# The Effect of Reducing Inspection Frequency

## A Study Authorized by the Mammography Quality Standards Reauthorization Act of 1998

In response to public concerns about the uniformity of quality provided by mammography facilities, Congress passed the Mammography Quality Standards Act of 1992 (MQSA or the Act). One of the concerns provided for by Congress was that all mammography facilities be inspected regularly to insure that they conform to certain basic quality levels. In particular, MQSA requires that facilities be inspected annually to ensure that requirements for personnel, equipment, and quality assurance practices are in place.

The Food and Drug Administration (FDA) started enforcing regulations for mammography facilities in October of 1994 and began inspecting these facilities in January of 1995. During the first few years the rate of compliance, as demonstrated by the annual inspection results, hovered around 60%. When Congress revised the Act under the Mammography Quality Standards Reauthorization Act of October 1998 (MQSRA), it included a provision allowing FDA to undertake an inspection demonstration program (IDP) to assess the feasibility and impact of conducting mammography inspections less frequently than annually. It retained the requirement for annual inspections for facilities not part of the IDP. According to MQSRA, the facilities selected to participate in the program should be "substantially free of incidents of noncompliance with the standards." The goal of the IDP was to evaluate if a reduction in the frequency of inspection for these facilities could be implemented without causing an increase in the rates of noncompliance.

As FDA began preparations in the spring of 1999 for the implementation of the program, it needed to take into account restrictions placed on the IDP by MQSRA and the additional restriction of States. For example, FDA was unable to include States that have mandates requiring annual inspections under their State laws. FDA decided to inspect selected facilities on a biennial basis to determine if missing one annual inspection would affect the facility performance as measured by the MQSA inspection.

FDA solicited and received comments on facility selection criteria from several sources including the Conference of Radiation Control Program Directors (CRCPD) and FDA's National Mammography Quality Assurance Advisory Committee. To assist our activities, the CRCPD created an inspection frequency task force to support FDA's effort. This group consisted of members for several State radiation programs and FDA regional offices.

In support of the program, the task force met with FDA headquarters personnel and provided assistance in determining the State participation and study group selection criteria. The group also assisted in the development of the biennial inspection format. The CRCPD also conducted a survey of all the States to determine if they had laws, regulations or policies regarding annual inspection of mammography facilities. It also

asked States whether they would be willing to participate in the program. The results of this survey, along with the facility selection criteria, were used to determine whether or not a State would participate in the IDP.

Ultimately, 14 States or other governmental jurisdictions were willing and qualified to participate in the program. Each agreed not to inspect the study group facilities under their own authority during the study period.

These jurisdictions were:

1. Arkansas
2. District of Columbia
3. Florida
4. Mississippi
5. New York (city)
6. New York (State)
7. Ohio
8. Oklahoma
9. Pennsylvania
10. Puerto Rico
11. South Dakota
12. Washington
13. Wisconsin
14. Wyoming

Three of the participating groups are not States. For convenience, the terms "State" or "States" will reference any or all of the above.

For a facility to be eligible to participate in the IDP, the facility had to:

- Anticipate maintaining full accreditation/certification throughout the inspection demonstration program
- Anticipate providing mammography services throughout the inspection demonstration program
- Have undergone at least two annual inspections under the final regulations
- Have had no inspection observations during the two most recent previous annual inspections under the final regulations
- Have had no regulatory action (i.e., compliance action), nor had been considered for such regulatory action by FDA or the State
- Have been selected by FDA to participate in the inspection demonstration program

FDA randomly selected study sites from the pool of eligible facilities located in the participating States. It was decided that the eligible facilities in the participating States would be divided into a study group and a control group with all selections being made on a random basis from the eligible pool. Two study groups were created, spaced six months apart. To reduce the possibility of selection of any facility that might withdraw

their certification in the interim and to minimize possible confusion that might result from facility personnel turnover, we phased the selection and notification of these groups based on their normal annual inspection dates. The notification provided six months prior notice to the study group facilities that they had been selected for the study. They were notified that they would not undergo an MQSA inspection in the first year of the biennial inspection cycle. They were also told that they must maintain facility records for the entire period until their next inspection. The first half of these, 77 study and 69 control facilities, were randomly selected from a population of 436 eligible facilities. The study group facilities were notified of their inclusion in the IDP in November 2001. The second group, of similar size, was selected from an eligible pool of 568 and notified in May 2002.

Throughout the planning stages of the IDP, FDA worked closely with the CRCPD's inspection frequency task force. One of the prime concerns of both the task force and FDA was the content of the biennial inspection procedure. It was agreed that the biennial inspection would look back over the entire two year period to verify compliance with the MQSA regulations. It would cover all of the same aspects of the annual inspections except for those specific areas where actual measurements required the inspector to be present as the data was collected; e.g., radiation measurements by the inspector.

The final configuration of the biennial inspection included all system performance tests using the same procedures as in an annual inspection, review of all quality control and personnel records since the last inspection, and two (one for each year when applicable) annual physicist survey reports. At the conclusion of the inspection, a single "IDP Post Inspection Report" was issued covering the two year period.

Due primarily to facility closures, by the time the IDP investigation phase was completed, the study group had dwindled to 146 facilities. The control facilities suffered similar attrition with only 132 facilities being available for the first annual inspection and 126 still being active for the second. The overall comparison of the highest level of inspection observation at the facilities over the two years covered by the IDP is shown in Table 1. It includes the results for both control group annual inspections, the single biennial inspection for the study group, and the results for the two annual inspections conducted on all other facilities over the same period. These data are separated out by group in Charts 1 through 5. The percent of facilities with a given level as the highest observation are compared in Chart 6.

Percent of Facilities with Highest Observation Level

| Highest Observation Level | Control Group '02-'03 | Control Group '03-'04 | Study Group '02-'04 | All Other Inspections '02-'03 | All Other Inspections '03-'04 |
|---|---|---|---|---|---|
| Level 1 | 0.76 | 0.79 | 2.74 | 2.41 | 1.90 |
| Level 2 | 17.42 | 14.29 | 27.40 | 25.03 | 21.27 |
| Level 3 | 6.06 | 10.32 | 12.33 | 9.14 | 9.10 |
| None | 75.76 | 74.60 | 57.53 | 63.42 | 67.72 |

Table 1

**Percent of Control Group Facilities by Highest Level Observation '02-'03**

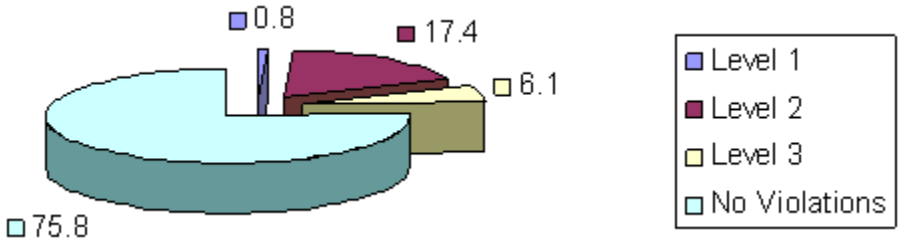


Chart 1

**Percent of Control Group Facilities by Highest Level Observation '03-'04**

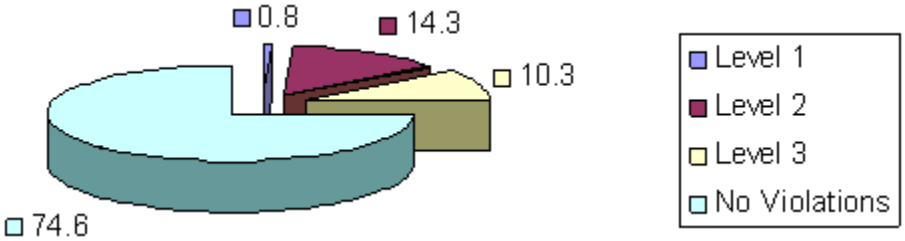


Chart 2

**Percent of Study Group Facilities by Highest Level Observation '02-'04**

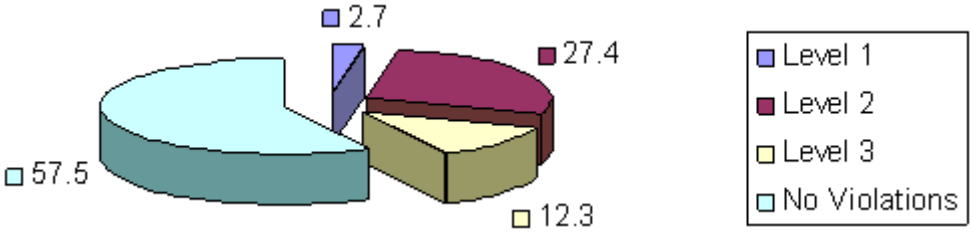


Chart 3

**Percent of All Other Inspections by Highest Level Observation '02-'03**

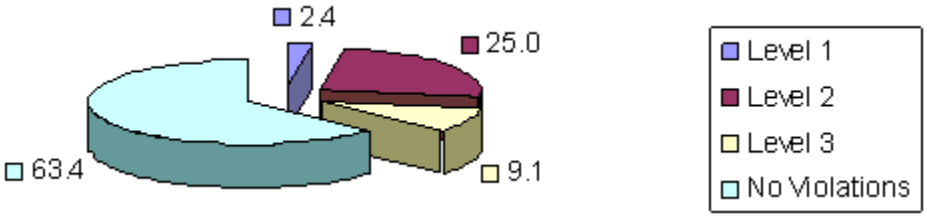


Chart 4

**Percent of All Other Inspections by Highest Level Observation '03-'04**

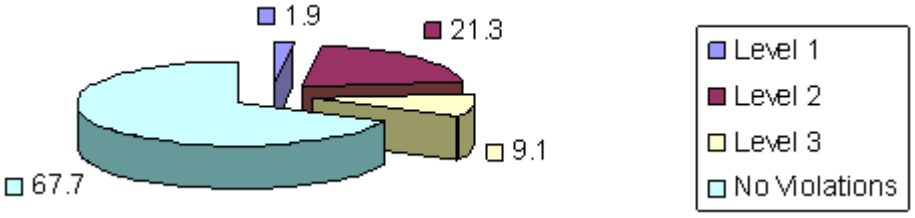


Chart 5

**Percent of Facilities by Highest Observation Level**

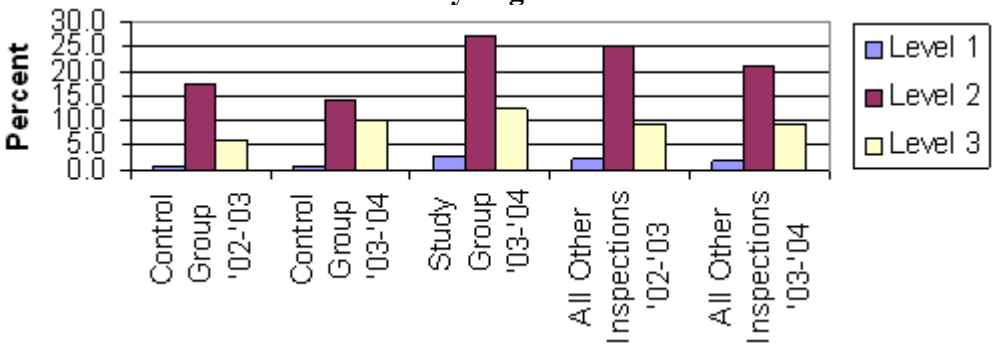


Chart 6

The information in Chart 6 relates only to the maximum level observation found at each facility. Each facility may have had multiple observations, either at that maximum or at lower levels. Table 2 shows the number of each level observation, the total observations and the number of facilities having any observation on the control and study group inspections. This is represented graphically in Chart 7.

**Number of Observations by Level**

| | Control 1 | Control 2 | Study Group |
|---|---|---|---|
| **Level 1** | 2 | 1 | 7 |
| **Level 2** | 44 | 46 | 101 |
| **Level 3** | 16 | 22 | 57 |
| **Total** | 62 | 69 | 165 |
| | | | |
| **# Facilities** | 32 | 32 | 62 |

**Table 2**

**Total Number of Observations by Level**

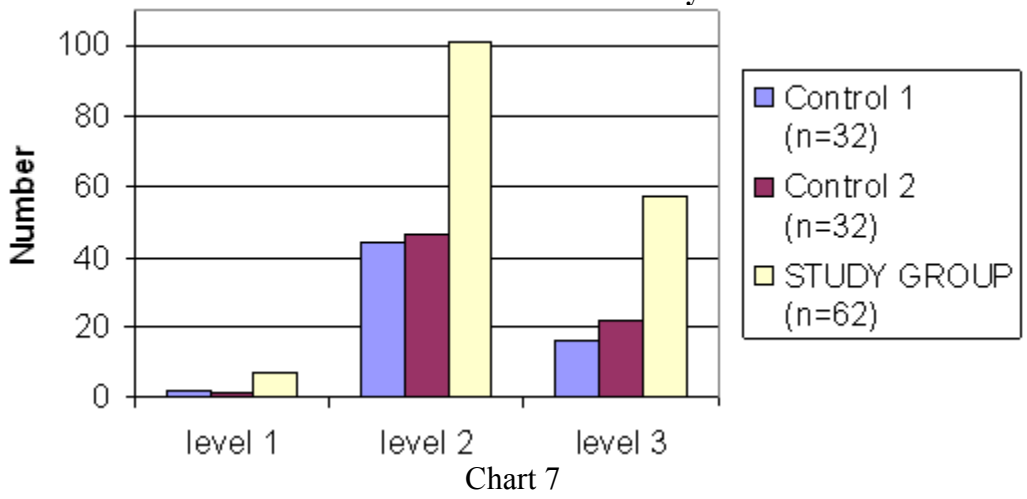


Chart 7

This chart shows that in addition to having a higher number of facilities at each maximum level, the study facilities had a greater number of total observations on a per facility basis. Based on the above observations, FDA chose to limit the IDP to the one biennial inspection cycle already performed. All mammography facilities are back on an annual inspection schedule at this time.