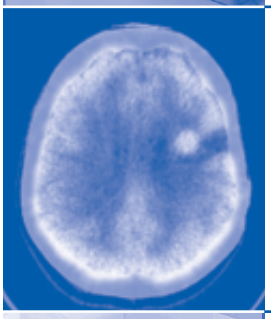

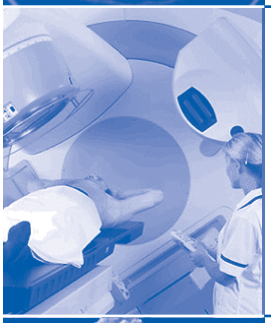

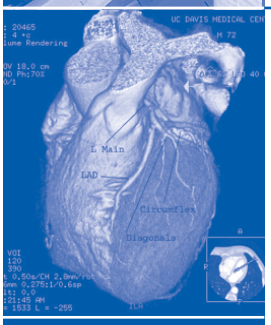

Forty-Third
Annual Meeting Program

Advances in Radiation Protection in Medicine

April 16-17, 2007

Crystal Forum
Crystal City Marriott
1999 Jefferson Davis Highway
Arlington, Virginia

NCRP
National Council on Radiation Protection & Measurements

Co-sponsors

American College of Radiology
Reston, Virginia

Xoran Technologies
Ann Arbor, Michigan

Introduction

Advances in Radiation Protection in Medicine

Forty-Third Annual Meeting of the National Council on Radiation Protection and Measurements (NCRP)

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.

Program Summary

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

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

9:40 am **Dose in Computed Tomography: How to Quantitate, How to Reduce**
Cynthia H. McCollough
Mayo Clinic

10:05 am **Break**

10:35 am **Pediatric Dose Reduction in Computed Tomography**
Donald P. Frush
Duke University Health Systems

11:00 am **Diagnostic Reference Levels for Medical Imaging with Ionizing Radiation: ICRP Guidance**
Marvin Rosenstein
ICRP Committee 3 (Protection in Medicine)

11:25 am **Capturing Patient Doses from Fluoroscopically-Based Diagnostic and Interventional Systems**
Stephen Balter
Columbia University Medical Center

11:50 am **Lunch**

Interdisciplinary Issues

Linda A. Kroger, Session Chair

1:30 pm **Update on Linear Nonthreshold Dose-Response Model and Implications for Diagnostic Radiology Procedures**
R. Julian Preston
U.S. Environmental Protection Agency

David J. Brenner
Columbia University

1:55 pm **Research Involving Human Subjects**
Richard L. Morin
Mayo Clinic

2:20 pm **Radiation and Pregnancy**
Claire Cousins
Cambridge University, UK

2:45 pm **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

3:35 pm **Combined Imaging Modalities: PET/CT and SPECT/CT**
Alan H. Maurer
Temple University School of Medicine

4:00 pm **PANEL DISCUSSION**
Julie E.K. Timins, Moderator

Program Summary

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 **Exposure 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

10:20 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**

Interventional Procedures

Charles E. Chambers, Session Chair

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**

Program Summary

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

3:10 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

3:35 pm — **Patient Susceptibility to Radiation-Induced Cancer and Second Cancers Following Radiotherapy Procedures**
James M. Allan
University of York, UK

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

Abstracts of Presentations

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

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 administrator 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 detecting 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 comprehensive 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 comprehensive for diagnostic and nuclear medicine examinations, and less complete for interventional 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 estimating 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 procedures, which have increased 10 to 15 % annually 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 evaluation 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. $CTDI_{vol}$ 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 $CTDI_{vol}$ on their console. This feature can allow the clinician to compare the radiation output from different imaging protocols. $CTDI_{vol}$ 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 $CTDI_{vol}$.

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

Non-CT Typical Effective Dose Values[a] (mSv)		CT Typical Effective Dose Values[a] (mSv)	
Hand radiograph	<0.1	Head	1 – 2
Dental bitewing	<0.1	Chest	5 – 7
Chest radiograph	0.1 – 0.2	Abdomen	5 – 7
Mammogram	0.3 – 0.6	Pelvis	3 – 4
Lumbar spine radiograph	0.5 – 1.5	Abdomen and pelvis	8 – 11
Barium enema exam	3 – 6	Coronary artery calcium	1 – 3
Coronary angiogram (diagnostic)	5 – 10	Coronary angiography	5 – 12
Sestamibi myocardial perfusion	13 – 16		
Thallium myocardial perfusion	35 – 40		

[a]Average U.S. annual effective dose equivalent 3.6 mSv (NCRP Report No. 93, 1987).

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.

10:05 am **Break**

10:35 am **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.

11:00 am

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.

11:25 am

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.

11:50 am **Lunch**

Interdisciplinary Issues

Linda A. Kroger, Session Chair

1:30 pm **Update on Linear Nonthreshold Dose-Response Model and Implications for Diagnostic Radiology Procedures**

R. Julian Preston
U.S. Environmental Protection Agency

David J. Brenner
Columbia University

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.

2:20 pm

Radiation and Pregnancy

Claire Cousins
Cambridge University, UK

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 wherever 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.

2:45 pm **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 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.

3:35 pm

Combined Imaging Modalities: PET/CT and SPECT/CT

Alan H. Maurer
Temple University School of 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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Abstracts of Presentations

Tuesday, April 17, 2007

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.

9:55 am

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 photostimulable 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.

10:20 am

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.

10:45 am

Trends in Utilization and Collective Doses from Medical Procedures

Mythreyi Bhargavan
American College of Radiology

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.

Abstracts of Presentations

11:10 am

Cone-Beam Imaging in Dentistry

Stuart C. White
University of California, Los Angeles

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.

11:35 am **Lunch**

Interventional Procedures

Charles E. Chambers, Session Chair

1:00 pm **Overview of Contemporary Interventional Fluoroscopy Procedures**

Donald L. Miller
National Naval Medical Center

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, embolizati on 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.

1:25 pm

Patient and Personnel Safety in Interventional Fluoroscopy Procedures

Louis K. Wagner
University of Texas

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.

1:50 pm

Technical Advances of Interventional Fluoroscopy and Flat-Panel Image Receptor

Pei-Jan P. Lin
Beth Israel Deaconess Medical Center

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.

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

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.

3:35 pm

Patient Susceptibility to Radiation-Induced Cancer and Second Cancers Following Radiotherapy Procedures

James M. Allan
University of York, UK

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.

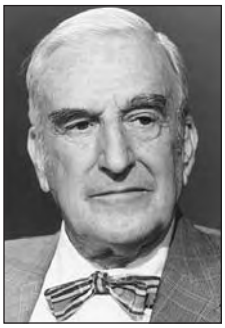
4:00 pm **Panel Discussion**
Stephanie K. Carlson, Moderator

4:40 pm **Closing Remarks**
Thomas S. Tenforde, President
National Council on Radiation Protection and Measurements

Mission Statement

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.

The Council's mission also encompasses the responsibility to facilitate and stimulate cooperation among organizations concerned with the scientific and related aspects of radiation protection and measurements.



L.S. Taylor
1929–1977

W.K. Sinclair
1977–1991

C.B. Meinhold
1991–2002

T.S.Tenforde
2002–

Recognized worldwide as an authority on radiation health protection for over 75 years.

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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)

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2008 Annual Meeting

Low Dose and Low Dose-Rate Radiation Effects and Models

April 7-8, 2008

Arlington, Virginia

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Radiation Protection in Medicine

Publication	Title	Price ($)
Report No. 151	Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities	100.00
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Commentary No. 7	Misadministration of Radioactive Material in Medicine — Scientific Background	25.00

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
[published in *Journal of Applied Clinical Medical Physics*, **7** (2006) 100–101]

"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
[published in *Physics in Medicine and Biology*, **50** (2005) 4243–4244]

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

Contracts/Grants/Contributors/Sponsors

These organizations have supported the work of the National Council on Radiation Protection and Measurements during the period of January 1, 2006 to December 31, 2006.

Contracts

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U.S. Navy

Grants

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National Aeronautics and Space Administration
National Cancer Institute
National Institute of Standards and Technology
U.S. Department of Energy
U.S. Nuclear Regulatory Commission

Contributors

American Academy of Health Physics
American Academy of Oral and Maxillofacial Radiology
American Association of Physicists in Medicine
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The Use and Misuse of Radiation in Medicine

James A. Brink, M.D.
Yale University School of Medicine

Disclosure

- General Electric: Medical Advisory Board
- Vital Images: Medical Advisory Board

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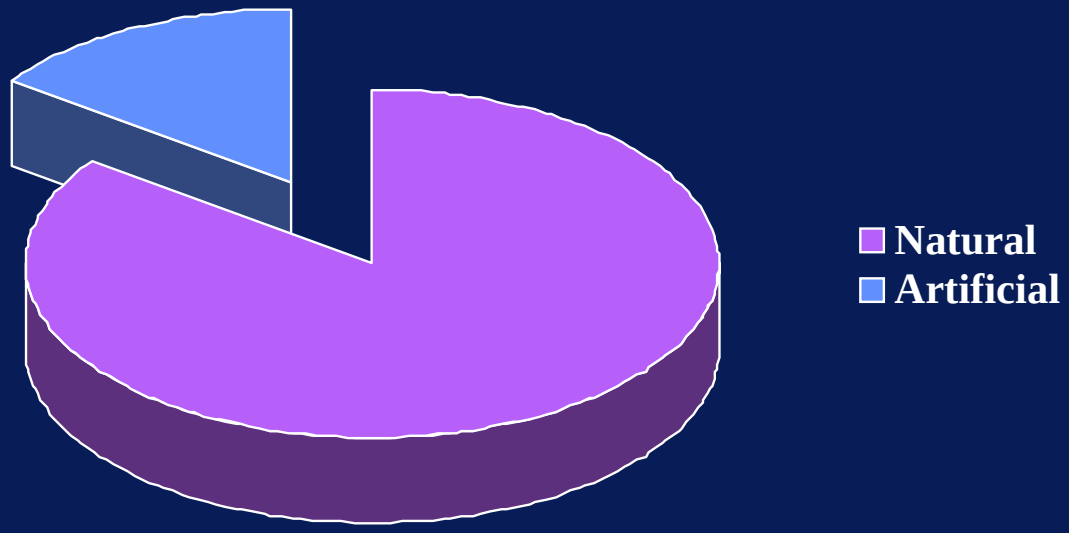
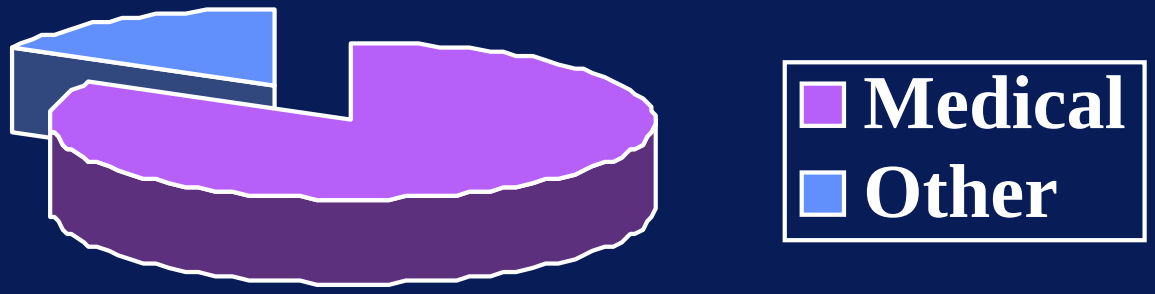
T. Rob Goodman, M.D.

Yale University School of Medicine

Human Radiation Exposure



Artificial Radiation Exposure



Radiation in Medicine

Diagnostic Uses

Therapeutic Uses

Diagnostic Uses for Radiation

Computed Tomography

Nuclear Medicine

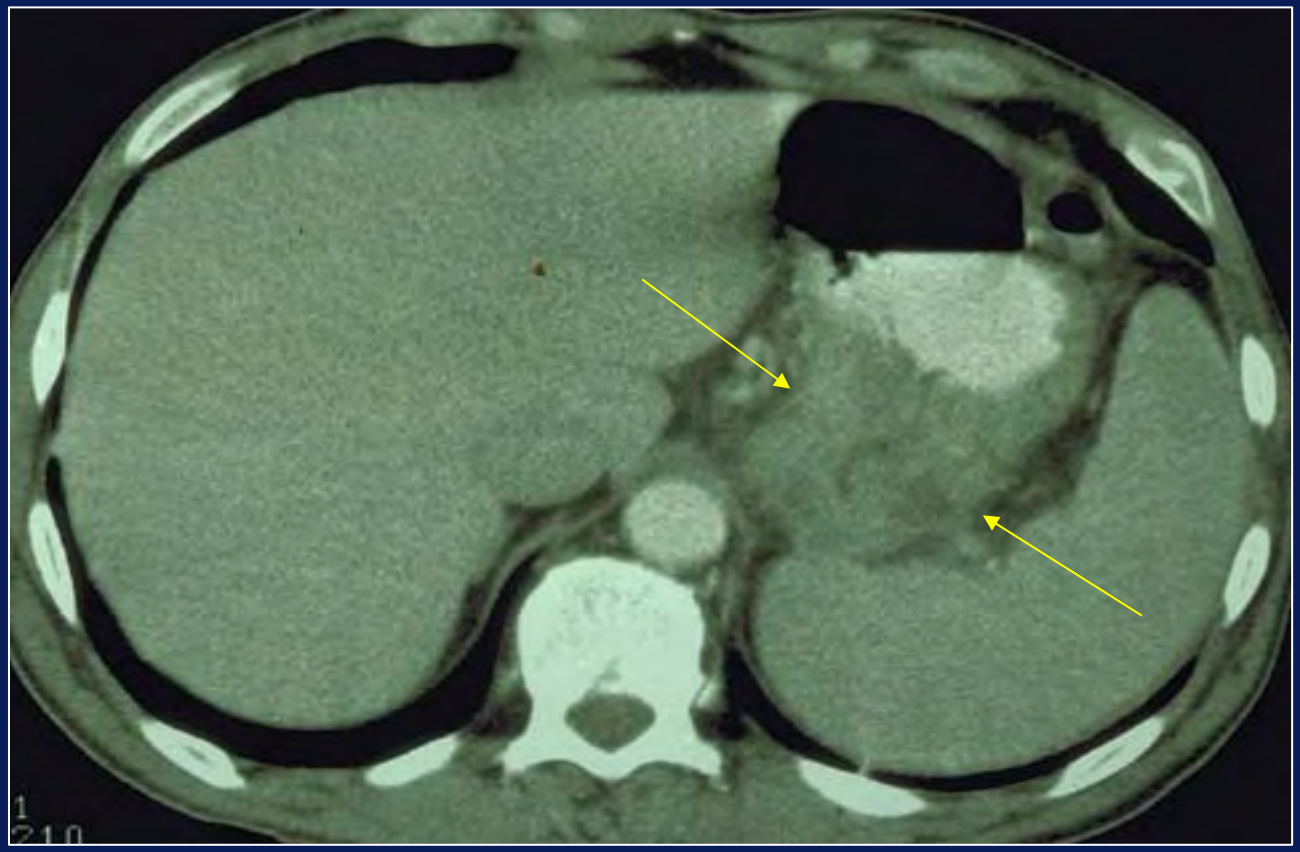
Radiography

Fluoroscopy

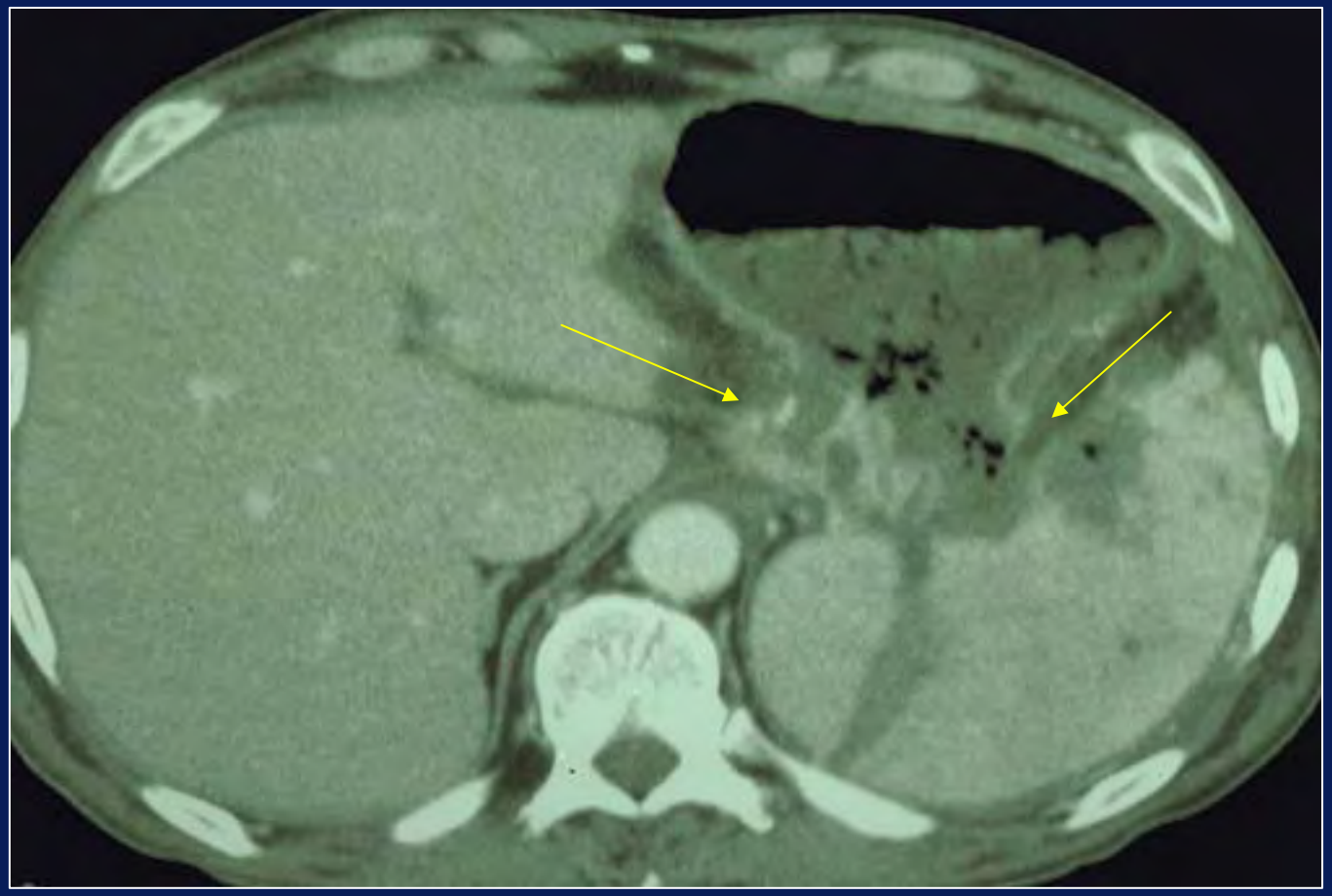
‘Benefits’ of MDCT

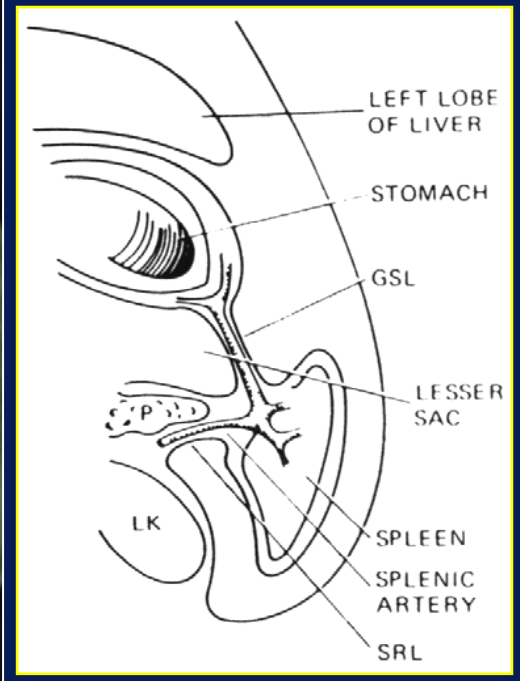
- Standard Axial Imaging
  - » Superb Anatomic Depiction
    - Head to toe
  - » Innumerable Diagnoses
    - Confirmed
    - Excluded

Gastric Carcinoma in Fundus



Lost to Follow-up for 6 Months



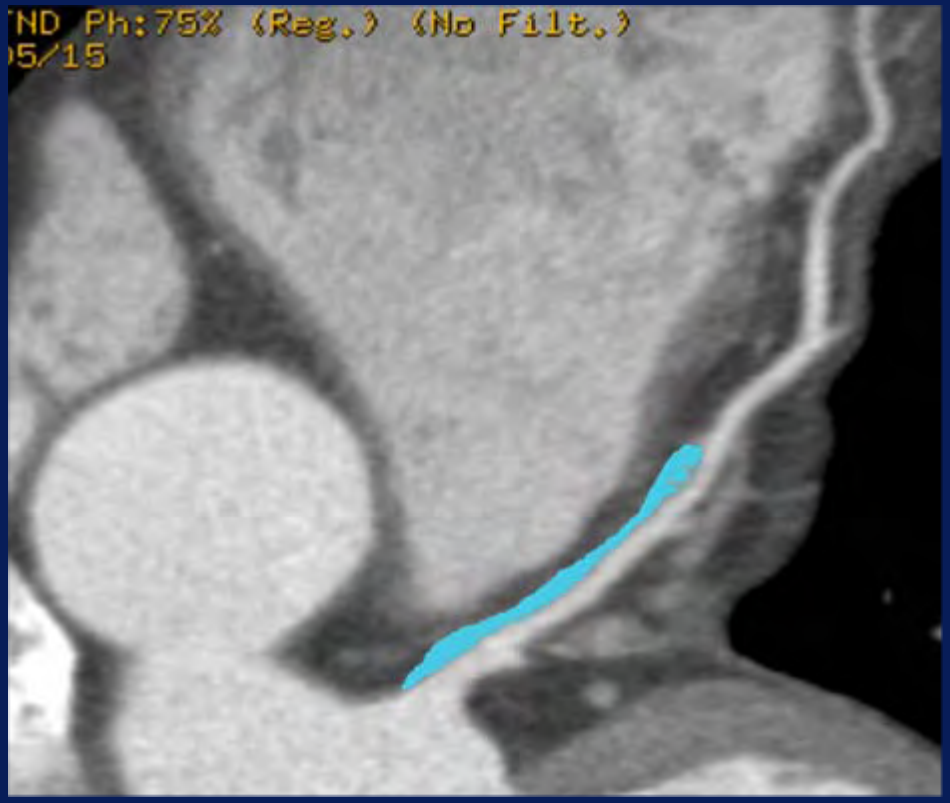


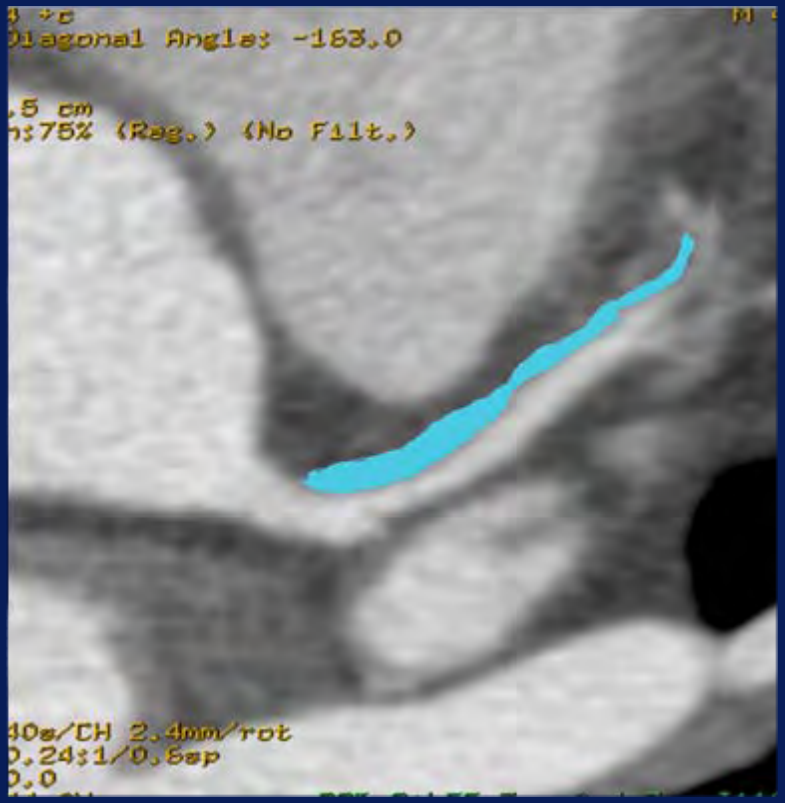
Malignant ulceration into spleen via gastrosplenic ligament

‘Benefits’ of MDCT

- New uses of CT imaging
  - »Renal/Ureteral Stone CT
  - »CT “Virtual” Colonoscopy
  - »CT Angiography of Head, Pulmonary Vessels, Aorta and Extremities
  - »Coronary CT Angiography

Diffuse Plaque in Proximal LAD





Radiation Dose

- CT has grown dramatically:
  - 3 million CT exams in 1981
  - 20 million CT exams in 1995
  - 35 million CT exams in 2000
  - 63 million CT exams in 2005

Mettler FA. Radiation Protection and Dosimetry, 2001
Niagara Health Quality Coalition, 2004

Typical Doses

• Chest study	0.10 mSv
• Cervical spine	0.11 mSv
• Pelvis	0.27 mSv
• Skull	0.31 mSv
• Upper GI	1.17 mSv
• Barium enema	2.98 mSv
• CT scan	18.0 mSv

Linnemann, 2001. Managing Radiation Medical Emergencies

Cancer Risk

- Fatal cancer risk to population 5% per Sv
  - Female neonate 30% per Sv
  - Male neonate 15% per Sv
  - Late middle-age 1% per Sv
- Presuming linear extrapolation to low dose:
  - Effective dose of 10 mSv Risk = 1 in 2000

Dixon, A.K. and P. Dendy, *Spiral CT: how much does radiation dose matter?* Lancet, 1998. **352**: p. 1082-3.

Atomic Bomb Survivor Data

- Biggest longitudinal study to date
  - 35,000 survivors exposed to doses < 150 mSv
  - Followed for cancer incidence over 55 years
  - Direct, statistically significant evidence for risk in the dose range from 5 to 150 mSv

Pierce, DA and Preston, DL. *Radiation-related cancer risks at low doses among atomic bomb survivors.* Radiation Research, 2000. **154**(2): p. 178-86.

Cancer Risk -- No Extrapolation

- Japanese survivors (lowest dose) 5 - 150 mSv
  - Small but statistically significant increased risk of developing cancer due to radiation
- Diagnostic CT 5 - 20 mSv

Pierce, DA and Preston, DL. *Radiation-related cancer risks at low doses among atomic bomb survivors.* Radiation Research, 2000. **154**(2): p. 178-86.

Relative Risk

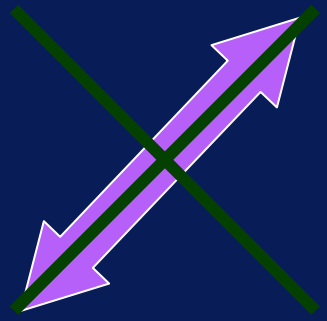
- To individual:
  - Lifetime risk of cancer: 20-25% (1 in 4 or 5)
  - Added risk: 0.05% (negligible, 1 in 2000)
- To population:
  - 62M CT scans year
  - Without CT: 13.778M will die of cancer
  - With CT: an additional 31K will die of cancer (13.809M)

Atomic Bomb - Additional Lessons

- Radiation-induced cancers appear at the same age as spontaneous cancers of the same type
- Risks persist throughout life
- Children are 10x more sensitive to radiation induced cancers than adults (girls > boys)
- Bone marrow, thyroid, breast, and lung are at greatest risk
- Risk from acute exposure appears similar to fractionated exposure (fluoro-->breast cancer)

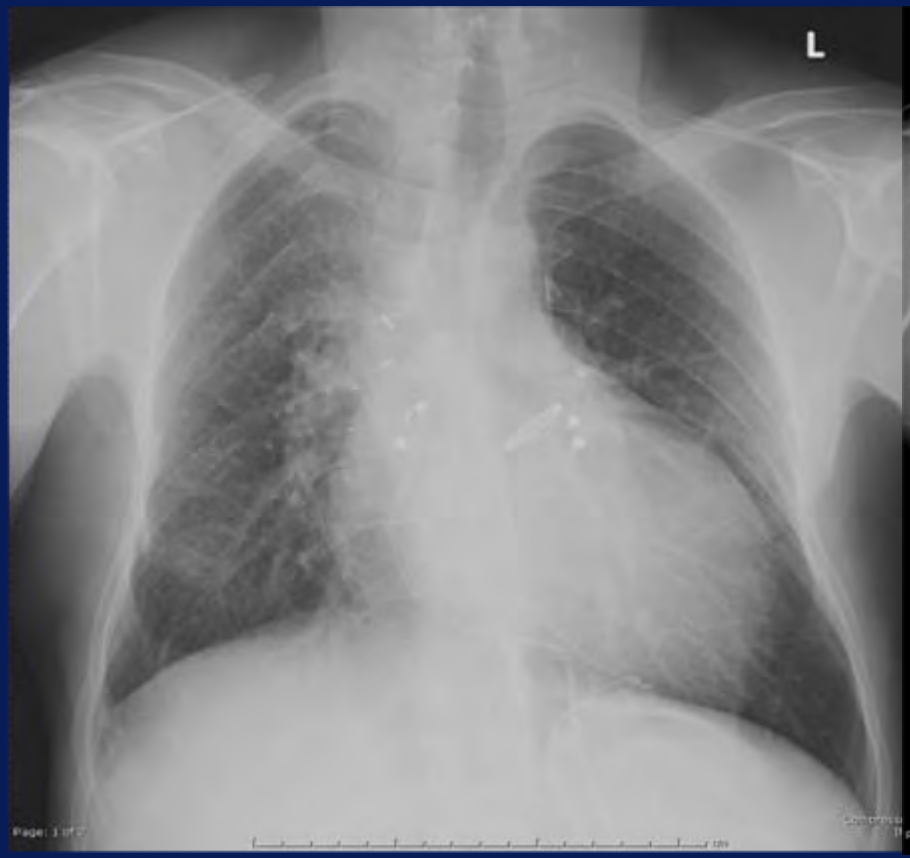
Radiography

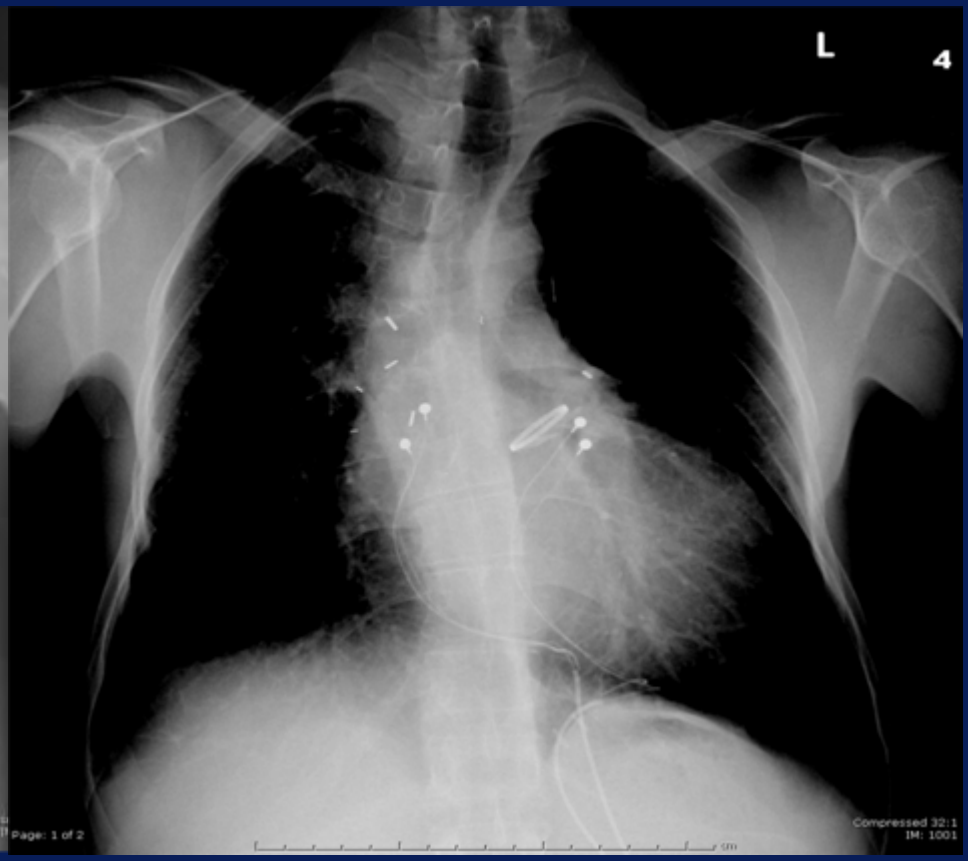
Image Quality



Radiation Dose

Computed Tomography



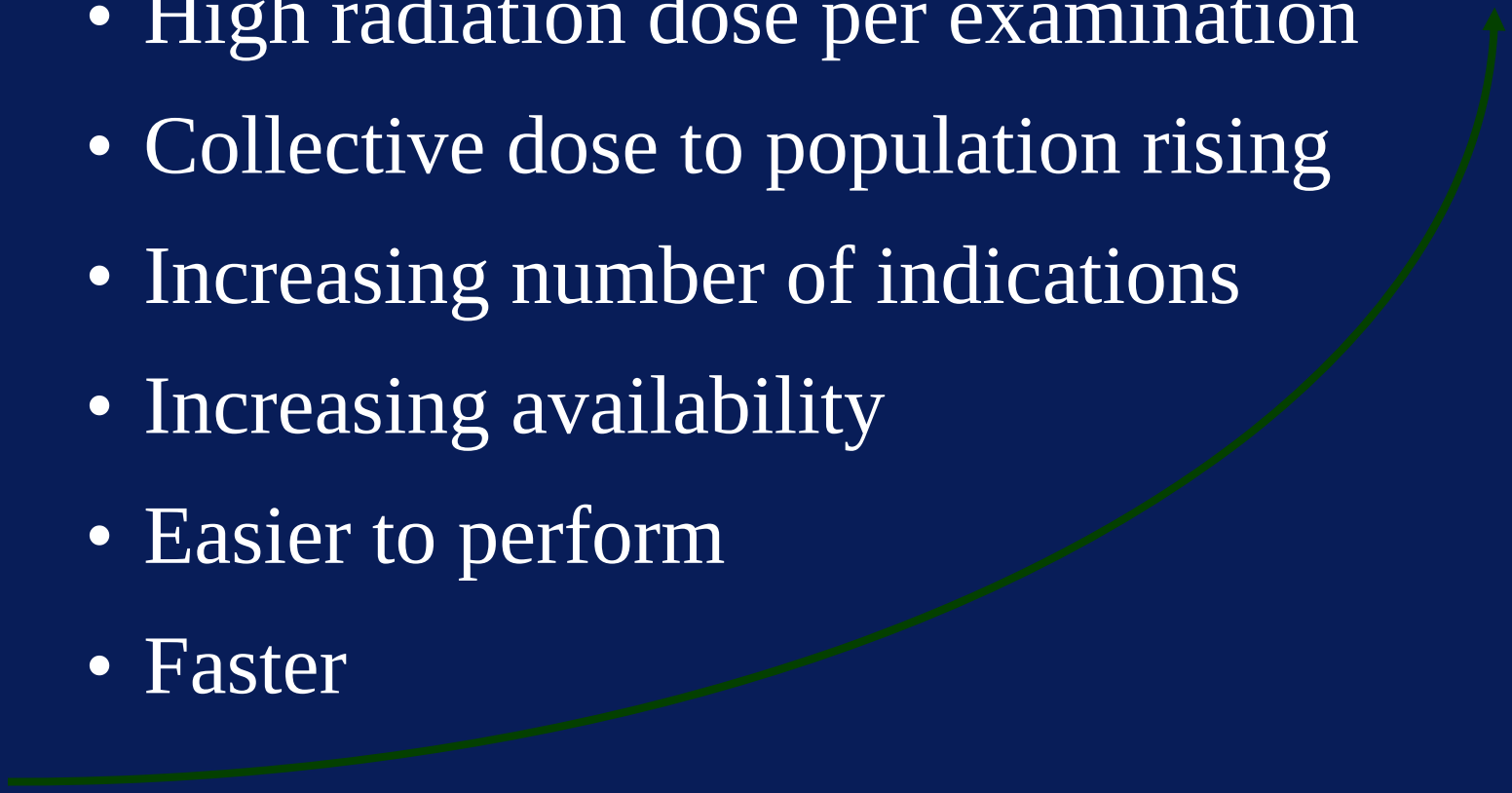


Correct exposure

Over exposure

Radiation Exposure from CT

- High radiation dose per examination
- Collective dose to population rising
- Increasing number of indications
- Increasing availability
- Easier to perform
- Faster



Appropriate Utilization

"I am an adult and a physician! You can't tell me when I should and shouldn't order a CT scan"

-- Anon (emergency physician)

Appropriate Utilization

"CT should be avoided when an ultrasound or MRI is of comparable diagnostic utility"

CT vs Ultrasound for Appendicitis

- 199 patients
- CT and ultrasound
- CT: 76% sensitivity
- Ultrasound: 79% sensitivity
- CT: 83% specificity
- Ultrasound: 78% specificity
- Both had accuracy of 78%

Poortman P et al. AJR 2004;231:393-398

Physician Education

- Adult CT patients for abdominal pain
- Questioned about consent, radiation risk and CXR equivalents
- Same questions asked of ED physicians

Lee CI, Haims AH, Monico EP, Brink JA, Forman HP.
Diagnostic CT scans: assessment of patient, physician, and radiologist awareness of radiation dose and possible risks.
Radiology 2004; 231: 393-398.

Physician Education

- 9% of physicians believed that there was an increased cancer risk from the CT request
- 44% of physicians believed that the CT had an equivalent dose to less than 10 CXRs

IRMER (2000)

- European Medical Exposures Directive
- Strict referral criteria
- Strict justification criteria
- Dose optimization requirement
- Dose exposure reference levels

Appropriate Utilization

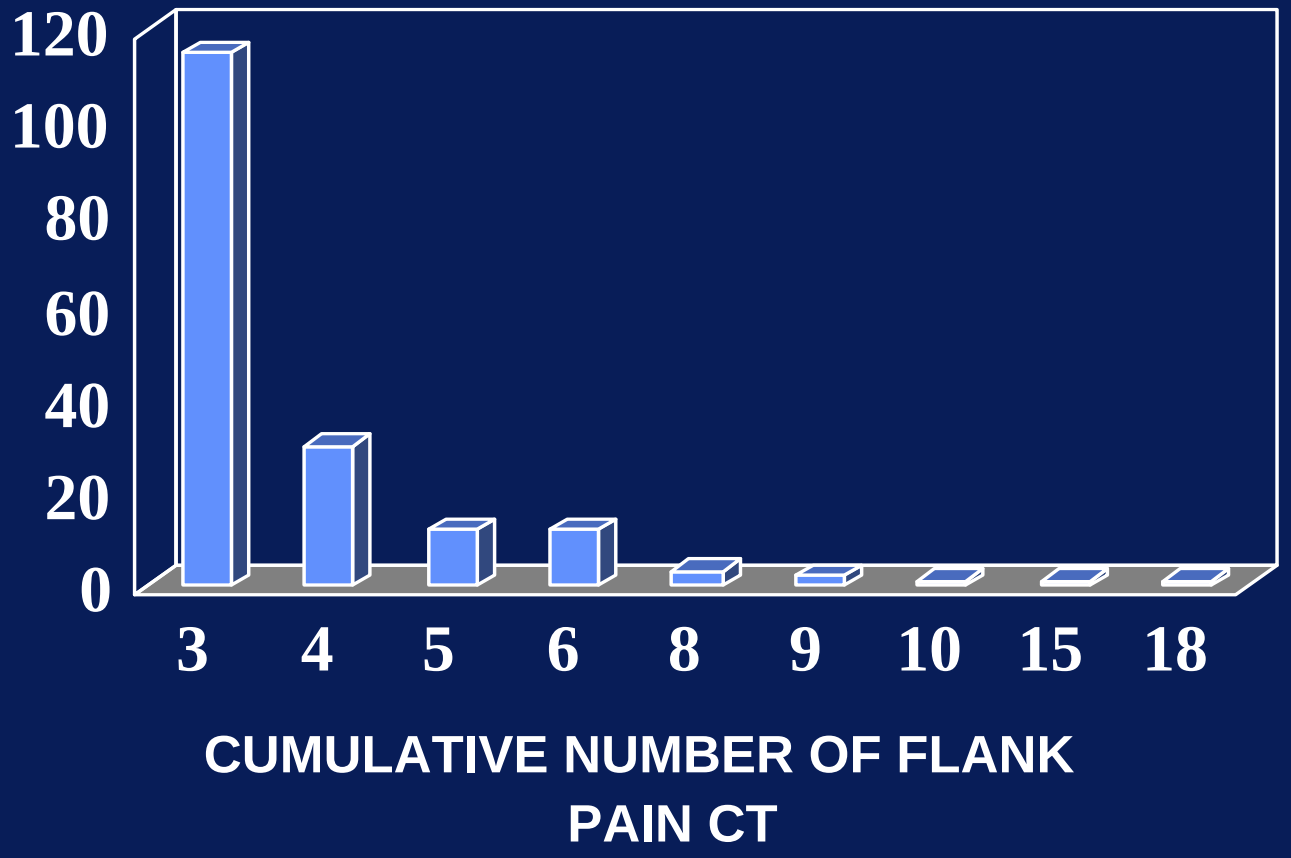
"CT should be avoided when prior diagnostic radiation exposure is excessive"

CT for Renal Colic

- 6 year period
- 5564 CT examinations for flank pain
- 3.9% had undergone ≥ 3 studies
- One patient had undergone 18 studies
- 18 studies = 154 mSv
- 1:133 cancer risk

Katz S, Saluja S, Brink JA, Forman HP. Radiation dose associated with unenhanced CT for suspected renal colic: impact of repetitive studies. AJR 2006;186:1120-1124.

176 Pts (3.9%) had 3 or more Flank Pain CTs



Average Flank Pain CT Dose

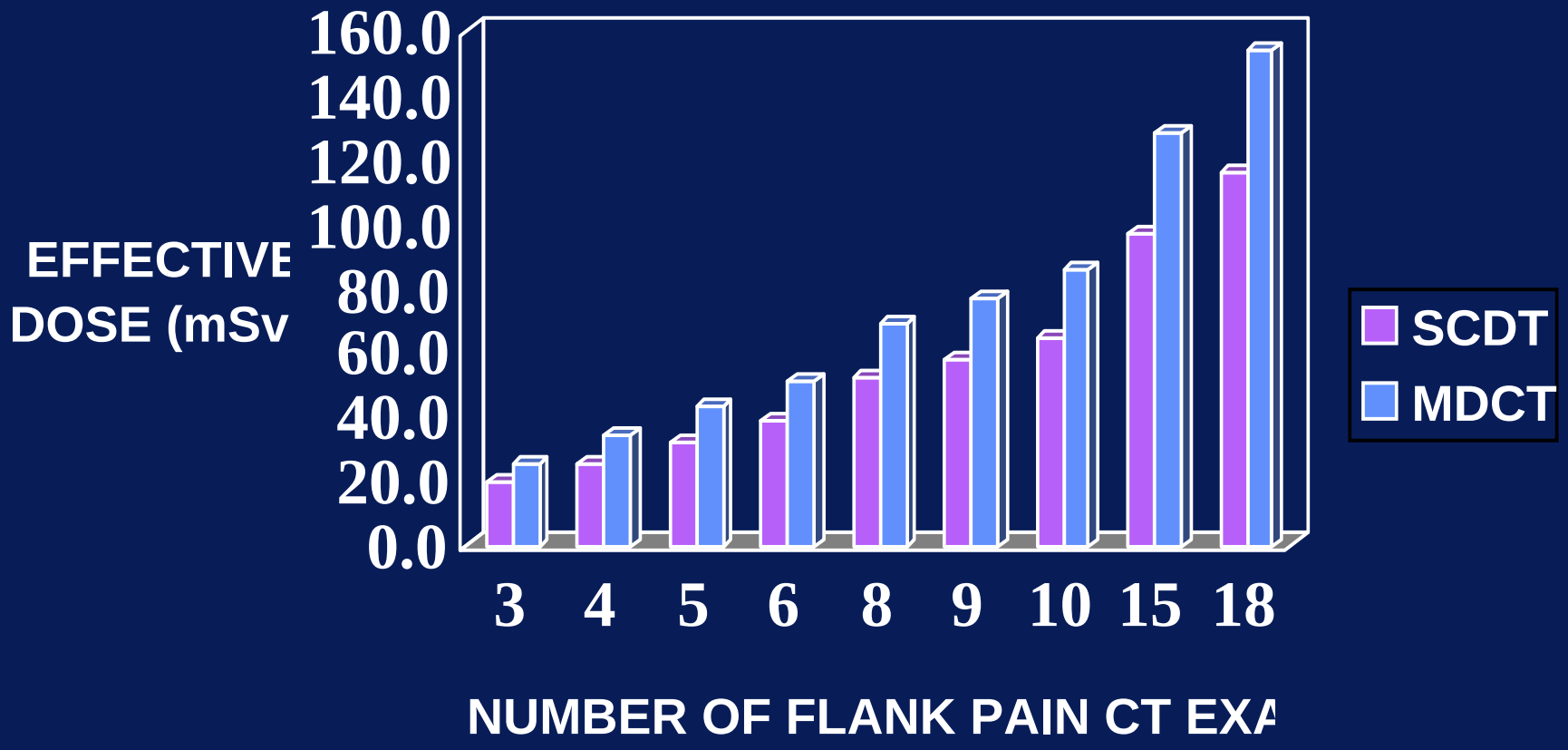
Mean Dose Length Product (DLP)

15 Randomly Selected Patients

SDCT = 460 mGy cm (6.5 mSv)

MDCT = 610 mGy cm (8.5 mSv)

Estimated Effective Dose



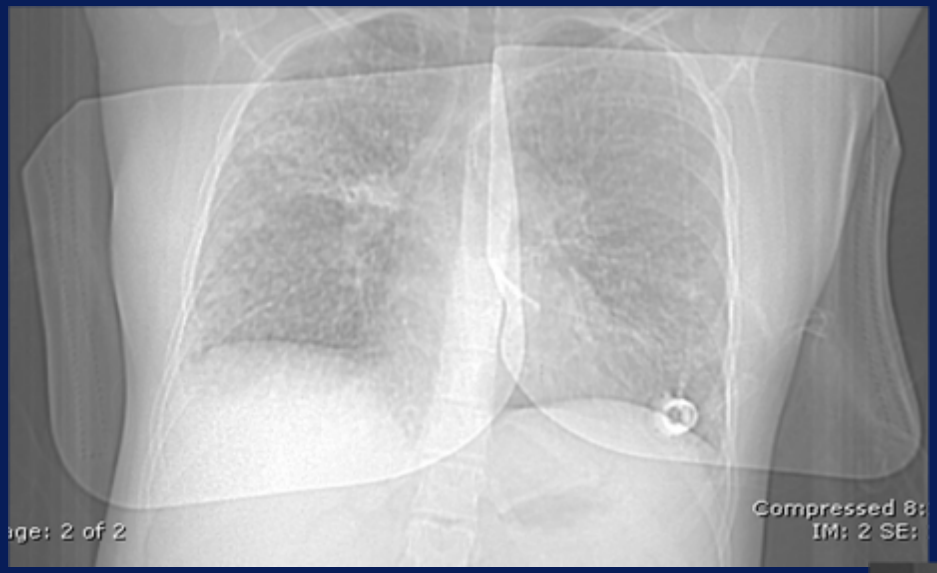
Appropriate Utilization

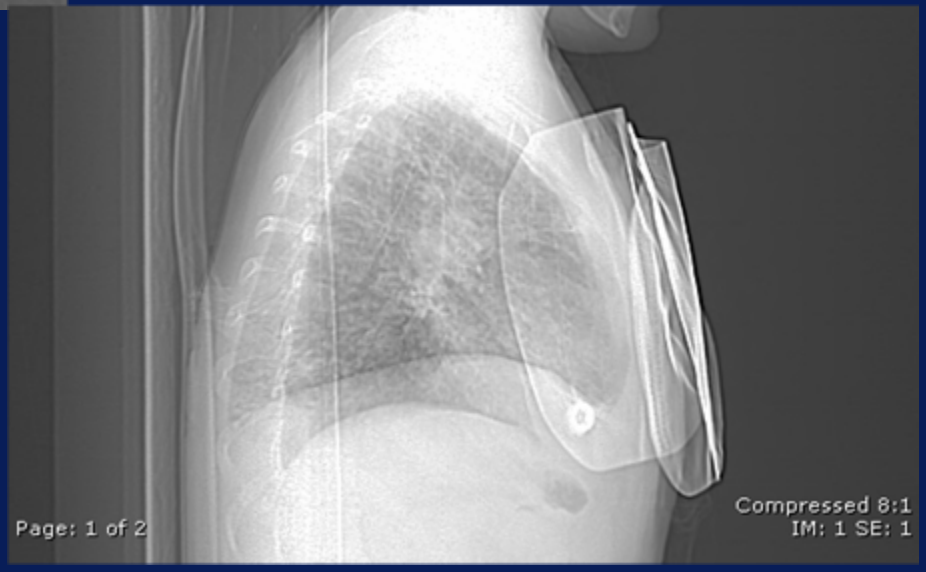
"CT technique should be tailored to the patient and his/her body habitus"

Patient Gender

- Breast Shields
  - Bismuth latex
  - Several sizes
  - Attenuates primary beam
  - Little effect on image quality

Breast Shields





Anthropomorphy

- Protocols based on:
  - –Pediatric weight
  - –Adult abdominal circumference

Image Quality, Weight and Abdominal Circumference

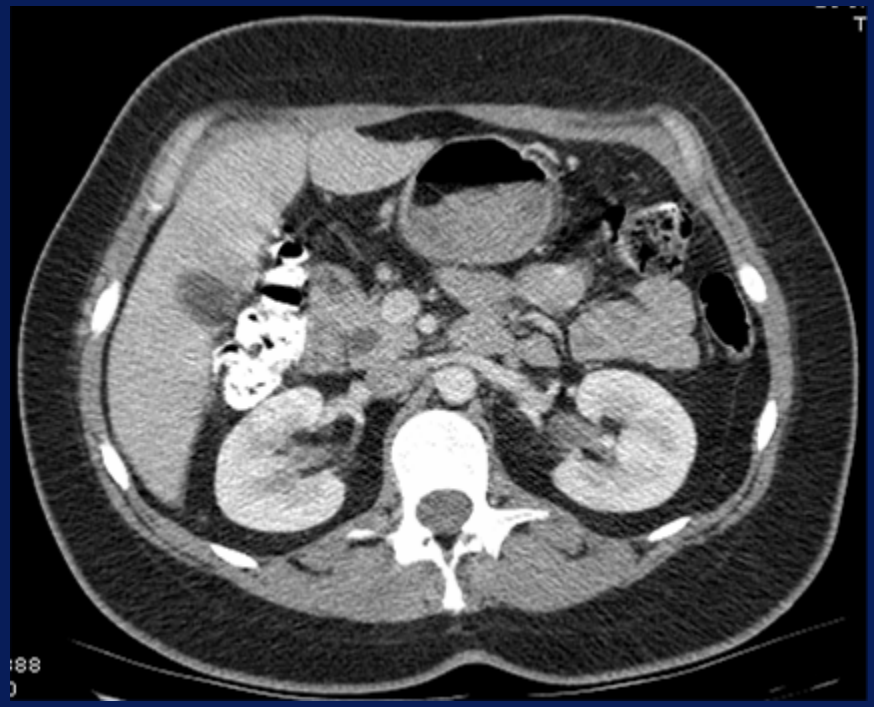
- Correlated image quality with:
  - –Weight
  - –Various abdominal dimensions

Kalra MK et al. Correlation of Patient Weight and Cross-Sectional Dimensions With Subjective Image Quality at Standard Dose Abdominal CT. Korean J Radiol 2003;4:234-238

Statistical Correlation Between Dimensions and Poor Image Quality Score

Parameter	p-value
Weight	0.003
Wall thickness	0.002
AP diameter	0.002
Transverse diameter	0.0001
Circumference	0.0002
Cross sectional area	0.0004

Comparison of weight based and AEC



Weight Based: 160 mA

Exam Description: CT SCAN ABD/PELVIS WIT

HFS

Dose Report

Series	Type	Scan Range (mm)	CTDIvol (mGy)	DLP (mGy-cm)	Phantom cm
1	Scout	-	-	-	-
2	Helical	S44.250-I450.750	8.14	421.84	Body 32
			Total Exam DLP:	421.84	

Appropriate Utilization

"CT technique should be monitored to insure that dose is as low as reasonable achievable"

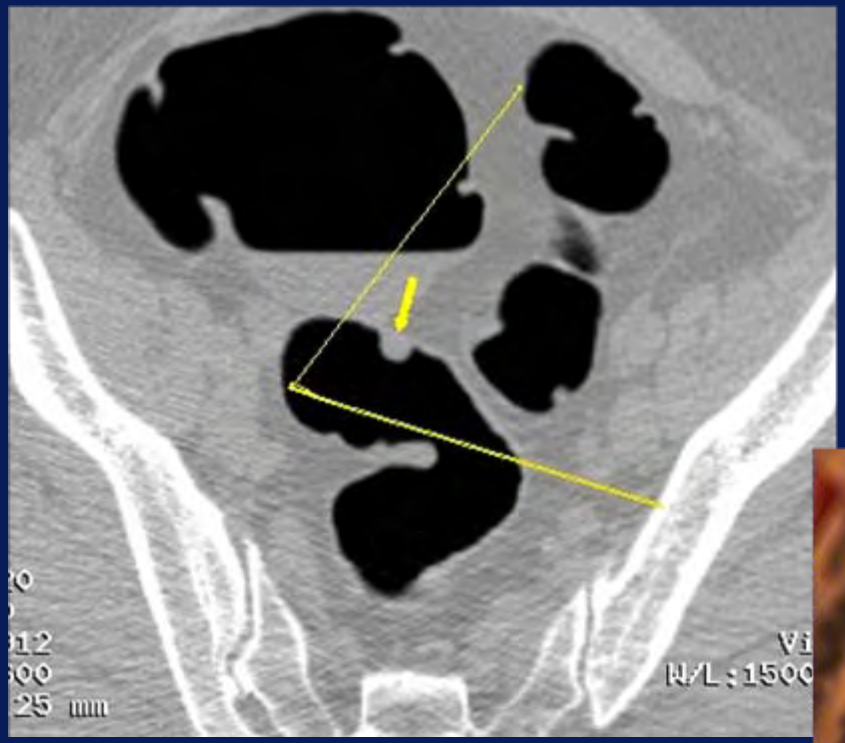
Radiation Dose Reduction

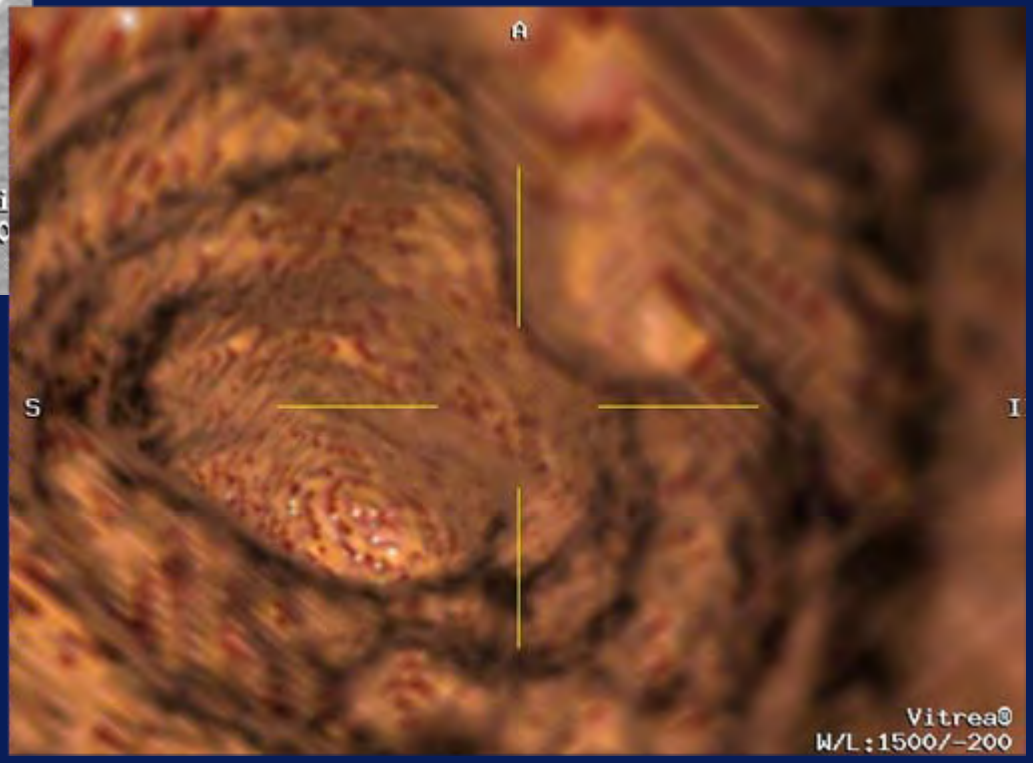
NYU: Siemens MDCT

- 4 x 1, pitch of 6 to 7
- 50 “effective” mAs
- Effective dose = 5 to 7 mSv
- Barium enema = 6 to 8 mSv

Macari et al. Radiology 2002; 224:383-392

9 mm Polyp: Sigmoid Colon

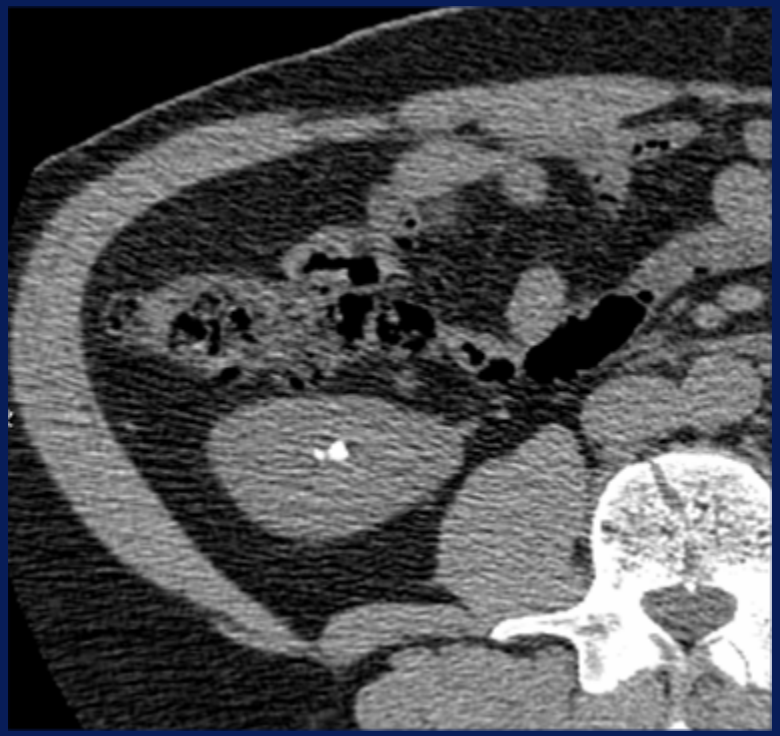




Thick from Thin

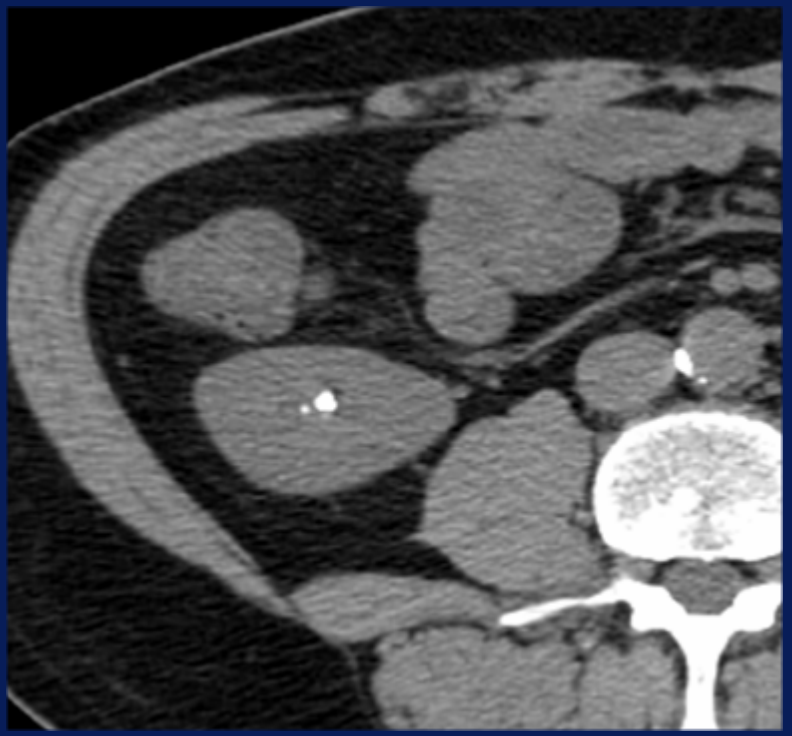
- For low contrast imaging (detection of liver lesions):
  - Improve noise characteristics with thick sections
    - » Retrospective reconstruction of thick sections from thin slice acquisition
    - » Sliding thick slab on image review station (needed!)

16 slice



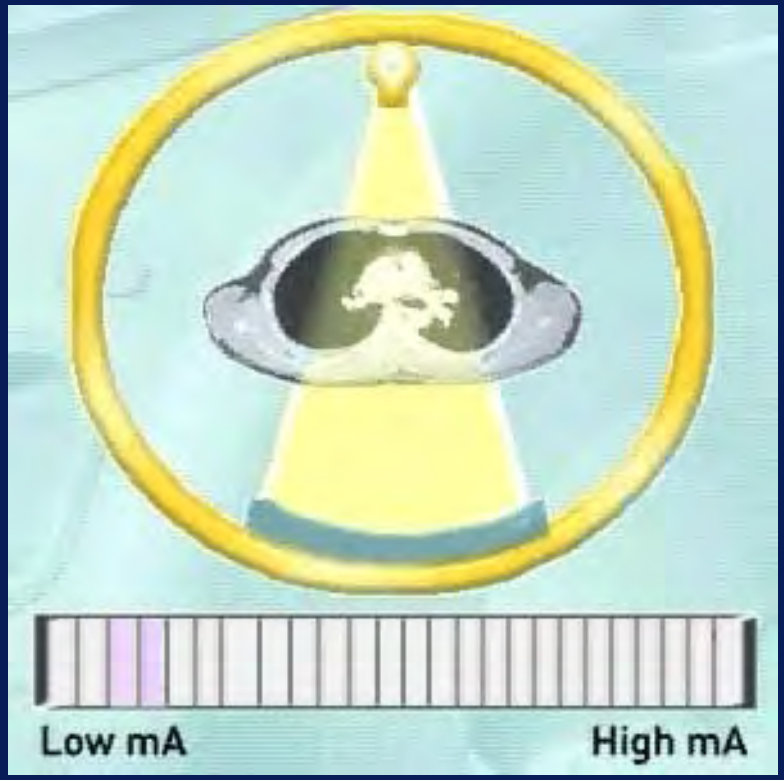
16x1.25, 2.5/2.5, 120kV
530msec, 439 mA, pitch = 1.375
effective mAs = 169.2 eff mAs

64 slice



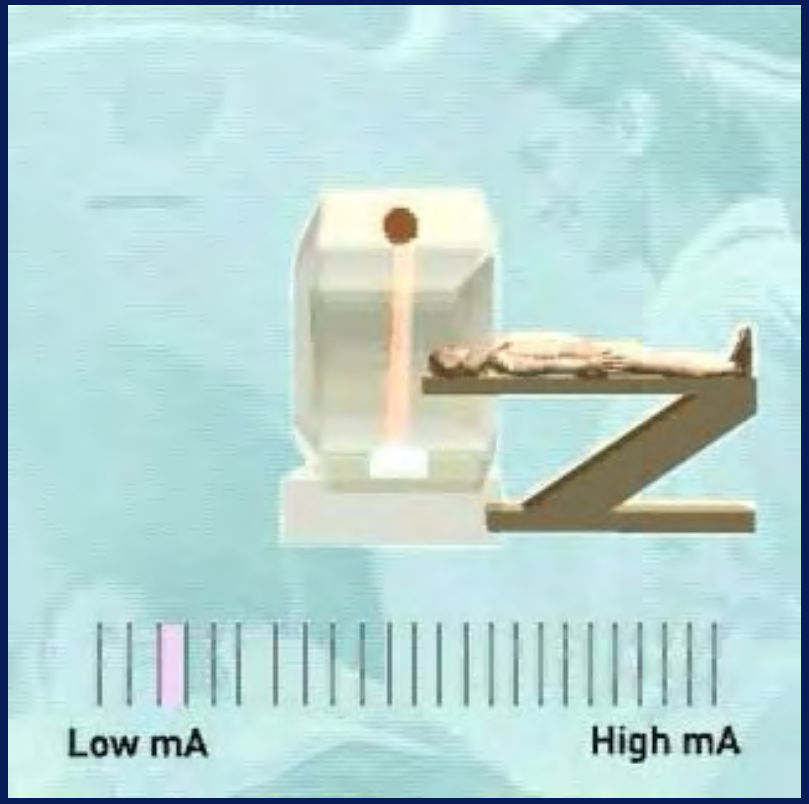
64x0.625, 2.5/2.5, 120kV
500msec, 637 mA, pitch = 0.984
effective mAs = 323.7 eff mAs

Tube Current Modulation: In Plane



Tube Current Modulation: Through Plane

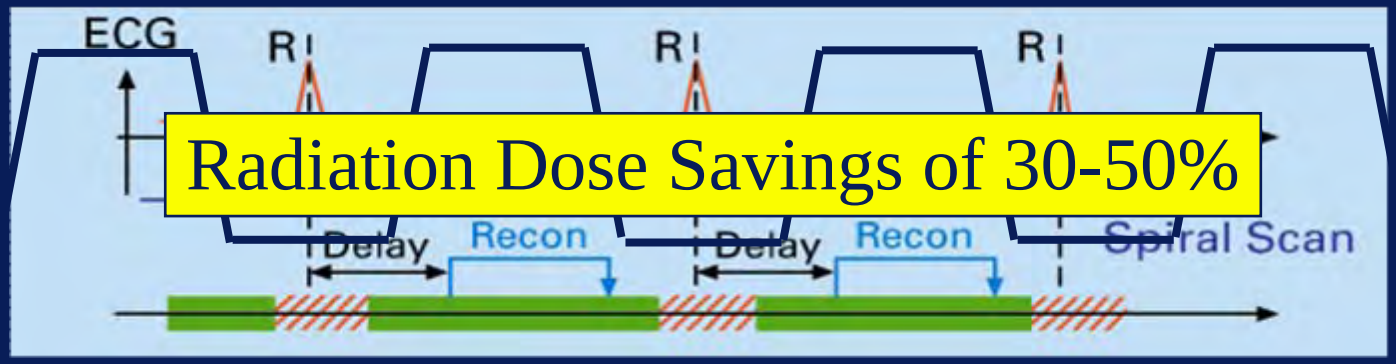
Tube Current Modulation: Combined

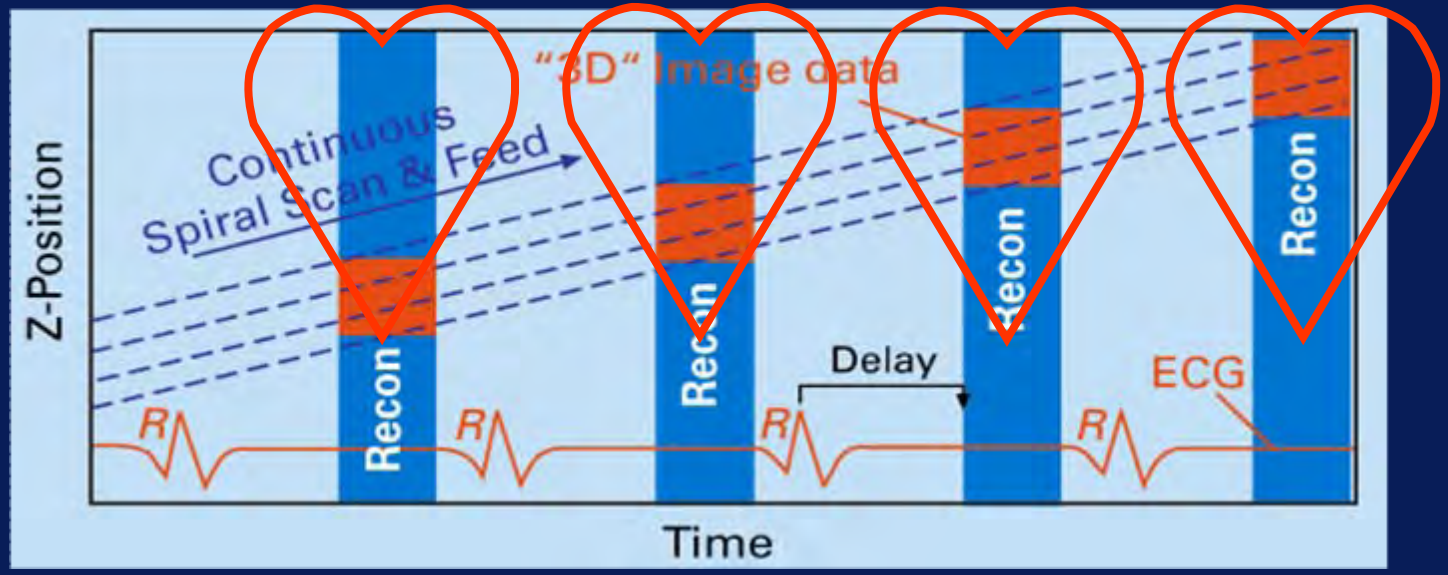


AEC:
Automatic
Exposure
Control

Radiation Dose Savings of up to 50%

ECG gating (Retrospective) + Tube Current Modulation



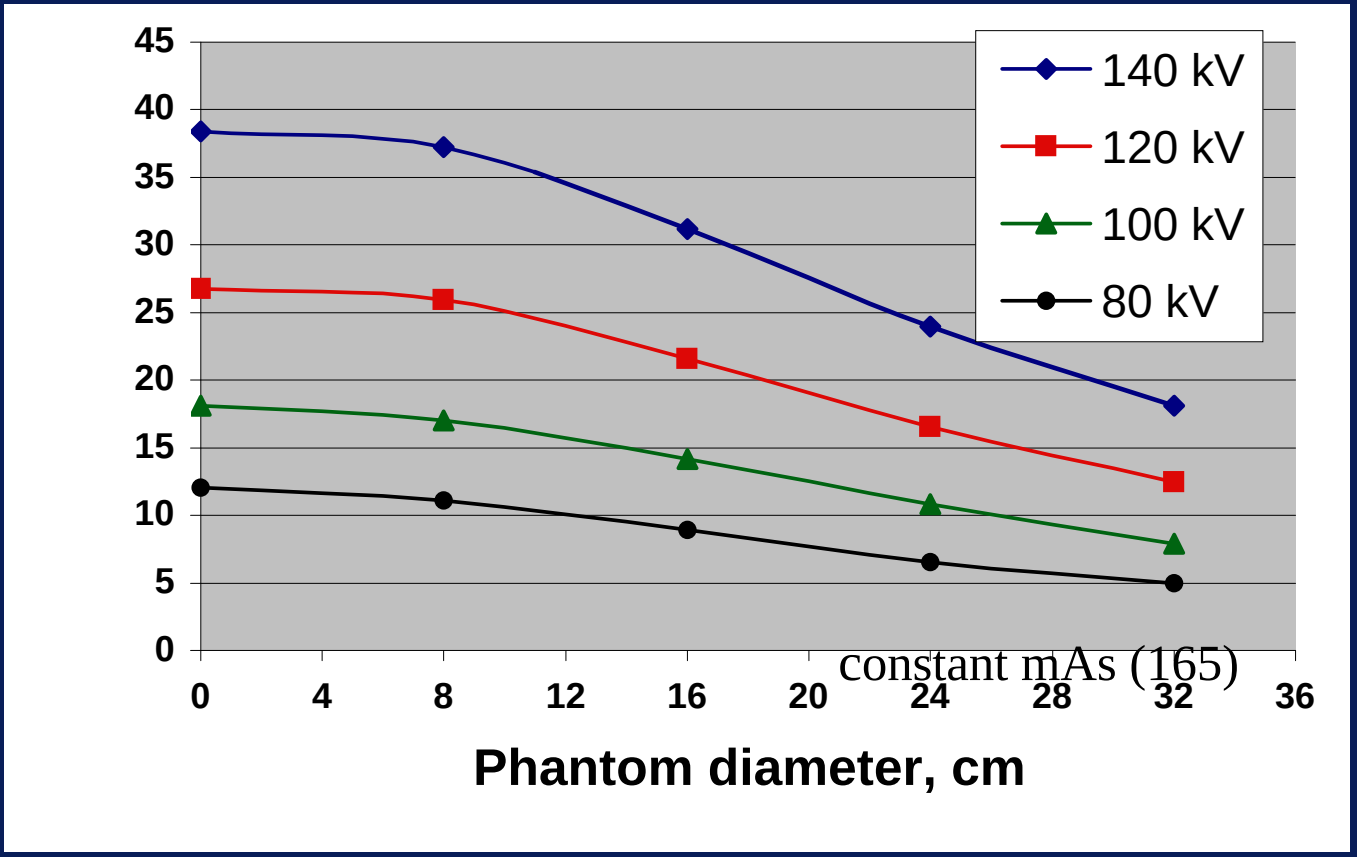


Low kVp -- Rationale

- K-edge of Iodine 32 keV
- Mean photon energy
  - 80 kVp 44 keV
  - 100 kVp 52 keV
  - 120 kVp 57 keV
  - 140 kVp 62 keV

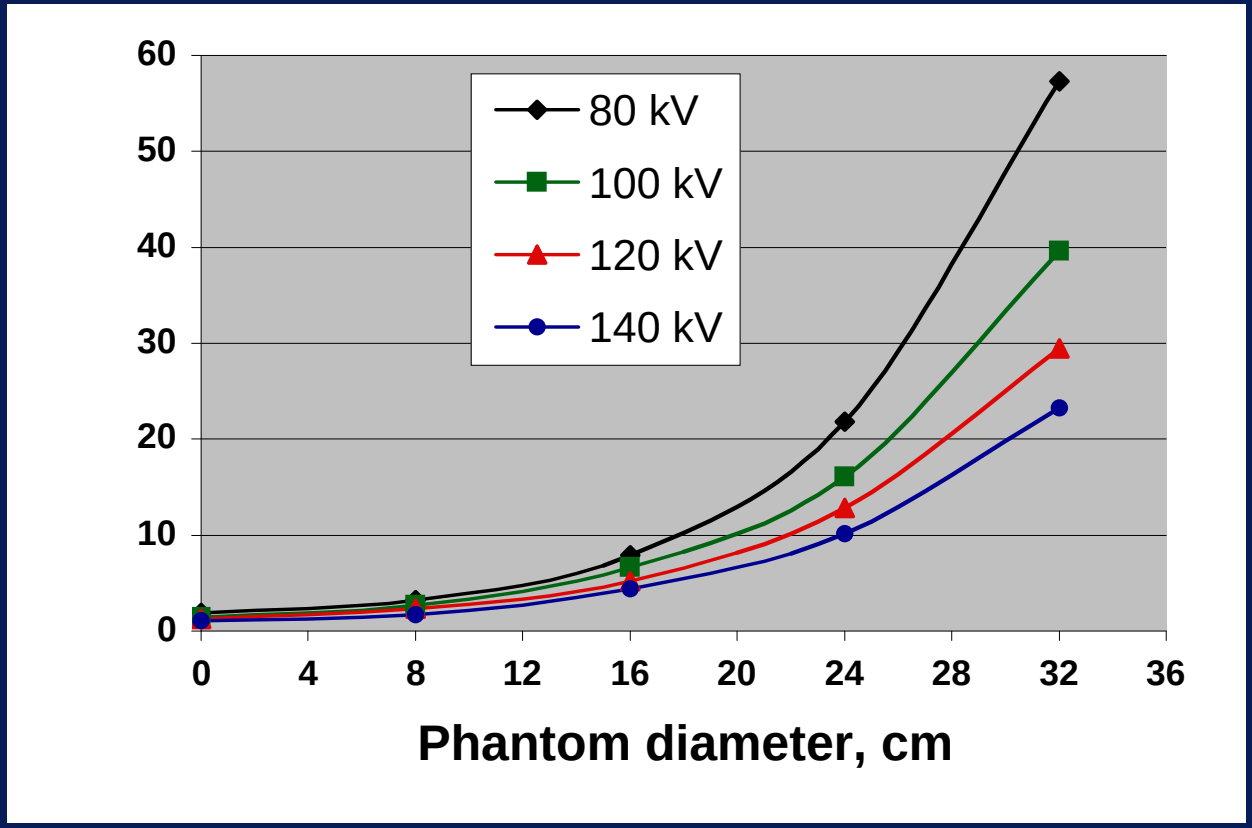
Huda W, et al. Radiology 2000; 217:430

Effect of kV on Dose



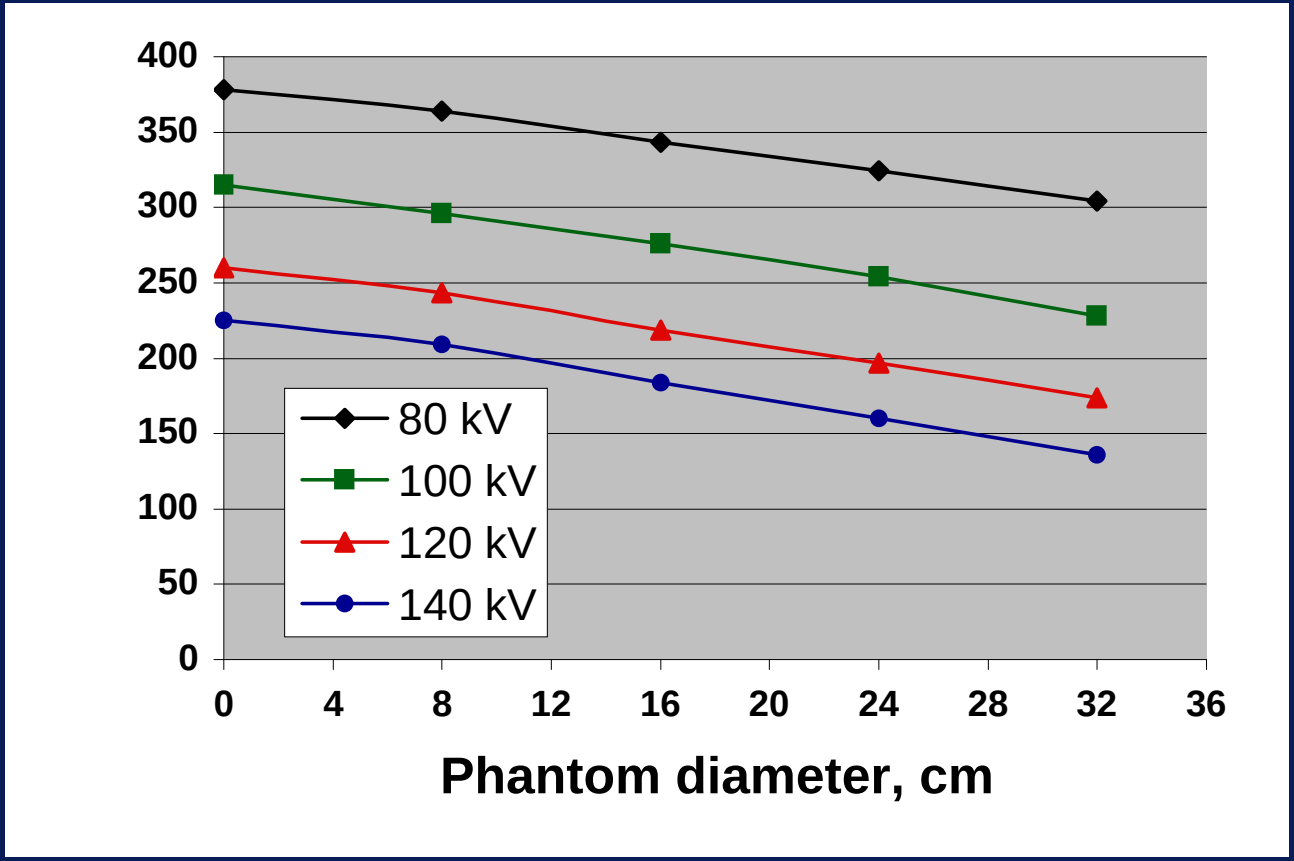
Courtesy of Marilyn Siegel, MD

Effective of kV on Image Noise



Courtesy of Marilyn Siegel, MD

Effect of kV on Iodine Contrast



Courtesy of Marilyn Siegel, MD

Low kV

- Chest CT: Improved detection of PE
  - –100 vs. 140 kVp
  - –Reduced radiation dose by 3x
    - »140 kVp -- 10.4 mGy
    - »100 kVp -- 3.4 mGy

Schueller-Weidekamm, et al. Radiology 2006;241:899

Low kV

- Abdominal CT: Phantom Study
  - –90 vs. 120 kVp
  - –Reduced radiation dose by 35%
    - »No loss of low contrast detectability
    - »Best for patients < 80 kg

Funama Y, et al. Radiology 2005;237:905

Low kV

- CT Angio: Phantom/Human Study
  - –80, 100, 120, 140 kVp
    - »91-94% increase in signal w/ 80 kVp
    - »Reduced radiation dose by 25-50%
    - »Equivalent 3-D renderings

Kalva, et al. JCAT 2005; 30:391-397

Dose Monitoring

Gated; No Tube Current Modulation

Exam Description: CT CHEST/ABD DISSECTIO

HFS

Dose Report

Series	Type	Scan Range (mm)	CTDIvol (mGy)	DLP (mGy-cm)	Phantom cm
1	Scout	-	-	-	-
2	Helical	S3.250-I271.750	17.42	591.82	Body 32
202	Axial	I100.000-I100.000	10.41	5.22	Body 32
3	Cardiac Helical	I2.000-I218.250	68.21	1713.89	Body 32
3	Cardiac Helical	I219.000-I399.000	50.58	1087.53	Body 32
			Total Exam DLP:	3398.46	

Effective Dose = DLP x 0.016 mSv/mGy-cm
= 54.4 mSv

Effective Dose

Estimate effective dose from DLP

Region	mSv / (mGy cm)
Head	0.0023
Chest	.017
Abdomen	.015
Pelvis	.019

Jessen KA. Applied Radiation and Isotopes, 1999; 165-172
(This method is used in the ACR CT Accreditation Program)

‘Broselow/Hinkle’ Pediatric Emergency System (Color-coded)

ACR CT Accreditation

- Dose data required for:
  - Adult Head
  - Adult Abdomen
  - Pedi (5yr old) Abdomen
- Dose metrics to be measured
  - CTDIw
  - DLP
  - Effective Dose

ACR CT Accreditation

- Dose metrics to be judged
  - CTDIw
  - DLP
  - Effective Dose
- Recommended CTDIw limit

	Initial	Revised
– Adult Head	60 mGy	75 mGy
– Adult Abdomen	35 mGy	25 mGy
– Pedi Abdomen	25 mGy	20 mGy

European Guidelines

Exam	CTDIw	DLP	Eff. Dose
Head	60	1050	2.4
Chest	30	650	11.1
Abd	35	800	12.0
Pelvis	35	600	11.4
Chest/Abd/Pel		2050	34.5

From Commissione Europea EUR 16260, EUR 16261, EUR 16262 ed EUR 16263

Estimate of Medical Radiation Exposure in the U.S. 2006

Preliminary Results of NCRP SC-6-2 Medical Subgroup

Annual Meeting of the NCRP

April 17-18, 2007

Crystal City, MD

Fred A. Mettler Jr., M.D., M.P.H

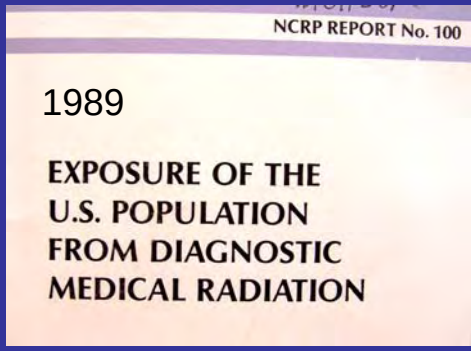
Medical Subgroup SC 6-2

- B. Thomadsen, Chairman, Univ of Wisc.
- M. Bhargavan, American College of Radiology
- D. Gilley, State of Florida
- J. Gray DIQUAD, LLC
- J. Lipoti, State of New Jersey
- M. Mahesh, Johns Hopkins Univ.
- J. McCrohan, U.S. F.D.A.
- F. Mettler, Univ of New Mexico VA
- T. Yoshizumi Duke Univ.

- M. Rosenstein Scientific NCRP Consultant
- K. Kase Stanford SC 6-2 Chair

Purpose

- Last major medical data 1980 (25 years ago)



- Estimate current
  - Number and types of procedures
  - Dose per procedure and collective dose
  - Examine past and future trends

- Modalities
  - Radiography, CT, Interventional, dental
  - Nuclear Medicine
  - Radiotherapy
- For use by
  - Individuals, manufacturers, practitioners and regulators

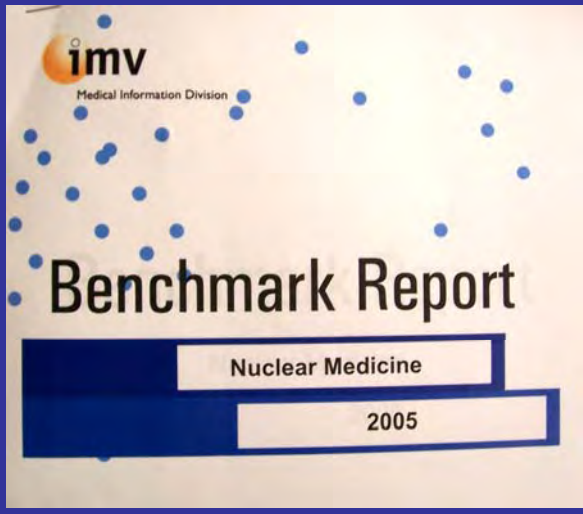
Assumptions

- Benefit exceeds risk: Issue not examined in this report
- Data sources: No one complete data set. Incomplete data sets required assumptions and cross checking between data sets
- RBE = 1
- Weighting Factors: Used ICRP 60 (1990). Past reports used older ICRP 26 (1977) and new factors are suggested

Major and minor data sources

- Commercial (IMV Benchmark)
- Medicare payment data (2003-2005)

- VA Health Care System
- Claims data from large national employer plan
- US FDA
- CRCPD
- State radiation programs
- Large hospitals
- American College of Radiology
- Industry sources
- Literature



Based on responses from 4,365 hospital and non-hospital sites out of an identified universe of 7,207 hospital and non-hospital sites

Preliminary Results (2006)

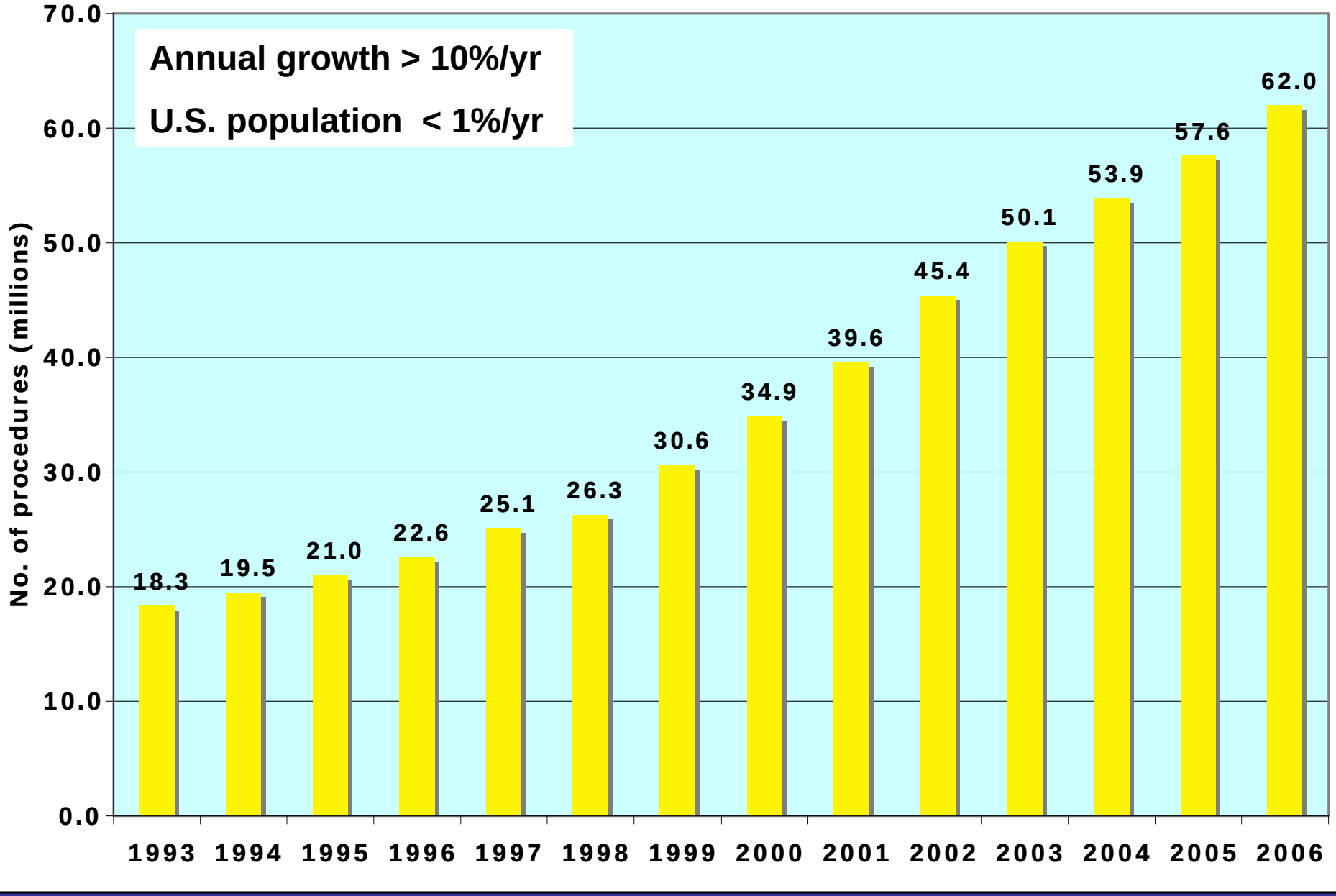
	Number procedures	Collective effective dose person Sv	Per caput (mSv)	% of dose
Radiography	250 million	175,000	0.6	19
Interventional	10 million (incl 4 cardiac)	90,000	0.3	9
CT	67 million	440,000	1.5	49
Mammography	38 million	2,200	_	<1
Dental	125 million	NA	_	<1
Nuclear Medicine	19 million	220,000	0.7	23
TOTAL	~ 500 million	~930,000	3.1	100
Radiotherapy	1 million patients			

Preliminary Results for CT

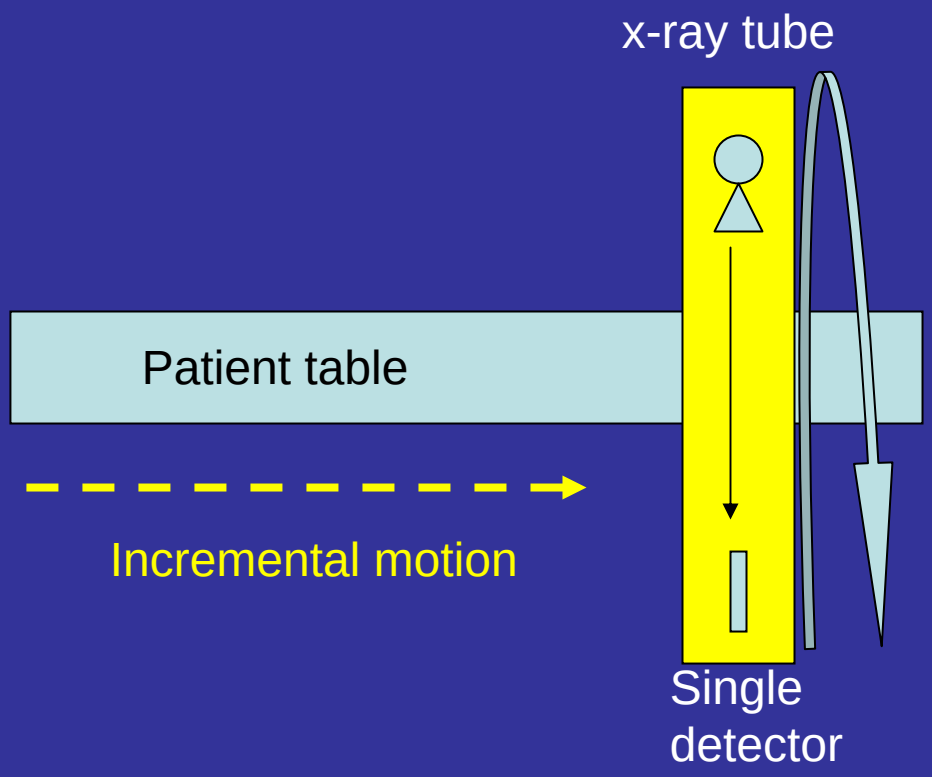
	Number (millions)	%	Collective dose person Sv	%
Head	19	28	38,000	8.7
Chest	11	16	74,000	17.0
Abd/Pelvis	25	25	254,000	58
Extremity	3	5	500	0.1
CT Angiogram	4	6	56,000	12.8
Miscellaneous	4	6	15,000	2.4
TOTAL	**67**	**100**	**440,000**	**100**

75%

CT procedures by year (millions)



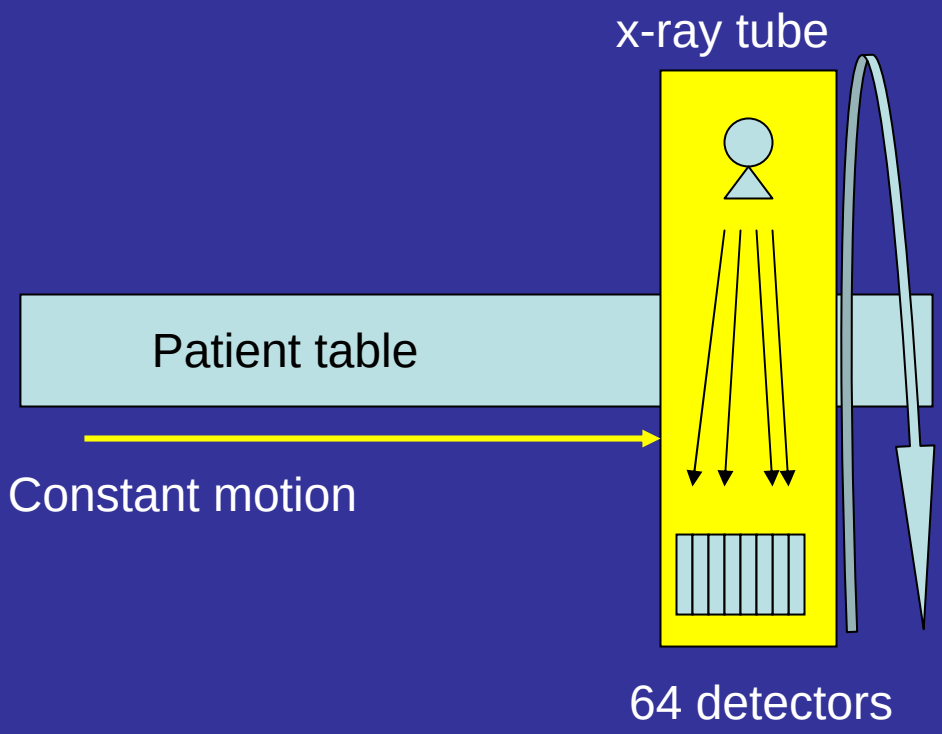
Single slice CT scanner



Tube rotates, image is obtained, then table moved incrementally and another tube rotation and another image obtained.

Scan time ~ 10-20 minutes

Multislice multidetector helical CT scanner



Constant tube rotation, constant table feed. More detectors.

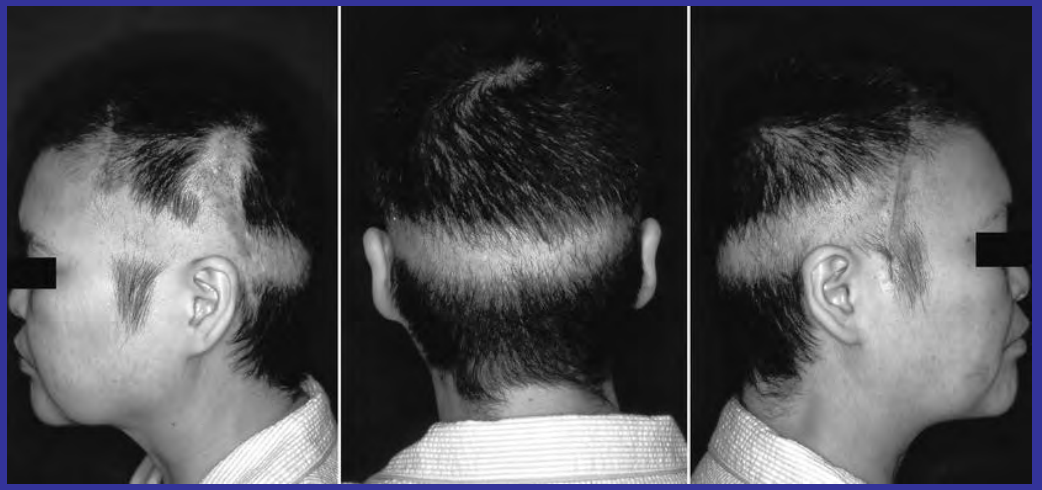
64 slices/images in 0.3 second

CT scanning delivers **high** radiation doses (stochastic risks)

- **“The absorbed doses to tissues from computed tomography (10-100 mGy) can often approach or exceed the levels known to increase the probability of cancer ”**
  - **International Commission on Radiological Protection (ICRP) Publication 87 (2000)**

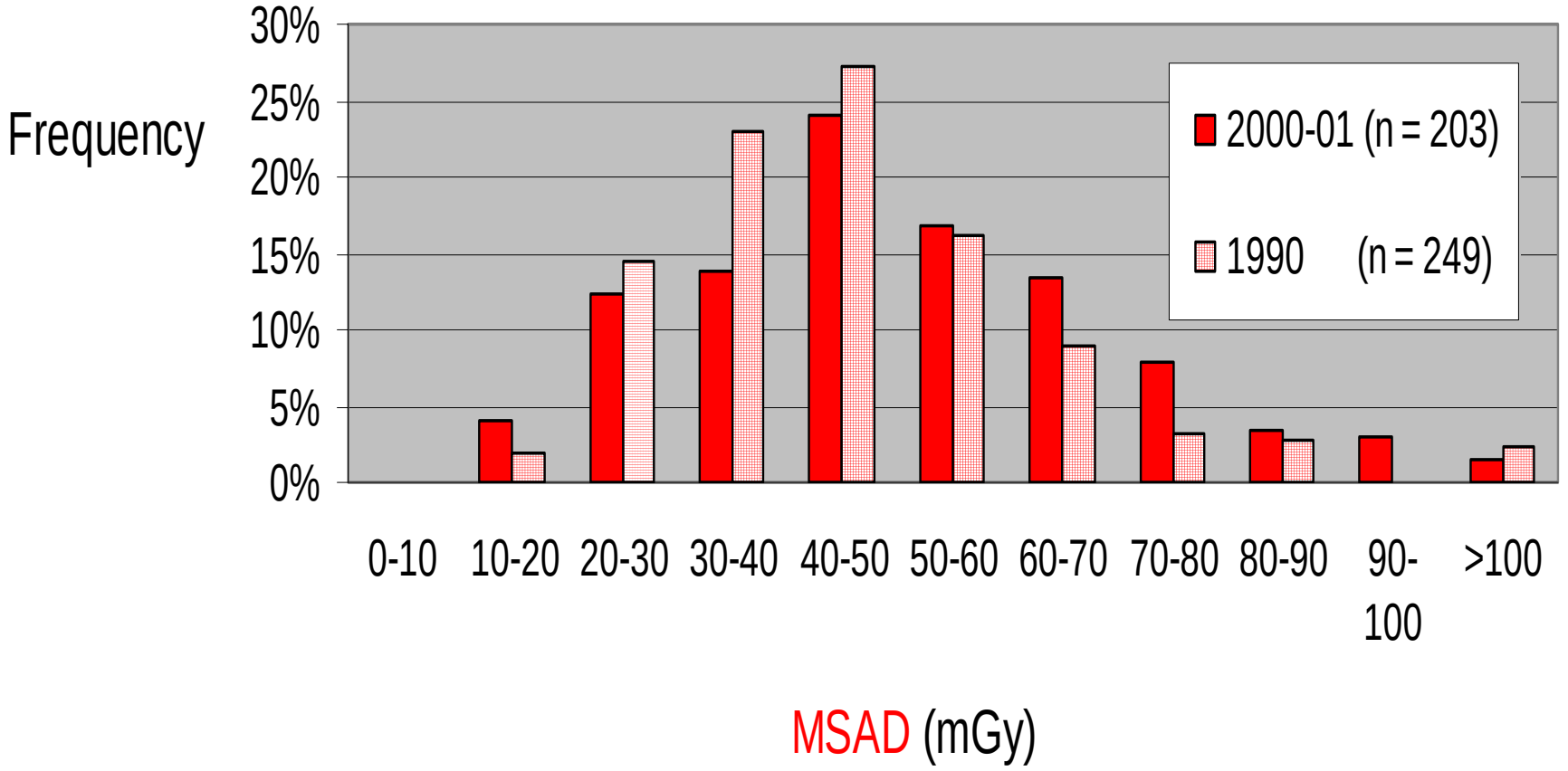
MDCT scanning in conjunction with DSA can cause deterministic effects

- **Imanishi *et al*. (2005)* reported three patients with temporary hair loss.**
  - **These patients had a combination of two DSA exams of the head and two or more MDCT perfusion studies with a tube current of 200 mA.**



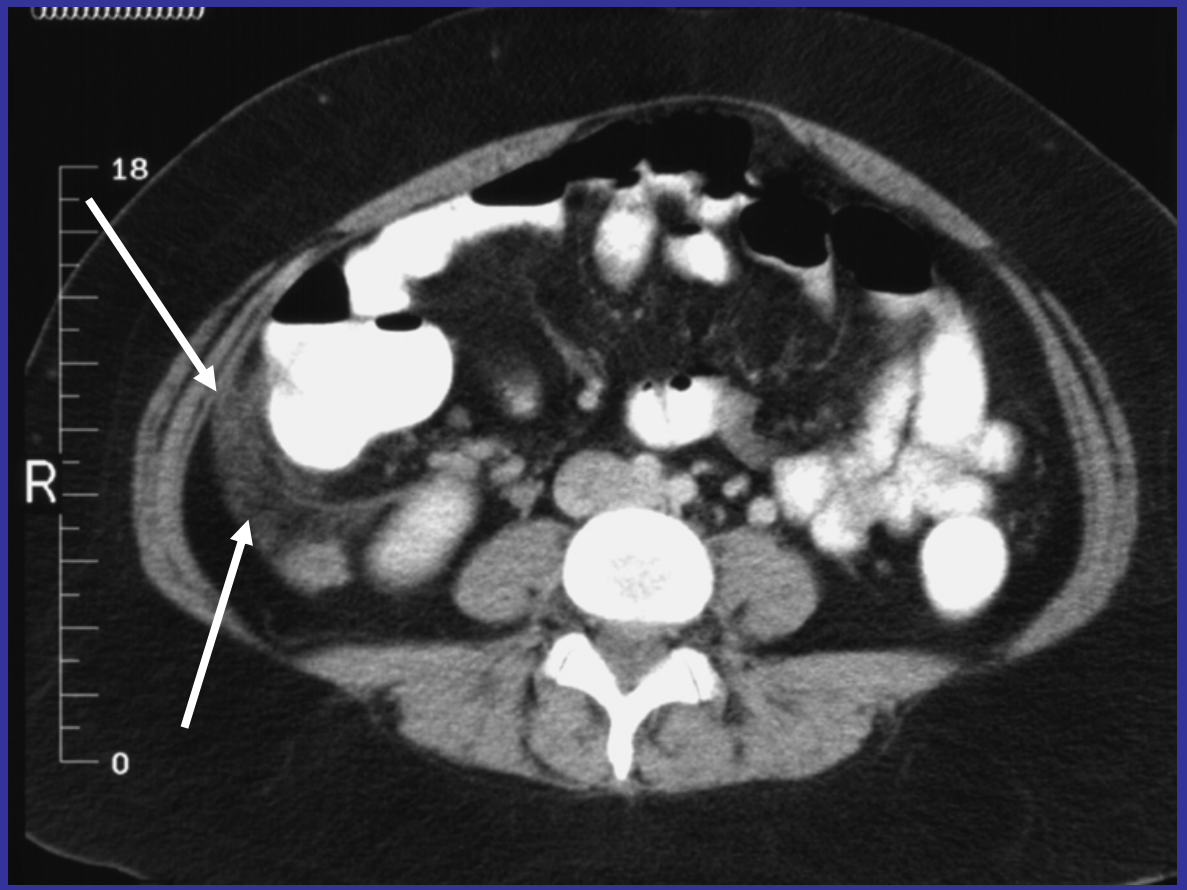
*Eur Radiol 15:41-46.

10-fold variation in CT scan doses



S. Stern, USFDA

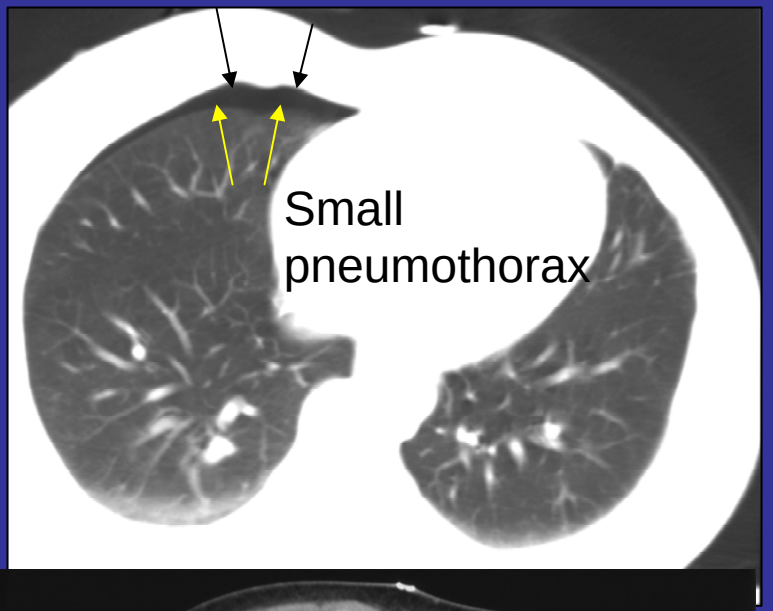
Appendicitis: edema around cecum



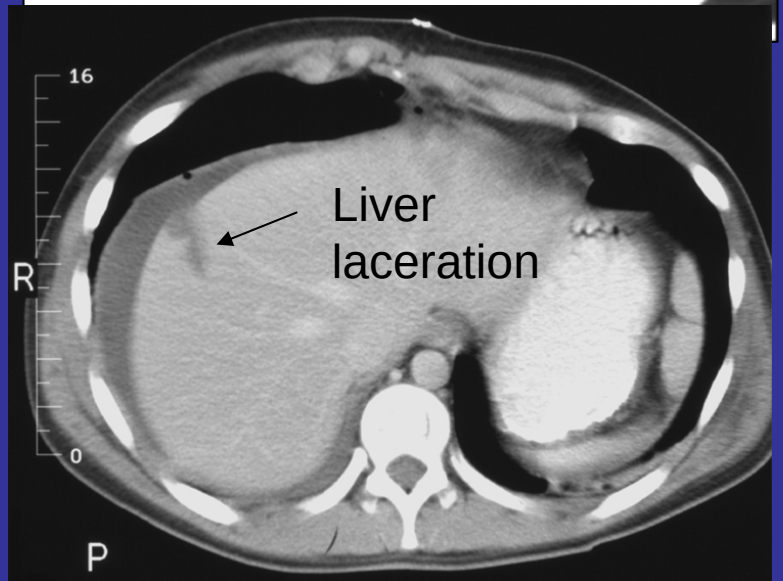
CT now used almost exclusively for diagnosis of appendicitis

Trauma

With new multi-slice CT scanners, head, neck, chest abdomen and pelvis can be scanned in 10-30 seconds

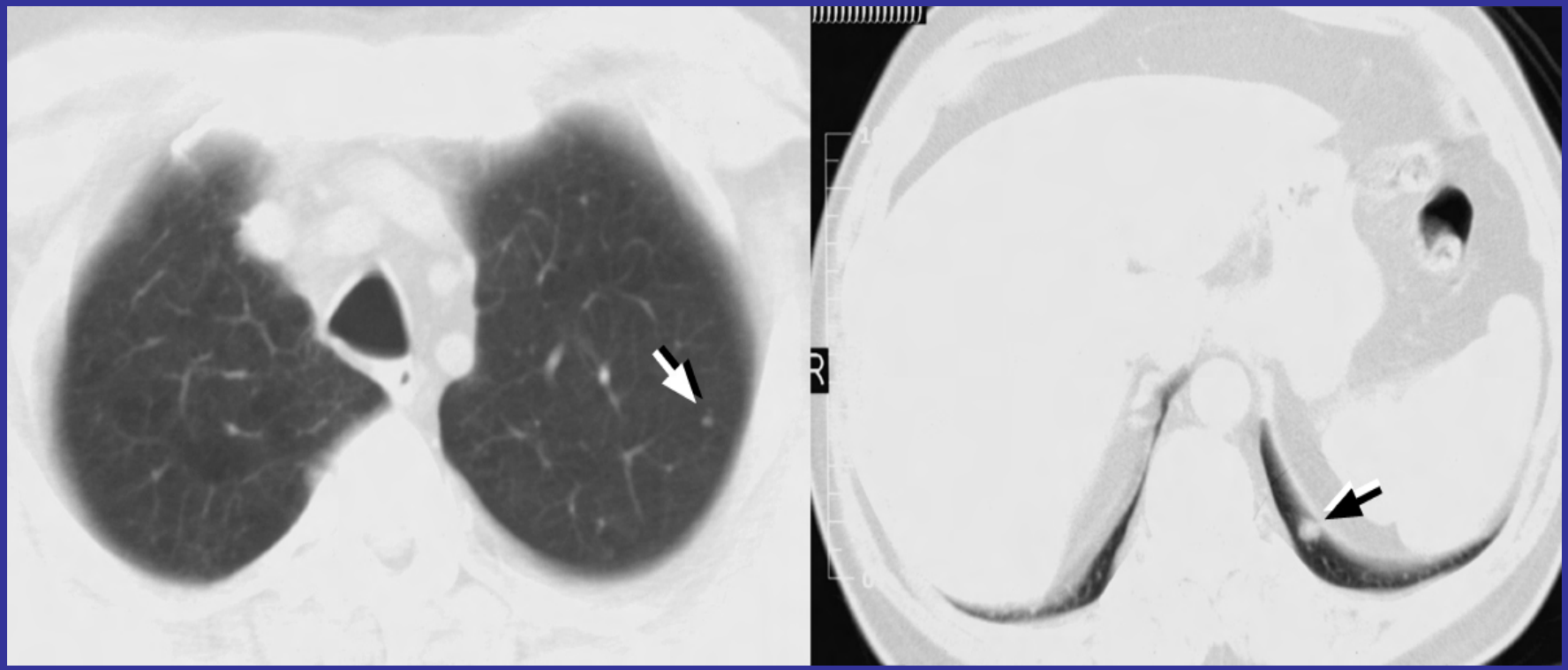


Many significant findings are seen which are difficult or impossible to see on plain x-rays

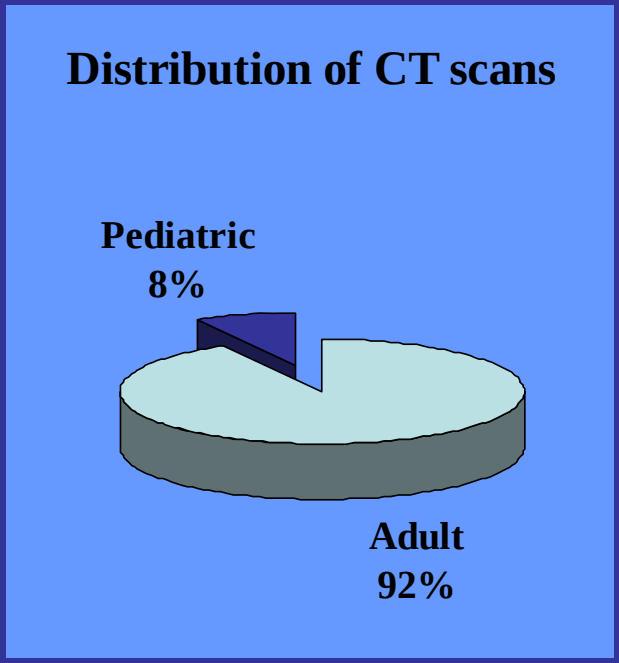


Fantastic but …..

CT screening for lung cancer and follow-up of lung nodules



Nodules as small as 2-3 mm are easily and commonly seen on CT but are too small to biopsy with a needle.

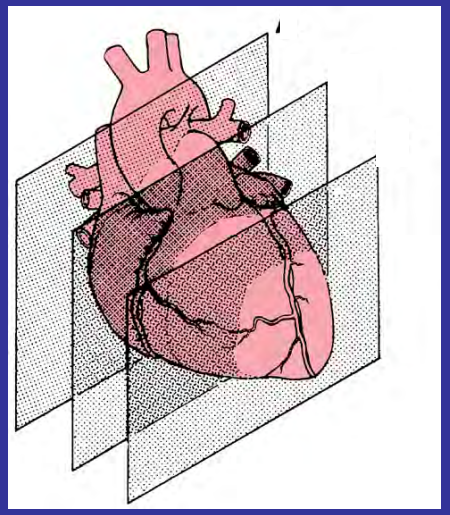


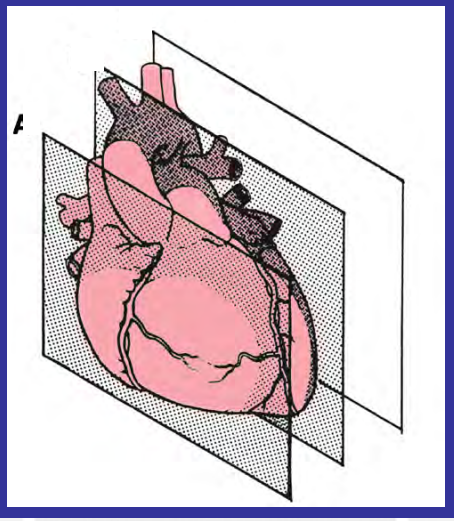
Children are likely to be at 2-5x higher cancer risk from radiation than are adults. Adult CT imaging parameters are often used inappropriately on children

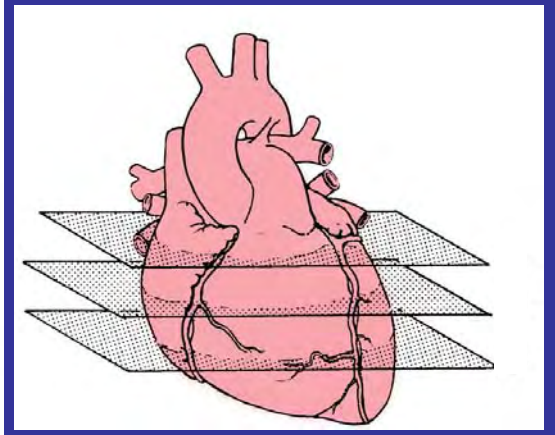
Preliminary Results for Nuclear Medicine (2005)

	Number millions	%	Collective dose Person Sv	%
Brain	<0.1	<2	250	0.1
Thyroid	< 0.1	<2	400	0.2
Lung	0.74	4	2000	0.9
Cardiac	9.80	57	188,000	85.2
GI	1.21	7	3500	1.6
Renal	0.47	3	650	0.3
Bone	3.45	20	20500	9.3
Infection	0.38	2	1300	0.6
Tumor	0.34	2	4000	1.8
Total	19	100	220000	100

Cardiac nuclear medicine

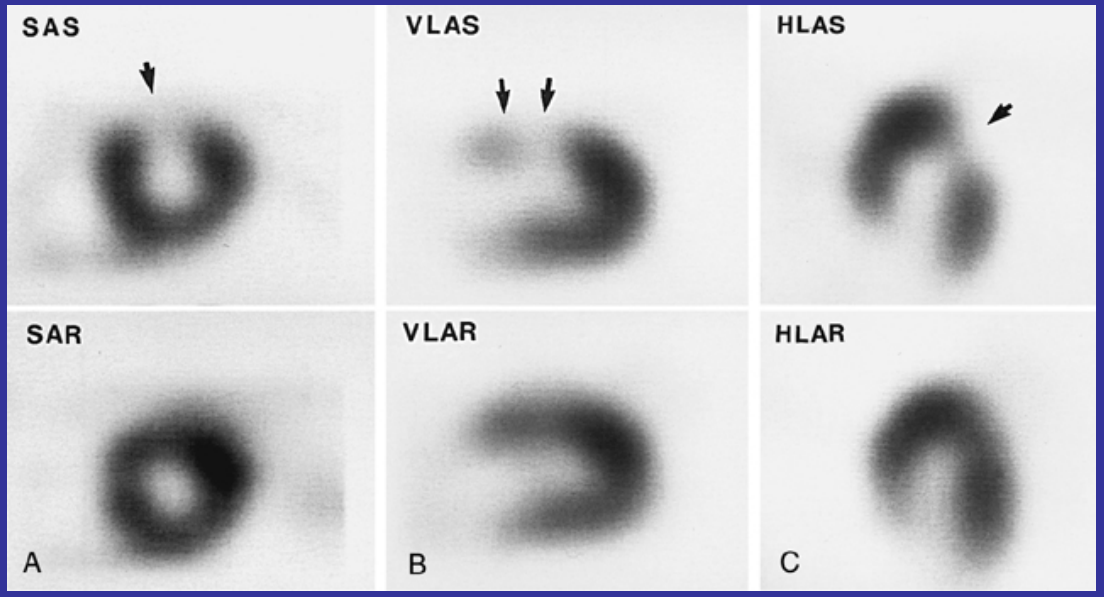






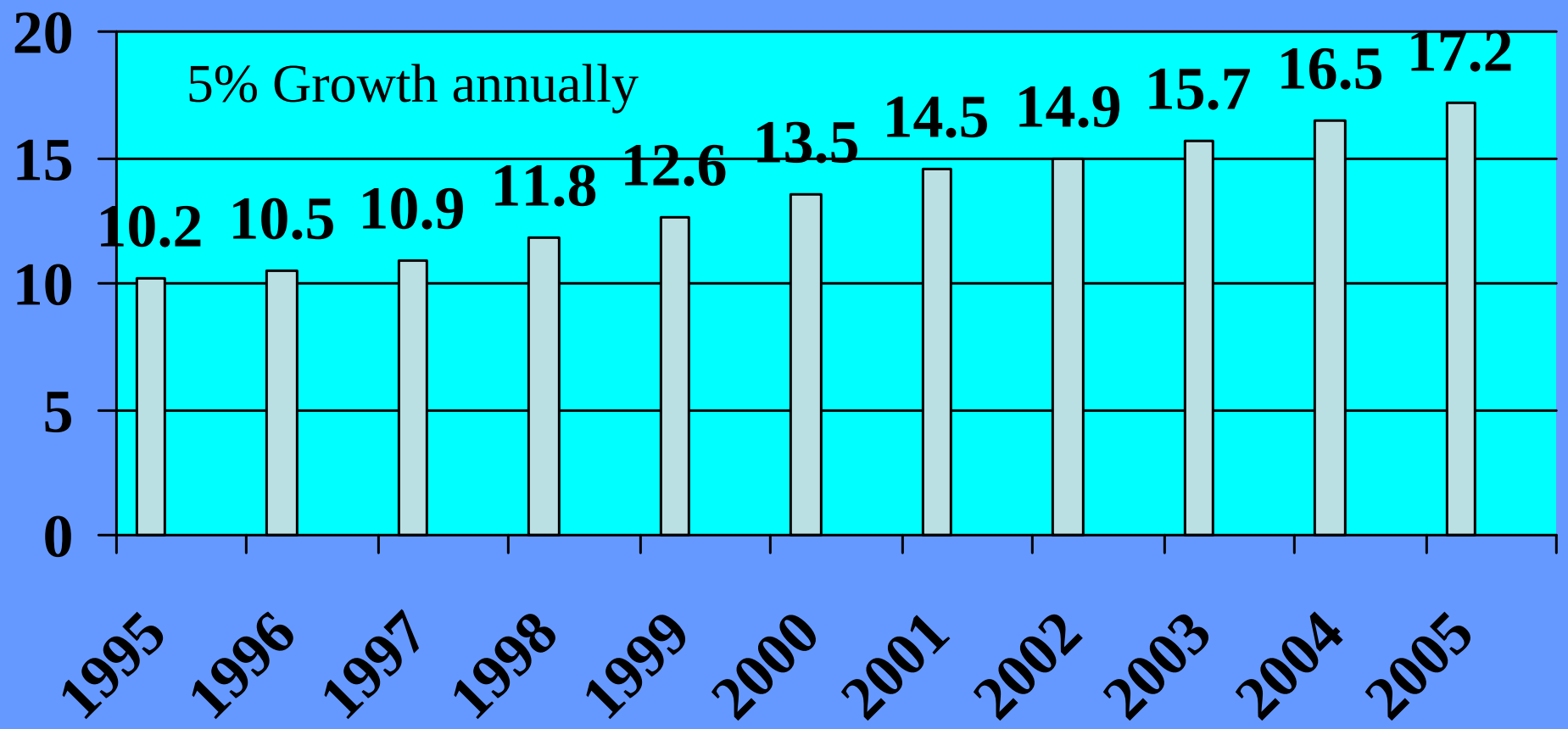
stress

rest



Ischemic area seen at stress fills in at rest

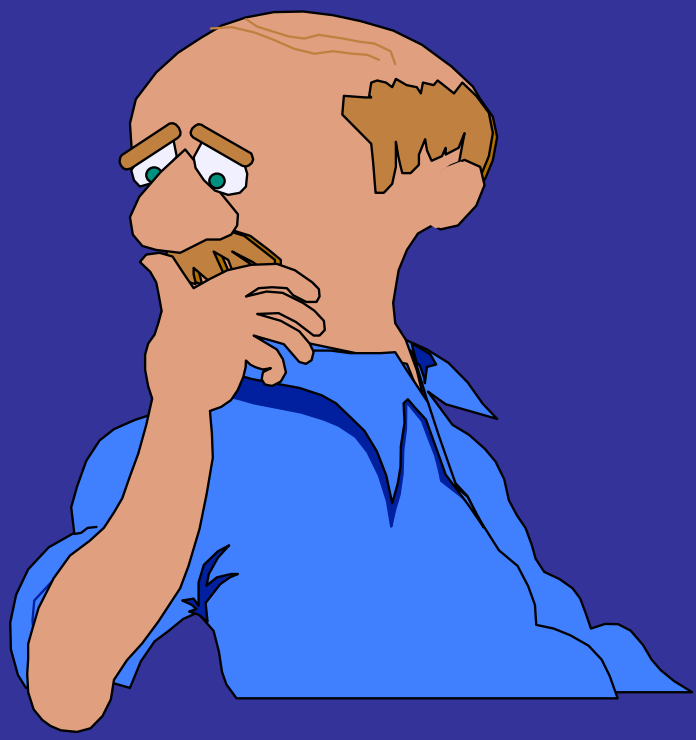
Nuclear medicine visits by year U.S.(millions)



Currently approximately 1 nuclear medicine procedure annually per 15 persons

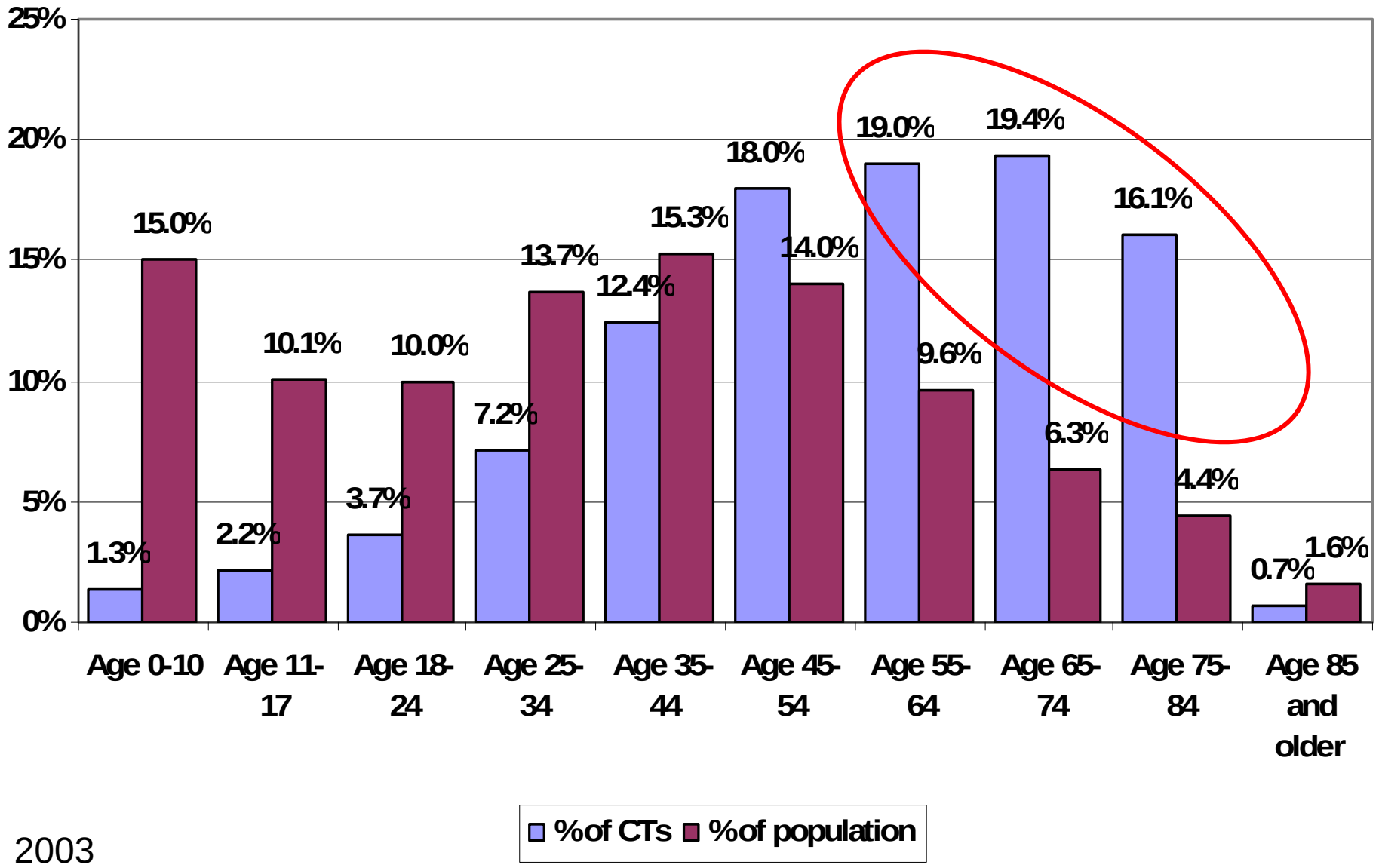
Isn’t the radiation risk lower because patients are older and don’t live as long ?

- Probably not much lower (maybe 35%)
- In the U.S. less than 5% of all examinations occur in the year prior to death
- A 65 year old has a 50/50 chance of making it to age 85



CT scans of abdomen and pelvis

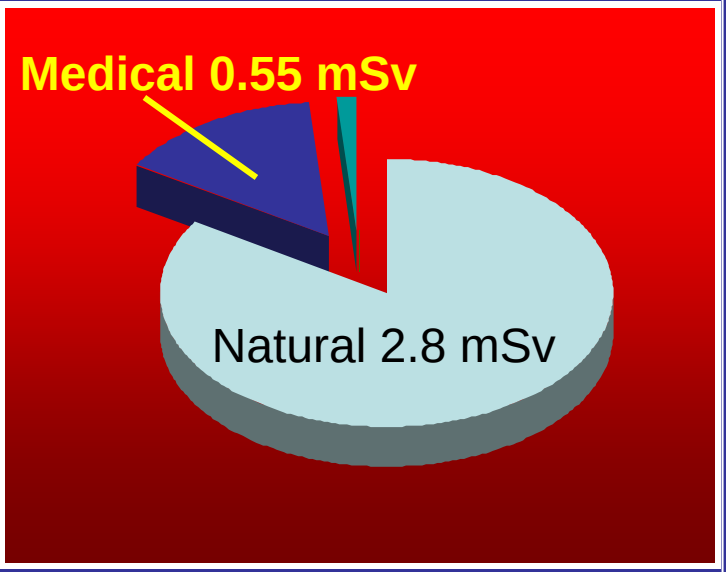
Exam distribution vs U.S. population



2003

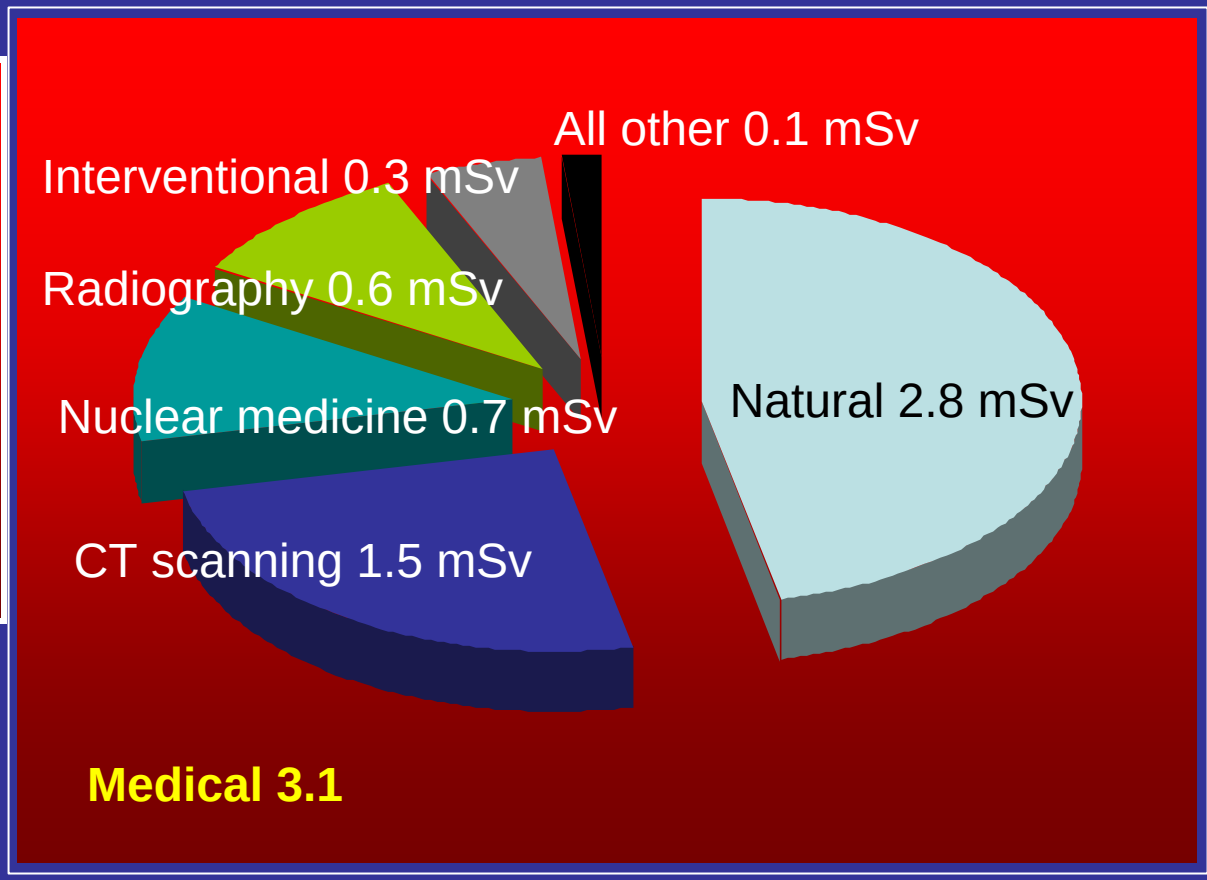
Estimate of changes in U. S. radiation exposure

U.S. 1980



3.6 mSv per caput

U.S. 2006



Total ~ 6.0 per caput

These results have not been reviewed
and approved by Council.
Not to be disseminated or referenced

- Estimates of effective dose as currently formulated are based on W_R of 1
- BEIR VII suggests an RBE of 2 for x-rays below about 200 keV based on chromosomal aberrations
- There is not yet a consensus in NCRP or ICRP to revise the current W_R from 1 to 2 for low-LET radiation

Comparison to other countries

Annual per caput effective dose (mSv)*

	x-ray	NM
U.S. (2006)	2.4	0.7
Canada (1997)	0.9	0.16
U.K. (1997)	0.3	0.04
Japan	1.7	
Germany (1997)	2.0	0.1
Spain (2005)	0.9	0.1

* For all individuals in the population

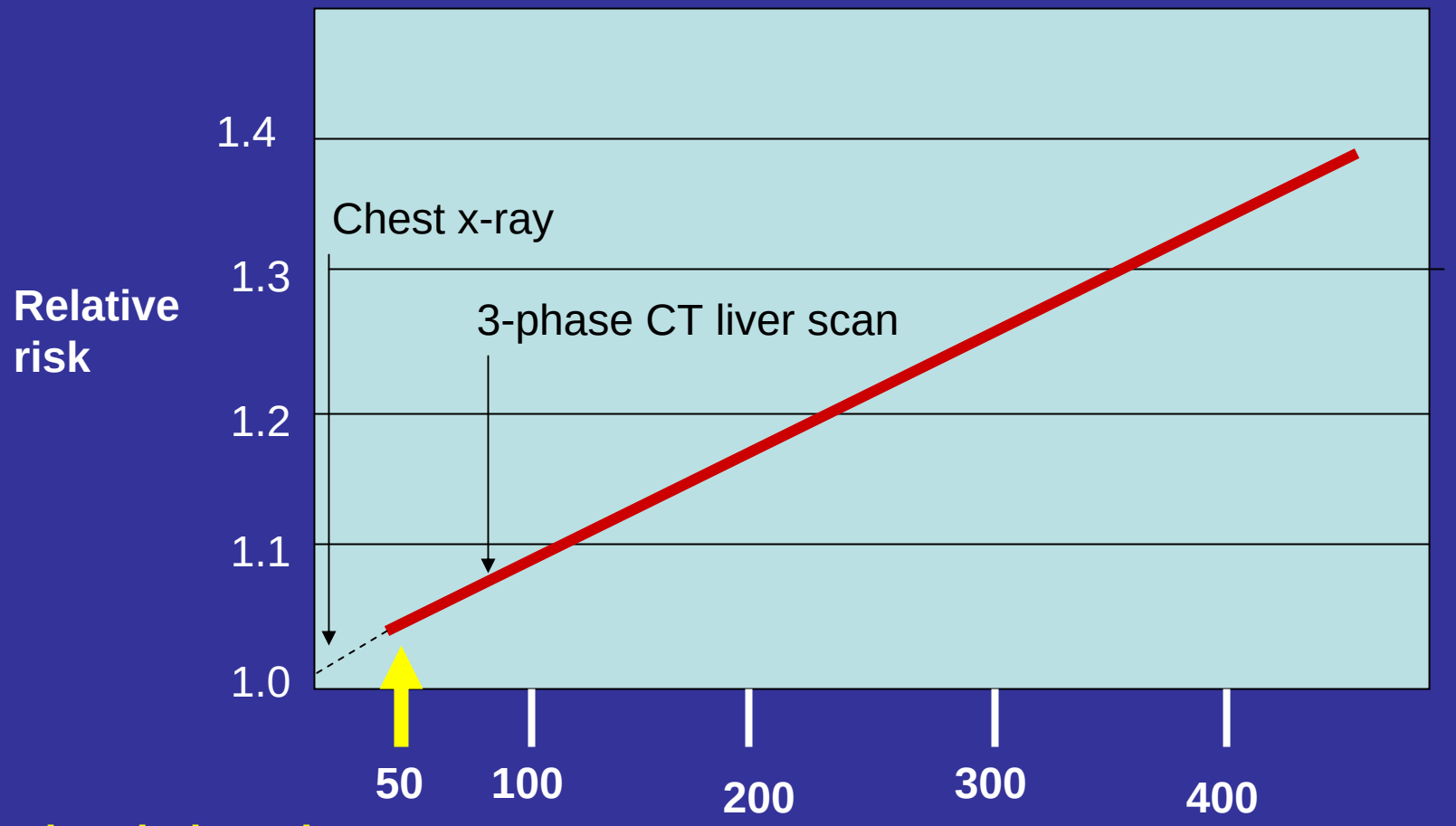
Application of results

- **The preliminary numbers and percentages of procedures appear reasonable and are not likely to change much**
- **Doses of procedures are averages. For an individual procedure the range may vary over factor of about 3-20**
- **Trends and dose estimates indicate potential areas where dose might be reduced**
- **Individuals may be able to obtain an order of magnitude estimate of their effective dose knowing what procedures they have had**

Application of results

- Especially for higher dose procedures, radiation dose does have a relation to potential detriment or risk
- Uncertainty relative to potential risk increases as doses get lower
- Collective doses for medicine should be taken with note of age and diseases
- Communication of results should not scare patients from having medically necessary procedures

Is there a cancer risk from x-ray ?



A-bomb data show a statistically significant increase at > 50-100 mGy

Conclusions and opinions

- Have we substantially increased the medical diagnostic uses of radiation (CT, digital, cardiac nuclear medicine) ? Absolutely
- Do we *think* we are practicing better medicine ? Yes
- Have we really shown an evidence-based benefit for any these procedures ? More clinical data are needed in order to draw firm conclusions

Conclusions and opinions

- **Recent increased uses have increased the radiation dose to the US public about 5 fold since 1980 (~0.55 to ~3.1)**
- **There is no question that CT doses are in the range *known* to increase the probability of cancer**
- **Effects of lower doses remain controversial**
- **Remember: medical radiation usually has direct benefit to individual**

MAYO CLINIC

Dose in Computed Tomography: How to quantitate, how to reduce

Cynthia H. McCollough, Ph.D.

Department of Radiology

Mayo Clinic College of Medicine

Rochester, MN

MAYO CLINIC

Overview

- **Dose in CT**
  - **How to quantitate: CT dose metrics**
  - **How to reduce: CT AEC**
- **CT Dose per exam versus *number of exams***
- The Fear Factor

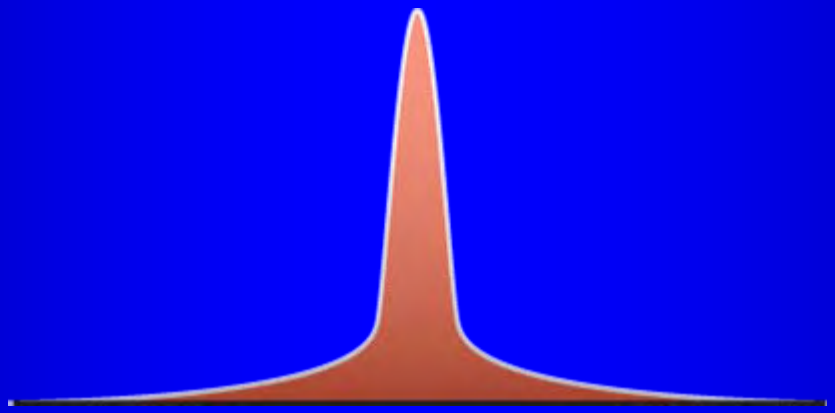
MAYO CLINIC

Fundamental CT Dose Descriptors

- Volume CT Dose Index
  - CTDIvol (mGy)
  - Average dose within the scan volume
- Dose Length Product
  - DLP (mGy•cm)
  - Integrated dose over the scan length
- Effective Dose
  - E (mSv)
  - Reflects relative biologic risk

MAYO CLINIC

Radiation Dose Profile
Single Axial Scan



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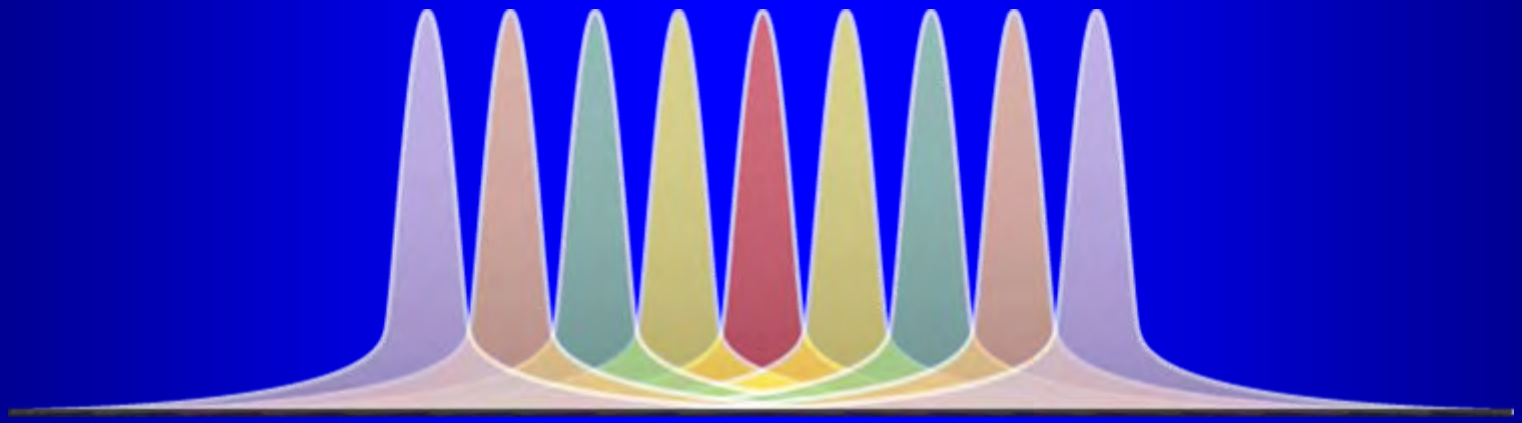
Radiation Dose Profile
Many Axial Scans



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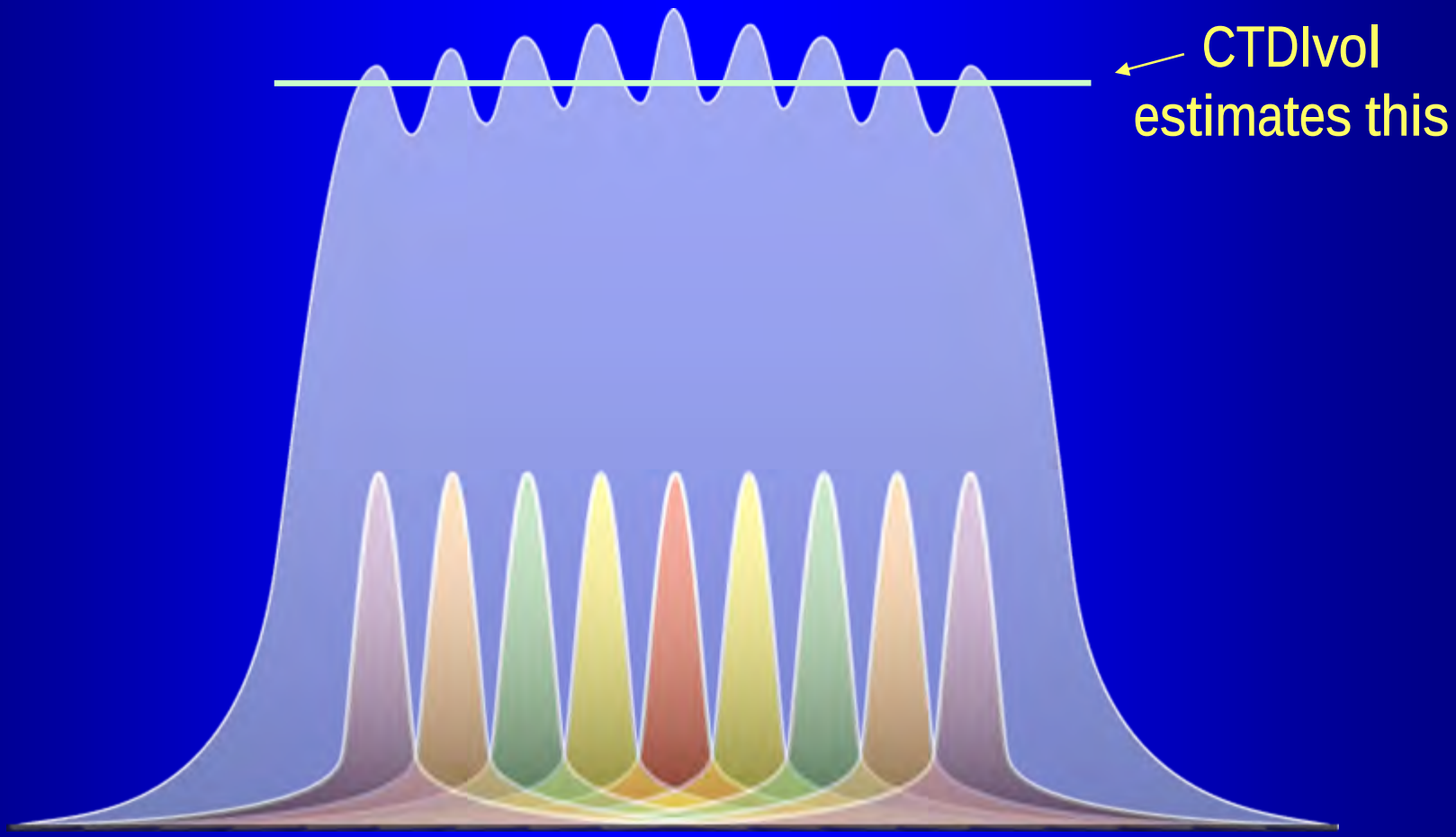
Volume CTDI



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CTDI ion chamber (100 mm long) $CTDI_{100}$

Acrylic CTDI phantoms

- 32 cm diameter (body)
- 16 cm diameter (head)
- Holes for measurements throughout FOV

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Volume CTDI ($CTDI_{vol}$)

- Uses Weighted $CTDI_{100}$ ($CTDI_w$) to account for variations across the FOV
- Takes into account scan overlap or gaps
- Represents an average dose in the central region of a multiple scan exam
  - To an acrylic cylinder
  - Of specific diameter and length (14 cm)
  - For a 100-mm integration

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$$CTDI_{vol} = \frac{1}{pitch} \bullet CTDI_{w}$$

estimate of average dose to volume

measurements from one axial scan

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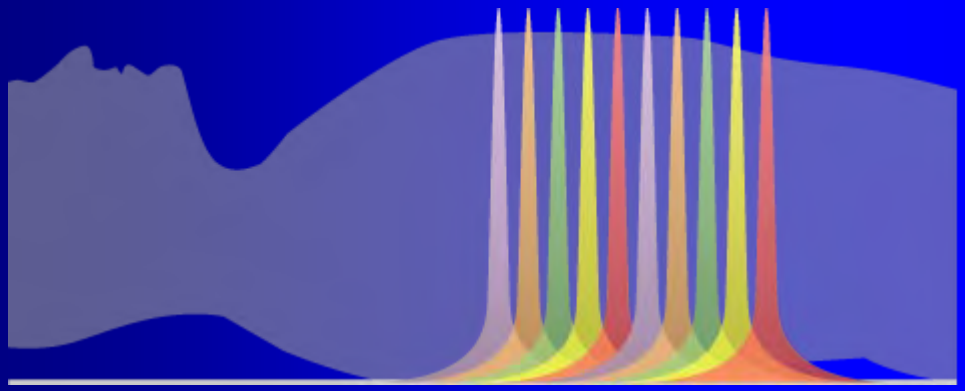
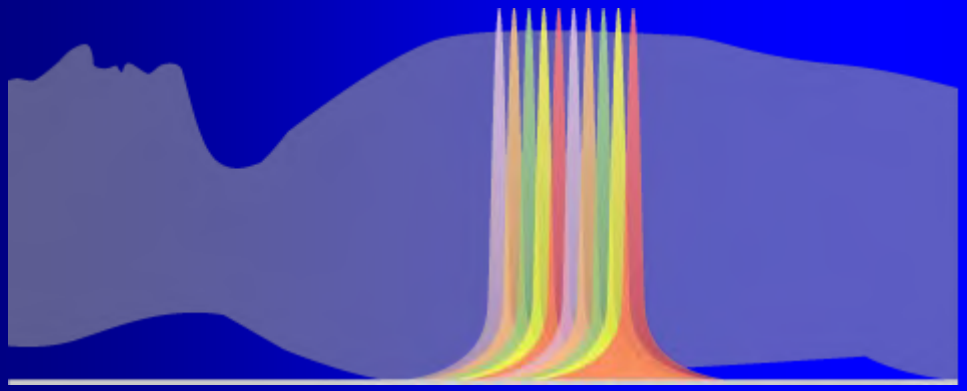
$CTDI_{volume}$



Ten 1-cm slices
Pitch = 1.0
$CTDI_{vol}$ = 20 mGy



Ten 1-cm slices
Pitch = 0.5
$CTDI_{vol}$ = 40 mGy

Lower pitch implies more dose (if all else equal)

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Dose Length Product (DLP)

Integrated dose in terms of total scan length

$$DLP = CTDI_{vol} \times \text{Scan Length}$$

(mGy) (cm)

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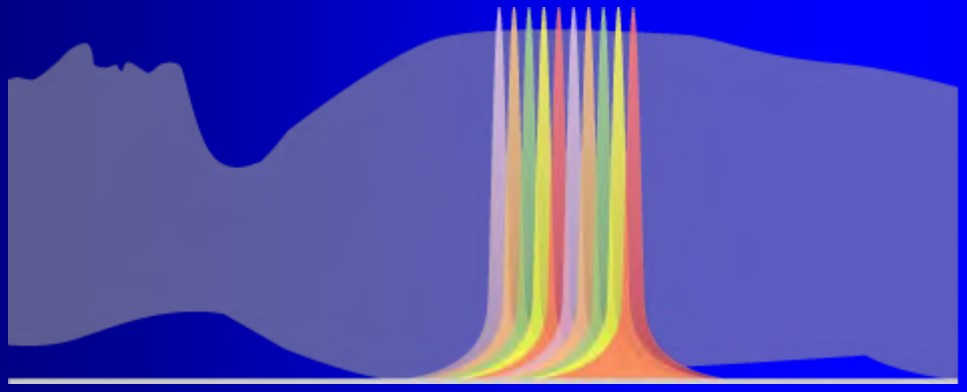
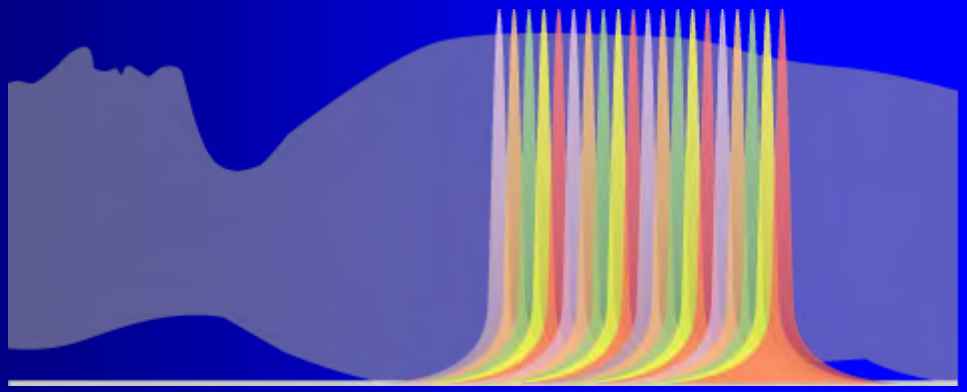
DLP



Ten 1-cm slices

$CTDI_{vol}$ = 20 mGy

DLP = 200 mGy-cm



Twenty 1-cm slices

$CTDI_{vol}$ STILL = 20 mGy

DLP = 400 mGy-cm

DLP represents the greater biological risk!

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When someone asks …

“What is the dose”

they typically mean

“What is the risk of biologic injury”

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What's my dose (risk)?

Radiation detriment better expressed by

Effective Dose

a *single dose parameter* which reflects the risk of a *non-uniform exposure* in terms of a whole-body exposure

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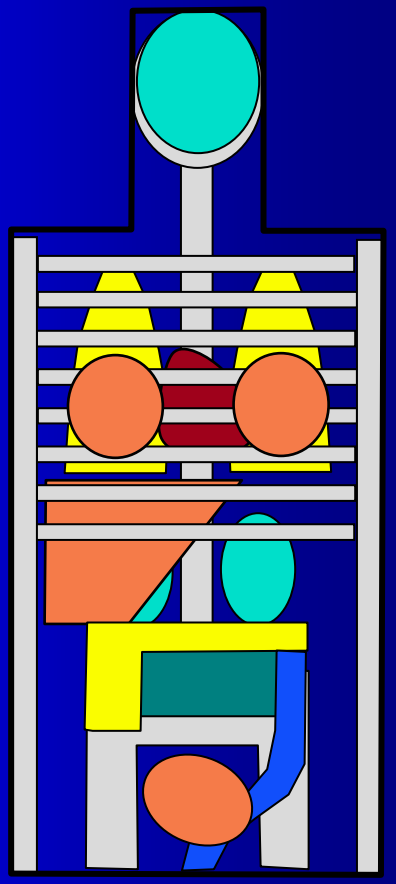
ICRP 60 Weighting Values*

Gonads	0.20
RBM, colon, lung, stomach	0.12
Bladder, breast, liver	0.05
Esophagus, thyroid	0.05
Skin, bone surface	0.01
Remainder	0.05
Σ	1.00



*Under revision

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Typical effective dose values

Non-CT Radiographic/Fluoroscopic

Hand radiograph	< 0.1 mSv
Dental bitewing	< 0.1 mSv
Chest radiograph	0.1 - 0.2 mSv
Mammogram	0.3 - 0.6 mSv
Lumbar spine radiograph	0.5 - 1.5 mSv
Barium enema exam	3 - 6 mSv
Coronary angiogram (Dx)	5 - 10 mSv

Average U.S. annual background radiation

≈ 3.0 mSv

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Typical effective dose values

Nuclear Medicine

Lung scan	2 - 3 mSv
Bone scan	3 - 5 mSv
Heart scan - Sestamibi	13 - 16 mSv
Heart scan - Thallium	35 - 40 mSv

Average U.S. annual background radiation
≈ 3.0 mSv

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Typical effective dose values

CT

Head CT	1 - 2 mSv
Chest CT	5 - 7 mSv
Abdomen CT	5 - 7 mSv
Pelvis CT	3 - 4 mSv
Abd & pelvis CT	8 - 11 mSv
Coronary artery calcium CT	1 - 3 mSv
Coronary CT angiography	5 - 14 mSv

Average U.S. annual background radiation

≈ 3.0 mSv

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Effective Dose …

- Is a weighted average over susceptible organs
- Was derived for radiation protection purposes
- Should be used as a broad measure of risk *(i.e. one or two significant digits are sufficient)*
- DOES NOT apply to any individual patient
- Is useful for…
  - Exam optimization
  - Risk comparisons between different exams
  - Risk information for IRB protocol review

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Overview

- Dose in CT
  - How to quantitate: CT dose metrics
  - How to reduce: CT AEC
- CT Dose per exam versus *number of exams*
- The Fear Factor

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Technical mechanisms for dose reduction in CT

- X-ray beam filtration
- X-ray beam collimation
- X-ray tube current (mA) modulation
- Detection system efficiency
- Noise reduction algorithms
- Automatic exposure control
  - mA and kVp optimization

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Dose management is about getting the *right dose*

for the *specific patient* and

the *specific diagnostic task*.

For large patients,

this can indeed mean a dose increase.

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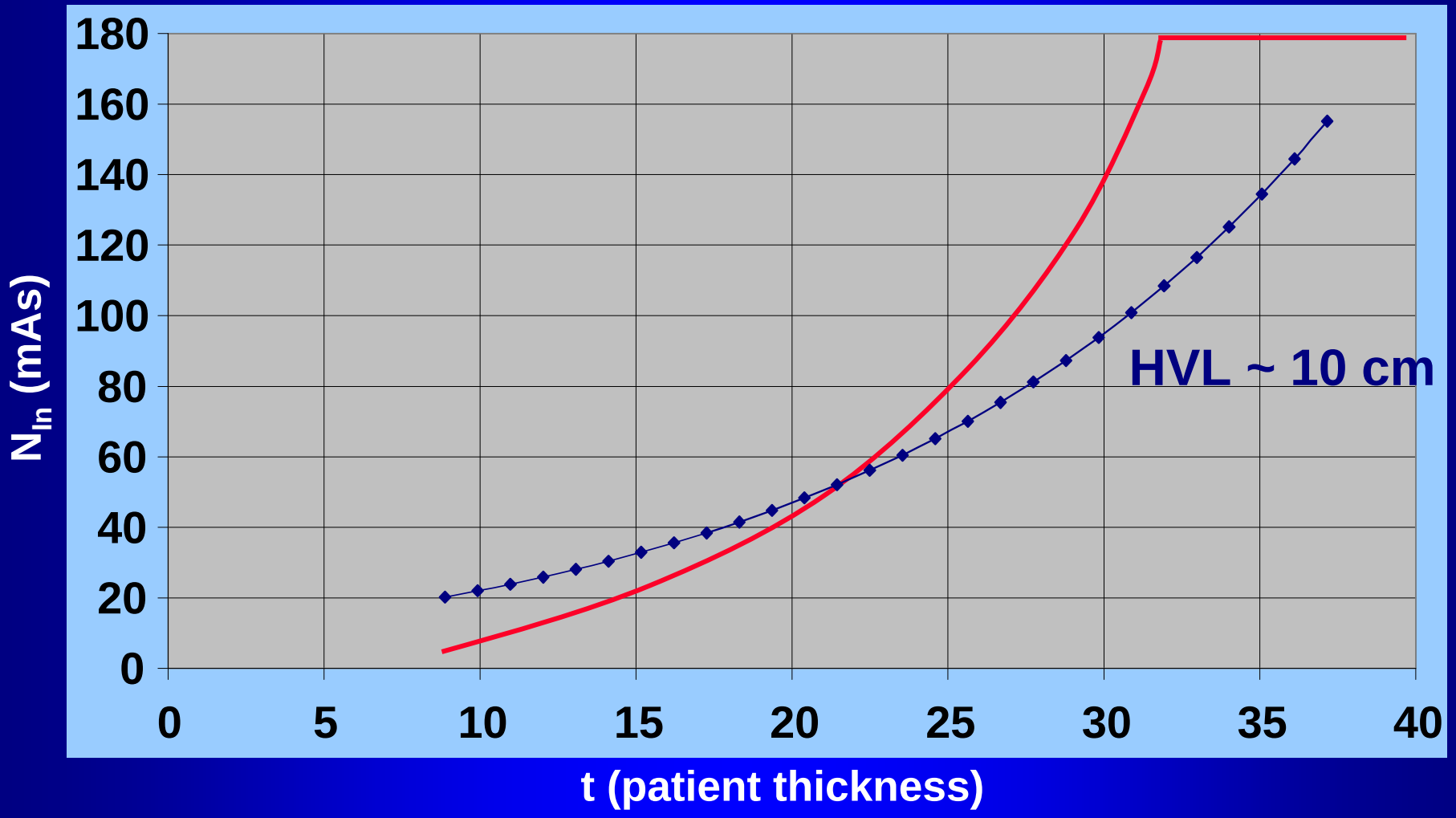
$$N_{In}\ (mAs) = N_{Out} \bullet \exp^{(0.693 \bullet t / HVL)}$$



Red curve shows the mAs required
***to keep image noise constant* as thickness is changed**

Half-value-layer (HVL) of soft tissue is approximately 6 cm

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Abd/Pelvis Technique Chart (pediatric and adult) — Lightspeed (QX/i and Plus)

Lateral patient width (cm)	Primary slice thickness (mm)	Mode (pitch)	Table speed (mm/rot)	Retro recon thickness' available (mm)		Lateral patient width (cm)	mA (at 0.8s)	kVp (at 0.8s)	mA (at 0.5s)	kVp (at 0.5s)
up to 14	3.75	HQ	7.5	2.5	5.0	up to 14	50	120	90	120
14.1 - 18	3.75	HQ	7.5	2.5	5.0	14.1 - 18	70	120	110	120
18.1 - 22	3.75	HQ	7.5	2.5	5.0	18.1 - 22	90	120	150	120
22.1 - 26	5	HQ	11.25	3.75	7.5	22.1 - 26	90	120	150	120
26.1 - 30	5	HQ	11.25	3.75	7.5	26.1 - 30	120	120	190	120
30.1 - 35	5	HQ	11.25	3.75	7.5	30.1 - 35	170	120	270	120
35.1 - 40	5	HQ	11.25	3.75	7.5	35.1 - 40	240	120	380	120
40.1 - 45	5	HQ	11.25	3.75	7.5	40.1 - 45	340	120	380*	140
45.1 - 50	5	HQ	11.25	3.75	7.5	45.1 - 50	350	140	380*	140

last modified 12/09/01

* mA limit reached - use the 0.8 sec option unless otherwise indicated

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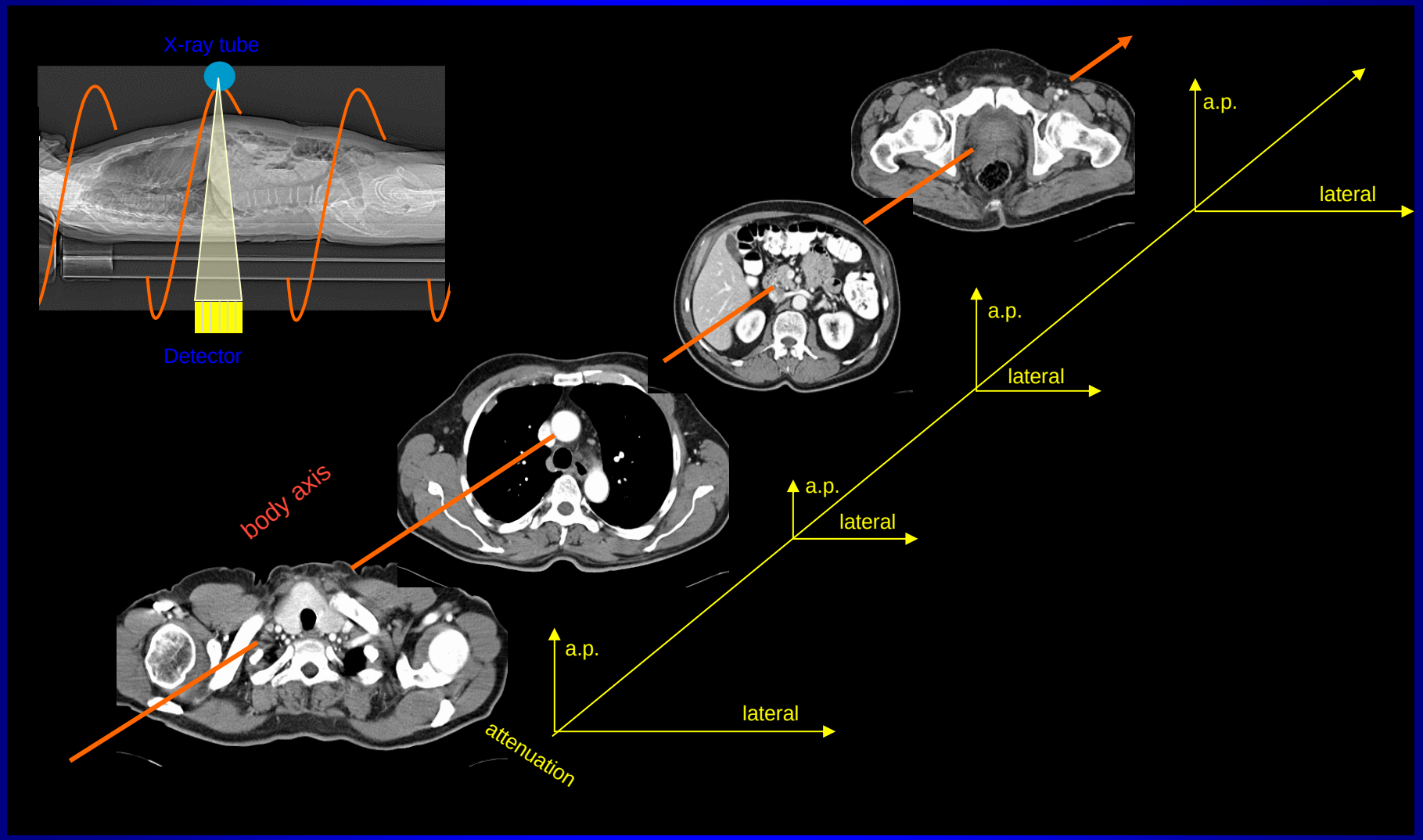
The human body is not a homogeneous cylinder
X-ray attenuation varies along the spiral path of a CT scan



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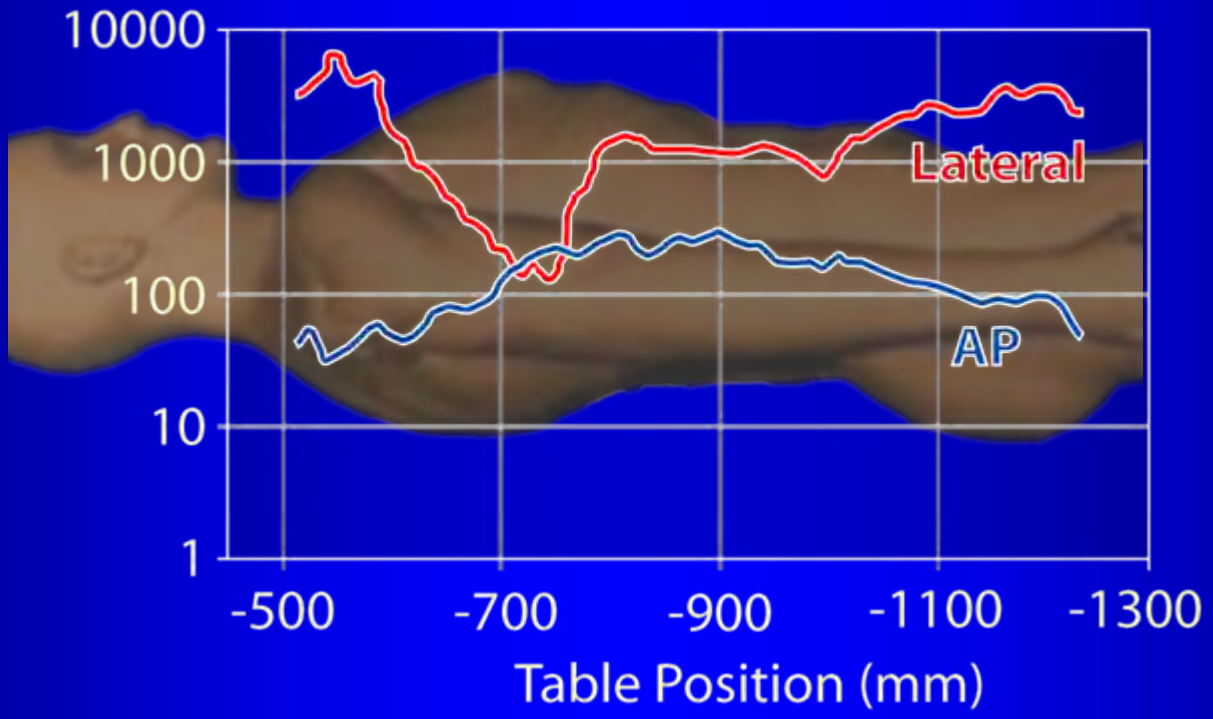
X-ray attenuation varies over body region & projection angle. The thickest projection determines image noise



To achieve “diagnostic” image quality at every location using the lowest dose, the system must adapt the mA at every location to the patient attenuation.

Automatic Exposure Control

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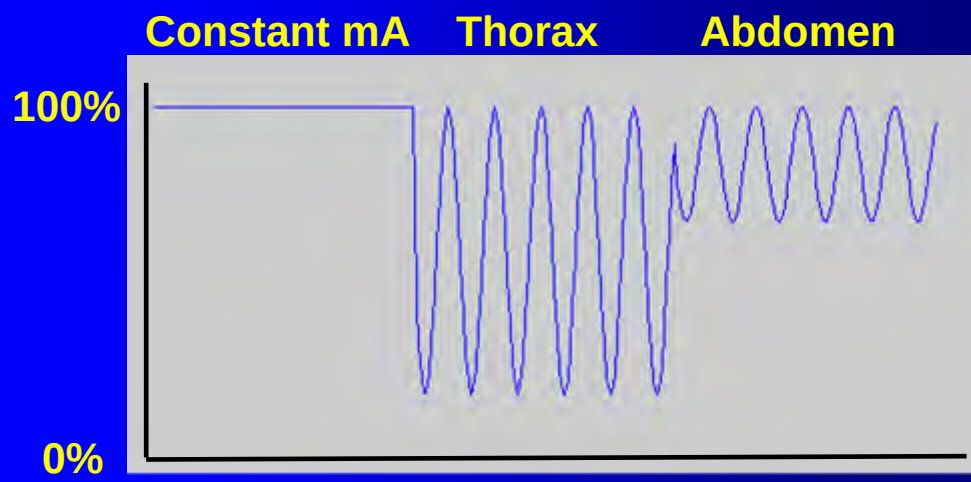
Angular (x,y) mA modulation

- mA varied angularly about the patient
  - (a.p. vs lateral)
- Operator chooses the initial mA(s) value
- mA modulated down from the initial value
- Some small increase in mA may be allowed in shoulders



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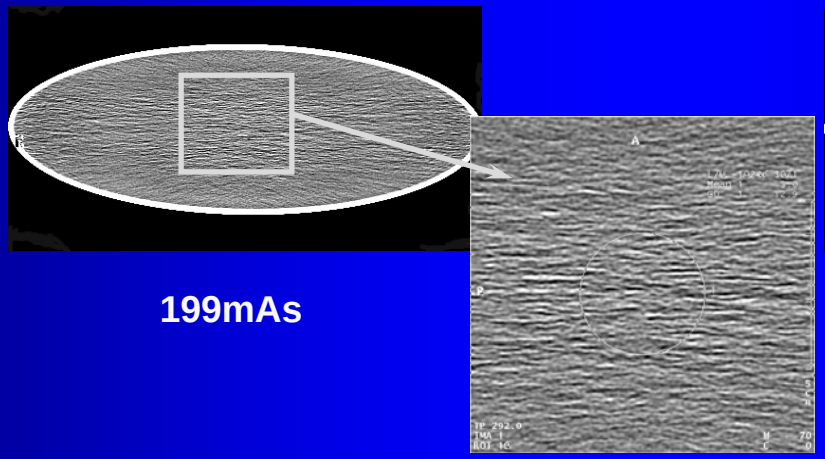
Benefits of mA Modulation

Shoulder phantom, 14cm x 40cm

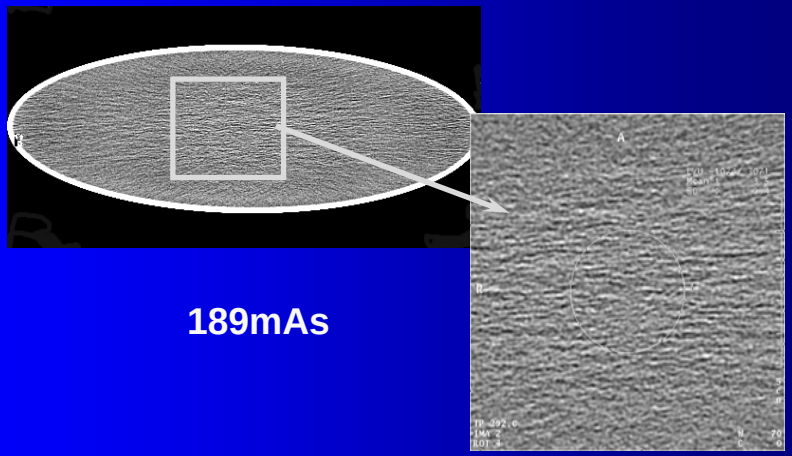
Scan with constant mA



199mAs

s = 12.9HU

Scan with mA modulation



189mAs

s = 9.4HU

For the same noise, dose could be reduced by 50% using angular mA modulation

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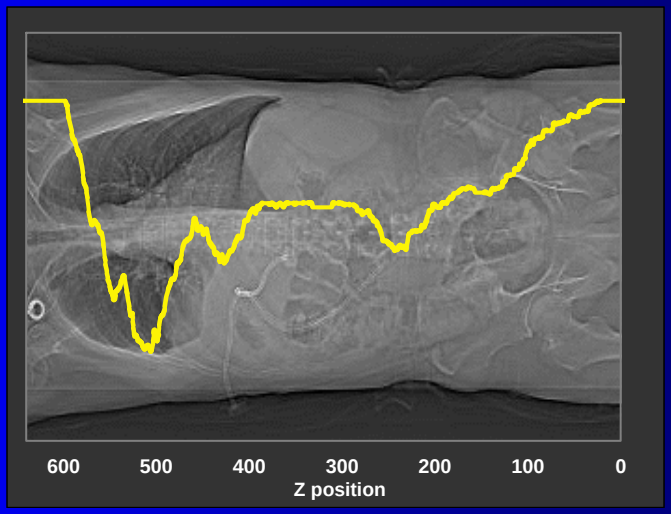
Longitudinal (z) mA modulation

- mA varied along the z axis
  - (shoulders vs. abdomen)
- Operator chooses the desired level of image quality
- mA modulated to provide desired level of IQ as the attenuation between anatomic region varies
- Increase in mA expected in shoulders, pelvis



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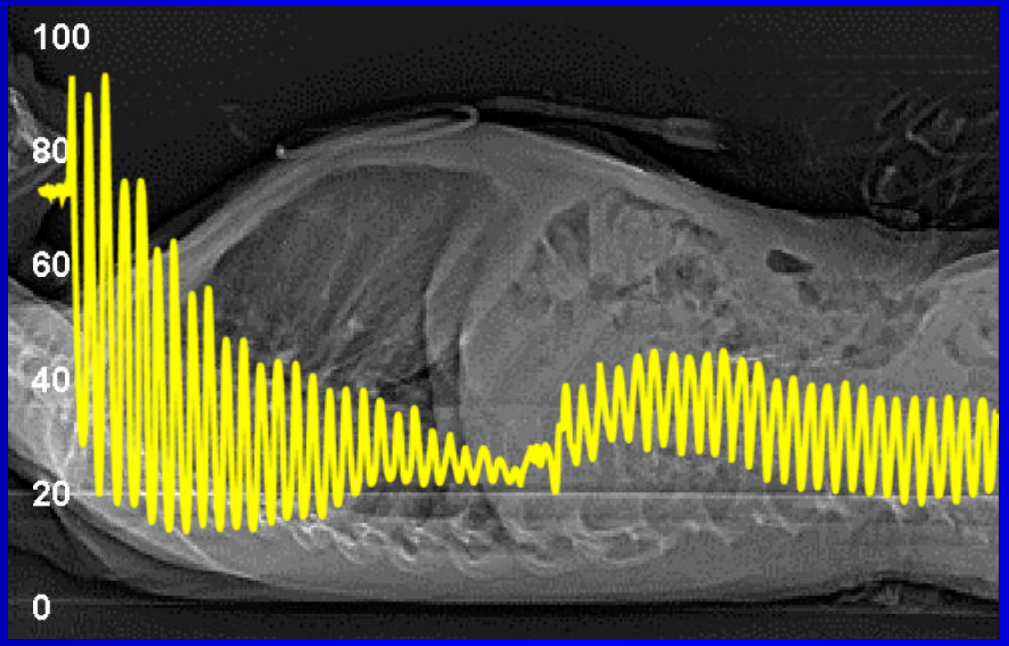
Angular and Z modulation

6 y.o. scanned with adult protocol

Reference eff. mAs = 165
Mean eff. mAs = 38



mA variation

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Automatic exposure control

- Analogous to photo-timing
- User determines IQ (noise) requirements (hard)
  - don't need "pretty" pictures for all diagnostic tasks
  - need to choose low noise, standard, or low dose dependent on the diagnostic task
- System determines the right mAs (easy)
- Should adjust mA
  - during rotation (x,y) and along z-direction

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IQ Selection Paradigms

- GE: Noise Index
  - Referenced to std. deviation of pixel values in a water phantom
- Philips: Reference Image
  - Automatic Current Setting (ACS)
  - Save an acceptable patient exam (including SurView)
  - Raw data and noise saved, used as later reference
- Siemens: Reference Effective mAs
  - Enter the effective mAs sites uses in standard (approx. 80 kg) patient
- Toshiba: Std. Deviation
  - Sure Exposure
  - Referenced to std. deviation of pixel values in an attenuation-equivalent water phantom
- All allow reference value to be stored with protocols

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Clinical IQ Assessment

- **Wilting JE, et al. A rational approach to dose reduction in CT: individualized scan protocols. *Eur Radiol* 2001**
  - **Presented constant noise images to radiologists**
  - **Pediatric to obese patients**
  - **Pediatric images were found unacceptable, even though they contained the same level of image noise**
- **Kalra M, et al. Multidetector CT Scanning of Abdomen and Pelvis: A Study for Optimization of Automatic Tube Current Modulation Technique in 120 Subjects (abstract) *RSNA* 2003**
  - **Lower Noise Index preferred for smaller patients**
  - **Higher Noise Index acceptable for larger patients**

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Conclusions regarding noise

- Equal noise is not the clinical ideal, *because* …
- Children don't have the fat planes between tissues and organs that adults do (fat planes enhance contrast and tissue differentiation)
- Details of interest are smaller in children, so greater CNR required
- Radiologists require higher image quality in children to ensure high diagnostic confidence
- Radiologists are accustomed to "reading through the noise" on large patients

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Overview

- **Dose in CT**
  - **How to quantitate: CT dose metrics**
  - **How to reduce: CT AEC**
- **CT Dose per exam versus *number of exams***
- The Fear Factor

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Question

- What is the impact of automated exposure control (AEC) on patient radiation dose?

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Methods

- Siemens Care Dose4D
  - x, y and z mA modulation
- Quality reference mAs
- For > 200 body CT exams, noted
  - patient size
  - eff. mAs from our technique chart
  - average eff. mAs over the entire AEC scan
  - eff. mAs for specific anatomic levels.

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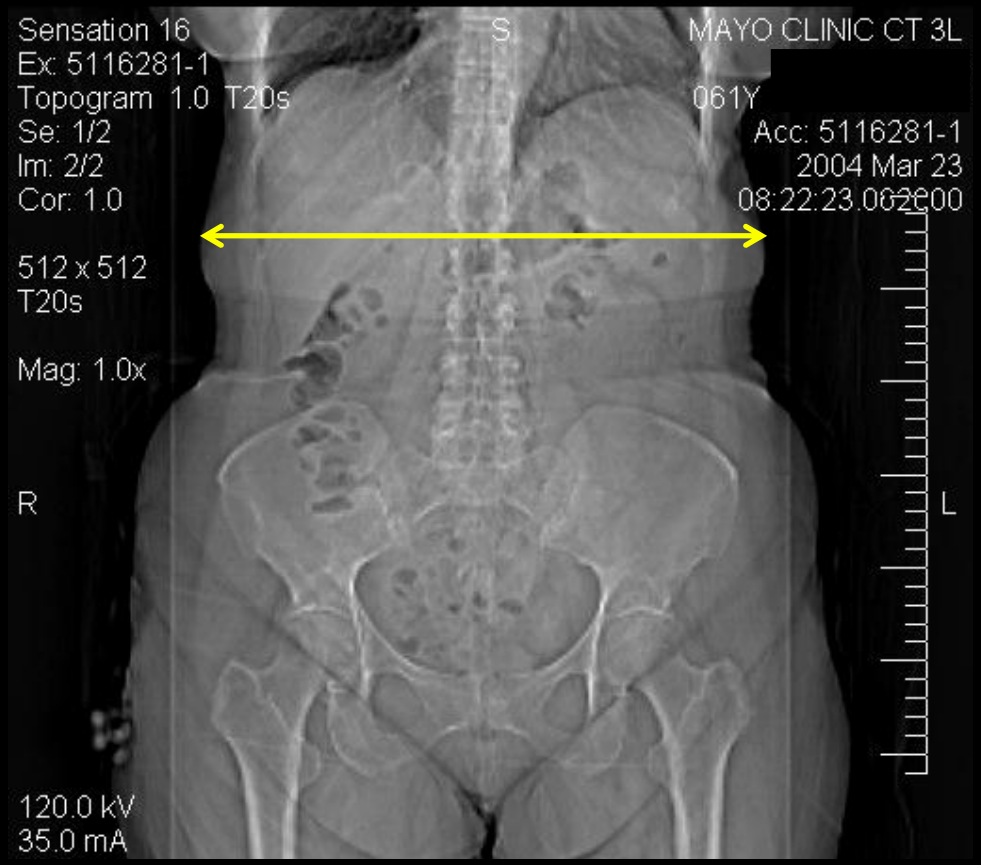
Results

- Image quality of AEC images deemed unchanged or improved relative to non-AEC exams
- Increased quality in large patients and streak-prone regions such as shoulders

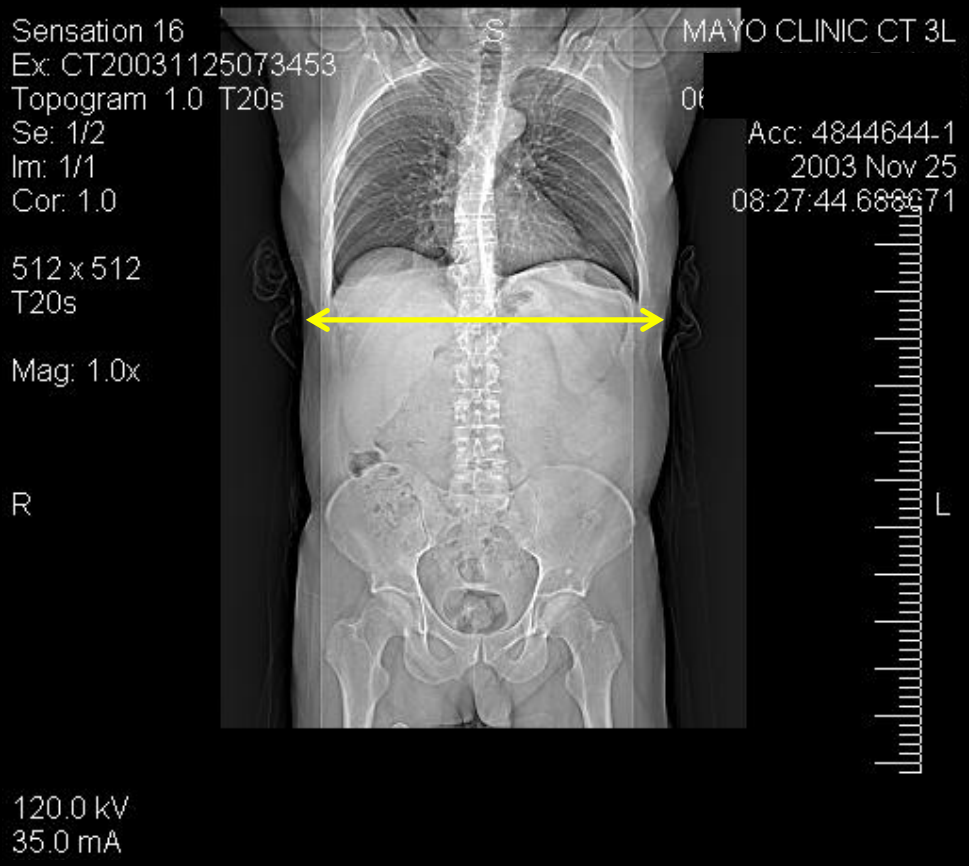
Routine Abd/Pelvis (5 mm)
Reference eff. mAs = 240

61 y.o. female
30 cm lateral width -> 120



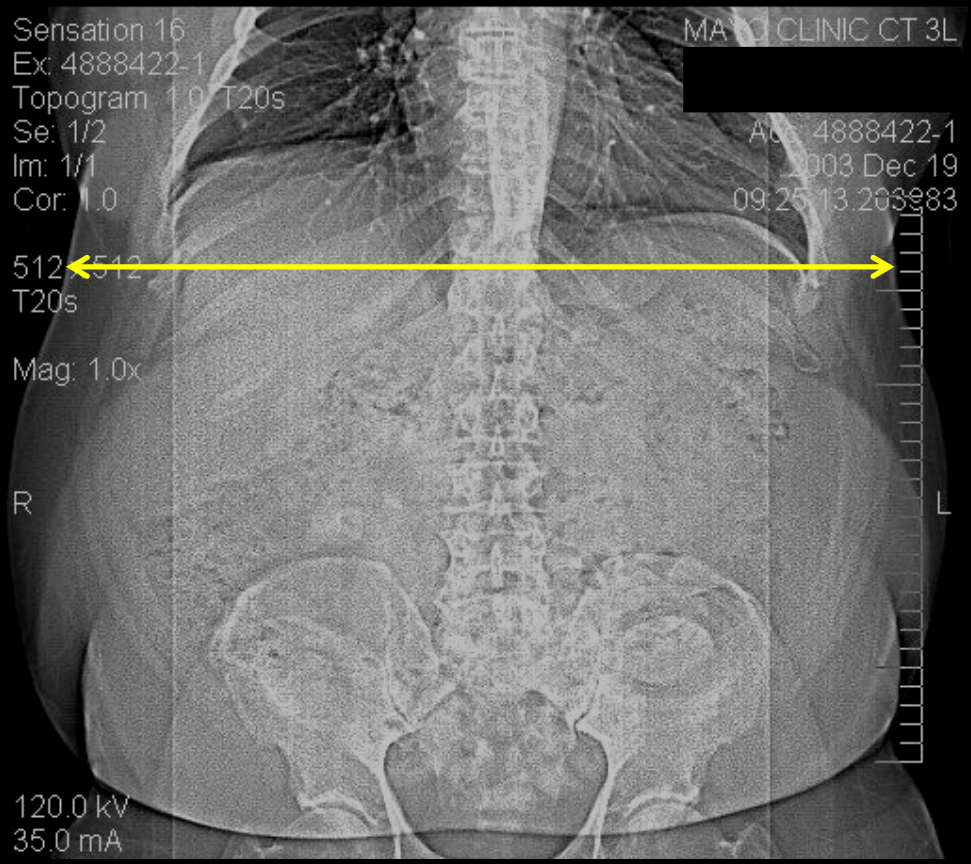
Routine Chest/Abdomen/Pelvis (5 mm)
Reference eff. mAs = 240

64 y.o. male
39 cm lateral width -> 240



Routine Abdomen/Pelvis (5 mm)
Reference eff. mAs = 240

51 y.o. male
48 cm lateral width ->350 @ 140 kVp



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Summary

- Wide range of body habitus
- No operator selection of x-ray technique
- All used default reference effective mAs
  - Thorax: 170 eff. mAs
  - Abdomen/Pelvis: 240 eff. mAs
  - CTA: 250 eff. mAs
  - Bi-phase liver: 350 eff. mAs

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Eff. mAs decreases relative to our technique charts

- Exam average 21.0%
- Upper lung 29.7%
- Breast 54.8%
- Liver 13.2%
- Pelvis 23.2%

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Eff. mAs decreases relative to a single eff. mAs value for all patients (i.e. no technique charts)

- Exam average 18.5%
- Slim patients 44.9%
- Large patients 3.1%

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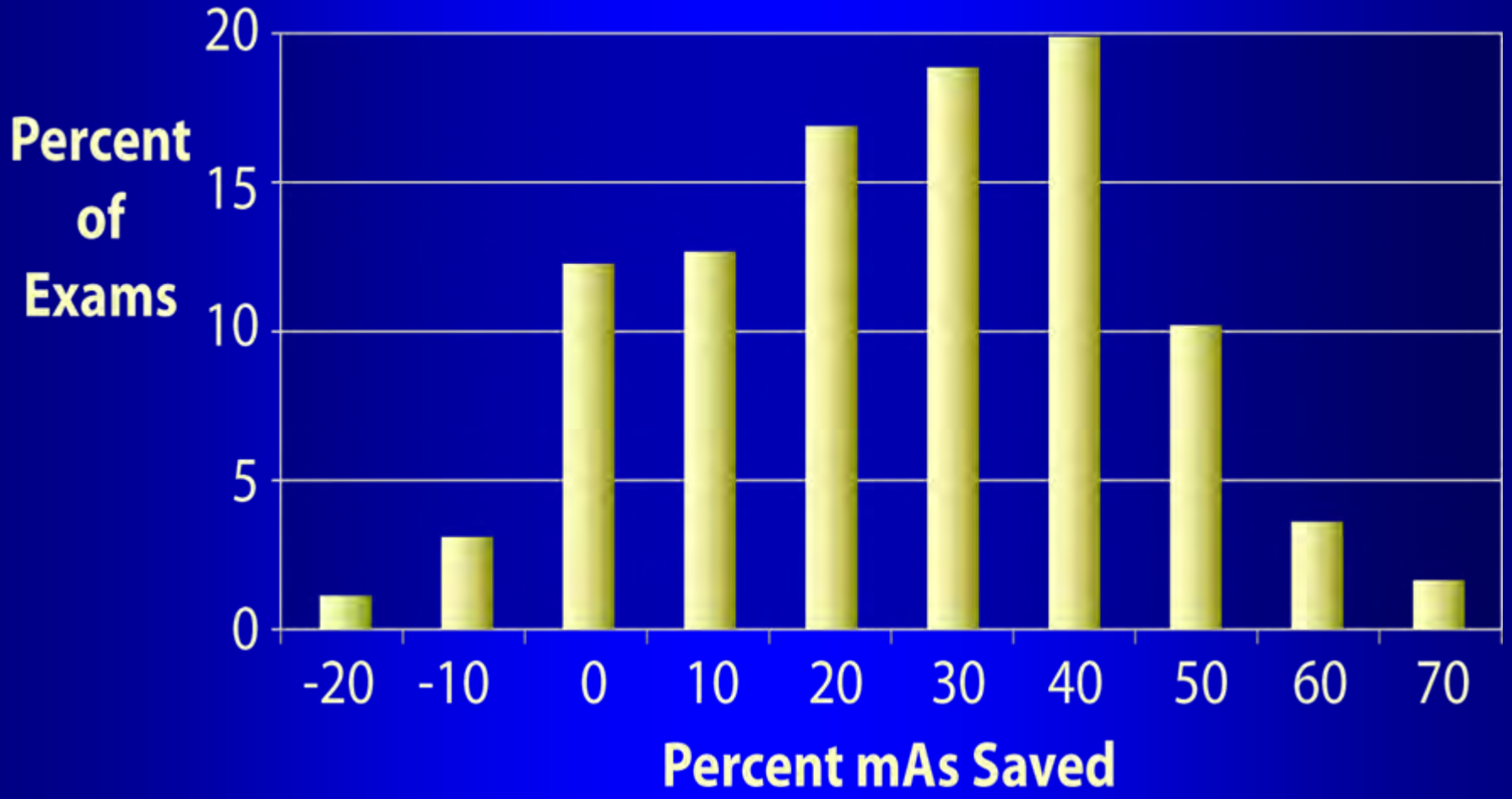
Relative to our technique charts …



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Question

- What is the impact of MDCT on patient radiation dose?

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“Dose” per exam

- CT scanner output has been measured and reported in an extremely consistent manner since ≈ 1981
- $CTDI_{100}$ -> $CTDI_{w}$ -> $CTDI_{vol}$
- How has dose per exam changed in past 2 decades?

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CT Dose per exam

- ***The radiation dose required to produce images of sufficient quality to answer the clinical question***

- **CTDIvol for a routine abdomen exam**

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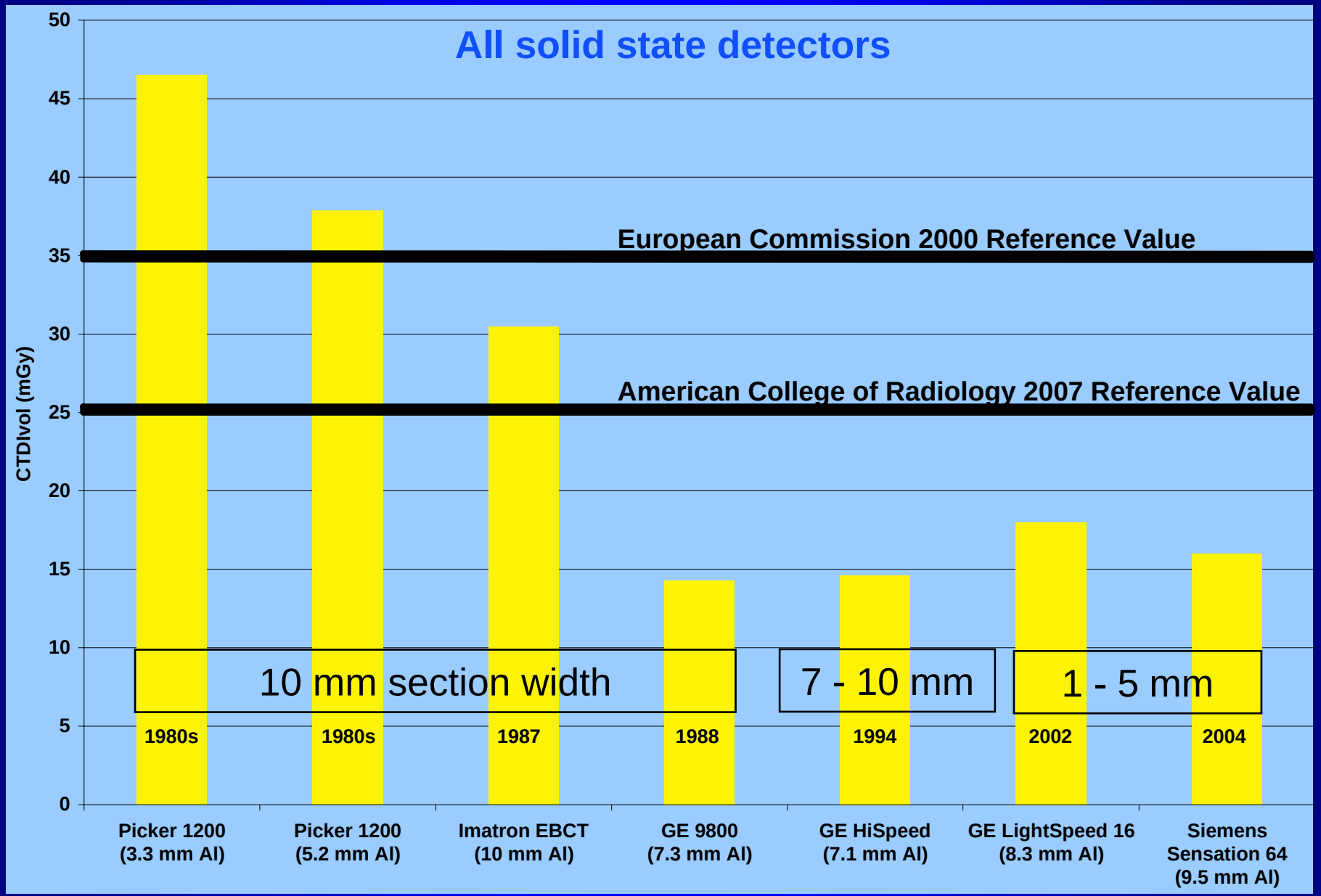
Routine Body CT Doses over 2 Decades



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Conclusions

- Dose per exam has decreased markedly since inception of CT, in parallel to considerable advances in capabilities
- Newer MDCT systems have eliminated the dose penalty of early MDCT systems for thin ($\leq$ 1.25 mm) images
- AEC systems can lower patient dose, even in large patients
- These technical advances have reduced the dose per exam, especially for thin-slice exams, by a factor of 2 or more

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Overview

- Dose in CT
  - How to quantitate: CT dose metrics
  - How to reduce: CT AEC
- CT Dose per exam versus *number of exams*
- The Fear Factor

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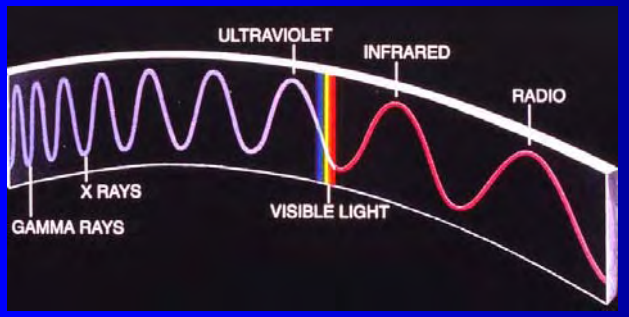
Difficulties in discussing radiation and risk

- Perception of risk increases when
  - I can't see it
  - I can't touch it
  - I can't measure it
  - I can't control it
    - Worse still if government or industry controls it
  - I'm not familiar with it
  - Experts tell me to "trust them"



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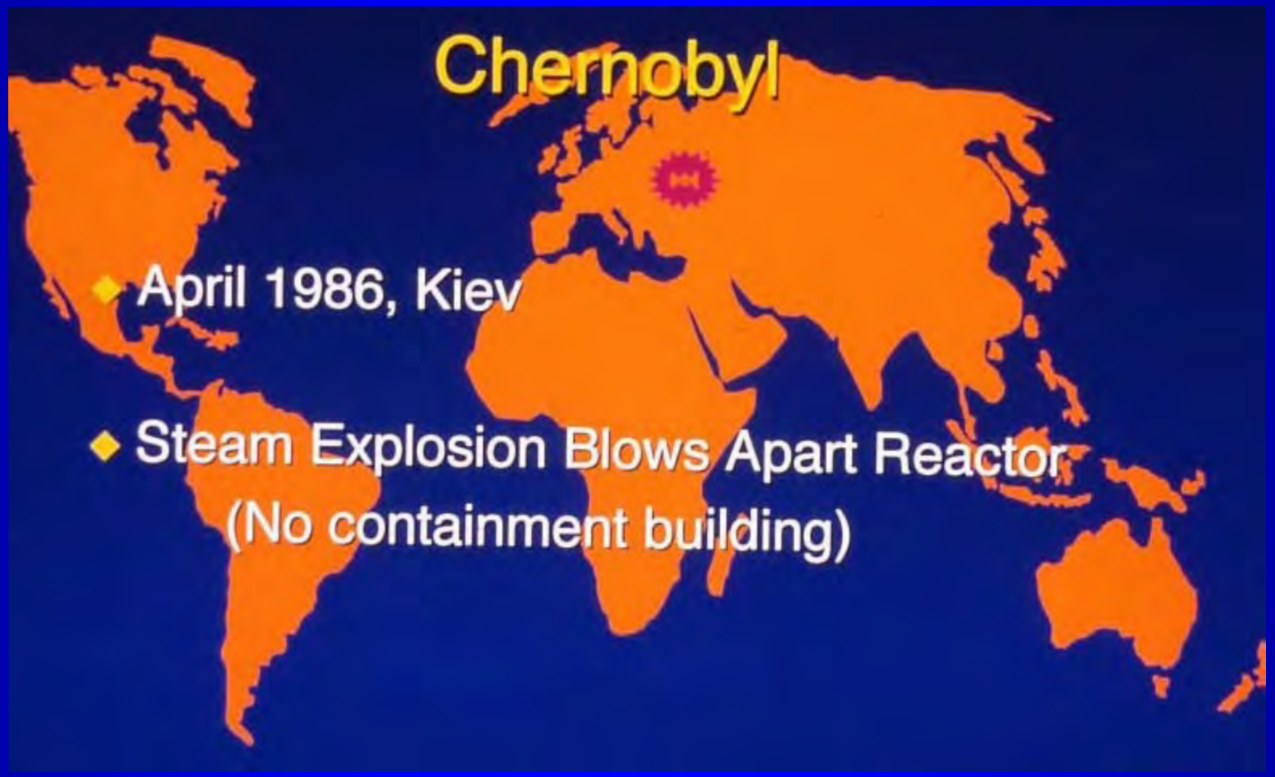

- **Released 17 MCi I-131, 2 MCi Cs-137**
- **200 workers > 1000 mSv**
- **30 deaths**
- **Average dose to 272,000 people within 200 miles = 200 mSv**

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January 22, 2001

- **“CT scans in children linked to cancer”**
  - **USA Today News**
- **"Each year, about 1.6 million children in the USA get CT scans to the head and abdomen -- and about 1,500 of those will die later in life of radiation-induced cancer, according to research out today."**

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Problems with media analyses of Brenner paper

- Incorrectly assume 0.18% ***statistical*** increase in risk per exam (relative to ≈ 25% background risk), multiplied by many exams, equals ***predictable*** deaths
- Buying 1000 lottery tickets DOES increase your odds of winning big …. but I wouldn't quit your day job just yet!

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It shouldn't be

"Is the CT safe?"

but rather

"Is the CT needed for patient care?"

- The imaging community should already have taken care of making the CT *as safe as possible*
  - Passionate adoption of ALARA
  - Automated or manual adaptation of technique for patient size/indication

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Summary

CT Dose
should not scare you

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CT Dose

- Scanner output is and has been well characterized since early days of CT using CTDI based metrics
- Dose per exam continues to decrease due to technology advances and methods to adapt dose to patient size
- Manual technique charts can be easily implemented by conscientious practices

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My Bigger Fears …

- Over use of CT
  - Over-dependence on the virtual physical exam
  - Defensive medicine and use of CT to triage ED patients
  - Patient insistence or primary care docs who provide imaging
- Not adapting scan to patient size or diagnostic task
- Media or others who exploit the fear factor
- Lack of education regarding radiation and its effects
- Fear Factor causing real emotional and physical harm
  - mild anxiety to paralyzing fear
  - refusing a needed CT exam
  - aborting a wanted child

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Appropriate Responses

- Outside Radiology
  - Prudent medicine, order only when needed
  - Restrict self-referral (patient or MD)
- Inside Radiology
  - Provide feedback / pushback to referring docs
  - Adapt scan to patient and indication
  - ALARA in equipment design and use
  - Mandatory accreditation and dose limits
  - Provide reassurance and education to the public

Pediatric Dose Reduction in Computed Tomography

Donald P. Frush, MD

Division of Pediatric Radiology
Department of Radiology
Duke University Medical Center

What we are really discussing here is a balance between safety (radiation dose) and image quality for CT in children. This balance comes through an understanding of MDCT dose, *why* we do CT, and *how* we do CT.

“Safety”…. Mining Tragedy

- **Multiple safety violations**
- **Significant violations**

These are not the issues….

“Safety”…. Mining Tragedy

- **Poor communication**
- **Poor response**
- **Poor response strategy**
- ***DENIAL***
- **Blame: eg “Bush administration…”**
- **Substrate of profit**

“Safety”…. Hospital Errors

- Poor communication
- Poor response
- Poor response strategy
- *DENIAL*
- Blame: personnel … *not* system
- Substrate of profit
  - Financial
  - Academic

Naval Aviation Mishap Rate

776 aircraft destroyed in 1954

FY 1950-96

Angled Carrier Decks

Naval Aviation Safety Center

NAMP est. 1959

RAG concept initiated

NATOPS initiated 1961

Squadron Safety program

System Safety Designated Aircraft

ACT

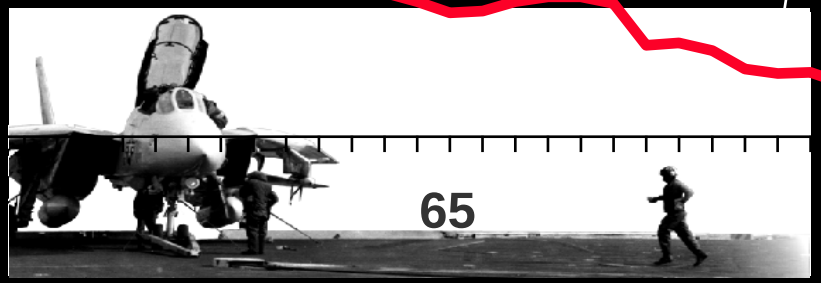
HFC's

39 aircraft destroyed in 1996

2.39

Class A Mishaps/100,000 Flight Hours

60
50
40
30
20
10
0



50 65 80 96

Fiscal Year

Lessons from Industry

Design improvements into the system…

- Avoid reliance on memory
- Use constraints, forcing functions
- *Simplify and standardize whenever possible*
- Promote effective team functioning, *communication*
- Include the consumer (patient) in the design of safe processes
- Measure results, monitor progress

What are “Safety” Issues in Radiology?

- MR compatibility
- Contrast reactions
- Medications: sedation for children
- Radiation dose
- IR

I consider the radiologist's responsibility with (radiation) dose to be the same as any physician's with (medication) dose.

Over (or under) dosing is a medical error.

Pediatric CT Quality

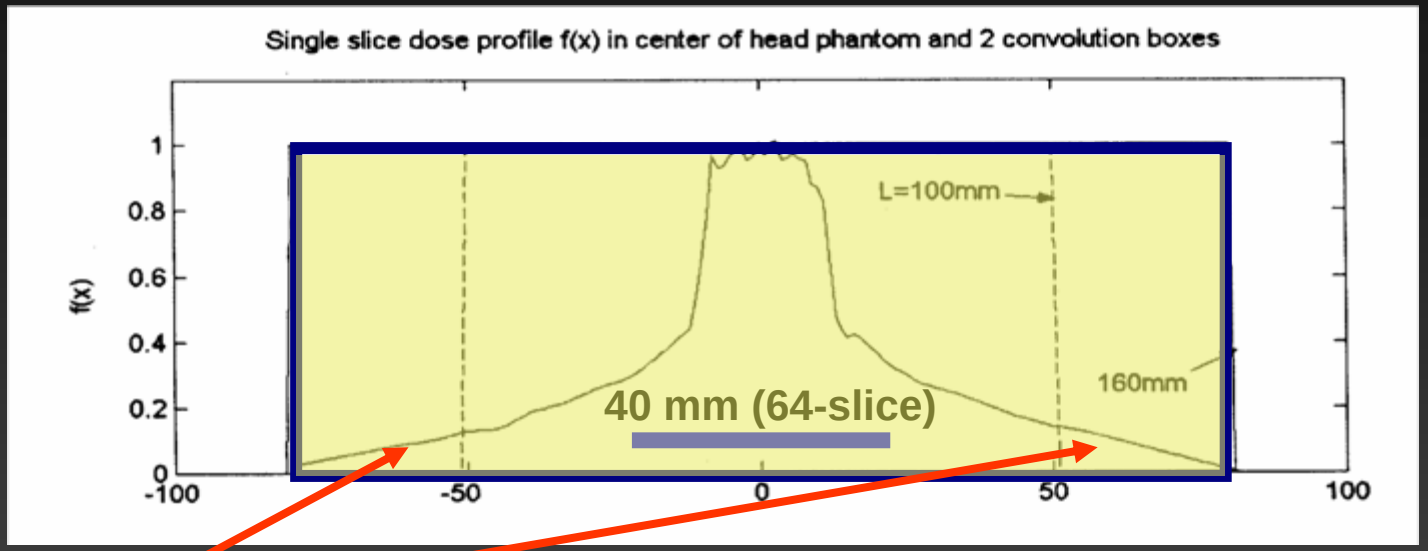
- Quality is task specific
- Quality is radiologist specific
- Quality is patient specific

Pediatric CT Quality

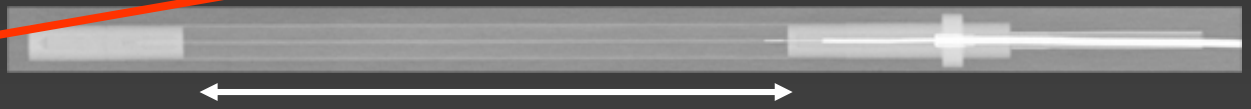
- **Quality is task specific**
- **Quality is radiologist specific**
- **Quality is patient specific**
- ***Image* quality does not always equal *study* quality**

Study Quality

The point is that protocols should serve as *guidelines* with individual adjustments as required. This requires effort.



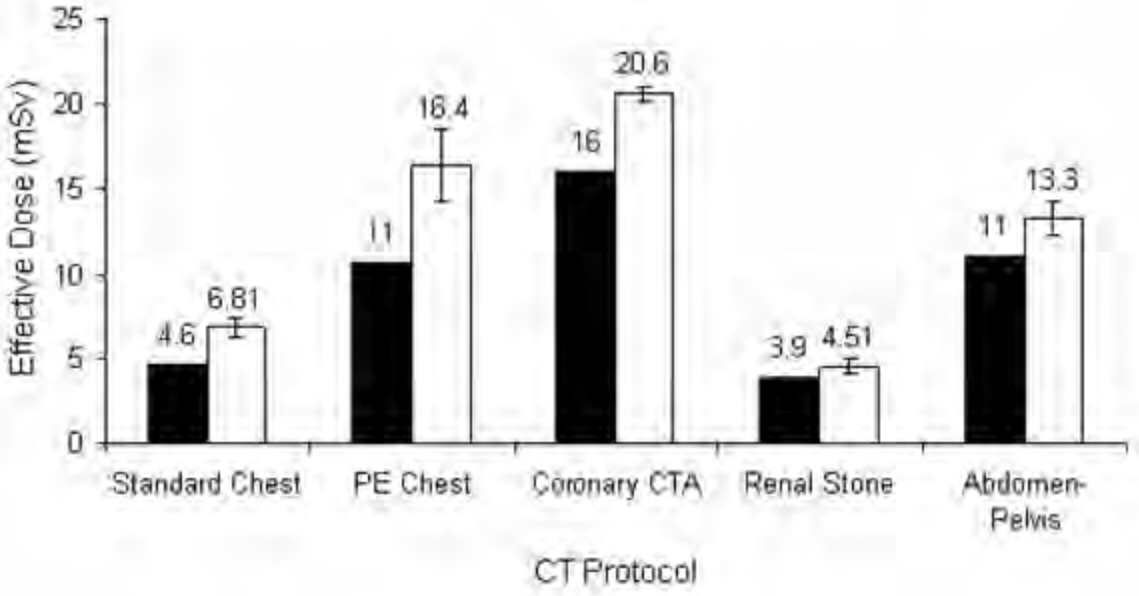
Missing tail



10 cm active length of ion chamber

CT pencil ion chamber no longer covers the <u>entire tail portion of the single slice profile</u>

Figure 1
Comparison of Effective Dose determined by the DLP method vs Direct Measurement with MOSFET technology and an Anthropomorphic Phantom



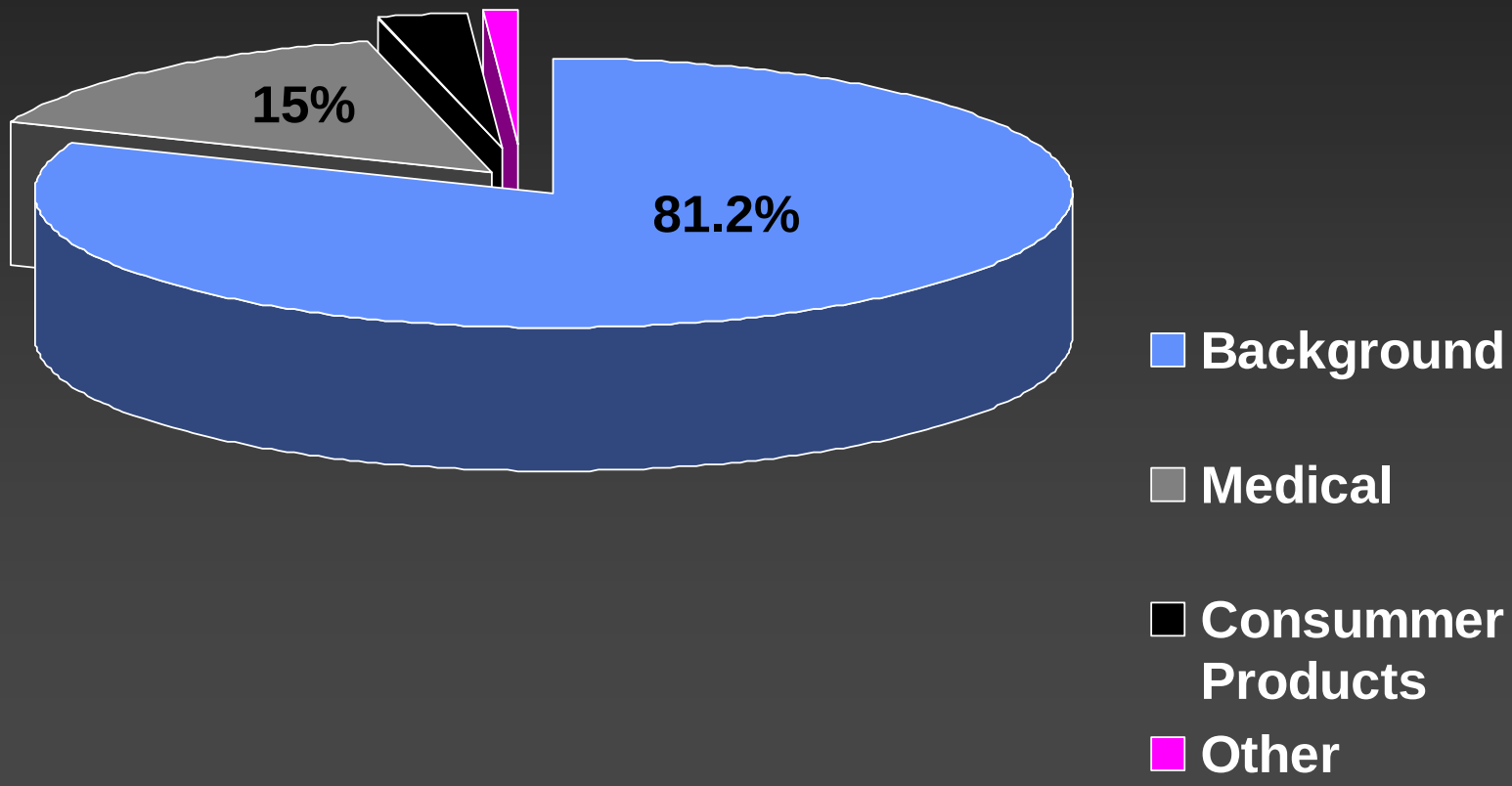
Black columns=DLP method determination
White columns=MOSFET method determination

Lynne Hurwitz MD in press JCAT

Typical Radiation Doses (mSv)

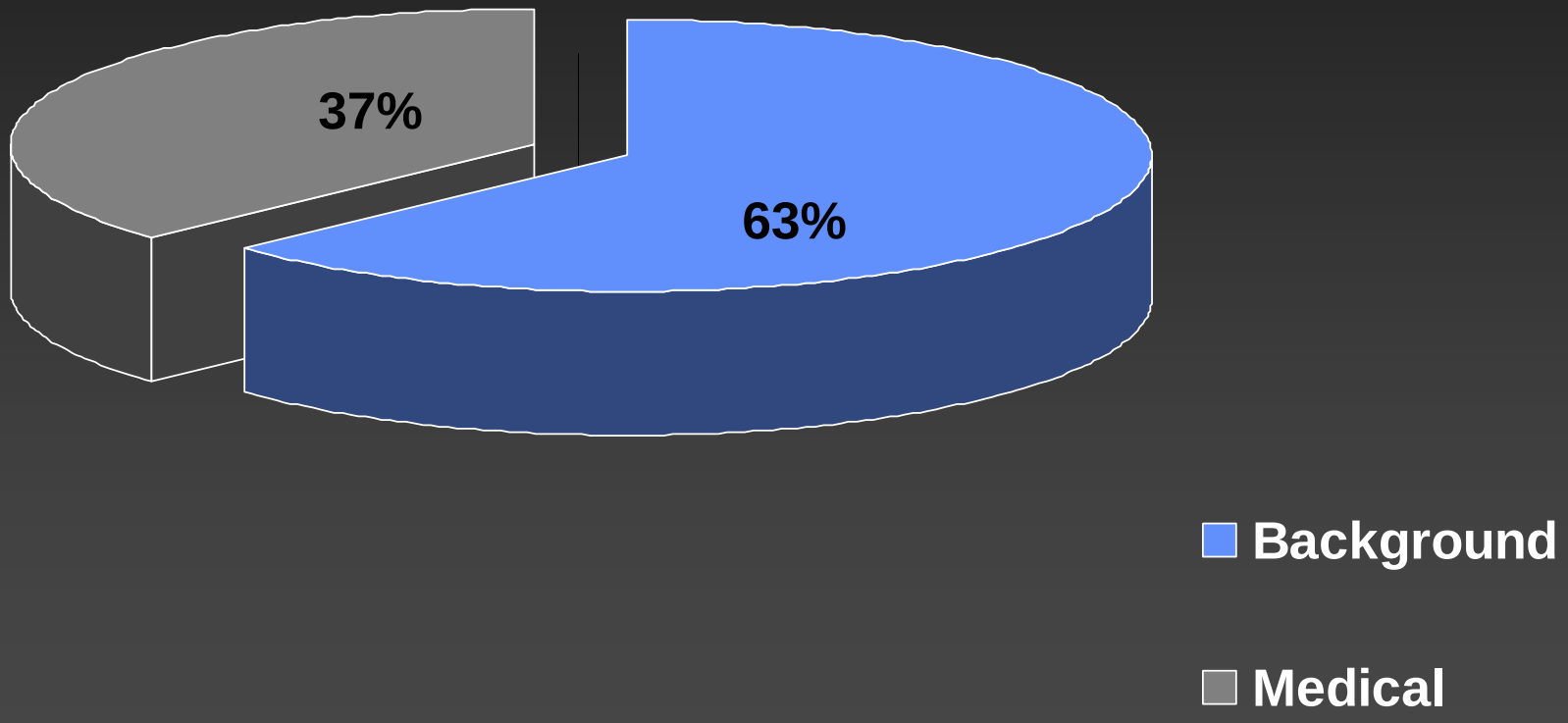
• Average annual technician dose	3.2
• Natural background (Denver)	3.5
• Dental x-rays	.09
• BE (marrow)	8.75
• CXR (marrow)	.01
• Mammogram (breast)	.5 - 7.0
• Airline passenger	.03
• Flight crew / attendants	1.6
• CT	*< 1.0 – 30 mSv*

Estimated Annual Radiation Exposure



Kimball's Biology; NCRP

Estimated Annual Radiation Exposure



Pediatric CT Doses *Higher*?

- **Unfamiliarity with**
  - pediatric disorders
  - normal variations
  - growth
  - complicated equipment
- **Few guidelines, no regulation**
- **Most pediatric imaging**
  - not in academic centers
  - not by subspecialists

Noise is greater concern…
default to higher dose?

64-slice MDCT

	ED (mSv)	SD (mSv)
Chest with modulation	3.05	0.14
Chest w/o modulation	3.05	0.14
Chest Extreme	42.95 !!!	0.55
Abdomen with modulation	7.32	0.33
Abdomen w/o modulation	6.34	0.35
Abdomen Extreme	118.9 !!!	1.85

CT: Patterns of Use

- 30 - 65 million examinations in U.S.
- Up to 7,000,000 pediatric CT examinations per year
- One CT for every 3.5 individuals in U.S. per year

Pediatric Body MDCT Technique

- Size adjusted
- Single phase
- Lower mA
- Lower kVp

Tube Current Modulation

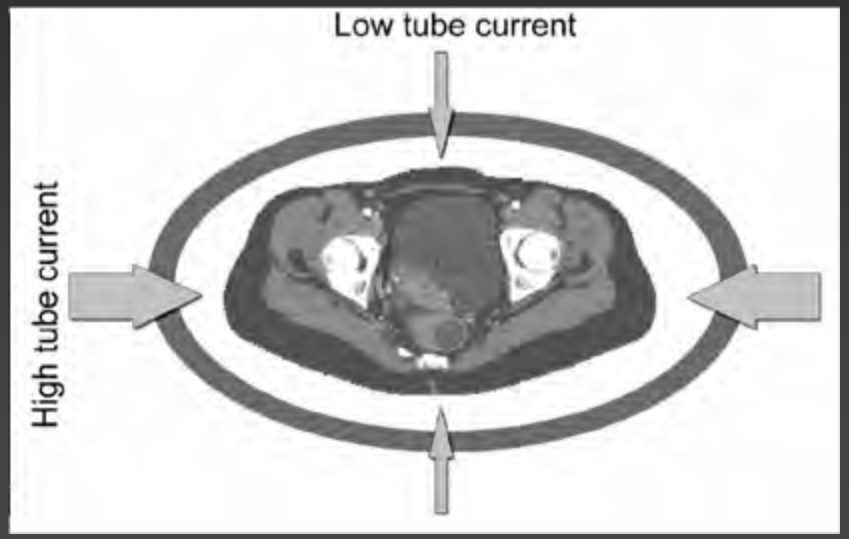
Manufacturer	Product Name	Method	Requires Scout
GE Healthcare	Smart Scan	x,y axis	No
GE Healthcare	Auto mA	z axis	Yes
GE Healthcare	Smart mA 3D	x,y,z axis	Yes
Philips	DOM	x,y axis	No
Philips	Z-DOM	x,y,z axis	Yes
Siemens	Care Dose	x,y axis	No
Siemens	Care Dose 4D	x,y,z axis	Yes
Toshiba	Real E.C.	z axis	Yes
Toshiba	Sure Exposure	x,y,z axis	Yes

McCollough et al. RadioGraphics 2006; 26:503-512

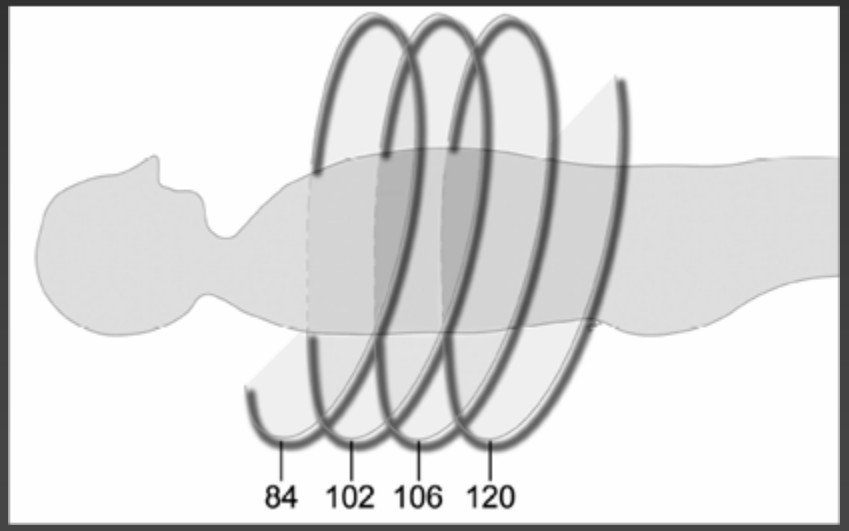
Tube Current Modulation

in pediatric applications, up to 60% dose reduction

Angular (x, y)



Z-axis



Kalra et al. Radiology 2004; 233:649-657

Pediatric CT: Clinical Considerations

- Dose and quality must be balanced
- Quality may be different in children
- Understand parameters
- Employ strategies for optimization

Diagnostic Reference Levels: ICRP Guidance

M. Rosenstein

NCRP Annual Meeting

April 16, 2007

First:

Some Historical Background

ICRP 60 (1991)

“Consideration should be given to the use of dose constraints, or investigation levels, selected by the appropriate professional or regulatory agency, for application in some common diagnostic procedures. They should be applied with flexibility to allow higher doses where indicated by sound clinical judgment.”

ICRP 73 (1996)

Diagnostic reference level

Advisory; form of investigation level

Diagnostic radiology & nuclear medicine

Selected by professional medical bodies

Percentile; specific to country or region

Easily measured quantity

Diagnostic Reference Level

Applied to a group of patients (or a phantom) that represents a standard-sized patient

Not applied to an individual patient!

Lots of Names & Some Different Aims

Diagnostic reference level [ICRP; EC; NRPB (UK)]
Patient exposure guide [CRCPD (US)]
Guidance level [IAEA]
Reference dose [NRPB (UK)]
Achievable dose [NRPB (UK)]
Reference dose value [EC]
Reference value [AAPM (US)]

Reference dose level [IPSM (UK)]
Maximum usual activity [ARSAC (UK)]
Limiting value [EC]
Suspension level [NRPB (UK)]
Dose limit [FDA (US)]

Lots of Quantities Used

Radiographs [ESD, ESAK, ESE & DAP]

Dental [PED & DWP]

Fluoroscopy rate [ESD rate, ESE rate & ESAK rate]

Radiology Examinations [DAP]

Computed Tomography [MSAD, CTDI, $CTDI_W$ & DLP]

Mammography [ESD, ESAK, AGD & MGD]

Nuclear Medicine [A]

Developed by Protection Authorities & Professionals

Diagnostic x-ray:

From distributions in region or country

Nuclear medicine:

From values based on accepted custom & practice

IPSM National Protocol [UK] (1992)

Reference dose levels

Radiographs & examinations

Rounded 3rd quartile values (UK surveys)

Average for 10+ adult patients (~70 kg)

"…could be construed as dose constraints that have been set at the national level."

IAEA Basic Safety Standards (1994)

Guidance levels

Radiographs; CT; mammography; fluoroscopy; nuclear medicine

Derived from wide-scale surveys for adults

Corrective actions if doses outside levels

NRPB Guidance [UK] (1999)

Reference doses (radiology)

Diagnostic reference levels (nuclear medicine)

Achievable doses (radiology)

Suspension levels (screening mammography)

EC Guidance (1999) [investigation level]

Diagnostic reference levels

Radiographs & fluoroscopy: average for 10+ adult patients (~70 kg); 3rd quartile

Mammography: for a standard phantom

Nuclear medicine: administered activity needed for good image; optimum values

EC Quality Criteria Reports (1993-1999)

Reference dose values (investigation)

General radiography; mammography; pediatric; CT

3rd quartile (European surveys)

Tied to diagnostic requirements, image criteria and good radiographic technique

Example: Urinary Tract; AP plain film (no contrast)

Image criteria

Reproduce urinary tract & kidney

Visualize muscle outlines & bones

Image calcifications of 1.0 mm

Good radiographic technique

Reference dose value: 10 mGy ESD

FDA Regulation [US] (1997)

Dose limit!

Mammography: CC view, phantom, clinical specs for standard breast, AGD

Adapted from ACR quality manual

Extensive regulatory program

MAMMOGRAPHY [values in mGy]	EC 1999	IAEA 1994	NRPB 1999	EC 1993	FDA 1997
LAT Breast	10				
MLO Breast	10		*3, 2, 1.5		
CC Breast	10		*3, 2, 1.5	12, 11, 2.3	[3]
Screen-film (no grid)		1			
Screen-film (grid)		3			
	ESD	AGD	MGD *Suspension level, Reference dose, Achievable dose	ESD, ESAK, AGD	AGD [Dose limit]

AAPM [US] (2005) [Radiol. 235:354]

Reference values (adults)

Radiographs (medical & dental)
Computed tomography; fluoroscopy rate

~ 80th percentile [U.S. surveys (NEXT)]

Voluntary use; not for regulatory purposes

Investigation levels have been applied in three distinct ways:

To triage outliers
To attain good practice
To attain optimal practice

ICRP Committee 3 guidance embraces all three

Second:

The ICRP System of Radiological Protection

As applied to medical exposure of patients

ICRP Radiological Protection Principles (Jan. 12, 2007 Draft):

Justification

Optimization of protection

Application of dose limits

Justification … 3 Levels

1st … societal

2nd … type of procedure

3rd … individual patient

Optimization of Protection

Dose constraint: inappropriate

Dose management still needed

[commensurate with medical purpose]

Application of Dose Limits

Not recommended:

may do more harm than good

Necessary clinical information for patient's health care

Medical Exposure of Patients

Emphasis

Justification of medical procedures

Optimization of protection

Third:

Current ICRP Committee 3 Guidance (Diagnostic Reference Levels)

Supporting Guidance 2
(Annals of the ICRP) [31(4) 2001] [p. 33-52]

Committee 3 Draft Building Block (Jan. 12, 2007)

Clinical Objective

Achieve acceptable image quality or adequate diagnostic information, consistent with medical imaging task

Radiological Protection Objective

Manage radiation dose to be commensurate with clinical task

Avoid radiation dose that does not contribute to medical imaging task

Uses

To **improve observed distribution**…
general medical imaging task

To **promote narrower range**…more
specific medical imaging task

To **promote optimum range**…
specified medical imaging protocol

Definitions

General medical imaging task

General clinical purpose

More specific medical imaging task

Defined clinical purpose; differences among facilities in details

Specified medical imaging protocol

Fully defined set of specifications

Examples: To improve distribution [general medical imaging task]

A radiographic projection (e.g. PA chest)

Entrance surface air kerma (no backscatter), or

Entrance surface dose (with backscatter) … mGy

A fluoroscopic examination (e.g. barium enema)

Well-defined anatomical region

Dose area product … mGy cm^2

Ex: To promote narrower range [more specific medical imaging task]

CT exam (e.g. routine abdomen scan)

Well-defined anatomical region
Dose length product … mGy cm

Specify clinical objective, image quality criteria & technical factors

CT systems may vary among facilities

Example: To promote optimum range [specified medical imaging protocol]

A CT protocol

Milliampere second … mAs

A nuclear medicine protocol

Administered activity … MBq

Define purpose, equipment, technique factors & patient characteristics

What about fluoroscopically (or computed tomography) guided interventional procedures?

For stochastic risks: Yes (in principle) ... but difficult to implement

For deterministic risks (e.g. skin injuries):

Not applicable ... see ICRP 85

(Annals of the ICRP) [30(2) 2000]

Flexible Application

Local objective defined; clinical and technical specifications defined

Value based on regional, national or local data

Measured quantity specified & practical

Illustrated by example

Capturing Patient Doses from Fluoroscopically Based Diagnostic and Interventional Systems

Presented at NCRP's Annual Meeting
APRIL 2007

Stephen Balter, Ph.D.

Columbia University Medical Center, New York, New York

Historical dose recording

- Non regulatory recommendations for dose recording
  - In some form since early 20th century
  - FDA Radiation "Passport" (circa 1970)
  - SIR Standard of practice (2004)
- Interventional
  - FDA Recommendation (1994):Record skin dose and location
  - IEC 60601-2-43 (2001): KAP and Dose at Reference Point
  - FDA Regulations (2005): Dose at Reference Point (new fluoroscopic equipment)
- DICOM MPPS Report (1996)
  - Assumes RIS and linkages
- EURATOM Directive (1997)
  - National Dose Recording Regulations
  - Primarily KAP (Stochastic Risk Concerns)
  - No formal scheme for recording
  - Space available in DICOM Headers

Why capture dose data?

- Patient risk supervision
  - Stochastic
  - Deterministic
- Quality Assurance
  - Departmental vs. Guidance Levels
  - Local deviations
    - Equipment
    - Operators

How much to capture?

- Stochastic risk to the population
  - Collect everything
  - Sampling
- Deterministic injury potential
  - Collect data on every procedure where injury is possible
- Quality Assurance
  - Collect everything?

Data elements

- Direct dose measurements
- Technical settings of equipment
- Irradiation geometry
- Patient and procedure data

Modalities

- Radiography and Fluoroscopy
  - Closed system with digital image capture
  - Independent image receptor with CR or DR
  - Film/screen image receptor
- Dental Radiography
  - DR image receptor
  - Film image receptor
- Computed Tomography

Interventional procedures

- Stochastic risks
  - Second largest contributor to patient effective dose
  - Open questions regarding radiation risk of the patient population (age, life expectancy)
- Deterministic injury
  - Almost all modern injuries attributed to fluoro guided interventions
  - Frequency may increase due to changes in medical practice
    - Relative risk vs. alternatives (Increased interventions)
    - Clinical complexity (Increasing dose per procedure)
    - Technology improvements (Decreasing dose per procedure due to improvements in equipment, medical devices, and clinical technique)

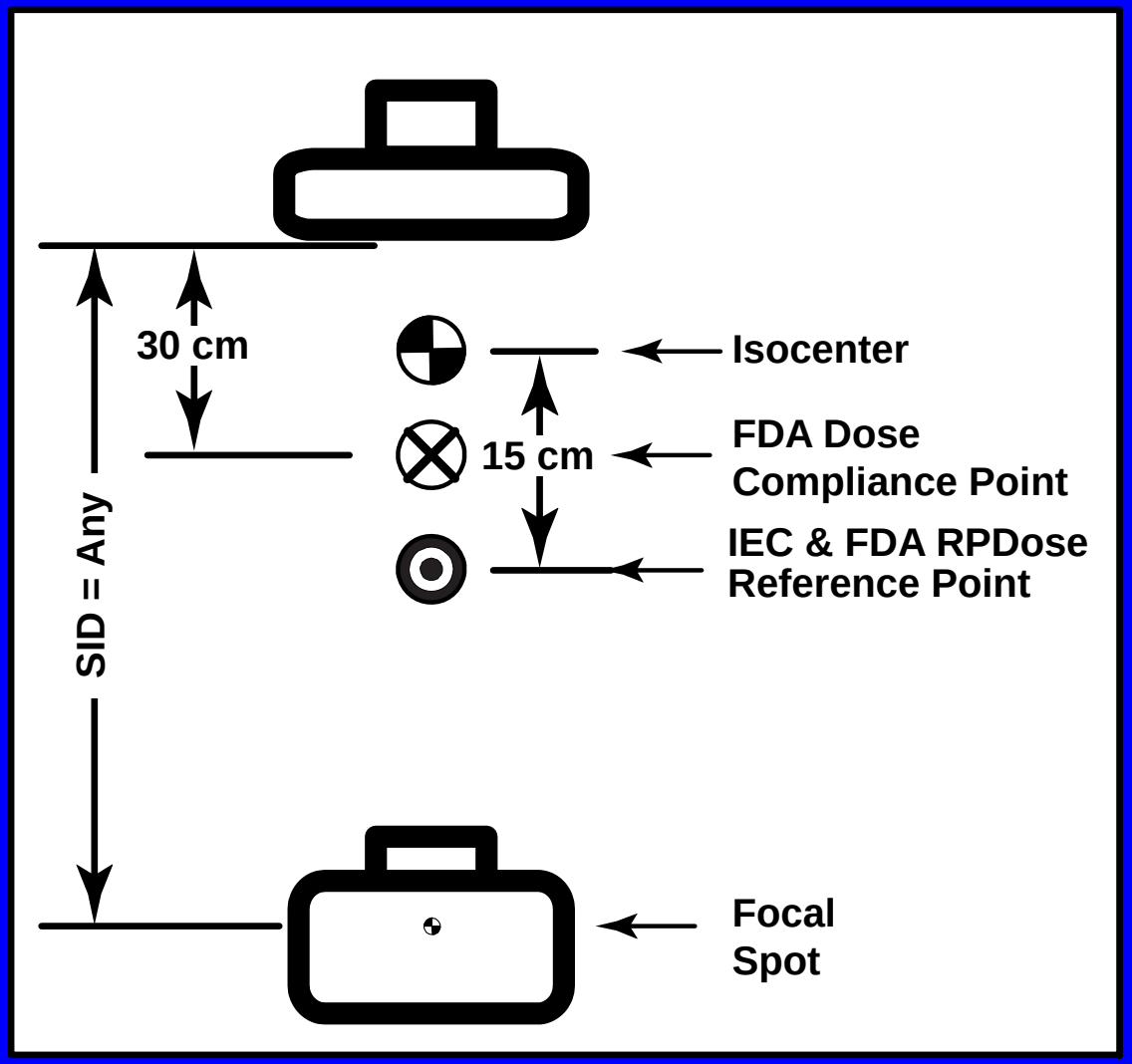
Technology - 2007

- All images via common digital video channel
- Feedback loop for Automatic Dose Rate Control (ADRC)
- Copper spectral shaping filters
- (Flat detector)
- IEC 60601-2-43

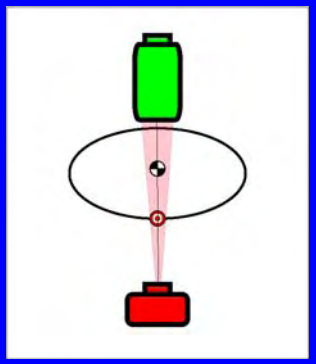
Available dose metrics

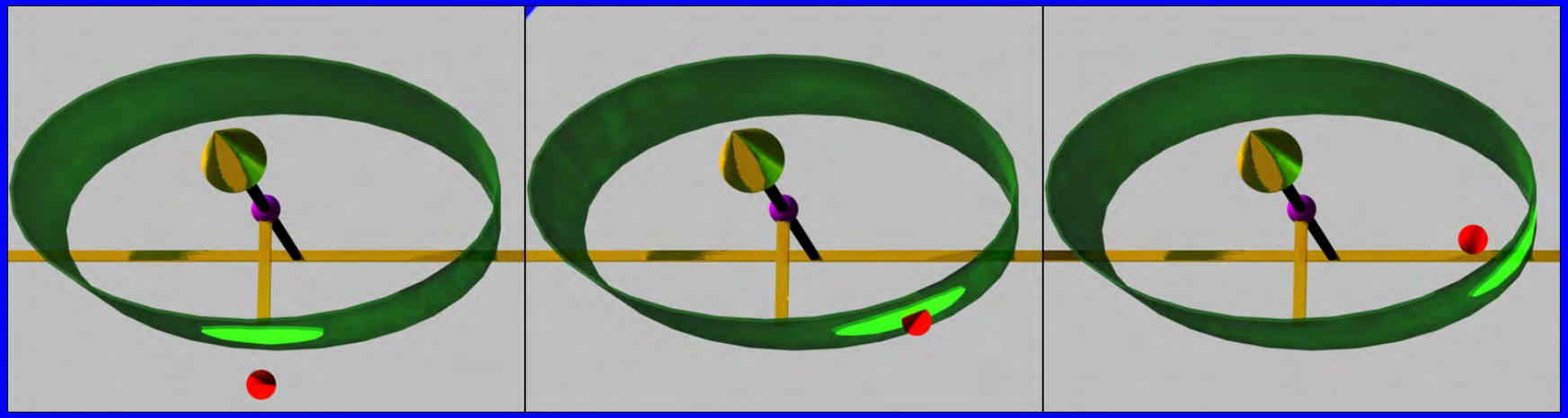
- Reference Point Dose (RPDose)
  - IEC 60601-2-43 (2000)
  - FDA (2005)
- Kerma Area Product (KAP)
  - IEC 60601-2-43 (2000)
  - Common in Europe
- Fluoroscopy Time
- ~~Skin Dose Maps~~

Dose reference point



Reference point ≈ skin





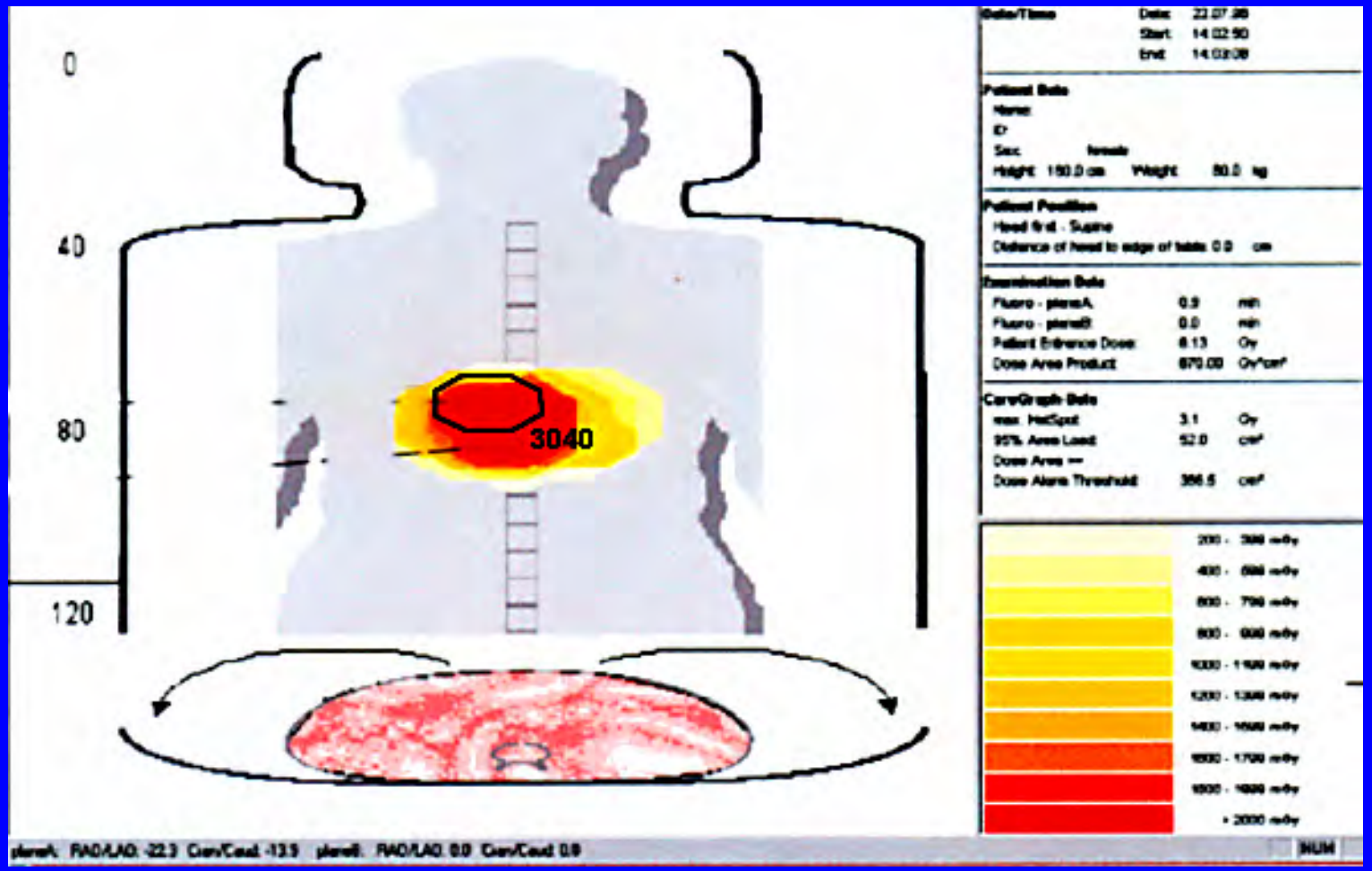
Reference Point Dose (RPDose)

- Total air kerma accumulated at the reference point from the beginning of the procedure. (called “cumulative dose” in the regs)
- Displayed to operators at the working position.
- Measured free in air.
- Table top and mattress attenuation?
  - Not standardized in either document.
  - Propose measurement without attenuation unless the attenuators are always in the beam.

Kerma Area Product (KAP)

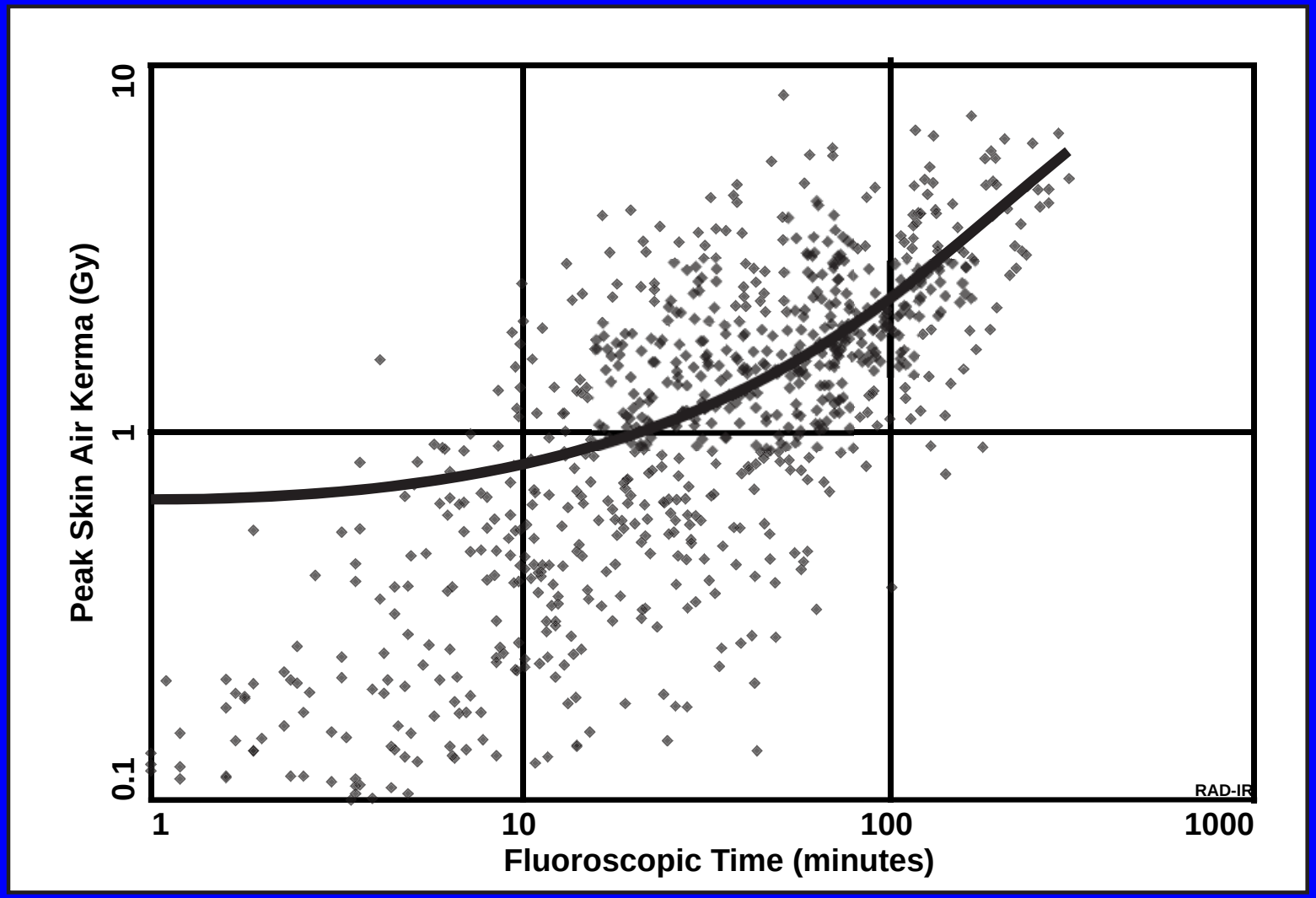
- Total KAP accumulated from the beginning of the procedure.
- Displayed to operators at the working position.
- Can be used to estimate RPDose (need to know field size at reference point)
- Measured free in air
- Table top and mattress attenuation?
  - Not standardized in either document
  - Propose measurement without attenuation unless the attenuators are always in the beam.

Skin dose mapping

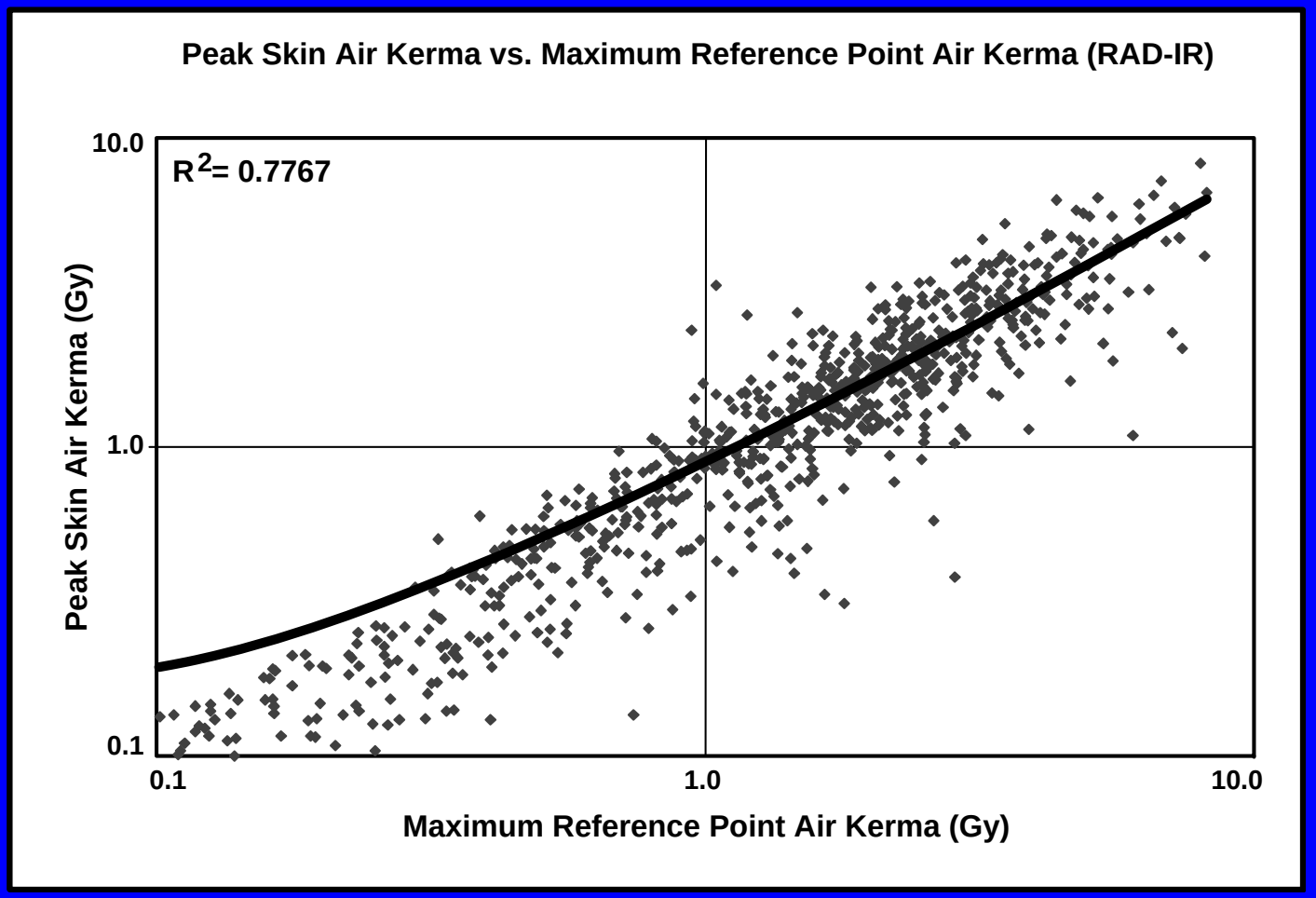


Illustrations courtesy of Siemens

Fluoroscopy time



RPDose



Data collection

- Manual
- Third party add-on
- Equipment internal service log
- DICOM
  - Header data
  - MPPS reports
- DICOM-DOSE reporting

DICOM-DOSE Project

- DICOM Limitations
  - Data is bound to DICOM digital images.
  - DICOM MPPS process needs tight coupling to an informatics system
- Project
  - The need for complete documentation of interventional procedures was presented to the IEC (62b MT38) by DIMOND
  - Co-developed with DICOM committee
  - Initial version covers all projection radiography and fluoroscopy (except mammography).

Milestones

03 Initial white paper by IEC 62b MT38

04 Informal discussions between chairs of IEC MT38 and DICOM Working Group 2

05 NOV: DICOM Supplement 94 Approved

07 JAN: IEC PAS and NWI submitted for vote

08 Commercial Implementation and Availability

Extensions

- Mammography: Should be rapid
- CT: Debate on what should be recorded

DICOM Supplement-94 Concepts

- Radiation Dose Structured Report (RDSR) introduced as a new DICOM object
- ACTORS (IHE) capable of managing RDSR can exist anywhere
  - RIS
  - PACS
  - Stand Alone
  - Non Networked
- This supplement was added to the DICOM standard in 2005

RDSR Outputs

- **Near Real Time**
  - Updated RDSR can be transmitted over network after each irradiation
- **Post Procedure**
  - Complete RDSR transmitted over network once procedure is marked as complete
- **Sneaker Net**
  - RDSRs stored in imaging system extracted on storage media and physically carried to AGENT
  - Present IEC draft requires storage of at least 500 RDSRs with or without network connections
- **ACTOR LOCATIONS**
  - PACS, RIS, Independent

RDSR Concepts

- EVERYTHING IN PUBLIC FIELDS
- Patient, Exam, and Facility Information
  - Existing DICOM processes provide deidentification when needed
- Generator and Dose Meter Information
- Captures all irradiations associated with a procedure (irrespective of image storage)
  - Procedure level summary data
  - Individual irradiation detailed data
- Allows value added post processing
  - Skin Dose Mapping
  - Patient totals over multiple procedures

RDSR Overview

RDSR Header **Status**

- Patient, Facility, Exam Descriptors
- System Descriptors (including calibration)
- Dose Summaries

IRRADIATION EVENT **Image UID**

- Generator Factors
- Beam Geometry Descriptors
- Dose Detail

Single Image Exam

RDSR Header **Complete**

- Patient, Facility, Exam Descriptors
- System Descriptors (including calibration)
- Dose Summaries

IRRADIATION EVENT **Image UID**

- Generator Factors
- Beam Geometry Descriptors
- Dose Detail

Multiple Irradiation Procedure 1

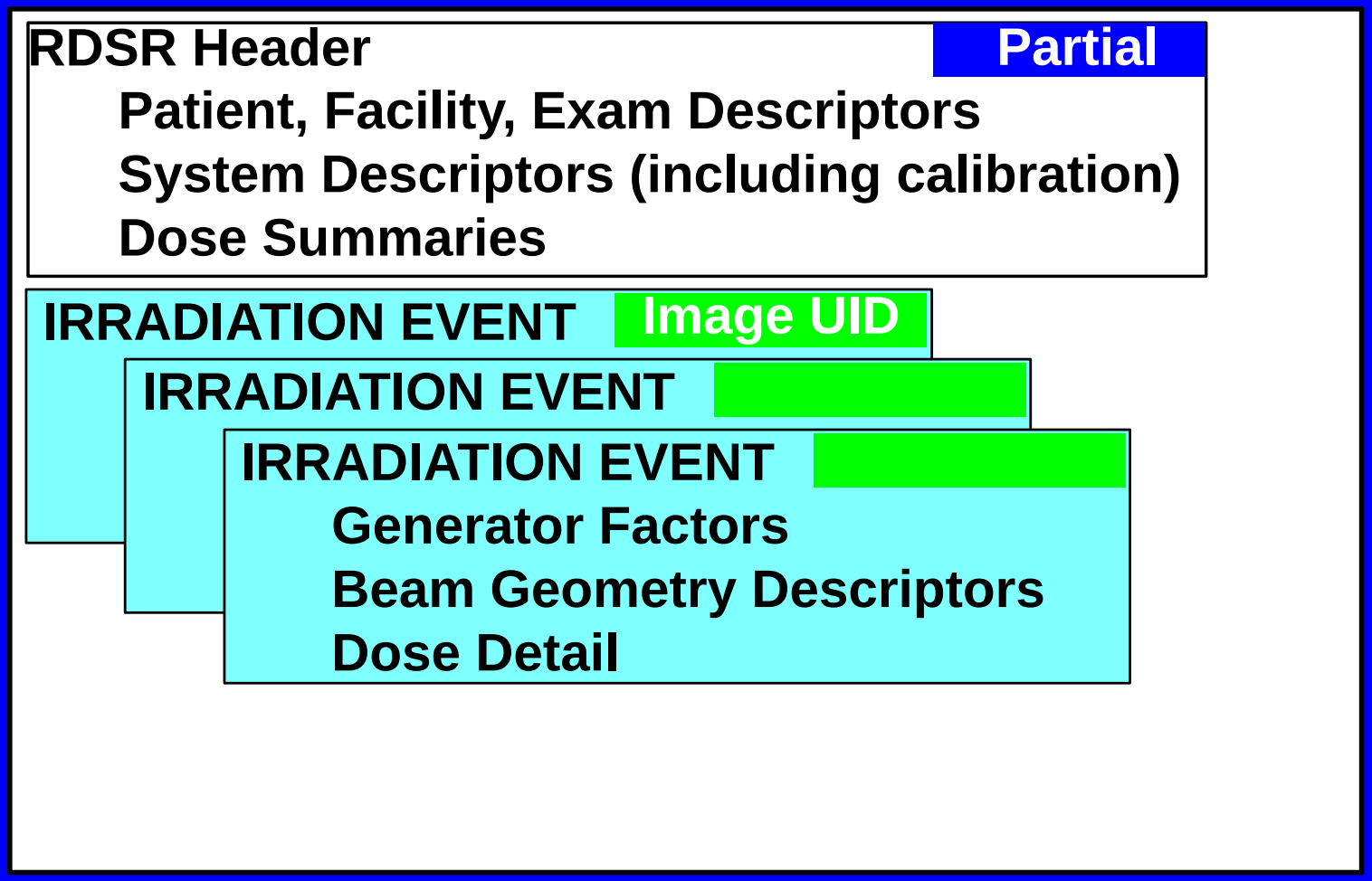
RDSR Header **Partial**

- Patient, Facility, Exam Descriptors
- System Descriptors (including calibration)
- Dose Summaries

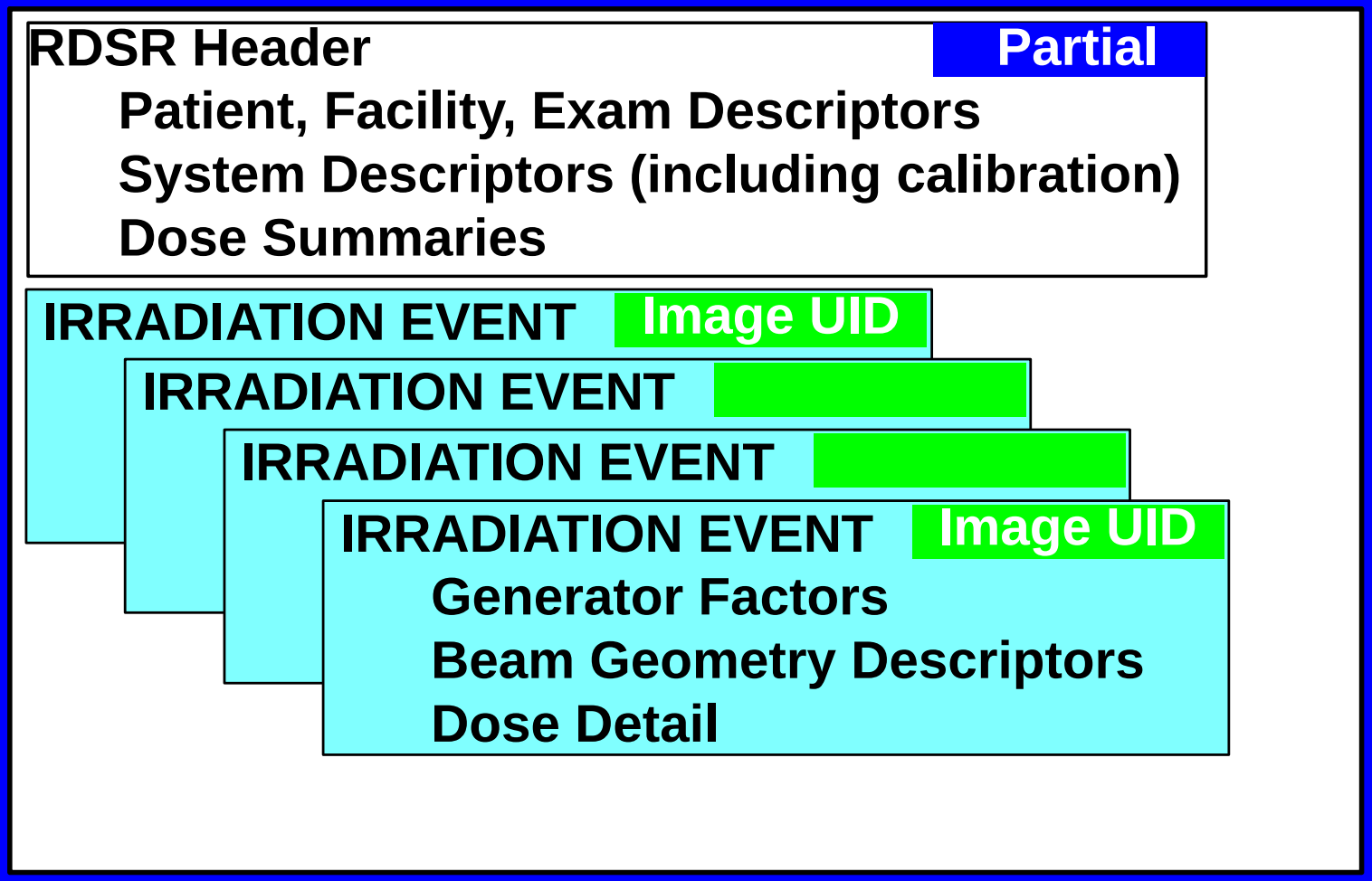
IRRADIATION EVENT **Image UID**

- Generator Factors
- Beam Geometry Descriptors
- Dose Detail

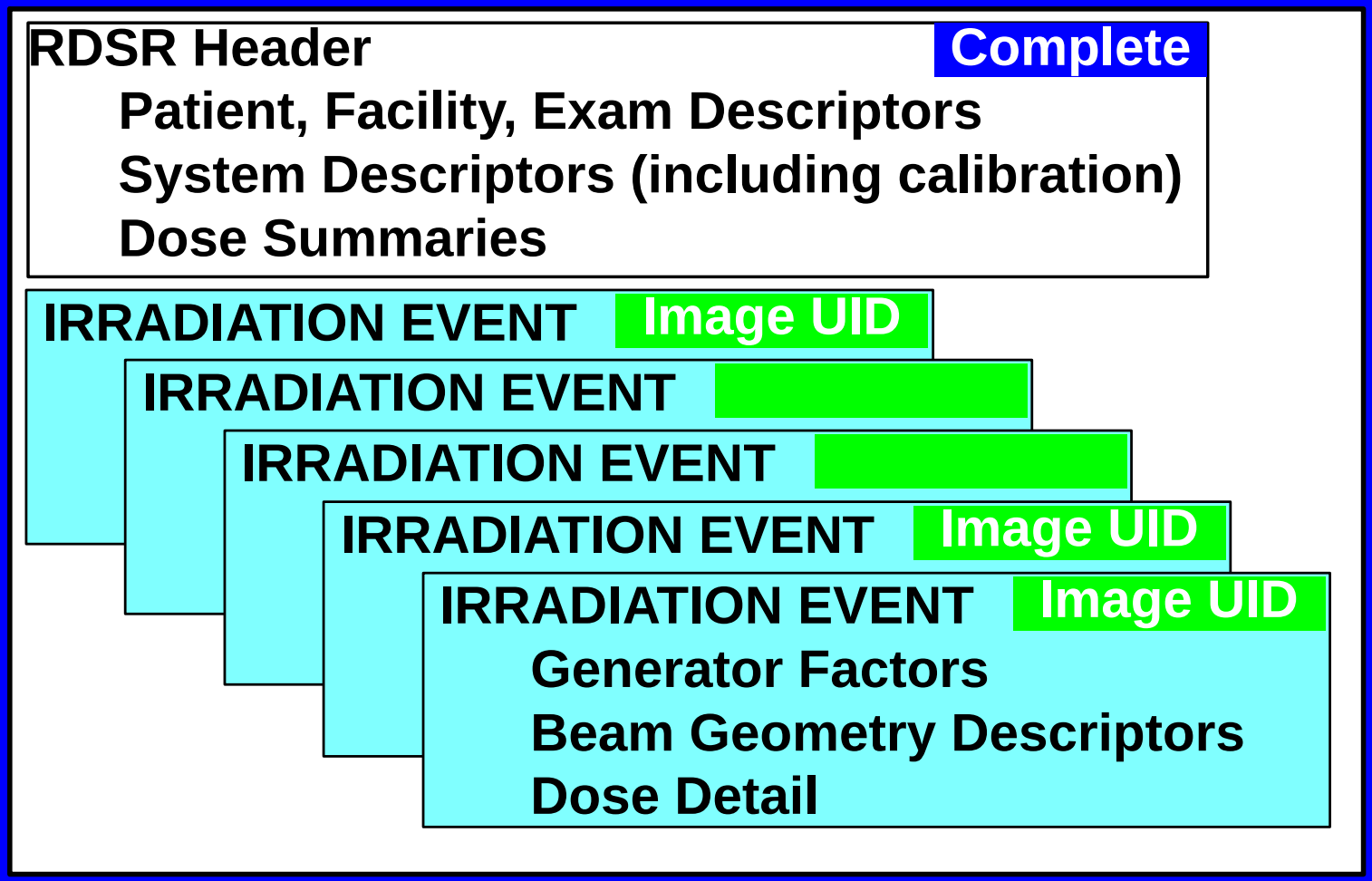
Multiple Irradiation Procedure 2



Multiple Irradiation Procedure 3



Multiple Irradiation Procedure F



IEC Overview

- Claimed compliance with an IEC standard assures minimum requirements
- IEC Compliance Levels

  Based on maximum expected cumulative Air Kerma at the IEC interventional reference point for any normal use of the equipment

  1: Stochastic Risk Only (< 2 Gy expected)

  2: Deterministic Injury Conceivable (> 2 Gy)

  3: Deterministic Injury Possible (> 7 Gy)

  Presently a place-holder in the standard

  Implementation planned when adequate dose-mapping software is available

IEC Level 1

Equipment where the estimated maximum cumulative Air Kerma for any examination (study) is expected to be less than two (2) gray (Gy) for all normal uses

The defining dose is the cumulative dose for a complete examination at the interventional reference point defined in IEC 60601-2-43 (for equipment capable of measuring Air Kerma at this point or

The equipment manufactures estimate of the cumulative dose for a complete examination at the closest point to the X-ray source where the patient's skin might be placed

IEC Level 2

Equipment where the estimated maximum cumulative Air Kerma for any examination (study) is expected to be more than two (2) gray (Gy) for any normal use

The defining dose is the cumulative dose for a complete examination at the interventional reference point defined in IEC 60601-2-43 (for equipment capable of measuring Air Kerma at this point or

The equipment manufactures estimate of the cumulative dose for a complete examination at the closest point to the X-ray source where the patient's skin might be placed

IEC Level 3 – Placeholder for now.

- ***Equipment where the estimated maximum cumulative Air Kerma for any examination (study) is expected to exceed seven (7) gray (Gy) for any normal use***

Not only stored digital images

- The RDSR is a DICOM object that is independent of any stored images
- Valid RDSRs can be generated by equipment used to produce stored or not-stored analog or digital images
- IEC proposes that RDSRs be stored by the imaging equipment (downloaded locally or via a network)

Verification of displayed “dose”

- Accuracy of display
  - IEC ± 50% (RPDose &KAP)
  - FDA ± 35% (RPDose)
  - Stability usually better
- Usually validated at factory
- Seldom validated by installers
- When verified as part of QA
  Should be able to maintain ± 20%

Uniform implementation date

- Technology items
  - Most elements already exist as internal service data.
  - Little or no added hardware needed.
  - Software service updates for installed base usually occur 1 – 2 times a year.
- Scheduled implementation benefits
  - Clinical community
  - Health monitoring agencies
  - Manufacturers
  - Patients
- Propose a mid 2008 implementation date.

Dose management technology

- Adequate data available now (2007)
- Automated management soon
- Implementation
  - DICOM & IEC documents available
  - Manufacturers have to implement
  - Professionals need to adopt
  - Regulatory requirement ?
- Value for money

Update on Linear Nonthreshold Dose-Response Model and Implications for Diagnostic Radiology Procedures

R. Julian Preston

U.S. Environmental Protection Agency

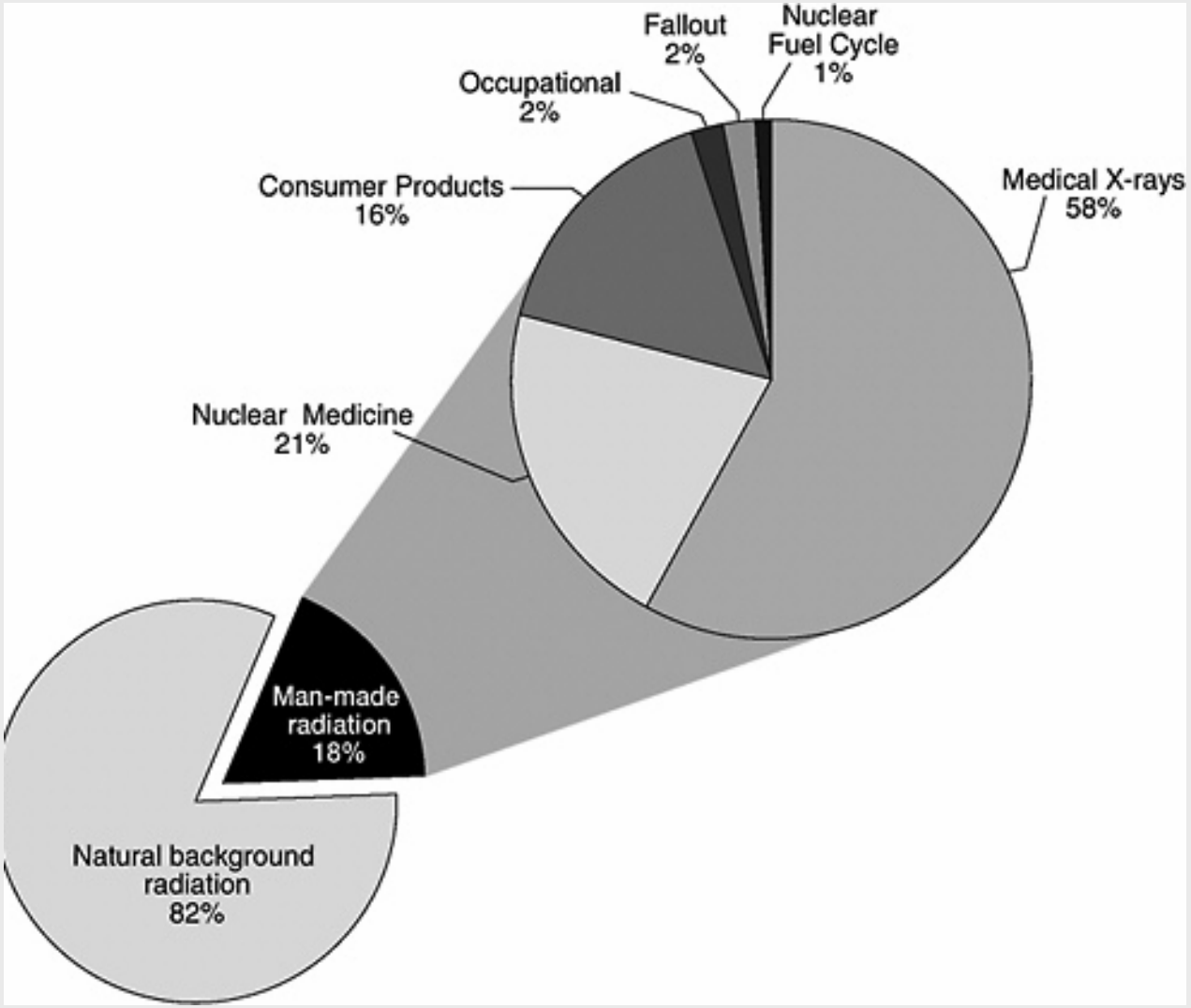
Research Triangle Park, NC

NCRP Annual Meeting 2007

Topics

- LNT and BEIR VII, ICRP and Cancer Risk Estimates
- Dose and Dose-Rate Effectiveness Factor (DDREF)
- Research Needs
- CT Screening as an Example of Applying Risk Estimates

Background and Man-Made Radiations



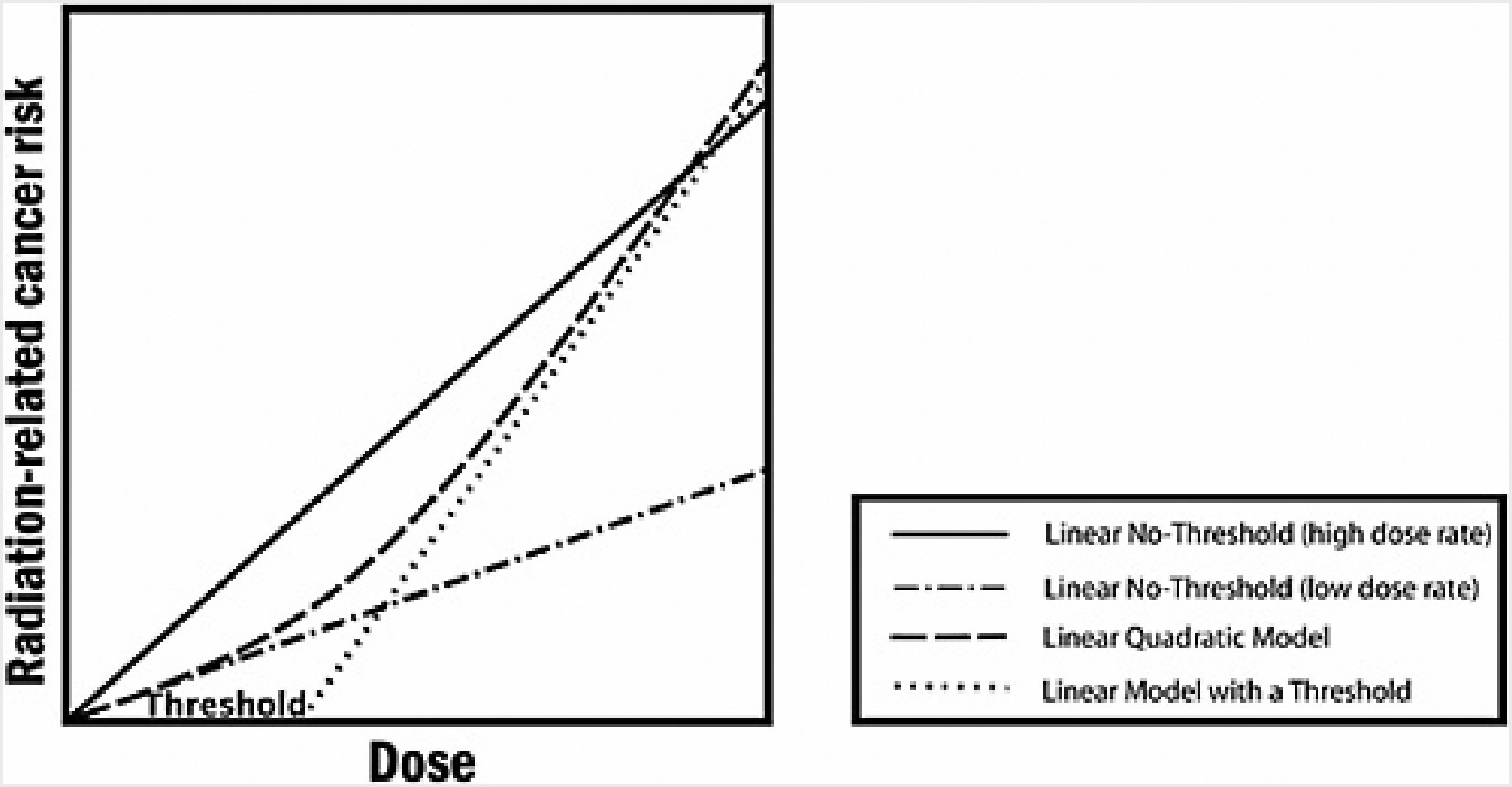
BEIR VII, NAS, 2006

TABLE 7-1 Estimated Range of Effective Doses from Diagnostic Radiation Exposures

Procedure	Type of Examination	Range of Doses
Conventional simple X-rays	Chest films X-rays of bones and skull X-ray of abdomen	0.02–10 mGy
Conventional complex X-rays	GI series Barium enema Intravenous urogram	3–10 mGy
Computed tomography (CT)	Head injuries Whole-body examinations	5–15 mGy
Spiral CT	Head injuries Whole-body examinations	10–20 mGy
Angiography	Coronary, aortic, peripheral, carotid, abdominal	10–200 mGy
Interventional procedures	Angioplasties with stent placement Percutaneous dilatations, closures, biopsy procedures	10–300 mGy
Internal emitters	Radioisotope studies	3–14 mSv

From BEIR VII

Linear Nonthreshold Model



From BEIR VII, NAS, 2006

Dose and Dose-Rate Effectiveness Factor (DDREF)

DDREF – A judged factor by which the radiation effect, per unit of dose, caused by a given high or moderate dose of radiation received at high dose rates is reduced when doses are low or are received at low dose rates.

What's New?

For the purpose of this particular presentation, there are four significant new reports that address the issue of LNT and radiation risks:

- Health Risks from Exposure to Low Levels of Ionizing Radiation – BEIR VII Phase 2 (2006)
- ICRP Report 99 – Low-Dose Extrapolation of Radiation-Related Cancer Risk (2005)
- Tubiana M et al. Dose-effect relationships and estimation of the carcinogenic effects of low doses of ionizing radiation, Institut de France Academie des Sciences (2005)
- ICRP 2007 Recommendations and Associated Annex on Biology and Epidemiology

Radiation Cancer Risk Estimates

The need is to estimate the lifetime risk of cancer resulting from any specified dose of ionizing radiation. The use (within the US) is to apply these estimates to exposure scenarios for groups within the US population. In addition, these risk estimates are used to establish radiation protection standards for the public and for occupationally exposed persons.

Data Sources

As for previous risk models, BEIR VII placed its reliance on the data for the Japanese atomic bomb survivors. The new information was the DS02 dosimetry and the cancer incidence data. Previously, mortality data were used. Incidence data have the advantage of including nonfatal cancers and of better diagnostic accuracy. Additional data for tumors following occupational and medical exposures were largely used to evaluate whether the conclusions from these studies were compatible with the atomic bomb survivor risk estimates.

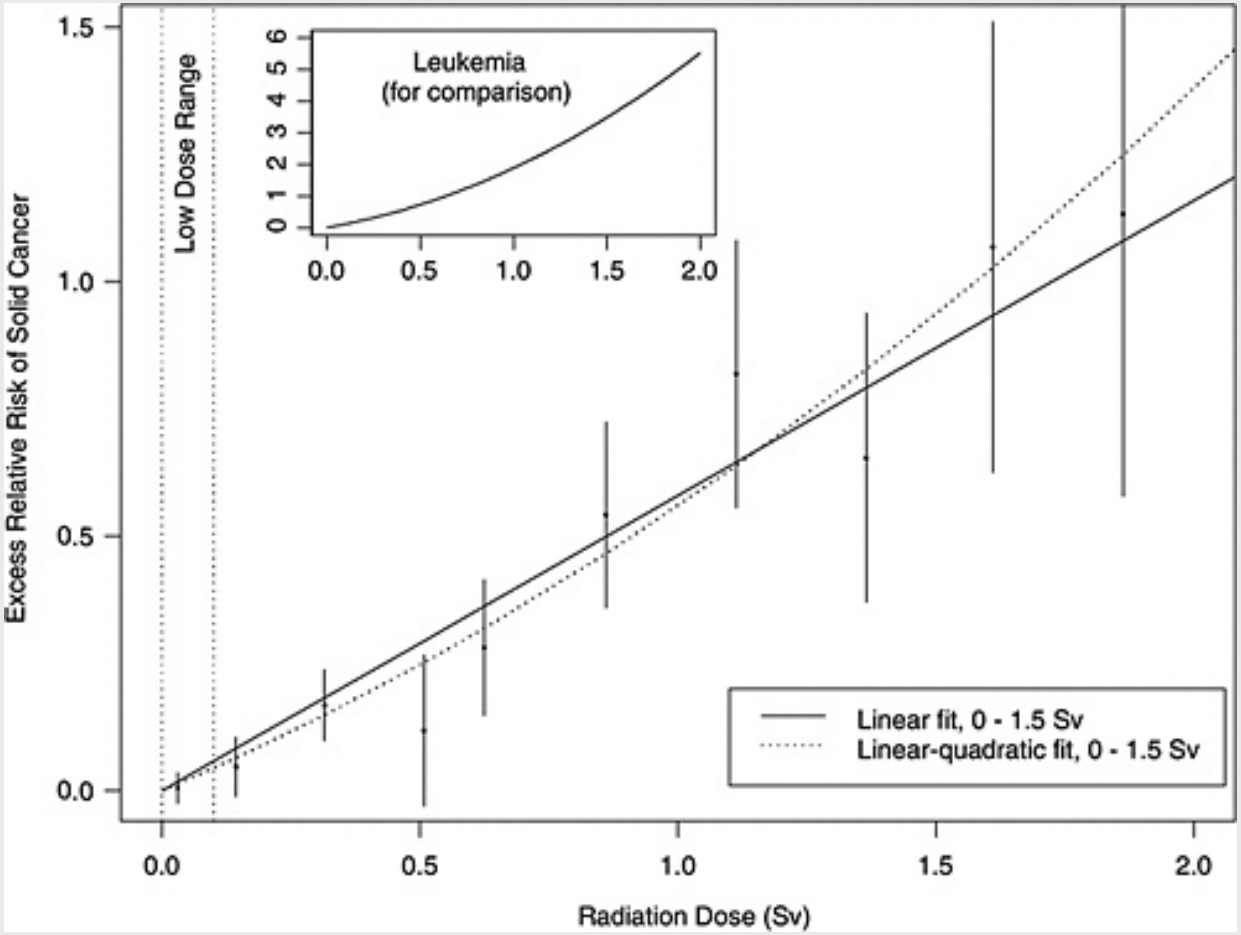
New Risk Estimates (I)

Overall, the magnitude of estimated risks for total cancer mortality or leukemia did not change greatly from estimates in past reports (BEIR V) or from UNSCEAR and ICRP estimates.

Risk Estimates (II)

For detriment-adjusted cancer incidence, the new estimates (ICRP 2007) are 5.5% per Sv for the whole population (4.1% per Sv for adults). The use of DS02 made only a small change to the estimates (~7%). Again, these are similar to the previous BEIR and ICRP risk estimates that were based on mortality.

These estimates are broadly in line with those obtained from the Cardis et al. (2007) study for low dose rate exposures in radiation workers in the nuclear industry.



Estimated ERR of solid cancers for Japanese atomic bomb survivors. Plotted points are estimated based on solid cancer incidence (averaged over sex and standardized to represent individuals exposed at age 30 who have attained age 60).

From BEIR VII

Conclusion on Risk Estimates

The difference between the linear and linear-quadratic models in the low-dose ranges is small relative to the error bars. For solid cancer incidence the linear-quadratic model did not offer a significant improvement in fit, and so the linear model was used. For leukemia, the linear-quadratic model was used since it fitted the data significantly better than the linear model.

Recommendation

- The BEIR VII Committee proposed that “current scientific evidence is consistent with the hypothesis that there is a linear, no threshold dose-response relationship between exposure to ionizing radiation and the development of cancer in humans”.

Research Needs

Does LNT either underestimate or overestimate the cancer risks at low doses? At present there is insufficient evidence for a role of these cellular responses in radiation carcinogenesis.

- There is a continued need to evaluate the relevance of adaptation, low-dose hypersensitivity, bystander effects, hormesis and genomic instability for radiation carcinogenesis.

DDREF

The BEIR VII Committee took a computational approach to the estimation of DDREF that was based on a Bayesian analysis of combined dose-response data. The Committee considered the following data sets: solid cancer incidence in the LSS cohort of Japanese atomic bomb survivors; cancer and life-shortening in animals; chromosome aberrations in human somatic cells.

DDREF

The BEIR VII Committee found a believable range of DDREF values for adjusting linear risk estimates from the LSS cohort to be 1.1 – 2.3. A value of 1.5 was selected for solid tumors.

ICRP proposes to continue to recommend a value of 2 while appreciating the need continually to consider lower values based on new research.

Radiation Risks and CT Screening

- Increasing interest in the use of full-body computed tomographic (CT) screening for healthy adults. Touted as having potential for early detection of a variety of diseases (e.g., lung cancer, coronary artery disease and colon cancer). Effectiveness is unclear. More attention paid to pros and cons of disease detection vs false-positive findings than to potential radiation risks.

Cancer Risks and CT Scans

Brenner and Elliston (2004) conducted an exercise to estimate the radiation-related cancer mortality risks associated with single and repeated full-body CT examinations by using standard radiation risk estimation methods.

Methods

Multiply estimated sex-, age- and organ-dependent lifetime cancer mortality risks (or detriment-adjusted cancer risks) by estimated organ doses. The resulting site-specific estimated cancer risks are summed to yield the overall lifetime cancer mortality risk (or detriment-adjusted cancer risk) estimates. These estimates are based on the LNT model.

Estimated Organ Doses for a Typical Full-Body CT Examination

Organ	Radiation Dose (mGy)
Thyroid	24.7
Bone surface	15.7
Esophagus	16.2
Lung	15.5
Stomach	14.4
Liver	14.0
Bladder	13.9
Breast (female)	12.3
Gonads (female)	12.2
Colon	11.6
Red bone marrow	9.9
Skin	7.5
Gonads (male)	2.6

Note.—Doses were estimated for a full-body CT examination with a Volume Zoom scanner (Siemens) operated at 120 kV and 230 true mAs with a pitch of 1.75. The examination was from the C3 vertebra through the symphysis pubis. Dose estimation was performed with the ImPACT CT patient dosimetry calculator (19). Note if a lower amperage setting is used, the doses would be proportionately lower. The total effective dose (weighted average of organ doses) is 13.5 mSv for females and 11.6 mSv for males.

From Brenner and Elliston, 2004

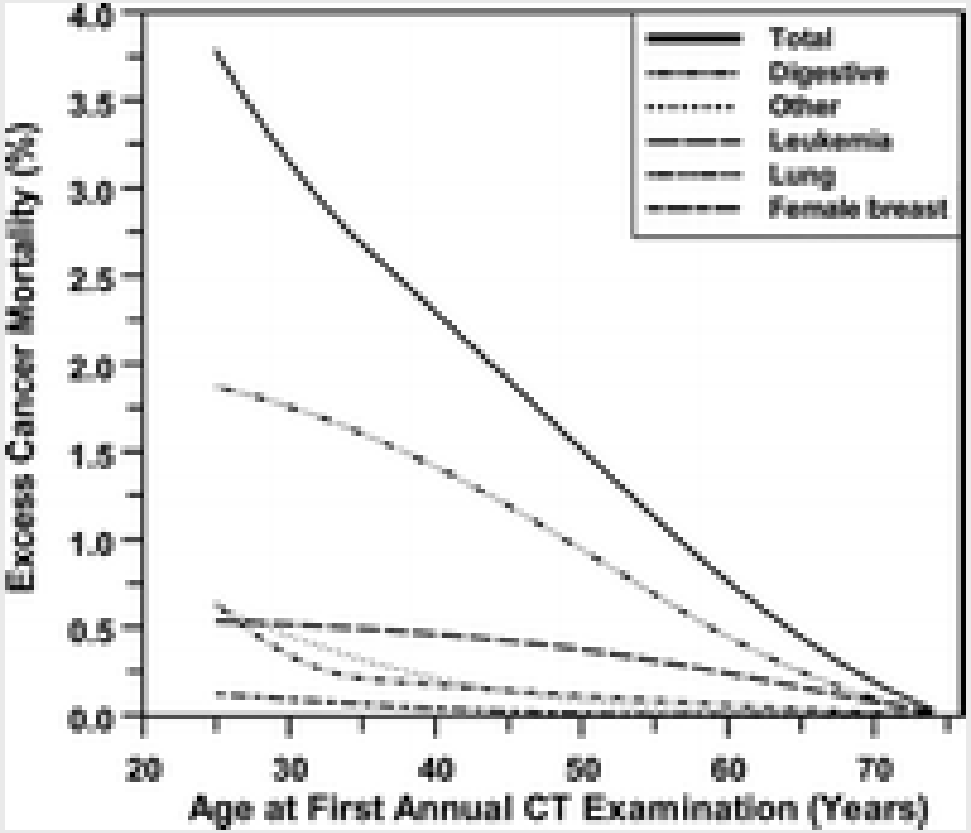


Figure 4. Graph shows excess cancer mortality risks estimated to be associated with radiation from annual full-body CT examinations. Annual examinations are assumed to commence at the specified age and continue until age 75.

From Brenner and Elliston, Radiology 232: 735-738, 2004

Risk Estimates from CT Scanning

- Estimated lifetime cancer mortality risks from a single full-body CT examination are about $8x10^{-4}$ for a 45-year-old adult and about $6x10^{-4}$ for a 65-year-old adult (with 95% CL of about 3.2 in either direction. For multiple exams, the risks are correspondingly higher – 30 annual exams for a 45-year-old adult would have an estimated lifetime cancer risk of 1.9% with CL of about 1.6.

Conclusions

- **The prevailing view from BEIR VII and ICRP (2007) is that the low dose dose-response for solid tumors is linear with no threshold – even when based on incidence**
- **The DDREF is chosen as 1.5 by BEIR VII and remains as 2 for ICRP**
- **There is a need to continue to evaluate the impact of new cellular data on the radiation carcinogenesis process at low exposure levels**
- **There is currently insufficient data to be able to estimate risks for non-cancer endpoints**
- **There appears to be no need to change current policy and practice for diagnostic radiological procedures based upon new cancer risk estimates**

Research Involving Human Subjects

Richard L. Morin, Ph.D.

Department of Radiology
Mayo Clinic Jacksonville

Research – Human Subjects

- History
- 45 CFR 46
- Definitions
- IRB Definition
- IRB Requirements

Research – Human Subjects
History

- 1946 – 23 Physicians Tried
- 1947 – Nuremberg Code
- 1953 – Tuskegee Study
- 1974 – Commission for Protection of Human Subjects
- 1978 – Belmont Report

Nazi War Crimes

- Three experiments to sterilize populations
- Typhus Vaccine
- Physician Researchers
- 729 Subjects – 154 Deaths

Nuremberg Code

Set 10 conditions which must be met before research involving human subjects is permissible.

The first international standard

USPHS Syphilis Study - Tuskegee

- Began in 1932
- 400 w/ - 200 w/o
- No informed consent
- 1936 – Lack of Tx evident – death rate 2X higher
- 1940s – not informed or Tx with penicillin
- 1972 – Press Reports (NYT)

Willowbrook Study

- 1963 - 1966
- Children – “mentality defective”
- Infected w/ hepatitis virus
- Uninformed Parents coerced into study

Jewish Chronic Disease Hospital

- 1963 – Nature of transplant rejection
- Injection of live Ca cells into pts w/ chronic disease
- Oral Consent – not documented
- Never told about live Ca cells

Mentally Challenged Boys

- 1945 – GI system physiology
- 19 boys
- Fed radioactive milk (Fe, Ca)
- Harvard / MIT

Belmont Report

- Respect for persons
- Beneficence
- Justice

Respect for persons

- Dignity & freedom of every person
- Requires informed consent

Beneficence

- Maximize Benefits
- Minimize Harm
- Reasonable Risk for expected benefits

Justice

- Equitable selection
- Equitable recruitment
- Fair Treatment

Autonomy

- Patient’s right to information
- Right to accept or reject treatment

US 45 CFR 46

- Codified principles of Belmont Report
- Minimal ethical & legal obligations of researchers & institutions
- Federally funded research
- Documented ethical principles, policies, and procedures
- Protect rights & welfare
- IRB

Institutional Review Boards

- Review & monitor research involving human subjects
- Protect rights & welfare of human subjects

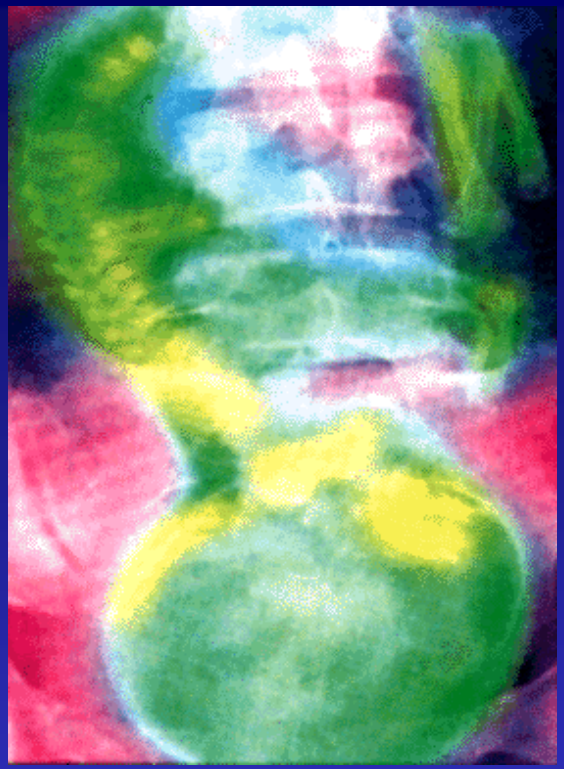
IRB Composition

- ≥ 5 Members
- Gender neutral
- Cannot be one profession
- ≥ 1 member science
- ≥ 1 member non – science
- ≥ 1 member not from institution

IRB Requirements

- Written procedures
- Review proposed research
- Expedited Review
- Minimize Risk
- Reasonable Risk
- Equitable subject selection
- Informed consent

Medical Radiation and Pregnancy



Dr. Claire Cousins

Consultant Vascular & Interventional Radiologist
Addenbrooke's Hospital, Cambridge UK &
Chair of ICRP Committee 3

Presentation

- Introduction
- Common medical problems in pregnancy
- Nuclear medicine and pregnancy
- Radiation risks to the fetus
- Radiation exposure and pregnant workers
- Personal experience

Introduction

- Every year thousands of pregnant women are exposed to ionizing radiation
- Anxiety is caused by lack of knowledge of the pregnant women and those caring for them
- The developing fetus is radiosensitive throughout the prenatal period
- Radiosensitivity varies during the developmental stages

Introduction

- For most patients, radiation exposure is medically appropriate and the radiation risk is minimal
- Occasionally, the exposure is inappropriate and the fetus may be at increased risk.
- Doses from diagnostic procedures that are performed correctly do not pose an increased risk to the fetus
- Higher doses from some therapeutic procedures can result in significant fetal harm

Pregnant or not?

- In females of childbearing age, an attempt must be made to determine who is, or could be, pregnant prior to the radiation exposure

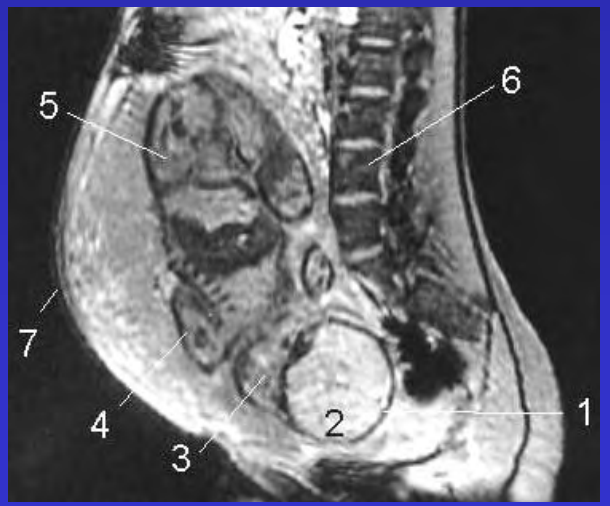
- Amenorrhoea in a regularly menstruating woman should be considered due to pregnancy until proven otherwise

Pregnant or not?

- Notices regarding possible pregnancy
  - at reception
  - in waiting room
  - in x-ray rooms
- Sign pregnancy form if:
  - exposure below diaphragm & above knees
  - aged 12-55 years
- Problems with language, embarrassment etc

Options

- Justification major importance
- Delay the procedure until after delivery if possible
- Consider using an alternate imaging modality, US or MRI



Options

- If a procedure is medically indicated, benefit to the mother must outweigh risk to the fetus
- A pregnant patient should not be denied essential investigation or treatment
- A modified procedure should be performed if diagnostic information is not compromised

Risks in a pregnant population not exposed to medical radiation

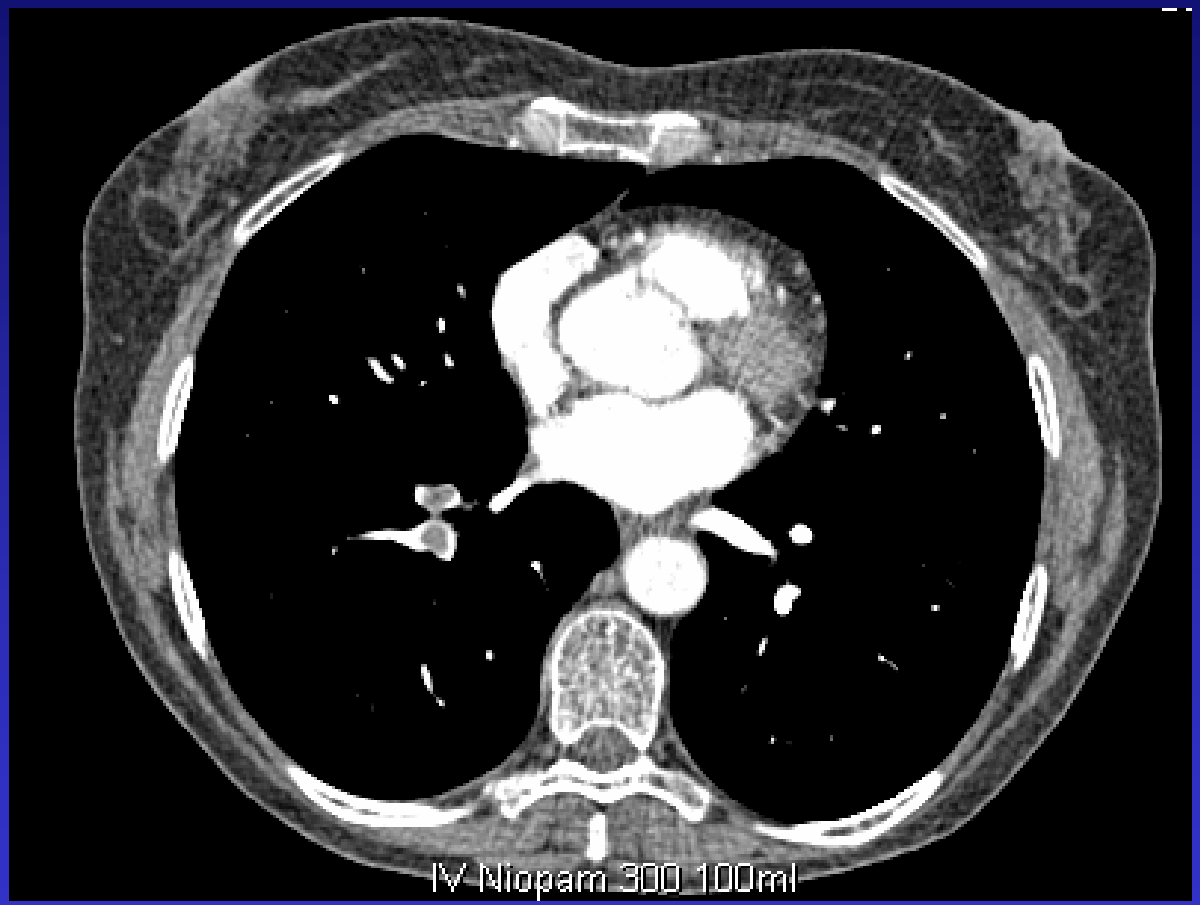
Risks:

- **Spontaneous abortion** **> 15%**
- **Incidence of genetic abnormalities** **4-10%**
- **Intrauterine growth retardation** **4%**
- **Incidence of major malformation** **2-4%**

Common problems in pregnancy

- Chest pain +/- shortness of breath
  ?pulmonary embolus
- Chest x-ray
- CT pulmonary angiography
- ?Nuclear medicine ventilation/perfusion scan

18 weeks pregnant – pulmonary embolism

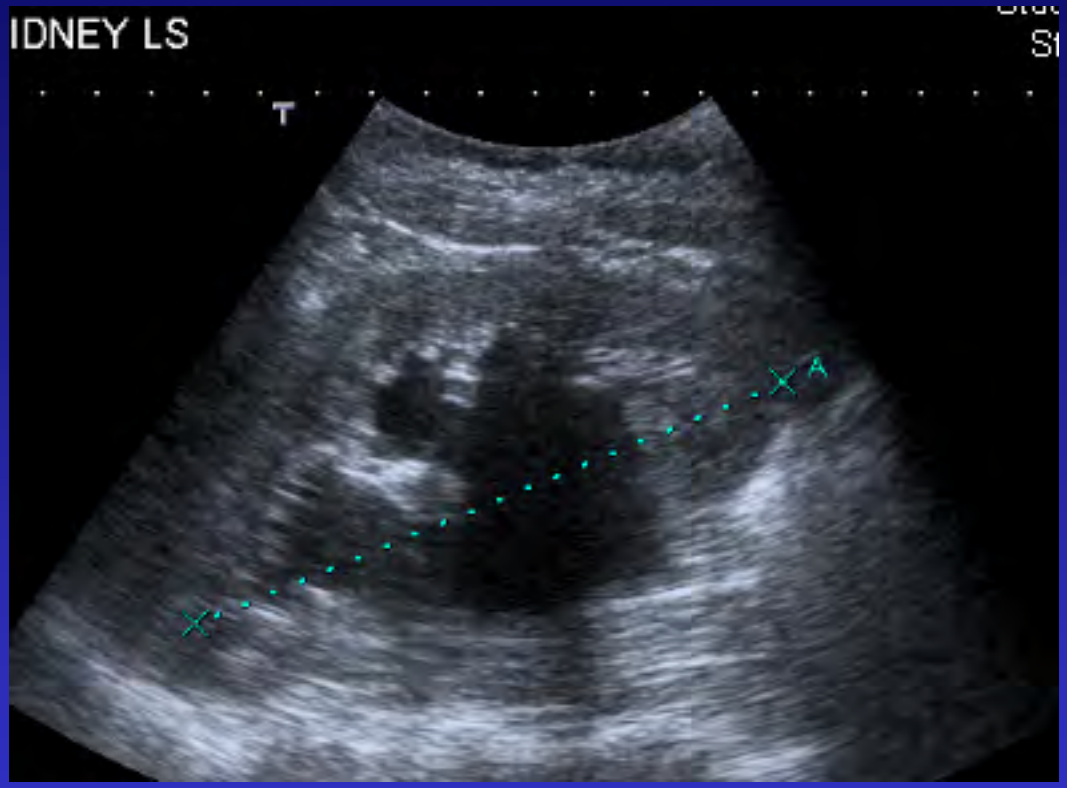


Fetal dose 0.2mGy

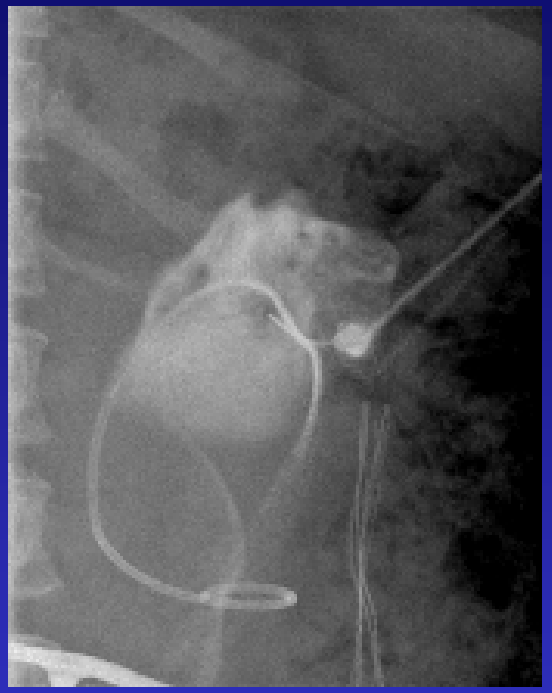
Common problems in pregnancy

- Right sided abdominal pain ?renal obstruction
- Ultrasound dilated collecting system ?functional or physiological
- Nephrostomy insertion may be required

31 weeks pregnant - Acute right abdominal pain



US dilated collecting system



Nephrostomy insertion

Fetal dose 1.3mGy

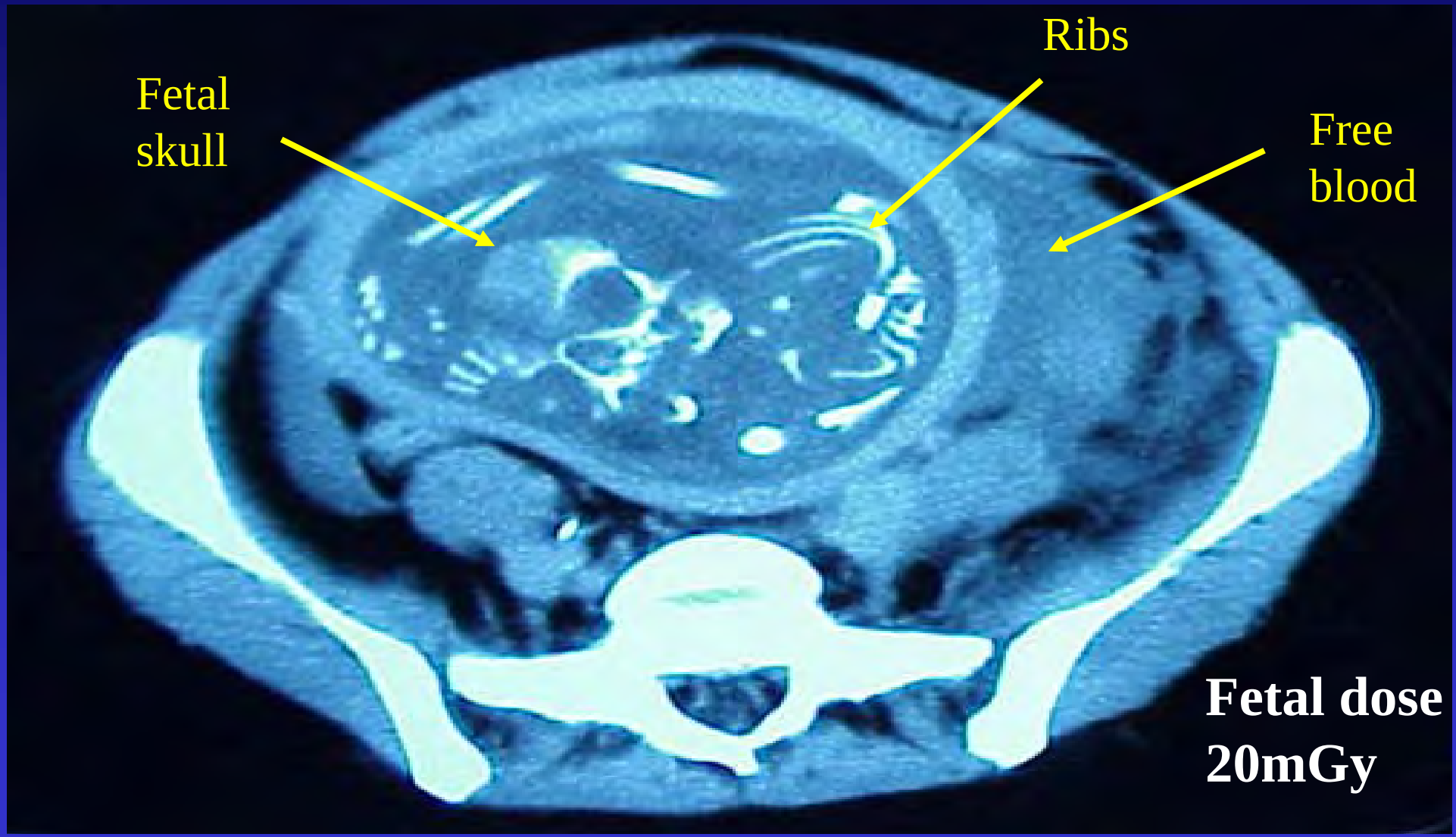
Common problems in pregnancy

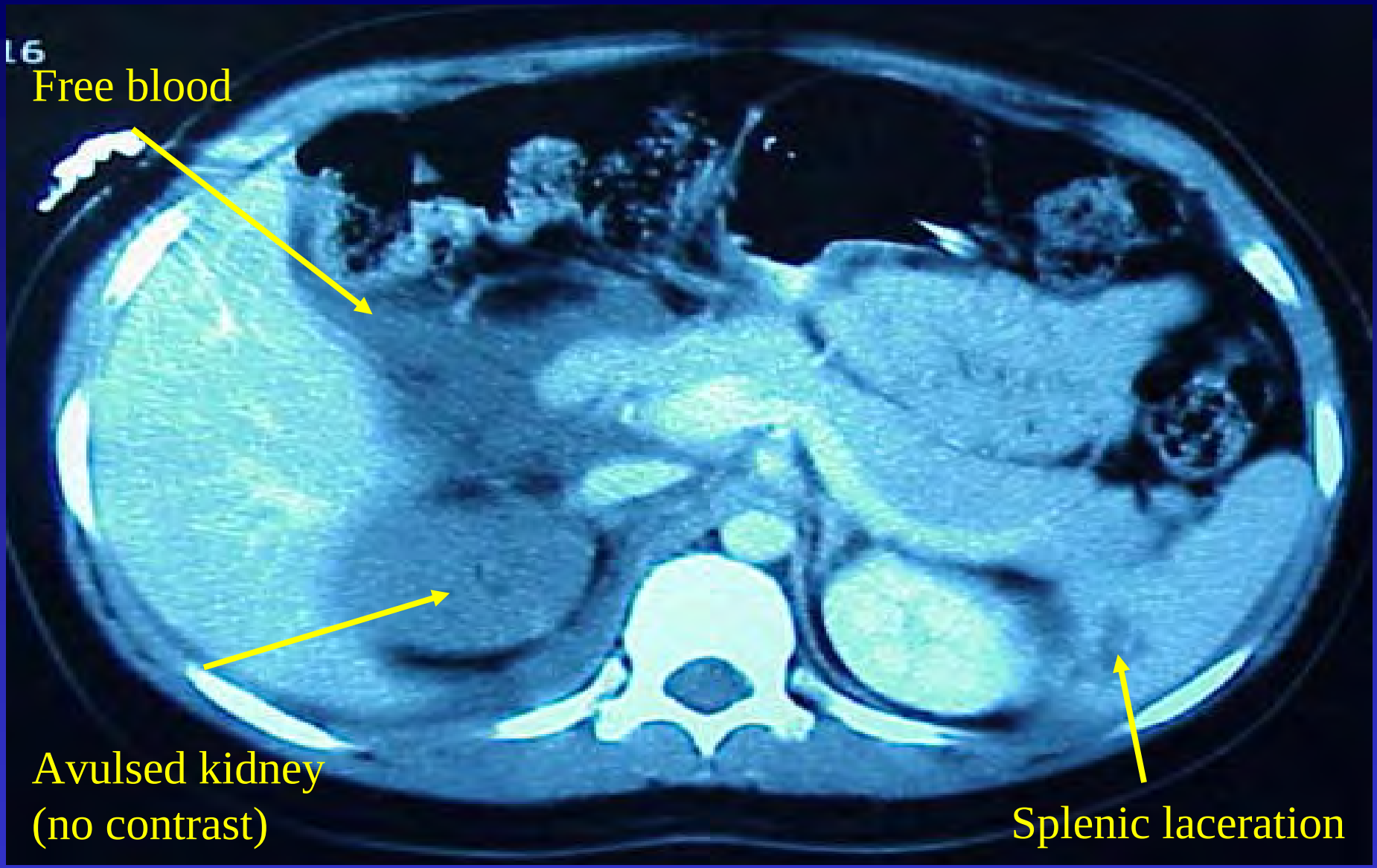
- Leg swelling +/- pain ?deep vein thrombosis
- Colour – Doppler ultrasound
- Depending on extent of thrombus, may require caval filter
- Remove following delivery

Less common problems in pregnancy

- Major trauma
- Mass lesion ?cancer
- Radiotherapy

CT pregnant female involved in a road traffic accident





Transferred to operating theatre. Mother & child survived

Approximate fetal doses from common diagnostic x-ray examinations

	Mean (mGy)	Maximum (mGy)
Chest	<0.01	<0.01
Abdomen	1.4	4.2
Pelvis	1.1	4.0
Thoracic spine	<0.01	<0.01
Lumbar spine	1.7	10.0

UK data 1998

Approximate fetal doses from fluoroscopic and computed tomography procedures

	Mean (mGy)	Maximum (mGy)
Barium meal	1.1	5.8
Barium enema	6.8	24
CT head	<0.005	<0.005
CT chest	0.06	0.96
CT abdomen	8.0	49
CT pelvis	25	79

UK data 1998

Approximate fetal doses for CT examinations in pregnancy (16 MDCT)

	Fetal dose 3 months (mGy)
Pulmonary embolism	0.7
Renal stone	4 – 7.2
Appendicitis	15 - 17

Hurwitz et al, 2006

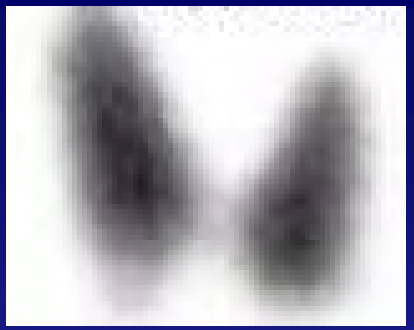
Informed consent

- A pregnant female is entitled to know the level of risk to the fetus that may result from in-utero exposure
- Extent of discussion depends on type of procedure
- Verbal consent may be adequate for low dose procedures e.g. chest x-ray
- When predicted fetal doses are >1 mGy, a more detailed explanation should be given and written consent obtained

High dose procedures

- Some interventional radiology procedures may give fetal doses in the range of 10-100 mGy
- Radiotherapy doses may be much higher
- If such high dose procedures have been performed it is important fetal dose and potential fetal risk is estimated by a qualified expert (medical physicist)

Nuclear Medicine and Pregnancy



- Short-lived radionuclides are used for most diagnostic procedures (e.g. ^{99m}Technetium)
- These do not cause large fetal doses
- Some radionuclides (e.g. ^{131}I as iodide & ^{32}P as phosphate) do cross the placenta and can pose fetal risks

Nuclear Medicine and Pregnancy

- Fetal thyroid begins to accumulate iodine after approximately 10 weeks gestation
- High fetal thyroid doses from radioiodine can result in permanent hypothyroidism
- Radioiodine therapy is contraindicated in pregnant patients and should only be administered if life saving

Approximate fetal dose from common nuclear medicine procedures

	Mean (mGy)	Maximum (mGy)
^{99m}Tc lung perfusion	0.2	0.4
^{99m}Tc lung ventilation	0.3	1.2
^{99m}Tc kidney (DTPA)	1.5	4.0
^{99m}Tc thyroid scan	0.7	1.6
^{99m}Tc bone scan	3.3	4.6
^{67}Ga infection	-	12.0
^{131}I Thyroid metastases	-	22.0

UK data 1998

Risk of hereditary disease and cancer after fetal diagnostic medical exposure to radiation

		Probability per exposure	Probability per exposure
	Mean fetal dose (mGy)	Hereditary disease	Fatal cancer to 15 years
Abdomen	1.4	1 in 30000	1 in 24000
Pelvis	1.1	1 in 38000	1 in 30000
Lumbar spine	1.7	1 in 24000	1 in 20000
Barium meal	1.1	1 in 38000	1 in 30000
Barium enema	6.8	1 in 6000	1 in 5000
CT abdomen	8.0	1 in 5000	1 in 4000
CT lumbar spine	2.4	1 in 24000	1 in 14000
CT pelvis	25	1 in 1700	1 in 1300
^{99m}Tc bone scan	3.3	1 in 13000	1 in 10000

UK data 1998

Radiation risks to the fetus

- Risks depend on stage of pregnancy and fetal dose
- Risks are most significant during organogenesis and decrease as pregnancy progresses

Malformations

- The threshold for malformations is 100-200 mGy (or even higher) and usually affect the central nervous system
- Diagnostic radiology or nuclear medicine procedures are unlikely to achieve these levels but interventional procedures or radiotherapy may do so

Brain development

- Weeks 8-15 gestation (window of cortical sensitivity) most significant for radiation damage
- Intelligence quotient (IQ) reduction documented in atomic bomb survivors with increasing dose >100mGy

Brain development

- Doses of 1000 mGy can result in severe mental retardation particularly during 8-15 weeks and to a lesser extent at 16-25 weeks
- Heterotopic grey matter & microcephaly main effects

Leukaemia and Cancer

- Rate of childhood cancer generally 1-3 per 1000
- Radiation shown to increase the risk for leukaemia and many types of cancer in adults and children
- Likely highest radiosensitivity with respect to cancer induction is at late stage fetogenesis
- Fetus is assumed to be as susceptible to the carcinogenic effects of radiation as the young child

Leukaemia and Cancer

- Relative risk may be up to 1.4 (40% increase over normal incidence) following a fetal dose of 10 mGy
- Individual risk remains small (0.3-0.4%) due to low incidence childhood cancer
- Risk of cancer at ages 0-15years is approximately 1 excess cancer death per 1,700 children exposed in utero to 10 mGy

Termination of pregnancy

- Termination of pregnancy after radiation exposure is an individual decision based on may factors
- Fetal doses of <100 mGy do not justify termination of pregnancy
- At <100mGy the probability a child will not have a malformation is 97% and not have cancer 99%

Termination of pregnancy

- At fetal doses in excess of 100 mGy, there can be fetal damage, the magnitude and type of which is a function of dose and stage of pregnancy
- High fetal doses (>500 mGy) in the first trimester result in a significant risk of growth retardation and CNS damage
- During late pregnancy this high dose is not likely to result in malformations or birth defects

Radiation research and pregnancy

- Involvement of pregnant females in radiation research is rare
- This should be discouraged unless pregnancy is an integral part of the research
- If performed, strict controls on the use of radiation to protect the fetus

Radiation Exposure & Pregnant Workers

Pregnant radiation workers:

- **are obliged to inform their employer of the pregnancy**
- **may continue to work with radiation providing there is reasonable assurance that fetal dose can be kept below 1 mGy during the pregnancy (ICRP)**
- **should be given the option of working in a position of reduced or no radiation if possible and desired**

Radiation Exposure & Pregnant Workers

In USA, NCRP recommends:

- **Dose limit of 0.5mSv per month of pregnancy**
- **5mSv for the entire gestation period**

Pregnancy & Interventional Radiology

Personal experience:

- **2 pregnancies**
- **4 sessions IR per week until 34 weeks**

Problems:

- **No option to change work practice as only one other interventionalist**
- **Tiredness**
- **Uncomfortable lead coats**

ICRP 84 Pregnancy & Medical Radiation

- Published 2000 & chaired by Prof Mettler
- To educate medical professionals
- Remains one of the best selling documents
- Translated into other languages and widely distributed
- Educational package on ICRP website which can be freely downloaded

Conclusions

- Radiation exposure during pregnancy exposes the fetus to risks
- These depend on gestation and dose
- Careful consideration of benefits and risks required
- Separate issues for pregnant workers and radiation
- Education of medical professionals essential

NCRP 2007 Annual Meeting
Advances in Radiation Protection in Medicine
Arlington, VA, April 16-17, 2007

Nuclear Medicine

Operational Radiation Safety for PET-CT, SPECT-CT, and Cyclotron Facilities

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Reference Documents

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- NUREG-1556, Vol 9, Rev 1. Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses, NRC, 2005.
- AAPM Task Force 108, PET and PET/CT Shielding Requirements, Med Phys 33: 4, 2006.

“PET” Cyclotrons

Lo-E (<20 MeV), *p, d* only - ^{11}C, ^{18}F *etc*

Hi-E (~30 MeV), *p*, α *etc* - + ^{86}Y, ^{124}I *etc*

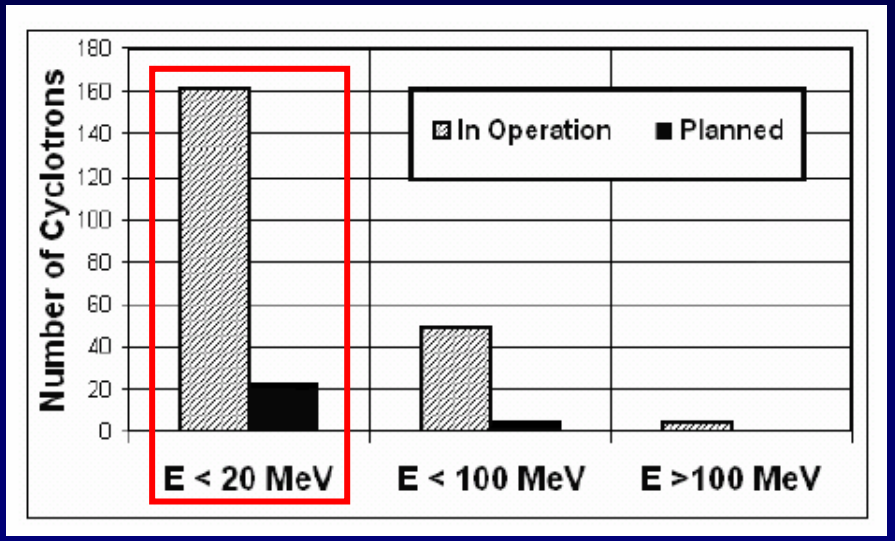
Design Considerations

- **Self-shielded *vs* Unshielded**
- **Floor loading**
- **Room shielding**
- **Activation products / Storage, disposal**
- **Interlocks / “On” alerts**
- **Room monitors**
- **Personnel dosimetry / Surveys**
- **“Panic” buttons**
- **Target assembly, servicing**
- **Exhaust monitoring / “Scrubbing”**
- **Hot cells, Robotics, Radiochemistry “boxes”**
- **RAM transport**
- **RAM waste disposal**

Cyclotrons

World-wide Cyclotron Census:
~230 (*ca* 2002) *

* Does NOT include cyclotrons for charged-particle radiation therapy

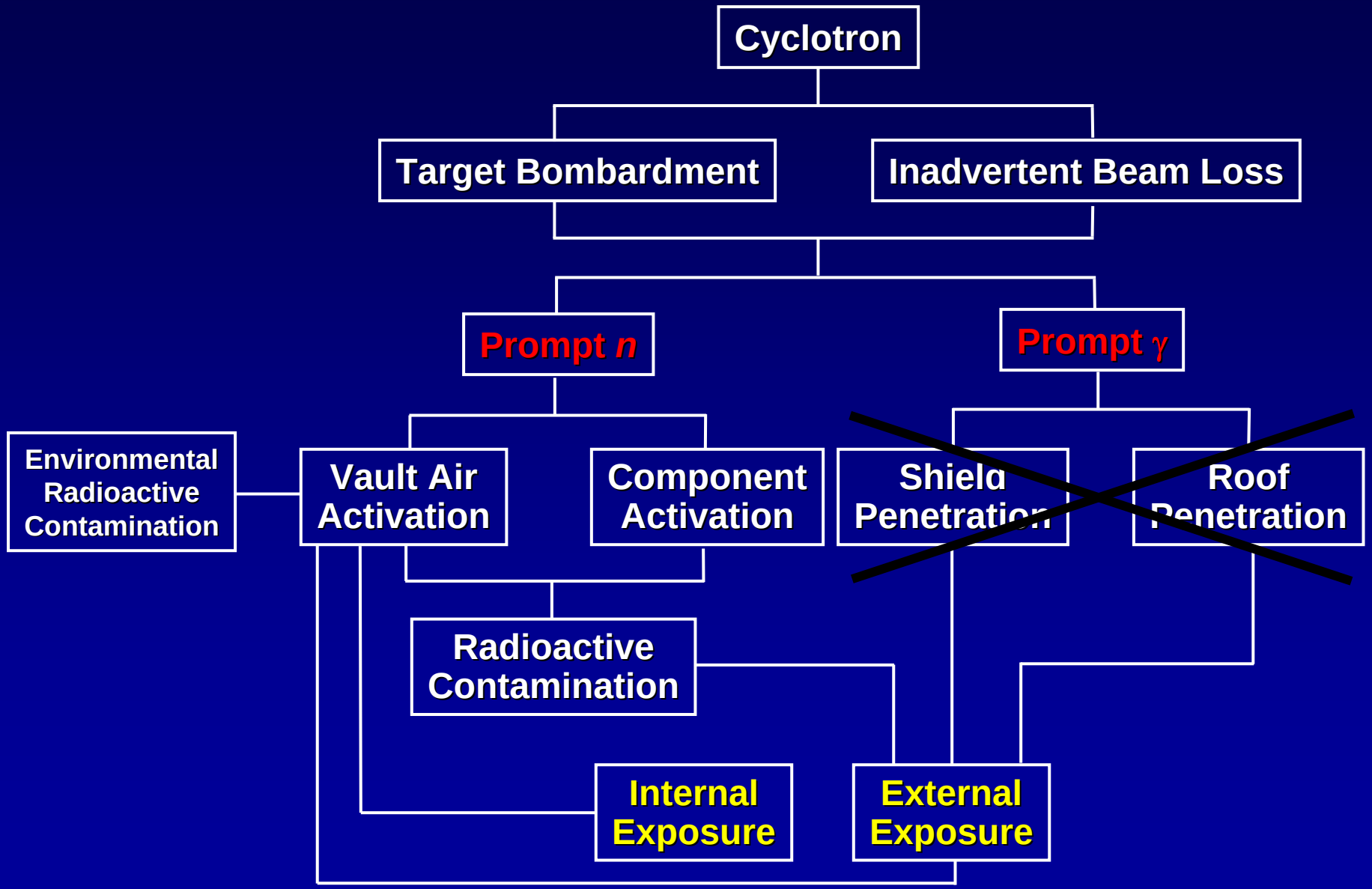


Murkherjee *et al*.

	Self-Shielded	**vs**	***Unshielded***
Internal components	Accessible		Restricted access
Vault (shielding)	Integrated*		Separate construction
Size (Footprint)	Small		Large - 2-3X
Cost	Lower		Higher
Availability	Readily available / Turn-key systems		Less widely available / Customized

* Shielding may still be problematic

Cyclotron Exposure Pathways



Cyclotron Activation Products

Component	Radionuclide	$T_{1/2}$	$E_{x,\gamma}$ (MeV)
***n* activation**			
Magnet yolk	^{54}Mn	312 d	0.835
	^{56}Mn	2.58 h	0.847
Magnet coils	^{64}Cu	12.8 h	0.511
Vacuum tank	^{24}Na	15 h	2.75
Concrete	^{28}Al	2.25 m	1.78
Air	^{41}Ar	1.8 h	1.29
***p* activation**			
Target window	^{52m}Mn	21 m	2.46
	^{52}Mn	5.7 d	4.13
	^{56}Co	78 d	2.30
	^{57}Co	271 d	0.122

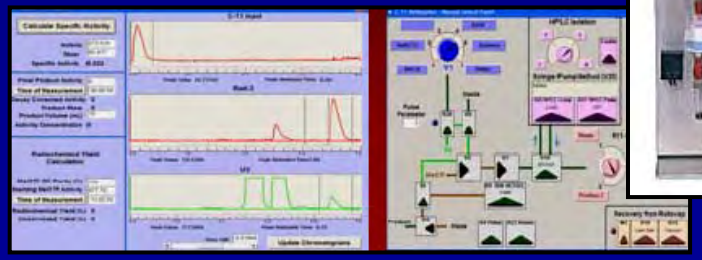
Workflow for Preparation of PET Radiotracers

Cyclotron production of radionuclide
~1 h

Automated transfer
< 10 m

Radiochemistry module

PC-controlled synthesis & HPLC purification of radiotracer
<1 h



Pneumatic (or manual) transfer
< 10 m

Dispensing & injection of radiotracer
<10 m

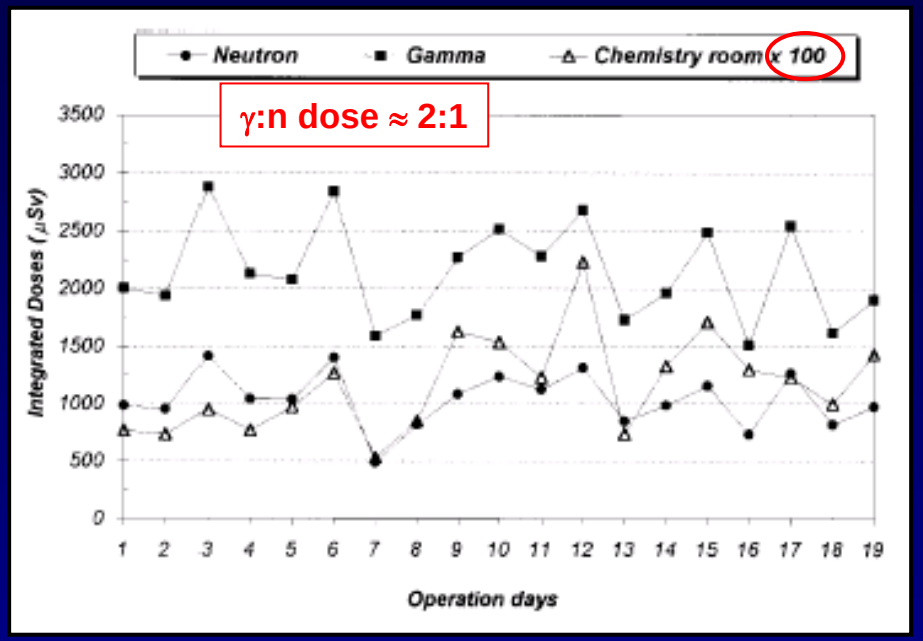
Cyclotron Exposures

12-MeV *p* machine (< 100 μA)

60 min @ 50μA: ~1,000 mCi ^{18}F
^{18}O(*p*,*n*)^{18}F

45-min synthesis: ~400 mCi ^{18}FDG
(40-60% yield)

~15 mCi /patient



Radiochemist exposures *

Whole body *(mrem)*	
Per month	28
Per procedure	1.4
Hand *(mrem)*	
Per procedure	270
Contributions	
Preparation	2%
Handling unshielded syringe (~100 mCi)	49%
Opening module	49%

* Highest staff exposures
Reduced by **half** with experience

Gonzalez *et al*. Eur J Nucl Med **26**: 894, 1999.

Personnel exposures *

Cyclotron vault	1/10	of MPD *
Radiochemistry lab	1/30	of MPD *
Outside facility	1/20	of MPD **
Bioassay samples	<5 Bq	

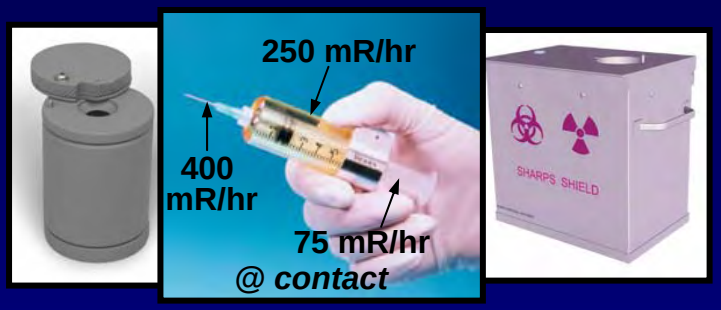
* Occupational MPD: 5 rem/y
Design goal (ALARA): 0.5 rem/y
** General-public MPD: 0.1 rem/y

Sharma et al. Rad Prot Dosim **118**: 431, 2006

^{18}F-FDG PET and PET/CT Workflow

Injection

10-15 mCi



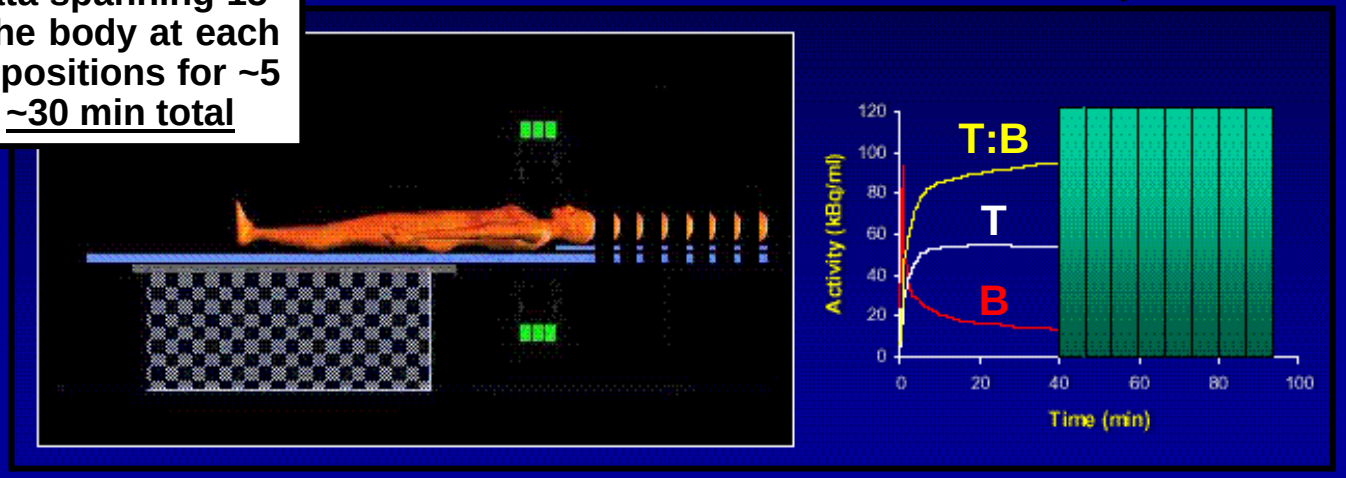
Uptake

Separate from main waiting area

40-80 min

Imaging

Acquire data spanning 15-25 cm of the body at each of 6-8 bed positions for ~5 min each - ~30 min total



SPECT/CT & PET/CT Shielding
Design Considerations

CT

- **Scan parameters:** mA
  kVp
  pitch *
- **Workload**
  ~15,000 mA-min/wk - CT
  ~7,500 mA-min/wk - PET/CT

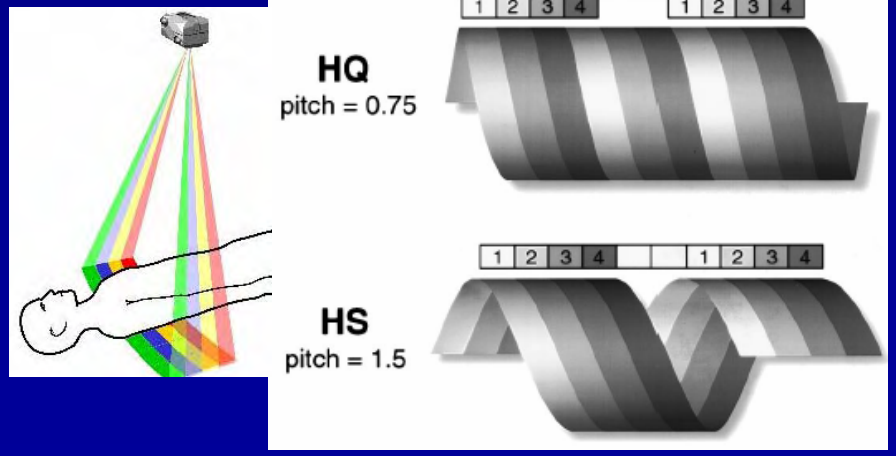
* Table travel (mm) per x-ray tube rotation / Slice thickness (mm)

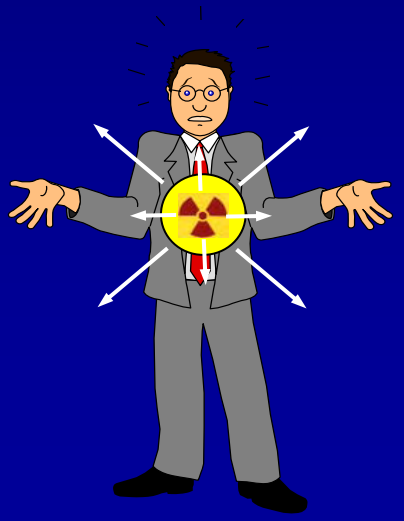
Pt dose ↓ as Pitch ↑ and mA, kVp ↓

SPECT & PET *

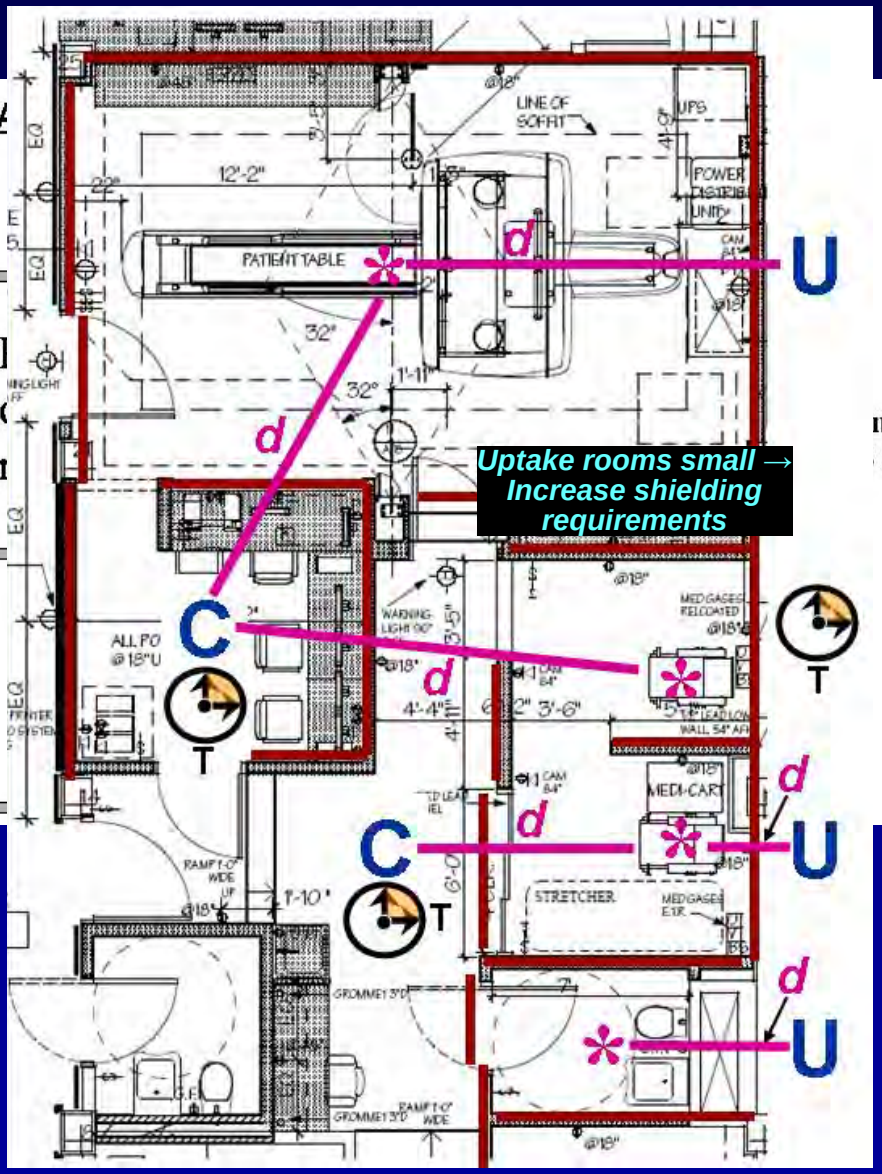
- **Scan parameters:** Adm activity
  Uptake period
  Scan length
- **Workload:** # patient/wk
- **Elimination rate:** Excretion
  Physical decay

* Effective self-absorption factor
  140 keV (^{99m}Tc): ~0.70
  511 keV: ~0.5





SPECT/CT & PET/CT Shielding
Design Considerations *cont*



- Patient throughput: # /wk
- Structural shielding
- Occupancy factor, T
- Target distance, d
- Dose limit, P *

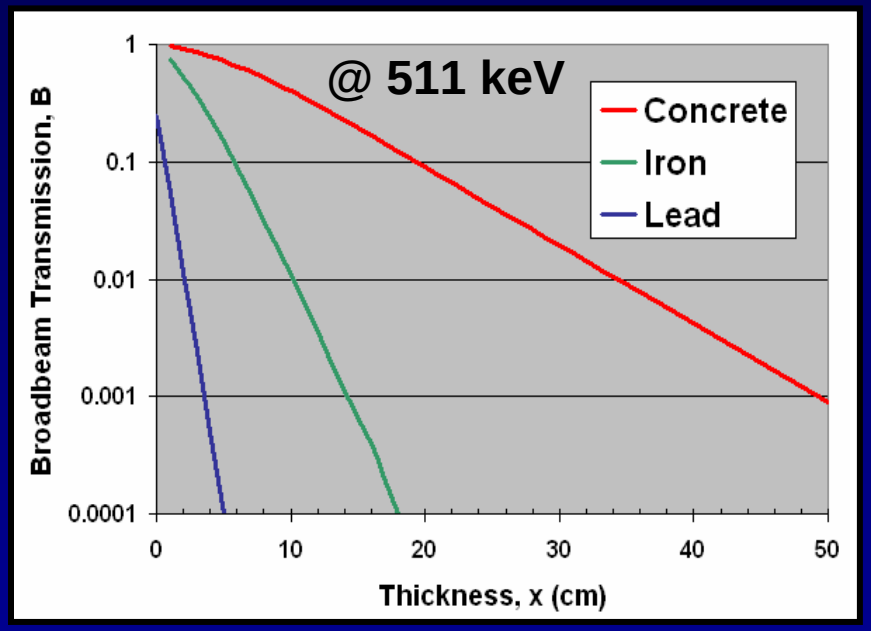
in Controlled (C) vs Uncontrolled (U) areas

*

Occupational MPD	=	5,000	mrem/yr
	=	100	mrem/wk
Design-Goal MPD	=	500	mrem/yr
	=	10	mrem/wk
General-Public MPD	=	100	mrem/yr
	=	2	mrem/wk

SPECT/CT & PET/CT Shielding Calculations

AAPM Task Force 108



$$B = \{[1 + (\beta/\alpha)]\, e^{\alpha\gamma x} - (\beta/\alpha)\}^{1/\gamma}$$

$$x = (1/\alpha\gamma)\, ln\, \{[B^{-\gamma} + (\beta/\alpha)] / [1 + (\beta/\alpha)]\}$$

Material	α (cm^{-1})	β (cm^{-1})	γ
Lead	1.54	-0.441	2.14
Concrete	0.154	-0.116	2.08
Iron	0.570	-0.306	0.633

Archer et al. Health Phys 44: 507, 1983.

140 kVp x-ray & 140-keV γ-ray transmission

<

1/10 of 511-keV γ-ray transmission

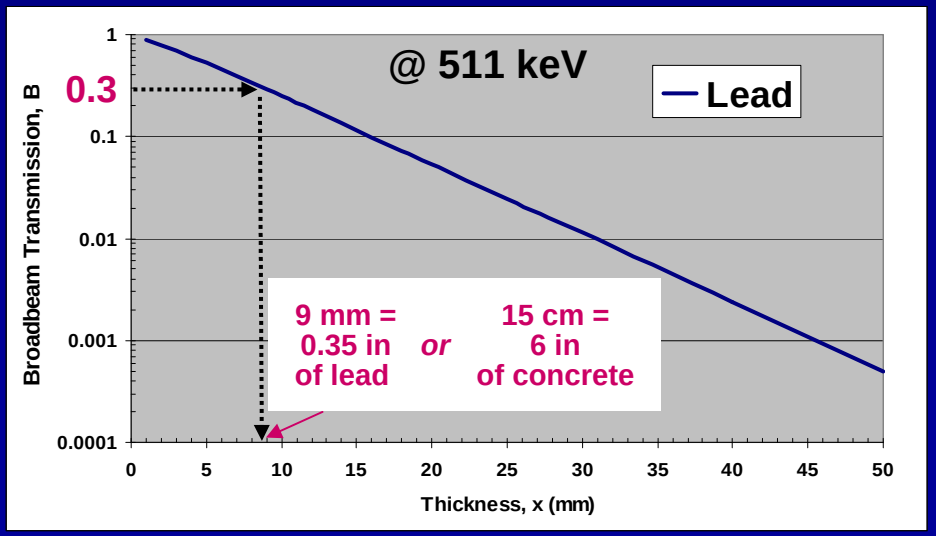
SPECT/CT & PET/CT Shielding Calculations
AAPM Task Group 108

t = 0 min, Δt = 45-90 min for FDG uptake
t = 45-90 min, Δt = 30 min for WB scan

$$D(d,t,\Delta t) = \frac{e^{-0.693t/T_p}\ \Gamma\ A\ f(t)\ f(\Delta t)\ S\ N\ T(d)}{d^2}\ 1.44\ \frac{T_p}{\Delta t}\left[1 - e^{-0.693\Delta t/T_p}\right]$$

- $e^{-0.693t/T_p}$: 110 min for ^{18}F
- Γ: 5.70 R-cm^2/mCi-hr for ^{18}F
- A: Administered activity — 15 mCi for ^{18}FDG
- $f(t)$: Fractional retained activity — *For scan* 80% for FDG after 45-90 min
- $f(\Delta t)$: Dose rate reduction factor
- S: Self-absorption Factor — ~0.5 for ^{18}F
- N: # Patients per Week
- $T(d)$: 1 - occupational; 0.25 - non-occupational

$$B = \frac{P}{D(d,t,\Delta t)}$$



PET & PET/CT Doses
Adult Doses for ^{18}FDG

		Dose (rem)			
	^{18}FDG *10 mCi*	PET w/ ^{68}Ge Transmission Scan	PET-CT w/ "Low-Dose" CT	PET-CT w/ "High-Quality" CT	PET-CT w/ "Diagnostic" CT
Bladder *	4.4	4.4	4.4	4.9	6.8
Bone Marrow	0.48	0.49	0.53	0.90	2.3
Breasts	0.34	0.35	0.38	0.69	1.8
Liver	0.58	0.60	0.66	1.2	3.2
Lungs	0.64	0.66	0.70	1.1	2.5
Ovaries	0.48	0.51	0.54	1.0	2.4
Effective Dose	1.1 **	1.1	1.2	1.7	3.3
Transmission Scan Contribution		*3%*	*9%*	*41%*	*71%*
		kVp	120	120	140
		mAs	10	60	190
		Pitch	1.5	1.5	1.25

* 3-hr voiding interval

** Effective dose equivalent

Adapted from NUREG/CR-6345 1996.
Groves *et al*. Br J Radiol 77: 662, 2004.
Huda & Vance. AJR 188: 540, 2007.
Fahey. Radiology on-line/pre-print, 2007.

Increasing Scan Speed and Patient Throughput in PET

~60 /day ~10 min

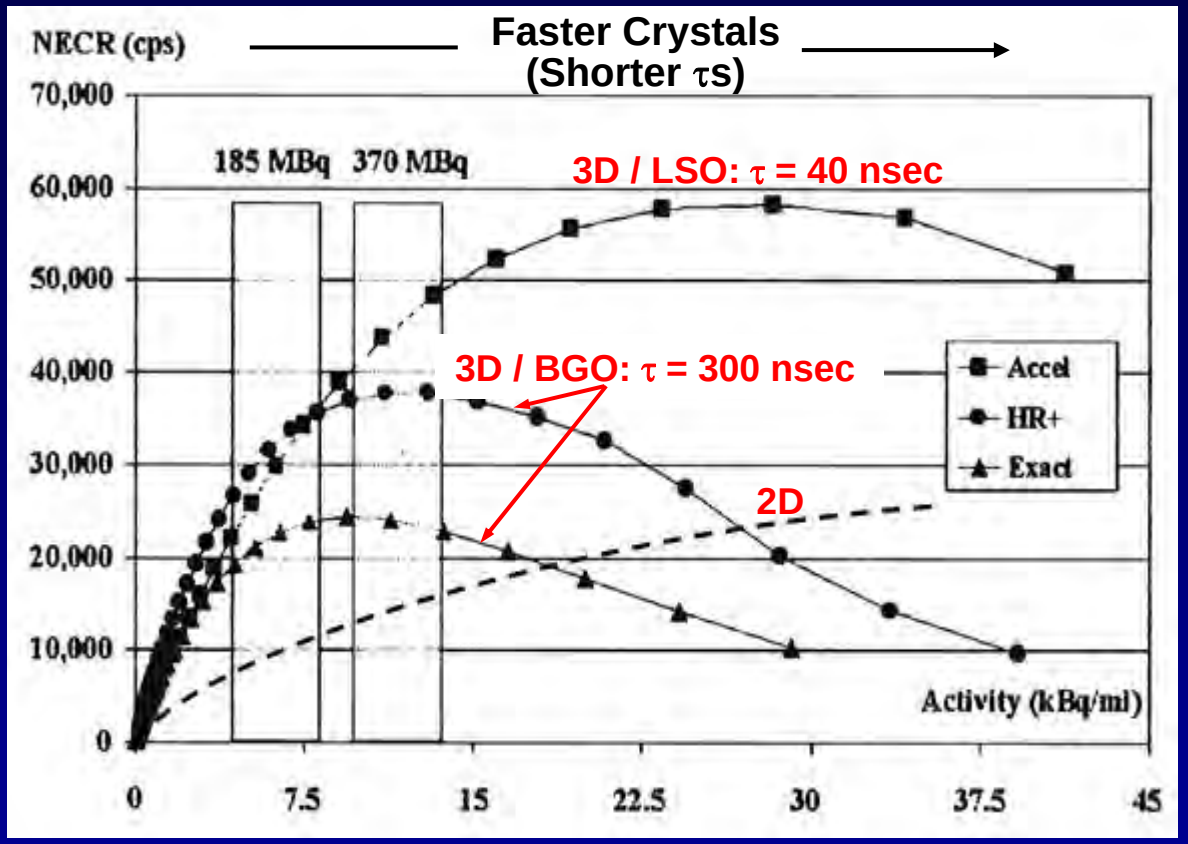
~20 /day ~30 min

~10 /day ~60 min

Patient Throughput

WB Scans

Noise-Equivalent Count Rate *vs* [A] in FOV



Tarantola, Zito *et al*. J Nucl Med 44: 756, 2003.

Adm Activity: 10 → 40 mCi → **Max normal-tissue dose: 4 → 16 rad**

Homeland Security

Impact of Radiation Detectors Deployed to Identify / Interdict Illicit Radioactive Sources

Threshold alarm exposure rates < 10 μR/hr → Sensitive!

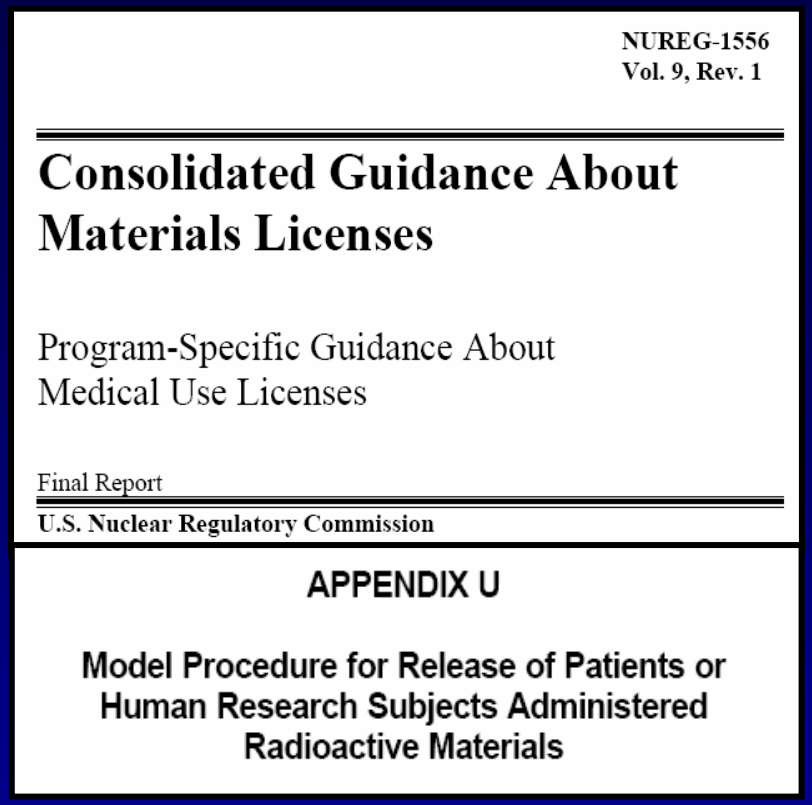
Radiopharmaceutical	Duration of "Trigger-able" Exposure Rates at 1 m
F18-FDG	1 d
Tc99m, I123-NaI	3 d
In111-WBCs	14 d
Ga67-citrate, Tl201-chloride	30 d
I131-iodide, -Bexxar - Tx	100 d

Courtesy of Dr. Lionel Zuckier

Patient Wallet Card to Notify Authorities

Ms./Mr. _____ had a Nuclear Medicine procedure at Hospital XYZ on _____ and may be detectably radioactive until _____.

Contact the Nuclear Medicine Department at (555) 123-4567 if there are questions or concerns.



Guidance for non-by-product materials such as ^{18}F *not* currently included*

- **Releasable & instruction-requiring activities > 100 mCi**
- **Stop breast-feeding for 6-12 hr**

* NRC *will* provide regulatory oversight

Releasable Activities and Dose Rates

^{99m}Tc	760	mCi,	59	mrem/hr @ 1 m
^{131}I	33	mCi,	7	mrem/hr @ 1m

Activities and Dose Rates at Release Requiring Radiation Safety Instructions

^{99m}Tc	150	mCi,	12	mrem/hr @ 1 m
^{131}I	7	mCi,	2	mrem/hr @ 1m

Activities at which Instructions are Required for Patients who are Breast-feeding a Baby

^{99m}Tc	1.3-30	mCi, stop for 6-24 hr
^{131}I	0.4	mCi, discontinue

Concluding Remarks

- In cyclotron, SPECT-CT, and PET-CT facilities, appropriate design and workflow can maintain *personnel* exposures below, and generally well below, regulatory limits.*
- In SPECT-CT and PET-CT, *patient* exposures, while not trivial, are within the "acceptable" range for Dx studies.
- Patient exposures are increasing (up to ~X) with the progression towards greater patient throughput (faster crystals / higher adm activity) and *diagnostic*-quality CT (higher kVp, mAs/ lower pitch) in multi-modality studies.
- Regulatory issues for radiopharmaceuticals and licensing issues for multi-modality devices are evolving.

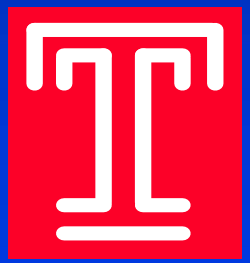
Thank You!

* Cyclotrons for radiation therapy introduce additional radiation safety issues
Up to 1/2" Pb shielding for PET-CT suite (*vs* 1/8" for CT only), up to 3/4" for Uptake room
For *crosstalk*, up to 3/4" Pb shielding (portable?) for nearby imaging (*eg* SPECT) units

Combined Imaging Modalities PET/CT and SPECT/CT

NCRP 2007 Annual Meeting
Advances in Radiation Protection in Medicine

Arlington, VA, April 16-17, 2007



Alan H. Maurer, M.D.
Director of Nuclear Medicine
Temple University Hospital
Fox Chase Cancer Center
Philadelphia, PA

Goals

- Historical background on PET and PET/CT
- Importance of functional/molecular imaging
- Why increasing use of fusion imaging?
  - PET/CT
  - SPECT/CT
- Some Clinical Applications
  - Oncologic
  - Neurologic
  - Cardiovascular
  - Other
- Future directions for image fusion

Review - History PET (From Research to Clinical Tool)

- 1930 - Increased glycolysis in tumor cells (Warberg)
- 1979 - FDG for cerebral glucose metabolism(Phelps et al)
- 1980's -Clinical research studies
  - 1980 - FDG in tumor animal models (Som et al)
  - 1982 - FDG in brain tumor (Patronas et al)
  - 1982 - FDG in colon cancer (Yonekura et al)
  - 1988 - Brain activation studies (Phelps UCLA)
- 1990's - Early clinical trials
  - Lymphoma
  - Lung Cancer
  - Breast Cancer
  - Colon cancer
  - Cardiac viability and stress perfusion(Detection of CAD)
- 2001 - HCFA(US Federal) Reimbursement Approval - Clinical Applications
- 2002 - Integrated PET/CT Fusion
- 2006-07
  - National Oncologic PET Registry (May 06)
  - Advances in camera technology (Time of Flight)
- Future? - Target Drug Therapy/New PET Radiopharmaceuticals

Why Did Medicare Cover PET ?

- Because conventional anatomic imaging (CT) misses things!
- Request for broad coverage submitted by PET community
  - 643 articles on 24,395 patients (*J Nucl Med* supp May 2001)
- Overall: Sensitivity = 84%, Specificity = 88%
- Change in management = 32%

Summary early PET studies

	Sens	Spec	Acc
Detection of Primary Lung Cancer	96%	88%	94%
Metastatic Staging/Lung Cancer PET	88%	91%	91%
CT	65%	60%	
Detection of Recurrent Lung Cancer	97%	77%	91%
Detection of Primary Breast Cancer	92%	97%	92%
Detection of Breast Cancer Axillary Nodes	82%	95%	90%
Detection of Recurrent Colorectal CA (increasing CEA)	94%		
Differentiate Locally Recurrent Colorectal CA vs Scar	95%	98%	96%
Detection of Primary Head/Neck Cancer	96%		
Detection of Nodal Mets Head/Neck Cancer	88%	93%	92%

Conti PS et al: Nuc Med Biol. 23;717-735, 1996

For Detecting Cancer CT Misses a Lot

Early data - PET vs CT

n = 8004 pts

	Sensitivity	Specificity
PET	**85%**	**89%**
CT	**66%**	**76%**

Medicare PET Coverage (Effective 7/1/01)

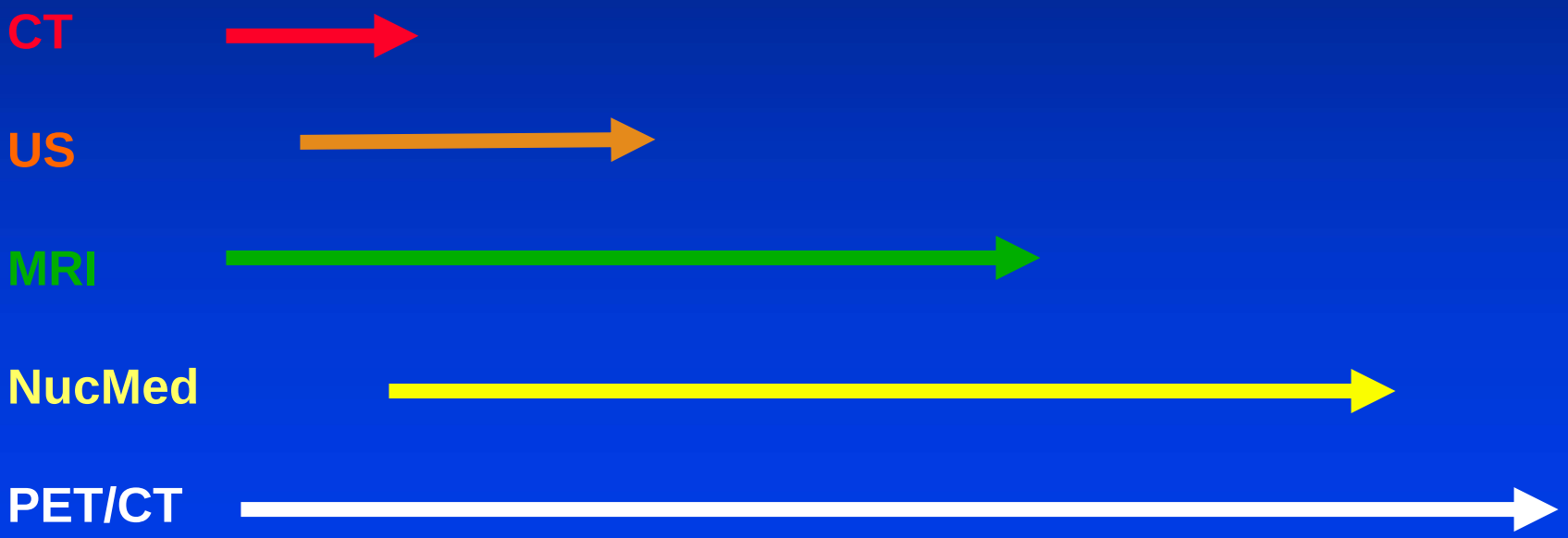
- **Oncology**
  - **Lung Cancer**
    - » **Characterization of solitary pulmonary nodule**
    - » **Diagnosis, staging, restaging - non small cell CA**
  - **Lymphoma**
    - » **Diagnosis, staging, restaging(Hodgkins/Non-Hodgkins)**
  - **Colorectal**
    - » **Diagnosis, staging, restaging**
  - **Melanoma**
    - » **Diagnosis, staging, restaging (Not for sentinal node)**
  - **Esophageal**
    - » **Diagnosis, staging, restaging**
  - **Head and Neck**
    - » **Diagnosis, staging, restaging(Excludes CNS or thyroid)**
  - **Breast Cancer**
    - » **Restaging(recurrent disease) + response to therapy***

Current Expanded Medicare Coverage

- National Oncologic PET Registry
  - All oncologic studies with approval
- First Time Registry
  - Important sign of future regulation and approvals

Anatomic vs Functional Imaging

Anatomy Physiology . . . . Metabolism. . . ....Molecular

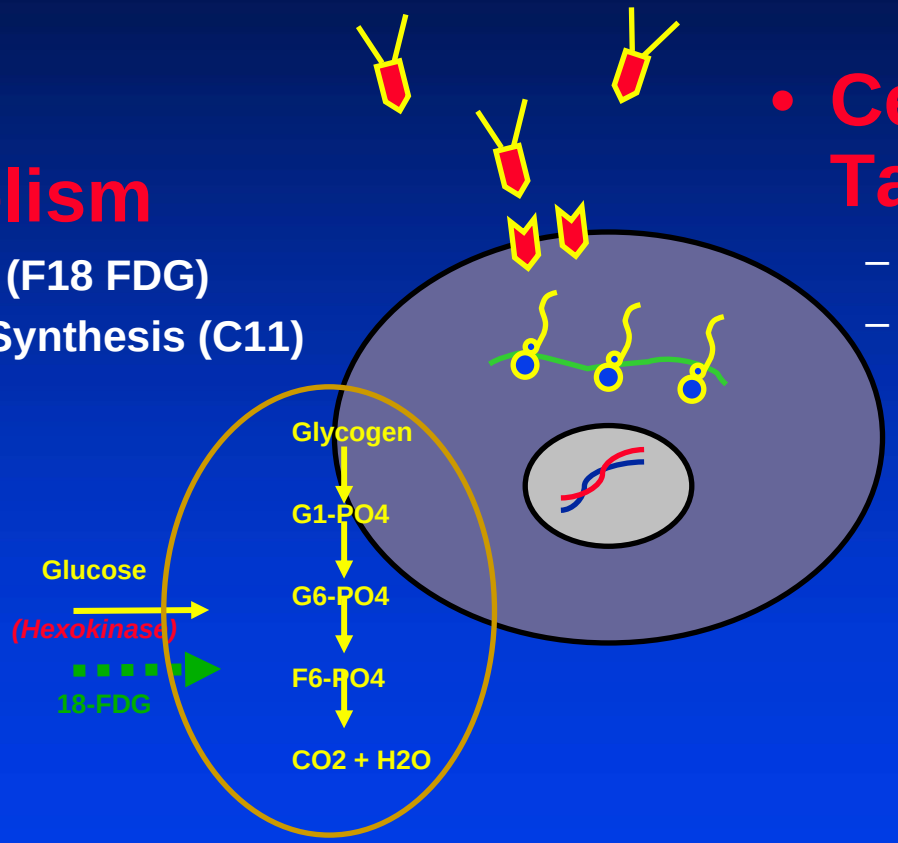


Molecular Imaging

- **Definition**
  - ***The in vivo characterization and measurement of biologic processes at the cellular and molecular level***
    - » **Weissleder R and Mahmood U. Radiology 2001;219:316**

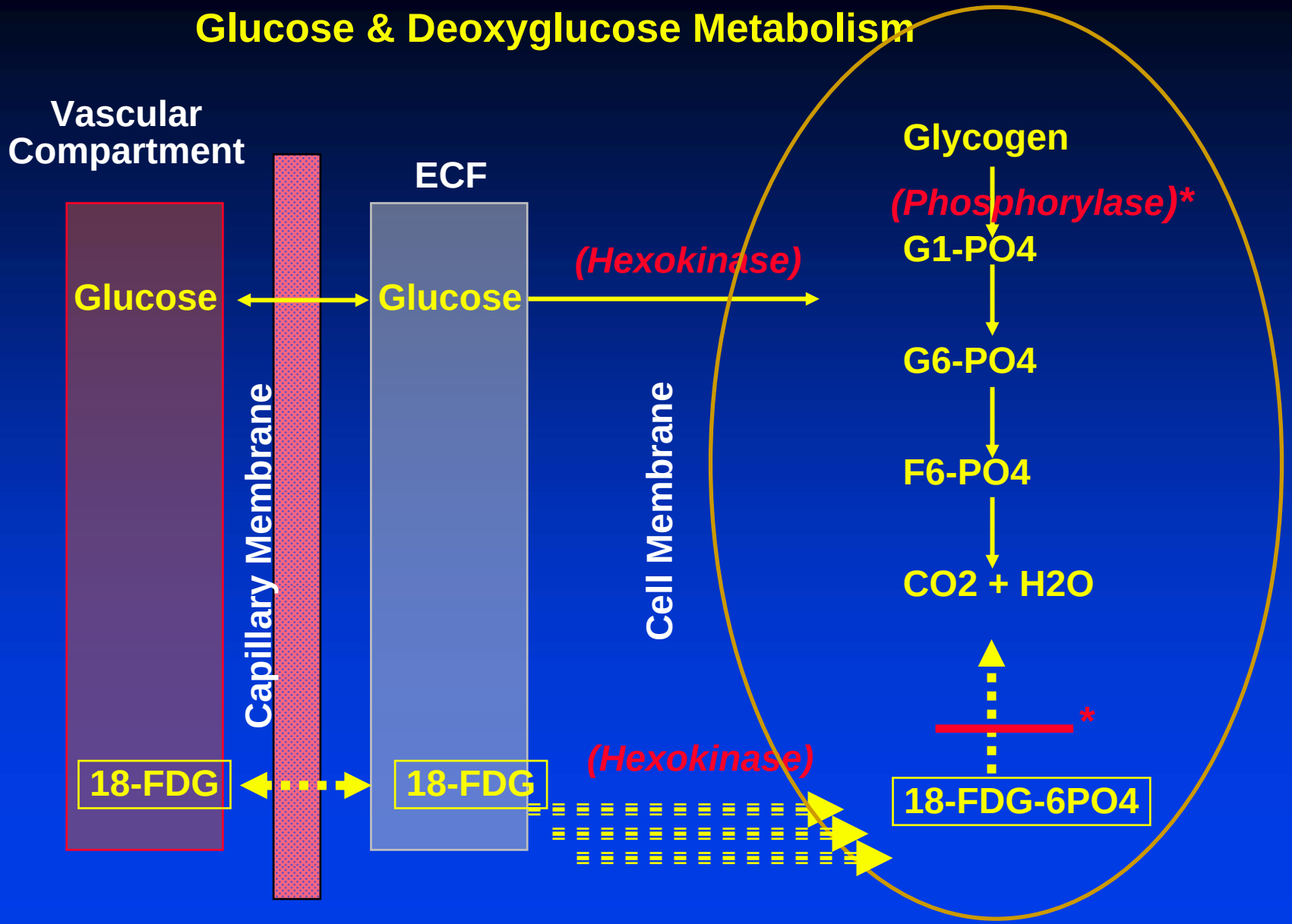
Molecular Imaging Probes

- **Metabolism**
  - Glucose (F18 FDG)
  - Protein Synthesis (C11)



- **Cellular/Molecular Targets**
  - Receptors
  - DNA precursors

Glucose & Deoxyglucose Metabolism



PET Radionuclides

Nuclide	Half-lfe	% β+	Daughter
C-11	20.3 m	99.8	B-11 (stable)
N-13	9.97 m	100	C-13 (stable)
O-15	2.03 m	99.9	N-15 (stable)
F-18	1.83 h	96.9	O-18 (stable)
Ga-68	1.13 h	90	Zn-68 (stable)
Rb-82	1.26 m	96	Kr-82 (stable)
Cu-62	9.73 m	97.8	Ni-62 (stable)
I-122	3.6 m	77	Te-122 (stable)

Cyclotron produced
Generator-produced

PET Metabolic Radiopharmaceuticals (Oncologic)

- Glucose Analogue (Glycolysis): FDG
  - » 2-(18-fluorine)-fluro-2-deoxy-D-glucose
- Thymidine Analogues (Protein Synthesis, cell proliferation*)
  - C-11 methionine
  - F-18 fluorothymidine
- Methionine Analogue*
  - C-11 methionine
- Amino Acid transport/DNA synthesis
  - C-11 tyrosine
  - C-11 thymidine
  - F-18 flurotyrosine
- Cell membrane metabolism
  - C-11 choline
  - F18-fluorocholine
  - C-11 acetate
- Tissue Hypoxia
  - F-18 fluoromisonidazole
- Receptor binding
  - Estrogen/Androgen) F18 fluroro-17-ß-estradiol

Other PET Molecular/Metabolic Agents

- Oxygen utilization
  - O-15
- Blood flow
  - NH-13
  - Rubidium -82 (cardiac generator)
- Bone Metabolism
  - F-18 fluoride
- Apoptosis
  - F18 annexin V

CT(Anatomic) Imaging

Advantages

- High tissue contrast
  - Oral/ IV enhancement
- Fast imaging times
  - High patient throughput
- Procedure guidance
  - Needle biopsy
  - RF ablation
- Availability
- Familiarity for referring MDs

Disadvantages

- Mass- benign/malignant?
- Size criteria for lymph nodes
  - Enlarged due to cancer?
  - Normal size nodes may contain tumor cells
- Response to Rx
  - Slow to show size change
  - Mass after Rx= scar or residual cancer?
- Lacks whole body imaging
  - Usually limited views

PET/Metabolic Imaging

Advantages

- Easy whole body imaging
- High Sens most tumors
  - High metabolic rate (FDG)
  - Detects very small quantity of tumor/receptors
  - + normal size lymph nodes
- Accurate Staging
- High rate of management changes (30-40%)
  - Usually Upstaging
- Rapid response to Rx

Disadvantages

- Limited anatomic resolution
  - No Longer ? PET/CT
- Limited availability
- Slow imaging times
  - New fast crystals
- Lack of standardization
  - Techniques
  - Especially SUVs
- Expense
- Limited acceptance

PET/CT Fusion
What's All The Excitement ?

- CT Can Miss Cancer
- PET Can Miss Cancer

- But Together they miss much less

- PET/CT becoming standard of care in oncology

Importance of (PET/CT) Co-registration

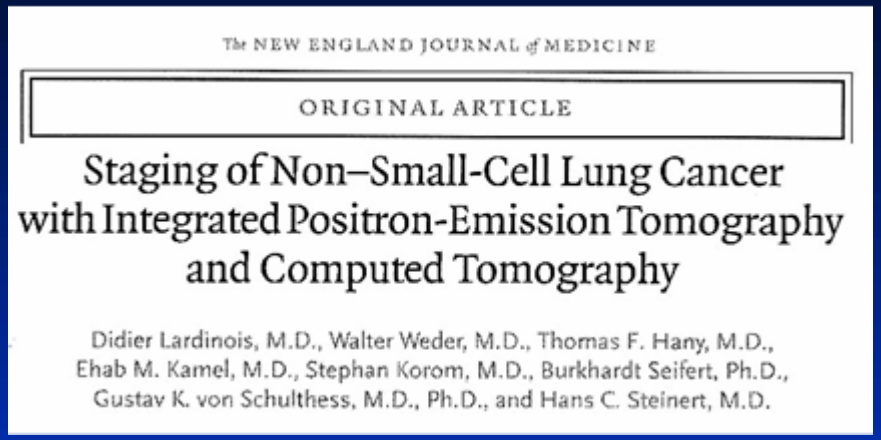
Fusing Form and Function

- Anatomic co-registration
- Attenuation correction
  - Absolute quantification
    - » SUV (gms glucose/gm tissue)

Role(s) of PET/CT

- Staging -
  - Accurate identification of site(s) of tumor
    - » TNM classification
      - T(umor) size, N(odes) involved, M(etastatic) locations
- Restaging/Response to therapy -
  - Role in directing therapy
    - » Chemotherapy
    - » Radiation planning
    - » Future?(cellular markers)
- Prognosis
- Diagnosis -
  - Role in Unknown primary
  - Unsuspected second primary
  - Direct procedure

Staging Lung Cancer - Integrated PET/CT



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Staging of Non–Small-Cell Lung Cancer with Integrated Positron-Emission Tomography and Computed Tomography

Didier Lardinois, M.D., Walter Weder, M.D., Thomas F. Hany, M.D., Ehab M. Kamel, M.D., Stephan Korom, M.D., Burkhardt Seifert, Ph.D., Gustav K. von Schulthess, M.D., Ph.D., and Hans C. Steinert, M.D.

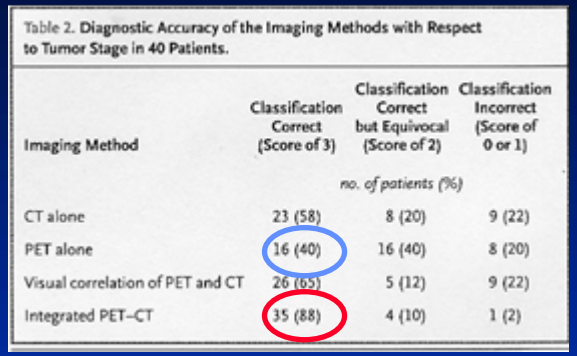


Table 2. Diagnostic Accuracy of the Imaging Methods with Respect to Tumor Stage in 40 Patients.

Imaging Method	Classification Correct (Score of 3)	Classification Correct but Equivocal (Score of 2)	Classification Incorrect (Score of 0 or 1)
	no. of patients (%)		
CT alone	23 (58)	8 (20)	9 (22)
PET alone	16 (40)	16 (40)	8 (20)
Visual correlation of PET and CT	26 (65)	5 (12)	9 (22)
Integrated PET–CT	35 (88)	4 (10)	1 (2)

- Prospective study 49 pts with NSCLC
- Test CT vs PET + CT vs PET/CT
- Surgery in 40/49 (82%)
- Integrated PET/CT yielded additional info in 20/49(41%)
  - Positive lymph nodes 9 pts
  - Chest wall infiltration 3 pts
  - Mediastinal invasion 3 pts
  - Tumor vs atelectasis/inflammation 7 pts
  - Distant mets in 2 pts

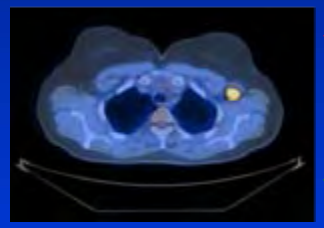
Lardinois et al: N Engl J Med 2003; 348: 2500-7

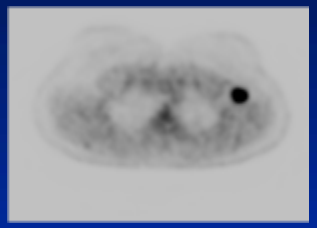
Importance of Integrated PET/CT

- **Increases diagnostic accuracy in ~10-50% of patients:**
  - Improving lesions detection on both PET and CT
  - Discriminating metastatic from physiologic foci
  - Localizing more precisely metastatic foci:
    - » Bone versus soft tissue
    - » Liver versus adjacent bowel
    - » Specific structures of the neck
- **Change in management in 10-30% of patients**

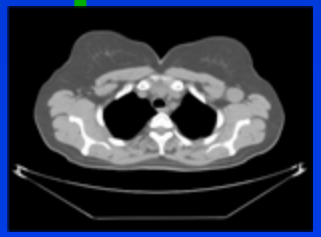
Bar-Shalom R, et al. J Nucl Med 2003;44:1200-1209.
Yeung HW, et al. J Nucl Med 2002;43:32P.
Dizendorf E, et al. J Nucl Med 2002;43:33P.

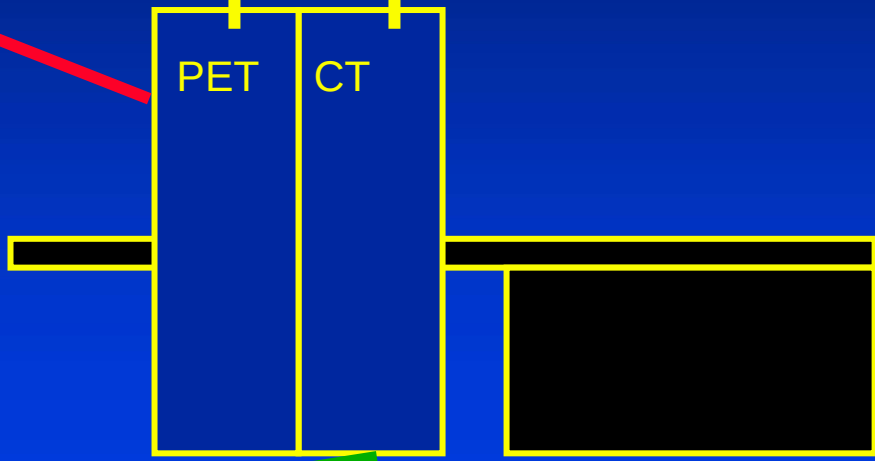
Integrated PET/CT System





Attenuation Correction





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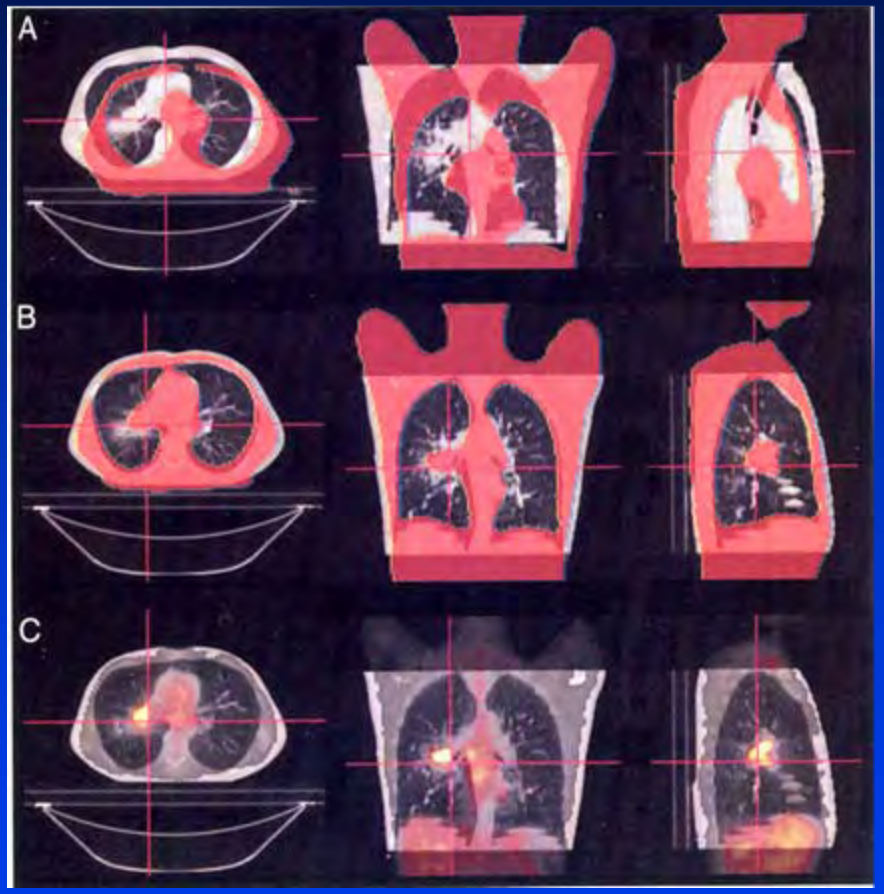
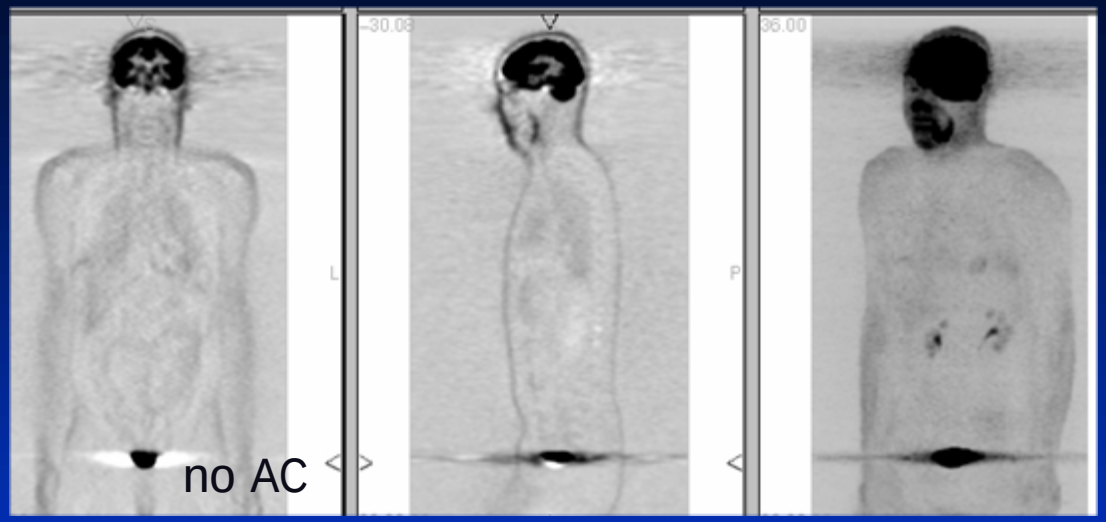
PET-CT Image Fusion Option (Non Integrated PET/CT)

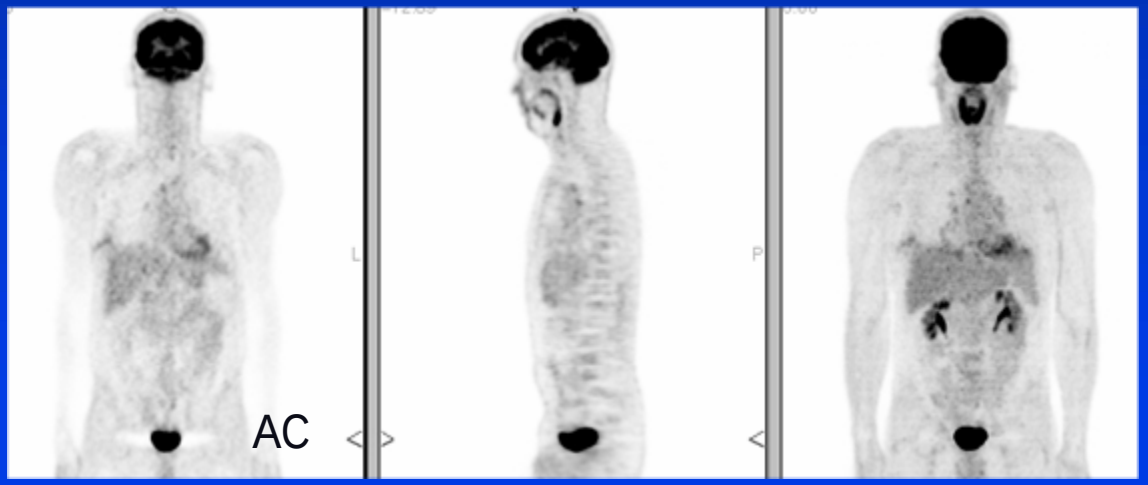
- Visual or Computer based techniques used
- Works in brain
  - Little change temporally
  - Rigid structure
- Lack of precise anatomic co-registration
  - Head neck flexion
  - Organs shift
  - Bowel moves
  - Tumors grow



Need for CT/Attenuation Correction

- **Improved anatomic delineation**
  - Lesions can be localized more accurately
- **Necessary for quantification (SUV)**
  - May be helpful for specific clinical situation
    e.g. indeterminate pulmonary nodules
  - Monitoring therapy
  - Prognosis





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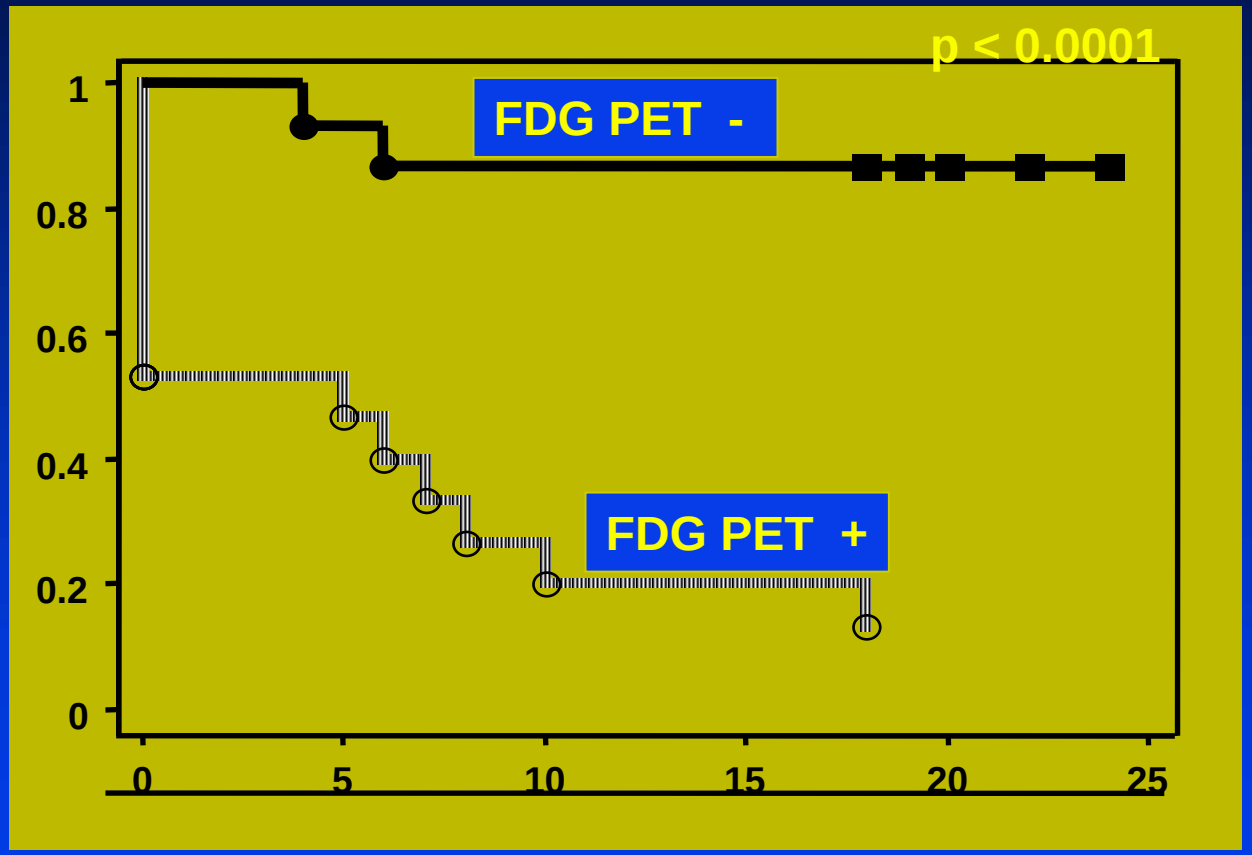
SUV Predicts Tumor Response After 1st Cycle of Chemotherapy Lymphoma

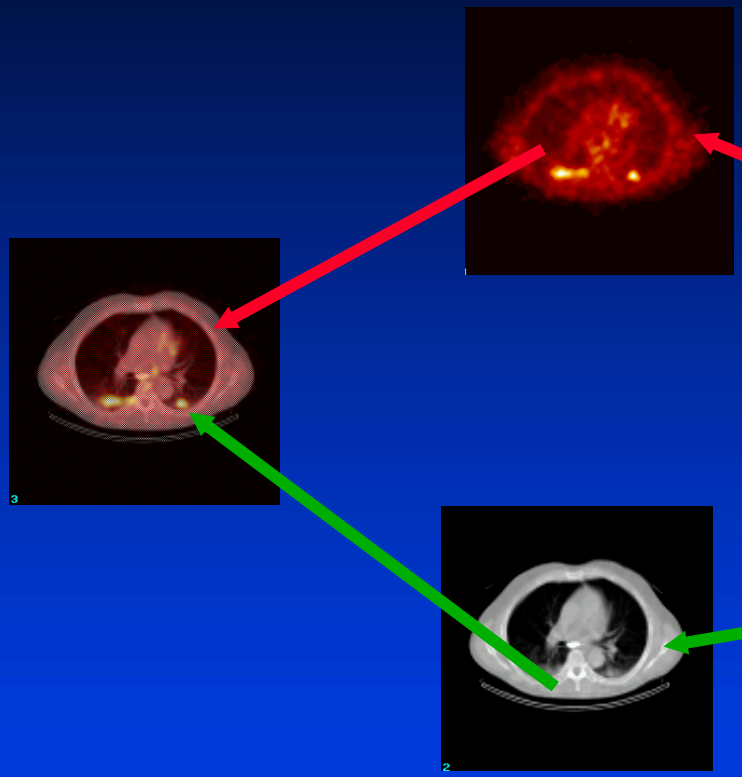


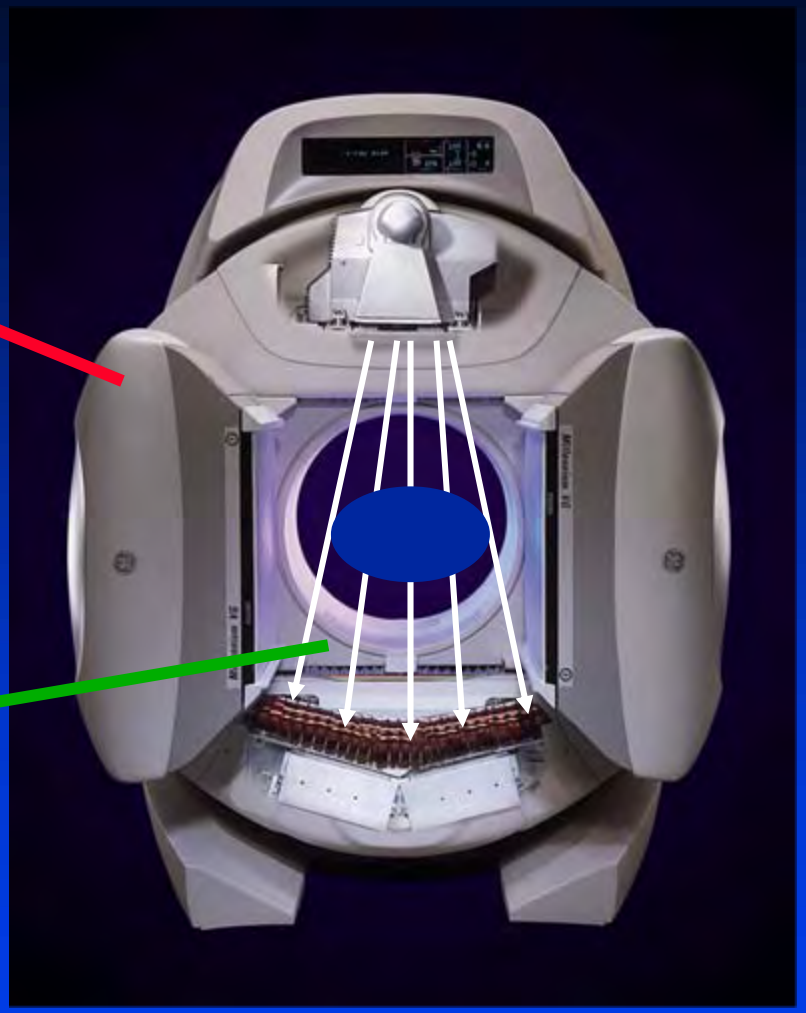
Radiation Therapy Planning in NSCLC using FDG PET

- Prospective study on 11 patients
  - Body cast for CT simulation and PET
  - CT and transmission and PET are registered
- Increase planned target volume (PTV) of ~19% in 7/11 patients due to distant LN metastases
- Decrease (PTV) of ~18% in 4/11 patients due to atelectasis
- PET improves tumor definition and may reduce geographic misses.

Erdi YE et al: Radiother Oncol 2002;62:51-60.

SPECT-CT Imaging (4 slice, low dose Hawkeye®)





Integrated system provides:

- **Optimal attenuation correction**
- **Fusion images for anatomical mapping**

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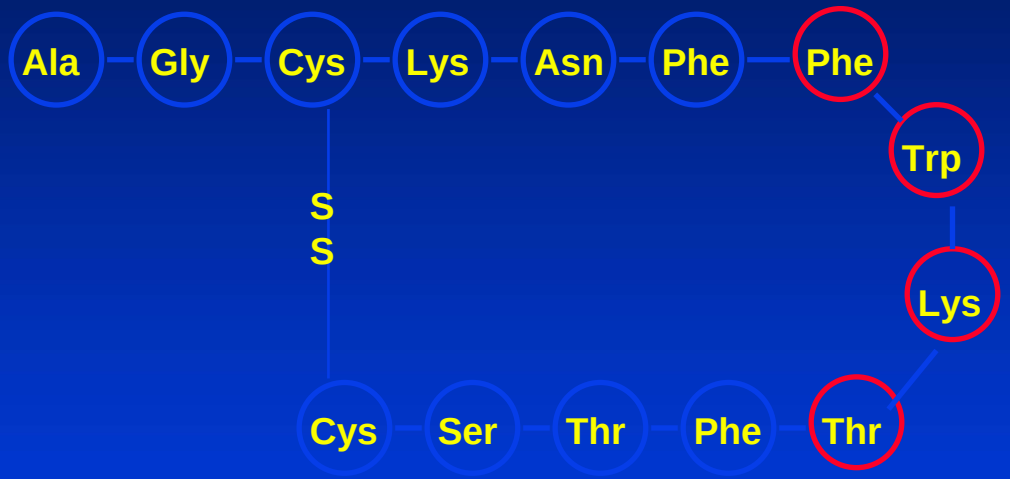
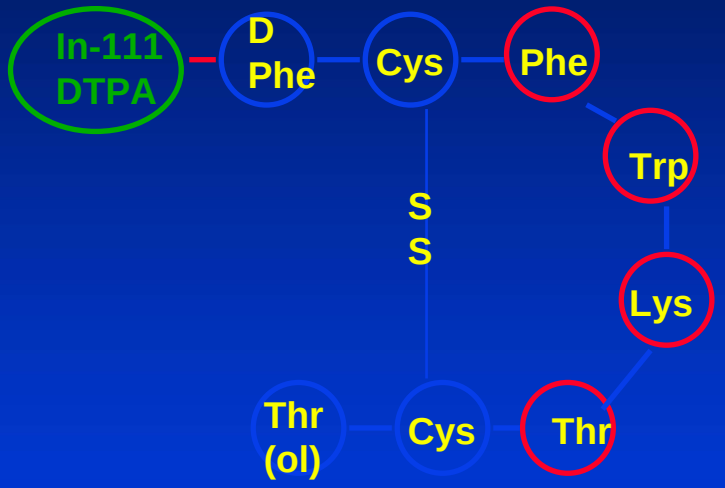
Non PET (Single Photon) Molecular Imaging

OctreoScan (In-111 Somatostatin) Peptide Imaging



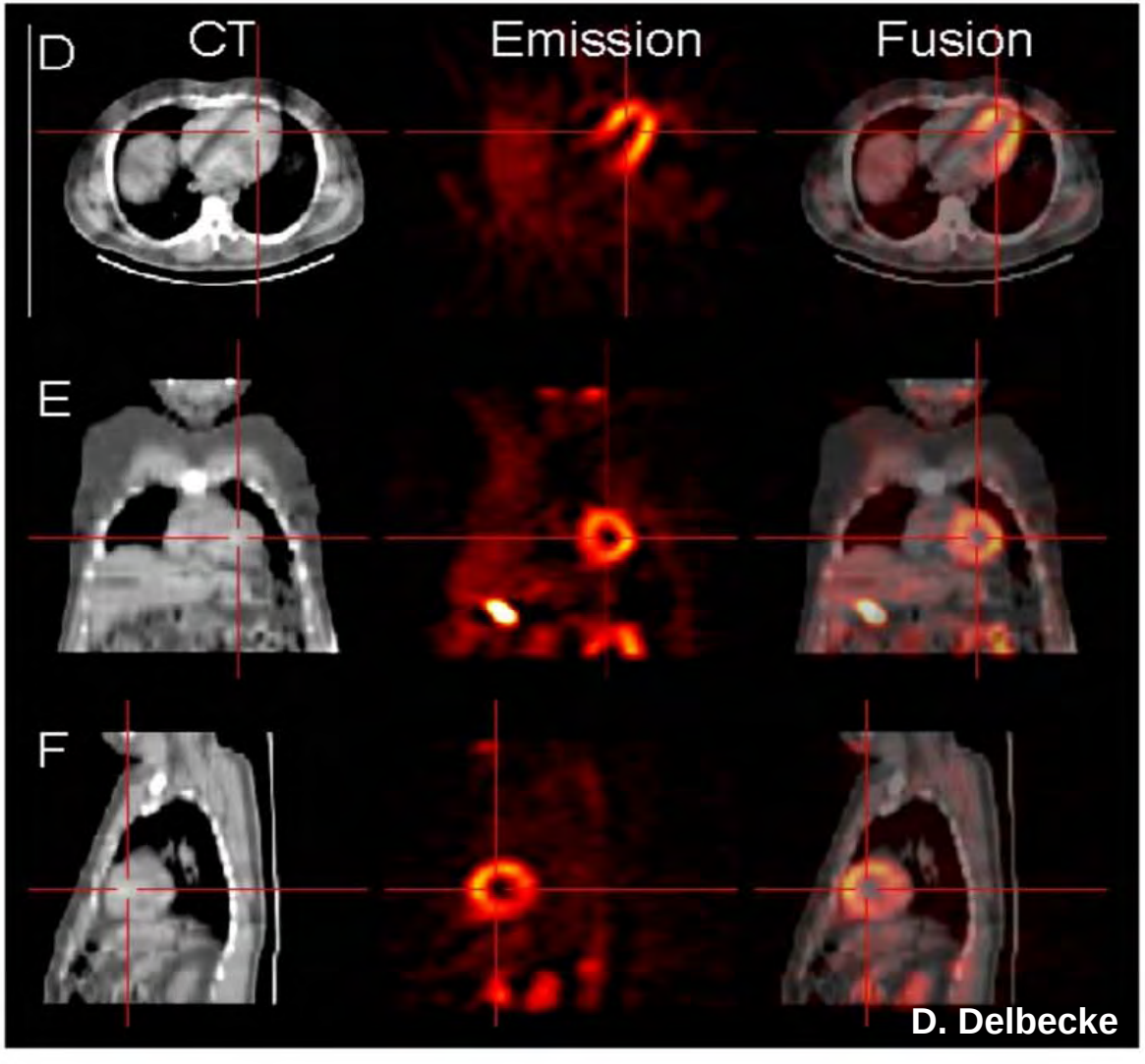


Human Somatostatin

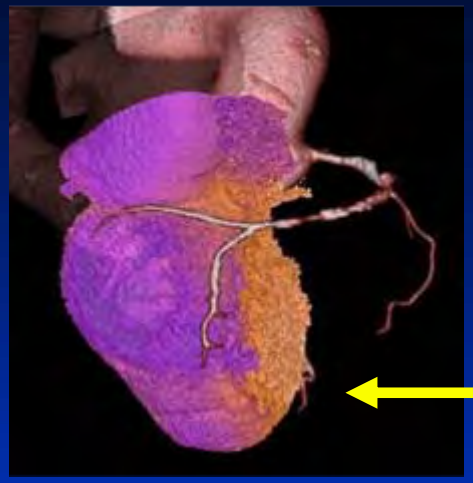
In-111 Octreotide(Sandostatin)
Pentetreotide (OctreoScan)

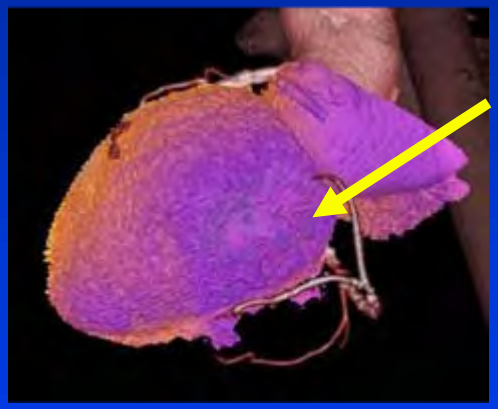
Receptor Site

Cardiac Attenuation Correction with low-dose CT

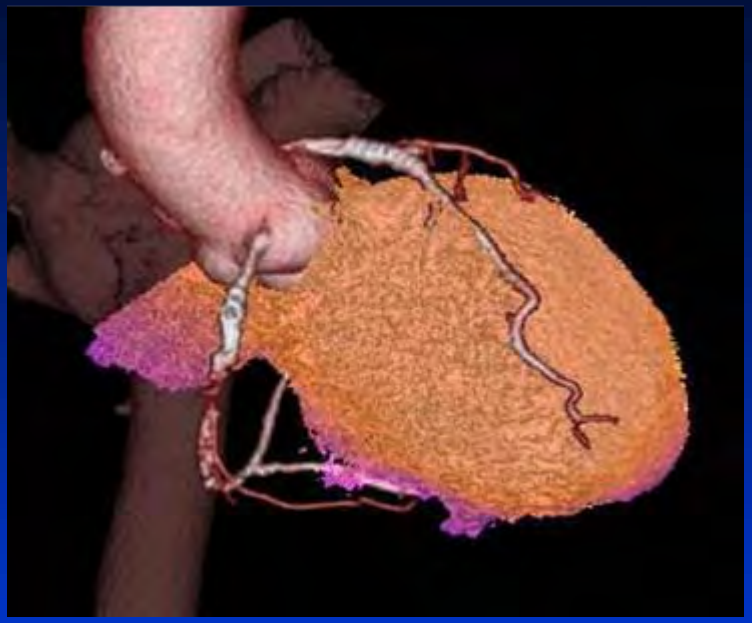


Fused SPECT Perfusion/CTA





Ischemia in inferior and lateral walls



Normal perfusion in anterior wall

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Exposure Reduction Through Quality Assurance for Diagnostic X-ray Procedures

Jill Lipoti

New Jersey Department of Environmental Protection

Outline

- History of Regulatory approaches
- Components of a Comprehensive Quality Assurance Program
- Choice of indicators – ESE and image quality
- Achievements
- Outreach
- Expansion to dental facilities

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Historical Focus of Inspection Program

- Number of Inspections
- Inspection Backlogs
- Number of Violations
- Violation Rates

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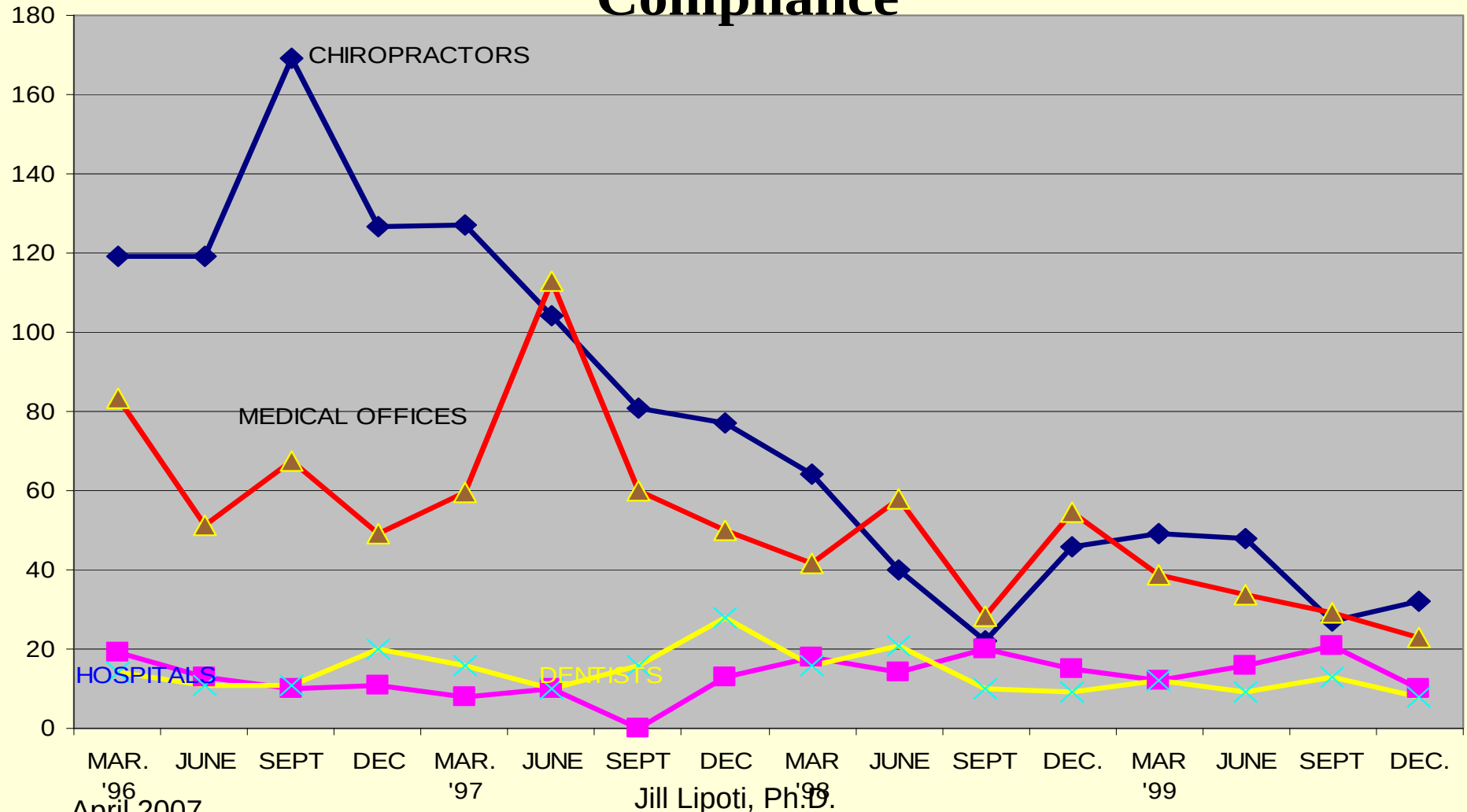
Early Non-Regulatory Outreach Efforts Provided Limited Improvements in Compliance



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Shortfalls of Historical Approach

- Facilities not taking responsibility for equipment
- Compliance rates steady after years of this approach with no significant improvements
- Delay in identifying and correcting faulty equipment
- High radiation exposure
- Poor image quality
- Important indicators not being evaluated

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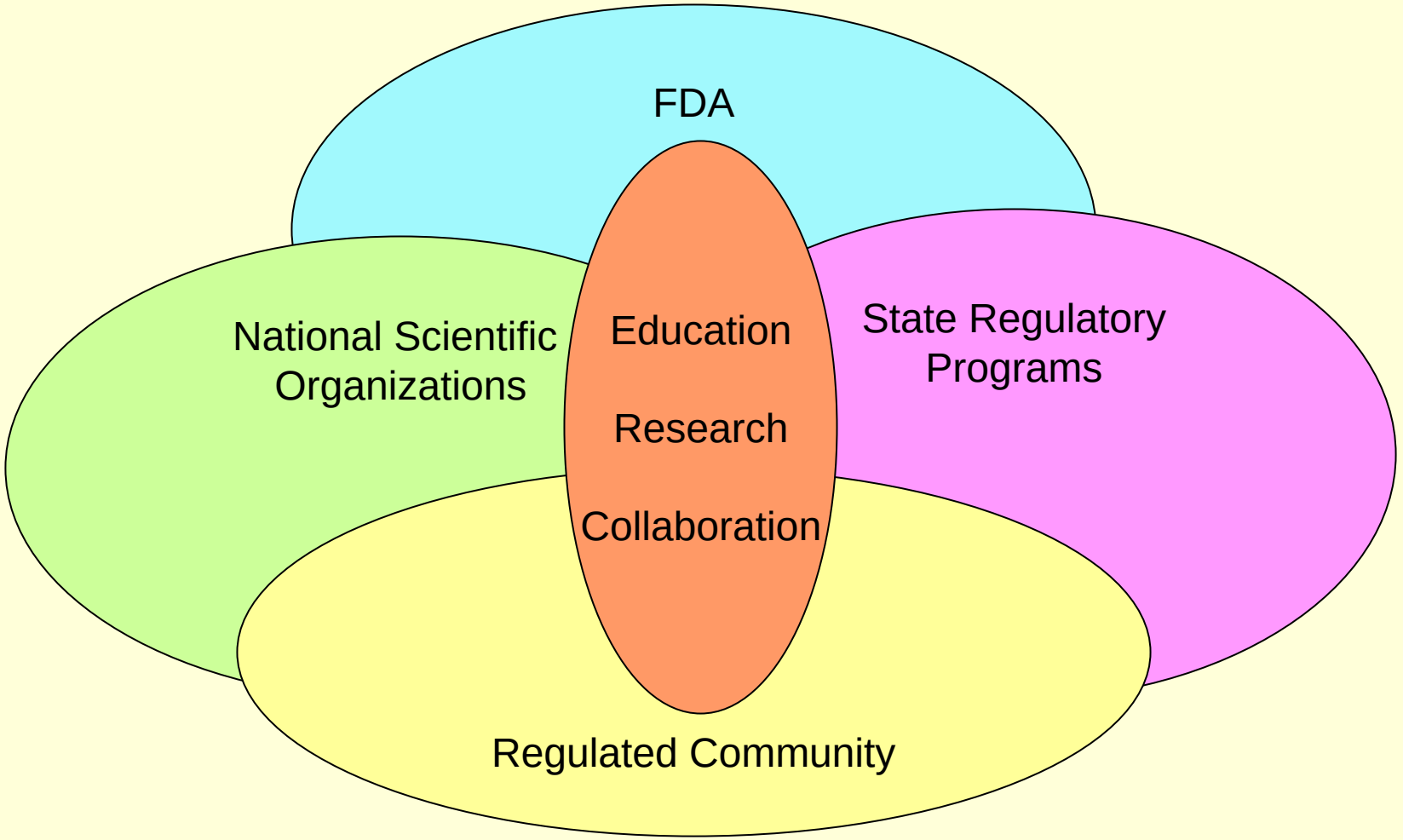
Why Quality Assurance?

- **Improves Protection of Public Health**
  - Reduces unnecessary radiation exposure
  - More timely equipment repair, less down time
  - Improved image quality resulting in better diagnosis and fewer repeat exposures
  - Improved understanding of x-ray risks and benefits
  - Closer ties with constituents

New Approach



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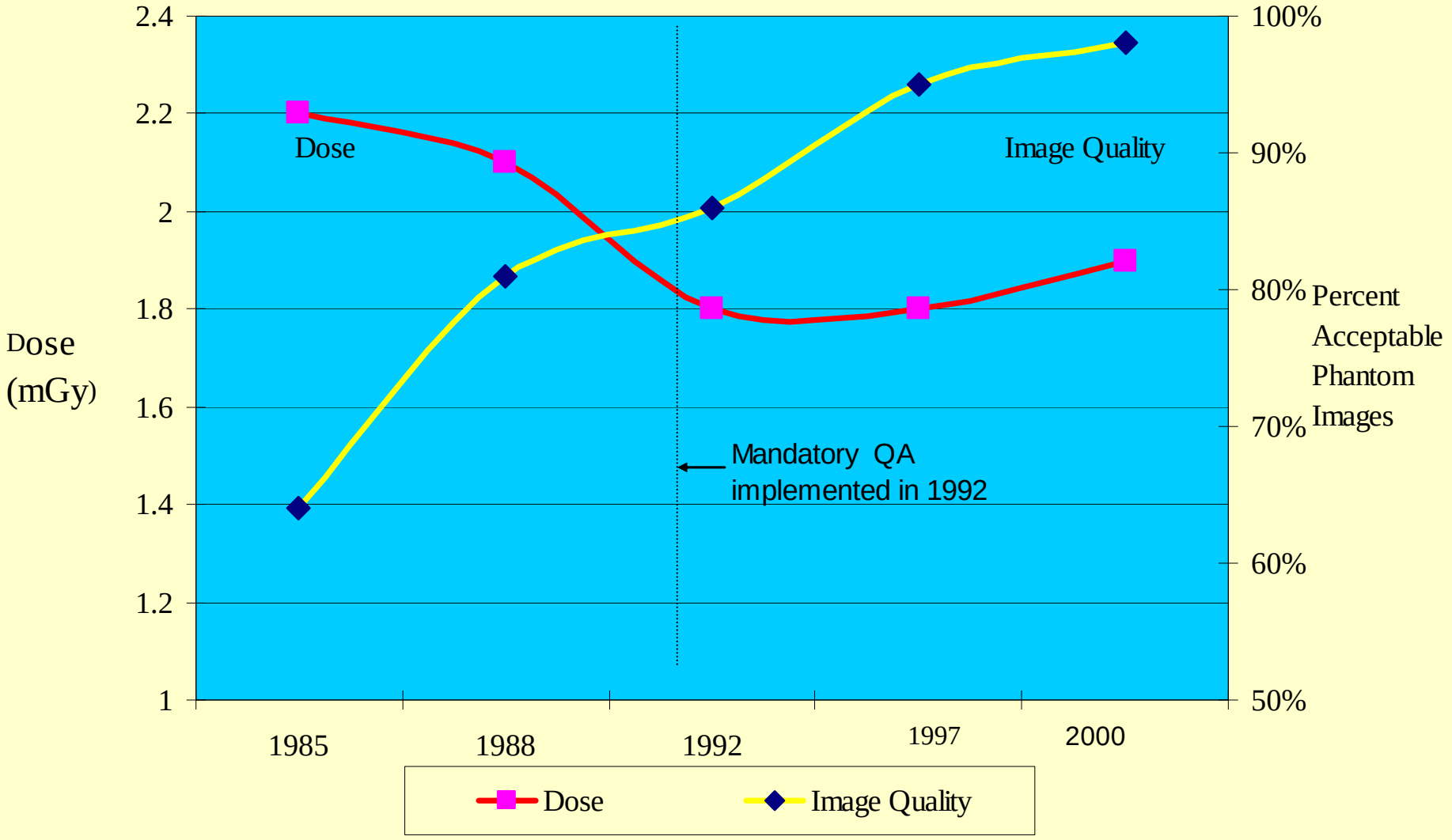
FDA MQSA Program Produced Marked Improvement in Image Quality & Patient Dose



Components Of A Comprehensive Quality Assurance Program

- Regulatory Requirements
- Certification of Qualified Medical Physics Professionals
- Compliance Guidance Documents for Users
- Training
- Periodic Quality Control Tests with Annual Review by Certified Professionals
- Compliance Inspections
- Measurable Performance Indicators

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Elements of New Jersey's QA Program

- Borrows key components from MQSA
  - Periodic quality control tests performed by facilities
    - densitometry/ sensitometry, light field alignment, reproducibility
  - Annual review by certified medical physicists
    - Half value layer, dose, image quality
  - Inspection by state regulators
    - Review QA records, dose and image quality tests

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Exposure Action Levels

Study/Action Level	LOW	AVERAGE	HIGH	EXTREMELY HIGH
CHEST	Less than 5	5 to 20	21 to30	Greater than 30
LS SPINE	Less than 100	100 to 450	451 to 600	Greater than 600
FOOT	Less than 5	5 to 30	31 to 40	Greater than 40

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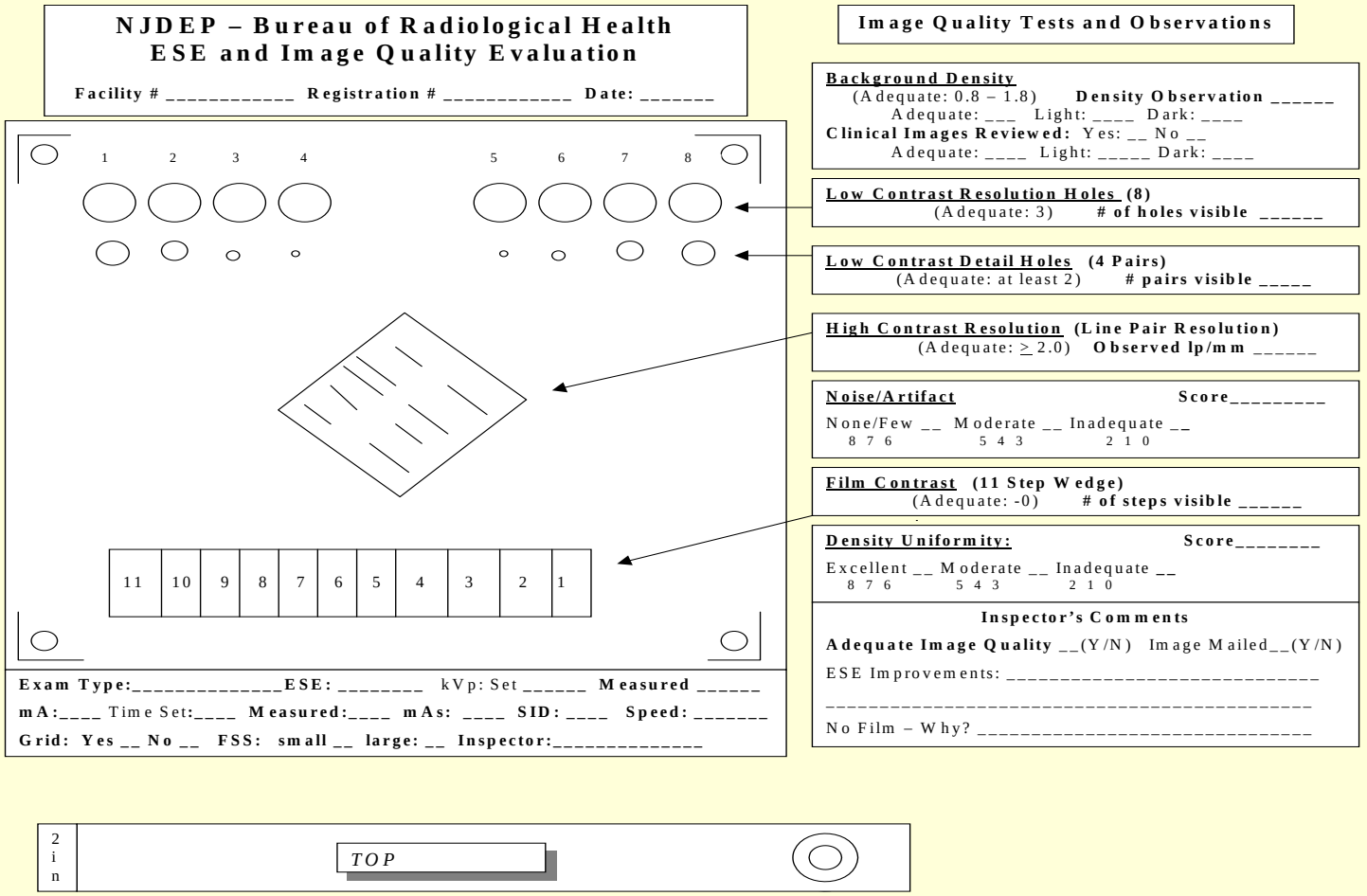
Image Quality Tool Developed



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Scoring System Developed (Maximum Score)

Background Density	25%
High Contrast Resolution (lp/mm)	20%
Noise/Artifacts	20%
Density Uniformity	10%
Low Contrast Resolution	10%
Low Contrast Detail	10%
Film Contrast (Step Wedge)	5%

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Outreach Documents

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Entrance Skin Exposure (ESE) Report

Machine Registration Number: 204986 **Manufacturer:** CONTINENTAL X-RAY CORP.

Facility ID: 110517 **Location:** Your Office

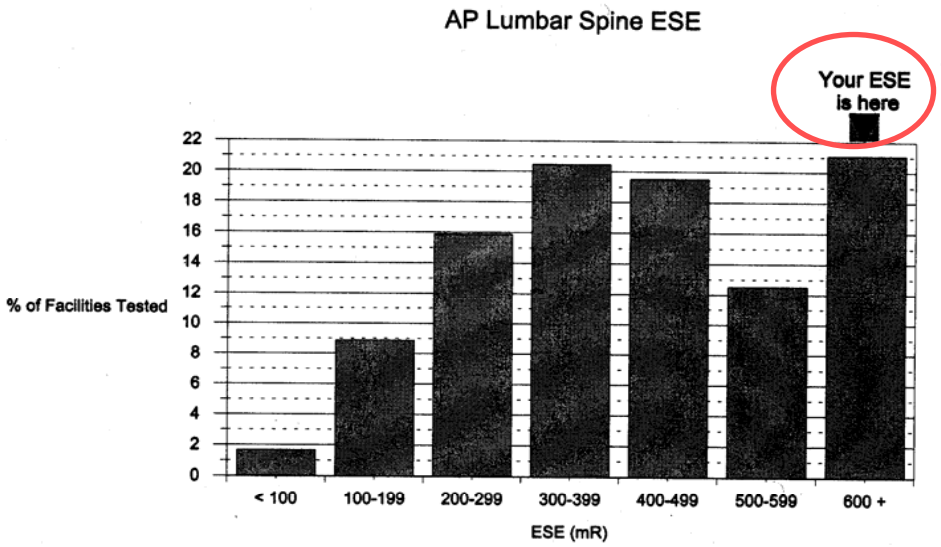
Exam Type: AP Lumbar Spine

Your ESE: 625 mR

Ranking: **Extremely High Radiation Exposure**

Your ESE, 625 mR, as demonstrated on the chart below, is extremely high compared with other similar facilities performing the same procedure on the same size patient. It is likely that your patients are receiving unnecessarily high and excessive radiation exposure. A high ESE usually results in a radiograph with excessive density (dark), loss of image quality, and unnecessary irradiation to the patient. The BRH is very concerned about this reading and is requesting that you consult with your medical physicist and investigate the cause(s) for the high exposure.

The BRH requests that you prepare and submit a report containing your finding(s) and corrective action(s) within 30 days of the date of this letter.



Facilities Subject to QA

	Nov 2001	Nov 2003	Nov 2006
Hospitals	94	89	82
Medical Offices	1494	1270	1334
Chiropractors	1293	886	796
Podiatrists	626	419	420
Industry, Schools, Gov't Facilities (estimate*)	35	35	35
Total	3542	2699	2667

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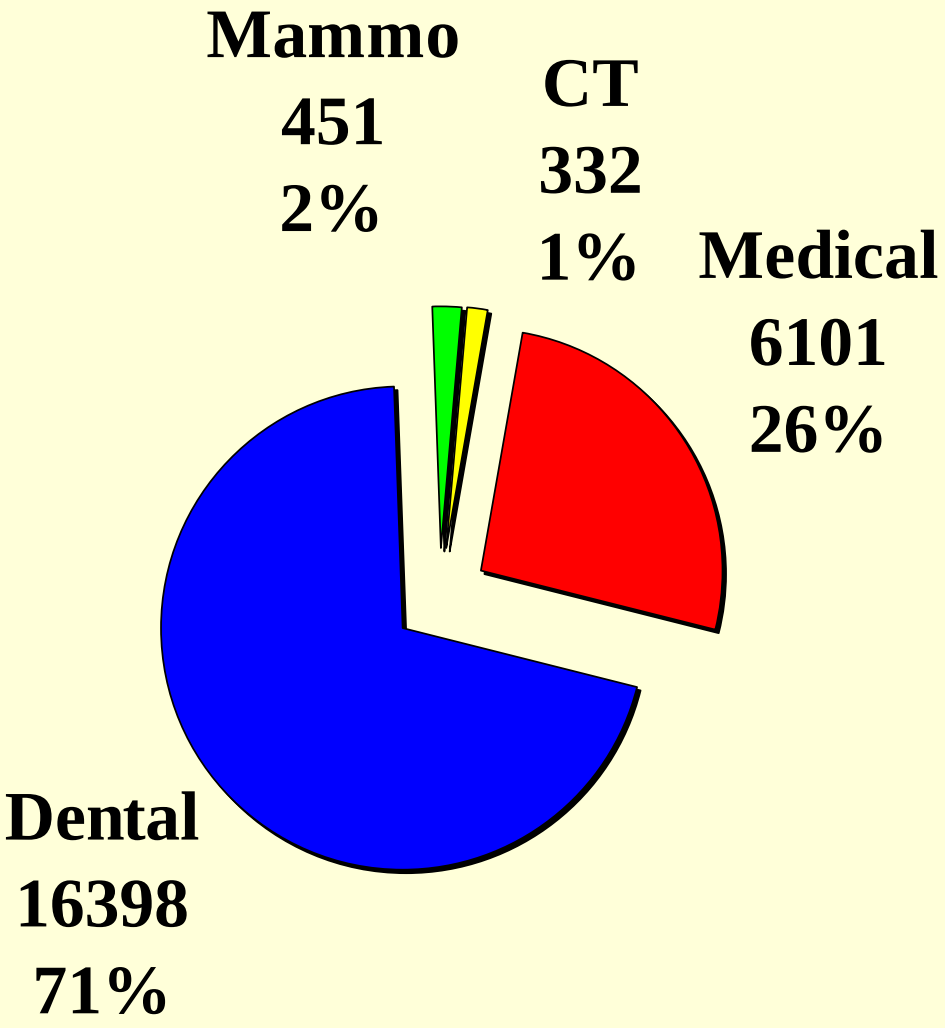
Distribution of NJ Registered X-ray Machines



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Achievements Realized

- Reductions in patient radiation exposure
- Improvements in diagnostic image quality
- Closer working relationship with physicists and regulated community

Reductions in ESE

	Prior to QA (mR)	After Yr 4 QA (mR)	Percent Reduction ESE
Foot	31.3	10.5	66.5%
Chest	22.2	11.9	46.4%
Lumbar Spine	525.1	345.2	34.3%

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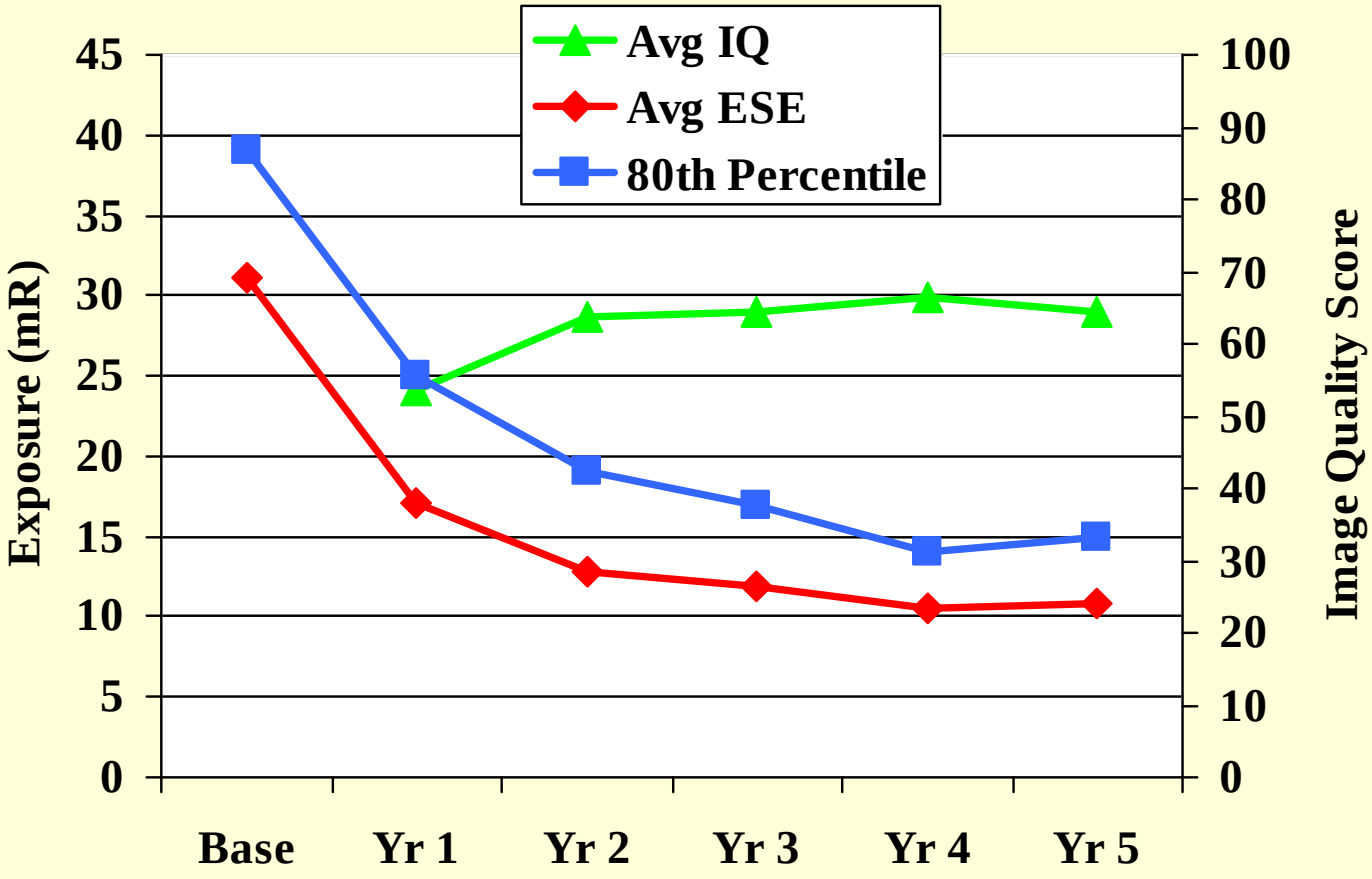
Foot ESE and IQ



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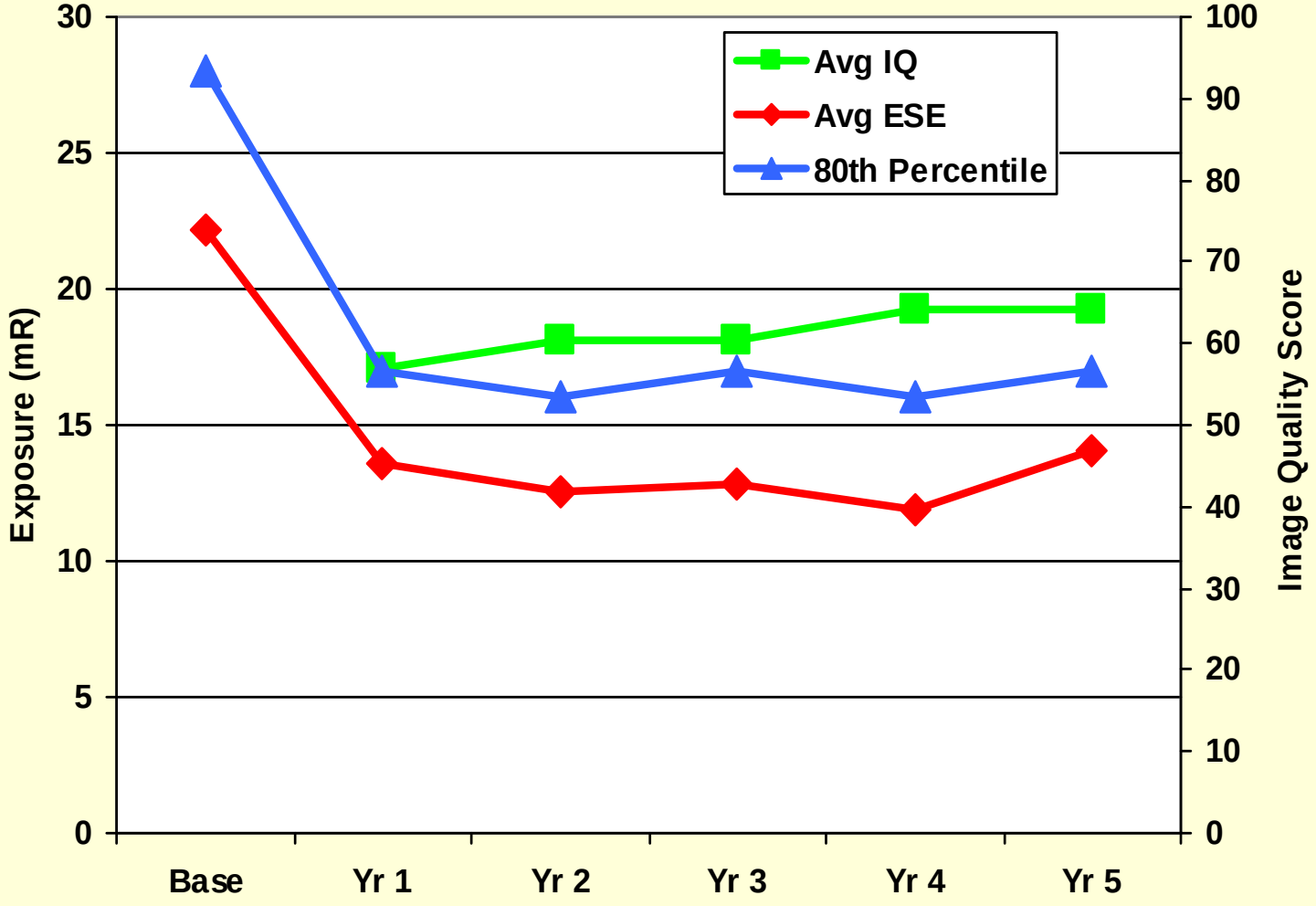
Chest ESE and IQ



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Lumbar Spine ESE and IQ

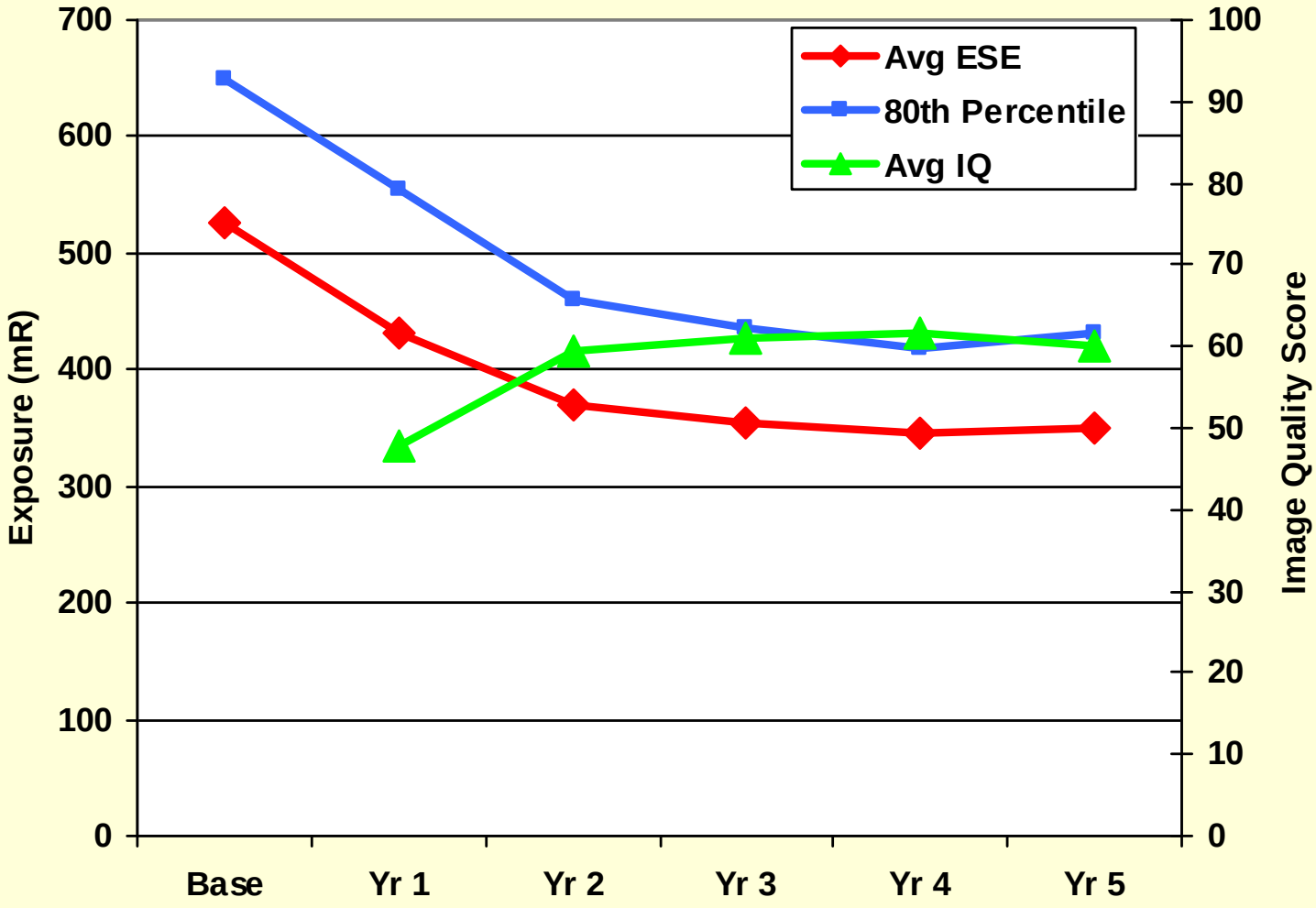

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Image Quality Improvements

	Average Score	Poor Images	Good to Excellent
YR1	51.3	10%	58%
YR2	60.6	2%	84%
YR 3	62.0	2%	87%
YR 4	63.2	1%	89%
YR 5	61.9	1%	88%

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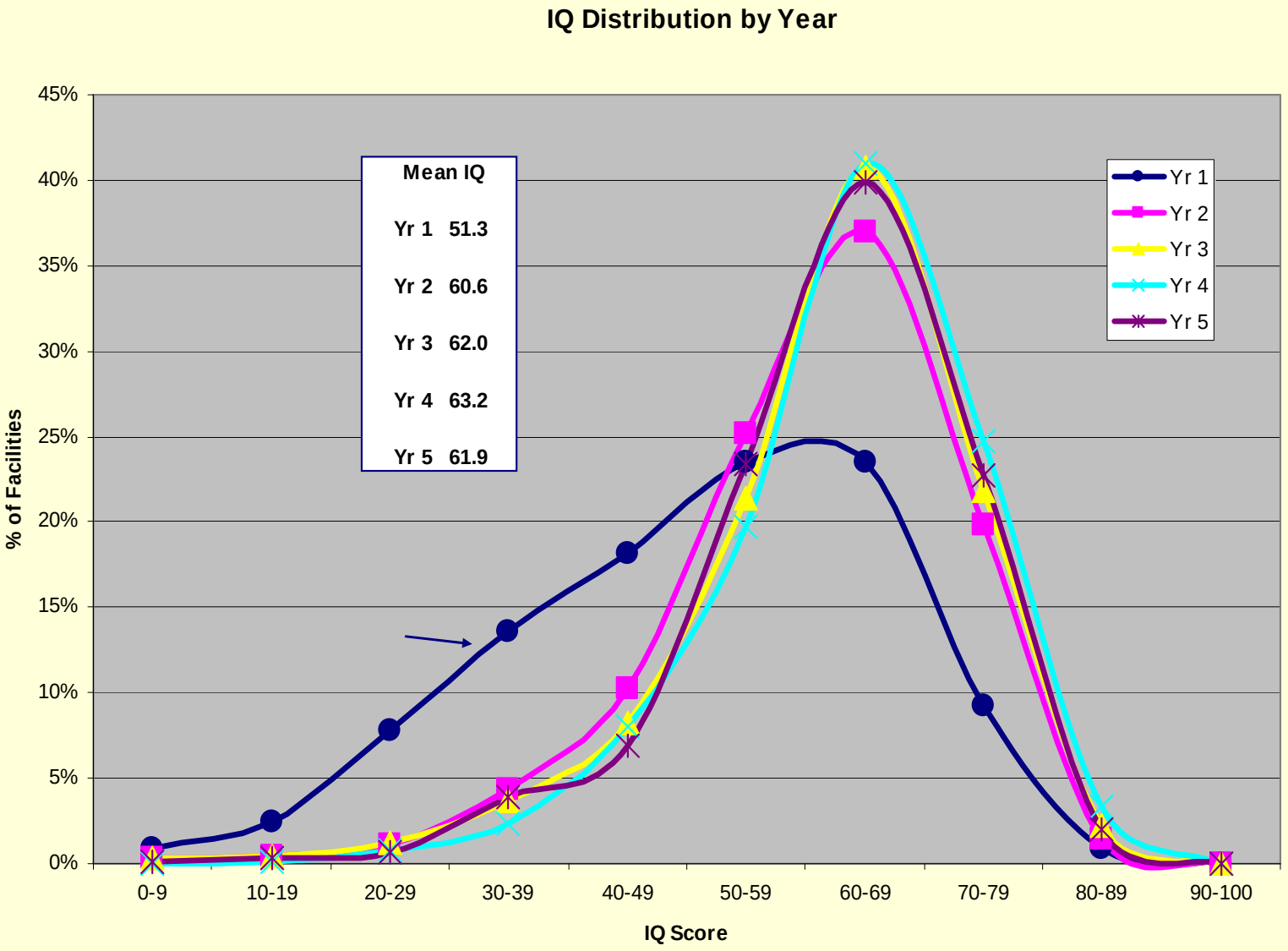

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Results of Collaboration

- Work with NJ medical physicists to standardize dose measurement and reporting for all NJ CT facilities
- First time New Jersey could compare CT doses and establish average doses by scan procedure
- Permits in depth evaluation of various machine types and factors that effects dose
- Will be able to advise CT community on ways to improve dose

CTDI Doses (mGy) By Procedure Type

Procedure/ Parameter	Adult Head	Adult Abdomen	Pediatric Abdomen
Number	141	134	121
CTDI(w) Mean	47.67	19.15	16.56
CTDI(w) 80th %tile	59.50	25.46	21.12
CTDI(vol) Mean	49.12	19.33	15.33
CTDI(vol) 80th %tile	60.40	26.00	21.20

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Baseline CTDI(vol) Doses (mGy)

Procedure	Adult Head	Adult Abdomen	Pediatric Abdomen
Mean	49.12	19.33	15.33
80th percentile	60.40	26.00	21.20

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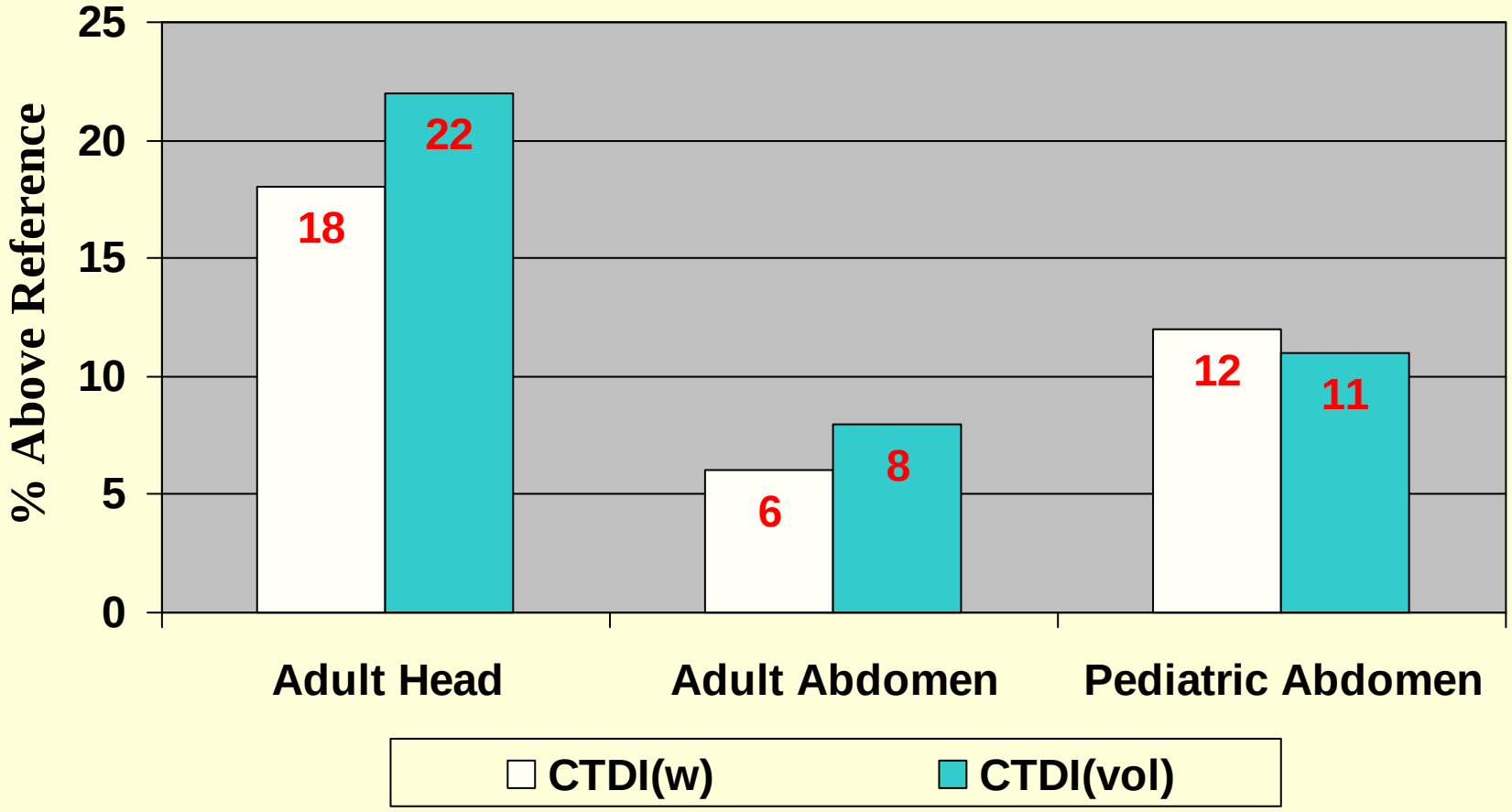
Percent of CT Doses Above Reference Levels



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New Jersey's Dental ESE Initiative

- Incorporates several components of medical QA program
- Measures ESE for intra-oral examinations
- Post inspection letter sent to facilities compares their dose to New Jersey facilities performing using same imaging systems
- Encourages facilities to switch to faster speed films and lower patient dose

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Dental ESE Reduction Initiative

- The Bureau has been collecting ESE on dental machines since February 2002.
- Mimic the ESE performance charts of our medical QA program.
- No IQ test is done on dental x-rays.
- Established ranges of low, average, high and extremely high ESE for each film speed encountered.
- No ranges established yet, for CR/Phosphorous film

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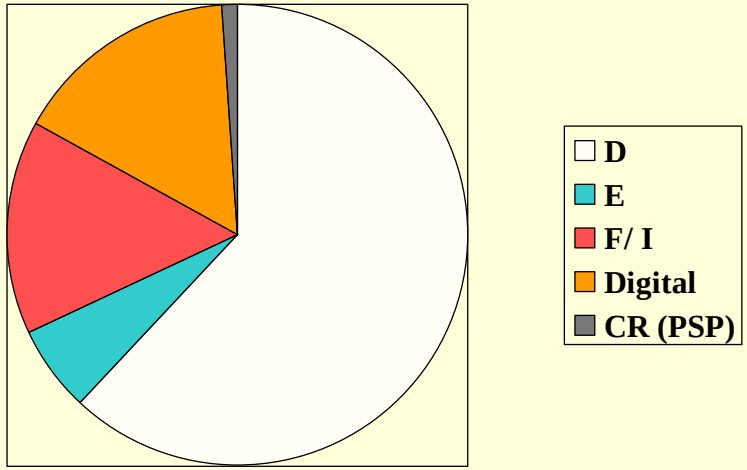
Distribution of Film Used in NJ

Film Speed	% Machines using
D	62.2
E	6.2
F & I	15.0
Digital	15.8
CR (PSP)	0.8



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Established ESE Action Levels
(1/12/02 to 6/30/05)

	ESE Range Values					
Film Speed	Low	Average	High	Ext High	Mean	Data (#)
D	0-149	150-350	351-500	> 500	232.6	5586
E	0-100	101-170	171-255	> 255	176.1	559
F&I	0-94	95-135	136-200	> 200	145.6	1352
DR	0-20	21-100	101-150	> 150	99.0	1416

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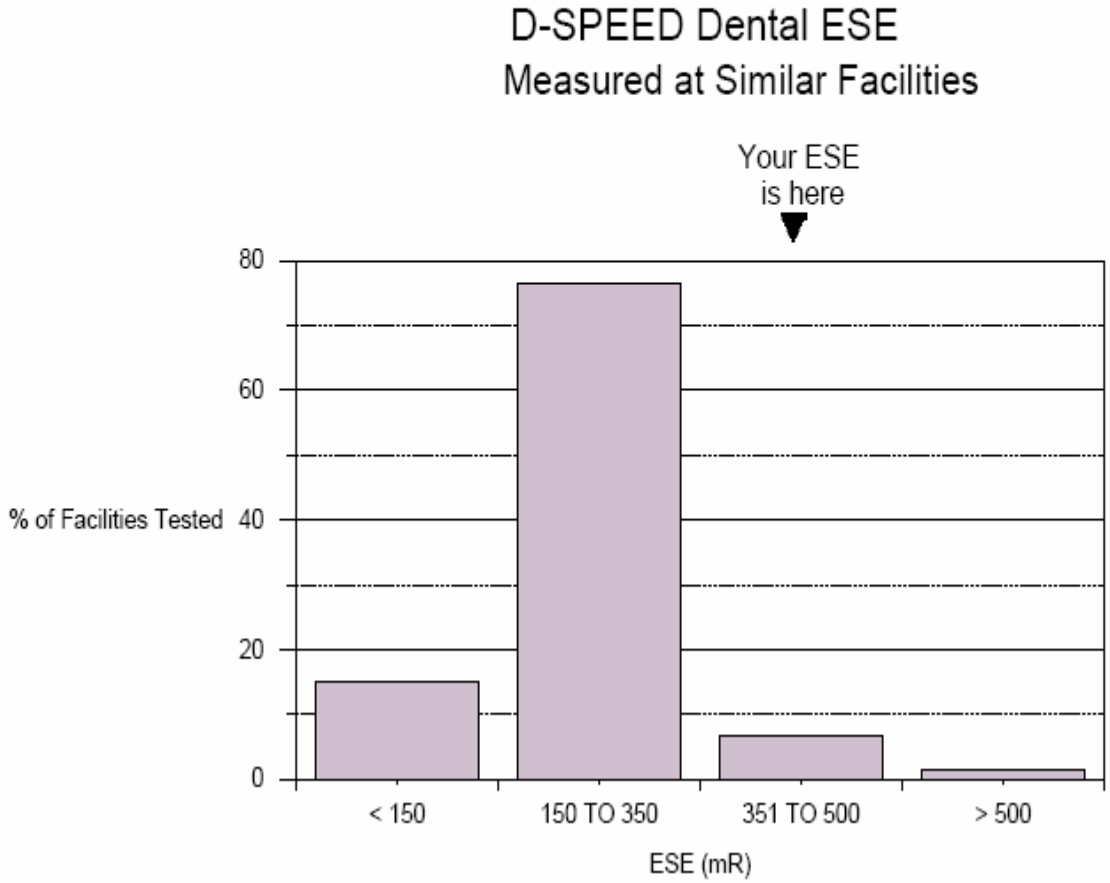
New Jersey DEP
Environmental Safety & Health

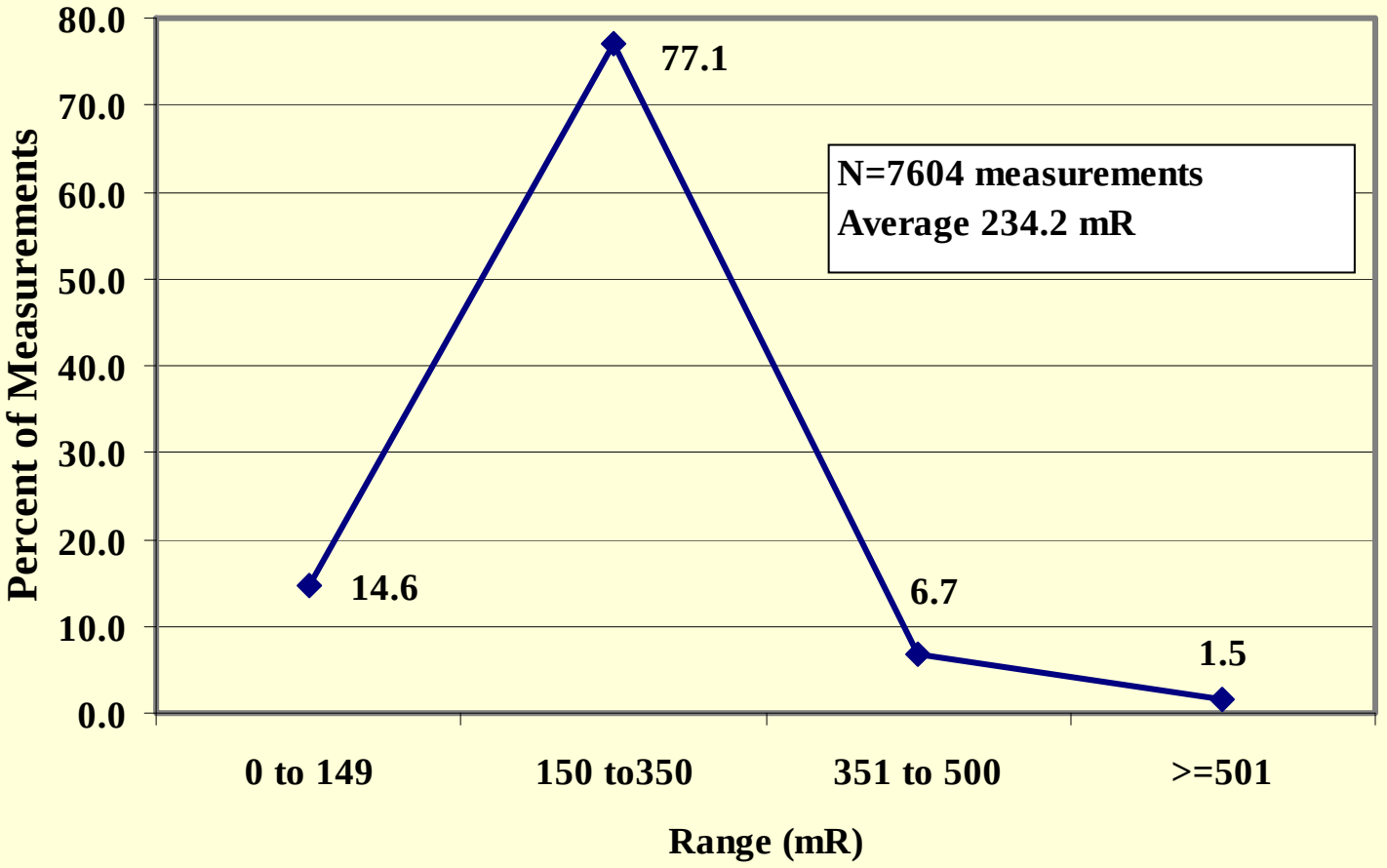
Sent Post Inspection Reports Detailing ESE Results

- Letters explain the factors that affect ESE
- Plots facilities dose as compared to the rest of NJ machines using same speed film
- Describes the category facility ESE measurement falls into
- Initiative started April 2005. Letters were mailed out to facilities dating back to April 2003

high ESE will usually result in a radiograph with excessive density; for example, images are dark and usually do not provide good diagnostic quality. This may result in your patients receiving additional and unnecessary radiation exposure. Please examine your dental radiographs. The Bureau recommends that you consult your film manufacturer's technical staff or a medical physicist and discuss ways to reduce your ESE. For a list of medical physicists, go to http://www.nj.gov/dep/rpp/download.htm and click on Quality Assurance or contact us at (609) 984-5370.



Dental Intraoral Entrance Skin Exposure
2/5/02 to 4/17/06
D speed



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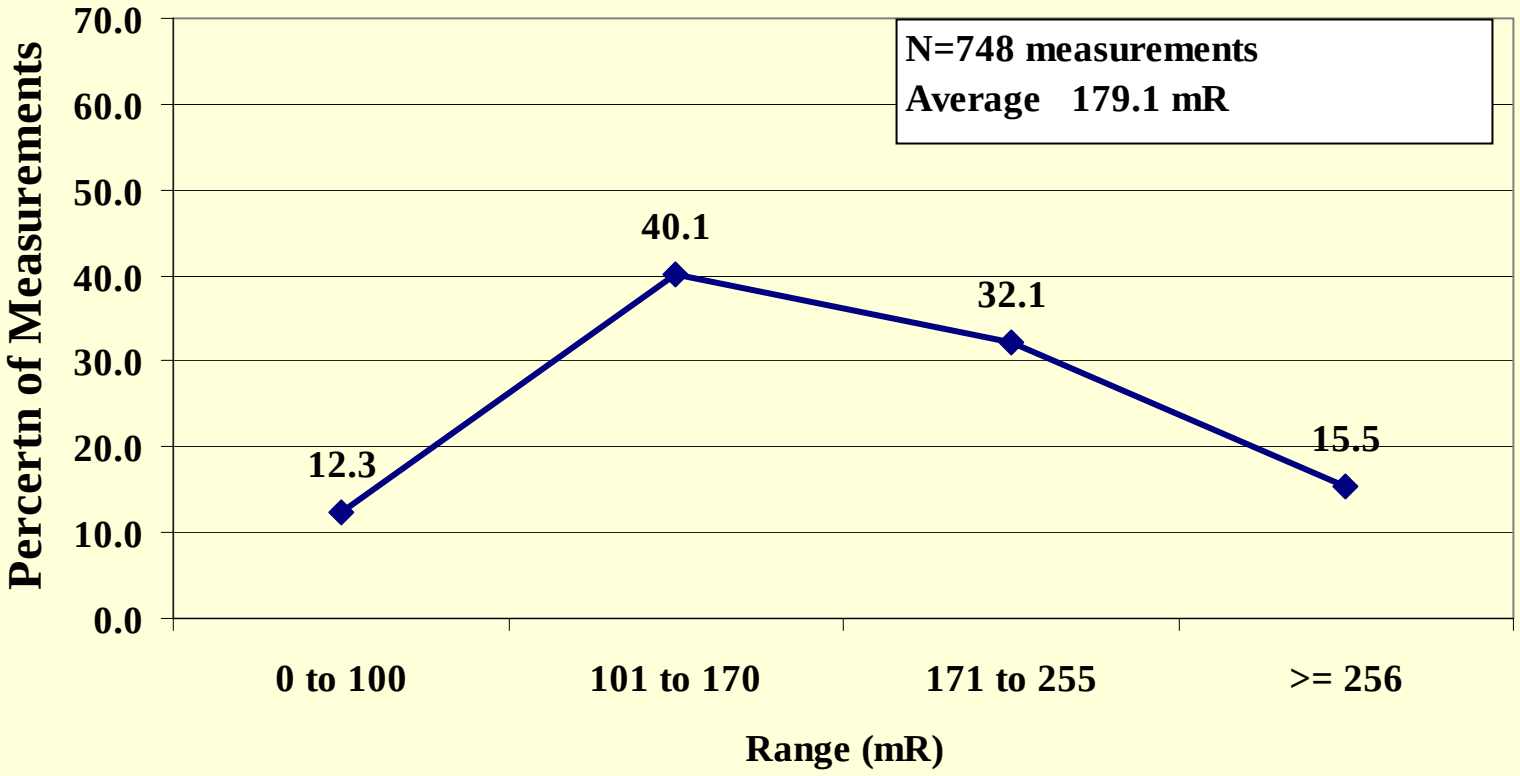
Dental Intraoral Entrance Skin Exposure
2/5/02 to 4/17/06
E speed



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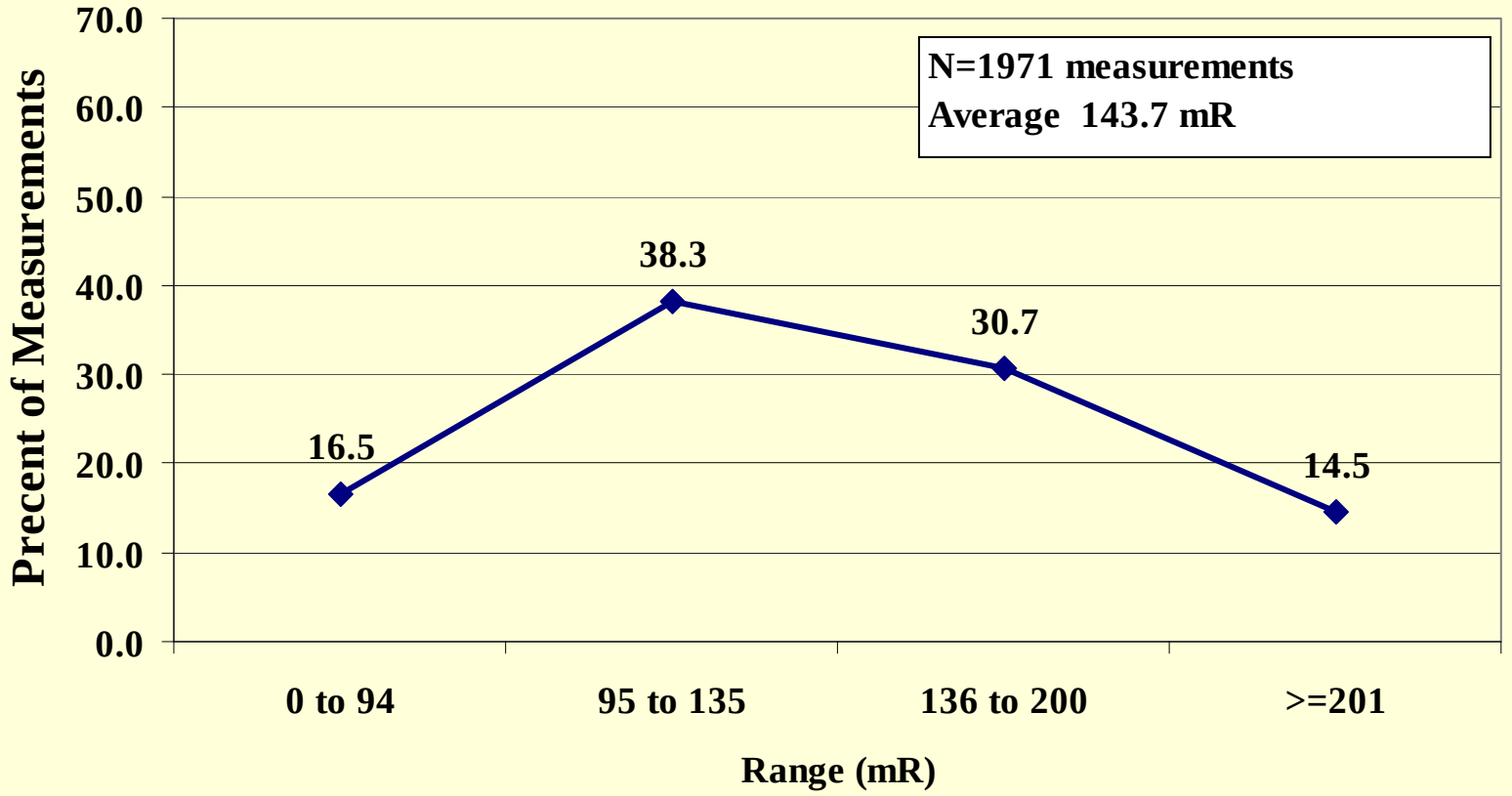
Dental Intraoral Entrance Skin Exposures
2/5/02 to 4/17/06
F & I speed



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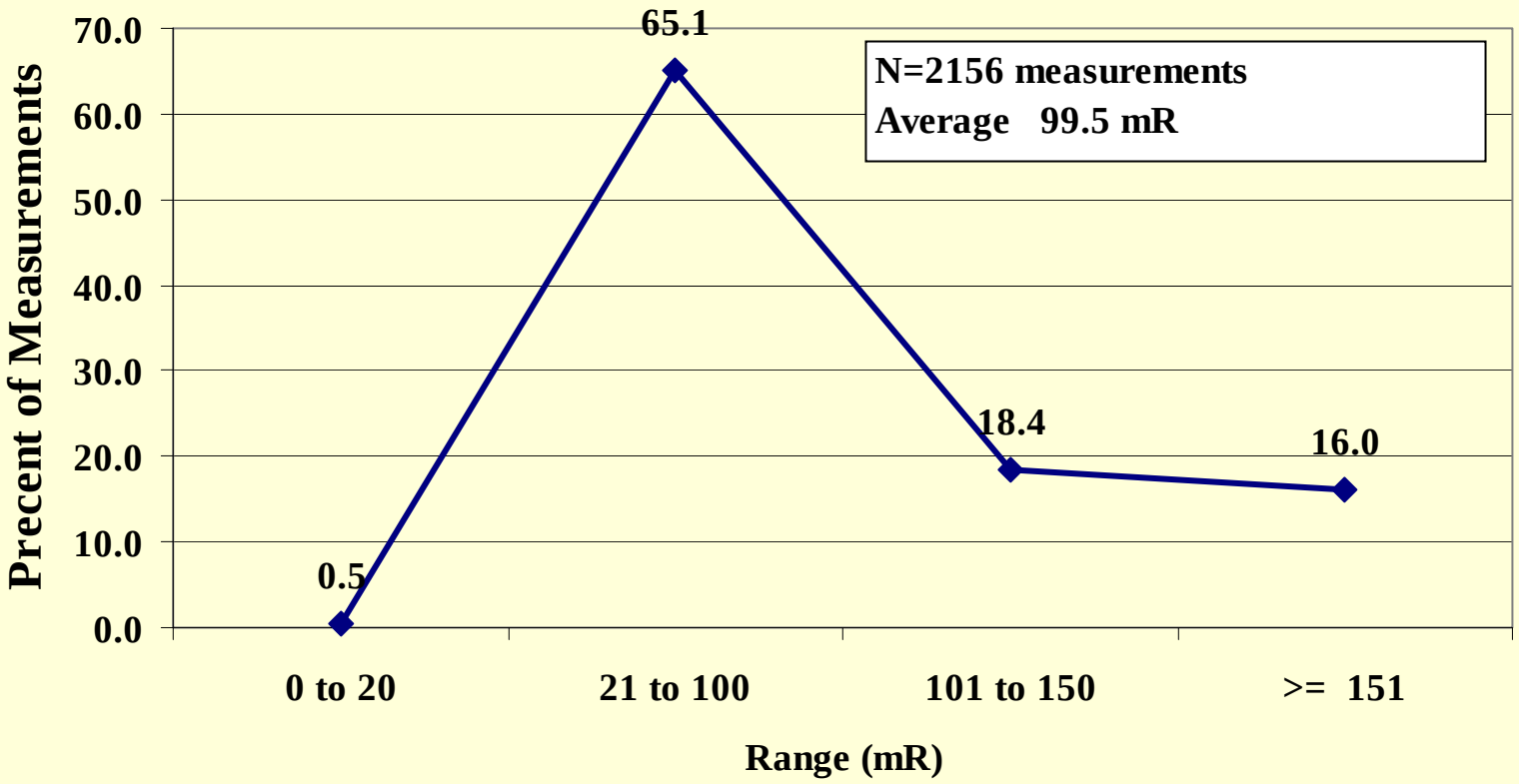
Dental Intraoral Entrance Skin Exposure
2/5/02 to 4/17/06
Digital



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Initial Inspections Completed

- As of June 30, 2006 all registered dental facilities (5,000) have received the post inspection ESE report
- As of July 1, 2006 the Bureau began conducting re-inspection of 600 dental machines with extremely high ESE
- Evaluate changes since receiving letter (ie. change to faster film, lowered ESE, etc)

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Early Re-Inspection Results

- To date 39% of machines with extremely high ESE were re-inspected
- How were improvements realized?
  - 27 machines (13%) changed to faster films
  - 105 machines (49%) reduced exposure time
- Unexpected negative results
  - 24 machines (11%) changed to slower speed films
  - 59 machines (27%) made no changes

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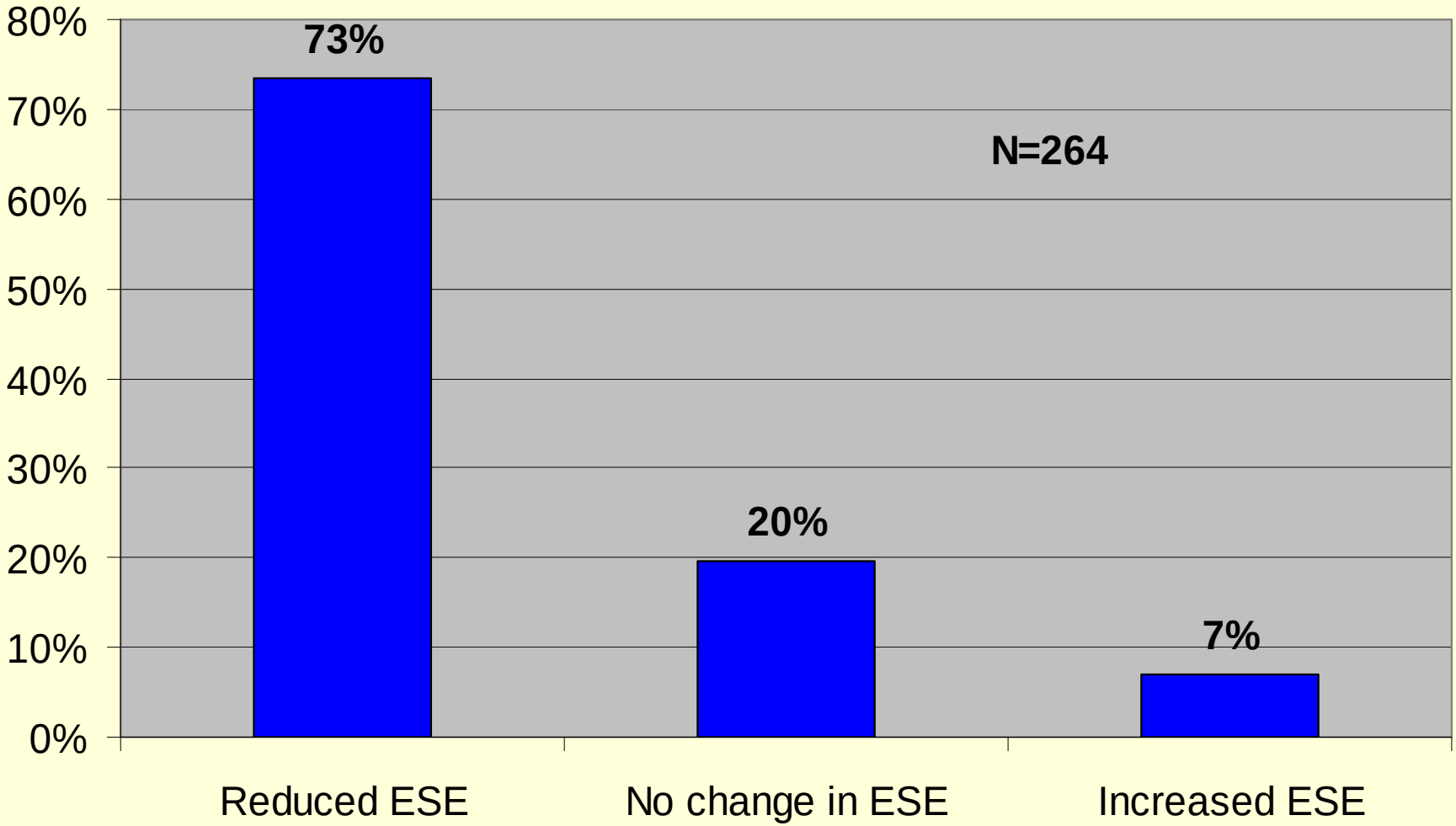
Results of Re-Inspection of Machines with Extremely High ESE



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Expanding Success To Larger Populations

- FDA MQSA provided the model
  - Reached 2% of Medical X-ray Equipment
- New Jersey Diagnostic QA Program
  - Reached a larger audience (26%)
- Voluntary Efforts with Dental Industry Completes the loop
  - Reaches the remaining 71 %

Relevance

- What you measure matters
  - Violation rates irrelevant, ESE and IQ relevant
- How you communicate matters
  - Letters to facility comparing them to peers
- Who is consulted matters
  - Collaborative approach involving physicists
- How digital is regulated will matter

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Advances in Radiation Protection in Medicine

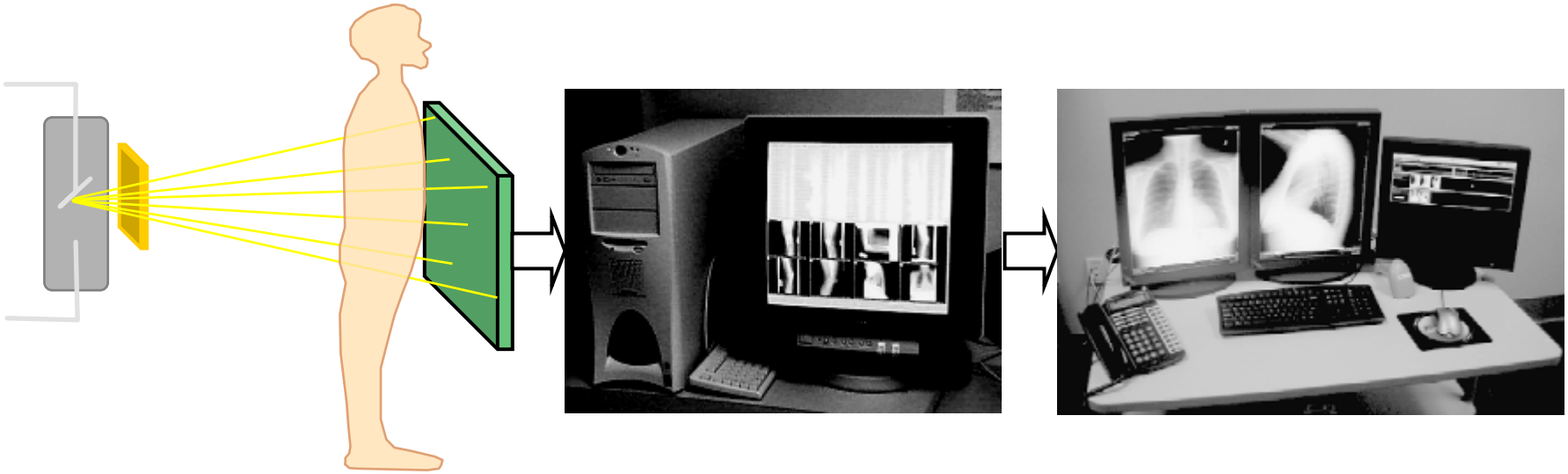
State of the Art: CR and DR …. "Digital Radiography"

J. Anthony Seibert, Ph.D.
Department of Radiology
University of California Davis
Sacramento, California

Widespread implementation of digital radiography is underway

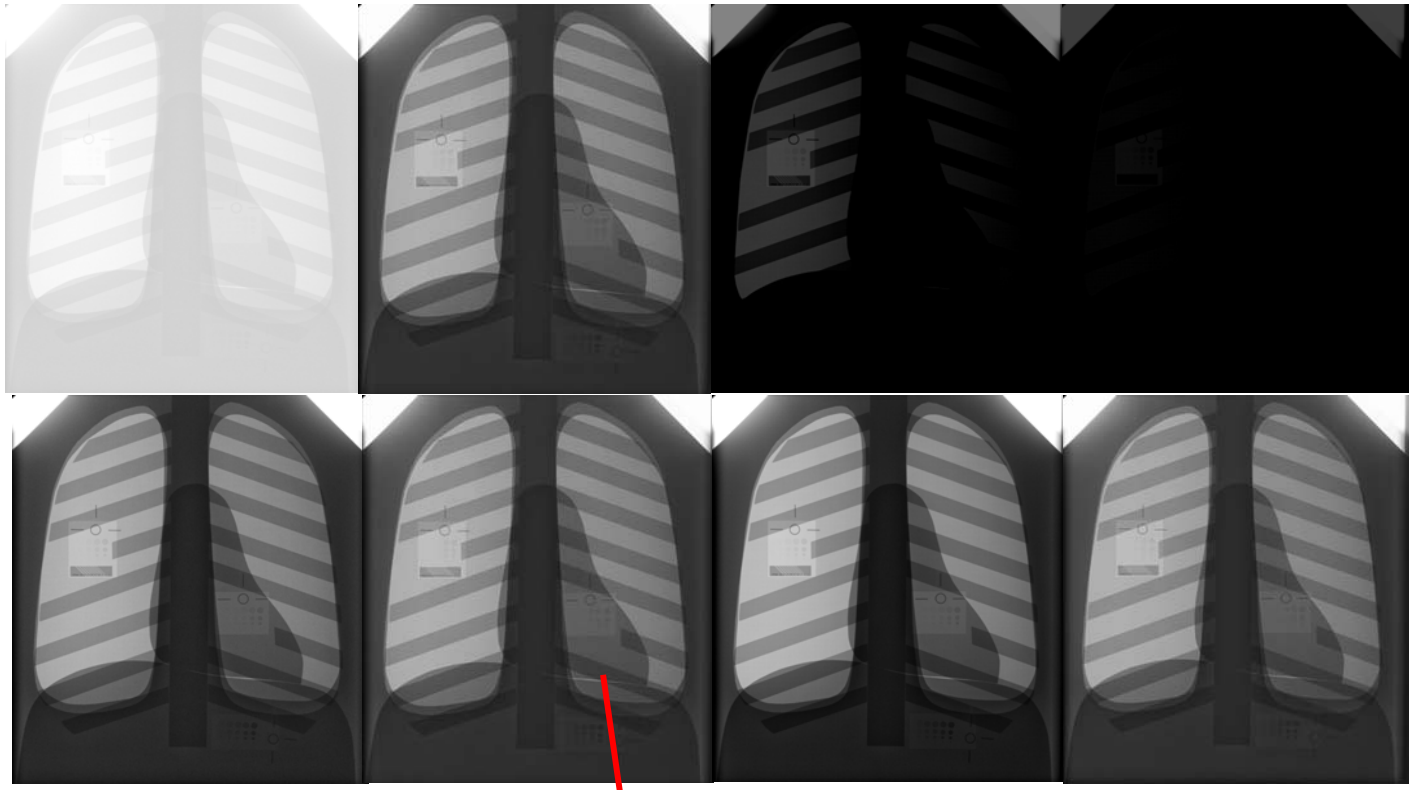
- Paradigm shift from screen-film operation
- Conceptual *and* technical challenges
- Digital radiography detector characteristics
  - Wide exposure latitude
  - Variable “speed” detector
  - Loss of immediate feedback to technologist
- Digital radiography outcomes
  - Variable image quality
  - **Patient overexposure can easily occur**
  - Digital system knowledge & continuous training req’d

Digital radiography image acquisition, display, and interpretation considerations



1.	2.	3.	4.	5.	6.
X-rays	Patient	Detector	Computer	PACS	Human
Exam type	Size	Technology	Digitization	Data delivery	Radiologist
kVp, mAs	Positioning	Resolution	Preprocessing	Data display	Knowledge
Tube filtration	Motion	Scatter, grid	Postprocessing	Data storage	Experience
Collimation	ESE, dose	DQE	Configuration	Workflow	Condition

Screen-film versus digital response



The bottom line: Image Quality

- Image quality is an indicator of the relevance of information presented in the image to the task we seek to accomplish using the image
- Considered in terms of portrayal of
  - Normal anatomy
  - Depiction of potential pathology
- Not necessarily the “same” in all images
- A constraining factor is *radiation dose*

Image Quality (IQ) in Pediatric Radiography

- Which has optimal IQ?
- Which has “appropriate” dose?
- Which is ALARA?
- Depending on diagnostic requirements, BOTH!

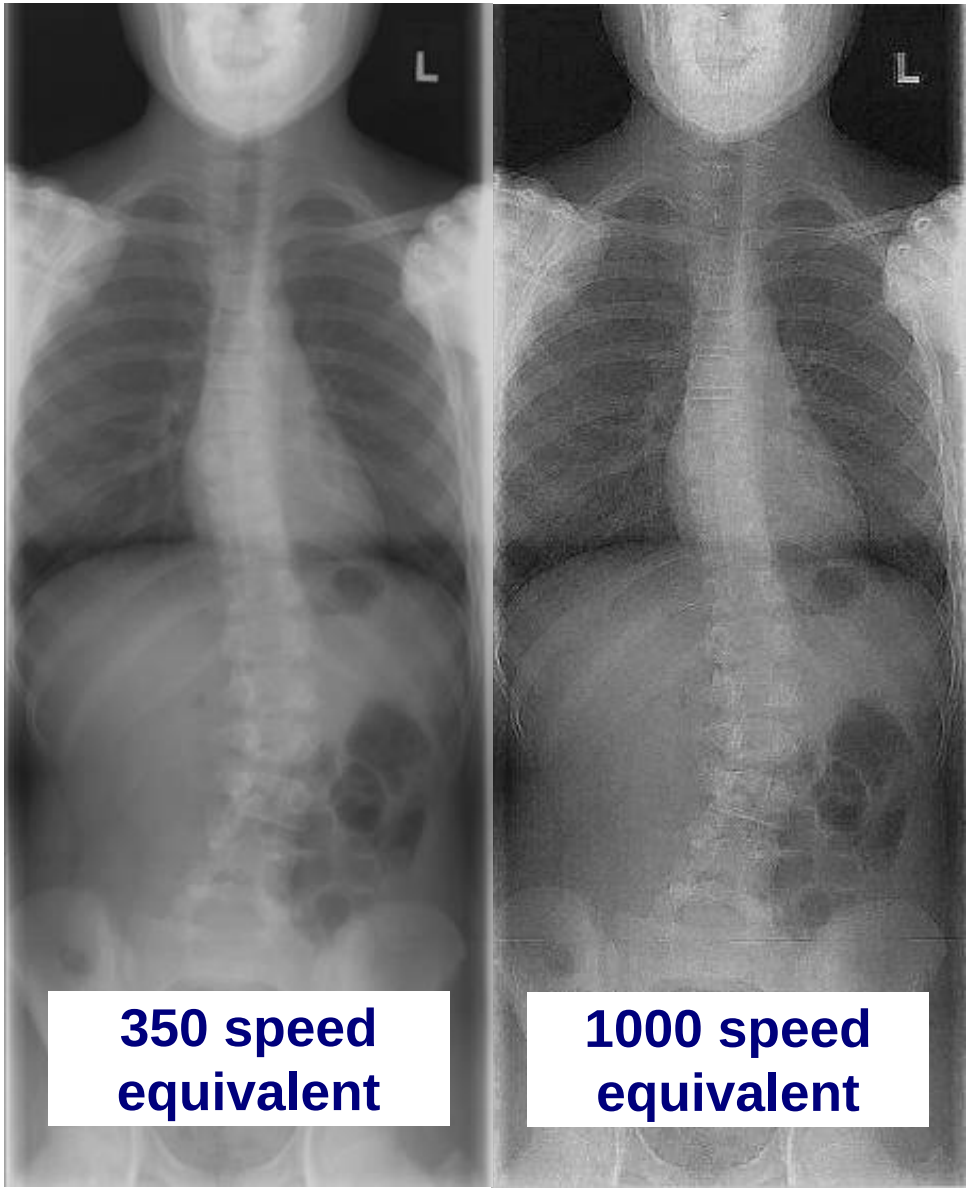


Image Quality considerations

- Spatial resolution, contrast resolution and DOSE
- Screen-film radiography
  - IQ “built in” to the characteristics of the film
  - Film is acquisition, display and archive medium
  - Patient dose is determined by screen-film speed
- **Digital radiography**
  - IQ dependent on Signal to Noise Ratio (SNR)
  - Separation of acquisition, display, and archive
  - **Patient dose can be variable** and dependent on required SNR and efficiency of the detector

Digital Radiography: the good, the bad, ……. and the ugly

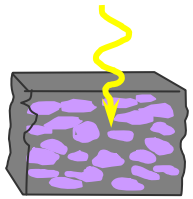
- The good: reduced retakes, image processing, electronic display & distribution
- The bad: technologist complacency, dependency on digital compensation, lack of feedback
- The ugly: hidden overexposures, dose creep, “bit-bucket” processing

…… “0%” retakes !!?? ….. I don’t think so…..

Digital detector technologies

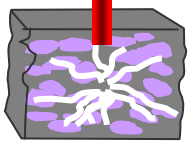
CR

BaFBr
Storage
Phosphor



Laser

Electronic
Processing

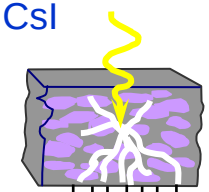


Photostimulated
luminescence
and digitization

Cassette-based
Passive readout

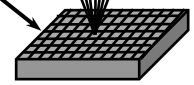
CCD

Gd_2O_2S or CsI
scintillator



Lens

CCD



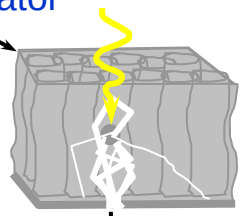
Focused light
to electrons to
digital signal

CCD detector housing

CsI TFT array

CsI scintillator

Columnar
crystals

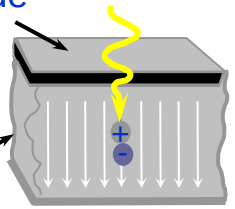


Light to photodiode
to charge collector

a-Se TFT array

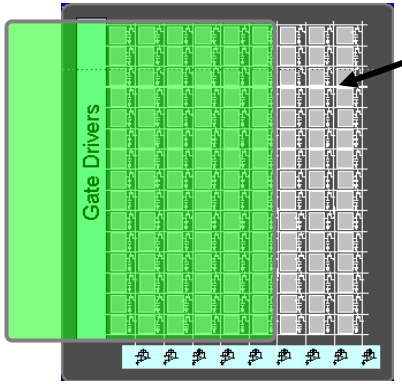
Electrode

a-Se
photoconductor



Charge collector

a-Silicon TFT



Integrated
Active readout

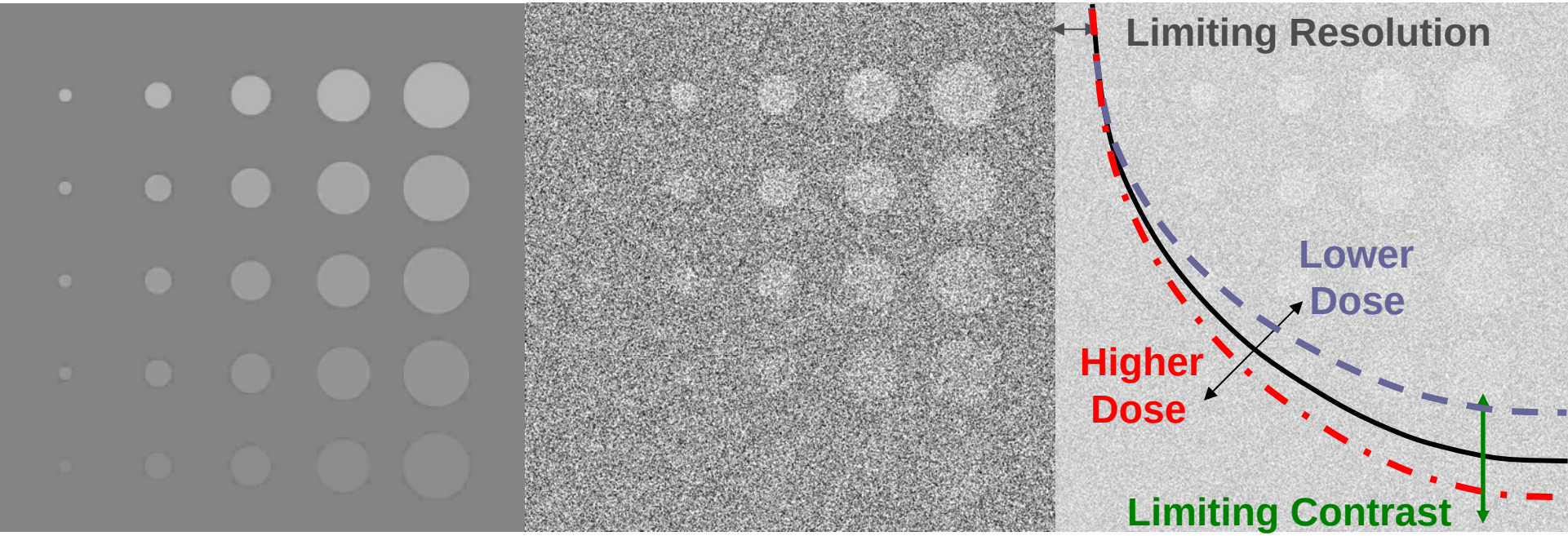
TFT housing

What determines *necessary* dose?

- Required SNR / CNR of examination
- Patient thickness (pediatric vs. adult!)
- X-ray acquisition techniques (kVp, mAs, distance)
- Detector absorption and conversion efficiency
- Detector electronic and stationary noise
- **Detective Quantum Efficiency (DQE)**
- Antiscatter grid, air gap
- Pre and post processing algorithms

How much dose *is* necessary?

Contrast Detail Phantom



Noiseless **Noisy** **Contrast-Detail**

Dependent on patient, type of examination, type of detector….

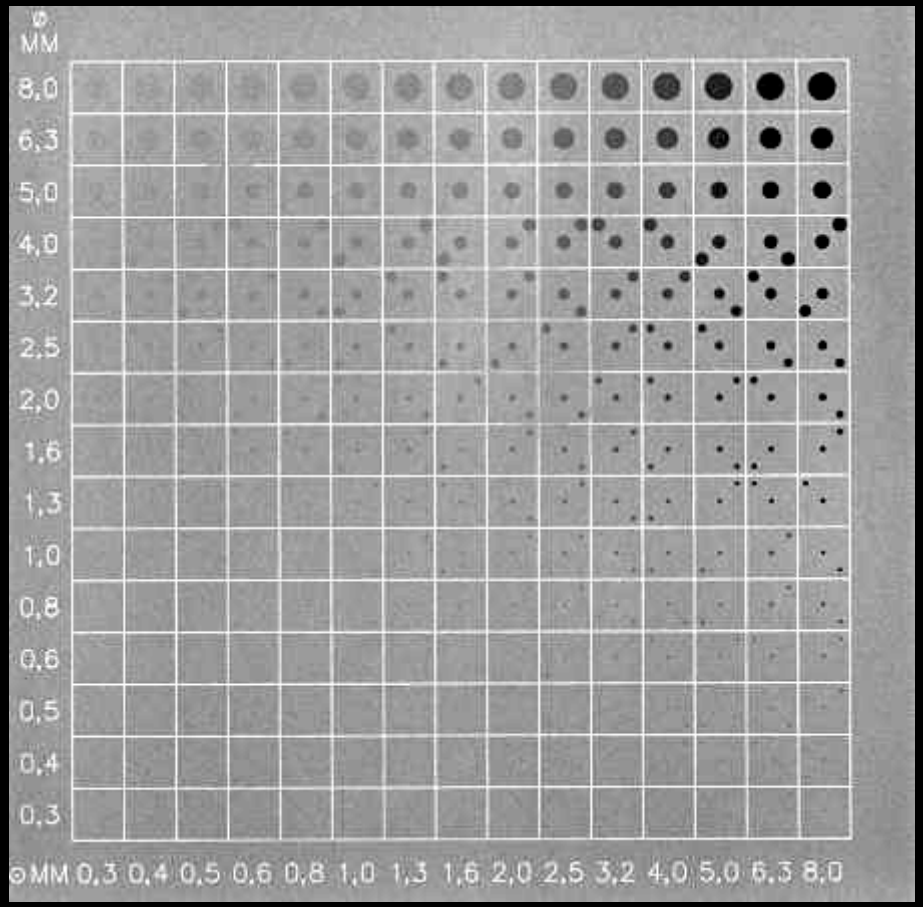
Acquisition techniques

- Patient thickness: Pediatric vs adult
  - “A child is not a small adult”… special considerations are needed
- kVp
  - Digital response is less sensitive than S/F; higher kVp increases transmission but reduces contrast and lowers detection efficiency
- mAs
  - Linearly varies with output; adjust for patient girth to maintain SNR
- Filtration
  - Removes lower energy photons in spectrum, but requires increase in technique (mAs or exposure time); should be used!
- Collimation
  - Strict collimation reduces volume, scatter, and patient dose
  - Careless collimation can result in image scaling errors
  - “Electronic” collimation can result in needless overexposure

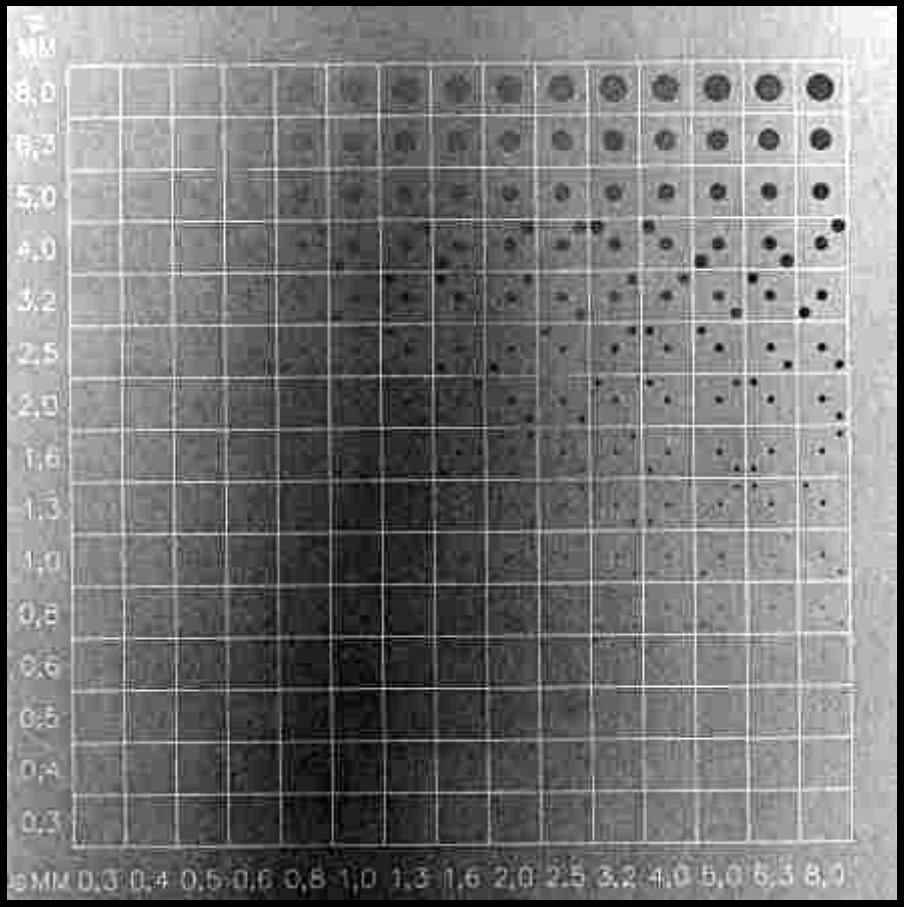
Grid?

- Recommended for large patients, and then selectively
- Reduces noise and improves subject contrast
- BaFBr and CsI x-ray converters *more sensitive* to scatter
- Requires **increase in radiation dose** (need to compensate for attenuated primary radiation by the grid)
- Types of recommended grids for digital radiography
  - **Grid ratio** 10:1–13:1 cassette stand; 6:1 – 8:1 for portable imaging
  - **Grid frequency** 40-50 cm^{-1} (moving); >65 cm^{-1} (fixed)
  - **Focal range** dependent on exam type
- Pitfalls: grid mis-positioning, improper SID, inappropriate grid ratio and/or frequency, *aliasing* in output image

SNR: quantum statistics **plus** other noise!



Good flat-field pre-processing



Inadequate flat-field pre-processing

Detective Quantum Efficiency

Measure of detector *information transfer* efficiency

- High DQE doesn't guarantee good image quality
- No substitute for appropriate radiographic technique and proper image processing
- Acquisition technique

  kV, mAs, SID, filters, grid
- Using similar technique and grid, **constant SNR requires dose proportional to DQE^{-1}**

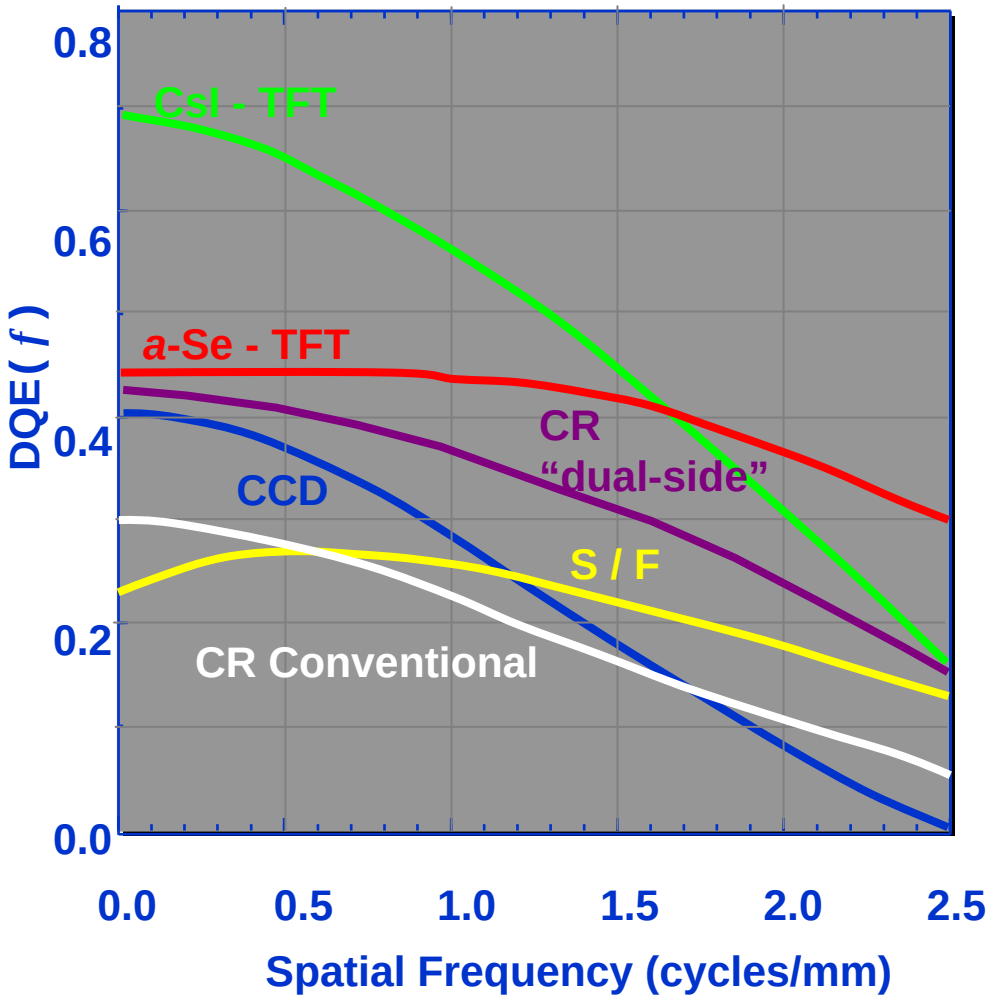
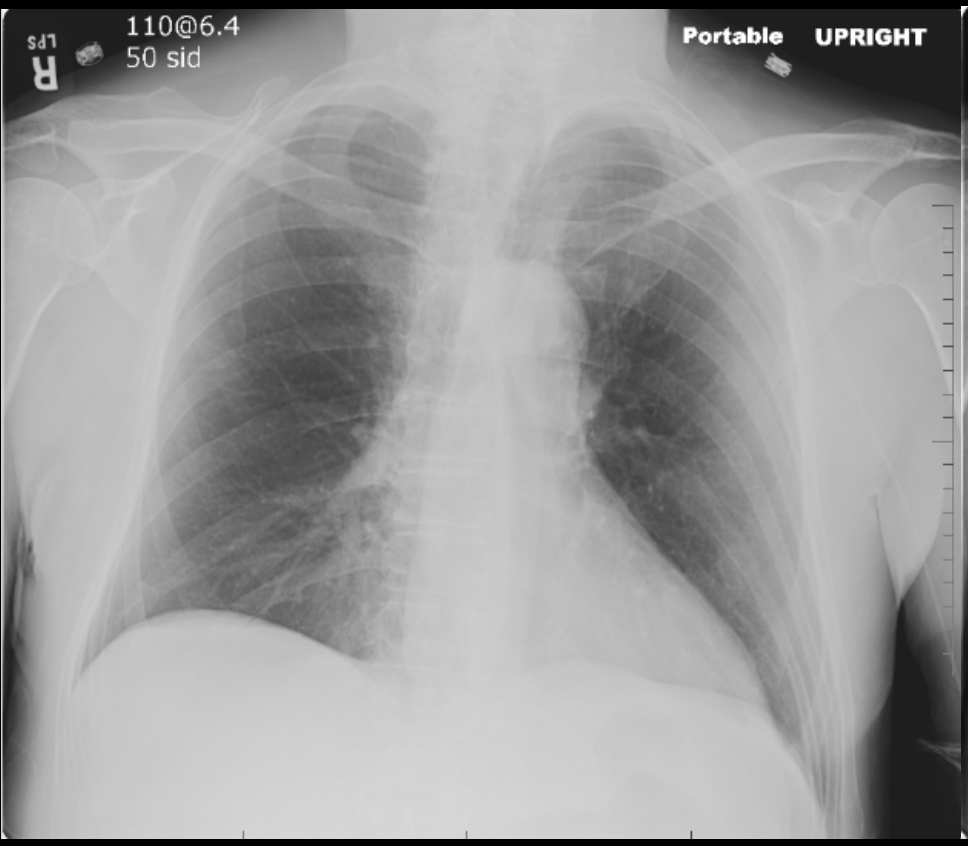
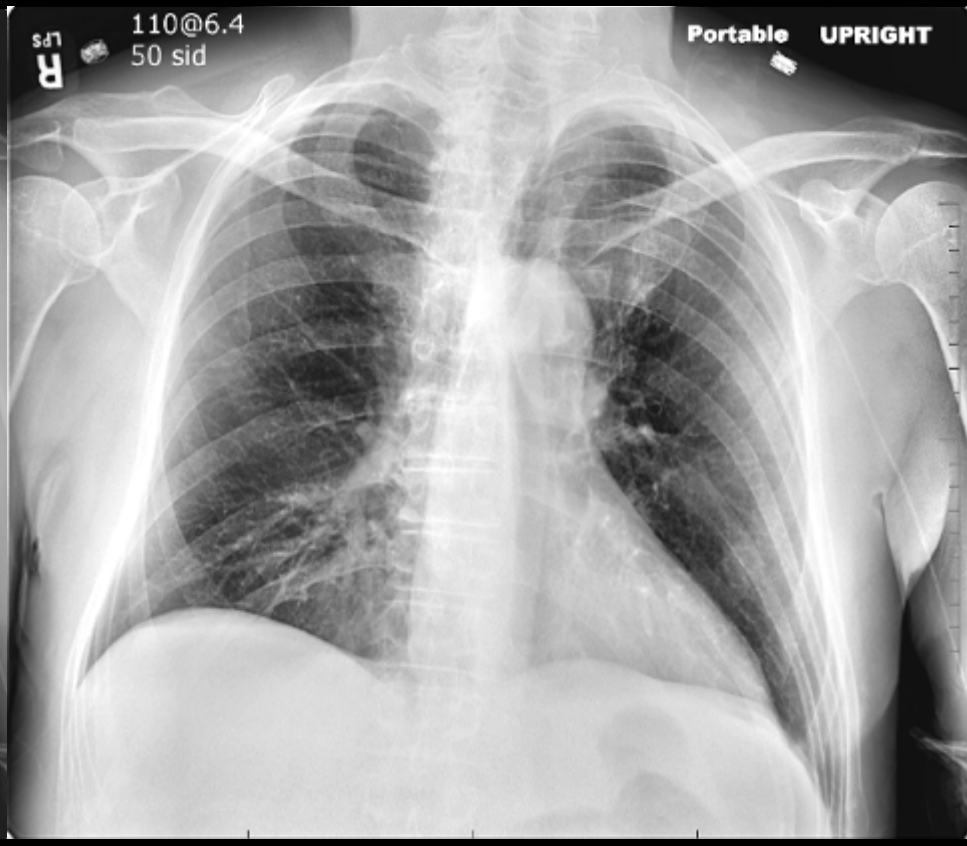


Image processing optimization

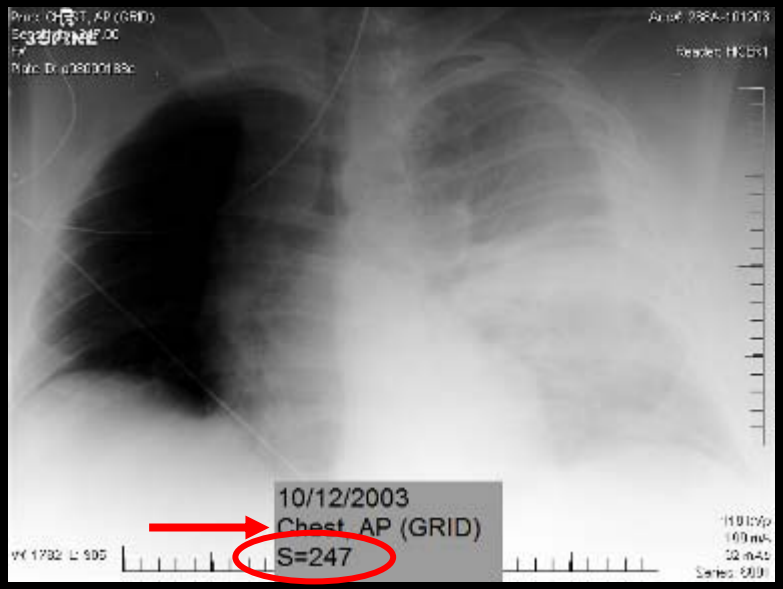


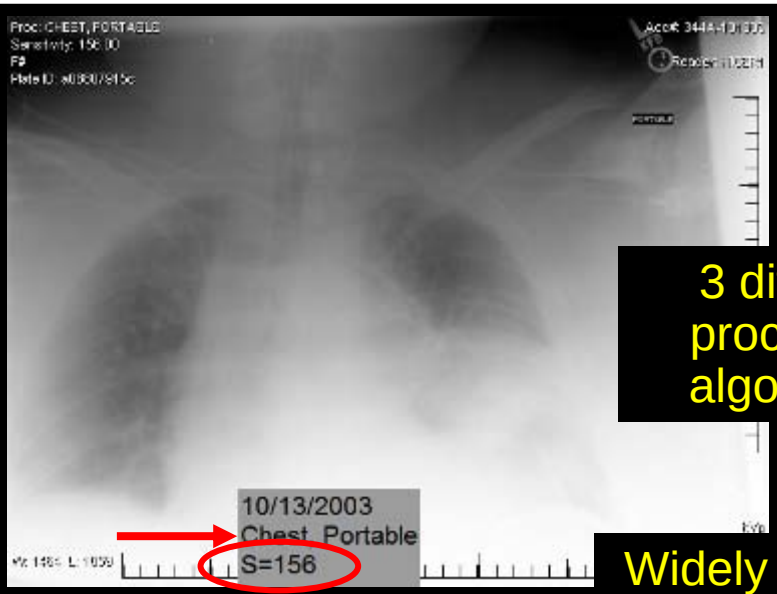
“For Presentation” Image



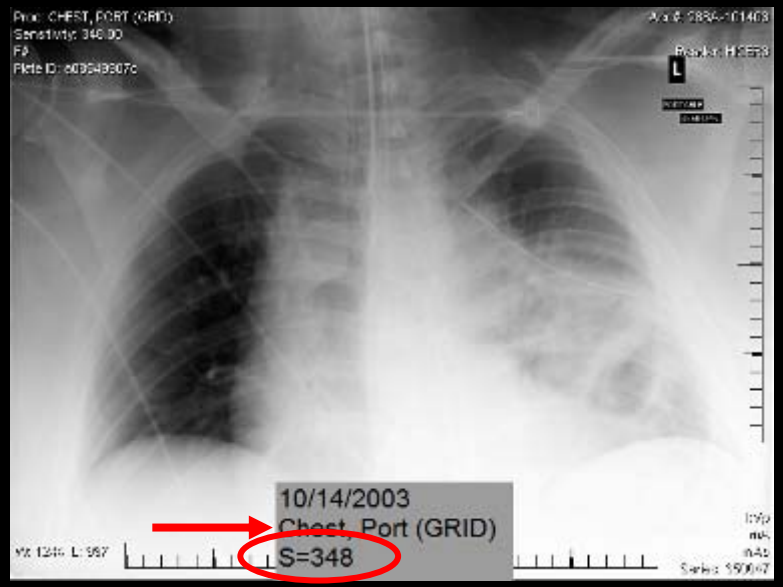
Contrast Limited Adaptive Histogram Equalization

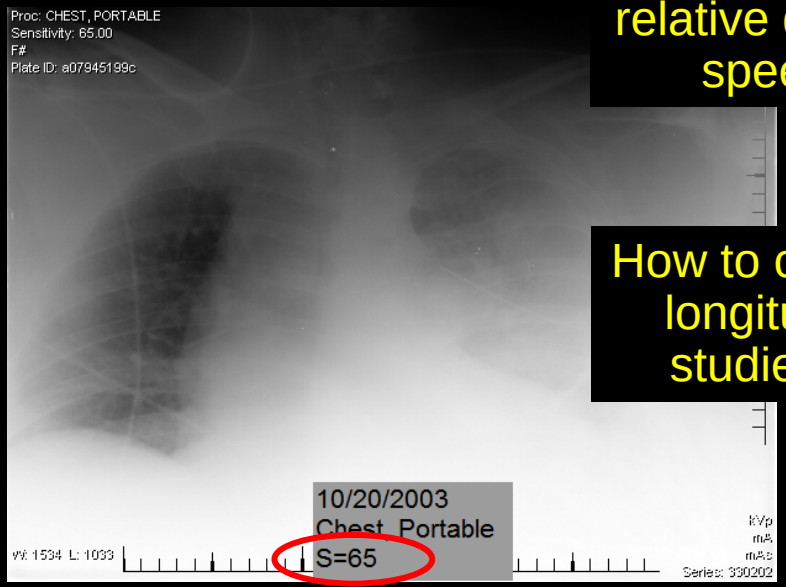
Need for Consistency & Reproducibility





3 different processing algorithms!





Widely different relative detector speeds!

How to compare longitudinal studies???

Consistency & Reproducibility

- More important than the “lowest” dose
- Standardize acq. techniques (e.g. adult port. CXR)
  - kVp: single kVp for all adult chest images
  - mAs: vary over 3 sizes, small, medium, large
  - Grid for all adult chest images
  - SID fixed at 50 inches (130 cm)
  - Short dimension, decubitus grid, >65 cm^{-1} frequency

Portable Radiographic Exposure Recommendations

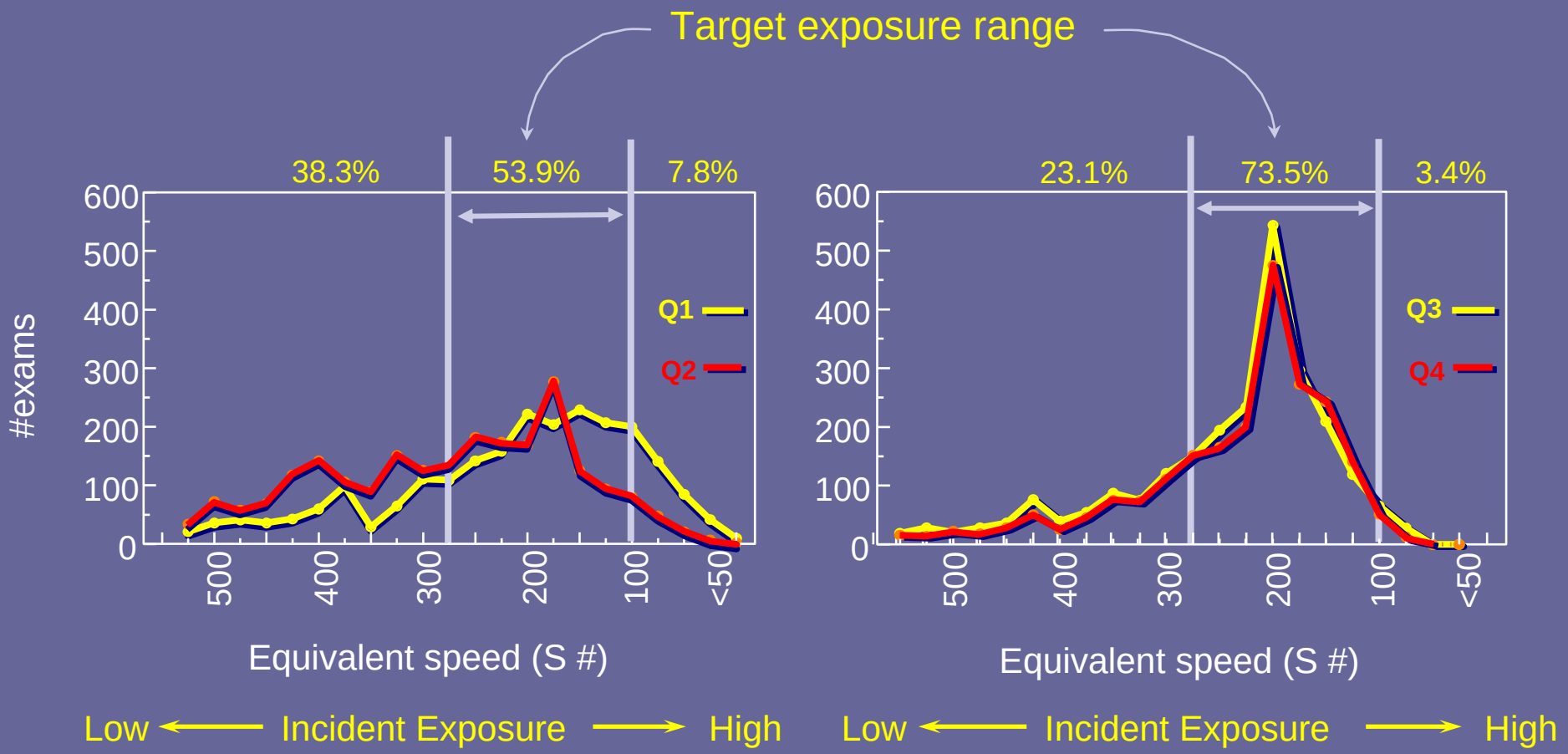
Anatomical Region	Exam	Measurement (CM)	SID	GRID	KVP	Small	Medium	Large
Chest*	Chest Portable AP	20-30 cm	50"	Yes*	110 kVp	6 mAs	10 mAs	12 mAs
*use short dimension (decubitus) grid, position cassette always cross-wise (landscape)						(20-25 cm)	(25-30 cm)	(>30 cm)

How much dose *is used*? ….**Exposure Index** for digital radiography

- *Estimated* incident exposure to detector
- Gives a *manufacturer-dependent* value to be used as feedback for “verification” of proper technique for patient size and exam requirements
  - **Fuji “S” number…. S ≅ 200 / Exposure (mR)**
  - **Agfa: LgM value… LgM = 2.22 + log *E* + log(*SCI*/200)**
  - **Kodak: Exposure Index… EI ≅1000×log (Exposure, mR)+ 2000**
  - **Many other manufacturers with distinct methods**
- Inconsistencies in determining exposure index values as well as non-standard EI algorithms are current problems

Use of exposure index as feedback

Adult portable chest exposures



First half, 1994: 4572 exams

Second half, 1994: 4661 exams

Guidelines for QC based on Exposure

typical adult chest exam at UCDMC, Fuji CR

System "speed"	Exposure	Indication
>1000	<0.2 mR	Underexposed: repeat
600 - 1000	0.3-0.2 mR	Underexposed: QC exception
300 - 600	1.0-0.3 mR	Underexposed: QC review
150 - 300	1.3-1.0 mR	Acceptable range
75 -150	2.7-1.3 mR	Overexposed: QC review
50 - 74	4.0-2.7 mR	Overexposed: QC exception
<50	>4.0 mR	Overexposed: repeat

Indications from Chuck Willis Ph.D.
M.D. Anderson Cancer Center

Exposure Index standardization effort

- AAPM task group 116
- Physicists, vendors, AAPM & IEC effort to provide
  - “vendor independent” exposure index
  - similar methods for calibration
  - specific DICOM metadata tags for recording data
  - ability to recalculate from recovered processing failures
- Currently in near-final draft stage; document should be available to the general public in 2007
- Implementation???

Conclusions

- Technology is continuously changing…. as should our understanding of digital radiography systems
- Flexibility is a double-edged sword– it cuts both ways…..
  - reduced retakes, but variability in image quality
  - variable speed, but need to tailor exposure to exam requirements
  - digital systems easier to use, but often more difficult to *correctly* use
- Understanding factors contributing to overall image quality based on acquisition, processing, and display *is necessary*
- When misused, digital radiography can result in unknown, needless overexposure (>10x !) and/or poor image quality

Conclusions

- Good image quality and *appropriate SNR* are more important than the lowest radiation dose
- *All* digital detectors should provide incident exposure level estimates
  - Physicists should understand how to calibrate and verify values
  - Radiologists and technologists should be aware of and use these indicators as a routine part of the examination and QC
- Initial training and continuous *retraining* of good digital radiography practice is a necessary part of maintaining any ***dose optimized*** DR system

MAMMOGRAPHY

Martin J. Yaffe, Ph.D.

Sunnybrook Health Sciences Centre
Department of Medical Biophysics
University of Toronto
Toronto, Canada

NCRP – Advances in Radiation Protection in Medicine

Arlington VA, April 17, 2007

Outline

- Motivation for and value of mammography
- Image quality factors
- Technical evolution of mammography
- Dose and risk
- Digital mammography
- New applications
  - CAD
  - Telemammography
  - Tomosynthesis
  - Contrast imaging

Breast Cancer

- Most frequently diagnosed cancer in N. American women
- 2nd largest cause of cancer mortality in women
- Causes suspected but not yet confirmed
  - Genetic, lifestyle (diet, alcohol, hormone use)

Mammography

- Can be used to detect small cancers, often before they have metastasized
- Cancer detected on the basis of:
  - Mass densities (and temporal change)
  - Microcalcifications
  - Architectural distortion
  - Asymmetry
- Features are often very subtle
  - Requires excellent image quality

Value of Mammography

- For diagnostic purposes, to characterize suspicious lesions in the breast
- For screening of asymptomatic women
  - 20-45% reduction in mortality in women aged 40-74 who participate in routine mammography screening programs
  - Benefit comes form earlier detection combined with improved therapies

Requirements for high quality mammography:

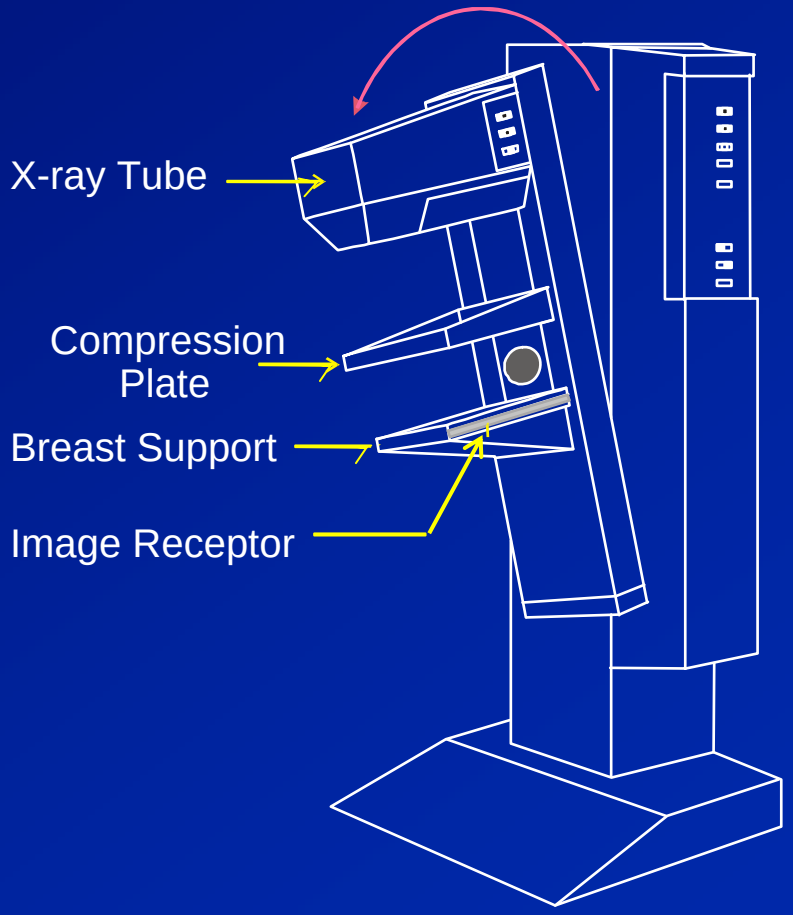
- Excellent contrast
- High spatial resolution
- Latitude
- Lowest Compatible dose

Evolution of Mammography

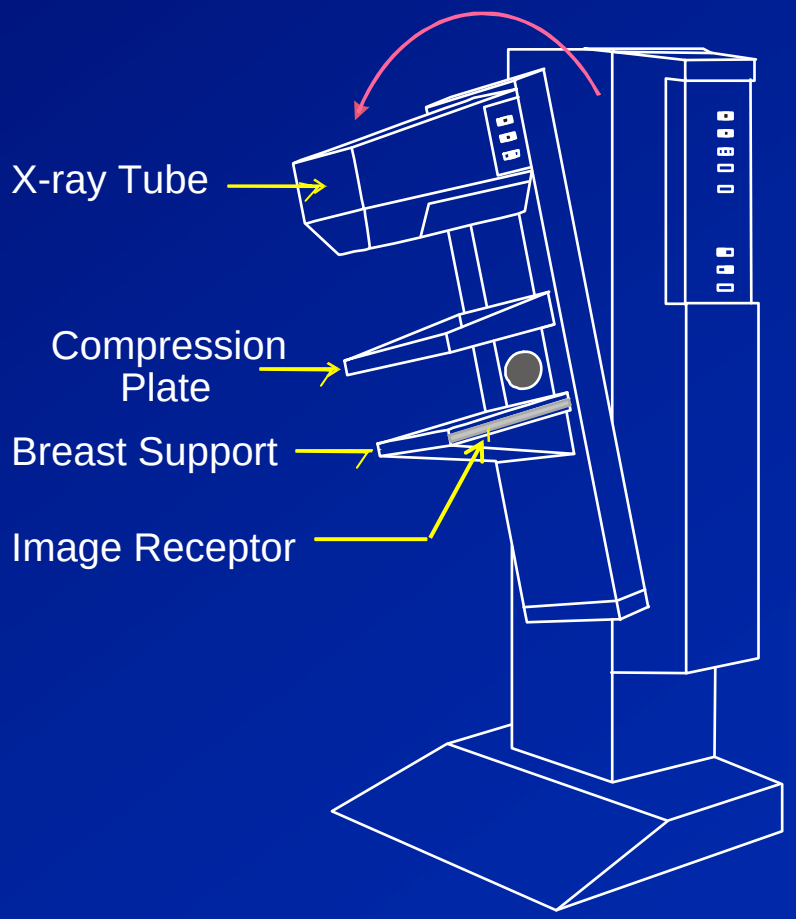
- Contrast
- Spatial resolution
- Dose
- Quality Standards
- New Technology

The Modern Mammography System

- Dedicated x-ray unit
- Low kVp, special x-ray source (target material, filter)
- Proper compression
- Grid
- High resolution screen
- Efficient use of radiation



- Specialized film characteristics
- Optimized processing
- Special viewing conditions



- Contrast

- In 1970s, Mo x-ray targets introduced – more optimal x-ray spectrum than general purpose W-anode sources
- Use of Mo filters
- In 90s, introduction of Rh anode for better penetration of dense breasts
- Rh filters to be used with Mo or Rh targets

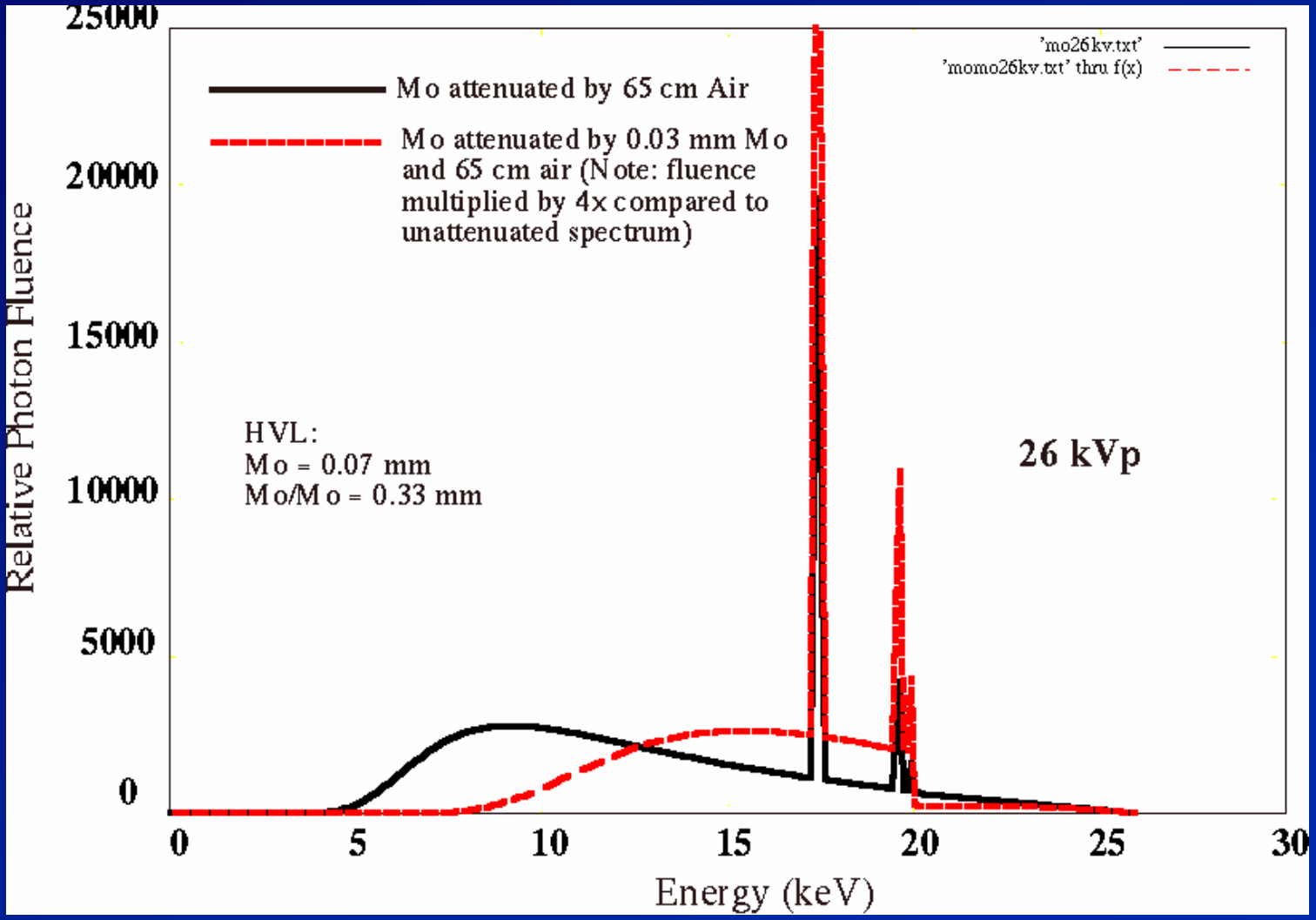
X-Ray Spectrum

- Target (anode) material
- kVp
- Filter type

The x-ray spectrum affects contrast and dose.

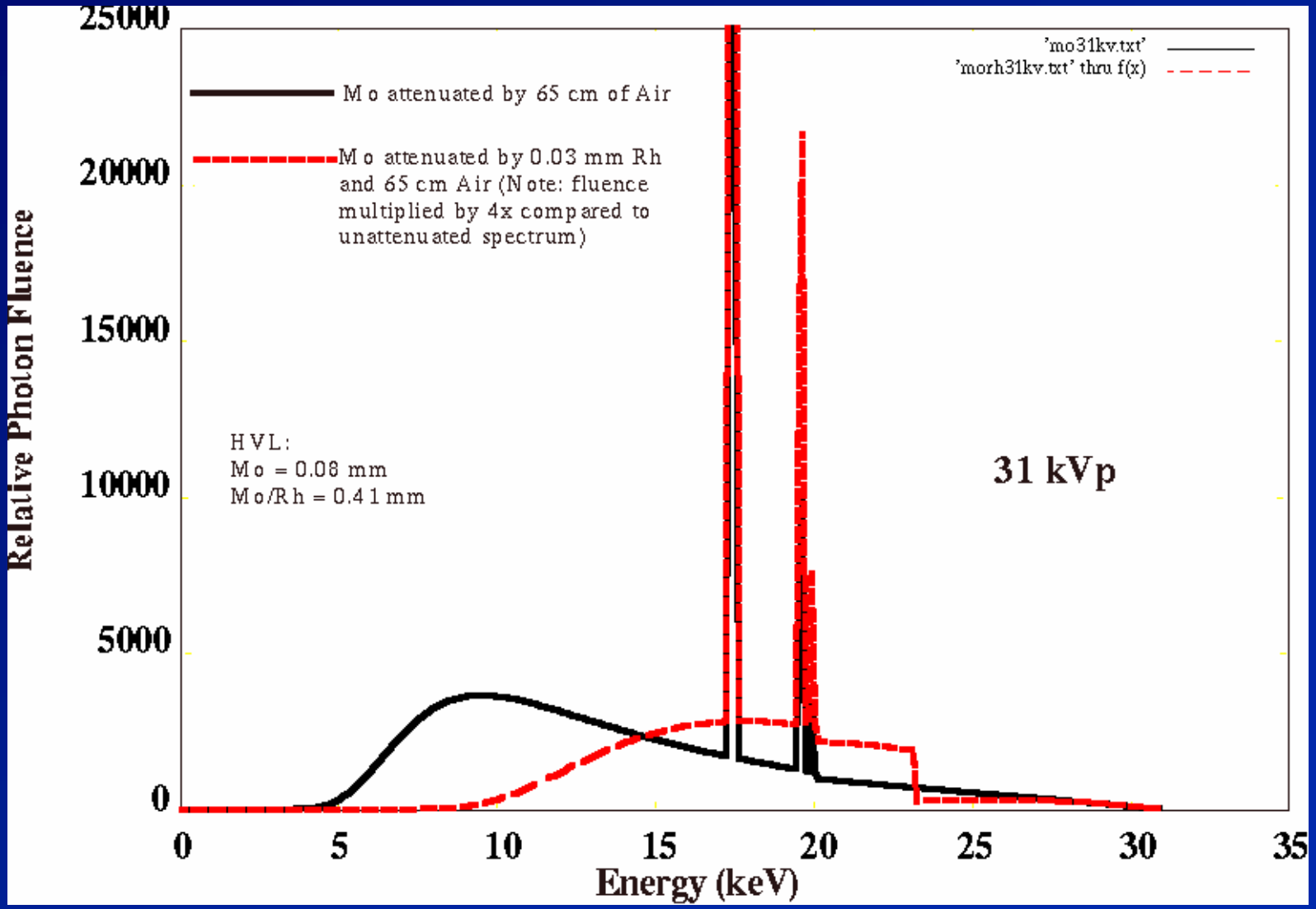
Spectra for Molybdenum Anode

Mo filter, at 26 kV



Spectra for Molybdenum Anode

Rh filter, at 31 kV



- Contrast

- In early 80s, introduction of:
  - dedicated mammography grid
  - Automatic exposure control to ensure that key anatomy is imaged with maximum contrast

Scatter

- Still important even at low kVp -

  - reduces contrast

- Grid will remove most of the scatter, But requires a 2 - 2.5x increase in dose

  - linear and 2-D grids

- Contrast

- Image receptors
  - Originally nonscreen film was mainly used (high dose, low contrast)
  - In early 70s, Xeroradiography (XR) using a selenium photoconductor as detector was introduced. Provided lower doses, wide latitude and “edge enhancement”
  - In early 70s, introduction of dedicated screen-film systems for mammography. Further dose reduction and better broad-area contrast than XR
  - 2000 Digital mammography

- Contrast

- Compression
  - Largely due to the work of one radiologist, Dr. Wende Logan, the importance of proper breast compression was recognized and taught.

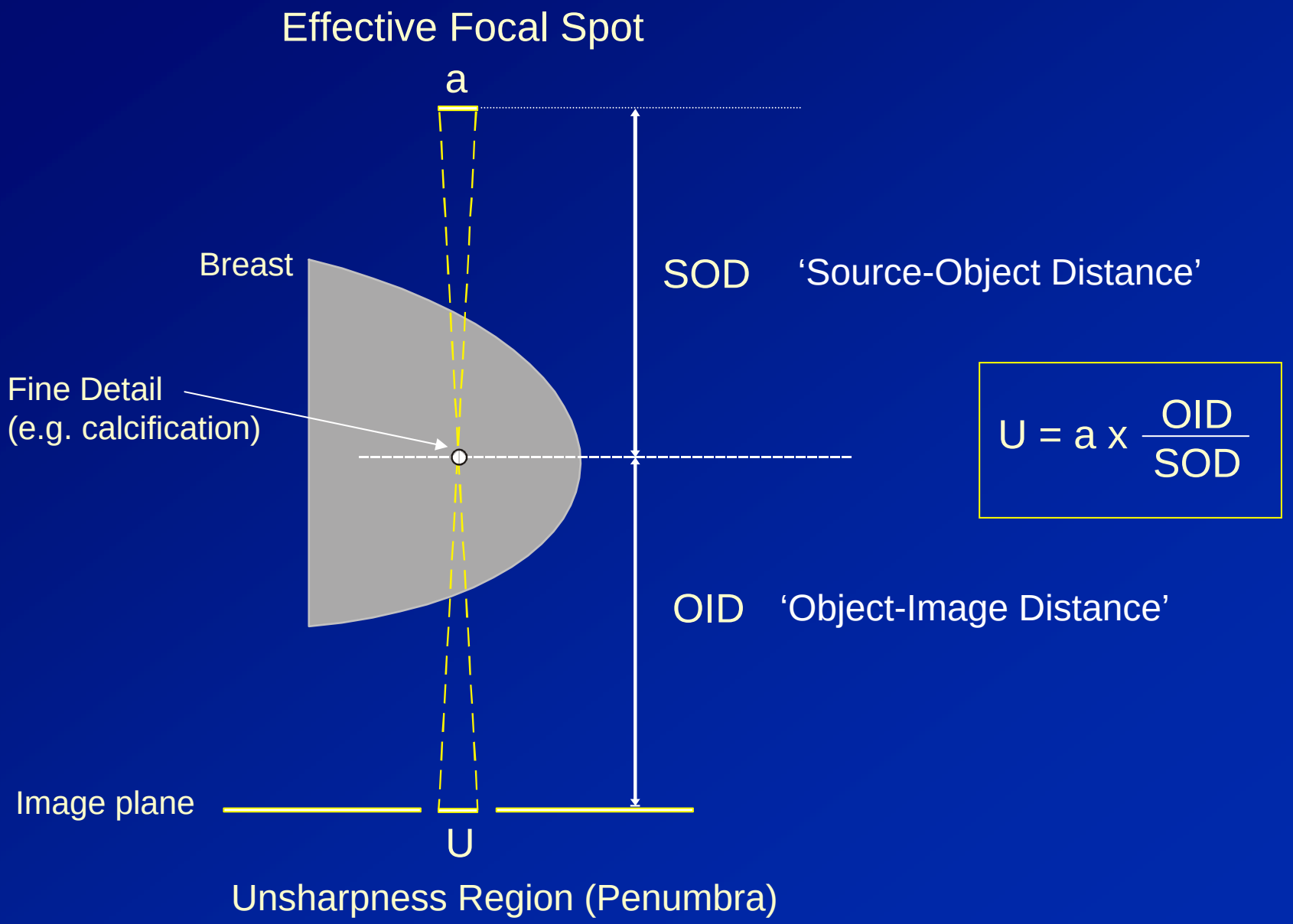
- Contrast

- Compression
  - minimizes superposition, makes cancers more conspicuous
  - ↓ scatter:primary ratio
  - ↓ latitude required by the film, allows use of higher contrast film
- Other benefits
  - ↓ dose to patient
  - ↓ anatomical motion (resolution)
  - ↓ magnification , ↓ focal spot unsharpness (resolution)

– Spatial Resolution

- Small focal spot x-ray sources
- Fixed source-image distance
- Firm compression (motion)
- High resolution single-screen image receptor

Unsharpness in the Image Plane



– Radiation dose

- Decreases in doses due to improved:
  - Quantum efficiency of screens
  - Sensitivity of film emulsions
  - Processing chemistry
  - Image processing and display
- Increases in dose (associated with better image quality due to:
  - Use of grid (Bucky factor 2-2.5)
  - Thin, high resolution screens
  - Reduced kV
  - Increased optical density images
  - Reduced film granularity

Era	Technology	Approx. Dose (mGy)*
1950's- 60s	Industrial nonscreen x-ray film	20-100
Early '70s	Medical nonscreen film	10-25
Mid '70s -	Xeroradiography	4-5
Mid '70s	Mammographic screen-film systems 1st gen	0.8
'80s, '90s	2nd gen S-F systems	0.5 (1.25 w grid)
'90s	3rd gen S-F	1.8
2000	Digital mammography	1.6-1.8

*per image for a 4.5 cm thick compressed, 50-50 breast.
Dose for a 2-view examination is double the above values.

Dose and Risk

$$R_A = \frac{D}{2} \cdot 10 \cdot e^{-0.05(Y_x - 25)} \cdot \left(\frac{Y}{50} \right)^n$$

Where R_A is no. of induced cancers/ (10,000 W-Yr, D is in Gy, Y_x is age of exposure and Y is attained age

For women <50, n=3.5

For women ≥50, n=1.0

Preston et al, Rad'n Res. 2002

Risk from mammography

Risk at age 65 from a 2-view mammography exam at age 40 – dose 3.6 mGy (1.8 mGy x 2)

2.1/ million

Risk from mammography

Risk at age 65 from annual 2-view mammography screening from 40-49 annual dose 3.6 mGy (1.8 mGy x 2)

17/ million

Risk from mammography

Integrated risk to age 85 from annual 2-view mammography screening from 40-49 annual dose 3.6 mGy (1.8 mGy x 2)

750/ million

Cancers expected in 40-49 age group (many potentially detectible by mammography): 13,000/ million

Risk from mammography

Integrated risk to age 85 from annual 2-view mammography screening from 40-59 annual dose 3.6 mGy (1.8 mGy x 2)

885/ million

Cancers expected in 40-59 age group (many potentially detectible by mammography): 37,000/ million

– Improved Skills

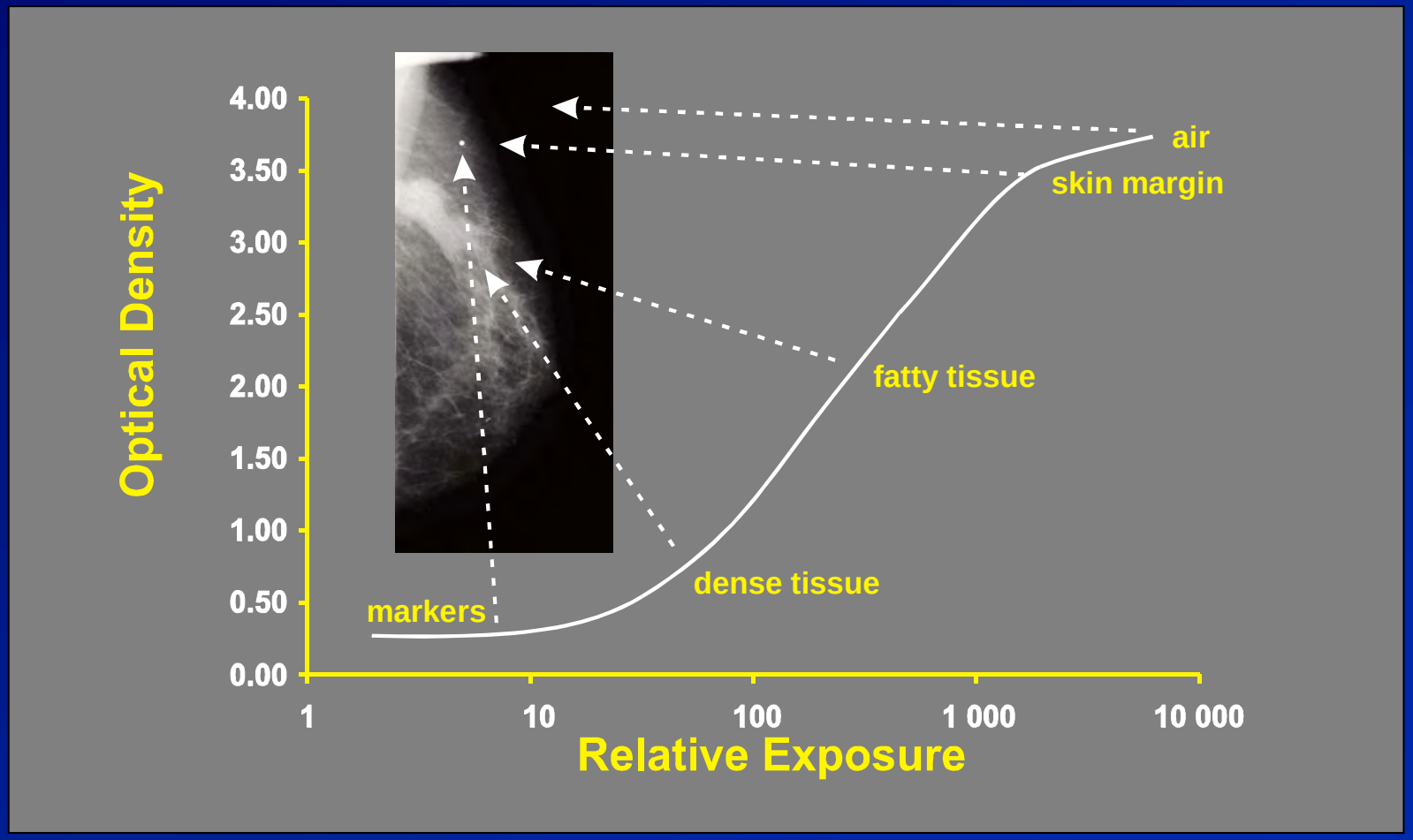
- Educational programs for radiologists, technologists and medical physicists (eg ACR/CDC Cooperative Agreement and its successors) provide training on:
- Optimal image acquisition, positioning and exposure factors
- Image interpretation
- System quality control and testing

– Quality Standards

- Quality control and accreditation programs
  - Voluntary – ACR MAP
  - Mandatory -MQSA

Screen-Film Mammography: Disadvantages

Compromise between display contrast and latitude



Digital Mammography

- An electronic detector replaces film to record x-rays transmitted through the breast

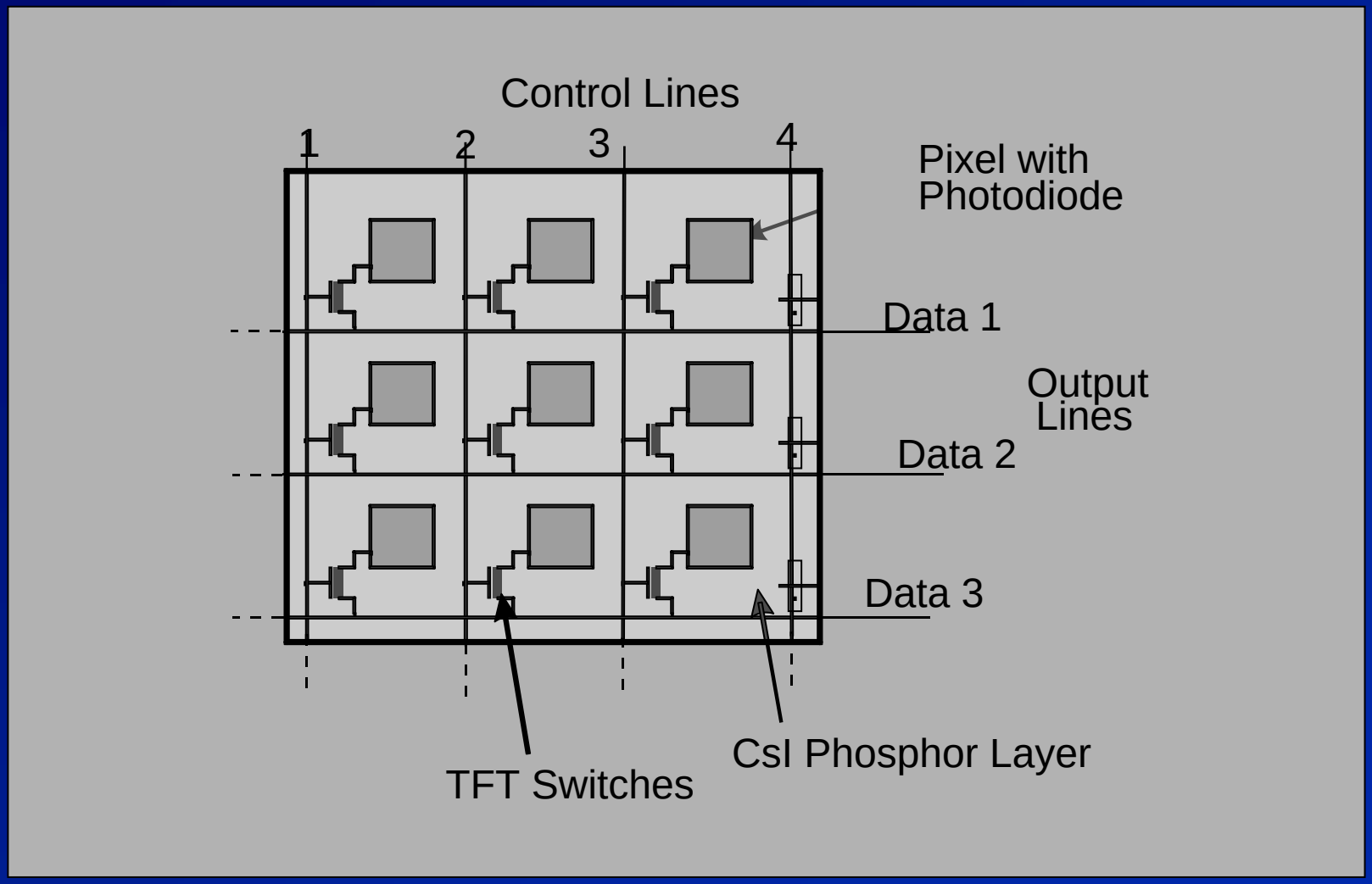
- Image data collected are stored in a computer from which it can then be:
  - processed and displayed
  - printed on film (laser printer)
  - archived

Advantages of Digital Mammography

- Images can be enhanced to improve visualization of disease (image processing)
- Allows detection of smaller, more subtle structures within the breast

Digital Mammography Unit

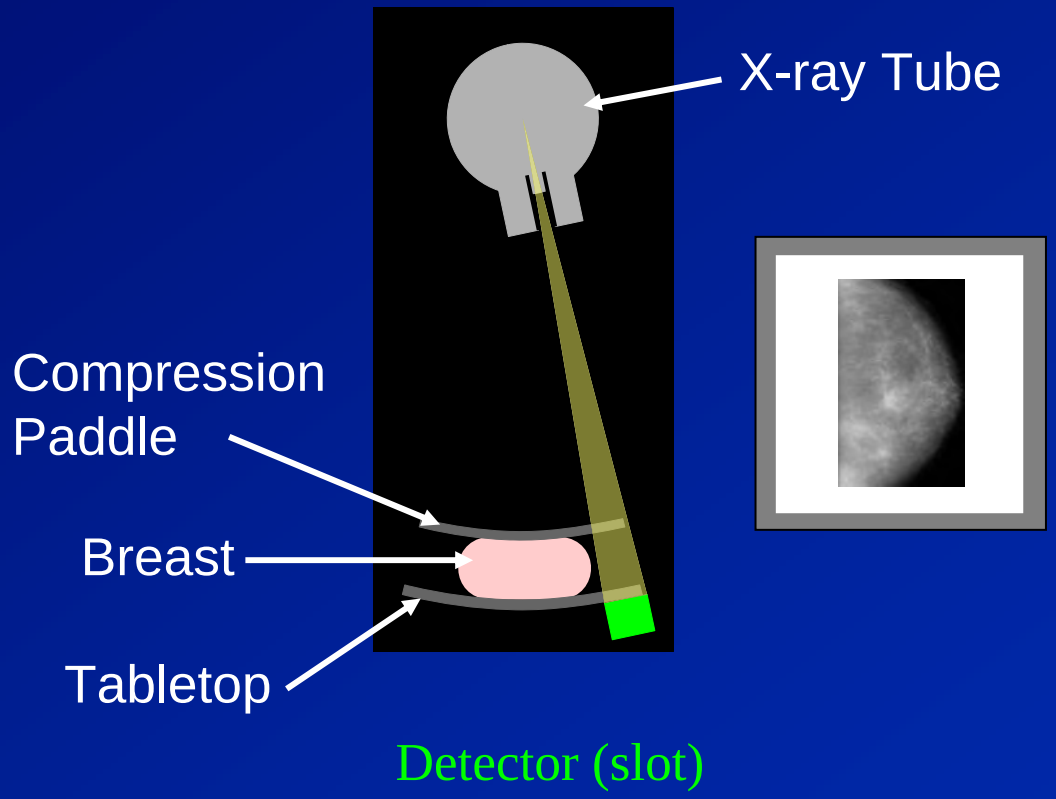
3. General Electric (GE): Flat Panel Detector



- GE Medical Systems, Milwaukee, Wis.

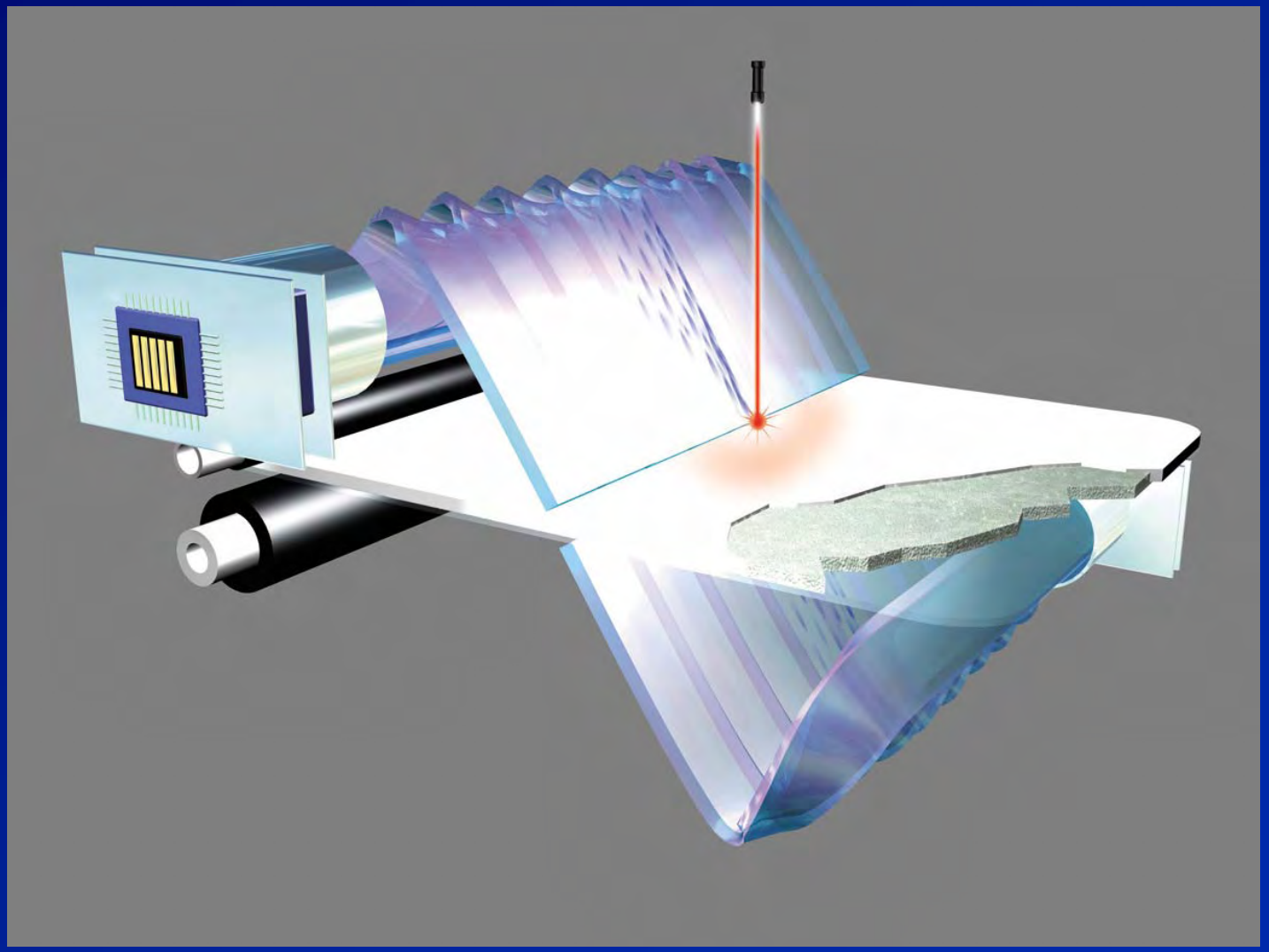
2. Fischer Imaging SenoScan

Digital Mammography Slot Scanned System

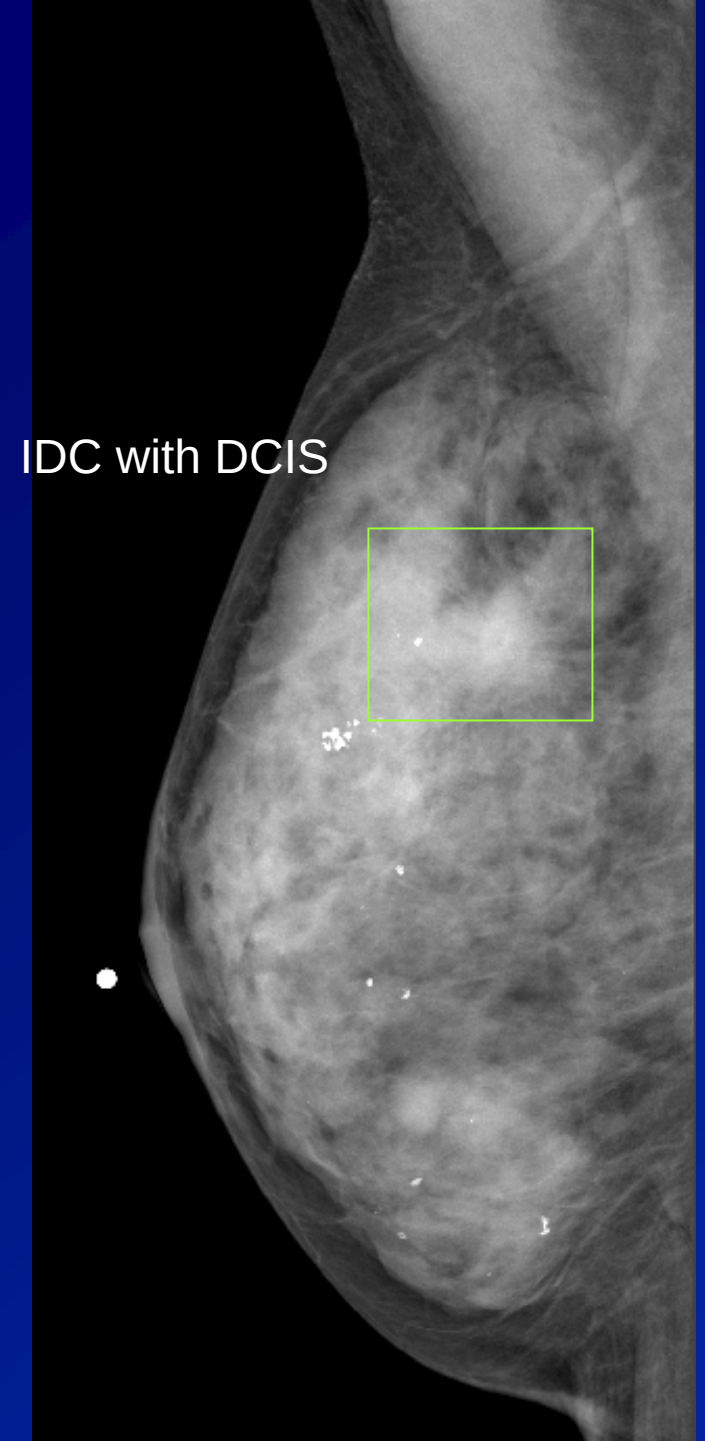


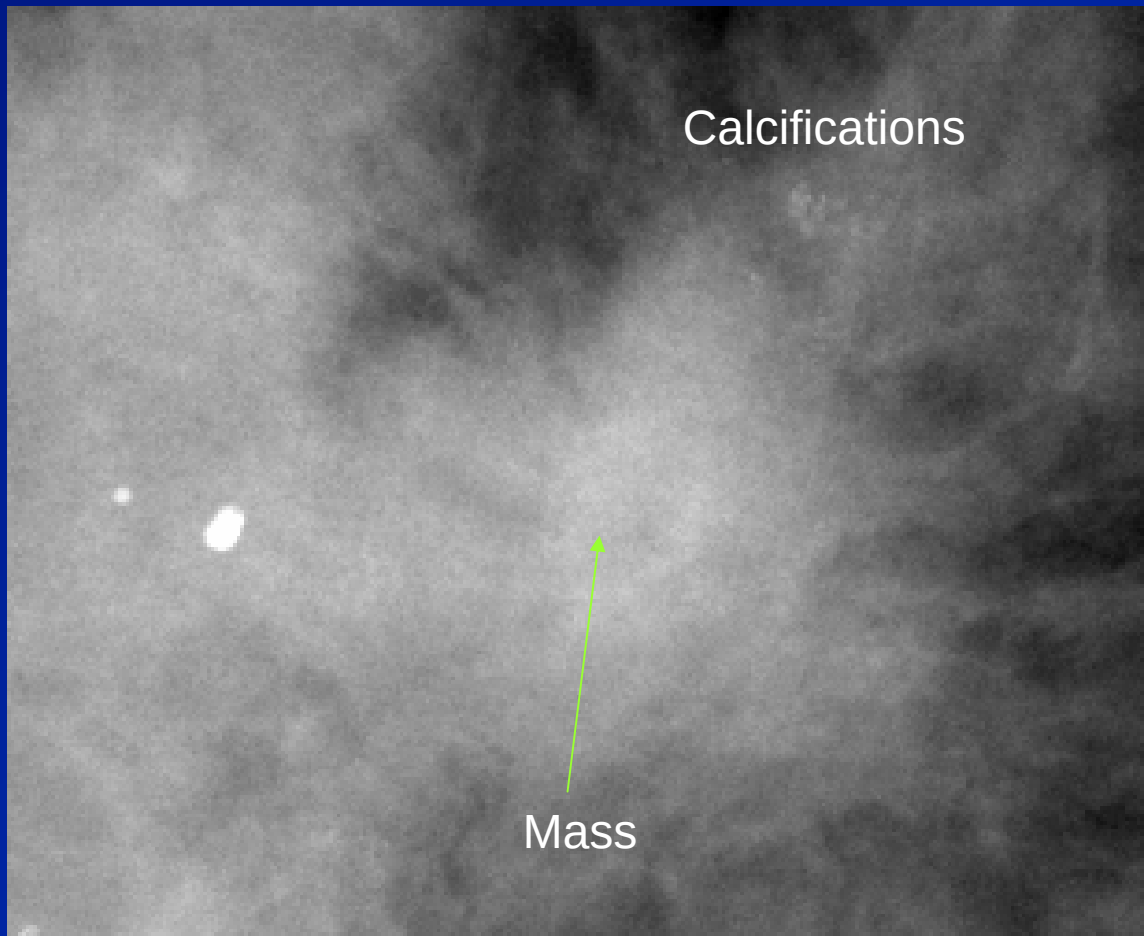
- Fischer Imaging, Denver, Colo

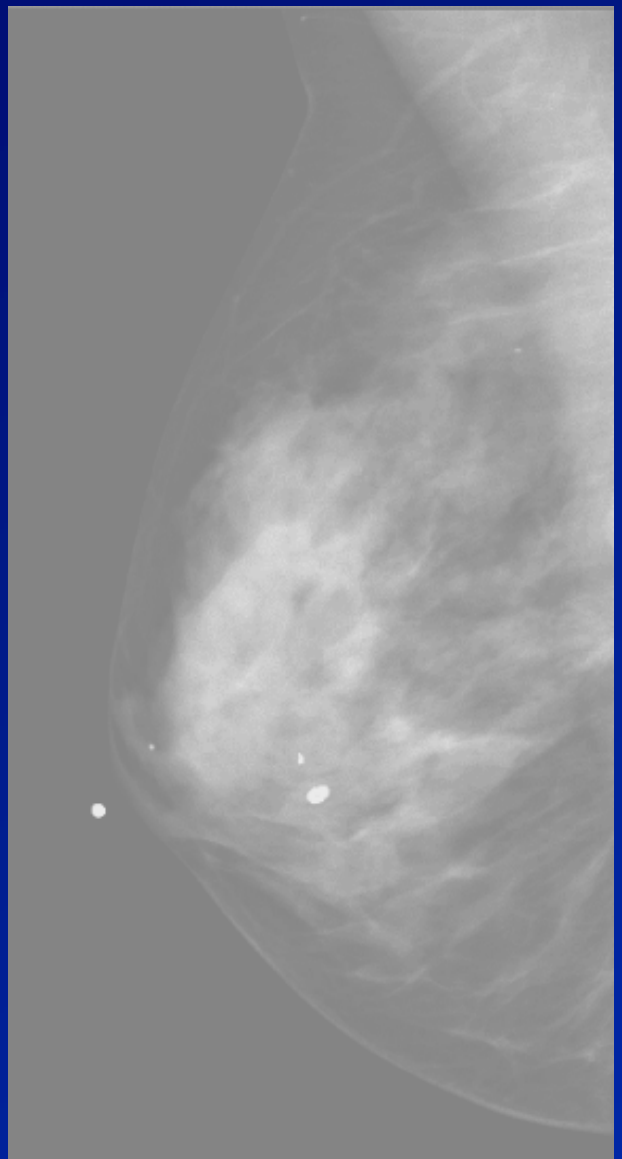
Dual-sided Reading

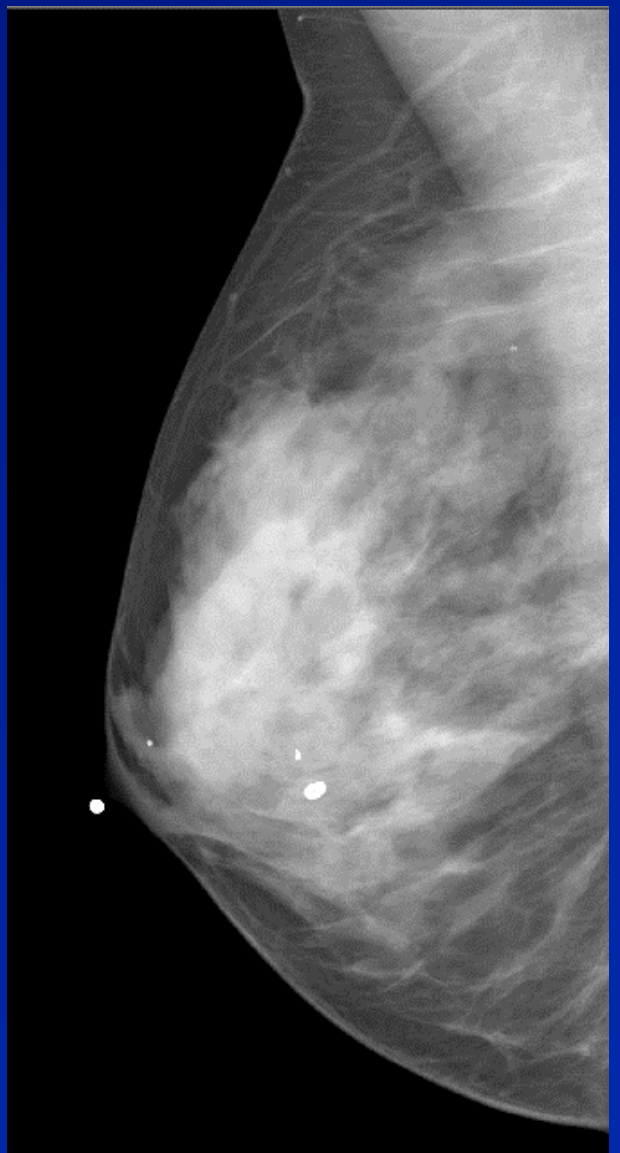


Effect of Noise - underexposure

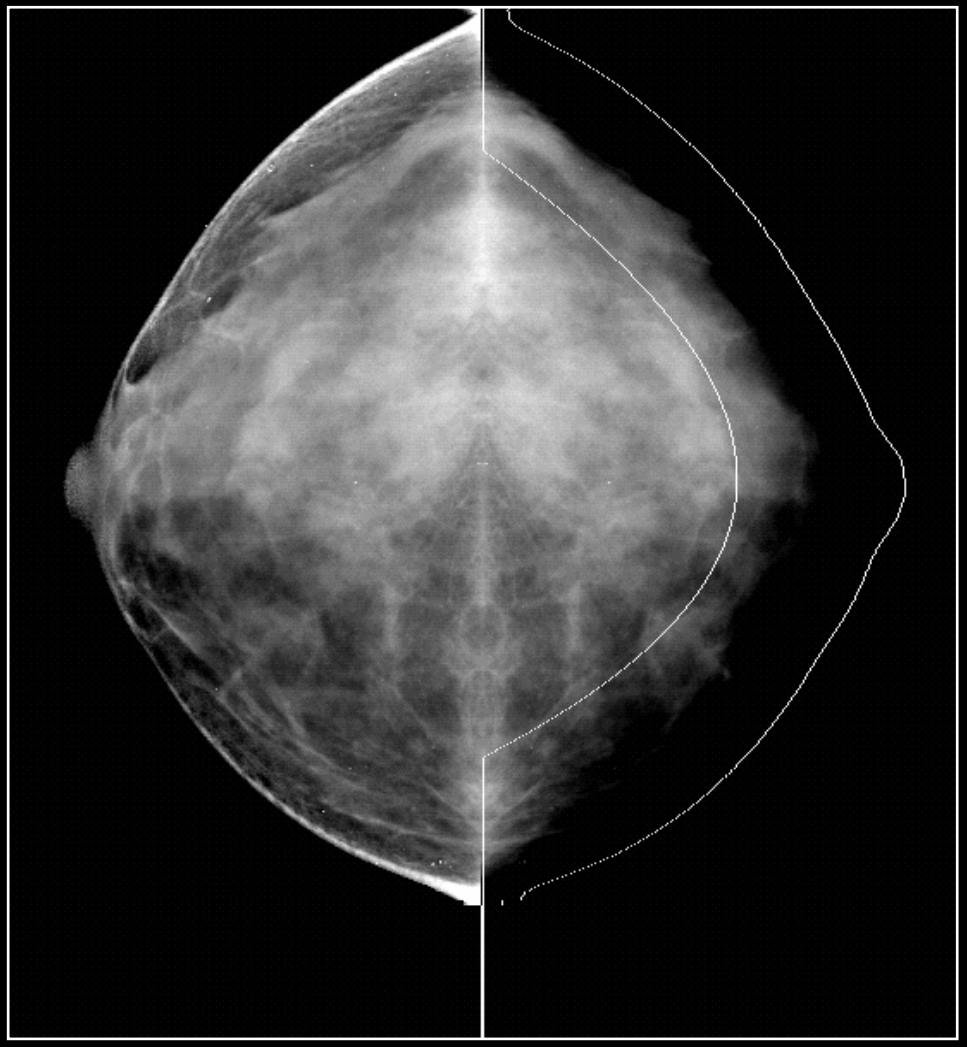








Enhancement Of Peripheral Tissue



Applications of Digital Mammography

- CAD - Computer Aided Detection/Diagnosis
- Telemammography/Teleradiology
- Tomosynthesis
- Risk Prediction
- Contrast - uptake studies

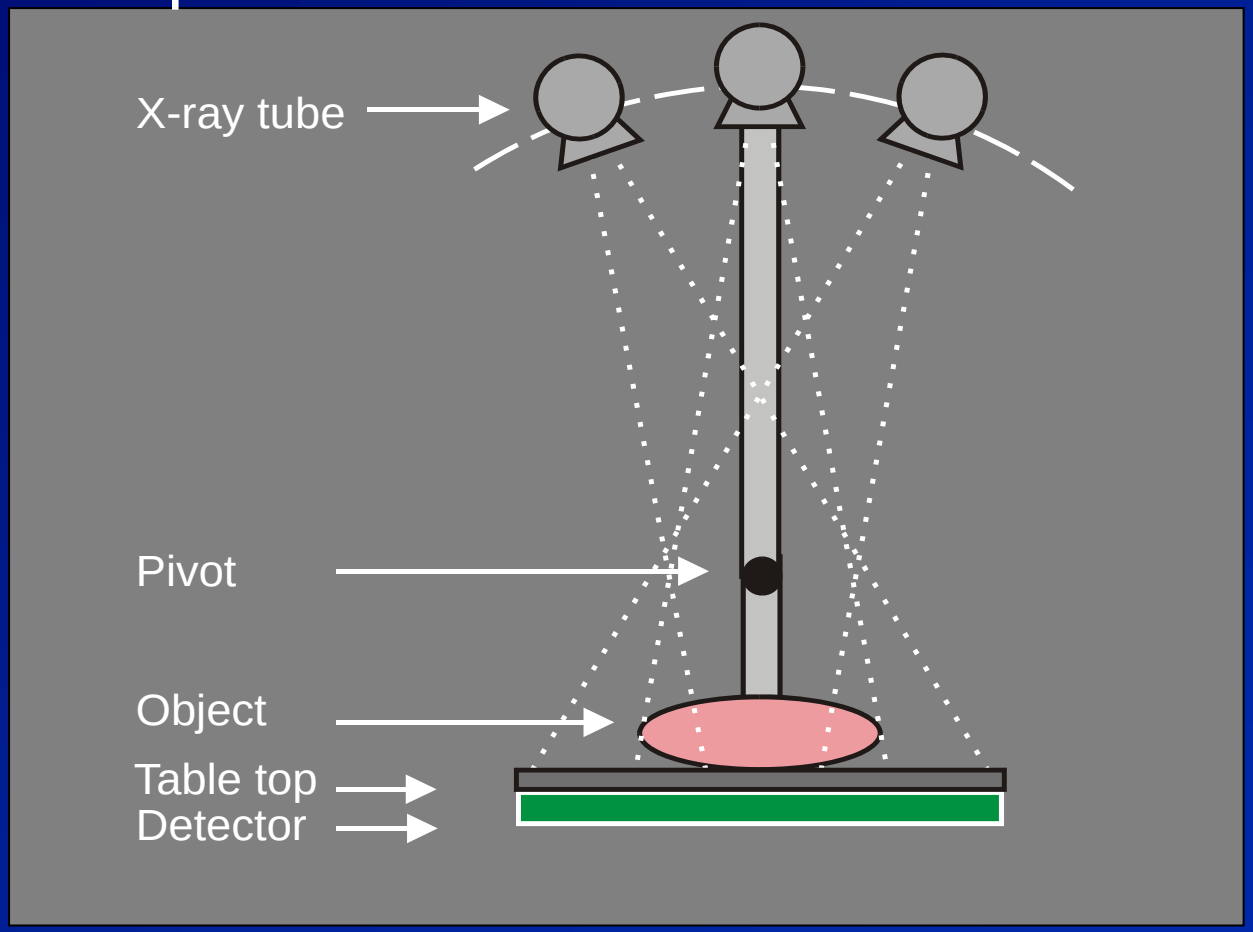
COMPUTER AIDED DETECTION / DIAGNOSIS (CAD)

- Detects suspicious lesions using:
  - feature detection
  - segmentation
  - neural networks
- Computer analysis characterizes detected lesions and predicts the probability of malignancy
- Radiologist uses the results of computer algorithm as a “second opinion”

I.e. Potential increase in accuracy

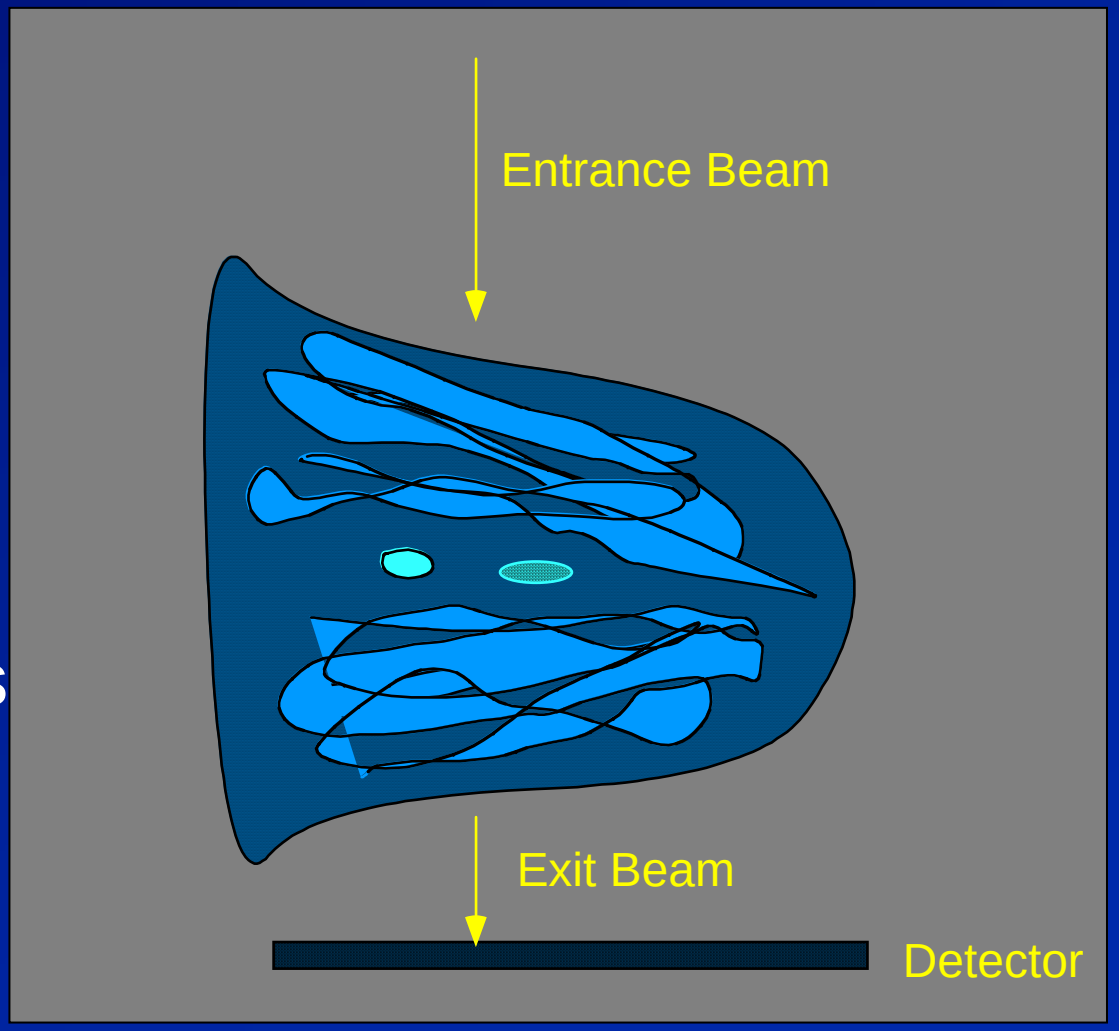
TOMOSYNTHESIS GEOMETRY

Technique that allows radiologist to view individual planes of the breast



Potential Use of Tomosynthesis in Breast Imaging:

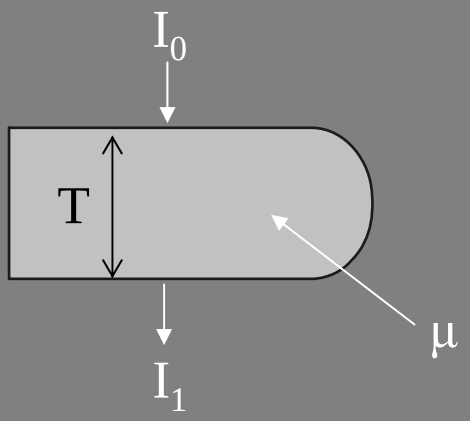
- Reduces the chance of missing cancers in radiologically dense fibroglandular tissue
- Fewer false positives



CONTRAST-UPTAKE STUDIES:

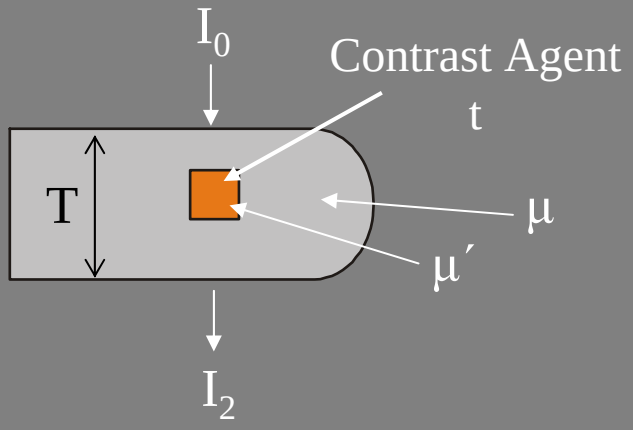
Digital Subtraction Mammography

Pre-Contrast



$$I_1 = I_0\, e^{-\mu t}$$

Post-Contrast



$$I_2 = I_0\, e^{-\mu(T-t)-\mu'}$$

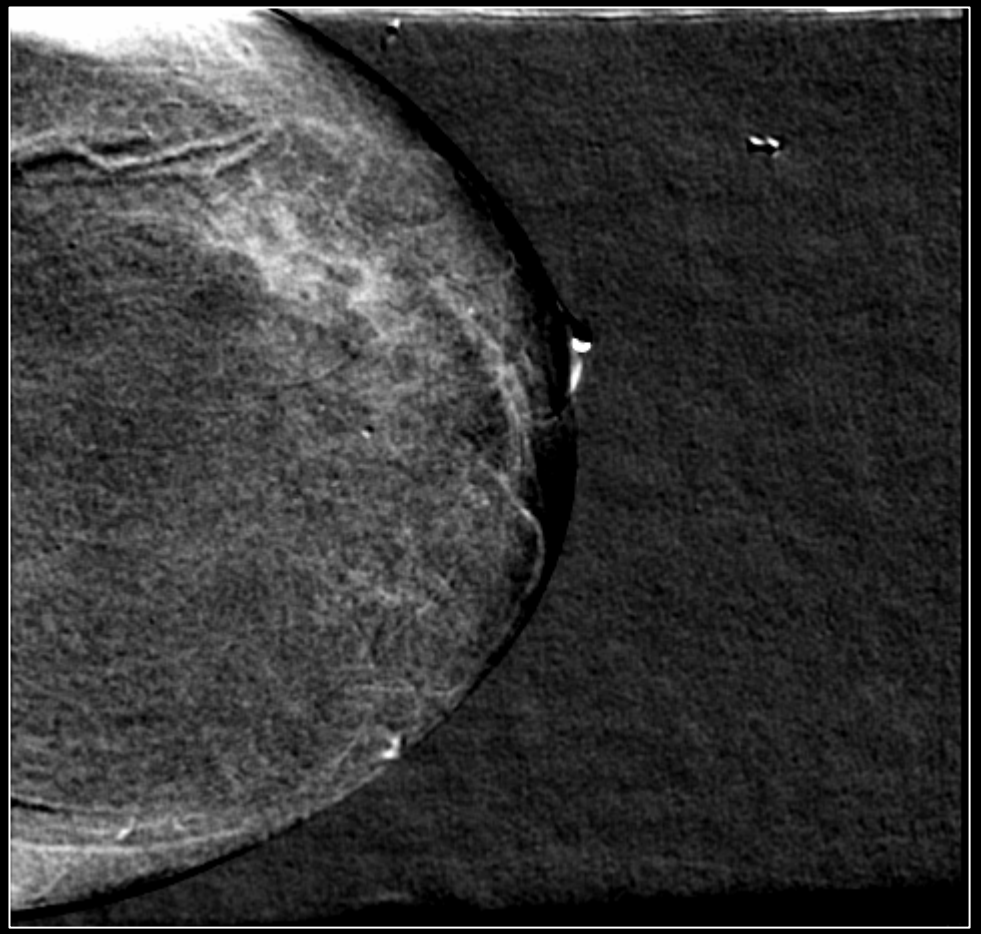
Linear Subtraction:

$$I_2 - I_1 = I_0\, e^{-\mu T}(e^{-t(\mu'-\mu)} - 1)$$

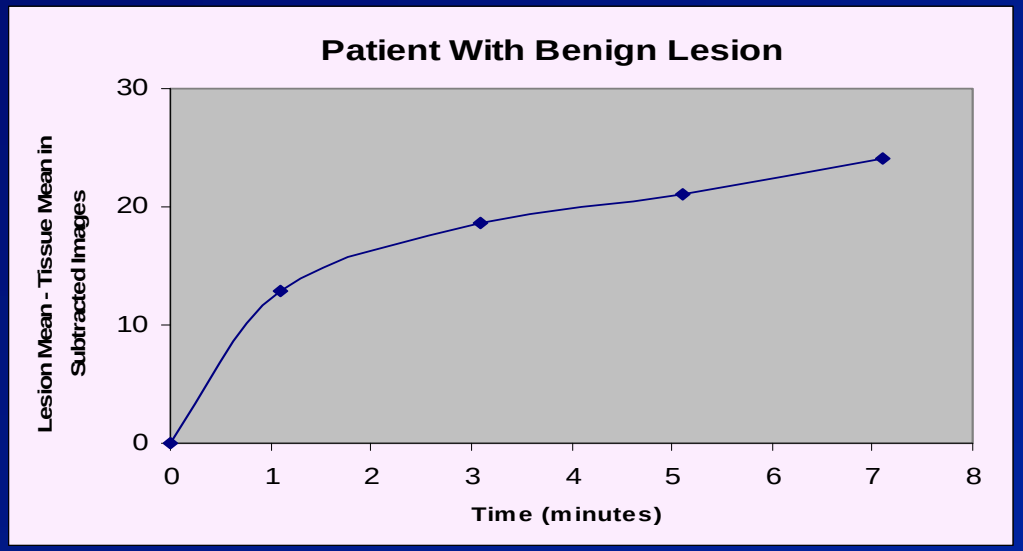
Logarithmic Subtraction:

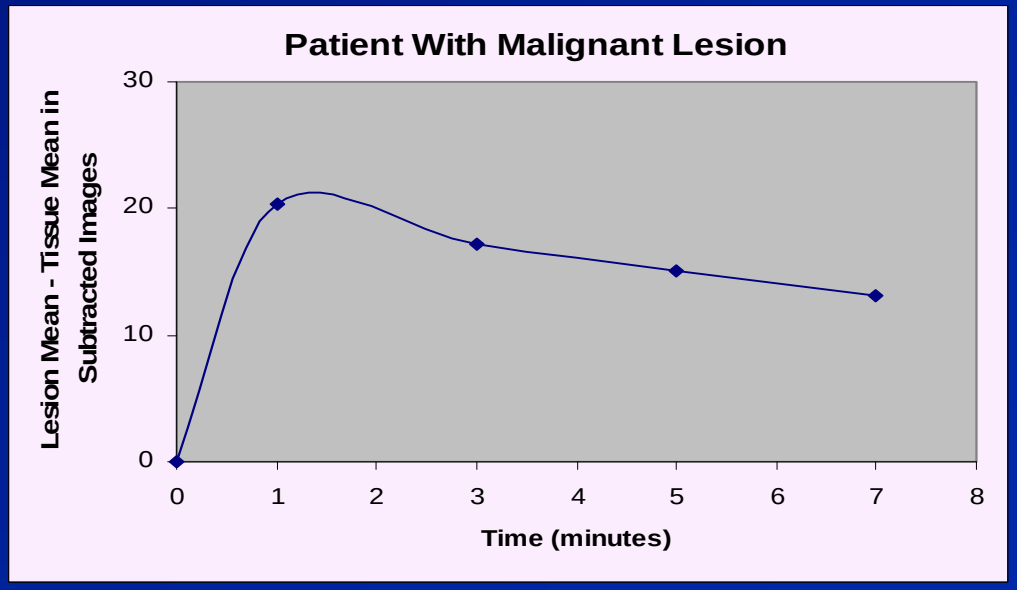
$$\ln I_2 - \ln I_1 = t(\mu - \mu')$$

DCIS With Invasive Component



Enhancement Kinetics





Quo Vadis?

- Mammography continues to play a key role in breast cancer detection and management
- Radiation doses have decreased while image quality has steadily improved.
- The radiation related risk of mammography is low in relation to its benefits.

Quo Vadis?

- Digital mammography and its applications will add new capabilities and valuable information
- New techniques will use information on biological function in addition to form for detection, diagnosis, therapy guidance and monitoring response to therapy

Trends In Utilization and Collective Doses From Medical Procedures

Mythreyi Bhargavan, Ph.D.

ACR Research Department

NCRP Annual Meeting, April 2007

Background

Estimated dose = Effective dose per procedure x
Number of procedures

Focus of this talk: Number of procedures

- For a certain level of effective dose per procedure for each category, we will examine trends in procedures over time to explore the contribution of volume growth to changes in radiation exposure

Preliminary Results (2006): From Mettler et al.

	Number procedures	Collective effective dose person Sv	Per caput (mSv)	% of per caput
Radiography	310 million	175,000	0.6	19
Interventional	2.9 million radiol 4.0 cardiac	90,000	0.3	9
CT	67 million	440,000	1.5	49
Mammography	38 million	2,200	_	<1
Dental	125 million	NA	_	<1
Nuclear Medicine	19 million	220,000	0.7	23
TOTAL	~ 550 million	~930,000	3.1	100
Radiotherapy	1 million patients			

Why is volume of medical procedures important?

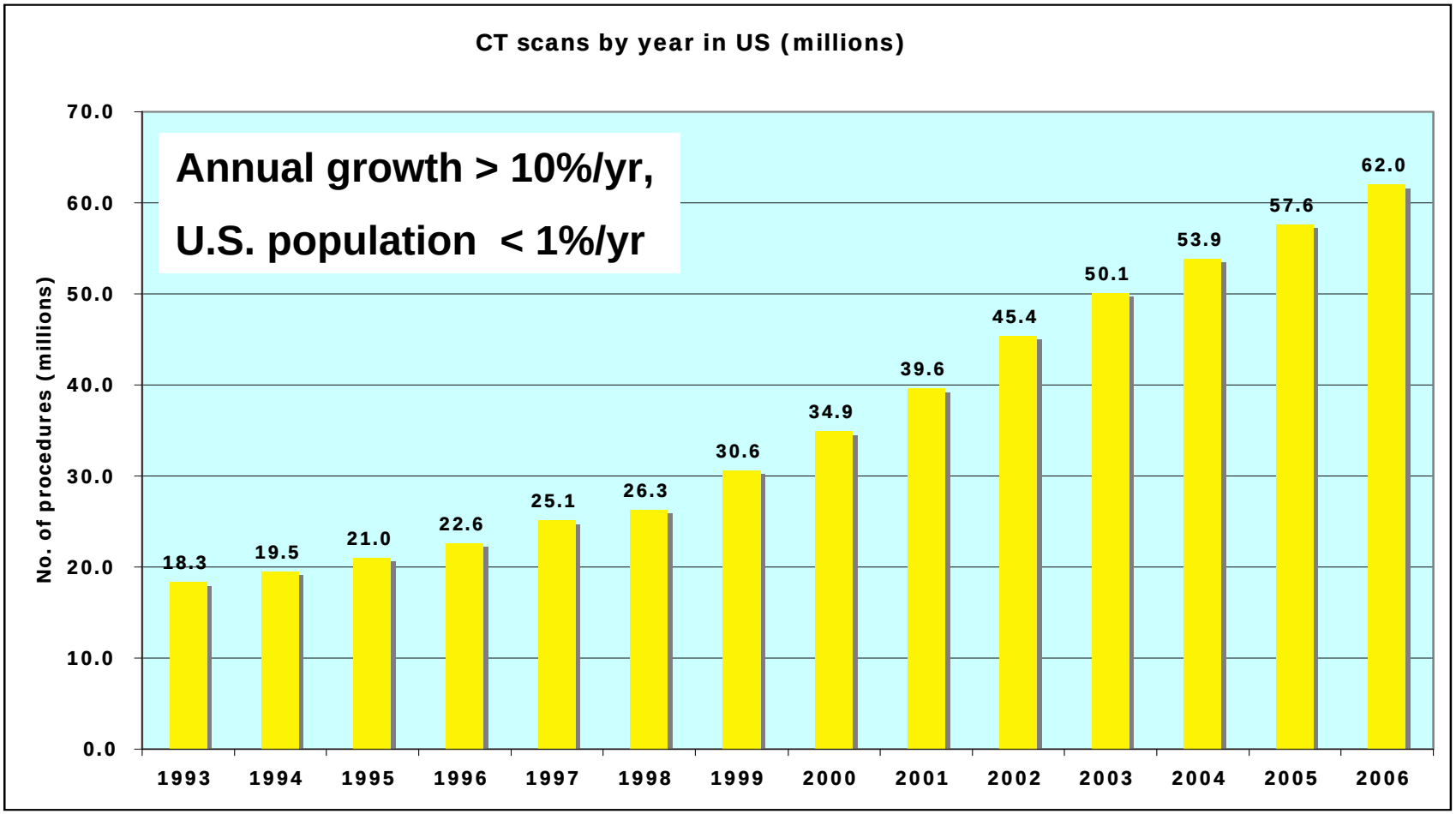
Average annual rates of growth, 1980-2006

	# of procedures	Average effective dose/ procedure	Collective effective dose (person Sv)
Radiography*	1.94%	2.38%	4.34%
CT	11.94%	7.35%	20.18%
Nuclear Medicine	3.76%	3.78%	7.68%

Sources: NCRP 100, Mettler presentation

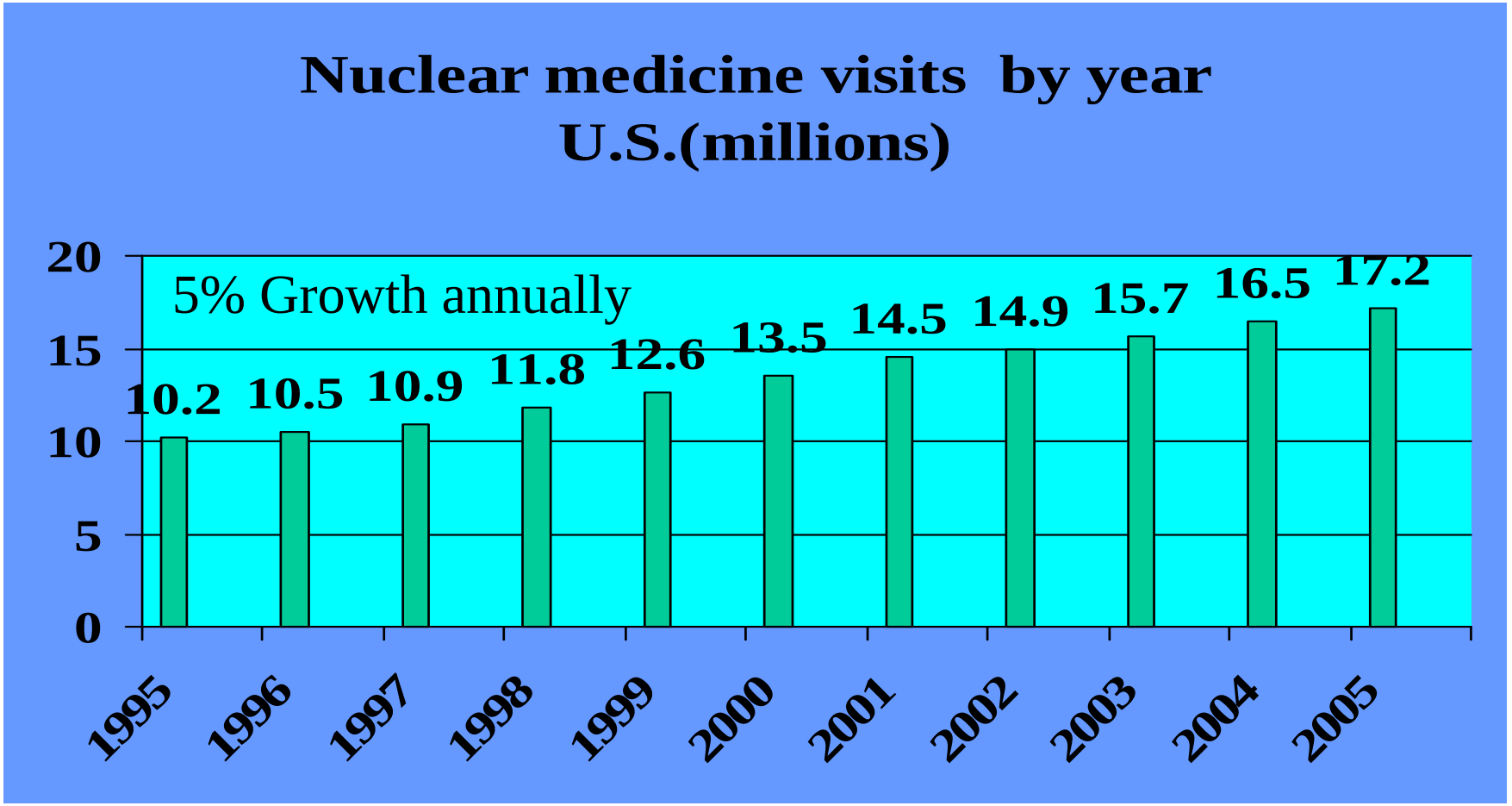
**includes interventional procedures and mammography*

- Imaging volume grew at least as rapidly as, or more rapidly than, dose per procedure



Currently approximately 1 CT per 5 persons.

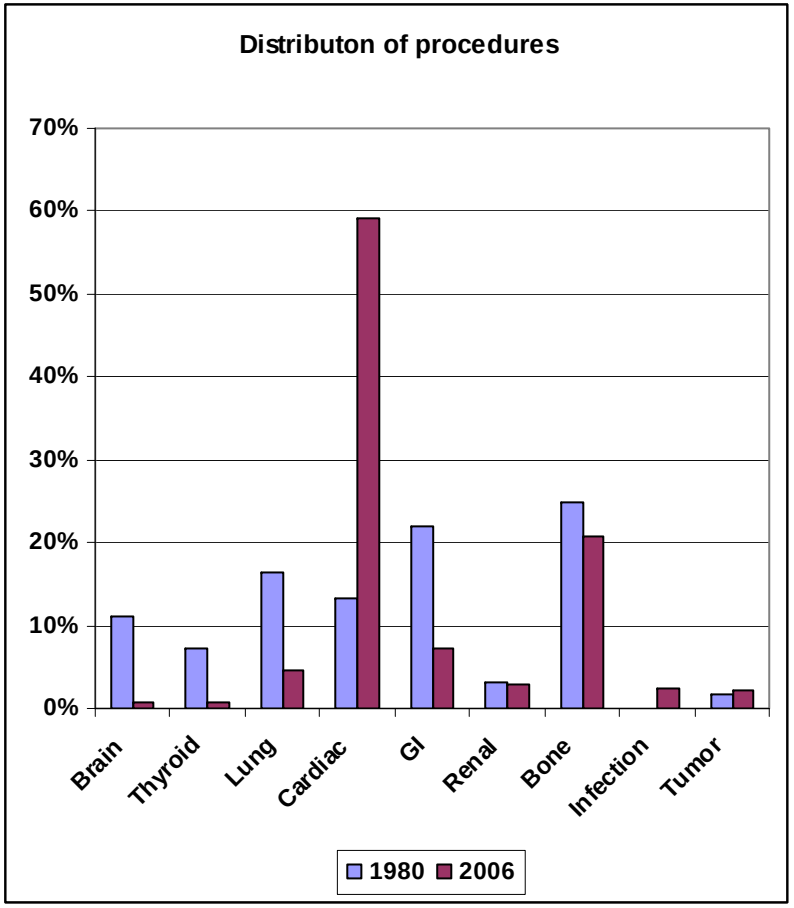
Source: IMV benchmark report, Mettler

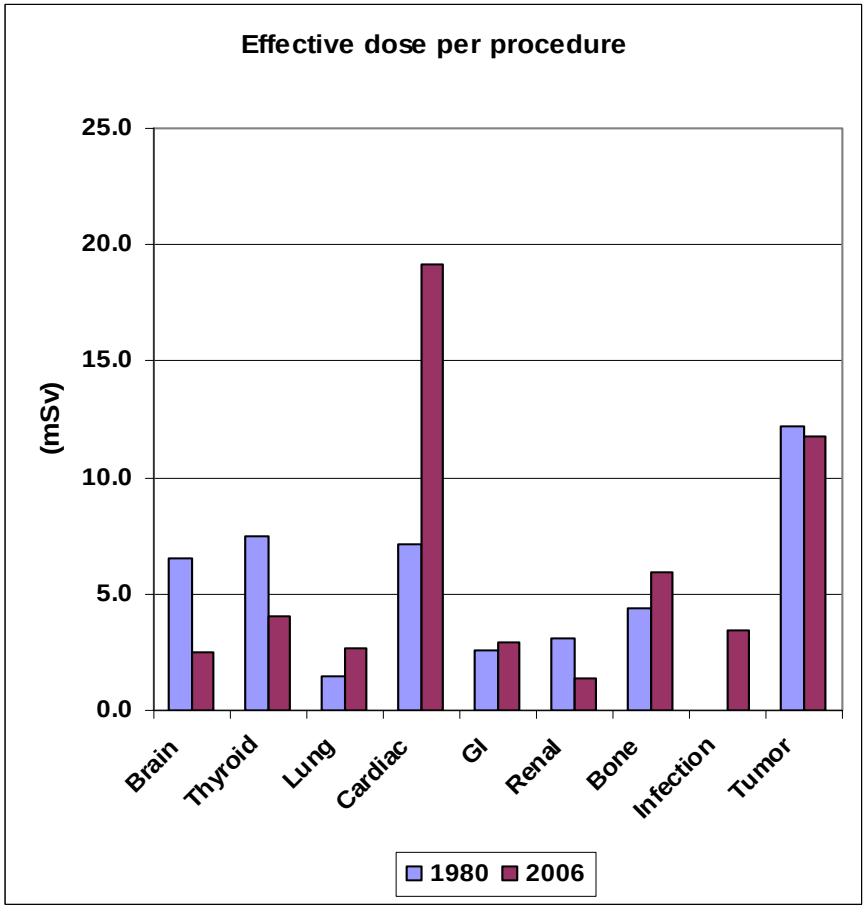


Currently approximately 1 nuclear medicine procedure annually per 15 persons

Source: IMV benchmark report, Mettler

Nuclear medicine: an illustration





Sources: NCRP 100, Mettler presentation

- Within each modality, dose per procedure grew primarily because of a rapid growth in procedures with high radiation doses

- This growth has accelerated over time in the past two decades, with very high rates over the past 5 years.

Recent growth in radiology procedures

- Blue Cost Blue Shield Medical Cost Reference Guide (2006): For the period 2001-2004
  - 38% increase in the number of diagnostic imaging centers and
  - 34% increase in diagnostic imaging procedures
- MedPAC data on Medicare spending on imaging
  - 10% annual increase between 1999 and 2003 and,
  - most recently, 16% increase between 2004 and 2005.

- *Some of this reported growth is in MRI and ultrasound imaging, which do not affect trends in radiation exposure.*

Outline of talk

- Examine trends in the utilization of
  - CT
  - Nuclear medicine
  - Fluoroscopy and other interventional procedures
  - Radiography, including mammograms

  and to a less detailed extent:
  - Radiation therapy/oncology
  - Dental radiology

Outline of talk

- For these modalities, we will explore long-term trends in utilization by
  - body part/organ system
  - place of service
  - physician specialty
- Age distribution of those receiving imaging
  - Age-specific trends

Primary data source

- Medicare claims for fee-for-service beneficiaries 1986-2004 (PSPS, formerly BMAD)
  - Long time series with consistent, high-quality data
  - 1/3-1/4 of total U.S. health care, but trends are generally representative of practice patterns in the population as a whole
  - But has no data on pediatrics

Additional data sources

- Market benchmarking reports from IMV Limited
- Public survey data from the Medical Expenditure Panel Surveys (Agency for Healthcare Quality and Research)
- Claims data from a large national employer's insurance plan

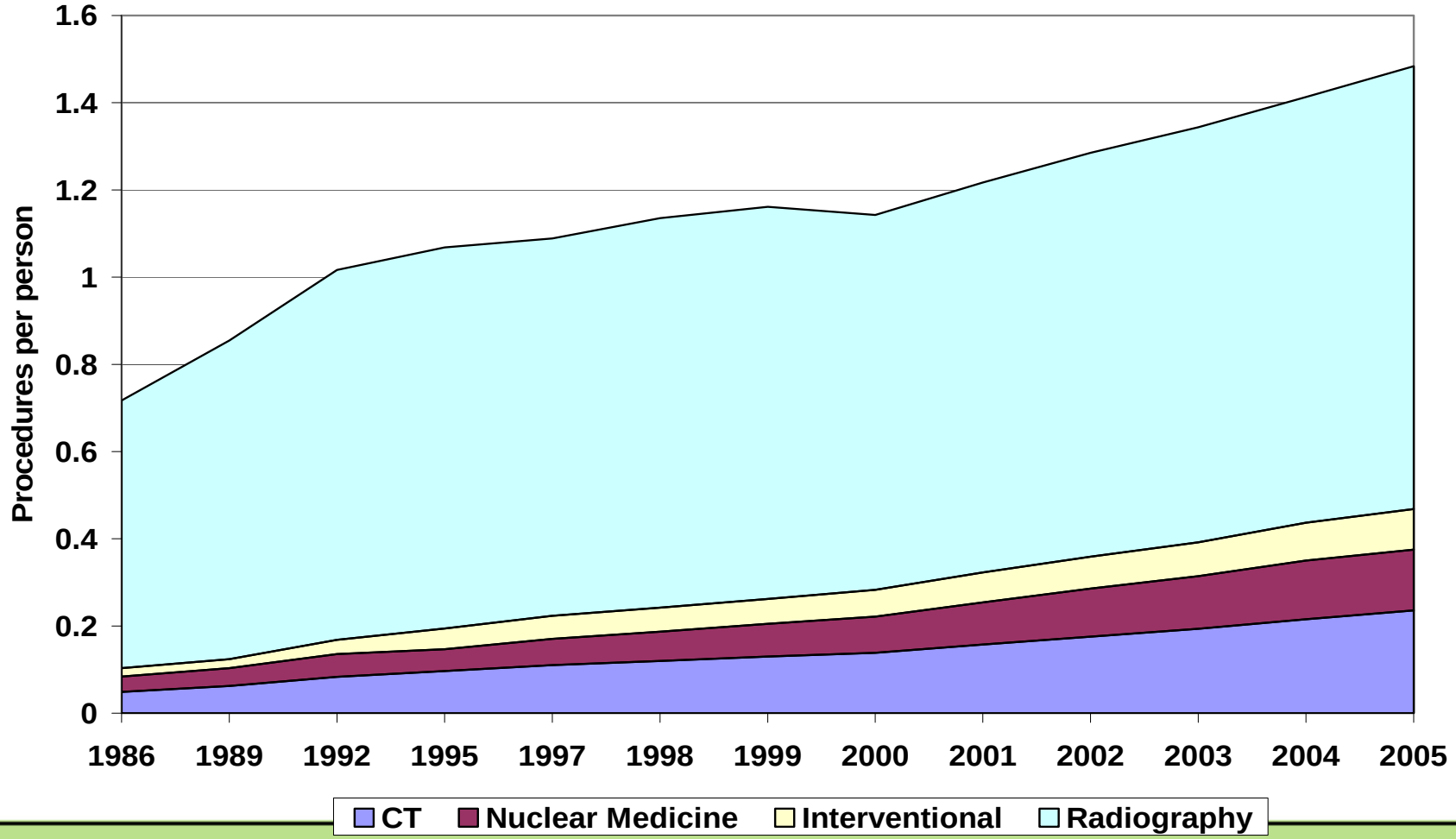
Trends in Medicare procedures per enrollee: Issues

For each modality:

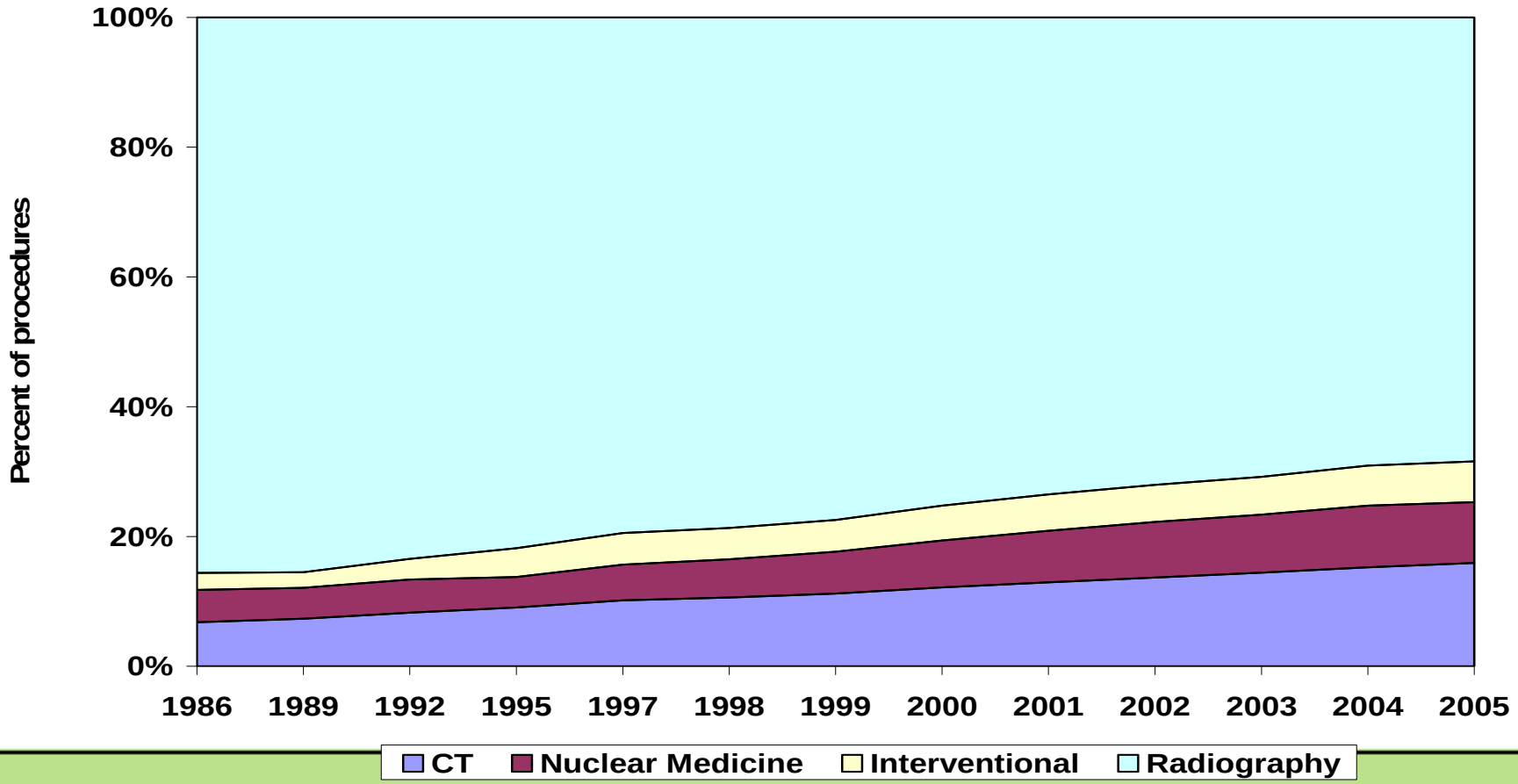
- What procedures are done: distribution across organ systems
- Where the procedures are done:
  - relative share of non-hospital imaging, where there might be less intensive oversight on safety issues
  - relative share of imaging in the ER where image ordering may not follow much planning
- Who does the procedures:
  - Compare imaging by radiologists, radiation oncologists, and nuclear medicine physicians to imaging by other specialties (to account for differences in levels of training in radiation safety)

Overview of growth in per capita radiology utilization

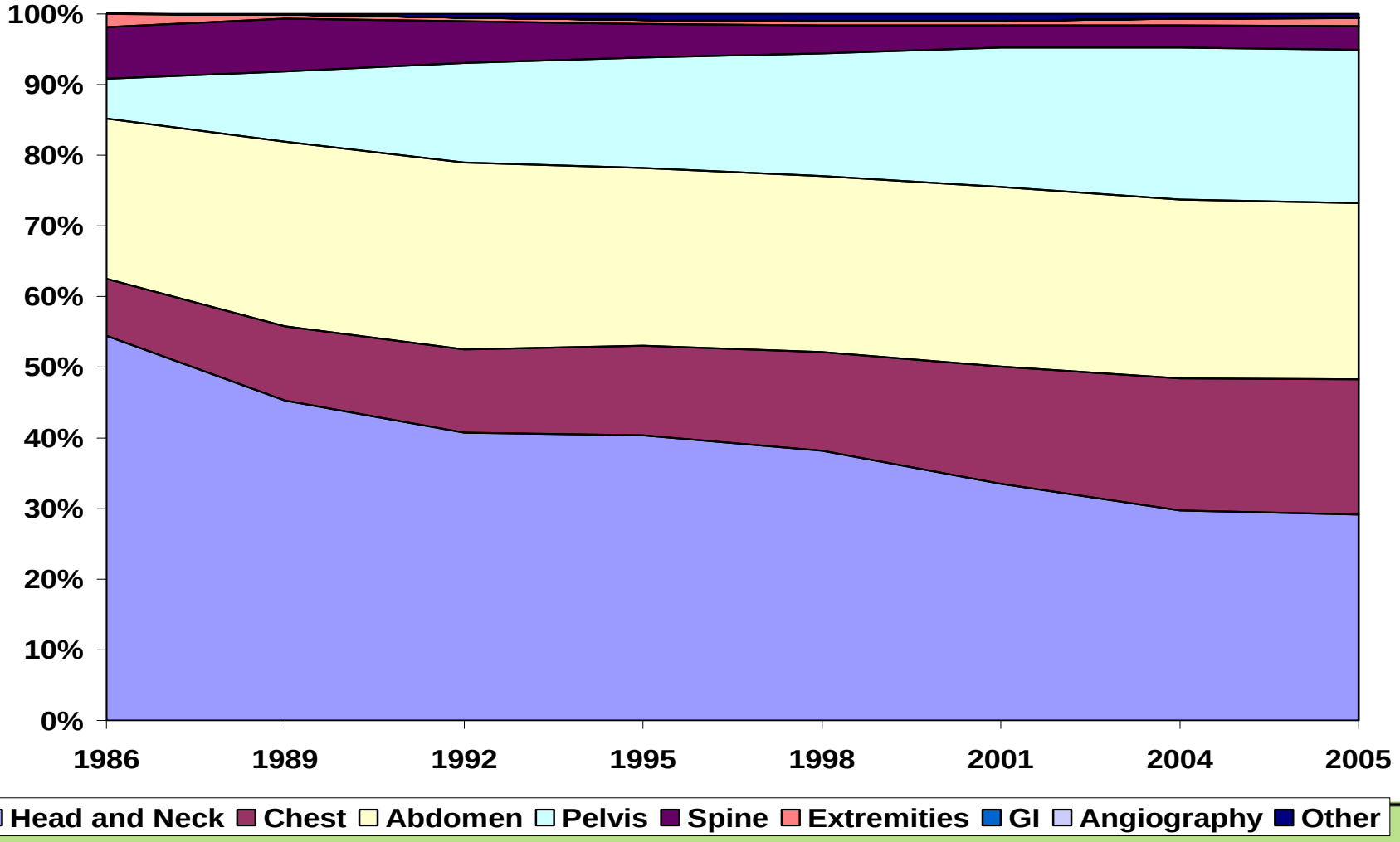
Country level estimates based on Medicare utilization



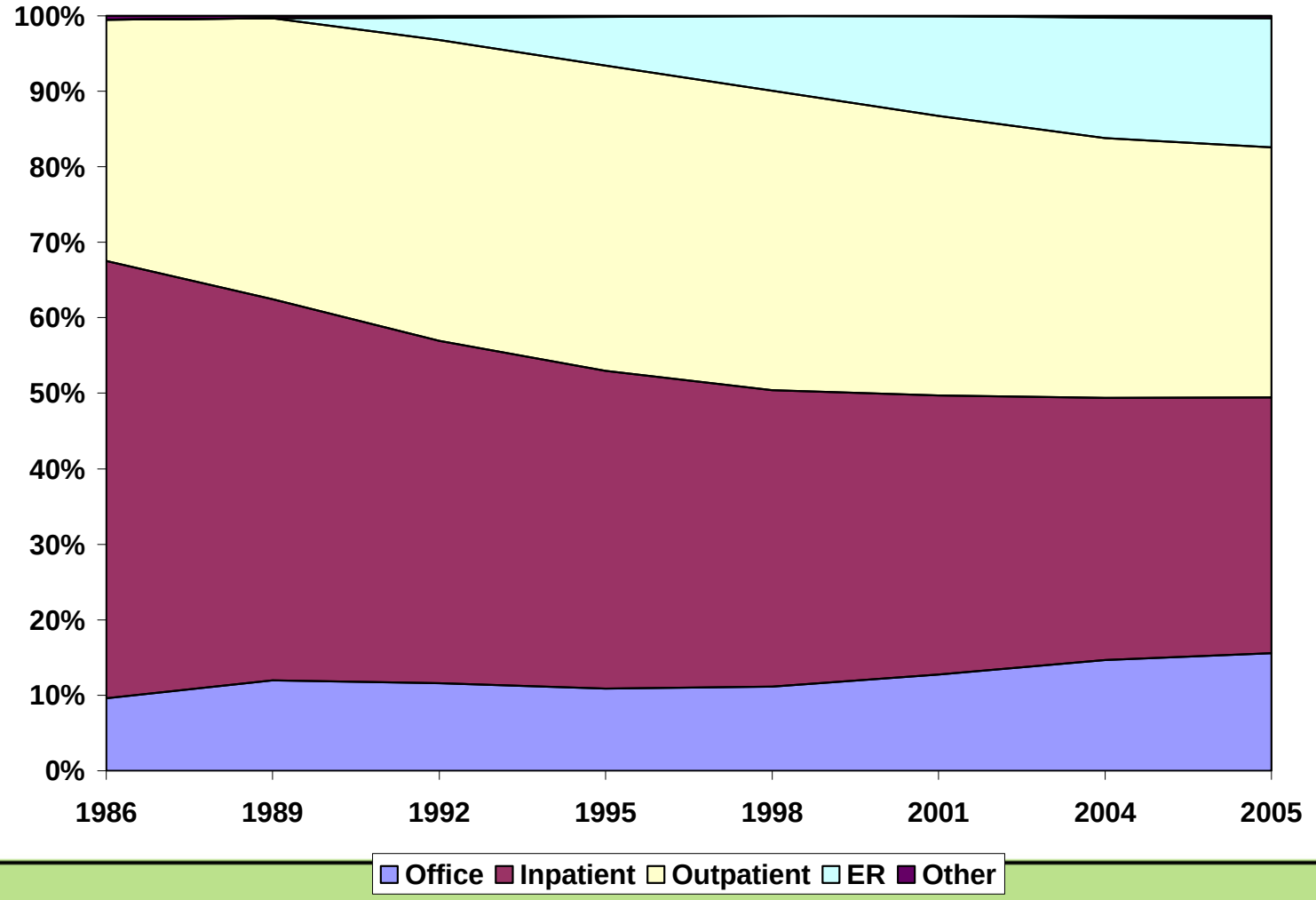
Overview of growth in imaging procedures: distribution



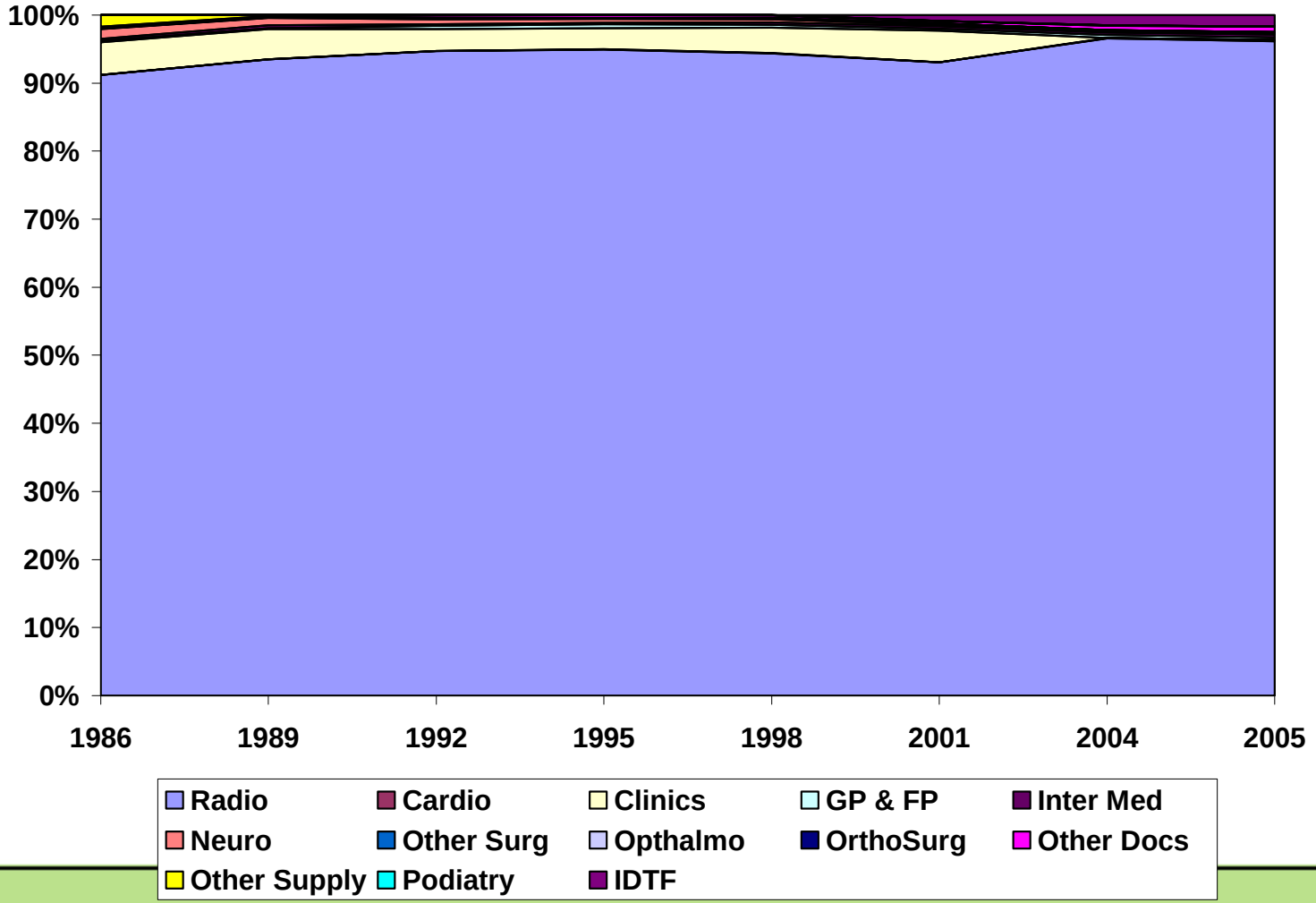
CT Imaging: Distribution across body parts



CT Imaging: Distribution across places of service



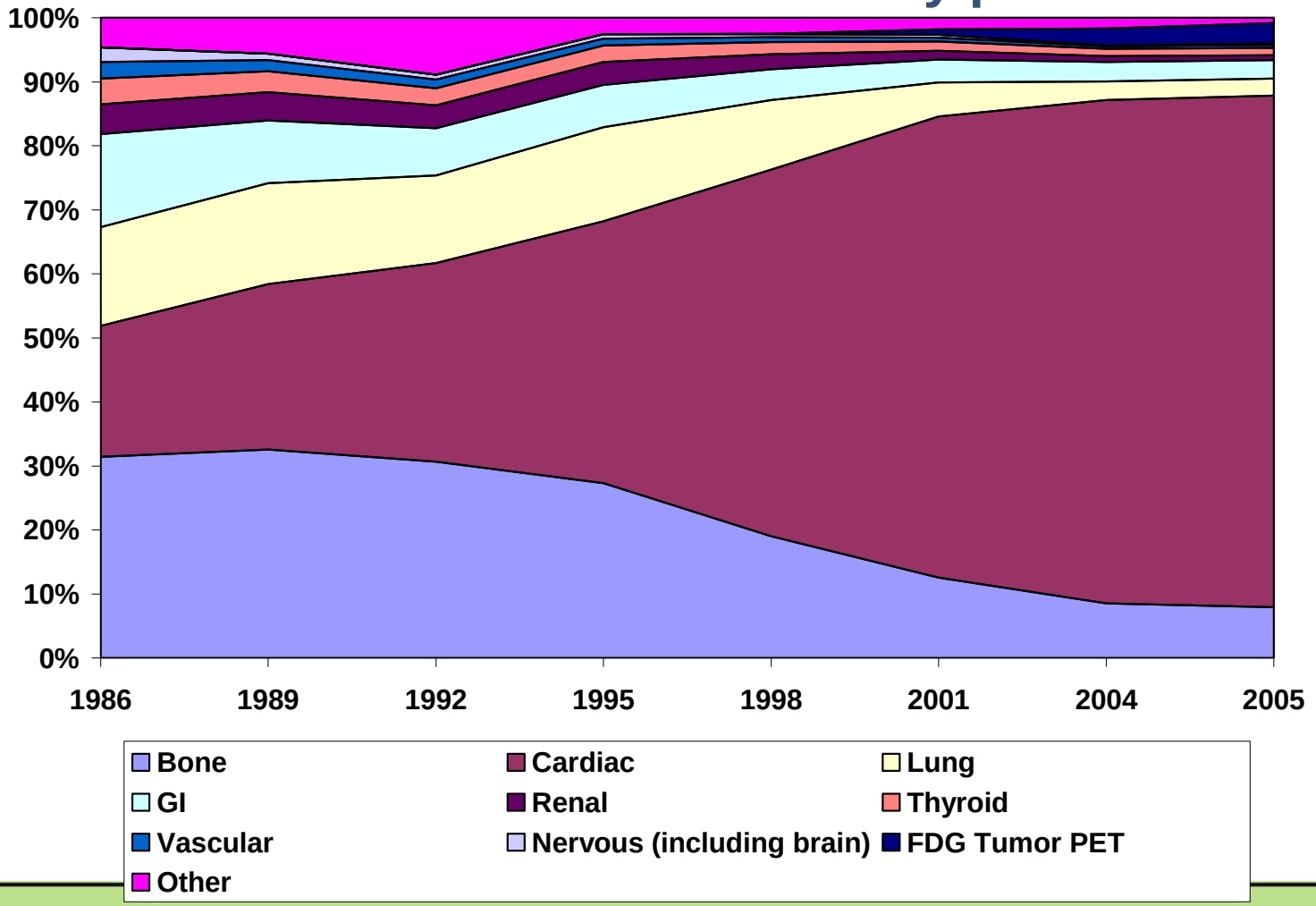
CT Imaging: Distribution across physician specialties



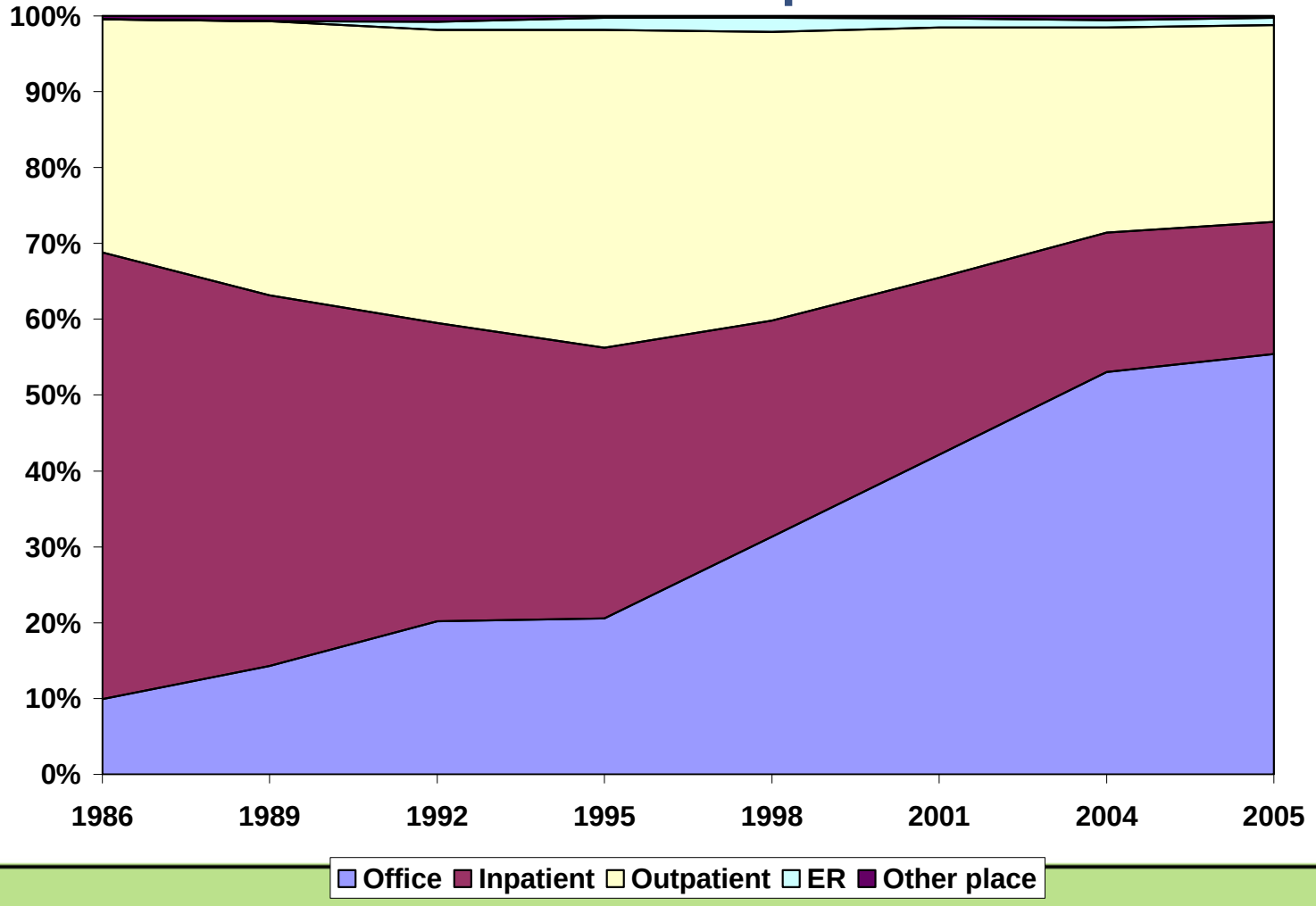
CT trends summary

- Shift towards more chest CTs and abdominal CTs
- More imaging in ERs

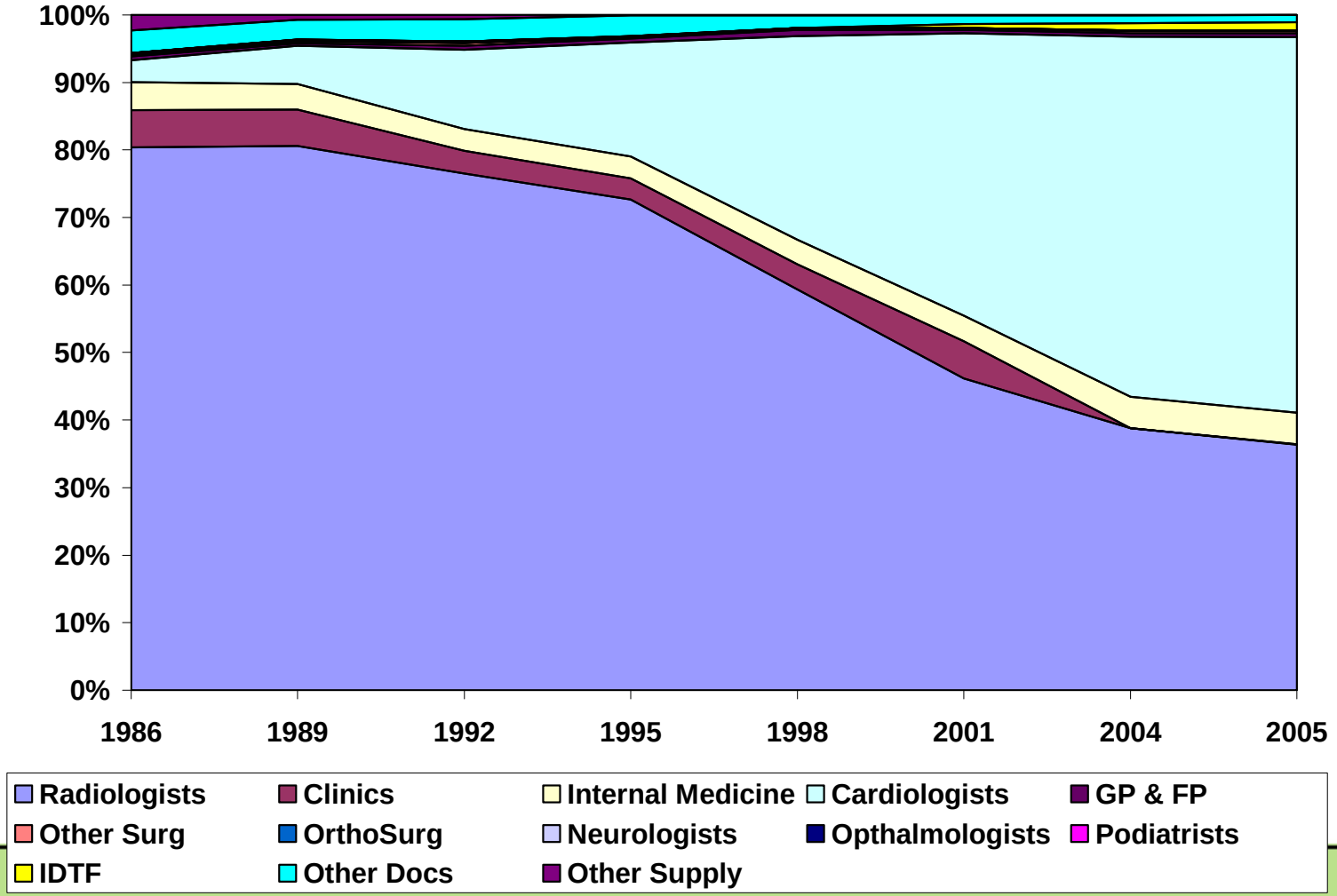
Nuclear medicine: Distribution across body parts



Nuclear medicine: Distribution across places of service



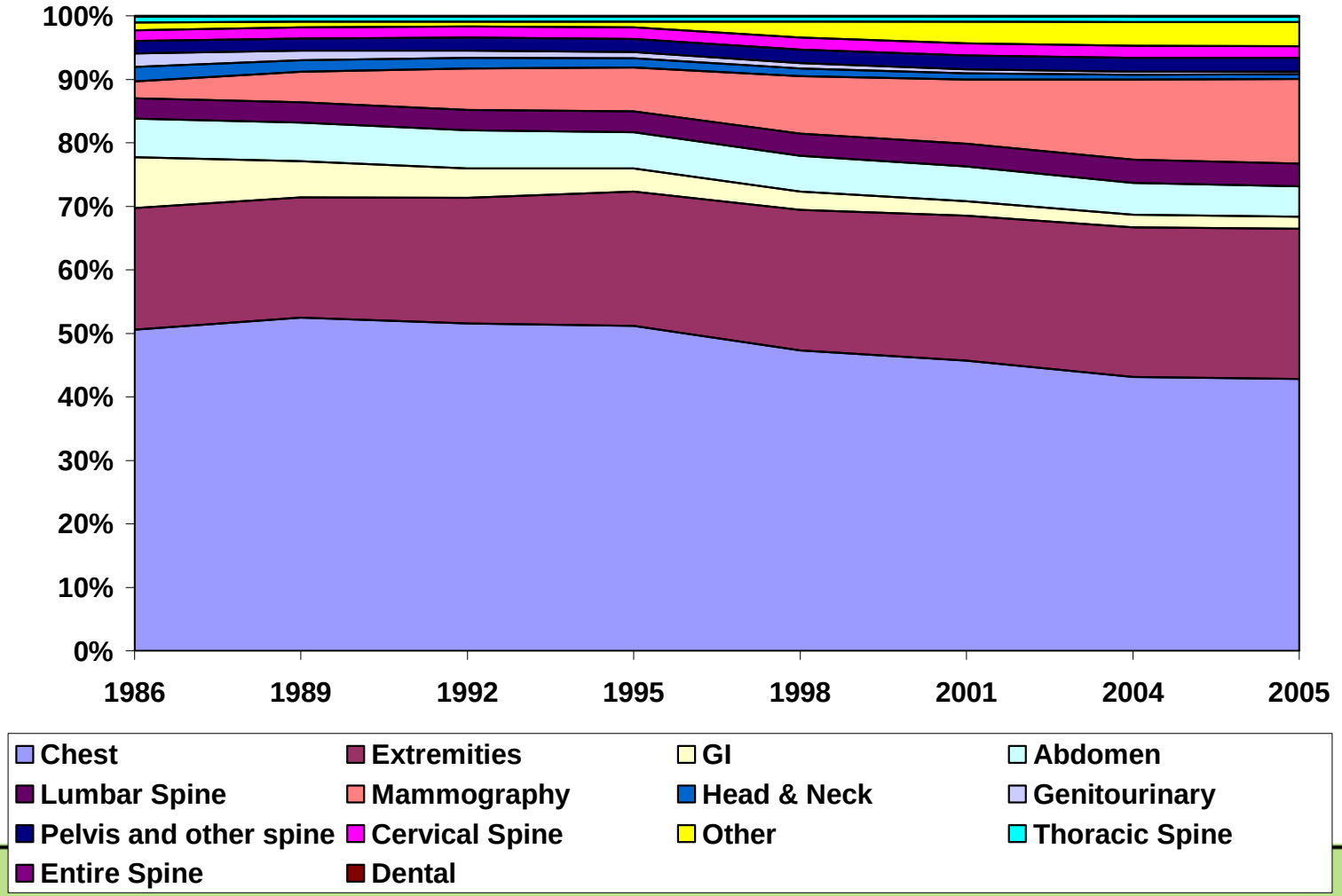
Nuclear medicine: Distribution across physician specialties



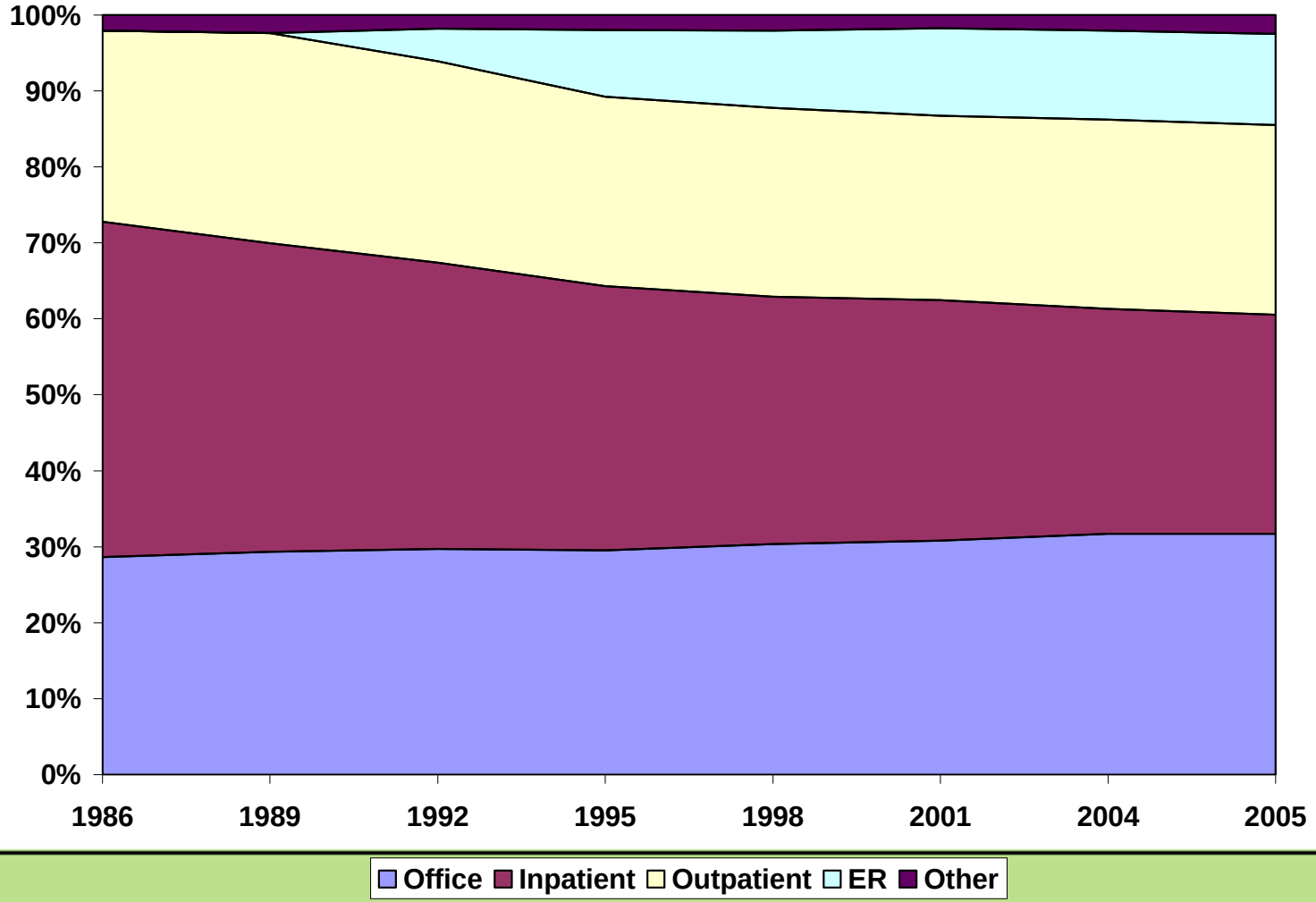
Nuclear medicine trends summary

- Dramatic expansion in cardiac imaging
- More recently, expansion in PET imaging for FDG tumors
- Large increase in share of cardiologists and of non-hospital imaging

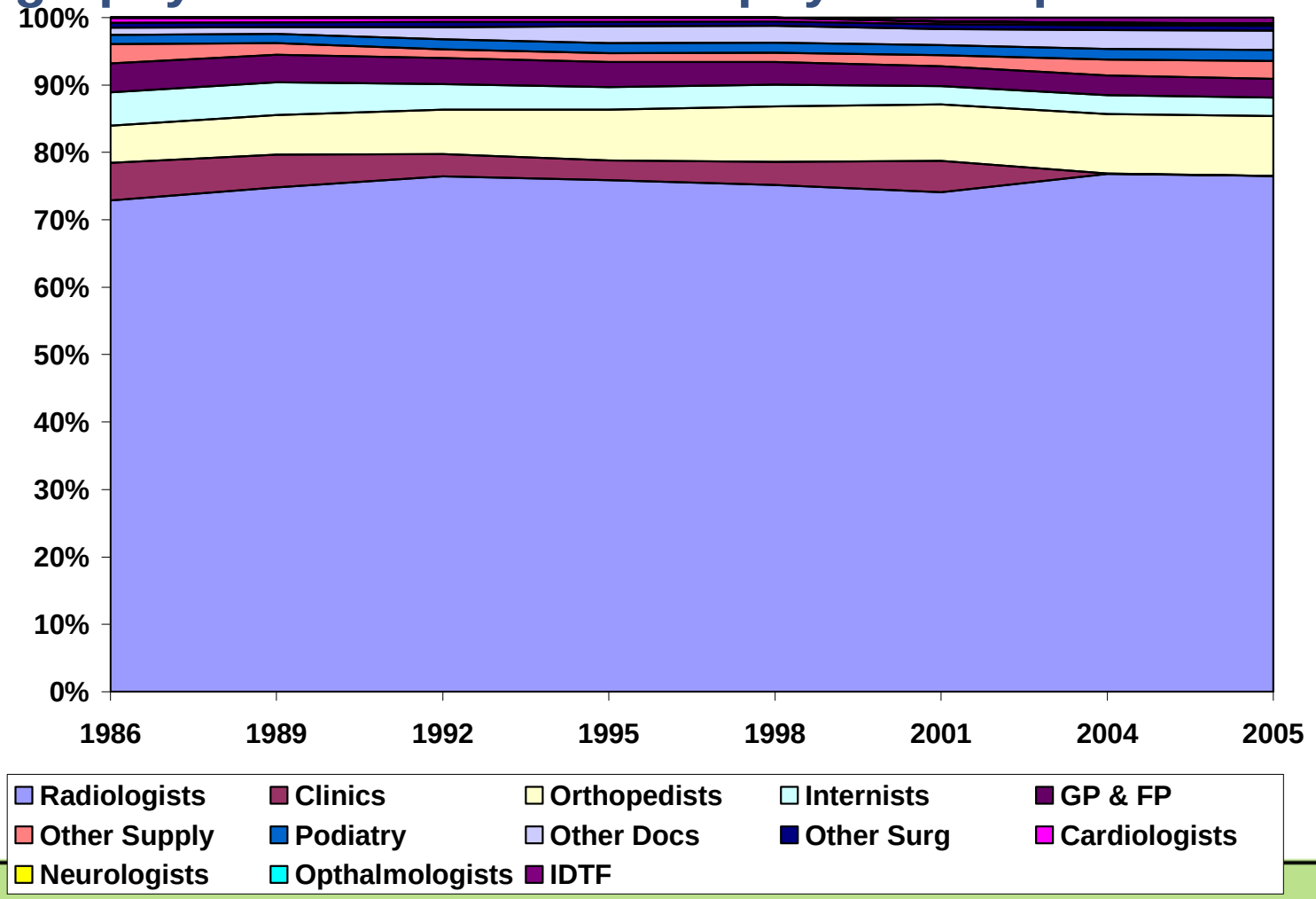
Radiography: Distribution across body parts



Radiography: Distribution across places of service



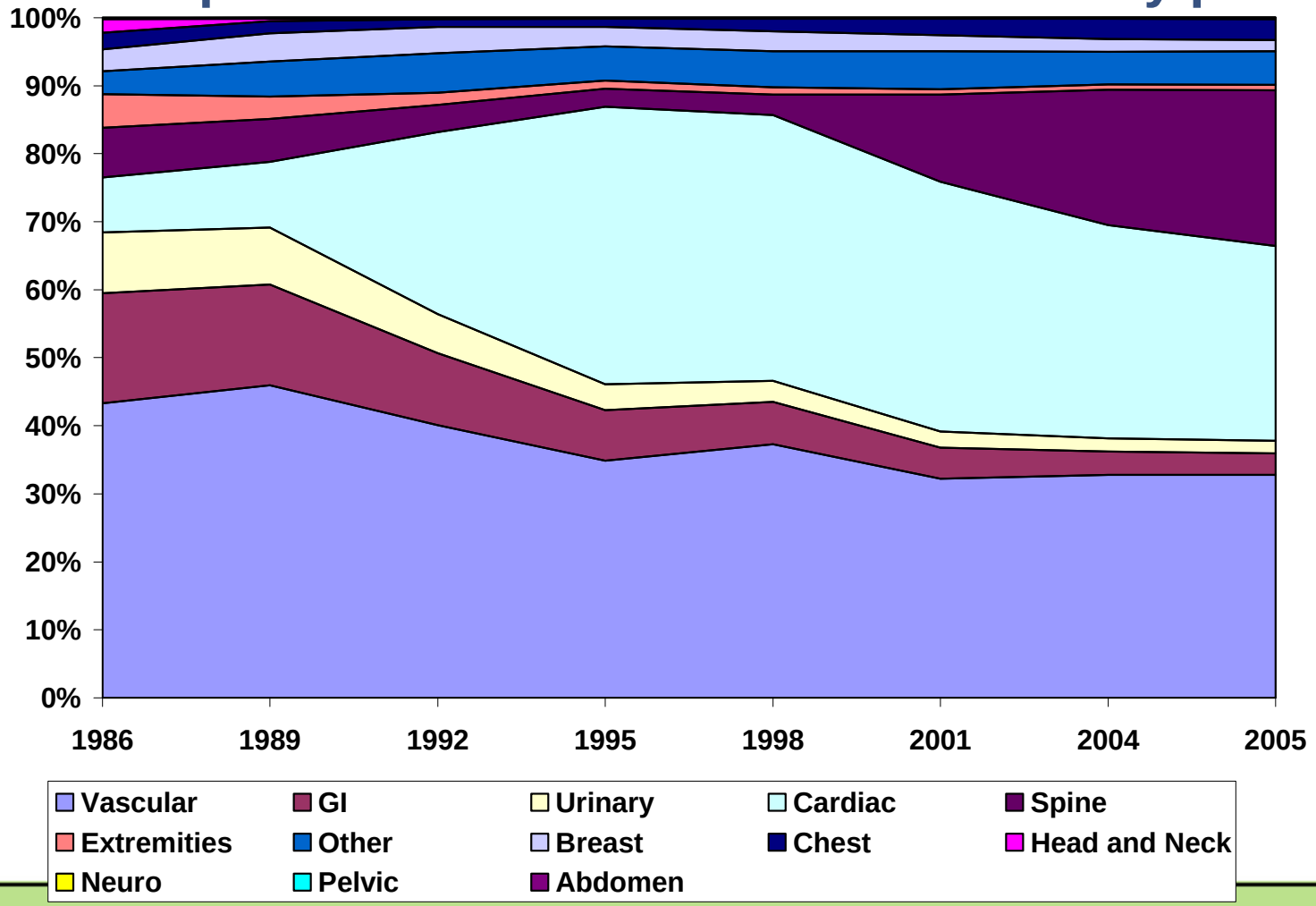
Radiography: Distribution across physician specialties



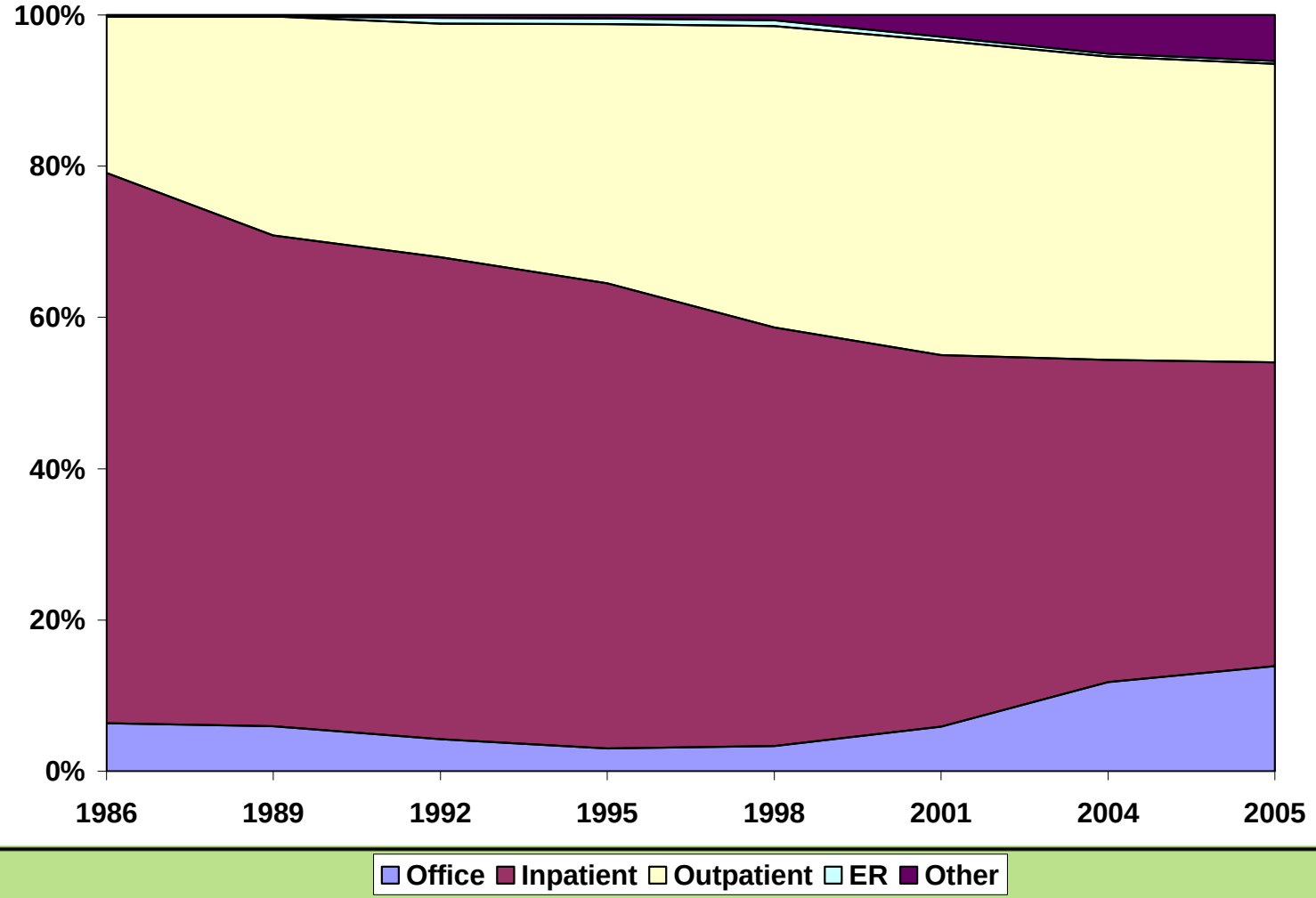
Radiography trends summary

- Overall, decreasing share of radiography.
- Still largest component of imaging by volume.
- Increasing share of non-hospital settings.
- Prominent share of orthopedists.

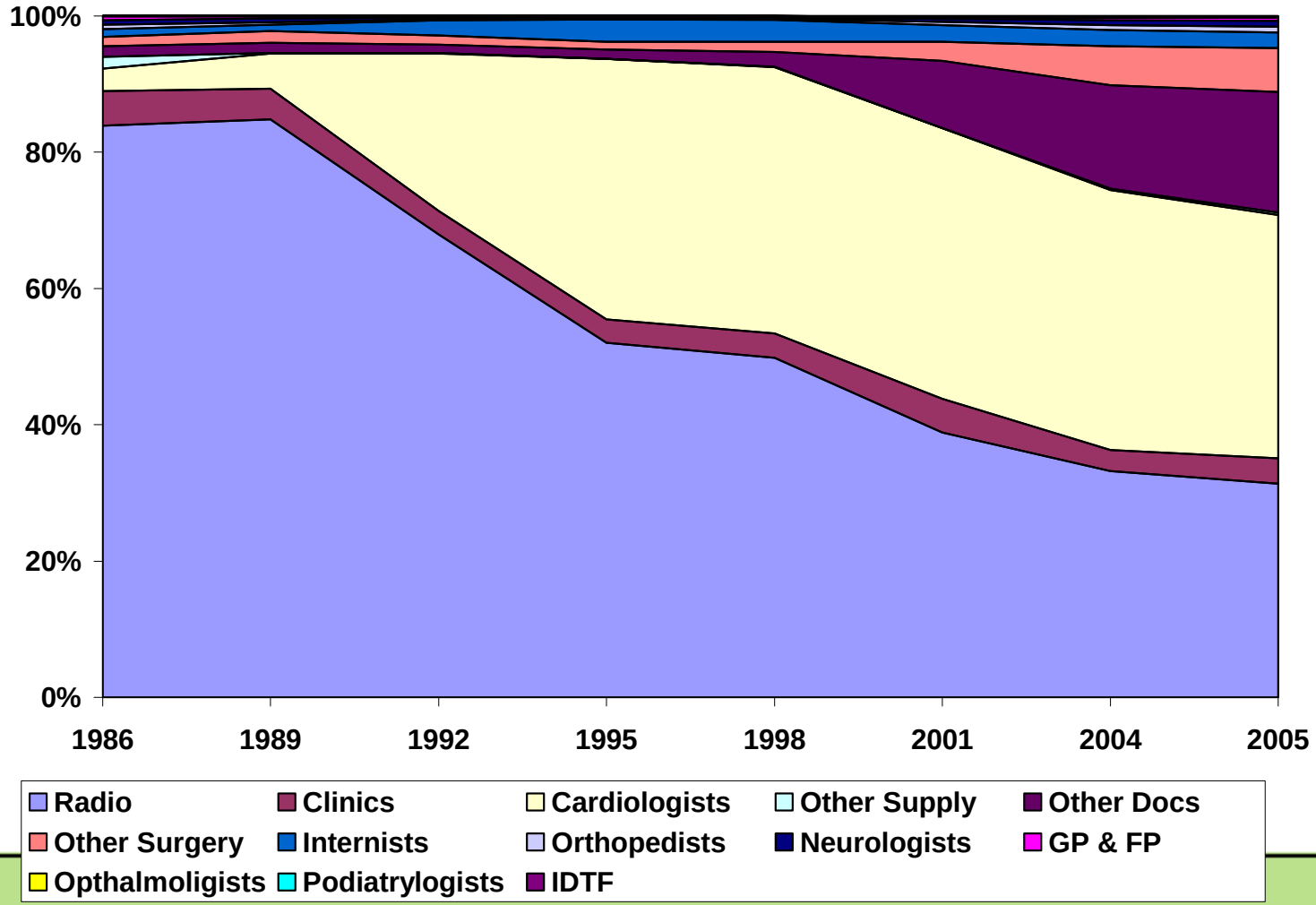
Interventional procedures: Distribution across body parts



Interventional procedures: Distribution across places of service



Interventional procedures: Distribution across physician specialties

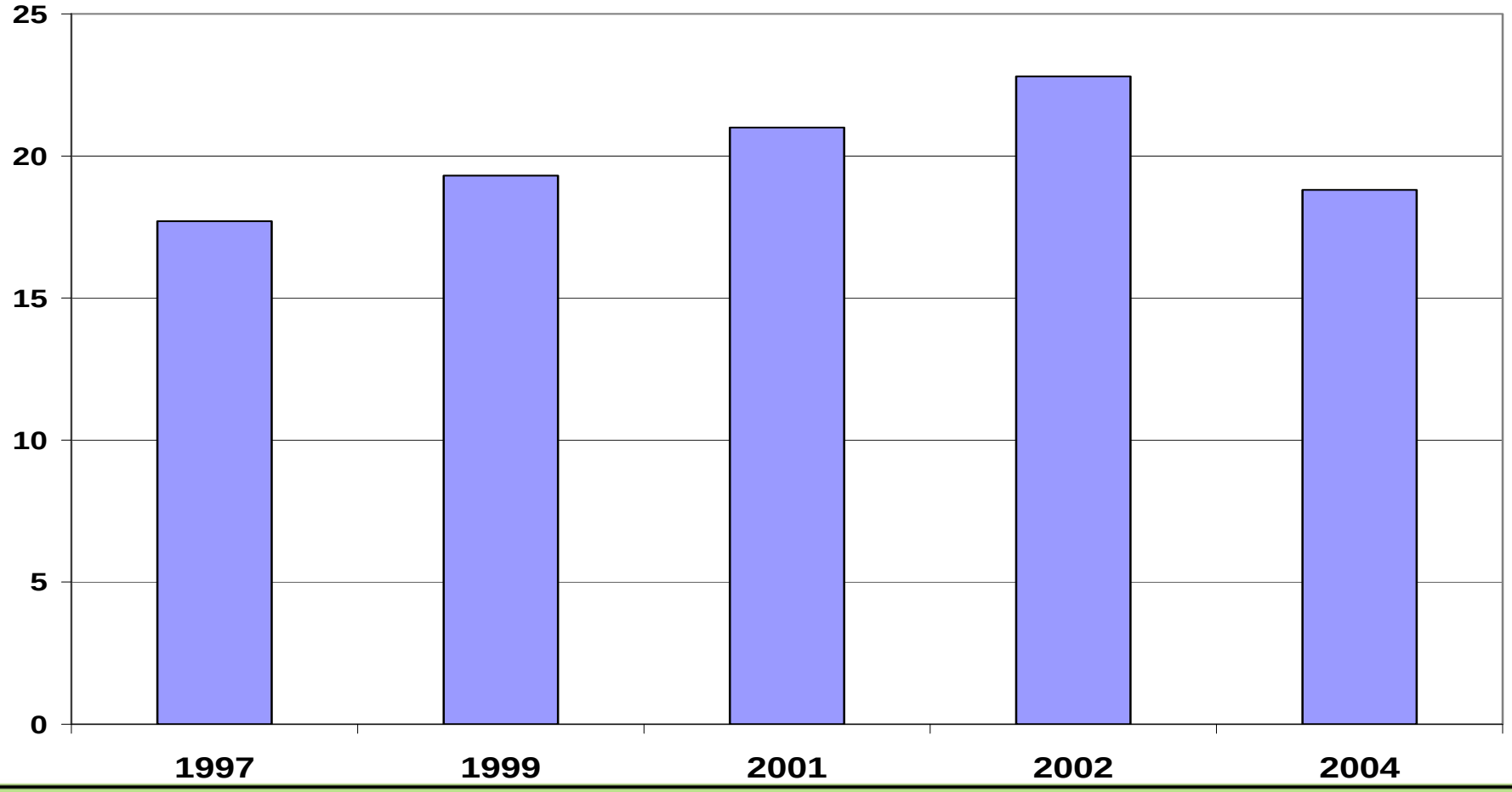


Interventional trends summary

- Much larger shares of cardiologists and neurologists now relative to 20 years ago
- Much smaller share of inpatient procedures relative to 20 years ago

Radiation oncology treatment visits, in millions

From IMV Radiation Oncology Benchmark Report, 2004

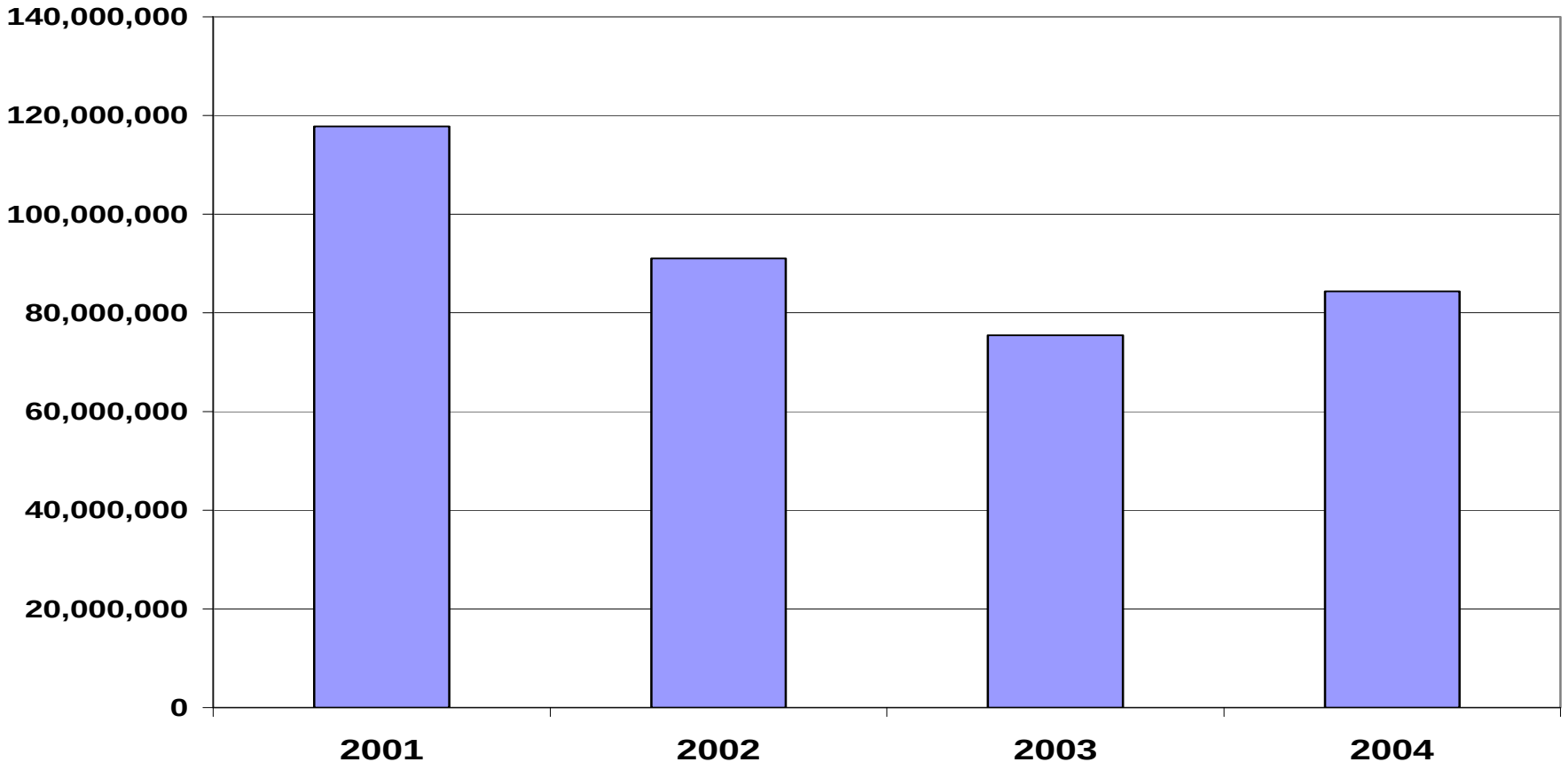


Radiation oncology summary

- Mostly in office and outpatient settings
- Almost all by radiation oncologists

Dental imaging: number of visits with dental x-rays

MEPS Survey data



Dental imaging: range of estimates on number of procedures

Preliminary data from NCRP 6-2, compiled by Dr. Gray

All numbers in millions

Source	# Dental Visits	# Dental visits with x-rays	# X-Ray Examinations	# Dental X-Ray Films Exposed
NEXT			221	886
FDA Staff			185	740
CDC	143			
Medical Expenditure Panel Survey		92		368
Industry Source			125	500

Other imaging

There is little information on procedures that are not reimbursed by major insurers. Examples:

- Full body CT screening
- Imaging by chiropractors

Who is getting these images?

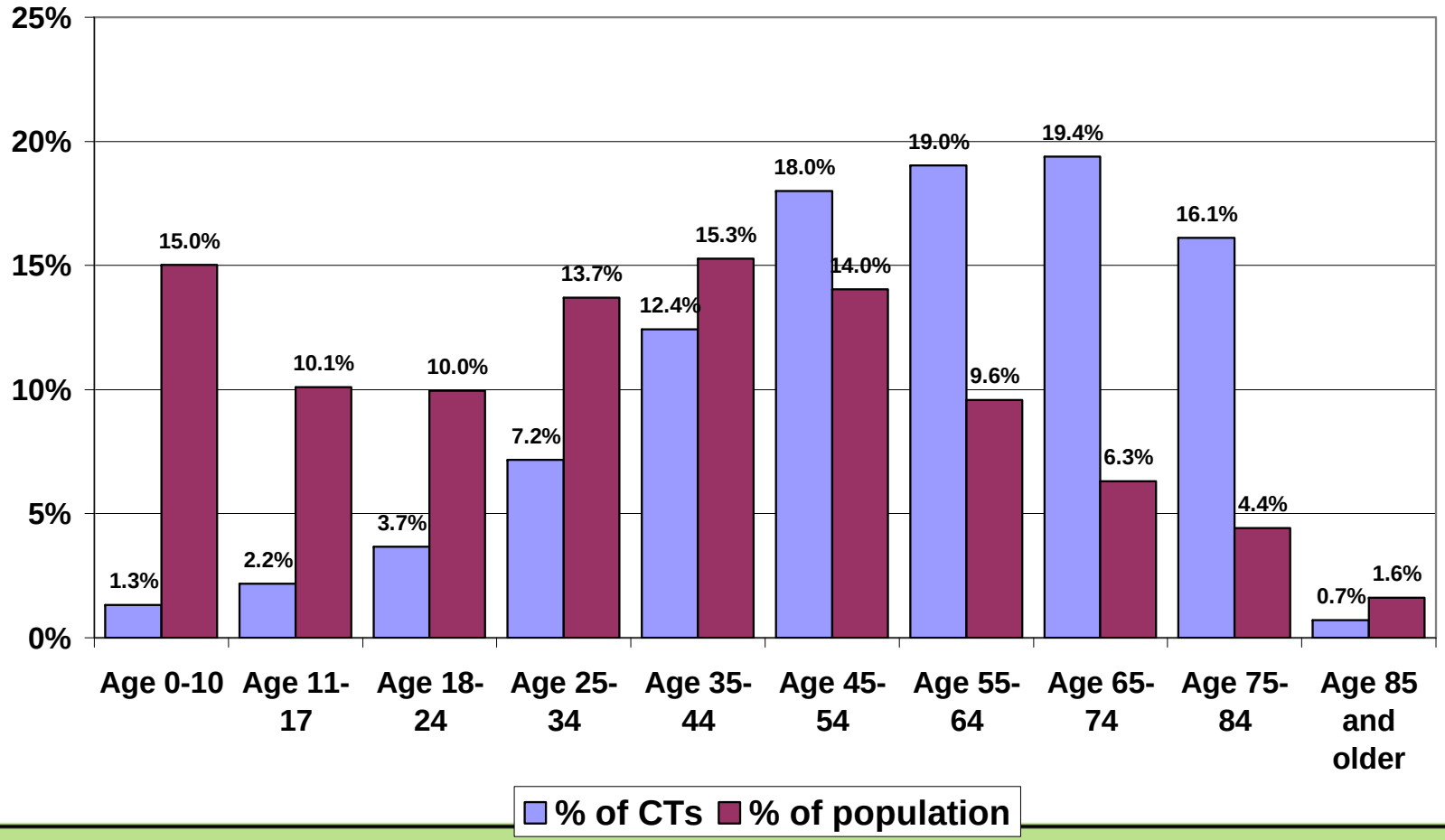
Each year

- Approximately 5% of the population gets a CT scan
- Approximately 7% has a mammogram
- 18-19% have x-ray images.

(Estimates based on data from the Medical Expenditure Panel Surveys)

ACR™ American College of Radiology

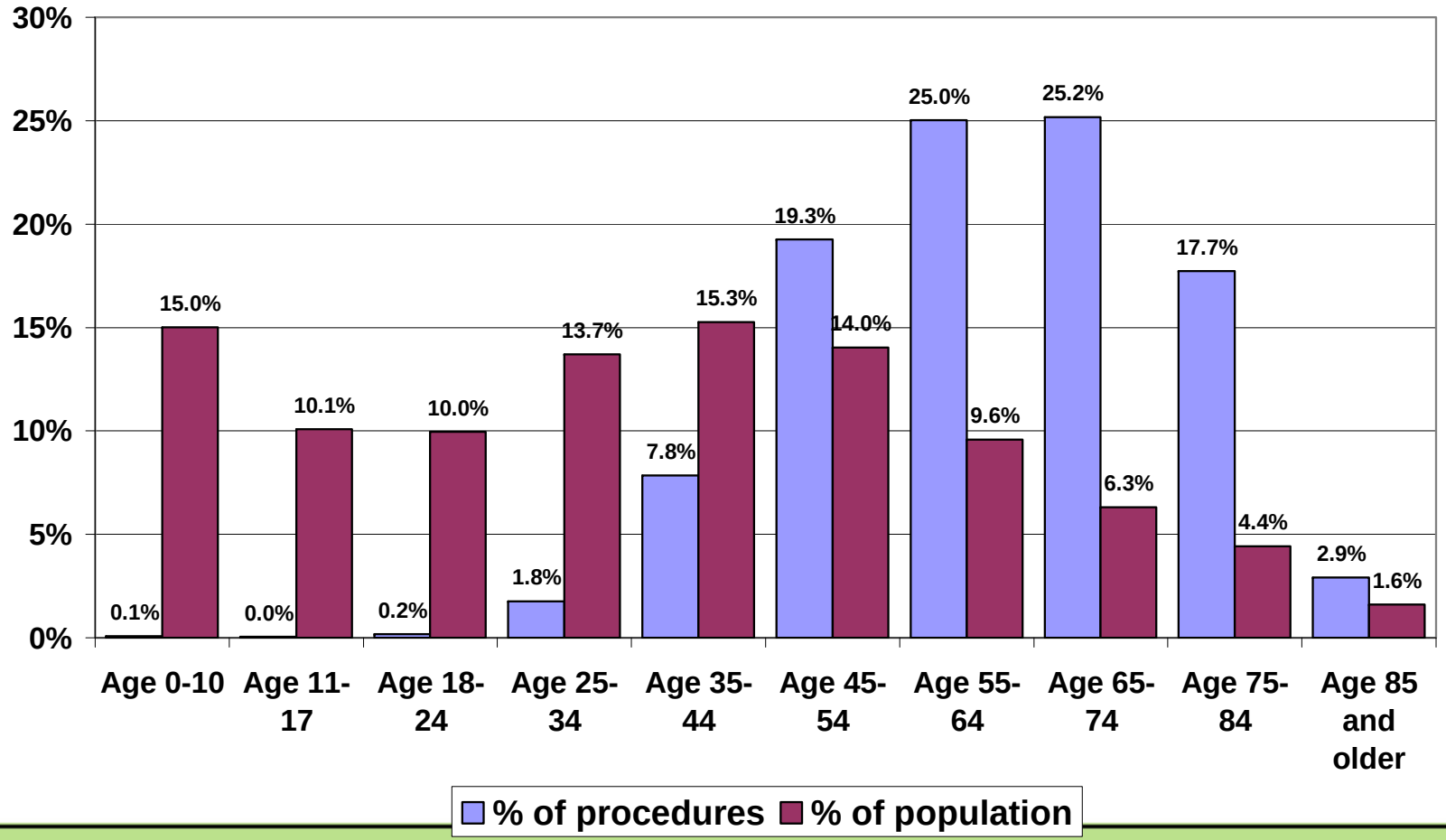
CT of the abdomen, pelvis, and chest: Age distribution, 2003
Reweighted to be representative of US population age distribution



Based on data from a large national employer plan

ACR™ American College of Radiology

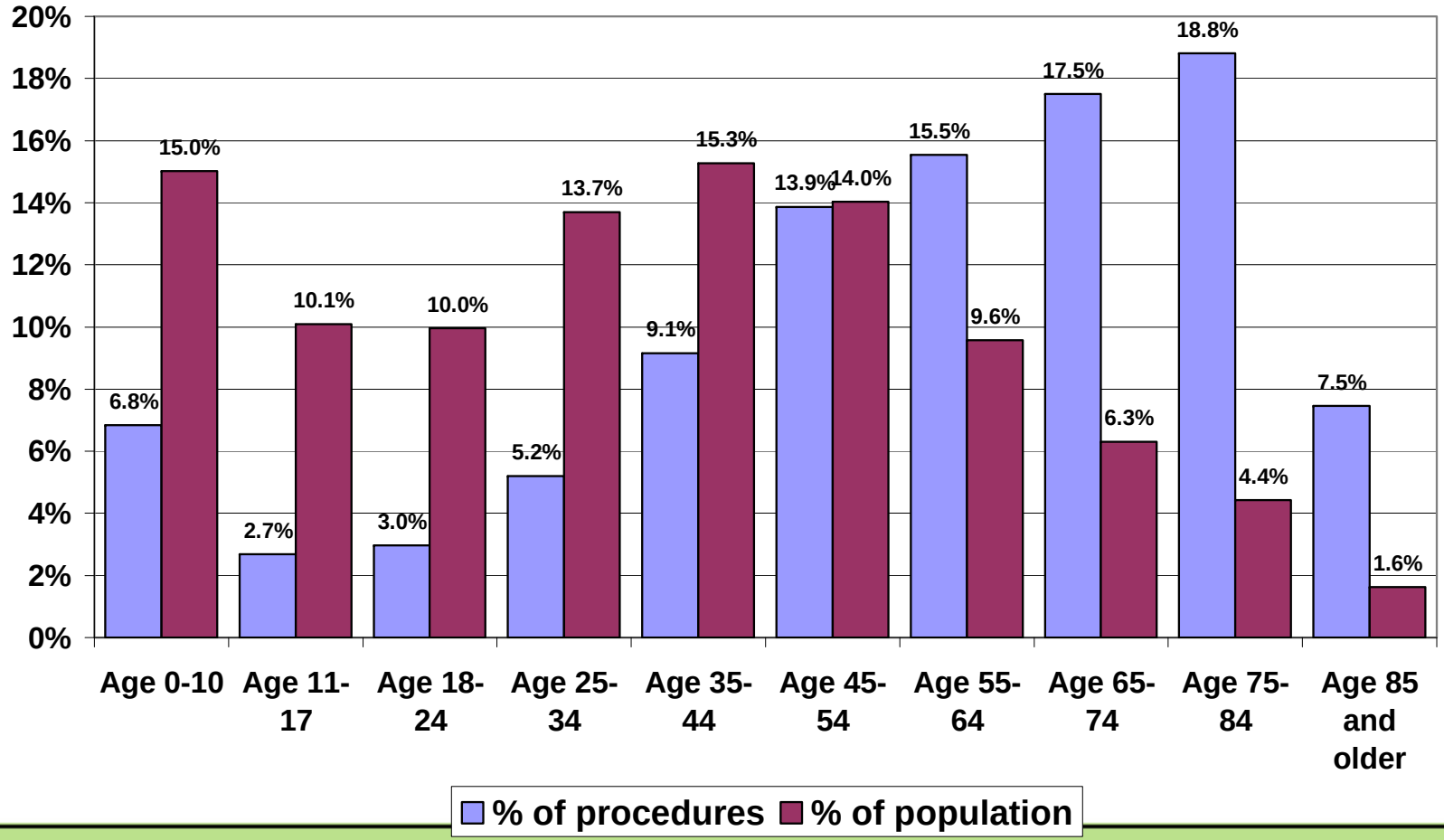
Cardiac nuclear medicine: Age distribution, 2003
Reweighted to be representative of US population age distribution



Based on data from a large national employer plan

ACR™ American College of Radiology

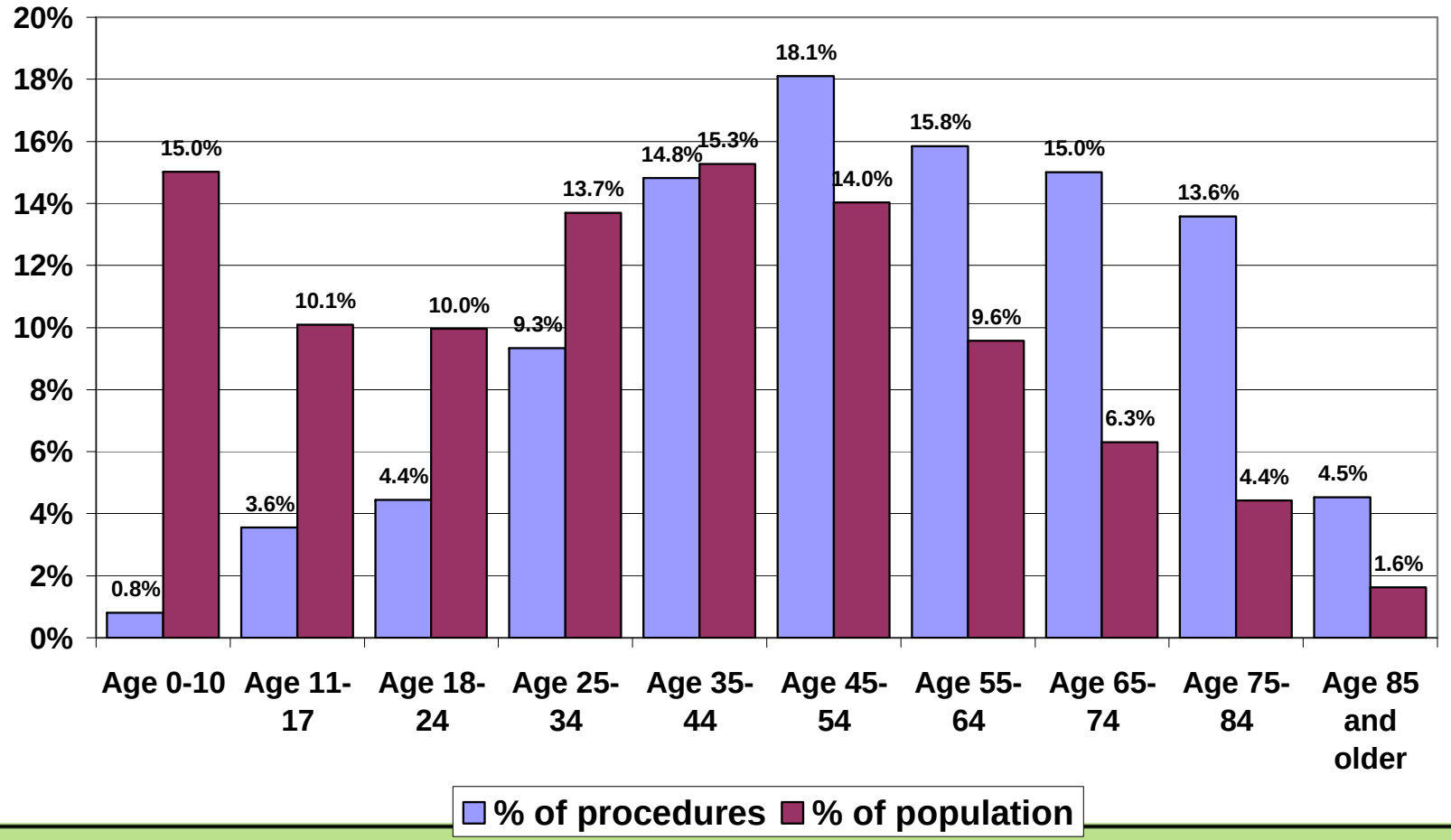
Chest x-rays: Age distribution, 2003
Reweighted to be representative of US population age distribution



Based on data from a large national employer plan

ACR™ American College of Radiology

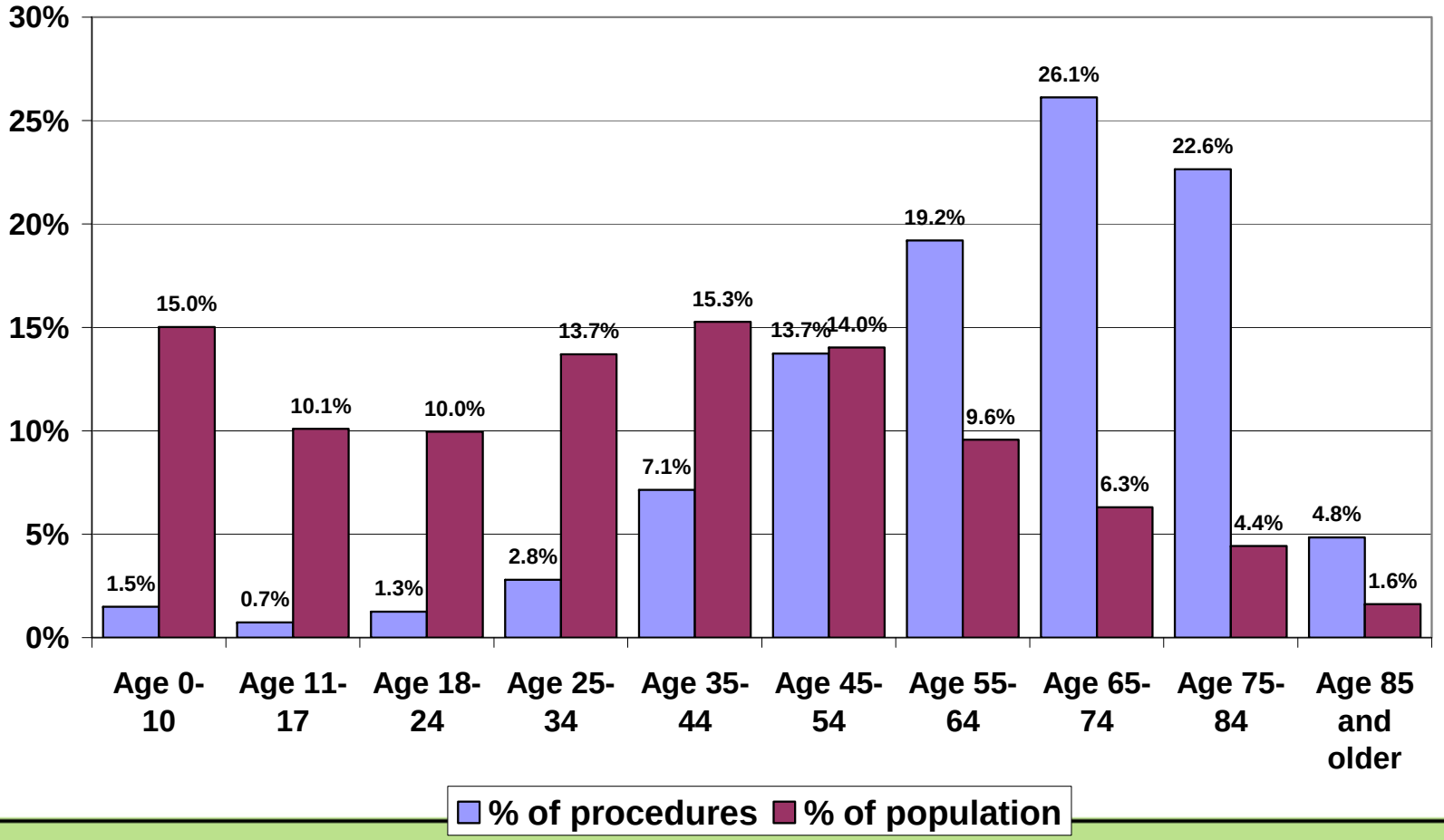
Lumbar Spine x-rays: Age distribution, 2003
Reweighted to be representative of US population age distribution



Based on data from a large national employer plan

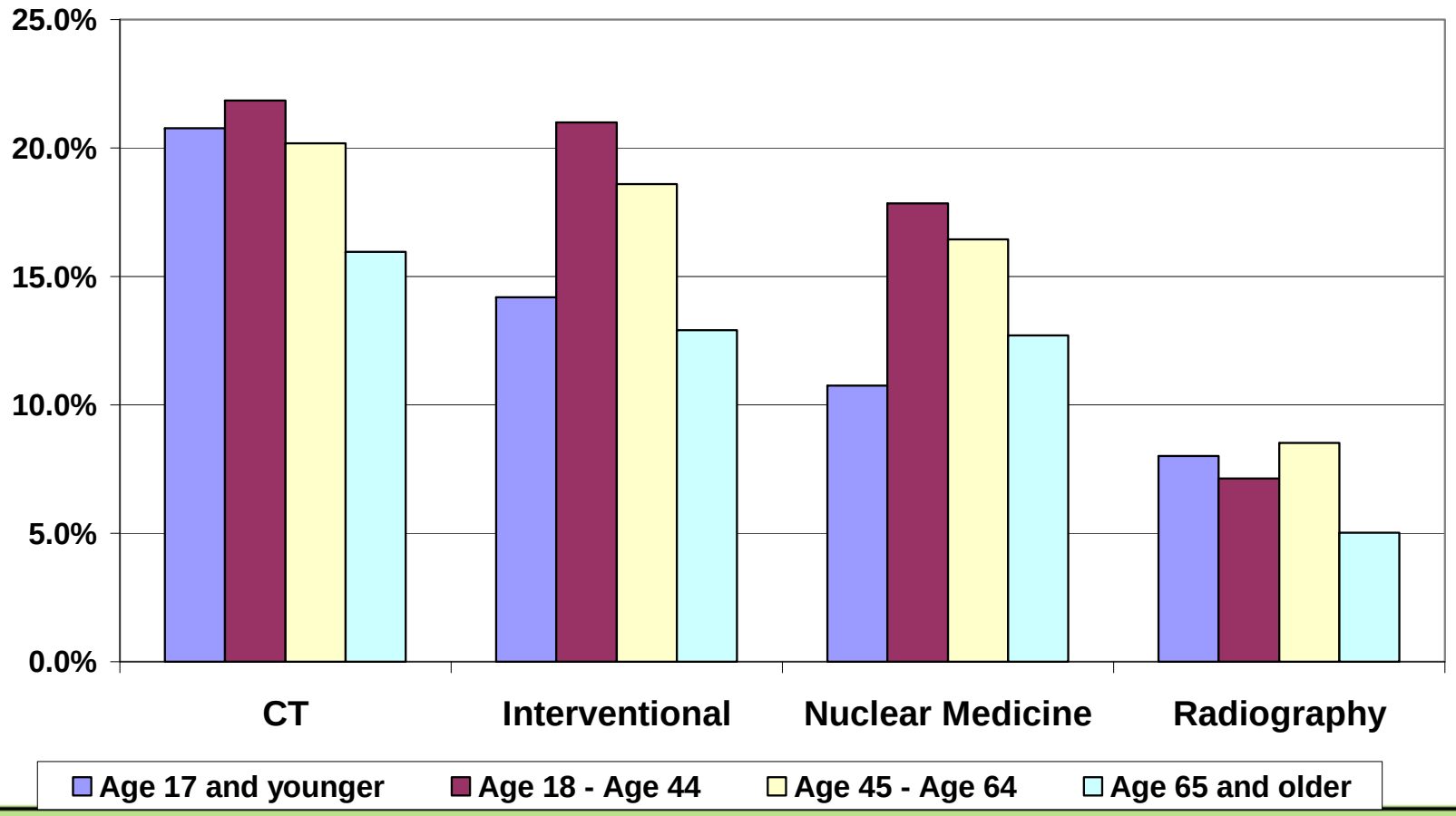
ACR™ American College of Radiology

Vascular interventional radiology procedures: Age distribution, 2003
Reweighted to be representative of US population age distribution



Based on data from a large national employer plan

Average annual growth in procedures per plan enrollee, by modality, 1999-2003



Based on data from a large national employer plan

Implications for policy

Recommendation Summary from ACR's Blue Ribbon Panel

- Develop a national database for collecting radiation dose indices from actual exams on digital x-ray systems in order to evaluate the range of exposures used in the US.
- Education of ordering physicians on the subject of appropriate utilization of imaging and radiation dose, in medical school, residency, and practice
- Standardization of radiation safety education for radiologists in training and CME in radiation safety.
- Safety training for radiation technologists
- Better resources for patients to understand radiation risks and benefits of imaging procedures
- Working with vendors as they standardize methods of describing and recording dose estimates for better tracking
- Encourage third-party payers to develop processes for identifying patients who have frequent exams with ionizing radiation

Cone-Beam Imaging in Dentistry

Stuart C. White
UCLA School of Dentistry
April 17, 2007

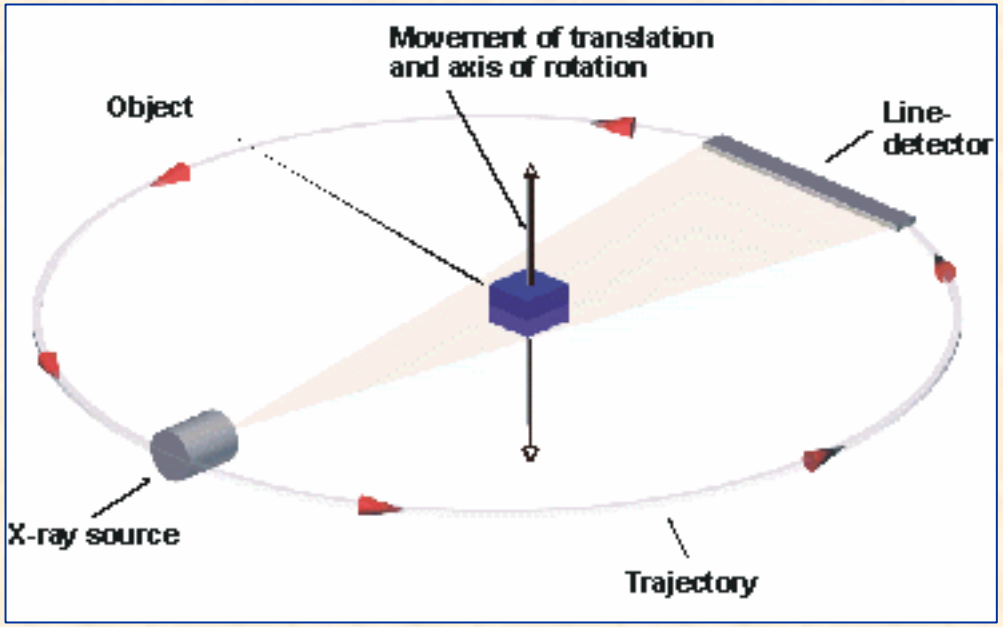
Overview

- What is cone-beam imaging?
- Dosimetry
- Applications in dentistry
  - ✓ Orthodontics
  - ✓ Implants
  - ✓ TMJ
  - ✓ Tooth related
- Issues to consider

Cone-Beam Imaging

- ~ 1000 dental machines installed worldwide - growing rapidly
  - US and Canada
  - Europe
  - Japan
- Panoramic machine manufacturers modifying their units for cone-beam imaging
- Locations
  - Universities
  - X-ray laboratories
  - Specialist's offices
- ~ $150K to $300K
  - Low for a hospital
  - High for a dental office

CT Image Capture

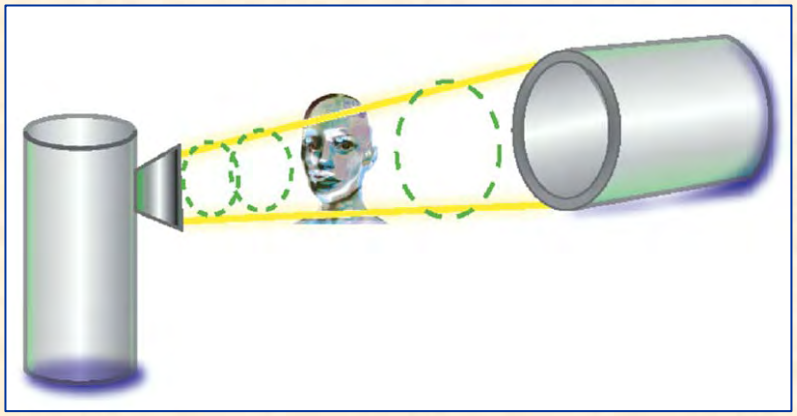


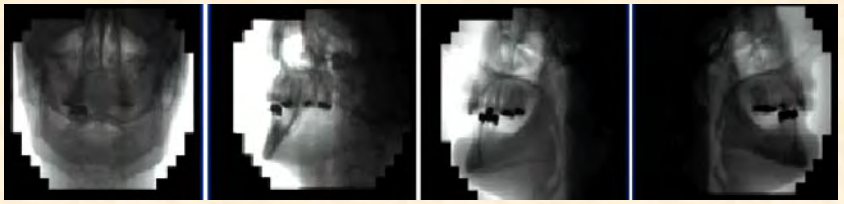
CT uses a narrow fan beam

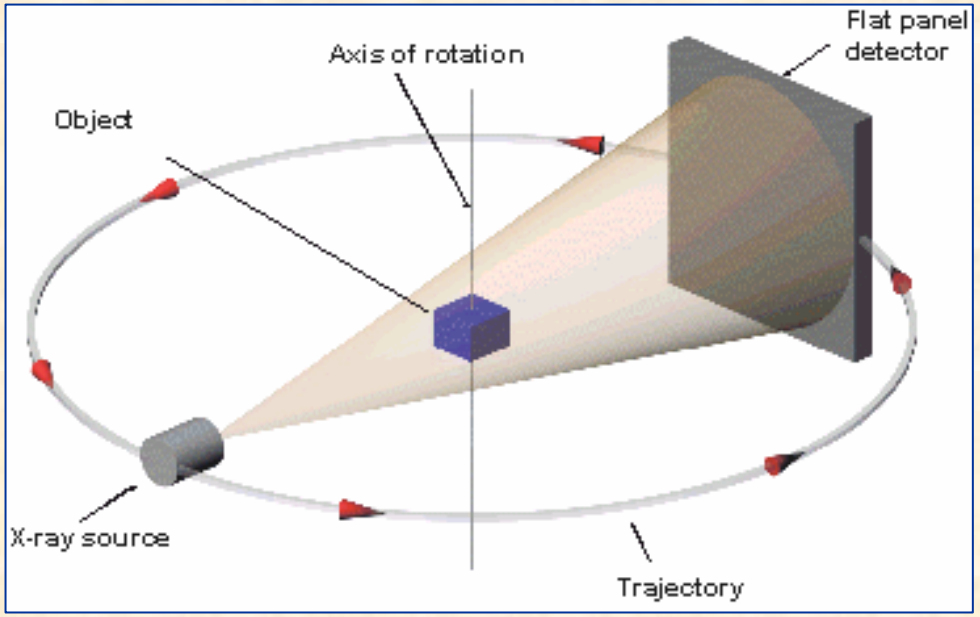
- Rotates around the object acquiring one or more thin slices with each rotation
- Multiple rotations around patient
- Fan beam avoids most scatter thus has good contrast resolution (soft tissues window)

Siemens, M. Simon and C. Sauerwein

Cone Beam Image Capture







Cone-beam imaging uses a cone-shaped beam

- Image captured in single rotation around patient
- Image captured with area (2D) sensor
- Various machines capture from 160 to 599 basis images
- Spatial resolution down to 0.125 mm

AFP and M. Simon and C. Sauerwein

Area (2D) Detectors

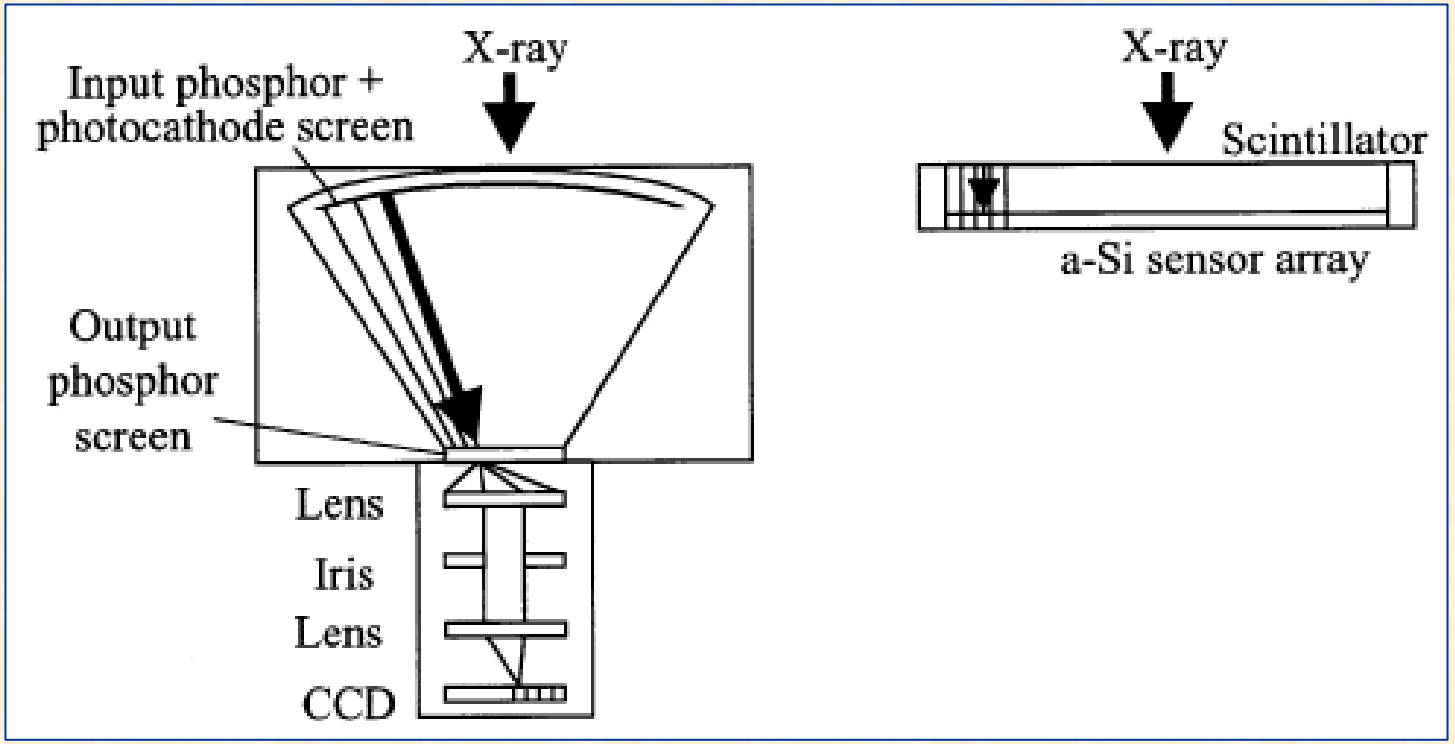
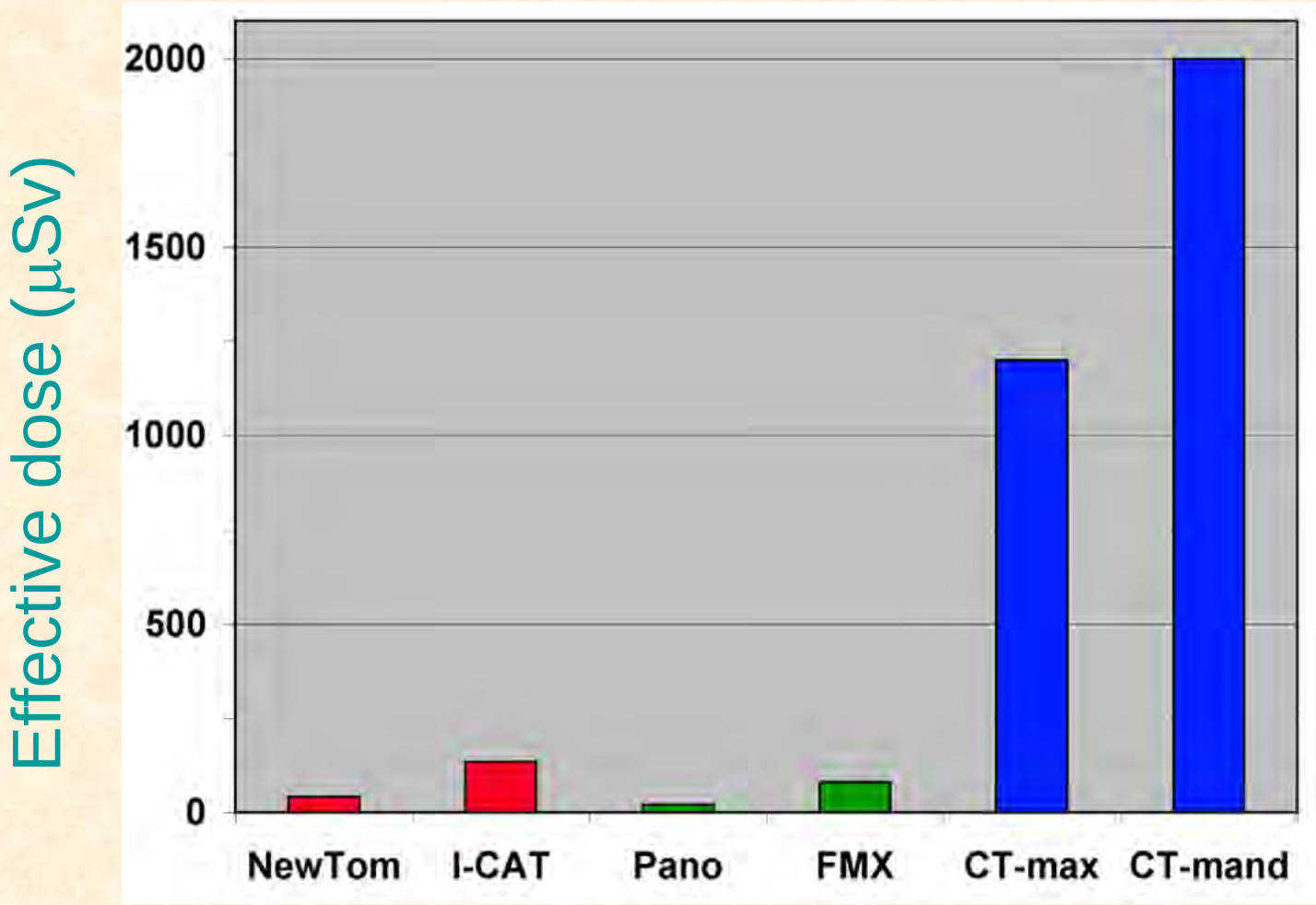


Image intensifier

Flat panel

R. Baba, Dentomaxillofacial Radio. 2004

Comparative Dosimetry



Dental Applications

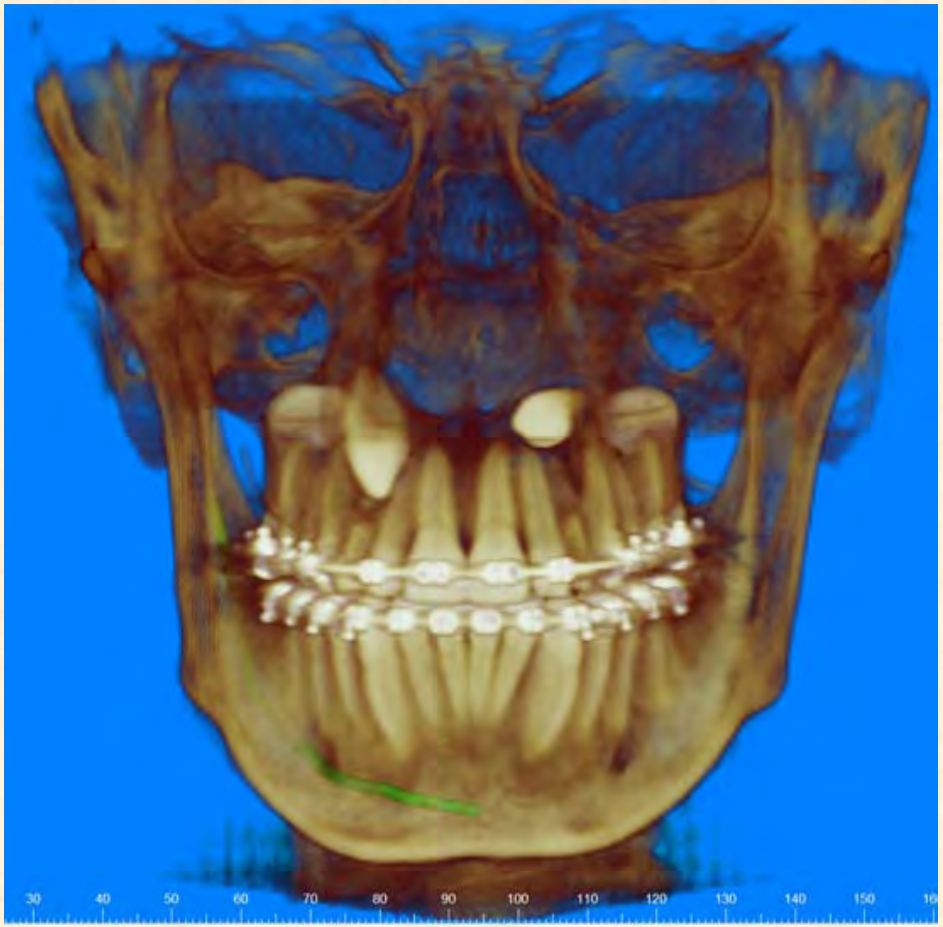
Broad acceptance in dentistry last five years

- Orthodontic treatment planning
- Dental implants
- Temporomandibular joints for osseous degenerative changes
- Evaluation of wisdom teeth vs. mandibular nerve
- Disease

Orthodontics

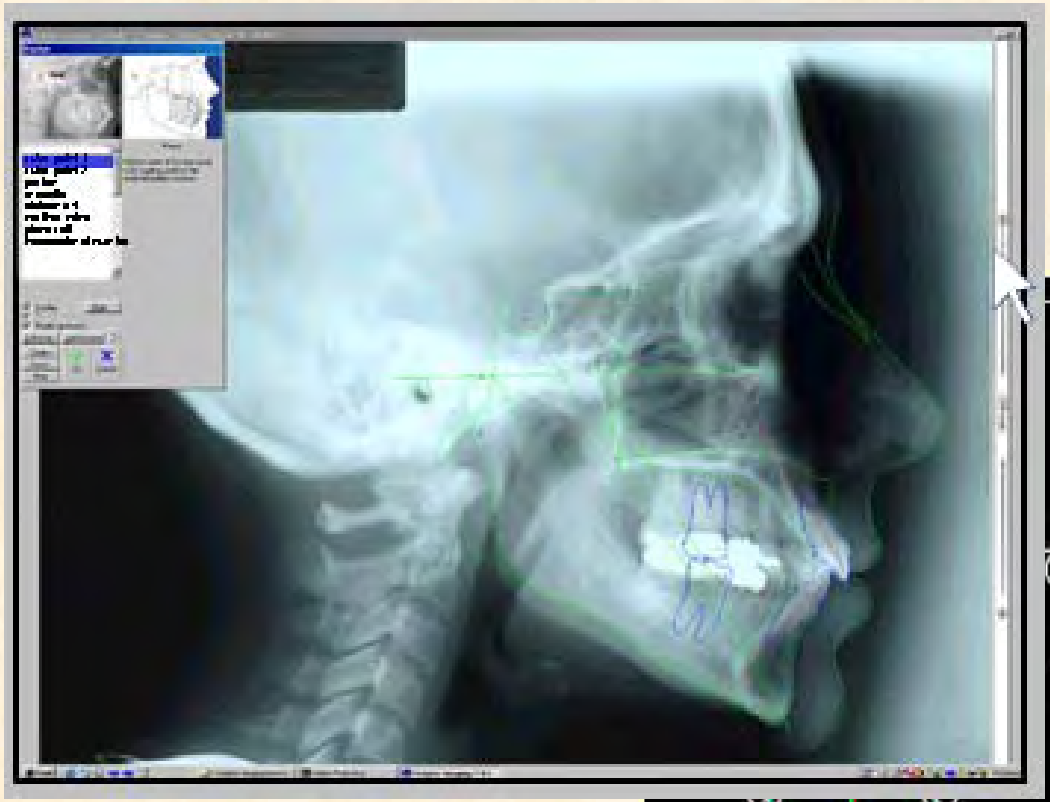
Need for

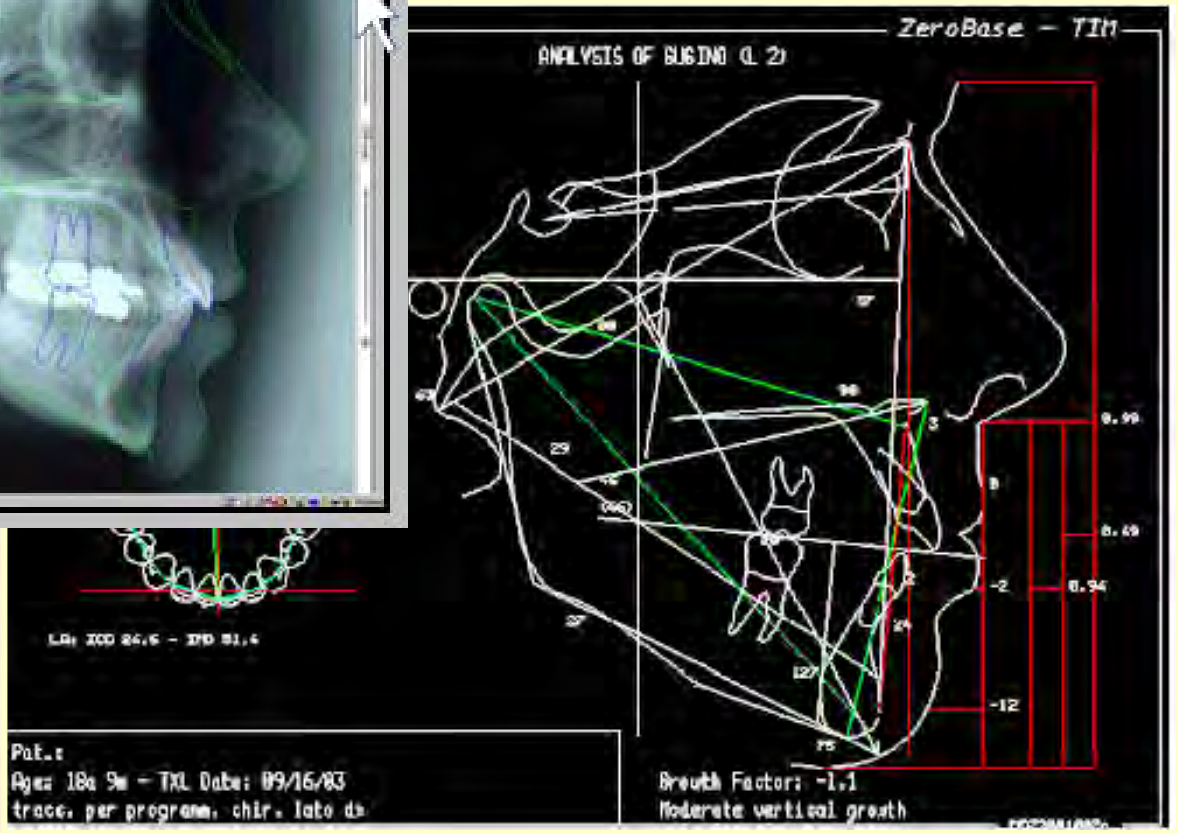
- Large image field for anatomic relationships
- Absolute measurements
- Comparison of before, middle, and end of treatment



Dolphin Imaging

Cephalometric Analysis





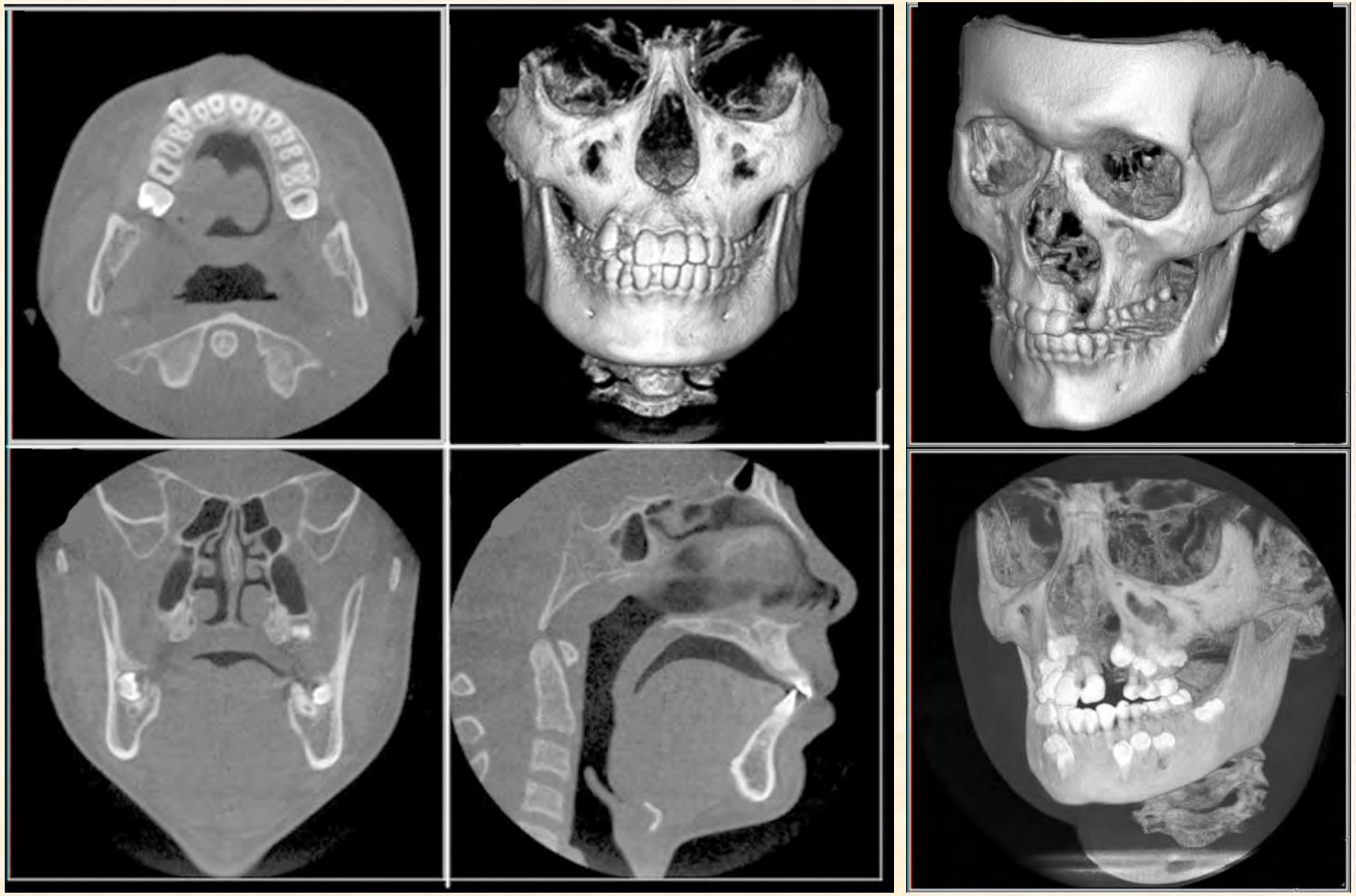
Uneven magnification distortion

Dolphin Imaging

Cephalometric Analysis

Absolute lengths and angles

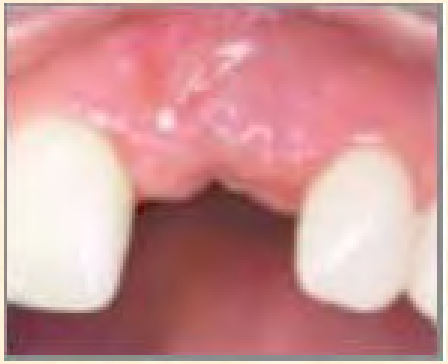
MPR Reconstructions

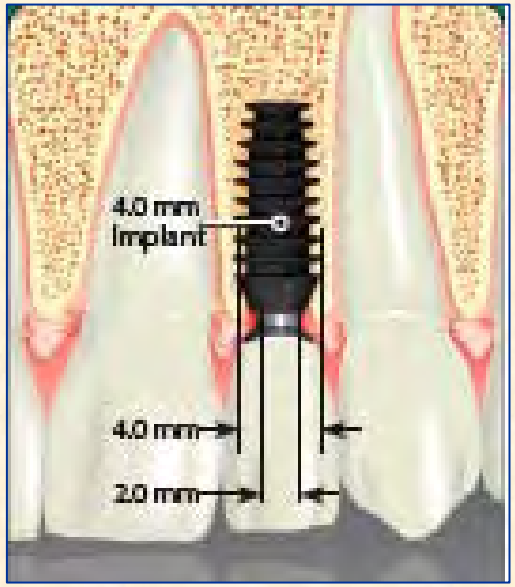


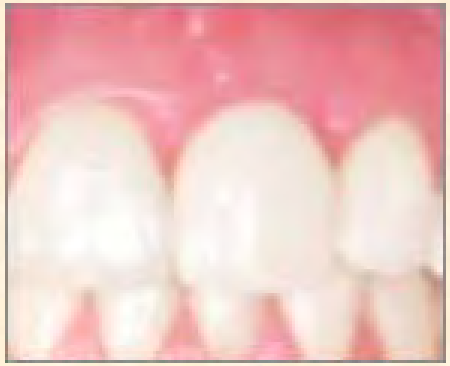
Dental Implants

Need for

- Absolute measurements
- Location of anatomic relevant objects such as mandibular nerve, maxillary sinus
- Precise control over angulation for geometric accuracy



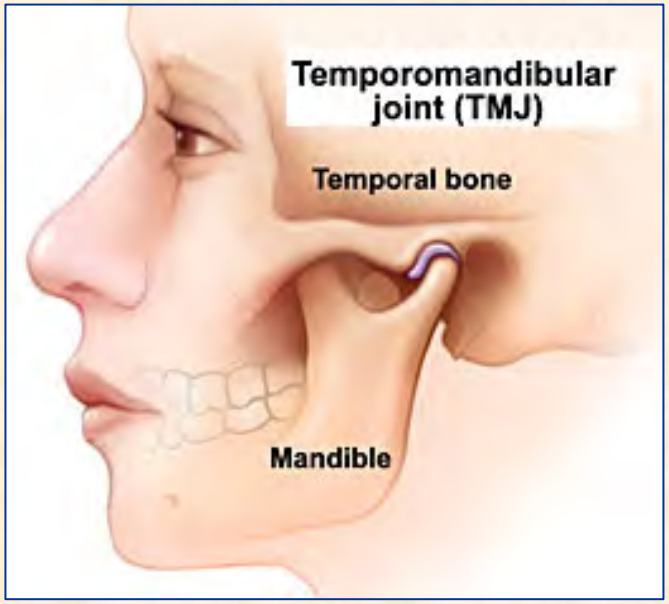


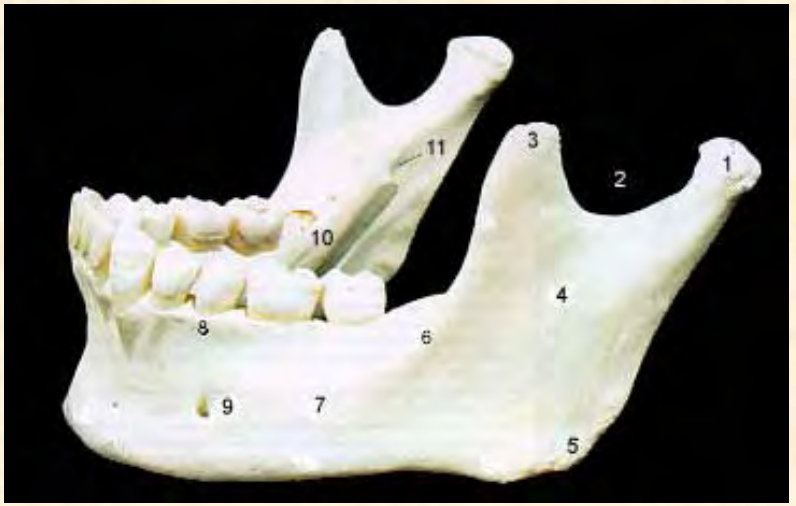


Temporomandibular Joint

Need for

- High resolution image of difficult object
  - ✓ Structure
  - ✓ Location
- Comparison of before, middle, and end treatment

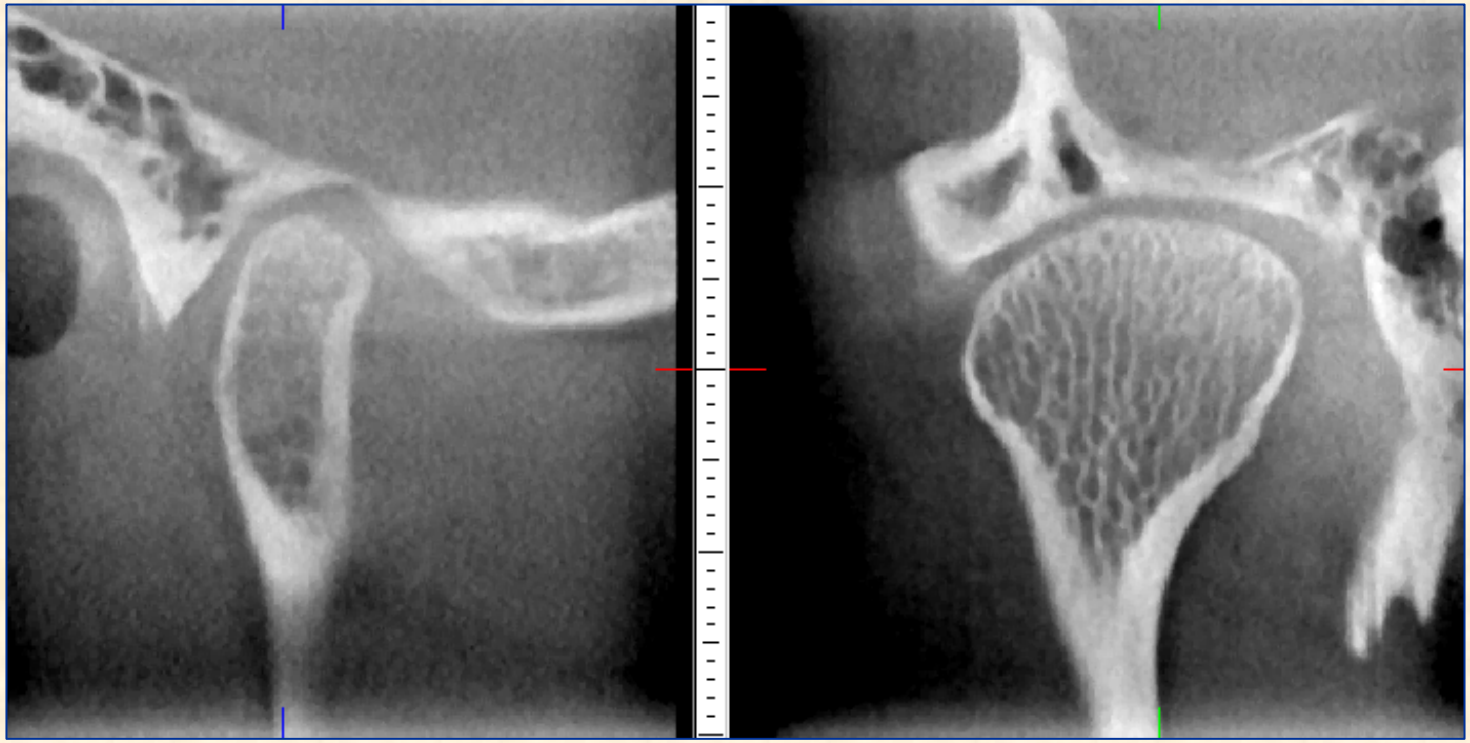




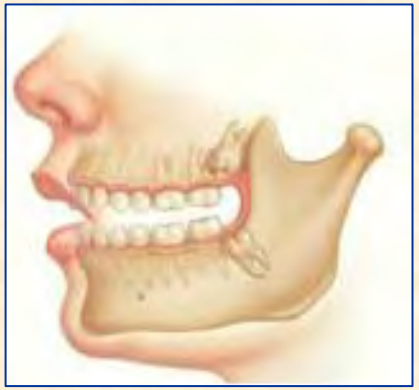
Temporomandibular Joint

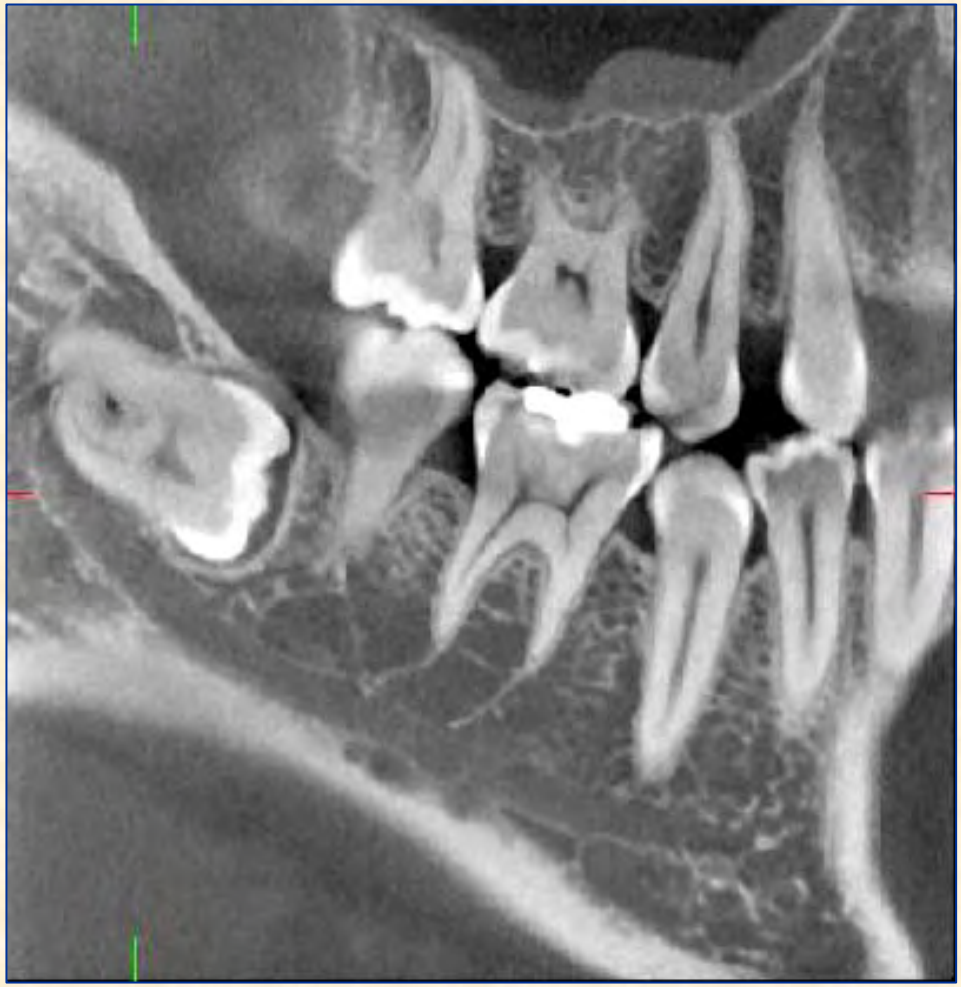
Lateral

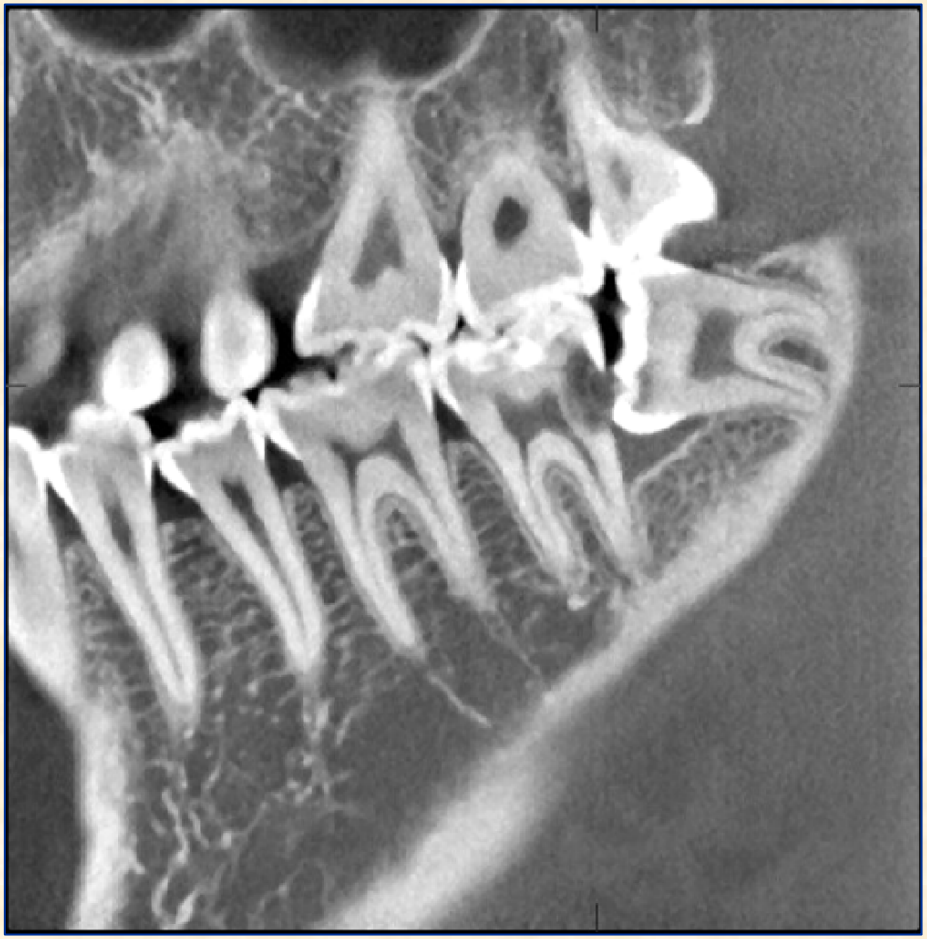
Frontal



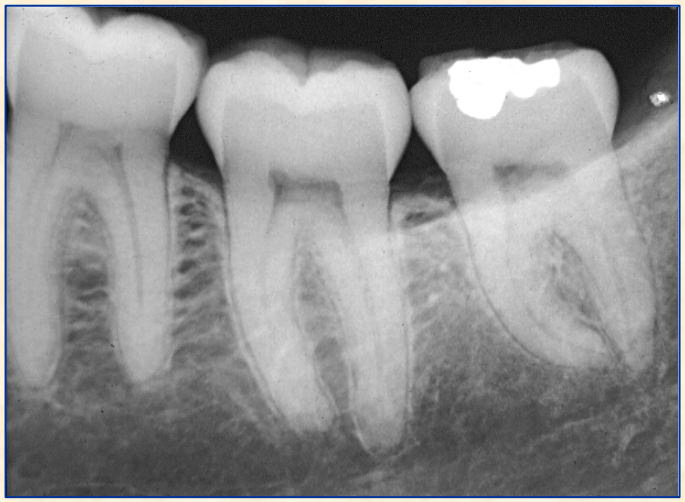
Mandibular 3rd molars (Wisdom teeth)





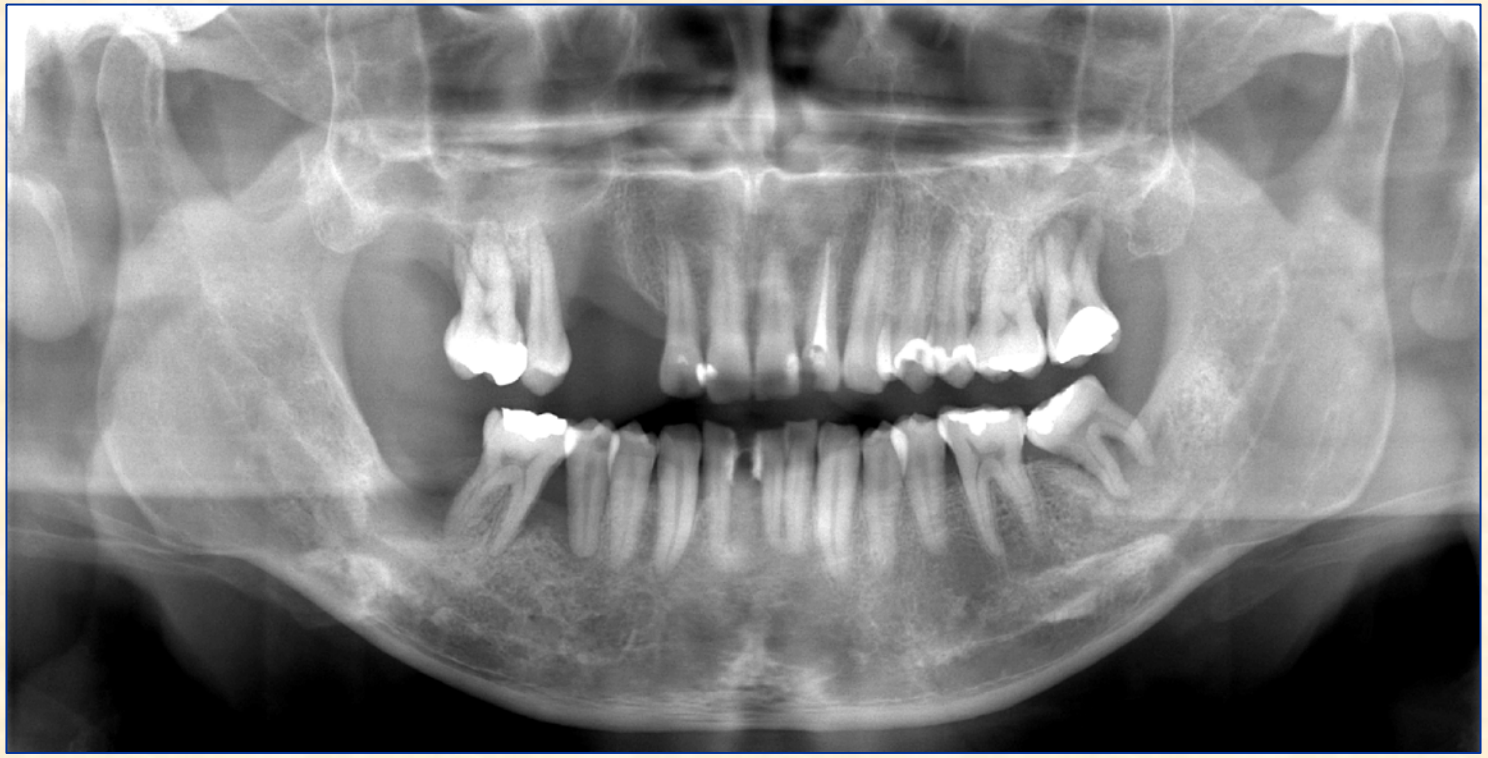


Dental Disease



Need for

- High resolution
- Slices, not projection views
  - Coronal and sagittal planes



Concerns

Machines

- Collimation not adjustable
- Continuous exposure
- mA fixed

Individuals making exposures may have limited knowledge of

- Operation of unit
- Recognition of anatomic landmarks
- Reconstructions
- Indications for making the examination

Individuals interpreting (or not) the whole volume

Summary

- Highly useful for multiple dental applications
  - ✓ Bone and teeth
  - ✓ Soft tissue/air interface
  - ✓ No soft tissue window
- Gaining acceptance rapidly
- Low dose compared to CT
- Rapid hardware and software development
- Opportunities for improving usage

Overview of Contemporary Interventional Fluoroscopy Procedures

Donald L. Miller, M.D., FACR

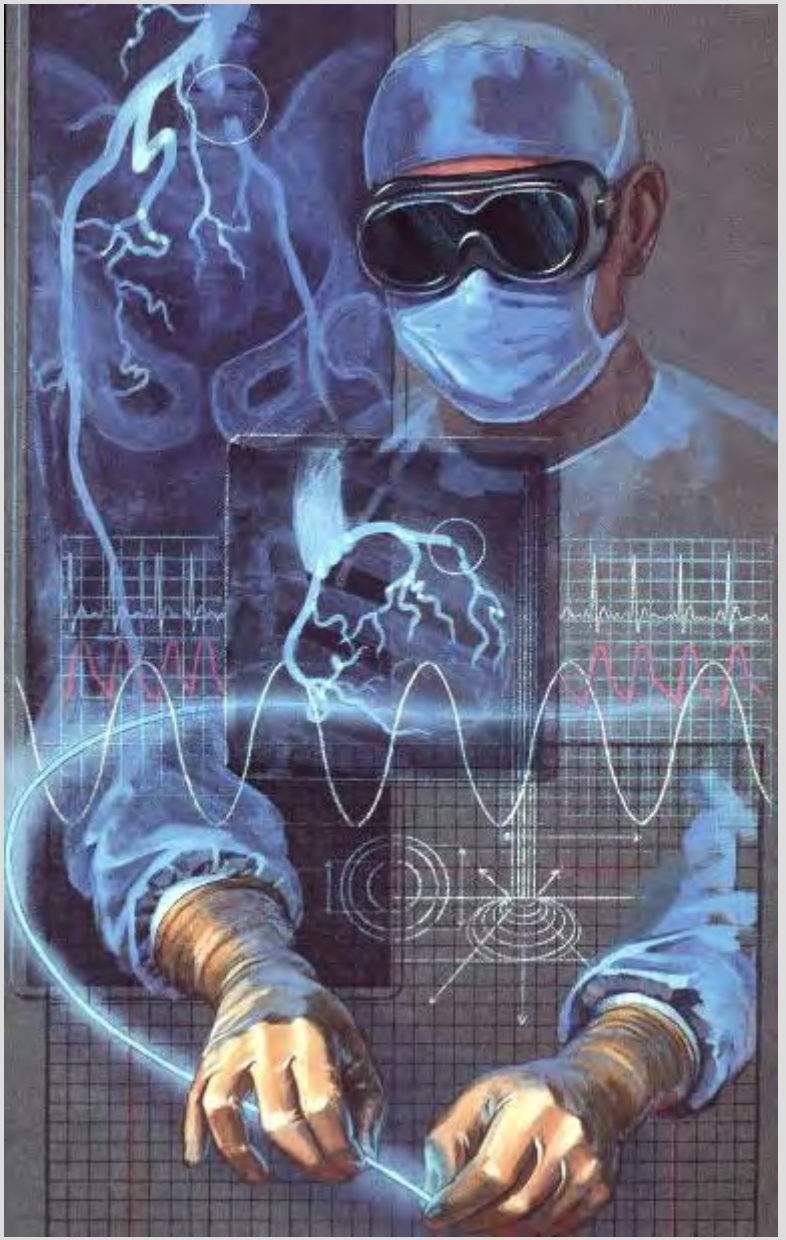
Professor of Radiology
Uniformed Services University
Bethesda, MD

Department of Radiology
National Naval Medical Center
Bethesda, MD

The views expressed in this presentation are those of the author and do not necessarily reflect the official policy or position of the Department of the Navy, Department of Defense, or the U.S. Government

Overview

- What is it?
- Risk/benefit analysis
- Patient doses
- Controlling dose



Interventional Fluoroscopy (IF)

- Use of fluoroscopy for *guidance* as small instruments (catheters, guidewires, balloons, stents, etc.) are manipulated through blood vessels or other pathways in the body
- Used to treat a wide variety of diseases and disorders in virtually every organ system

Benefits

As compared to surgery, interventional fluoroscopy procedures generally result in:

- Smaller incisions
- Less pain
- Shorter recovery time
- Fewer complications

Risk/Benefit Analysis

- Occupational exposure
  - Stochastic risk for population
  - Economic benefit for individuals
  - Both can be quantified

Risk/Benefit Analysis

Diagnostic X-rays

- Stochastic risk (population)
  - Can be quantified
- Procedure risk (individual)
  - None/minimal
- Medical benefit (individual)
  - Difficult to quantify
  - What is the value of a negative study?
  - What is the value of a diagnosis?

Risk/Benefit Analysis

Interventional fluoroscopy

- Stochastic risk (population)
  - Can be quantified
- Deterministic risk (individual)
  - Can be quantified (probability and severity) if skin dose is known
- Procedure risk (individual)
  - Can be quantified, far exceeds radiation risk
- Benefit (individual)
  - Can be quantified; for successful procedures, exceeds all risks

Benefit

Easy to quantify benefit

- Relief of symptoms—quality of life
- Increased life span
- Decreased morbidity compared to surgery
- Shorter recovery compared to surgery

Risk Comparison

- Radiation risk << procedural risk
- Coronary artery disease
  - Procedural risk: 30 day rate of heart attack, stroke, or death:[†]

    CABG 17% PTCA 2%
  - Radiation risk: estimated probability of skin injury from a PTCA:[§]

    < 0.03%

[†]Lee MS, et al. J Am Coll Cardiol 2006; 47:864-870

[§]Padovani R, et al. Radiat Prot Dosim 2005; 117:247-250

Stochastic vs. Deterministic

Most patients have a limited life expectancy

- Serious co-morbidities (atherosclerosis, diabetes, cancer, liver or kidney failure)
- Older individuals

- Deterministic injury more important for individuals than stochastic effects

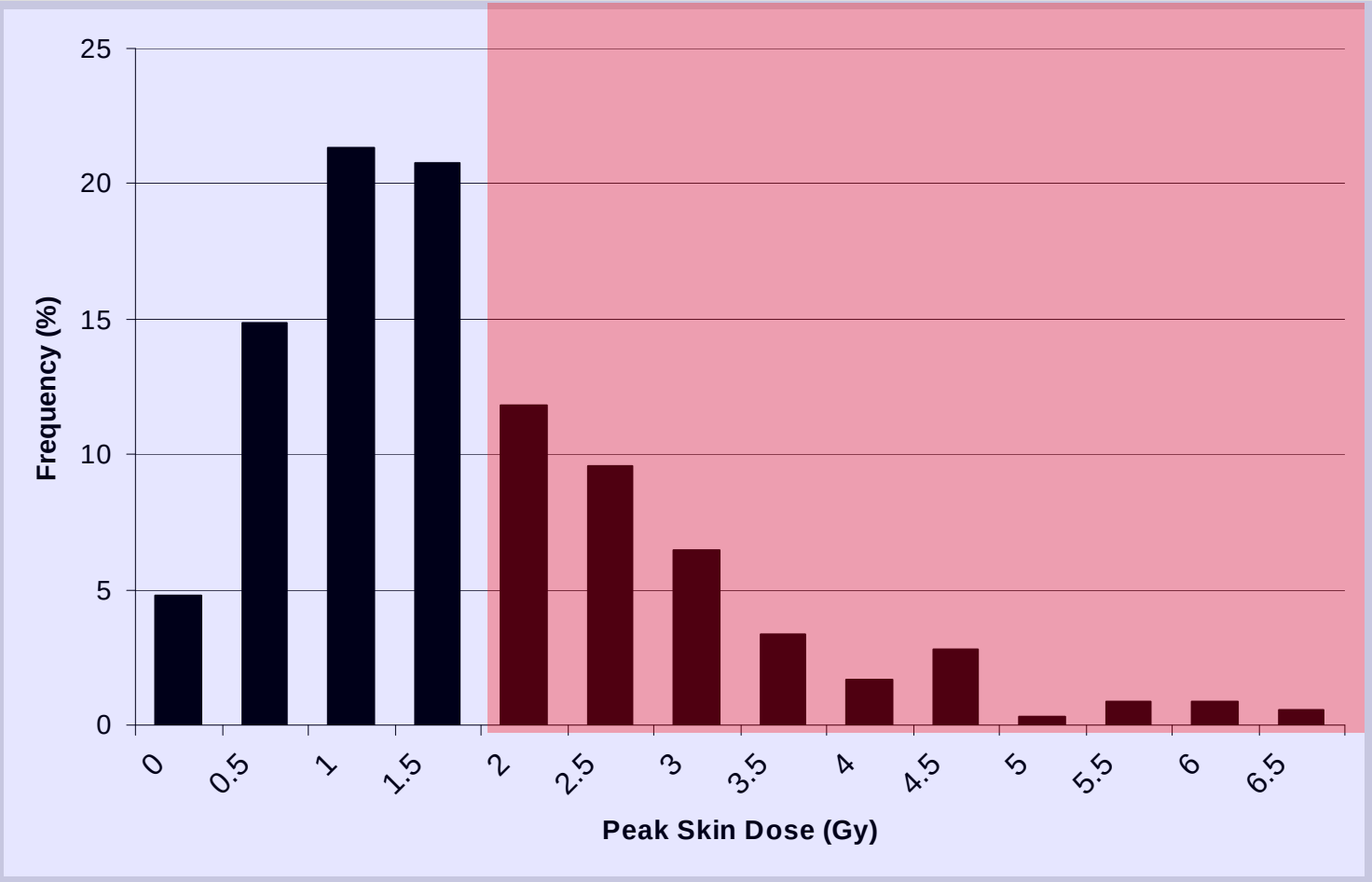
Patient Doses in IF

- For a single procedure at a single medical center, patient dose can vary enormously
- Ratio of minimum to maximum KAP often exceeds 100, may exceed 1000
  - Type of procedure
  - Patient factors
  - Procedure complexity

Tsalafoutas IA, et al. J Vasc Interv Radiol 2006; 17:1489-1498

Skin Dose

Peak Skin Dose for 356 Neuroembolization Cases



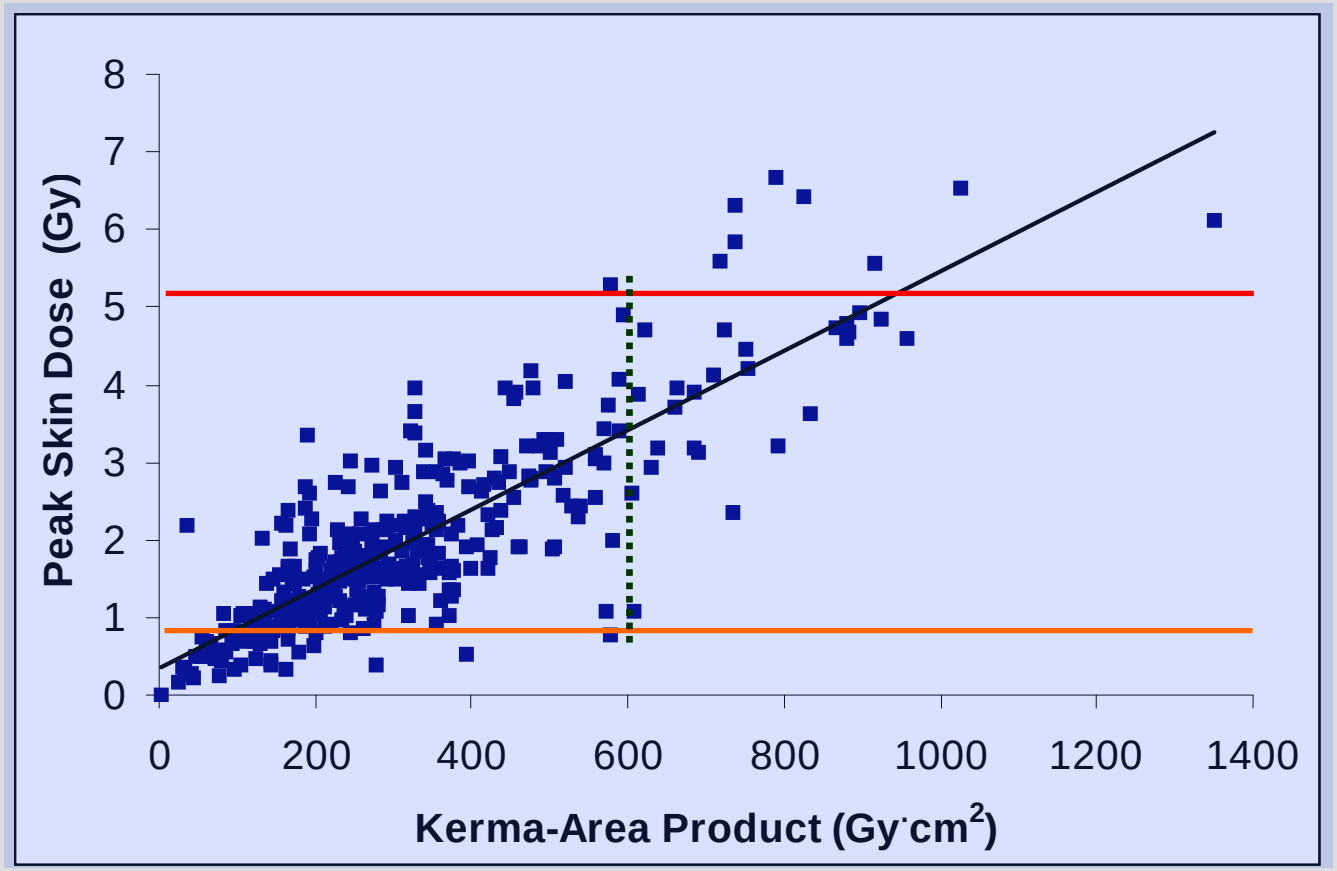
Miller DL et al. J Vasc Interv Radiol 2003; 14:977-990

KAP and Skin Dose

- Complex relationship between kerma-area product (KAP) and skin dose, dependent on
  - Procedure type
  - Technical protocols
  - Equipment set-up
  - Operator technique
- Highly specific for procedure / operator / medical center
- KAP useful for stochastic risk, less so for deterministic risk

Trianni A, et al. Radiat Prot Dosim 2005; 117:241-246

Maximum ESD vs. KAP for 356 Neuroembolization Procedures



Adapted from Miller DL et al. J Vasc Interv Radiol 2003; 14:977-990

Classification

- Based on deterministic risk
- Low dose
  - skin doses > 2 Gy essentially do not occur
- Medium dose
  - occasional cases of the procedure may result in skin doses > 2 Gy
- High dose
  - cases of the procedure result in skin doses > 2 Gy on a regular basis

High Dose

Cerebral embolization

- Tumor, aneurysms, vascular malformations

356 cases:

Mean KAP 320 Gy·cm^2

Mean IEC CD 3.8 Gy

Mean ESD 2 Gy, maximum 6.7 Gy

- 17% > 3 Gy
- 4% > 5 Gy

Miller DL, et al. J Vasc Interv Radiol 2003; 14:977-990

Cardiac

- Two procedures with potential for high patient doses:
  - PTCA
  - Radiofrequency (RF) ablation—performed for treatment of cardiac dysrhythmias
- Wide variations in dose
  - Patient factors
  - Procedure complexity

KAP—Cardiac

- PTCA
  - Range 14 - 116 Gy·cm^2 (1208 patients)†
  - Mean 149 Gy·cm^2 (172 patients)‡
- RF ablation
  - Range 95 – 257 Gy·cm^2 (960 patients)†
  - Mean 110 Gy·cm^2 (28 patients)‡

†Padovani R, Quai E. Radiat Prot Dosim 2005; 117:217-221

‡Chida K, et al. AJR 2006; 186:774-778

Skin Dose—Cardiac

- PTCA
  - Highest skin dose 1.8 Gy†
  - Highest skin dose 3.4 Gy‡
  - Highest skin dose 9.7 Gy, median skin dose 4.6 Gy§
- RF ablation
  - Mean skin dose 1.5, 1.8 Gy†
  - Maximum skin dose > 7 Gy in 1% of cases*

†Padovani R, Quai E. Radiat Prot Dosim 2005; 117:217-221

‡Trianni A, et al. Radiat Prot Dosim 2005; 117:241-246

§Suzuki S, et al. Circ J 2006; 70:44-48.

*Rosenthal LS, et al. Am J Cardiol 1998; 82:451-458

High Dose Procedures

- Cardiac
  - PTCA
  - RF ablation
- Non-cardiac
  - Embolization
  - TIPS creation
  - Angioplasty in the abdomen or pelvis

Skin Injuries

73 skin injuries, by procedure type

Procedure	No.	%
PTCA	47	64
RF ablation	12	16
TIPS creation	7	10
Neuroembolization	3	4
Other	4	5

Koenig TR, et al. AJR 2001; 177:3-11

Goal

- Controlling dose is not the same as minimizing dose
- Optimize patient dose
  - Dose reduction technologies
  - Operator education/motivation
- Optimize skin dose
  - Real-time skin dose mapping
  - Operator education/motivation

Skin Dose Mapping

- Reducing skin dose requires real-time knowledge
  - Dose
  - Dose distribution
- Real-time skin dose map

Operators

- Radiology
- Cardiology
- Vascular surgery
- Orthopedic surgery
- Neurosurgery
- Anesthesiology
- Gastroenterology
- Urology
- Nephrology
- And others…

The same procedure may be performed by different physicians

- Radiologists, cardiologists and vascular surgeons all treat renal artery stenoses

Operator Issues

- Insufficient training
- Lack of awareness
- Belief that current knowledge base is adequate

Recommendations

- Increased emphasis on radiation safety
  - Regulators (States)
  - Accreditation bodies (Joint Commission)
  - Medical specialty societies
  - Board certification examinations
- Better technology
  - Real-time skin dose mapping
  - Dose-reduction technology

Summary

- IF procedures increasing in variety; replacing surgery
- Clear benefit
- Wide variation in patient dose within and among procedures
- Radiation risk is low compared to other procedural risks
- Deterministic risk of concern

Summary

- Procedure categories based on deterministic risk: low, intermediate and high dose
- Dose optimization requires
  - Dose-reduction technology
  - Real-time skin dose map essential
  - Operator education
  - Increased attention by regulators, accreditation bodies, physician organizations

Beth Israel Deaconess Medical center

Harvard Medical School

Technical Advances of Interventional Fluoroscopy And Flat Panel Image Receptor

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Attention.

- What is being discussed here in this talk has been available for several years on image intensified fluoroscopy imaging systems and is NOT necessarily available with Flat Panel Image Detector only.
- The flat panel image detector has advantage in image processing and wider dynamic range, but it is expensive.
- The thrust of this talk is focused on the Automatic Image Quality and Exposure Control Logic. It is not intended to compare the performance the image intensified system against the flat panel image detector system.
- The rotational angiography capability to produce CT-like images and 3D images are still being improved.

Features Designed to Reduce Patient Exposure (Air Kerma)

(1) Last Image Hold (LIH),

(2) Fluoroscopic image loop

(3) Pulsed Fluoroscopy; 30, 15, 7.5 f/s

(4) Interleaved Pulsed Fluoroscopy;
15 f/s pulse rate displayed at 30 f/s,

(5) Spectral Shaping Filters

(6) Automatic Image Quality & Exposure Control Logic

Features Designed to Reduce Patient Exposure (Air Kerma)

(1) Last Image Hold (LIH)

"Last Image Hold" feature permits fluoroscopist to stop the radiation to the patient with the last frame of fluoroscopic image displayed on the monitor. This permits the fluoroscopist to attend to matters pertain to the catheterization and consider the "next" move with the last image displayed!

Features Designed to Reduce Patient Exposure (Air Kerma)

(2) Fluoroscopic image loop,

Typically, this feature will “loop” the last 10 seconds (300 frames) of fluoroscopic images.

This is a dynamic display which takes place of the “Last Image Hold”.

Features Designed to Reduce Patient Exposure (Air Kerma)

(3) Pulsed Fluoroscopy; 30, 15, 7.5 f/s

(a) Compared against the 30 f/s continuous fluoroscopy, the 30 f/s pulsed fluoroscopy generally has less motion unsharpness and can be setup to reduce patient exposure.

(b) Pulse rates less than 30 f/s show reduced patient exposure.

Features Designed to Reduce Patient Exposure (Air Kerma)

(4) Interleaved Pulsed Fluoroscopy;15 f/s pulse rate displayed at 30 f/s,

(a) As the lower pulse rate of 15 f/s becomes the prerequisite to reduced patient exposure, one frame of 15 f/s image can be displayed twice before advancing to the next image.

(b) Displaying each frame of the 15 f/s images twice improves the continuity of motion. This is similar to the 30 f/s cine images were projrcted twice by the use of a shutter to achieve the 60 f/s motion continuity.

Features Designed to Reduce Patient Exposure (Air Kerma)

(5) Spectral Shaping Filters

(a) Use of 0.1 mmCu ~ 0.3 mmCu in place of the aluminum filter resulted in reduced patient exposure in early version of spectral shaping filter application in cardiovascular imaging systems.

(b) Cu filters ranging 0.1 mm to 0.9 mm are being employed for cardiovascular angiographic equipment.

Features Designed to Reduce Patient Exposure (Air Kerma)

(5) Automatic Image Quality & Exposure Control Logic

(a) A sophisticated software programming is required to respond to a change in the copper filter thickness.

(b) The automatic control logic may be designed to various imaging parameters including the focal spot size, kVp, mA, pulse width, etc.

Features Designed to Reduce Patient Exposure (Air Kerma)

(5) Spectral Shaping Filters

(c) Heavy copper filter preferentially removed low energy photons and the mean x-ray beam energy is, thus, increased.

(d) For the same applied tube potential this would require a higher “tube current” to produce an acceptable image quality. --- Thus, a “high power” x-ray tube is required.

What is in the New Generation of Cardiovascular Imaging Systems?

(1) High Anode Heat Capacity X-ray Tube

(2) Heat Exchanger to lower tube housing heat accumulation

(3) Pulsed X-ray capable Generator (Power Train)

(4) Spectral Shaping Filters

(5) Automatic Dose and Image Quality Control Logic

High Anode Heat Capacity X-ray Tube

(a) Up to ~1000 DSA images @ variable frame rates and long “RUN” time,

(b) Up to 10 runs of cine studies @15f/s for typically 8~10 second runs,

(c) Prolonged fluoroscopy examination time

- On average: 30~40 minutes
- Often 80~100 minutes and even longer

Heat Exchanger to lower tube housing heat accumulation

- Oil cooled heat exchanger
- Direct air cooled heat exchanger

Pulsed X-ray capable Generator (Power Train)

- Minimum pulse width; 1 mSec.
- Pulse rates; variable at low pulse rates
- 7.5, 15, 30 pps (pulse per second)

Spectral Shaping Filter

- Typically Copper Filter is employed
- 0.1, 0.2, 0.3, 0.6, 0.9 mmCu

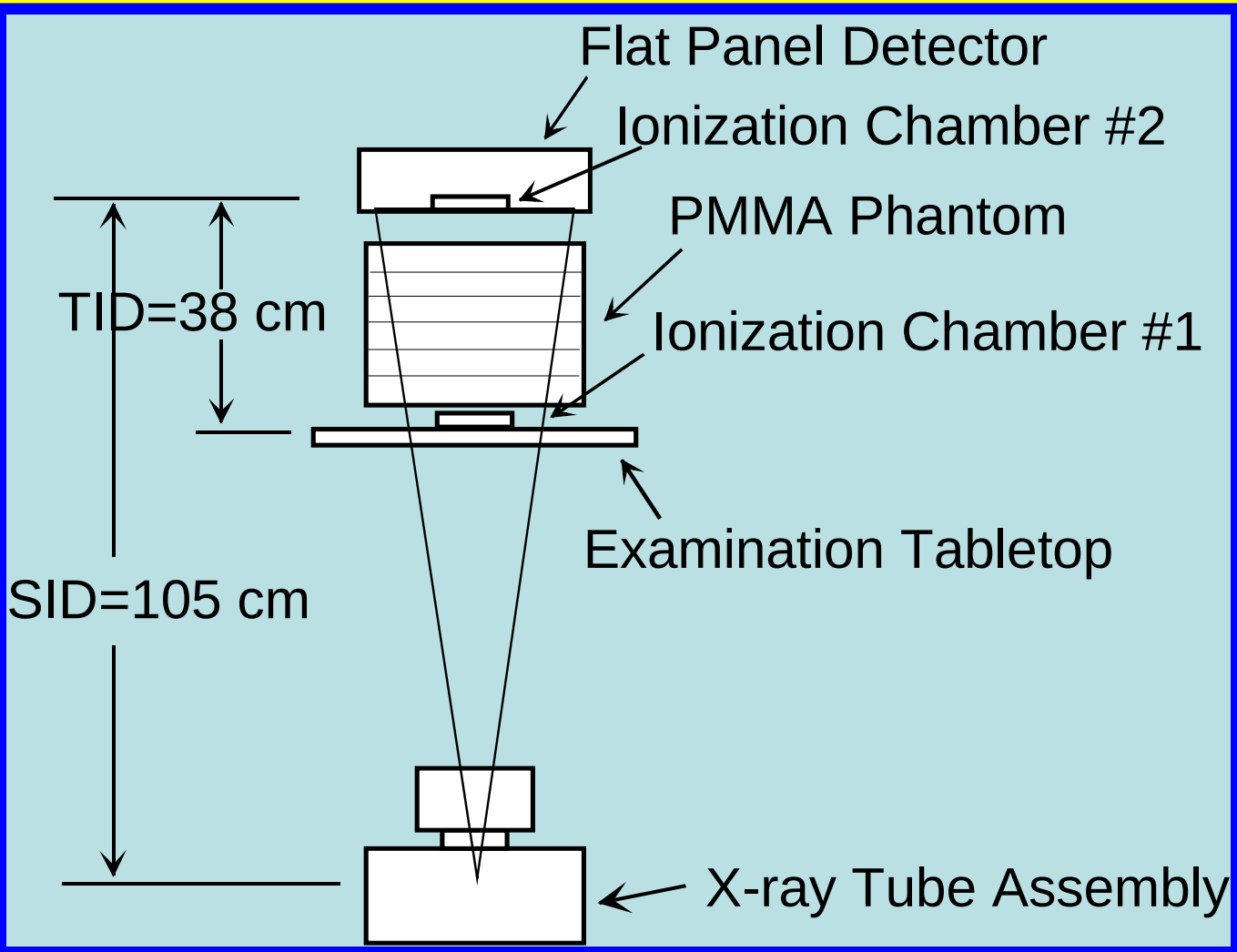
Automatic Image Quality & Exposure Control Logic

- Varies copper filter thickness as a function of patient thickness
- Varies “kVp”, and “mAs”
- Varies “Focal Spots” during DR image acquisition.

Automatic Image Quality and Exposure Control (AIQRC) Logic

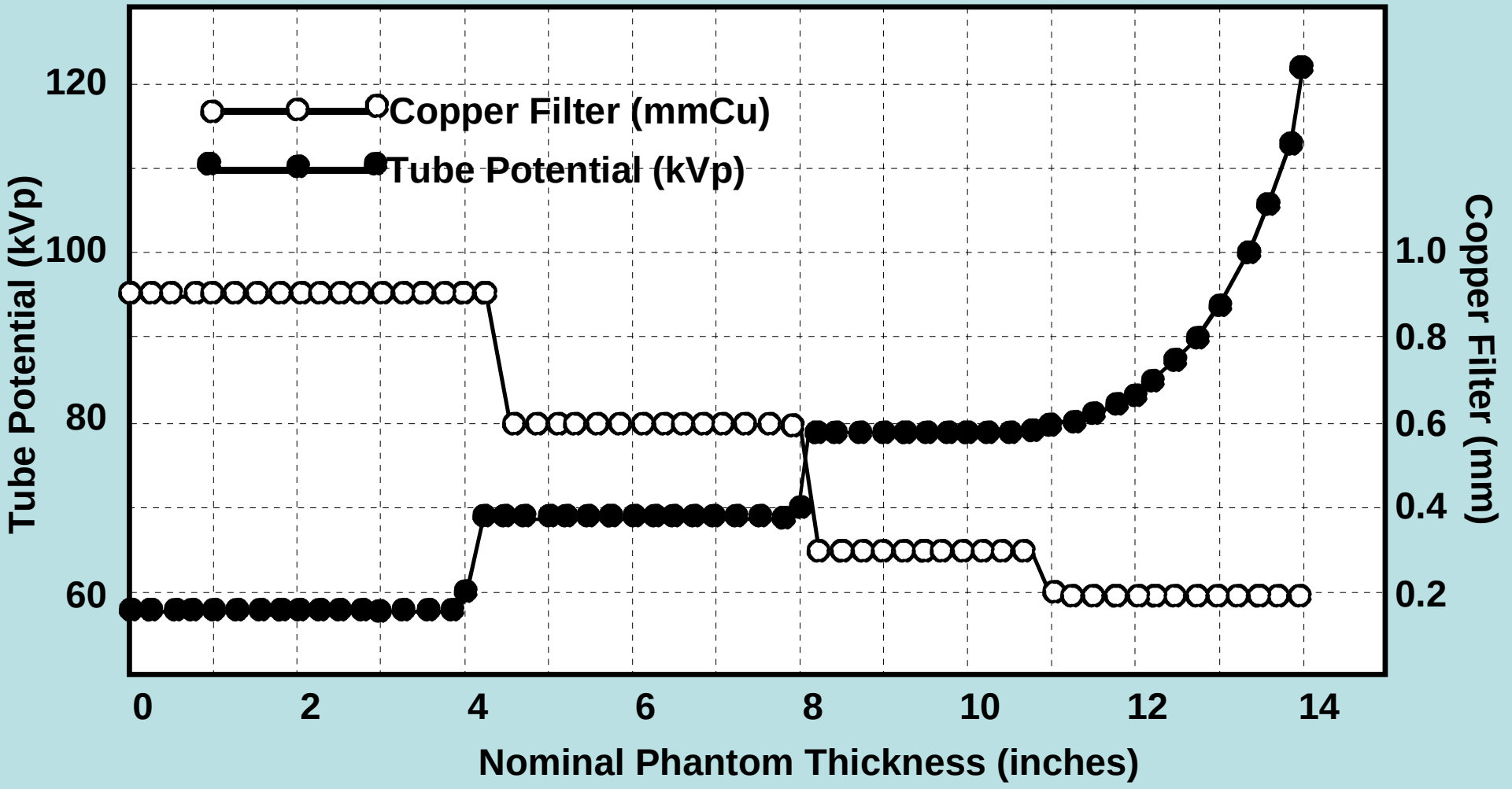
- Fluoroscopic exposure parameters vary as functions of “Patient Thickness”,
- Focal spot selection (switching) CAN be programmed into the AIQRC depending on the Power Loading to the anode,
- Copper filters (mmCu) are introduced into the primary x-ray beam in accordance to the penetration sensed by the flat panel detector.
- Upon reaching the maximum allowable tube loading condition, the AIQRC works just like the classical Automatic Brightness Control logic; iso-watt loading.

Verification Testing of the Automatic Image Quality & Exposure Control Logic

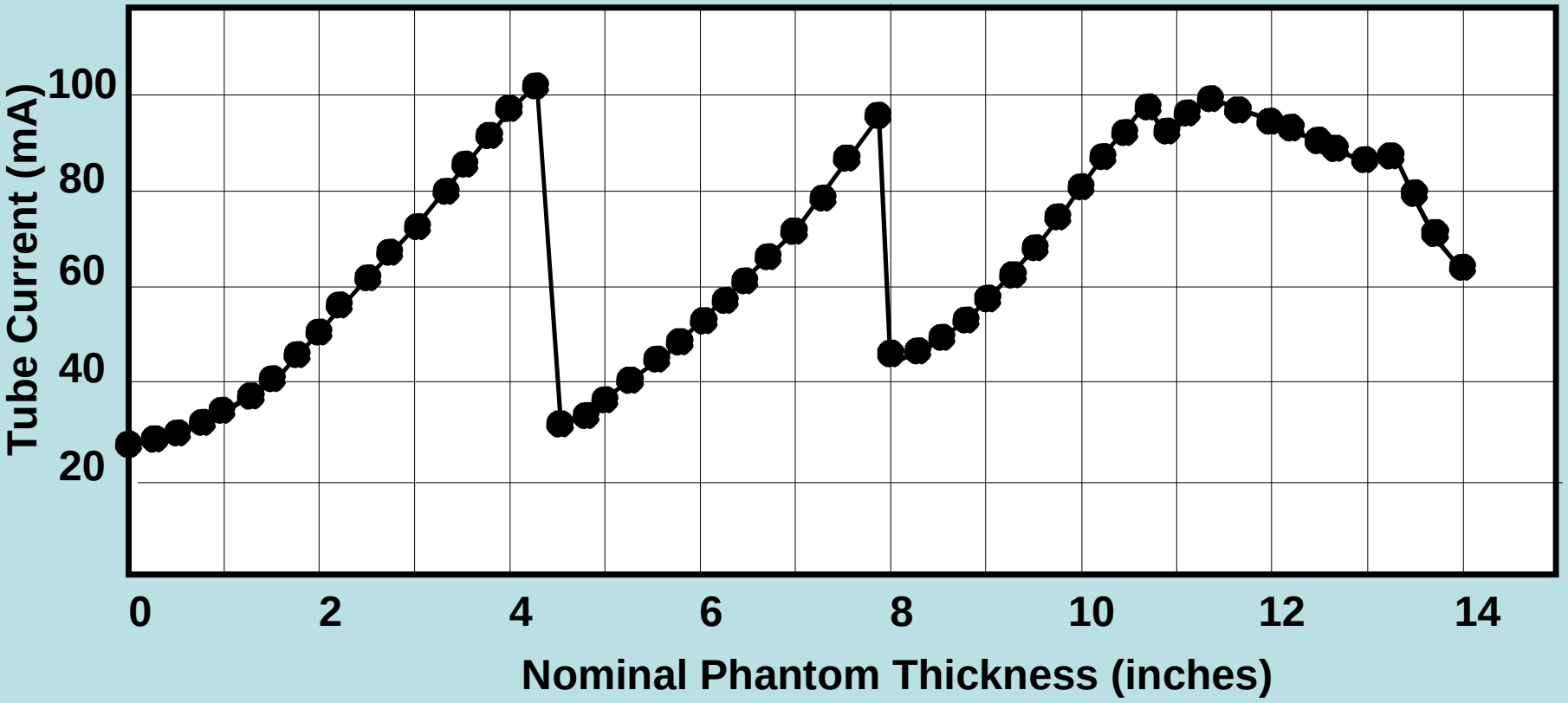


Geometrical Arrangement

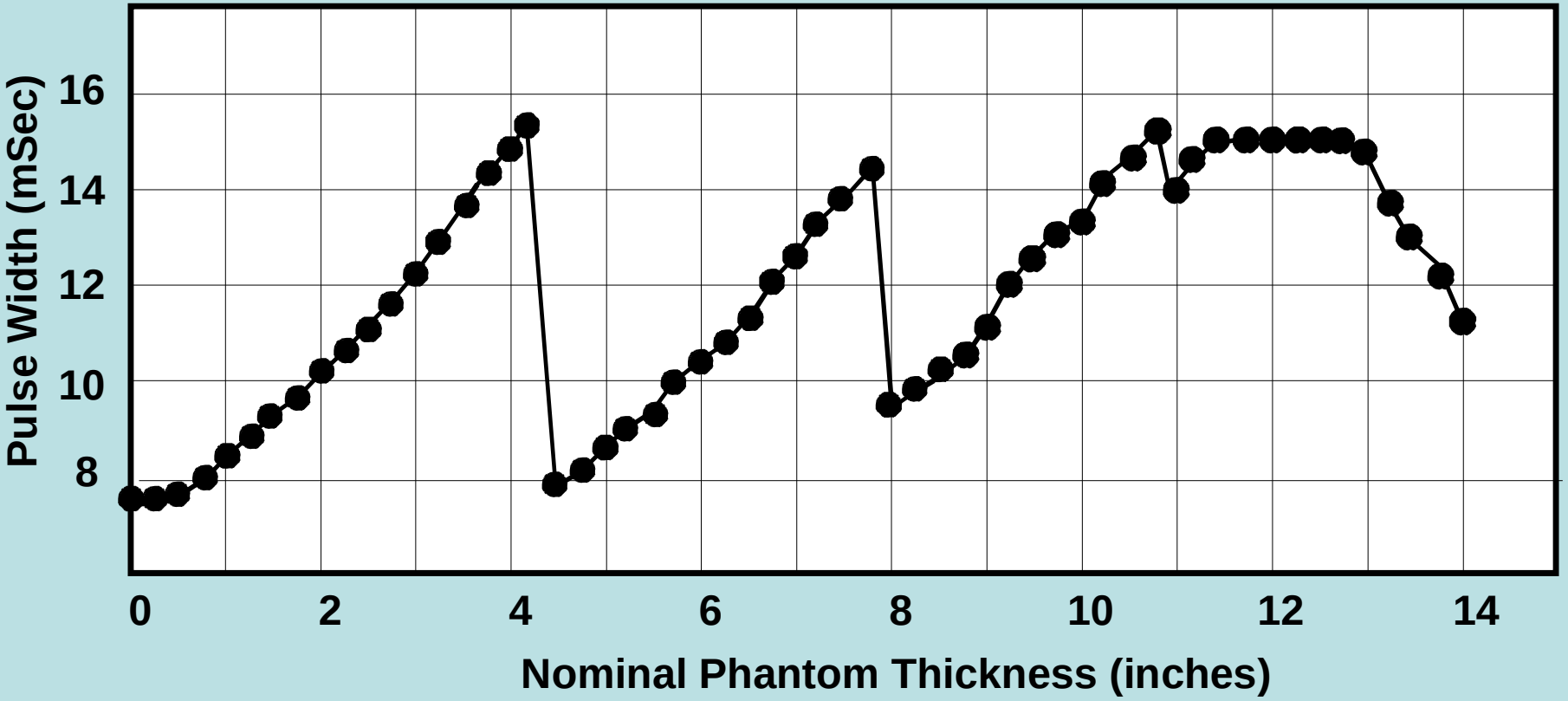
Tube Potential (kVp) and Filter Thickness (mmCu) vs. PMMA Thickness (inches)

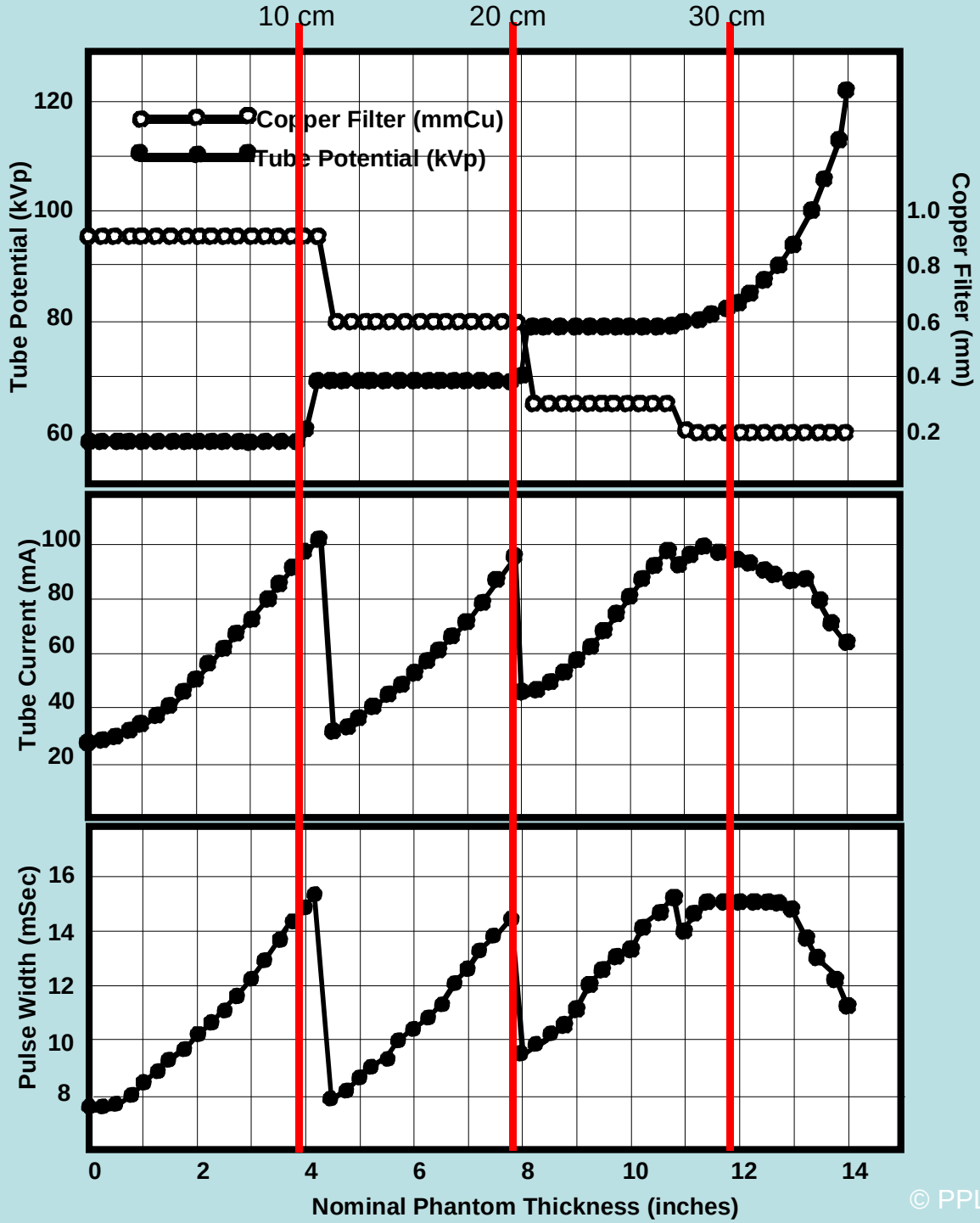


Tube Current (mA) vs. PMMA Thickness (inches)



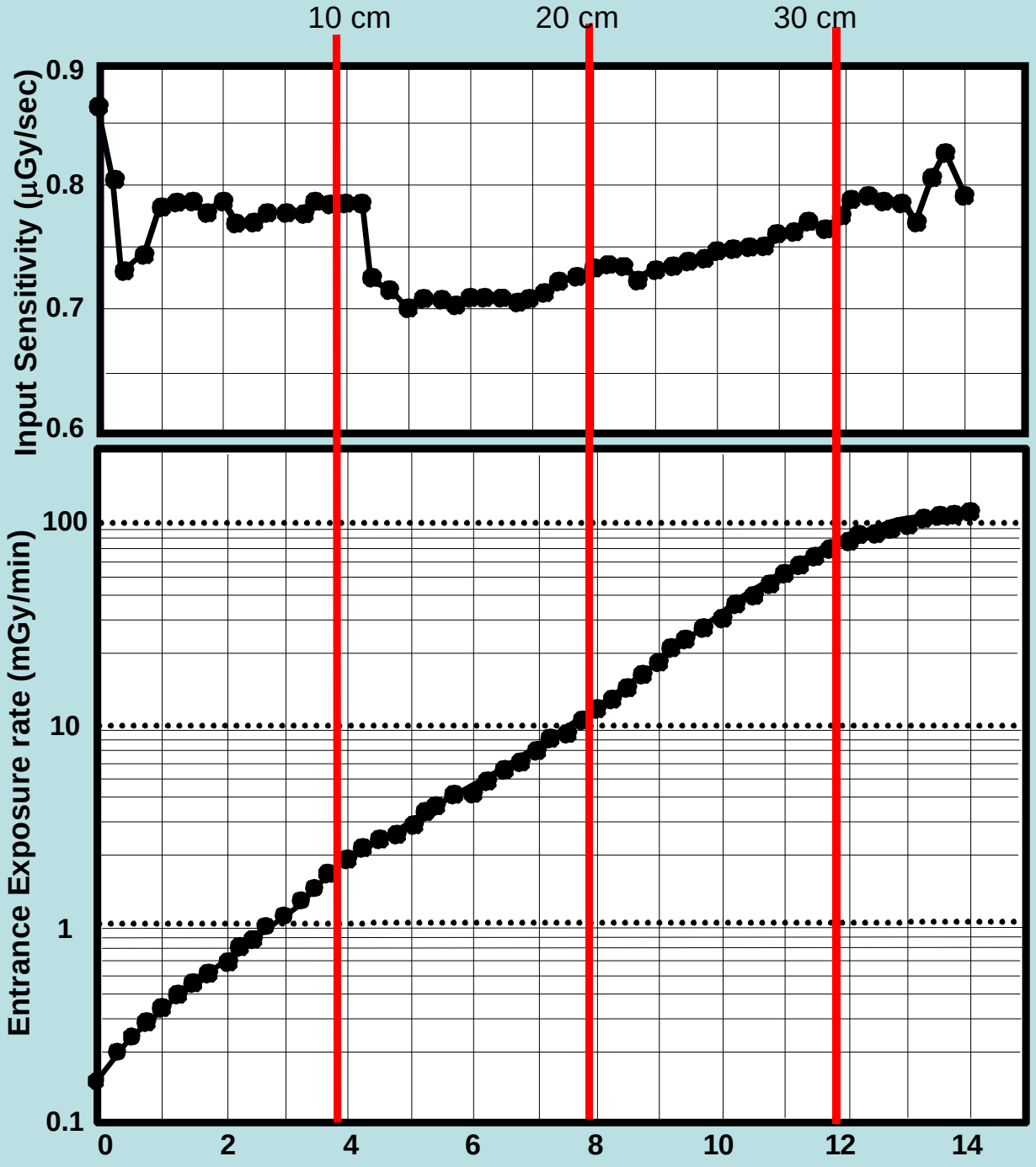
Pulse Width (mSec) vs. PMMA Thickness (inches)





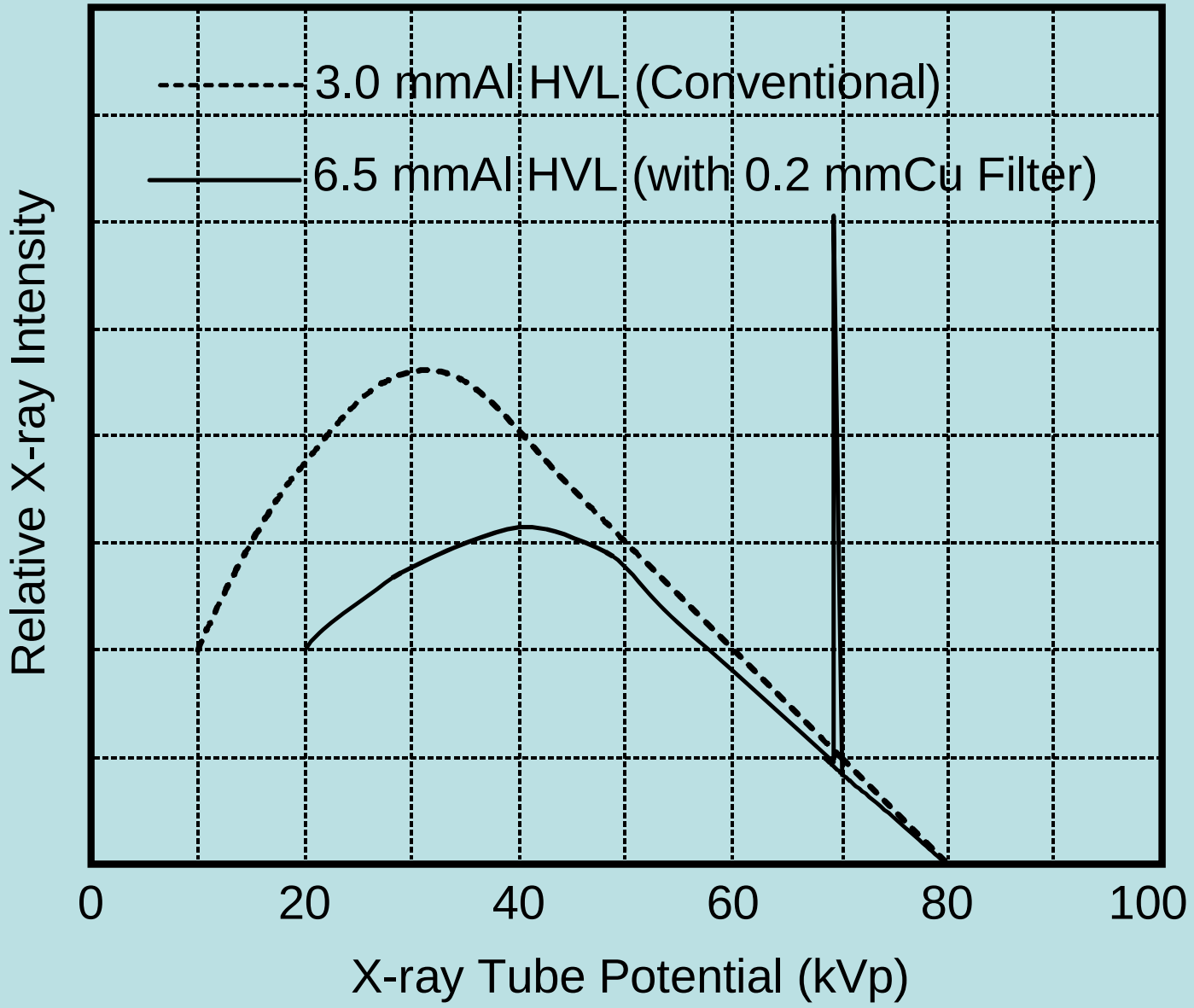
Input Sensitivity in front of the Flat Panel Image Detector

Patient Skin Dose (Air Kerma)



Why Better Image Quality & Lower Patient Dose?

- Image quality is “better” because of consistently lower tube potential is employed---higher image contrast!
- Radiation dose to the patients, especially, small and average size patient, is significantly reduced due to the use of spectral shaping filters --- considerably amount of low energy portion of spectrum is removed before hitting the patient.



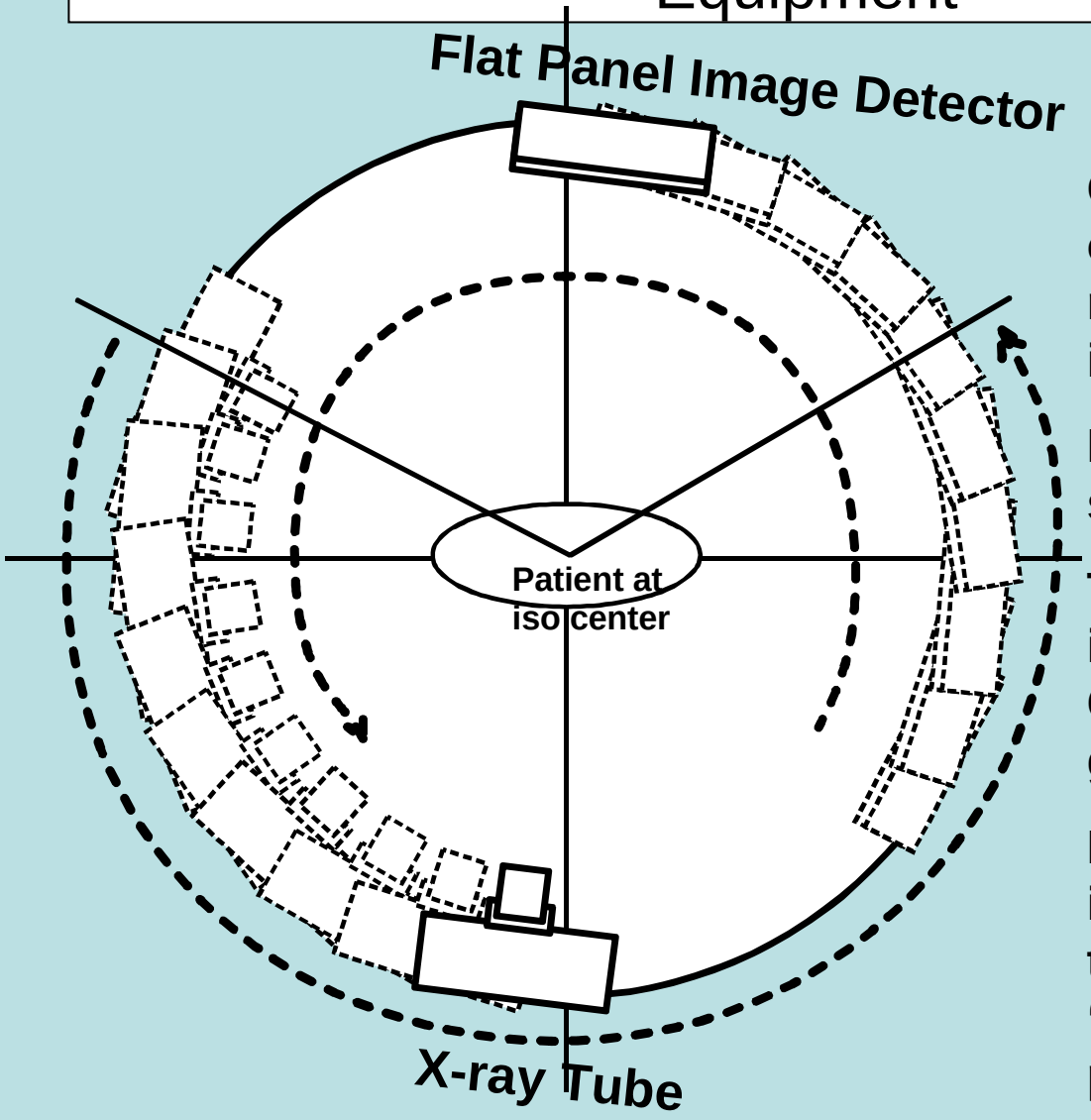
Schematic X-ray Spectra of (a) Conventional Filter; 3.0 mmAl HVL and (b) Heavily Filtered 6.5 mmAl HVL; 0.2 mmCu Filter.

Rotational Angiography

The C-arm frontal plane is employed for the raw data acquisition.

		3D Imaging	CT-like
Scan Parameters For CT 16 cm CTDI Phantom		70 kVp/20 mA per frame (AEC)	
Siemens File Name		5S-1KDR	10S-1KDR
Angle of Rotation		192°	204.8°
Angles Per Frame		1.5°	0.8°
Number of Frames		128	256
Peripheral Dose (reference only @ 12 O'clock)	mR	452	947
	mGy	3.84	8.05
Center Dose (reference only)	mR	9	12
	mGy	0.077	0.102
Matrix Size		1024 X 1024	1024 X 1024

Simplified Basic Principle of CT-like Image and 3D Image Reconstruction with Rotational Angiography Equipment



One projection image is obtained every 1.5^{o} of rotation resulting in 128 images in 5 seconds.

Each image has a matrix size of 1024 X 1024.

Through back projection image reconstruction the CT-like images can be generated.

For a 512 X 512 CT-like image, two pixel rows of the projected image is "binned" together for processing.

NCRP: Advances in Radiation Protection in Medicine
Arlington, VA, April 16-17, 2007

New Technologies in Radiation Therapy: Ensuring Patient Safety, Radiation Safety and Regulatory Issues in Radiation Oncology

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How has QA Changed With The Advent of Computerized Linacs, IMRT, & IGRT?

In the low-tech days

1. Treatment planning intuitive, hand check mu settings
2. Therapist sets up patient from paper chart
3. Treatment devices (wedges, blocks, compensators) visible
4. Primitive Record/Verify; computer checks human setup

In the hi-tech days

1. Inverse planning is black box, no hand calcs
2. Patient setup downloaded from file, auto setup
3. MLC/DMLC motion can only be `seen' on computer
4. Therapist checks computer setup from paper chart

Dangers of The Hi-Tech Approach

1. Systematic errors are harder to detect
2. Humans lulled into false sense of security. Don't thoroughly check computers
3. Many components of treatment are too complex for humans to check directly (e.g., dynamic MLC files, MU calcs for IMRT)
4. Many treatment aids/devices are invisible
5. Errors made on day 1 can propagate thru entire course of treatment via auto-setup
6. Operators have poor understanding of how software works
7. Too easy to click `over ride'
8. Continuing education: manufacturers training programs often inadequate

Major Categories of Human Errors (most → least likely)

1. Staff follows policy, but makes human error (e.g.; policy says treatment plan to be checked before first treatment, but second checker fails to detect error)
2. Staff does not follow policy (e.g.; treatment plan not checked)
3. Policy deficient (e.g.; there was no policy to check plan)
4. Zebra errors: bizarre sequence of events, almost impossible to foresee or prevent (the lunch break affair)

Treatment Errors Caused by Machines

1. Modern Linac and hardware rarely fail and rarely result in patient mistreatment ***unless*** compounded by human error.

2. More software bugs than hardware failures. Software bugs can be devastating.

3. People who write software don't know how a clinic works, and people who work in a clinic don't know how software works (Men are from Mars, women are from Venus).

Inverse Treatment Planning Is Not Intuitive:

1. We don’t know what dose volume constraints are physically achievable or optimum
2. Why does optimization failed-
    a. was objective function reasonable ?
    b. were dose constraints achievable ?
    c. algorithm stuck in local minimum ?
3. Many IMRT plans are worse than conventional plans
4. `Hand' calculations to verify plans NOT POSSIBLE
5. *in vivo* dosimetry, confirmation of beam delivery, and dose distributions more complicated
6. `Leap of faith' ---> trust you computers
7. Comprehensive QA Program tailored to IMRT

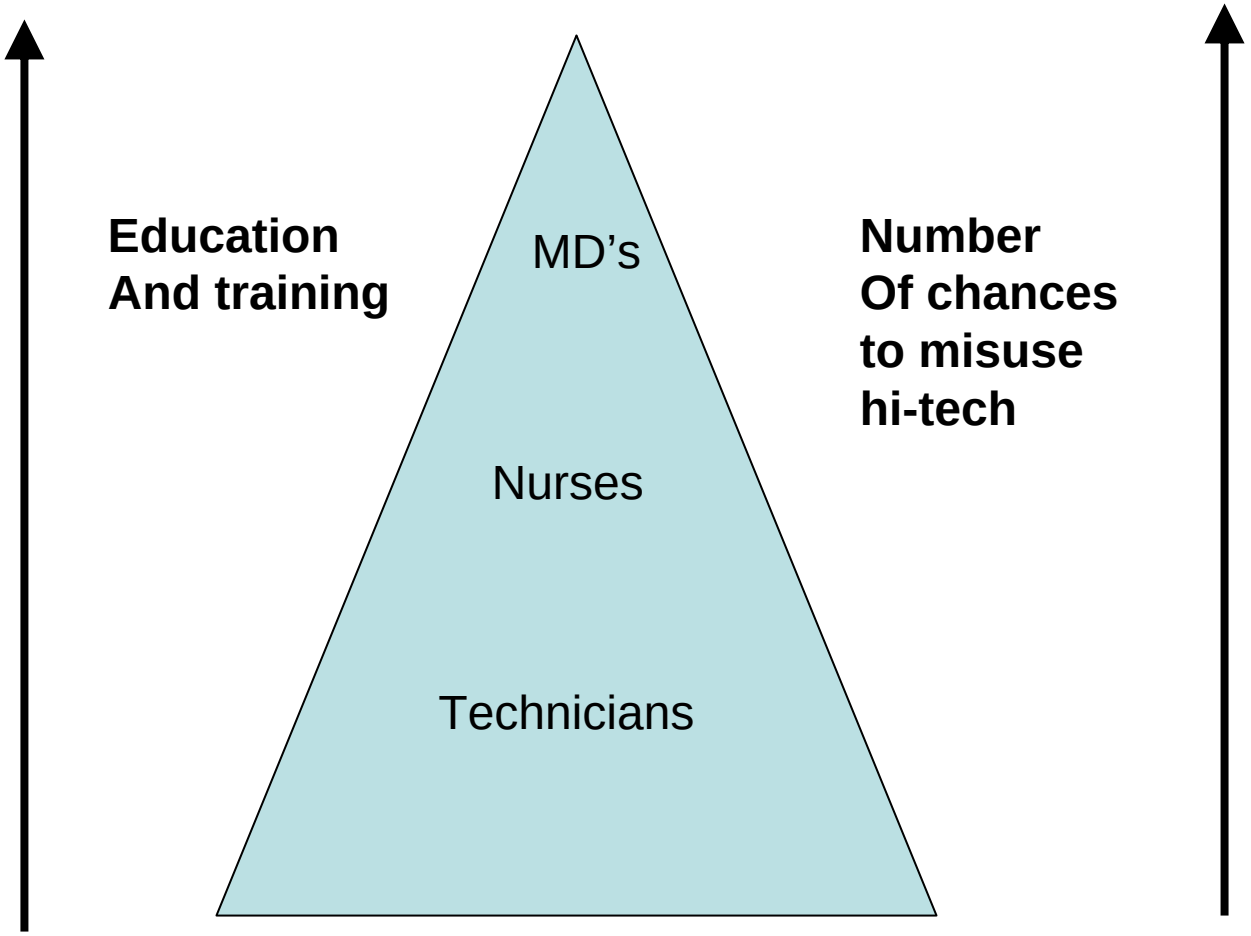
Other QA Differences Between IMRT and 3D planning

1. 2-3 times more monitor units--> MLC leakage and scatter

2. Room shielding design

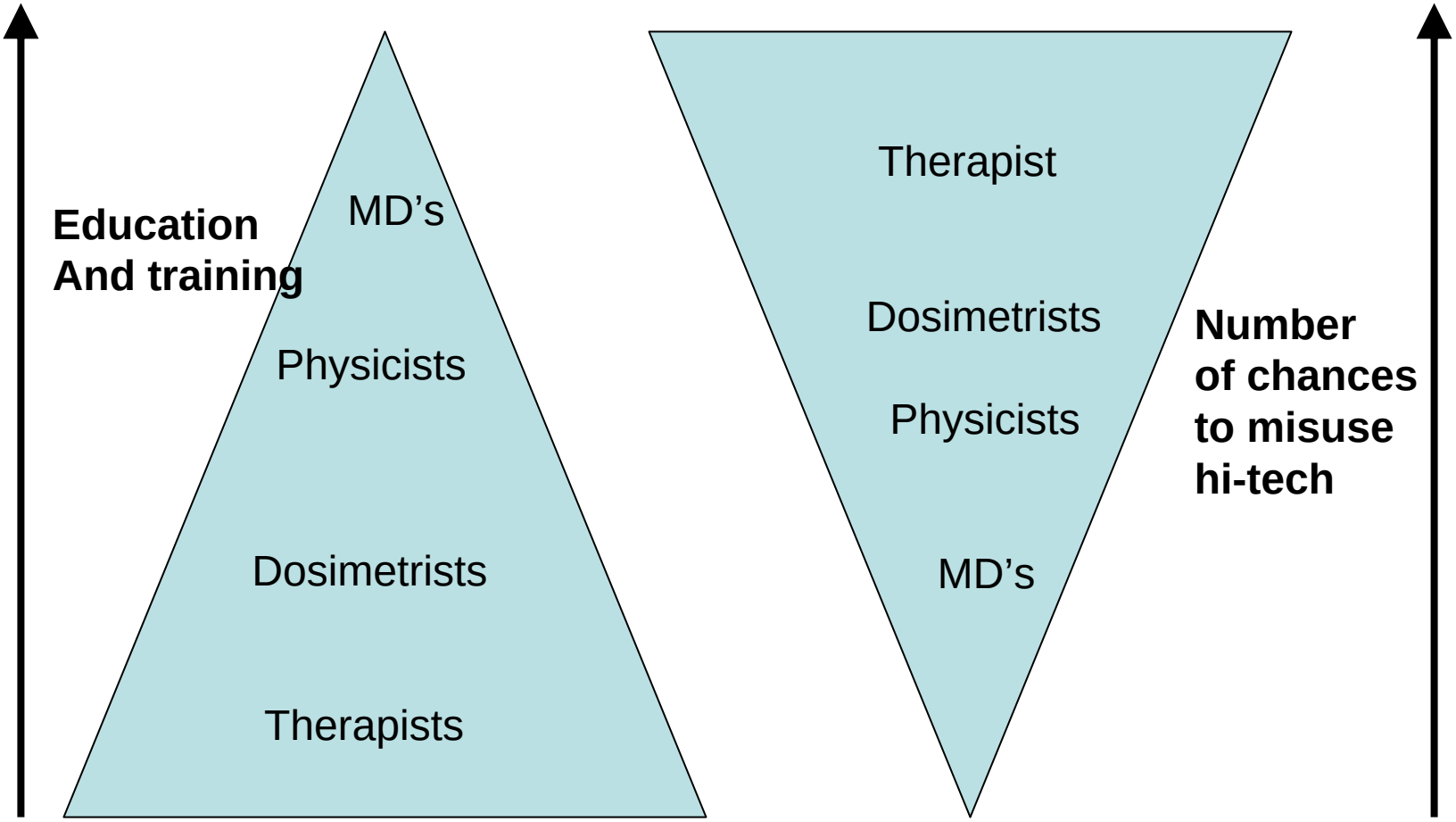
3. Patient whole body dose, neutron dose increase
   (6, 15, or 18 MV?)

Use of High Tech In Surgery

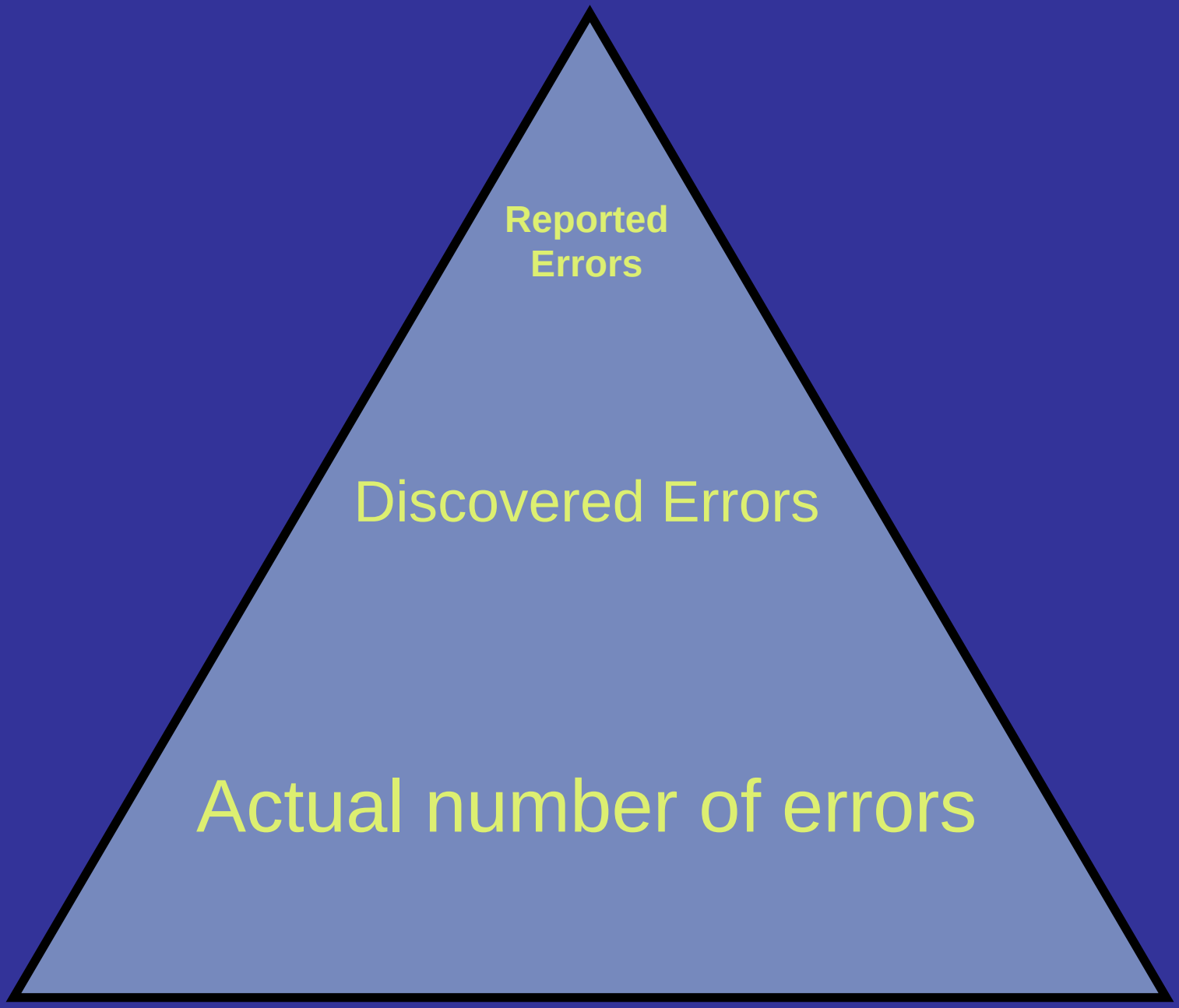


e.g.; robotics, lasers, laproscopic

Use of Hi-Tech in RT: inverted training/culpability Pyramid



e.g.; Linac, MLC, IGRT, R/V, treatment planning


Reported Errors
Discovered Errors
Actual number of errors

Hypotheticial treatment errors that might have occurred at a large fictitious cancer center in a fictitious city of 8 million people.

Nothing is foolproof for the sufficiently talented fool

R/V systems, computer controlled Linacs, image guided patient positioning systems, etc. reduce but do no prevent errors. More importantly, they enable human operators to make different kinds of errors faster and more efficiently.

There is a point of diminishing returns in designing a QA process. Exceed the maximum number of steps, forms, or people in a QA process and the error rate will increase rather than decreases.

DMLC Error: IMRT treatment with open MLC leaves:

- DMLC field selected for treatment after a static MLC treatment
- DMLC plan loaded, leaves retracted for light field use
- “Go” selected, leaves fail to return to prescribed position
- All systems allow treatment to proceed with retracted leaves
- Therapist fails to detect error

Why:

- Software did anticipate this sequence of events
- Could only have happened with exactly the right wrong timing (the Zebra)
- Very similar to Therac-25 disaster

MLC Error (FSRT) Event Sequence:

- FSRS treatment scheduled right after DMLC treatment
- At end of DMLC treatment leaves are all closed
- BrainLab mMLC attached to Linac below regular MLC
- Therapist does not retract primary MLC leaves
- Primary MLC leaf position not detected by R&V (thinks it's SRS)
- Patient treated with correct mMLC apertures and closed primary MLC

Why:

- Software not designed for two MLC's
- Light field not normally used for SRS
- Another Zebra

Record/Verify Systematic Error with DMLC:

- DMLC (v1) created from TPS and sent to R/V
- Dosimetry checks done
- Plan changed
- MU (only) manually edited in R&V
- No Independent Check of Data
- Difference too subtle to see on Portal Image Check

Why:

- Human error
- Improper understanding of software (change in TP system doesn't automatically get transferred to R/V)

Other R/V Errors

- Random
  - Incomplete/inaccurate field scheduling or treatment history leading to mis-treatment
  - Inappropriate over-ride by therapists
- Systematic (for an individual patient)
  - Incorrect parameters entered pre-treatment
    - Beam Parameters
    - Energy
    - MLC/DMLC Files
    - Monitor Unit Settings
  - May not be caught by portal imaging

New Paradigm for QA

Most errors are NOT systematic. They are patient specific. Therefore QA should shift from equipment focused to patient focused.

Patient Specific QA:

- Treatment plan check (more difficult than before)
- R/V, file check-sums *(each fraction)*
- Independent MU check, dosimetry, portal images
- Log file analysis, chamber measurement, film dosimetry

Machine Specific QA:

- Film test
- Dosimetry test
- Drift test
- MLC and IGRT tests

MLC Specific QA

Mechanical stability

Accuracy of leaf positioning (gaps)

- **Leaf calibration**
  "Picket fence" film pattern
- **Gap calibration vs time and vs gantry and collimator angle**
- **Leaf speed / positioning**
  Preventive maintenance
  Log file analysis

Donald Rumsfeld on `The Unknown'

As we know,
There are known knowns.
There are things we know we know.
We also know
There are known unknowns.
That is to say
We know there are some things
We do not know.

But there are also unknown unknowns,
The ones we don't know
We don't know.