



A Guide for Establishing a Credentialing and Privileging Program for Users of Fluoroscopic Equipment in Healthcare Organizations

Report of AAPM Task Group 124

**AAPM Education Council
Medical Physics Education of Physicians Committee**

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Task Group 124 Members

Mary E. Moore (Chair)

Benjamin R. Archer

Stephen Balter

Joel E. Gray

Alan M. Jackson

Rosemary Kennedy

Pei-Jan Paul Lin

Melissa C. Martin

Edward L. Nickoloff

Phillip L. Rauch

Mark S. Rzeszutarski

Douglas Shearer

Keith J. Strauss

Louis K. Wagner

Lynne Fairbent, AAPM Staff

Approvals:

Task Group 124 Members – June 28, 2012

Medical Physics Education of Physicians Committee – July 13, 2012

AAPM Education Council – October 18, 2012

Consultants:

The Task Group wishes to express its appreciation for the assistance provided
by the following consultants:

Libby F. Brateman, Karen L. Brown, Priscilla F. Butler,

Charles E. Chambers, and Gerald A. White

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1. Introduction

Developing a credentialing and privileging program for clinical fluoroscopy users involves more than developing and providing a didactic component. Establishing a program requires formal support by healthcare management, as well as acceptance and participation by the medical staff. While credentials review and the privileging process is well known by physicians who have been granted privileges at hospitals and other health care facilities, medical physicists and health physicists may not be as well acquainted with the process and corresponding requirements.

This report is designed so that each section is essentially self contained to facilitate use by the reader who needs information from a specific section. As a result, redundancies occur.

This guide is intended to assist the qualified medical physicist (QMP), the radiation safety officer (RSO), credentialing staff, and chairs of affected departments by providing an overview of the credentialing process and guidance for incorporating fluoroscopy users into the process. Resources and recommendations for developing and maintaining a fluoroscopy safety training program are also provided.

Fluoroscopy use in nearly all areas of medicine continues to increase. This rise in use has largely become possible due to design improvements that make it easier for users to produce clinically useful images. Concurrently, fluoroscopy equipment, including mobile units, has increased in capacity and complexity. To date there is no nationally accepted uniform standard for education and training on the safe use of fluoroscopy. This report is an effort towards that goal.

Training for the safe use of fluoroscopy has not kept pace with expanding clinical applications. Fluoroscopy credentialing and privileging programs are needed because of the tremendous growth in the use of fluoroscopy by individuals whose medical education originally did not include formal training in fluoroscopy. Physician specialists utilizing fluoroscopy include radiologists, cardiologists, gastroenterologists, orthopedic and vascular surgeons, neurologists, urologists, pulmonologists, pain management specialists, and radiation oncologists. Non-physician fluoroscopy users include radiology assistants, speech pathologists, nurse practitioners, physician assistants, and radiologic technologists. Many have not been trained in the principles of radiation protection, radiation biology, radiation or imaging physics, radiologic anatomy and physiology, electrical safety, positioning, or equipment operation. Training fluoroscopy operators and staff in imaging physics and radiation management should lead to improved patient care through the more judicious application of fluoroscopy imaging.

Without proper education, training, and experience, the patient, operator, support staff, and facility are at increased risk for radiation related injuries. Even with adequate staff training and experience and with properly functioning equipment, the risk of serious injury can be high whenever multiple fluoroscopically guided interventional procedures are performed on the same patient within a short period of time. An example of serious injury is shown in Figure 1.

Because radiologists, cardiologists, imaging medical physicists, and radiologic technologists are trained in the applications and use of fluoroscopy and associated radiation safety aspects, they should participate in the development and implementation of training programs and be part of the credentialing process as well. RSOs should also participate to assure radiation safety compliance, program coordination, and oversight.

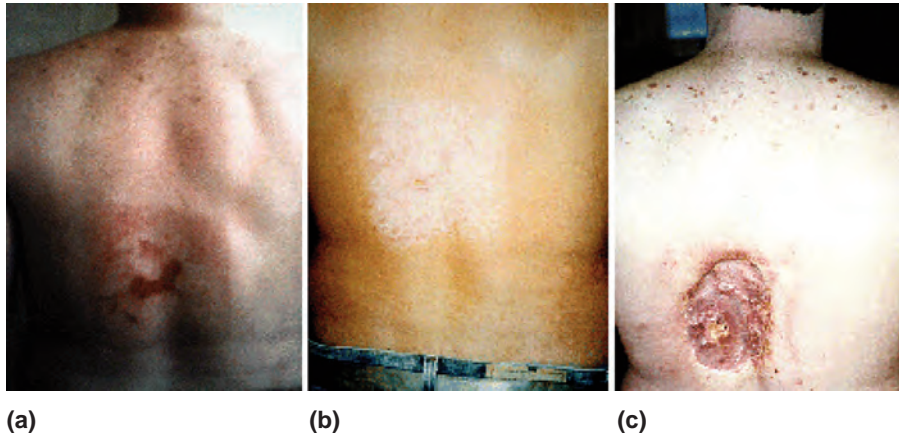


Figure 1. Sequence of images shows progression of radiation injury in 40-year-old man who underwent multiple coronary angiography and angioplasty procedures. Image (a) is 6 to 8 weeks after exposure and shows prolonged erythema with mauve central area, suggestive of ischemia. Image (b) is 16 to 21 weeks following exposure; depigmented skin with central area of necrosis is seen. (c) Image at 18 to 21 months shows deep necrosis with atrophic borders. This sequence is available on the U.S. Food and Drug Administration (FDA) web site and is in the public domain (Shope 1995) and was subsequently printed in Shope (1996).

2. Purposes of a Credentialing and Privileging Program

Credentialing and privileging programs exist to assure competency. Privileges are granted to individuals with appropriate training and experience.

The areas critical for fluoroscopy competency include clinical training and expertise, technical knowledge of mechanical and electrical safety, of radiation safety, radiation biology, and radiological imaging physics as well as competency operating the equipment.

Achieving competency as a fluoroscopy user entails both didactic and hands-on training and experience.

Fluoroscopy is an interactive imaging procedure requiring proper equipment positioning for the correct anatomical projection and for the lowest possible radiation dose to the patient. This requires knowledge of radiologic anatomy and physiology in order to provide clinically relevant information while minimizing fluoroscopic exposure time. The operator has to simultaneously operate the fluoroscopy pedal, manipulate a catheter or administer contrast, look at a monitor to evaluate the image, be aware of the patient's condition, and assure minimal fluoroscopy exposure time. Supervised practice is required to accomplish this multifaceted process and to avoid the tendency of operators keeping their foot on the exposure pedal while not viewing the images on the monitor.

With regard to education and training, this guide addresses the safety and medical physics aspects of fluoroscopy use. *Clinical training requirements and competency for performing specific clinical procedures, interpreting clinical images for diagnosis, and any associated emergency responses are beyond the scope of this report.*

3. Credentialing, Privileging, State Licensure, and Regulations

The terms “credentialing” and “privileging” are often incorrectly used interchangeably. It is important to distinguish between these two related but separate and distinct processes. This section explains the basics of credentialing and privileging, and provides guidance for the implementation of these processes at medical institutions.

Credentialing and privileging are an essential part of healthcare administration in all medical facilities (Harrington et al. 2005). This process is required by organizations such as the Joint Commission (TJC) [formerly known as The Joint Commission for the Accreditation of Healthcare Organizations (JCAHO)] and other accrediting organizations. They are also typically required by insurance companies as part of quality assurance requirements for reimbursement.

Credentialing is the collection of relevant data regarding training and experience of an applicant for privileges. Typically, the burden is placed on the applicant to provide the information required for credentialing. The type of information needed should be clearly spelled out in the organization’s credentialing policies and procedures manual.

Credentialing applies to all licensed independent practitioners (LIPs). LIPs are typically physicians, dentists, and podiatrists. However, allied health professionals (AHPs) (e.g., radiology assistants, speech pathologists, nurse practitioners, physician assistants, and radiologic technologists) are taking on more responsibilities of LIPs and may also require credentialing.

Credentialing includes multiple processes including credential verification. Credentials should include initial and continuing medical education, training, and experience specifically related to fluoroscopy usage and radiation safety. However, this information must be verified to assure it is authentic and valid. This is often done by in-house staff (credentialing services professionals, or CSPs) and by commercial credentials verification organizations (CVOs) under the direction of the medical director, credentials committee, or medical executive committee (MEC). In large organizations the medical director may delegate some, or all, of the responsibilities to the department chair or clinical services chief.

The medical director or CSP is also responsible for assuring appropriate continuing medical education (CME) and maintaining documentation of all CME for credentialed and privileged staff. The Center for Affordable Quality Healthcare (CAQH) has established an on-line credentialing information system to aid in record keeping for initial and continuing education. The CAQH system could be productively used to track fluoroscopy education across institutions.

Privileges delineate which medical procedures a staff member may perform. These core privileges may be global in nature (e.g., diagnostic imaging procedures) or more specific (e.g., a list of specific modalities such as computed tomography (CT), magnetic resonance imaging (MRI), film radiography, ultrasound, vascular interventional procedures, etc.). In some specialties (e.g., pulmonary), the list of the applicant’s privileges does not always identify which procedures involve the use of fluoroscopy. This prohibits easy identification of fluoroscopy users. Consequently, it is essential that the department chairs identify which procedures require the use of fluoroscopy.

The medical director or department chair is required to review each completed application and make recommendations to the MEC regarding the suitability of credentials for the privileges requested. The MEC makes recommendations either to the medical director or the governing board, depending on the structure defined in the by-laws. The governing board (medical board of

directors) is ultimately responsible for oversight of the process and making the final decisions regarding clinical privileges.

Formal denial or revocation of clinical privileges may have serious consequences for the applicant. Based on the Health Care Quality Improvement Act of 1986 (http://www.ssa.gov/OP_Home/comp2/F099-660.html), a governing board must report any denial of privileges to the National Practitioner Data Bank through the state medical licensing board.

The Joint Commission requires an organization to review and revise clinical privileges and appointments at least every 2 years. Consequently, all accredited facilities must have a re-privileging process clearly defined in its by-laws and procedures manual.

Re-privileging procedures require review of many aspects, including past credentials and continuing education, as well as patterns of care as demonstrated by compliance with policies, rules, and regulations of the organization. Moreover, continuing education relevant to patient and staff radiation protection needs to be part of the re-privileging procedures. Re-privileging should also include a review of the individual's fluoroscopy times, patient doses (if available), and personal dosimetry. The re-privileging 2-year cycle is an ideal opportunity to require completion of another course about fluoroscopy safety (including an examination) and hands-on training on new equipment.

Peer review is an important part of this ongoing process. As such, the quality of practice by an individual can and should be reviewed at a frequency consistent with institutional policy, and one that will allow the identification of issues for quality improvement.

It is clear that credentialing, privileging, and re-privileging are complex and time-consuming processes. Four primary reasons for assuring that these processes are valid and fair include:

1. To assure clinical and technical competence to correctly and safely perform procedures utilizing fluoroscopy;
2. To assure and improve the quality of healthcare provided by the institution;
3. To improve and assure radiation safety for patients and hospital staff; and
4. To assure and maintain a proper and consistent standard of patient care.

Credentialing and privileging are part of the administrative oversight of healthcare quality and, as such, provide an important key to quality medical care. The use of radiation in the practice of medicine is a significant part of overall medical care. Radiation use is significantly improved by requiring staff to participate in a credentialing and privileging process for fluoroscopy users.

Emergency privileges may be necessary to provide a pathway for medical professionals to provide medical care during completion of the credentialing and privileging process. A process for approving emergency privileges for new users needs to be addressed in the facility's fluoroscopy policy.

Licensure refers to the official or legal permission to practice in an occupation as evidenced by documentation issued by a state in the form of a license or registration. It is important to recognize that an individual may be licensed to practice medicine but may not have the specific privileges to perform fluoroscopy or other special x-ray procedures at an institution.

Regulations regarding the use of x-ray equipment are developed, promulgated, and enforced by the appropriate state authority, (e.g., state radiation control program). All users of x-ray

equipment are required to comply with these regulations, which are designed to minimize radiation dose to both patients and staff.

Different state regulations have been, or are in the process of being, promulgated which allow physicians and non-physician licensed practitioners to perform a variety of fluoroscopy procedures.

State regulations should require approved operators to master the technical aspects of using each type of fluoroscopic unit for which they are approved. Users should know how to safely setup, position, and operate the equipment. They also should know the techniques to use to produce adequate image quality, how to interpret fluoroscopic images accurately, and, simultaneously, how to manage radiation dose.

4. Overview of the Process for Establishing a Credentialing and Privileging Program

Determine the Need for a Fluoroscopy Credentialing Program at your Facility.

The determination should answer the following questions: Who uses fluoroscopy equipment? How and where is it used?

The radiation safety committee (RSC) is the logical group to determine if formalized review and approval of fluoroscopy users is needed at your facility. The RSO, the QMP, as well as the chairs and administrators of departments using fluoroscopy, should assist the RSC in developing a viable policy. In facilities without an RSC, the Medical Director, assisted by designated staff, should make this determination.

Learn the Fundamentals of Credentialing and Privileging Program Requirements.

Contact your Medical Staff Office (MSO) for information about your facility's credentialing and privileging process. Determine your facility's process for establishing and integrating a new program into the current credentialing and privileging program.

Determine Staffing Needs and Expertise Required to Develop, Support, and Maintain a Credentialing and Privileging Program.

Obtain Support for Establishing a Program.

It is essential for medical leadership and administration to fully support the program. Without this support, the effort will not be able to be sustained.

Develop a Policy.

The policy should identify specific program responsibilities, review and approval procedures, required credentials for initial privileges, and requirements for re-privileging. It should specify that only approved users may operate fluoroscopy equipment, require an updated list of currently privileged approved users be provided to the applicable departments, identify where and under what conditions the equipment may be used, and for which procedures.

Implement and Maintain a Fluoroscopy Credentialing Program that ensures fluoroscopy privileges are approved for only qualified individuals, as determined by the policy, all applicable state and federal regulations, facility and accreditation program requirements, and standards.

Develop a Competency-Based Training Program for applicants who have not obtained the required training and experience, or who need refresher training.

Maintain Records and Issue Approved User Certification.

Assess Program Compliance and Applicability through periodic review.

5. Fluoroscopy Users, Location of Use, and Compliance

Identification of Current Fluoroscopy Users, Their Training, and Experience.

A systematic approach is necessary to identify all users of fluoroscopy equipment. The institution's credentialing and privileging program should be able to identify clinical users. However, the list of privileges may not clearly identify which procedures utilize fluoroscopy. Department chairs should assure the list of privileges for their department clearly identifies those involving the use of fluoroscopic equipment, the type of equipment, and the procedures. Information about fluoroscopy usage can be effectively gained by reviewing x-ray-producing equipment registrations and performing site interviews. Departments which log fluoroscopy times often include patient and physician names, procedure type, and total fluoroscopy times. Billing records or equipment schedules can be used to determine which individuals provide fluoroscopy services. Personnel radiation dosimetry records can also be used to help identify users. It can be a challenge to identify all users or all groups of users in large and varied organizations, especially those with multiple locations.

While privileges are granted to licensed practitioners to perform clinical procedures that utilize fluoroscopy, it is not uncommon for radiologic technologists to set up, initially position, and reposition the x-ray tube during procedures and to energize the beam at the specific direction of the licensed practitioner. In some facilities, other individuals, such as nurses or medical technologists, perform these functions. In other situations, the licensed practitioner positions and repositions the x-ray tube and energizes the beam without assistance.

Once users have been identified, the MSO should be able to provide information about the different residencies and fellowship programs that include radiologic physics, radiation biology, and radiation safety as part of their training programs. Training program information for non-physician licensed practitioners who use fluoroscopy equipment should also be maintained by the MSO. The range of training will vary from only on-the-job experience with no didactic component to competency-based evaluation after the individual received a specified number of hours of didactic training and performed a minimum number of cases under direct supervision.

Locations of Use.

Clinical use of fluoroscopy is commonly found in the locations listed in Table 1. Three dimensional (3D) fluoroscopy, or cone beam CT fluoroscopy, is used in interventional radiology, cardiology, vascular and neurological surgery, and radiation oncology.

Compliance with Regulations and Accreditation Requirements.

A number of states have regulations that specify who may operate x-ray equipment, and the scope of practice of physicians, nurses, and radiologic technologists. Some accreditation agencies have similar requirements or guidelines. It is important to ensure that the facility’s policies and procedures incorporate these requirements, as applicable.

Table 1. Fluoroscopy Locations of Clinical Use

Medical Specialty	Location or Procedure
Anesthesia	Operating room
Cardiology	Cardiac catheterization laboratory Electrophysiology laboratory Cardiac intensive care unit Hybrid Operating Room
Emergency Department	Trauma patient evaluation
Gastroenterology	Endoscopy room
Pain Management	Operating room, clinic
Pulmonology	Bronchoscopy room
Surgery: Vascular Surgery Neurosurgery Orthopedic General Surgery Cardiac surgery	Operating room Hybrid operating room
Radiation Oncology	Linear accelerator vault on-board imaging (OBI) Simulator room
Radiology	General Fluoroscopy Upper GI and barium enema rooms Interventional radiology and special procedures Cone beam CT (3D) fluoroscopy CT fluoroscopy
Speech Pathology	Radiology or operating room
Urology	Operating room or clinic

6. Basic Elements of a Credentialing and Privileging Program

Administrative Elements and Structure of a Healthcare Facility Credentialing and Privileging Program.

To establish a fluoroscopy credentialing and privileging program, one must first determine the particular institution's structure for reviewing credentials of physicians and other licensed practitioners. The review process should involve the following groups.

The **Medical Staff Office (MSO)** should provide management and oversight of all medical staff credentialing and privileging, develop and maintain operational procedures for the privileging process, and provide administrative support to the Credentials Committee and the Medical Staff Executive Committee.

The **Radiation Safety Committee (RSC)** is responsible for reviewing and approving authorized users of radioactive materials and radiation-producing equipment. Approval is granted after review and verification that the applicant's credentials comply with relevant regulatory and institutional requirements. The review process should be such that RSC approval is received prior to, and incorporated into, the reviews by the credentials committee and medical staff executive committee before final privileges are granted.

The **Credentials Committee (CC)** is responsible for reviewing all initial and reappointment applications for medical staff membership and clinical privileges, and it should develop policies and procedures for all credentialing activities at an institution.

The **Medical Staff Executive Committee (MSEC)** is a high-level institutional committee and is responsible to the board of directors for all clinical operational policies and standards. Membership could include the chiefs of all major clinical services, the chair of the credentials committee, the chief medical officer, the president, and others.

The **Board of Directors (BOD)**, the governing body of the institution, is responsible for assuring that the institution fulfills its mission and vision. The BOD approves physician and other licensed independent practitioner privileges based on recommendations of the MSEC. The process should assure RSC recommendation for approval accompanies MSEC's recommendations before initial and emergency privileges are approved. The chief executive officer (CEO) may be the final approving official for the institution, in lieu of the BOD.

Administrative Process for Establishing a Credentialing and Privileging Program.

There are five major aspects of establishing a credentialing and privileging program:

- Medical staff and management approval and support
- Policy development process (see Figure 2)
- Policy content approval
- Policy implementation
- Program implementation and maintenance

These are discussed in the next section.

CREDENTIALING AND PRIVILEGING PROGRAM FOR FLUOROSCOPY USERS

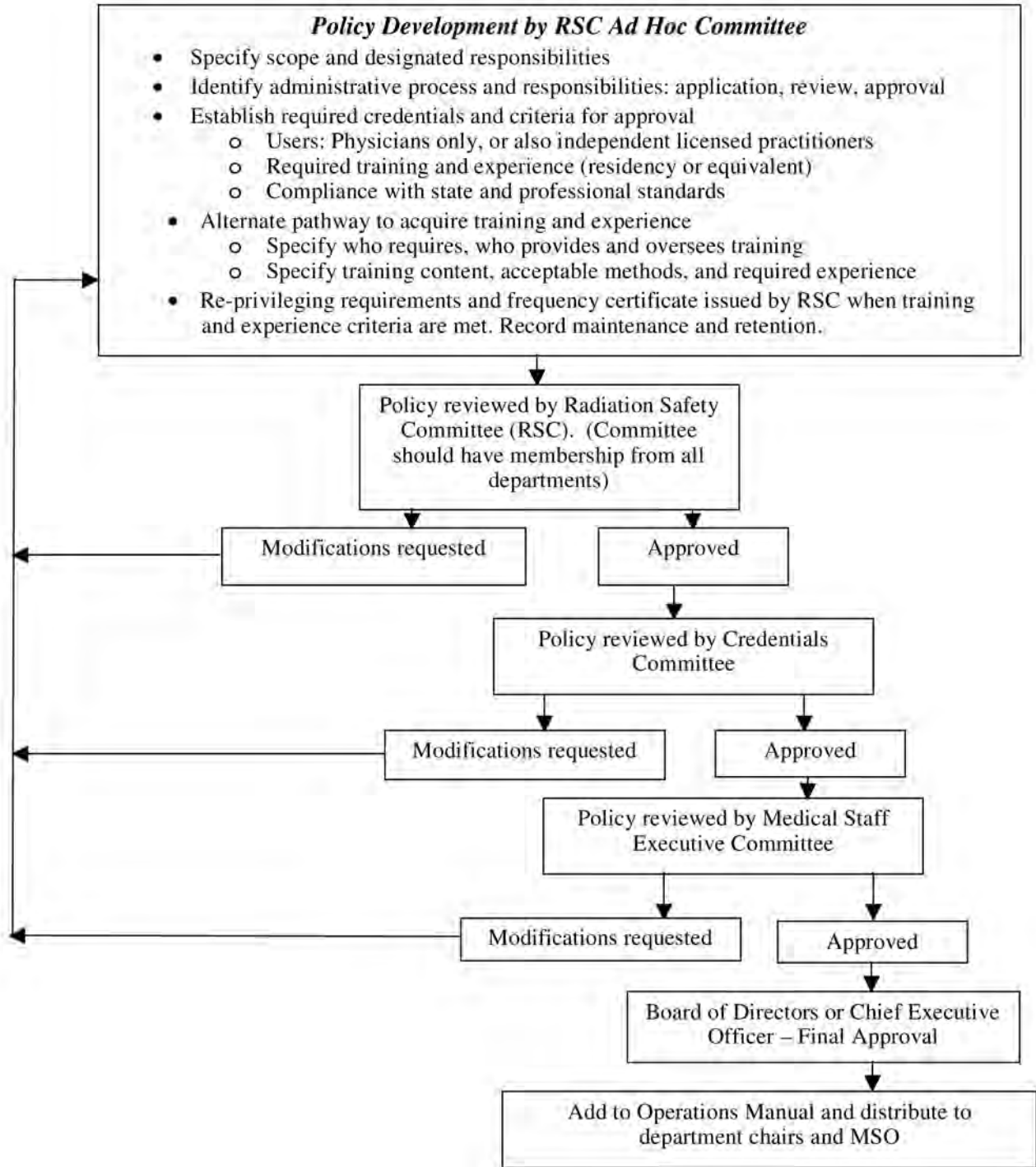


Figure 2. A model for developing a policy for a Fluoroscopy Credentialing and Privileging Program. (Note: Not all elements will apply to all facilities.)

7. Guidance for Policy Development and Implementation

The elements shown in Figure 2 are provided to assist facilities with developing a written policy. The policy establishing a fluoroscopy credentialing and privileging program should address administrative and professional responsibilities. Clear lines of communication need to be established between those requesting privileges and the groups that approve privileges. Fluoroscopy privileges should not be granted to applicants who do not have the required credentials.

Because privileges are granted by the institution, the proposed fluoroscopy privileging policy should be an institutional policy rather than departmental. Each facility has its own review process, but typically it should be supported by the chairs of the departments involved. It is advisable to include them or their designees in drafting the facility policy. These physicians, a QMP, the RSO, and a representative from the medical staff office are recommended to comprise the core team to draft the policy. After the department chairs have approved the draft, it should be approved by the RSC and the MSEC or the BOD. It should be noted that without the support of the chairs of the departments of surgery and medicine, the new policy is not likely to be approved by the medical staff executive committee or the board of directors.

Administrative Process for Policy Development.

In facilities without an RSC, an RSO, or a qualified medical imaging physicist, the medical director, or an individual with equivalent medical and administrative authority, should be responsible for developing and implementing a policy. The medical director may elect to obtain the assistance of a QMP to develop the policy.

At facilities with an RSC and an RSO, the administrative process to establish a fluoroscopy privileging program should begin with the RSC assigning content experts to draft a policy outlining the program, and an ad hoc committee to review it and guide its development.

The individuals drafting the policy should have technical knowledge of fluoroscopy equipment and safety, how and where it is used in the institution, and a working knowledge of the administrative structure of the institution. A QMP, the RSO, and relevant clinician experts would be appropriate appointees to draft the policy.

The ad hoc committee should include content experts, representatives from all the major departments or divisions whose staff need to be privileged, and a representative from the MSO. The RSC should appoint a chair of this ad hoc committee and set a schedule for development, reporting back on progress and issues, and completion of the policy. The chair of the ad hoc committee will then take the completed policy to the full RSC for approval.

Basic Policy Elements.

The policy needs to comply with state regulations and accreditation standards. The policy should include a procedure for MSO and RSC interactions for the management review process for each privileging and re-privileging application. Points of contact for each office should be identified.

Training and experience requirements should be specified in the policy to assure consistency, and that operators have sufficient education and training for competency.

CREDENTIALING AND PRIVILEGING PROGRAM FOR FLUOROSCOPY USERS

The policy should specify who is eligible for fluoroscopy privileges, and who reviews credentials to determine acceptability. Eligibility is based on the applicant possessing the required training and experience specified in the policy.

Fluoroscopy by its nature is a dynamic process. The fluoroscopy user must be able to interpret anatomy and physiology accurately as normal or abnormal by viewing radiological images on the monitor while simultaneously operating the equipment using a foot pedal and manually manipulating the patient, the imaging equipment, and possibly a catheter. As such, both didactic training and hands-on experience are essential to assure the user operates the equipment safely and obtains acceptable image quality. Training limited to only hands-on operation of the equipment without any didactic content is not adequate; conversely, having acquired only didactic information is also not adequate. Knowing the principles does not prepare the operator to implement them without previous practice and experience operating the equipment.

Several levels of training may be necessary for user qualifications to be appropriate. The types of cases performed, the type of fluoroscopy equipment, and the applicant's training and experience credentials should be the basis for determining the type of training needed. Three levels of training, based on increasing risk, are recommended and described in "Guidance for a Training Program" in Section 9 of this report.

Training requirements are included in some state regulations. Professional organizations have also published training and experience recommendations in documentations such as AAPM Report No. 58 entitled "Managing the Use of Fluoroscopy in Medical Institutions" (AAPM 1998); NCRP Report No. 168 entitled "Radiation Dose Management for Fluoroscopically-Guided Interventional Medical Procedures" (NCRP 2011), as well as materials contained in this report. The American College of Radiology (ACR), the American College of Cardiology (ACC), the American Heart Association (AHA), the Society for Cardiovascular Angiography and Intervention (SCAI), and the Society for Interventional Radiology (SIR) all publish practice guidelines that include training recommendations that can be found on their respective websites.

The policy should include an acceptable alternative training and experience pathway for applicants whose formal education did not include fluoroscopy competency-based training and experience. Depending on the available qualified staff, the policy may also include establishing an in-house training program as the alternative pathway. If this option is included, the policy needs to identify who will conduct the training, who will maintain training records, the topics to be covered, competency demonstration, testing requirements, and privilege renewal requirements.

Reciprocity of training received at other institutions should also be addressed. At a minimum, written documentation of training received elsewhere and that facility's curriculum outline should be required. The institution may choose to use its examination process to determine the level of knowledge gained elsewhere. If the applicant satisfactorily passes the written examination, then only hands-on training on the specific equipment to be used and on institution procedures might be required.

The policy should identify the RSC as the group to approve those individuals who will provide the training and experience. If the facility does not have an RSC, then the medical director would make this determination.

Records maintenance and retention should be addressed in the policy. Training records should be maintained by the RSO or individual appointed by the RSC. The criteria for determining the RSC designee should include the individual's expertise, the availability of adequate administrative help with record keeping, and the individual's willingness to supervise the program. In most cases this individual should be either the RSO or a QMP. This RSC designee should issue a training certificate to the MSO and the applicant when training is completed.

Policy Review and Approval Process.

A typical review and approval process is summarized in Figure 2.

The RSC should review the draft policy, and either approve the policy and send it forward, or return it to the ad hoc committee for changes or additions.

Once approved, the MSO should receive the fluoroscopy privileging policy from the RSC and schedule its review by the credentials committee.

The credentials committee should review the policy and either approve it or send it back to the RSC with comments for improvement and resubmission. It is expected that the credentials committee should ask the RSC chair or designee to be present at its discussion of the policy to provide clarification, if needed. On approval, the credentials committee should authorize the RSC chair to submit the policy to the MSEC for its approval and enactment.

Two duties of the MSEC are to review and approve policies relating to privileging, and to review individual privilege recommendations (new and re-appointments) submitted by the credentials committee, and, if appropriate, recommend the BOD approve the privileges.

During the development of the draft policy, it is advisable for the RSC chair (or designee) to contact the chairs of the departments affected by the policy to obtain their input, to answer any questions, and to elicit their support. These contacts should be in conjunction with each department's RSC representative. Similarly, formal support and authorization by administrative and medical staff management should be sought.

Prior to the MSEC meeting at which the draft policy will be presented, the chair of the MSEC should circulate the draft and encourage discussion with those drafting the policy. After approval of the policy by the MSEC, it is forwarded to the BOD or to Executive Management, such as the Chief Executive Officer (CEO), for final approval.

Delineation of the Authority to Approve or Suspend Fluoroscopy Privileges.

Hospitals modify privileges according to their policies and medical staff rules. For this program two credentialing reviews occur: One through the medical staff office and one through the RSC. Maintaining approval sequencing and communication between the MSO and the RSC is a challenge and a continuing process.

Once an application is approved by the medical executive board, the MSO issues notification of fluoroscopy privileges for specific clinical procedure(s) for individuals on specified fluoroscopic equipment. The privilege request form should identify which procedures utilize fluoroscopy and the specific fluoroscopy equipment.

CREENTIALING AND PRIVILEGING PROGRAM FOR FLUOROSCOPY USERS

The RSC has the authority and responsibility to approve all users and locations of use of fluoroscopy equipment. The following points should be considered as part of the process:

- Because of the higher potential for patient injury, the RSC may wish to focus its initial efforts on interventional fluoroscopy procedures.
- Board certification, training, and experience documentation for interventional fluoroscopy physicians is submitted to the RSC as part of its approval review process.
- The training required by certain medical specialty boards may sufficiently cover part or all of the fluoroscopy safety training. The RSC should evaluate which boards satisfy their requirements to streamline the approval process.
- Residents and fellows may use fluoroscopy equipment under the supervision of an individual who is personally privileged to perform the procedure in process and is physically present with residents and fellows when they operate fluoroscopy equipment.
- All physicians and independent licensed practitioners should have had, or be required to receive, basic fluoroscopy safety training when requesting privileges, even if a radiologic technologist operates the fluoroscopy equipment at the direction of a physician.
- The facility needs to establish credentialing criteria for physicians and licensed independent practitioners who did not receive formal fluoroscopy training during their residencies. These criteria should be equivalent to those met by privileged users for the risk level and type of fluoroscopy unit(s) and procedures for which privileges are requested. These criteria should also be recognized as compliant with professional standards and within the scope of practice designated for the licensed practitioner.

Fluoroscopy use is not as controlled as radiographic procedures. Radiologists, cardiologists, surgeons, pulmonologists, and pain management physicians all use fluoroscopy equipment. Residents and fellows are not individually approved because they are supervised by a privileged user. It should be stressed that a privileged user is required to be physically present with residents and fellows when they perform fluoroscopic procedures.

The RSC has the authority to suspend its approvals, and must inform the MEC of any suspensions. The MEC has the authority to revoke, to suspend, or to not renew privileges. A recommendation to suspend fluoroscopic privileges should be based on a professional review of the individual's clinical use of fluoroscopic equipment in consultation with the chair of the department, a qualified imaging medical physicist, and the RSO.

Policy Implementation.

The facility's policy should identify the policy implementation process and contain provisions to verify implementation. The policy should clearly define lines of responsibility, authority, communication, and coordination.

The institution's policy concerning implementation of the fluoroscopy privileging program also needs to be well documented. A frequently updated database on the institution's internal website of all current privileged users may be an effective resource to communicate who has fluoroscopic privileges within the institution. Written policies should specify any grace periods for

previously privileged individuals who fail to update their privileges prior to expiration of their current privileges.

Professional review of the individual's credentials determines whether the applicant qualifies for fluoroscopy privileges as an independent operator. This professional review of credentials should be done in consultation with a QMP and a clinician approved for clinical fluoroscopy privileges for the same or similar procedures.

Examples of acceptable training and experience are board certification by the appropriate professional specialty board for which privileges are requested, or completion of a training program equivalent to that received in an Accreditation Council for Graduate Medical Education (ACGME) approved radiology or cardiology residency and advanced fellowship program. Advanced training and experience is an essential patient safety issue for high-risk category procedures such as interventional neurological, vascular, and cardiac procedures. Specialty residencies other than radiology and cardiology may have added fluoroscopy training to their programs, which may qualify the applicant to be approved for the type of fluoroscopy privileges requested. This can be verified on the ACGME website (www.acgme.org).

Before approving a request, facilities should require all applicants to complete equipment-specific operational competency testing to demonstrate that they know how to set up, position, and operate the requested type of fluoroscopy equipment. This is particularly important if the fluoroscopy equipment is new, or new to the user. A logical person to evaluate this knowledge is a clinician already approved to use that equipment. In some cases, this training will need to be provided by the equipment vendor (applications training) or an experienced radiologic technologist. Individuals with no prior supervised hands-on training may not have acquired the competency to operate the equipment in a manner consistent with the radiation protection philosophy of keeping radiation doses "as low as reasonably achievable" (ALARA).

8. Credentialing and Privileging Program Implementation

Administrative organizations as well as regulatory and accreditation requirements are different for various types of facilities. As a result, all facilities do not have an RSC, RSO, QMP, or MSO personnel. Typically, there is an administrator, or supervisory staff person, who oversees the areas of responsibility of a QMP or RSO. Consequently, consultants should be contracted to perform the QMP and RSO functions.

Administrative Process for Program Implementation.

Senior management support and concurrence are essential for establishing and maintaining both the credentialing and training programs. Without it, program implementation and sustainability are not possible.

The process for implementing the program should be contained in a procedure jointly developed by the MSO, the RSO, the RSC chair, and affected department chairs. It should be approved by both the Radiation Safety and the Credentials Committees.

The following descriptions of responsibilities are assigned to TJC-accredited hospitals and are presented for guidance. Facilities that do not have an MSO, an RSC or an RSO, have at least one employee assigned the responsibility for receiving and preparing documentation for submission to the chief medical officer, or other official, who approves and grants privileges.

Administrative Personnel Responsibilities.

Medical Staff Office. The MSO has overall ongoing responsibility for ensuring program elements contained in the policy and the operating procedures are implemented. These should include developing a fluoroscopy privileges request form, notifying the RSO of new requests for fluoroscopy privileges, and providing copies of designated information. The fluoroscopy privileges form should be developed in conjunction with the RSC and department chairs, and it should require submission of documentation showing satisfactory completion of RSC approved training for the applicable risk level(s), e.g., mini C-arm training should differ from that required for interventional procedures.

The completed fluoroscopy privileges request form should be accompanied by the authorized fluoroscopy user-training certificate (Figure 3) signed by the RSC official. The fluoroscopy training certificate should specify which risk level is approved, and have an expiration date that corresponds to the date retraining is required. The latter may be mandated by state regulations; if not, the RSC should decide on the appropriate interval. It is suggested that the approval interval correspond to the facility's re-privileging schedule.

The MSO typically maintains the records associated with the fluoroscopy privileging program in compliance with state or local regulations. However, the RSO should also maintain copies of records and a master list of approved fluoroscopy users.

After the MSO receives the signed privilege request form and all the required supporting documentation from the department chair, the MSO staff should contact the RSO and provide copies of the designated information.

Department Chair. The department chair's ongoing responsibility is to review training and experience of applicants, to evaluate their competency, and to ensure compliance with facility policies. Following this review, if no deficiencies are found, the chair signs the applicant's request for either initial privileges or renewal of existing privileges and submits it to the MSO for processing. Department chairs should ensure their Privilege Request Form identifies the procedures for which fluoroscopy will be performed. This will alert the MSO staff to contact the RSO, or person responsible for radiation safety.

Each department chair should be required by policy to have a procedure in place for continual monitoring of fluoroscopy use by the fluoroscopy authorized users in order to assure such usage is safe and appropriate. Also, department chairs need to assist with establishing and maintaining a fluoroscopy clinical practice training program and provide continuing education opportunities for their staff. Facility policy should also require each chair to provide and support the criteria used to determine whether or not fluoroscopy privileges should be renewed.

Authorized Fluoroscopy User Certificate

Facility's Name and Address

(Name of Approved Authorized Fluoroscopy User)

is authorized to use fluoroscopy x-ray equipment for patient diagnosis or treatment under the guidance of fluoroscopy in compliance with the following conditions:

Prerequisite Training

_____ *Fluoroscopy training and experience are current and risk appropriate*

_____ *Satisfactory completion of required risk level fluoroscopy training*

Authorized Procedures

(e.g., upper GI-BE, interventional vascular, interventional cardiac, pain management, endoscopy, etc.)

Authorized Risk Level

(Low, Moderate, High)

Authorized Fluoroscopy Equipment

(e.g., under table, mini-C-arm, mobile C-arm, ceiling mounted C-arm)

Approved Location(s) of Use

(e.g. Radiology, Cardiology, Endoscopy, Operating Room, ICU, etc.)

_____ *Signature of RSC Chair or Facility Representative* _____ *Date Approved*

_____ *Title* _____ **Expiration Date**

Note: A copy of a current fluoroscopy authorized user training certificate should be submitted with the applicant's request for privileges.

Figure 3. Sample Authorized Fluoroscopy User Certificate.

Medical Director of a Section. Department chairs of large departments, such as cardiology and radiology, frequently delegate responsibility for ongoing quality improvement and training to the medical director of a section. The role of these key individuals should be identified in the facility policy. The section medical director and nurse manager typically work together to maintain compliance and to manage quality improvement during daily operations.

Radiation Safety Officer. The Radiation Safety Officer, or person assigned radiation safety responsibility, should assist the MSO staff by providing a list of required information and documentation the applicants are to submit for the risk level of fluoroscopy use they want to perform. The list should ensure compliance with state regulations and facility accreditation program(s) requirements.

The role of the RSO in a credentialing program will depend on the training and background of the RSO. The RSO may be a radiologist with special competence in interventional fluoroscopy, nuclear medicine, radiation oncology, or some other specialty within radiology. The RSO may be a QMP with expertise in clinical imaging, radiation therapy, nuclear medicine, radiation protection, or some combination of these different areas of expertise. The RSO may be primarily a health physicist within a medical institution directing an institution-wide radiation protection program, or may specialize in imaging physics and work full time within radiology. Finally, if no medical physics support is available at the institution, the RSO may be a nuclear medicine technologist or a radiologic technologist. The RSO will typically be involved in record keeping or other administrative aspects of the program but may not be personally qualified to provide evaluations or training.

Qualified Medical Physicist. The QMP may perform the same function as the RSO in supporting the MSO and reviewing submitted documentation supporting the privilege request to determine compliance with requirements. The QMP may have the lead in developing didactic content and providing training in the safe operation of fluoroscopy equipment.

Radiologic Technologist. Radiologic technologists often assist licensed practitioners with fluoroscopy procedures. They should be aware of the existence of the fluoroscopy privileging program, know who is approved, and understand that they can take their concerns to the QMP or the RSO. Technologists have valuable training and experience in using fluoroscopy equipment and implementing radiation safety practices. They often are the ones to record fluoroscopy exposure times and dose levels, if available on the equipment. Their role in training and fluoroscopy use should be identified in the institutional plan.

Nurse Manager. The nurse manager's roles and responsibilities are institution specific. Those managers of departments or divisions where fluoroscopy equipment is used should be made aware of the fluoroscopy privileging program. Some department or division chairs may delegate management of physician privileging logistics to their nurse manager. If so, the role for ensuring compliance should be outlined in a department-specific procedure. The nurse manager, or designee, is usually responsible for ensuring personnel radiation dosimeter badges are issued to designated personnel in the department or division.

Privilege Application Review Process.

Preparation of Standard Operating Procedure for Application Reviews. Typically, this preparation is performed by the director of the MSO, the RSC chair, or designee, and the RSO before the program is implemented. A written procedure describing the review process for fluoroscopy privileging applications that complies with the facility's policy and accreditation requirements is implemented by the MSO. Communication and coordination between the MSO and the RSO should also be addressed in the procedure.

For offices or facilities that do not have an MSO or an RSO, the designated individual with the responsibility for reviewing applications should draft the procedure to ensure review consistency and have it approved by the Chief Medical Officer or BOD.

Privilege Application Submittal to the Medical Staff Office. When a department chair requests privileges for either a new practitioner or for re-privileging a currently approved user, the MSO provides the prospective applicant with a form listing an appropriate delineation of privileges. The privileges form should include fluoroscopy use as an option, or identify which requested procedures utilize fluoroscopy. A similar process should be used if a current physician wishes to add fluoroscopy use privileges in the period between re-privileging.

As with all applications, the MSO reviews the request for privileges. If fluoroscopy use is requested, the MSO will require fluoroscopy training documentation to be submitted. The MSO will contact either the RSO or the QMP to review the fluoroscopy credentials and to determine compliance with policy and applicable regulations.

Privilege Application Review by RSO and RSC. After receiving the name and supporting documentation, the RSO, or individual assigned this responsibility, reviews the information against a checklist to determine compliance with facility policy, state regulations, and related accreditation program requirements for new applicants. This information is presented to the RSC for their evaluation and approval.

The RSC, or designated individual with this responsibility, verifies that the applicant meets the required criteria specified in the facility policy and state regulations. As part of the review before determining if approval is appropriate, the RSC may require the department chair, the RSO, or QMP to determine if the applicant demonstrated any negative practices such as:

- Excessively long fluoroscopy procedure times and high patient doses
- High or missing personnel dosimeter readings
- Unsafe radiation safety practices
- Failure to successfully complete the educational requirements
- Failure to complete hands-on training requirements
- Failure to meet CME requirements.

The RSC forwards the results, via the RSO, of its review to the MSO for transmission to the credentials committee recommending either approval of the privileges, or referral back to the applicant for additional information, action, or training.

If approved, the RSO notifies the MSO staff, updates the RSO's master list of approved fluoroscopy authorized users, and prepares the fluoroscopy authorized user certificate. Figure 3 shows a sample fluoroscopy authorized user certificate.

Tracking, Evaluation, Compliance Audit, and Record Keeping Responsibilities.

Tracking Fluoroscopy Use Within the Institution. A list of users with fluoroscopy privileges issued by the RSC should be maintained by designated personnel for each department or division using fluoroscopy equipment. Also, the list should include fluoroscopy equipment to be used, room number, procedures to be done, typical skin doses for the procedures, and a list of types of personnel routinely present during fluoroscopy requiring radiation monitoring (e.g., physicians, nurses, technologists). Any change or additions should be managed by submission of an amendment to the individual's authorized fluoroscopy user certificate that is submitted to the RSO.

The Quality Management Program Policy for Evaluating Fluoroscopy Use. The institution should develop a Quality Management Program Policy that requires identification of procedures that could result in skin damage and reporting requirements for these procedures to the RSC at defined intervals (e.g., quarterly). Audit procedures should be designed to ensure sentinel events are identified promptly, reported to the institution's Risk Management Office and followed up appropriately. The Quality Management and Radiation Safety Programs should identify levels of risk based on skin dose for which the patient or referring physician should be notified. Notification should include the dose received and the associated risks. Patient dose monitoring should also include detecting high doses that may not exceed established risk levels, but when seen frequently, indicate the existence of a potential problem. The program should also specify when informed consent about fluoroscopy risks is required to be obtained prior to a procedure. Development of skin damage risk statement language will require RSC designees to work with the individuals who oversee informed consent at the institution.

Compliance with Facility Policy by Fluoroscopy Users. Privilege issues should be addressed under the credentialing committee procedures already in place. TJC's required credentialing program mandates all licensed independent practitioners have sufficient training and experience to justify the privileges granted.

The MSO should be responsible for initiating action when an untrained physician is identified.

Audit of the Fluoroscopy Privileging Program. The fluoroscopic privileging program should be audited annually by an oversight committee that is not involved in the day-to-day management of the program. Typically, this oversight committee is the institution's RSC. Factors to be reviewed and evaluated include written examination pass rates, undue delays in the granting of privileges, accuracy of the privileged user data base, management of prior privileged individuals who have difficulty in renewing their privileges, complaints by prospective new or experienced users, and the ability to prevent non-privileged users from conducting fluoroscopic examinations.

Recordkeeping Requirements. The institution needs to retain records in accordance with local and state regulations, and accreditation program requirements, as well as with the facility's policies. This responsibility is typically assigned to the MSO staff. But the RSO should also retain records in support of the RSC's evaluation. The RSO should also be available during inspections to provide and discuss records as necessary.

Figure 4 shows a sample process for granting fluoroscopy privileges.

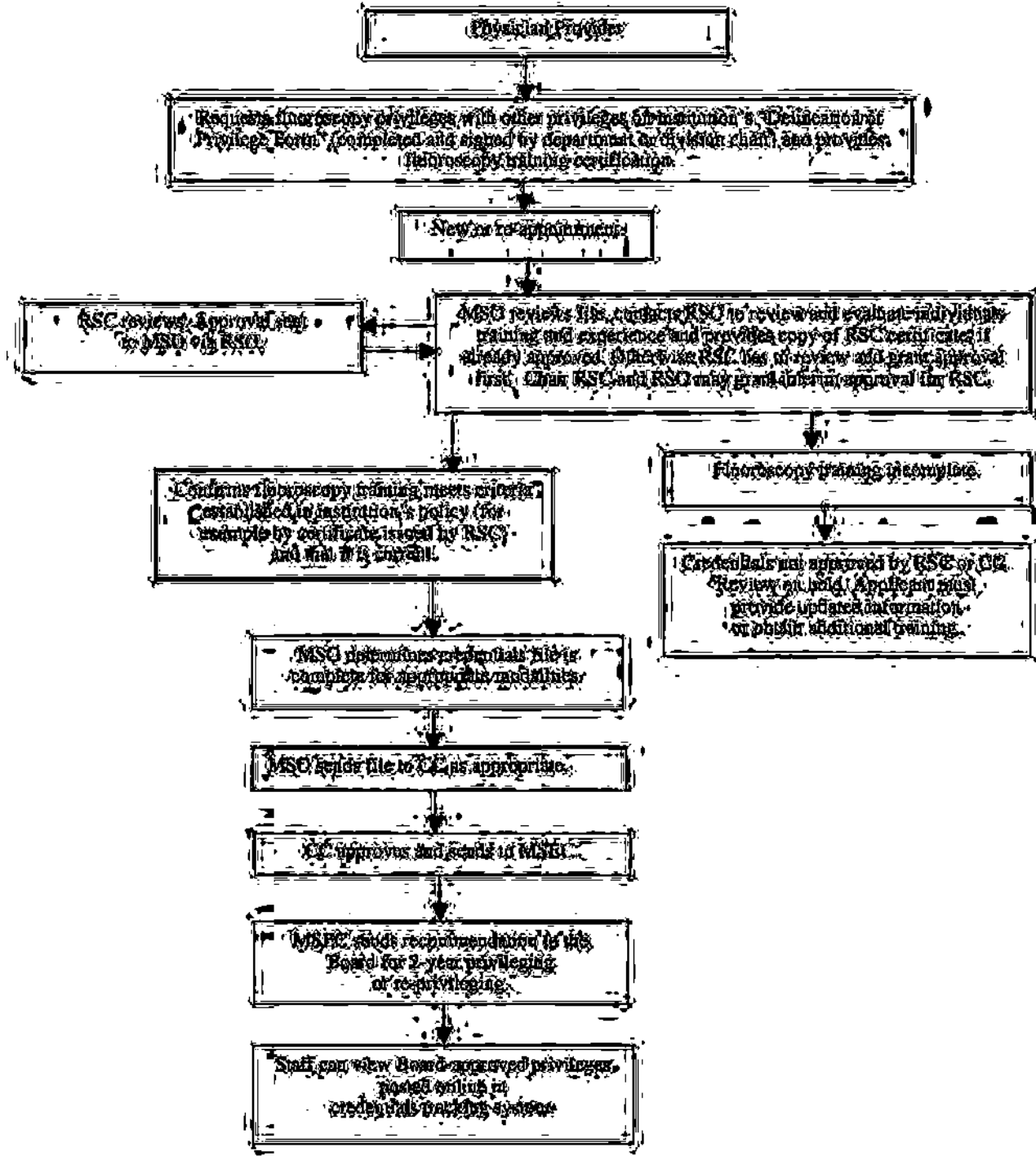


Figure 4. Sample Process for Granting Fluoroscopy Privileges.

9. Fluoroscopy Training Program Recommendations

Scope.

Training necessary to obtain competency to perform the clinical component of a procedure and the expertise to diagnostically interpret fluoroscopy images is outside the scope of this report. The user's clinical professional training (e.g., residency requirements) addresses those aspects.

This document addresses the technical and safety components of fluoroscopy use including necessary training based upon the risk levels of radiation exposure to the patient.

Objective of a Fluoroscopy Training Program.

The objective of the fluoroscopy safety training program recommendations in this report is for clinical users to learn how to operate fluoroscopy x-ray equipment correctly and safely as they simultaneously perform a clinical procedure. This process is analogous to driving a car with a manual transmission. Studying the operator's manual provides information about the principles of operation, but practice is needed to obtain hand, eye, and foot coordination in order to drive a car safely and to operate a fluoroscopy unit safely. Safe operation of a fluoroscopy x-ray unit means patient and staff radiation dose levels are as low as reasonably achievable (ALARA) for the type of procedure being performed and that acceptable clinical image quality is consistently obtained.

The focus of the recommendations presented in this report is a process for structuring a competency and risk-based training program to enable a clinical user to acquire the competency needed to safely and expertly use fluoroscopy equipment for all risk level procedures. Knowledge of dose reduction procedures and techniques, the physics and radiation biology basis for these procedures, and how to implement them as part of the clinical procedure allow the user to implement appropriate changes that reduce risk.

Procedures requiring long fluoroscopy times resulting in high skin doses are of special concern for both patients and staff. Users authorized for fluoroscopy for these procedures must have in-depth training and experience to maximize patient and staff safety. Patient injuries from these types of procedures prompted the FDA 1994 advisory for facilities to identify procedures that could result in high skin doses to patients (FDA 1994). The states regulate the users, and the FDA regulates the manufacturers. In 2010, the FDA reaffirmed their initiatives to reduce unnecessary radiation exposures from medical imaging. This effort is summarized on the FDA web page (<http://www.fda.gov/Radiation-EmittingProducts/RadiationDoseReduction/default.htm>), where the FDA addresses personnel qualifications, education, appropriate use, equipment safety features, tracking radiation safety metrics, and related references. This website also summarizes the efforts by Centers for Medicare and Medicaid Services (CMS), the state regulatory agencies, and the development of a federal guidance document entitled "Federal Radiation Protection Guidance for Diagnostic and Interventional X-ray Procedures (FGR-14)."

Also, in November 2005 TJC classified a fluoroscopy dose to a patient of 1500 rad (15 Gy) to a single field as a Sentinel Event. This designation of radiation overdose as a Reviewable Sentinel Event was updated in their March 7, 2006 guidance (http://www.jointcommission.org/assets/1/18/Radiation_Overdose.pdf). While this level of

radiation dose may appear highly unlikely, it can, and does, occur. TJC's expanded sentinel event definition requires a facility to be able to determine patient dose and to assess if the sentinel event level has been reached or exceeded.

Compliance Requirements for Fluoroscopy Training.

The fluoroscopy training program developed by an institution must comply with state regulations. State regulations applicable to the facility should be checked to determine who may operate fluoroscopy equipment to image patients, and the level of training and experience required for fluoroscopy users. Some states (e.g., *New Jersey Administrative Code 7:28-19.1*) specify that only licensed physicians and licensed radiologic technologists working within their scope of practice may operate fluoroscopy equipment. California, Massachusetts, and Colorado have regulations regarding fluoroscopy training requirements. The Rocky Mountain Chapter of the AAPM provides an on-line Fluoroscopy Training Program accepted by Colorado as compliant with their regulations (<http://chapter.aapm.org/rockymtn.ftm>).

To maintain regulatory compliance, the training program also needs to include any regulatory requirements that may be more restrictive than the TJC requirement. For example, at least one state (Massachusetts, 105 *CMR* 120.405 (L)(5)) currently requires any examination resulting in a cumulative skin dose of 2 Gy or more “. . . shall be noted in the patient's medical record and reviewed by the facility's Radiation Safety Committee.”

Administrative Elements of a Training Program.

Satisfactory completion of a fluoroscopic training program is considered an essential credentialing requirement for granting fluoroscopy use privileges.

Proper administrative elements in a training program for fluoroscopy users are necessary to assure the success of the program. These elements include defined administrative personnel responsibilities, training reciprocity, trainer qualifications, and program design and content. Availability of didactic training is a key administrative element of a successful program, and may be delivered by didactic lecture or appropriate web-based modules.

Administrative Personnel.

Individuals with the responsibility for administratively managing the institution's privileging program and for conducting its fluoroscopy training program should be identified in the facility's policy. Discussions between the privileging program coordinator and the individual responsible for training fluoroscopy users will reveal how best to coordinate communications and to incorporate the fluoroscopy training process into the larger program of institution credentialing and privileging.

The institution's fluoroscopy privileging program coordinator can assist fluoroscopy users with applying for the correct privileges. This individual can best explain the administrative processes currently within the institution that allow a physician to apply for certain privileges and receive those privileges from the institution's Board of Directors or equivalent. The individual(s) charged with the responsibility for the fluoroscopy training program should identify key individual(s) within their institution who will provide the training.

Coordinating the training and privileging programs allows the established institution's privileging program to manage notifications, deadlines, and tracking of compliance, associated with obtaining and maintaining fluoroscopic privileges through multiple privileging cycles.

Reciprocity for Privileges and Training.

Each individual institution needs to accurately document its position on this important administrative element in its program policy. It should address how, or if, training reciprocity will be accepted for fluoroscopy users currently on staff when the program is initiated and for future new users. It should address a method for determining the equivalence of a fluoroscopy privileging program in another healthcare organization.

Applicants privileged by another entity should provide documentation of their training and experience as part of the credentialing process supporting their requested privileges at their new institution. Direct communication between designated individuals who conduct training at both facilities, such as the RSO or a QMP, would be a viable method to verify information submitted and to obtain clarifications.

If the previous training and experience acquired at another facility are found to be timely and equivalent, then the submitted documentation could be accepted in lieu of completing the in-house training program. However, it is recommended that all fluoroscopy privilege applicants complete and pass the written examination on didactic content. While the basic training may be equivalent for the two institutions, policies and procedure may be different.

As more institutions develop privileging programs, reciprocity acceptance will probably become more common.

Categories of Applicants for Fluoroscopy Privileges.

Applicants most likely fall into one of the following general categories: active and inactive experienced users, and untrained applicants.

(a) Active Fluoroscopy Users.

These individuals tend to consist of two groups:

- (1) Those with formal competency-based training consisting of didactic and supervised hands-on experience acquired during a residency or other special training program.
- (2) Those who acquired "on-the-job" experience as an ancillary part of learning how to perform a clinical procedure that utilizes fluoroscopy. They have had no formal didactic or operational training in imaging physics, fluoroscopy, x-ray equipment design, equipment dose reduction techniques, radiation biology, or radiation safety.

The training needs are different for these two groups. The institution needs a clear policy on how it defines and documents the required training and experience for these two types of "experienced" users. This policy should identify how the facility will manage the experienced users on staff when the institution initially implements its

fluoroscopy training program and when new experienced users are hired after program implementation. The policy also needs to assure that the acquired experience is relatively recent and that the applicant has maintained proficiency.

Reasonable accommodation for experienced fluoroscopy users depends on the timeliness and extent of their previous training and experience. For example, evaluation of an experienced user's training and experience will indicate whether it is appropriate for that individual to bypass the didactic training and take the written examination.

Reasonable accommodation for hands-on refresher training for an experienced user with previous formal competency-based operational training should be determined by the timeliness of their use of the fluoroscopy equipment, the number of procedures performed on that equipment, and whether or not new equipment was acquired, or operational features were added.

Reasonable accommodation for experienced fluoroscopy users moving from a different institution is the same as that for a privileged practitioner on staff, i.e., the extent and timeliness of their previous training and experience. Evaluation of the new experienced user's training and experience will indicate whether it is appropriate for that individual to bypass the didactic training and take the written examination.

After passing the written didactic content examination, both existing and new experienced users should participate in the "hands-on" training and demonstrate their competency operating the specific fluoroscopy equipment they will use. This is important for the new experienced user, because the new facility may have fluoroscopy equipment manufactured by vendors different from those used at the previous location. While the basic elements are the same, different design features are provided by different vendors. These differences include, but are not limited to, different location of operational controls, how the automatic fluoroscopy mode functions, fixed vs. variable x-ray source-to-skin distances, orientation of fluoroscopic images, etc. As a result, following the instructor's review of operational equipment features and methods to reduce patient dose, or those shown on a training video, the applicant may need time to practice operating the equipment before taking the competency demonstration examination.

Prior to completing and passing the hands-on training and examination, but after passing the written examination, the new user with experience acquired outside the institution should be allowed to conduct fluoroscopic examinations under the supervision of a currently privileged user.

If any experienced user fails the didactic course content examination, that individual should complete the didactic training and take the examination again. The individual should only be allowed to conduct fluoroscopic examinations under the personal supervision of a currently privileged fluoroscopy user until after the examination on didactic course content and operational competency have been satisfactorily completed.

(b) Experienced but No Didactic Training or Supervised Competency Training.

Applicants with experience acquired “on-the-job,” but who have had no didactic training, should complete the didactic component, pass the written examination, attend the “hands-on demonstration” for the fluoroscopy equipment they will use, and perform procedures under supervision until deemed ready to take an operational competency examination.

The supervising privileged fluoroscopy user should provide written evaluation of the applicant’s competency and proficiency using the specified fluoroscopy equipment and if the applicant was found to be competent.

(c) Inactive Fluoroscopy Users.

Inactive experienced users are those who have not performed any fluoroscopy clinical procedures within the time frame designated by the facility’s policy. State regulations or TJC may specify the time frame when an inactive user must be re-credentialed before fluoroscopy privileges can be renewed.

The facility policy should identify requirements for approved users to maintain their proficiency operating fluoroscopy equipment (minimum number of procedures performed per year). Current experience should be addressed during the privilege renewal process. The department chairs typically are required to evaluate competency as one criterion to support their request and recommendation for privileges.

(d) No Prior Training or Experience.

Historically, individuals with no prior training or experience were trainees in a residency or fellowship program whose didactic and operational training, experience, and competency requirements are specified by their ACGME-approved residency program. The facility is usually required by the residency program to provide direct supervision by a privileged user in that specialty and in accordance with their residency requirements. The Residency Program Director oversees the facility’s program to ensure compliance with the accreditation requirements and is the primary point of contact for information. If fluoroscopy equipment is operated during any residency, then didactic and hands-on training should be required and the residents should be tested and required to pass both examinations. Such a requirement would help eliminate the increasing number of users who acquire on-the-job experience without learning the imaging physics, radiation biology and radiation safety principles needed to understand the effects of radiation, how to perform low-dose fluoroscopy, and how to produce acceptable image quality.

However, a number of medical specialties have started to independently perform procedures that utilize fluoroscopy. These fluoroscopy users should be required to complete all four phases of the training program (didactic training, passage of written examination, hands-on training, and supervised demonstration of competency operating the equipment) prior to receiving fluoroscopy privileges.

Acceptable Qualifications and Training for Users of Fluoroscopy Equipment.

Historically, physicians who have completed an ACGME-approved residency program that includes fluoroscopy training consisting of didactic content, supervised training for operating the equipment, and evaluation of applicant's fluoroscopy operational competency have been considered qualified to operate all types of fluoroscopy equipment. Historically, these residencies have been limited to radiology and cardiology.

Radiology and cardiology physicians receive both basic and advanced training in interventional procedures that utilize fluoroscopy. They also provide certification in both standard residencies and the advanced training sub-specialties. Their privileges reflect the level of training received. Their advanced training is consistent with recommendations presented in this report for the High-Risk Level procedures.

The ACGME website (www.acgme.org) provides information about the content of individual residency programs for different specialties. This website allows a facility to identify other physician specialties that provide fluoroscopy training and related didactic course work in radiologic physics and radiation safety. It also allows the facility to evaluate whether the applicant's training credentials are appropriate for the fluoroscopy privilege requested.

Physicians (e.g., GI, pulmonary, surgery, etc.) and non-physician practitioners (e.g., physician assistants and nurse practitioners) who have had no didactic training in fluoroscopy will need significantly more extensive training than radiologists or cardiologists. Each facility should determine whether it is able to provide the level of training necessary for these users to operate fluoroscopy equipment safely as independent users, or whether it can provide training sufficient for them to perform the procedures safely when assisted by a radiologic technologist.

A computerized review program alone is not sufficient training for fluoroscopy users with no, or very limited, previous training.

Post-residency training is being offered by an increasing number of professional organizations to provide the training needed for obtaining fluoroscopy privileges.

The scope of training should be commensurate with the risk and complexity of the procedures to be performed. Training should include medical imaging and physics, radiation biology, radiation safety, equipment design (including operational features), and hands-on training and experience.

Acceptable qualifications and training for users of fluoroscopic equipment is based on three risk levels: Low, Moderate, and High Risk.

All training programs should require the following for all three risk levels:

- Training and experience that complies with the institution's credentials requirements for the fluoroscopy risk level of the clinical examinations or procedures being requested
- Didactic training commensurate with fluoroscopy risk level
- Satisfactory completion of an examination on didactic material
- Applicant's successful demonstration of competency implementing safe practices while performing clinical procedures utilizing fluoroscopy equipment commensurate with assigned risk levels.

The three recommended levels of training based on risk are outlined in Table 2.

CREDENTIALING AND PRIVILEGING PROGRAM FOR FLUOROSCOPY USERS

Table 2. Levels of Risk and Initial Training Required*

Risk Levels	Equipment and Procedures	Recommended <u>Minimum</u> Duration of Training	Didactic Training Course Content Based on Risk
<i>Low</i>	Mini C-arms— Extremity Imaging Mobile C-arms— Orthopedic reductions Simple Line placements	Two hours didactic lecture and “hands-on” demonstration, followed by practice, and competency examination	Overview: Reason for training and associated risks Basic properties of radiation Units of measurement Interpreting DAP (dose-area product) values & air kerma Biological effects Sources of radiation exposure Radiation protection methods for patients and staff Patient exposure and positioning Image recording and processing Quality control and assurance Regulations and site policies Electrical safety How to operate the fluoroscopy equipment to be used
<i>Moderate</i>	Mobile C-arms— Pain management Bronchoscopy Orthopedic surgery GI-GU Urology Speech pathology R-F with under table x-ray tubes and remote R-F systems with over table x-ray tubes— Upper GI, BEs Speech pathology	Four hours didactic lecture and “hands-on” demonstration, followed by practice, and competency examination	Overview: Reason for training and associated risks Basic properties of radiation Units of measurement and dose Interpreting DAP and other dose display values Biological effects Sources of radiation exposure Radiation protection methods for patients and staff Virtual collimation, fluoro loop Pulsed vs. continuous fluoro Patient exposure and positioning Frame rates Image recording and processing Procedures related to specific equipment Quality control and assurance Regulations and site policies Electrical safety How to operate the fluoroscopy equipment to be used
<i>High</i>	Interventional floor and ceiling mounted C-arms and robotic C-arms— Examinations performed in radiology, cardiology, electro-physiology Hybrid operating room	Eight hours didactic lecture and “hands-on” demonstration, followed by practice and competency examination	Moderate level risk topics as a refresher course <i>Plus</i> Methods to reduce patient dose using advanced imaging and recording features such as – Digital subtraction – Cine-like digital imaging and record mode utilization – Image fusion with CT, MRI, or ultrasound – Software-guided needle localizations – CT fluoro, cone-beam CT, and 3D imaging – Virtual needle guidance – Robotics

*Initial training applies for new applicants. Continuing education (refresher training) is addressed in Appendix A, Section 3.

All three levels of training should be designed to comply with the institution's privileging requirements for clinical examinations in addition to the other requirements listed for each level.

10. Training Program Overview

The content of the curriculum should enable the fluoroscopy operator to produce and maintain diagnostically acceptable image quality while optimizing patient doses. Didactic presentations that utilize clinical applications and examples pertinent to the user's actual practice hold the interest and attention of the user better than a curriculum centered on general radiation protection principles and regulations. The curriculum should be developed by a QMP who has a good understanding of both imaging physics and the details of the particular user's clinical procedures. Such a QMP is able to interweave radiation protection principles into an effective clinical technique presentation to which the users can relate since they immediately understand the benefit of using appropriate techniques. Classic radiation protection lectures on fluoroscopic principles that fail to provide practical application to the user's actual practice are quickly forgotten.

The scope of training should be commensurate with the risk and complexity of the procedures to be performed. Training content should address the applicant's lack of prior training in medical imaging and radiation safety, and lack of supervised hands-on experience.

The training should cover basic radiation protection considerations including radiation safety principles, radiation health effects, personnel monitoring, patient dosimetry, hospital policies, state regulations, and practice guidelines. In addition to radiation protection, the course should include information on basic x-ray physics, fluoroscopic imaging technology, equipment design, image quality optimization, radiation dose reduction techniques for the patients and staff, quality control, and quality assurance. After these fundamental principles are discussed, users should receive instruction on the unique operational features of the specific fluoroscopy imaging equipment they will be using ("hands-on" demonstration). The fundamental principles address the objectives and the hands-on demonstration addresses the proper operation of the equipment for optimization of image quality and dose.

Three levels of training content are recommended as outlined in Table 2, which relates training content with the associated risk levels for the procedures and fluoroscopy equipment used.

It is difficult for facilities without medical physics staff to provide training. However, no facility would knowingly grant privileges to an inadequately trained practitioner. Because the practitioners control the use of the fluoroscopy equipment, and, consequently, the doses to the patients and staff, they should receive basic fluoroscopy training at the appropriate risk level.

For practitioners with limited training, the facility should ensure that a radiologic technologist sets up and positions the fluoroscopy equipment and positions the patient. The radiologic technologist can help ensure patient dose minimization by operating the foot pedal at the direction of the practitioner and ensuring that the patient is not exposed to radiation when the practitioner is not looking at the monitor. This process enables the radiologic technologist to assist the practitioner with reducing unnecessary radiation dose, and to reinforce radiation safety training. Consequently, the radiologic technologist must be fully trained on basic and advanced imaging options.

In summary, applicants lacking either training or experience should successfully accomplish the following:

- Complete didactic training at the appropriate fluoroscopy risk level for their specialty and the procedures they will perform
- Pass an examination on the didactic material
- Successfully demonstrate competency at the fluoroscopy risk level needed for their practice
- Receive written evaluation by the supervising privileged fluoroscopy user regarding the applicant's competency using the specified fluoroscopy equipment.

See Appendix A for additional information and guidance on training programs.

11. Summary

This report is an effort to educate the medical physicist and RSO on the basics of credentialing and privileging programs to enable them to participate effectively in that process. It also is a guide for developing a risk-based and competency-based training program. This guide assists with identifying and standardizing appropriate credentials and training for fluoroscopy users.

State medical licensing boards, radiation control offices, and accreditation programs, such as The Joint Commission, specify required credentials for different medical specialties. However, there are no uniform, nationally accepted basic training and credential requirements for all categories of fluoroscopy users.

Professional medical organizations should work together to identify and develop consensus regarding basic didactic topics and operational competency standards for all fluoroscopy users. Such standards should be considered essential training requirements for their respective residency programs, and would provide consistency in credentials for fluoroscopy privileging. This AAPM report and NCRP Report No. 168 (NCRP 2011) are two current efforts to provide these standards.

Education and training for users of fluoroscopy equipment is essential for quality patient care and for patient and staff radiation safety. These goals can best be accomplished by a credentialing and privileging program at the institutional level.

Abbreviations and Acronyms

ABHP	American Board of Health Physics
ABMP	American Board of Medical Physics
ABR	American Board of Radiology
ACC	American College of Cardiology
ACGME	Accreditation Council for Graduate Medical Education
ACR	American College of Radiology
AHA	American Heart Association
AHP	Allied Health Professional
ALARA	As Low As Reasonably Achievable
ARRT	American Registry of Radiologic Technologists
BE	Barium enema
BOD	Board of Directors
CAQH	Center for Affordable Quality Healthcare
CBMP	Canadian Board of Medical Physics
CC	Credentials Committee
CEO	Chief Executive Officer
CME	Continuing Medical Education
CMS	Centers for Medicare and Medicaid Services
CSP	Credentialing Services Professionals
CT	Computed Tomography
CVO	Credentials Verification Organizations (usually commercial firms)
DAP	Dose-Area Product
FDA	Food and Drug Administration
GI-GU	Gastrointestinal-Genitourinary
JCAHO	See TJC
LIP	Licensed Independent Practitioners
MEC	Medical Executive Committee
MRI	Magnetic Resonance Imaging
MSEC	Medical Staff Executive Committee

CREDENTIALING AND PRIVILEGING PROGRAM FOR FLUOROSCOPY USERS

MSO	Medical Staff Office
NCRP	National Council on Radiation Protection and Measurement
OBI	On-Board Imaging
QMP	Qualified Medical Physicist
RF	Radiographic Fluoroscopic x-ray
RSC	Radiation Safety Committee
RSNA	Radiological Society of North America
RSO	Radiation Safety Officer
SCAI	The Society for Cardiovascular Angiography and Intervention
SIR	Society for Interventional Radiology
3D	Three-dimensional
TJC	The Joint Commission, previously known as the Joint Commission on the Accreditation of Health Care Organizations

Appendix A

Training Program Overview

1. Instructional Methods

Didactic Presentations.

Individuals learn in a variety of ways. Some learn by reading, while others from hands-on experience. The best method of instruction depends on many factors such as the age and personality of the trainee. Classroom style lectures allow a skilled lecturer to adapt content to the actual audience. Lectures provide both the trainees and the instructor the opportunity to ask questions. The lecturer can include “hands-on” training. Unfortunately, course participants have demanding jobs with severe time constraints that make scheduling difficult. This limitation is avoided by self-directed training available as reading materials, web-based modules, or videos for didactic content and to illustrate operational controls and systems on the fluoroscopy equipment. However, competency implementing the principles described in the didactic presentation is acquired by the applicant operating the fluoroscopy equipment under the supervision and guidance by a privileged experienced user.

Regardless of the instructional methods employed, institutions should monitor the effectiveness of the instruction provided. Course participants can help instructors adjust the level of the material and provide basic feedback regarding portions of the course materials that need improvement. Instructors should focus on material that directly relates to clinical use. Many topics that are important from a scientific standpoint may be rightfully viewed as esoteric by clinical staff. While trainee satisfaction is important, the program must foster efficient and responsible clinical use. Audits of use in clinical areas are a very important part of evaluating training effectiveness, as are reviews of patient and staff doses.

Hands-On Training on Fluoroscopy Equipment.

A good guide for any training program is that knowledge precedes implementation. Principles of equipment operation, imaging physics, radiation biology, and radiation safety must be understood before they can be implemented correctly.

All applicants should have had prior training in operating the specific fluoroscopy equipment before they use that equipment clinically. This training is accomplished by a process that begins with the didactic information being supplemented by a qualified instructor demonstrating how to use the equipment, and the operational controls on the unit they will use clinically.

A vendor’s applications specialist will provide initial training on new fluoroscopy equipment. This hands-on training could be performed in conjunction with one of the qualified trainers. This training should be customized for the specialty and should highlight special equipment image quality and radiation safety features available.

After receiving the hands-on training, and before being approved as an independent user, applicants should also receive direct supervision while they begin to use the equipment in order to develop both competency and proficiency in the safe operation of that equipment. They should demonstrate their ability to operate the fluoroscopy equipment to achieve acceptable image quality using available methods to reduce radiation dose to the patient and staff. These techniques should include proper collimation, minimal patient-receptor distance, maximum patient-to-source distance, pulsed fluoroscopy modes, and other applicable dose reduction options.

A training tool to support the didactic lectures would be a demonstration video of the imaging equipment controls and systems. It could be viewed at any time and can be replayed as often as needed. Whether the operational aspect is obtained from a video or a demonstration, it needs to be followed by in-person supervision of the applicant's implementation of the information learned from the video.

The applicant's competency could be determined by another, previously authorized fluoroscopy user for that piece of equipment, by a QMP or another person recognized as qualified by the RSC, or as identified in the facility's policy.

2. Examinations and Assessment

Examination on Didactic Material.

The applicant's knowledge needs to be evaluated prior to the initial clinical use of fluoroscopy equipment. The applicant should take and pass a written examination on the didactic content. The specific score required for passing is up to the judgment of the trainer, but generally a passing rate of 70% is appropriate. The applicants should be provided with feedback regarding the questions they failed. If test failure occurs, applicants should be given different tests for subsequent examinations. Applicants failing the exam three times should repeat the didactic portion of the course.

Applicants should be clearly warned that the inability to successfully complete the written examination and hands-on assessment process, or their use of unsafe clinical practices, will result in a denial of privileges to perform fluoroscopy at the medical facility.

Operational Competency Examination.

An approved fluoroscopy user should evaluate the applicant's operational expertise with respect to optimizing image quality and radiation dose. This evaluation should be considered as another teaching opportunity.

3. Continuing Education and Training

Frequency of training must be consistent with state regulations and the facility's accreditation requirements. Didactic retraining should occur at least once prior to renewal of the authorized user's privileges. For active, experienced users, hands-on training should occur on new fluoroscopy models acquired by the institution prior to use by that authorized individual. The user should demonstrate competency during the hands-on training by operating any new fluo-

roscopy equipment, new dose reduction, or image quality features that recently became available prior to first use and prior to that user's fluoroscopic privileges being renewed.

Fluoroscopy privilege renewal should be synchronized with the institution's physicians' privileging processes, which streamlines the administrative process. This would incorporate the management of notifications, deadlines, and tracking of compliance for fluoroscopic equipment users into the established privileging processes already in place within the institution.

Facility policy needs to address how compliance with medical licensing, specialty certification, and facility accreditation continuing education requirements will be maintained.

4. Trainers and Their Qualifications

The most complete and comprehensive training programs for users of fluoroscopy equipment are found in institutions with full-time staff members charged with the responsibility of administering and conducting the program.

A key factor for a successful training program is having qualified trainers, whether they are full-time employees or consultants. Many facilities do not have QMPs or RSOs as full time employees. RSOs are frequently experts in handling radioactive materials, but have limited medical imaging experience. To address these limitations, some facilities contract with their consultant QMP to provide the required training in conjunction with the facility's full-time staff.

Other facilities have implemented computer-based training programs for fluoroscopy users, or for those users identified as needing additional training. It should be noted that a computer-based review program alone is not sufficient for fluoroscopy users with no previous training.

Typically, trainers include the following either individually or as a team: A QMP, medical health physicist, RSO, radiologic technologist, and a radiologist, cardiologist, or other licensed independent practitioner approved as an authorized fluoroscopy user. Vendor applications specialists are a resource that should be utilized for hands-on equipment training.

A QMP, as defined by the AAPM, should have certification by the American Board of Radiology (ABR), the American Board of Medical Physics (ABMP), or the Canadian Board of Medical Physics (CBMP). (www.aapm.org/org/policies/details.asp?id=3168type=PP). The appropriate fields of certification from the ABR are either Diagnostic Medical Physics or Radiological Physics. The appropriate field of certification from the CBMP is Diagnostic Imaging Physics.

Health physicists should be certified by the ABMP in Medical Health Physics, or American Board of Health Physics (ABHP).

In many cases, management of the training program is shared by the QMP and medical health physicist, with the former addressing clinical training issues and the latter addressing administrative and compliance aspects of the program. The QMP typically develops the curriculum and teaches the majority of the didactic lectures. A certified medical health physicist with clinical imaging experience may also work with fluoroscopy clinicians to address image quality and radiation dose issues, provide radiation safety, guidance and lectures, and maintain training documentation for the RSC.

After either the QMP or medical health physicist develops the hands-on training module, the QMP, an approved user, or a radiologic technologist may perform the hands-on training on the x-ray equipment and document the user's demonstrated competency.

The radiologic technologist should be registered by the American Registry of Radiologic Technologists (ARRT) and have training commensurate with the complexity of the equipment being used and procedures being performed. The ARRT is a resource for information about safety and image quality during procedures, and for conducting hands-on training.

A radiologist or a cardiologist who performs fluoroscopy procedures may be the designated individual to provide lectures or hands-on training to other fluoroscopy applicants. A curriculum that is centered on clinical applications and examples that use clinical fluoroscopic techniques designed to maintain or improve image quality while reducing patient dose hold the attention and interest of physicians more effectively than a curriculum centered on radiation protection principles and regulations.

Physicians and other licensed practitioners, who are not radiologists or cardiologists, should have certification by the clinical board applicable to their specialty, provided their training and certification examinations include fluoroscopy and dose management. If their training and certification examinations do not include fluoroscopy and dose management, then the credentialing criteria developed by radiology and cardiology for fluoroscopy users should apply.

Applications specialists are best qualified to demonstrate the operational features of new imaging equipment. The majority of these individuals are radiologic technologists who are trained to explain the various features and options, and to relate them to the clinical use of the equipment. Although they are trained in clinical applications of the equipment, they do not necessarily have the background necessary to teach the imaging and radiation dose management principles that form the core of the curriculum of a good fluoroscopy training program.

Biomedical engineering or other service personnel typically are not involved in fluoroscopy training programs. Their training and experience are focused on the engineering aspects of the components rather than maintaining clinical image quality and radiation dose management during clinical procedures.

Appendix B

Training Resources

The “Sources for Existing Fluoroscopy Training Programs” listed above can be found in the Educators Resource Guide on the AAPM website: <http://www.aapm.org/education/ERG/FLUORO/>.

1. Sources for Existing Fluoroscopy Training Programs

AAPM Rocky Mountain Chapter. The chapter has a web-based training program, examination, and certificate for compliance with Colorado regulations. Available at <http://www.cdphe.state.co.us/hm/rad/xray/fluorotraining.pdf>.

American Association of Physicists in Medicine. *Managing the Use of Fluoroscopy in Medical Institutions*. AAPM Report No. 58. College Park, Maryland: AAPM, 1998. A didactic syllabus and test is available at: http://www.aapm.org/pubs/reports/RPT_58.pdf.

Google.com. Search the terms “fluoroscopy training” or “fluoroscopy radiation safety” for university training programs available on-line.

2. Sources of Information for Developing a Training Program

American Association of Physicists in Medicine. *A Guide to the Teaching of Clinical Radiological Physics to Residents in Diagnostic and Therapeutic Radiology*. AAPM Report No. 64. College Park, MD: AAPM, 1999. Available at <http://www.aapm.org/pubs/reports/64/index.html>.

American College of Radiology. ACR practice guidelines for specific procedures. Available at <http://www.acr.org/Quality-Safety/Standards-Guidelines/Practice-Guidelines-by-Modality/General-Diagnostic>.

American College of Radiology. *ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures*. Reston, VA: ACR, 2008. Available at <http://www.acr.org/Quality-Safety/Standards-Guidelines>.

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- Image Gently. Guidance for pediatric interventional radiologists for dose reduction is found at <http://spr.affiniscape.com/associations/5364/ig/index.cfm?page=603>. This program has expanded its campaign to reduce pediatric radiation doses from CT procedures to now include fluoroscopy. See <http://www.pedrad.org/associations/5364/ig/?page=604>.
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- Society of Interventional Radiology. Society’s home web page has sub-sites for consensus, credentialing, safety, and emerging technologies statements. See www.sirweb.org/.

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