Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Division of Mammography Quality and Radiation Programs (DMQRP)

Support for Analyses of the Mammography Quality Standards Act (MQSA)

Task No. G01 — Contract No. 223-94-5528

Mammography Quality Standards Act (MQSA) Inspection Procedures:

A Customer Service Survey Among Mammogram Facilities

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Prepared by
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1. INTRODUCTION

The Food and Drug Administration's (FDA) Division of Mammography Quality and Radiation Program (DMQRP) is responsible for enforcing the policies and procedures of the Mammography Quality Standards Act (MQSA) of 1992. This program requires all mammography facilities regulated under the auspices of MQSA to have on-site annual inspections. This study was designed to assess the perceptions of mammography facilities concerning these inspections and the inspectors that carry them out.

2. STUDY OBJECTIVE

The National Mammography Quality Assurance Advisory Committee (NMQAAC) recommended that DMQRP administer a survey of mammography facilities to obtain facility opinions about current MQSA inspection procedures and to elicit suggestions for streamlining and increasing the inspection's efficacy with the goal of maintaining a higher level of diagnostic practice. DMQRP will use the survey information in preparation of reports to GAO. This survey fulfills phase one of Executive Order 12862 that requires Federal agencies to "survey customers to determine the kind and quality of services that they want and their level of satisfaction with existing services."

The customer satisfaction survey among mammography facilities, "regulated entities," was based on each mammography facility's most recent MQSA inspection. The objective was to gather information about the existing MQSA inspection process, as it is perceived by the facilities, and identify problems or areas for improvement in the process that are practical and feasible.

To this end, the analysis allowed for assessment of each facility based on the facility's specific characteristics and experiences with the inspection process. This analysis, as well as the overall results of the survey, will allow DMQRP to target inspection improvement efforts to varying degrees depending upon the findings for each type of facility.

3. SURVEY METHOD AND INSTRUMENT DEVELOPMENT

The survey questions were developed with the goal of covering the area of the pre-inspection experience, inspection process, the inspector, inspection results, material left after the inspection is completed, benefit to the facility from the inspection, billing, and facility support activities (i.e., written materials and 1-800 phone service).

3.1 PRETESTING

Dr. James Swinehart of Public Communications Resources, Inc., conducted the pre-testing of the survey instrument and the cover letters. There were three phases in the pre-testing of the survey materials with facility representatives.

1. Phase I — Phone interviews with two New York facility representatives.
2. Phase II — Focus group in Baltimore with Baltimore area facility representatives.
3. Phase III —Phone interviews with nine nationally dispersed facility representatives.

3.1.1 Phase I — Phone interviews, New York facility representatives

Dr. Swinehart conducted the phone interviews. Booz·Allen & Hamilton Inc. (Booz·Allen) provided the names and demographic information of 21 facilities in New York. The pre-test survey materials included the following: (1) the questionnaire (draft dated 2/12/97); (2) a letter from FDA; and (3) a cover letter from Booz·Allen.

Two facility representatives were interviewed after reading the draft cover letters and completing the initial version of the questionnaire. One person was a relatively new employee of a radiology facility that serves a diverse clientele; the other (an administrator) was a long-term employee of a radiology practice in an affluent area. The facilities were inspected in April and August of 1996 respectively, both by the same inspector.

3.1.2 Phase II — Focus group in Baltimore, Baltimore facility representatives

Dr. Swinehart conducted a two-hour focus group with facility representatives from the Baltimore area at the offices of the Family Research Group, a facility equipped with viewing rooms and audiotaping capability, in Baltimore, Maryland on February 25, 1997. Baltimore was chosen because it provided access to representatives from a diverse array of mammography facilities. Further, the facility was within reasonable driving distance of Washington and thus permitted observation of the group by staff of the FDA and Booz·Allen.

Dr. Swinehart intended to have nine participants in the group. To allow for possible no-shows, twelve potential participants were recruited by telephone from a list of forty facility representatives (contact person) who had at least one MQSA inspection identified by Booz·Allen from the MPRIS database.

The twelve persons were chosen to reflect diversity on four dimensions:

1. Type of facility (hospital, radiology practice, HMO)
2. Occupation (office manager, mammographer, technologist)
3. Date of last inspection
4. Name of inspector.

An incentive fee of $75 was paid to each of the eleven people who appeared for the session. Nine participated throughout, and two others were allowed to leave after they had filled out a prototype survey questionnaire.

All of the participants were women. They had been associated with mammography facilities for periods ranging from four years to 18 years. In the facilities they represented, the number of mammograms performed ranged from 40 to 900 per month; the average was approximately 300 per month.

3.1.3 Phase III — Phone interviews, Nationally dispersed facility representatives

Dr. Swinehart conducted the interviews with facility representatives from a diverse sample of facilities across the United States. Interviewees were recruited from a list of facility representatives supplied by the survey contractor. The persons interviewed were from nine states in four time zones: Eastern (Florida and Maryland); Central (Iowa, Kansas, and Wisconsin); Mountain (Colorado); and Pacific (California, Oregon, and Washington). Given their varied locations, it is highly likely that no two facilities were inspected by the same person.

All interviewees represented facilities that were inspected in 1996: one in March, one in June, one in July, one in August, one in September, three in October, and one in November. Their work settings included medical groups, imaging centers, radiology practices, and a hospital. Most of the persons interviewed were technicians or administrators, and each was the primary contact person for a facility's most recent MQSA inspection.

Prospective interviewees were told that questions were being pre-tested for a survey to be conducted with mammography facility representatives the following month. After being faxed a copy of the questionnaire and two cover letters, each person was given a day to review them before being called back for an interview. All were told that their questionnaire answers would remain confidential. They were also told that they did not need to return the completed form, which they had in hand for reference while being interviewed. The interviews were conducted March 6-10, 1997.

3.2 NOTIFICATION TO DIFFERENT MAMMOGRAPHY GROUPS

The following individuals were sent copies of the letter and an initial draft of the survey. They were informed that the survey was going to be administered within their organizations and they were asked to provide any input that they wished to provide.

1. MQSA Working Group State members:

- Julia Schmitt (NE)
- Cass Kaufman (CA)
- Ed Gloor (CA)
- Jennifer Elee (LA)
- Shanna Hellmuth (AZ)
- Judy Koch (TX)
- Bruce Matkovich (MI)
- Linda Plusquellic (ME)
- Joyce Ziesler (NJ).

1. National Mammography Quality Assurance Advisory Committee members:

- Priscilla Fay Butler, M.S., Associate Professor, Department of Radiology, The George Washington University Medical Center
- Rita W. Heinlein, R.T., Director, Mammography Consulting and Educational Services
- Edward Hendrick, Ph.D., University of Colorado Health Sciences Center, Division of Radiological Sciences, Department of Radiology
- Kathleen A. Kaufman, B.S., R.T, Los Angeles County Department of Health Services
- Marsha T. Oakley, B.S.N., R.N., Arm-in-Arm
- Robert Smith, Ph.D., Senior Director for Detection Programs, Detection and Treatment Department, American Cancer Society
- Michael N. Linver, M.D., Medical Director, Women's Medical Imaging Center, X-Ray Associates of New Mexico.

2. Regional Radiological Health Representatives (RRHR).

- Ron Bernacki - Northeast Region, DHHS, FDA Northeast Regional Office
- Larry Rourk - Mid-Atlantic Region, DHHS, FDA Mid-Atlantic Regional Office
- Tom Trout - Southeast Region, DHHS, FDA Southeast Regional Office
- Lynn Jenkins - Midwest Region, DHHS, FDA Midwest Regional Office
- Belinda Collins - Southwest Region, FDA Southwest Regional Office
- Ken Miles - Pacific Region, FDA Pacific Regional Office

1. Office of Regulatory Affairs (ORA), Deborah Ralston

2. Senior Director for Detection Programs, American Cancer Society, Robert Smith, Ph.D.

3.3 OMB APPROVAL OF SURVEY AND SURVEY METHOD

The following two FDA representatives assisted in the preparation of Office of Management and Budget (OMB) materials and facilitated the OMB approval process.

FDA Point of Contact: Peggy Wolff, 301/827-1223, fax: 301/594-0060

FDA Statistician: Dale Madden, 301/827-5256, fax: 301/827-5260

After being reviewed by the FDA Statistician, the survey materials were delivered to the FDA Point of Contact on March 14, 1997. The comments from OMB were incorporated into the questionnaire and the cover letter. Approval for conducting the survey was given on April 17, 1997. The survey was given OMB approval number 0937-0201, expiration date of June 30, 1997.

3.4 INTERNAL BENCHMARKING

On October 1, 1997, Dr. Lee Friedman of Booz·Allen facilitated a working group meeting among FDA mammography leaders. In this meeting, FDA staff identified the levels of performance that they felt the FDA inspectors should be attaining as measured by the survey. In addition, the staff identified the types of performance benchmarks that would be obtained with respect to the inspection process (see Appendix A).

The following members represented their respective branch of DMQRP.

Deputy Director	John McCrohan
Information Management Branch	Babette Anderson.
Inspection Support Branch	Kathleen Franke, Chief Denise Robinson Walid Mourad Charles Gunzburg Joanne Choy Randy Pack
Outreach Staff	Carole Sierka
Mammography Standard Branch	Roger Burkhart Al VanDeGriek
SFA contractor	Vickie Jermgian

4. SAMPLING AND ANALYSIS METHODOLOGY

The following section describes the sample design, sampling frame and design, initial data analysis and factor analysis.

4.1 THE MOST RECENT INSPECTION WAS THE FOCUS OF THE SURVEY

The inspector is a major factor in the facility's experience and a major source of variation that was captured in the sample. Over 200 inspectors perform annual inspections for the facilities across the United States; some of them have inspected well over 100 facilities where others have inspected only one facility. Therefore, for the sample, Booz·Allen was primarily interested in ensuring adequate representation of the facilities that each inspector inspected.

4.2 SAMPLING FRAME AND DESIGN

The MPRIS database provided the population data for this study. The MPRIS database contains all the inspection data for all facilities that have had an MQSA inspection. A component of MPRIS is facility certification data, which contains information on the status of each facility's certification. This data was used to verify if the facilities were still in operation, in order to ensure that a questionnaire would not be sent to a closed facility.

On March 6, 1997, the sample was created from the MPRIS database, using stratified random sampling. The sample was stratified in proportion to the number of facilities inspected by each inspector within the population. (For example, given a population of 100 facilities, suppose that Inspector A inspects 50%, whereas Inspector B and Inspector C each inspect

25% of the facilities, respectively. In order to arrive at a proportional stratified random sample of twenty persons, the sample would include 10 facilities from Inspector A and 5 facilities each from Inspector B and Inspector C). In addition, if the percentage of facilities inspected was less than 1% for a given inspector, then at least one facility was to be included in the survey for that inspector. All inspectors had at least one of their facilities included in the sample.

The sample strata were defined as the facilities each inspector inspected according to each facility's most recent inspection. The sampling frame for this study consisted of 9,456 facilities and excluded the 29 facilities used in the pre-testing of the survey and 376 facilities whose certification had expired, according to the MPRIS certification database. For the inspectors who performed inspections on only a few facilities, at least one facility was selected to obtain coverage of facilities for all inspectors. The sample for this survey included 1,038 facilities with 240 different inspectors represented. The breakout of the facilities represented in the sample including the ID number of the inspector responsible for their inspections are presented in Appendix B.

4.3 METHOD FOR ADDRESSING NONRESPONSE AND BIAS

The following measures were taken to minimize the effect of non-response and any bias introduced.

Booz·Allen monitored the responses as they were received, and conducted a follow-up mailing to non-respondents. The follow-up mailing was a postcard sent to the facilities that had not yet responded.

Factors thought to influence the experience of a facility with an annual inspection were the type of facility, whether the facility was found to be in compliance or not, and how many inspections the facility had been through. These are potential sources of variation that are necessary to capture in the sample. Booz·Allen compared the achieved sample to the population counts for each of these factors. The results of these comparisons reflected similar distributions, which indicates there is adequate representation of each of these factors in the sample. Table 4.1 illustrates the comparisons between the population and sample surveyed.

Table 4.1: Comparison of Population and Sample Counts

Type of Facility	Population	Pct. Distr.	Allocated Sample	Pct. Distr.	Achieved Sample	Pct. Distr.
Private Practice	2,040	21.58%	227	21.87%	136	20.18%
Hospital	4,405	46.59%	476	45.86%	322	47.77%
Multiple Specialty Practice	1,888	19.97%	198	19.08%	130	19.29%
Mobile Unit	206	2.18%	30	2.89%	18	2.67%
School	8	0.08%	2	0.19%	0	0.00%
Private Laboratory	134	1.42%	9	0.87%	6	0.89%
Health Agency	77	0.81%	7	0.67%	4	0.59%
Industry	10	0.11%	0	0.00%	0	0.00%
Nursing Home	1	0.01%	1	0.10%	0	0.00%
Breast clinic	374	3.96%	46	4.43%	37	5.49%
Other	312	3.30%	42	4.05%	21	3.12%
Total	**9,455**		**1,038**		**674**	
Inspection Rounds						
Inspection Round	Population	Pct. Distr.	Allocated Sample	Pct. Distr.	Achieved Sample	Pct. Distr.
1	406	4.29%	52	5.01%	29	4.30%
2	4,811	50.88%	516	49.71%	330	48.96%
3	4,239	44.83%	470	45.28%	315	46.74%
Total	**9,456**		**1,038**		**674**	
Level of Non-compliance						
Level of Non-compliance	Population	Pct. Distr.	Allocated Sample	Pct. Distr.	Achieved Sample	Pct. Distr.
1	180	1.90%	30	2.89%	26	3.86%
2	1,213	12.83%	202	19.46%	179	26.56%
3	3,790	40.08%	461	44.41%	314	46.59%
None	4,273	45.19%	345	33.24%	155	23.00%
Total	**9,456**		**1,038**		**674**	

This sample design was reviewed and approved by FDA statisticians. Booz·Allen performed all of the statistical analysis for the survey and maintained the respondents' confidentiality.

4.4 QUALITY CONTROL OF SURVEY

Quality control was a very important step in the methodology employed by Booz·Allen. In order to ensure strict control, standard operating procedures (SOP) were developed. These SOPs outlined procedures for the receipt of the survey, the actual quality checking of the data, editing of the quality checked data, and quality checking of the edited data. This SOP document is included in Appendix C.

4.5 STATISTICAL ANALYSIS METHOD

4.5.1 Comment Coding

Each of the five sections of the survey allowed space for respondents to provide verbatim comments concerning the inspection process. These comments were transcribed and analyzed via contextual analysis. The results of this analysis can be found in Appendix D. In addition to the contextual analysis, representative comments can be found at the conclusion of each survey section covered in Section 5.1 (Descriptive Statistics).

4.5.2 Descriptive Statistics

Upon receipt of all survey responses, Booz·Allen designed a survey response database using SAS (Statistical Analysis Systems, a statistical package) and prepared the data for analysis. Initial analysis consisted of computing descriptive statistics (means and frequency percentages, as appropriate) for each of the variables on the survey. These statistics were then compared with the previously established internal benchmarks. In addition, comparisons were conducted using a reasonable standard (set by Booz·Allen) of 70% favorable response for a given item. The performance standards set by Booz·Allen constitute the basis for the interpretation of the general findings, conclusions and recommendations presented in Section 6 (Discussion).

4.5.3 Factor Analysis

Factor Analysis of the mammography facility satisfaction survey was used to determine the underlying constructs (Factors) that contribute to the general construct that Booz·Allen and the FDA currently refer to as "facility satisfaction." Booz·Allen conducted a factor analysis of the survey responses in order to determine these underlying factors or dimensions as they are measured by the survey. Specifically, a principal axis factor analysis was performed. A Harris-Kaiser orthoblique rotation was applied to the factor pattern matrix to enhance interpretability of the factors. The Harris-Kaiser orthobliquc rotation was chosen because it does not force othogonality on what could be correlated factors. Furthermore, it allows for secondary factor loadings. A more detailed description of the variables employed and the analysis conducted can be found in Appendix E. One of the key benefits of performing this factor analysis was the derivation of factor scores for each type of mammography facility.

4.5.4 Analysis of Variance (ANOVA) of Factor Scores

A factor score is an index of a facility's level of satisfaction on a particular factor. A hypothetical example will help illustrate the meaning and importance of factor scores. Suppose that upon doing the factor analysis, two factors emerged: "quality of the inspection procedures" and "usefulness of the inspection." Each mammography facility would receive a factor score on each of the factors. For example, it could be apparent that "Facility A" was pleased with the quality of inspection procedures and the usefulness of the inspection, but 'Facility B" was not. Knowing this information, one could immediately determine how to intervene to improve satisfaction at "Facility B." In this study, the factor scores were evaluated for facilities with different characteristics to determine for which factors (e.g., inspection quality and inspection usefulness) those types of facilities were most or least satisfied. This is useful because facilities with different characteristics can have very different experiences with the inspection, and, therefore, may have different needs. The results of these analyses and the conclusions and recommendations drawn from them are discussed in detail in Sections 5 and 6 respectively. A more detailed description of the variables employed and the analysis accompany the discussion of the factor analysis found in Appendix E.

5. RESULTS

This section outlines the findings of the descriptive statistics and comparison with FDA benchmarks, the factor analysis and the subsequent ANOVA.

5.1 DESCRIPTIVE STATISTICS

Initial analyses consisted of calculating frequency percentages and means, where appropriate for each survey item. The results of these analyses are presented in detail in Appendix F. Based on these descriptive statistics some clear findings concerning facility experiences and opinions with the inspection process were uncovered. These results were especially useful in light of the benchmark percentages obtained during the FDA internal benchmark focus group described in Section 3 (Methodology). Booz·Allen's report of the findings based on FDA-based benchmarked standards can be found in Appendix G. Although this analysis was useful, the lack of established benchmarks for numerous items led Booz·Allen to generate its own performance benchmark standard based on its extensive experience in analyzing and interpreting customer satisfaction survey data. Comparison of these descriptive statistics, relevant to the reasonable standard of 70% of facilities responding favorably (rating "6 or 7") to a given item, revealed findings similar to the FDA-based benchmark comparisons.

Table 5.1 provides findings of means and percentages for items dealing with the pre-inspection preparation process.

Table 5.1: Pre-Inspection Preparation Process

Survey Item	More than 10 days	5 - 9 days	Less than 4 days
1. How much notice did you have before the inspection (N=669)	69.1	26.5	4.4
Survey Item		**Average**	
2. In your view, how much advance notice should a facility have about an upcoming inspection? (N=665)		16.4 days	
3. After being notified of the upcoming inspection, how many hours did you spend preparing? (N=641)		8.7 hours	
Survey Item	**Percentage of Facilities Rating 6 or 7**	**Percentage of Facilities Rating 3 thru 5**	**Percentage of Facilities Rating 2 or 1**
4. How do you feel about the time it took for you to prepare for the inspection? 1 (Excessive) 7 (Minimal) (N=659)	64.3	34.6	1.1

As Table 5.1 indicates facilities would like to receive more than 10 days notice (M=16.4 days), and 69.1% of facilities actually received this level of notice. Facilities indicated that it took them a minimal amount of time (64.3% rated "6 or 7") to prepare for the inspections. These two findings appear to contradict each other, as the average number of hours that it took to prepare for an inspection (8.7 hours or approximately one day) was rated as minimal, yet facilities feel that they need over 16 days notice before an inspection. Although the data supports the notion that the inspection requires minimal preparation time, the following representative comments, obtained from survey respondents, reveal that the major issue is the rescheduling of patients and making time for the inspection during office hours.

- "Provide enough time, since we have >2 months schedule filled, difficult to cancel patients."
- "One week for a diagnostic center is not enough time to reschedule biopsy and diagnostic patients as well as clinic's Dr. appointments."
- "The person scheduling the inspector was adamant about the date. I was on vacation and he would not put the inspection off a couple of days."
- "Just enough advance notice to schedule an open day"
- "Due to full MMG schedule we need at least 30 days to block time for inspection so it doesn't interfere with patient care."

Table 5.2 illustrates percentages regarding items dealing with the usefulness of pre-inspection materials.

Table 5.2: Pre-Inspection Process (Usefulness of Materials)

Survey Item	Percentage of Facilities Rating 6 or 7	Percentage of Facilities Rating 3 thru 5	Percentage of Facilities Rating
5a. How useful were the following publications and resources in preparing for the inspection: Mammography Matters? 1 (Not useful at all) 7 (Very Useful) (N = 625)	60.6	38.1	1.3
5b. How useful were the following publications and resources in preparing for the inspection: Federal Register? 1 (Not Useful At All) 7 (Very Useful) (N = 501)	35.5	51.9	12.6
5c How useful were the following publications and resources in preparing for the inspection: MQSA Internet Homepage? 1 (Not Useful At All) 7 (Very Useful) (N = 61)	26.2	41.0	32.8
5d How useful were the following publications and resources in preparing for the inspection: FDA/MQSA Hotline 1 (Not Useful At All) 7 (Very Useful) (N = 312)	32.4	51.3	16.3
5e How useful were the following publications and resources in preparing for the inspection: FDA -Medical Physicist's Annual Survey Requirements? 1 (Not Useful At All) 7 (Very Useful) (N = 619)	50.5	42.9	6.6
5f How useful were the following publications and resources in preparing for the inspection: Information provided directly from inspector when the inspection was scheduled? 1 (Not Useful At All) 7 (Very Useful) (N = 581)	65.1	29.4	5.5
5g How useful were the following publications and resources in preparing for the inspection: "What mammography facility should do to prepare..." packet 1 (Not Useful At All) 7 (Very Useful) (N = 569)	70.5	27.6	1.9
6. To what extent were staff members able to utilize these publications and resources to prepare to the inspection? 1 (Not At All) 7 (A Great Deal) (N=637)	47.2	47.9	4.9
7. When using the 1-800 FDA/MQSA Hotline, how would you rate the FDA's responsiveness to your questions and/or comments 1 (Poor) 7 (Excellent) (N=271)	48.7	48.0	3.3

As Table 5.2 demonstrates, Usefulness of Pre-Inspection materials is rated relatively low depending on the item. The range of respondents rating these items either "6 or 7" varied from 26.2% to 70.5%. Only Item 5g attained a reasonable standard of 70% (rating "6 or 7"). Very few facilities rated this information at the lowest level ("1 or 2"). Most other respondents rated these materials in the midrange (27.6% to 51.3%) which represents an opportunity for FDA to improve communications. As the following representative comments show, most respondents would like to be kept "up-to-date" with what the inspection requires and have this information communicated in laymen's terms.

- "A more; TO THE FACT of what is needed by us; AN OUTLINE, rather than pages and pages of explaining and notification of any changes!!"
- "If there are any changes - let us know immediately by sending a flyer. Some wording in the Federal Register was wordy and unclear. Spell everything out. Let us know exactly what you want."
- "Annual, detailed checklist - this would help ensure all materials ready for inspection & speed inspection."
- "1. Please use simple language 2. When the hotline is called occasionally they do not know the answer or what is required 3. Please update all inspectors on what is required - each one checks for different priorities."
- "The Federal Register, as talking with other mammographers, is more on a "lawyers" level. It would be helpful to have something written in "lay" terms."

Table 5.3 shows means and percentages of items concerning the inspection process.

Table 5.3: Inspection Process

Survey Item			Average
9. How many mammography units do you have at your site? (N=674)			1.4
10. On average, how many mammograms does your site perform on a daily basis? (N=658)			16.2
11. Approximately how many mammograms did your facility perform on the day of the inspection? (N=647)			8.7 daily
12. How many hours did the complete inspection take at your facility? (N=658)			5.7 hours
Survey Item	**Percentage of Facilities Rating 6 or 7**	**Percentage of Facilities Rating 3 thru 5**	**Percentage of Facilities Rating 2 or 1**
13. How do you feel about the time your equipment could not be used because of the inspection? 1 (Excessive) 7 (Minimal) (N = 665)	69.4	26.8	3.8
14. Thinking back to your FIRST MQSA inspection, how would you rate the inspection process at that time? 1 (Poor) 7 (Excellent) (N = 614)	45.8	48.5	5.7
15. Now thinking of your MOST RECENT MQSA inspection, how would you rate the inspection process? 1 (Poor) 7 (Excellent) (N = 642)	75.5	23.7	.8

Based on Table 5.3, the inspection process and the time it takes to complete the inspection meet the Booz·Allen set standard of 70%. Most respondents (69.4%) rated the time required to complete the inspection (average = 5.7 hours) in the minimal range ("6 or 7"). In addition, 75.5% of facilities rated the most recent inspection in the excellent range, an improvement of 29.7% over the FIRST MQSA inspection. Very few respondents recorded comments for this section of the survey; however, the following comments are representative of facilities recommendations for standardizing the process.

- "More consistency on the part of the inspectors as to what they are looking for in some areas. Not always the same. You follow one person and it's wrong for the next inspector."
- "All inspectors do not interpret the rules identically - forms that other inspectors accepted were not accepted by our inspector."
- "It appears each inspector interprets regulations differently. Continuity would make inspection less nerve racking."

Table 5.4 presents percentages concerning the inspector's demeanor and performance (professionalism, timeliness, etc.).

Table 5.4: Inspector

Survey Item	Percentage of Facilities Rating 6 or 7	Percentage of Facilities Rating 3 thru 5	Percentage Facilities Ratin
17a. To what extent was the person who inspected your facility: polite/ courteous/respectful? 1 (Not At All) 7 (Very) (N = 670)	91.0	8.6	.40
17b. To what extent was the person who inspected your facility: helpful? 1 (Not At All) 7 (Very) (N = 669)	87.5	11.3	1.2
17c. To what extent was the person who inspected your facility: knowledgeable about mammography? 1 (Not At All) 7 (Very) (N = 664)	80.7	18.2	1.1
17d. To what extent was the person who inspected your facility: knowledgeable about the inspection process? 1 (Not At All) 7 (Very) (N = 670)	88.0	11.7	.3
17e. To what extent was the person who inspected your facility: accommodating with respect to patient scheduling? 1 (Not At All) 7 (Very) (N = 655)	86.6	12	1.4
17f . To what extent was the person who inspected your facility: prepared with the equipment needed for the inspection? 1 (Not At All) 7 (Very) (N = 670)	93.5	6.1	.4
22. How would you feel about the same inspector evaluating your agency again? 1 (Very Uneasy) 7 (Very Comfortable) (N = 668)	87.7	10.7	1.6

Survey Item	Yes
18. Did the inspector volunteer a phone number to contact him/her, at the time the inspection appointment was made? (N=615)	97.6
19. Did the inspector arrive at the scheduled time? (N = 658)	94.7
20. Was the inspector completed in the amount of time you were told to expect? (N = 643)	95.0
21. Did the inspector answer your questions (N = 659)	98.9
23. Is the 1-800 FDA/MQSA Hotline a good way to provide feedback to FDA about inspectors? (N = 235)	94.9

As Table 5.4 demonstrates, the facilities rated the inspectors high on all items with every item attaining the 70% standard. In fact, the range for Items 17a to 17f, and Item 22 varied from 80.7% to 93.5% in the "6 or 7" range. The remaining items in Table 5.4 were dichotomous (yes/no) items. Respondent ratings were also highly favorable for these items, ranging from 94.7% to 98.9% ("yes"). Similar to the data presented in Table 5.4, the following representative comments were highly favorable concerning the inspectors.

- "Our inspector is excellent. One reason I believe for this is she had spent years as a technician herself. "If you can walk the walk, you can talk the talk!"
- "No suggestions. Our inspection went smoothly, and our inspector was very informative and helpful."
- "The inspector was very professional and helpful."

Other respondents felt that the inspectors should follow more standardized criteria.

- "Have people who understand mammography and know what they are doing. Standard MQSA manual, so everything is centralized and familiar"
- "Again, I feel the inspection should be more standardized, with each inspector requiring to see the same information on a specific form."
- "More consistency amongst the various inspectors. Elimination of recommendations that are not within the MQSA guidelines."

Table 5.5 shows items associated with the inspection results.

Table 5.5: Inspection Results

Survey Item	Percentage of Facilities Rating 6 or 7	Percentage of Facilities Rating 3 thru 5	Percentage o Facilities Ratin or 1
25. Test results were provided in the inspection report. How useful were these results in identifying areas for improvement? 1 (Not At all) 7 (Entirely) (N = 697)	71.5	27.0	1.51
26. Did you feel that the results were valid? 1 (Not At All) 7 (Entirely) (N = 645)	80.9	18.5	.6
28. How well did the cover letter, concerning the inspection report, explain how to respond to the inspection findings? 1 (Very Poorly) 7 (Very Well) (N=609)	88.0	11.7	.3
29. To what extent, if any, do you feel the information provided by the inspector will help you prepare for the future inspections? 1 (Not At All) 7 (Entirely) (N = 662)	73.7	23.7	2.6
30. To what extent, if any, do you feel the inspection was educational? 1 (Not At All) 7 (Entirely) (N = 661)	57.6	38.1	4.3
31. To what extent, if any, do you feel the inspection was beneficial to your facility (was a positive experience)? 1 (Not At All) 7 (Entirely) (N = 666)	63.5	32.3	4.2

As Table 5.5 demonstrates, the facilities rated the inspection results relatively high on all items. With the exception of questions 30 and 31, all items attained the 70% standard. The range for items achieving ratings of "6 or 7" was 57.6% to 88%. The fact that considerably fewer facilities considered the inspection highly "educational" or "beneficial" (Items 30 and 31, respectively) represents an area for improvement in the inspection process as well as the results provided. Likewise, the comments provided by respondents did not dispute the accuracy of the results, but instead focused on the process as a nuisance. Virtually, nothing is mentioned about the possible benefits or educational value of the inspections.

- "I am sure that there are other facilities in our same situation that would rather have one inspection a year lasting two days than five inspections scattered."

- "Numbers are correct. [But], if we have to keep processor strips and plot graphs why doesn't someone check them?"

Table 5.6 shows items dealing with the billing process associated with the inspections.

Table 5.6: Inspection Billing

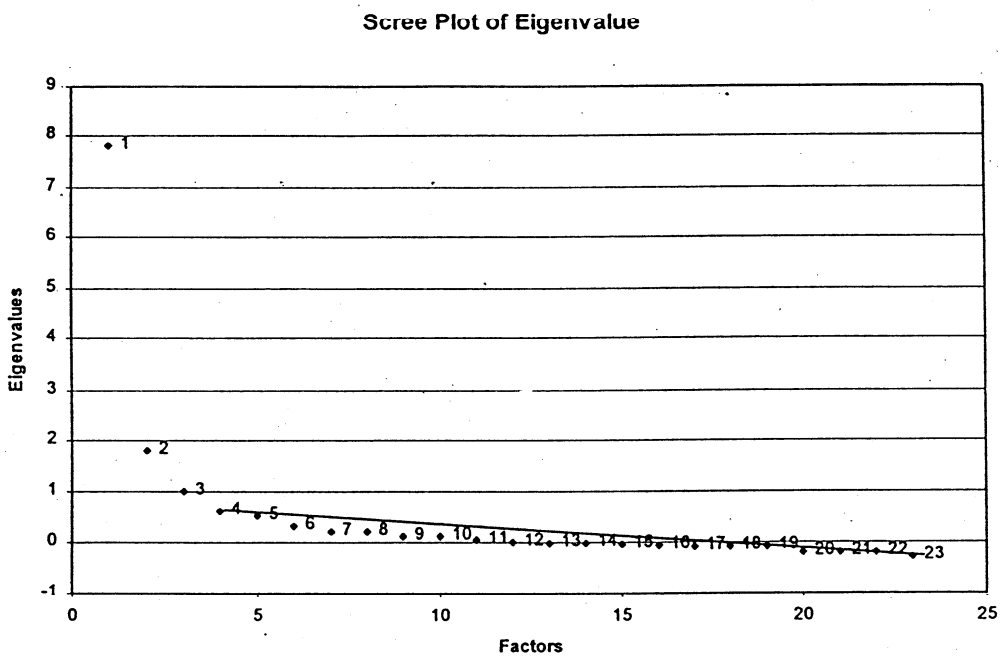
Survey Item	4 weeks or less	8 weeks or less	9 weeks or greater
33. How long did it take to receive the bill for your most recent inspection? (N = 189)	75.1	16.9	8.0
Survey Item	**Yes**		**No**
34. Were you billed accurately? (N=444)	97.1		2.9

As shown in Table 5.6, inspections are billed in a timely and accurate manner relevant to the 70% standard. Respondents did not provide any written comments concerning the billing of inspections.

5.2 FACTOR ANALYSIS

The factor analysis revealed three potential factor solutions. In order to determine the appropriate number of factors, the scree plot presented in Figure 5.1 was used to narrow the possible solutions to two or three factors.

Figure 5.1: Scree Plot



According to this scree plot the factors level off after three factors, indicating that there is very little gain in attempting to establish more than a three-factor solution.

This finding was further supported by examining the actual eigenvalues and variance explained for each factor solution. Table 5.7 outlines the variance explained and shows the rationale behind using the three-factor solution over the two-factor solution.

Table 5.7: Variance Explained

	Factor 1- Inspector Quality	Factor 2- Inspection Usefulness	Factor 3- Usefulness of Pre-Inspection Preparation Materials
Eigenvalue	7.8	1.8	1
Variance Explained	69.9	15.9	8.9
Cumulative Varience Explained	69.9	86.9	94.8

As shown in Table 5.7 the two-factor solution accounts for 86.9 percent of the variance, while the three-factor solution accounts for 94.8 percent of the variance. In addition, the three factor solution provides a greater level of interpretative detail by splitting inspection usefulness into two categories: Inspection Usefulness and Usefulness of Pre-Inspection Preparation Materials. Based on these findings and comparisons of the rotated factor structures for the two, three and four factor solutions, (see Appendix H), the three-factor solution was chosen as the most relevant and valid factor structure for the survey. Table 5.8 outlines the specific items that load on each of the three factors.

Table 5.8: Rotated Factor Structure - 3 Factor Solution

Rotated Factor Pattern - 3 Factor Solution			
	Item Loading		
Survey Item	Factor 1- Inspector Quality	Factor 2- Inspection Usefulness	Factor 3- Usefulness of Pre-Inspection Preparation Materials
Inspector - Helpful	***85****	10	1
Inspector - Polite/Courteous/Respectful	***79****	3	-2
Inspector - Knowledgeable about Inspection	***76****	15	5
Comfort Level for Having Inspector Back	***74****	15	-1
Inspector - Knowledgeable about Mammography	***73****	14	2
Inspector Prepared with Equipment	***73****	5	2
Inspector - Accomodated with Schedule	***64****	15	3
Rating for the Most Recent Inspection	***58****	27	5
Equipment Down Time	***35****	21	5
Test Results Useful for Improvement	4	***70****	4
Inspection was a Positive Experience	21	***69****	9
Inspection was Educational	17	***65****	8
Information Will be Useful for Next Inspection	24	***63****	4
The Test Results are Valid	15	***59****	-1
Cover Letter Communicates Action	6	***52****	2
Usefulness of Information from Inspection	17	29	24
Rating for the First Inspection	14	24	3
Time to Prepare	9	23	5
Usefulness of Mammography Matters	-2	-4	***60****
Staff Utilization of Publications and Resources	3	8	***59****
Usefulness of Packet "What a Facility..."	5	11	***58****
Usefulness of Physicist Survey	3	12	***54****
Usefulness of Federal Register	-1	3	***50****

** Factor Loadings of 30 or Greater Were Used for Interpretation*

As Table 5.8 illustrates, items dealing with inspector quality loaded highest on Factor 1, items dealing with the usefulness of the inspection loaded highest on Factor 2 and items dealing with the usefulness of pre-inspection preparation materials loaded highest on Factor 3.

5.3 ANALYSIS OF VARIANCE (ANOVA)

Once the three-factor solution was interpreted and judged to be valid, each facility's factor scores were saved (only facilities with consistent data on each factor could be included). These factor scores were used to determine what differences existed between different types of facilities [as evidenced by other survey items or through data derived from the MPRIS database (see Appendix E)]. The results of these ANOVAs revealed several significant differences among facilities depending upon the factor. The following findings are organized according to the types of characteristics/responses of the facilities (independent variables).

Inspector Experience

The factor scores for Factor 2 (inspection usefulness) were significantly different as a function of the number of inspections an inspector had performed ($p < .05$).

- Facilities where inspections were conducted by inspectors who had performed more than 10 previous inspections (N=75) rated inspection usefulness significantly higher than in facilities where inspectors had conducted less than 5 previous inspections (N=79).

Timeliness of Inspection

The factor scores for Factors 1 and 2 (inspector quality and inspection usefulness) were significantly different as a function of the amount of time an inspector took to complete an inspection ($p < .05$).

- Facilities where inspectors took less than 5 hours to complete an inspection rated inspector quality significantly higher (N=116) than those where inspectors took between 5 and 10 hours to complete inspections (N=80).

- Facilities where inspectors took less than 5 hours to complete an inspection rated inspection usefulness significantly higher (N=116) than those where inspectors took between 5 and 10 hours to complete inspections (N=80).

  - It should be noted that inspector experience is mildly related to inspection timeliness. Specifically, the more inspections an inspector has performed, the

less time it takes him or her to perform an inspection (r = -.08; p < .05; N = 658).

The factor scores for Factors 1 and 2 (inspector quality and inspection usefulness) were significantly different as a function of whether or not the inspection was completed in the amount of time expected (p < .05).

- Where inspections were completed within the time expected (N=195) respondents rated inspector quality significantly higher than in those facilities where inspections were not completed within the time expected (N=11).

- Where inspections were completed within the time expected (N=195) respondents rated inspection usefulness significantly higher than in those facilities where inspections were not completed within the time expected (N=11).

Due to the small number of facilities where inspections were not completed within the time expected, the aforementioned ANOVA findings should be interpreted with caution.

Inspector Courtesy

The factor scores for Factor 1 (inspector quality) were significantly different as a function of whether or not the inspector arrived when scheduled (p < .05) and "The number of days notified of the inspection" (p < .05).

- Facilities where inspectors arrive when scheduled (N=197) rated inspector quality significantly higher than those where inspectors arrived behind schedule (N=12).

  - Due to the small number of facilities where inspectors did not arrive on schedule, the aforementioned ANOVA finding should be interpreted with caution.

- Where at least 5 days notice was given before the inspection (N=78) facilities rated inspector quality significantly higher than where only 4 days notice was given (N=56).

Other Characteristics

The factor scores for Factors 2 and 3 (inspection usefulness and usefulness of pre-inspection preparation materials) were significantly different as a function of the region (according to the U.S. Census) where facilities were located (p < .05).

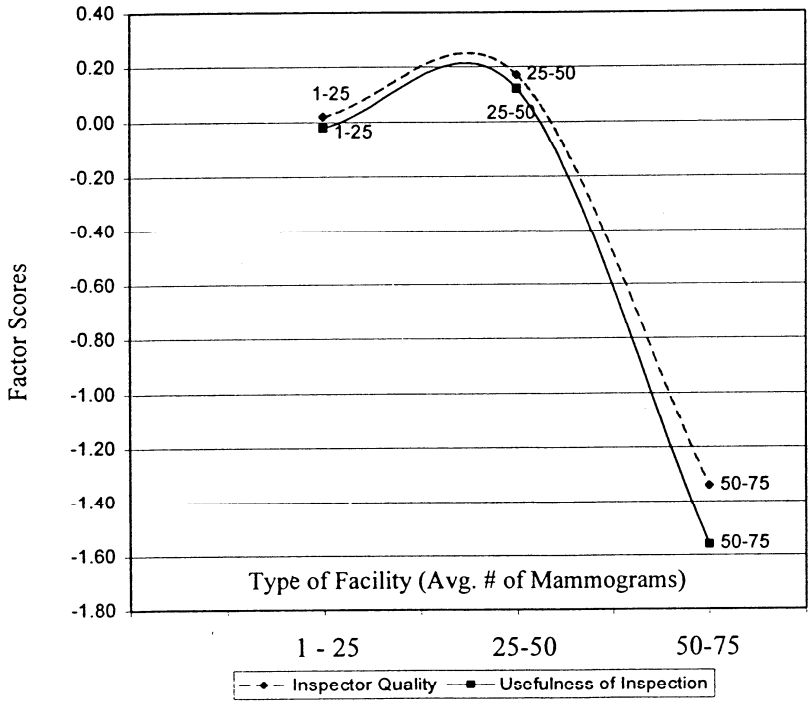
- Facilities in the South (N=73) rated inspector quality higher than those in the Northeast (N=44).

- Facilities in the Northeast (N=44) and the South (N=73) rated the usefulness of pre-inspection preparation material higher than facilities in the West (N=34).

The factor scores for Factors 1 and 2 (inspector quality and inspection usefulness) were significantly different as a function of the average number of mammograms performed daily ($p < .05$).

As demonstrated in Figure 6.1, a curvilinear relationship exists between inspector quality, inspection usefulness and the average number of mammograms conducted daily. Figure 5.2 illustrates this relationship.

Figure 5.2: Average Number of Mammograms Daily by Factor Scores (1 and 2)



- Facilities where 25 to 50 (N=29) mammograms were performed daily rated inspection usefulness significantly higher than facilities where 1 to 25 (N=178) mammograms were performed daily.

- Facilities where 25 to 50 (N=29) mammograms were performed daily rated inspection usefulness significantly higher than facilities where greater than 50 (N=6) mammograms were performed daily.

- Facilities where 1 to 25 (N=178) mammograms were performed daily rated inspection usefulness significantly higher than facilities where greater than 50 (N=6) mammograms were performed daily.

- Facilities where 25 to 50 mammograms were performed daily (N=29) rated inspector quality significantly higher than facilities where greater than 50 (N=6) mammograms were performed daily. (Inexplicably, this relationship was only found in this specific case. This is in contrast to the inspection usefulness factor, for which there were statistically significant differences for all levels of the variable "number of mammograms performed daily.").

Due to the small number of facilities conducting greater than 50 mammograms, the aforementioned ANOVA findings should be interpreted with caution.

6. DISCUSSION

This section outlines the conclusions and recommendations derived from the findings of the Mammography Quality Standards Act (MQSA) Inspection: An Assessment of Facility Experiences and Opinions Survey.

6.1 CONCLUSIONS

The survey results interpreted with respect to Booz·Allen's performance standards indicated that facilities were satisfied with most of the major areas addressed by the survey, especially the pre-inspection process, the inspection process, the inspector and billing. Based on analysis of the data relevant to a reasonable standard (70% favorable ratings) and FDA-based benchmarks two areas of concern were found.

- Despite receiving sufficient notification of upcoming inspection, (69.1% received greater than 10 days notice), facilities indicated that they would like to receive an average of 16.4 days notice (only 38.9% received this level of notice). This would allow them time to reschedule patients around the inspection (based on qualitative data).

- The usefulness of materials provided to facilities in order to help them prepare for the inspection process was rated low (facilities rating these items "6 or 7" ranged from 26.2% to 70.5%)

Facilities felt strongly that the inspection process improved considerably from the first inspection to the most recent. It should be noted that there was a small positive correlation between the level of satisfaction with the most recent inspection and the level of noncompliance that the facility was evaluated to have received ($r = .29$; $p < .0002$; $N = 674$).

Specifically, inspection satisfaction was diminished when one's facility received a negative evaluation.

Nevertheless, as Table 6.1 illustrates, overall facility satisfaction (with the most recent inspection) is quite high, regardless of whether FDA- based benchmarks or the Booz·Allen-based 70% standard is applied.

Table 6.1: Comparison of First Inspection with Most Recent Inspection

Inspection	Meeting FDA Benchmarks	Exceeding FDA Benchmarks	70% rating 6 or 7
FIRST	81.9%	65%	45.8%
MOST RECENT	95%	90.8%	75.5%

In addition, the inspector was generally viewed as competent, professional, knowledgeable and courteous (ratings of "6 or 7" ranged from 80.7% to 93.5% for these types of items).

Based upon the factor analysis results, the facility inspection survey measures three dimensions: Inspector Quality, Inspection Usefulness and Usefulness of Pre-Inspection Preparation Materials. Using these factors, and results from survey items not included in the factor analysis [i.e., background items and data from the MPRIS database (see Appendix E for the specific items employed in this analysis)], numerous differences emerged among facilities. These findings depended upon the factor being considered. Based upon these findings the following conclusion can be reached concerning the three factors (Inspector Quality, Inspection Usefulness, and Usefulness of Pre-Inspection Preparation Materials).

- Inspection satisfaction ratings were greater for inspectors with greater experience conducting inspections (more than 10 previous inspections).
- Inspectors who completed inspections in a timely manner (less than 5 hours) provided both higher quality inspections and more useful information to facilities.
- Inspectors who do a better job of managing the facility's expectations (i.e., let them know how much time the inspection will take and then meet this goal) provided both higher quality inspections and more useful information to facilities.
- Courteous inspectors (those who arrived on schedule, gave sufficient notice of the inspection) provided a higher quality inspection.
- Facility perceptions of the usefulness of inspections and the usefulness of pre-inspection preparation materials vary depending on the region where a facility was located.

- Inspector usefulness was rated higher in the South than in the Northeast
- Facilities in the Northeast and the South found pre-inspection preparation materials more useful than did those in the West.

6.2 RECOMMENDATIONS

FDA should be pleased with the high levels of facility satisfaction with inspectors as well as the inspection process. Nevertheless, it is evident that inspection satisfaction rises dramatically from the first inspection to the most recent inspection. This could be due to the benefits of experience. On the other hand, it could be due to the facility having a better understanding of what is expected of them during an inspection, or a combination of both explanations. Booz·Allen recommends that the following initiatives be taken to address this issue.

- FDA should invest in experiential-based training featuring simulated inspections to provide inspectors with broader experience in varied inspection situations. Alternatively, FDA should allow new or less experienced inspectors (having conducted less than 10 inspections) to shadow or be mentored by more experienced inspectors (having conducted more than 10 inspections).

- FDA should establish a service level agreement process between inspectors and facilities so that both facilities and inspectors will know what to expect and what is expected from the inspection process. This process should be grounded by a standardized set of operating procedures to ensure that all inspectors are well versed in what to look for and all facilities know what they need to do to pass inspection.

  A service level agreement is a document or understanding that is formally developed between two parties (in this case the inspector and the facility) so that both will have a clear understanding of the service(s) that they are providing and or receiving. It is essentially a contract that states that the first party will provide the following services in the following ways and to which the second party agrees and is made fully aware of the benefits of such services.

One of the major findings of this study involved the low ratings of the usefulness of pre-inspection preparation materials. There was also some doubt concerning the educational value of the inspection process. Booz·Allen recommends that during their visit, inspectors spend some time reviewing pre-inspection materials with the facility representatives. At the beginning of each inspection, the inspector should explain what they are going to do and why. Inspectors should explain why each requirement is important to the certification process and how it can benefit facilities' patient care responsibilities. At the conclusion of

the inspection, inspectors should devote some time to answering questions which facility representatives may have concerning the inspection or the inspection process.

The FDA should conduct a best practice study focused on inspection usefulness and the usefulness of pre-inspection preparation materials by region.

- The study should focus on the South where both inspection usefulness and usefulness of pre-inspection preparation materials were rated high and the Northeast where usefulness of pre-inspection preparation materials was rated high.

- The objective of this study should be to determine why these regions received higher ratings and transfer these findings to the other regions by means of training or improving the materials, services or procedures.

The FDA should provide hands on customer service training to inspectors responsible for facilities having low factor scores in these areas.

Based on input from inspectors responsible for facilities with high factor scores, the FDA should develop standard procedures to promote inspector courtesy, timeliness and general interpersonal skills (i.e., notifying facilities or managing expectations).