Presidential Report on Radiation Protection Advice: Screening of Humans for Security Purposes Using Ionizing Radiation Scanning Systems

A Report Prepared by the National Council on Radiation Protection and Measurements

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Preface

This Presidential Report from the National Council on Radiation Protection and Measurements (NCRP) has been prepared at the request of the Food and Drug Administration (FDA). FDA has the responsibility for regulating the manufacture of electronic products that emit ionizing and nonionizing radiation and is working with the Transportation Security Administration (TSA), which has the responsibility of providing security measures for transportation activities. The FDA asked the NCRP for advice on radiation protection issues concerning exposure to ionizing radiation from radiation-producing devices used for non-medical security purposes. These devices, particularly x-ray scanning systems, are being evaluated by various agencies (*e.g.*, U.S. Customs Service and TSA) for use in security screening of humans.

The use of such scanning devices involves a broad societal decision that needs to be made through appropriate procedures by the authorities utilizing the x-ray producing electronic products (and other types of ionizing radiation producing systems) as a security device for screening humans. This report provides an evaluation of radiation levels, radiation risk, and radiation protection measures that should be taken into consideration by implementing authorities. However, the NCRP cannot render an opinion of the net benefit of using these devices based on the ionizing radiation aspects alone.

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1. Summary

This Presidential Report from the National Council on Radiation Protection and Measurements (NCRP) presents radiation protection advice concerning ionizing radiation-producing devices that are being evaluated for various uses in screening of humans for the purpose of security. Chief among the devices being evaluated at the present time are scanning systems that utilize x rays. This report addresses systems utilizing ionizing radiation, but also describes briefly some systems under consideration that utilize nonionizing radiation sources (see Section 3.4).

The report stresses that this advice is limited to radiation matters such as the levels of radiation exposure encountered, the radiation risk associated with ionizing radiation in general (as well as the risk associated with the actual levels encountered), and application of NCRP radiation protection principles to this radiation source. The overall justification for use of such devices for specific security applications and what constitutes a net benefit to society are broader questions that are outside of NCRP's role as defined by its Congressional charter.

Government agencies and other institutions are considering the use of ionizing radiation scanning systems for national security, protection of life, detection of contraband, or the prevention of significant economic loss. These applications might involve scanning a large number of members of the general public or they might involve the investigation of a small number of suspected individuals. The benefit of such procedures would be to a segment of society or society as a whole, as would be the case for national security or detection of contraband.

Two types of x-ray scanning systems currently exist for security screening of individuals: backscatter systems and transmission systems. With backscatter systems, the x rays do not penetrate to depths much beyond the surface of the individual, so they are useful for imaging objects hidden under clothing but are not useful for detecting objects hidden in body cavities. Backscatter systems are currently being used in the United States by the Customs Service and by several prisons for interdiction of drugs, weapons, and contraband. A typical scan lasts about eight seconds and results in an effective dose (see Section 2.3) of approximately 0.03 microsievert (μSv)[1] to the individual. With transmission systems, the x rays traverse through the body, similar to a medical x ray, so that objects that have been swallowed or hidden in body cavities may be visible. At least one model of a transmission scanning system is currently used outside the United States to screen workers exiting mines (*e.g.*, diamond mines) and at customs checkpoints in lieu of invasive body-cavity inspection. Subjects being scanned move through the beam in approximately 10 seconds and the effective dose per scan is on the order of 3 to 6 μSv.

Possible future developments for systems to scan humans using ionizing radiation are: combination systems using backscatter and transmission, systems using gamma rays, scanning of passenger vehicles at customs checkpoints or vulnerable bridges or tunnels, software algorithms that alleviate privacy concerns by recognizing and avoiding depiction of human anatomy, and improved imaging technology or radiation detection that permits the use of lower levels of radiation exposure (see Section 3.3).

Presently, there are also security scanners for the inspection of trucks, sea containers, train cars, or other cargo containers that use either gamma rays emitted by a radionuclide (*e.g.*, ^{137}Cs or ^{60}Co) or machine-generated radiation (*e.g.*, x rays or neutrons). Although these systems are not intended to expose human beings intentionally, stowaways hiding inside the container or vehicle being inspected can be exposed. Radiation doses from these systems that would be received by humans hiding in the cargo compartment are in the range of less than one to approximately 100 μSv per scan for the radionuclide or x-ray sources. In addition, a Pulsed Fast Neutron Analysis (PFNA) system is being evaluated for use in scanning cargo with neutrons. This system can identify a number of illicit materials by the pattern of the resulting gamma radiation. The radiation protection advice for PFNA systems is the subject of two previous NCRP Presidential Reports (NCRP, 2002; NCRP, 2003).

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[1] 1 μSv is equal to 0.1 mrem (millirem) in the previous system of units for radiation doses.

Screening systems that do not utilize ionizing radiation are also available and the following types are rapidly evolving: trace-chemical detection devices, millimeter-wave holographic imagers, dielectric portals, ultrasound imagers, and quadrupole resonance analyzers (see Section 3.4). Such devices should be evaluated as alternatives to systems that utilize ionizing radiation.

The goal of radiation protection is to prevent the occurrence of serious radiation-induced acute and chronic deterministic effects (*e.g.*, cataracts) and to reduce the potential for stochastic effects (*e.g.*, cancers) in exposed persons to a degree that is acceptable in relation to the benefits to the individual and to society from the activities that generate such exposures (NCRP, 1993). Section 5 and Appendix A of this report discuss health effects related to exposure to low doses of ionizing radiation. The radiation protection principles underlying NCRP recommendations are: justification of the practice; keeping radiation exposures as low as reasonably achievable, economic and social factors being taken into account (the ALARA principle); and dose limits for individuals (see Section 6).

NCRP (1993) recommended that the annual dose limit for a member of the general public for continuous or frequent exposure should not exceed an effective dose of 1 mSv, excluding exposures from natural background and from medical care. This recommendation is designed to limit exposure of members of the public to reasonable levels of risk comparable to other common risks (NCRP, 1993). However, because a member of the public might be exposed to more than one source of man-made radiation in a year, NCRP (1993) recommended that:

> "…whenever the potential exists for exposure of an individual member of the public to exceed 25 percent of the annual effective dose limit as a result of irradiation attributable to a single site, the site operator should ensure that the annual exposure of the maximally exposed individual, from all man-made exposures (excepting that individual's medical exposure), does not exceed 1 mSv on a continuous basis. Alternatively, if such an assessment is not conducted, no single source or set of sources under one control should result in an individual being exposed to more than 0.25 mSv annually."

It is this administrative control to 0.25 mSv effective dose (or less) per year for a member of the public (for a single source or set of sources under one control) that this report recommends be used for individuals undergoing security screening procedures with x-ray scanning devices. In this report, the term “under one control” typically refers to the use of ionizing radiation scanning systems at one or more security checkpoints at a given venue (such as multiple checkpoints at a given airport).

NCRP (1993) also includes the concept of a Negligible Individual Dose (NID), first introduced by NCRP (1987). The NID is the effective dose corresponding to the level of average annual excess risk of fatal health effects attributable to radiation exposure below which effort to further reduce the exposure to an individual is not warranted. The NID was set at an annual effective dose of 10 µSv (0.01 mSv) per source or practice. This concept is useful in developing radiation protection advice for exposures from the x-ray scanning systems, and in helping to put levels of effective dose per scan encountered with an x-ray scanning system into perspective.

This NCRP Presidential Report recommends classifying scanning systems that utilize ionizing radiation for security screening of humans into two categories: *general-use systems* and *limited-use systems*.

General-Use Systems

General-use systems should adhere to an effective dose of 0.1 µSv or less per scan, and can be used mostly without regard to the number of individuals scanned or the number of scans per individual in a year.

An effective dose of 0.1 µSv per scan would allow 2,500 scans of an individual annually (*i.e.*, if each scan required 0.1 µSv) without exceeding the administrative control of 0.25 mSv to a member of the general public for a single source or set of sources under one control. Assuming 250 workdays per year, this would correspond to an average of 10 scans each day, a frequency that is unlikely to be encountered. An effective dose of 0.1 µSv (or less) per scan is consistent with the American National

Standards Institute (ANSI) standard which recommends that value (or less) per scan for security scanners (ANSI, 2002).

Limited-Use Systems

Limited-use systems include all other ionizing radiation scanning systems that require effective doses per scan greater than 0.1 µSv and less than or equal to 10 µSv. These systems should be used with discretion in terms of the number of individuals scanned and the number of scans per individual in a year. At 10 µSv per scan, an effective dose of 0.25 mSv would be reached after 25 scans.

The users of these systems will need to determine how to implement the use of a *limited-use system* to provide reasonable assurance that the annual effective dose to an individual is 0.25 mSv or less for a single source or set of sources at a given venue. This report recognizes that providing reasonable assurance that individuals will not exceed 0.25 mSv per year may be difficult to implement. However, users of these systems must accept such responsibility.

Manufacturers of *limited-use systems* should always design the systems to utilize the lowest amount of radiation (below 10 µSv per scan) commensurate with the required imaging performance of the device, in keeping with the ALARA principle (see Section 6).

Manufacturers of all ionizing radiation scanning systems should provide the user with information on the effective dose to an individual per scan (for each possible operational mode), using appropriate calculations such as the ANSI (2002) method, and taking account of the x-ray energy spectrum for each operational mode of the system. In addition, the manufacturer will need to provide the corresponding values of a readily measured field quantity (such as air kerma) for each mode of operation. Such information will be necessary in routine practice to verify the system performance for a given mode of operation, and to assist the user in achieving the administrative control of 0.25 mSv effective dose (or less) per year. This verification procedure assumes that the relationship between the field quantity and the resulting effective dose is relatively constant for a given mode of operation.

A number of other considerations, important to the implementation of the radiation protection advice set out above for *general-use* and *limited-use systems*, are listed in the Conclusions (Section 10).

This report recommends that the annual effective dose limit for public bystanders (*i.e.*, individuals not undergoing scanning) should be the same as that for individual members of the public (*i.e.*, 1 mSv for continuous or frequent exposure from all relevant sources), and should be implemented in the same manner as for individuals undergoing scanning by adhering to the administrative control of 0.25 mSv effective dose (or less) per year for a single source or set of sources at a given venue. This report also recommends that scanning systems be designed and installed in such a way as to allow the same level of control on effective dose for operators as for members of the general public.

2. Introduction

The FDA asked the National Council on Radiation Protection and Measurements (NCRP) for advice on radiation protection issues concerning exposure to ionizing radiation from radiation-producing devices used for non-medical security purposes. These devices, particularly x-ray scanning systems, are being considered for use by various agencies (*e.g.*, U.S. Customs Service and Transportation Security Administration) for use in security screening of humans.

This NCRP Presidential Report addresses: (1) the types of ionizing radiation scanning systems that are being proposed for use in screening humans; (2) the circumstances under which individuals might be scanned by the devices; (3) the possible types of sites of use of the security devices; (4) the levels of ionizing radiation received from these devices by individuals being scanned for security purposes; (5) the potential for adverse health outcomes from these devices; (6) the limitation of radiation exposure to individuals who undergo scanning for security purposes, and (7) the limitation of general public exposure from use of ionizing radiation from these scanning devices.

2.1 Scope of FDA Request

In particular, FDA asked NCRP to address the following topics:

- "Risk assessment (including genetic risks and cancer);
- Appropriate use conditions and locations of equipment;
- Targeted and susceptible populations (frequent flyers, prison visitors, women of childbearing age, children, *etc.*);
- Single examination dose limits, repeat exposures, operator exposure and annual exposure/dose limits;
- Need for and appropriate use of "informed consent";
- Operator experience and training in the context of "image" quality;

- What constitutes a "net benefit" [protecting life (weapons), catching contraband, reducing losses (theft), *etc.*];
- Record keeping of an individual's exposure; and
- General screening versus evaluations of a targeted individual."

2.2 Scope of NCRP Advice

The radiation protection advice in this report addresses the topics above and other related topics in the following ways:

- It is compatible with the existing NCRP system of radiation protection recommended in NCRP Report No. 116, "Limitation of Exposure to Ionizing Radiation" (NCRP, 1993), but also takes into account the enhanced concern for security in the United States.
- It includes a brief review of the known risks from ionizing radiation (*e.g.*, genetic effects, cancer mortality and morbidity) and particularly the significance of those risks at the radiation levels resulting from the use of these scanning devices.
- It points out that justification of the use of such devices (*e.g.*, at airports, bus stations, gangways to ships, or other locations) and what constitutes a "net benefit" (*e.g.*, protection of life from weapons, or detection of contraband) are broader societal questions and outside of NCRP's role as defined by its Congressional charter.
- It considers the groups of individuals that would be screened or otherwise investigated with scanners for security purposes (*e.g.*, individuals being inspected for contraband or other reasons). It also considers special subgroups such as pregnant women (for protection of the embryo or fetus) and individuals who might undergo multiple exposures (*e.g.*, frequent flyers, prison visitors).
- It provides recommendations for keeping radiation doses commensurate with the need to obtain useful images for security purposes. It also addresses the ALARA principle (see Section 6.1) and its application to the use of security

devices. Consideration is given to the doses resulting from single and multiple inspections of scanned individuals, and to the doses to system operators and public bystanders (*i.e.*, persons other than the individuals scanned).

- It includes the need for appropriate communication with the affected parties (*i.e.*, individuals who are scanned and operators of devices) concerning radiation exposure and its possible consequences, and the need for responsible parties to provide such information that is easy to understand and presented in the individual’s primary language.
- It addresses the requirements for training and experience of operators of the scanning devices concerning radiation exposure aspects. The requirements will vary depending on the detection capabilities of the scanning device and the associated radiation risk to operators and to individuals exposed to the radiation produced by the imaging system. The training requirements depend on the manufacturer’s specifications, plus decisions by the authorized agency on the types of material to be detected (*e.g.*, plastic explosives, firearms, other contraband) and the necessary image quality needed to detect the items.
- It addresses the possible need for record keeping for radiation exposure of the various scanned individuals or groups, including when record keeping might be necessary, who should keep the records and the quantities to be recorded.
- It addresses initial and periodic testing of the scanning systems to ensure conformance with the appropriate effective dose per scan criterion.
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2.3 Effective Dose

Radiation doses from exposures that may result in delayed stochastic effects are expressed in the quantity effective dose (E):

$$E = \sum_{\mathrm{T}} w_{\mathrm{T}} H_{\mathrm{T}} , \tag{2.1}$$

where H_T is the equivalent dose in an organ or tissue T, and w_T is the tissue weighting factor that accounts for the radiation sensitivity of organ or tissue T. In this Report, effective doses are given in millisievert (mSv) or microsievert (μSv).

The equivalent dose (H_T) (also given in mSv or μSv) is obtained as:

$$H_T = \sum_R w_R D_{T,R} \ , \qquad (2.2)$$

where $D_{T,R}$ is the mean absorbed dose [in milligray (mGy) or microgray (μGy)] in an organ or tissue T due to a given type of radiation R, and w_R is the radiation weighting factor that accounts for the biological effectiveness of radiation type R. For external exposure, w_R applies to the type of radiation incident on the body.

The purpose of effective dose is to place on a common scale the radiation doses: (1) from different types of ionizing radiation that have different biological effectiveness, and (2) in different organs or tissues that have different radiation sensitivities. When the type of radiation interacting with the human body is x or gamma rays, w_R is assigned the value of one (ICRP, 1991; NCRP, 1993). The values of w_T for the various organs or tissues are the same for all radiations and can be found in ICRP (1991) or NCRP (1993).

3. Description of Scanners

3.1 Existing Scanners for Screening Humans

Two types of x-ray scanning systems currently exist for the security screening of individuals. They may be classified as backscatter systems and transmission systems.

3.1.1 *Backscatter Systems*

Backscatter systems use a narrow beam that scans the subject at high speed (“flying spot”) left to right and top to bottom much like the electron beam inside a television tube. Large detectors on the same side of the subject as the x-ray source detect backscattered radiation and a computer image is formed within a few seconds. Most of the radiation detected is scattered near the surface of the skin, hence the backscatter systems are useful for imaging objects hidden under clothing. They are not useful for detecting objects hidden in body cavities. Privacy concerns have been raised because of the ability of these systems to “see” through clothing. Usually a person is scanned twice, once from the front and once from the back. Sometimes lateral scans are also performed. These systems are being used in the United States by the Customs Service and by several prisons for interdiction of drugs, weapons, and contraband.

Two backscatter systems, shown in Figures 3.1 and 3.2, are currently available, each from a different manufacturer. Each system consists of a closet-size cabinet enclosing the high voltage supply, x-ray tube, beam limitation mechanisms, detectors, and all the moving parts. The current systems use fixed peak kilovoltage (kVp) and current [milliampere (mA)] settings for the x-ray source. The settings are approximately 50 kVp and 5 mA for one system and 125 kVp and 4 mA for the other. The total aluminum-equivalent filtration is about 1 mm for the 50 kVp system and 1.5 mm for the 125 kVp system. Approximate x-ray energy spectra for similar values of

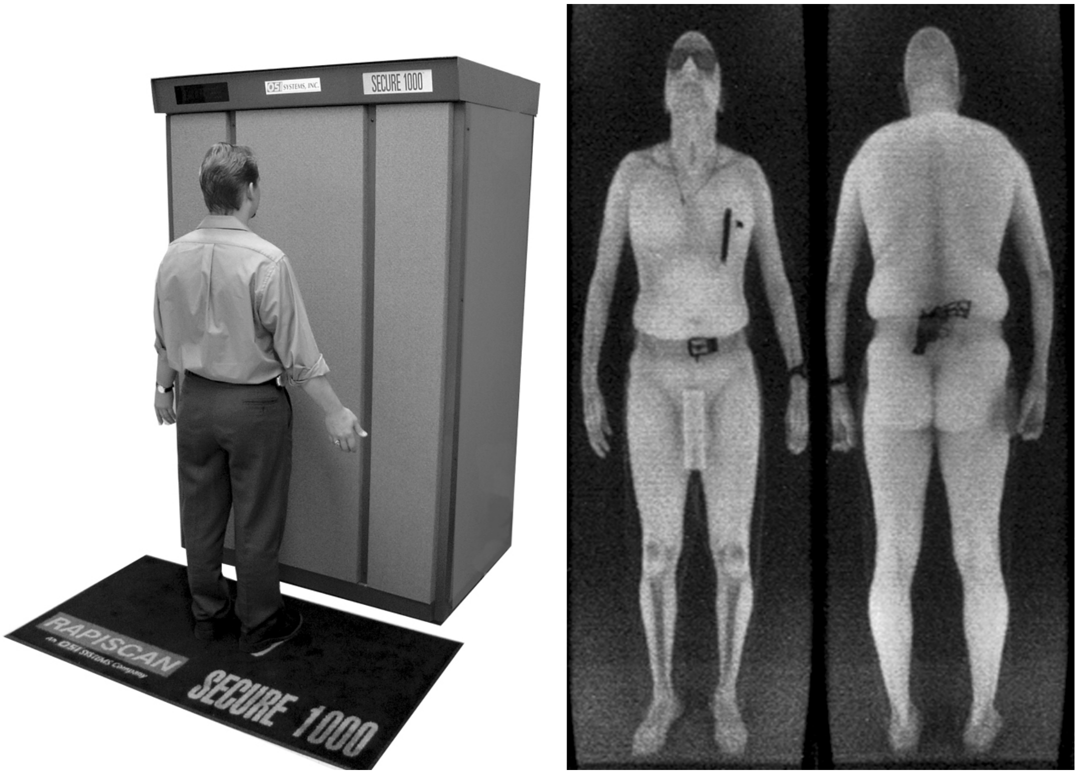

Fig. 3.1. Rapiscan's Secure 1000™ backscatter system and sample images. Photographs courtesy of Rapiscan Security Products, Inc., Hawthorne, California.

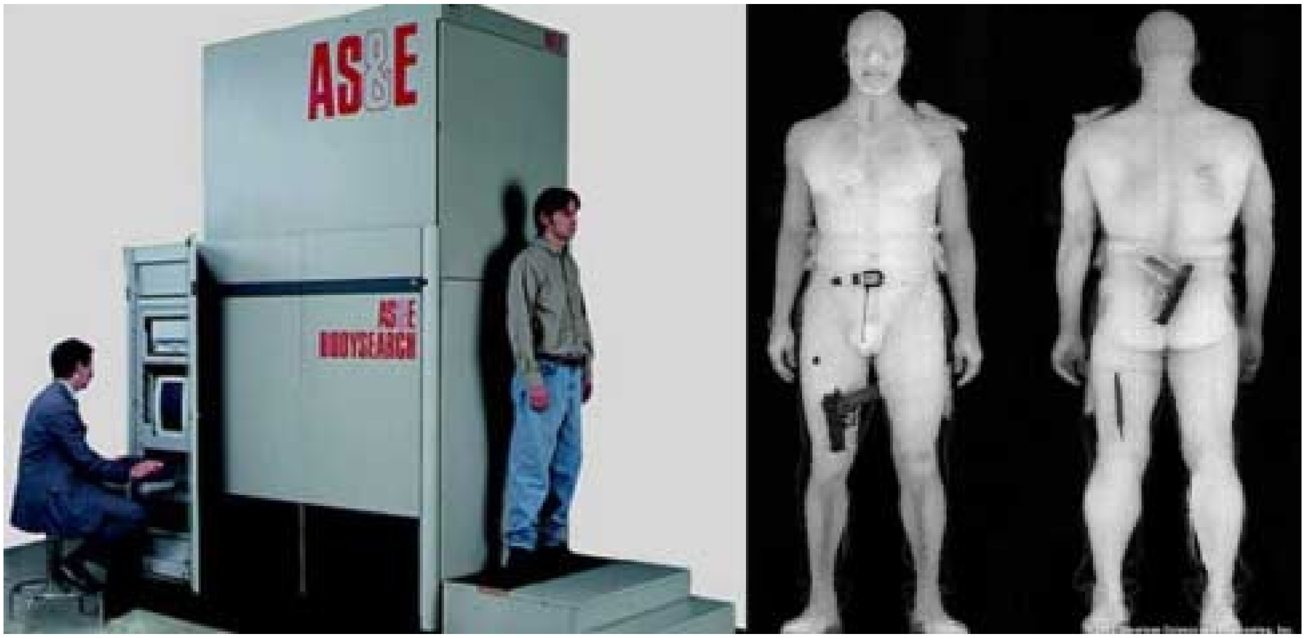

Fig. 3.2. American Science and Engineering's BodySearch™ backscatter system and sample images. Photographs courtesy of American Science and Engineering, Inc., Billerica, Massachusetts.

kVp and total filtration [as well as the half-value layer (HVL) for the spectra] are shown in the upper part of Figure 3.3. The subject stands in front of the cabinet and is scanned by an x-ray beam having a cross-sectional area of approximately 25 and 7 mm^2 for the two systems, respectively. The scan takes about 8 seconds. The systems are operated and the image viewed on the monitor of an external computer. Each system has a lighted sign on the scanning side of the cabinet to indicate when an x-ray scan is in progress. Interlock systems will stop x-ray production whenever a malfunction prevents the beam from moving and when one of several operating parameters monitored exceeds limits. The features of the two backscatter systems described in this paragraph are from Smith (2003)[2] and Schueller (2003)[3].

Radiation measurements on the two systems yielded the following[4]:

	50 kVp system	125 kVp system
Effective dose for anterior view	0.03 µSv per scan	0.03 µSv per scan
Effective dose for posterior view	0.01 µSv per scan	0.02 µSv per scan
Operator dose	indistinguishable from background	
Bystander dose (outside primary beam)	indistinguishable from background	

3.1.2 *Transmission Systems*

At least one transmission scanning system is being manufactured and is currently used outside the United States. This system is shown in Figure 3.4 and uses a vertical fan-shaped beam of x rays and a linear array of detectors. The subject stands on a

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[2] Smith, S. (2003). Personal communication (Spectrum San Diego, Inc., San Diego, California).

[3] Schueller, R. (2003). Personal communication (American Science and Engineering, Inc., Billerica, Massachusetts).

[4] Effective doses were derived using field measurements by the ANSI N43.17 subcommittee and calculations following the methodology described by ANSI (2002).

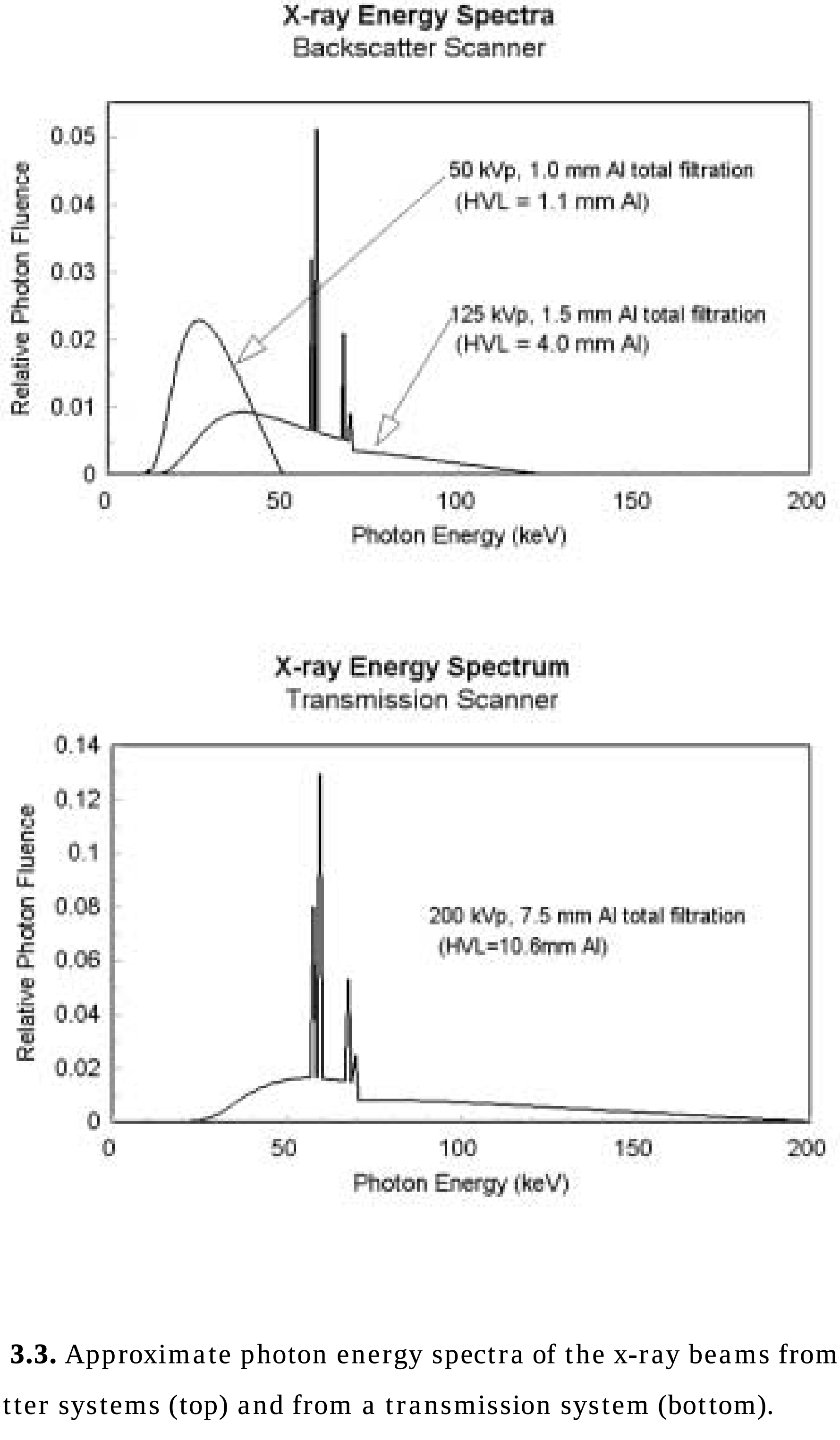

Fig. 3.3. Approximate photon energy spectra of the x-ray beams from two backscatter systems (top) and from a transmission system (bottom).

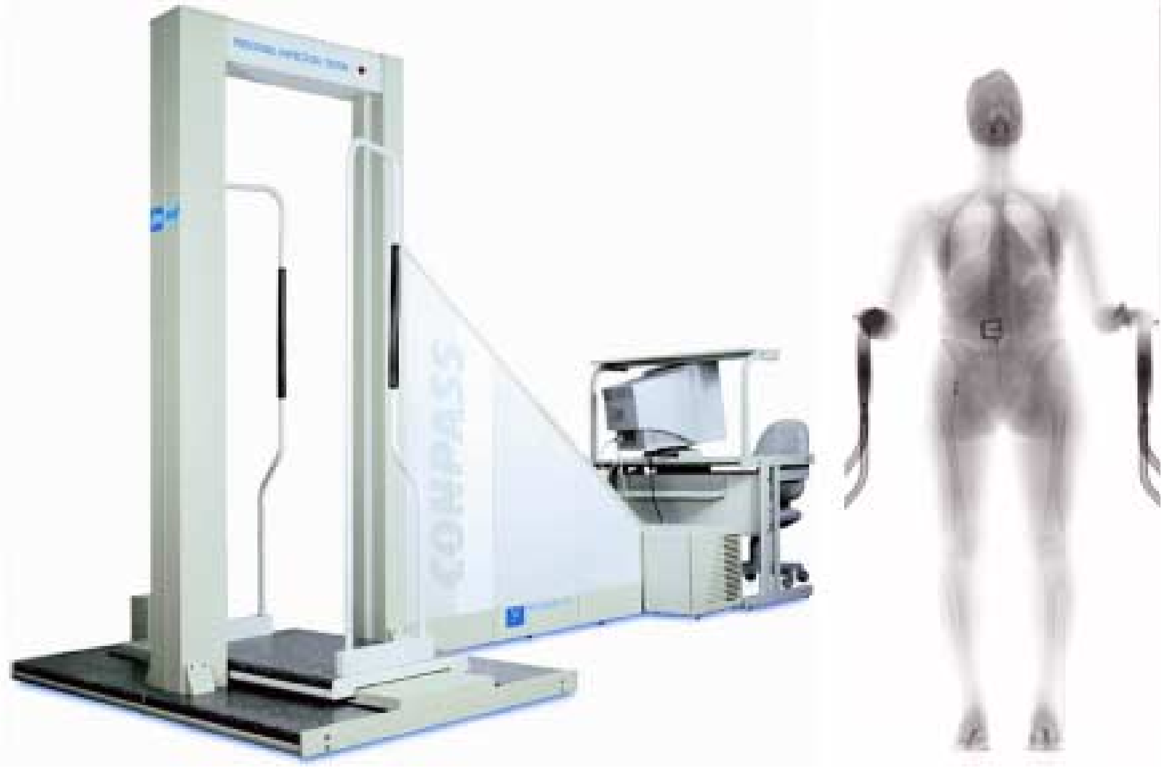

Fig. 3.4. The Conpass transmission system and sample image. Photographs courtesy of X-ray Equipment Company, Miami, Florida.

motorized platform between the x-ray tube and the detector array at about 2 m from the focal spot of the x-ray tube. The subject is asked to hold on to handrails as the platform moves the individual through the beam. The beam is approximately 3 mm wide and 2 m high at the center of the moving platform. The subject moves through the beam in approximately 10 seconds.

Following a scan, it takes approximately three seconds for the image to be formed and displayed. This system is capable of operating up to 200 kVp and up to 5 mA, and has a total aluminum-equivalent filtration of about 7 or 8 mm. An approximation of the resulting x-ray energy spectrum at 200 kVp [as well as the half-value layer (HVL) for the spectrum] is shown in the lower part of Figure 3.3. The effective dose to a scanned individual is estimated to be in the range of 3 to 6 μSv per scan (Cerra, 2003)[5]. This is based on measurements by Smit (2003)[6] and Ashtari (2003)[7] at representative operating conditions and following the methodology described by ANSI (2002). The features of the transmission system described in the above two paragraphs are from Ashtari (2003)[7] and Carter (2003)[8].

Because the radiation detected has traversed the entire body, objects that have been swallowed or hidden in body cavities might be visible. Unlike the backscatter-produced image, which is a topograph, the transmission image shows objects and body parts superimposed, much like a medical x-ray image. For this reason, a higher degree of image interpretation is necessary. The ability to select technique factors (*i.e.*, kVp and mA) also requires a skilled operator. The system is large and requires approximately 11 m^2 of floor space. Radiation scattered into surrounding areas may be a concern. The system is currently being used outside the United States to screen

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[5] Cerra, F. (2003). Personal communication (Food and Drug Administration, Rockville, Maryland).

[6] Smit, K.J. (2003). “Regulatory Control of X-ray Equipment Used in the Mining Industry in South Africa to Screen Workers for Security Purposes”. Presented at 35th National Conference on Radiation Control, (South Africa Department of Health, Bellville, South Africa).

[7] Ashtari, M. (2003). Personal communication (Long Island Jewish Medical Center, New Hyde Park, New York).

[8] Carter, K.W. (2003). Personal communication (X-ray Equipment Company, Miami, Florida).

workers exiting diamond mines to prevent theft, and at customs checkpoints in lieu of a strip search and invasive body-cavity inspection.

3.2 Existing Cargo Scanners

There are a number of scanning systems in use for the inspection of trucks, sea containers, train cars, or other cargo containers. These systems use either gamma rays emitted by a radionuclide (*e.g.*, ^{137}Cs or ^{60}Co) or machine-generated radiation (*e.g.*, x rays or neutrons). They are used by the Customs Service to screen a portion of an extremely large number of cargo containers and vehicles entering the country. Although these systems are not intended to expose human beings to radiation intentionally, and drivers are not in the vehicle when it is scanned, occasionally stowaways are discovered hiding inside the container or vehicle being inspected.

Cargo inspection scanners currently use gamma rays from ^{137}Cs or ^{60}Co to produce conventional transmission images. X rays at 450 kVp are used for both transmission and backscatter imaging of trucks and cargo. Accelerator-produced x rays up to 6 MeV are used to inspect containers in shipyards. Khan *et al.* (2001) studied the potential radiation doses from the various systems to locations where stowaways might hide in the cargo compartment. Measurements were made in the presence of an anthropomorphic phantom in different positions in an appropriate cargo compartment for each system tested. The reported "radiation doses" ranged from less than 0.1 µSv to about 100 µSv per scan[9].

Pulsed Fast Neutron Analysis (PFNA) systems scan cargo with short pulses of neutrons and collect the resulting gamma radiation. Elemental signatures are automatically compared to stored data for a number of illicit materials. The system generates an image of the cargo container or truck displaying the position and

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[9] Data were reported as "radiation doses" in mrem, but the quantities measured were not specified.

quantity of contraband. Radiation protection issues of PFNA systems are the subjects of two recent Presidential Reports (NCRP, 2002; 2003).

3.3 Possible Future Developments

As the need for security screening remains high and government agencies search for new tools to combat terrorist acts, technologies employing ionizing radiation to image illicit materials will continue to evolve. Possible future developments for scanning individuals may include combination systems using backscatter or transmission, or transmission systems using a “flying spot” method rather than a fan-shaped beam and linear detector array. This method is already being used for baggage and cargo. Smaller versions of cargo scanners using radionuclides that emit gamma rays are being developed for security screening of individuals.

An idea that has been considered involves scanning vehicles and their occupants at customs checkpoints or even at the approach of a vulnerable bridge or tunnel. Covert systems capable of scanning a vehicle traveling at five to 30 mph are possible.

Software algorithms may be developed for a number of desired functions. The possibility of alleviating privacy concerns through the use of programming capable of recognizing and hiding human anatomy has already been explored. Smart programs may be written to recognize shapes, optimize machine settings for selected purposes, or identify certain materials, possibly by changing the radiation energy spectrum in order to extract differential information.

Future advances in radiation detection and imaging technology may result in a reduction of the minimum radiation exposure necessary to achieve an adequate image. Present technology may also assume different forms. For example, systems may be disguised within decorative portals for the covert screening of individuals passing through the portals. Smaller transmission systems may be produced for the sole purpose of imaging stomach contents in order to search people suspected of having swallowed contraband. Rapid advances in the nonionizing screening technologies described in the next section are also expected.

3.4 Alternatives to Ionizing Radiation Scanning Systems

Alternatives to systems that use ionizing radiation should be evaluated when considering a screening system. Everyone is familiar with the metal detector portals and hand wands used in airports worldwide. Other screening technologies that do not use ionizing radiation are rapidly evolving. They include trace-chemical detection devices, millimeter-wave holographic imagers, dielectric portals, ultrasound imagers, and quadrupole resonance analyzers. One potential problem arises from the fact that some nonionizing radiation sources can interfere with the function of implanted medical devices (*e.g.*, pacemakers and defibrillators).

A wide range of trace-chemical detection devices has been developed and more are under development. Trace-chemical detectors can be in the form of hand-held devices, bench-top instruments, or portals. Some require physical contact to collect samples of trace chemicals from the surface of an individual’s clothing or skin. Others use a gentle stream of air to dislodge and collect particles. Through various methods of analysis, trace-chemical detectors can recognize targeted chemical compounds, including explosives, narcotics, chemical warfare agents, and toxic substances. Trained animals are also used in some situations.

A new technology that may gain importance in security-screening applications uses millimeter waves (high-frequency microwaves) to construct a three-dimensional holographic image of the body. The millimeter waves penetrate clothing but are reflected from the skin and other objects. The image is obtained by bombarding the body with low-power levels of millimeter waves from all directions and analyzing the resulting radar signals. This technology can produce high-resolution images.

Another technology using low-power microwave radiation consists of arrays of microwave dielectrometers in a portal. The system performs and maps a large number of measurements of the dielectric constant through isolated volumes of the body. The measurements are then compared to expected values in order to detect extraneous objects. The system, currently under development, may be used to find hidden metals, plastics, liquids, ceramics, and certain powders.

Ultrasonic imaging technology is also being investigated for security screening applications. Ultrasound has the ability to penetrate through closed windows, doors, or walls. Hand-held acoustic sensors may be used much like a video camcorder to image hidden objects at a distance.

Quadrupole resonance analysis is similar to magnetic resonance imaging but does not require a magnet. It uses low-intensity pulses of carefully tuned radio waves to probe the molecular structure of objects. Currently, quadrupole resonance systems are being developed for the detection of explosives in checked luggage.

4. Scanning System Usage

There are various reasons why the use of security-screening devices may be desired by government agencies and other institutions, including national security, protection of life, detection of contraband, or the prevention of economic loss. The individuals scanned might be private citizens, employees, prison inmates, customers, students, travelers and others. Institutions may want to indiscriminately screen members of the general public or they may have a need to investigate a small number of suspected individuals.

When some risk of health effects may be involved in the screening, as is the case with scanning systems using ionizing radiation, then the benefits of the use must be taken into consideration. In medical diagnostic and therapeutic uses of radiation, the benefits to the patient usually far outweigh the risks and are often obvious. When radiation is used for security screening, the benefit is generally not to the individual being scanned, but rather to a segment of society or society as a whole, as would be the case for national security or detection of contraband.

4.1 Present Uses

Some prison systems in the United States have used or are using backscatter systems. In some cases the inmates are scanned when moving from one area to another. In other cases visitors are scanned before admittance to the prison. These uses are both for the protection of life and detection of contraband. Life is protected not only by the detection of weapons, but sometimes also by detection of the presence of contraband, which creates an unsafe environment for prisoners and guards. Use of the scanning systems in prisons may result in frequent and regular exposures to certain individuals.

The U.S. Customs Service uses backscatter systems at major airports for second-tier inspections of people arriving into the country. Individuals selected for inspection are informed of the potential x-ray exposure and given the option of a pat-down search. The purpose of use is mainly for the detection of contraband, although any resulting reduction in drug trafficking may save lives. In addition, the U.S. Customs Service may sometimes require detainees suspected of having swallowed packets containing drugs to undergo a medical x-ray examination off-site. This need might be served in the future by an x-ray transmission scanning system. In some foreign countries, transmission systems are already being used by customs agents for this purpose and in lieu of body-cavity searches.

Besides the direct screening of individuals, the U.S. Customs Service also screens a large number of vehicles and cargo containers entering the country. On occasion people being smuggled into the country have been found by the scanning systems. Some of the people found had already died from heat or dehydration; others may have been saved by their discovery. The only known use of x-ray scanning systems for the prevention of economic loss at this time is the use of transmission systems outside the United States to screen workers on exit from diamond, gold and platinum mines.

4.2 Proposed New Uses

X-ray scanning systems for screening individuals have been proposed for a multitude of public places and more can be conceived. The following is a list that appeared on a recent advertisement for the transmission system: airports, nuclear power stations, embassies, banks, prisons, mines (diamond, gold and platinum), courthouses, government buildings, and presidential palaces. The use of transmission systems may constitute a new use in the United States when it is necessary to search inside a person’s body for a justified purpose.

5. Summary of Ionizing Radiation Detriment

5.1 Genetic (Hereditary) Risk

The most recent calculations of genetic risk from radiation exposure of humans have been provided by UNSCEAR (2001). The approach used represents a departure from approaches used for previous estimates, and has taken advantage of the increasing knowledge of the molecular basis of inherited diseases. Thus, the UNSCEAR (2001) genetic risk estimates are based on the use of human spontaneous mutation data (as opposed to mouse data) and mouse radiation-induced mutation data. The lack of observed inherited effects for radiation-exposed humans still necessitates the use of data for radiation-induced mutations in the mouse.

The specific approach used is described in Section A.1 in Appendix A. Overall, the predicted risks for the first generation (3,000 to 4,700 cases per million progeny per Gy of parental radiation, *i.e.*, per Gy of gonadal absorbed dose) are about 0.4 to 0.6 percent of the spontaneous frequency (730,000 per million) (UNSCEAR, 2001). These risks only rise by a very small increment if the population in every generation receives 1 Gy of parental radiation.

The genetic risk from exposure to current backscatter and transmission type x-ray scanning devices will be very low given that the gonadal absorbed dose per scan is in the μGy range. Multiple scans in a year at such gonadal absorbed doses per scan would result in no observed increase in genetic effects in the U.S. population.

5.2 Cancer Risks Attributable to Low Doses of Ionizing Radiation

The question of the biological effects of low levels of radiation has been investigated and debated for more than a century. There are data from the available human epidemiological studies that suggest equivalent doses as low as 50 mSv in one year or as low as 100 mSv over a lifetime (in addition to natural background) may produce an increased risk of deleterious consequences in man, both in terms of cancer and non-cancer endpoints (see Sections 5.2.1 and 5.2.2). At lower doses, progressively larger epidemiological studies would be required to evaluate the risk. For example, if the excess risk were proportional to the radiation dose and if a sample size of 500 persons were needed to determine the effect of a high, 1,000 mGy absorbed dose, a sample of 50,000 might be needed for a 100 mGy absorbed dose, and about five million for a 10 mGy absorbed dose (Land, 1980; Pochin, 1976). In other words, to obtain statistical precision and power, the necessary sample size increases approximately as the inverse square of the dose.

In considering the effects of low doses of radiation, it is also important to make the distinction between doses delivered acutely over a very short period of time (such as the atomic bomb exposures), and protracted exposure (such as occupational exposure). Generally speaking, protracted exposures to sparsely ionizing radiation such as x or gamma rays are associated with lower risks than those resulting from an acute exposure at the same total dose (NCRP, 1980).

5.2.1 *Acute Low-dose Exposures*

There are data for exposed human populations that suggest an increase in risk for cancer mortality at acute equivalent doses as low as 50 mSv, and more limited data that suggest an increase in some cancer risks at acute doses as low as about 10 mSv. Some details of the principal studies for acute doses (Doll and Wakefield, 1977; Pierce and Preston, 2000; Pierce *et. al*, 1996*; Ron et. al.*, 1995) are given in Section A.2.1 of Appendix A. It is unlikely that we will ever be able to directly generate risk estimates at significantly lower doses. However, the fact that the sensitivity of the studies does not allow for direct estimates of cancer risk at lower doses does not imply any conclusion, one way or another, on whether there actually are increases in cancer risk at these lower acute doses.

5.2.2 *Protracted Low-dose Exposures*

There are data that suggest an increase in some cancer risks in humans for protracted equivalent doses as low as 100 mSv, and more limited data that suggest an increase in risk at protracted doses as low as about 50 mSv. Some details of the principal studies for protracted doses (Ashmore *et. al.*, 1998; Cardis *et. al.*, 1995; Gilbert, 2001; Morin Doody *et. al.*, 2000; Muirhead *et. al.*, 1999; Ron *et. al.*, 1989; Sont *et. al.*, 2001) are given in Section A.2.2 of Appendix A. As expected, these doses are somewhat higher than those for acute exposures, as protraction of exposure generally decreases the risks of sparsely ionizing radiation such as x or gamma rays. As with acute exposures, it is unlikely that we will be able to directly generate risk estimates at tissue or organ equivalent doses much less than approximately 50 mSv. Again, the fact that cancer risks cannot be directly estimated at lower doses does not imply any conclusion, one way or another, on whether there actually are increases in cancer risk at these lower protracted doses.

The low-dose exposures associated with the ionizing radiation scanning systems used for screening humans for security purposes that will generally be well separated in time can generally be categorized as protracted low-dose exposures.

5.2.3 *Extrapolation of Risks to Lower Doses*

At absorbed doses below which statistically significant risks have been demonstrated [*i.e.*, 50 to 100 mGy (protracted exposure) or 10 to 50 mGy (acute exposure)], the shape of the appropriate dose-response curve is not known, because the signal to noise ratio of epidemiological or even laboratory data becomes too small. All the dose-response relationships shown in Figure 5.1 are possible descriptors of low-dose radiation oncogenesis, and different endpoints (*e.g.*, carcinoma versus sarcoma induction, breast-cancer versus lung-cancer induction) may well show qualitatively different dose-response relationships.

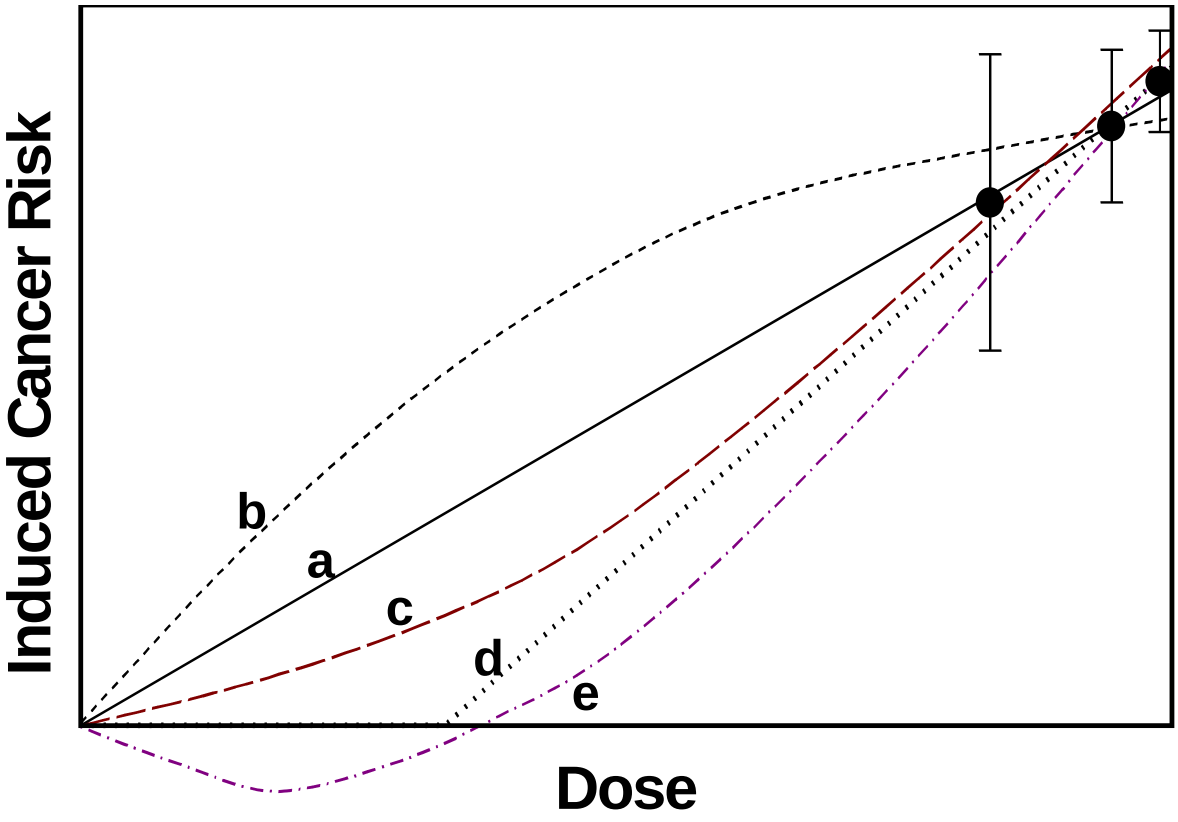

Fig. 5.1. Possible dose-response relationships for low-dose radiation oncogenesis: (a) linear, without threshold; b) downwardly curving: larger risks at low doses than predicted from higher doses; (c) upwardly curving: lower risks at low doses than predicted from higher doses; (d) threshold: zero risk at low doses, risk increases at higher doses; and (e) hormetic: benefit at low doses, risk increases at higher doses.

At the low and intermediate absorbed doses (0.2 to 1 Gy) that are generally amenable to investigation, there is a wealth of data, both from epidemiological studies and from laboratory studies, that is consistent with a linear dose-response relationship. The data are extensively reviewed in the recent NCRP Report No. 136 (NCRP, 2001), which concluded "although other dose-response relationships for the mutagenic and carcinogenic effects of low-level radiation cannot be excluded, no alternate dose-response relationship appears to be more plausible than the linear-nonthreshold model on the basis of present scientific knowledge".

Based on a linear relationship between risk and dose at low doses or low-dose rates, the International Commission on Radiological Protection (ICRP) provides estimates of cancer mortality risk as shown in Table 5.1. In using these population risk estimates, it is important to bear in mind that certain subgroups [*e.g.*, children, the developing embryo or fetus, and genetically susceptible individuals, such as individuals who are heterozygous for the Ataxia Telangiectasia gene (ICRP, 1998)] will exhibit higher risks, while other subgroups, such as elderly individuals, will exhibit lower risks. Additional discussion on the radiation sensitive subgroups in the population is given in Section A.2.3 of Appendix A.

Table 5.1—*Nominal lifetime low-dose or low-dose-rate risk estimates for cancer mortality from ionizing radiation (in percent per Sv*[a]*) (ICRP, 1991*)

	Lifetime Risk
Working Population[b]	4 percent per Sv
Whole Population[c]	5 percent per Sv

[a] "Sv" refers to the quantity effective dose.

[b] A population of working adults of both sexes.

[c] A population of all ages and both sexes.

6. Summary of NCRP System of Radiation Protection

6.1 System of Dose Limitation

The most recent NCRP recommendations on the system of dose limitation for workers and the public were issued in NCRP Report No. 116 (NCRP, 1993).

The goal of radiation protection is to prevent the occurrence of serious radiation-induced conditions (acute and chronic deterministic effects, *e.g.*, cataracts) in exposed persons and to reduce the potential for stochastic effects (*e.g.*, cancers) in exposed persons to a degree that is acceptable in relation to the benefits to the individual and to society from the activities that generate such exposures (NCRP, 1993).

The radiation protection principles underlying the NCRP recommendations are justification, the ALARA principle, and individual dose limits, as follows:

1. The need to justify any activity that involves radiation exposure on the basis that the expected benefits to society exceed the overall societal cost (*i.e.*, justification).
2. The need to ensure that the total societal detriment from such justifiable activities or practices is maintained as low as reasonably achievable, economic and social factors being taken into account (*i.e.*, the ALARA principle).
3. The need to apply individual dose limits to ensure that the procedures of justification and ALARA do not result in individuals or groups of individuals exceeding levels of acceptable risk (*i.e.*, dose limitation).

The individual dose limits exclude exposure to radiation from natural background sources and exposure of patients to radiation for medical purposes.

For workers, the system of dose limitation is based upon constraining the additional lifetime risk of fatal cancer to less than three percent for the maximally exposed individual. NCRP's overriding recommendation applied a nominal risk estimate of four percent per Sv (0.004 percent per mSv), utilizing the linear non-threshold hypothesis (NCRP, 2001), and suggested a lifetime limitation scheme (cumulative dose limit) for workers. For example, the limitation in risk, for fatal cancer, at age 65 would be 650 mSv times 0.004 percent per mSv, which is 2.6 percent. In consideration of these risk levels, NCRP recommended that the cumulative effective dose for a worker not exceed the age of the worker in years times 10 mSv and that any annual effective dose not exceed 50 mSv.

For members of the public, NCRP observed that the nominal risk estimate of fatal cancer associated with exposure to radiation was five percent per Sv (0.005 percent per mSv). The larger risk estimate for members of the public reflects potential exposure at all ages, including infants, children and adults. NCRP also noted that the average annual exposure to natural background radiation, excluding radon, results in an effective dose of about 1 mSv. Considering the increased potential period of exposure over a lifetime (assuming a 75 year lifetime) and the wider range of sensitivities to be found in the general population, NCRP recommended that the annual effective dose limit for a member of the general public for continuous or frequent exposure should not exceed 1 mSv. This limit assumes that the exposure occurs every year (*i.e.*, 1 mSv per year times 75 years), or a lifetime effective dose of 75 mSv. This recommendation is designed to limit exposure of members of the public to reasonable levels of risk that are comparable to risks from other common sources (NCRP, 1993).

Furthermore, a maximum annual effective dose limit of 5 mSv is recommended for infrequent annual exposures. This limit is recommended because an annual effective dose in excess of the 1 mSv recommendation, usually to a small group of people, need not be regarded as especially hazardous, provided this dose does not occur often to the same groups and that the average exposure to individuals in these groups does not exceed an annual effective dose of about 1 mSv.

Because a member of the public might be exposed to more than one source of radiation in a year, NCRP (1993) recommended that

> "…whenever the potential exists for exposure of an individual member of the public to exceed 25 percent of the annual effective dose limit as a result of irradiation attributable to a single site, the site operator should ensure that the annual exposure of the maximally exposed individual, from all man-made exposures (excepting that individual's medical exposure), does not exceed 1 mSv on a continuous basis. Alternatively, if such an assessment is not conducted, no single source or set of sources under one control should result in an individual being exposed to more than 0.25 mSv annually."

It is this administrative control of 0.25 mSv effective dose (or less) per year for a member of the public (for a single source or set of sources under one control) that this report recommends be used for individuals undergoing security screening procedures with x-ray scanning devices. In this report, the term "under one control" typically refers to the use of ionizing radiation scanning systems at one or more security checkpoints at a given venue (such as multiple checkpoints at a given airport).

NCRP (1993) addressed radiation protection of the embryo or fetus in the specific case of a pregnant radiation worker, once she has declared her pregnancy. For the embryo or fetus potentially exposed in the occupational environment, NCRP (1993) recommended an equivalent dose limit of 0.5 mSv per month. This monthly limit was developed to sufficiently protect the embryo or fetus from the relevant harmful radiation effects, effects that might also result from exposure to other ionizing radiation sources. Therefore, this report applies this monthly equivalent dose limit to the case of exposure from x-ray scanning systems used for security screening. Also, for the purposes of this report, the equivalent dose to the embryo or fetus is assumed to be numerically similar (*i.e.*, generally equal to or less than) the effective dose to the pregnant woman for the same radiation exposure from an x-ray scanning system. This assumption is justified for external, whole-body exposures to a uniform photon beam incident from the front, back or sides of the woman's body, based on comparison of the relevant conversion coefficients presented by ICRP (1996) or ICRU (1998).

6.2 Negligible Individual Dose

NCRP (1993) includes the concept of an annual Negligible Individual Dose (NID) and set the annual NID at 0.01 mSv (10 µSv) effective dose. This concept was first introduced in NCRP (1987) and is the effective dose corresponding to the level of average annual excess risk of fatal health effects attributable to radiation below which an effort to reduce the radiation exposure to an individual is not warranted. This concept takes into account the fact that the random variation in the risk due to all causes other than radiation is much larger than the incremental increase in the risk due to the NID. The value of 0.01 mSv per year is considered an NID per source or practice (NCRP, 1993).

6.3 Collective Dose

NCRP has not recommended limits for collective dose but recommends it be considered as one of the means for assessing the acceptability of a facility or practice (NCRP, 1995). Collective dose is most useful when population characteristics such as age and gender are known. When these are poorly defined, uncertain or subject to change over time, collective dose should be used with caution. If the uncertainty in the number of individuals being summed is large (*e.g.*, one or more orders of magnitude), collective dose should not be used as a surrogate for risk even at relatively high levels of radiation dose. Application of collective dose should be limited to stochastic effects in dose ranges where the risk is assumed proportional to the dose and not dose rate dependent. When the range of individual doses spans several orders of magnitude, the distribution should be characterized by dividing it into several ranges of individual doses, each covering no more than two or three orders of magnitude, with the population size, mean individual dose, collective dose and uncertainty being considered for each range.

Although NCRP has utilized the non-threshold hypothesis for the purpose of radiation protection, it is pointed out in NCRP (1993) that making an assessment of collective dose when the annual doses to an individual are less than 0.01 mSv (10 μSv) may not be cost effective. From another point of view, NCRP cannot exclude the possibility of a fatal cancer attributable to radiation in a very large population of people exposed to very low doses of radiation, but the same could be said for many other types of unregulated exposures.

6.4 Record Keeping

Records of radiation doses can serve a variety of purposes that include evaluating the effectiveness of a radiation protection program, providing data for epidemiological studies, demonstrating compliance with regulatory requirements, and providing information for making or contesting claims for radiation-induced health effects (NCRP, 1992). Records should identify the exposure category of each person for whom records are kept at each point in time. The content of the records maintained for an individual is dependent on the nature of the activity and the magnitude of potential risk. A discussion of record keeping for individuals scanned by *general-use* and *limited-use systems* is given in Section 7.2.

7. Application of NCRP System of Dose Limitation to Scanners

7.1 Intentional Radiation Exposure of Humans for Security Purposes

In exposing humans to radiation for security purposes, the question arises as to what dose limitation procedure should apply to such persons. The American National Standards Institute, Inc. (ANSI) has approved a standard for scanning systems using x rays and recommended that the effective dose per scan should be 0.1 µSv or less (ANSI, 2002). The recommendation was developed taking into account NCRP statements on risk estimates and its recommendations regarding the ALARA principle, the NID, and the effective dose limits for members of the public. An additional consideration is the prospect of multiple exposures of such individuals. ANSI (2002) discusses minimum information that should be provided to each person being scanned.

It is also possible that an embryo or fetus could be unknowingly exposed to an x-ray security scanning system either because the mother was unaware of her pregnancy or chose not to declare her pregnancy to the operator prior to being scanned. This possibility is discussed below.

This report recommends classifying scanning systems that utilize ionizing radiation for security screening of humans into two categories: *general-use systems* and *limited-use systems*.

General-Use Systems

General-use systems would be used mostly without regard to the number of individuals scanned or the number of scans per individual in a year, and should adhere to an effective dose of 0.1 µSv or less per scan. These systems would be appropriate for screening all members of the general public passing through a checkpoint, provided that the implementing agency has established the justification for such a screening procedure. The checkpoint in question is generally a security venue, and no attempt would be made (for the purpose of radiation protection) to limit the screening to only a selected portion of those seeking passage.

An effective dose of 0.1 µSv per scan would allow 2,500 scans of an individual annually without exceeding the administrative control of 0.25 mSv effective dose (or less) to a member of the general public for a single source or set of sources at a given venue. Assuming 250 workdays per year, this would correspond to an average of 10 scans each day, a frequency that is unlikely to be encountered. The administrative control of 0.25 mSv will also ensure that during the gestation period an embryo or fetus will not receive a monthly equivalent dose exceeding one-half of the monthly equivalent dose limit recommended in NCRP (1993) for the embryo or fetus of a pregnant radiation worker (see Section 6.1). An effective dose of 0.1 µSv (or less) per scan is consistent with the ANSI standard, which recommends that value (or less) per scan for security scanners (ANSI, 2002).

Limited-Use Systems

Limited-use systems would be used with discretion in terms of the number of individuals scanned and the number of scans per individual in a year, and would include all ionizing radiation scanning systems that require effective doses per scan greater than 0.1 µSv and less than or equal to 10 µSv per scan. At 10 µSv per scan, an effective dose of 0.25 mSv would be reached after only 25 scans. An example of when such systems might be used is if individuals have been properly identified and selected by the law enforcement agency for additional security screening due to a higher suspicion of illegal activity, and the *limited-use system* provides additional information compared with other types of scanning systems. An effective dose of 10 µSv or less per scan appears to be sufficient for all types of systems currently available, and should be sufficient for other ionizing radiation scanning systems under development. Manufacturers should design scanning systems as far below 10 µSv per scan as feasible, consistent with obtaining images adequate for security purposes.

Transmission systems delivering effective doses under 1 μSv per scan might be achieved using presently available technology.

Fifty scans in one month, at the maximum of 10 μSv per scan, would reach the monthly equivalent dose limit recommended in NCRP (1993) for the embryo or fetus of a pregnant radiation worker (see Section 6.1), and would exceed (by a factor of two) the annual administrative control of 0.25 mSv for a member of the public. Twenty-five scans, at the maximum of 10 μSv per scan, would reach the annual administrative control of 0.25 mSv effective dose (or less) to a member of the general public for a single source or set of sources at a given venue. The administrative control of 0.25 mSv is more restrictive, and the use of it as a guide will help to ensure that during the gestation period, an embryo or fetus will not receive a monthly equivalent dose exceeding one-half of the monthly equivalent dose limit recommended for the embryo or fetus of a pregnant radiation worker. This potential equivalent dose to the embryo or fetus from *limited-use systems* reemphasizes the need for constraint on the use of these scanning systems.

It is important that users determine how to implement *limited-use systems* to provide reasonable assurance that the annual effective dose to an individual is 0.25 mSv or less from a single source or set of sources under one control. Typically, “under one control” would refer to the use of scanning systems at one or more security checkpoints at a given venue. This report recognizes that providing reasonable assurance that individuals will not exceed 0.25 mSv per year may be difficult to implement. However, users of these systems must accept such responsibility (see Section 7.2). In the case of a pregnant woman, alternative investigative choices should be considered when there is a need to screen the woman with a *limited-use system*.

Manufacturers of all ionizing radiation scanning systems should provide the user with information on the effective dose to an individual per scan (for each possible operational mode) using appropriate calculations, such as the ANSI (2002) method, taking account of the x-ray energy spectrum for each operational mode of the system. In addition, the manufacturer will need to provide the corresponding values of a readily measured field quantity (such as air kerma) for the given mode of operation. Such information will be necessary in routine practice to verify the system performance for a given mode of operation, and to assist the user in achieving the administrative control of 0.25 mSv effective dose (or less) per year at a given venue.

7.2 Record Keeping for Scanned Individuals

Since it will be unlikely that *general-use systems* will result in annual effective doses received by individual members of the public exceeding the administrative control of 0.25 mSv per year (for a single source or set of sources at a given venue), record keeping of individual doses from these systems is not necessary.

For *limited-use systems*, some form of record keeping might be necessary, especially when there is a chance that the administrative control on effective dose may be exceeded. For example, for systems operating at 10 µSv per scan, an individual receiving 25 scans per year at one venue would reach the administrative control of 0.25 mSv. If the same individual receives 100 such scans per year at multiple venues (with no more than 0.25 mSv for a given venue), that individual would reach the dose limit of 1 mSv recommended in NCRP (1993). For systems that can operate at lower doses per scan (*e.g.*, 1 µSv per scan), the administrative control and dose limit would be reached after an individual has 250 and 1,000 such scans, respectively.

The deployment of *limited-use systems* involves the potential for a limited number of individuals to exceed the 0.25 mSv per year administrative control on effective dose (for a single venue), and the 1 mSv annual dose limit (for all relevant radiation sources, see Section 6.1). Therefore, these systems require discretion in and limitation of their use. Users of such systems must assume the responsibility of limiting the use of the systems, and of developing written protocols to ensure that individuals are not likely to exceed the administrative control on effective dose (for a given venue) that is recommended in this report.

Likewise, for the same reasons, a burden is placed on the designers and developers of such systems to improve the technology as much as possible in order to lower the required dose per scan, in keeping with the ALARA principle.

The matter of record keeping for *limited-use systems* is most important for circumstances where the exposed individual is employed at the facility using the scanning system or is a frequent visitor to it. For example, at a prison such individuals could include guards, frequent visitors to prisoners, and contractors working in the prison. Record keeping for a given venue is the responsibility of the facility using the system. The pertinent records include: (1) the maximum estimated effective dose per scan or the actual effective dose per scan if known, (2) the number of times and dates when an individual was scanned, and (3) the cumulative effective dose to the individual over the past twelve months. Typically, this information should be available from the initial and periodic testing of the scanning systems to confirm the effective dose per scan for each scanning unit (see Section 7.4).

7.3 Radiation Protection for Operators and Public Bystanders

NCRP (1993) recommends an annual effective dose of 1 mSv as the limit for continuous or frequent exposure of members of the public from the sum of all relevant radiation exposures (see Section 6.1). This report recommends that the annual effective dose limit for public bystanders (*i.e.*, individuals not undergoing scanning) should be the same as that for individual members of the public (*i.e.*, 1 mSv), and should be implemented in the same manner as for individuals undergoing scanning by adhering to the administrative control of 0.25 mSv effective dose (or less) per year for a single source or set of sources at a given venue. This report also recommends that scanning systems be designed and installed in such a way as to allow the same level of control on effective dose for operators as for members of the general public.

7.4 Initial and Periodic Testing of Equipment

The recommendation of this report for *general-use systems* is that the effective dose per scan should not exceed 0.1 μSv. This is based on the observation that at this effective dose per scan, it is unlikely that the annual effective dose to an individual will exceed 0.25 mSv for a single source or set of sources at a given venue.

The recommendation in this report for *limited-use systems* is that the effective dose per scan can exceed 0.1 μSv, but should not exceed 10 μSv. Users of these scanning systems should document the effective dose per scan for these systems and also ensure that the annual effective dose to an individual does not exceed the administrative control of 0.25 mSv (or less) effective dose per year (for a given venue). Conformance with this administrative control can be achieved by recording information that identifies the scanned individuals and the number of scans for each individual. Personal dosimetry for each individual is not necessary since the performance characteristics of the scanning unit (*i.e.*, the effective dose per scan) will be recorded from the appropriate testing of the unit.

Therefore, each general-use and limited-use scanning unit should be tested initially and on an annual basis to ensure that the radiation output from the unit complies with the design objectives and with this report's recommendations on effective dose per scan. The scanning unit should also be tested after any maintenance or incident that may affect the radiation shielding or radiation output of the unit. In addition, radiation levels around the units should be monitored to verify that the potential effective dose to operators or other individuals in the areas remain within the administrative control recommended in this report (see Section 7.3). All such testing should be done by a qualified expert (NCRP, 2000a).

7.5 Inadvertent Radiation Exposure of Humans as a Result of Cargo Scanning

ANSI (2002) assumes that exposed persons are knowingly scanned by the operator. NCRP (2002), in its Presidential Report on Radiation Protection Advice for Pulsed Fast Neutron Analysis (PFNA) System Used in Security Surveillance, recommended that the PFNA system, which is not intended to scan humans, be designed and operated in a manner that ensures that an inadvertently exposed person will receive an effective dose of less than 1 mSv. This limit can be raised to 5 mSv, if necessary, to achieve national security objectives. As noted in Section 6, a limit of 5 mSv is allowed for infrequent annual exposures to members of the public. NCRP (2003) also recommended that the PFNA system be designed and operated in accordance with the ALARA principle.

In forming these recommendations, NRCP (2002) considered that:

- An inadvertently exposed person would be exposed only once, or at most only a few times, to the PFNA system,
- The dose limit should be consistent with previous NCRP recommendations and provide a level of protection consistent with that accorded to members of the public, and
- The limit should consider the requirement for protecting individuals of all ages.

Finally, the law enforcement authority responsible for the system should provide information about the exposure to individuals known to have been inadvertently exposed. The information should be easy to understand and presented in a language understood by the individual or through a translator, where practicable.

8. Training

8.1 Training of Operators

NCRP Report No. 134 (NCRP, 2000b) lists four important reasons for training:

- The development of worker skills through training enables the individual to perform tasks efficiently and with confidence.
- When individuals are aware that there is some risk associated with their exposure, they can become active participants in the decision to accept and, where possible, to reduce such risks as part of their job.
- The number and seriousness of accidents can be reduced through training.
- Workers who are properly trained will be aware of the regulatory requirements associated with their activities that involve radiation or radioactive materials (if applicable).

A fifth important reason, in the case of the ionizing radiation scanning systems, is to prepare workers to provide members of the public that are being scanned with adequate and correct answers to questions about the radiation risk associated with the scanning procedure.

These are all appropriate and compelling reasons for the need for radiation safety training for individuals involved in the use of ionizing radiation scanning devices for security screening, even when the output from the device is low and would appear to present minimal exposure potential for the operator. Training can be used to reassure the operators, answer any questions that they might have and provide guidance for keeping their exposures as low as reasonably achievable (the ALARA principle) (NCRP, 1993). Training can also reemphasize that there are inappropriate procedures in using the scanning device, or modifications to the safety features of the scanning device, that could lead to increases in exposure potential for operators or individuals being scanned. The operator of any scanning device has a responsibility of ensuring the least amount of exposure to the individual being examined as well as to themselves while providing security for the area and preventing anyone from entering the area and receiving inadvertent exposure. To ensure the safe operation of these scanning devices, operators should receive appropriate training before being granted approval to use the devices.

NCRP Reports No. 127 (NCRP, 1998), No. 133 (NCRP 2000a) and No. 134 (NCRP, 2000b) provide guidance on evaluating job situations involving radiation sources and designing commensurate radiation safety training programs. For the use of ionizing radiation scanning devices for screening, it would appear that, at a minimum, for radiation protection purposes, the following topics should be covered in the training programs:

- Radiation dose units
- Production of x rays
- Effects of peak x-ray voltage, x-ray tube current and x-ray beam filtration on radiation dose
- Safety features built into the scanning devices
- Radiations from radionuclide sources (if applicable)
- Distance from the x-ray tube or source versus dose rate
- Time, distance and shielding in radiation protection
- Scattered radiation doses
- Transmitted radiation doses
- Leakage radiation doses
- Doses to individuals scanned
- Potential doses to operators
- Comparison of doses from various sources
- Occupational versus non-occupational doses
- Controls on dose for individuals being scanned
- The concept and practice of the ALARA principle
- Biological effects of radiation
- Recognition of radiation sensitive populations
- Radiation measuring devices
- Use of personal monitors

- Use of area radiation monitors
- Image production, quality assurance and interpretation
- Effectively answering questions about ionizing radiation
- Security requirements for x-ray generating units
- Security requirements for radionuclide sources (if applicable)

8.2 Retraining for Operators

Operators of the ionizing radiation scanning devices should receive refresher radiation safety training on an annual basis and understanding of the training should be verified through testing. The retraining need not be as extensive as the initial training, but should be adequate to verify retention of the necessary information required for safe operation of the units.

9. Communication of Information Related to Scanner Safety

The FDA requested that this report consider the concept of “informed consent.” The effective doses that would be received from the scanning devices considered in this report are at a level at which the “consent” aspect of informed consent would not be indicated. However, it is important that all scanned individuals be well informed about the security screening process, its benefits and its potential risks. Information, in lay language, about the security screening process, its benefits and its potential risks should be provided to individuals prior to their being scanned.

Such information should be disseminated via easily obtained pamphlets and appropriately located explanatory posters. The information provided should be consistent with the NCRP system of radiation protection and it would be helpful to include comparative doses such as the radiation dose from air travel or natural background (*e.g.*, one scan with a *general-use system* at 0.1 μSv is equivalent to roughly 15 minutes of natural background radiation, and one scan with a *limited-use system* at 10 μSv is approximately equal to one day of natural background radiation).

10. Conclusions

In this NCRP Presidential Report, for the purpose of radiation protection it is recommended that there should be two categories of ionizing radiation devices used for scanning humans for security screening purposes, *general-use systems* and *limited-use systems*. An effective dose of 0.1 μSv (or less) per scan is the basic criterion for distinguishing between the two categories. Both categories of systems should meet the recommended administrative control for a member of the public of 0.25 mSv (or less) effective dose per year for a single source or set of sources under one control. Typically, "under one control" would refer to the use of scanning systems at one or more security checkpoints at a given venue (such as multiple checkpoints at a given airport). Additional conclusions concerning the implementation of this radiation protection advice are given below for each category.

General-Use Systems that Utilize Ionizing Radiation

- The effective dose from each scan should be 0.1 μSv or less, and the total effective dose for any individual should be 0.25 mSv or less in a year from scanning systems used at a single venue.
- It would require at least 100 scans of the same individual in a year (at 0.1 μSv per scan) to reach the NID of 10 μSv, and at least 2,500 such scans of the same individual in a year to reach the administrative control on annual effective dose for a single venue of 0.25 mSv.
- The criterion on effective dose from each scan of 0.1 μSv or less is consistent with the recommendation presented by ANSI (2002).
- Manufacturers of *general-use systems* should provide the user with information on the effective dose to an individual per scan for each mode of operation of the system, using a method of determining effective dose per scan that is consistent with the methodology presented by ANSI (2002). Additionally, manufacturers should provide the corresponding value of a readily measured field quantity (such as air kerma) for the given mode of operation, to be used to verify system performance.

- If available, alternate systems not employing ionizing radiation should be considered first.
- It is not necessary to keep records of ionizing radiation exposure to individuals for *general-use systems*. However, it is necessary to test and record that the scanning unit is meeting the effective dose per scan criterion of 0.1 µSv or less.
- Given the low levels of effective dose involved per scan (and the resultant low levels of equivalent dose per scan to the embryo or fetus of a pregnant woman), no special precautions are required for the embryo or fetus of a pregnant woman, for infants, or for children.

Limited-Use Systems that Utilize Ionizing Radiation

- These systems include scanning devices that exceed an effective dose of 0.1 µSv per scan, but the scanning device should not exceed 10 µSv per scan. In addition, the total effective dose for any individual should be 0.25 mSv or less in a year from *limited-use systems* used at a single venue.
- If available, alternate systems not employing ionizing radiation should be considered first.
- Users of *limited-use systems* should determine how to keep the total effective dose to any individual to 0.25 mSv or less in a year from a single source or set of sources under one control (*e.g.*, by limiting the number of scans of any individual at a given venue).
- Manufacturers of *limited-use systems* should provide the user with information on the effective dose to an individual per scan for each mode of operation of the system, using a method of determining effective dose per scan that is consistent with the methodology presented by ANSI (2002). Additionally, manufacturers should provide the corresponding value of a readily measured field quantity (such as air kerma) for the given mode of operation, to be used to verify system performance.
- *Limited-use systems* should always be designed and operated to utilize the lowest amount of radiation (below 10 µSv effective dose per scan) commensurate with the required imaging performance of the device.

- Collective dose may be a useful consideration in applying the ALARA principle to *limited-use systems*, but the guidance and caveats for the use of collective dose provided in NCRP Report No. 116 (NCRP, 1993) and NCRP Report No. 121 (NCRP, 1995) should be followed.
- Alternative investigative choices should be considered for children and pregnant women when there is a need to screen them with a *limited-use system*.

Appendix A.

Additional Background on Ionizing Radiation Detriment

A.1 Genetic (Hereditary) Risk

Genetic risk for radiation exposures has been calculated for the different classes of endpoint (*i.e.*, dominant diseases, recessive diseases, chromosomal translocations, and irregularly inherited diseases) based largely upon mouse data, because of a lack of observation of inherited effects in the offspring of irradiated parents such as for the A-bomb survivors (NAS/NRC, 1990; UNSCEAR, 1993). The uncertainties in the genetic risk are for extrapolation from radiation-induced effects in the mouse to those for humans and, as identified recently, a concern over the magnitude of the spontaneous frequency of mutations in the mouse (Russell and Russell, 1997; Selby, 1998). This latter concern is important because the genetic risk has been calculated based upon the doubling dose, which is the dose of radiation that doubles the spontaneous rate. Thus, if the spontaneous frequency of mutations is much higher than previously thought, the doubling dose would be higher and the genetic risk correspondingly lower. To circumvent this concern and to begin to take advantage of an increasing knowledge of the molecular basis for human diseases, UNSCEAR (2001) has proposed to calculate the genetic risk based upon human spontaneous mutation data and mouse radiation-induced mutation data. The lack of an observed inherited effect for radiation-exposed humans (as noted above) still necessitates the use of data on radiation-induced mutations in the mouse.

The specific approach taken is somewhat complex in nature. However, in simple terms; the risk is estimated as a product of two quantities:

$$\text{Risk per unit dose} = P \times (1/DD), \qquad \text{(A.1)}$$

where P is the baseline incidence and $1/DD$ is the relative mutation risk (or reciprocal of the doubling dose, DD). UNSCEAR (2001) presents the estimates of genetic risks for the different classes of disorders; all values are expressed as per Gy of parental irradiation (*i.e.*, gonadal absorbed dose) per one million progeny. For the first generation the risks are: autosomal dominant and linked diseases, 750 to 1,550 cases (background 16,500 per million live births); autosomal recessive diseases, 0 cases (background 2,500 per million live births); chronic multifactorial diseases, 250 to 1,200 cases (background 650,000 per million live births); and congenital abnormalities 2,000 cases (background 60,000 cases per million live births). Overall, the predicted risks for the first generation (3,000 to 4,700 cases per million progeny per Gy of parental irradiation) are about 0.4 percent to 0.6 percent of the background frequency (730,000 per million) (UNSCEAR. 2001).

If a population is exposed to 1 Gy of parental radiation in every generation, the risk in the second generation (including the accumulated risk from the first generation) is higher, but still constitutes only about 0.5 percent to 0.9 percent of the background frequency. Based on these risk assessments, it is predicted that no increase in germinal mutations would be detectable above the spontaneous incidence for the atomic-bomb survivors (UNSCEAR, 2001).

A.2 Cancer Risks Attributable to Low Doses of Ionizing Radiation

A.2.1 *Acute Low-dose Exposures*

The epidemiological studies for acute, low-dose exposures with by far the highest statistical power are those related to the atomic-bomb survivors. Both cancer incidence (Pierce and Preston, 2000) and cancer mortality (Pierce *et al.*, 1996) have been studied, as well as non-cancer related mortality (Shimizu *et al.*, 1999). The atomic-bomb survivors were exposed to a variety of radiation doses, from very high to very low.

In the most recent published report (Pierce *et al*., 1996) on cancer mortality in the life-span study cohort (1950-1990), the individuals in the equivalent dose category from 5 to 50 mSv show a significant (*p*=0.02) increase in solid-cancer related mortality. The lowest dose category in the exposed population (5 to 20 mSv) is associated with an increased cancer mortality risk, though imprecisely characterized (excess relative risk 0.026 ± 0.021). There is the possibility of bias in these low-dose cancer mortality risk estimates, for example from possible differential recording of cancer mortality as a function of distance from the explosion. There is less potential for such bias in the cancer incidence studies, and the atomic-bomb survivors in the equivalent dose range from 5 to 100 mSv show a significantly increased solid cancer incidence (p=0.05) compared with the population that was exposed to less than 5 mSv (Pierce and Preston, 2000).

The atomic-bomb survivor data discussed above is, of course, an average over individuals of all ages. One approach to improving the precision of the estimated risks at lower doses is to focus on exposed children, or individuals exposed *in utero*. The reasoning here is the expectation that the risks associated with such exposures would be higher, because of the larger proportion of actively dividing cells with decreasing age, and also because of the longer time available for a potential cancer actually to be expressed.

Two examples here are the study of thyroid cancer from external irradiation of children, and the study of childhood cancer after medical diagnostic exposures to the fetus. A pooled analysis (Ron *et al.*, 1995) of five separate studies showed clear evidence for an increased risk of thyroid cancer at a mean thyroid absorbed dose of 50 mGy (absorbed dose interval 10 to 90 mGy). There have been many analyses of cancer rates following medical diagnostic fetal irradiation; a recent detailed analysis of the various studies of the risk of childhood cancers from acute *in utero* absorbed doses of about 10 mGy concluded that such doses do cause a statistically significant increase in the risk of childhood cancer (Doll and Wakeford, 1997).

A.2.2 *Protracted Low-dose Exposures*

Much attention has been given to studies of radiation workers who were chronically exposed to low radiation doses. A three-country study (*i.e.*, United States, Canada and United Kingdom) (Cardis *et al.*, 1995), a United Kingdom (U.K.) study (Muirhead *et al*., 1999), and Canadian studies (Ashmore *et al*., 1998; Sont *et al*., 2001) have been reported, and all the studies have been reviewed by Gilbert (2001). Statistically significant excess cancer incidence and mortality risks for solid cancers were found in the Canadian studies (mean effective dose of 6.5 mSv). However, neither the three-country study nor the U.K. study (both of which had higher mean doses: 40 mSv and 30 mSv, respectively) showed a statistically significant increase in solid cancer risk, although the U.K. study did show statistical significance on the basis of a trend with dose. All three studies suggested an increased risk for leukemia, which was statistically significant in the three-country study, borderline significant in the U.K. study, and non-significant in the Canadian studies.

As with the acute exposures, it is helpful here to look at situations in which children were exposed, as the risks are expected to be higher, and therefore more easily detectable at low doses. The U.S. scoliosis cohort study (Morin Doody *et al*., 2000) of females under age 20 exposed to multiple diagnostic x rays (mean breast absorbed dose of 108 mGy in 25 exposures) demonstrated a statistically significant increased risk for breast cancer; the excess risk was still statistically significant when the analysis was limited to individuals with breast doses between 10 and 90 mGy. In addition, the scalp ringworm study of Ron *et al*. (1989) demonstrated a statistically significant increase in thyroid cancer risk in individuals who were exposed as children to fractionated doses (five daily fractions, mean total thyroid absorbed dose of 90 mGy); the excess risk was still statistically significant when the analysis was limited to individuals with thyroid doses between 50 and 80 mGy.

A.2.3 *Radiation Sensitive Subgroups*

There are several groups of individuals who are significantly more sensitive than average, and these may need special consideration:

- Infants and children;
- Individuals with genetically based hypersensitivity to ionizing radiation;
- The developing embryo or fetus of a pregnant woman.

The risk for radiation-induced cancer increases with decreasing age at time of exposure (ICRP, 1991). Very roughly, a neonate is about three times more sensitive than a 25 year old adult.

There is reasonable evidence that three to five percent of the population is significantly more sensitive to ionizing radiation than average (*e.g.*, Schultheiss *et al.*, 1995), and it has long been speculated that this hypersensitivity is genetically based. It is important to note that there is not as yet direct evidence for human subgroups that have increased susceptibility to radiation-induced cancer, although there is suggestive evidence from oncogenic transformation studies of *ATM* heterozygote mouse embryos (Smilenov *et al.*, 2001). However, it is too early in the scientific research on this hypersensitivity to be able to take into account the significance of radiosensitive subgroups (ICRP, 1998), and risk estimates for the general population might currently be sufficiently stringent to protect these subgroups.

The developing embryo and fetus are especially sensitive to ionizing radiation. Risk estimates for congenital malformations and functional impairment after *in utero* exposure are typically an order of magnitude higher than those for radiation-induced cancer. It may well be that deterministic endpoints such as congenital malformations have a threshold in dose, below which the risk is zero. Visual inspection of the data often suggests that a threshold may exist, but little statistical support is available, except in the case of mental retardation (Otake and Schull, 1998).

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