1. Executive Summary

1.1 General

The "fluoroscope" is defined as an instrument used chiefly in industry and in the practice of medicine for observing the internal structure of objects (such as the living body) by means of the shadow cast by the object examined upon a fluorescent screen when placed between the screen and a source of x rays.

The simple "fluoroscopic screen" referred to in this definition has been replaced in current medical practice by vacuum-tube image intensifiers and solid-state detectors. These devices are collectively called "image receptors."

Conventional radiography in medicine is preferred for the acquisition of static images (*e.g.*, chest radiography). Medical fluoroscopy is normally reserved for the observation of moving objects. Fluoroscopes have two main modes of operation:

- *fluoroscopy*: intended to observe moving objects for relatively long periods of time (seconds to minutes) without the intent of preserving the images; and
- *fluorography*: intended to record images of moving objects for a few seconds at a time (*e.g.*, cinefluorography of the heart).

The production of fluorographic images requires air-kerma rates (incident on the patient's skin) that are usually 10 to 100 times higher than for fluoroscopic images of the same patient and anatomical view. Traditionally, fluoroscopic, fluorographic, and radiographic images were acquired and managed using somewhat different technologies. At present, a state-of-the-art fluoroscopic system is able to produce all three classes of images using a single image-acquisition and image-processing chain. The production of the different classes of images is determined by the selection of technical factors in the imaging system. The boundary between fluoroscopy and fluorography has been further blurred in those systems that offer the possibility of retrospectively storing the last several seconds of fluoroscopy. This can reduce total patient dose by eliminating the need for fluorographic documentation in those situations where the previous fluoroscopic sequence meets clinical requirements.

These state-of-the-art fluoroscopic systems are now extensively used to conduct diagnostic or therapeutic interventional medical procedures performed *via* percutaneous or other access routes in order to:

- localize or characterize a lesion, diagnostic site, or treatment site;
- to monitor the procedure; or
- to control and document therapy.

The term *fluoroscopically-guided interventional* (FGI) procedure is used to describe this practice of medicine.

This Report is focused on the use of fluoroscopic systems as a tool for guiding diagnostic and therapeutic procedures because higher radiation doses (compared to conventional radiography and fluoroscopy) are received regularly from some types of FGI procedures and occasionally from many other types of FGI procedures. Other medical applications of fluoroscopy (*e.g.*, examination of the gastrointestinal system, guiding open surgical procedures) are outside the scope of this Report. Computed-tomography-guided interventional (CTGI) procedures are not discussed in detail due to continuing changes in the technology driven by the evolution of multi-slice computed tomography (CT) detectors. However, the principles presented in this Report are generally applicable to these domains. Most of the recommendations contained in this Report should be applied in all settings where fluoroscopic guidance is used.

Within the context of radiation dose management, the goal of this Report is to supply information that helps optimize patient outcomes without compromising worker safety. However, radiation is not the only risk to which patients and workers are exposed. In many cases, radiation is a minor component of overall risk. In these situations, too great a focus on radiation safety (*e.g.*, the use of unnecessarily thick lead aprons) may reduce the overall safety of patients or workers.

Some beneficial, clinically-justified FGI procedures, even when optimized for radiation protection, deliver substantial doses of radiation to patients. This puts the patient at risk for radiogenic stochastic effects and occasionally induces radiogenic deterministic effects. However, a complete risk analysis usually identifies many other procedural hazards and will often conclude that radiation is one of the lesser hazards from FGI procedures. While the decision to conduct an FGI procedure assumes that the use of ionizing radiation is warranted by the disease state for which the patient undergoes treatment, the benefits, risks, and alternative procedures that do not require the use of ionizing radiation should be considered.

FGI procedures should only be performed when there is the expectation of a benefit to the patient. At present, many medically necessary x-ray image-guided procedures (including FGI procedures using fixed or mobile equipment and CTGI procedures) can only be performed by physicians and support staff positioned adjacent to the patient. These individuals are unavoidably irradiated while performing their duties. Provided that appropriate radiation protection methods are applied, staff occupational exposure is justified if the procedure is itself justified, and the occupational exposure adheres to the as low as reasonably achievable (ALARA) principle. The ALARA principle should be applied without compromising either patient safety or the clinical procedure and without unacceptably increasing workers' nonradiation risks (*e.g.*, spinal injuries related to wearing inappropriately heavy lead aprons). In this context, worker irradiation is considered to be an unavoidable part of the social cost of providing FGI procedures.

Sections 2 through 6 of this Report are organized by the following topics:

- general information (Section 2) (includes scope, FGI procedures, efficacy and benefit-cost, justification and benefit-risk, physics and dosimetry, radiation biology);
- fluoroscopy equipment and facilities (Section 3);
- protection of the patient (Section 4);
- protection of staff (Section 5); and
- administrative and regulatory considerations (Section 6).

This material is intended to provide background information for readers, including facility administrative and management executives, professionals participating in or supporting FGI procedures, and regulatory officials. The contents of many of the sections are supplemented by materials in the appendices. Because of the diversity of FGI procedures it is impracticable to supply a complete handbook on this topic.

1.2 Recommendations

The National Council on Radiation Protection and Measurements (NCRP) recommendations in this Report are listed in Table 1.1 for ready reference. The recommendations are consecutively numbered in the order they appear in the text of this Report, and the subsection in which each statement appears and is discussed is noted in the right-hand column. The recommendations should not be read in isolation. *The reader should consult the indicated subsections for more complete explanations and further information.*

TABLE 1.1—*NCRP Report No. 168 recommendations.*

Number	Recommendation	Section
1	Radiation risk *should* be one of the many risks included in the benefit-risk analysis of FGI procedures.	2.4
2	The measured dose quantities air kerma-area product (P_{KA}) and air kerma at the reference point ($K_{a,r}$) *should* be used to compare similar FGI procedures. In this Report, P_{KA} and $K_{a,r}$ refer to the cumulative value for the FGI procedure.	2.5
3	Effective dose (E) *shall not* be used for quantitative estimates of stochastic radiation risk for individual patients or patient groups (the appropriate approach to obtain quantitative estimates is discussed in Section 2.6.3.3). Effective dose (E) *may* be used as a qualitative indicator of stochastic radiation risk for classifying different types of procedures into broad risk categories (as suggested in Table 2.4).	2.6.3.3
4	Peak tissue dose *shall* be used to evaluate the potential for deterministic effects in specific tissues. Examples include peak dose to the skin or to the lens of the eye.	2.6.4.2
5	An FGI procedure *should* be classified as a potentially-high radiation dose procedure if more than 5 % of cases of that procedure result in $K_{a,r}$ exceeding 3 Gy or P_{KA} exceeding 300 Gy cm^2.	3
6	Potentially-high radiation dose procedures *should* be performed using equipment designed for this intended use.	3.1.2
7	If fluoroscopes are intended to be routinely used for procedures that have the potential for high patient doses (*i.e.*, $K_{a,r} > 3$ Gy), the units either *should* be equipped or upgraded with add-on dose-monitoring equipment that monitors $K_{a,r}$ or the units *should* be replaced with a modern machine.	3.1.2

8	Equipment that is routinely used for pediatric procedures *should* be appropriately designed, equipped and configured for this purpose.	3.1.3
9	For newly designed and remodeled existing facilities, all spaces outside the procedure room (including control rooms) *should* be designed to limit E to not more than 1 mSv y^{-1}.	3.2
10	For newly designed and remodeled existing facilities, spaces within the FGI-procedure room intended exclusively for routine clinical monitoring of patients (or similar activities) *should* be shielded to limit E to not more than 1 mSv y^{-1}. Individuals working behind such barriers *shall* be monitored for radiation exposure.	3.2
11	Door interlocks that interrupt x-ray production *shall not* be permitted at any entrances to FGI-procedure rooms.	3.2
12	Procedure planning for FGI procedures on pregnant patients *shall* include feasible modifications to minimize dose to the embryo and fetus.	4.2.2
13	Fluoroscopy time *should not* be used as the only dose indicator during potentially-high radiation dose FGI procedures. All available dose indicators *shall* be used in such procedures.	4.2.4.1
14	Interventionalists *shall* be responsible for patient radiation levels during FGI procedures and *shall* ensure that radiation dose accumulation is continuously monitored during the procedure.	4.3.3.2
15	Patient dose data *shall* be recorded in the patient's medical record at the conclusion of each procedure. This *shall* include all of the following that are available from the system: peak skin dose ($D_{skin,max}$), $K_{a,r}$, P_{KA}, fluoroscopy time, and number of fluorographic images.	4.3.4.1

TABLE 1.1—(*continued*)

Number	Recommendation	Section
16	If a substantial radiation dose level (SRDL) (Table 4.7 and Section 4.3.4.2) is exceeded while performing an FGI procedure, the interventionalist *shall* place a note in the medical record, immediately after completing the procedure, that justifies the radiation dose level used.	4.3.4.3
17	If an SRDL is exceeded for an FGI procedure, the patient and any caregivers *should* be informed, prior to discharge, about possible deterministic effects and recommended follow-up. If fluoroscopy time exceeds the SRDL, but other measured dose metrics do not exceed the SRDL, patient information and follow-up *may not* be necessary.	4.3.4.4
18	Follow-up for possible deterministic effects *shall* remain the responsibility of the interventionalist for at least 1 y after an FGI procedure. Follow-up *may* be performed by another healthcare provider who remains in contact with the interventionalist. All relevant signs and symptoms (Table 2.5) *should* be regarded as radiogenic unless an alternative diagnosis is established.	4.3.4.4
19	Facilities *shall* have a process to review radiation doses for patients undergoing FGI procedures. Advisory data based on measured dosimetric quantities (in particular P_{KA} or $K_{a,r}$ to manage overall performance, and $K_{a,r}$ to manage deterministic effects) *should* be used for quality assurance purposes.	4.3.5.3
20	Each individual present in an FGI-procedure room while a procedure is in progress *shall* have appropriate radiation protection training.	5.2
21	Each individual present in an FGI-procedure room while a procedure is in progress *shall* be provided with and *shall* use appropriate radiation protective equipment.	5.5.5

22	Policies and procedures *should* be in place so that in the event of a time-critical urgent or emergent situation, as defined in this Report (Table 5.3), advanced provision exists for exceeding an annual occupational dose limit.	5.7.1
23	Determinations of occupational doses *shall* take into account the personal protective equipment used by each individual in the FGI-procedure environment in order to properly assess compliance with occupational dose limits.	5.7.3
24	Two personal dosimeters, one worn under the protective apron and a second worn at neck level above protective garments, are preferred and *should* be used in the FGI-procedure environment. A single personal dosimeter worn at neck level above protective garments *may* be used in the FGI-procedure environment. A single personal dosimeter worn under the protective apron *shall not* be used in the FGI-procedure environment.	5.7.3
25	Monitoring of equivalent dose to the lens of the eye *should* be performed with a personal dosimeter placed either at the collar level outside any radiation protective garment or near the eyes.	5.7.3
26	Investigations *should* occur if personal-dosimeter readings for an individual are substantially *above* or *below* the expected range for that individual's duties.	5.7.4
27	Every person who operates FGI equipment or supervises the use of FGI equipment *shall* have current training in the safe use of that specific equipment.	6
28	An FGI procedure *shall* be performed or supervised only by a physician or other medical professional with fluoroscopic and clinical privileges appropriate to the specific procedure.	6.3.1

TABLE 1.1—(*continued*)

Number	Recommendation	Section
29	Standards and guidelines provided by professional societies *shall* be considered when establishing radiation-related resources, and quality and performance requirements.	6.4.2
30	Interventionalists and qualified physicists *should* participate in the process for purchase and configuration of new fluoroscopes and fluoroscopy facilities.	6.4.2
31	A qualified physicist *shall* perform acceptance and commissioning tests before first clinical use of new, newly-installed, or newly-repaired fluoroscopy equipment, and *shall* perform subsequent periodic tests as part of a technical quality-control program.	6.4.2

These NCRP recommendations are expressed in terms of *shall* (or *shall not*), *should* (or *should not*), and *may,* each term italicized, where:

- *shall* (or *shall not*) indicates a recommendation from NCRP that is necessary to meet the currently accepted standards of radiation protection;
- *should* (or *should not*) indicates an advisory recommendation from NCRP that is to be applied when practicable or practical (*e.g.*, cost-effective); and
- *may* (or *may not*) indicates a reasonable practice that is permissible.

When the terms should and may appear in this Report in the context of their general usage, they are not italicized.

In this Report, the terms *interventionalist* and *qualified physicist* are defined as follows:

- *interventionalist*: an individual who has been granted clinical privileges to perform or supervise FGI procedures in a facility, and who is personally responsible for the use of radiation during a specific FGI procedure in that facility.
- *qualified physicist*: a medical physicist or medical health physicist who is competent to conduct the radiation protection functions for FGI-procedure equipment and facilities described in this Report. The qualified physicist is a person who is certified by the American Board of Radiology, American Board of Medical Physics, American Board of Health Physics, or Canadian College of Physicists in Medicine.