



CAR Standards for the Utilization of Fluoroscopic Equipment

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The standards of the Canadian Association of Radiologists (CAR) are not rules, but are guidelines that attempt to define principles of practice that should generally produce radiological care. The physician and medical high-quality physicist may modify an existing standard as determined by the individual patient and available resources. Adherence to CAR standards will not assure a successful outcome in every situation. The standards should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results. The standards are not intended to establish a legal standard of care or conduct, and deviation from a standard does not, in and of itself, indicate or imply that such medical practice is below an acceptable level of care. The ultimate judgment regarding the propriety of any specific procedure or course of conduct must be made by the physician and medical physicist in light of all circumstances presented by the individual situation.

I. PREAMBLE

Fluoroscopy is a basic tool in imaging practice. In spite of legislative regulations, there is the potential for a wide range of image quality, accompanied by a definite risk of radiation exposure to patient and operator.

The issue of image quality and dose are aggravated by varying utilisation practices, aging fluoroscopic equipment, multiple variables in the imaging chain, and an increasing utilisation of fluoroscopic equipment by non-radiologists. Furthermore, the emergence of Interventional Radiology is placing greater demands, with particular emphasis on the duration of the procedure and the need for higher resolution. These important issues are also being raised by other jurisdictions in the United States of America and Europe.

Thus, the scene is set for the need to develop technical and clinical standards for fluoroscopic examinations, which can be used at a national level as a blueprint or guide for realistic application of fluoroscopic technology in clinical radiology.

These standards for fluoroscopic examinations will be presented in the following sections:

TRAINING AND QUALIFICATIONS
TECHNICAL STANDARDS
CLINICAL STANDARDS
CURRENT AND FUTURE TRENDS

II. TRAINING AND QUALIFICATIONS

A. Radiologists qualifications

That Physicians involved in the performance, supervision and interpretation of fluorocopyphy should be Diagnostic Radiologists and must have a Fellowship or Certification in Diagnostic Radiology with the Royal College of Physicians and Surgeons of Canada and/or the Collège des médecins du Québec. Also acceptable are foreign Specialist qualifications if the Radiologist so qualified holds an appointment in Radiology with a Canadian University.

As new imaging modalities and interventional techniques are developed additional clinical training, under supervision and with proper documentation, should be obtained before radiologists interpret or perform such examinations or procedures independently. Such additional training must meet with pertinent provincial/regional regulations. Continuing professional development must meet with the requirements of the Maintenance of Certification Program of the Royal College of Physicians and Surgeons of Canada.

STANDARD #1

A. Radiologists

Radiology training programmes will have a mandatory programme with regard to training of future

radiologists in fluoroscopic techniques. This will include theoretical and practical considerations covering both the physics of fluoroscopy and its clinical application.

B. Non-Radiologists (M.D.)

The Credentials Committee of every hospital should require evidence of training in fluoroscopic procedures for those physicians who utilise fluoroscopy without supervision of a radiologist and/or x-ray technologist.

NOTE: AN EXCELLENT PROTOCOL REGARDING TRAINING HAS BEEN PROPOSED BY S.C.P. Lam and L.C. Swayne (see bibliography).

STANDARD #2

No fluoroscopic procedure by non-radiologist M.D. should be undertaken out of the hospital environment.

C. Technical Qualifications

The medical radiation technologist must have Canadian Association of Medical Radiation Technologist Certification or be certified by an equivalent licensing body recognized by the C.A.M.R.T.

Under the overall supervision of the radiologists, the technologist will have the responsibility for patient comfort and safety for examination preparation and performance and for image technical evaluation and quality and applicable quality assurance.

The training of technologists engaged in specialty activities shall meet with applicable and valid national and provincial specialty qualifications. Continued education of technologists is encouraged by the C.A.M.R.T. and should meet pertinent provincial regulations. The technologist should have training in fluoroscopy either in his/her training curriculum or through special courses and must perform fluoroscopy on a regular basis.

STANDARD #3

There should be mandatory training of technologists on fluoroscopic positioning techniques and the recording of fluoroscopic times for all examinations. Monitoring of these fluoro times would become part of the Quality Management Programme.

III. TECHNICAL STANDARDS

Some technical standards with regard to fluoroscopic equipment are clearly demarcated at international (I.C.R.), national (RED Act - Radiation Emission Devices Act) Canadian Standards Association (CSA) and provincial (H.A.R.P. - Healing Arts Radiation Protection Act Ontario) levels. Such standards are non-negotiable and must be met prior to the purchase and installation of any such equipment. Furthermore, these facilities are examined regularly by various inspection services and should be regularly monitored by a Quality Control Programme.

However, each facility should aim beyond these minimal requirements. The authors recommend implementation of a Quality Management Programme as suggested by the Canadian Association of Radiologists (1993). This document is intended to reflect a commitment by the Canadian Association of Radiologists toward bridging the gap between **Quality Control**, **Quality Assurance** and **Continuing Quality Improvement** and also encouraging the concept of **Quality Management**. The thrust of this initiative is that fluoroscopic equipment and its utilisation in office practice and in all areas of the hospital (including operating rooms and clinical suites) should come under the direct influence of the radiology facility Total Quality Management Programme. This Programme should actively pursue Continuing Quality Improvement of fluoroscopic services by establishing and monitoring reproducible standards of equipment performance, clinical utilisation and cost/benefit to the patient and hospital.

STANDARD #4

All Fluoroscopy Systems will be incorporated into a Quality Management Programme. All such endeavors will be documented.

In addition to the Total Quality Management Programme, there are three other issues which deserve more detailed technical description in this section. These are:-

1. UTILISATION OF T.V. SYSTEMS VERSUS MIRROR OPTICS

2. EQUIPMENT PURCHASE
3. POSITIONING OF PATIENTS BY FLUOROSCOPY

A. UTILISATION OF T.V. SYSTEMS VERSUS MIRROR OPTICS

In the early days of image intensification (late 1950's), the output phosphor was viewed by a mirror system. This provided good viewing facilities once the technique was mastered. However, the advent of television systems rapidly replaced this method so that the examinations could be viewed on a television monitor. Fluoroscopic resolution has improved over the years, and high-line television cameras and monitors are now available in the marketplace, and there are new technologies currently in development which will yield even further improvement. As these advances are being made, many of the older television systems in radiology practice are deteriorating, and there is evidence to support the view that mirror optics is now becoming more frequently used. A dispassionate observer would comment that there are two levels of standards as far as fluoroscopic examinations are required.

STANDARD #5

The long term use of mirror optics for fluoroscopy is only acceptable for operators with extensive experience with this older technology. All systems using mirror optics should be upgraded to television capability.

B. EQUIPMENT PURCHASE

As indicated above, there is a wide range of quality with regard to fluoroscopic equipment and the following guidelines are suggested:

1. Determine the number and types of examination to be undertaken (i.e. is angiography likely to be required?)
2. Determine which imaging modalities will be required (i.e. ciné or 100 mm cameras etc.).
3. A decision should be made at an early stage whether or not a digital fluoroscopic system would handle all requirements.
4. If #3 is positive, then the Request For Proposal (RFP) should be modified to exclude 100mm cameras, cine cameras, videotape recorders etc., etc.
5. The Request For Proposal (RFP) must identify the amount of resolution, the geometry, and the quality of the imaging chain (including the TV camera).
6. All stakeholders in the routine use of the equipment should provide input into the final decision.

STANDARD #6

Budgetary considerations should be a part of equipment selection, but must never compromise the basic requirements of equipment quality and performance determined by the Imaging Department.

C. POSITIONING OF PATIENTS BY FLUOROSCOPY

It is apparent that under certain circumstances remote control tables are being utilised for positioning by fluoroscopy prior to exposures for routine radiography. Whereas it is understood that this concept has been in place for over 25 years, the practice is to be discouraged because of the potential of adding significant doses during the fluoroscopic portion of the examination.

There are arguments for permitting this process under the following circumstances only: -

1. In emergency situations where the technologist should have received full training.
2. The equipment utilised should possess the capability of pulsed fluoroscopy and last image hold.

STANDARD #7

Positioning of patients for radiographic examination by fluoroscopy should only be allowed under strict controlled conditions.

IV. CLINICAL STANDARDS

A. FLUOROSCOPIC TIMERS AND ALARMS

STANDARD #8

The fluoroscopic timer will be turned to the zero position prior to each fluoroscopic examination. The duration of the fluoroscopy will be documented at the end of the procedure.

B. IN-ROOM PROTOCOL FOR RADIATION PROTECTION

STANDARD #9

There will be a protocol for full radiation protection of both patients and staff. This will be dictated by an overall assumption that radiation exposure will be kept to an absolute minimum within the concept of sound clinical judgement necessary for accurate diagnosis.

STANDARD #10

All standards documented by national and/or provincial technologist organisations will be adhered to. Specifically no technologist, or other allied health professional, should be expected to remain in any fluoroscopy room during fluoroscopy or film exposure except during extenuating circumstances (i.e. hands-on patient care). This standard particularly applies to remote controlled fluoroscopic units.

C. OVERHEAD TUBES VERSUS UNDER TABLE LOCATION

STANDARD #11

All x-ray tubes utilised for fluoroscopy must be recognised as being a potential source of high radiation dose, either due to position or utilisation. Particular concern will be applied to the overhead tube position so that full lead protection devices can be made available.

D. GEOMETRY OF SYSTEM

STANDARD #12

All systems should normally be used with the maximum S.I.D. (Source Intensifier Distance).

E. LOCATION OF IMAGE INTENSIFIER IN RELATION TO PATIENT AND SELECTION OF FIELD SIZE

STANDARD #13

The image intensifier will be as close to the patient as is reasonable possible. In addition to this, the electronic zoom should be used with discretion and each should be selected according to current clinical need. In essence, selection of smaller sizes will increase resolution but diminish the field covered. This compromise occurs with a rise in the radiation exposure to the patient.

F. CONING AND AREA OF INTEREST

STANDARD #14

Fluoroscopy should be confined to the area of interest and all other maneuvers should be undertaken without fluoroscopic control. As the area of interest is being examined, automatic coning must function, and, ideally, this should be augmented by manual coning discipline.

G. POSITIONING OF PATIENT PRIOR TO UTILISING FLUOROSCOPY

STANDARD #15

The image intensifier and fluoroscopic chain should not be used as a positioning device and/or "gunsight" during the fluoroscopic examination. In other words, the patient should be positioned, as far as possible, without a fluoroscopic image.

H. TROUBLE-SHOOTING SHORT LIST IF IMAGE QUALITY IS THOUGHT TO BE INADEQUATE

STANDARD #16

Assessment of the fluoroscopic image is often a subjective impression not based upon technical or hard data. This is compounded by the fact that most fluoroscopic installations experience multiple users. All concerns regarding image quality on the fluoroscopic monitor should be documented and possible remedial in-house actions should be undertaken prior to calling for service. Under ideal circumstances each facility should incorporate objective test objects into the Quality Management Programme.

STANDARD #17

The TV monitor should be stabilised for optimal visualisation of any given imaging chain. Once this

setting is standardised it should not be modified manually without adhering to the Quality Control Protocol. All fluoroscopic monitors should be viewed with low ambient light intensity.

I. VISUAL ACUITY

The prime objective in radiology practice is to produce a quality image for diagnosis. One of the most important areas, particularly with the new digital technology, is the quality of the fluoroscopic image. However the observer perception of such an image might be impaired by sub-optimal visual acuity of the observer.

STANDARD #18

All imaging physicians should have an annual evaluation of their visual acuity. This should include near and distant vision. Correction lenses, if necessary should be used at all times.

V. CURRENT AND FUTURE TRENDS

A. Current Digital Systems (1993)

Digital fluoroscopic systems, including Digital Subtraction Angiography (DSA), are available in the marketplace. The acquisition of such a system must be a conscious policy decision with a departmental commitment for success. To a large extent, the specifications for these systems are easily available from the manufacturers and must be explored in-depth prior to purchase.

The following standards should be borne in mind: -

STANDARD #19

All digital fluoroscopic systems must meet the declared specifications issued by the manufacturer and dose levels must be within legislated limits. All other Standards in this document still apply.

STANDARD #20

Add-on digital fluoroscopic units should only be considered after full evaluation of the image intensifier and video camera already in place.

STANDARD #21

The hardcopy device must be fully integrated so that the final hard copy on file reflects the quality seen on the television monitor.

STANDARD #22

All operators (radiologist and technologist) should be conversant with the technology and use it to maximum benefit of the patient.

VI. NEW DEVELOPMENTS

It should be recognised that new technology is being developed as a potential replacement of the image intensifier and TV camera (CCD cameras, x-icon systems and flat panel systems). Although no standards are currently written for these potential developments, it is important to realise that further changes might be on the horizon. For practical purposes, most of the standards already identified would be applicable to these new technologies.

VII. SUMMARY

The above document is intended to act as a blueprint for those utilising fluoroscopic equipment which includes a reasonable bibliography if further reading is required. It does not intend to direct the reader toward any particular type of equipment or technology, but does emphasise the fact that there are probably more variables for the radiologist to consider than in any other imaging technology. An in-depth knowledge of such variables, with their potential impact on image quality, should be a mandatory educational requirement and be intimately related to a Total Quality Management Programme. Finally, the potential of new technology emphasises the need to review such STANDARDS on an on-going basis.