Mammography Quality Standards Act (MQSA)

Analyses of Compliance Cases and Inspection Citations

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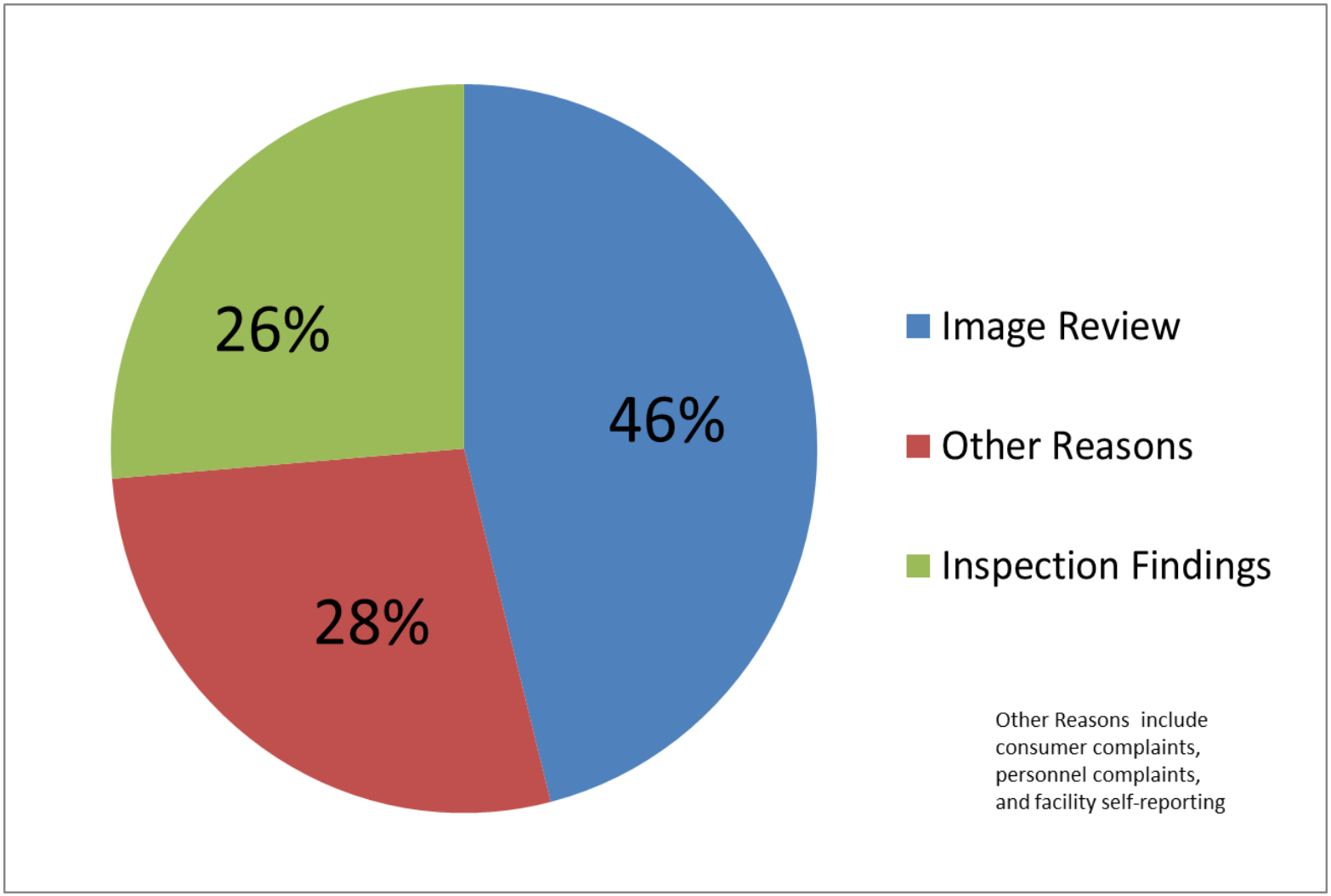
What We Did:

- In 2015 undertook analysis of compliance cases from 2001 to 2015
- Looked at the various imaging modalities, mammography procedure volumes, accreditation deficiencies, and compliance actions
- In early 2016 we looked at inspection citations for each inspection question

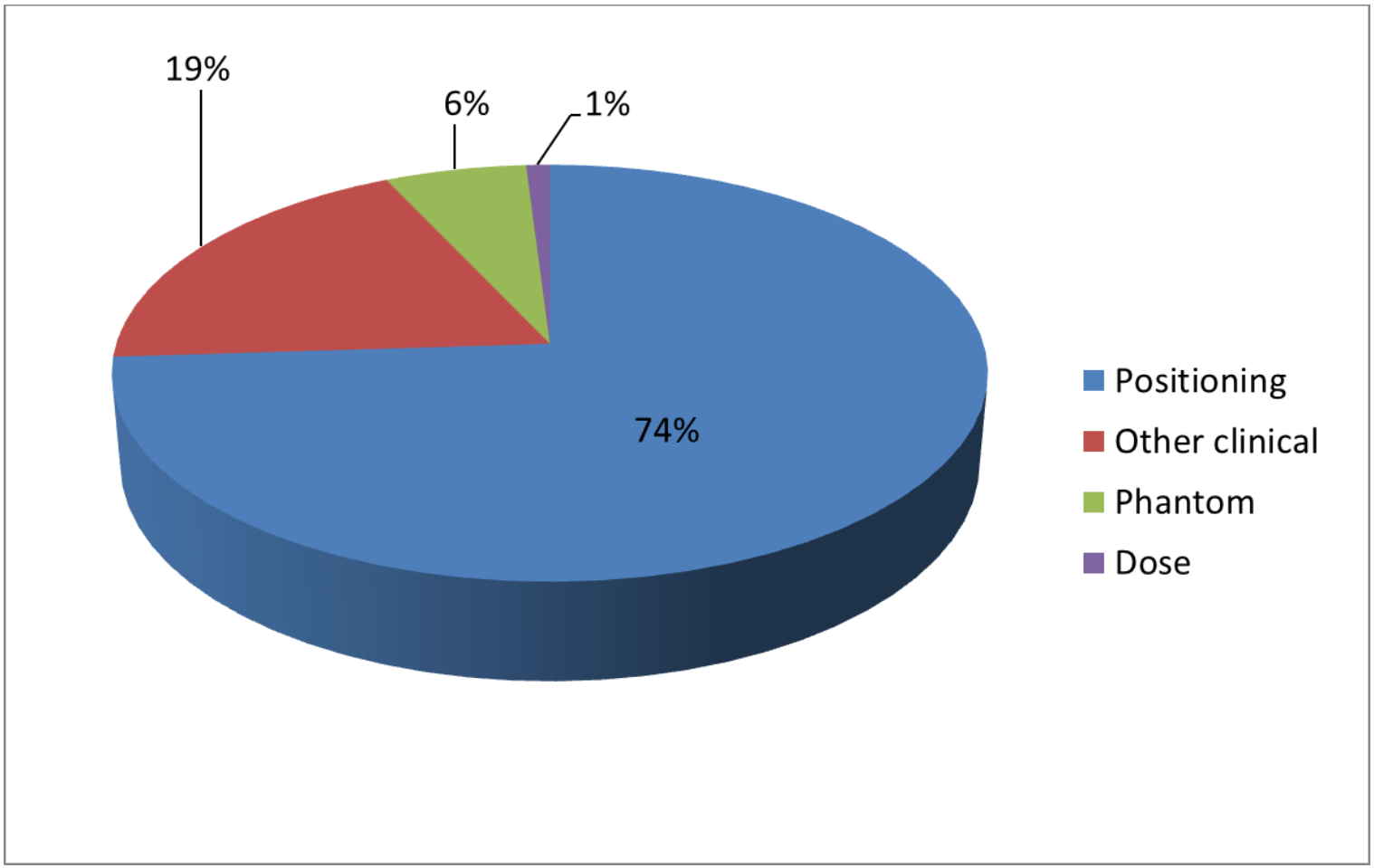
What We Learned: Compliance Cases

- Our compliance cases come more often from image reviews than inspections
- Equipment is almost never the issue
- Low volume is a factor
- Screen/film is a factor
- Positioning is the Achilles Heel

Origin of Additional Mammography Reviews 2009-2015



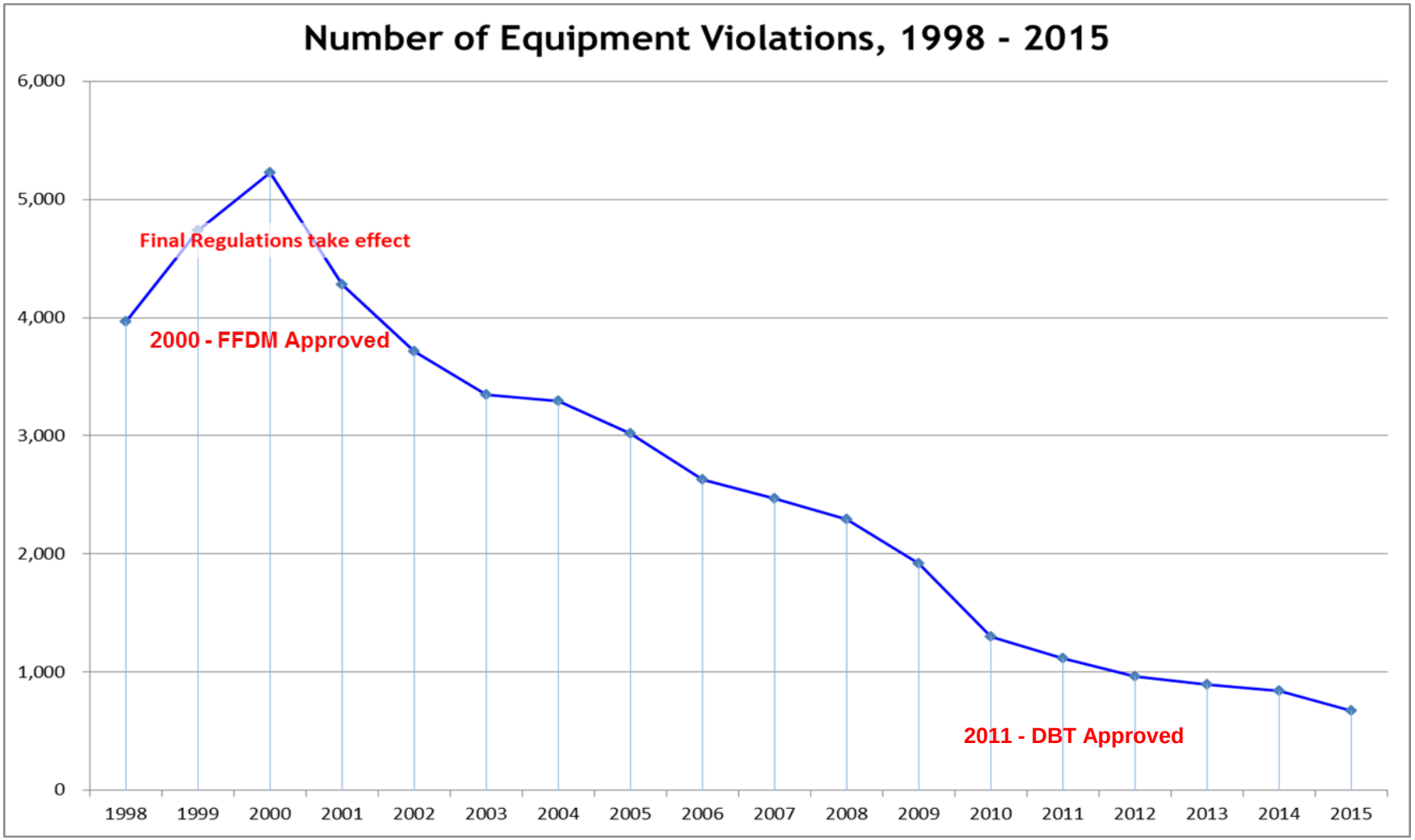
ACR First Attempt Accreditation Deficiencies 2015



Accreditation Failures

- 2014 – 93% of ACR unit accreditation failures were clinical image failures; of those 63% were for positioning.
- 2015 – 84% of ACR unit accreditation failures were clinical image failures; of those 79% were for positioning.
- The Iowa and Texas accreditation bodies report similar clinical image failure rates due to positioning, of 75% to 94%.

Equipment Violations History



Compliance Cases and Volume

- The national average number of mammography procedures performed per year per facility is 4,480.
- Of the 117 facilities which have had AMRs since 2001, the average number of annual procedures performed by those facilities was 2,756.
- For the 35 facilities since 2001 ordered to perform a PPN, their average number of annual procedures performed by those facilities was 1,852.
- Only 5 of the PPN facilities performed more than the national average of procedures.

PPNs, Inspection Findings and Image Receptors

- Of the 24 facilities ordered to perform Patient/Provider Notifications since 2009, 13 (approx. 54%) had no inspection violations in the year of the PPN order
- From 2009 through 2015, 38% of all PPNs involved screen-film facilities
- In 2015, 33% of PPNs still involved screen-film facilities, even though screen-film accounted for only 3% of certified facilities

Inspection Citation Analysis

- Some questions have very low citation rates
- Should we remove some inspection questions ?
- Should we elevate some inspection questions?

Removal of Inspection Questions

- Regulation remains intact; but no longer covered during MQSA inspections.
- Facilities still must comply with all MQSA requirements
- Reclaimed inspection time for possible new questions

Questions Being Removed

- No SOP for Infection Control?
- Required personnel documents available?

REMOVED: "No SOP for Infection Control?"

- The risk level for removing this question from the inspection software is very low.
- Most facilities have higher level SOPs for decontamination and cleaning of any equipment that comes in contact with patients. The higher level procedures are routinely reviewed by other private, State and Federal bodies.
- Facilities can incorporate the procedures for cleaning and disinfecting mammography equipment, and the methods for documenting facility compliance with MQSA infection control procedures, into the existing higher level SOP's for decontamination and cleaning of medical equipment.
- The level 2 citation will be removed.

REMOVED: “Required personnel documents available?”

- Facilities may not gather and prepare personnel documentation in advance of the inspection.
- This can lead to increased inspection times and level 1 and/or level 2 personnel citations that include the names of the individuals whose documentation was incomplete, if the facility does not provide the required documentation within 5 days after the on-site inspection.
- Inspectors will be instructed to use the Inspection Confirmation Notice to remind facilities to have personnel documentation ready on the day of the inspection.
- The level 3 citation will be removed.

Level 3 Questions Elevated to Level 2 Citations

- The QA program is inadequate.
- The compression device QC is not adequate.
- The repeat analysis QC is not adequate.
- Corrective action was not taken when called for in the medical physicist's survey report.
- The medical physicist's survey is incomplete because tests were inadequate or not done.

The MQSA program considers Level 3s to be the most minor of violations, with the facility not required to do any more than correct the violation before their next inspection. However, if repeated, we then treat Level 3 violations as equivalent to a Level 2; we treat repeat Level 2s as equivalent to a Level 1. If an otherwise “minor” violation is of sufficient seriousness that, if repeated, it could eventually become equivalent to a Level 1, then it is serious enough that we should not consider it to be minor. We believe these five noncompliances are serious enough that we should cite them initially at a Level 2. After these noncompliances are promoted, there will no longer be any Level 3 citations.

Clarifying Questions?

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Questions to the Committee

- Does the compliance case analysis reflect what is seen in the clinical practice of mammography?
- Are there any other inspection questions that could/should be eliminated?
- How do you think the elimination of Level 3 violations will be received by facilities?