



Mandatory Licensure for Radiologic Personnel

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Foreword

About the Author

Christopher Jason Tien will graduate in 2007 with a B.S. degree from the University of Michigan in Nuclear Engineering & Radiological Sciences along with his minor in mathematics. He is currently enrolled in the Sequential Graduate-Undergraduate Studies Program, and will graduate from the University of Michigan with a M.S. degree in 2008.

About the Washington Internships for Students in Engineering (WISE) Program

The Washington Internships for Students of Engineering (WISE) program was founded in 1980. This collaborative effort among several engineering societies has become one of the premier Washington internship programs. Its goal is to groom future leaders in the engineering profession who are aware of and can contribute to the important intersections of technology and public policy. This multi-society program is supported by the American Association of Engineering Societies. Please see <http://www.wise-intern.org> for more information.

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1. Introduction

Radiological procedures are only as effective as the people performing them. For example, an underexposed chest x-ray will not yield a useful diagnosis such as tuberculosis or pneumonia [Legislative]. Likewise, an improperly delivered therapeutic dose will most likely do more harm than good. In order to be useful for diagnosis or therapeutic purposes, radiological procedures have to be delivered with precision.

Radiation causes damage to tissue: there must be a balance struck between the amounts of radiation delivered and the possible damage the radiation could cause to make the correct diagnosis. According to the commonly accepted linear no-threshold hypothesis, any amount of radiation causes damage. Therefore, it is important to minimize radiation. In order to be clinically useful, radiological procedures must meet a certain high standard of quality. “Accurate diagnosis is virtually impossible without quality medical imaging information and quality information is best provided by radiologic personnel educated in anatomy, positioning, exposure technique, and radiation safety” [Legislative].

Congress has already recognized this need for regulation among radiologists. As early as the 1960’s, certain states began to look into the possibility of developing a law which would enable enforcement of regulation, and subsequently, the licensure that would come with it.

The scope of this paper will be limited to ionizing radiation since it is both the “typical” aspect of radiological procedure and also because it is the most – and may be the only – dangerous aspect. Before reading the rest of this paper, it is also important to note that there are other radiological personnel in the hospital such as a medical physicist, a radiologist or a nuclear medicine specialist. All the same, 90% of the time it is the technician who measures out the dosage and 90% of the time it is the technician who delivers the physical dosage to the patient. These other personnel (e.g. medical physicists, radiologists, nuclear medicine specialists) are licensed and have rules and regulations regarding their conduct and performance. Therefore, for the remainder of this paper, radiologic personnel will be taken to mean technicians or technologists.

History

In 1965, New York extended its medical licensing procedures to include personnel who operated radiologic equipment. It was the first state to put regulations for radiologic personnel into legislation. The “intent was to minimize the public’s unnecessary exposure to potentially hazardous radiation delivered during medical imaging procedures” [Legislature].

However, this wording did not specifically include radiation therapists or nuclear medicine technologists – who were most likely the ones operating the machines. Furthermore, the educational requirements “were not equivalent to the two-year educational program recommended by the American College of Radiology and the American Registry of Radiologic Technologists” [Legislature]. In an effort to amend this, New York later changed its laws in

order to extend the opportunity to attend a radiologic technology school to students who had neither a high school diploma nor an equivalent.

Soon after, in 1969, New Jersey and California also extended their licensing procedures to cover any personnel who operated radiologic equipment. While New Jersey's was very similar to New York's, California took a radically different approach with as many as nine different categories of radiologic technicians, each having its own role and rank.

The new, stringent California law contrasted starkly with the older, relaxed New York law and set a precedent for wholly different standards within each state. Other states seemed ready to adopt their own standards, creating the potential for a patchwork of state licensure laws that would end up ignoring the minimum educational standards recommended by the profession.

Troubled about the idea of no uniform federal standard, Senator Jennings Randolph of West Virginia introduced a bill in 1970 with the idea of establishing federal minimum standards for education and licensure of radiologic technologists. In theory, there could be 50 states with 50 different standards. However, with the passage of this bill, each state agreed upon a federal standard and worked to stay at or above that level. In other words, this bill allowed each state the opportunity to adopt its own standards – as long as they were at least as stringent as the federal standards.

As the bill gained momentum and other politicians became aware of the old educational standards, many grew concerned about the state of disarray in which the states were falling into.

In 1979, only nine states had enacted licensure laws for radiologic personnel. Just as Randolph and his supporters had feared, each state's laws were so varied that the quality of health care depended on the State of treatment. Additionally, radiologic technologists who had to relocate had to deal with severe employment difficulties. For example, the California licensure law had nine classifications for radiologic technicians, based on the location of the radiographic examination. The nine "limited permit" classifications' workers, such as "chest technologists" or "skull technologists," were extremely specialized. Because of this, workers in California did not meet standards for other states and either had to retrain in other states or simply work in a state which did not certify its technologists.

In either situation, the technologists' qualifications were not enough to meet the qualifications of another state because each state's standards were not at the uniform level or because one state's standards were at a lower level than the Federal level.

It was not until 1978 that the newly renamed "Consumer-Patient Radiation Health and Safety Act" was considered by the full Senate. It was the subject of Congressional hearings in 1978, 1979, and 1980. In 1981, Senator Randolph reintroduced the Consumer-Patient Radiation Health and Safety Act in the Senate. One month later, it was reintroduced in the House of Representatives.

As Congressional debate continued on throughout the entire summer of 1981, Senator Randolph's aides bluntly informed him that he had to make a decision: to change the proposal's

mandatory licensure clause to a “strongly advise” clause or to once again risk defeat of the entire bill. Claiming that he was worried about the public health, Randolph wanted to get any version of this regulation into legislation. His aides made the point that the legislation did have a good chance of dying if the bill was so stringent. In the end, Senator Randolph reluctantly agreed to make the bill voluntary.

After 13 years, in February 1981, both houses of Congress passed the Consumer-Patient Radiation Health and Safety Act of 1981. The Act’s Statement of Findings reads:

The Congress finds that –

- (1) it is the interest of public health and safety to minimize unnecessary exposure to potentially hazardous radiation due to medical and dental radiologic procedures;
- (2) it is in the interest of public health and safety to have a continuing supply of adequately educated persons and appropriate accreditation and certification programs administered by State governments;
- (3) the protection of public health and safety from unnecessary exposure to potentially hazardous radiation due to medical and dental radiologic procedures and the assurance of efficacious procedures are the responsibility of State and Federal governments;
- (4) persons who administer radiologic procedures, including procedures at Federal facilities, should be required to demonstrate competence by reason of education, training, and experience; and
- (5) The administration of radiologic procedures and the effect on individuals of such procedures has a substantial and direct effect upon United States interstate commerce. [United]

Additionally, the act required the Secretary of Health and Human Services to develop federal standards for the certification of radiologic personnel and the accreditation of educational programs in radiologic technology. It also required the federal government to provide the states with a model statute for licensure [United]. This federal standard was developed to explicitly apply to radiologic technologists and did not apply to the personnel (e.g., doctors, pharmacists, medical physicists) which the Nuclear Regulatory Commission (NRC) has jurisdiction over.

The Secretary did not publish the draft until July 1983. In fact, the Final Rule was not published in the Federal Register until December 1985.

As of today, eleven states (see Figure 1.1) have taken advantage of the wording which does not make the adoption of the federal model statute mandatory. Since compliance with standards was – and still is – voluntary, each state was free to establish its guidelines. These eleven states have taken no action to endorse any type of guidelines. In other words, in almost 24% of U.S. states (including the District of Columbia), individuals are not required to demonstrate any level of competence before being allowed to administer potentially dangerous doses of radiation to patients. Most people would probably feel uncomfortable having a nuclear-powered instrument, which is regulated by the Nuclear Regulatory Commission, operated by hospital personnel who do not even need to have GED’s. Although highly unlikely, literally, anyone off of the street can be hired in the morning and be operating this potentially dangerous equipment the same afternoon.

Besides this course of action, many states have opted to not completely adopt the federal standards, instead relying heavily on their original state standards. For example, Delaware – a state which actually has some licensing – does not require personnel to complete any formal

classroom education in radiologic technology; they need only to pass a state licensing examination, part of their original standards.

U.S. States with Licensure/Certification Laws or Regulations

See Appendix A for more information

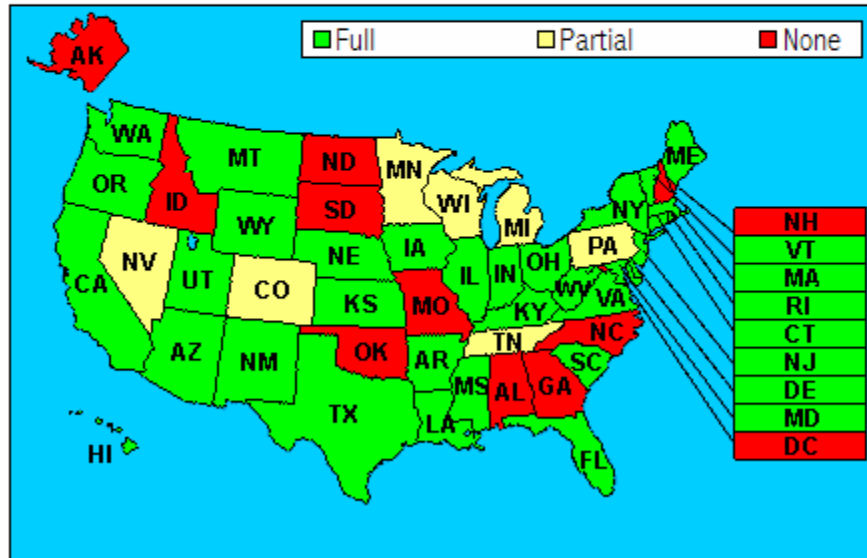


Figure 1.1. U.S. States with Licensure/Certification Laws or Regulations

2. Background

This section of the paper will investigate the interactions between radiation and people such as patients and workers. It will also investigate the effects of radiation on humans. Lastly, it will discuss the basics of radiological procedures and give some background on licensure.

About Radiation – Radiation for the Patient

Annually, more than 300 million radiologic procedures are performed annually in the United States [Legislative]. New procedures such as gamma knife technology allow doctors to deliver over 200 beams of radiation with scalpel-like precision directly to brain tumors and lesions without invasive surgery, reducing recovery time and lowering cost. Brachytherapy is a procedure whereby a doctor implants radioactive sources in or near tissue to deliver a customized radiation dose for prostate cancer. Radioactive Iodine capsules are ingested in order to correct the symptoms of hyperthyroidism.

Radiation has provided enormous benefits to society primarily as a life-saving tool in the diagnosis and treatment of disease. Through the 100-plus year history – starting with the use of the x-ray – imaging has grown into a very sophisticated science that plays a major role in the assessment of virtually all diseases. In fact, virtually every individual who will read this paper has probably had an x-ray examination performed in the last three years.

Data published by the Federal government tells us that the number of U.S. citizens receiving x-ray examinations has risen from 108 million in 1964, to 130 million in 1970, to approximately 350 million in 1996, and the number of x-ray and other diagnostic imaging examinations performed each year is increasing in all age groups [Legislative]. This marked increase in x-ray usage is attributed to greater sophistication of equipment, such as three-dimensional computed tomography and magnetic resonance imaging.

Furthermore, more than 16 million men, women and children need nuclear medicine procedures [Cannon DOE]. Nuclear medicine imaging procedures contribute extensively to an accurate diagnosis and an effective treatment for patients with cancers as well as other serious disorders.

Nuclear medicine procedures expose patients to about the same amount of radiation as they receive in a few months of normal living from background radiation levels [Cannon Molecular] (see Table 2.1) (See Appendix B).

Source or Limit	mrem
Approximate daily background dose from natural sources	0.3
Approximate dose for a 10-hour plane flight	3
Typical dose from a medical or dental x-ray	10-20
Typical dose from medical X-rays and treatments	70

Table 2.1. Approximates Dosages from Different Sources

Many people believe that radiation is inherently dangerous to the patient. While radiation *is*, in fact, potentially dangerous around irresponsible people, the benefits that patients receive from appropriately indicated, appropriately performed diagnostic imaging greatly outweigh potential risks stemming from the radiation exposure. Indeed, the benefits of nuclear medicine can only be really maximized when these procedures are performed by certified professionals [Cannon Molecular]. Any hazards that are present can be essentially minimized if the procedures are performed by certified professionals.

Diagnostic x-rays differ from other manmade radiation sources. Some human exposures to radiation are meant to cause a detrimental effect, such as the nuclear bomb. Some human exposures are not meant to happen at all, such as careless nuclear waste storage. However, exposures to radiation through an x-ray are desired and produce a positive effect: a diagnostic image of the human body. The production of radiation as utilized in the practice of medicine is an invaluable tool in the diagnosis and treatment of disease. Even so, the utilization of radiation in medicine is not without risks and an inherent potential of biological damage to healthy tissue. Any exposure to ionizing radiation, however small the dose, increases the risk of developing cancer, leukemia, cataracts, blood disorders, and birth defects or mental retardation in developing fetuses. Any unnecessary exposure therefore produces a risk without benefit to the patient.

Unfortunately, the improper utilization and production of excessive and unnecessary medical radiation exposure is a widespread practice throughout the nation. Over utilization, as well as improper utilization, of radiation in the practice of medicine is a genuine health hazard to the public and must be dealt with now. A physician using x-ray equipment in his practice is under no obligation to ascertain or require any credential or specific education of the person he or she employs to operate the equipment. While highly unlikely, it is legally and literally possible for anyone off of the street to be hired this morning and be operating this potentially dangerous equipment this afternoon. Radiation is not detected by the senses of sight, hearing, touch, smell or taste. Without sufficient knowledge of its application, the operator has the potential to produce biological damage not only to the patient, but to himself or herself as well.

Radiation in the healing arts is the largest source of exposure of the U.S. population to man-made radiation [Committee]. Medical uses of radiation are by far the largest source of man-made exposure of the public; medical exposure is one of the only facets of radiation exposure that can be controlled. The only way to ensure highest quality health care is by minimizing this exposure. Sadly, the FDA Bureau of Radiologic Health has estimated that 30% of exposures to man-made radiation are unnecessary [ASRT].

Depending on the analysis desired, diagnostic information can be obtained using gamma rays emitted by radioactive materials introduced into the patient by injection, ingestion or inhalation. With nuclear materials located internally rather than externally through imaging, it is especially important that the correct dosage is administered because there is no safety barrier between the radioactive materials and the internal organs¹.

¹ Once a patient has ingested, inhaled, or been injected with a radiopharmaceutical they become, in a sense, a living, moving source of radiation. Other patients and possibly even the people visiting them can be irradiated simply by being in their proximity.

After diagnosis, radiation can be further used in medicine to kill cancerous cells. There are techniques like radiotherapy, in which beams of high energy X rays or gamma rays are aimed to killed diseased tissue. Radiotherapy can also include a substance that is temporarily inserted in a radioactive solution [International]. This type of procedure is potentially very dangerous because just a slightly deviant shot or a wrong dosage could easily kill the wrong cells.

About Radiation – Radiation for the Worker

People may be exposed to radiation through their occupations. Some workers may be exposed occasionally, while others are exposed daily. For example, depending on their department, some employees in medical facilities may be exposed on a daily basis to radiation from radioactive material or radiation-producing devices, while some employees in the same facilities may be exposed to no radiation from radioactive material or radiation-producing devices (Keep in mind that everyone, however, is exposed at all times to naturally occurring radiation sources in the environment) [NCRP 105]. Thus, these occupational workers, such as physicians, radiological and nuclear medicine technologists may be exposed to additional radiation above natural background because their occupation routinely requires working with or near sources of radiation [NCRP 105].

Note that radiation from medical procedures differs from background radiation because medical exposure is normally restricted to a portion of the body and takes place over times that vary from a fraction of a second to minutes rather than over a small dosage over a larger portion of the body over a larger period of time [NCRP 105].

It is interesting to note that radiation workers, on the whole, have comparable risks of cancers as “normal” workers. “From the limited information available, it seems that annual fatal accident rates (non-radiation) may be of the order of 0.25×10^{-4} for occupations involving radiation exposure. For the radiation component, the average annual effective dose is taken to be 2.3 mSv, which, utilizing the nominal value of lifetime risk of fatal cancer of 10^{-2} Sv^{-1} , yields, eventually, an annual risk of 0.25×10^{-4} , comparable with the non-radiation fatal accident rate for occupations involving radiation exposure. Thus, radiation workers have ultimately a total annual risk of fatality of 0.5×10^{-4} , similar to that for workers in “safe” industries” [NCRP 102].

The Effects of Radiation

There are two hypotheses about the effects that radiation can have on a person. The threshold hypothesis holds that radiation can only be harmful when sustained above a certain level. On the other hand, the no-threshold hypothesis claims that any exposure to radiation can be harmful (or can increase the risk of cancer)” [Ionizing]. Based on current scientific evidence, the federal government has adopted the linear “no-threshold” hypothesis and believes that medical personnel who are always receiving radiation are also increasing their risk of cancers (see Figure 2.1) (See Appendix C).

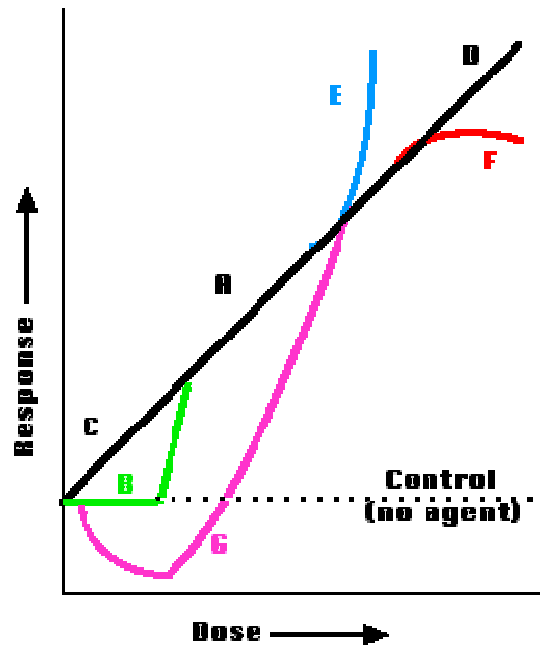


Figure 2.1. A Dose-Response Curve.

(A) Linear response curve. (B) Threshold response curve. (C) Linear No Threshold Response Curve (LNT). Note that even at zero dose, the line does not intercept the origin because even unexposed animals (including people) show a spontaneous level of response (e.g., tumors). (G) **Hormesis**. There is evidence that for very special cases, increasing the dose actually reduces the response below control levels. At very high doses, the rate of response may increase faster than the dose (E) as, for example, the probability of a single cell suffering **two** mutations increases. On the other hand, very high doses may kill off damaged cells before they can develop into tumors (F).

The “no-threshold” hypothesis postulates that the chance of a fatal cancer from radiation exposure increases in proportion to the magnitude of the exposure, and the risk is as high for chronic exposure as it is for acute exposure. In other words, it is assumed that no radiation exposure is completely risk free” [Ionizing]. Thus, according to this nationally accepted model, even one extra exposure can significantly increase the chance for cancer. Add the fact that radiation has been proven to affect genetic and hereditary cells, and one can see why exposure is taken so seriously.

On June 30, 2005, the National Academy of Sciences released the Seventh Biological Effects of Ionizing Radiation report on “Health Risks from Exposure to Low Levels of Ionizing Radiation” or BEIR VII and reaffirmed its previous stance that even very low doses of radiation can cause cancer. Furthermore, the Academy now believes that risks from low dose radiation could be even greater than previously thought.

The reason that there is debate about the threshold vs. no-threshold models is that there are many sources of uncertainty in the biokinetic models². For example, “variation in exposure may arise from individual differences in genetic constitution, age, sex, pregnancy, lactation, exercise, disease, stress, infection, smoking, alcohol intakes, renal function, liver function, GI function, cardiovascular function, dietary factors, circadian and seasonal variations, barometric pressure, and exposure to sunlight or pollen” [NCRP 15].

Please see Appendix B for more information about the Sources of Radiation and Appendix C for more information about the Effects of Radiation.

About Radiological Procedures

An important concept of radiological procedure is the idea of an optimal method which will maximize information while minimizing radiation dose to the patient, the expense involved, and the discomfort that may occur.

“When a radiograph is obtained for a specific purpose, an image with less than optimal definition is actually acceptable if it will answer the clinical problem. For example it is acceptable to use a faster image receptor for barium enema examinations than for chest radiographs. Similarly, in the follow-up radiographic examination of the spine of a child with scoliosis, the fine, detailed information necessary on the first radiograph is not necessary to evaluate changes in the degree of curvature. Hence, a very fast (low-dose) system can be used. On the other hand, if there is a question of bony abnormality in that same curved spine, or if the symptoms relate to bone pain, a more detailed follow-up study is needed. Similarly, a partially fogged radiograph of the spine in a follow-up examination is acceptable if the curvature is still visible... – NCRP 99

The number of radiographs considered to be optimal for an examination continues to be a subject of controversy: by limiting the number of radiographs, it will minimize the exposure time. However, that potentially truncated exposure time is directly proportional with the probability of acquiring an accurate diagnosis. Radiation risks and cost must be balanced against the completeness of the examination. It is important to decide whether the accuracy of a standard examination could be enhanced or, in fact be, diminished by adding other views. Finally, underlying the whole problem is the difficulty in placing a value judgment on inaccurate diagnoses in one or more patients, when most patients are diagnosed accurately [NCRP 99].

There a large difference between whole body dose, and doses to only part of the body. The "whole body dose" is the total energy absorbed by the body, divided by its total mass. This is a fairly meaningful quantity if the whole body is irradiated in a more or less uniform manner. If the energy deposition is localized, like in a hospital setting, however, taking the energy deposited in a small mass of tissue and dividing by the mass of the whole body (usually assumed to be about 70 kg) produces a number that may have little meaning biologically. Whole-body dose is often reported for both internal and external types of radiation exposure, but it is sometimes not the quantity of most interest to radiation protection, so it should be used with caution.

² Some scientists have strongly advocated animal testing. However, even they have conceded that “extrapolations to human beings from these experiments are problematic and despite the large amount of data accumulated, uncertainties remain regarding the effects of radiation at low doses and low dose rates.

About Licensure

Professional licensure is a process by which a governmental agency grants permission to an individual to engage in a given occupation. To earn a license, the individual must prove that he or she has attained the minimum degree of competency required to ensure that the public health, safety and welfare will be protected.

An impartial – which is usually unattached to the government – group, like the NCEES for professional engineering, sets the criteria for licensure and administers the examination (or other instruments) used to determine eligibility for licensure. An individual usually has to engage in activities such as obtaining a certain type of degree while receiving a certain number of continuing education credit hours, and passing oral examinations and/or random inspections. The state then grants permission to an individual to engage in a certain activity, if it decides to accept the grading criteria used by the “impartial group.” Note, that in some cases, it is the Federal government acting through agencies like the Nuclear Regulatory Commission, that do the licensing, of specific personnel, such as nuclear reactor operators.

States already license most professions such as teachers, architects, real estate agents, building contractors. Most states even license professions that probably would pose no immediate danger if incorrectly performed, such as barbers. However, states do also license professions that are dangerous such as those who are in the health professions. Optometrists, dietitians, physical therapists, chiropractors, pharmacists, and nurses are all licensed by the states that they work in.

In the case of radiologic personnel, there are more than a few certification boards such as the American Registry of Radiologic Technologists, the Nuclear Medicine Technology Certification Board, Cardiovascular Credentialing International, the Commission on Accreditation in Allied Health Programs, the Joint Review Committee on Education in Radiologic Technology, the Joint Review Committee on Nuclear Medicine Technology, and the Joint Review Committee on Cardiovascular Technology, among others.

3. The Issues

It was not until the late 80's that the public began to see the full power – and the full danger that came with it – of radiation. In 1988, a 9 year-old child died of a radiation-induced respiratory failure after receiving an accidental double-dose of cobalt-60 radiation aimed at a tumor in his sinus cavity. In 1989, a widely publicized story included a story of an Ohio woman who actually had a hole burned into her chest while receiving radiation meant to treat her breast cancer. Later, these cases were made into somewhat of a public spectacle after Senator John Glenn held Congressional hearings in order to investigate these reports: why was radiation, which was supposed to heal, actually mutilating and killing these people? Regardless of certifications, these were two brutally distinct involving radiation misadministrations.

“90% or more of the handling of nuclear medicine material – except during fluoroscopy and interventional surgery – is done by technicians or technologists” [Piccone]. In other words, while there are other workers – such as radiologists or nuclear medicine specialists who are responsible for determining the optimal x-ray exposure or radiopharmaceutical dosage, and in the case of a radiopharmaceutical, nuclear pharmacists who are responsible for dispensing the correct material – the end-product always passes through the technician or technologist. Therefore, a technicians or technologist are, in fact, always responsible for whatever situation they are in. For example, the radiologist will provide a range of dose to provide, and it is the technicians' job to convey that amount of radiation. In the case of radiopharmaceutical, pharmacists simply prescribe a certain amount of dosage, but it is ultimately the technicians who administer the IV and catheters, drawn from containers which contain much more material than is necessary for one operation.

As was mentioned previously, other radiologic personnel such as medical physicists, radiologists, radiation safety officers and nuclear medicine specialists are fully licensed, while technologists and technicians remain unlicensed. This section will investigate the reasons why licensure should be implemented: increased quality, increased safety, and lowered costs.

Quality

Today, more than ever, radiology is playing a role in more and more Americans' lives. For example, it is estimated that seven out of ten Americans undergo some type of radiologic procedure annually, whether it as common as a dental x-ray or something as cutting-edge as a “gamma-knife” brain treatment [Legislature].

In order to ensure patient safety and reduce radiation exposure dose during radiologic procedures, the United Nations Scientific Committee on the Effects of Atomic Radiation made the following recommendations:

- 1.) Reduce the number of radiographs per patient
- 2.) Reduce the time and intensity of exposure
- 3.) When fluoroscopy is not essential, use conventional radiography
- 4.) Use the smallest possible field size
- 5.) Avoid inclusion of the gonads in the primary beam

- 6.) Protect testicles with gonadal shields
- 7.) Properly train and supervise staff engaged in these examinations

With the exception of (7), all of these factors are under the direct control of the radiologic personnel. Properly educated, certified and licensed radiologic technologists understand the importance of protecting patients from overexposure to radiation, and they take steps to control the size and intensity of the x-ray beam. “That is exactly why certification or licensure is extremely important” [Piccone].

When the equipment is well controlled, most images of poor quality are due to improper technique selection (under and over exposure) and positioning [NCRP 99]. Positioning of the patient and exposure control are, in fact, the responsibility of the technologist. The individual controls the intensity of the beam, the duration of the exposure, and also the shielding. These factors largely determine whether an image will provide the required diagnostic information [NCRP 99]. Simply the wrong position during an exposure or even the wrong exposure technique slashes the quality of the image dramatically.

Obviously an image of poor quality can lead to an incorrect – or even absence of the – diagnosis of illness and disease. This type of misdiagnosis often leads to delays in treatment, and sometimes ultimately tragic consequences.

It is also worthy to note that radiologic personnel are not only responsible for diagnostic procedures but also for therapeutic procedures. In other words, they are not just involved in procedures such as radiography, but also in cancer-killing radiation treatments. “The delivery of this amount of radiation is especially dangerous and requires a heavily certified, skilled operator” [Haas-Wilson]. Indeed, this radiation is designed to kill cells, and the person who physically has control over which cells are killed is the radiologic technologist or technician.

“Just as a certified mammographer who practices under MQSA-certification knows which views and positioning techniques to use to produce the best image, radiologic technologists who are certified in radiation therapy know how to deliver the precise dose of radiation to a diseased area while sparing surrounding tissues” [ASRT].

Radiologic procedures are sometimes repeated when the images are of such poor quality that no diagnostic information can be garnered from them. In this situation, there is a risk of repeating the hazardous procedure. Usually, this risk involves the unproductive radiation. Indeed, it requires a 200% overall radiation dose as the entire procedure is reproduced.

Studies show that patients may receive 100 times more radiation for the same x-ray examination because of unqualified operators [ASRT].

Safety

There is no denying that radiological sciences’ value is tremendous. Whenever any recognizable association, such as the National Council on Radiation Protection, the Nuclear Regulatory Commission or the National Academy of Sciences, acknowledges radiation in diagnosis,

treatment, and management of disease, they call it something to the effect of “invaluable,” “immeasurable,” or “the most promising technology of the century.” However, immediately after such a bold claim is made, they leave a loophole for escape: “but most radiologic procedures also carry a potential health risk, and radiation can be harmful or even deadly if misadministered” [Ionizing] [NCRP 15] [Legislative].

The commonly accepted, no-threshold linear model, proposes that all radiation causes damage. Radiation has been shown to cause damage from burns or vomiting to spontaneous abortion to increasing the likelihood of leukemia and other cancers. However, the no-threshold linear model also postulates that all dosages are cumulative. Therefore, the effects of low-level radiation can take awhile to show up – sometimes as long as 20 years [Committee]. In fact, the National Cancer Institute estimates that the long-term effects of overexposure to radiation during diagnostic x-ray examinations alone may be responsible for more than 3,500 cancer deaths a year.

With the dangers of radiation ever-present, it is therefore important that the technologist strive for high-quality images on the first attempt. This is the most important goal because it is a well-known fact that the radiation received by a given patient for a particular procedure varies considerably. One particularly illustrative example comes from a 1979 Canadian study which concludes that there are significant variations in the amount of radiation delivered among patients receiving diagnostic x-rays. Note that although this was not performed in the United States, Canadians have the same, if not stricter, standards than the U.S.

In this particular study, 30 radiology facilities were audited without any advance notice. Random patients were selected to wear dosimeters – devices which would record the amount of radiation received – during common diagnostic procedures. Using dosimeters, the researchers reasoned, would provide an objective record of the amount of radiation received rather than the technique.

The evidence was rather shocking: the dose to the skin for a lateral chest x-ray ranged from 24 millirads to 150 millirads; radiation dose during x-ray examination of the upper gastrointestinal tract ranged from 1.6 rads to 90 rads.; and dose delivered during gallbladder examinations ranged from 4 rads to 48 rads (see Table 3.1). The authors were, in fact, quoted attributing the variation in dosage directly to the knowledge of and technique used by the equipment operator.

	Low	High	Difference
Chest X-Ray	0.024 rem	0.15 rem	6x
Gastrointestinal	1.6 rem	90 rem	56.25x
Gallbladder	4 rem	48 rem	12x

Table 3.1. Range of Radiation Among Patients

It is astounding to see that, with regard to a gastrointestinal radiologic examination, there is more than 50 times more radiation in one hospital than there is at another. Furthermore, there is always at least one order of magnitude of difference between the low and high dosage in each

type of scan³. In other words, assuming a linear model, the wrong choice of hospitals could mean more than 50 times the incremental risk of cancer.

Surprisingly, there is no universal agreement on an optimal dose for a specific examination. Obviously, this optimal dose is also very patient-dependent. Regardless, too small a dose may fail to record enough information to lead to diagnosis and, in this case, the patient receives unproductive irradiation because the patient may have to be either irradiated again or just go around with extra radiation with no diagnosis [NCRP 99]. Therefore, the researchers in the Canadian study had expected to see a little bit of a range between the low and high dosage, just not to this magnitude.

In both underexposed and overexposed films, a subtle fracture or lesion can be missed. In either case, if the need to repeat the examination arises, it requires the patient to be exposed to additional radiation. Perhaps it is comforting to realize that the amount of radiation if used correctly, in diagnostic radiology is associated with a low risk to the individual patient compared with other risks in the environment and is less hazardous than the failure to obtain a correct diagnosis [NCRP 99].

In another study on radiologic technique, two researchers decided to go further and actually test the education of the radiologic personnel individually, rather than the entire hospital on the whole – as the Canadian study did. They gathered data from 2,934 randomly selected x-ray operators nationwide. This selection included 1,789 certified radiologic technologists, 692 operators with no education or certification in radiologic technology and 453 practitioner operators. With so many certified radiologic technologists, the authors reasoned that it would be easy to find a few operators who would perform badly – their data proved them wrong.

The authors of the so-called collimation-study decided to publish their data in the Nationwide Evaluation of X-ray Trends (NEXT) program, where they concluded that certified radiologic personnel delivered significantly lower radiation dose to the patient than untrained operators during x-ray examinations of the lumbosacral spine, cervical spine, lateral skull and abdomen. Later, the authors of the collimation-study stated that “these data give clear evidence of the need for trained operators and the need for continuing education of radiologic technologists.”

Each time a misadministration (See Appendix D) occurs of any kind, whether it is in a hospital, power plant, or during transport, it must be reported to the Nuclear Regulatory Commission (NRC). If it is a medical procedure, the NRC only has jurisdiction over it if they use nuclear material byproducts. Each month, the NRC publishes a report about the previous month and publishes it online. Each year, the NRC publishes a report about the previous year and publishes it both online and in hard-copy. The most medically-relevant materials administered by the NRC include radiopharmaceuticals used during nuclear medicine and radiation therapy procedures [NRC].

Following the NRC trends, states with nonexistent or lenient licensure of radiologic personnel have higher numbers of misadministrations in comparison with states that have licensure for

³ The exception is chest x-rays, where the difference is a factor of 6. However, using one significant digit - rounding to .02 to low dose and 0.2 for high dose – yields exactly one order of magnitude.

their radiologic personnel [NRC]. Thus, it can be shown that properly educated and properly licensed radiologic personnel deliver safer radiologic personnel by comparing the number of radiation misadministrations in licensure states with those of nonlicensure states in the same time period.

Alabama, a state that does not license radiologic technologists, reported 42 misadministrations to the NRC between 1981 and 1997. In contrast, California, a state that does license radiologic technologists, reported only 29 misadministrations during the same period of time [NRC]. However, the variable that must be considered is the population, assuming that the number of medical radiation procedures is roughly proportional to population – which it has been shown to be true [Anderson]. With more than 30 million residents, California has more than seven times the population of Alabama, which has 4 million residents (see Table 3.2).

NRC Misadministrations		
Alabama vs. California, 1981-97		
	Alabama	California
License R.T.	NO	YES
Number of Misadministrations	42	29
Avg. Misadministrations per Year	2.47	1.71
-----	-----	-----
Population	4 million	30 million
Avg. Misadministrations per Year per million residents	0.62	0.057

Figure 3.2. NRC Misadministrations, AL vs. CA, 1981-97

Comparing the number of misadministrations per capita, there is another alarming order of difference seen between licensed and unlicensed technologists – this time, in the average number of serious misadministrations per year million residents rather than the amount of radiation received during a scan.

Besides comparisons between licensed vs. unlicensed states, looking at misadministrations allows for comparisons between periods of nonlicensure vs. periods of licensure for the same state. The NRC has records online for certain states which go back to their transition periods. By doing an analysis in this way, the assumption that the number of procedures is proportional to population (when comparing two states such as Alabama vs. California) is not as prominent because it is relatively the same population, and thus, it does not have the potential to create such a large error.

By comparing a state to itself, all other variables can be eliminated except time and education (and perhaps technology). However, overall, this data supports the idea that mandatory licensing and certification for radiologic technologists reduces the number of misadministrations. There have been three real “transition” states: Massachusetts, Ohio, and Minnesota. Moreover, each and every one of them provides ample evidence in support of mandatory education.

From 1981 to 1990, Massachusetts reported 55 misadministrations during nuclear medicine procedures to the NRC. Since licensure was enacted at the end of 1990 until late 2004, the state has reported only seven misadministrations (see Table 3.3).

From 1981 to 1995, Ohio reported 47 misadministrations during nuclear medicine procedures to the NRC. Since licensure was enacted in 1995 until late 2004, the state has reported only one misadministration (see Table 3.3).

In 1997, Minnesota, which actually had one of the highest levels of radiopharmaceutical misadministrations in the nation, began to see the same trend as other states – a large drop in error – since it enacted a law requiring licensure.

NRC Misadministrations		
Before Licensure vs. After Licensure, 1981-2005		
	Massachusetts	Ohio
Before Licensure		
Time Period Recorded	1981-90	1981-95
Number of Misadministrations	55	47
Avg. Misadministrations per Year	5.5	3.1
After Licensure		
Time Period Recorded	1991-2005	1991-2005
Number of Misadministrations	7	1
Avg. Misadministrations per Year	0.047	0.067

Table 3.3. NRC Administrations in MA and OH Before vs. After Licensure, 1981-97

Results seen in Ohio, Massachusetts, and Minnesota prove that “enactment of a comprehensive licensure and certification program for radiologic personnel can reduce the number of examination errors, thus ensuring exam quality and improving patient safety.”

Note that the population in the states did not stay constant, and presumably, the number of procedures is proportional to the number of population [Anderson]. Therefore, it is reasonable to assume that the number of procedures in the ten years between 1981 and 1990 is far less than the number in the almost fourteen years that followed. This makes the data much more impressive, in that there are fewer mistakes for more procedures.

Ohio, Massachusetts, and Minnesota are all agreement-states – where the NRC relinquishes control – and the states have a bit more freedom over the extent of the reports that they submit. Therefore, it is important to be cautious when interpreting these data because the reported numbers are probably not completely accurate. However, if anything, this would have increased the numbers in the past and simply made the case that licensure made an even more dramatic impact as the numbers before licensure went up while the numbers after licensure went down [Piccone].

It is also noteworthy that some supporters also have stated that hospitals “should also strive to reduce risks other than radiation (but are still inherently involved with radiologic procedures), such as those associated with the administration of intravascular contrast media or the use of needles, catheters, and accessories” [NCRP 99].

Economic Cost

The NCRP comes right out and says it: “Diagnostic image obtained with a minimum of technical and clerical errors should result in a lower cost per examination” [NCRP 99].

Personnel must be paid, regardless of the number of patients seen, as most are paid on a salary basis. As procedures are repeated, there are fewer patients seen, with same amount of money spent on scans. Therefore, additional scans mean that there is more spent money per patient. From a strictly economic perspective, a higher specific cost per patient is a serious indicator of trouble with efficiency.

Additionally, a repeat radiologic procedure involves a large decrease in patient flow, an opportunity cost lost, as the personnel – the technicians, the radiologists, and the receptionists – are busy with the patients who are being treated for the second time instead of a new patient being treated for the first time. Obviously, patients value their time too: as they spend more and more time waiting to be seen, they become more inconvenienced and may decide to switch to a more efficient hospital. It makes sense that patients who feel their time has been wasted in addition to being irradiated extraneously irradiated would be very likely to switch to a more efficient hospital.

According to numerous studies, between 7 percent and 10 percent of all x-ray examinations performed in the U.S. are performed as repeated examinations [Brody] [Fleming] [Ionizing]. According to a 1992 study, about 50% of repeated images result from exposure errors – something easily avoidable with the correct personnel and/or the adequate education. Furthermore, 30% of repeated images result from positioning errors – another factor within the direct control of the person performing the exam, which could be easily remedied with the right education (see Figure 3.1).

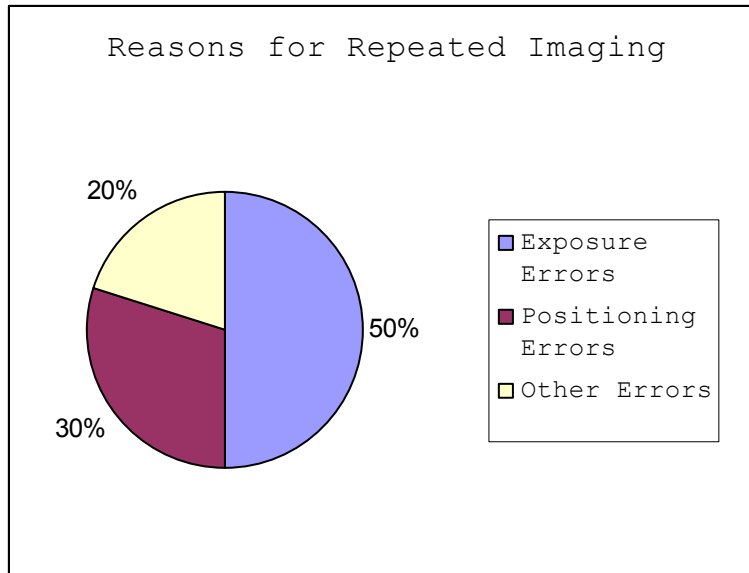


Figure 3.1. Reasons for Repeated Imaging

In other words, these studies are repeated because of errors of the radiological personnel: improper positioning, incorrect exposure, use of the wrong technique, poor patient instructions or errors in film processing and development. These were all problems which could compromise quality and safety. However, the fact is that cost is what many hospitals care about most.

Besides exposing the patient to double the dosage, a repeated examination costs the U.S. health care system millions of dollar in needless medical bills. Not only are labor and time wasted, but radiographic film and processing chemicals are certainly squandered when the image that they exposed is simply discarded.

In fact, it is estimated that the U.S. spends approximately \$20 billion a year on diagnostic x-ray examinations [ASRT]. X-ray examinations actually represent 3.5% of the nation’s total spending on health care [Smith]. So assuming the low-end 7% repeat-rate, almost \$1.5 billion is wasted annually on unnecessary, repeated x-ray procedures [Brody] [Fleming] [Ionizing].

A 1997 study showed that accurate radiologic imaging of patients with chest pain can decrease the misdiagnosis of heart attack. The study showed that chest x-rays, nuclear medicine scans, ultrasound examinations, magnetic resonance imaging scans or computed tomography procedures can be used to correctly diagnose the cause of a patient’s chest pain, in many cases ruling out heart attacks or other dangerous conditions. In fact, by offering radiologic imaging of patients experiencing chest pain at just one hospital in Miami, misdiagnoses of heart attacks were reduced and \$5.2 million was saved during an 18-month period.

With regulations were in place, there was not an extra cost, “Barnes (a small hospital) actually reported an initial savings of \$27,000 (in 1976)... from implementation of a quality control program in a radiology department... The primary cost saving of a quality assurance program is the result of a decrease in repeat studies” [NCRP 99]. This translates to around \$90,000 in 2004-dollars [CPI].

A report on California after 10 years of requiring licensure for radiologic technologists after receiving an order to determine the economic effects of mandatory licensure showed that for the 10-year period, overall medical fees increased 92.7% throughout the state, while fees for radiology services only increased 59.2%. Again, the study showed that “certification has not caused increases in the costs of radiology services, but rather has helped to reduce in increasing costs of health care through knowledgeable radiologic technologists; competent in reducing not only radiation exposure to the consumer-patient, but also in reducing waste of medical supplies, technologist and patient time and the wear of radiologic equipment from improper use” [Legislative].

4. Conclusions & Recommendations

Conclusions

The health of the public can only benefit from properly certified and fully licensed radiologic personnel. “No matter what the radiologic procedure, the technologist’s detailed knowledge of anatomy, careful application of radiation and skillful operation of sophisticated medical equipment are the keys to success” [Legislative].

In order to stop invasive cancers, radiation treatments must be precise. In order to be clinically useful, diagnostic imaging examinations must be accurate. This is simply not possible without uniform mandatory education requirements for the personnel operating the equipment which disperses this radiation. By ensuring that medical imaging and radiation therapy professionals are properly educated and credentialed, medical errors may be reduced. In fact, if implemented properly, a mandatory education program will increase quality, increase safety, and lower cost.

Competence is necessary when one individual is responsible for controlling the intensity of the beam, the duration of exposure, and the shielding. There is a delicate balance between the amount of radiation administered in order to correctly diagnose a potential disease and the amount of radiation which would be more dangerous than the potential disease. In a therapeutic setting, the trade-off between radiation to the cancerous cells and radiation to the rest of the body is a delicate one. Anything that will cut down time and exposure is a major breakthrough and welcomed: trained radiologic personnel can cut down this exposure time regardless of the procedure required and, at the same time, deliver a lower dosage.

According to the National Academy of Sciences/National Research Council’s Committee on Biological Effects of Ionizing Radiation, medical diagnostic radiology accounts for about 90 percent of the total man-made radiation dose to the U.S. population. More importantly, the report also explicitly states that much of this radiation is excessive and unnecessary because it is either inappropriately delivered or inaccurately delivered. Furthermore, The National Cancer Institute estimates that the long-term effects of overexposure to radiation during diagnostic x-ray examinations alone may be responsible for more than 3,500 cancer deaths a year.

It has been shown that certified radiologic personnel deliver lower dosages (Brody) (Ionizing) (ASRT) (Legislative). Specifically, a patient undergoing the same x-ray examination may receive 100 times more radiation depending on the skill-level of the operator of the equipment. Similarly, comparing the number of NRC misadministrations per capita, there is an entire order of magnitude difference (per year per million people) between licensed vs. unlicensed states. This same trend appears when comparing states which have changed status from unlicensed to licensed.

Accurate radiologic procedures, which are performed correctly the first time, can save billions (starting at around 1.5 billion) of dollars per year in the long run for health care, hospitals, and patients. According to a 1992 study, about 50% of repeated images result from exposure errors – something easily avoidable with the correct personnel and/or the adequate education. Furthermore, 30% of repeated images result from positioning errors – another factor within the

direct control of the person performing the exam. Both “positioning” and “exposure” are core classes in the current licensure program.

There are many who disagree with the proposition of mandatory education requirements of radiologic personnel, using cost as their primary argument: the establishment of federal minimum standards and state licensure laws for personnel who operate radiologic equipment would reduce the number of radiologic personnel and drive up health care costs because it would cause salaries to rise [Federal].

However, a look back on states which have endorsed licensing clearly shows that this is not true [Frequently]. A 1976 study of three states that established licensure laws for radiologic personnel in the 1960’s – New York, New Jersey and California – shows that mandatory state licensure “had no significant impact upon technologist manpower” in terms of recruitment, availability or compensation... Regulation of radiologic personnel would not increase health care costs; rather, it would reduce costs by ensuring quality examinations” [Legislative]. “Pay-scales are what they are and, most likely, will stay that way” [Piccone].

During a 10-year period of licensure for California, overall medical fees increased 92.7% throughout the state, while fees for radiology services increased only 59.2%. Regulation would not increase health care costs; rather, it would reduce costs by ensuring quality exams performed by knowledgeable radiologic technologists; capable of reducing not only radiation exposure to the consumer-patient, but also in reducing waste of medical supplies, technologist and patient time, and the wear of radiologic equipment from improper use. Approximately \$1.5 billion is wasted annually on unnecessary, repeated x-ray procedures alone – not including the money lost due to potential patient flow, or other opportunity costs (Legislative).

There are currently no existing laws in the States that mandate education. There have been voluntarily established federal standards – these standards are adequate to protect the general public. However, the ones who are currently trained to this level are actual licensed practitioners. The ones who have not met this standard are the ones who are not certified. They are the ones who are unlicensed and are the general practitioners. The untrained and uneducated practitioners do not meet these standards and that is what we seek to fix.

An estimated 40% of operators administering ionizing radiation have no formal education in radiologic technology (Legislative). Additionally, 11 states have opted out of the federal standards completely. In other words, in almost 24% of our states (including the District of Columbia), individuals are not legally required to demonstrate any level of competence before being allowed to administer potentially dangerous doses of radiation to patients. With these numbers, it can be shown that these same radiologic personnel can inadvertently overturn any benefit that could have been derived from a procedure.

The federal government regulates the equipment that the hospital uses through the Nuclear Regulatory Commission and, to a lesser degree, the Food and Drug Administration’s Bureau of Radiological Health. However, neither organization regulates the technicians that operate the equipment. This situation is somewhat analogous to a car: like your car, the operator determines

the use and abuse of this equipment. No one would permit his or her car, even with all of its safety features, to be operated by someone who was not properly licensed.

To put it rather bluntly, when asked about licensure, NRC medical physicist Josephine Piccone replied, “I don’t really know why this hasn’t been enacted... There are absolutely no disadvantages to licensure or certification” [Piccone].

Potential Problems

The most eye-catching problem with licensure could be with training schools putting out appropriate numbers of graduates to fill the need. However, this is not an issue to be concerned about at this point” [Piccone].

The most educated operators would be those with college degrees. Certainly, looking at the college graduation rates in the past few years along with the number of licensed practicing radiologic personnel or in the ASRT, and comparing it with the possible number of jobs, there are more than enough qualified candidates. Yet “even if there was eventually a shortage of workers, the new trainees would just have to have more on-the-job training – something easily addressed” [Piccone].

While a college degree would be optimal, it is clear that some sort of specialized training would be sufficient. Again, college would be the preferred method. However, by “establishing curricula and institutions, which could include colleges, but might also include community colleges, technical training centers, or in-house programs run by or for hospitals, that would provide the training necessary to achieve licensure... a high-school diploma plus specialized training ought to be enough for a technician” [Levin].

Others complain that licensing radiologic personnel will cause competition, but the ASRT’s public stance is that licensing radiologic technologists will not restrict competition any more than requiring licensure for nurses, doctors, pharmacists, or physical therapists did [ASRT].

Others complain that those who have practiced for a number of years will be unfairly removed from their jobs. However, there will be a “grandfather” clause included so that current operators who have not graduated from prescribed educational programs will still be eligible to practice if/when this bill passes, which will recognize the years of experience. Note that those who qualify will still have to take a performance exam. This will also prevent patient care from being compromised through an immediate large reduction of the number of practicing radiologic technologists.

Recommendations

Uniform licensure laws and regulations are so important that the Pew Health Professions Commission recently released a report in 1995. It stated that:

One of the biggest barriers to effective and fair use of health professionals in the United States is the lack of uniform personnel regulations across state lines... Standardized in neither form nor substance, the variations in language, laws and regulations are more than confusing. They inhibit access by consumers to health practitioners, unfairly restrict practitioners and prohibit the use of emerging health technologies across state lines. - Pew Health Report, 1995

“The current lack of uniform education standards for operators of radiologic equipment poses a hazard to the public. State and federal standards will ensure a minimum level of education, knowledge, and skill for the operators of radiologic equipment. Ultimately, they will reflect the radiologic personnel’s ability to provide the highest quality of patient care.”

We must stand in opposition to any open door policy that would allow an unqualified operator to continue to administer excessive medical examinations. As mentioned previously, allowing an unlicensed operator to operate a licensed piece of equipment is even more dangerous than allowing an unlicensed driver to operate an insured car.

Licensure would assure the highest quality personnel through competency-based educational programs, the administration of a performance-oriented certification examination and continuing education requirements to maintain certification.

The 1981 Consumer-Patient Radiation Health and Safety Act should be updated and modified. Once this has been done, the provision will become “mandatory compliance” with the federal standard. The next step is to establish a credible federal standard and to enforce it.

Agreement State v2.0

In Agreement State v1.0, the commercial use of most types of radioactive materials in the United States is controlled by the NRC. A company that wants to use radioactive materials obtains a license from the NRC. The NRC inspects each licensed facility periodically to ensure that it is complying with all applicable regulations and the requirements of its license [NRC].

Federal law also permits a state to reach an agreement with the NRC allowing that state to regulate the use of the NRC-licensed radioactive materials within its borders.

Agreement State v2.0 would be an upgraded version of Agreement State v1.0 in which personnel, rather than materials, would be regulated and states must meet or exceed these established mandatory minimum Federal standards, making them responsible for licensure. This “program” should be eventually implemented on all 50 states.

Enforcement should be done by the agencies that already oversee medical uses of radiation such as the NRC or the FDA Bureau of Radiological Health. Another possible suggestion has been to

“turn all medical radiation regulation, including x-rays, over to the NRC and set licensing standards for NRC to enforce either directly or via Agreement States” [Levin].

Educational Standards

Currently, licensure requires attendance of a recognized (usually a 24+ month) radiological school. However, a highly specialized curriculum provided by community colleges, technical training centers, or in-house programs in hospitals should provide the training necessary to achieve licensure [Levin]. Nevertheless, whether the potential licensee attends a highly prestigious college or a highly specialized community college, the licensee should have taken courses in: radiation protection, radiation biology, radiation and electrical physics, anatomy and physiology, pathology, emergency care, patient care, darkroom procedure, film processing, and perhaps some extra electives such as digital processing, or medical computer skills.

In order to demonstrate competency, hospitals should continue to recognize the results of existing examinations such as those of the: American Registry of Radiologic Technologists, Nuclear Medicine Technology Certification Board, Cardiovascular Credentialing International, Commission on Accreditation in Allied Health Programs, Joint Review Committee on Education in Radiologic Technology, Joint Review Committee on Nuclear Medicine Technology, Joint Review Committee on Cardiovascular Technology.

However, during the transition to licensure, limited licenses could be established as temporary solution. Although the number of semester hours should be specified and the language of the document should be very specific on which examinations the licensee will be permitted to perform. The “grandfather” clause should be implemented: current operators who have not graduated from prescribed educational programs will still be eligible to practice if/when this bill passes, which will recognize the years of experience. Again, they will still have to take a performance exam. This will also prevent patient care from being compromised through an immediate large reduction of the number of practicing radiologic technologists.

Continuing Competency

The International Atomic Energy Agency recognized the importance of radiation education and in 1996 changed its “Management Requirements” to include a provision about technician education. Indeed, they have a strong belief in “limiting the contribution of human error to accidents and other events that could give rise to exposures. This can be achieved by ensuring that all personnel on whom protection and safety depend are appropriately trained and qualified” [International].

The Institute of Medicine also recognized the importance of radiation educational and in 1999 released their report “To Err is Human.” This report was a compilation of medical errors occurring in a variety of health care settings; how and why they occurred; and what could be done to prevent them. The most important of these is Recommendation 7.2, which deals with performance standards and expectations for health professionals. It suggests that, “Health Professional licensing bodies should:

- 1.) Implement periodic reexaminations and relicensing of doctors, nurses and other key providers, based on both competence and knowledge of safety practices; and
- 2.) Work with certifying and credentialing organizations to develop more effective methods to identify unsafe providers and take action.”

A certain amount of education should be necessary. This is easily implemented by including a simple clause setting a classroom-hours-per-year quota as part of the licensure or certification for a given State. “Human factors are of utmost importance in quality assurance and therefore personnel education should be continuous” [NCRP 99]. This will keep personnel up to date on the newest machines and also on the newest techniques and will also make sure that skills are as sharp as they need to be.

Periodic evaluations and audits should be conducted without any advance notice. Technique audits can be done much the same way that they are done today: random patients are chosen to wear dosimeters, which record the amount of radiation that they receive during a given procedure.

5. Works Cited

- Albright, David and Barbour, Lauren. Developing Comparisons for Risks Due to Plutonium Inhalation and Carbon Tetrachloride Exposure. 1999. Institute for Science and International Security. 2 July 2005. <<http://www.isis-online.org/publications/tab6.html>>.
- American Society of Radiologic Technologists. Congressman Chip Pickering Introduces Bill to Improve Quality of Patient Care. 2005. American Society of Radiologic Technologists. 21 June 2005. <<http://www.asrt.org/Content/News/PressRoom/PR2005/Congressma050322.aspx>>.
- ASRT Legislative Guidebook for State and Federal Legislation. 2004. American Society of Radiologic Technologists. 27 June 2005. <http://www.asrt.org/media/PDF/legislative_guidebook.pdf>.
- Anderson, Ralph. Personal Interview. 21 June 2005.
- Basics of Nuclear Radiation. 2004. Rae Systems. 8 July 2005. <www.raesystems.com/~raedocs/App_Tech_Notes/Tech_Notes/TN-176_Basics_of_Nuclear_Radiation.pdf>.
- Brody, R. "All About X-Rays." 50 Plus. June 1984:32-6.
- Cannon, Hugh. Molecular/Nuclear Imaging by Qualified Providers Benefits Patients, Outweighs Potential Risks. 2005. Society of Nuclear Medicine. 14 June 2005. <<http://www.acnponline.org/index.cfm?PageID=3618&RPID=3527>>.
- . CARE Bill Reintroduced in the House. 2005. American College of Nuclear Physicians 14 June 2005. <<http://www.acnponline.org/index.cfm?PageID=3844&RPID=3527>>.
- . DOE Budget Cuts Will Affect the Future of Nuclear Medicine. 2005. Society of Nuclear Medicine and American College of Nuclear Physicians. 14 June 2005. <<http://www.acnponline.org/index.cfm?PageID=3657&RPID=3527>>.
- . House Energy & Water Development Appropriations Subcommittee Recommends \$35 Million for the Medical Applications and Measurement Science Program. 2005. Society of Nuclear Medicine and American College of Nuclear Physicians. 14 June 2005 <<http://www.acnponline.org/index.cfm?PageID=3991&RPID=3527>>.
- . Society of Nuclear Medicine Urges Congress to Save Research Efforts, Restore Crucial Funding in DOE Budget. 2005. Society of Nuclear Medicine. 14 June 2005. <<http://www.acnponline.org/index.cfm?PageID=3796&RPID=3527>>.

Committee on the Biological Effect of Ionizing Radiations. The Effects on Populations of Exposure to Low Levels of Ionizing Radiation: 1980. Washington: National Academy Press, 1980.

Consumer Assurance of Radiologic Excellence Act. 2005. TheOrator. 22 June 2005. <<http://www.theorator.com/bills109/hr1426.html>>.

“Cosponsors.” CARE Bill. 2005. American Society of Radiologic Technologists. 21 June 2005. <<http://www.asrt.org/content/GovernmentRelations/CAREBill/CoSponsors.aspx>>.

CPI Inflation Calculator. 2005. National Aeronautics and Space Administration. 21 July 2005. <<http://www1.jsc.nasa.gov/bv2/inflatecpi.html>>.

D’Arrigo, Diane and Folkers, Cynthia. All Levels of Radiation Confirmed to Cause Cancer. 2005. Common Dreams Progressive Newswire. 8 July 2005.

Dietlein M, Knapp WH and Kauterbach KW, Schicha H. “Economic Evaluation Studies in Nuclear Medicine: The Need for Standardization.” Eur J Nucl Med. 26:6(1999),663-80. 22 June 2005. <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10967623&dopt=Abstract>.

Draft HHS Regulations. 2004. Alliance for Quality Medical Imaging and Radiation Therapy. 22 June 2005. <<http://www.asrt.org/media/pdf/DraftRegulations.pdf>>.

Dunn, Barbara. University Health Systems Hospitals Earn Top Honors for Patient Satisfaction. 2005. University Health Systems of Eastern Carolina. 22 June 2005. <<http://www.uhseast.com/body.cfm?id=21&action=detail&ref=103>>.

Economic Evaluation of Radiopharmaceutical Research at NIST. 1997. National Institute of Standards and Technology. 22 June 2005. <<http://www.nist.gov/director/prog-ofc/Radiop~1.doc>>.

“EPA - Calculate Your Radiation Dose?” EPA’s Radiation Protection Programs: Perspectives. 2004. Environmental Protection Agency. 12 July 2005. <<http://www.epa.gov/radiation/students/calculate.html>>.

Estimating Cancer Risks. 2005. Kimball, John W. 25 July 2005. <<http://users.rcn.com/jkimball.ma.ultranet/BiologyPages/C/CancerRisk.html>>.

“Federal Minimum Standards.” CARE Bill. 2005. American Society of Radiologic Technologists. 27 June 2005. <http://www.asrt.org/content/GovernmentRelations/CAREBill/Federal_Minimum_Standards.aspx>.

- Fleming, MF, Archer, VE. "Ionizing Radiation: Health Hazards of Medical Uses." Journal of Medical Consultation. 29(1984):167-84.
- "Frequently Asked Questions." PET Scan. 2005. PET.connect. 22 June 2005.
<<http://www.petscaninfo.com/zportal/portals/pat/faq>>.
- Haas-Wilson, Deborah. "The Regulations of Health Care Professionals Other than Physicians." Regulation: The Cato Review of Business and Government 15.4(1992):40-6.
- HSA Health Plans. 2005. HSA. 22 June 2005.
<http://www.hsa.co.uk/our_products/personal_medical_plans/direct/frequently_asked_questions.asp>.
- History and Purpose. 2005. Joint Review Committee on Education Programs in Nuclear Medicine Technology. 17 June 2005. <<http://www.jrcnmt.org/historypurpose.asp>>.
- International Atomic Energy Agency, Radiation Safety. Austria: International Atomic Energy Agency, 1996.
- Ionizing Radiation Fact Sheets Series: No. 2. 1998. Environmental Protection Agency. 14 June 2005. <<http://www.epa.gov/radiation/docs/ionize/402-f-98-010.html>>
- Levin, Alan E. "Re: Comments on your Paper." E-mail to the author. 29 July 2005.
- Levin, Alan E. "Re: Medical Physics Paper." E-mail to the author. 22 June 2005.
- "Legislative Guidebook" CARE Bill. 2004. American Society of Radiologic Technologists. 27 June 2005. <http://www.asrt.org/media/PDF/legislative_guidebook.pdf>.
- Medical Imaging Comes into Focus. 2004. Nightly Business Report. 22 June 2005.
<<http://nightlybusiness.org/transcript/2004/transcript040904.html>>.
- Miller, Kenneth L. CRC Handbook of Management of Radiation Protection Programs (2nd ed.). Ann Arbor: CRC Press, 1993.
- Miller, Lantz. "New Boss in Town Touts Self-Regulation." Journal of Nuclear Medicine 34.10(1993),23-4,35N.
- Model State Consumer Assurance of Radiologic Excellence (CARE Act). 30 Oct 2003. American Society of Radiologic Technologists 22 June 2005.
<<http://www.asrt.org/media/pdf/Modelstatelicensurelaw0704.pdf>>.
- Mossman, Kenneth L. "Medical Testing: Issues and Ethics." Forum: For Applied Research and Public Policy 12.3(1997),6.

National Council on Radiation Protection and Measurements. NCRP Report No. 99: Quality Assurance for Diagnostic Imaging. Bethesda: NCRP, 1990.

---. NCRP Report No. 102: Medical X-Ray, Electron Beam and Gamma-Ray Protection for Energies up to 50 MeV. Bethesda: NCRP, 1990.

---. NCRP Report No. 105: Radiation Protection for Medical and Allied Health Personnel. Bethesda: NCRP, 1989.

---. NCRP Commentary No. 15: Evaluating the Reliability of Biokinetic and Dosimetric Models and Parameters Used to Assess Individual Doses for Risk Assessment Purposes. Bethesda: NCRP, 1998.

Newman, Mark A. "NRC Proposed Amendments: Too Little, Too Late?" Journal of Nuclear Medicine 34.9(1993), 25N.

Newsline of the Journal of Nuclear Medicine. "Reforms and Restructuring Highlight Mid-Winter Business Meeting." Journal of Nuclear Medicine 34.12(1993),32,34N.

NRC: Event Notification Reports for 2005. 2005. Nuclear Regulatory Commission. 15 June 2005. <<http://www.nrc.gov/reading-rm/doc-collections/event-status/event/2005/index.html>>.

Piccione, Josephine. Personal Interview. 20 July 2005.

"Position Statement." CARE Bill. 2005. American Society of Radiologic Technologists. 27 June 2005.
<<http://www.asrt.org/content/GovernmentRelations/CAREBill/CAREBillPositionStatement.aspx>>.

Public Department of Health, Education, and Welfare. Interagency Task Force on the Health Effects of Ionizing Radiation. Washington: National Academy Press, 1980.

"Radiation" Yankee Nuclear Power Plant. 2005. Yankee Rowe Power Plant. 25 July 2005.
<http://www.yankee.com/license_radiation.html>.

Ragains, Patrick. Citing Government Information Sources Using MLA (Modern Language Association) Style. 2004. University of Nevada – Reno, Business and Government Information Library. 24 June 2005.
<<http://www.library.unr.edu/depts/bgic/guides/government/cite.html>>.

Shanahan, Maryanne. "Nuclear Regulation: Toward A Balanced Perspective." Journal of Nuclear Medicine 34.10(1993),17-8,32N.

Sigurdson, Alice J. et al. "Cancer Incidence in the U.S. Radiologic Technologists Health Study, 1983-1998." Cancer 97:12(2003),3080-9.

Smith, R. "Paving Nuclear's Future." William Beaumont Hospitals. 2004. Imaging Economics. 22 June 2005. <<http://www.imagingeconomics.com/library/200406-04.asp>>

State Programs. 2005. NeedyMeds, Inc. 10 July 2005.
<www.needymeds.com/indices/stateprograms.shtml>.

United States. Cong. Senate. 109th Congress, 1st Session. H.R. 1426, A Bill To Amend Title XIX of the Social Security Act to Provide Public Access to Quality Medical Imaging Procedures and Radiation Therapy Procedures [introduced in the U.S. Senate; 17 March 2005]. 109th Congress. <http://www.asrt.org/media/pdf/care_bill.pdf>.

---. Cong. Senate. 108th Congress, 1st Session. S. 1197, A Bill To Amend the Public Health Service Act to Ensure the Safety and Accuracy of Medical Imaging Examinations and Radiation Therapy Treatments [introduced in the U.S. Senate; 5 June 2003]. 108th Congress. <http://www.asrt.org/media/pdf/radcare_bill.pdf>.

"Using Modern Language Association (MLA) Format." Purdue Online Writing Lab. 2003. Purdue University. 21 June 2005.
<http://www.owl.english.purdue.edu/handouts/research/r_mla.html>.

WING Act – Workforce Investment for Next-Generation Technologies Act. 2005. TheOrator. 14 June 2005. <<http://www.theorator.com/bills109/s833.html>>.

6. Appendices

Appendix A. U.S. States with Licensure/Certification Laws or Regulations

U.S. States (34) with Licensure/Certification Laws or Regulations and Year of Implementation

Arizona	1977	Kentucky	1978	Ohio	1995
Arkansas	1999	Louisiana	1984	Oregon	1979
California	1969	Maine	1984	Rhode Island	1994
Connecticut	1993	Maryland	1992	South Carolina	1999
Delaware	1989	Massachusetts	1987	Texas	1987
Florida	1979	Mississippi	1996	Utah	1989
Hawaii	1974	Montana	1977	Vermont	1984
Illinois	1990	Nebraska	1987	Virginia	1997
Indiana	1982	New Jersey	1968	Washington	1991
Iowa	1987	New Mexico	1983	West Virginia	1997
Kansas	2004	New York	1965	Wyoming	1985

U.S. States (7) with Partial Licensure Laws and/or Other Forms of Regulation

Colorado	Laws for mammography and limited (non-ARRT registered) licensure only
Michigan	Laws for mammography only
Nevada	Laws for mammography only
Pennsylvania	Technologists who have not passed the ARRT or other board- approved examination must pass a state examination in order to perform patient examinations in physician, osteopathic physician, podiatrist, chiropractic, or dentist offices
Minnesota	Operator of any x-ray equipment for human use must be either a registered radiologic technologist through the ARRT, a licensed person from another state (they are given an x-ray operator equivalent standing) or have passed one of Minnesota's state approved examinations.
Tennessee	Technologists who have not passed the ARRT or other board- approved examination must pass a state examination in order to perform patient examinations in physician, osteopathic physician, podiatrist, chiropractic, or dentist offices
Wisconsin	Requires that all CT & Radiation Therapists be ARRT certified

U.S. States (10 + 1) without Licensure Laws or with Legislative Proposals being considered

Alabama	Idaho	North Carolina
Alaska	Missouri	North Dakota
District of Columbia	New Hampshire	Oklahoma
Georgia		South Dakota

Appendix B. The Sources of Radiation

When the public is surveyed about “possible sources of radiation,” many people consider only power plants and atomic bombs [International]. What many people fail to realize is that at any given moment, a person is receiving radiation. All people are chronically exposed to background levels of radiation present in the environment [Ionizing]. The earth contains radioactive elements, many of which are taken into the body through ingestion and inhalation. These elements thereby accumulate in the tissues of the body. For example, a significant component of the background dose equivalent to the body results from internally deposited ^{40}K , a radioactive component of food-stuffs [NCRP 105].

Source	mrem
Cosmic	
Cosmic radiation at sea level (from outer space)	26
Elevation (in feet) of Home	
up to 1000 ft	2
1000-2000 ft	5
2000-3000 ft	9
3000-4000 ft	15
4000-5000 ft	21
5000-6000 ft	29
6000-7000 ft	40
7000-8000 ft	53
> 8000 ft	70
Terrestrial (from the ground)	
Region of the US	
Gulf Coast	23
Atlantic Coast	23
Colorado Plateau	90
Elsewhere in the US	46
Internal Radiation (in your body)	
Food and water (ex. K-40)	40
From air (radon)	200
Plutonium Powered Pacemakers	100
Porcelain Crowns or False Teeth	0.07

Figure 8. Sources of Radiation

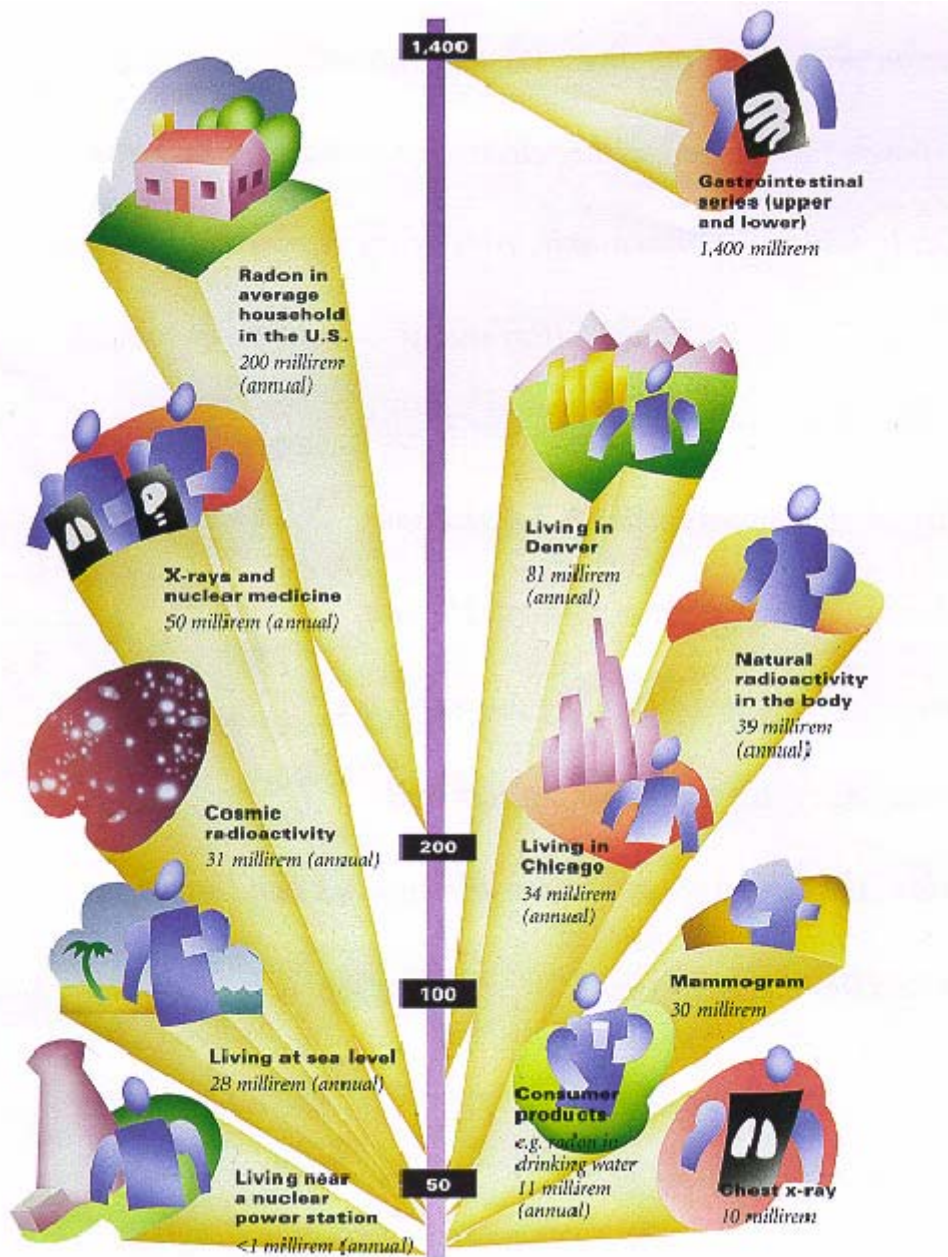


Figure 9. Sources of Radiation

Appendix C. The Effects of Radiation

There are two hypotheses for the effects that radiation can have on a person. There is the threshold hypothesis, which holds that radiation can only be harmful when sustained above a certain level. On the other hand, there is the no-threshold model, which claims that any exposure to radiation can be harmful (or can increase the risk of cancer)” [Ionizing]. Based on current scientific evidence, the EPA takes the linear “no-threshold” hypothesis and believes that medical personnel who are always receiving radiation are also increasing their risk of cancers.

The EPA also takes the stance that the chance of a fatal cancer from radiation exposure increases in proportion to the magnitude of the exposure and the risk is as high for chronic exposure as it is for acute exposure. In other words, it is assumed that no radiation exposure is completely risk free” [Ionizing]. Thus, according to this nationally accepted hypothesis, even one extra exposure can significantly increase the chance for cancer. Add in the fact that radiation has been proven to affect genetic and hereditary cells, and one can see why exposure is taken so seriously.

On June 30 2005, the National Academies of Sciences released BEIR VII or seventh Biological Effects of Ionizing Radiation report on “Health Risks from Exposure to Low Levels of Ionizing Radiation” and reconfirmed their previous stance that even very low doses of radiation can cause cancer. Furthermore, they now believe that risks from low dose radiation could be even greater than previously thought.

The reason that there is debate about the threshold vs. no-threshold hypotheses is that there are many sources of uncertainty in the biokinetic models. For example, “variation in exposure may arise from individual differences in genetic constitution, age, sex, pregnancy, lactation, exercise, disease, stress, infection, smoking, alcohol intakes, renal function, liver function, GI function, cardiovascular function, dietary factors, circadian and seasonal variations, barometric pressure, and exposure to sunlight or pollen” [NCRP 15].

Some scientists have strongly advocated animal testing. However, even they have conceded that “extrapolations to human beings from these experiments are problematic and despite the large amount of data accumulated, uncertainties remain regarding the effects of radiation at low doses and low dose rates. The most reliably estimated risks are those associated with doses of 1 Gy (100 rad) or more” [NCRP 105].

Appendix D. Misadministrations Defined

Excerpted from Part 35 of NRC Regulations (10 CFR)

According to the NRC, a medical misadministration is

(1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

(i) The total dose delivered differs from the prescribed dose by 20 percent or more;

(ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

OR

(2) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following--

(i) An administration of a wrong radioactive drug containing byproduct material;

(ii) An administration of a radioactive drug containing byproduct material by the wrong route of administration;

(iii) An administration of a dose or dosage to the wrong individual or human research subject;

(iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(v) A leaking sealed source.

OR

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).