NORTHERN ARIZONA UNIVERSITY

X-Ray Safety Manual

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***Contact and additional program information for the NAU Radiation Safety Officer and X-ray safety program are available on the NAU EH&S website. http://nau.edu/Research/Compliance/Environmental-Health-and-Safety/ or by using the EH&S Switchboard (928)-523-7288 or regulatorycompliance@nau.edu**

Scope and Applicability

NAU procures and uses analytical x-ray equipment under regulations issued by the Arizona Radiation Regulatory Agency (AZRRA). Use of this equipment at NAU is subject to inspection and review by personnel from AZRRA and regulations require that NAU personnel use AZRRA approved procedures for the control of all analytical x-ray equipment. AZRRA also requires that analytical x-ray equipment be registered with that agency. If AZRRA finds that NAU is not in compliance with state regulations, they may issue fines, or in the case of serious infractions, suspend or revoke analytical x-ray equipment use campus wide. In order to ensure compliance with Arizona regulations for the control of ionizing radiation, it is essential that NAU personnel understand and follow the provisions of NAU's x-ray safety program.

This Program applies to all personnel working at or visiting NAU who procure or utilize analytical x-ray equipment. The Arizona Radiation Regulatory Agency defines analytical x-ray equipment as any device which utilizes x-rays for examining the structure and/or composition of materials. This includes x-ray diffraction and x-ray fluorescence analysis equipment.

AZRRA Rules and Regulations, and supporting documentation are on file in the Office of Radiation Safety and are available for review by NAU personnel.

Section I - Overview of Safety Requirements for Analytical X-Ray Equipment

1.1 Acquisition and registration of X-Ray Equipment

Registrants seeking to purchase or acquire X-Ray equipment must either purchase this equipment using the NAU purchasing codes below, or independently contact NAU EH&S for guidance before proceeding. Registration for all Analytical x-ray equipment must be kept on file with the NAU Office of Environmental Health and Safety (EH&S), who will register the equipment with AZRRA. The registrant must be a full time faculty, academic professional, or staff member at NAU who bears overall responsibility for safe use of registered equipment. New equipment must be registered prior to operation. The NAU codes for ordering new x-ray or X-Ray Equipment are:

89800	X-Ray/Radiological Equipment (Not Dental) Non Capital <$5K
89868	X-Ray and Radiological Equipment (Recycled)
89880	X-Ray/Radiological Equipment (Except Dental) Capital >$5K
89899	X-Ray/Radiological Supplies

1.2 Training

All individuals operating analytical x-ray equipment must obtain training on the hazards associated with the equipment and proper safety control measures. NAU offers an online training for general X-ray safety (Link Coming Soon). Completion of this training plus any equipment or department specific training must be completed prior to operation of the equipment by an individual.

1.3 Safety Control Measures

Analytical x-ray equipment must be operated under administrative and/or engineering control measures approved by NAU EH&S or the Radiation Safety Officer. Where applicable, these measures shall include written procedures for operation and alignment, periodic testing of interlocks and safety devices, proper labeling of equipment and posting of rooms, and limits on radiation fields produced by the equipment.

1.4 Safety Surveys

Periodic safety surveys of analytical x-ray equipment will be conducted by NAU EH&S staff.

Section II - Radiation Safety Organization at NAU

2.1 Radiation Safety Committee

NAU governs the use of analytical x-ray equipment through the Radiation Safety Committee. This committee is a group of professionals at NAU to establish policy and regulations for the use of radiation sources and to oversee all aspects of radiation safety. The committee meets when necessary to review activity or changes to the university's radiation safety program.

2.2 Radiation Safety Officer

The Radiation Safety Officer is responsible for designing and implementing the radiation safety program elements as decided upon by the RSC. He is assisted by the staff of NAU EH&S.

Specific duties of the Radiation Safety Officer and his staff include:

a. Furnishing consulting services on all aspects of radiation safety and protection.
b. Conducting surveys and making hazard evaluations for analytical x-ray equipment.
c. Assuring that the prescribed control measures are in effect, recommending or approving substitute or alternate control measures when the primary ones are not feasible or practical, and periodically auditing the status of those control measures in use.
d. Approving standard operating procedures, alignment procedures, and other procedures that may be part of the requirements for administrative and procedural control measures.
e. Distributing and processing personnel monitoring devices, and maintaining personnel exposure records.
f. Insuring that personnel are properly instructed in the appropriate procedures for using analytical x-ray equipment.
g. Maintaining a current inventory of all analytical x-ray equipment at NAU.
h. Ensure that NAU maintains compliance with all applicable state and federal laws related to X-ray and radiation safety.

The Radiation Safety Officer has the authority to restrict or terminate use of X-Ray Equipment in cases where use is determined to be in violation of regulations or otherwise represents a radiological hazard. Such actions may be reviewed by the Radiation Safety Committee when needed.

2.3 Registrants

All analytical x-ray equipment at NAU must be registered with NAU EH&S, who in turn maintains the required device registrations with AZRRA. All analytical x-ray equipment must be registered to a faculty, academic professional, or staff member of NAU who maintains responsibility for all aspects of safety for the registered equipment. Specific responsibilities of the registrant include:

a. Registration of new equipment with the Radiation Safety Officer/NAU EH&S within 30 days of receipt and prior to operation.
b. Ensuring that operators are properly trained and made aware of hazards associated with the equipment prior to operation of the equipment. Required training may require EH&S administered online or in person training for x-ray devices as well as lab specific training administered by the registrant.

2.4 Operators

Individuals who operate analytical x-ray equipment must obtain safety training from NAU EH&S prior to use of the equipment. They must also obtain instruction from the registrant on specific operating procedures for the equipment.

Section III – Registration and Use of Equipment

3.1 Registration of Analytical X-Ray Equipment

All analytical x-ray equipment at NAU must be registered with the Radiation Safety Officer/NAU EH&S. Registrants must be full time faculty, academic professional, or staff of NAU.

Analytical x-ray equipment is registered by contacting the Radiation Safety Officer or NAU EH&S, who will schedule a site inspection/consultation before filing the required equipment registration with AZRRA. Registration shall be completed within 30 days of receipt of new equipment or reconfiguration of existing equipment, and prior to operation of the equipment.

3.2 Training Required for Operators

NAU EH&S offers online X-ray Safety training which is mandatory for all authorized equipment operators. This training is designed to cover basic safety issues which are consistent with all x-ray equipment. This training is intended to be complemented with equipment or site specific training which is performed by the Registrant for all authorized users on his/her equipment**.**

Operators must receive training in the following topics:

a. Types and amounts of radiation to which workers could be exposed;
b. Health effects of exposure to low doses of ionizing radiation;
c. Precautions and procedures to minimize exposure to ionizing radiation;
d. Applicable provisions of AZRRA Rules and Regulations, and rules and regulations established by NAU;
e. Responsibilities of personnel using X-Ray Equipment including the need to bring violations of AZRRA and NAU Rules and Regulations to the attention of NAU EH&S;
f. Response in the event of exposures to radiation and other emergencies;
g. Rights of workers to have access to radiation exposure records.
h. Correct procedures for safe and effective operation of the analytical x-ray equipment.

Section IV - Personnel Dosimetry

In instances which operators may be partially or completely within the regulated area during operation or maintenance of x-ray equipment (IE no shielding between equipment and operator), exposure monitoring may be required. Determination of the need for exposure monitoring will be made by the Radiation Safety Officer at the time of the initial registration, during consultation for changes to device or safety equipment configuration, or during periodic audits.

4.1 TLD Badges

TLD badges are used at NAU to monitor personnel for exposure of the body to penetrating ionizing radiation such as gamma and x-rays, and exposure of the skin to less penetrating radiation such as beta particles. For most individuals, results of the TLD badge readings are also used as estimates for the exposure of the lens of the eye. TLD badges are required for operators of most analytical x-ray equipment at NAU. They are not required for some cabinet type equipment.

TLD badges must be worn on the trunk of the body at or above the waist. Dosimetry devices must not be taken home or left in laboratory areas where they may be exposed to radiation or excessive heat or humidity.

4.2 Extremity Dosimetry

Ring dosimetry devices are used at NAU to monitor for radiation exposure to the hands are issued to most personnel using analytical x-ray equipment. Ring badges must be worn with the sensitive portion of the ring towards the source.

4.3 Dosimeter Exchange

TLD badges and rings are exchanged on a quarterly basis. NAU EH&S personnel hand deliver badges and rings to department offices during the last few days of each quarter. Used dosimetry devices must be picked up by, or hand delivered to NAU EH&S. Dosimetry devices should be returned to NAU EH&S during the first 5 working days of the new quarter. Campus mail must not be used. This policy has been established to avoid exposure of TLDs and rings to sources of radiation, heat, and humidity during transit and maintain the chain of custody.

4.4 Lost or Damaged Dosimeters

Periodically, dosimetry devices are lost or damaged. This should be reported to NAU EH&S staff immediately so that replacement dosimeters can be issued.

4.5 Regulatory Dose Limits

4.5.1 Limits for Radiation Workers

AZRRA has imposed limits on the dose of ionizing radiation which may be received by individuals working with sources of ionizing radiation. These limits are shown in Table 4-1.

Annual Limit, whichever is the more limiting between:

a. Total Effective Dose Equivalent
b. Sum of the deep dose equivalent and committed dose equivalent to any organ or tissue other than the lens of the eye

Annual Limit, which is the more limiting of: a. Total Effective Dose Equivalent b. Sum of the deep dose equivalent and committed dose equivalent to any organ or tissue other than the lens of the eye	 5 rem (0.05 Sv) 50 rem (0.5 Sv)
Eye Dose Equivalent	15 rem (0.15 Sv)
Shallow Dose Equivalent to the skin or to each of the extremities	50 rem (0.5 Sv)

Table 4-1 Regulatory Dose Limits

4.5.2 Limits to the Embryo-Fetus of Declared Pregnant Workers

Due to concerns about prenatal radiation exposure (See Appendix A) AZRRA regulations provide separate limits for the embryo/fetus of Declared Pregnant Workers. The limit is 0.5 rem dose equivalent to the fetus during pregnancy. This limit applies only for workers who have formally declared pregnancy. In addition to other recipients, declaration of pregnancy should be sent to the Radiation Safety Officer and include the estimated date of conception.

Individuals concerned about radiation and pregnancy should feel free to speak to the Radiation Safety Officer.

4.5.3. Limits for Members of the Public

The regulatory limit for members of the public is 0.1 rem total effective dose equivalent per year. This limit applies to all individuals who are not trained to work with sources of ionizing radiation. At NAU this includes most faculty, staff and students.

4.6 ALARA

In view of uncertainties that exist concerning the health effects of exposure to low doses of Radiation (see Appendix B), it is prudent to keep doses to personnel "as low as is reasonably achievable" (ALARA). Each user of radiation sources at NAU has the responsibility to incorporate shielding and protective devices, and to take any other steps required to keep doses ALARA.

4.7 Investigation Levels

In order to maintain ALARA levels of exposure, investigational levels have been established at NAU. These dose levels are shown in Table 4-2.

Personnel exposures equal to or greater than investigational Level I, are reviewed by the RSO, who reports the results to the RSC at their next regularly scheduled meeting. The RSC may require corrective actions on the part of the RSO or registrant.

Personnel exposures equal to or exceeding Investigational Level II are investigated in a timely manner by the RSO who takes immediate action if warranted. A report of the investigation, actions taken, and a copy of the individual's radiation dosimetry history is included in that individuals records, and a report with personal data redacted may be presented to the RSC at their next scheduled meeting following completion of the investigation. The RSC may impose restrictions on future use as warranted.

Investigational limits exceeding those listed in Table 4-2 may be established by the RSC for a worker or group of workers when the higher investigational levels are consistent with good ALARA practice for the work being conducted by the individual or group.

Limit	**Level (rem/quarter)**	
	Level I	**Level II**
Total Effective Dose Equivalent	0.065	0.200
Eye Dose Equivalent	0.180	0.600
Shallow Dose Equivalent to the Skin or to each of the Extremities	0.625	2.000

Table 4-2 Investigational Dose Levels

4.8 Reports to Workers on Radiation Dosimetry

NAU EH&S maintains records on results of radiation dosimetry for personnel enrolled in the NAU dosimetry program. Individual records are available for review by these personnel.

4.8.1 Review of Records in EH&S

Personnel issued dosimeter devices are welcome to review dosimetry results on file with NAU EH&S. This review should be arrnged with the RSO. Personnel must present positive identification before gaining access to dosimetry results since these records are covered by state and federal privacy laws.

4.8.2 Annual Dosimetry Report

During the spring of each year, a report on dosimetry results for the previous calendar year is sent to each individual issued dosimeters at NAU. A summary of dosimetry results with personal information redacted is also sent to the registrant responsible for supervising the work requiring dosimetry.

4.8.3 Notification of Results Exceeding Investigation Limits

Personnel are notified quickly of results which exceed Investigation Levels listed in Table 4-2. Personnel are not notified quarterly of routine dosimetry results which do not exceed the Investigation Levels.

4.9 Radiation Dosimetry Units

The following paragraphs explain the dosimetry units used in this chapter.

4.9.1 Absorbed Dose

The amount of energy absorbed by irradiated tissue is an important variable in the assessment of radiation risk and damage. The absorbed dose is defined as the energy absorbed per unit mass of tissue. The traditional unit for absorbed dose is the rad.

1 rad = 100 erg / gram

The rad is being replaced by a new unit based on the International System of Units (SI). The new unit is the Gray.

1 Gray = 1 joule / kg

Spending a little time with the units will reveal that

1 Gray = 100 rad

4.9.2 Dose Equivalent

Alpha, beta, gamma/x-radiation, and neutrons differ in the damage produced for a given absorbed dose. Special units of dose equivalent are used to adjust the absorbed dose for this difference. The traditional unit of dose equivalent is the rem.

1 rem = 1 rad x Q

Q is called the quality factor and is assigned to radiation based on the relative risk for a given dose. Currently, a quality factor of 1 is used for photons, electrons, and positrons. A quality factor of from 2.3 to 10 is used for neutrons, depending on their energy, and a quality factor of 20 is used for alpha particles. The SI unit for dose equivalent is the Sievert.

1 Sievert = 1 Gray x Q

RADIATION TYPE	Q
x and gamma rays	1
beta particles	1
alpha particles	20
neutrons	2.3 to 10

Table 4-3 Radiation Quality Factors

4.9.3 Exposure

The energy absorbed by irradiated tissue is rarely measured directly. Most radiation detection instrumentation used in radiation protection measures the number of ion pairs produced in a volume of gas. The traditional unit used to measure ionization in air is the roentgen:

1 Roentgen = 2.58×10^{4} coulombs / kg air

The roentgen is defined only for x-rays and gamma rays. It is not used for beta, alpha, or neutron radiation.

Exposure of 1 roentgen of radiation results in an absorbed dose to tissue of 0.97 rad. For purposes of radiation protection and dosimetry, it is usually assumed that the roentgen, rad, and rem are numerically equivalent for gamma rays and x-rays.

4.9.4 Effective Dose Equivalent

The various organs and tissues in the body differ in their sensitivity to radiation. The bone marrow and other blood forming tissues of the body are much more sensitive to radiation than the skin. In order to quantify the risk from radiation exposure when the body is not irradiated uniformly (different doses are delivered to different organs or tissues) a unit called the effective dose equivalent has been developed. The effective dose equivalent is given the symbol H and is defined as:

$$H = \sum D_i W_i$$

Where DI is the dose equivalent received by the *i*th tissue or organ, and WI is a weighting factor which is assigned to the *i*th tissue or organ depending on its sensitivity to radiation. Weighting factors currently in use are listed in the accompanying table. The units of the effective dose equivalent are the rem and the Sievert depending on which is used for the individual tissue or organ dose equivalent.

TISSUE	WEIGHTING FACTOR
Gonads	0.25
Breast	0.15
Red Bone Marrow	0.12
Lung	0.12
Thyroid	0.03
Bone Surfaces	0.03
Remainder	0.30
Whole Body	1.00
The 0.30 for remainder results from 0.06 for each of 5 remaining organs, excluding the skin and the lens of the eye, that receive the highest doses.	

Table 4-4 Effective Dose Equivalent Weighting Factors

4.9.5 Committed Effective Dose Equivalent

When radioactive materials are inhaled, ingested, or otherwise internalized, they may be retained in some tissues for a long period of time. In some cases a fraction of the material may remain in the body for years. The committed effective dose equivalent is the effective dose equivalent that will be received from an intake of radioactive material by an individual during the 50 year period following the intake.

4.9.6 Deep Dose Equivalent

The deep dose equivalent is the dose equivalent at a tissue depth of 1 cm.

4.9.7 Shallow Dose Equivalent
The shallow dose equivalent is the dose equivalent at a tissue depth of 0.0007 cm averaged over an area of 1 square centimeter.

4.9.8 Eye Dose Equivalent
The eye dose equivalent is the dose equivalent to the lens of the eye.

4.9.9 Total Effective Dose Equivalent
The total effective dose equivalent is the sum of the committed effective dose equivalent for all intakes of radioactive material and the deep dose equivalent to the whole body resulting from exposure to external sources of radiation.

Section V - Radiation Control Measures for Analytical X-Ray Equipment

5.1 Administrative Requirements for Use of Analytical X-Ray Equipment

5.1.1. Registration
Analytical x-ray equipment at NAU must be registered to a single member of the faculty, academic professional, or staff who bears responsibility for safe use of the equipment by all other individuals (Refer to Section III).

5.1.2. Notification of Receipt of Equipment
NAU EH&S must be notified within 30 working days of the receipt of analytical x-ray equipment or reconfiguration of existing equipment (Refer to Section III).

5.1.3. Radiation Surveys of Equipment
After initial installation, and upon completion of alterations or maintenance, NAU EH&S must conduct a survey for radiation leakage before the unit may be placed in service. Surveys may be scheduled through by contacting the RSO, or NAU EH&S.

5.1.4. Maintenance
Only maintenance personnel with adequate training to perform the task may install, repair, or make other than routine changes to the x-ray generating apparatus and the tube housing apparatus.

5.1.5 Testing of Safety Devices
Safety interlocks and other safety devices will be tested semi-annually by registrants. Records of these tests should be kept with the equipment by the registrant for review by Office of Radiation Safety or AZRRA personnel. Device interlock inspections forms may be downloaded from the EH&S website. (Provide link to form)

5.1.6. Emergency Procedures
Written emergency procedures pertaining to radiation safety shall be established for each x-ray producing apparatus. Emergency Procedures must be approved by the Radiation Safety Officer and posted in a conspicuous location. These procedures shall list the telephone number(s) of the Radiation Safety Officer, telephone number of the responsible registrant for that equipment, and at a minimum include the following actions to be taken in case of a known, or suspected accident involving radiation exposure:

a. Notify the Radiation Safety Officer, and
b. Arrange for medical examination.

In the event of a known or suspected accidental exposure exceeding established exposure limits, operators must immediately follow the posted emergency procedures. If medical attention or treatment is required,

arrangements for medical intervention shall be made first. Notifications to the Radiation Safety Officer and Registrant may be made once the medical needs of the exposed party are met.

5.1.7. Unattended Use of Equipment

Analytical x-ray equipment must not be left unattended while energized unless:

a. An interlock device is provided to prevent accidental entry into the primary beam, and
b. The stray radiation at any accessible point at a distance of 10 inches from the tube housing containment, as measured with monitoring instrument appropriate for the energy range generated, is no greater than 2mR per hour.

5.2 Equipment Requirements

5.2.1. Labeling

All analytical x-ray equipment must be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:

a. "**CAUTION - HIGH INTENSITY X-RAY BEAM**", or words having a similar intent, on the x-ray source housing; and
b. "**CAUTION - RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED**", or words having similar intent, near any switch that energizes an x-ray tube.

5.2.2. Visual Indicators

a. The primary on-off switch for each tube must include a visual indication of the tube status, in the form of a warning light on the control console and a warning light on the tube housing, wired so that the x-ray tube cannot be energized if the warning light fails. Such lights must operate at all times when the tube is energized and must light at no other times.

b. A shutter status (open or closed) indication must be provided in the area adjacent to the tube head so that the position of the shutter is readily discernible.

5.2.3. Interlocks

a. An interlock device which prevents entry of limbs, fingers, hands, wrists, etc., into the primary beam or causes the primary beam to be shut off, must be utilized, unless otherwise approved by the Radiation Safety Officer.
b. In the event that an interlock is activated, it must not be possible to resume operation without resetting the beam "**ON**" switch at the control panel.

5.2.4. Beam Shutters

On open-beam configurations, each port on the radiation source housing must be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

5.3. Facility Requirements

5.3.1. Dedicated Work Space

a. X-ray diffraction and spectrographic equipment must be operated in a dedicated work space/room separate from other work areas, unless otherwise approved by the Radiation Safety Officer or NAU EH&S.
b. Access to rooms containing analytical x-ray equipment must be secured, or the unit itself must be secured to prevent unauthorized use of equipment.
c. All installations must display warning signs on the outside of all entrances to the room. Warning signs may be requested by contacting NAU EH&S.

5.4. Radiation Limits

5.4.1. General

The local components of an analytical x-ray system must be located and arranged, and must include sufficient shielding or access control such that no radiation levels in excess of 80 mR per hour will exist in areas accessible to the fingers, hands, or forearms, or in excess of 5 mR per hour will exist in areas accessible to the whole body, lens of the eyes, blood forming organs, or gonads. When analytical x-ray equipment is placed in a room utilized by personnel other than operators of the x-ray producing equipment, the limits for these radiation levels will be reduced by a factor of twenty.

5.4.2. Other Radiation Limits

a. Each x-ray tube housing must be so constructed that with all shutters closed the leakage radiation measured at a distance of 5 cm from its surface is not capable of producing a dose in excess of 2.5 mrem in one hour at any specified tube rating.
b. Each x-ray generating device must be supplied with a protective cabinet which limits leakage radiation measured at a distance of 5 cm from its surface such that it is not capable of producing a dose in excess of 0.25 mrem in one hour.
c. Any apparatus utilized in beam alignment procedures must be designed in such a way that excessive radiation will not strike the operator. Particular attention should be given to viewing devices, in order to ascertain that lenses and other transparent components attenuate the beam to an acceptable level.

5.5 Requirements of Users

5.5.1. Training and Other Responsibilities

No individual will be permitted to act as an operator of a particular instrument prior to completing an acceptable amount of training in the correct use of specific equipment and in radiation safety (refer to Section III). Operators are responsible for:

a. Keeping radiation exposure to themselves and others as low as is practical.
b. Being familiar with safety procedures as they apply to each instrument.
c. Wearing of personnel monitoring devices, if required.
d. Notifying the Radiation Safety Officer of known or suspected excessive radiation exposures.

5.5.2. Bypassing or Altering Interlocks and Safety Devices

If it becomes necessary to temporarily intentionally alter safety devices, such as bypassing interlocks or removing a shield, such action shall be:

a. Specified in writing and posted near the x-ray tube housing so that other persons will know the existing status of the machine.
b. Approved by EH&S or the Radiation Safety Officer prior to proceeding.
c. Terminated as soon as possible.

5.5.3. Other

a. Personnel must not expose any part of their body to the primary beam.
b. Unused tube head ports must be secured in the closed position. These must be checked prior use when the machine has been left unattended.

Appendix A: U.S.N.R.C INSTRUCTION CONCERNING PRENATAL RADIATION EXPOSURE

U.S. NUCLEAR REGULATORY COMMISSION

Revision 3
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REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 8.13

(Draft was issued as DG-8014)

INSTRUCTION CONCERNING PRENATAL RADIATION EXPOSURE

A. INTRODUCTION

The Code of Federal Regulations in 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," in Section 19.12, "Instructions to Workers," requires instruction in "the health protection problems associated with exposure to radiation and/or radioactive material, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed." The instructions must be "commensurate with potential radiological health protection problems present in the work place."

The Nuclear Regulatory Commission's (NRC's) regulations on radiation protection are specified in 10 CFR Part 20, "Standards for Protection Against Radiation"; and 10 CFR 20.1208, "Dose to an Embryo/Fetus," requires licensees to "ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv)." Section 20.1208 also requires licensees to "make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman." A declared pregnant woman is defined in 10 CFR 20.1003 as a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

This regulatory guide is intended to provide information to pregnant women, and other personnel, to help them make decisions regarding radiation exposure during pregnancy. This Regulatory Guide 8.13 supplements Regulatory Guide 8.29, "Instruction Concerning Risks from Occupational Radiation Exposure" (Ref. 1), which contains a broad discussion of the risks from exposure to ionizing radiation.

Other sections of the NRC's regulations also specify requirements for monitoring external and internal occupational dose to a declared pregnant woman. In 10 CFR 20.1502, "Conditions Requiring Individual Monitoring of External and Internal Occupational Dose," licensees are required to monitor the occupational dose to a declared pregnant woman, using an individual monitoring device, if it is likely that the declared pregnant woman will receive, from external sources, a deep dose equivalent in excess of 0.1 rem (1 mSv). According to Paragraph (e) of 10 CFR 20.2106, "Records of Individual Monitoring Results," the licensee must maintain records of dose to an embryo/fetus if monitoring was required, and the records of dose to the embryo/fetus must be kept with the records of dose to the declared pregnant woman. The declaration of pregnancy must be kept on file, but may be maintained separately from the dose records. The licensee must retain the re-

quired form or record until the Commission terminates each pertinent license requiring the record.

The information collections in this regulatory guide are covered by the requirements of 10 CFR Parts 19 or 20, which were approved by the Office of Management and Budget, approval numbers 3150-0044 and 3150-0014, respectively. The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

B. DISCUSSION

As discussed in Regulatory Guide 8.29 (Ref. 1), exposure to any level of radiation is assumed to carry with it a certain amount of risk. In the absence of scientific certainty regarding the relationship between low dose exposure and health effects, and as a conservative assumption for radiation protection purposes, the scientific community generally assumes that any exposure to ionizing radiation may cause undesirable biological effects and that the likelihood of these effects increases as the dose increases. At the occupational dose limit for the whole body of 5 rem (50 mSv) per year, the risk is believed to be very low.

The magnitude of risk of childhood cancer following in utero exposure is uncertain in that both negative and positive studies have been reported. The data from these studies "are consistent with a lifetime cancer risk resulting from exposure during gestation which is two to three times that for the adult" (NCRP Report No. 116, Ref. 2). The NRC has reviewed the available scientific literature and has concluded that the 0.5 rem (5 mSv) limit specified in 10 CFR 20.1208 provides an adequate margin of protection for the embryo/fetus. This dose limit reflects the desire to limit the total lifetime risk of leukemia and other cancers associated with radiation exposure during pregnancy.

In order for a pregnant worker to take advantage of the lower exposure limit and dose monitoring provisions specified in 10 CFR Part 20, the woman must declare her pregnancy in writing to the licensee. A form letter for declaring pregnancy is provided in this guide or the licensee may use its own form letter for declaring pregnancy. A separate written declaration should be submitted for each pregnancy.

C. REGULATORY POSITION

1. Who Should Receive Instruction

Female workers who require training under 10 CFR 19.12 should be provided with the information contained in this guide. In addition to the information contained in Regulatory Guide 8.29 (Ref. 1), this information may be included as part of the training required under 10 CFR 19.12.

2. Providing Instruction

The occupational worker may be given a copy of this guide with its Appendix, an explanation of the contents of the guide, and an opportunity to ask questions and request additional information. The information in this guide and Appendix should also be provided to any worker or supervisor who may be affected by a declaration of pregnancy or who may have to take some action in response to such a declaration.

Classroom instruction may supplement the written information. If the licensee provides classroom instruction, the instructor should have some knowledge of the biological effects of radiation to be able to answer questions that may go beyond the information provided in this guide. Videotaped presentations may be used for classroom instruction. Regardless of whether the licensee provides classroom training, the licensee should give workers the opportunity to ask questions about information contained in this Regulatory Guide 8.13. The licensee may take credit for instruction that the worker has received within the past year at other licensed facilities or in other courses or training.

3. Licensee's Policy on Declared Pregnant Women

The instruction provided should describe the licensee's specific policy on declared pregnant women, including how those policies may affect a woman's work situation. In particular, the instruction should include a description of the licensee's policies, if any, that may affect the declared pregnant woman's work situation after she has filed a written declaration of pregnancy consistent with 10 CFR 20.1208.

The instruction should also identify who to contact for additional information as well as identify who should receive the written declaration of pregnancy. The recipient of the woman's declaration may be identified by name (e.g., John Smith), position (e.g., immediate supervisor, the radiation safety officer), or department (e.g., the personnel department).

4. Duration of Lower Dose Limits for the Embryo/Fetus

The lower dose limit for the embryo/fetus should remain in effect until the woman withdraws the declaration in writing or the woman is no longer pregnant. If a declaration of pregnancy is withdrawn, the dose limit for the embryo/fetus would apply only to the time from the estimated date of conception until the time the declaration is withdrawn. If the declaration is

not withdrawn, the written declaration may be considered expired one year after submission.

5. Substantial Variations Above a Uniform Monthly Dose Rate

According to 10 CFR 20.1208(b), "The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in paragraph (a) of this section," that is, 0.5 rem (5 mSv) to the embryo/fetus. The National Council on Radiation Protection and Measurements (NCRP) recommends a monthly equivalent dose limit of 0.05 rem (0.5 mSv) to the embryo/fetus once the pregnancy is known (Ref. 2). In view of the NCRP recommendation, any monthly dose of less than 0.1 rem (1 mSv) may be considered as not a substantial variation above a uniform monthly dose rate and as such will not require licensee justification. However, a monthly dose greater than 0.1 rem (1 mSv) should be justified by the licensee.

D. IMPLEMENTATION

The purpose of this section is to provide information to licensees and applicants regarding the NRC staff's plans for using this regulatory guide.

Unless a licensee or an applicant proposes an acceptable alternative method for complying with the specified portions of the NRC's regulations, the methods described in this guide will be used by the NRC staff in the evaluation of instructions to workers on the radiation exposure of pregnant women.

REFERENCES

1. USNRC, "Instruction Concerning Risks from Occupational Radiation Exposure," Regulatory Guide 8.29, Revision 1, February 1996.

2. National Council on Radiation Protection and Measurements, *Limitation of Exposure to Ionizing Radiation*, NCRP Report No. 116, Bethesda, MD, 1993.

provides an adequate margin of protection for the embryo/fetus. This dose limit reflects the desire to limit the total lifetime risk of leukemia and other cancers. If this dose limit is exceeded, the total lifetime risk of cancer to the embryo/fetus may increase incrementally. However, the decision on what level of risk to accept is yours. More detailed information on potential risk to the embryo/fetus from radiation exposure can be found in References 2-10.

8. What effect will formally declaring my pregnancy have on my job status?

Only the licensee can tell you what effect a written declaration of pregnancy will have on your job status. As part of your radiation safety training, the licensee should tell you the company's policies with respect to the job status of declared pregnant women. In addition, before you declare your pregnancy, you may want to talk to your supervisor or your radiation safety officer and ask what a declaration of pregnancy would mean specifically for you and your job status.

In many cases you can continue in your present job with no change and still meet the dose limit for the embryo/fetus. For example, most commercial power reactor workers (approximately 93%) receive, in 12 months, occupational radiation doses that are less than 0.5 rem (5 mSv) (Ref. 11). The licensee may also consider the likelihood of increased radiation exposures from accidents and abnormal events before making a decision to allow you to continue in your present job.

If your current work might cause the dose to your embryo/fetus to exceed 0.5 rem (5 mSv), the licensee has various options. It is possible that the licensee can and will make a reasonable accommodation that will allow you to continue performing your current job, for example, by having another qualified employee do a small part of the job that accounts for some of your radiation exposure.

9. What information must I provide in my written declaration of pregnancy?

You should provide, in writing, your name, a declaration that you are pregnant, the estimated date of conception (only the month and year need be given), and the date that you give the letter to the licensee. A form letter that you can use is included at the end of these questions and answers. You may use that letter, use a form letter the licensee has provided to you, or write your own letter.

10. To declare my pregnancy, do I have to have documented medical proof that I am pregnant?

NRC regulations do not require that you provide medical proof of your pregnancy. However, NRC regulations do not preclude the licensee from requesting medical documentation of your pregnancy, especially if a change in your duties is necessary in order to comply with the 0.5 rem (5 mSv) dose limit.

11. Can I tell the licensee orally rather than in writing that I am pregnant?

No. The regulations require that the declaration must be in writing.

12. If I have not declared my pregnancy in writing, but the licensee suspects that I am pregnant, do the lower dose limits apply?

No. The lower dose limits for pregnant women apply only if you have declared your pregnancy in writing. The United States Supreme Court has ruled (in *United Automobile Workers International Union v. Johnson Controls, Inc.*, 1991) that "Decisions about the welfare of future children must be left to the parents who conceive, bear, support, and raise them rather than to the employers who hire those parents" (Reference 7). The Supreme Court also ruled that your employer may not restrict you from a specific job "because of concerns about the next generation." Thus, the lower limits apply only if you choose to declare your pregnancy in writing.

13. If I am planning to become pregnant but am not yet pregnant and I inform the licensee of that in writing, do the lower dose limits apply?

No. The requirement for lower limits applies only if you declare in writing that you are already pregnant.

14. What if I have a miscarriage or find out that I am not pregnant?

If you have declared your pregnancy in writing, you should promptly inform the licensee in writing that you are no longer pregnant. However, if you have not formally declared your pregnancy in writing, you need not inform the licensee of your nonpregnant status.

15. How long is the lower dose limit in effect?

The dose to the embryo/fetus must be limited until you withdraw your declaration in writing or you inform the licensee in writing that you are no longer pregnant. If the declaration is not withdrawn, the written declaration may be considered expired one year after submission.

16. If I have declared my pregnancy in writing, can I revoke my declaration of pregnancy even if I am still pregnant?

Yes, you may. The choice is entirely yours. If you revoke your declaration of pregnancy, the lower dose limit for the embryo/fetus no longer applies.

17. What if I work under contract at a licensed facility?

The regulations state that you should formally declare your pregnancy to the licensee in writing. The licensee has the responsibility to limit the dose to the embryo/fetus.

18. Where can I get additional information?

The references to this Appendix contain helpful information, especially Reference 3, NRC's Regulatory Guide 8.29, "Instruction Concerning Risks from Occupational Radiation Exposure," for general information on radiation risks. The licensee should be able to give this document to you.

For information on legal aspects, see Reference 7, "The Rock and the Hard Place: Employer Liability to Fertile or Pregnant Employees and Their Unborn Children—What Can the Employer Do?" which is an article in the journal *Radiation Protection Management*.

You may telephone the NRC Headquarters at (301) 415-7000. Legal questions should be directed to the Office of the General Counsel, and technical questions should be directed to the Division of Industrial and Medical Nuclear Safety.

You may also telephone the NRC Regional Offices at the following numbers: Region I, (610) 337-5000; Region II, (404) 562-4400; Region III, (630) 829-9500; and Region IV, (817) 860-8100. Legal questions should be directed to the Regional Counsel, and technical questions should be directed to the Division of Nuclear Materials Safety.

REFERENCES FOR APPENDIX

1. National Council on Radiation Protection and Measurements, *Limitation of Exposure to Ionizing Radiation*, NCRP Report No. 116, Bethesda, MD, 1993.

2. International Commission on Radiological Protection, *1990 Recommendations of the International Commission on Radiological Protection*, ICRP Publication 60, Ann. ICRP 21: No. 1-3, Pergamon Press, Oxford, UK, 1991.

3. USNRC, "Instruction Concerning Risks from Occupational Radiation Exposure," Regulatory Guide 8.29, Revision 1, February 1996.[1] (Electronically available at www.nrc.gov/NRC/RG/index.html)

4. Committee on the Biological Effects of Ionizing Radiations, National Research Council, *Health Effects of Exposure to Low Levels of Ionizing Radiation* (BEIR V), National Academy Press, Washington, DC, 1990.

5. United Nations Scientific Committee on the Effects of Atomic Radiation, *Sources and Effects of Ionizing Radiation*, United Nations, New York, 1993.

6. R. Doll and R. Wakeford, "Risk of Childhood Cancer from Fetal Irradiation," *The British Journal of Radiology*, 70, 130-139, 1997.

7. David Wiedis, Donald E. Jose, and Timm O. Phoebe, "The Rock and the Hard Place: Employer Liability to Fertile or Pregnant Employees and Their Unborn Children—What Can the Employer Do?" *Radiation Protection Management, 11,* 41-49, January/February 1994.

8. National Council on Radiation Protection and Measurements, *Considerations Regarding the Unintended Radiation Exposure of the Embryo, Fetus, or Nursing Child*, NCRP Commentary No. 9, Bethesda, MD, 1994.

9. National Council on Radiation Protection and Measurements, *Risk Estimates for Radiation Protection*, NCRP Report No. 115, Bethesda, MD, 1993.

10. National Radiological Protection Board, *Advice on Exposure to Ionising Radiation During Pregnancy*, National Radiological Protection Board, Chilton, Didcot, UK, 1998.

11. M.L. Thomas and D. Hagemeyer, "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities, 1996," Twenty-Ninth Annual Report, NUREG-0713, Vol. 18, USNRC, 1998.[2]

[1]Single copies of regulatory guides, both active and draft, and draft NUREG documents may be obtained free of charge by writing the Reproduction and Distribution Services Section, OCIO, USNRC, Washington, DC 20555–0001, or by fax to (301)415–2289, or by email to <DISTRIBUTION@NRC.GOV>. Active guides may also be purchased from the National Technical Information Service on a standing order basis. Details on this service may be obtained by writing NTIS, 5285 Port Royal Road, Springfield, VA 22161. Copies of active and draft guides are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW., Washington, DC; the PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202)634–3273; fax (202)634–3343.

[2]Copies are available at current rates from the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402–9328 (telephone (202)512–1800); or from the National Technical Information Service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161. Copies are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW., Washington, DC; the PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202)634–3273; fax (202)634–3343.

FORM LETTER FOR DECLARING PREGNANCY

This form letter is provided for your convenience. To make your written declaration of pregnancy, you may fill in the blanks in this form letter, you may use a form letter the licensee has provided to you, or you may write your own letter.

DECLARATION OF PREGNANCY

To:_____

In accordance with the NRC's regulations at 10 CFR 20.1208, "Dose to an Embryo/Fetus," I am declaring that I am pregnant. I believe I became pregnant in_____ (only the month and year need be provided).

I understand the radiation dose to my embryo/fetus during my entire pregnancy will not be allowed to exceed 0.5 rem (5 millisievert) (unless that dose has already been exceeded between the time of conception and submitting this letter). I also understand that meeting the lower dose limit may require a change in job or job responsibilities during my pregnancy.

_____
(Your signature)

_____
(Your name printed)

_____
(Date)

REGULATORY ANALYSIS

A separate regulatory analysis was not prepared for this regulatory guide. A regulatory analysis prepared for 10 CFR Part 20, "Standards for Protection Against Radiation" (56 FR 23360), provides the regulatory basis for this guide and examines the costs and benefits of the rule as implemented by the guide. A copy of the "Regulatory Analysis for the Revision of 10 CFR Part 20" (PNL-6712, November 1988) is available for inspection and copying for a fee at the NRC Public Document Room, 2120 L Street NW, Washington, DC, as an enclosure to Part 20 (56 FR 23360).

APPENDIX

QUESTIONS AND ANSWERS CONCERNING PRENATAL RADIATION EXPOSURE

1. Why am I receiving this information?

The NRC's regulations (in 10 CFR 19.12, "Instructions to Workers") require that licensees instruct individuals working with licensed radioactive materials in radiation protection as appropriate for the situation. The instruction below describes information that occupational workers and their supervisors should know about the radiation exposure of the embryo/fetus of pregnant women.

The regulations allow a pregnant woman to decide whether she wants to formally declare her pregnancy to take advantage of lower dose limits for the embryo/fetus. This instruction provides information to help women make an informed decision whether to declare a pregnancy.

2. If I become pregnant, am I required to declare my pregnancy?

No. The choice whether to declare your pregnancy is completely voluntary. If you choose to declare your pregnancy, you must do so in writing and a lower radiation dose limit will apply to your embryo/fetus. If you choose not to declare your pregnancy, you and your embryo/fetus will continue to be subject to the same radiation dose limits that apply to other occupational workers.

3. If I declare my pregnancy in writing, what happens?

If you choose to declare your pregnancy in writing, the licensee must take measures to limit the dose to your embryo/fetus to 0.5 rem (5 millisievert) during the entire pregnancy. This is one-tenth of the dose that an occupational worker may receive in a year. If you have already received a dose exceeding 0.5 rem (5 mSv) in the period between conception and the declaration of your pregnancy, an additional dose of 0.05 rem (0.5 mSv) is allowed during the remainder of the pregnancy. In addition, 10 CFR 20.1208, "Dose to an Embryo/Fetus," requires licensees to make efforts to avoid substantial variation above a uniform monthly dose rate so that all the 0.5 rem (5 mSv) allowed dose does not occur in a short period during the pregnancy.

This may mean that, if you declare your pregnancy, the licensee may not permit you to do some of your normal job functions if those functions would have allowed you to receive more than 0.5 rem, and you may not be able to have some emergency response responsibilities.

4. Why do the regulations have a lower dose limit for the embryo/fetus of a declared pregnant woman than for a pregnant worker who has not declared?

A lower dose limit for the embryo/fetus of a declared pregnant woman is based on a consideration of greater sensitivity to radiation of the embryo/fetus and the involuntary nature of the exposure. Several scientific advisory groups have recommended (References 1 and 2) that the dose to the embryo/fetus be limited to a fraction of the occupational dose limit.

5. What are the potentially harmful effects of radiation exposure to my embryo/fetus?

The occurrence and severity of health effects caused by ionizing radiation are dependent upon the type and total dose of radiation received, as well as the time period over which the exposure was received. See Regulatory Guide 8.29, "Instruction Concerning Risks from Occupational Exposure" (Ref. 3), for more information. The main concern is embryo/fetal susceptibility to the harmful effects of radiation such as cancer.

6. Are there any risks of genetic defects?

Although radiation injury has been induced experimentally in rodents and insects, and in the experiments was transmitted and became manifest as hereditary disorders in their offspring, radiation has not been identified as a cause of such effect in humans. Therefore, the risk of genetic effects attributable to radiation exposure is speculative. For example, no genetic effects have been documented in any of the Japanese atomic bomb survivors, their children, or their grandchildren.

7. What if I decide that I do not want any radiation exposure at all during my pregnancy?

You may ask your employer for a job that does not involve any exposure at all to occupational radiation dose, but your employer is not obligated to provide you with a job involving no radiation exposure. Even if you receive no occupational exposure at all, your embryo/fetus will receive some radiation dose (on average 75 mrem (0.75 mSv)) during your pregnancy from natural background radiation.

The NRC has reviewed the available scientific literature and concluded that the 0.5 rem (5 mSv) limit

Appendix B: USNRC INSTRUCTION CONCERNING RISKS FROM OCCUPATIONAL RADIATION EXPOSURE

U.S. NUCLEAR REGULATORY COMMISSION

Revision 1
February 1996

REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 8.29

(Draft was issued as DG-8012)

INSTRUCTION CONCERNING RISKS FROM OCCUPATIONAL RADIATION EXPOSURE

A. INTRODUCTION

Section 19.12 of 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," requires that all individuals who in the course of their employment are likely to receive in a year an occupational dose in excess of 100 mrem (1 mSv) be instructed in the health protection issues associated with exposure to radioactive materials or radiation. Section 20.1206 of 10 CFR Part 20, "Standards for Protection Against Radiation," requires that before a planned special exposure occurs the individuals involved are, among other things, to be informed of the estimated doses and associated risks.

This regulatory guide describes the information that should be provided to workers by licensees about health risks from occupational exposure. This revision conforms to the revision of 10 CFR Part 20 that became effective on June 20, 1991, to be implemented by licensees no later than January 1, 1994. The revision of 10 CFR Part 20 establishes new dose limits based on the effective dose equivalent (EDE), requires the summing of internal and external dose, establishes a requirement that licensees use procedures and engineering controls to the extent practicable to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA), provides for planned special exposures, establishes a dose limit for the embryo/fetus of an occupationally exposed declared pregnant woman, and explicitly states that Part 20 is not to be construed as limiting action that may be necessary to protect health and safety during emergencies.

Any information collection activities mentioned in this regulatory guide are contained as requirements in 10 CFR Part 19 or 10 CFR Part 20. These regulations provide the regulatory bases for this guide. The information collection requirements in 10 CFR Parts 19 and 20 have been cleared under OMB Clearance Nos. 3150-0044 and 3150-0014, respectively.

B. DISCUSSION

It is important to qualify the material presented in this guide with the following considerations.

The coefficient used in this guide for occupational radiation risk estimates, 4×10^{-4} health effects per rem, is based on data obtained at much higher doses and dose rates than those encountered by workers. The risk coefficient obtained at high doses and dose rates was reduced to account for the reduced effectiveness of lower doses and dose rates in producing the stochastic effects observed in studies of exposed humans.

The assumption of a linear extrapolation from the lowest doses at which effects are observable down to

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This guide was issued after consideration of comments received from the public. Comments and suggestions for improvements in these guides are encouraged at all times, and guides will be revised, as appropriate, to accommodate comments and to reflect new information or experience.

Written comments may be submitted to the Rules Review and Directives Branch, DFIPS, ADM, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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the occupational range has considerable uncertainty. The report of the Committee on the Biological Effects of Ionizing Radiation (Ref. 1) states that

> "... departure from linearity cannot be excluded at low doses below the range of observation. Such departures could be in the direction of either an increased or decreased risk. Moreover, epidemiologic data cannot rigorously exclude the existence of a threshold in the 100 mrem dose range. Thus, the possibility that there may be no risk from exposures comparable to external natural background radiation cannot be ruled out. At such low doses and dose rates, it must be acknowledged that the lower limit of the range of uncertainty in the risk estimates extends to zero."

The issue of beneficial effects from low doses, or hormesis, in cellular systems is addressed by the United Nations Scientific Committee on the Effects of Atomic Radiation (Ref. 2). UNSCEAR states that "... it would be premature to conclude that cellular adaptive responses could convey possible beneficial effects to the organism that would outweigh the detrimental effects of exposures to low doses of low-LET radiation."

In the absence of scientific certainty regarding the relationship between low doses and health effects, and as a conservative assumption for radiation protection purposes, the scientific community generally assumes that any exposure to ionizing radiation can cause biological effects that may be harmful to the exposed person and that the magnitude or probability of these effects is directly proportional to the dose. These effects may be classified into three categories:

> *Somatic Effects:* Physical effects occurring in the exposed person. These effects may be observable after a large or acute dose (e.g., 100 rems[1] (1 Sv) or more to the whole body in a few hours); or they may be effects such as cancer that may occur years after exposure to radiation.
>
> *Genetic Effects:* Abnormalities that may occur in the future children of exposed individuals and in subsequent generations (genetic effects exceeding normal incidence have not been observed in any of the studies of human populations).
>
> *Teratogenic Effects:* Effects such as cancer or congenital malformation that may be observed in children who were exposed during the fetal and embryonic stages of development (these effects have been observed from high, i.e., above 20 rems (0.2 Sv), acute exposures).

The normal incidence of effects from natural and manmade causes is significant. For example, approximately 20% of people die from various forms of cancer whether or not they ever receive occupational exposure to radiation. To avoid increasing the incidence of such biological effects, regulatory controls are imposed on occupational doses to adults and minors and on doses to the embryo/fetus from occupational exposures of declared pregnant women.

Radiation protection training for workers who are occupationally exposed to ionizing radiation is an essential component of any program designed to ensure compliance with NRC regulations. A clear understanding of what is presently known about the biological risks associated with exposure to radiation will result in more effective radiation protection training and should generate more interest on the part of the workers in complying with radiation protection standards. In addition, pregnant women and other occupationally exposed workers should have available to them relevant information on radiation risks to enable them to make informed decisions regarding the acceptance of these risks. It is intended that workers who receive this instruction will develop respect for the risks involved, rather than excessive fear or indifference.

C. REGULATORY POSITION

Instruction to workers performed in compliance with 10 CFR 19.12 should be given prior to occupational exposure and periodically thereafter. The frequency of retraining might range from annually for licensees with complex operations such as nuclear power plants, to every three years for licensees who possess, for example, only low-activity sealed sources. If a worker is to participate in a planned special exposure, the worker should be informed of the associated risks in compliance with 10 CFR 20.1206.

In providing instruction concerning health protection problems associated with exposure to radiation, all occupationally exposed workers and their supervisors should be given specific instruction on the risk of biological effects resulting from exposure to radiation. The extent of these instructions should be commensurate with the radiological risks present in the workplace.

The instruction should be presented orally, in printed form, or in any other effective communication media to workers and supervisors. The appendix to this guide provides useful information for demonstrating compliance with the training requirements in 10 CFR Parts 19 and 20. Individuals should be given an opportunity to discuss the information and to ask questions. Testing is recommended, and each trainee should be asked to acknowledge in writing that the instruction has been received and understood.

[1] In the International System of Units (SI), the rem is replaced by the sievert; 100 rems is equal to 1 sievert (Sv).

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC staff's plans for using this regulatory guide.

Except in those cases in which an applicant or licensee proposes acceptable alternative methods for complying with specified portions of the Commission's regulations, the guidance and instructional materials in this guide will be used in the evaluation of applications for new licenses, license renewals, and license amendments and for evaluating compliance with 10 CFR 19.12 and 10 CFR Part 20.

REFERENCES

1. National Research Council, *Health Effects of Exposure to Low Levels of Ionizing Radiation*, Report of the Committee on the Biological Effects of Ionizing Radiation (BEIR V), National Academy Press, Washington, DC, 1990.
2. United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), *Sources and Effects of Ionizing Radiation*, United Nations, New York, 1993.

APPENDIX

INSTRUCTION CONCERNING RISKS FROM OCCUPATIONAL RADIATION EXPOSURE

This instructional material is intended to provide the user with the best available information about the health risks from occupational exposure to ionizing radiation. Ionizing radiation consists of energy or small particles, such as gamma rays and beta and alpha particles, emitted from radioactive materials, which can cause chemical or physical damage when they deposit energy in living tissue. A question and answer format is used. Many of the questions or subjects were developed by the NRC staff in consultation with workers, union representatives, and licensee representatives experienced in radiation protection training.

This Revision 1 to Regulatory Guide 8.29 updates the material in the original guide on biological effects and risks and on typical occupational exposure. Additionally, it conforms to the revised 10 CFR Part 20, "Standards for Protection Against Radiation," which was required to be implemented by licensees no later than January 1, 1994. The information in this appendix is intended to help develop respect by workers for the risks associated with radiation, rather than unjustified fear or lack of concern. Additional guidance concerning other topics in radiation protection training is provided in other NRC regulatory guides.

1. What is meant by health risk?

A health risk is generally thought of as something that may endanger health. Scientists consider health risk to be the statistical probability or mathematical chance that personal injury, illness, or death may result from some action. Most people do not think about health risks in terms of mathematics. Instead, most of us consider the health risk of a particular action in terms of whether we believe that particular action will, or will not, cause us some harm. The intent of this appendix is to provide estimates of, and explain the bases for, the risk of injury, illness, or death from occupational radiation exposure. Risk can be quantified in terms of the probability of a health effect per unit of dose received.

When x-rays, gamma rays, and ionizing particles interact with living materials such as our bodies, they may deposit enough energy to cause biological damage. Radiation can cause several different types of events such as the very small physical displacement of molecules, changing a molecule to a different form, or ionization, which is the removal of electrons from atoms and molecules. When the quantity of radiation energy deposited in living tissue is high enough, biological damage can occur as a result of chemical bonds being broken and cells being damaged or killed. These effects can result in observable clinical symptoms.

The basic unit for measuring absorbed radiation is the rad. One rad (0.01 gray in the International System of units) equals the absorption of 100 ergs (a small but measurable amount of energy) in a gram of material such as tissue exposed to radiation. To reflect biological risk, rads must be converted to rems. The new international unit is the sievert (100 rems = 1 Sv). This conversion accounts for the differences in the effectiveness of different types of radiation in causing damage. The rem is used to estimate biological risk. For beta and gamma radiation, a rem is considered equal to a rad.

2. What are the possible health effects of exposure to radiation?

Health effects from exposure to radiation range from no effect at all to death, including diseases such as leukemia or bone, breast, and lung cancer. Very high (100s of rads), short-term doses of radiation have been known to cause prompt (or early) effects, such as vomiting and diarrhea,[1] skin burns, cataracts, and even death. It is suspected that radiation exposure may be linked to the potential for genetic effects in the children of exposed parents. Also, children who were exposed to high doses (20 or more rads) of radiation prior to birth (as an embryo/fetus) have shown an increased risk of mental retardation and other congenital malformations. These effects (with the exception of genetic effects) have been observed in various studies of medical radiologists, uranium miners, radium workers, radiotherapy patients, and the people exposed to radiation from atomic bombs dropped on Japan. In addition, radiation effects studies with laboratory animals, in which the animals were given relatively high doses, have provided extensive data on radiation-induced health effects, including genetic effects.

It is important to note that these kinds of health effects result from high doses, compared to occupational levels, delivered over a relatively short period of time.

Although studies have not shown a consistent cause-and-effect relationship between current levels of occupational radiation exposure and biological effects, it is prudent from a worker protection perspective to assume that some effects may occur.

[1]These symptoms are early indicators of what is referred to as the acute radiation syndrome, caused by high doses delivered over a short time period, which includes damage to the blood-forming organs such as bone marrow, damage to the gastrointestinal system, and, at very high doses, can include damage to the central nervous system.

3. What is meant by early effects and delayed or late effects?

EARLY EFFECTS

Early effects, which are also called immediate or prompt effects, are those that occur shortly after a large exposure that is delivered within hours to a few days. They are observable after receiving a very large dose in a short period of time, for example, 300 rads (3 Gy) received within a few minutes to a few days. Early effects are not caused at the levels of radiation exposure allowed under the NRC's occupational limits.

Early effects occur when the radiation dose is large enough to cause extensive biological damage to cells so that large numbers of cells are killed. For early effects to occur, this radiation dose must be received within a short time period. This type of dose is called an acute dose or acute exposure. The same dose received over a long time period would not cause the same effect. Our body's natural biological processes are constantly repairing damaged cells and replacing dead cells; if the cell damage is spread over time, our body is capable of repairing or replacing some of the damaged cells, reducing the observable adverse conditions.

For example, a dose to the whole body of about 300–500 rads (3–5 Gy), more than 60 times the annual occupational dose limit, if received within a short time period (e.g., a few hours) will cause vomiting and diarrhea within a few hours; loss of hair, fever, and weight loss within a few weeks; and about a 50 percent chance of death if medical treatment is not provided. These effects would not occur if the same dose were accumulated gradually over many weeks or months (Refs. 1 and 2). Thus, one of the justifications for establishing annual dose limits is to ensure that occupational dose is spread out in time.

It is important to distinguish between whole body and partial body exposure. A localized dose to a small volume of the body would not produce the same effect as a whole body dose of the same magnitude. For example, if only the hand were exposed, the effect would mainly be limited to the skin and underlying tissue of the hand. An acute dose of 400 to 600 rads (4–6 Gy) to the hand would cause skin reddening; recovery would occur over the following months and no long-term damage would be expected. An acute dose of this magnitude to the whole body could cause death within a short time without medical treatment. Medical treatment would lessen the magnitude of the effects and the chance of death; however, it would not totally eliminate the effects or the chance of death.

DELAYED EFFECTS

Delayed effects may occur years after exposure. These effects are caused indirectly when the radiation changes parts of the cells in the body, which causes the normal function of the cell to change, for example, normal healthy cells turn into cancer cells. The potential for these delayed health effects is one of the main concerns addressed when setting limits on occupational doses.

A delayed effect of special interest is genetic effects. Genetic effects may occur if there is radiation damage to the cells of the gonads (sperm or eggs). These effects may show up as genetic defects in the children of the exposed individual and succeeding generations. However, if any genetic effects (i.e., effects in addition to the normal expected number) have been caused by radiation, the numbers are too small to have been observed in human populations exposed to radiation. For example, the atomic bomb survivors (from Hiroshima and Nagasaki) have not shown any significant radiation-related increases in genetic defects (Ref. 3). Effects have been observed in animal studies conducted at very high levels of exposure and it is known that radiation can cause changes in the genes in cells of the human body. However, it is believed that by maintaining worker exposures below the NRC limits and consistent with ALARA, a margin of safety is provided such that the risk of genetic effects is almost eliminated.

4. What is the difference between acute and chronic radiation dose?

Acute radiation dose usually refers to a large dose of radiation received in a short period of time. Chronic dose refers to the sum of small doses received repeatedly over long time periods, for example, 20 mrem (or millirem, which is 1-thousandth of a rem) (0.2 mSv) per week every week for several years. It is assumed for radiation protection purposes that any radiation dose, either acute or chronic, may cause delayed effects. However, only large acute doses cause early effects; chronic doses within the occupational dose limits do not cause early effects. Since the NRC limits do not permit large acute doses, concern with occupational radiation risk is primarily focused on controlling chronic exposure for which possible delayed effects, such as cancer, are of concern.

The difference between acute and chronic radiation exposure can be shown by using exposure to the sun's rays as an example. An intense exposure to the sun can result in painful burning, peeling, and growing of new skin. However, repeated short exposures provide time for the skin to be repaired between exposures. Whether exposure to the sun's rays is long term or spread over short periods, some of the injury may not be repaired and may eventually result in skin cancer.

Cataracts are an interesting case because they can be caused by both acute and chronic radiation. A certain threshold level of dose to the lens of the eye is required before there is any observable visual impairment, and the impairment remains after the exposure is stopped. The threshold for cataract development

from acute exposure is an acute dose on the order of 100 rads (1 Gy). Further, a cumulative dose of 800 rads (8 Gy) from protracted exposures over many years to the lens of the eye has been linked to some level of visual impairment (Refs. 1 and 4). These doses exceed the amount that may be accumulated by the lens from normal occupational exposure under the current regulations.

5. What is meant by external and internal exposure?

A worker's occupational dose may be caused by exposure to radiation that originates outside the body, called "external exposure," or by exposure to radiation from radioactive material that has been taken into the body, called "internal exposure." Most NRC-licensed activities involve little, if any, internal exposure. It is the current scientific consensus that a rem of radiation dose has the same biological risk regardless of whether it is from an external or an internal source. The NRC requires that dose from external exposure and dose from internal exposure be added together, if each exceeds 10% of the annual limit, and that the total be within occupational limits. The sum of external and internal dose is called the total effective dose equivalent (TEDE) and is expressed in units of rems (Sv).

Although unlikely, radioactive materials may enter the body through breathing, eating, drinking, or open wounds, or they may be absorbed through the skin. The intake of radioactive materials by workers is generally due to breathing contaminated air. Radioactive materials may be present as fine dust or gases in the workplace atmosphere. The surfaces of equipment and workbenches may be contaminated, and these materials can be resuspended in air during work activities.

If any radioactive material enters the body, the material goes to various organs or is excreted, depending on the biochemistry of the material. Most radioisotopes are excreted from the body in a few days. For example, a fraction of any uranium taken into the body will deposit in the bones, where it remains for a longer time. Uranium is slowly eliminated from the body, mostly by way of the kidneys. Most workers are not exposed to uranium. Radioactive iodine is preferentially deposited in the thyroid gland, which is located in the neck.

To limit risk to specific organs and the total body, an annual limit on intake (ALI) has been established for each radionuclide. When more than one radionuclide is involved, the intake amount of each radionuclide is reduced proportionally. NRC regulations specify the concentrations of radioactive material in the air to which a worker may be exposed for 2,000 working hours in a year. These concentrations are termed the derived air concentrations (DACs). These limits are the total amounts allowed if no external radiation is received. The resulting dose from the internal radiation sources (from breathing air at 1 DAC) is the maximum allowed to an organ or to the worker's whole body.

6. How does radiation cause cancer?

The mechanisms of radiation-induced cancer are not completely understood. When radiation interacts with the cells of our bodies, a number of events can occur. The damaged cells can repair themselves and permanent damage is not caused. The cells can die, much like the large numbers of cells that die every day in our bodies, and be replaced through the normal biological processes. Or a change can occur in the cell's reproductive structure, the cells can mutate and subsequently be repaired without effect, or they can form precancerous cells, which may become cancerous. Radiation is only one of many agents with the potential for causing cancer, and cancer caused by radiation cannot be distinguished from cancer attributable to any other cause.

Radiobiologists have studied the relationship between large doses of radiation and cancer (Refs. 5 and 6). These studies indicate that damage or change to genes in the cell nucleus is the main cause of radiation-induced cancer. This damage may occur directly through the interaction of the ionizing radiation in the cell or indirectly through the actions of chemical products produced by radiation interactions within cells. Cells are able to repair most damage within hours; however, some cells may not be repaired properly. Such misrepaired damage is thought to be the origin of cancer, but misrepair does not always cause cancer. Some cell changes are benign or the cell may die; these changes do not lead to cancer.

Many factors such as age, general health, inherited traits, sex, as well as exposure to other cancer-causing agents such as cigarette smoke can affect susceptibility to the cancer-causing effects of radiation. Many diseases are caused by the interaction of several factors, and these interactions appear to increase the susceptibility to cancer.

7. Who developed radiation risk estimates?

Radiation risk estimates were developed by several national and international scientific organizations over the last 40 years. These organizations include the National Academy of Sciences (which has issued several reports from the Committee on the Biological Effects of Ionizing Radiations, BEIR), the National Council on Radiation Protection and Measurements (NCRP), the International Commission on Radiological Protection (ICRP), and the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR). Each of these organizations continues to review new research findings on radiation health risks.

Several reports from these organizations present new findings on radiation risks based upon revised estimates of radiation dose to survivors of the atomic bombing at Hiroshima and Nagasaki. For example, UNSCEAR published risk estimates in 1988 and 1993 (Refs. 5 and 6). The NCRP also published a report in 1988, "New Dosimetry at Hiroshima and Nagasaki and Its Implications for Risk Estimates" (Ref. 7). In January 1990, the National Academy of Sciences released the fifth report of the BEIR Committee, "Health Effects of Exposure to Low Levels of Ionizing Radiation" (Ref. 4). Each of these publications also provides extensive bibliographies on other published studies concerning radiation health effects for those who may wish to read further on this subject.

8. What are the estimates of the risk of fatal cancer from radiation exposure?

We don't know exactly what the chances are of getting cancer from a low-level radiation dose, primarily because the few effects that may occur cannot be distinguished from normally occurring cancers. However, we can make estimates based on extrapolation from extensive knowledge from scientific research on high dose effects. The estimates of radiation effects at high doses are better known than are those of most chemical carcinogens (Ref. 8).

From currently available data, the NRC has adopted a risk value for an occupational dose of 1 rem (0.01 Sv) Total Effective Dose Equivalent (TEDE) of 4 in 10,000 of developing a fatal cancer, or approximately 1 chance in 2,500 of fatal cancer per rem of TEDE received. The uncertainty associated with this risk estimate does not rule out the possibility of higher risk, or the possibility that the risk may even be zero at low occupational doses and dose rates.

The radiation risk incurred by a worker depends on the amount of dose received. Under the linear model explained above, a worker who receives 5 rems (0.05 Sv) in a year incurs 10 times as much risk as another worker who receives only 0.5 rem (0.005 Sv). Only a very few workers receive doses near 5 rems (0.05 Sv) per year (Ref. 9).

According to the BEIR V report (Ref. 4), approximately one in five adults normally will die from cancer from all possible causes such as smoking, food, alcohol, drugs, air pollutants, natural background radiation, and inherited traits. Thus, in any group of 10,000 workers, we can estimate that about 2,000 (20%) will die from cancer without any occupational radiation exposure.

To explain the significance of these estimates, we will use as an example a group of 10,000 people, each exposed to 1 rem (0.01 Sv) of ionizing radiation. Using the risk factor of 4 effects per 10,000 rem of dose, we estimate that 4 of the 10,000 people might die from delayed cancer because of that 1-rem dose (although the actual number could be more or less than 4) in addition to the 2,000 normal cancer fatalities expected to occur in that group from all other causes. This means that a 1-rem (0.01 Sv) dose may increase an individual worker's chances of dying from cancer from 20 percent to 20.04 percent. If one's lifetime occupational dose is 10 rems, we could raise the estimate to 20.4 percent. A lifetime dose of 100 rems may increase chances of dying from cancer from 20 to 24 percent. The average measurable dose for radiation workers reported to the NRC was 0.31 rem (0.0031 Sv) for 1993 (Ref. 9). Today, very few workers ever accumulate 100 rems (1 Sv) in a working lifetime, and the average career dose of workers at NRC-licensed facilities is 1.5 rems (0.015 Sv), which represents an estimated increase from 20 to about 20.06 percent in the risk of dying from cancer.

It is important to understand the probability factors here. A similar question would be, "If you select one card from a full deck of cards, will you get the ace of spades?" This question cannot be answered with a simple yes or no. The best answer is that your chance is 1 in 52. However, if 1000 people each select one card from full decks, we can predict that about 20 of them will get an ace of spades. Each person will have 1 chance in 52 of drawing the ace of spades, but there is no way we can predict which persons will get that card. The issue is further complicated by the fact that in a drawing by 1000 people, we might get only 15 successes, and in another, perhaps 25 correct cards in 1000 draws. We can say that if you receive a radiation dose, you will have increased your chances of eventually developing cancer. It is assumed that the more radiation exposure you get, the more you increase your chances of cancer.

The normal chance of dying from cancer is about one in five for persons who have not received any occupational radiation dose. The additional chance of developing fatal cancer from an occupational exposure of 1 rem (0.01 Sv) is about the same as the chance of drawing any ace from a full deck of cards three times in a row. The additional chance of dying from cancer from an occupational exposure of 10 rem (0.1 Sv) is about equal to your chance of drawing two aces successively on the first two draws from a full deck of cards.

It is important to realize that these risk numbers are only estimates based on data for people and research animals exposed to high levels of radiation in short periods of time. There is still uncertainty with regard to estimates of radiation risk from low levels of exposure. Many difficulties are involved in designing research studies that can accurately measure the projected small increases in cancer cases that might be caused by low exposures to radiation as compared to the normal rate of cancer.

These estimates are considered by the NRC staff to be the best available for the worker to use to make an informed decision concerning acceptance of the risks associated with exposure to radiation. A worker who decides to accept this risk should try to keep exposure to radiation as low as is reasonably achievable (ALARA) to avoid unnecessary risk.

9. If I receive a radiation dose that is within occupational limits, will it cause me to get cancer?

Probably not. Based on the risk estimates previously discussed, the risk of cancer from doses below the occupational limits is believed to be small. Assessment of the cancer risks that may be associated with low doses of radiation are projected from data available at doses larger than 10 rems (0.1 Sv) (Ref. 3). For radiation protection purposes, these estimates are made using the straight line portion of the linear quadratic model (Curve 2 in Figure 1). We have data on cancer probabilities only for high doses, as shown by the solid line in Figure 1. Only in studies involving radiation doses above occupational limits are there dependable determinations of the risk of cancer, primarily because below the limits the effect is small compared to differences in the normal cancer incidence from year to year and place to place. The ICRP, NCRP, and other standards-setting organizations assume for radiation protection purposes that there is some risk, no matter how small the dose (Curves 1 and 2). Some scientists believe that the risk drops off to zero at some low dose (Curve 3), the threshold effect. The ICRP and NCRP endorse the linear quadratic model as a conservative means of assuring safety (Curve 2).

For regulatory purposes, the NRC uses the straight line portion of Curve 2, which shows the number of effects decreasing linearly as the dose decreases. Because the scientific evidence does not conclusively demonstrate whether there is or is not an effect at low doses, the NRC assumes for radiation protection purposes, that even small doses have some chance of causing cancer. Thus, a principle of radiation protection is to do more than merely meet the allowed regulatory limits; doses should be kept as low as is reasonably achievable (ALARA). This is as true for natural carcinogens such as sunlight and natural radiation as it is for those that are manmade, such as cigarette smoke, smog, and x-rays.

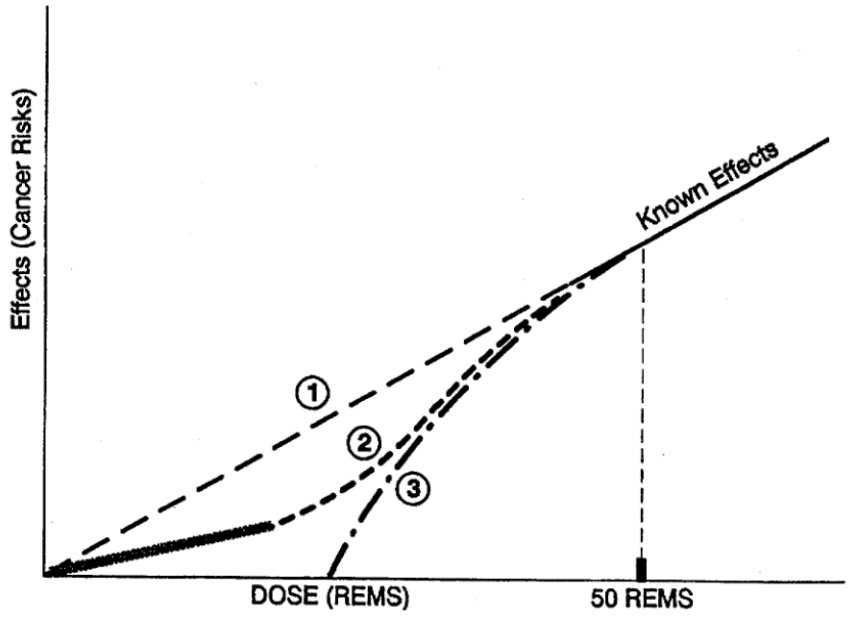

Figure 1. Some Proposed Models for How the Effects of Radiation Vary With Doses at Low Levels

10. How can we compare the risk of cancer from radiation to other kinds of health risks?

One way to make these comparisons is to compare the average number of days of life expectancy lost because of the effects associated with each particular health risk. Estimates are calculated by looking at a large number of persons, recording the age when death occurs from specific causes, and estimating the average number of days of life lost as a result of these early deaths. The total number of days of life lost is then averaged over the total observed group.

Several studies have compared the average days of life lost from exposure to radiation with the number of days lost as a result of being exposed to other health risks. The word "average" is important because an individual who gets cancer loses about 15 years of life expectancy, while his or her coworkers do not suffer any loss.

Some representative numbers are presented in Table 1. For categories of NRC-regulated industries with larger doses, the average measurable occupational dose in 1993 was 0.31 rem (0.0031 Sv). A simple calculation based on the article by Cohen and Lee (Ref. 10) shows that 0.3 rem (0.003 Sv) per year from age 18 to 65 results in an average loss of 15 days. These estimates indicate that the health risks from occupational radiation exposure are smaller than the risks associated with many other events or activities we encounter and accept in normal day-to-day activities.

It is also useful to compare the estimated average number of days of life lost from occupational exposure to radiation with the number of days lost as a result of working in several types of industries. Table 2 shows average days of life expectancy lost as a result of fatal work-related accidents. Table 2 does not include nonaccident types of occupational risks such as occupational disease and stress because the data are not available.

These comparisons are not ideal because we are comparing the possible effects of chronic exposure to radiation to different kinds of risk such as accidental death, in which death is inevitable if the event occurs. This is the best we can do because good data are not available on chronic exposure to other workplace carcinogens. Also, the estimates of loss of life expectancy for workers from radiation-induced cancer do not take into consideration the competing effect on the life expectancy of the workers from industrial accidents.

11. What are the health risks from radiation exposure to the embryo/fetus?

During certain stages of development, the embryo/fetus is believed to be more sensitive to radiation damage than adults. Studies of atomic bomb survivors exposed to acute radiation doses exceeding 20 rads (0.2 Gy) during pregnancy show that children born after receiving these doses have a higher risk of mental retardation. Other studies suggest that an association exists between exposure to diagnostic x-rays before birth and carcinogenic effects in childhood and in adult life. Scientists are uncertain about the magnitude of the risk. Some studies show the embryo/fetus to be more sensitive to radiation-induced cancer than adults, but other studies do not. In recognition of the possibility of increased radiation sensitivity, and because dose to the

Table 1 Estimated Loss of Life Expectancy from Health Risks[a]

Health Risk	*Estimate of Life Expectancy Lost (average)*	
Smoking 20 cigarettes a day		6 years
Overweight (by 15%)		2 years
Alcohol consumption (U.S. average)		1 year
All accidents combined		1 year
Motor vehicle accidents	207 days	
Home accidents	74 days	
Drowning	24 days	
All natural hazards (earthquake, lightning, flood, etc.)		7 days
Medical radiation		6 days
Occupational Exposure		
0.3 rem/y from age 18 to 65	15 days	
1 rem/y from age 18 to 65	51 days	

[a]Adapted from Reference 10.

Table 2 Estimated Loss of Life Expectancy from Industrial Accidents[a]

Industry Type	*Estimated Days of Life Expectancy Lost (Average)*
All industries	60
Agriculture	320
Construction	227
Mining and Quarrying	167
Transportation and Public Utilities	160
Government	60
Manufacturing	40
Trade	27
Services	27

[a]Adapted from Reference 10.

embryo/fetus is involuntary on the part of the embryo/fetus, a more restrictive dose limit has been established for the embryo/fetus of a declared pregnant radiation worker. See Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure."

If an occupationally exposed woman declares her pregnancy in writing, she is subject to the more restrictive dose limits for the embryo/fetus during the remainder of the pregnancy. The dose limit of 500 mrems (5 mSv) for the total gestation period applies to the embryo/fetus and is controlled by restricting the exposure to the declared pregnant woman. Restricting the woman's occupational exposure, if she declares her pregnancy, raises questions about individual privacy rights, equal employment opportunities, and the possible loss of income. Because of these concerns, the declaration of pregnancy by a female radiation worker is voluntary. Also, the declaration of pregnancy can be withdrawn for any reason, for example, if the woman believes that her benefits from receiving the occupational exposure would outweigh the risk to her embryo/fetus from the radiation exposure.

12. Can a worker become sterile or impotent from normal occupational radiation exposure?

No. Temporary or permanent sterility cannot be caused by radiation at the levels allowed under NRC's occupational limits. There is a threshold below which these effects do not occur. Acute doses on the order of 10 rems (0.1 Sv) to the testes can result in a measurable but temporary reduction in sperm count. Temporary sterility (suppression of ovulation) has been observed in women who have received acute doses of 150 rads (1.5 Gy). The estimated threshold (acute) radiation dose for induction of permanent sterility is about 200 rads (2 Gy) for men and about 350 rads (3.5 Gy) for women (Refs. 1 and 4). These doses are far greater than the NRC s occupational dose limits for workers.

Although acute doses can affect fertility by reducing sperm count or suppressing ovulation, they do not have any direct effect on one's ability to function sexually. No evidence exists to suggest that exposures within the NRC's occupational limits have any effect on the ability to function sexually.

13. What are the NRC occupational dose limits?

For adults, an annual limit that does not exceed:

- 5 rems (0.05 Sv) for the total effective dose equivalent (TEDE), which is the sum of the deep dose equivalent (DDE) from external exposure to the whole body and the committed effective dose equivalent (CEDE) from intakes of radioactive material.
- 50 rems (0.5 Sv) for the total organ dose equivalent (TODE), which is the sum of the DDE from external exposure to the whole body and the committed dose equivalent (CDE) from intakes of radioactive material to any individual organ or tissue, other than the lens of the eye.
- 15 rems (0.15 Sv) for the lens dose equivalent (LDE), which is the external dose to the lens of the eye.
- 50 rems (0.5 Sv) for the shallow dose equivalent (SDE), which is the external dose to the skin or to any extremity.

For minor workers, the annual occupational dose limits are 10 percent of the dose limits for adult workers.

For protection of the embryo/fetus of a declared pregnant woman, the dose limit is 0.5 rem (5 mSv) during the entire pregnancy.

The occupational dose limit for adult workers of 5 rems (0.05 Sv) TEDE is based on consideration of the potential for delayed biological effects. The 5-rem (0.05 Sv) limit, together with application of the concept of keeping occupational doses ALARA, provides a level of risk of delayed effects considered acceptable by the NRC. The limits for individual organs are below the dose levels at which early biological effects are observed in the individual organs.

The dose limit for the embryo/fetus of a declared pregnant woman is based on a consideration of the possibility of greater sensitivity to radiation of the embryo/fetus and the involuntary nature of the exposure.

14. What is meant by ALARA?

ALARA means "as low as is reasonably achievable." In addition to providing an upper limit on an individual's permissible radiation dose, the NRC requires that its licensees establish radiation protection

programs and use procedures and engineering controls to achieve occupational doses, and doses to the public, as far below the limits as is reasonably achievable. "Reasonably achievable" also means "to the extent practicable." What is practicable depends on the purpose of the job, the state of technology, the costs for averting doses, and the benefits. Although implementation of the ALARA principle is a required integral part of each licensee's radiation protection program, it does not mean that each radiation exposure must be kept to an absolute minimum, but rather that "reasonable" efforts must be made to avert dose. In practice, ALARA includes planning tasks involving radiation exposure so as to reduce dose to individual workers and the work group.

There are several ways to control radiation doses, e.g., limiting the time in radiation areas, maintaining distance from sources of radiation, and providing shielding of radiation sources to reduce dose. The use of engineering controls, from the design of facilities and equipment to the actual set-up and conduct of work activities, is also an important element of the ALARA concept.

An ALARA analysis should be used in determining whether the use of respiratory protection is advisable. In evaluating whether or not to use respirators, the goal should be to achieve the optimal sum of external and internal doses. For example, the use of respirators can lead to increased work time within radiation areas, which increases external dose. The advantage of using respirators to reduce internal exposure must be evaluated against the increased external exposure and related stresses caused by the use of respirators. Heat stress, reduced visibility, and reduced communication associated with the use of respirators could expose a worker to far greater risks than are associated with the internal dose avoided by use of the respirator. To the extent practical, engineering controls, such as containments and ventilation systems, should be used to reduce workplace airborne radioactive materials.

15. What are background radiation exposures?

The average person is constantly exposed to ionizing radiation from several sources. Our environment and even the human body contain naturally occurring radioactive materials (e.g., potassium-40) that contribute to the radiation dose that we receive. The largest source of natural background radiation exposure is terrestrial radon, a colorless, odorless, chemically inert gas, which causes about 55 percent of our average, nonoccupational exposure. Cosmic radiation originating in space contributes additional exposure. The use of x-rays and radioactive materials in medicine and dentistry adds to our population exposure. As shown below in Table 3, the average person receives an annual radiation dose of about 0.36 rem (3.6 mSv). By age 20, the average person will accumulate over 7 rems (70 mSv) of dose. By age 50, the total dose is up to 18 rems (180 mSv). After 70 years of exposure this dose is up to 25 rems (250 mSv).

Table 3 Average Annual Effective Dose Equivalent to Individuals in the U.S.[a]

Source	*Effective Dose Equivalent (mrems)*	
Natural		
Radon	200	
Other than Radon	100	
Total		300
Nuclear Fuel Cycle		0.05
Consumer Products[b]		9
Medical		
Diagnostic X-rays	39	
Nuclear Medicine	14	
Total		53
Total		about 360 mrems/year

[a]Adapted from Table 8.1, NCRP 93 (Ref. 11).

[b]Includes building material, television receivers, luminous watches, smoke detectors, etc. (from Table 5.1, NCRP 93, Ref. 11).

16. What are the typical radiation doses received by workers?

For 1993, the NRC received reports on about a quarter of a million people who were monitored for occupational exposure to radiation. Almost half of those monitored had no measurable doses. The other half had an average dose of about 310 mrem (3.1 mSv) for the year. Of these, 93 percent received an annual dose of less than 1 rem (10 mSv); 98.7 percent received less than 2 rems (20 mSv); and the highest reported dose was for two individuals who each received between 5 and 6 rems (50 and 60 mSv).

Table 4 lists average occupational doses for workers (persons who had measurable doses) in various occupations based on 1993 data. It is important to note that beginning in 1994, licensees have been required to sum external and internal doses and certain licensees are required to submit annual reports. Certain types of licensees such as nuclear fuel fabricators may report a significant increase in worker doses because of the exposure to long-lived airborne radionuclides and the requirement to add the resultant internal dose to the calculation of occupational doses.

Table 4 Reported Occupational Doses for 1993[a]

Occupational Subgroup	Average Measurable Dose per Worker (millirems)
Industrial Radiography	540
Commercial Nuclear Power Reactors	310
Manufacturing and Distribution of Radioactive Materials	300
Low-Level Radioactive Waste Disposal	270
Independent Spent Nuclear Fuel Storage	260
Nuclear Fuel Fabrication	130

[a]From Table 3.1 in NUREG–0713 (Ref. 9).

17. How do I know how much my occupational dose (exposure) is?

If you are likely to receive more than 10 percent of the annual dose limits, the NRC requires your employer, the NRC licensee, to monitor your dose, to maintain records of your dose, and, at least on an annual basis for the types of licensees listed in 10 CFR 20.2206, "Reports of Individual Monitoring," to inform both you and the NRC of your dose. The purpose of this monitoring and reporting is so that the NRC can be sure that licensees are complying with the occupational dose limits and the ALARA principle.

External exposures are monitored by using individual monitoring devices. These devices are required to be used if it appears likely that external exposure will exceed 10 percent of the allowed annual dose, i.e., 0.5 rem (5 mSv). The most commonly used monitoring devices are film badges, thermoluminescence dosimeters (TLDs), electronic dosimeters, and direct reading pocket dosimeters.

With respect to internal exposure, your employer is required to monitor your occupational intake of radioactive material and assess the resulting dose if it appears likely that you will receive greater than 10 percent of the annual limit on intake (ALI) from intakes in 1 year. Internal exposure can be estimated by measuring the radiation emitted from the body (for example, with a "whole body counter") or by measuring the radioactive materials contained in biological samples such as urine or feces. Dose estimates can also be made if one knows how much radioactive material was in the air and the length of time during which the air was breathed.

18. What happens if a worker exceeds the annual dose limit?

If a worker receives a dose in excess of any of the annual dose limits, the regulations prohibit any occupational exposure during the remainder of the year in which the limit is exceeded. The licensee is also required to file an overexposure report with the NRC and provide a copy to the individual who received the dose. The licensee may be subject to NRC enforcement action such as a fine (civil penalty), just as individuals are subject to a traffic fine for exceeding a speed limit. The fines and, in some serious or repetitive cases, suspension of a license are intended to encourage licensees to comply with the regulations.

Radiation protection limits do not define safe or unsafe levels of radiation exposure. Exceeding a limit does not mean that you will get cancer. For radiation protection purposes, it is assumed that risks are related to the size of the radiation dose. Therefore, when your dose is higher your risk is also considered to be higher. These limits are similar to highway speed limits. If you drive at 70 mph, your risk is higher than at 55 mph, even though you may not actually have an accident. Those who set speed limits have determined that the risks of driving in excess of the speed limit are not acceptable. In the same way, the revised 10 CFR Part 20 establishes a limit for normal occupational exposure of 5 rems (0.05 Sv) a year. Although you will not necessarily get cancer or some other radiation effect at doses above the limit, it does mean that the licensee's safety program has failed in some way. Investigation is warranted to determine the cause and correct the conditions leading to the dose in excess of the limit.

19. What is meant by a "planned special exposure"?

A "planned special exposure" (PSE) is an infrequent exposure to radiation, separate from and in addition to the radiation received under the annual occupational limits. The licensee can authorize additional dose in any one year that is equal to the annual occupational dose limit as long as the individual's total dose from PSEs does not exceed five times the annual dose limit during the individual's lifetime. For example, licensees may authorize PSEs for an adult radiation worker to receive doses up to an additional 5 rems (0.05 Sv) in a year above the 5-rem (0.05–Sv) annual TEDE occupational dose limit. Each worker is limited to no more than 25 rems (0.25 Sv) from planned special exposures in his or her lifetime. Such exposures are only allowed in exceptional situations when alternatives for avoiding the additional exposure are not available or are impractical.

Before the licensee authorizes a PSE, the licensee must ensure that the worker is informed of the purpose and circumstances of the planned operation, the estimated doses expected, and the procedures to keep the doses ALARA while considering other risks that may

be present. (See Regulatory Guide 8.35, "Planned Special Exposures.")

20. Why do some facilities establish administrative control levels that are below the NRC limits?

There are two reasons. First, the NRC regulations state that licensees must take steps to keep exposures to radiation ALARA. Specific approval from the licensee for workers to receive doses in excess of administrative limits usually results in more critical risk-benefit analyses as each additional increment of dose is approved for a worker. Secondly, an administrative control level that is set lower than the NRC limit provides a safety margin designed to help the licensee avoid doses to workers in excess of the limit.

21. Why aren't medical exposures considered as part of a worker's allowed dose?

NRC rules exempt medical exposure, but equal doses of medical and occupational radiation have equal risks. Medical exposure to radiation is justified for reasons that are quite different from the reasons for occupational exposure. A physician prescribing an x-ray, for example, makes a medical judgment that the benefit to the patient from the resulting medical information justifies the risk associated with the radiation. This judgment may or may not be accepted by the patient. Similarly, each worker must decide on the benefits and acceptability of occupational radiation risk, just as each worker must decide on the acceptability of any other occupational hazard.

Consider a worker who receives a dose of 3 rems (0.03 Sv) from a series of x-rays in connection with an injury or illness. This dose and any associated risk must be justified on medical grounds. If the worker had also received 2 rems (0.02 Sv) on the job, the combined dose of 5 rems (0.05 Sv) would in no way incapacitate the worker. Restricting the worker from additional job exposure during the remainder of the year would not have any effect on the risk from the 3 rems (0.03 Sv) already received from the medical exposure. If the individual worker accepts the risks associated with the x-rays on the basis of the medical benefits and accepts the risks associated with job-related exposure on the basis of employment benefits, it would be unreasonable to restrict the worker from employment involving exposure to radiation for the remainder of the year.

22. How should radiation risks be considered in an emergency?

Emergencies are "unplanned" events in which actions to save lives or property may warrant additional doses for which no particular limit applies. The revised 10 CFR Part 20 does not set any dose limits for emergency or lifesaving activities and states that nothing in Part 20 "shall be construed as limiting actions that may be necessary to protect health and safety."

Rare situations may occur in which a dose in excess of occupational limits would be unavoidable in order to carry out a lifesaving operation or to avoid a large dose to large populations. However, persons called upon to undertake any emergency operation should do so only on a voluntary basis and with full awareness of the risks involved.

For perspective, the Environmental Protection Agency (EPA) has published emergency dose guidelines (Ref. 2). These guidelines state that doses to all workers during emergencies should, to the extent practicable, be limited to 5 rems (0.05 Sv). The EPA further states that there are some emergency situations for which higher limits may be justified. The dose resulting from such emergency exposures should be limited to 10 rems (0.1 Sv) for protecting valuable property, and to 25 rems (0.25 Sv) for lifesaving activities and the protection of large populations. In the context of this guidance, the dose to workers that is incurred for the protection of large populations might be considered justified for situations in which the collective dose to others that is avoided as a result of the emergency operation is significantly larger than that incurred by the workers involved.

Table 5 presents the estimates of the fatal cancer risk for a group of 1,000 workers of various ages, assuming that each worker received an acute dose of 25 rems (0.25 Sv) in the course of assisting in an emergency. The estimates show that a 25-rem emergency dose might increase an individual's chances of developing fatal cancer from about 20% to about 21%.

Table 5
Risk of Premature Death from Exposure to 25-Rems (0.25-Sv) Acute Dose

Age at Exposure (years)	*Estimated Risk of Premature Death (Deaths per 1,000 Persons Exposed)*
20–30	9.1
30–40	7.2
40–50	5.3
50–60	3.5

Source: EPA–400–R–92–001 (Ref. 2).

23. How were radiation dose limits established?

The NRC radiation dose limits in 10 CFR Part 20 were established by the NRC based on the recommendations of the ICRP and NCRP as endorsed in Federal radiation protection guidance developed by the EPA

(Ref. 12). The limits were recommended by the ICRP and NCRP with the objective of ensuring that working in a radiation-related industry was as safe as working in other comparable industries. The dose limits and the principle of ALARA should ensure that risks to workers are maintained indistinguishable from risks from background radiation.

24. Several scientific reports have recommended that the NRC establish lower dose limits. Does the NRC plan to reduce the regulatory limits?

Since publication of the NRC's proposed rule in 1986, the ICRP in 1990 revised its recommendations for radiation protection based on newer studies of radiation risks (Ref. 13), and the NCRP followed with a revision to its recommendations in 1993. The ICRP recommended a limit of 10 rems (0.1 Sv) effective dose equivalent (from internal and external sources), over a 5-year period with no more than 5 rems (0.05 Sv) in 1 year (Ref. 13). The NCRP recommended a cumulative limit in rems, not to exceed the individual's age in years, with no more than 5 rems (0.05 Sv) in any year (Ref. 14).

The NRC does not believe that additional reductions in the dose limits are required at this time. Because of the practice of maintaining radiation exposures ALARA (as low as is reasonably achievable), the average radiation dose to occupationally exposed persons is well below the limits in the current Part 20 that became mandatory January 1, 1994, and the average doses to radiation workers are below the new limits recommended by the ICRP and the NCRP.

25. What are the options if a worker decides that the risks associated with occupational radiation exposure are too high?

If the risks from exposure to occupational radiation are unacceptable to a worker, he or she can request a transfer to a job that does not involve exposure to radiation. However, the risks associated with the exposure to radiation that workers, on the average, actually receive are comparable to risks in other industries and are considered acceptable by the scientific groups that have studied them. An employer is not obligated to guarantee a transfer if a worker decides not to accept an assignment that requires exposure to radiation.

Any worker has the option of seeking other employment in a nonradiation occupation. However, the studies that have compared occupational risks in the nuclear industry to those in other job areas indicate that nuclear work is relatively safe. Thus, a worker may find different kinds of risk but will not necessarily find significantly lower risks in another job.

26. Where can one get additional information on radiation risk?

The following list suggests sources of useful information on radiation risk:

- The employer—the radiation protection or health physics office where a worker is employed.
- Nuclear Regulatory Commission Regional Offices:

King of Prussia, Pennsylvania	(610) 337–5000
Atlanta, Georgia	(404) 331–4503
Lisle, Illinois	(708) 829–9500
Arlington, Texas	(817) 860–8100

- U.S. Nuclear Regulatory Commission
  Headquarters
  Radiation Protection & Health Effects Branch
  Office of Nuclear Regulatory Research
  Washington, DC 20555
  Telephone: (301) 415–6187
- Department of Health and Human Services
  Center for Devices and Radiological Health
  1390 Piccard Drive, MS HFZ–1
  Rockville, MD 20850
  Telephone: (301) 443–4690
- U.S. Environmental Protection Agency
  Office of Radiation and Indoor Air
  Criteria and Standards Division
  401 M Street NW.
  Washington, DC 20460
  Telephone: (202) 233–9290

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*Copies are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW., Washington, DC; the PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202) 634-3273; fax (202) 634-3343. Copies may be purchased at current rates from the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328 (telephone (202) 512-2249); or from the National Technical Information Service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161.

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[2]Single copies of regulatory guides may be obtained free of charge by writing the Office of Administration, Attn: Distribution and Services Section, USNRC, Washington, DC 20555, or by fax at (301) 415–2260. Copies are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW., Washington, DC; the PDR's mailing address is Mail Stop LL–6, Washington, DC 20555–0001; telephone (202) 634–3273; fax (202) 634–3343.

REGULATORY ANALYSIS

A separate regulatory analysis was not prepared for this Revision 1 to Regulatory Guide 8.29. A value/impact statement, which evaluated essentially the same subjects as are discussed in a regulatory analysis, accompanied Regulatory Guide 8.29 when it was issued in July 1981.

This Revision 1 to Regulatory Guide 8.29 is needed to conform with the Revised 10 CFR Part 20, "Standards for Protection Against Radiation," as published May 21, 1991 (56 FR 23360). The regulatory analysis prepared for 10 CFR Part 20 provides the regulatory basis for this Revision 1 of Regulatory Guide 8.29, and it examines the costs and benefits of the rule as implemented by the guide. A copy of the "Regulatory Analysis for the Revision of 10 CFR Part 20" (PNL–6712, November 1988), is available for inspection and copying for a fee in the NRC's Public Document Room at 2120 L Street NW., Washington, DC 20555–0001.