APPENDIX II

Mammography Legislation

Appendix II-A

*Argentine Mammography Law**

* Taken from: Argentina, Ministerio de Salud y Acción Social. *Normas relativas a la instalación y funcionamiento de equipos generadores de rayos X*. Buenos Aires: MSAS; 1991. (Free translation).

Argentine Republic

National Executive Branch
Ministry of Health and Social Action

Standards regarding the installation and operation of x-ray generating equipment

Law N° 17 557/67
Decree N° 6.320/68
Decree N° 1.648/70
(Modification of Decree N° 6.320/68)
Resolution N° 2.680/68
Resolution N° 273/86
(Modification of Resolution 2680/68)
Directive N° 30/91
Resolution N° 631/90
Directive N° 259/91
Directive N° 560/91
Resolution N° 61/92

Buenos Aires
1993

Directive (SASPS) N° 560. 26 March 1991.

Having examined File 1-2020-24832/90-2. and
Considering

that mammography is a recognized method for the diagnosis of preclinical breast cancer;

that the survival rate depends on the stage at which the disease is diagnosed, the 5-year survival rate being more than 90% for stage I;

that the induction of breast cancer by ***ionizing radiation*** is probably a linear function of the ***absorbed dose***;

that it is essential that all ***exposures*** to ***ionizing radiation*** be kept as low as is reasonably achievable;

that the present action is taken in accordance with Article 19 of Decree N° 6320/68, a regulation under Law N° 17,557;

The Under Secretary of Health Services and Programs Administration therefore directs that:

Article 1 --- Mammographies shall be carried out in installations ***licensed*** to this end, in accordance with the provisions of Law N° 17,557, and they shall meet the technical specifications described in Annexes I and II, which are part of the present directive.

Article 2 --- The ***practices*** alluded to in the foregoing article shall always be conducted by a medical professional who possesses the required individual ***authorization*** (Article 17 of Decree N° 6320/68).

Article 3 --- Mammograms shall be interpreted by medical professionals who have received specialized training in this area in establishments recognized by the Ministry of Health and Social Action. Auxiliary personnel shall also have received training in mammography techniques in similar establishments

Article 4 --- Mammographies shall be performed only with dedicated radiological equipment specially designed for this purpose; the equipment shall have a target material, focal spot, and filtration suited to the image receptor utilized.

Article 5 Radiographic films with intensifying screens especially designed for mammography or Xerox systems shall be used as image receptors. In no case shall radiographic films without intensifying screens be utilized.

Article 6 --- Mammography equipment shall have a suitable breast compressor.

Article 7 --- The quality of the radiological images produced shall be verified periodically through the establishment of ***quality assurance*** programs. The programs shall monitor each phase of the operations of mammography installations and shall include quality management inspection techniques and procedures The

inspection techniques shall include monitoring, evaluation, and maintenance in optimum condition of all performance characteristics that can be defined, measured, and controlled. Administrative management procedures shall be aimed at ensuring that the techniques are implemented, that they are evaluated correctly, and that the necessary corrective measures are taken.

Article 8 --- The ***doses*** produced by techniques used in mammography shall be measured. The entrance values measured shall be converted to ***average mammary glandular doses*** using the conversion table in Annex II. It is recommended that the ***average glandular dose*** for breast tissue 4.5 cm thick not exceed 1 mGy for film-screen systems without antiscatter grids and 4 mGy for film-screen systems with antiscatter grids or Xerox systems ***Doses*** exceeding these values are not justified.

Article 9 --- The Advisory Commission on Mammography is hereby created; the Commission shall be made up of representatives of the technical areas of medical radiation physics at the national and provincial levels and representatives of the Argentine Societies of Mastology, Gynecology, Radiology, Diagnostic Imaging, and Radiation Therapy.

Article 10 --- The Commission shall be chaired by the Under Secretary for Health Services and Programs Administration or an official designated by him and shall be coordinated by the representative of the corresponding technical area at the national level.

Article 11 --- The Commission's functions shall be to advise the authorities and institutions concerned with mammography on matters relating to the subject and to promote further study with a view to updating the present standards.

Article 12 --- This directive shall be recorded, disseminated, published, transmitted to the National Bureau of Records, and filed.

Annex I

	Target Material	Focal Spot	Total Filtration
Mammography with film-screen	molybdenum	0.3-0.6 mm	0.03 mm Mo
Magnification technique*	molybdenum	0.1-0.3 mm	0.03 mm Mo
Xerox system	molybdenum	0.5-1.0 mm	1-1.5 mm Al

* requires low-ripple *generator* (triphase rectification or high frequency).

Annex II

Average mammary glandular dose, D_{gN}, per unit of *exposure* in air (rad/R)

(cGy/ 2.58 x 10^{-4} C kg^{-1})

Breast Thickness (cm)	Mo Target Half-Value Layer (mm Al)		W Target Half-Value Layer (mm Al)				
-	0.31	0.30	0.8	1 0	1.2	1.4	1.6
3 0	0.22	0.22	0 47	0 535	0.595	0.645	0 71
3.5	0.195	0 20	0.43	0 49	0.55	0.605	0.665
4.0	0.175	0.185	0.395	0 455	0.515	0.57	0.63
4.5	0.155	0.17	0.365	0.425	0.48	0.54	0 595
5 0	0 14	0.15	0 335	0.395	0.45	0.51	0.565
5 5	0 125	0.14	0 315	0.375	0.425	0 485	0.54
6.0	0 115	0.125	0 295	0.35	0.40	0 46	0 515
6.5	0.105	0 11	0.275	0 33	0 38	0.435	0 49
7.0	0.095	0 10	0.26	0 31	0.36	0.415	0 47
7.5	-	-	0.245	0 29	0.34	0 395	0.445
8 0	-	-	0.23	0.275	0.325	0 375	0 425

Appendix II-B

United States Mammography Law

Summary Review (1995) of the 1992

Mammography Quality Standards Act (MQSA)[*]

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* Taken from: United States, Food and Drug Administration, Division of Mammography Quality and Radiation Programs. *What a mammography facility should do to prepare for the MQSA inspection.* Rockville: FDA; 1995.

What a Mammography Facility should Do to Prepare for the MQSA Inspection

The Mammography Quality Standards Act (MQSA) of 1992 requires that, starting October 1, 1994, each facility conducting mammography in the United States (except those of the Department of Veterans Affairs) be certified by the Food and Drug Administration (FDA) and undergo an annual MQSA inspection.

This document gives an overview of the inspection procedures that will be followed. It also describes facility responsibilities and recommends actions that the facility may take prior to the inspection to minimize disruption and inspection time.

Each inspection will be scheduled with the facility in advance (at least 5 working days notice), will include equipment tests and records review, and will be followed by a summary report. The exception to advance scheduling will be in certain cases where FDA has reason to believe that conditions at the facility may present a threat to public health.

INTRODUCTION

MQSA requires that all mammography facilities:

- Meet quality standards for personnel, equipment, maximum allowable radiation ***dose***, ***quality assurance***, medical audit (system to track positive mammographic findings) and outcome analysis, and record keeping and reporting.
- Apply for and become accredited by an FDA-approved accreditation body. Currently, the American College of Radiology (ACR) and the States of Iowa, California, and Arkansas are FDA-approved accreditation bodies.

When a facility is accredited, the accreditation body notifies the FDA and the FDA issues an MQSA certificate to the facility. The facility must display the certificate where it can be viewed by mammography examinees (patients).

Since October 1, 1994, only certified mammography facilities may lawfully conduct mammography. Once certified, each facility must maintain its certified status by:

- Having an annual survey performed by a qualified medical physicist,
- Undergoing periodic audits and/or clinical image reviews by the accreditation body,
- Permitting an annual inspection conducted by an FDA-certified MQSA inspector,
- Paying an inspection fee (and re-inspection fee, where applicable), and
- Correcting any deficiencies found during inspections.

Since October 1, 1994, the Health Care Financing Administration (HCFA) has been accepting MQSA certification as evidence of compliance with mammography quality standards. Only MQSA certified facilities will receive Medicare/Medicaid payment for screening and diagnostic mammography.

FACILITY INSPECTION

Certified MQSA inspectors will check the facility's compliance with MQSA quality standards during each inspection, and any deficiencies found must be corrected. The quality standards were published as federal regulations in the December 21, 1993 issue of the *Federal Register* and amended in the September 30, 1994 issue, and were previously mailed to all mammography facilities. The required records listed in this document are based on these standards. Items and issues in the required records that are not specifically addressed in the standards, are based on FDA policy and interpretative guidelines.

To keep inspection costs to a minimum without compromising the quality required by MQSA, the scope of the MQSA inspection will be limited to items that have the most direct bearing on facility performance and mammographic quality. However, in order to eliminate the need for a separate and additional State mammography inspection, some States may add to the MQSA inspection some elements that are required by their State laws. Facilities should be aware of their State radiation control program requirements.

MQSA inspection procedures are designed to cover the following areas:

- Equipment performance (including image quality and ***dose***)
- ***Quality Assurance (QA)*** records
- ***Quality Control (QC)*** records and tests
  - Technologist tests
  - Medical physicist's annual survey report
- Medical audit and outcome analysis records
- Medical records (mammography reports and films)
- Personnel qualification records

Based on the scope of the tests and records review outlined below and our experience with MQSA inspections to date, the average on-site inspection time for a facility with a single ***x-ray*** unit is estimated to be about six hours.

We estimate that the inspector will require one hour to test each mammography ***x-ray*** unit and darkroom/film processor combination. The remainder of the inspector's time will be spent reviewing facility records. We recommend that you schedule a block of time for the testing of each ***x-ray*** unit and film processor combination to help minimize any inconvenience to patient care from the inspection process. For the remainder to the inspection time, staff may conduct their usual duties but should be available during the records review portion, should the inspector have questions or need assistance.

PRIOR NOTIFICATION

A facility normally will receive at least five business days advance notice before an inspection. The inspector will schedule a mutually agreeable inspection date. FDA recommends that the facility prepare for the inspection in advance, primarily by assembling in one location the records the inspector will need to review, such as ***QA/QC*** records, medical audit and outcome analysis records, the physicist's report and personnel qualification records. These records are described more fully below Organizing these records before the inspector arrives will minimize disruption to services and avoid searching for documents during the

inspection. Whenever possible, certified MQSA inspectors have been advised to hold off any questions they have until the end of the inspection, in order to allow facility personnel to attend to their normal duties for most of the day.

SCOPE OF THE INSPECTION

At the outset of the inspection, the inspector will meet briefly with a facility representative(s) who is referred to in our program as the "Facility Contact," such as the radiology administrator, radiologist, chief technologist or ***QC*** technologist, to verify preliminary facility information. The inspector will then briefly review the inspection agenda with that person(s). When the inspection is completed, the inspector will again meet with the facility representative(s) to review inspection results.

INSPECTION DATA COLLECTED

The inspection will cover the tests and records review outlined below and will use a laptop computer and an inspection software program to input inspection data. The order in which the tests and records review are performed may be varied to minimize interruption of the facility's normal schedule [1]

Equipment tests

These tests should take about one hour per ***x-ray*** unit/processor. For most of the tests, the inspector will use the facility's film and cassettes with technique factors that the facility normally uses for their average breast examination. The inspector will request assistance from one of the facility's technologists in setting-up technique factors, operating the equipment, and any other preparatory work needed for each of the following tests:

1. Collimation Assessment (***x-ray*** field/image receptor and image receptor/compression device alignments).
2. Entrance Skin ***Exposure*** and ***Exposure*** Reproducibility.
3. Beam Quality (***half-value layer*** [HVL]) Measurement (this test and the previous one are used for ***dose*** calculation).
4. ***Phantom*** Image Quality Evaluation (including ***phantom*** scoring).
5. Processor Evaluation and Darkroom Fog.

Records

Quality Assurance (QA) Program The ***QA*** program should include the following information (Ref 1992 and 1994 ACR *Mammography Quality Control [MQC] Manual*, radiologist's section):

1. Personnel responsibilities and procedures for ***QA/QC*** testing (procedures used may be the same as those contained in the ACR MQC Manual).
2. Procedures for equipment use and maintenance (equip. owner/operator's manual) for both the ***x-ray*** units(s) and processor(s).

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[1] Contents of the data entry screens used by the inspector are shown at the end of the document where this appendix was taken from, but are not reproduced here.

3. Equipment service records (***x-ray*** unit(s) and processor(s)).
4. Mammographic technique charts, including information pertinent to optimizing mammographic quality, such as positioning and compression.
5 Any other ***QA***-related written policies, procedures, and records.

Quality Control (QC) Tests. Records of the 11 tests/tasks listed below should be available (Ref. 1992 & 1994 ACR *MQC Manual*, technologist's section). We expect facilities not to take clinical images when any critical parameter that monitors the daily performance of the processor, exceeds action ***limits***. Also, the repeat analysis test should be conducted quarterly and should include all the films taken in the quarter regardless of how many patients were examined in the quarter. In general, the facility's ***QC*** records should show that all tests were:

- conducted at the appropriate frequencies,
- conducted properly (using parameter values as recommended in the ACR manuals),
- followed by documented corrective actions when necessary.

The inspector will review past records (1) over the indicated period listed for each, or (2) back to the date of the original accreditation, whichever is the shortest:

- The previous 12 months records for each of the following:
  1. Darkroom Cleanliness
  2. Processor ***Quality Control***
  3. Screen Cleanliness
  4. Viewboxes and Viewing Conditions
  5. ***Phantom*** Images
  6 Visual Check List
  7. Repeat Analysis
  8. Analysis of Fixer Retention in Film
  9. Darkroom Fog
  10. Screen-Film Contact
  11. Compression
- Actual sensitometric film strips for the previous 30 days of mammographic film processing and charting of the strips for the previous 12 months.
- ***Phantom*** images and charting for the previous 12 months.
- Images from screen-film contact and darkroom fog tests for the previous 12 months.

Mobile Mammography. The requirements for mobile radiographic units are the same as for fixed units. This means that the ***exposure*** and development of a ***phantom*** image after each relocation of a mobile unit and prior to patient ***exposure***, which was previously required for Medicare and Medicaid payment under the Health Care Financing Administration (HCFA), is no longer required under the MQSA interim final regulations.

Although the 1992 version of the ACR *MQC Manual* includes the recommendation that a ***phantom*** image be exposed after each relocation of a mobile unit, there was no suggestion that the image be processed and scored prior

to patient imaging. The 1994 version of the ACR manual does not include any recommendations on ***phantom*** images specific to mobile units. Therefore, the only ***phantom*** images required are those exposed monthly. Certified MQSA inspectors will simply ask to see records of the monthly ***phantom*** images for a mobile unit, just as for a fixed unit.

Medical Physicist's Survey Report. The most recent annual report covering an evaluation of the 11 technologist's ***QC*** program tests and the 10 physicist's ***QC*** tests (Ref 1992 & 1994 ACR *MQC Manual*, medical physicist's section) for each ***x-ray*** unit.

Personnel Qualifications. The required records for each personnel category are listed below and must be available for the inspector to review (please refer to the Note following each professional category):

Interpreting Physician

1 License to practice medicine in the State, and
2. certificate in radiology or diagnostic radiology from any of the following boards:
   - The American Board of Radiology (ABR)
   - The American Osteopathic Board of Radiology (AOBR)
   - The Royal College of Physicians and Surgeons of Canada (RCPSC), or:

   Documented 2 months full-time training in mammography interpretation, including radiation physics, radiation effects, and radiation protection, and
3. Documents showing 40 hours of continuing medical education (CME) in mammography (time spent in residency specifically devoted to mammography can be included), and
4. Documents showing initial experience in reading/interpretation of mammograms from 240 patients during any 6 month period preceding October 1, 1994. Any such experience acquired after October 1, 1994, must be under the supervision of a qualified interpreting physician, and
5. Documents showing continuing experience in reading and interpreting mammograms from the examinations of an average of at least 40 patients per month over 24 months, and
6. Documents showing an average of five CME credits per year in mammography.

Note 1: Double reading/interpreting of mammograms, or summing of reading/interpreting from different facilities is permitted in calculating the total mammographic examinations for items 4 and 5 above.

Note 2: If documentation is not available for interpreting physicians, attestation will be acceptable for items 3 and 4 for CME and experience acquired prior to October 1, 1994.

Note 3 The starting date for meeting the requirements in items 5 and 6 above is the later of October 1, 1994 or the date the physician met the requirements in items 1-4 above

Note 4: Failure to meet the continuing experience requirement in item 5 above will not be considered a noncompliance until at least 2 years after the physician's starting date (as defined in note 3). Likewise, failure to meet the CME requirement in item 6 above will not be considered a noncompliance until 3 years after the physician's starting date. However, in order to be prepared for the future, the facility should begin keeping records on progress towards meeting the starting date requirements for each physician.

Radiologic Technologist

1. General/full ***license*** to perform radiographic procedures in a State, or Certificate from either one of the following two boards:
   - The American Registry of Radiologic Technologists (ARRT)
   - The American Registry of Clinical Radiography Technologists (ARCRT), (only general radiologic technology certification, not advanced certification in mammography, is required), and
2. Documents showing either:
   - training specific to mammography (40 credit hours or equivalent), or
   - one year experience in performing mammography (or 100 exams), and
3. Documents showing an average of five continuing education units (CEUs) per year in mammography.

Note 1. If documentation is not available for radiologic technologists, attestation will be acceptable for item 2 above for training or experience acquired prior to October 1, 1994.

Note 2: The starting date for meeting the CEU requirements in item 3 above is the later of October 1, 1994 or the date the technologist met the requirements in items 1 and 2 above.

Note 3: Failure to meet the requirements in item 3 above will not be considered a noncompliance until 3 years after the technologist's starting date. However, in order to be prepared for the future, the facility should begin keeping records on progress towards meeting the starting date requirements for each technologist.

Medical Physicist

1. a. State License, or:
   b. State Approval, or:
   c. Certificate in diagnostic radiological physics or radiological physics from either one of the following boards:
      - The American Board of Radiology (ABR)
      - The American Board of Medical Physics (ABMP), or:
   d i. M.S. degree or higher in one of the following fields: physics, medical physics, applied physics, biophysics, health physics, engineering, radiation science, or in public health with a BA/BS in physical science, and
      ii. Documents showing one year training in diagnostic radiologic physics, and

iii. Documents showing two years experience in mammography surveys (or 20 surveys), and

2. Documents showing an average of five (CMEs per year in mammography.

Note 1: If documentation is not available for medical physicists, attestation will be acceptable for items 1d.ii and 1d.iii for training and experience acquired prior to October 1, 1994.

Note 2: The starting date for meeting the CME requirements in item 2 above is the later of October 1, 1994 or the date the physicist met the requirement in item 1 above.

Note 3: Failure to meet the requirement in item 2 above will not be considered a noncompliance until 3 years after the physicist's starting date. However, in order to be prepared for the future, the facility should begin keeping records on progress towards meeting the starting date requirements for each physicist.

Medical Records

These are the examinee (patient) permanent records of mammography reports and films (mammograms).

Examinee (patient) Permanent Records (reports and films)

The inspector will randomly select records dated after October 1, 1994, to ensure that both films and reports are being retained at the facility or at another identifiable location.

Mammography Reports

The inspector will ask for a sample of a report that the facility sent (or would send) to a referring health care provider and a sample of a lay summary of positive mammographic findings that the facility sent (or would send) to a self-referred examinee (if the facility provides services to self-referred examinees). Additionally, the inspector will randomly select reports that were done after October 1, 1994, to verify that these reports have an interpreting physician identified (signed) and that they contain the results of the examination. The facility should also be prepared to explain its procedure for communicating test results to referring physicians and self-referred examinees.

Medical Audit and Outcome Analysis

Each facility must have a system to track positive mammographic findings and a process to correlate such findings with the biopsy results the facility has obtained. The audit system need not be computerized. "Positive" mammograms refer to mammograms interpreted as suspicious for cancer or highly suggestive of cancer or where biopsy is recommended. The minimum biopsy data, when obtained, should indicate if the specimen was benign or malignant. The inspector will examine the facility's tracking system and inquire as to how the facility obtains biopsy results. The inspector will also request to see examples of biopsy results that the facility has obtained or, if no biopsies were obtained, documentation of attempts to get this information.

AFTER THE INSPECTION

The inspector will review the results of the inspection with the facility representative(s) and either leave a summary of the inspector's findings with him/her, or mail this summary to the facility within two weeks. In some cases, the facility will be requested to respond to the FDA within 30 days after receiving the summary regarding its plans for correcting identified deficiencies. In other cases, the facility will be expected to correct the deficiencies, but will not be required to follow with a written response.

If major deficiencies are found, the facility will receive a letter from the FDA addressed to the facility's "Responsible Person." This should be a person who has the authority to make vital operational and financial decisions concerning corrective actions that are required to bring the facility into compliance. The letter will describe the deficiencies that need to be corrected. All deficiencies are expected to be corrected as soon as possible. When it is determined that the deficiencies found could affect mammographic quality directly, the facility should correct the deficiencies before conducting further mammography examinations. Facilities that continue to operate under deficient conditions are subject to certificate suspension and other sanctions.

FDA will bill each facility after the inspection. The bill is addressed to the facility's billing name (if different) and to the attention of the person responsible for paying the bills such as the accountant or financial officer. The bill is due 30 days after it is received by the facility. Certain "governmental entities" are exempt from the inspection fee. The inspection fee for fiscal year 1995 is $1,178 for a facility with one mammography unit, $152 for each additional unit and $670 for any follow-up inspections needed.[2] Facilities will receive information on inspection fees and governmental entity exemption criteria in a separate mailing. FDA is committed to improving nationwide mammography services. To this end, the FDA's objective is to ensure that all facilities achieve the minimum quality standards set by MQSA so that all women will receive quality mammography services.

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[2] Fees still in effect in 1997