Forty-Third
Annual Meeting Program

Advances in Radiation Protection in Medicine

April 16-17, 2007

Crystal Forum
Crystal City Marriott
1999 Jefferson Davis Highway
Arlington, Virginia
Co-sponsors

American College of Radiology
Reston, Virginia

Xoran Technologies
Ann Arbor, Michigan
During the past two decades remarkable progress has been made in the development and application of new medical technologies that utilize radiation for the early detection and effective treatment of cancer and other diseases. These advances, however, are accompanied by many questions about how to maximize medical benefits to patients, while controlling and reducing their risks from exposure to ionizing radiation. These issues are the theme of the 2007 NCRP Annual Meeting.

Although the many advances in medical radiation technology have represented significant gains in the prognosis for early disease detection and therapy, there are issues regarding the safety of these new radiation modalities that are of current interest and concern to the medical community. Among these are the administration of higher radiation doses to patients from imaging modalities such as computed tomography than from conventional radiography. Similarly, combined modality imaging and nuclear medicine procedures used in cardiology and other diagnostic procedures are associated with relatively high patient doses. In addition, the increased use of image-guided interventional therapeutic procedures has increased the radiation exposure of both patients and medical practitioners. Special concerns have been raised regarding use of the newer radiation modalities in pediatric radiology and in imaging and radiotherapy procedures with pregnant women.

NCRP’s 2007 Annual Meeting features presentations by physicians, medical physicists, and experts in radiation health effects who will discuss the rapid growth in use of relatively new medical radiation diagnostic and therapeutic procedures, and the current state of understanding of radiation doses received by patients and the associated health risks. Topical areas of focus at the meeting will include diagnostic radiology, nuclear medicine, interventional radiology, radiation oncology, and interdisciplinary issues such as the implications of radiation dose-response models for the prediction of long-term patient responses to irradiation from diagnostic and therapeutic procedures.

The 2007 meeting is the third in a series of NCRP Annual Meetings on the subject of radiation protection in medicine. The first two meetings were held in 1992 and 1999, and the proceedings can be obtained at the website [http://NCRPpublications.org](http://NCRPpublications.org).
### Monday, April 16, 2007

#### Opening Session

**8:00 am**
**Welcome**
*Thomas S. Tenforde, President*
National Council on Radiation Protection and Measurements

**8:15 am**
**Fourth Annual Warren K. Sinclair Keynote Address**
*Use and Misuse of Radiation in Medicine*
*James A. Brink*
Yale University

#### Diagnostic Radiology I

**Cynthia C. Cardwell, Session Chair**

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<td>Magnitude of Radiation Uses and Doses in the United States: NCRP</td>
<td>Fred A. Mettler, Jr.</td>
<td>New Mexico Federal Regional Medical Center</td>
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<td>9:40 am</td>
<td>Dose in Computed Tomography: How to Quantitate, How to Reduce</td>
<td>Cynthia H. McCollough</td>
<td>Mayo Clinic</td>
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<td>10:05 am</td>
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<td>10:35 am</td>
<td>Pediatric Dose Reduction in Computed Tomography</td>
<td>Donald P. Frush</td>
<td>Duke University Health Systems</td>
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<td>Diagnostic Reference Levels for Medical Imaging with Ionizing Radiation: ICRP Guidance</td>
<td>Marvin Rosenstein</td>
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#### Interdisciplinary Issues

**Linda A. Kroger, Session Chair**

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<td>Update on Linear Nonthreshold Dose-Response Model and Implications for Diagnostic Radiology Procedures</td>
<td>Robert L. Ullrich</td>
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<td>Research Involving Human Subjects</td>
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<td>Claire Cousins</td>
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#### Nuclear Medicine

**Edwin M. Leidholdt, Session Chair**

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<td>3:10 pm</td>
<td>Operational Radiation Safety for PET, PET/CT, and Cyclotron Facilities</td>
<td>Pat Zanzonico</td>
<td>Memorial Sloan-Kettering Cancer Center</td>
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<td>Combined Imaging Modalities: PET/CT and SPECT/CT</td>
<td>Alan H. Maurer</td>
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<td>PANEL DISCUSSION</td>
<td>Julie E.K. Timins, Moderator</td>
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4:40 pm  Break

Thirty-First Lauriston S.
Taylor Lecture on
Radiation Protection
and Measurements

5:00 pm  Introduction of the Lecturer
Raymond Guilmette

The Quest for Therapeutic
Actinide Chelators
Patricia W. Durbin
Lawrence Berkeley National Laboratory

6:00 pm  Reception in Honor of the Lecturer

Tuesday, April 17, 2007

8:00 am  Business Session

9:00 am  Break

Diagnostic Radiology II
Thomas Ohlhaber, Session Chair

9:30 am  Based on Reduction Through Quality
Assurance for Diagnostic X-Ray
Procedures
Jill A. Lipoti
New Jersey Department of Environmental
Protection

9:55 am  State of Art: Computed Radiography
and Digital Radiography
J. Anthony Seibert
University of California Davis Medical Center

10:00 am  Developments in Mammography
Martin J. Yaffe
Sunnybrook Health Sciences Centre,
University of Toronto

10:45 am  Trends in Utilization and Collective
Doses from Medical Procedures
Mythreyi Bhargavan
American College of Radiology

11:10 am  Cone-Beam Imaging in Dentistry
Stuart C. White
University of California, Los Angeles

11:35 am  Lunch

1:00 pm  Overview of Contemporary
Interventional Procedures
Donald L. Miller
National Naval Medical Center

1:25 pm  Patient and Personnel Safety in
Interventional Fluoroscopy Procedures
Louis K. Wagner
University of Texas

1:50 pm  Technical Advances of Interventional
Fluoroscopy and Flat-Panel Image
Receptor
Pei-Jan P. Lin
Beth Israel Deaconess Medical Center

2:15 pm  Break
Radiation Oncology

Theodore L. Phillips, Session Chair

2:45 pm

New Technologies in Radiation Therapy: Ensuring Patient Safety, Radiation Safety, and Regulatory Issues in Radiation Oncology
Howard L. Amols
Memorial Sloan-Kettering Cancer Center

3:00 pm

Dose to Normal Tissues Outside the Radiation Therapy Patient's Treated Volume: A Review of Different Radiation Therapy Techniques
James A. Purdy
University of California Davis Medical Center

3:30 pm

Patient Susceptibility to Radiation-Induced Cancer and Second Cancers Following Radiotherapy Procedures
James M. Allan
University of York, UK

3:45 pm

Panel Discussion
Stephanie K. Carlson, Moderator

4:00 pm

Closing Remarks
Thomas S. Tenforde, President
National Council on Radiation Protection and Measurements
While radiation is used in many branches of medicine for worthwhile diagnostic and therapeutic purposes, the potential for misuse seems greatest in diagnostic imaging. And among imaging tests that use ionizing radiation, the potential impact of misuse is greatest with computed tomography (CT).

“I am an adult and a physician! I don’t need your approval for CT scans that are necessary for my patients!” Such statements reflect the growing frustration among healthcare professionals who struggle with appropriate utilization of medical imaging tests that use relatively high doses of ionizing radiation. In an era focused on “pay for performance,” it is easy to focus on the radiation dose associated with a particular examination. There are numerous technical factors that may be manipulated, modulated or filtered to produce a dose that is as low as reasonably achievable. However, appropriate utilization of these tests is a more difficult issue to address. In our own hospital, the physician responsible for this quote is charged with improving the quality of our emergency services by maximizing throughput and minimizing length of stay. Having carte blanche access to imaging tests is viewed as a quality enhancer, owing to the time saved by not having to engage in a discussion about the risks versus benefits of a CT scan in a particular patient. However, by eliminating the need for this consultation, the responsibility of the radiologist as the “keeper of the keys” to potentially harmful medical imaging is eliminated. As a result, utilization soars and diagnostic yield plummets. In addition to the potentially harmful effects on individual patients, technical and professional imaging resources are strained by the added work burden, and patients with appropriate medical indications may be underserved owing to the high volume of relatively unnecessary imaging studies that must be performed.

The potential benefit that comes with medical imaging in patients with known diagnoses must be weighed against the risks of ionizing radiation, taking into account the patient’s age, gender and body part to be examined. In most primary clinical circumstances, the benefits outweigh the risks, particularly given the potential for diagnoses yet unfound. However, the serial evaluation of known clinical conditions for interval change may represent “low hanging fruit” in the war on over-utilization of potentially harmful imaging tests. Intensive educational efforts must be directed at the medical community at large to inspire a change in diagnostic algorithms to include one set of imaging tests for primary diagnosis and another for follow-up of known pathology. Such a culture change must
extend from the most senior healthcare administra-
tor to the most junior healthcare professional who is charged with acquiring the
necessary imaging tests.

The use of ionizing radiation in medical imaging is extending rapidly beyond evaluation of
patients with known or suspected diagnoses to include several screening applications.
While screening mammography was the only such application in use for several decades,
we have seen a rapid emergence of screening
CT applications in the colon, heart and lungs. Each of these tests are proposed for patients
with risk factors for a particular diagnosis and no signs or symptoms. Most analyses to-date
focus on the cost of screening with such tests and do not factor in the risk of a fatal cancer
from the related radiation exposure. Both must be considered relative to the benefit of detect-
ing the diagnosis during its preclinical phase and potentially curing it before it becomes
lethal.

Diagnostic Radiology I

Cynthia C. Cardwell, Session Chair

9:15 am

Magnitude of Radiation Uses and Doses in the United States:
NCRP Scientific Committee 6-2 Analysis of Medical Exposures
Fred A. Mettler, Jr.
New Mexico Federal Regional Medical Center

NCRP Scientific Committee 6-2 (SC 6-2) is currently working to estimate the radiation
exposure of the U.S. population from all sources and will produce an NCRP report in
2008. One subcommittee is specifically evaluating medical patient exposures. The last com-
prehensive evaluation regarding the types of medical radiation procedures, their magnitude,
and annual per capita effective doses was done more than two decades ago.

The medical subcommittee has examined a variety of data sources, including commercial
surveys, Medicare, U.S. Department of Veterans Affairs, and insurance carrier data.
The data sources are primarily from 2004 and 2005. These data files are the most compre-
hensive for diagnostic and nuclear medicine examinations, and less complete for interven-
tional procedures and radiation therapy. This information has provided a realistic estimate of
the number and types of examinations being done, as well as the breakdown by broad age
groups. The subcommittee also has collected and analyzed data on the absorbed dose,
computed tomography (CT) dose index, and other parameters necessary to estimate effective
dose per procedure and ultimately, collective dose to the U.S. population. An issue that
remains is the most appropriate values of radiation weighting factors to be used in estimat-
ing effective doses for diagnostic x-ray and nuclear medicine examinations.

What has become clear from this study is that medical exposures have increased rapidly over
the past two decades, not only in number but also in dose. The largest increase has come
from increased use of CT scanning proce-
dures, which have increased 10 to 15 % annu-
ally while the U.S. population has increased at
<1 % per year. There were about three million
CT scans performed in the United States in
1980, and this number has grown to about 60
million CT scans in 2005 (an average of about
one scan for every five persons). Much of the
increase has come from an increasing number
of CT machines, newer and faster technology,
and new clinical uses of CT such as the evalu-
ation of pulmonary emboli, lung nodules, and
abdominal pain. Assuming a radiation weighting factor of one, the effective doses from CT scans range from 1 to 10 mSv per exam, and many patients have more than one examination. Collective effective doses from CT are estimated to be in the range of 300,000 person-Sv annually.

Another large and rapidly growing source of patient exposures is from cardiac nuclear medicine studies, with an effective dose of about 10 mSv per examination. There are approximately 20 million nuclear medicine scans done annually in the United States, of which about two-thirds are cardiac studies. The collective dose from nuclear medicine procedures on an annual basis is estimated to be about 220,000 person-Sv. It is interesting to compare these medical doses with the global collective dose from the Chernobyl accident of about 600,000 person-Sv.

Currently, it appears that the increasing use of medical radiation technology is likely to result in per capita annual doses close to, or greater than, the natural background exposure level in the United States. However, it is important to bear in mind that substantial clinical benefits often result from exposures associated with diagnostic and therapeutic medical radiation procedures. It should, however, be noted that age and illness of the medical population is not taken into account with effective dose calculations.

The SC 6-2 subcommittee is also addressing potential increases in the use of radiation in medicine, and the doses to which patients have been exposed since 2005 and to which they are likely to be exposed in the near future. Areas of interest include, among other exposures associated with the introduction of digital filmless radiology systems, 64-slice CT scanners, combined positron emission tomography and CT scanners, combined single photon positron emission tomography and CT scanners, and CT screening for coronary artery stenosis and calcification.

9:40 am

Dose in Computed Tomography: How to Quantitate, How to Reduce
Cynthia H. McCollough
Mayo Clinic

The fundamental radiation dose parameter in computed tomography (CT) is the CT dose index (CTDI). CTDI represents the integral under the radiation dose profile of a single-axial scan, estimates the average dose from a multiple-scan examination, and is a directly measurable and standardized quantity. CTDIvol is a radiation dose parameter defined by the International Electrotechnical Commission that provides a single-dose parameter, based on a directly and easily measured quantity, which represents the dose within the scan volume to a standardized phantom. All current CT scanners display the value for CTDIvol on their console. This feature can allow the clinician to compare the radiation output from different imaging protocols. CTDIvol is expressed in the unit of milligray (mGy). Dose-length product [DLP (mGy cm⁻¹)] is derived from the product of the scan length (cm) and CTDIvol.

The parameter of greatest interest in assessing and comparing radiation doses and biologic risk is the effective dose. It is calculated from organ dose estimates using weighting coefficients prescribed by the International Commission on Radiological Protection, which have evolved over time. It is a single-dose parameter that reflects the risk of a nonuniform exposure in terms of a whole-body exposure. Effective dose is expressed in the unit of millisievert (mSv).

To manage the dose from CT while maintaining diagnostic image quality, scanner manufacturers have implemented several technical features, including more aggressive beam...
filtration, tube current (milliampere) modulation schemes, noise-reducing image filters, and specialized pediatric protocols. Modulation of the tube current is an effective method of managing the dose. However, the distinctions between the various tube current modulation products are not clear from the product names or descriptions. Depending on the scanner model, the tube current may be modulated according to patient attenuation or a sinusoidal-type function. The modulation may be fully preprogrammed, implemented in near-real time by using a feedback mechanism, or achieved with both preprogramming and a feedback loop. The dose modulation may occur angularly around the patient, along the long axis of the patient, or both. Finally, the system may allow use of one of several algorithms to automatically adjust the current to achieve the desired image quality. Modulation both angularly around the patient and along the z-axis is optimal, but the tube current must be appropriately adapted to patient size for diagnostic image quality to be achieved. Dose reductions of 20 to 40% have been reported using milliampere modulation schemes. In cardiac CT, even more aggressive dose reductions can be achieved by reducing the tube current during specific portions of the cardiac cycle.

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<tr>
<th>Non-CT Typical Effective Dose Values* (mSv)</th>
<th>CT Typical Effective Dose Values* (mSv)</th>
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<td>Dental bitewing</td>
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<td>Chest radiograph</td>
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<td>Mammogram</td>
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<td>Lumbar spine radiograph</td>
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<td>Barium enema exam</td>
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<td>Coronary angiogram (diagnostic)</td>
<td>Coronary angiography</td>
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<td>Sestamibi myocardial perfusion</td>
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<td>Thallium myocardial perfusion</td>
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Break

Pediatric Dose Reduction in Computed Tomography

Donald P. Frush
Duke University Health Systems

Patient safety is a central issue in medical imaging and radiation protection continues to be a key component in a safety program. The balance between radiation dose and image quality should be the perspective when addressing the issue of radiation protection. Discussing the balance between dose and image quality in pediatric computed tomography (CT) is important for several reasons. First, the use of all CT, including pediatric CT, is increasing and techniques for CT in children may be relatively unfamiliar. Second, there are additional considerations for radiation dose assessment and risk in children compared with adults. Finally, there are unique aspects when addressing pediatric CT quality. The discussion of pediatric CT dose and image quality is also justified as there is currently no regulation in
the United States for the practice of CT for adults or children.

CT provides extremely useful information and current practice indicates that it is becoming the primary modality for evaluation of a variety of disorders in both adults and children. This is especially evident in the emergency setting. For example, CT is replacing ultrasound in the evaluation of pediatric appendicitis. Contemporary practice is not always based on outcome, but can be driven by marketing, economics, and public opinion. Just as CT use has outpaced justification in many settings, it has also been difficult for the radiologist to keep up with technologic advancements, such as cardiac-gated CT, and automatic tube current modulation. For example, with automatic tube current modulation, the appropriate level of noise for diagnostic quality may be different in infants and children than in adults. In addition to this potential unfamiliarity with rapidly advancing technology, the majority of radiologists have no training in pediatric imaging after residency. Ironically, these same individuals are responsible for the majority of pediatric imaging.

Determining the dose from multidetector array CT is problematic. For example, the dose-length product is a commonly used estimation of dose, but this method is imprecise. The dose resulting from CT can be substantial and CT provides the highest dose of all medical imaging using ionizing radiation. We found, using a 5 y-old anthropomorphic phantom, that we could configure an exam to give an effective dose of nearly 120 mSv (unpublished data). Children’s tissues and organs are more radiosensitive (at least two times), and the potential for cancer development is more substantive given the greater number of years of life. In addition, the dose delivered to a child is higher than that to an adult when similar settings are used.

Study quality may be different in pediatric CT. First, the spectrum of injury and illness is different in children and the imaging features may be unfamiliar to radiologists, especially if pediatric examinations are infrequent in practice. Structures are often smaller, as well. These factors can translate to a need for higher image quality, and higher radiation doses. As mentioned above, the amount of acceptable noise may be lower with CT in young children and infants.

In conclusion, an understanding of the unique considerations for the balance between image quality and dose is critical for appropriate pediatric CT.

Diagnostic Reference Levels for Medical Imaging with Ionizing Radiation: ICRP Guidance

Marvin Rosenstein
ICRP Committee 3 (Protection in Medicine)

In International Commission on Radiological Protection (ICRP) Publication 60, reference levels were described as values of measured quantities at which some specified action or decision should be taken. One particular form of reference level, the diagnostic reference level (DRL) applies specifically to medical imaging with ionizing radiation (i.e., medical imaging with x rays or through diagnostic nuclear medicine). Use of DRLs is a mechanism to manage patient radiation dose to be commensurate with the medical purpose.

DRLs have no direct linkage to the ICRP numerical values for dose limits or dose constraints. DRLs should be selected by professional medical bodies often in conjunction with health and radiation protection authorities and their values will be specific to a country or region. DRLs are a guide to encourage good
clinical practice. It is inappropriate to use them for regulatory or commercial purposes.

The objective of a DRL is to help avoid radiation dose to the patient that does not contribute to the clinical purpose of a medical imaging task. This is accomplished by comparison between the numerical value of the DRL and the mean or other appropriate value observed in practice for a suitable reference group of patients or a suitable reference phantom. A reference group of patients is usually defined within a certain range of physical parameters (e.g., height, weight). A DRL is not applied to individual patients.

A DRL can be used to:

• improve a regional, national or local distribution of observed results for a general medical imaging task, by reducing the frequency of unjustified high or low values;
• promote attainment of a narrower range of values that represent good practice for a more specific medical imaging task; or
• promote attainment of an optimum range of values for a specified medical imaging protocol.

These uses are differentiated by the degree of specification for the clinical and technical conditions selected for a given medical imaging task. Appropriate local review and action is taken when the value observed in practice is consistently outside the selected upper or lower level.

The guiding principles for setting a DRL are:

• regional, national or local objective is clearly defined, including the degree of specification of clinical and technical conditions for the medical imaging task;
• selected value of DRL is based on relevant regional, national or local data;
• quantity used for DRL can be obtained in a practical way;
• quantity used for DRL is a suitable measure of the relative change in patient tissue doses and, therefore, of the relative change in patient risk for the given medical imaging task; and
• manner in which DRL is to be applied in practice is clearly illustrated.

Authorized bodies are encouraged to set DRLs that best meet their specific needs and that are consistent for the regional, national or local area to which they apply.

The content of the current draft of the new set of ICRP recommendations and related guidance that apply to DRLs is reviewed.

Capturing Patient Doses from Fluoroscopically-Based Diagnostic and Interventional Systems
Stephen Balter
Columbia University Medical Center

Patient dose data collected from diagnostic and interventional medical procedures has several uses. These can be grouped into the categories of patient risk supervision and departmental quality assurance. Risk supervision includes evaluation of the stochastic radiation load on the population and the management of individual patients receiving deterministic levels of radiation. Quality assurance includes evaluation of departmental performance against guidance levels and the evaluation of individual systems and operators against departmental norms.

The range of imaging technologies and procedures is large. Fluoroscopic-based procedures can produce high individual procedure “dose” relative to most other imaging procedures. Therefore, this presentation focuses on fluoroscopy, including the varieties of radiography.
usually accompanying fluoroscopically-based procedures.

Modern fluoroscopic systems are capable of accumulating the total air kerma delivered to a reference point during a procedure, kerma area product, as well as older items such as fluoroscopic time and technical procedural values. The two direct measurements provide a much better indication of patient risk than the older items. In particular, fluoroscopic time should not be the only dose metric used to manage high-dose interventional procedures.

Dose collection is in a transition between manual recordings of data from an individual imaging system to more highly automated technologies. The Digital Imaging and Communications in Medicine (DICOM) standard and the DICOM-DOSE project (a joint International Electrotechnical Commission-DICOM initiative) have the potential of enabling collection of complete dose data from all modalities irrespective of storage of the associated images.

Data should be collected for all procedures where there is any possibility of a deterministic radiation injury. Appropriately sampled data should be sufficient for quality assurance purposes and for estimating stochastic risk. Oversampling in these cases will increase the costs of data management without a commensurate improvement in the reliability of the conclusions.

Diagnostic radiology is a significant and growing source of population exposure to ionizing radiation, in large part because of the rapid increase in computed tomography (CT) imaging. While organ doses from CT examinations are still relatively small, they are much higher than for conventional radiographs, and thus it is important that the risk/benefit balance be critically examined. A linear nonthreshold dose-response model (or a model in which low-dose cancer risks per unit dose are larger than derived from extrapolation of higher-dose risks) would imply that there is potential cause for concern about this rapid increase in CT-based diagnostic imaging. On the other hand, there would be less concern if low-dose cancer risks per unit dose are less than those derived from extrapolation of higher-dose risks.

While there is convincing epidemiological evidence that doses of ionizing radiation above about 100 mGy may increase the risk for cancer in adults, at lower doses even the largest epidemiological studies have insufficient power, and so it is necessary to rely on models for extrapolation of potential risks. For children, or individuals in utero, there is plausible epidemiological evidence for increased cancer
risk at lower doses, corresponding to the well-established observation that radiosensitivity increases with decreasing age; this is of some significance because of the rapid increase in pediatric CT, particularly for confirming appendicitis.

Two expert reports have been published recently which give diametrically opposing opinions. The Biological Effects of Ionizing Radiation (BEIR) VII report, from the National Academy of Sciences, concludes that, at low doses, as the dose is lowered, the cancer risk simply decreases proportionately (a “linear nonthreshold” model) down to arbitrarily low doses. By contrast, a publication of the French Academy of Sciences suggests that, at very low doses, the risk per unit dose for ionizing radiation-induced cancer is lower than that established at higher doses; they go on to suggest that the induced cancer risks at very low doses may well be effectively zero, or even negative.

This is clearly an important issue for diagnostic radiology. The arguments revolve around the biological processes, at the molecular, cellular and tissue levels, that are involved in radiation response at very low doses (below ~100 mGy), compared with higher doses. There is no doubt that the linear (nonthreshold) approach for extrapolating risks to low doses (which has been adopted by most national and international organizations) can and should be critically examined. The arguments for a linear nonthreshold model at very low doses are plausible, but rely on assumptions about single cells primarily acting autonomously, which are unlikely to be completely correct. However, at this time it is unknown whether deviations from the predictions of this linear approach will be large or small, nor even whether they will increase or decrease low-dose cancer risk estimates. We are only just beginning to scratch the surface of our understanding of the impact of intercellular interactions and tissue interactions on very low-dose cancer risks, and so it is premature at this time to be advocating changes in policy or practice.

1:55 pm

Research Involving Human Subjects
Richard L. Morin
Mayo Clinic

Human subjects have been involved in research studies for centuries. Originally, they literally were subjects, often unaware that they were involved in research studies involving drugs, devices, surgical techniques, or radiation exposure among others. The use of humans in research studies is important since animal models do not always accurately predict human response. However, the times have truly changed. Currently, humans involved in research are not just subjects but volunteers. The regulations (both state and federal) regarding human use in research have progressed to protect the safety and quality of both the human interactions and the research studies.

The current legislated structure of institutional review boards (IRB) has provided the necessary basis and review procedures for human-use research studies. In addition, the mandatory education of principal investigators and coinvestigators regarding both abuse and improper use of humans in research, in addition to both local and federal regulation, has raised considerable consciousness regarding these issues. This has also led to increased scrutiny regarding external funding. It will be important to continue to have voluntary human involvement in research, mostly due to the natural variation among humans and the small differences sought to be discerned.

Studies involving ionizing radiation will continue to receive heightened scrutiny due to the ever increasing pace of new technology development and the continued debate regarding
the effects of ionizing radiation at diagnostic imaging exposure levels. The IRB assessment of relative exposure levels for diagnostic imaging research studies will continue to receive close attention. Thus, these open discussions will continue to protect the public health and safety, as well as ensure that modern research techniques are utilized to develop new strategies for the safe and high-quality diagnosis and management of disease.

Every year thousands of pregnant women are exposed to radiation, either as patients or as employees working with radiation. This often causes anxiety largely due to lack of knowledge of the women themselves, but also of those either working with them or caring for them. The first instinct is to avoid radiation during pregnancy, however this is not always possible as a pregnant patient may need investigation and treatment and an employee may have no option but to continue working.

It is always advisable to assume that amenorrhoea in a regularly menstruating woman is due to pregnancy until proven otherwise. Diagnostic or therapeutic procedures involving radiation should be delayed until after pregnancy whenever possible. If a procedure is considered medically indicated, the benefit to the mother should outweigh the risk to the fetus. This is the principle of justification which adopts more importance in a pregnant patient. Pregnant patients may be exposed to radiation from radiological examinations, nuclear medicine procedures, and occasionally radiotherapy treatment.

Most diagnostic procedures if performed correctly with appropriate optimization do not pose an increased risk to the fetus. The dose to the fetus is obviously increased if the pelvis or abdomen is included in the primary beam. Higher doses from therapeutic procedures or radiotherapy can cause significant fetal harm, particularly if the pelvis is irradiated. The majority of diagnostic nuclear medicine procedures use short-lived radionuclides that do not result in a large fetal dose. Some radionuclides (e.g., radioiodides) cross the placenta causing a more significant risk particularly to the fetal thyroid.

The risk to the fetus from radiation is greatest during organogenesis and the first trimester. The risks include nervous system abnormalities, malformations and cancer both in childhood and later life.

Informed consent has to be obtained from the patient after a full discussion of risk relative to the procedure and this is important when the predicted dose is >1 mGy. This may be difficult in an emergency situation when the patient is unable to give consent, and in such circumstances the family should be counseled if possible. Fetal doses <100 mGy should not be considered a reason for terminating pregnancy because this is not justified on the basis of radiation risk. At higher fetal doses, individual circumstances have to be discussed and informed decisions made.

Medical radiation workers are obliged to inform their employer if they are pregnant. When a pregnancy has been declared, the International Commission on Radiological Protection (ICRP) recommends an equivalent dose of not >1 mSv should be applied to the fetus. This advice differs from the recommendations in United States of a dose limit of 0.5 mSv per month of pregnancy and 5 mSv for the entire gestational period. Depending on duties and individual choice, a worker may continue their job unchanged or decide, if possible, to move to a position of reduced or no radiation exposure.
As a full-time vascular and interventional radiologist, I have personal experience of two pregnancies as a medical radiation worker and important issues are discussed.

ICRP Publication 84 addresses the issues of pregnancy and medical radiation. This Report was written with the intention of educating medical staff involved in everyday decision making and has been widely distributed. A free slide set is available on the subject and can be downloaded from the ICRP website.

Break

Nuclear Medicine

Edwin M. Leidholdt, Session Chair

3:10 pm

Operational Radiation Safety for PET, PET/CT, and Cyclotron Facilities

Pat Zanzonico
Memorial Sloan-Kettering Cancer Center

Positron emission tomography (PET) is now an essential and cost-effective imaging modality in clinical practice. The definitive demonstration of the clinical efficacy of, and the resulting rapid growth of, reimbursable indications for $^{18}$F-fluoro-deoxyglucose (FDG) PET, the proliferation of high-performance turn-key PET and PET/computed tomography (CT) scanners, and the widespread availability of FDG have combined to propel this dramatic advance. FDG, by far the most widely used radiopharmaceutical for clinical PET imaging in general and oncologic PET imaging in particular, is highly accurate in detecting (~90%) and staging tumors, monitoring of therapy response, and differentiation of benign from malignant lesions.

Several factors (the relatively high administered activities [e.g., 370 to 740 MBq (10 to 20 mCi) of FDG], the high patient throughput (up to 30 patients per day), and, in particular, the uniquely high energies (for a nuclear medicine setting) of the 511 keV positron-electron annihilation gamma rays) make shielding requirements, workflow, and other radiation protection issues important considerations in the design of a PET or PET/CT facility. While these topics have been addressed in various publications, the Report of Task Group 108 of the American Association of Physicists in Medicine [Medical Physics (2006) 33(3)] provides a comprehensive summary of shielding design and related considerations, along with illustrative calculations.

PET is dependent on the availability of short-lived $^{18}$F ($T_{1/2} = 110$ min) primarily in the form of FDG, either produced in-house or purchased commercially. PET using shorter-lived positron emitters such as $^{11}$C (20 min), $^{13}$N (10 min), and $^{15}$O (2 min), on the other hand, is impractical without an in-house cyclotron. Medical cyclotrons and associated radiochemistry facilities are now fairly numerous (well over 100 worldwide) and, of course, present their own radiation safety issues. In addition to the radioactive product, sources of exposure include neutrons, a common end-product of the nuclear reactions used to produce positron-emitting radionuclides, and radioactive activation products in the various cyclotron components and surrounding concrete. A key decision in the installation of such a facility is the choice between an unshielded and self-shielded cyclotron. While experienced personnel generally prefer the unshielded design because shielding restricts access for repair
and maintenance, the popular self-shielded configuration avoids the expensive and time-consuming construction of a concrete vault and reduces ambient neutron and gamma-ray radiation levels to the point that the cyclotron could be located within the radiochemistry laboratory. The design of that laboratory, largely dictated by the short half-life of $^{18}$F and other positron-emitting radionuclides, is intended to provide expeditious, short-distance transport of the starting material (i.e., the cyclotron-produced radionuclide), reagents, and packaging/dispensing materials. All such laboratories nowadays include lead-lined hot cells equipped with manipulator arms, computer-controlled radiosynthesis units ("boxes"), and air extraction capabilities for passing air through a charcoal filter to trap radioactive gases and volatiles before release to the general environment.

Published studies have shown that the radiation doses to personnel working in PET or PET/CT facilities and in cyclotron and associated radiochemistry facilities can be maintained below, and generally well below, the pertinent regulatory limits; the highest doses, not surprisingly, are generally accrued by radiochemistry personnel. This presentation will review the basic radiation safety aspects, including shielding, facility design, and workflow, of these increasingly important facilities in modern medicine.

Nuclear medicine has long been recognized for its value as a functional imaging modality which provides unique information related to cellular and organ function including: blood flow, biochemistry, and metabolism. Traditional nuclear medicine drugs (radiopharmaceuticals) have utilized single-photon emitters for detection by conventional gamma cameras and since the early 1990s have been used for tomographic imaging [single photon emission computed tomography (SPECT)]. Because of their chemical structure, SPECT radiopharmaceuticals permit only limited evaluation of certain metabolic processes. Positron emission tomography (PET) radiopharmaceuticals were previously utilized solely in academic medical centers because of the need for a local cyclotron to produce these imaging agents. Their importance, however, has long been recognized as they permit more advanced imaging of processes such as glucose metabolism, protein synthesis, gene expression, tissue hypoxia, and receptors at a cellular level.

Recently, PET imaging has rapidly been adopted into clinical practice in community hospitals and outpatient imaging centers as commercial suppliers have made the PET radiopharmaceutical $^{18}$F fluoro-deoxyglucose (FDG) widely available, and PET studies have been approved for reimbursement for a wide range of applications. While PET cameras have improved anatomic resolution compared to SPECT cameras the spatial resolution of both SPECT and PET remains limited when compared to x-ray (transmission) computed tomography (CT). CT is known to provide very high-quality imaging which depicts anatomic detail with high spatial resolution. Combined imaging devices now integrate both SPECT and PET cameras with CT scanners into a single device (SPECT/CT or PET/CT). These new imaging devices now provide both the metabolic and functional information from SPECT or PET combined with the high spatial resolution and anatomic information of CT. Because the two sets of images are fused, areas of normal and abnormal metabolic activity can be mapped to recognizable anatomic structures. This fusion of function and anatomy has quickly demonstrated its clinical value particularly in the areas of oncology, cardiology
and neurology. PET/CT is currently most commonly used in the area of oncology where it has demonstrated advantages over PET alone or CT alone not only for diagnosis but also for initial staging of a patient’s cancer and for assessing the patient’s response to therapy and, if needed, later restaging. PET/CT has become accepted as a standard of care for judging the effectiveness of treatment for many cancer patients. Studies have shown that while PET and CT are complementary, the fusion of both modalities results in much higher diagnostic accuracy. Based on this PET/CT experience there is now increasing utilization of SPECT/CT for other more routine nuclear medicine studies.

In this lecture, the current clinical applications of SPECT/CT and PET/CT fusion imaging are discussed. This fusion of nuclear medicine imaging with CT comes with some obvious increase in radiation exposure to patients. In addition to an introduction to the current technologies, the methods being employed to maximize the information from these studies, while reducing as much as possible the inherent radiation exposure to the patients, are also discussed.

4:00 pm

PANEL DISCUSSION
Julie E.K. Timins, Moderator

4:40 pm

Break

Thirty-First Lauriston S. Taylor Lecture on Radiation Protection and Measurements

5:00 pm

Introduction of the Lecturer
Raymond Guilmette

The Quest for Therapeutic Actinide Chelators
Patricia W. Durbin
Lawrence Berkeley National Laboratory

6:00 pm

Reception in Honor of the Lecturer
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8:00 am  Business Session

9:00 am  Break

Diagnostic Radiology II

Thomas Ohlhaber, Session Chair

9:30 am  Exposure Reduction Through Quality Assurance for Diagnostic X-Ray Procedures

Jill A. Lipoti
New Jersey Department of Environmental Protection

Traditional state x-ray inspection programs concentrate on measurement of x-ray machine parameters such as kilovolt peak and milliampere, timer accuracy, collimation, etc. In 1996, the New Jersey Radiation Control Program began a paradigm shift from the traditional inspection to an outcome-based inspection that concentrated on two indicators of performance: image quality and entrance skin exposure (ESE). Through extensive outreach and involvement of stakeholders, a new approach was designed that placed an emphasis on quality assurance. Key to the positive outcome has been the credentialing of medical physicists.

On January 16, 2001, the final regulation entitled “Quality Assurance Programs for Medical Diagnostic X-ray Installations” (N.J.A.C. 7:28-22) was adopted. The new regulations require that each facility using diagnostic medical x-ray equipment (including radiographic, fluoroscopic, x-ray bone densitometric, and computed tomographic) must establish and carry out a quality assurance program. The new regulation specifies the quality control tests, frequencies and standards that are part of the quality assurance program. To assist physicians, chiropractors, podiatrists and the radiologic technologists employed by them, four compliance guidance documents were prepared: Quality Assurance Manual, Radiographic Quality Control, Fluoroscopic Quality Control, and Computed Tomography Quality Control. Five years of data have been gathered during inspections. Both entrance skin exposure and image quality are checked and the inspectors conduct an audit of the facility’s quality assurance program. Entrance skin exposure has been decreased by 34 % for lumbar spine, 46 % for chest, and 66 % for foot x-ray procedures.

Criteria for image quality have been developed and tested. When the Bureau of Radiological Health inspects a facility, an image of a phantom is taken and scored by the inspector. Six criteria are evaluated (background density, high contrast resolution, noise and artifacts, density uniformity, low contrast detail, and low contrast resolution). When the inspection results are input into the computer, a report is generated and sent to each facility. This report scores each of the six tests as excellent, good, fair or poor, and provides an overall score of the image quality. Facilities with poor image quality scores are asked to consult with their physicist, determine the cause, make changes, and send a report of their findings and corrective actions to the Bureau of Radiological Health within 30 d. Image quality has improved by 22 %.
In April 2005, quality improvement initiatives were extended to the larger dental x-ray community. Through outreach and information sharing, stakeholders were instructed in the factors that affect patient radiation exposure and image quality and were encouraged to take actions to improve in these areas. Information on patient ESE at dental facilities has been collected since 2002. All registered dental facilities (5,000) have received an ESE report comparing their results to the rest of the dental facilities in New Jersey. As of July 1, 2006 the Bureau of Radiological Health began conducting re-inspection of dental machines beginning with those with extremely high ESE. Results of this effort are presented.

State of the Art: Computed Radiography and Digital Radiography

J. Anthony Seibert
University of California Davis Medical Center

The widespread implementation of digital radiography (DR) for medical imaging applications has increased the need to keep up with rapidly changing technology and the paradigm shift confronting all users, including technologists, radiologists and physicists. DR devices for diagnostic medical imaging can be classified into two major categories: (1) cassette-based, passive detectors, chiefly the domain of photo-stimulable storage phosphor systems, also known as computed radiography (CR); (2) cassette-less, integrated detectors using active readout devices, which include charge-coupled device and thin-film transistor arrays. These latter systems are often categorized as “direct” or “digital” radiography (DR). Technological advances are blurring the differences between CR and DR, as there are CR systems available with integrated, high speed readout, and some DR devices with a portable, cassette-based form factor. Advanced applications made possible by high throughput, flat-panel DR detectors are becoming an important part of the clinical routine and future expectations. Examples include dual-energy radiography and digital tomosynthesis. Fully three-dimensional cone-beam computed tomography, achieved by rotating a two-dimensional digital detector around the object with full volumetric reconstruction, is providing cross-sectional and volumetric views for angiography and breast imaging.

Image quality, of paramount importance for any digital detector, is largely determined by image pre- and post-processing algorithms, requiring proper setup and tuning during initial implementation, acceptance testing, and quality control. A common misperception is that all DR devices can produce acceptable images at a lower patient dose due to internal scaling and signal adjustment compared to typical screen-film cassettes such as rare-earth 400-speed systems. In fact, however, some digital systems require as much as a twofold higher radiation dose for similar signal to noise characteristics because of poorer quantum detection efficiency and resultant higher noise (quantum mottle and electronic noise), while others require the same or slightly lower dose. For all digital systems, unintentional overexposure of the patient is possible without any direct knowledge by the technologist or radiologist, as the images have high signal to noise ratio and nothing apparently “wrong.” This is problematic, either because of unavailable feedback that overexposure has occurred, or inadequate knowledge by the user regarding the exposure index value provided by the manufacturer. Technologists must be made aware of potential overexposure tendencies, and pay close attention to radiographic techniques and patient dose. Technique charts should be posted at all operator consoles and with portable equipment. Additionally, radiologists should be aware of, understand, be able to determine, and monitor the exposure index. A complicating factor is the many different exposure index schemes reported by the various detector systems. The American
Association of Physicists in Medicine is currently working on a proposal to standardize the exposure index in cooperation with equipment manufacturers for all CR and DR devices. This is one of many steps that will assist in the proper use of DR systems. Ultimately, the users of such devices must be aware of the issues and methods for optimization of image quality at the lowest achievable dose.

**Developments in Mammography**

*Martin J. Yaffe*

Sunnybrook Health Sciences Centre, University of Toronto

Mammography has long been established as a useful tool for finding breast cancer in suspicious areas in the breast, identified by a woman or her physician. More recently, the contribution of screen-film mammography to reduction of mortality from breast cancer, when used for routine screening of asymptomatic women over the age of 40 has been clearly demonstrated.

Early mammography systems were relatively primitive in design and the direct exposure film image receptors were inefficient, requiring rather high doses (~20 mGy) to the breast. In the 1970s, 1980s and 1990s, considerable technical development took place to optimize image acquisition and display including introduction of intensifying screens, fixed focal-film distances, new target-filter combinations, improved breast compression, automatic exposure control, grids, better films and processing methods, and dedicated viewing systems. These developments resulted in images of improved diagnostic quality produced at considerably lower dose. In fact, doses dropped to the point where the signal to noise ratio and contrast of mammograms suffered. As the importance of adequate contrast and spatial resolution along with low noise in ensuring high diagnostic quality became better appreciated, doses gradually increased to stabilize at a higher level but still markedly below doses used in the early 1970s.

Despite these developments in screen-film mammography, there were fundamental barriers related to contrast, dynamic range, detector efficiency, and image viewing that limited the performance of mammography. Digital mammography addressed these limitations by decoupling image acquisition, storage and display, and attempting to optimize each of these processes separately. Mammograms could be viewed on a computer monitor, enhanced digitally and easily transmitted from one location to another. The recently-published results of the Digital Mammography Imaging Screening Trial showed that for certain groups of women digital mammography provided greater sensitivity of cancer detection in screening than film.

There are still important challenges for breast cancer detection. Digital mammography is far from perfect and variability of performance of interpreters is a major factor responsible for this. It is essential to ensure that x rays are used as efficiently as possible to produce useful diagnostic information. This can be achieved in part through improved quality control procedures and also by leveraging new breast imaging applications on the platform of digital mammography. These include computer-assisted detection and diagnosis to maximize performance of the interpreter, three-dimensional techniques like tomosynthesis or dedicated breast computed tomography to improve conspicuity of cancers by eliminating superposition effects, contrast imaging to exploit functional changes occurring with cancer, and many other new techniques.

Additionally, there is the opportunity to employ modalities that provide complementary information and do not require the use of ionizing radiation such as breast magnetic resonance imaging and ultrasound.
In the end, the most effective way to find breast cancer at an early enough stage where it is virtually 100 % curable may be through tracers, which are molecularly targeted to the cancer. This is an exciting area which is still in its infancy.

Estimates of collective radiation doses from medical procedures primarily use data from two sources: volumes of procedures and dose per procedure. This presentation will describe available data on volumes of procedures, the rates at which they have grown in recent years, and how these data are used in estimating collective doses.

The rate of growth of medical procedures overall, and the dramatic growth in the volume of imaging procedures in particular, have been the subject of much attention during the past 5 y. The Blue Cross-Blue Shield Medical Cost Reference Guide for 2006 reports a 38 % increase in the number of diagnostic imaging centers and a 34 % increase in diagnostic imaging procedures between 2001 and 2004. The growth in imaging has not been uniform across imaging modalities, sites of service, physician types, or over time. For example, the utilization of general radiography has been relatively stable, but the volume of computed tomography imaging has been growing at over 10 % per year since 2001. Procedures in nonhospital settings have been growing much more rapidly than inpatient procedures. The growth in the volume of procedures by nonradiologists in nonhospital settings has been much more rapid than the corresponding imaging by radiologists. While the volume of imaging procedures has been growing throughout the last decade, the rates of growth have been much higher in recent years.

This presentation will bring together recent information from a variety of sources (Medicare, private surveys of facilities, public-use surveys, and other publicly reported data) to illustrate the trends in medical imaging and radiation therapy procedures in the United States during the past decade. Special attention will be paid to differences in growth rates across sites of service and imaging by “nonradiological” physicians, because these could be associated with wide variation in types of equipment, levels of regulation and oversight, and knowledge and experience related to radiation safety. There will be a description of the distribution of imaging volume by patient age, particularly imaging for pediatric patients versus adult patients, because these groups receive different doses. The presentation will illustrate the differences in trends across age groups and explore which types of procedures grew most rapidly for each group.

Data availability is not uniform for all types of imaging; for example, there is not as much information on dental imaging as there is on other medical imaging. In general, procedures that are not covered by major insurance payers are difficult to track down, but are small enough in total volume as to not affect the overall findings.

Radiation therapy procedures affect a very small proportion of the population, and their overall volume has not grown as dramatically as that of medical imaging. However, there have been significant changes in patterns of care over time with notable implications for patient dose. The presentation will include compiled published information on some of these trends.

Finally, there will be discussion of some implications of the growth in diagnostic radiation utilization and collective dose for treating physicians and the need for increased awareness and caution on their part.
Cone-beam imaging is being used in radiotherapy for positioning and treatment planning, scientifically for scanning small animals, and for a variety of industrial applications. During the last 5 y cone-beam imaging has also gained a broad acceptance in dentistry, especially in the United States, Europe, Japan and Canada. Currently there are about 1,000 machines worldwide and the number of installations is growing rapidly. Further, some manufacturers of conventional panoramic machines are modifying their units for cone-beam imaging.

Cone-beam machines emit an x-ray beam shaped like a cone rather than as a fan as in a computed tomography (CT) machine. After this beam passes through the patient the remnant beam is captured on an amorphous silicon flat panel or image intensifier/charge-coupled detector. Unlike CT, there is no post-patient collimation. As a result the image is captured with few wasted photons but is degraded by scattered radiation. The beam diameter is up to 12 inches in diameter and exposes the region of interest in one pass around the patient. Various machines capture from 160 to 599 basis images. These images are used to compute a volume from which axial, sagittal or coronal images, or planar or curved reconstructions in any arbitrary plane can be extracted. Three-dimensional images of bone or soft tissue surfaces can be generated.

In dentistry the most common indications for cone-beam imaging are assessment of the jaws for placement of dental implants, evaluation of the temporomandibular joints for osseous degenerative changes, examination of teeth and facial structures for orthodontic treatment planning, and evaluation of the proximity of lower wisdom teeth to the mandibular nerve prior to extraction. These imaging needs all rely on the three-dimensional nature of the image reconstructions. Cone-beam images are attractive in dentistry because the image quality is superior to conventional tomography that it replaced. Cone-beam images also replace panoramic images for some of these needs but are unlikely to soon replace conventional intraoral periapical or bitewing images. Cone-beam images also can be displayed without magnification, a feature that is particularly important for placement of implants and orthodontic treatment planning. The main limitations of dental cone-beam images compared to conventional CT are the lack of a soft-tissue window and higher image noise.

The radiation dose from cone-beam imaging depends on the specific brand as well as the exposure factors used and can vary by a factor of 20 times. At the low end the effective dose is about 44 μSv for a large field of view. This value is less than a conventional full-mouth set of dental x-ray views, six to seven times a panoramic view, and perhaps 2 to 5 % of a conventional CT of the same region. The cost of the equipment is relatively low, about $150,000 to $300,000. Most dental cone-beam units are used in universities, offices of orthodontists, oral surgeons and periodontists, and in dental x-ray laboratories. A major issue to be considered is the training of individuals making and interpreting cone-beam images, both in terms of technical operation of the units as well as their qualifications for evaluating the whole imaged volume.
Interventional fluoroscopy procedures use ionizing radiation for guidance as small instruments such as catheters are manipulated through blood vessels or other pathways in the body. As compared to open surgical procedures, interventional fluoroscopy procedures require a very small incision and permit shorter recovery times. As a result, these procedures have become very common. As an example, in 2002 an estimated 657,000 percutaneous transluminal coronary angioplasty procedures were performed in adults in the United States. From 1996 to 2000, the rate of coronary artery stent insertions doubled from 157 to 318 per 100,000 adults aged 45 to 64.

At the same time, more complex interventional fluoroscopy procedures have been introduced. This is due to the development of new devices and procedures, such as endografts for the treatment of abdominal aortic aneurysms, the development of vertebroplasty, kyphoplasty and uterine artery embolization, and increasing use of fluoroscopic guidance during complex endoscopic biliary and upper urinary tract procedures. As the complexity of these procedures has increased, radiation doses to patients and healthcare personnel have also increased.

Many interventional fluoroscopy procedures have the potential for high patient radiation doses, and some (particularly embolization procedures) are typically high-dose procedures. Absorbed skin doses >5 Gy may occur. Because most patients are past reproductive age and have serious underlying medical problems, their life expectancy is shortened as compared to the general population. As a result, deterministic radiation effects, principally skin injury, are usually of greater concern than stochastic effects. Fortunately, serious injuries are uncommon. The majority of reported radiation-induced skin injuries have been associated with coronary artery angioplasty and stent placement, cardiac radiofrequency ablation procedures, embolization procedures, or transjugular intrahepatic portosystemic shunt creation.

The risk/benefit analysis for interventional fluoroscopy procedures differs from the analysis for diagnostic radiology procedures. Unlike diagnostic radiology procedures, all interventional fluoroscopy procedures provide a clear benefit for the patient. In addition, the risk of radiation-related injury is far less than that for other procedure-related complications, so the risk/benefit analysis is relatively straightforward. The patient is far more likely to be injured by catheter manipulation than by the radiation beam.

An important goal of all interventional fluoroscopy is to achieve clinical success using the least amount of radiation consistent with adequate imaging guidance. However, most interventional procedures require high quality images, long fluoroscopy time, or both. It is critically important to train operators how to achieve the maximum possible dose reduction consistent with acceptable image quality. Simple techniques exist which can accomplish this. These include the use of reduced-dose pulsed fluoroscopy, collimation, and dose spreading. These techniques are simple, but
they require modern, well-maintained equipment, operator education and motivation.

Many interventional fluoroscopy procedures were developed by radiologists, but these procedures are now performed by a rapidly expanding number of healthcare providers in a wide range of medical specialties. These include cardiology, vascular surgery, neurosurgery, pain management, orthopedic surgery, and many other medical and surgical disciplines.

Training in radiation physics, biology and safety has long been incorporated into radiology residency programs. The cardiology and pain management medical communities have recently recognized the need for training in radiation physics and radiation safety. Unfortunately, most other operators have little training in radiation science or protection measures, and are not motivated to become trained.

Training requirements may be mandated by professional societies, accreditation organizations such as the Joint Commission on Accreditation of Healthcare Organizations, or governmental regulation. In the United States, only the individual states have the authority to require a specific knowledge base prior to operation of fluoroscopy equipment. To date, only a handful of states have mandated specific training and licensing for physicians who perform fluoroscopy.

Physicians, technologists, medical physicists, fluoroscopy equipment manufacturers, and medical and governmental organizations share the responsibility to optimize radiation doses to patients undergoing interventional fluoroscopy.

Radiation-induced stochastic and deterministic effects in patients and in practitioners exist. Circumstances responsible for documented effects provide an abundance of information regarding practice techniques and habits that must be in place to prevent deterministic effects and to appropriately limit the occurrence of stochastic effects. Radiation management to limit risk must be balanced against certain factors indigenous to medical procedures. For example, the medical benefit of a procedure must be considered in an appropriate manner relative to the overall risk, of which radiation represents only one agent of concern. For practitioners, the regard for radiation safety must be considered in light of the risks that certain radiation-protection practices pose to the practitioner. An example of this is the consideration of the protection provided by a lead apron versus the weight of that lead apron and the ergonomic considerations associated with that weight. The risk of injury to the spine from a heavy lead apron is as important a consideration as radiation-induced disease.

Risks to patients from complex fluoroscopically-guided procedures are associated with long fluoroscopy times, irradiation through thick body parts, and no monitoring of dose to the patient, among other things. Despite these facts, in facilities where injuries have occurred few had initiated any actions in response to the 1994 advisory of the U.S. Food and Drug Administration (FDA) about the means to avoid them. Many had disregarded the warning because fluoroscopically-induced radiation injury was rare and the FDA advisory was not regulatory.

In response to the fact that dose monitoring has previously not been readily available, the FDA now requires that manufacturers incorporate dose monitoring devices into their fluoroscopic equipment. However, simply requiring manufacturers to provide dose information will
have little benefit if physicians are not trained in the use of such information.

Physicians are sometimes misled by manufacturers who tout that their equipment is “low dose.” For example, while some have claimed great strides in dose reduction with modern flat-panel devices, patients still have been injured from procedures that employ these machines. Further, while many modern machines are equipped with high-powered technology to reduce dose and dose rate to the patient, training of users in the full scope of dose management techniques is lacking. The bottom line is that the Achilles heel of all dose management and dose limiting devices is the training that the user has in employing them. This presentation will focus on the lessons learned from radiation injuries and will try to identify shortfalls in the methods so far promoted to limit radiation risk in medicine.

During the past decade, interventional fluoroscopic systems equipped with image intensifiers have benefitted from technical advances in x-ray tube, x-ray generator, and spectral-shaping filter technologies. While the photoconductor (or phosphor plate) x-ray detectors and signal capture thin-film transistor arrays and charge-coupled devices are analog in nature, not until the advent of flat-panel image receptors would fluoroscopy become a totally digital process throughout the entire imaging chain.

The high heat capacity x-ray tube, the medium-frequency inverter type generator with high performance switching capability, and the patient dose reduction spectral-shaping filter had already been implemented on image-intensified fluoroscopy systems. These three underlying technologies were tied together through the automatic “image quality” control logic so that patients receiving cardiovascular angiography procedures can benefit from “lower patient dose” with “high image quality.”

The flat-panel image receptor streamlined the image processing due to its “digital” nature, and eliminated the need to perform analog-to-digital conversion at the point of image acquisition. While the changeover from image-intensified fluoroscopy system to flat-panel image receptor fluoroscopy system is part of the ongoing “digitization of radiology,” the value of the flat-panel image receptor may have to be evaluated from various angles including, but not limited to patient dose, image quality, and clinical application capabilities. It is believed that the advantage of the flat-panel image receptor is yet to be explored fully.

For instance, the flat-panel image receptor is not necessarily without any disadvantage as compared to image intensifiers; the cost of the equipment is probably the most obvious. However, there is a potential of further lowering the patient dose through a calibration process in which the flat-panel input dose rate may be set to one-half of what is being used today. Thus, further reducing the patient dose by a factor of two is not unrealistic.

In this presentation, the main thrust is to understand the details of the automatic “image quality” control logic as seen from a fluoroscopist’s point of view, and to show how the control logic “ties” three technological advancements together to provide low radiation dose to the patient and yet make high-quality fluoroscopic images available for manipulation of catheters. A secondary purpose is to show how three-dimensional angiography, by providing computed-tomography-like images, can result in reduction of patient dose indirectly. Although “rotational
three-dimensional angiography” was also available with an image-intensified fluoroscopy system, the flat-panel image receptor system is able to accomplish the same task faster and with considerable ease.

New technologies such as intensity modulated radiation therapy (IMRT), image guided radiation therapy (IGRT), computer controlled linear accelerators (LINACs), computerized record and verify (RV) systems, electronic charts, digital imaging, etc., have revolutionized radiation therapy over the past 10 to 15 y. Quality assurance as historically practiced and as recommended in reports such as (1) Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40. [Medical Physics (1994) 21, 581–618], and (2) AAPM Radiation Therapy Committee Task Group 53: Quality Assurance for Clinical Radiotherapy Treatment Planning [Medical Physics (1998) 25, 1773] is in many respects obsolete and impractical. The quantity of data created by an IMRT treatment plan that must be transferred to a LINAC coupled with the complexity of the dose calculations make it impossible to “hand check” a treatment plan in the traditional sense. RV systems first introduced 10 to 15 y ago began as computers checking humans; did the radiation therapist set the LINAC correctly, etc? But over the years RV has evolved into more complex systems that now actually “run” the LINAC rather than merely monitor the actions of human operators. RV has evolved into humans checking computers rather than computers checking humans. Often it means one computer checking another computer.

The more recent introduction of IGRT is leading to more reliance on computer control of patient setup and even real-time corrections for intrafractional patient motion, with much of this also falling into the category of humans checking computers. In short, the increasing complexity of radiation therapy technology and the quantity of data required to define a treatment plan and patient treatment has made traditional quality assurance virtually impossible.

Perhaps as a result we are seeing an increasing fraction of medical and seminal events in radiation therapy caused either by improper use and/or understanding of new technology; communication failures between computers; corrupted, improperly created, or improperly transferred data files; and “software bugs.” In our experience errors in radiation therapy are, with rare exceptions, never the result of hardware failures anymore. The growth of inter- and intracranial radiosurgery, use of hypofractionation, complexity of treatment plans, IGRT, and increasing financial pressures to treat more patients in less time will continue to fuel this reliance on high technology and in particular, complex computer software.

In the areas of diagnosis, treatment simulation, tumor contouring, and treatment planning we are also witnessing an increasing reliance on complex, software driven multi-modality...
imaging technology. Combinations of computed tomography, magnetic resonance imaging, magnetic resonance spectroscopic imaging, single photon emission computed tomography, and positron emission tomography image fusion are fast becoming commonplace for many types of radiation therapy treatment plans. Quality assurance for these modalities is often beyond the expertise of the radiation therapy physicist, and we increasingly rely on manufacturer-supplied image transfer, fusion imaging, and picture archiving and communication computer systems with little understanding of how they work.

Clinical practitioners as well as government regulatory agencies are coming to the realization that quality assurance for new technologies, especially computer software, is a major challenge. Increasing reliance on technology for tumor definition, contouring, and real-time corrections of radiation delivery coupled with decreasing treatment field margins and dose escalation pose challenges and dangers of a completely different nature than what we have historically dealt with, and this has changed the very nature of quality assurance.

3:10 pm

Dose to Normal Tissues Outside the Radiation Therapy Patient’s Treated Volume: A Review of Different Radiation Therapy Techniques

James A. Purdy
University of California Davis Medical Center

Radiation therapy treatment planning and delivery capabilities have changed dramatically since the introduction of three-dimensional treatment planning and continue to change in response to the implementation of new advanced technologies. Powerful x-ray computed-tomography simulation and three-dimensional treatment planning systems have been commercially available since the early 1990s and three-dimensional conformal radiation therapy (CRT) is now firmly in place as the standard of practice in clinics around the world. Medical accelerator manufacturers have employed advanced computer technology to produce treatment planning/delivery systems capable of precise shaping of dose distributions via computer-controlled multileaf collimator systems, by which the beam fluence is varied optimally to achieve the desired dose distribution. This mode of conformal therapy is referred to as intensity modulated radiation therapy (IMRT), and is capable of generating precise conformal dose distributions including concave isodose volumes which provide conformal target volume coverage and avoidance of specific sensitive normal tissue structures. The increasing use of IMRT has focused attention on the need to better account for both intra- and interfraction spatial uncertainties, which has helped spur the development of treatment machines with integrated planar and volumetric advanced imaging capabilities, providing what is now referred to as image-guided IMRT, or simply image-guided radiation therapy. In addition, there is a growing interest in replacing x rays with protons because of the physical characteristics of the Bragg energy-deposition curve, which peaks at the end of the particle range, and eventually with even heavier charged particles to take advantage of the greater density of energy deposition close to the Bragg peak and hence larger relative biological effect.

For all of these conformal modalities, the challenge of treatment planning is to create an arrangement of beams that delivers the prescribed dose to the target (tumor) volume, while keeping the dose to critical normal tissues low enough to minimize the risk of serious complications. Thus, it is essential that accurate dose-volume tolerance data for the irradiated normal tissues be available along with accurate data for the specific conformal modality used regarding peripheral dose or whole-body dose (i.e., the dose the patient
receives outside of the geometric confines of the treatment beams).

Three-dimensional CRT, IMRT and proton beam therapy all provide improved target coverage and lower doses to surrounding normal tissues as compared to two-dimensional radiation therapy techniques. However, these are achieved at the expense of more volume of normal tissue receiving some dose and/or higher whole-body doses to distant normal tissues. These higher whole-body doses are the result of increased x-ray leakage radiation from longer beam-on times associated with IMRT and neutron leakage radiation associated with high-energy x-ray beams (>10 MV) and proton beams.

This presentation will review the dose distributions for the various conformal radiation therapy techniques and the current status of available data for normal tissues, and whole-body dose. In addition, an update on current efforts in clinical trials that use these advanced technologies and the reporting of volume and dose data will be presented.

Cancer survivors are at a significantly increased risk of developing a second malignancy as a consequence of the radiotherapy used to treat their primary malignancy. Such is the problem that second malignancies are one of the leading causes of death in long-term survivors of Hodgkin’s lymphoma. Much research has focused on elucidating the relationship between radiation dose and site-specific cancer risk, and how this relationship is affected by host factors such as age, gender, co-morbidities, and exposure to other potential carcinogens.

By contrast, there is a relative paucity of data on host genetic susceptibility to second primary cancers following radiation exposure. Animal model systems suggest a strong genetic basis underlying susceptibility to radiogenic cancer. In humans, research has focused on investigating loci with relatively rare putative high-penetrance risk alleles, such as ataxia telangiectasia (ATM) and Nijmegen breakage syndrome 1 (NBS1). However, genetic susceptibility to radiogenic cancer and other late effects of radiation exposure may be determined predominantly by co-inheritance of low-penetrance risk alleles, and how these interact with each other (gene-gene interactions) and with radiation dose (gene-exposure interactions). The development of high-density polymorphism arrays represents a promising approach in the search for genetic risk alleles conferring susceptibility to radiogenic cancer.

In addition to host factors and inherent genetic susceptibility, there is evidence to suggest that the phenotype of the putative target cell for transformation can impact on the risk of developing cancer after radiation exposure. For example, cells actively proliferating at the time of exposure are predicted to be more susceptible to the adverse effects of radiation. In support of this, experimental evidence demonstrates that dividing cells are more likely to fix deoxyribonucleic acid (DNA) damage into mutation than nondividing cells and are, therefore, more susceptible to transformation. In some tissues, such as the breast, cellular proliferation is inversely correlated with age. As such, we might predict that radiogenic cancer risk would be higher in younger premenopausal women than older or postmenopausal women. Indeed, this seems to be the case. Data such as these suggest that the pathological response to radiation-induced DNA damage at the time of exposure, specifically the balance between mutation and death...
at the cellular level, might ultimately determine risk of transformation. However, this model remains to be challenged.

In summary, patient susceptibility to radiation-induced cancer is likely to be determined by interacting genotypic and phenotypic characteristics. Despite its apparent complexity, an understanding of susceptibility to radiotherapy-induced cancers could lead to therapeutic benefit such that patients at high risk could be identified. Moreover, it is envisaged that a focus on understanding the factors that predispose to the development of radiotherapy-induced cancers will also provide a sound basis for the study of other late effects in cancer survivors.

4:00 pm

Panel Discussion

Stephanie K. Carlson, Moderator

4:40 pm

Closing Remarks

Thomas S. Tenforde, President
National Council on Radiation Protection and Measurements
The National Council on Radiation Protection and Measurements (NCRP) seeks to formulate and widely disseminate information, guidance and recommendations on radiation protection and measurements which represent the consensus of leading scientific experts. The Council monitors areas in which the development and publication of NCRP materials can make an important contribution to the public interest.

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Registration
Monday, April 16, 2007 7:00 am – 5:00 pm
Tuesday, April 17, 2007 7:00 am – 1:00 pm
(No registration fee)

Register online (http://registration.ncrponline.org)

2008 Annual Meeting
Low Dose and Low Dose-Rate Radiation Effects and Models

April 7-8, 2008
Arlington, Virginia
Radiation Protection in Medicine

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Excerpts from recent reviews of NCRP reports:

“This report [NCRP Report No. 151] has been long awaited by the therapy community and it serves at least two distinct communities of physicists: those newly entering the field that do not have a library shelf full of previous NCRP reports and the other group are the more experienced physicists that have all of the previous reports.”

J.B. Smathers  

“In conclusion NCRP Report 147 is well written and easily readable, and provides reference data in a manner that is easy to follow.”

G.J. Chalmers  

Reports and commentaries are available from the NCRP website, [http://NCRPpublications.org](http://NCRPpublications.org), in both soft- and hardcopy formats. Complete book reviews of recent NCRP publications are also available at this website.
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