

MQSA COMPLIANCE UPDATE

National Mammography Quality
Assurance Advisory Committee

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Objectives

- Overview of MQSA compliance issues
- Voluntary compliance and use of Warning Letters
- Describe the Previous Warning Letter Strategy (before 10/1/2003)
- Describe the New Warning Letter Strategy (after 10/1/2003)

MQSA Key Features

- Balance between compliance and access to mammography
- Emphasizes voluntary compliance

Voluntary Compliance

- Official regulatory philosophy of FDA
- Allow firms opportunity to correct problems before FDA takes regulatory action
- Most firms will comply given chance
- Conserves resources – regulatory cases costly and time consuming

Prior Notice

- Key feature of voluntary compliance philosophy
- Warn firm that failure to correct could result in regulatory action
- Most common method – Warning Letter
- Not appropriate for danger to health or intentional, gross, or flagrant violations

Warning Letters

- Identification of violations from inspection
- Violations are serious in nature
- Failure to correct could result in regulatory action
- Listing of possible regulatory actions
- Request for response regarding corrective actions (15 working days)

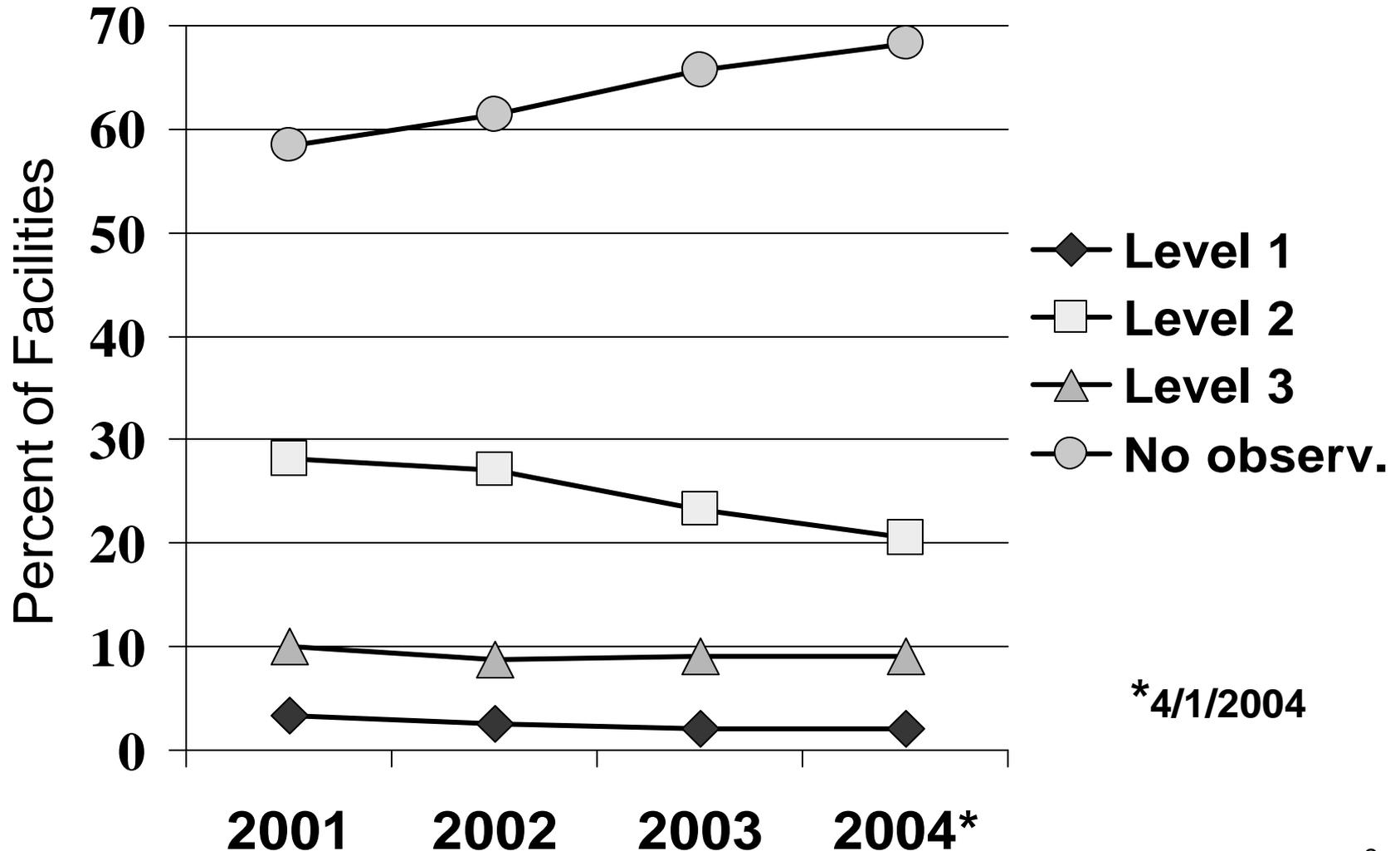
Inspections and Enforcement

- Annual inspections of facilities
- Enforcement - inspection follow-up including Warning Letters, follow-up inspections, regulatory actions
- Regulatory actions include directed plans of correction, suspensions, revocations, civil money penalties, injunctions, and patient/physician notifications

Structure of Inspection Observations

- **Level 1** – Significant potential to compromise mammography quality
- **Level 2** - Moderate potential to compromise mammography quality
- **Level 3** - Minor potential to compromise mammography quality

Inspection Observations by Level (as of October 1st)



Inspection Process

- Inspector uses laptop computer during inspection
- MQSA Facility Inspection Report - detailing the inspection observations
- *Important Information About Your MQSA Inspection* - provided to facility
 - Indicates most serious observation with instructions on responding to observations
- Inspection data uploaded to MQSA database (MPRIS)

Previous Post Inspection Strategy

- Level 1/Repeat Level 2 – facility told to correct ASAP, may get Warning Letter.
Warning Letter - response within 15 days
- Level 2/Repeat Level 3 – response within 30 days
- Level 3 – recheck at the next annual inspection

Regulatory Action History (1995 – Present)

- Warning Letters – up to 300 in a year
- Additional Mammography Reviews – 58
- Patient Physician Notifications – 14
- Follow-up Inspections (\$878) – 70
- Directed Plans of Corrections – 5
- Civil Money Penalties – 2
- Suspensions – 2
- Similar State Actions - 98

Critiques of MQSA

- Warning Letters without significant violation present
 - (“unlicensed” interpreting physician)
- Relatively few enforcement actions for number of Warning Letters
- Too little attention to facility’s inspection history
- Warning Letter not as effective for mammography facilities as for product manufacturers
- Other approaches (e.g. follow-up inspection) could be more effective

Post Inspection Strategy

■ Previous

- Level 1/Repeat Level 2 – FDA sends Warning Letter
- Level 2/Repeat Level 3 – response within 30 days.
- Level 3 – recheck at next inspection

■ New

- Level 1/Repeat Level 2 – **response within 15 days**
- Level 2/Repeat Level 3 – response within 30 days
- Level 3 – recheck at next inspection

New Post Inspection Strategy

Next steps

- If response to Level 1 or 2 observations unsatisfactory or missing - further contact with facility
- If further contact does not result in a satisfactory resolution, an MQSA follow-up inspection may be done by FDA with \$878 (Warning Letter, recommendation for regulatory action)

New Post Inspection Strategy

Next steps continued

- If follow-up inspection shows continuing problems – Warning Letter
- Previous Warning Letter – possible regulatory action

New Post Inspection Strategy

Next steps continued

- Compliance inspection (no fee) - two to three months after the Warning Letter
- If the compliance inspection shows continuing problems – possible regulatory action

Summary

- New strategy should result in:
 - Quicker facility response to serious observations
 - More effective correction motivated by prospect of follow-up inspection
 - “More meaningful” Warning Letters sent to worst offenders
 - Regulatory action taken against worst offenders