



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

July 2, 1998

Dear MQSA Facility Representative:

We want to thank you for participating in a recent national survey to determine mammography facilities' reactions to the Mammography Quality Standards Act (MQSA) inspection. The survey was conducted last spring by Booz Allen Hamilton (BAH) under a contract with the Food and Drug Administration. While maintaining the confidentiality of your participation, BAH supplied the Division of Mammography Quality and Radiation Programs (DMQRP) with a full report on the survey. Subsequently, R.O.W. Sciences took over the contract and has prepared the enclosed summary report that highlights the findings.

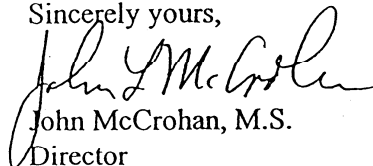
There were generally high levels of satisfaction with the inspectors and the inspection process. For example, the vast majority of facilities felt very comfortable with having the same inspector return. Facilities also reported that the inspection process improved considerably from their first MQSA inspection to their most recent one. The comments we received, which indicated that more guidance is desired by facilities in preparing for an MQSA inspection, will help guide DMQRP as we develop our procedures and policies.

The full report, as well as all materials and resources mentioned in either the summary or full report, may be obtained by faxing your request to 301-986-8015, by accessing our Web site at www.fda.gov/cdrh/dmqrp.html, or by writing to us at:

MQSA
c/o SciComm
P.O. Box 30224
Bethesda, MD 20824-9998

Thank you again for participating in this survey.

Sincerely yours,



John McCrohan, M.S.
Director

Division of Mammography Quality
and Radiation Programs, HFZ-240
Office of Health and Industry Programs
Center for Devices and Radiological Health

SUMMARY OF MAJOR FINDINGS FROM FACILITY INSPECTION SATISFACTION SURVEY

A sample of mammography facilities was surveyed in April 1997 to assess staff perception about their annual MQSA inspections and the inspectors who carried them out. All facilities in the FDA database were grouped by the inspector who performed their most recent inspection before the sampling was carried out. Thus, the study sample included a representative number of facilities for each inspector.

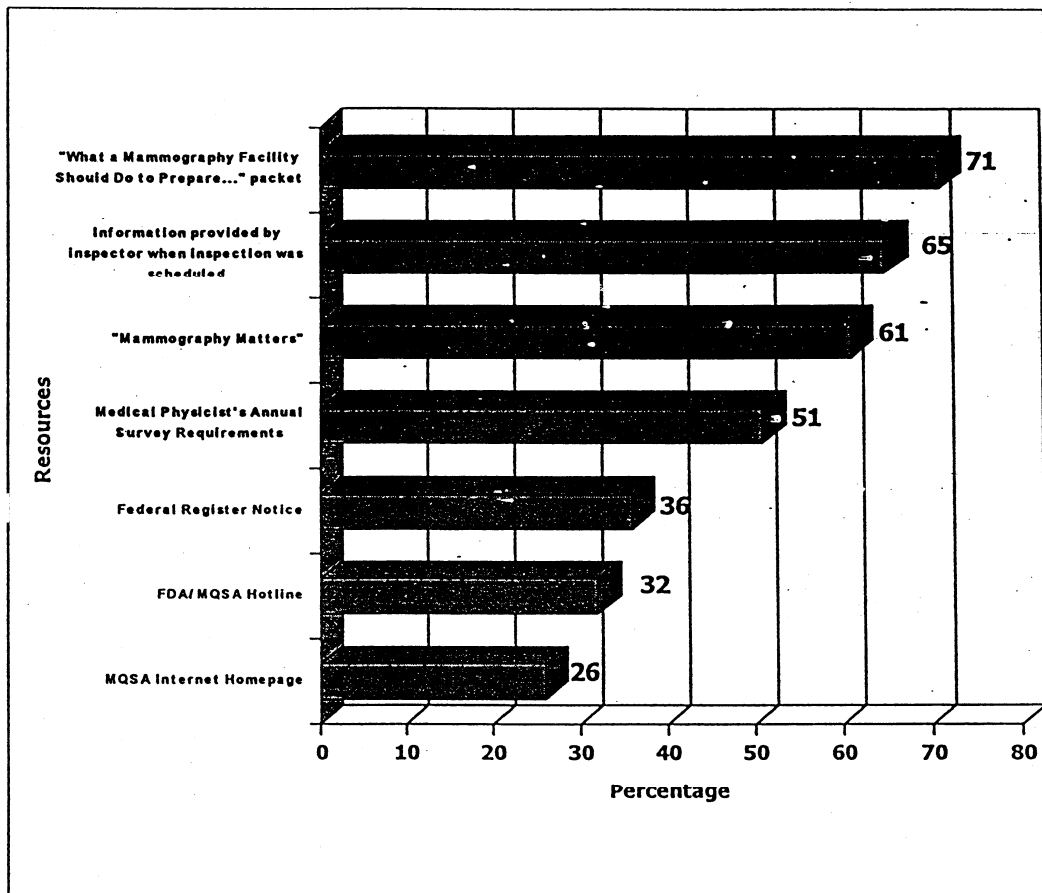
- 1,038 facilities were sampled (out of 9,456 eligible facilities)
- 674 facilities returned completed questionnaires

Profile of Respondents

- 48% were hospital-based radiology or mammography centers
- 75% were single-unit facilities
- 73% had participated in two inspections

Pre-Inspection Process

Percentages* of Facilities Finding Various Resources Very Useful in Preparing for the Inspection



*Please note that each reported percentage is based on the number of respondents providing a rating for that particular resource.

Notification of Inspection

About three-quarters (77%) of the respondents reported that they had received as much advance notification before the inspection as they needed.

Inspection Process

Assessment of Time Spent on Inspection

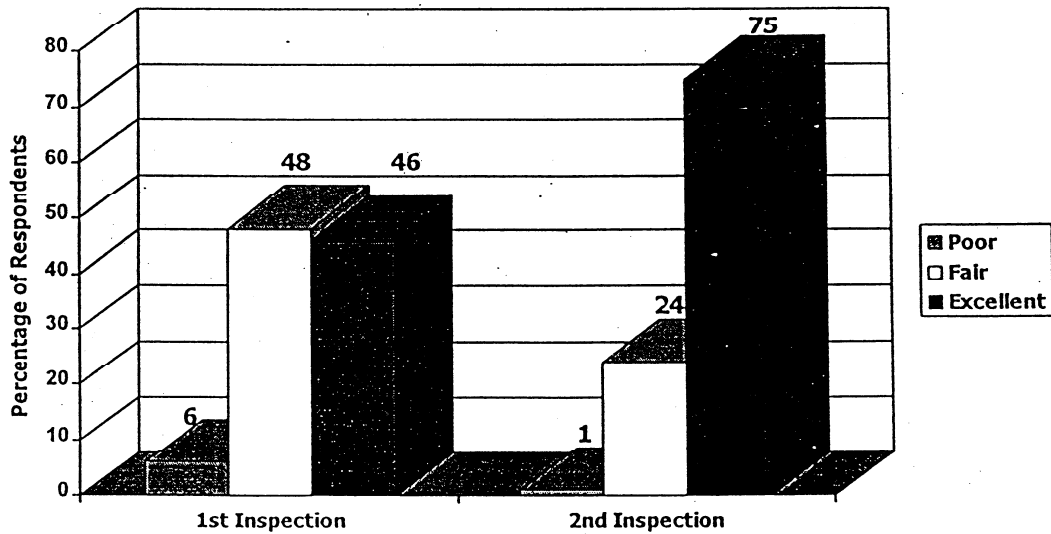
Number of hours spent preparing for upcoming inspection:

0 to 4 hours	46%
4.5 to 8 hours	31%
9 to 16 hours	13%
17 to 150 hour:	10%

Number of hours for complete inspection of facility:

1 to 4 hours	41%
4.5 to 8 hours	52%
9 to 40 hours	7%

**Comparison of First and Most Recent
MQSA Inspection Process Ratings**



Professionalism of Inspector

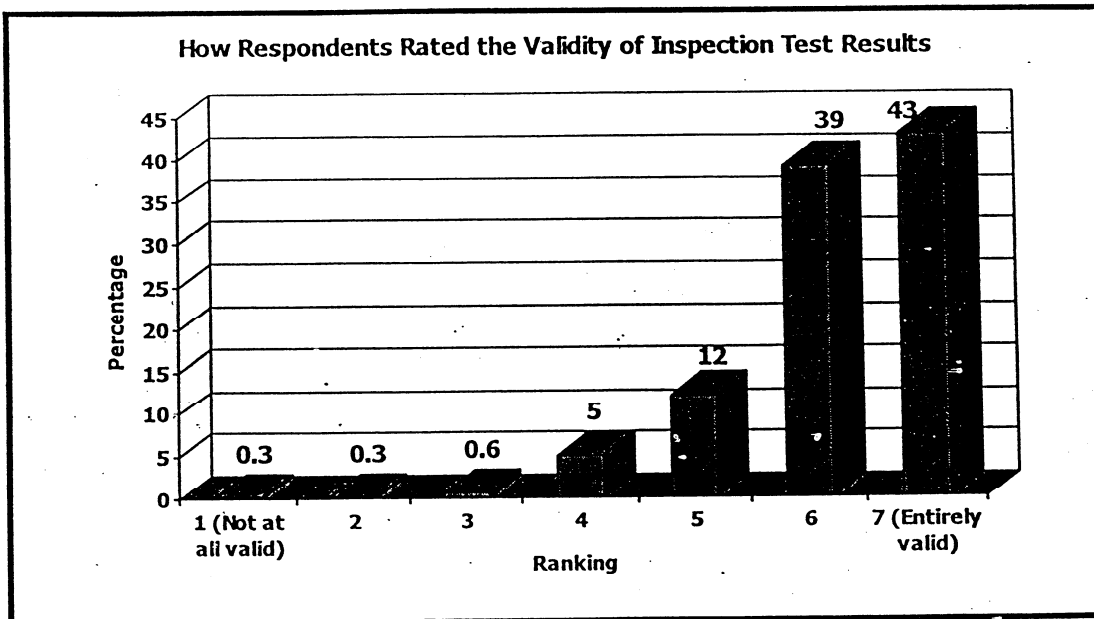
Percentage of respondents finding the person who inspected their facility to be...

- very polite, courteous, and respectful. 91%
- very helpful. 87%
- very knowledgeable about mammography. 81%
- very knowledgeable about the inspection process. 88%
- very accommodating with respect to patient scheduling. 87%
- very prepared with the equipment needed for the inspection. 94%

Percentage of respondents reporting that the...

- inspector volunteered a phone number to contact him/her at the time the inspection appointment was made. 99%
- inspector arrived at the scheduled time. 95%
- inspection was completed in the amount of time they were told to expect. 95%
- inspector answered their questions. 99%
- 1-800-FDA/MQSA Hotline was a good way to provide feedback to FDA about inspectors. 95%

Inspection Results



Percentage of respondents reporting that the...

- test results provided in the inspection report were very useful in identifying areas for improvement. 72%
- information provided by the inspector helped them a great deal in preparing for future inspections. 74%
- inspection was very educational. 58%
- inspection was very beneficial to their facility (was a very positive experience). 64%

Factors Related to Perceived Usefulness of Inspection

Respondents perceived their inspection to be more useful when their inspector was more experienced and when the process took less time.