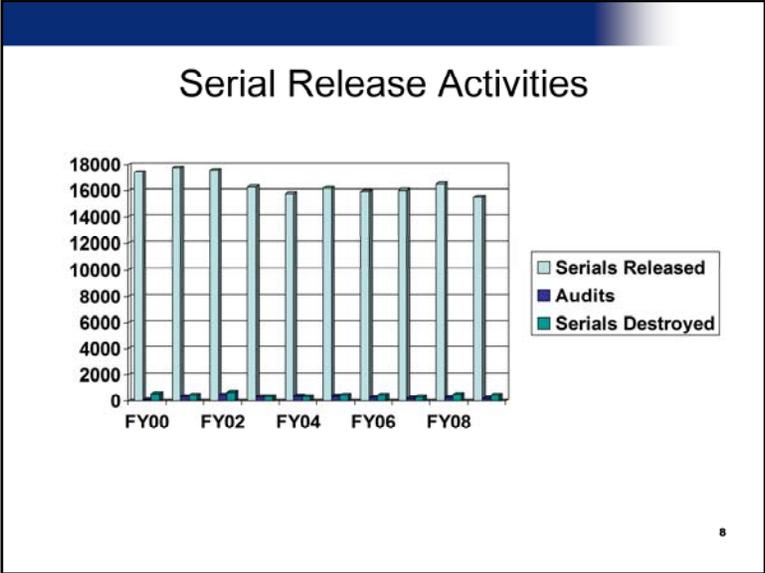
13 Prelicensing/New Facilities inspections and License Termination (24% decrease)

0 inspections to approve facilities for biosecurity level BL-2 or BL-3 (same)

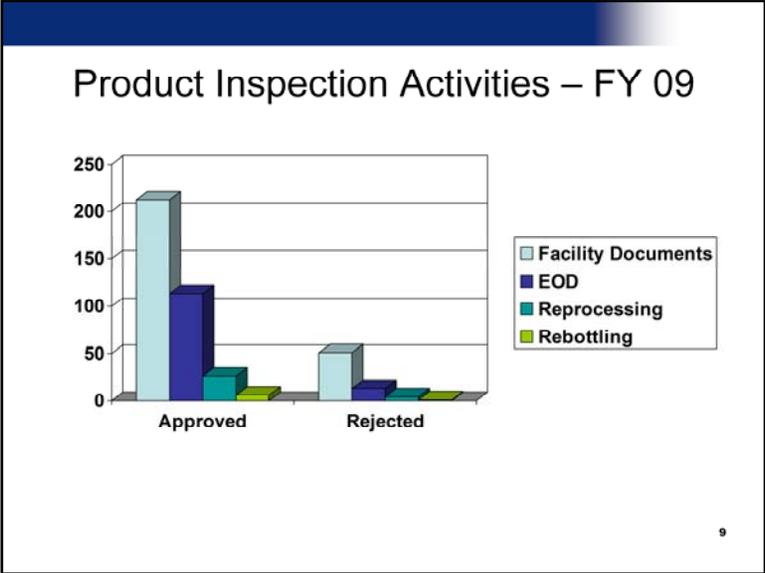
7 inspections for immunogenicity or other studies (65% decrease)

1 investigations (same)

9 Select Agent (23% increase)

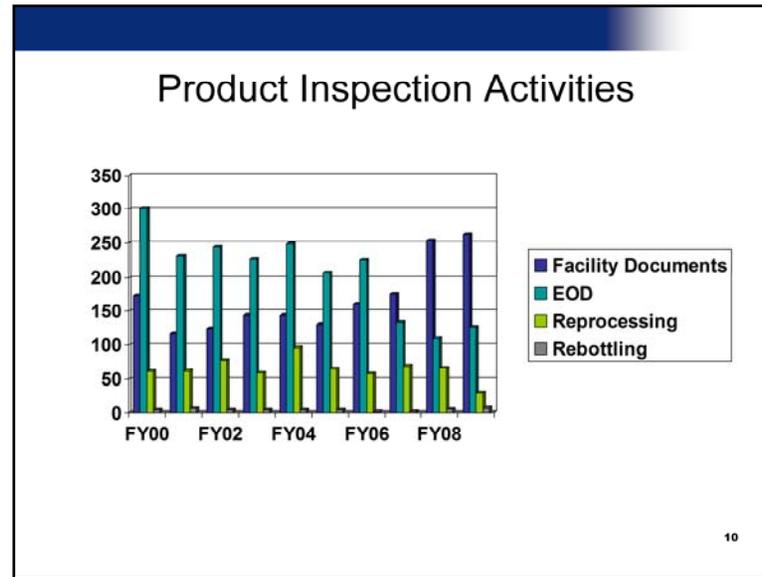


|                   | FY00  | FY01  | FY02  | FY03  | FY04  | FY05  | FY06  | FY07  | FY08  | FY09  |
|-------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| Serials Released  | 17388 | 17748 | 17576 | 16255 | 15789 | 16178 | 15945 | 16021 | 16502 | 15513 |
| Audits            | 109   | 363   | 455   | 337   | 388   | 398   | 271   | 214   | 280   | 234   |
| Serials Destroyed | 596   | 473   | 701   | 366   | 371   | 468   | 439   | 346   | 514   | 465   |



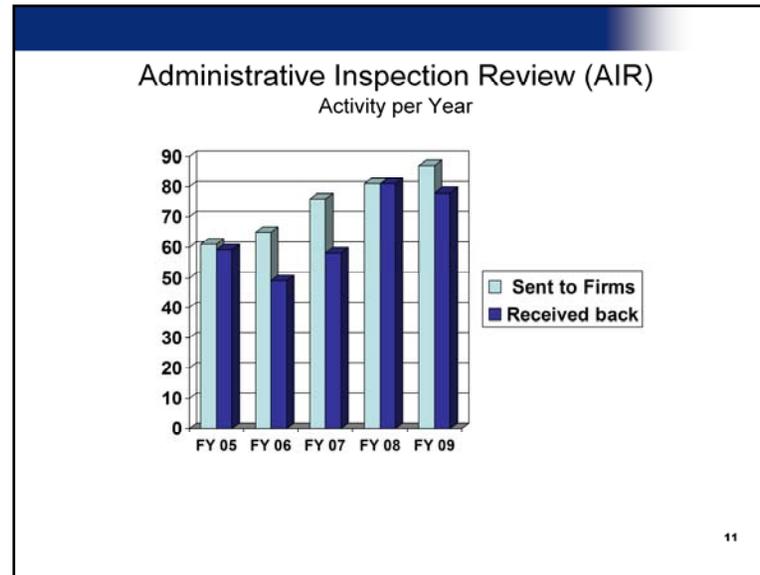
FY 2009

|                    |              |           |                                   |
|--------------------|--------------|-----------|-----------------------------------|
| Facility Documents | Approved 212 | Denied 51 | Total 263 (up 10 from last year)  |
| EOD                | Approved 114 | Denied 13 | Total 127 (up 17 from last year)  |
| Reprocessing       | Approved 26  | Denied 4  | Total 30 (down 36 from last year) |
| Rebottling         | Approved 6   | Denied 1  | Total 7 (up 2 from last year)     |



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|                     | FY00 | FY01 | FY02 | FY03 | FY04 | FY05 | FY06 | FY07 | FY08 | FY09 |
|---------------------|------|------|------|------|------|------|------|------|------|------|
| Facility Documents  | 174  | 118  | 125  | 144  | 144  | 131  | 161  | 176  | 253  | 263  |
| Extension of Dating | 301  | 231  | 244  | 227  | 249  | 207  | 225  | 134  | 110  | 127  |
| Reprocessing        | 61   | 62   | 78   | 59   | 96   | 65   | 58   | 69   | 66   | 30   |
| Rebottling          | 4    | 6    | 4    | 4    | 4    | 4    | 1    | 2    | 5    | 7    |



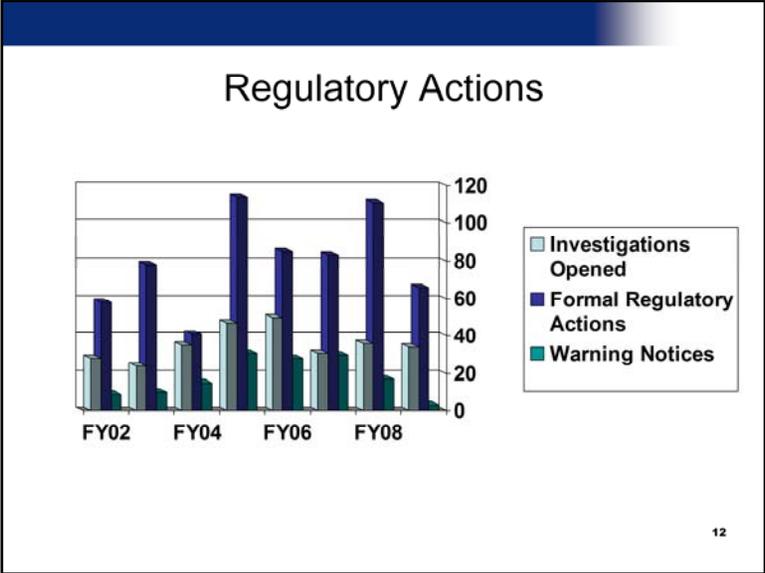
FY 2005 – 61 reviews sent to firms (59 received back from the firms). ~97%

FY 2006 – 66 reviews sent to firms (49 received back from the firms). ~74%

FY 2007 – 76 reviews sent to firms (58 received back from firms) 76%

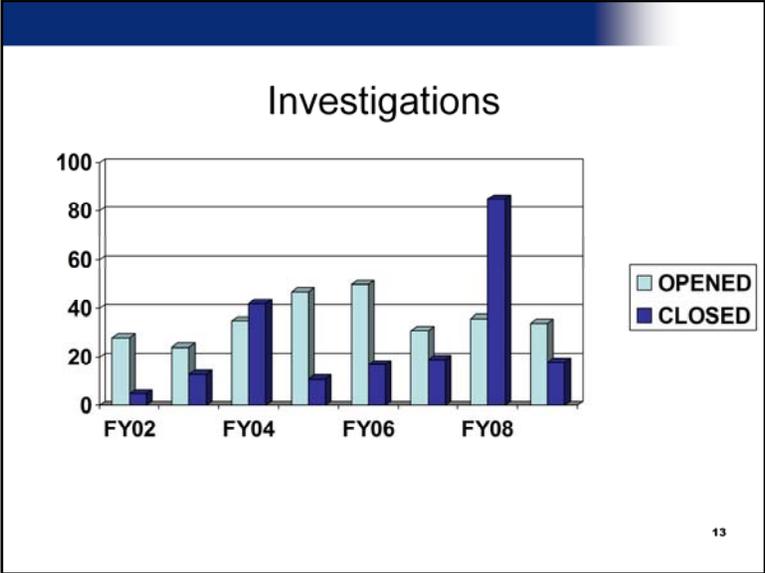
FY 2008 – 81 reviews sent to firm (81 received back from firms) 100% Implemented more stringent reminders, including Letters of Advice

FY 2009 – 87 reviews sent to firms (78 received back from firms). ~90%



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|                           | FY02 | FY03 | FY04 | FY05 | FY06 | FY07 | FY08 | FY09 |
|---------------------------|------|------|------|------|------|------|------|------|
| Investigations Opened     | 28   | 24   | 35   | 47   | 50   | 31   | 36   | 34   |
| Formal Regulatory Actions | 58   | 78   | 41   | 114  | 85   | 83   | 111  | 66   |
| Warning Notices           | 9    | 10   | 15   | 31   | 28   | 30   | 17   | 3    |



|        | FY02 | FY03 | FY04 | FY05 | FY06 | FY07 | FY08 | FY09 |
|--------|------|------|------|------|------|------|------|------|
| OPENED | 28   | 24   | 35   | 47   | 50   | 31   | 36   | 34   |
| CLOSED | 5    | 13   | 42   | 11   | 17   | 19   | 85   | 18   |

FY 08 - More closed than opened due to backlog

FY 09 – Reduction in investigations handled due to business plan strategies