2012
RATIONALE

PART Z

MEDICAL CREDENTIALING

Background and History

Medical radiologic technologists are medical personnel who perform diagnostic imaging examinations with x-ray and radioactive pharmaceuticals, and administer radiation therapy treatments. Individuals performing imaging examinations are responsible for accurately positioning patients and ensuring that a quality diagnostic image is produced, with minimal radiation exposure. These individuals work closely with physicians who interpret medical images to either diagnose or rule out disease or injury. For the images to be interpreted correctly, the imaging exam must be performed properly. Radiologic technologists who perform radiation therapy procedures deliver high doses of radiation to treat cancer and other diseases.

The need for regulation of these individuals to ensure some acceptable level of education or competency is universally recognized. However, current laws regulating medical radiation technologists vary widely from state to state. Eight states (Alabama, Alaska, Georgia, Idaho, Missouri, North Carolina, Oklahoma, South Dakota) and the District of Columbia have no regulations, and five states (Colorado, Michigan, Nevada, New Hampshire, and Wisconsin) have partial regulations which only pertain to specific modalities such as mammography, therapy or CT. Efforts at the state level to provide for legislative authority to initiate medical credentialing or upgrade existing regulations vary.

In order to achieve some type of nationwide uniformity of basic educational and credentialing standards, the American Society of Radiologic Technologists (ASRT) introduced legislation in the 1999 Congressional session. The legislation, now known as the Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy (CARE) bill would apply to all 50 states, and is envisioned to ensure that patients undergoing all types of radiologic procedures have the same assurance of quality as those receiving mammograms under the provisions of the Mammography Quality Standards Act. However, despite the best efforts of the ASRT, and the Alliance for Quality Medical Imaging and Radiation Therapy, a group of 20 radiologic science organizations representing more than 750,000 imaging technologists, radiation therapists and medical physicists, the legislation has not yet been enacted.

Regulation of medical radiologic technologists has long been the responsibility of the states. This Part is intended to assist any state in initiating, expanding or standardizing their regulatory efforts in this area.

Specific Provisions

Sec.Z.2 - Definitions.

Accreditation - states will need to determine a specific name for their credentialing process, accreditation, credentialing, certification, licensure, etc., for which this definition can be interchangeable.

Act - appropriate enabling legislation will be required for enactment of this Part.

Applies ionizing radiation - Care needs to be given with to what extent this definition will be applied, or whether specific tasks, such as positioning the patient or film are included. A liberal interpretation could result in limiting the activities of the medical dosimetrist or physicist, or even service engineers or darkroom techs. This is unnecessary. Applies ionizing radiation means energizing the x-ray beam, and who ever does so takes full responsibility for the exposure.

Approved program - is defined as a formal education program accredited by one of the mechanisms listed in the definition. Since states can count on the integrity of this process, there is no further need to review or approve any of these programs.

Board - enabling legislation will create an advisory board or committee to assist the state program in promulgating or revising its regulations. Typically, members will consist of physicians and technologists who practice in the fields of diagnostic radiography, nuclear medicine and therapy, additional physicians who do not specialize in radiology, a chiropractic physician, medical physicist, and anyone else deemed appropriate.

Limited diagnostic radiographer - the statement at the end of this definition prohibits these individuals from performing any radiographic exam for a portable x-ray service provider (also defined). Such companies are Medicare certified and provide portable x-ray services, primarily to nursing homes. Part 486.104(a) of the Medicare Standard for Portable X-ray Machine Service Providers requires that the x-ray machine operator basically have an educational background that would allow them to be eligible for the ARRT radiography exam (additional standards for individuals whose training was completed prior to 1960 or 1966 are no longer considered relevant). However, this particular prohibition, as worded, will disallow the use of any accredited limited diagnostic radiographer (even those with the documented education) to be employed as such by a portable x-ray service provider. This was done with the additional realization that the high ethical standards of conduct required of all ARRT radiographers would severely restrict the opportunities for fraud and abuse that have been documented among some of these providers.

Sec.Z.3 - Exemptions.

Dentists - the vast majority of the x-ray units in these offices are rather simple, with low radiation output and small beam sizes. Although a few of the Cone Beam CT (CBCT) units are beginning to appear in these offices, they are small and compact, with exposure levels significantly lower than that of a regular CT unit (approximately twice the exposure of a panoramic procedure for a typical full field view). As such, even with the occasional CBCT unit, an exemption of this group is appropriate, included in the proposed CARE bill and well established among the various regulatory programs. As such, any attempt to do otherwise will be strongly opposed.

Podiatrist - these individuals may also lobby to have operators of their units exempt. Like dental x-ray units, they are of low output, and confined to radiographs of the foot and ankle. Any fluoroscopic applications in a podiatric office would be performed by the practitioner. If desired, exemption language is included in Z.3.

Physician assistants / advanced practice nurses - state laws grant physicians the authority to delegate a broad range of tasks to these individuals. However, state laws and regulations governing other professions or areas of health care may contradict this legal authority. This then results in these individuals being either exempted from operator or accreditation requirements (similar to licensed practitioners) to prohibitions against their use of any x-ray or fluoroscopic equipment. The purpose of Part Z is to protect the public from individuals who are not adequately trained to use ionizing radiation safely. However, one must also recognize and acknowledge a supervising physician's ability to plan for the proper utilization of these individuals in a manner that is consistent with their training and experience, the physician's delegatory decision process, the policies of applicable facilities and the needs of the patients seen in the practice. As such, it appears reasonable to consider and include a specific exemption, for interventional fluoroscopic procedures performed under the direct or personal supervision of a responsible physician, for these individuals. This particular position is also supported by ACR Technical Standard For Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008, Resolution 6), and in particular Section III (E) which states: "Other ancillary personnel who are qualified and duly licensed or certified under applicable state law may, under the supervision of a radiologist or other qualified physician, perform specific interventional fluoroscopic or other image guided procedures. Supervision by a radiologist or other qualified physician must be direct or personal, and must comply with local, state, and federal regulations." The support of the ACR in this matter will effectively mute any objections from other professional societies. However**,** if adequate radiation safety training becomes an issue of concern**,** (the ACR notes that the individual should have received formal training in radiation management) regulatory language should then be considered to allow physician assistants and advanced practice nurses authorization to perform interventional fluoroscopic procedures upon completion of a radiation safety course that can reasonably be completed by a working medical professional.

In June, 2011 the Committee received an email for the ARRT's Director of Government Affairs noting that the ARRT, ACR, ASRT and the American Association of Physician Assistants are in agreement that anyone operating a fluoroscope should be properly educated and that should include 40 hours of didactic and 40 hours of clinical training in addition to passing a valid fluoroscopy exam. However, in reviewing this matter the Committee still believes that any additional training/education or exam requirement is unnecessary for the following reasons: the exemption is limited to interventional fluoroscopic procedures while under the personal (in the room) or direct (immediately available) supervision of the responsible physician. As such, if the physician is present during the procedure, why would the individual's training or competency become in issue? If it is, and brought to the attention of the radiology manager, who is that individual going to contact to correct the matter, the hospital's medical physicist and radiology staff or the state regulatory agency?

Nuclear medicine and therapy technologist (CT) - Nuclear medicine and therapy technologists are now being allowed (with appropriate education, training and clinical experience) to sit for the ARRT CT certification exam. Successful applicants are now requesting a regulatory change (must be

radiographers) in order to perform these examinations. Since they have passed the CT exam one cannot argue that they are unqualified. As such, Part Z needed to be modified in order to accommodate them. This was done by proposing an exemption (from the radiography requirement) for these individuals, which will also eliminate the need for a separate accreditation category (and fee). Although the vast majority of radiographers, who may represent around 85% of all technologists, and the professional societies representing them will not be enamored with this proposal, it cannot be successfully challenged on a health or safety basis (they're qualified). However, this expected reaction of the radiographers can also be tempered by every ones realization that the decision to allow non-radiographers to sit for the CT certification exam was made by the ARRT, with the concurrence of the ASRT.

PET/CT and SPEC/CT - this section is also proposing an exemption (from the radiography requirement) for an accredited nuclear medicine technologist to operate the CT component of a PET/CT or SPEC/CT unit when used in the dual combination mode, without any additional education of certification requirements. This position does not appear to pose any health or safety concerns and will again eliminate the need for an additional accreditation category (fusion imaging specialist) and fee. If necessary, consideration can be given to requiring these individuals to also complete a typical manufacturer's training course for new CT operators. Such courses are usually 15 hours in length, and include equipment operation, contrast media, sectional anatomy and CT radiation protection. Any requirement that the CT portion of the exam must be performed by an accredited radiographer is impractical and unwarranted.

Bone densitometry - this section also proposes an exemption for individuals, who under the general supervision of a licensed practitioner perform bone densitometry. In examining this issue there appears to be universal agreement that the radiation exposure to the operator and patient is minimal, and that the operator has little control over the overall quality of the exam. Although proper positioning may be an issue, especially with repeat or follow-up exams, it is a matter that can be easily addressed by the responsible physician. As such regulating the operator does not appear to be a health or safety issue, and may in fact limit its availability. The ASRT has taken a position that individuals performing bone densitometry exams should be credentialed. However, in order to effectively challenge this exemption, one would have to demonstrate to the regulatory agency that an operator exemption for bone densitometry would result in undue hazard to public health and safety, which appears unlikely.

Sec. Z.5 - Examination Requirements**.**

Radiologist assistant - two separate certification pathways exist for the radiologist assistant, the Registered Radiology Assistant (R.R.A.) through the ARRT, and the Radiology Practitioner Assistant (RPA) through the CBRBA. The American College of Radiology has expressed concerns over the recognition of the CBRPA certification, specifically, the lack of oversight from national organizations and scope of practice issues**.** The ASRT and the ACR are also continuing with efforts at the state level to pass legislation which will exclude the RPA pathway, even in states in which no RPAs are employed or reside. They were successful in doing so in Oklahoma, even though this state has no legislation addressing overall medical credentialing. The CPRPA apparently intends to challenge the laws in each state that does so.

Presently, the ACR, ASRT, CPRPA and the Society of Radiology Physician Extenders (SPRE), which is composed of both R.R.A. and RPA members, are cooperating to pass legislation in the U.S. Congress that would recognize an RA as either an R.R.A. certified by the ARRT, or an RPA certified by the CBRPA. Once passed, this bill would then allow Medicare reimbursement for RA procedures and supervision levels that are defined in existing state law. Again, all groups involved, ACR, ASRT, ARRT, CBRPA and the SPRE are presently supporting this legislative effort.

A number of states have already recognized the dual certification pathway and the number of CBRPA certified individuals greatly outnumber those certified by the ARRT, of which the majority are RPAs who completed the R.R.A. exam. Since the CBRPA is established and viable, in this regulatory approach the dual certification pathway is recommended, unless existing state statute specifically excludes.

In this regulatory approach the required supervising board certified radiologist will have complete control of the individual's duties and responsibilities. Additionally, the facility's credentialing committee and/or medical staff and the board certified radiologist will also determine the role delineation of each individual and the level of supervision required, which will be formalized in a letter of delegation or agreement with the Agency. The ACR continues to strongly disagree with this particular approach, and has requested that the scope of practice and supervision requirement be specified by rule. However, in an ARRT document reflecting entry-level clinical activities (role delineation) for radiologist assistants (RRA), the ARRT notes that any exclusion of a procedure is not intended to limit the procedures performed by a radiologist assistant, provided that appropriate education, training, and competence assessment has been documented. The document further notes that the actual level of radiologist supervision for the radiologist assistant in practice will depend on the individual's experience as well as state, insurer, institutional, and employer requirements. This further complicates any desire by a regulatory body to specify by rule the procedures which can be performed and the level of supervision required, especially for a field in which the number and types of procedures are rapidly expanding. However, professional standards (ASRT Practice Standards and the CBRPA Standards of Practice) for these individuals will keep pace with this evolution. States referencing such national standards rather than a list of specific procedures will build flexibility into their regulatory mechanism. Due to the training and knowledge of the board certified radiologist involved, it is unlikely that any individual would be allowed to perform a radiological procedure without adequate supervision or appropriate training or competence assessment. As such any additional regulatory efforts in further controlling or defining this specific relationship with the radiologist assistant, and the exams which can be performed, appear unwarranted.

Chiropractic radiography - individuals performing radiographic exams in a chiropractor's office must be either a radiographer, chiropractic radiographer or an appropriately accredited limited diagnostic radiographer (usually spine, extremity).

Limited diagnostic radiography exam - this particular exam was developed and is administered by the ARRT. It is a computer based exam, which is available at some 200 test centers throughout the United States. The exam consists of a core module containing 100 questions on radiation protection, equipment operation and quality control, image production and evaluation and patient care and education. There are also specific questions (20) relating to radiography of the chest, extremities (25), skull/sinuses (20), spine (25), and podiatric region (20). The passing score requirements vary widely from state to state. However, in a December 1994 publication, the ARRT recommended to

all licensing states that, for simplicity and consistency (and ease in reciprocity), they adopt a single passing score of 65% for any combination of the exam. This recommendation has been adopted, and results in the passing criteria noted below:

Chest	CH (20) + Core (100) ≥ 78
Extremity	EX (25) + Core (100) ≥ 81
Skull/Sinuses	SK (20) + Core (100) ≥ 78
Spine	SP (25) + Core (100) ≥ 81
Podiatric	PD (20) + Core (100) ≥ 78

States should recognize that the 65 percent combo passing criteria will generate numerous comments from various groups and individuals noting that this proposed passing criteria is either too high or too low. Various scoring scenarios will also be raised, and in particular the possibility that a test applicant could score an 81 on the core section, and miss all of the questions in the specific groups. In such a scenario, the state will still issue a full, limited accreditation (it appears inconceivable that one could score so highly on the core section and miss all other questions). Nevertheless, it should be noted that the ARRT is no doubt familiar with all these various exam scenarios, and still stands by its recommendation.

Additionally, recommendations will be made that these individuals must first complete a training program, specified by rule, before being eligible to sit for the exam. Although there is no consistency in the education provided to limited exam applicants, and training requirements vary greatly from state to state, the ARRT took this into consideration when they established the minimum passing score necessary for a borderline candidate to demonstrate competency. As such, one's educational background or experience should be irrelevant, and one only needs to demonstrate the required competency by passing the exam.

In summary, there will be two main issues associated with this discussion. The health and safety issue as to whether the 65 combo score is an acceptable passing score, and the issue as to whether as a regulatory agency, one wishes to make it more difficult for limited applicants to enter into this field. Based on the organization's experience and reputation, it is unlikely that anyone will question the validity of the ARRT exam. Implementing the ARRT recommended scoring criteria should also make the state's position in this matter beyond reproach.

Podiatric radiographers - unless exempted, individuals performing radiographic exams in a podiatrist's office will need to be either a radiographer or an appropriately accredited limited diagnostic radiographer (having passed the podiatric or extremity exam). In order to utilize the limited exam, states will need to enter into a contract with the ARRT.

Sec.Z.6 - Application for Accreditation**.**

Many states are now refusing to issue or renew licenses or accreditations if applicants are delinquent in the repayment of an educational loan or child support. If applicable, the appropriate rule and citation should be noted in this section.

Persons applying for active status accreditation as a radiographer, nuclear medicine technologist, therapist, radiologist assistant, nuclear medicine advance associate or chiropractic radiographer must

submit evidence of registration, certification, etc., from the appropriate organization. This will demonstrate that at some point, they were eligible to sit for and then passed the required exam. However, they are not required to maintain their registry or certification at the time of initial application or renewal. Although this is often a job requirement, and few individuals may choose not to, it cannot be a regulatory requirement. Despite its desirability, states have not been able to require membership in professional societies or organizations as a condition for the issuance of accreditation.

Sec. Z.7 - Initial Issuance of Accreditation**.**

Individuals may not legally perform medical radiation technology without valid accreditation, or without the expressed written approval of the Agency during such time as an application may be pending (receipt of completed application, documentation of qualifications, the required fee and no other outstanding issues). This written approval can be issued by e-mail or fax to the individual's supervisor and is good for a period of 10 days, which is sufficient for the Agency to process, print and mail the required certificate of accreditation.

Conditional Accreditation Type I (grandfathering) - any state that wishes to initiate a program for the credentialing of medical radiation technologist will not be successful in doing so without a grandfathering provision for those presently working in the field, for the last 24 months, before the rule became effective. This grandfathering period (which is negotiable) would then be open for perhaps 2 or 3 years, before closing. However, once issued, it will be renewable, in accordance with Sec.Z.8. Attempts to require any type of documented training program or competency exam for these individuals will only provide additional fodder for opponents of medical credentialing (its not grandfathering), and will not be successful.

As proposed, numerous potentially unqualified individuals may be credentialed simply upon receipt of a statement from a licensed practitioner that they are competent, and have worked in the field for the past two years. However, there will be no implied guarantee to any of these individuals that they would be able to work anywhere within the state, as "conditions of employment" (ARRT registered, etc) will still apply.

As regulators and stakeholders it is sometimes necessary to look at an issue with a bigger lens (where do we wish to be in 20 to 30 years). This is almost impossible to do, but necessary. Illinois required credentialing of medical radiation technologist in 1984, with a grandfathering provision which was inserted in the enabling legislation (it would not have passed without). Grandfathering closed in Illinois in 1990. Since the program's inception, Illinois has issued a total of 1402 grandfathered credentials. However, as of September 2011, out of 14,200 active accreditations there are now only 128.

It is important for new credentialing states to recognize that this grandfathering feature will be a very contentious and unsettling issue for thousands of their technologists who are qualified by virtue of education and certification to perform these procedures. Their understanding and support of this item is crucial and required (they will later become the program's strongest supporters). They and all other stakeholders must also come to recognize that without this feature, efforts to accomplish initial credentialing of medical radiation technologists will continue to fail.

Conditional Accreditation Type II (community hardship) - if necessary, new credentialing states may also wish to consider and utilize this particular type of accreditation if conditions within their state appear applicable (Alaska) and to counter arguments from opponents of credentialing that the unavailability of qualified individuals will have a detrimental effect on the health care in a given locality, which is already isolated and underserved. Effective resistance to this feature can be muted by the state's adherence to a strict, structured determination criterion as specified in Z.7a.v.

Sec. Z.9 - Requirements for Renewal of Accreditation.

The requirements for renewal are specific in this section (completed application and fee). It also contains a requirement for continuing education (CE), which is specified in Section Z.9.

CE is a mandatory requirement for any individual who wishes to renew or reinstate their professional registry (ARRT) or certification (NMTCB/CBRPA). As such, the vast majority of the technologists in any given state will be complying with this requirement. Its rationale is that with advancing technology and changing job duties, technologists need to continually update their knowledge and skills to remain competent and prevent professional obsolescence. These are worthy goals for professional societies. However, from a regulatory position, CE will not assure competency, nor is one's failure to obtain the required CE a health or safety issue (one cannot argue that a technologist is a hazard to their patient if that have not completed the required hours of CE for renewal). As such, states will need to decide as to whether CE should be a regulatory requirement for renewal of accreditation.

If CE is required, a record keeping mechanism to ensure compliance for each individual is strongly discouraged. Per Z.9d, technologists seeking renewal will attest on the renewal application that they have the required number of CE credits. Within 30 days of receipt of these attestations the Agency would then randomly select 10 percent of the respondents for a CE audit, and ask the individuals selected to provide copies of their CE documentation (failure to respond to this audit request or provide acceptable documentation may result in a refusal to renew, as noted in Z.11xv). Technologists registered/certified with the ARRT, NMTCB or CBRPA, who are in compliance with CE requirements or on CE probation need not be required to produce CE documentation if they are selected for the CE audit (each of these individuals is already subject to a 10% random CE audit by their respective certification bodies).

In addition, if CE is required, please note that the registry's CE biennium is based on the technologist's birth month, whereas the state's accreditation period will be based on when the individual first applied. These two periods will rarely overlap, but is rectified by the inclusion of Section Z.9e.

Sec. Z.11 - Suspension, Revocation and Denial of Accreditation.

This section, as well as the Z.13 (civil penalties) must contain the standard due process provisions that vary somewhat from state to state (right to a hearing, appeal mechanisms, etc).

Sec. Z.13 - Civil Penalties.

Not all states have implemented civil penalties, and some other states may choose not to apply civil penalties to accreditation violations. In either case, the assessment of civil penalties against registrants or licensees who allow individuals to perform medical radiation procedures without valid accreditation will act as a strong deterrent, and should be seriously considered. However, for violations of 30 days or less, by policy, states may wish to cite the violation, without assessing a civil penalty.

Appendix A - Radiographic Procedures by Type of Limited Accreditation.

States should note that the projections listed in the Appendix are anatomic structures which are specifically covered on the ARRT Limited Scope of Practice in Radiography examination. In adding any additional projections (ribs, hips, pelvic, etc), states will need to realize that these will not be specifically covered in the exam. However, there are presently 20 questions on the chest exam and 25 each for the extremity and spine exam. If the ARRT agreed to cover any additional projection, it might only add one specific question to the total. As such, if a limited exam applicant passes the core, chest, extremity and/or spine sections, arguments might be made that they could adequately perform a rib or perhaps a pelvic exam (neither of which is listed in Appendix A), without a health or safety concern. Adding any additional projections is a matter that needs to be thoroughly discussed with the state's Advisory Committee, as well as the consequences of not doing so (a limited chest radiographer who performs a rib exam).

Medical Dosimetrists.

The Committee was asked to consider a credentialing mechanism which would allow any board certified medical dosimetrist to perform brachytherapy. After discussions with members of the American Association of Medical Dosimetrist (AAMD), which included how they define brachytherapy therapy, the following response was obtained:

For a certified medical dosimetrist, brachytheraphy includes, but is not limited to, the following activities: treatment planning associated calculations, source assay, and source inventory and source preparation.

As such it is the Task Group's consensus that the certified medical dosimetrist is considered qualified to do all of the above listed tasks, with the exception of administrating ionizing radiation to a patient. However, it is also recognized that presently, unless specifically prohibited by state statute or rule, NRC regulations allow other individuals to administer ionizing radiation to patients provided it is done so under the supervision of an authorized user.

Although this issue may need to be revisited at a later date, Part Z as currently proposed will specifically prohibit any individual who is not a physician or accredited medical radiation therapist from applying ionizing radiation to a patient.

Matters for Future Consideration.

As currently proposed, the radiologist assistant can only work under the supervision and authorization of a board certified radiologist. However, a number of other specialty physicians (orthopedic, urology and cardiology) are beginning to inquire about the possibility of utilizing these

individuals in a manner similar to that of a radiologist. At some point this option may need to be further explored.