

**New York State Department of Health
Bureau of Environmental Radiation Protection**

Guide for Radiation Safety/Quality Assurance Program in Small Facilities

Part II – Fluoroscopic Equipment

Introduction

A. Purpose

This guide describes the type and extent of information and standards by which the New York State Department of Health will evaluate fluoroscopic equipment as part of the Radiation Safety/Quality Assurance Program in Small Facilities. Requirements for radiographic equipment are described in Part I of this guide. Our Department has implemented this program to reduce radiation exposure and to optimize diagnostic image quality. It is our goal to assist facilities to be more actively involved and responsible for Quality Assurance in their practices. Facilities may substitute quality control tests if the tests are deemed equivalent by the Department prior to their implementation.

References can be found in the bibliography to assist you with test procedures and to answer questions not addressed in this brief guide.

B. ALARA (As Low As Reasonably Achievable)

The regulations in Part 16 and this guide have been established on the ALARA Principle to assure that the benefits of the use of ionizing radiation exceed the risks to the individual and the public health and safety.

C. Limits and Standards

The control limits and standards used in this guide have been taken from the Federal Performance Standard for Diagnostic X-ray Equipment, Part 16, and other references listed in the bibliography. **Equipment problems should be corrected and documented expeditiously and shall be corrected with appropriate documentation within sixty (60) days of discovery.**

D. Authority

The statutory authority for these rules and regulations is found in the New York State Public Health Law, Section 225. The Radiation Safety/Quality Assurance requirements are outlined in Sections 16.5 and 16.23 of Part 16 of Chapter 1 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations. Please note that this program is in addition to and does not replace other sections of Part 16, which pertain to your operation.

Radiation Safety/Quality Assurance Program

A. Radiation Safety/Quality Assurance Responsibility

The physician who registers the radiation equipment is responsible for radiation safety and quality assurance and the implementation of this program.

B. Records

1. Manual

Each facility will establish a manual that includes the following items:

- a. a list of the tests to be performed and the frequency of performance;
- b. the acceptability limits for each test;
- c. a brief description of the procedures to be used for each test;
- d. a list of the equipment to be used for testing; and
- e. sample forms to be used for each test.

2. Equipment Records

Records shall be maintained for each x-ray tube and include:

- a. the initial test results (acceptance testing and radiation safety survey as appropriate);
- b. the current year;
- c. one set of test results from each intervening year to show changes over time.
Records of repairs and other pertinent data shall also be available.

3. Fluoroscopic Exposure Rates for Selected X-ray Examinations

Fluoroscopic exposure rates for the patient phantoms specified in Section 16.58(a)(9) of Part 16 for the most common examinations shall be posted so that they are conspicuous to the operator of each fluoroscopic unit. These measurements will be repeated every two years.

4. QC Records for Test Equipment

For QC test equipment, which requires calibration, records shall be maintained and available for review.

5. Radiation Safety Policies and Procedures

The written policies and procedures must be available for the holding of patients, use of gonad shielding, pregnant patients and operators and personnel monitoring.

C. Equipment Monitoring

Each facility shall make or have made the following tests, at the frequency specified, and maintain records of the data. If at the time of inspection, significant equipment malfunctions are found the facility may be required to perform more frequent testing to ensure good diagnostic image quality. A list of tests can be found on page 9 of this guide.

This guide describes a basic Radiation Safety/Quality Assurance Program and represents only a portion of the Quality Control tests your facility may choose to perform as part of an individualized program.

Test Frequency – Annually

1. Collimators – Fluoroscopic

a. Image Receptor/X-ray Field Alignment

For certified image intensified equipment, the x-ray beam shall not exceed the visible area of the image receptor by more than 3% of the SID in any one dimension or by a total of 4% of the SID in both dimensions.

For non-certified image intensified equipment, the x-ray beam shall not exceed the dimensions of the 1/1 spot film.

For non-image intensified equipment, the x-ray field size shall not extend beyond the visible area of the image receptor.

b. X-ray Field/Spot Film Sizing

For those units with spot film devices, the exposed field of a collimated spot film shall be equal to or smaller than the format size chosen by the operator. The horizontal and vertical misalignment of the exposed field cannot exceed 3% of the SID in one of these dimensions, or 4% of the SID for both dimensions.

Example: A 8"x10" cassette is loaded into the spot film holder. A 4 on 1 format is selected. The exposed field size for the 4 on 1 format would be expected to be equal to or less than 4"x5" at the spot film plane.

2. Timer – Fluoroscopic

a. Certified equipment shall indicate with a signal audible to the operator the termination of a pre-set time interval, not to exceed five (5) minutes. When engaged, the signal must continue until the reset button is depressed.

- b. For uncertified equipment the passage of a pre-set time, not to exceed five (5) minutes, must be indicated by a signal audible to the operator or by an interruption of the fluoroscopic beam.

3. Exposure Rate Measurements

- a. Maximum exposure rates for certified fluoroscopic equipment manufactured before May 19, 1995:
 - Automatic Mode: 10 R/minute
 - Manual Mode: 5 R/minute
 - High Level Control (HLC) Mode: 5 R/minute (when not operating in HLC)
 - HLC Mode: 20 R/minute (when operating in HLC and not recording the image)
- b. Certified fluoroscopic equipment manufactured after May 19, 1995 and capable producing a radiation exposure rate in excess of 5 R/min must have automatic exposure rate control. Such equipment is limited to a maximum exposure rate of 10 R/minute.
- c. Certified fluoroscopic equipment manufactured after May 19, 1995 and having HLC must meet requirement 3(b). Such units are limited to 20 R/min when operating in HLC and not recording the image in a pulsed mode.
- d. Uncertified fluoroscopic equipment is limited to a maximum exposure rate of 10 R/min.
- e. The fluoroscopic exposure rate in automatic and/or manual mode must not exceed 5 R/min when measured with a patient equivalent phantom composed of 1½ inches of Type 1100 aluminum and 0.5 mm of copper or an equivalent device.

4. Fluoroscopic Image Evaluation

- a. Spatial Resolution

The spatial resolution of the fluoroscopic system shall be measured using a test tool composed of a line pair plate with discreet line pair groups and a maximum lead foil thickness of 0.1 mm or an equivalent device. The minimum spatial resolution at the center of the beam for a 6 inch field of view (FOV) is 2 line pairs per mm. The minimum spatial resolution for all other FOVs shall be determined by the following equation:

$$2 \text{ lp/mm} \times (6 \text{ inches/size of the FOV used}) = \text{minimum number of lp/mm.}$$

- b. Low Contrast Performance

The low contrast performance of the fluoroscopic system shall resolve a minimum hole size of 3 mm using a test tool composed of a 1.0 mm aluminum sheet with two sets of

four holes of dimension 1.0, 3.0, 5.0 and 7.0 mm and 1½ inches of Type 1100 aluminum or an equivalent device.

5. Spot Film Reproducibility

For those systems that possess spot film devices, the output recorded during the acquisition of a series of four exposures shall not have a difference greater than 10% among any of the exposure measurements. If any of the measurements differ by more than 10%, six additional exposure measurements must be made and the coefficient of variation of the exposure measurements must be calculated. The coefficient of variation shall be no greater than 0.05 and shall be determined by the equation:

$$\frac{S}{X} \leq 0.05$$

where X is the average of the exposure measurements and S is the standard deviation of the exposure measurements.

6. Interlocks

All interlocks shall forbid exposure when in the open position.

7. Half-Value Layer (HVL)

a. For certified equipment, the minimum HVL shall not be less than;

| X-ray Tube Voltage Designed Operating Range | kVp Measured | Al (mm) |
|---|-----------------|---------|
| Below 50 | 30 | 0.3 |
| | 40 | 0.4 |
| | 49 | 0.5 |
| 50-70 | 50 | 1.2 |
| | 60 | 1.3 |
| | 70 | 1.5 |
| | 71 | 2.1 |
| Above 70 | 80 | 2.3 |
| | 90 | 2.5 |
| | 100 | 2.7 |
| | 110 | 3.0 |
| | 120 | 3.2 |
| | 130 | 3.5 |
| | 140 | 3.8 |
| | 150 | 4.1 |

- b. For non-certified equipment the minimum aluminum equivalent of the total filtration in the useful beam shall not be less than:

| Operative kVp | Minimum Total Filtration (Inherent Plus Added) |
|---------------|---|
| Below 50 | 0.5 mm Al |
| 50-70 | 1.5 mm Al |
| Above 70 | 2.5 mm Al |

D. Log Book

Each facility shall maintain a log book or an equivalent record keeping system that contains the patient's name, date of exam, type of examination performed, the amount of fluoroscopic on-time and when applicable the reason for holding the patient.

E. Technique Chart

Each facility shall have an appropriate technique chart posted in a conspicuous location available for operators to consult. This chart shall include those factors necessary to perform overhead and spot films.

F. Protective Aprons, Gloves, and Shielding

Records shall be maintained that demonstrate aprons, gloves, and shields have been visually inspected for damage and checked fluoroscopically for cracks and other damage.

G. Equipment Operation

During the x-ray generator warm-up and before x-raying the first patient, the operator will check the fluoroscopy equipment for indicator malfunction and unsafe mechanical and electrical safety conditions. Suggestions for visual and manual checks would include, but are not limited to, evaluation of locks, power assistance, smoothness of movement, compression device, fluoroscopic timer, lead drapes, park position interrupt, fluoroscopic monitors, fluoroscopic shutters, switches, lights, and meters.

BIBLIOGRAPHY

1. Acceptance Testing of Radiological Imaging Equipment. Edited by Pei-Jan Paul Lin, AAPM-ACR-SRE, 1982.
2. A Basic Quality Assurance Program for Small Diagnostic Radiology Facilities. FDA 83-8210.
3. Calculation of Patient Skin Dose from Diagnostic X-ray Procedures. I.R. Edmons, British Journal of Radiology 57:733-734, 1984.
4. Checklist for Establishing a Diagnostic Radiology Quality Assurance Program. FDA 83-8219.
5. Quality Control in Diagnostic Radiology. American Association of Physicists in Medicine, Report 74, July 2002.
6. Medical Radiation Exposure of Pregnant and Potentially Pregnant Women, National Council on Radiation Protection and Measurements, (NCRP) No. 54, 1977.
7. National Conference of Referral Criteria for X-ray Examinations. FDA 79-8083.
8. Patient Radiation Exposure in Diagnostic X-ray Exposure: An Overview. FDA 79-8217.
9. Performance Specifications for Diagnostic X-ray Exposure. W.R. Hendee, et. al., Radiology 120, 490-412, 1976.
10. Physics of Medical Imaging, Edited by A. Haus, AAPM, 1979.
11. Quality Assurance in Diagnostic Imaging. Gray, et. al. University Park Press, Baltimore, 1983.
12. Quality Assurance for Diagnostic Imaging Equipment, National Council on Radiation Protection and Measurements (NCRP), No. 99, 1988.
13. Regulations for the Administration and Enforcement of the Radiation Control for Health and Safety Act of 1968. USDHHS, April 2003.
14. Title 10 Official Code of Rules and Regulations for the State of New York Chapter 1, Part 16, "Ionizing Radiation", February 2004.

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APPENDIX A

Quality Control Tests for Fluoroscopic Equipment

Each Day of Operation

Equipment functioning
Indicators and mechanical and safety checks

Annual

Collimator
X-ray field-image receptor alignment
X-ray field-spot film sizing

Fluoroscopic Timer

Tabletop Radiation Output Measurements

Fluoroscopic Image Evaluation
Spatial resolution
Low contrast performance

Spot Film Reproducibility

Interlocks

Half-Value Layer

Aprons, gloves and drapes

APPENDIX B-1

Policy and Procedures for Patient Holding

The facility shall include the following information in its Policy and Procedures Manual item for those situations where patient holding may be necessary:

1. A list of the x-ray projections where holding devices cannot be utilized;
2. Who will hold;
3. The existing restraining devices available;
4. The use of protective garments; and
5. Where to find the log of those individuals who hold. This log will include date, number of views, and the name of the holder, their exposure and the reason holding was necessary.

APPENDIX B-2

Policy and Procedures for Pregnant Workers

The facility must use the requirements in Part 16 of 10NYCRR to establish their Policy and Procedure Manual item regarding pregnant employees.

The following information shall be included:

1. The method of instructing workers as to the requirements of Sections 16.2(a)(29) and 16.6(h) of Part 16 with regard to voluntarily declaring a pregnancy.
2. The method of ensuring that the embryo/fetus of a declared pregnant worker does not receive a monthly total effective dose equivalent of more than 50 mrem and total dose for the gestation period of more than 500 mrem.
3. The method of informing declared pregnant workers of their monthly exposure and total exposure for the gestation period.
4. The facility policy regarding work assignments for declared pregnant workers.

APPENDIX B-3

Policy and Procedures for Pregnant Patients

The facility shall include the following information in its Policy and Procedures manual item regarding pregnant and potentially pregnant patients:

1. Method of establishing which patients may be pregnant;
2. Policy for determining need for x-ray examination in pregnant patients;
3. X-ray techniques for minimizing fetal exposure;
4. Method of determining exposure to fetus; and
5. Procedures to be followed in advising the woman and her practitioner of the exposure received by the fetus.

APPENDIX B-4

Policy and Procedures Regarding the Use of Gonad Shielding

The facility must use the requirements contained in Section 16.53(b)(6), 16.56(c)(3) and 16.57(c)(2) of Part 16 and may use the information provided in the attached Federal regulations for the administration of the "Radiation Control of Health and Safety Act of 1968" to establish their Policy and Procedures Manual item regarding the use of gonad shielding.

The following information shall be included:

1. The x-ray examinations which require gonad shielding;
2. The method(s) of shielding available; and
3. The age limit for use of gonad shielding.

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 1000--GENERAL

Subpart C--Radiation Protection Recommendations

Sec. 1000.50 Recommendation for the use of specific area gonad shielding on patients during medical diagnostic x-ray procedures.

Specific area gonad shielding covers an area slightly larger than the region of the gonads. It may therefore be used without interfering with the objectives of the examination to protect the germinal tissue of patients from radiation exposure that may cause genetic mutations during many medical x-ray procedures in which the gonads lie within or are in close proximity to the x-ray field. Such shielding should be provided when the following conditions exist:

(a) The gonads will lie within the primary x-ray field, or within close proximity (about 5 centimeters), despite proper beam limitation. Except as provided in paragraph (b) or (c) of this section:

(1) Specific area testicular shielding should always be used during those examinations in which the testes usually are in the primary x-ray field, such as examinations of the pelvis, hip, and upper femur;

(2) Specific area testicular shielding may also be warranted during other examinations of the abdominal region in which the testes may lie within or in close proximity to the primary x-ray field, depending upon the size of the patient and the examination techniques and equipment employed. Some examples of these are: Abdominal, lumbar spine and lumbosacral spine examinations, intravenous pyelograms, and abdominal scout film for barium enemas and upper GI series. Each x-ray facility should evaluate its procedures, techniques, and equipment and compile a list of such examinations for which specific area testicular shielding should be routinely considered for use. As a basis for judgment, specific area testicular shielding should be considered for all examinations of male patients in which the pubic symphysis will be visualized on the film;

(3) Specific area gonad shielding should never be used as a substitute for careful patient positioning, the use of correct technique factors and film processing, or proper beam limitation (confinement of the x-ray field to the area of diagnostic interest), because this could result in unnecessary doses to other sensitive tissues and could adversely affect the quality of the radiograph; and

(4) Specific area gonad shielding should provide attenuation of x-rays at least equivalent to that afforded by 0.25 millimeter of lead.

(b) The clinical objectives of the examination will not be compromised.

(1) Specific area testicular shielding usually does not obscure needed information except in a few cases such as oblique views of the hip, retrograde urethrograms and voiding cystourethrograms, visualization of the rectum and, occasionally, the pubic symphysis. Consequently, specific area testicular shielding should be considered for use in the majority of x-ray examinations of male patients in which the testes will lie within the primary beam or within 5 centimeters of its edge. It is not always possible to position shields on male patients

so that no bone is obscured. Therefore, if all bone structure of the pelvic area must be visualized for a particular patient, the use of shielding should be carefully evaluated. The decision concerning the applicability of shielding for an individual patient is dependent upon consideration of the patient's unique anthropometric characteristics and the diagnostic information needs of the examination.

(2) The use of specific area ovarian shielding is frequently impractical at present because the exact location of the ovaries is difficult to estimate, and the shield may obscure visualization of portions of adjacent structures such as the spine, ureters, and small and large bowels. However, it may be possible for practitioners to use specific area ovarian shielding during selected views in some examinations.

(c) The patient has a reasonable reproductive potential.

(1) Specific area shielding need not be used on patients who cannot or are not likely to have children in the future.

(2) The following table of statistical data regarding the average number of children expected by potential parents in various age categories during their remaining lifetimes is provided for x-ray facilities that wish to use it as a basis for judging reproductive potential:

Expected Number of Future Children Versus Age of Potential Parent \1-----

| Age | Male parent | Female parent |
|---------------|-------------|---------------|
| Fetus..... | 2.6 | 2.6 |
| 0 to 4..... | 2.6 | 2.5 |
| 5 to 9..... | 2.7 | 2.5 |
| 10 to 14..... | 2.7 | 2.6 |
| 15 to 19..... | 2.7 | 2.6 |
| 20 to 24..... | 2.6 | 2.2 |
| 25 to 29..... | 2.0 | 1.4 |
| 30 to 34..... | 1.1 | .6 |
| 35 to 39..... | .5 | .2 |
| 40 to 44..... | .2 | .04 |
| 45 to 49..... | .07 | 0 |
| 50 to 54..... | .03 | 0 |
| 55 to 64..... | .01 | 0 |
| Over 65..... | 0 | 0 |

\1\ Derived from data published by the National Center for Health Statistics, ``Final Natality Statistics 1970,`` HRA 74-1120, vol. 22, No. 12, Mar. 20, 1974.

[41 FR 30328, July 23, 1976; 41 FR 31812, July 30, 1976]

APPENDIX B-5

Policy and Procedures of Personnel Monitoring

The facility using personnel monitoring shall include the following information in its Policy and Procedures manual:

1. The name of the person responsible for distribution, collection and records of badges;
2. The location of controls;
3. A prohibition against intentionally exposing the control or personnel badge; and
4. The location of records and policy regarding notification of personnel of exposures.

APPENDIX C-1

Low Contrast Performance

Low contrast performance refers to the ability of a system to image low contrast objects or structures. While high contrast resolution will suffer markedly from changes in focusing of the imaging components, it will not show significant changes when increases in quantum or electronic noise occur. Low contrast performance will be significantly degraded when electronic or quantum noise increases.

Test equipment required

1. Two three-quarter inch thick aluminum plates, 7 inch (18 cm) squares.
2. One sheet of 1.0 mm aluminum 7 inch (18 cm) square, with two sets of four holes ranging from 1 mm to 7 mm (one-sixteenth to one-fourth inch).

Procedure

Insert the hole-drilled aluminum sheet between the aluminum plates and place on top of the x-ray table (with mobile c-arms, it will be necessary to place the phantom directly on the image intensifier assembly). Place the image intensifier assembly approximately 12" away from the phantom. Collimate to the size of the phantom and allow the automatic brightness control to stabilize. The fluoro kVp should be approximately 80 kVp. At this point, it may be necessary to adjust the contrast and brightness on the TV monitor for the best visualization of the penetrometer holes. Both holes of the same size must be seen in order to count them as one hole set. Record the minimum hole size that is seen.

Results

Systems that are used for chest fluoroscopy, angiography and other low contrast procedures, require that the low contrast performance be optimal. Digital subtraction angiography, by its very nature, mandates the necessity for excellent low contrast performance.

Note: An equivalent quality control test may be substituted if approved by the Department prior to implementation.

APPENDIX C-2

Spatial Resolution

Various elements of the fluoroscopic system may shift out of focus causing a decrease of system resolving power. The electron lenses in the image intensifier and the ion pump may derive power from the same voltage divider so a variation in this voltage may cause the system to shift out of focus. Camera and collimating lenses may be moved relative to their focal planes and TV focus may drift as components age.

Discussion

The image intensifier (II) is composed of an anode, a cathode, and focusing electrodes (electronic lens) enclosed in an evacuated glass (some may be metal) envelope. The cathode is composed of an input phosphor and photocathode assembly. In modern II tubes, cesium iodide is used as the input phosphor. A vapor deposition process permits more cesium iodide to be packed together. Quantum detection efficiency is increased greatly as compared to zinc cadmium sulfide phosphors. In addition, the resolution due to a "light piping" effect of the light produced by the phosphor is increased. The electronic lenses focus the electrons produced by the photocathode, on to the output phosphor while they are accelerated by the anode (+25,000). From the output phosphor, the image is transported by a series of lenses or fiber-optic bundles to a TV camera, cine camera, photospot camera, or direct viewing. Since contrast plays a direct role in image quality, low kVp should be used with a high Z material to yield high contrast. We are not checking contrast, but resolution. Because of the physical shape of the II image quality will always be better in the center as compared to the edges.

Test Equipment Required

1. Line Pair Test Tool
2. One 0.75 inch (19 mm) thickness of Type 1100 aluminum

Procedure

Place the line pair test tool on the aluminum block. The line patterns should be oriented 45 degrees to the raster lines of the monitor. Position the image intensifier so that the test tool is 12 inches (30 cm) from the intensifier's entrance surface. If the system has variable source to image distance (SID), the measurement SID must not exceed 40 inches (100 cm). The image receptor of the fluoroscopic system must be operated in the largest available field of view (FOV) that does not exceed six inches (15 cm). If all the FOVs exceed six inches the system must be operated in the smallest FOV. Collimate the fluoroscopic beam to the size of the aluminum block. Activate the fluoroscope and allow the system to stabilize. Adjust the contrast and/or brightness of the monitor in order to obtain the best quality image. Record the maximum number of line pairs per millimeter (lp/mm) that can be seen on the monitor.

Results

The minimum number of lp/mm that must be resolved by the system is given by the equation:

$$2 \text{ lp/mm} \times (6 \text{ inches (15cm)} / \text{size of FOV used}) = \text{minimum number of lp/mm.}$$