and shampoo as usual. Rinse thoroughly. A fine-toothed comb or a special lice/nit removing comb may be used to help remove dead lice or their eggs (nits) from hair. A second treatment must be done in 7 to 10 days to kill any newly hatched lice."

(e) *Other required statements.*

(1) "*Head Lice*: Head lice live on the scalp and lay small white eggs (nits) on the hair shaft close to the scalp. The nits are most easily found on the nape of the neck or behind the ears. All personal headgear, scarfs, coats, and bed linen should be disinfected by machine washing in hot water and drying, using the hot cycle of a dryer for at least 20 minutes. Personal articles of clothing or bedding that cannot be washed may be dry-cleaned, sealed in a plastic bag for a period of about 2 weeks, or sprayed with a product specifically designed for this purpose. Personal combs and brushes may be disinfected by soaking in hot water (above 130 °F) for 5 to 10 minutes. Thorough vacuuming of rooms inhabited by infected patients is recommended."

(2) "*Pubic (Crab) Lice*: Pubic lice may be transmitted by sexual contact; therefore, sexual partners should be treated simultaneously to avoid reinfestation. The lice are very small and look almost like brown or grey dots on the skin. Pubic lice usually cause intense itching and lay small white eggs (nits) on the hair shaft generally close to the skin surface. In hairy individuals, pubic lice may be present on the short hairs of the thighs and trunk, underarms, and occasionally on the beard and mustache. Underwear should be disinfected by machine washing in hot water; then drying, using the hot cycle for at least 20 minutes."

(3) "*Body Lice*: Body lice and their eggs are generally found in the seams of clothing, particularly in the waistline and armpit area. They move to the skin to feed, then return to the seams of the clothing where they lay their eggs. Clothing worn and not laundered before treatment should be disinfected by the same procedure as described for head lice, except that sealing clothing in a plastic bag is not recommended for body lice because the nits (eggs) from these lice can remain dormant for a period of up to 30 days."

Dated: October 29, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–30429 Filed 12–13–93; 8:45 am]

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Part IV

Department of Energy

10 CFR Part 835
Occupational Radiation Protection; Final Rule

DEPARTMENT OF ENERGY

10 CFR Part 835

Occupational Radiation Protection

AGENCY: Department of Energy.

ACTION: Final rule.

SUMMARY: The Department of Energy (DOE) is promulgating primary standards for occupational radiation protection of workers at its facilities. This action is necessary to codify requirements currently contained in DOE directives. The provisions of this final rule are DOE nuclear safety requirements which, if violated, will provide the basis for the assessment of civil and criminal penalties under the Price-Anderson Amendments Act (PAAA) of 1988.

EFFECTIVE DATE: This regulation becomes effective January 13, 1993.

FOR FURTHER INFORMATION CONTACT: Joel L. Rabovsky, U.S. Department of Energy, Office of Health Physics and Industrial Hygiene Programs, EH–41, Washington, DC 20585, (301) 903–2135.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Purpose of the Rule

For the Department of Energy (DOE), this final rule implements the Radiation Protection Guidance to Federal Agencies for Occupational Exposure, discussed under section B, below, and other radiation protection standards. The final rule also addresses recommendations generated by authoritative organizations, e.g., the National Council on Radiation Protection and Measurements (NCRP) and International Commission on Radiological Protection (ICRP). The final rule helps to ensure that DOE facilities are operated in a manner such that occupational radiation exposure to workers is maintained within acceptable limits and as far below these limits as is reasonably achievable.

In general, this final rule codifies existing DOE radiation protection directives. This final rule provides nuclear safety requirements which, if violated, will provide a basis for the assessment of civil and criminal penalties under the Price-Anderson Amendments Act (PAAA) of 1988, Public Law 100–408, August 20, 1988.

B. Process Used To Establish Radiation Protection Standards

Government agencies such as the Department of Energy establish basic radiation protection standards that are consistent with the Radiation Protection Guidance to Federal Agencies for Occupational Workers, issued by the President on January 20, 1987.[1] This guidance, prepared by interagency committees under the leadership of the Environmental Protection Agency (EPA), is generally consistent with recommendations published by the ICRP and NCRP. In the preparation of their reports, the NCRP and ICRP scientific committees rely heavily on information published by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the Committee on the Biological Effects of Ionizing Radiation (BEIR). The UNSCEAR and BEIR reports contain detailed radiobiological and epidemiological information acquired on a worldwide basis. Through this system, U.S. Federal agencies maintain consistency in their basic standards and promote an international consensus on radiation protection standards.

C. Background

On December 9, 1991, the DOE published a proposed rule for public comment in the **Federal Register** (56 FR 64334). The public comment period ended on March 25, 1992. The DOE received thirty-two individual comment letters. In addition, a public hearing was held on February 27, 1992, in Germantown, Maryland. Comment letters were received from private individuals, DOE contractors, other Federal agencies, attorneys representing commercial interests, and the commercial nuclear power industry. Each comment was analyzed and the results of this analysis are discussed in section V. Section V also describes how the proposed rule was changed as a result of the comments from the public.

II. Discussion

A. ICRP Methodology

This section provides a brief explanation of the ICRP methodology on which the Presidential guidance, current DOE radiation protection standards (DOE Order 5480.11, "Radiation Protection for Occupational Workers"), and this final rule are based. The ICRP methodology is outlined in ICRP Publication 26.[2] It identifies two basic types of radiation-induced health effects: Stochastic and nonstochastic.

Radiation-induced health effects which do not have threshold doses are referred to as "stochastic effects." Examples include cancer and hereditary effects. The objective of the ICRP recommendations is to limit the probability of stochastic effects to acceptable levels. For these effects, the severity is not dose dependent—that is, once caused, a malignancy from 100 rems (1 sievert) is no worse than one from 50 rems (0.5 sievert). However, the probability of occurrence does increase as the dose increases. The Department currently accepts the assumption used by authoritative national and international organizations that there are no thresholds for stochastic effects.

Nonstochastic effects can only be manifested if a threshold dose is exceeded; therefore, the objective of the ICRP recommendations is to maintain personnel exposure below the threshold doses in order to prevent these effects. The nonstochastic effects become more severe as the dose increases above threshold levels. Examples of nonstochastic effects include cataracts of the eye and decreased sperm production. More recent scientific recommendations refer to these effects

[1] Radiation Protection Guidance to the Federal Agencies for Occupational Exposure. 52 FR 2822.

[2] International Commission on Radiological Protection. Recommendations of the International Commission on Radiological Protection. ICRP Publication 26, Annals of the ICRP 1, (3). Pergamon Press, New York, 1977.

as "deterministic."[3] This convention will be followed throughout this preamble.

1. Stochastic Effects

For stochastic effects, ICRP Publication 26 adopted the level of risk associated with a dose of 5 rems (0.05 sievert) in a year, delivered uniformly over the whole body, as the basis for the occupational dose limitation system. The risk of excess fatal cancers and serious genetic effects identified in ICRP Publication 26 is 1.65×10^{-4} per person-rem (1.65×10^{-2} per person-sievert). For protection against stochastic effects from intakes, the annual limit on intake (ALI) for each radionuclide is the quantity that, if taken into the body, would cause the same stochastic risk as a uniform, whole body dose of 5 rems (0.05 sievert) in a year.

In ICRP Publication 26, the absorbed dose and dose equivalent quantities are consistent with previous ICRP publications. The new quantities and terminology used to facilitate implementation of the ICRP Publication 26 recommendations are explained in the following discussions. Although all organs and tissues receive the same dose equivalent under uniform exposure conditions, the cancer risks are often not the same. Each organ or tissue contributes its own fraction of the total risk. This fraction is the weighting factor (w_T), and the sum of the weighting factors is unity. The product of the weighting factor and the dose equivalent is referred to as the effective dose equivalent (EDE). The EDE can be applied to both external and internal irradiation. Also, EDE may be applied to either individual organs and tissues or the sum over all organs and tissues. The Department has chosen to specify the use of deep dose equivalent to account for EDE from external exposure. The units used for EDE are either the rem or sievert (Sv).

The committed dose equivalent (CDE) is the 50-year integrated dose equivalent to a specific organ or tissue resulting from the intake of a radionuclide. The committed effective dose equivalent (CEDE) is the same quantity as the CDE, with the exception that each organ or tissue CDE is multiplied by the weighting factor (w_T). If more than one organ or tissue is irradiated, the CEDE for the exposed person is the sum of the weighted CDE to the individual organs and tissues.

[3] International Commission on Radiological Protection. 1990 Recommendations of the International Commission on Radiological Protection. ICRP Publication 60, Annals of the ICRP 21, (1–3). Pergamon Press, New York, 1991.

The sum of the EDE from external sources and CEDE for internal exposure is the total effective dose equivalent (TEDE). The occupational TEDE limit is 5 rems (0.05 Sv) in a year. The sum of the TEDE recorded for an individual for each year is the cumulative total effective dose equivalent (CTEDE). The units used for CDE, CEDE, TEDE, and CTEDE are either the rem or sievert (1 rem = 0.01 Sv).

2. Deterministic Effects

Technical justification for the ICRP position on deterministic effects is presented in ICRP Publication 41.[4] According to this position, deterministic effects, with the exception of cataracts, will not occur among adults if the combined dose from external and internal radiation to any organ or tissue is limited to or less than 50 rems (0.5 Sv) a year; the dose limit for the lens of the eye is 15 rems (0.15 Sv). (In ICRP terminology, the words "organ and tissue" are used interchangeably to designate specific parts of the entire body.) Therefore, to be consistent with ICRP recommendations, it is necessary to ensure that no organ or tissue exceeds this annual (or yearly) limit.

B. Limiting Values for Radiation Exposure

Limiting values for a variety of circumstances involving potential exposure to radiation and radioactive material are promulgated in this final rule. Under this final rule, the internal component of the DOE occupational exposure limits (see § 835.202) is based on the concept of a 50-year committed dose instead of an annual committed dose. Because of the significance of this issue of committed dose, the Department solicited input during the public comment period. The Department's analysis of the resultant public comments verified the effectiveness of both approaches for worker protection. However, as pointed out by a significant number of public comments, the use of a 50-year committed dose provides additional benefits. These benefits are:

—Consistency with the recommendations of national and international scientific committees and other Federal regulatory agencies;
—Simplification of record keeping associated with internal dose;
—Simplification of the transfer of workers between DOE and U S. Nuclear Regulatory Commission (NRC) regulated facilities; and
—Consistency between the DOE limits for occupational exposure and the limits used by DOE for protection of members of the public.

As a result of the analysis of public comments, DOE has adopted the use of a 50-year committed dose for determining compliance with the occupational limits on exposure to radiation.

The considerations discussed in the sections below were used in developing the regulatory standards presented in the final rule:

1. Protection Against Stochastic Effects (§ 835.202)

a. *Atomic bomb survivor study.* Two developments in the atomic bomb survivor study have warranted an increase in risk estimates for radiation-induced cancers over those presented in ICRP Publication 26. In 1981, a reassessment of the radiation doses received by the survivors indicated that any gamma-radiation-induced malignancies at Nagasaki had been caused by less radiation than previously believed.[5] However, the opposite effect was observed among the Hiroshima survivors. The new dose estimates include more consideration for shielding by structures and for shielding by tissues overlying the affected organs. The overall impact of the revised dosimetry was summarized by Dr. Warren Sinclair, NCRP President, as follows:

> Many of the changes made in the dosimetry tend to cancel so that the net effect of the dosimetry on the risk estimates for cancer is to increase them by a factor of between 1 and 2 depending on the location of the organ in the body.[6]

The second (and more important) consideration was the greater occurrence of deaths from solid tumors among survivors than had been predicted by the models used to determine the ICRP Publication 26 risk estimates.[7]

b. *DOE analysis of recent risk estimates.* The reassessment of the radiation doses received by the atomic bomb survivors has been analyzed in reports published by UNSCEAR in

[4] International Commission on Radiological Protection. Nonstochastic Effects of Ionizing Radiation. ICRP Publication 41, Volume 14, No. 3 Pergamon Press, New York, 1983.

[5] National Research Council, Advisory Committee on the Radiation Effects Research Foundation. An Assessment of the New Dosimetry for A-Bomb Survivors. Washington, DC, National Academy Press, 1987.

[6] United States Nuclear Regulatory Commission. Workshop on Rules for Exemption from Regulatory Control, NUREG/CP–0101, 1989.

[7] Radiation Effects Research Foundation. Comparison of Risk Coefficients for Site-Specific Cancer Mortality Based on the DS86 and T65R Shielded Kerma and Organ Doses. Life Span Study Report II, Part 1, RERF TR 12–87, 1987

1988[8] and the BEIR V Committee in 1990.[9] These reports concluded that risk estimates for radiation-induced cancers are greater than previously predicted. With the publication of the BEIR V Report, DOE established two committees to review the impact of the reports; the Technical Review Committee (TRC) to perform an external and independent scientific assessment and the Internal Review Committee (IRC) to identify concerns which could affect current DOE Orders and operations. The TRC report[10] recommended no immediate change in current DOE directives. The report stated that the difference in the BEIR V cancer risk estimates, as compared to the 1980 BEIR III[11] estimates, may be reduced significantly when the BEIR V risk estimates are appropriately applied to the nuclear workforce. The IRC subsequently concluded that the increased risk cited in the BEIR V Report does not justify immediate revisions of the DOE occupational exposure limits, but did recommend that DOE increase its emphasis on implementation of the As Low As Reasonably Achievable (ALARA) concept.[12]

c. *Dose-reduction alternatives.* In light of the increased risk estimates published in the 1988 UNSCEAR and 1990 BEIR V reports, DOE has considered a number of approaches, including ALARA, to reduce the dose received by DOE employees. In evaluating each alternative, the anticipated effectiveness in reducing overall risk to DOE employees has been weighed against possible detrimental effects resulting from each approach.

(1) *Lowering the annual dose limit.* The Department considered lowering the annual dose limits to control stochastic effects but concluded that this approach would decrease operational flexibility without reducing overall radiation risk. Decreasing the dose limit to 2 or 3 rems (0.02 or 0.03 Sv) per year would have a direct effect on very few DOE workers and would not appreciably reduce the collective dose to occupationally exposed employees. Reductions in the limit to levels which would affect a majority of the DOE employees could severely limit operational flexibility while increasing the average and collective dose to workers.

(2) *Adopting the NCRP lifetime dose limit.* The Department considered adopting the suggestion in NCRP Report 91[13] that a worker's lifetime dose in rem should not exceed his or her age in years. Because lifetime doses among DOE workers are in general so far below this value, a lifetime limit would not provide significant reduction in average and collective dose to DOE workers. In addition, there is a possibility that a worker's future employment could be jeopardized if an individual receives high exposures early in his or her career.

(3) *Compromise between a lifetime limit and a lower annual limit.* The ICRP recommendations presented in its Publication 60 change their system of dose limitation. The ICRP now recommends an occupational dose limited to 10 rems (0.1 Sv) over 5 consecutive years such that no dose in a single year exceeds 5 rems (0.05 Sv). By limiting dose in this manner and providing for dose optimization, ICRP believes they obtained some of the benefits of a lifetime dose limitation system while avoiding some of the detriments of this approach. One benefit of the system is the allowance for flexibility in adjusting annual dose limits to meet operational needs. Detriments include jeopardizing a worker's future employment and logistical concerns in implementing a 5 year limit. DOE does not believe that the approach suggested in ICRP Publication 60 would appreciably reduce collective dose to occupationally exposed personnel. The ICRP recommendations are currently being reviewed by the U.S. radiation protection community and have not been incorporated into Federal Guidance. Consequently, DOE did not decide to incorporate these recommendations into the final rule at this time.

(4) *Emphasis on ALARA implementation.* Increasing emphasis on ALARA program implementation, either by itself or in conjunction with one of the three dose reduction alternatives discussed above, would be an effective method of reducing doses received by DOE employees. Coupling an increased ALARA emphasis with another dose reduction alternative, however, would carry the potential for the detrimental effects described above.

d. *Dose-reduction approach chosen by DOE.* In light of the potential detrimental effects discussed above, the DOE believes that dose reduction can best be achieved by maintaining the proposed regulatory limits and increasing emphasis on ALARA program implementation. The imposition of a lifetime cumulative dose limit was considered to be more appropriate as an administrative versus regulatory limit to control individual exposure. Maintaining the proposed regulatory limits also provides consistency with the limits contained in the Presidential guidance to Federal agencies.

Emphasis on ALARA program implementation has proven effective in maintaining the occupational doses for Departmental and contractor employees well below the current regulatory limits and those recently recommended by the ICRP. According to the most recent three years of available data,[14] total collective dose for all DOE workers from external exposure and the average DOE individual worker dose has decreased. The total collective dose for all monitored DOE workers was 3,655 person-rem (36.55 person-Sv) in 1988, 3,073 person-rem (30.73 person-Sv) in 1989, and 2,074 person-rem (20.74 person-Sv) in 1990. Average worker doses were 115 mrem (1.15 mSv) in 1988, 92 mrem (0.92 mSv) in 1989, and 71 mrem (0.71 mSv) in 1990. Over this period of time, the number of monitored workers has increased from 81,629 in 1988 to 90,882 in 1989 and to 99,443 in 1990.

During this same period, of those employees monitored receiving measurable exposure, data show that 34 workers received in excess of 2 rems (0.02 Sv) in 1988, 21 in 1989, and 7 in 1990. No individual occupational dose exceeded 3 rems (0.03 Sv) in any of these years. However, further reductions for certain employees could be achieved

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[8] United Nations Scientific Committee on the Effects of Atomic Radiation. Sources, Effects and Risks of Ionizing Radiation, Report to the General Assembly with Annexes. United Nations Publications, New York, 1988

[9] National Research Council, Committee on Biological Effects of Ionizing Radiation, Health Effects of Exposure to Low Levels of Ionizing Radiation—BEIR V, Washington, DC, National Academy Press, 1990.

[10] DOE Technical Review Committee. A Technical Review and Assessment of the BEIR V Report. DOE/EH–0149T. March 1990.

[11] National Research Council, Advisory Committee on the Biological Effects of Ionizing Radiation. The Effects on Populations of Exposure to Low Levels of Ionizing Radiation. 1980 BEIR III. Washington, DC: National Academy Press, 1980.

[12] Assistant Secretary for the Environment, Safety and Health. Final Report to the Secretary of Energy, Implications of the BEIR V Report to the Department of Energy. DOE/EH–0158T. August 1990.

[13] National Council on Radiation Protection and Measurements. Recommendations on Limits for Exposure to Ionizing Radiation. Report No. 91. Bethesda, MD, 1987.

[14] Assistant Secretary for Environment, Safety and Health, Twenty-first Annual Report/Radiation Exposures for DOE and DOE Contractor Employees-1988. DOE/EH–0171P, December 1990.

Assistant Secretary for Environment, Safety and Health, Twenty-second Annual Report/Radiation Exposures for DOE and DOE Contractor Employees-1989. DOE/EH–0286P, December 1992.

Assistant Secretary for Environment, Safety and Health, Twenty-third Annual Report/Radiation Exposures for DOE and DOE Contractor Employees-1990. DOE/EH–0287P, *In Press.*

through greater emphasis on ALARA implementation.

DOE will continue to evaluate the recommendations of the ICRP and other expert bodies, and participate in the deliberations of the U.S. Committee on Interagency Radiation Research and Policy Coordination and any interagency task force convened by the EPA to consider revised Federal radiation protection guidance. Any future reductions in the dose limits by the DOE would be the subject of a future rulemaking proceeding.

e. *Basic elements of an ALARA program.* The method of implementing an ALARA program is highly dependent on facility conditions. To provide an objective basis for implementation and assessment of DOE ALARA requirements, each ALARA program is expected to address, at a minimum, the following basic elements:

—*Policy.* Establish commitment and participation of all management and workforce levels.
—*Training.* Require for managers and workers involved with any aspect of radiological operations.
—*Design.* Ensure integration of appropriate methods for maintaining occupational exposures ALARA during design.
—*Procedures.* Provide direction for maintaining occupational exposures ALARA.
—*Planning.* Integrate measures for maintaining occupational exposures ALARA for specific operations.
—*Internal audits.* Conduct comprehensive audits periodically and report results to the highest management levels.
—*Records.* Maintain documentation to demonstrate compliance.

Section 835.101 of the final rule requires that an occupational radiation protection program include the ALARA concept. ALARA records are required under § 835.704 and training requirements for workers are provided under subpart J. During the design of new facilities and for facility modifications, the use of ALARA optimization techniques is specifically required under §§ 835.1001 and 835.1002. Exposure levels in the workplace must be maintained ALARA as required under § 835.1003.

2. Protection Against Deterministic Effects (§ 835.202)

ICRP Publication 41 provides the data base supporting the position that, with the exception of the lens of the eye, deterministic effects will not be observed in organs and tissues receiving a dose less than 50 rems (0.5 Sv) in a year. The Department has not identified more recent radiobiological information indicating that this dose limit should be changed and notes that ICRP has retained this value in the recent revision of its recommendations contained in ICRP Publication 60. For these reasons, the Department establishes a limit of 50 rems (0.5 Sv) in a year from the sum of the CDE and external dose to prevent occurrence of deterministic effects to organs and tissues other than the lens of the eye. In keeping with current Federal Guidance, a limiting value of 15 rems (0.15 Sv) a year has been retained for the lens of the eye.

3. Protection of the Embryo/Fetus (§ 835.206)

The 1987 Presidential guidance to Federal agencies states:

> The dose equivalent to an unborn (embryo/fetus) as a result of occupational exposure of a woman who has declared that she is pregnant should be maintained as low as reasonably achievable, and in any case should not exceed 0.5 rem (0.005 sievert) during the entire gestation period. Efforts should be made to avoid substantial variation above the uniform monthly exposure rate that would satisfy this limiting value.

The Department has followed this guidance. The dose limit for controlling prenatal exposure to the embryo/fetus is provided in § 835.206. The 0.5 rem (0.005 sievert) limit applies only to the embryo/fetus of any woman who has voluntarily declared her pregnancy for the purpose of providing additional protection to her embryo/fetus from occupational exposure. The decision to formally declare a pregnancy for the purpose of application of the lower occupational exposure limit for the protection of the woman's embryo/fetus is left as the responsibility of the pregnant worker. The Department believes that this approach is consistent with the provisions of Title VII of the Civil Rights Act of 1964, as amended, regarding discrimination in employment practices. The recommendation to avoid non-uniform exposure rates arises from information obtained in the study of atomic bomb survivors, which revealed that an embryo/fetus irradiated at high dose rates may be particularly susceptible during sensitive periods to certain deleterious effects. For example, during the first trimester of pregnancy, significant radiation exposure could lead to severe mental retardation.

4. Planned Special Exposures (§ 835.204)

The Department provides for planned special exposures in the final rule. Certain employees have skills important to plant and public safety and, for this and other reasons, it is recognized that unusual conditions can arise in which higher-than-normal doses can be justified. Under approved, well-justified, well-planned, well-controlled, highly infrequent and unusual conditions, operating management would be permitted to allow specified individuals doses exceeding the 5 rems (0.05 Sv) per year limit. The planned special exposure provision does not apply to emergency conditions. During an emergency there may not be adequate time for the extensive planning or approvals required under § 835.204. Other provisions are made in the final rule for accidents and emergency situations (see section E below). The term "unusual conditions" is made clear in the final rule by specifying that alternatives which would preclude exposures higher than the prescribed dose limits must be either unavailable or impractical. At least one of these conditions must exist before a planned special exposure can be considered.

The total dose from planned special exposures for an employee during any given year cannot exceed 5 rems (0.05 Sv). This is in addition to the 5 rems (0.05 Sv) dose limit provided in § 835.202. Thus, apart from emergency situations, the maximum annual dose that an employee could receive would be 10 rems (0.1 Sv). An employee could receive no more than 25 rems (0.25 Sv) of planned special exposures from DOE and non-DOE operations during his/her career. Every planned special exposure must be approved in advance by the DOE and requires the informed consent of the employee involved. Documentation of each planned special exposure is required to be recorded in the employee's occupational exposure file and provided to the employee.

C. Radiation Safety Training

Two categories of employees defined in the final rule are subject to the requirements in this part for radiation safety training: general employees and radiological workers. A general employee is any individual (DOE personnel, DOE contractor, or subcontractor employee) who performs work for, or in conjunction with, the DOE, or utilizes DOE facilities. This includes individuals considered to be radiological workers. The final rule establishes training requirements for each category.

All general employees who may enter a controlled area at a DOE facility are required under § 835.901 to receive radiation safety training before any potential exposure to radiation or radioactive material at that facility. In addition, these employees must also be

retrained whenever the radiation protection policies and procedures are significantly changed. General employees are also subject to refresher training every 2 years. The level of training would be commensurate with the potential radiation protection problems encountered by the employee.

Radiological workers are required under § 835.902 to be trained to ensure familiarization with the fundamentals of radiation protection and the ALARA concept. Retraining is required every 2 years. Radiological workers must complete their training and successfully demonstrate their knowledge before performing work in a radiological area. During field training, untrained radiological workers are required to be accompanied by and under the direct supervision of a trained radiological worker. The training emphasizes procedures specific to the individual's job assignment and is commensurate with his or her work assignment.

Although not explicitly stated in the final rule, training on generic subject matter for radiological workers and radiological control technicians may be waived for individuals who pass a comprehensive examination. Individuals are still required to be trained on subject matter specific to a given facility or site.

D. Control of Exposure to Radiation and Radioactive Material

1. Introduction

The final rule incorporates a number of requirements that would: (1) Control the extent of occupational exposures to radiation and radioactive material; (2) establish controls over entry into areas in which such exposures could occur; and (3) ensure warnings to workers whenever radiation and radioactive material are present. These combined measures provide a high degree of assurance that workers would not be inadvertently or unknowingly exposed to radiation or radioactive material.

The final rule requires routine monitoring of individuals and the workplace. The measurement of individual occupational exposures is accomplished by requiring personnel radiation dosimetry devices for all employees likely to receive a prescribed fraction of the allowable annual radiation dose. In addition, possible internal exposure of an employee from the intake of radioactive material is measured using the appropriate bioassay technique, such as whole body counting or analysis of excreta. The results of air sampling data may be used to assign an internal dose if bioassay results are unavailable, or if they are inadequate, or if internal dose estimates based on representative air concentration values are demonstrated to be as accurate or more accurate than bioassay results.

Areas where radiation or radioactive material may be present must be monitored for possible airborne and surface radioactive contamination as well as for radiation. Concentrations of airborne radioactive material must be measured by analyzing samples representative of the air at work locations. Real-time releases of airborne radioactive material must be detected by stationary air monitoring instruments equipped with alarm devices.

Requirements for controlling personnel exposure to radiation, airborne radioactivity, and surface contamination are established. All personnel and equipment leaving a radiological area must be monitored for surface contamination. Limiting values for contamination are provided in appendix D. Contamination levels higher than these limiting values are not allowed outside of radiological areas except in the case of fixed contamination under prescribed conditions.

Any area where radiation and/or radioactive contamination levels are above specified values must have access controls commensurate with the level of the hazard. These controls may include barricades, control devices on entrances, locks, alarms, and direct surveillance.

In order to make employees aware of radiation and contamination conditions (surface and airborne), the final rule requires that signs be clearly posted to identify those areas that are controlled to manage potential exposures and those areas where radiation levels exceed certain values. Containers of radioactive material and radioactive items are required to be properly labeled to provide information needed for purposes of radiation protection and the prevention of inadvertent transfer to locations outside of radiological areas.

The system of control is intended to ensure: (1) That occupational exposures are maintained at ALARA levels; (2) that the Department's limiting values are not exceeded; (3) that employees are aware of and prepared to cope with emergency conditions; and (4) employees are not inadvertently exposed to radiation or radioactive material.

2. Control of External Radiation Dose

The control of occupational exposures to radiation is required to be implemented through facility design and engineering controls, together with such procedural controls as work-area monitoring and posting, control of work-area access, and individual monitoring and dose assessment. Collectively, these controls will provide assurance that exposures are maintained ALARA and within the Department's limiting values. Workplace monitoring provides a control mechanism to detect and quantify external radiation levels, enables measures to be taken to prevent unanticipated and unplanned exposures, and contributes to maintaining actual exposures ALARA.

The final rule does not prescribe specific types and frequencies of workplace monitoring. As specified in § 835.401, the monitoring must be routine and sufficient to control potential sources of radiation and demonstrate compliance with the radiation protection program and other requirements of this final rule (e.g., area posting and occupational dose limits). Determining the frequencies and locations of workplace monitoring is the responsibility of each site and must be commensurate with the actual work and exposure situations.

3. Control of Internal Radiation Dose

To the extent reasonably achievable, system and facility design and engineering controls, such as containment and ventilation systems, must be used as the primary mechanism for confining radioactive material and ensuring that radioactive material intakes (and resultant internal doses) are maintained at ALARA levels. Operational controls must also be established to minimize potential inhalation exposures.

Section 835.403 requires that measurements of radioactivity concentrations in workplace air be performed. Periodic air sampling must be performed in areas where employees are likely to exceed 2 percent or more of the ALI values discussed in the final rule. Continuous, real-time monitoring must be performed in areas where an individual could be exposed to airborne radioactivity concentrations exceeding the derived air concentration (DAC) values set forth in the final rule. Real-time monitors must have an alarm capability and have sufficient sensitivity to alert potentially exposed individuals that their immediate action is necessary to minimize or terminate an inhalation exposure. The final rule addresses requirements for bioassay measurements (measurements of radioactive material within and excreted from the body) to determine the magnitude of internal doses and includes directions regarding which employees should be included in bioassay programs. These measurements also confirm the effectiveness of the

confinement and air monitoring systems.

4. Releases of Materials and Equipment

Contamination control programs must include the establishment of limits on the amount of fixed and removable contamination that could be transferred from a radiological area to a controlled area. The regulatory framework for such controls is established in § 835.1101. The criteria for unrestricted release of property from DOE facilities are currently set forth in DOE Order 5400.5, "Radiation Protection of the Public and Environment." DOE has addressed such releases in the proposed rule, 10 CFR part 834.

The final rule specifies that material and equipment in radiological areas cannot be removed to controlled areas unless measurements are made to establish that removable contamination meets specified limits and the combination of fixed and removable contamination does not exceed other specified limits provided in appendix D. There are provisions, however, that permit conditional or controlled removal of contaminated material and equipment to controlled areas under specified conditions.

5. Records

The final rule establishes requirements for the documentation and maintenance of records of working conditions as well as for subsequent evaluations of radiation protection compliance and performance in subpart H. Records that are specifically required include those necessary to demonstrate compliance with the ALARA provisions of the final rule.

Individual occupational dose records must be maintained to provide individual external and internal dose measurement data for each worker. In addition, the data necessary to allow future verification or reassessment of the recorded doses must be recorded.

The final rule also requires that records be maintained of: (1) Radiological conditions under which individuals were exposed; (2) other facility information pertinent to exposures; (3) results of surveys for the release of material and equipment; and (4) results of surveys for radiation and radioactive material in the workplace.

Each individual's training as a general employee and as a radiological worker must be recorded. Where appropriate, demonstration and documentation of proficiency is required.

Records are to be retained until final disposition is authorized by DOE. It is the Department's intention that records be retained consistent with the principles contained in DOE Order 1324.2A, "Records Disposition."

6. Reports

On an annual basis, each DOE- or DOE contractor-operated facility must provide each individual monitored for occupational exposure a radiation dose report of their occupational exposure at that facility as required under subpart I. In addition, each individual's radiation exposure data, including any current estimate, would always be available to him or her, upon request. Certain required reports to DOE include personnel exposure data. Copies of any DOE report identifying an individual by name must be sent to that person.

E. Accidents and Emergencies

For emergency situations, general employees could be allowed to exceed the dose limits specified in §§ 835.202 and 835.205, provided that all of the conditions specified in subpart N are met. The level of exposure permitted will depend upon the severity of the emergency situation. Exposures up to 2 times the annual dose limits could be permitted to protect against property loss. Higher exposures, up to 5 times the annual dose limits or greater, could be permitted to save lives and protect public health. The Department believes that the judgments involved in lifesaving situations and the protection of public health and safety are complex and not appropriate for generic rulemaking.

The doses allowed in subpart N of the final rule are in addition to those allowed under normal operating conditions, including planned special exposures. The determination of how much exposure an employee had already received during the current year is not a prerequisite for emergency dose approval and duty assignment.

The final rule requires that the details of any exposure in excess of the annual dose limits be documented in the occupational exposure record of the affected employee. In addition, the incident must be investigated and the results reported to DOE. Departmental requirements for occurrence reporting and processing provide a mechanism for such investigations and reports. The employee must not be allowed to receive further exposure until approval is first obtained from the contractor management and responsible DOE field organization. Also, the employee must receive counseling from the appropriate health experts regarding the consequences of receiving additional occupational exposure that year and the affected employee must agree to return to radiological work. The operation that caused the exposure must cease pending a finding by DOE that the conditions that caused the exposure had been eliminated.

The final rule requires both fixed (area) and personal nuclear accident dosimeters. These dosimeters provide a method for measuring radiation doses to employees as a result of a nuclear criticality accident within a workplace.

F. DOE Guidance Documents

DOE recognizes that individuals performing DOE activities covered under the scope of this final rule have a reasonable expectation to know what the Department considers acceptable with respect to compliance. To provide this understanding, the Department has initiated a program to develop and issue regulatory guidance documents covering specific topical areas of the final rule (i.e., training, posting, internal dosimetry, etc.). Other guidance is planned that will provide information on the application of the final rule to major classes of DOE facilities and activities (i.e., uranium facilities, tritium facilities, radiation-generating devices, etc.).

Two types of regulatory guidance documents are planned: guidance for implementing the provisions of the final rule and guidance providing technical clarification. Implementation guidance is intended to identify and make available to DOE contractors basic program elements and acceptable methods for implementing specific provisions of the final rule. Technical guidance will describe and disseminate technical methods and techniques for fulfilling implementation guidance and, in turn, the requirements in the final rule.

Unlike the requirements specifically set forth in the final rule, the provisions in guidance documents are not mandatory. They are intended solely to describe the rationale for and the objectives of regulatory requirements and/or to identify acceptable methods for implementing regulatory requirements. Failure to follow a guidance document does not in itself indicate non-compliance with a specific requirement in the final rule. A finding of non-compliance must be based on a failure to satisfy the regulatory requirement. Following a guidance document, however, will ordinarily create a presumption of compliance with a related regulatory requirement.

Regulatory guidance documents on the following topics are planned for issuance soon after the final rule is published. Copies will be made available at the DOE Freedom of Information Reading Room.

—Portable Instrument Calibration;
—Radiological Posting and Labeling;
—Radiological Training Program; and
—Radiation-Generating Devices.

Other documents will cover such topics as:

—Sealed Radioactive Source Accountability;
—Internal Dosimetry Program;
—Tritium, Plutonium, Uranium Facility Radiological Control Programs;
—Contamination Control;
—Air Sampling and Monitoring;
—External Dosimetry;
—ALARA;
—Dose Reporting;
—Fetal Exposure;
—Radiological Surveys;
—Records; and
—Radiation Protection Programs.

Regulatory guidance documents are intended to be living documents and will be updated to reflect advances in a particular area, as well as comments from the users of the guidance documents. DOE intends ordinarily to issue guidance documents initially on an interim basis, while soliciting comments. This approach will expedite the availability of guidance, while facilitating the use of feedback.

In addition to the documents discussed previously, the Department has issued the Radiological Control Manual. Although not a regulatory document, the provisions in the Manual also identify acceptable approaches for meeting the requirements of this final rule. Section III.B provides additional information concerning the Manual.

G. Transition From DOE Order 5480.11 to Part 835

This final rule becomes effective 30 days after its publication in the **Federal Register**. The Department recognizes, however, that the process of identifying and implementing all the actions needed for full compliance with the requirements contained in the final rule will take longer than 30 days. Therefore, the final rule provides for the submission of a radiation protection program for each DOE activity by January 1, 1995 that sets forth the plans, schedules, and other measures for achieving compliance with the requirements of this final rule by January 1, 1996. Once approved by the Department, a radiation protection program will describe the actions that will be taken to comply with the requirements of this final rule.

Prior to the approval of the radiation protection program, a contractor may desire guidance as to what level of compliance the Department expects. The occupational radiation protection standards currently contained in DOE Order 5480.11 provide a level of protection which is largely equivalent to that provided by the final rule. Therefore, contractors meeting these standards (to the extent they are contractually obligated to do so on the effective date of the final rule) will be treated as being in compliance with part 835.

As part of the transition to a radiological protection program based on part 835, the Department intends to revise DOE Order 5480.11. Specifically, the Order will be revised to incorporate, by reference, the provisions of the final rule and to delete any corresponding existing provisions from the Order. In addition, the Department will revise the Order to make explicit that DOE Federal employees must comply with requirements of part 835.

The transition from DOE Order 5480.11 to part 835 should not result in the unnecessary repetition of work already in progress or completed in the area of radiation protection. DOE expects that many of the actions currently being taken to comply with contractual obligations can continue or be modified to achieve compliance with the requirements of part 835. In particular, DOE expects radiation protection programs to incorporate existing programs, plans, and actions to the extent practical.

H. Resource Allocation/Costs

The Department solicited comments concerning the potential costs and benefits of this regulation when the proposed rule was issued for public comment. Specifically, the Department sought information addressing the specific nature and scope of the additional cost to which contractors would be subjected as a result of implementing the final rule (i.e., the projected additional cost over the present cost for radiation protection programs). The Department requested that this information include an explanation why these costs were not already addressed in the current contractual relationship or PAAA. Several comments were provided on this subject.

1. Referencing the NRC's cost-benefit analysis result for revising 10 CFR part 20, commenters stated that the cost would outweigh the benefits. These commenters identified the cost of record keeping requirements associated with determination of annual effective dose equivalent and control of these records as the most significant cost.

2. Other commenters indicated that the costs associated with complying with the proposed DOE nuclear safety standards (i.e., parts 820, 830, and 835) would be very high and, in many cases, not commensurate with the benefits. The commenters estimated an increase in manpower of 20 to 25 percent to implement the proposed parts 820, 830, and 835.

3. Commenters stated that the successful implementation of the proposed rule is questionable without significant improvement in the existing infrastructure within the DOE complex. Comments also stated that DOE should revisit the issue of resource allocations for implementation of this final rule.

4. Commenters noted that additional capital costs would be involved in upgrading and procuring real-time air monitoring equipment. They stated that commercial equipment capable of meeting the proposed detection capability standards when applied to field conditions at remedial action sites is not currently available. Costs were estimated by two commenters to be $500,000 and $1,000,000, respectively, during the first year of implementation, with recurring annual maintenance and calibration costs estimated at $200,000 and $300,000, respectively.

In general, commenters did not provide any specific information relative to cost other than for air monitoring at remedial action sites. Since the requirements contained in the final rule appeared to a large extent in DOE Order 5480.11, issued in 1988, and have been planned or implemented throughout the complex, the Department believes that small additional costs are associated with implementing the final rule. The Department believes that essentially the same level of worker protection intended in the proposed rule can be achieved without the large increase in cost associated with the development and procurement of new technology.

In considering the comments on the ability to meet proposed detection capability standards, the final rule does not define a detection limit for continuous air monitors. This issue will be addressed in regulatory guidance in such a manner which permits continued use of most of the current technologies in use in the DOE complex.

I. Relationship Between the Proposed Requirements and Those of the NRC

When the proposed rule was promulgated for public comment, DOE requested comments concerning the differences between its proposed requirements and those of the NRC. In particular, DOE solicited comments on the relative merits of the "annual dose" method for evaluating internal exposure proposed by DOE and the "committed

dose" method for evaluating internal exposure used by NRC. Some commenters recommended that the Department unilaterally adopt the occupational radiation protection standards promulgated by the NRC in 10 CFR part 20. They argued that there was a basic need for consistency among agencies in their occupational radiation protection standards, particularly as occupational workers may move between the DOE and commercial sectors. They emphasized the importance for consistency in the method for evaluating internal exposure and that the NRC approach of using committed dose was a technically superior method.

While agreeing with the goal of consistency, the Department believes that it must promulgate its own standards because of the unique nature and diversity of radiological activities within the DOE complex compared to the commercial sector regulated by the NRC. Issuing this final rule also allows the Department to establish more rigorous requirements than those contained in 10 CFR part 20 in areas of particular concern to the DOE. Specific examples include contamination control, posting, and dosimetry.

The Department modified the final rule to make it more consistent with 10 CFR part 20. Most significantly, the DOE final rule uses the committed dose method for evaluation against the regulatory dose limits.

The following areas were also changed from the proposed rule for consistency with the revised 10 CFR part 20: Determination of prior exposure; control of access to high and very high radiation areas; posting; control of embryo/fetus dose; definition of high and very high radiation areas; provisions for planned special exposures; provisions for monitoring minors and declared pregnant workers; written dose estimates provided to terminating workers; and use of air sample results for internal dose determination. These changes are discussed in much greater detail in section V.

J. Related Areas Not Addressed in Final Rule

Commenters noted the absence of requirements related to the areas of packaging and transportation of radioactive material, respiratory protection, and transfer or discharge of radioactive waste. Although these topics are related to the general area of occupational radiation protection, DOE requirements for each of these areas are included in various DOE Orders and are consequently not duplicated in the final rule. DOE Orders 1540.1, "Materials Transportation and Traffic Management," 1540.2, "Hazardous Material Packaging for Transport—Administrative Procedures," 1540.3, "Base Technology for Radioactive Material Transportation Packaging Systems," and 5480.3, "Safety Requirements for the Packaging and Transportation of Hazardous Materials, Hazardous Substances, and Hazardous Wastes," contain requirements related to the packaging and transportation of radioactive material, including radioactive wastes. DOE Order 5480.4, "Environmental Protection, Safety, and Health Protection Standards," requires the use of American National Standards Institute (ANSI) standard Z88.2–1980 [15] on respiratory protection. DOE Order 5400.5 contains requirements related to effluent and waste discharge.

K. Support of Rulemaking

Some commenters enthusiastically supported the codification of DOE health and safety requirements. They stated that codification is desirable because it provides more vigorous external review, greater assurance that DOE facilities are operated safely, and greater assurance that radiation exposures are maintained ALARA. Commenters discussed the importance for DOE regulations to be practical, technically justified, and to afford workers the highest level of protection.

L. Naval Nuclear Propulsion Program

Executive Order 12344, statutorily prescribed by Pub. L. 98–525 (42 U.S.C. 7158, note), establishes the responsibilities and authorities of the Director, Naval Nuclear Propulsion Program (who is also the Deputy Assistant Secretary for Naval Reactors within the DOE) over all facilities and activities which comprise the Program, a joint Navy-DOE organization. This final rule is not applicable to the Naval Nuclear Propulsion Program. The Director shall maintain a program to assure compliance with the Atomic Energy Act of 1954, as amended.

III. Developments Since the Proposed Rule Was Issued

The following developments took place after the proposed rule had been issued for public comment in December, 1991. Although these developments are independent of the rulemaking, they are discussed due to their significance in the area of occupational radiation protection.

A. Defense Nuclear Facilities Safety Board Recommendation 91–6

On December 19, 1991, the Defense Nuclear Facilities Safety Board (Board) issued Recommendation 91–6 dealing with radiation protection concerns throughout the DOE defense nuclear facilities complex. The Board recommended several actions be taken by the Department to improve radiological protection performance. These actions included issuing a Secretarial level policy statement emphasizing the Department's commitment to improving radiological protection throughout the DOE complex. Enhancement of the radiation protection training program was identified in the Board's recommendations. The Board also recommended that DOE critically examine the existing radiation protection infrastructure within DOE, upgrade occurrence reporting, and examine DOE radiation protection standards against national and international standards and guidance.

In a letter to the Board dated January 31, 1992, as amended March 30, 1992, DOE accepted the Board's recommendations and committed to address them. An implementation plan addressing these recommendations was provided to the Board on June 21, 1993. This implementation plan was determined to be acceptable by the Board.

B. DOE Radiological Control Manual

In a January 16, 1992, memorandum to the heads of DOE Elements involved in managing radiological programs, the Secretary of Energy directed a series of initiatives to enhance the conduct of radiological operations within the Department. In this memorandum, the Assistant Secretary of Environment, Safety and Health was directed to develop a comprehensive and definitive radiological control manual. The DOE Radiological Control Manual (Manual) was approved by the Secretary and promulgated with DOE Notice 5480.6, "Radiological Control," in July, 1992.

The Manual is not regulatory in nature. Rather, it is intended to provide detailed guidance on the best practices currently available in the area of radiological control. DOE will rely on the Manual in fulfilling its managerial responsibilities for the DOE complex and will use the contracting process to make the Manual applicable to management and operating contractors. DOE believes the Manual and part 835 should be complementary and, to that end, endeavored to make the Manual consistent with decisions anticipated in

[15] American National Standards Institute. Practices for Respiratory Protection. ANSI Z88.2–1980. American National Standards Institute, New York, New York.

the part 835 rulemaking process. Because of this complementary relationship, a contractor may consider citing all or part of its site-specific radiological control manual to fulfill the requirements for a Radiation Protection Program (RPP) in § 835.101 where the site-specific manual and the RPP cover the same subject matter. Since compliance with the RPP is a requirement of § 835.101(a), the citing of a provision of a site-specific manual or any other document will make compliance with the cited provision a requirement.

C. Energy Policy Act of 1992

The Energy Policy Act of 1992 (Pub. L. 102–486) amended the Atomic Energy Act to create the United States Uranium Enrichment Corporation to conduct commercial enrichment activities at facilities leased from the Department. In particular, the Atomic Energy Act was amended to add section 1701 which provides for the issuance of regulations by the Nuclear Regulatory Commission to govern those facilities leased by the Corporation and for the certification by the Commission of compliance with those regulations. This certification process is in lieu of licensing by the Commission. Accordingly, the exclusion in § 835.1 has been revised in the final rule to make clear that the exclusion of activities regulated through a license by the Commission includes those enrichment activities of the Corporation which have been certified pursuant to section 1701 of the Atomic Energy Act.

IV. Issues Being Resolved Separately

A. Sealed Sources

The Department established an interim policy and guidance for sealed radioactive source accountability in DOE Notice 5400.9, "Sealed Radioactive Source Accountability." The interim policy described in this Notice applies to all Departmental Elements and to contractors performing work for the Department. The Notice was issued as a result of numerous reports of improper storage, transfers, and loss of accountability of sealed radioactive sources at several Departmental facilities. The policy contained in the Notice will be published in the Federal Register in a future proposed rulemaking for the benefit of public comment.

B. Tritium Release Limits

During the original proposed rulemaking on 10 CFR part 835, the Department reserved the surface radioactivity values for tritium organic compounds, surfaces contaminated by HT, HTO, and metal tritide aerosols contained in appendix D. As a result of public comments received on the proposed rule, the Department subsequently identified an appropriate value for inclusion in appendix D which will be published in the Federal Register in a future proposed rulemaking for additional public comment.

V. Summary of Public Comments and Changes From the Proposed Rule

The purpose of this section is to respond to specific comments concerning the proposed rule and to explain and highlight the principal changes made in the final rule. This section presents, by corresponding section of the final rule, the principal public comments, a DOE response to the comments (where appropriate), and a summary of the principal changes that were made in the final rule. The following discussion may help explain the final rule, but is not intended to create any additional requirement not already in the text of the final rule.

Subpart A—General Provisions

Section 835.1 Scope

Final rule: The statement of scope remains essentially the same as in the proposed rule except that the references to "workers and other persons" was changed to "individuals" and "facilities" was changed to "activities" in paragraph (a). These changes were made in order to help assure consistent application of the regulation. The exclusions from the requirements now include radiation doses resulting from voluntary participation in medical research programs.

Comment: Comprehensive requirements. Several commenters discussed the specificity of the language contained in the proposed rule. Some comments emphasized the need for comprehensive prescriptive requirements which are clear in language and intent. Others noted that regulations which were too prescriptive would not be beneficial, possibly inhibiting innovative approaches to achieving compliance. One commenter who preferred comprehensive requirements stated that, for example, a quantitative definition of the term "likely" would simplify the interpretation of the regulation.

Response: Because of the breadth of application, the requirements in part 835 must be general and cannot specify every circumstance at each facility. The requirements in part 835 are designed to provide the framework for all DOE contractors and to establish provisions that the DOE considers to be fundamental to basic radiation protection. Basically, the Department believes that part 835 is as prescriptive as it can be and still apply to the broad range of activities in the DOE complex. For example, the use of the term "likely" throughout the final rule allows the use of professional judgment and experience to make decisions in specific circumstances while providing the flexibility necessary to implement the final rule under a broad range of activities.

Section 835.2 Definitions

General: Commenters on this section typically requested additional clarification of proposed definitions, suggested that several undefined terms be defined, or proposed modifications to definitions for consistency with 10 CFR part 20.

Response: Several terms which commenters requested to be defined are commonly understood terms in the radiation protection field or within the DOE complex. Where it is not intended for their definition to carry any specific regulatory meaning, no definition was provided. Other terms where definitions suggested by the public comments carry a specific regulatory connotation have been added to the list of definitions. These are listed below. Terms which were deleted in the final rule are also listed below. Some definitions were modified to improve consistency between the final rule and 10 CFR part 20.

Final rule:

1. New terms. In response to public comment, the following additional terms have been defined in the final rule:

Section 835.2(a)—General terms.

a. "Airborne radioactivity area"
b. "Bioassay"
c. "Contamination area"
d. "Declared pregnant worker"
e. "Entrance or access point"
f. "High contamination area"
g. "High radiation area"
h. "Individual"
i. "Member of the public"
j. "Minor"
k. "Radiation"
l. "Radiation area"
m. "Survey"
n. "Very high radiation area"
o. "Year"

Section 835.2(b)—Radiation dose terms.

p. "External dose or exposure"
q. "Internal dose or exposure"
r. "Lifetime occupational dose"
s. "Total effective dose equivalent"
t. "Whole body"

2. *Modified definitions.* In response to public comment, the following definitions have been modified from the definitions in the proposed rule:

Section 835.2(a)—General terms.

a. "Airborne radioactive material"
b. "Annual limit on intake"
c. "Background"
d. "Calibration"
e. "Derived air concentration"
f. "DOE activities"
g. "Occupational exposure"
h. "Radiological area"

Section 835.2(b)—Radiation dose terms.

i. "Absorbed dose"
j. "Committed effective dose equivalent"
k. "Dose equivalent"
l. "Lens of the eye dose equivalent"
m. "Weighting factor"

3. *Terms and definitions deleted or replaced.* Several definitions were deleted or replaced because the terms were not used in the final rule:

a. "Occupational worker" has been replaced by "general employee."

b. "Radiation worker" has been replaced by "radiological worker."

c. "Annual dose equivalent" has been deleted.

d. "Annual effective dose equivalent" has been deleted.

e. "Collective dose equivalent and collective effective dose equivalent" have been replaced by "collective dose."

f. "Cumulative annual effective dose equivalent" has been deleted.

Comment: Radioactive material. Many commenters suggested the need for a definition for "radioactive material" due to its extensive usage in the proposed rule.

Response: DOE has elected not to provide a quantitative definition for the term "radioactive material." For those instances in which a regulatory requirement related to radioactive material is imposed, a specific quantity or measurement is given as part of the requirement.

Comment: Quality factors for neutrons. The quality factor is the conversion factor between the absorbed dose (rad) and the dose equivalent (rem). Several publications [16] have recommended changes in neutron quality factors that are a factor of 2 higher than those in the proposed part 835. These changes would raise the quality factor for fast neutrons from 10 to 20.

Response: Increases in the quality factor for neutrons are suggested by the results of some animal experimental data on the relative biological effectiveness (RBE) of neutrons. However, there appears to be considerable uncertainty as to whether the data actually demonstrate increased hazard for neutrons. Because the RBE is defined as a ratio of doses to produce equivalent biological effects, it is not clear whether the apparent increase in the neutron RBE is due to the increased effectiveness of neutrons or whether it actually results from the decreased effectiveness of the reference gamma radiation at low doses. It should be noted that the neutron quality factors contained in the recently revised 10 CFR part 20 are consistent with this part. No change is currently envisioned until a uniform Federal approach is established.

Comment: Quality factor tables. Commenters questioned the accuracy and utility of the table of neutron quality factors presented in the proposed rule. Consistency with 10 CFR part 20 was also addressed.

Response: The tables in the proposed and final rules were taken from NCRP Report No. 38 [17] and are appropriate for the neutron dose equivalent at a soft tissue depth of 1 centimeter (which is the depth specified for the determination of the deep dose equivalent). More recent tables from ICRP incorporate a factor of 2 increase in the neutron quality factor, which, as previously discussed, has not yet been accepted by Federal agencies.

Differences between this part and 10 CFR part 20 are insignificant. The table in this part shows two values for neutron quality factors based on neutron energy level (greater than 10 keV and less than 10 keV). 10 CFR part 20 only shows one quality factor for neutrons with unknown energy.

The final rule retains the two energy-dependent quality factors for neutrons. Sufficient information is typically available for activities with neutron exposure to determine whether or not neutron energies exceed 10 keV. If sufficient information is not available, then the higher quality factor should conservatively be used.

Comment: Representative. Some commenters discussed the definition of "representative" relative to activities at remedial action sites, indicating the need to identify additional parameters other than those presented in the proposed rule. Particle size distribution, lung solubility, depth of burial, and self absorption were suggested as appropriate when evaluating the representativeness of samples taken at remedial action sites.

Response: Those parameters which are necessary to make samples representative for a given activity must be determined for that activity in order to demonstrate compliance with the final rule.

Comment: Weighting factor. The absence of a weighting factor for whole body exposure in the weighting factor table was of concern to some commenters.

Response: The commenters noted that, as proposed, § 835.203(d) (§ 835.203(c) in the final rule) provided that a weighting factor equal to 1 could be used for determining external effective dose equivalent in the case of uniform irradiation of the whole body. The NRC includes this reference in their table of weighting factors presented in 10 CFR part 20.

Final rule: To assure consistent implementation of its requirements, the final rule contains a whole body weighting factor of 1 in the table of "Weighting Factors for Various Tissues." A clarifying footnote reflecting the requirements of § 835.203(c) is also provided.

Section 835.3 General Rule

Final rule: Section 835.3(a)(3) has been removed from the final rule. The proposed provision would have made it an act of non-compliance with part 835 to violate Federal regulations such as NRC or Occupational Safety and Health Administration (OSHA) occupational radiation protection regulations. Unavoidably cumbersome memoranda of understanding would be needed to coordinate enforcement of these regulations.

Comment: Reference to other proposed rules. Several commenters questioned the appropriateness of referring to other proposed nuclear safety rules.

Response and final rule: References to other DOE proposed rules have been removed from the final rule.

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[16] International Commission on Radiological Units and Measurement. The Quality Factor in Radiation Protection. ICRU Report No. 40. ICRU Publications, Bethesda, MD, 1988.

International Commission on Radiological Protection. Data for Use in Protection Against External Radiation. ICRP Publication No. 51. Pergamon Press, New York, 1988.

International Commission on Radiological Protection. Statement from the 1985 Paris Meeting of the (ICRP). British Journal of Radiology, Vol. 58, page 910: 1985: also Health Physics, 48(6): 828–829 (June 1985).

International Commission on Radiological Protection. ICRP Statement from 1987 Washington Meeting. Health Physics, 53(3): 335–342 (1987).

International Commission on Radiological Protection. The Metabolism of Plutonium and Related Elements. ICRP Publication No. 48. Pergamon Press, New York, 1986.

[17] National Council on Radiation Protection and Measurements. Protection Against Neutron Radiation. NCRP Report No. 38. Bethesda, MD, 1987.

Comment: Enforcement actions. Several comments were received regarding DOE enforcement of the provisions of the final rule. Commenters were concerned that potential penalties applicable to violations of the final rule would be extended to actions inconsistent with the requirements of programs, plans, schedules, or other processes developed to comply with the provisions of the final rule. Other commenters were concerned that the proposed rule was possibly not specific enough to fairly subject the Department's contractors to civil and criminal penalties in the event that the provisions of the final rule were not fully complied with.

Response: The Department's objective in promulgating this part is to establish standards for the protection of its workers from occupational exposure to ionizing radiation. Enforcement of the provisions of the final rule, including any required programs, plans, schedules, and other processes, is integral to the effectiveness of the final rule. Departmental enforcement activities will be commensurate with the severity of the infraction. Provisions to permit changes to programs, plans, and schedules are included under § 835.101. Relief from obsolete programs, plans, and schedules can be obtained if these provisions are met and properly justified.

Comment: Exemptions and interpretations. Commenters suggested the need for establishing a process within the final rule that allows for regulated activities to demonstrate a need for modification or exemption from the requirements of the final rule. A process for handling official interpretations of any of the final rule's requirements was also suggested.

Response: The formal processes for applying for either an exemption from or an interpretation of any nuclear safety requirement has been provided in 10 CFR part 820.

New Section 835.4 Radiological Units

Comment: Radiological units. Several commenters preferred the use of "International System of Units" (SI) in lieu of "special units" which are currently used.

Response: "Special units" and SI units appear in the text of the final rule to increase the familiarity within the DOE complex with SI units. The DOE has decided that regulatory adoption of SI units is not necessary at this time. However, as the national move to metrication continues, as anticipated in section 5164 of the Omnibus Trade and Competitiveness Act of 1988 (Pub. L. 100–418), at some later time there may be amendments to this part that would require the use of SI units only (becquerel, gray, and sievert).

Final rule: Section 835.4 was added to the final rule which describes the requirement to use the older radiological "special units" in records or reports.

Comment: Units of radiation dose and units of radioactivity. Several commenters suggested the need to define the units used for radiation dose and radioactivity.

Response: The definitions for terms related to radioactivity are provided in § 835.2(a). The terms related to radiation dose are provided in § 835.2(b). Included in these definitions are the applicable units. For example, the definition of "derived air concentration (DAC)" is presented in terms of activity per unit volume (e.g., μCi/ml or Bq/m^3); other portions of the final rule provide radioactivity units when providing contamination limits (e.g., dpm/100 cm^2 in appendix D). Since the terms are in conventionally used units, no additional definition was deemed necessary.

Subpart B—Radiation Protection Programs

Section 835.101 Radiation Protection Programs

Comment: Codification of the ALARA process. Commenters raised the concern that codification of the ALARA process will have serious legal implications for the DOE radiation protection community. In addition, commenters expressed a need for clarification on the DOE policy concerning the methods for and extent of implementation of the ALARA process.

Response and final rule: DOE does not intend to establish ALARA as a duty of care for purposes of tort litigation. The regulations require that the ALARA process be applied, but do not require that dose levels be ALARA.

Comment: Radiation Protection Program (RPP) updates. As stated in the proposed rule, the RPP must be updated and submitted whenever a change or addition is made and prior to the initiation of a new task. Several commenters stated that this requirement could adversely impact contractor programs. In addition, several commenters requested a clearer definition of the DOE offices, Headquarters, area office, and local offices involved in the approval and modification process of the RPP.

Response: The DOE recognizes the need to provide flexibility in allowing changes to a RPP which do not diminish the program's effectiveness. The important aspect of the RPP is to protect the safety and health of workers at DOE sites and members of the public. Where changes to the RPP do not reduce its effectiveness, prior DOE approval is not required for the change to be effective. Of course, where there is no prior approval, the contractor has the burden of demonstrating there is no reduction in the level of worker protection.

Final rule: The final rule includes provisions that permit changes, additions, or updates to be made to the RPP without Departmental approval as long as the changes do not decrease the effectiveness of the RPP and the RPP, as changed, continues to meet the requirement of subpart B. However, all changes must be submitted to DOE for review and may be modified or rescinded by DOE.

Comment: Schedule for compliance and initial submittal of RPP. A number of comments was received concerning the time allowed for initial submission of the RPP, the time permitted for compliance with the final rule, the time permitted for submitting updates to the RPP, and the time permitted for approval of any modifications to the RPP.

Response: With the exception of the time allowed for existing activities to submit the RPP to DOE for approval, the times listed in § 835.101 are considered sufficient for the actions required. In particular, a period of 2 years for implementation of the final rule is considered adequate in light of the efforts that have already been made by DOE facilities in connection with DOE Order 5480.11 and the Radiological Control Manual. However, to ameliorate the impact of changes in record keeping, reporting, and calculation of internal dose required by the final rule, the provisions should be implemented at the beginning of a calendar year. Accordingly, the actual time period permitted for implementation of the final rule may be somewhat more or less than two years, depending on the effective date of the final rule. For the initial submission of the RPP, 180 days may not provide sufficient time to prepare a RPP that meets the requirements of this subpart given the many other requirements to which the DOE radiation safety community is currently subject.

Final rule: The final rule specifies the dates for submittal of RPP and implementation of the final rule. The latest date for initial submission of the RPP is January 1, 1995 and the latest date for implementation of the final rule is January 1, 1996.

Comment: Radiological Control Manual. Comments were received concerning the relationship of the RPP

to the Radiological Control Manual and other DOE directives.

Response: The provisions in the final rule and the DOE Radiological Control Manual are intended to be consistent. The final rule provides the regulatory requirements of the DOE for the protection of individuals from radiation exposure associated with DOE activities. The Manual provides a detailed best practices approach to radiation protection which typically exceeds these requirements. To avoid unnecessary duplication of plans, one acceptable method for meeting the RPP requirements of § 835.101 will consist of development of a document that cites the applicable sections of the site-specific Radiological Control Manual.

Like the Radiological Control Manual, DOE directives do not create regulatory requirements. Many of the requirements in part 835, however, are based on provisions in DOE directives. Thus, in many instances, contractors may already be taking actions under their contracts that are now required by the final rule. Accordingly, actions already taken under DOE directives may be incorporated by the RPP if these actions duplicate a RPP requirement (i.e., reporting requirements in DOE Order 5000.3B, "Occurrence Reporting and Processing of Operations Information," dosimetry program accreditation requirements in DOE Order 5480.15, "Department of Energy Laboratory Accreditation Program for Personnel Dosimetry," and sealed source requirements detailed in DOE Notice 5400.9, "Sealed Radioactive Source Accountability").

Comment: Single site RPP. There were several concerns about development of a single RPP encompassing all activities at a site. A single RPP does not allow enough flexibility to manage operations in a cost effective manner or be tailored to site-specific parameters of a remedial action site. The extent of what encompasses a site exacerbated the concern regarding a single site RPP.

Response: The purpose of the proposed requirement for a single site RPP reflected the Department's commitment for consistency in site radiation protection programs. In light of the significant comments received and in acknowledgement of the diversity of organizations and activities at a single site, the Department has eliminated the requirement for single site RPPs. The Department remains committed to consistent site radiation protection programs and encourages the development of single RPPs encompassing all site activities wherever feasible.

Section 835.102 Internal Audits

Comment: Who performs the internal audit. The proposed rule is not clear on the internal organization that performs the audit, the required functional elements of the program, the required program content, and level of implementation, nor does the proposed rule address nonconformance.

Response: Acceptable methods for conducting the audit process will be identified in regulatory guidance.

Comment: Audit frequency. The NRC requires an annual program review, while the proposed rule requires an internal audit not less than once every three years.

Response: The internal audit is only one part of a comprehensive assessment program which also includes reviews, investigations, and self assessments. In light of the number of assessments currently required of a DOE facility, an internal audit every three years is considered sufficient to determine compliance with the final rule and confirm that optimization techniques are utilized in controlling exposure to radiation.

Subpart C—Standards for Internal and External Exposure

Comment: Compliance with 40 CFR part 190. Comments noted that 10 CFR part 20 contains provisions for compliance with 40 CFR part 190 but part 835 contains no such provisions.

Response and final rule: 40 CFR part 190 contains requirements related to doses to members of the public arising from discharges to the environment. Radiation protection standards for the public and environment are currently addressed in DOE Order 5400.5; DOE is in the process of codifying these standards in proposed rule 10 CFR part 834.

Section 835.202 Occupational Exposure Limits for General Employees

Final rule: The term "occupational worker" has been replaced with "general employee" to provide consistent use of terminology throughout DOE documents. Some editorial changes were made to accommodate changing the basis for the dose limits from "annual effective dose equivalent" (AEDE) to "committed effective dose equivalent" (CEDE). Other editorial changes were made to assure consistent application of the regulation.

Comment: Effective dose equivalent. Most of the comments regarding the issue of whether to use AEDE or CEDE for internal exposure supported adopting the CEDE methodology. Comments stated that for evaluating compliance with the annual dose limit, the AEDE is a more accurate method to use.

Response: The use of either CEDE or AEDE for evaluating internal doses affords workers adequate protection. DOE has adopted CEDE for the following reasons:

1. To provide consistency with scientific recommendations.
2. To facilitate the transfer of workers between DOE and NRC regulated facilities.
3. To simplify record keeping by recording all internal exposure in the year of intake.

Final rule: Provisions in the final rule have been modified wherever necessary to accommodate the use of CEDE.

Comment: Consideration of previous exposure. Comments stated that there is no specific provision to reduce an individual worker's exposure limit due to occupational exposure received during that calendar year from a previous employer or facility. Another commenter questioned the absence of provisions for integrating exposures acquired at other sites or facilities.

Response and final rule: Clarification has been added to the final rule to assure that previous occupational exposure is included when demonstrating compliance with the occupational exposure limits. Subpart H now contains a provision requiring documentation of all occupational exposure received by an individual during the current year. A provision for a written estimate signed by the affected individual has been included in the final rule. This provision will facilitate site access for transient workers.

Comment: Intake of soluble uranium. Commenters noted that a provision contained in 10 CFR part 20 limiting occupational exposure to soluble uranium to 10 milligrams per week due to its chemical toxicity does not appear in the proposed rule.

Response: Provisions related to the chemical toxicity of soluble uranium are addressed under DOE industrial hygiene directives.

Comment: Dosimetry monitoring devices to determine effective dose equivalent. Comments noted that existing technology does not permit the use of a single dosimeter reading for calculation of effective dose equivalent from external irradiation. Accordingly, external doses should only be expressed in terms of dose equivalent until such time as the technology exists to be able to estimate effective dose equivalent from a single personnel dosimeter measurement. Comments noted that the proposed rule provides for the special case of uniform whole body exposure

where the weighting factor is 1. According to the comments, there are many exposure situations at DOE facilities which involve non-uniform exposure to the whole body.

Response: DOE is aware that current dosimetry techniques do not allow a practical determination of EDE resulting from external exposures. There are many exposure situations at DOE facilities involving non-uniform radiation fields. Until a practical approach to determining EDE is developed, assessing external doses in non-uniform radiation fields will be considered by DOE on a case-by-case basis.

Final rule: The final rule contains provisions to allow use of external EDE. The provision to use a weighting factor of 1 for uniform external irradiation has been added to the weighting factors for various tissues table in subpart A. The final rule has also been modified to allow the deep dose equivalent to be used as effective dose equivalent for external exposures.

Comment: Extremity and skin dose limits. Comments suggested that the proposed rule be clarified to state 50 rems (0.5 Sv) as the dose limit to each extremity and to state the skin dose limit with the extremity limit, rather than stating it with the limit for organs and tissues.

Response and final rule: The final rule has been modified to state a shallow dose equivalent limit of 50 rems (0.5 Sv) to any extremity. It was also modified to state the skin and extremity dose limits together.

Section 835.203 Combining Internal and External Dose Equivalents Resulting From DOE Activities

Comment: Intake through wounds or absorption through skin. Comments noted that intake through wounds or absorption through skin is not addressed in the proposed rule.

Response: Intake, as used in the final rule, does not exclude any pathway through which radioactive material can enter the body.

Comment: Combining internal and external EDE components. Several commenters requested clarification on how to obtain the annual effective dose equivalent as stated in the proposed rule.

Response and final rule: This section has been modified to require determination of "total effective dose equivalent" instead of "annual effective dose equivalent."

Section 835.204 Planned Special Exposures

Comment: Incorporation of planned special exposures (PSEs) into the final rule. Comments suggested that personnel exposure data for more recent years do not support the need for planned special exposures. Other commenters felt that the spirit of the Secretary of Energy's "Ten Point Plan" emphasizing environment, safety, and health over production (dated June 27, 1989) was not followed by incorporating the PSE into the proposed rule. Other comments indicated that the wording in the proposed rule did not emphasize the exceptional nature of the use of PSEs.

Response: Certain workers have skills important to plant and public safety and, for this and other reasons, it is recognized that unusual conditions may arise in which higher-than-normal doses can be justified. The Federal Guidance approved by the President specifically allows for the use of PSEs in such instances. The provision for PSEs has been retained for consistency with the Federal Guidance and to provide operational flexibility. It has been emphasized in the final rule that the use of PSEs must be reserved for exceptional situations where other alternatives that might prevent a radiological worker from exceeding the usual occupational exposure limits are unavailable or impractical.

Comment: Lifetime limit for PSEs. Several commenters suggested the need to limit the total amount of "planned special exposure" an individual can receive such as with a lifetime PSE dose limit. Future PSEs for these individuals should be controlled. Additionally, implementation of the provisions of the proposed rule could eventually preclude some individuals from receiving PSEs at NRC licensees. Comments also suggested that the proposed rule did not clearly indicate whether or not PSEs were contingent on the determination of prior PSEs and lifetime dose.

Response: The specific requirement to determine the individual's dose from all previous PSEs and all other doses in excess of the occupational dose limits (e.g., overexposure) prior to requesting an individual to participate in an authorized planned special exposure has been added to the final rule. This is to assure consistent implementation when determining the individual's available PSE dose. Additionally, a 25 rem (0.25 Sv) limit on cumulative total effective dose equivalent for PSEs has been added to the final rule.

Comment: Conditions which must be met prior to a PSE. Comments noted that the PSE requirements contained in 10 CFR part 20 list conditions which must be met prior to a planned special exposure. These conditions were not listed in the proposed rule. Several commenters questioned the absence of requiring the affected individual's informed consent and appropriate training prior to the PSE. Employer involvement was also raised.

Response: DOE recognizes the importance of obtaining the consent of all individuals involved, as well as their employers, prior to a PSE. Equally important is how well the individual is informed about the PSE's purpose and potential risks. 10 CFR part 835 has been modified to address the concerns stated in a number of comments. As a part of this modification the final rule was structured similarly to 10 CFR part 20.

Final rule: 10 CFR part 835 has been modified to provide the following:

(1) A stronger statement as to when a PSE should be considered;

(2) The individual's employer must be a part of the PSE request process;

(3) Joint approval from the appropriate DOE Headquarters program office and the Assistant Secretary for Environment, Safety and Health must be received prior to the PSE;

(4) Previous PSE and emergency doses are accounted for prior to requesting an individual to participate in an authorized PSE;

(5) A limit for cumulative total effective dose equivalent;

(6) Each individual must be informed of the PSE's purpose, procedures to be used, estimated doses, potential risks, radiological conditions, and other hazards which might be involved in performing the task and instructed in the measures to keep their dose ALARA; and

(7) Records of the PSE must be maintained and a written report submitted within 30 days after the PSE.

Section 835.205 Determination of Compliance for Non-uniform Exposure of the Skin

Comment: Determining non-uniform exposure for the skin. Comments stated that the NRC addressed determination of non-uniform exposure for the skin in a generic information notice rather than in 10 CFR part 20.

Response: In light of operational conditions at DOE facilities and to assure consistent implementation throughout the DOE complex, these provisions are considered sufficiently important to be retained in the final rule.

Comment: Record keeping. Comments suggested that the proposed rule's

requirements are much more detailed than those currently in DOE Order 5480.11 and would be nearly impossible to achieve because they impose technically infeasible performance requirements on the radiation dosimetry program. Additionally, the resulting complications to the record keeping requirements are unwarranted.

Response: Although worded slightly different, the requirements in this section are identical to those in DOE Order 5480.11 and are considered appropriate for the final rule.

Section 835.206 Limits for the Embryo/Fetus

Comment: Use of the term unborn child. Commenters suggested replacing the term "unborn child" with "embryo/fetus" because this is the term used in the scientific and medical communities and has been adopted by the NRC.

Response and final rule: The term "embryo/fetus" has replaced "unborn child" throughout the final rule.

Comment: Johnson Controls Case. Commenters questioned the legality of the proposed rule under Title VII of the Civil Rights Act of 1964, as amended by the Pregnancy Discrimination Act in light of the Supreme Court decision in *International Union, UAW* v. *Johnson Controls,* 111 S.Ct. 1196 (1991). Additional clarification to include the phrase "and requests a dose equivalent limitation for the protection of the unborn child" after the word "pregnant" was suggested.

Response: The limits for the embryo/fetus do not violate Title VII because a separate dose limit for embryo/fetus does not apply unless a woman has voluntarily declared her pregnancy in writing to her employer for purposes of application of the lower dose limit to the embryo/fetus. The choice of protection of the embryo/fetus is for the woman to make, not the employer. The final rule states that the declaration of pregnancy can be voluntarily revoked.

Comment: Use of the term "female occupational worker." Comments stated that reference to female occupational worker is contradictory and should be female radiation worker due to the definition of radiation worker (i.e., any individual likely to receive greater than 0.1 rem (1 mSv) in a year).

Response: For consistency, the final rule should refer to the proper "class" of worker. Since the purpose of this section of the rule is protection of the embryo/fetus, the protection must begin with exposure to the mother. Due to the provisions for a uniform exposure rate over the gestation period, controls may be instituted at less than the 100 mrem (1 mSv) level which defines a radiological worker.

Final rule: The term "declared pregnant worker" has been adopted for use in the final rule to identify a woman who has voluntarily informed her employer, in writing, of her pregnancy for the purpose of exercising reduced exposure limits for protection of her embryo/fetus. Maintaining documentation of the written declaration of pregnancy has been added as a requirement in the records section of the final rule.

Comment: Dose to the embryo/fetus. Commenters stated that the proposed rule was not clear whether both external and internal doses were to be considered with respect to the embryo/fetus dose.

Response and final rule: The limit to the embryo/fetus considers both internal and external dose. Provisions have been added to the individual monitoring section of the final rule which clarify monitoring requirements for declared pregnant workers. External and internal monitoring is required when a dose equivalent to the embryo/fetus is expected to exceed 10 percent of the dose limit for the embryo/fetus of a declared pregnant worker.

Comment: Assessing fetal exposure. The methodology to calculate an internal dose component for dose to the embryo/fetus is not provided by ICRP or NCRP. No ICRP-approved biokinetic models exist to accurately determine fetal exposure. It was also noted that there were no biokinetic models available for calculating the dose equivalent contribution from maternal intake of radionuclides. ICRP Publication 60 now recommends that maternal intake be limited to 1/20 ALI during the gestation period. Guidance to comply with the proposed rule's requirements was requested.

Response: No additional provisions were made to the final rule which explicitly address assessing fetal exposure. DOE has implementation guidance under development which addresses the concerns raised regarding assessment of fetal exposure. This guide will consider all pertinent information, including ICRP Publication 60, in its development. The NRC also has plans to provide its licensees with a regulatory guide addressing this issue. When available, the regulatory guide will be reviewed to determine whether it is applicable to DOE activities.

Comment: Embryo/fetus limit compared to limits for minors and members of the public. Several comments stated that the dose equivalent limit for the embryo/fetus was five times greater than the dose limit for minors or members of the public.

Response: The Department dose limit for the embryo/fetus is consistent with the 1987 Federal Guidance approved by the President and 10 CFR part 20. This limit is based on an exposure to the embryo/fetus during the gestation period rather than the lifetime exposure assumed in the basis for the dose limits for members of the public and minors. The higher limit provides occupational flexibility for the mother.

Comment: Meeting monitoring requirements. Comments suggested that meeting the monitoring requirements for declared pregnant workers will be difficult to comply with under existing external dosimetry capabilities without concurrent time limits on the mother for access to radiation areas.

Response and final rule: Monitoring is required when it is likely that 10 percent of the dose limit will be exceeded, equating to 50 mrem (0.5 mSv). This is well above the detection limit for dosimetry systems meeting DOELAP accreditation criteria.

Comment: Frequent dose evaluations. Commenters requested clarification on the reference to "frequent dose evaluations." Of particular concern was internal dose assessments and the availability of an acceptable method.

Response: Frequent dose evaluation is no longer a requirement. Evaluation is required, through monitoring, whenever the dose is expected to exceed 10 percent of the dose limit.

Final rule: The final rule has been modified to require that substantial variation above a uniform exposure rate that would satisfy the limits of this section be avoided.

Comment: Conditions for compliance when the dose limit is exceeded prior to pregnancy declaration. Commenters expressed a concern that an employer may be in violation of the rule if the dose limits in § 835.206 were exceeded prior to pregnancy declaration.

Response and final rule: It is the employer's responsibility to limit a general employee's total effective dose equivalent to 5 rems (0.05 Sv) in a year. Only when a female worker declares her pregnancy can the employer control the dose to the embryo/fetus in order to avoid exceeding the limits provided in this section. Therefore, if the woman has exceeded the 500 mrem (5 mSv) limit prior to declaring pregnancy, the employer would violate the final rule only if the "now" declared pregnant worker was assigned to tasks where additional occupational exposure is likely during the remaining gestation period.

Section 835.207 Limits for Minors

Comment: Precluding employment of minors. Commenters suggested that this section be reworded to preclude employment of persons under 18 years of age, but allow visits in controlled areas under stipulated conditions.

Response and final rule: This comment addresses employment policy which is beyond the scope of this regulation.

Comment: Dose limit for minors. The difference between the proposed rule's limit of 100 mrem (1 mSv) per year for minors and 10 CFR part 20 limit was observed by commenters.

Response and final rule: The 100 mrem (1 mSv) limit contained in the final rule is taken from existing requirements contained in DOE Order 5480.11.

Section 835.208 Limits for Members of the Public Entering a Controlled Area

Comment: Limits for members of the public. Limits in the proposed rule imply that the public is allowed to enter areas where the potential of internal exposure exists. Visitors should not be allowed to enter Airborne Radioactivity Areas or Radiation Areas without appropriate training.

Response: The limit for members of the public entering a controlled area is consistent with existing directives and provides a mechanism to allow individuals who are not performing radiological work, such as visiting dignitaries, access to a DOE site or facility. Associated with this access may be some incidental radiation exposure. This access must be controlled commensurate with the potential hazard involved and is typically controlled through specialized training and personnel escorts. Protection of members of the public entering controlled areas is assured through compliance with the dose limits specified in this final rule. Each site or facility must institute controls sufficient to assure compliance with the final rule.

Comment: Organ and tissue limits for members of the public. The proposed rule limits members of the public entering a controlled area to an annual dose equivalent, to any organ or tissue, to 5 rems (0.05 Sv). 10 CFR part 20 limits exposure of members of the public in controlled areas to the same limits as individual members of the public (total effective dose equivalent of 0.1 rem (1 mSv)). However, 10 CFR part 20 does not discuss the annual dose equivalent to organs or tissues.

Response and final rule: The dose equivalent to any organ or tissue in an individual who receives a total effective dose equivalent of 100 mrem (1 mSv) will be less than 5 rems (0.05 Sv). Therefore, the 100 mrem (1 mSv) whole body limit is always more restrictive than the organ dose limit and a separate organ and tissue limit is not necessary.

Section 835.209 Concentrations of Radioactive Material in Air

Final rule: The title of this section was modified to reflect the deletion of requirements relative to concentrations of radioactive material in drinking water in response to public comments. DOE Order 5400.5 contains standards for concentrations of radioactive material in drinking water; DOE intends to include similar provisions in subsequent rulemaking.

Comment: DAC Values. The requirement for use of DACs should be deleted or reworded, ensuring that the reader understands that the DAC values are supplied as a means for retroactively controlling exposures from airborne radioactivity and are themselves not limits.

Response: The final rule relies on the use of DAC values for posting of airborne radioactivity areas. This is an affirmative measure to prevent workers from inadvertently being exposed to airborne radioactive material. Additionally, air sampling results are typically compared to DAC values to determine the effectiveness of engineering controls used to minimize airborne contamination and identify the need for respiratory protection for workers.

Comment: Bioassay results. Several commenters questioned the emphasis placed on the use of bioassay results in preference to using air sampling results to assign internal dose to workers. The approach discussed in the proposed rule contrasts with the revised 10 CFR part 20, which allows either method to be used. Others commented that the use of personal air samplers or breathing zone air samples would provide a more accurate indication of worker intake for difficult to detect radionuclides.

Response: Demonstrating compliance with the internal monitoring requirements of § 835.402 (c) and (d) is more difficult for certain radionuclides. Accordingly, more flexibility is needed to permit the use of air concentration values if bioassay data are either unavailable or inadequate. Additionally, provision for the adjustment of DACs based on the physical and chemical characteristics of the material are contained in appendix A. Implementation guidance for internal dosimetry is under development.

Final rule: The final rule has been modified to provide more latitude in determining dose from airborne concentration measurement.

Comment: Consumption of food or drink within an area controlled for radiological purposes. Comments stated that it is not good radiological protection practice to allow consumption of food or drink within an area controlled for radiological purposes. 10 CFR part 835 should prohibit or strongly limit consumption of food or drink in controlled areas.

Response: Eating, drinking, smoking, and chewing are typically prohibited in radiologically controlled areas. There are circumstances where water is provided for workers to prevent dehydration.

Subpart E—Monitoring in the Workplace

General: A general concern was raised with regard to the practicality of implementing the air sampling, radon monitoring, and release survey requirements at a remedial action site. The commenter suggested that remedial action sites differ from fixed sites for several reasons, including:

(1) Remedial action sites are confronted with situations that are in flux, and

(2) The activities taking place at these sites do not lend themselves to the controls and monitoring requirements that were proposed.

The Department was urged to recognize the special concerns at a remedial action site and establish provisions that ensure worker safety, but do not impede the progress of remedial actions.

Response: The Department is sensitive to the comments regarding remedial action sites. As stated throughout this preamble, the final rule is applicable to all DOE facilities conducting radiological activities as provided in subpart A. The final rule allows the flexibility necessary to accommodate the broad spectrum of applications within the DOE complex. As discussed in § 835.101(c), "the content of each RPP shall be commensurate with the nature of the activities performed . . ." Where provisions of the final rule are genuinely not feasible for a specific activity, an exemption process for nuclear safety regulations has been provided in 10 CFR part 820.

Section 835.401 General Requirements

Comment: Monitoring for changes in radiological conditions. With regard to the requirements to monitor individuals and areas to detect changes in radiological conditions (§ 835.401(a)(3)), some commenters were concerned that

the time interval required to detect changes was subject to varying interpretation.

Response and final rule: Although this concern was specific to airborne monitoring when high levels of radon are present, alarming devices are used to warn workers of changes in radiological conditions which could affect their health and safety. Smaller changes which would be detected through routine monitoring and would not affect the workers' health and safety should be used to indicate adverse trends. This allows early detection and corrective action before a problem arises.

Comment: Instrumentation selection and calibration. Several commenters suggested that specific instrumentation requirements be identified in § 835.401(c), including what constitutes an acceptable calibration program. Some commenters felt that only in-service instruments should be required to have their calibration maintained. The need to perform routine operability testing was also questioned by some commenters.

Response: The words "instruments used," as stated in the final rule, refer to instruments which are available for use to monitor the workplace. Operability checks are essential to the effective use of instrumentation.

Final rule: Incorporated into the final rule is an editorial change to § 835.401(c)(1) clarifying that maintenance is conducted on a periodic basis and calibration is conducted on an established frequency of at least once per year. The final rule sets the minimum standard for instrument calibration, but more frequent calibration may be warranted in specific situations.

Section 835.402 Individual Monitoring

General: As a result of the change from annual effective dose equivalent (AEDE) to committed effective dose equivalent (CEDE), many changes to individual monitoring requirements were necessary. These changes included removing references to annual effective dose equivalent and other annual doses which are no longer applicable. The term "year" was specifically defined to facilitate consistent understanding of the requirements related to committed effective dose equivalent.

Comment: Thresholds for individual monitoring. Several comments raised issues related to setting thresholds for individual monitoring. Specific concern was expressed with requiring individual monitoring at 2 percent of the whole body limit for occupational exposure versus a 10 percent threshold for extremity, skin, and lens of the eye. Differences between DOE and NRC monitoring thresholds were questioned. Comments also noted that the proposed rule contained no monitoring requirements for minors, members of the public, or declared pregnant workers.

Response: Due to the unique and diverse activities conducted by the DOE, the Department has chosen to require individual whole body monitoring at levels lower than those required by the NRC (i.e., at 2% rather than 10% of the limit).

Under the proposed rule, individual monitoring would not be explicitly required for minors or members of the public entering a controlled area at a DOE site since these individuals would not be permitted to exceed the individual monitoring threshold for adult workers. Declared pregnant workers would require monitoring only if their exposure was expected to exceed 0.1 rem (1 mSv) under the proposed rule.

Final rule: The Department has decided to adopt an approach similar to that used in 10 CFR part 20. The individual monitoring threshold for workers remains at 2 percent of the occupational exposure limit in the final rule. Individual monitoring is now required for minors or members of the public likely to exceed 50 percent of the occupational exposure limits identified in § 835.207 or § 835.208, respectively, from either external or internal sources. Declared pregnant workers would require individual monitoring if they were likely to exceed 10 percent of the limit in § 835.206 from external or internal sources.

Comment: Personal dosimetry. Comments questioned the application of the term "dosimetry." Other comments suggested that the proposed rule implied that an individual worker could be subject to enforcement action if his dosimetry was improperly worn.

Response: The term "dosimetry" is used to encompass the instrumentation and processes used to determine an individual's radiation exposure. Dosimetry may consist of thermoluminescent dosimeters and pocket ionization chambers to measure the level of exposure to external radiation and the calculations used to determine internal dose from bioassay measurement results. Therefore, the term "dosimetry" is properly used in the final rule.

Personnel improperly using dosimetry may be indicative of a management problem. It is therefore incumbent on management to ensure that measures are in place to assure workers are informed as to the correct procedure for use and placement of personal dosimeters. This is typically included in general employee radiological training. While individuals who willfully violate these procedures may be subject to disciplinary action from their employer, they would not typically be subject to regulatory enforcement.

Comment: Methods for monitoring external radiation exposure. Regulatory guidance describing appropriate methods for monitoring external doses to the skin, extremity, and the lens of the eye was suggested.

Response and final rule: Regulatory guidance on external dosimetry programs is planned. This guidance will include methods for monitoring external radiation exposure to workers.

Comment: Internal dose assessment. The need for regulatory guidance to provide the necessary direction for the design and conduct of a bioassay and internal dose assessment program was suggested.

Response: Regulatory guidance addressing this concern is under development.

Comment: DOELAP. Commenters were concerned with the requirement for accreditation of personnel dosimetry programs in accordance with the DOE Laboratory Accreditation Program for Personnel Dosimetry (DOELAP). Since the DOELAP reference is to be included in the final rule, the procedures for altering the technical performance specifications of the DOELAP program should also be specified in an appropriate section of the final rule. Otherwise, the technical requirements of DOELAP could be modified in a way which could cause DOE facilities to become in non-compliance with the final rule.

Response and final rule: DOE considers the requirement for DOELAP accreditation of personnel dosimetry programs to be necessary to ensure accurate and reliable measurements of personnel dose. The suggestion to include additional DOELAP procedures in the final rule is unnecessary; these procedures are contained in DOE Order 5480.15 and supporting documents which receive DOE-wide review and comment prior to all substantive revisions. Accordingly, no change in the final rule was made.

Comment: Individual monitoring in high and very high radiation areas. Comments suggested the need to require individual monitoring for personnel entering high or very high radiation areas.

Response and final rule: Section 835.402(a)(4) of the final rule requires that individuals entering a high or very high radiation area be provided and use

personnel dosimetry. This requirement has been added for two reasons: (1) To ensure worker protection in the presence of high radiation areas or fields and (2) to make the final rule consistent with the provisions in 10 CFR part 20.

Section 835.403 Area Monitoring

Comment: Air sampling. Several commenters raised concerns regarding the requirement promulgated in the proposed rule for air sampling in areas where an individual is likely to be exposed to greater than 2 percent of the ALI values. There was some concern over the detection capability of the instrumentation available to analyze air samples, units of measurement used, occupancy time, and specification of the type or method of sampling required.

Response and final rule: Two percent of an ALI is equivalent to 40 DAC-hours. This limit is appropriately independent of occupancy time and detecting this level should not be a problem with available air sampling techniques.

Comment: Representative sampling. According to some commenters, determining whether air samples are representative at remedial action project sites is difficult.

Response and final rule: The language in the final rule does not specify the need for air samples taken as part of general area monitoring to be "representative of ambient air" as originally proposed. Although this should remain the objective of such monitoring, representative sampling is more relevant to sampling used to assign internal dose. Consequently, § 835.209 of the final rule requires that all surveys be representative when used for assigning internal dose. In § 835.403(a)(1), the final rule requires that samples be taken in order to "detect and evaluate the level or concentration of airborne radioactive material at work locations."

Comment: Real-time air monitoring. Comments were received which took issue with the requirement for real-time air monitoring to be capable of measuring at least 8 DAC-hours under laboratory conditions. The commenters felt that this requirement was unreasonable and unnecessary for several reasons: (1) Real-time air monitors, such as continuous air monitors, are not used in the determination of individual exposure; (2) the 8 DAC-hour requirement does not improve worker protection and is inconsistent with other radiological programs; (3) it causes instrumentation to be out of compliance without a supportable basis; and (4) factors such as dust loading and high radon backgrounds could affect the establishment of reliable alarm set points at this level.

Response and final rule: Since 1989, the Department has recommended in DOE Order 5480.11 that air monitors be capable of measuring one DAC when averaged over 8 hours (e.g., 8 DAC-hours). Consistently since that time, certain DOE activities have indicated an inability to meet that recommendation. Accordingly, DOE has decided to delete the 8 DAC-hour requirement from the final rule.

Comment: Real-time air monitoring at 10 percent DAC. The level at which real-time air monitoring was required was questioned because the 10 percent of a DAC value appeared overly conservative. Additionally, the requirement to provide real-time air monitoring at 10 percent of the derived air concentration should be specified in terms of temporal and spatial averages instead of simply DAC because workplace airborne concentrations are extremely variable over time and space.

Response: The purpose of real-time air monitoring is to provide early warning of an immediate and significant exposure hazard. The Department recognizes that the 0.1 DAC threshold is conservative and may not be directly indicative of a significant exposure hazard. Raising this monitoring threshold is responsive to public comments while ensuring the objectives of real-time air monitoring are met.

The monitoring threshold is stated in relation to the DAC without a specific temporal averaging period which is left to site-specific considerations. The higher threshold provides the flexibility suggested in the comment.

Final rule: The Department has reconsidered the level at which real-time air monitoring is required and, accordingly, has increased this level to 1 DAC in the final rule.

Comment: Use of the term "sufficient." The use of the term "sufficient" in § 835.403(a)(3) is very broad in scope and not very definitive.

Response: The sensitivity of the real-time air monitors is dictated by site situations which include consideration for the type, quantities, and level of hazard of radioactive material present. Additional definition is inappropriate due to the wide scope of activities within the DOE complex.

Comment: Radiation monitoring. Several commenters were unclear as to how to interpret the requirements for monitoring radiation in the workplace contained in § 835.403(b) of the proposed rule. Three specific issues were identified in these comments: (1) What type of instrumentation is appropriate for stationary instruments, (2) specifying a threshold for requiring stationary monitors, and (3) the dose rate survey requirements are too vague.

Response: (1) With regard to instrumentation used for stationary (area) monitoring, the final rule specifically states that the instruments must be capable of measuring radiation dose rates for the purpose of controlling exposure. In this case, the use of passive devices, such as thermoluminescent dosimeters or film badges, would not meet the requirements of the regulation. Active monitoring, such as area radiation monitors with local alarm and remote indication or portable survey instruments, would satisfy the requirements of § 835.403(b). (2) Each facility has dose rate characteristics unique to its operation. Therefore, it would be difficult and inappropriate to provide details in the final rule as suggested by the commenters. It is not the intention of DOE to specify monitoring thresholds for use of fixed radiation monitors. The requirement in the final rule provides flexibility to allow sites to choose monitoring methods considering personnel safety and site-specific restrictions. (3) Dose rate survey types and frequencies are usually established at intervals and locations dependent on the type and level of hazards associated with the facility operation. To maintain an effective program, each facility typically establishes the appropriate criteria for performing dose rate surveys based on the actual work and exposure situations. The program requirement should be identified in the site radiation protection program and implemented by any necessary site-specific procedure.

Section 835.404 Radioactive Contamination Control and Monitoring

Final rule: The title of this section was changed to remove the emphasis on surface contamination control and monitoring since the final rule addresses contamination control, in general. The first paragraph, § 835.404(a), reflects this change, and emphasizes that instrumentation and techniques are used to "ensure" rather than "assure" compliance with the requirements of this section. Additionally, the order in which some of the paragraphs appeared in the proposed rule has been changed and presented in a more logical order in the final rule.

Comment: Volumetric contamination. Some commenters indicated that the proposed rule did not address contamination in the outdoor work environment, such as contaminated soil, or items with contamination distributed in the matrix of the material and

activated materials. Exemption from the requirements of § 835.404 in these cases was suggested.

Response and final rule: The Department has not developed generically applicable criteria for the free release of material which has been contaminated in volume (e.g., soil, smelted contaminated material, etc.). Appendix D only addresses surface contamination limits and specifically excludes soil contamination. DOE Order 5400.5 specifies surface contamination limits for release of property for unrestricted use, but specifically acknowledges that generic volumetric contamination limits are not provided.

Comment: Contamination control. The wording in § 835.404(b) was perceived as too restrictive. Comments noted that the word "preclude" means "to make impossible." The inadvertent transfer of contamination to locations outside of radiological areas cannot be precluded, but can be prevented. The commenters were concerned with the high potential for enforcement action for any failure to preclude inadvertent contamination.

Response and final rule: The paragraph was rewritten to reflect the Department's concern with regard to the spread of contamination. The emphasis in the final rule is on preventing the spread of contamination.

Comment: Ad hoc controls. Several commenters raised concerns with the intent of proposed § 835.404(c). These concerns indicated confusion regarding the actions to be taken upon discovery of contamination outside radiological areas and the limitation of the requirements of the proposed paragraph only to removable contamination on indoor surfaces.

Response and final rule: The entire section addresses the measures to be taken for controlling contamination in the workplace including: (1) Instruments and techniques used to detect contamination, (2) maintenance of appropriate controls to prevent the spread of contamination, (3) posting of contaminated areas, and (4) entry and exit controls, procedures, and monitoring. In considering the public comments on paragraph (c), the DOE staff determined that not including this paragraph in the final rule would be most responsive to the public comments. The controls described in this section are applicable whether the contamination is discovered in established radiological areas or outside of them.

Comment: Fixed contamination outside of radiological areas. Commenters suggested that the proposed § 835.404(d) be rewritten to specifically identify the requirements and protective measures to be used in controlling areas with fixed contamination outside of radiological areas. Commenters noted the proposed requirements left approval authority to the Head of the DOE Operations Office which could lead to inconsistent application of the protective measures. Commenters also indicated the subject of immobilized fixed surface contamination, such as that covered by paint or other surface covering, was not addressed.

Response: When considering the public comments, the Department was in the process of developing controls for areas where levels of fixed contamination have exceeded those specified in appendix D. These controls specifically reference treating fixed contamination with paint or other surface covering.

Final rule: Since the Department has now developed standards for these situations, they are included in the final rule. The proposed rule was modified to include the detail suggested by some commenters. DOE Operations Office approval is, therefore, no longer required. These changes are reflected in § 835.404 (d) and (e) of the final rule.

Comment: Contamination limits. Some comments indicated that this section failed to provide guidance on personnel and personal property contamination limits.

Response and final rule: As currently addressed under DOE Order 5480.11, any detectable contamination on personnel or personal property should be removed by appropriate decontamination methods before being released. The final rule addresses individual monitoring for contamination in § 835.404(f).

Comment: Monitoring personnel upon exit from contaminated areas. Some comments discussed the need to address situations where the monitoring of personnel immediately upon their exit from a contaminated area may be impractical because of high background dose rates or physical limitations. Some commenters also noted that personnel contamination monitoring is not appropriate for certain radionuclides, such as tritium.

Response and final rule: The final rule now contains wording which provides flexibility for alternate monitoring procedures when personnel monitoring immediately upon exiting a contaminated area is not practical.

Comment: Protective clothing and control techniques. Additional detail regarding the protective clothing requirements contained in the proposed rule was suggested by some commenters. Other commenters disagreed, noting that the proposed rule was inappropriately prescriptive in requiring protective clothing. Commenters noted that the control techniques required in the proposed rule were redundant to other requirements in § 835.404. The use of the term "preclude" was also discussed. Therefore, the deletion of § 835.404(g) was suggested.

Response and final rule: The Department recognized the redundancy of the requirements for control techniques and has removed them from § 835.404(g) of the final rule. The final rule retains general requirements for protective clothing.

Subpart F—Entry Control Program

Section 835.501 Radiological Areas

Comment: Use of administrative procedures. Commenters suggested that portions of § 835.501(c) and (d) dealing with the use of administrative procedures to control entry into radiological areas were redundant.

Response: The review of the proposed rule in response to public comments revealed that this section of the proposed rule contained redundant provisions concerning the use of administrative procedures in lieu of physical controls.

Final rule: Because this redundancy could lead to misinterpretation of the intention of DOE in this area, the proposed rule was modified as follows:

1. Section 835.501(c)(4): "Locked entrance ways; and" was changed to "locked entrance ways; or". This change was made to emphasize that the use of administrative controls (see following paragraph) was one acceptable approach to entry control as opposed to always being associated with other entry control methods.

2. Section 835.501(c)(5): "Administrative procedure" was changed to "Administrative controls" to differentiate between a method used to control entry (administrative control) and the procedures used to implement the methods of entry control.

3. Section 835.501(d)(1) was deleted. The administrative procedure requirements are stated in § 835.501(d).

4. Section 835.501(d)(3) was deleted. The requirements of this provision are stated in § 835.501 (c)(5) and (d).

5. The remaining provisions of § 835.501(d) were combined into one provision.

Section 835.502 High and Very High Radiation Areas

Comment: Access controls for high and very high radiation areas. A

significant number of comments were received concerning the level of entry controls associated with high and very high radiation areas and the differences between this section and the corresponding sections in 10 CFR part 20. Commenters suggested the following changes to the proposed rule: (1) Divide the section in the proposed rule on high radiation areas into separate sections on high and very high radiation areas, (2) apply the access controls for very high radiation areas to high radiation areas, (3) clarify the provisions in the proposed rule for entry control to very high radiation areas by replacing them with the provisions in 10 CFR part 20 for entry control to very high radiation areas containing irradiators, and (4) ensure that alarms used for entry control purposes warn the activity supervisor of inadvertent entries.

Response: 10 CFR part 20 defines a very high radiation area as an area where a worker could be exposed to 500 rads (5 Gy) or more in one hour. This differs significantly from the definition in the proposed rule of 5 rems (0.05 Sv) or more in one hour. Accordingly, the DOE and NRC entry control requirements for high and very high radiation areas differed significantly. However, to establish greater consistency in radiation protection standards, DOE has adopted the NRC definitions for radiation, high radiation and very high radiation areas. In light of this change, DOE has revised the provisions of the proposed rule for entry control to high and very high radiation areas along lines that are similar to 10 CFR part 20. The overall result of these changes is to increase the levels of access control for high radiation areas as suggested by the majority of the commenters. In terms of dose rates, stringent entry controls are now required for radiation fields that could result in doses greater than 1 rem (0.01 Sv) in an hour as opposed to radiation fields that could result in a dose greater than 5 rems (0.05 Sv) in an hour.

Final rule: In response to the change in definitions of radiation areas coupled with public comments, the proposed rule has been revised as follows:

1. The title to this section has been changed from "Very high radiation areas" to "High and very high radiation areas." This section has been divided into § 835 502(a) "High radiation areas" and § 835.502(b) "Very high radiation areas."

2. Six methods are presented that specify acceptable methods of entry control for high radiation areas. Note that although the definition of high radiation area applies to areas containing radiation fields that could produce doses greater than 0.1 rem (1 mSv) in an hour, the stringent entry controls to a high radiation area are not required unless the radiation field could produce a dose of 1 rem (0.01 Sv) in an hour.

3. The proposed rule was revised so that an alarm that is set off by an individual entering a high radiation area alerts the activity supervisor of the entry.

4. A provision consistent with 10 CFR part 20 has been added which allows for direct or electronic surveillance has been added.

5. A provision was added to the final rule that requires entry controls which are more restrictive than those required for high radiation areas be applied to very high radiation areas. Unlike the NRC, there are not significant numbers of DOE facilities that are similar to each other. Accordingly, it was not considered necessary to provide additional requirements on entry controls for specific types of facilities or activities, as the NRC did for irradiators.

Comment: Access controls for field radiography. It was pointed out that posting and other controls were not specified for field radiography.

Response. The posting requirements of the proposed rule are considered appropriate for field radiography. Although the general provisions of § 835.501(a) apply to field radiography, the proposed rule did not impose specific requirements applicable to field radiography, on entry controls to high and very high radiation areas. Field radiography was explicitly exempted from the access control provisions for high radiation areas.

Final rule: To clarify the DOE position on entry controls for field radiography, the statement exempting field radiography from the provisions of § 835.502 was deleted. A new provision was added to the final rule to provide a method of entry control that is compatible with field radiography operations.

Comment: Exits from radiological areas. Comments suggested that the rule incorporate the applicable OSHA regulations dealing with exits from potentially hazardous areas.

Response: The provisions of the proposed rule, § 835.501(e), stated that no control(s) shall be installed in any radiological area that would prevent rapid evacuation of personnel under emergency conditions. This provision is considered sufficient to provide the necessary guidance needed to ensure the rapid and safe evacuation of personnel.

Final rule: To clarify the DOE position, the wording in § 835.502(c) and § 835.501(e) were made consistent.

Comment: Therapy patients and radioactive packages. Commenters pointed out that the proposed rule does not address access control to areas with patients receiving radioactive therapy and areas where radioactive packages are stored.

Response: DOE has minimal involvement with administration of radionuclides to radioactive therapy patients. Consequently, separate provisions for these situations are not included in the final rule. The limits and controls in the final rule pertain to all DOE activities conducting radiological operations, including radiation therapy.

Comment: Specificity of access control. Comments suggested that the level of access control for each radiological area (i.e., high radiation, airborne radioactivity, and contamination areas) be specified.

Response The access control requirements specific to high and very high radiation areas have been clarified. Because of the potential for immediate danger resulting from entry into other radiological areas is not as great as for high and very high radiation areas, the general provisions of § 835.501 are considered appropriate for areas not controlled as high and very high radiation areas. However, specific requirements for monitoring equipment and protective clothing are associated with entry into some of these areas. These requirements are specified in subpart E.

Subpart G—Posting and Labeling

Section 835 601 General Requirements

Comment. Comparison to 10 CFR part 20. Several comments were received which noted that the provisions for posting and labeling contained in 10 CFR part 20 should be considered in part 835. To ensure reasonable and adequate control of radioactive material in containers, more specific requirements and reasonable exceptions for the posting and labeling of containers should be incorporated from 10 CFR part 20. Nothing was stated in the proposed rule regarding posting areas where radioactive material is stored. DOE should require the same posting as required by 10 CFR part 20 to alert personnel in the vicinity of the presence of radioactive material.

Response: The requirements in the final rule do not apply to activities or licensed material that are regulated by the NRC (see § 835.1(b)(1) of the final rule). Section 835 601(a) specifies the

labeling of containers of radioactive material if adequate warning is not provided by control measures and required posting. Rulemaking on sealed radioactive source accountability control which will address accountability, labeling, storage, inventory, integrity testing, and control of radioactive sources is planned.

Comment: Standard for signs. The standard for signs (including the standard radiation symbol) should be included in the rule. Guidance must be provided on obtaining "approved" signs and identification of the approving organization within DOE. ANSI trefoil design should be acceptable to comply with the regulation. Requirements for the color of the text should be specified.

Response Guidance for DOE approved signs will be provided in the regulatory guidance on posting and labeling. This will include information on the symbol and acceptable color of the text. The Department prefers to cite industry standards, such as ANSI, in regulatory guidance rather than codification through regulation.

Comment: Radiation symbol. Typical radiation warning symbols are magenta (or purple) with a yellow background. General safety postings use yellow and black. The use of yellow and magenta (or purple) would be more informative and act as a better warning than yellow and black.

Response: Although the "magenta on yellow" color scheme has provided a unique warning of possible radiation hazards, the use of "black on yellow" is also acceptable and consistent with 10 CFR part 20. The fading of the magenta color in sunlight may reduce the visibility of the sign in time thereby diminishing the warning's effectiveness.

Section 835.602 Controlled Areas

Comment: Posting of controlled areas. Comments suggested that the reason for the area being controlled should be specified on the posting. Posting of areas should not be needed when contamination levels and dose rates pose essentially no potential exposure.

Response. Posting of controlled areas warns workers that they will be entering an area where they might encounter radioactive material and therefore must be more vigilant. However, it is not the Department's intention that controlled areas be posted when radiation fields and radioactive material in these areas do not require additional posting under the provisions of § 835.603. Specifying the reason for posting a controlled area is inconsistent with the philosophy of providing more definitive posting closer to the actual hazard (e.g., radiation, contamination, or airborne).

Comment: Approval of signs. Comments suggested that the requirement for approval of signs used to post controlled areas by DOE seemed to be unnecessary. Suggestions to provide guidance specifying the content required on these signs including the standard radiation symbol were offered.

Response and final rule: The final rule has been modified to no longer require signs used to post controlled areas be approved by the Head of the appropriate DOE field organization. Selection and approval remains the responsibility of the contractor to avoid conflict with local security requirements for posting controlled areas.

Section 835.603 Radiological Areas

General: The proposed rule defined radiation area, high radiation area, very high radiation area, and airborne radioactivity area in conjunction with the posting requirements for these areas. These definitions are now included in § 835.2(a).

Comment· Definition of area postings. The terms "radiation area," "high radiation area," and "very high radiation area" should be defined in § 835.2 and only describe specific wording on signs required for posting in § 835.603.

Response and final rule: The definitions for the terms "radiation area," "high radiation area," and "very high radiation area" have been included in § 835.2(a).

Comment: Postings. Comments suggested that, for consistency with 10 CFR part 20, the sign for a radiation area should read, "CAUTION, RADIATION AREA." The sign for a high radiation area should read, "DANGER, HIGH RADIATION AREA." The sign for a very high radiation area should read, "DANGER, VERY HIGH RADIATION AREA."

Response and final rule: The requirements for the wording on the signs have been modified to add the words "CAUTION" for radiation areas, "DANGER" for high radiation areas, and "GRAVE DANGER" for very high radiation areas.

Comment: Very high radiation area dose rate. The dose rate specifications for very high radiation areas differ from 10 CFR part 20, 5 rems (0 05 Sv) or greater in 1 hour at 30 cm from the radiation source versus 500 rads (5 Gy) in 1 hour at 1 meter from a radiation source. These limits should be the same due to the transient nature of radiological workers.

Response and final rule: The dose rate specification for a very high radiation area has been changed to an absorbed dose in excess of 500 rads (5 Gy) in one hour at one meter from a radiation source.

Comment: Posting of dose rate. Clarification on whether the dose rate reported on the posting should be based on a contact reading or a reading 30 cm from the source was suggested. Compliance with the proposed § 835.603(c) would mandate changes to the posting required for identification of radiation areas. In contrast to listing the dose rate range on a sign, an effective entry control program provides radiological information at normal access points or at specific job sites. Comments suggested that § 835.603 specify the implementation of an entry control program through which personnel entry will be managed.

Response and final rule: The detailed information regarding the reporting of specific dose rate information on required postings has been determined to be too detailed to be contained in the final rule. Consequently, the proposed requirement to post dose rate information on or in conjunction with each required sign has not been included in the final rule.

With regard to the alternative of implementing an entry control program, § 835.501(d) specifies that administrative procedures for activities in radiological areas be developed which "require authorizations (to perform work within the area) that include work-specific radiation protection measures specific for the authorized work."

Comment: Posting airborne radioactivity areas. Several commenters discussed concerns regarding posting of airborne radioactivity areas at 10 percent DAC. Some stated concern that the use of instantaneous concentration values would present economic difficulties. The comments also stated that DOE should employ the standard practice currently utilized by contractors of averaging concentration over an 8 hour work shift. Other comments stated that DOE and NRC definitions for "airborne radioactivity areas" should be coordinated to minimize confusion between similar work groups. 10 CFR part 20 defines airborne radioactivity areas as areas either exceeding the DAC values or an area in which an individual with no respiratory protection could receive more than 0.6 ALI or 12 DAC-hours (during the hours they are present during the week).

Response: The reliance on intake or exposure determined over a period of time, such as NRC's 12 DAC-hours during a week, has caused implementation concerns. NRC licensees must now consider how many

hours in a week a worker could be exposed to airborne radioactive material. Licensees need this information to calculate at what percent of DAC an area will be posted. Many NRC licensees will be posting at nearly 30 percent of the DAC values (12 DAC-hours/40 hours=0.3 DAC).

The use of standard air sampling techniques inherently provides an average concentration of airborne radioactivity over the sampling period (typically per shift or per day). Rather than specify an averaging time period, and potentially require modification of facility sampling times, the original value of 10 percent DAC is retained. This does not preclude the use of averaging when determining the need to post airborne radioactivity areas.

Comment. Alternate wording. Allowing the DOE field organization to determine alternative wording for radiological signs does not promote standardization throughout the DOE complex. To keep from confusing radiological workers working at different DOE sites, or even different facilities within a site, standardization for posting and labeling is essential.

Response and final rule: The statements that allowed alternative wording for signs posted to delineate radiological areas have been deleted.

Comment: Posting for areas with surface contamination. The proposed rule requires posting of surface contamination areas whereas 10 CFR part 20 does not address this subject.

Response: DOE considers that the posting requirements for surface contamination areas are essential for protection of its workers from surface contamination.

Comment: Distinguishing between "surface contamination areas" and "high surface contamination areas." The need to distinguish between "surface contamination areas" and "high surface contamination areas" was questioned. Entry requirements will be the same in most cases. However, if not, entry requirements and contamination levels can be clearly stated on the posting. The separate posting could be confusing.

Response: Separate posting for surface and high surface contamination areas is consistent with the graded approach for radiation areas. As contamination levels increase, the level of protective clothing and other requirements increase. High surface contamination areas require a buffer zone between the exit from the higher level contamination area and any cleaner area (e.g., exit from a high surface contamination area to a surface contamination area or from a surface contamination area to a clean area). Separate postings should increase the employees' awareness of the level of radiological hazard associated with the posted area and would not be confusing.

Comment: Posting of "high surface contamination areas." As proposed, § 835.603(e) indicated that a high surface contamination area was to be posted when the contamination levels exactly equal the values listed in appendix D

Response and final rule: The final rule (§ 835.603(f)) has been modified to read "greater than 100 times the value listed in appendix D of this part."

Subpart H—Records

General: Demonstration of compliance with the provisions of the rule requires that certain documentation and records be maintained. The absence of detailed requirements in the proposed rule resulted in several comments requesting clarification for records required by the rule. The final rule contains detailed provisions for records, where appropriate. This detail will facilitate consistent implementation of the final rule throughout the DOE complex.

Final rule: This subpart was restructured to better organize the requirements into appropriate sections for general provisions, individual monitoring records, monitoring and workplace records, and administrative records.

Section 835.701 General Provisions (Proposed § 835.701 Documentation Requirements)

Comment. Records retention. The periods for retention of records required in the proposed rule was not specified. Comments suggested that periods of retention be addressed.

Response and final rule. The final rule has been clarified by adding a new paragraph requiring that records be retained until final disposition is authorized by DOE. Other records retention provisions are set forth in DOE Order 1324.2A. It is the Department's intention that records be retained consistent with the principles contained in DOE Order 1324.2A.

Section 835.702 Individual Monitoring Records (Proposed 835 701 Documentation Requirements)

Final rule: Numerous changes to the proposed individual monitoring requirements were made to reflect the change from using an AEDE to a CEDE dose limitation system. Section 835.701(c) and (e) of the proposed rule were consolidated into § 835.702(a) of the final rule. Section 835.702(c) of the final rule reflects numerous editorial modifications to the provisions originally proposed in § 835.701(g).

Comment· Clarification of documentation requirements. Several commenters noted the need for clarifications in the proposed records requirements for internal dose determination, dose to the embryo/fetus, and data for verification or recalculation of historical doses.

Response and final rule: The final rule now contains provisions for records of estimated intake and radionuclide identity (§ 835.702(c)(4)(iii)) and dose equivalent to the embryo/fetus of a declared pregnant worker (§ 835.702(c)(6)). Clarification of the provision in § 835.701(j) of the proposed rule for records of data necessary to validate or reassess recorded doses was included in § 835.702(g) of the final rule.

Comment. Prior occupational exposure Several commenters noted that the proposed rule did not explicitly require the accounting for occupational exposure from non-DOE activities. This could allow individuals to exceed the annual limit recommendations contained in the Federal Guidance approved by the President in 1987.

Response: The Department does not want any individual to exceed the annual occupational exposure limit. Emphasis must be placed on the need to determine prior occupational exposure during the year and maintain records of this exposure for each affected individual. Therefore, the final rule (§ 835.702(d)) requires that documentation of all prior occupational exposure an individual received during the current year be obtained. This information will be used to demonstrate compliance with the provisions of § 835.202 for limiting annual occupational exposure.

Comment. Lens of the eye Comments noted that the annual dose equivalent to the lens of the eye is not typically assessed at some facilities.

Response: Assessments are made as applicable for the radiological hazards encountered. More specifically, records need to be maintained only if monitoring was required under § 835.402. Therefore, if the lens of the eye dose equivalent is not required to be monitored, then records for such monitoring are not required.

Section 835.703 Monitoring and Workplace Records (Proposed Section 835 702 Monitoring and Area Control Records)

Final rule: Section 835.703(a) in the final rule consolidates the records required regarding the results of radiological surveys which were

contained in three different paragraphs in the proposed rule. Records for the results of surveys, measurements, and calculations used to determine individual occupational exposure from internal and external sources are discussed in § 835.703(b) of the final rule which replaced two paragraphs in the proposed rule. Section 835 703(d) was added to identify the records required as a result of the provisions for maintenance and calibration of survey instrumentation and explicitly state the requirement implied in § 835.703(a) of the proposed rule.

Comment· Records of the surveys for the release of personal property. Commenters stated that it would be impractical to document results of surveys for the release of personal property. Comments indicated that all items should be surveyed prior to release from a controlled area to an uncontrolled area, but that only the results of surveys of equipment and material be documented.

Response and final rule: Upon consideration of the public comments, the Department has removed the requirements for maintaining records of surveys of the release of personal property. It was the Department's original intent not to overburden DOE contractors with excessive record keeping requirements. Accordingly, the final rule addresses records of surveys for the release of material and equipment. Records explicitly related to release requirements of material and equipment are contained in § 835.1101(d) of the final rule. The conditions for permitting release from radiological areas are specified in § 835 1101 (c) and (d).

Section 835.704 Administrative Records

General: This section contains the records requirements for administrative provisions in the rule. These include training and ALARA records, for example.

Comment ALARA program documentation. A number of commenters indicated that the requirement to have a formal ALARA program and maintain the volume of associated individual and survey records would result in substantial increased costs due to the manpower necessary to support additional record keeping and procedural requirements. Several comments were made about the lack of guidance on the retention of records.

Response: Similar provisions for records to those proposed in the rule already appear in DOE Order 5480 11. The final rule provides more details than the existing Orders and defines the records required to be maintained and retained to demonstrate compliance with the final rule.

Final rule: The Department has included records requirements in the final rule which are necessary to document compliance with the provisions of the rule. The final rule requires records of ALARA actions for the radiation protection program and facility design activities.

Two paragraphs regarding records requirements which were not addressed in the proposed rule were added. These clarify documentation requirements for provisions contained in the final rule. Paragraph (c) of this section provides for documentation of the results of internal audits. Paragraph (d) of this section requires that written declarations of pregnancy of individuals be maintained

An editorial clarification to § 835.703(b) of the proposed rule is now reflected in § 835.704(e) of the final rule.

Subpart I—Reports to Individuals

Section 835.801 Reports to Individuals

Final rule: The final rule contains provisions to report radiation exposure data to individuals following termination of employment at a DOE facility and to all DOE workers on an annual basis. The information requirements for these reports are shown in § 835.702(c). Although the final rule specifically requires an annual report for each DOE worker, duplicate information need not be provided when a complete record has been provided following termination.

Comment: Clarification of the terms "workers" and "employees." The use of the terms "worker(s)" and "employee(s)" interchangeably in this paragraph was confusing and should be clarified.

Response: A review of the proposed rule indicates that the interchangeable use of the terms "worker(s)" and "employee(s)" detracts from the clarity of the rule. This source of confusion could prevent some individuals who should receive reports under the provisions of the rule from receiving these reports.

Final rule: The terms "worker(s)" and "employee(s)" have been replaced by the term "individual(s)" throughout the final rule.

Comment· Termination reports. Several comments were received concerning termination reports. Specific comments were: (1) Allowing a maximum of 90 days after termination before a termination report must be provided to an individual is too short to permit proper evaluation of internal doses in some cases, (2) there are no provisions for providing an individual with a written estimate of current year dose at the time of termination, and (3) for the case of subcontractor personnel employed on a temporary basis, does DOE expect a termination report to be issued after each termination in the calendar quarter?

Response: It is the Department's position that the 90 day period after termination allowed for responding to a request for a termination report is sufficient to allow determination of internal dose in most cases. Where a reliable determination of the internal dose is not available, a statement should be included in the report to that effect.

The Department agrees with the need to provide written dose estimates to individuals terminating employment. Adopting such a provision will facilitate the transfer of workers between DOE facilities and NRC licensed facilities.

For the case of employees hired on a temporary basis several times during a calendar quarter, a termination report is not required each time the individual's period of employment ends unless requested by the employee. However, even if a termination report is requested each time an individual's period of employment ends, the 90 day period permitted before the report is provided to the individual could allow several terminations to be included in one termination report. This concern reinforces the DOE position that a provision permitting written dose estimates be included in the final rule.

Final rule: Section 835.801(b) requires that a written dose estimate be provided upon request to an employee at the time of termination.

Comment· Annual report to individuals. Comments on the annual report to individuals dealt with questions concerning the specific types of information to be included in this report, how far back in time cumulative dose should be assessed from, and who is responsible for providing these reports to subcontractor employees.

Response: The categories of dose information required to be recorded in § 835.702(c) of the final rule are required to be included in the annual report. Cumulative dose is to be recorded from January 1, 1989. The final rule clearly identifies the contractor as being responsible for ensuring that annual occupational exposure information is provided to individuals employed at a facility or site.

Final rule: Section 835.801(a) was revised to provide specific information on the content of dose reports provided by DOE facilities and activities to monitored individuals. The data

recorded under § 835.702(c) are specifically required to be reported.

Comment: Occurrence reporting. Comments questioned whether individuals identified in reports required by proposed § 830.350 must receive copies of such reports each time one is transmitted to DOE or do these individuals need only receive a copy of the final report.

Response: Copies of reports containing individual dose information required under Departmental requirements for occurrence reporting and processing must be sent to individuals identified in these reports.

Comment. Planned special exposure. Comments recommended providing an exposure report to individuals no later than 30 days after a planned special exposure.

Response: Section 835.204(e) of the final rule requires that reports of doses received during the planned special exposure be submitted to DOE. Accordingly, a copy of this report should be provided to the exposed individual.

Final rule: Section 835.801(e) has been modified to require that reports of doses received during planned special exposures be transmitted to the exposed individual at a time no later than the time this information is transmitted to DOE.

Subpart J—Radiation Safety Training

Comment: Training content. Comments noted that this subpart provides a welcome feature in that it clearly allows for the training content to be specifically tailored to the activities conducted at a given facility.

Comment: Comparison to 10 CFR part 20 Comments noted that 10 CFR part 20 does not discuss radiation safety training requirements.

Response: NRC requires radiation safety training in 10 CFR part 19 DOE considers the training program requirements as an essential provision in the rule.

Section 835 901 General Employees

Comment. Minimum generic subject matter. DOE Order 5480.11 provides minimum generic subject matter standards while the proposed rule did not. Identifying required subject matter for occupational worker training will help standardize such training across the DOE complex.

Response: Providing the generic subject matter requirements is considered too detailed for the rule. Specific training subject matter is presented in the DOE standardized core training.

Comment: Prenatal exposure risk information. Comments suggested that this section contained detail which was more appropriate for a "lower tier document" and was inconsistent with the level of detail contained in this subpart. References to providing prenatal exposure risk information was also viewed as possibly discriminatory since radiation safety orientation should provide information regarding risks to all occupational workers, not just women.

Response and final rule: The final rule has been modified to omit reference to specific subject matter requirements. The DOE standardized core training provides the subject matter requirements to be used throughout the DOE complex. This standardized core training for radiological workers includes material on prenatal exposure risks, the applicable exposure limit, and DOE policies related to the voluntary declaration of pregnancy.

Comment: Training to enter a controlled area. Commenters noted that when a controlled area encompasses a very large area, such as the Idaho Chemical Processing Plant or the Oak Ridge K–25 site, that a facility for training would have to be set up outside the controlled area since occupational workers would be required to be trained to gain access to the controlled area. It was suggested that untrained occupational workers be allowed to be escorted by trained individuals. Commenters also suggested modifying the language in the proposed rule such as requiring the radiation safety orientation "prior to potential exposure to radiation" rather than "admission to controlled areas" or training be given to "all occupational workers who may be granted unescorted access to a controlled area." Other comments suggested that the possibility of entry into a controlled area, rather than simply the admission to a controlled area, should be used as a criterion for requiring the orientation training for occupational workers.

Response A Departmental objective is that appropriate protection be provided to its workers. This includes provisions for training prior to performing radiological work or receiving radiological exposure. For consistency, the final rule no longer refers to orientation, but provides training requirements for general employees, radiological workers, and radiological control technicians. As presented, the final rule allows access to controlled areas prior to training if the individual will not receive occupational exposure. Appropriate controls, however, must be in place to ensure that these personnel receive no occupational exposure.

Final rule: The final rule has been modified to require that radiation safety training be given to general employees prior to receiving occupational exposure during access to controlled areas.

Comment: Examinations. Several commenters questioned the need for occupational workers entering a controlled area who receive radiation safety orientation to demonstrate their understanding of that material by passing an examination.

Response: Many standard training practices, especially those in the commercial nuclear industry, include requirements for individuals to demonstrate knowledge through successful completion of an examination. This serves to document that personnel granted unescorted access understand where access is permitted and which areas to avoid. The purpose of the examination is not to inconvenience individuals, but to assure a minimal level of knowledge which assures the individual's radiation safety.

Comment: Training at other sites or facilities. Comments suggested deletion of the reference to "at that facility" in the requirements for radiation safety orientation discussed in the first sentence of § 835.901(a) of the proposed rule. In a similar vein, other comments questioned if it is required for employees with certified training from other sites be examined for knowledge or radiation safety and suggested that the reference to training from another facility is more appropriate for regulatory guidance.

Response and final rule: Permission to accept generic training provided by other sites or facilities is an important concept and is appropriate for inclusion in the rule. An individual who has received the generic training at another site or facility would only need to be trained and examined on the site-specific information. The proposed rule was modified to accommodate the transfer of generic radiation safety training between sites.

Comment: Retraining. Retraining frequency and clarification as to what constitutes significant change were questioned by some commenters. A suggestion to incorporate retraining frequency into regulatory guidance was offered.

Response: Stating the interval at which retraining is to be provided is considered essential to this subpart. Retraining is to be provided to all general employees who received the initial training and whose assignment would require them to enter controlled areas where they may receive

occupational exposure. Discretion is purposely left to the site to evaluate the significance of changes to radiation protection policies and procedures.

Section 835.902 Radiological Workers

Comment: Radiological worker's level of training. Comments questioned the discussion in the introductory remarks of the proposed rule with regard to the Department's policy of making safety a line management responsibility. The commenter suggested that in order to achieve this goal, additional training of radiation workers may be required.

Response: A radiological worker who is informed, alert, and aware of the radiological conditions and hazards in the work area will be able to minimize exposure while performing work tasks. Standardized DOE training materials emphasize the importance of the worker's role in maintaining radiation safety.

Comment: Training preceding assignment. Commenters noted that the statement that "training shall precede assignment as a radiation worker, or it may be concurrent with assignment as a radiation worker if the worker is accompanied by and under the direct supervision of a trained radiation worker" is contradictory.

Response and final rule The language in the final rule was changed to clarify the requirement.

Comment. Level of detail related to subject matter. Comments indicated a need to develop more comprehensive radiation worker training for their activity. Other comments suggested the need for additional specificity of subject matter to clarify the requirements of the proposed rule. Additional clarification was requested regarding what is to be demonstrated as part of the examination (i.e., general radiation safety concepts or specific tasks, such as self-monitoring for contamination). Commenters felt the need to "demonstrate" (i.e., encompassing practical factors) should be determined by a job/task analysis and was inappropriate to be included in the proposed rule. Clarification regarding what constitutes "demonstration" was requested.

Response: The standardized core training currently provides the subject matter requirements for radiological worker training to be used throughout the DOE complex. Most site-specific training includes a demonstration (e.g., donning and removing protective clothing and equipment) to verify the individual's knowledge and capability to function safely in radiological areas.

Final rule: The final rule does not require the "demonstration prior to an unsupervised assignment."

Comment: Testing radiological workers. Comments suggested that the proposed rule leaves several important issues related to testing radiological workers unresolved; such as what to do with employees failing the exam and whether or not retraining also includes re-testing.

Response: The level of detail requested with regard to administering and evaluating examinations is provided in DOE's standardized core training documents.

Comment: Retraining. Comments suggested deleting the reference to a retraining frequency of every 2 years and including it in guidance.

Response: Stating the interval at which retraining is to be provided is considered essential to this subpart. The final rule provides the maximum allowable time before an individual must be retrained.

Section 835.903 Radiological Control Technicians

Comment: Details on methods. Comments suggested that the proposed rule was too specific regarding "details on methods" and recommended this level of detail be addressed in implementation guidance.

Response: The specifics of the training are included in standardized DOE core training materials. Requiring classroom and applied training is considered essential to assure consistent application of the final rule.

Comment: Training preceding performance of tasks. Comments noted that the statement "training shall precede performance of tasks assigned to radiation protection technicians, or if the individual is accompanied by and under the direct supervision of a trained person, it may be concurrent with such task assignments" is contradictory.

Response and final rule: The language in the final rule was changed to clarify the requirement.

Subpart K—Design and Control

Section 835.1001 Design and Control

Comment: Terminology. Commenters felt that this section could be improved by eliminating the word "workplace" from the term "controlled workplace areas," and requiring that equipment design as well as facility design be used as a method to maintain radiation exposures as low as reasonably achievable

Response: The clarification obtained by accepting the suggested changes will strengthen this section and reduce implementation difficulties within the DOE complex. In addition, the introductory sentence of this section has been edited in light of DOE intention to codify the ALARA process based primarily on the methods used to achieve ALARA objectives.

Final rule: Section 835.1001 of the proposed rule was revised in accordance with the considerations discussed above. Because a new provision to the rule has been added in response to the following comment, this section has been listed as § 835.1001(a) in the final rule.

Comment: Applicability at remediation sites. Comments strongly suggested that the primary methods for workplace controls described in the proposed rule will not work at remediation sites. These sites can only use administrative controls to regulate radiation exposure in the workplace. DOE needs to state that administrative controls may be used as a primary control method if physical design controls are not practical.

Response: Physical design controls for radiation exposure are intended primarily for use in workplaces that are located within structures providing a foundation for the installation of these features. The types of activities occurring at remediation sites are not performed within structures. Thus, physical design controls may be impractical and administrative controls will be required to control radiation exposure. In addition, it is likely portions of the decontamination and decommissioning efforts facing DOE in the near future will be performed at locations in which utilization of physical controls is impractical. To provide the flexibility necessary to address these types of activities, DOE agrees that the proposed rule should be modified to allow the use of administrative controls under certain conditions.

Final rule: Section 835.1001(b) has been added to the final rule to explicitly permit the use of administrative controls for specific activities where the use of physical design features are demonstrated impractical.

Section 835.1002 Facility Design and Modifications

Comment: Design objectives for controlling personnel exposure. A number of comments were received concerning the design objectives for controlling personnel exposure. Specific comments were as follows: (1) The time period over which the design objective for average exposure levels during continuous occupancy is to be maintained should be specified, (2) the design objective for continuous exposure should be set at 0.1 rem (1 mSv) from external sources, (3) the

design objective should be changed to a design requirement, and (4) an allowance for evaluation of the cost benefit should be added to the expectation of limiting a radiation worker's exposure in areas where exposure is generally not continuous.

Response: (1) The Department agrees that for clarity in implementing the provisions of this section, the time period over which the average exposure levels to be maintained should be specified.

(2) A design objective of 0.1 rem (1 mSv) in one year for continuous exposure is not considered necessary to ensure that DOE workers are properly protected. The current design goal of 1 rem (0.01 Sv) in a year for continuous exposure is one fifth of the occupational dose limit in § 835.202. Average yearly dose to individuals exposed at DOE facilities is only a fraction of this level as discussed in section II.B.1.c. The costs associated with modifying facility design to reduce exposure rates by 90 percent, when the anticipated dose to DOE employees could not be greatly reduced, is not considered necessary when comparing costs and resulting benefits.

(3) Changing the design objective to a design requirement will force all activities to meet the specific dose levels specified in the final rule regardless of any extenuating circumstances. The requirements in the proposed rule provide the flexibility to encompass situations where it is impractical to meet design goals either because of excessive costs (cost benefit considerations) or other extenuating circumstances.

(4) As previously stated, using the term "design objective" instead of "design requirement" provides allowance for evaluation of the cost versus benefit in the application of design features to limit worker exposure.

Final rule: Section 835.1002(b) was modified to specify that the design objective for continuous occupancy is based upon 2000 hours per year.

Comment: Dose reduction objectives. The design objective which states, "under normal conditions to avoid releases to the workplace atmosphere," is intended to prevent internal exposure. ALARA activities are expected to optimize AEDE (TEDE in the final rule). The two objectives, preventing internal exposure and optimizing TEDE, are not always compatible.

Response: The two objectives, preventing internal exposure and optimizing TEDE, are not incompatible. The requirement to avoid releases of radioactive material to the workplace is the basic approach to maintaining control of the workplace and reducing the probability of internal exposure. This requirement is intended to reduce the possibility of a situation occurring in which an individual could be internally exposed. However, in cases where a release of material has occurred, the objective is to reduce the total dose received by an individual from internal and external sources to as low as reasonably achievable.

Section 835.1003 Control Procedures

Comment: Redundant requirements. All of the requirements in this section appear elsewhere in the proposed rule. If this paragraph is retained, and a DOE contractor were to violate one of its requirements, the contractor would also violate another requirement and thus be in double jeopardy.

Response: The intent of this section is to specify requirements for the control of exposure levels permitted in the workplace. All other sections of the proposed rule provide limitations on the dose actually received by an individual, but do not place any limitations on exposure levels permitted in the workplace. This section provides the levels of external radiation fields and concentrations of radioactive material necessary to demonstrate control of the workplace environment. Although the provisions in this section are not intended to place a contractor in "double jeopardy," doses to individuals that exceed the limits specified in other parts of the proposed rule are considered indications that a contractor is not properly controlling the workplace environment. Note that compliance with the provisions of this section are intended to be demonstrated through the methods used for workplace monitoring specified in subpart E.

Final rule: To clarify the intent of this section the following changes have been made to the final rule:

1. The provision in § 835.1003(a) has been modified to include the use of design features and administrative control procedures in the control of the workplace.

2. All of subpart E, as opposed to § 835.402, has been referenced in § 835.1003(b) in regard to the methods used to demonstrate compliance with this section. This revision was made to include the methods used for workplace monitoring among the methods used to demonstrate compliance with this section.

Subpart L—Releases of Materials and Equipment From Radiological Areas

Section 835.1101 Releases of Materials and Equipment From Radiological Areas

Comment: Difference from 10 CFR part 20. The proposed rule addressed requirements for the release of materials and equipment from radiological areas that are not included in 10 CFR part 20.

Response: Although there are differences between 10 CFR parts 835 and 20, the purpose of both parts to regulate the respective activities to achieve optimal protection for the worker, public, and environment is identical. DOE has chosen to address requirements regarding release of materials and equipment which the NRC has chosen not to.

Comment: Clarification for use of this section. Clarify whether the requirements in this section of the proposed rule apply to radiological areas established for external radiation control purposes only.

Response: The provisions for release of contaminated material only apply to radiological areas established to control surface or airborne radioactive material. It is expected that an area posted solely for the presence of external radiation would not contain material or equipment with contamination levels that exceed the levels listed in appendix D. If a contaminated item was found in a radiological area originally established only for external radiation control, this area would be re-posted to indicate the presence of contamination.

Comment: Requirements for releasing radioactive material to an uncontrolled area. Requirements for releasing radioactive material from controlled areas and/or radiological areas to an uncontrolled area should be provided.

Response: Provisions for the release of radioactive material to uncontrolled areas are contained in DOE Order 5400.5; DOE intends to incorporate these provisions in subsequent rulemaking.

Comment: Remedial action sites. For remedial action sites, commenters stated that alternative provisions must be established which ensure worker safety and allow for daily release of materials and equipment from radiological areas without unduly burdening the contractor with monitoring and reporting requirements.

Commenters noted that the requirements for release of equipment from contaminated radiological areas, when coupled with the requirements for controlling inadvertent transfer of removable surface contamination to locations outside of radiological areas, are not workable at some remediation

sites. Similar provisions in existing DOE Orders have been modified to accommodate specific operations. Surveys adequate to demonstrate compliance with the criteria of this section, under conditions at remedial sites, are impossible to perform in a timely manner. Without the exceptions described above, the cost of doing business would escalate.

Response: With regard to worker protection at remedial action sites, regulatory guidance is planned which will address concerns specific to these operations.

The subject requirements for control and release of material from radiological areas are considered basic and necessary to DOE radiological operations. Requests for exemptions from these requirements are highly dependent on site-specific factors and compensatory measures. Such requests for exemptions must be handled in accordance with 10 CFR part 820.

Comment: Survey requirements for remedial action sites. Requiring air sampling, radon monitoring, and release surveys are neither practical nor feasible to implement at a remedial action site.

Response: The level and scope of surveys are dictated by the nature of the site's/facility's operations. As many of the remedial action site operators' concerns, as possible, will be addressed by regulatory guidance. These concerns may be addressed through the exemption request process as provided in 10 CFR part 820. The conditions for release of materials and equipment from radiological areas established to control surface or airborne radioactive material, as listed in the proposed rule, were retained.

Comment Conditional release criteria. The conditional release criteria specified in this section should be modified to reflect the detection capabilities of available field instrumentation. The proposed rule applies to movement of material and equipment from radiological areas to controlled areas which implies a level of control is implemented. Field instrumentation with the sensitivity to detect appendix D levels is not available. Laboratory equipment would need to be purchased. Existing portable radiation detection instruments in use at some sites, which are representative of the best available technology, are not capable of detecting some of the contamination levels specified in appendix D (e.g., $^{90}Sr/^{90}Y$, ^{129}I, $^{226}Ra/^{226}Ac$). Changing the wording to "under laboratory conditions" was suggested.

Response and final rule: The final rule has been modified in appendix D, raising the transuranics value from 300 dpm/100 cm^2 to 500 dpm/100 cm^2. Any other requests for exceptions and exemptions to the final rule can be submitted to DOE under the provisions of 10 CFR part 820

Comment: Control procedures. Minimally acceptable monitoring and control procedures for movement of contaminated materials from one radiological area to another should be required and described.

Response: Regulatory guidance will be developed describing acceptable methods for complying with the provisions of the final rule on the movement of contaminated material between radiological areas.

Comment: Removable contamination. Commenters indicated that § 835 1101(c) of the proposed rule was unclear since it only addressed fixed contamination. With the controls specified in the proposed paragraph, removable contamination below some reasonable level should be included in addition to fixed contamination.

Response and final rule: The final rule was clarified to include the provisions for removable contamination specified in appendix D.

Comment: Release record. Records are not necessary for release from a radiological area to a controlled area because of the continuing control of the item or material. Comments suggest that the records requirement be applied only to the unrestricted release from the controlled area.

Response: Records of the items released from a radiological area are needed to ensure that the item can be tracked and that the radiological history of the item is known.

Comment: Survey date. Clarify the wording, "the date the last monitoring operation," so that the intent, "the date on which the release survey was performed," is clear.

Response and final rule: The wording "the date the last monitoring operation" was replaced with "the date on which the release survey was performed."

Subpart N—Accidents and Emergencies (Proposed Subpart M)

General: Comments were received on the appropriateness of the section on accidents and emergencies in the Department's standards for occupational radiation protection. Of particular note was a comparison to 10 CFR part 20, which does not contain similar provisions.

Response: In reconsidering the purpose of this subpart, the Department provides requirements for controlling exposures under accident and emergency conditions. In order to convey only those requirements necessary to assure that worker health and safety is maintained, however, the subpart was edited to delete sections not directly applicable to the control of exposure to DOE employees under accident and emergency conditions.

Section 835.1301 General Provisions (Proposed Section 835.1201 Accidental and Emergency Exposures)

Final rule: The title of this section was changed to more clearly reflect the contents of the section. Other changes to the language in this section were made in order to assure the uniform application of the provisions of the final rule throughout the DOE complex. These changes were editorial only and did not affect the technical content of the language in the rule.

Section 835.1302 Emergency Exposure Situations. (Proposed Sections 835.1202 General Considerations and 835.1203 Emergency Situations)

Final rule: The title of this section was changed to reflect clearly the contents of the section. Guidelines for controlling emergency exposures were moved into this section from proposed § 835.1203 and condensed into a tabular format for easier understanding which clarifies the Departmental policy regarding emergency exposures. The final rule only provides emergency exposure guidelines for preventing major property damage and lifesaving or protection of large populations. Emergency exposure guidelines for the recovery of deceased victims are no longer specified in this rule because such guidelines are more appropriately covered by site procedures.

The references to an Emergency Director were removed since this title could vary from site to site. This level of specificity was inconsistent with the purpose of the rule to provide requirements for controlling exposure under accident and emergency conditions. Emergency response directives provide DOE standards regarding emergency response organization.

Section 835.1304 Nuclear Accident Dosimetry. (Proposed Section 835.1204 Nuclear Accident Dosimetry)

Comment· Nuclear accident dosimetry accuracy. Commenters noted that this section places accuracy requirements on nuclear accident dosimetry which may not be attainable There does not appear to be a way for facilities to test their systems against these criteria because there is no well-characterized irradiation facility in operation. The two year implementation

period may not be sufficient to resolve this issue.

Response: Although the accuracy requirements for nuclear accident dosimetry, as presented in the proposed rule, are largely identical to the requirements of DOE Order 5480.11, the Department acknowledges that capability to demonstrate compliance with this accuracy requirement is subject to availability of an appropriate irradiation facility.

Final rule: The final rule no longer contains any language regarding the accuracy requirements for nuclear accident dosimetry. The final rule describes the necessary elements for nuclear accident dosimetry programs.

Appendix A—Derived Air Concentrations (DAC) for Controlling Radiation Exposure to Workers at DOE Facilities

Comment: Difference between 10 CFR parts 20 and 835. Commenters noted that the proposed rule did not contain the level of detail contained in the discussion in appendix B to 10 CFR part 20.

Response: DOE emphasizes determination of internal dose using bioassay measurements instead of air monitoring data; therefore, much of the information in appendix B to 10 CFR part 20 is not applicable to 10 CFR part 835.

Final rule: The final rule has been modified to list descriptive derived air concentration (DAC) information, formerly addressed in appendix E, in appendix A.

Comment: Units for derived air concentrations. The commenter stated that appendix A is somewhat confusing by having both μCi and Bq listed. It was suggested to either list one value or list the isotope once and list both values in the same location.

Response: Use of the SI units is discussed in response to comments in subpart A of the final rule. Federal Guidance Report No. 11 presents both μCi and Bq units, while 10 CFR part 20 uses only μCi.

Final rule: The tables presented in the proposed rule have been edited. These tables now list each isotope and both μCi and Bq values together.

Comment: DAC tables. Comments suggested that an additional footnote be added which would allow the facility to specify which set of DAC tables (conventional or SI units) would be used.

Response and final rule: The final rule has been edited to present both units in a clear format for reference with scientific standards. However, to assure consistent application of the regulation, the final rule has been modified to specify the use of special units.

Comment: Dose conversion factors for ^{222}Rn. Commenters noted that there are no dose conversion factors for ^{222}Rn documented in Federal Guidance Report No. 11. It is further suggested that a DOE guidance document be developed describing the acceptable methods for assessing, monitoring, and reporting a worker's dose that is caused by exposure to radon and its progeny.

Response: Footnote 4 of the proposed rule states that the values presented for protection from radon combined with its short-lived daughters are based on information given in ICRP Publication 32: "Limits for Inhalation of Radon Daughters by Workers" and Federal Guidance Report No. 11. Although the values for protection against radon are not in Federal Guidance Report No. 11, a discussion on radon and its decay products is provided in section II of the report. Information for assessing dose from radon exposure will be provided in regulatory guidance currently under development.

Appendix D—Surface Radioactivity Values

Final rule: Editorial changes were made to correct typographical errors.

Comment: Conditional release at "below detectable levels." Comments recommended that a caveat be added to appendix D to allow conditional release at "below detectable levels" where the appendix D levels cannot be verified with currently available state-of-the-art field instrumentation.

Comment: Instrument detection capabilities for transuranics. Comments suggested that the values in appendix D for transuranics should indicate use of an instrument capable of detecting 300 dpm under laboratory conditions but should recognize that it is currently impossible to reliably meet such values under all possible conditions in the field.

Response and final rule: The final rule has been modified in appendix D, raising the transuranics value from 300 dpm/100 cm^2 to 500 dpm/100 cm^2. Any other requests for exceptions and exemptions to the rule can be submitted to DOE under the provisions of 10 CFR part 820.

Comment: Contamination levels for ^{14}C and tritium. Commenters requested that a set of limits be established for tritium, one of the most prevalent nuclides found in research protocols at DOE sites. Comments suggested that guidance on contamination limits for both removable and fixed plus removable contamination levels for ^{3}H and ^{14}C be provided. Comments also suggested that the proposed limit be published in the **Federal Register** for public review and comment. It was recommended the tritium contamination limits be set at 10,000 dpm/100 cm^2.

Response: The contamination levels for ^{14}C are provided in the "beta-gamma emitters" group. The contamination levels for tritium will be provided in an amendment to this rule and issued for public comment.

Comment: Footnote 3 applicability. Comments stated that it is not clear if footnote 3 is applicable only for assessments of fixed plus removable contamination values, or if it is also applicable for removable values.

Response: Footnote 3 is applicable to the total value of fixed and removable contamination.

Appendix E—Derived Air Concentrations for Controlling Radiation Exposure to Workers at DOE Facilities

Comment: Comparison to 10 CFR part 20. Comments noted that the proposed rule does not contain the level of detail contained in the discussion section in appendix B of 10 CFR part 20.

Response and final rule: Appendix E provided descriptive information on other appendices. The final rule has been modified to place this information into the respective appendix.

VI. Review Under Executive Order 12291

Executive Order 12291, Federal Regulations, requires that a regulatory impact analysis be prepared prior to the promulgation of a "major rule." The DOE has concluded that this action is not a "major rule" for purpose of the Executive Order because its promulgation will not result in any of the following:

(1) An annual effect on the economy of $100 million or more;

(2) A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or

(3) Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States based enterprises to compete in domestic or export market.

Pursuant to section 3(c) of E.O. 12291, this rule was submitted to the Director of the Office of Management and Budget. The Director has concluded his review under that Executive Order.

VII. Final Regulatory Flexibility Analysis

This final rule was reviewed under the Regulatory Flexibility Act of 1980, Pub. L. 96–354, which requires preparation of a regulatory flexibility analysis for any rule that is likely to have significant economic impact on a substantial number of small entities. DOE certifies that this regulation will not have a significant economic impact on a substantial number of small entities; therefore, no regulatory flexibility analysis has been prepared.

VIII. Paperwork Reduction Act Statement

The information and reporting requirements in this part are not substantially different from existing reporting requirements contained in DOE contracts with DOE prime contractors covered by this rule. Some new reporting requirements are required for subcontractors and suppliers to the DOE contractors covered by this rule. DOE will submit the collection of any new information requests concerning this rule to the Office of Management and Budget for approval in accordance with the Paperwork Reduction Act of 1980, 44 U.S.C. 3501.1 *et seq.*, and the procedures implementing that Act, 5 CFR 1320.1 *et seq.*

IX. Finding of No Significant Environmental Impact

The DOE has reviewed the promulgation of 10 CFR part 835 under the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*) and the Council on Environmental Quality regulations for implementing NEPA. The Department has completed an Environmental Assessment and on the basis of that information has issued a Finding of No Significant Impact (FONSI) for this rule. The Environmental Assessment and FONSI are available for inspection at the DOE Freedom of Information Reading Room, 1E–190, 1000 Independence Ave. SW., Washington DC 20585, between the hours of 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

X. Review Under Executive Order 12612

Executive Order 12612, 52 FR 41 685 (October 30, 1987) requires that regulations, rules, legislation, and any other policy actions be reviewed for any substantial direct effects on States, on the relationship between the National Government and the States, or in the distribution of power and responsibilities among various levels of government. If there are sufficient substantial direct effects, then the Executive Order requires preparation of a federalism assessment to be used in all decisions involved in promulgating and implementing a policy action.

This rule will not have a substantial direct effect on the institutional interests or traditional functions of States.

XI. Review Under Executive Order 12778

Section 2 of Executive Order 12778 instructs each agency subject to Executive Order 12291 to adhere to certain requirements in promulgating new regulations and reviewing existing regulations. These requirements, set forth in paragraphs 2(a) and (b)(2), include eliminating drafting errors and needless ambiguity, drafting the regulations to minimize litigation, providing clear and certain legal standards for affected legal conduct, and promoting simplification and burden reduction. Agencies are also instructed to make every reasonable effort to ensure that the regulation: Specifies clearly any preemptive effect; describes any administrative proceedings; and defines key terms. DOE certifies that the final rule meets the requirements of paragraphs 2 (a) and (b) of Executive Order 12778.

List of Subjects in 10 CFR Part 835

Emergency radiation exposures, Nuclear material, Occupational safety and health, Radiation exposures, Radiation protection, Radioactive material, Reporting and record keeping requirements, Safety during emergencies, Training.

Issued in Washington, DC, on November 1, 1993.

Tara O'Toole,

Assistant Secretary, Environment, Safety and Health.

For the reason set forth in the preamble, title 10, chapter III, of the Code of Federal Regulations is amended by adding a new part 835 as set forth below.

PART 835—OCCUPATIONAL RADIATION PROTECTION

Subpart A—General Provisions

Sec.

Subpart B—Radiation Protection Programs

Subpart C—Standards for Internal and External Exposure

Subpart D—[Reserved]

Subpart E—Monitoring in the Workplace

Subpart F—Entry Control Program

Subpart G—Posting and Labeling

Subpart H—Records

Subpart I—Reports to Individuals

Subpart J—Radiation Safety Training

Subpart K—Design and Control

Subpart L—Releases of Materials and Equipment From Radiological Areas

Subpart M—[Reserved]

Subpart N—Accidents and Emergencies

Authority: 42 U.S.C. 2201; 7191.

Subpart A—General Provisions

§ 835.1 Scope.

(a) *General.* The rules in this part establish radiation protection standards, limits, and program requirements for protecting individuals from ionizing radiation resulting from the conduct of DOE activities.

(b) *Exclusion.* The requirements in this part do not apply to:

(1) Activities that are regulated through a license by the Nuclear Regulatory Commission or a State under an Agreement with the Nuclear Regulatory Commission, including activities certified by the Nuclear Regulatory Commission under section 1701 of the Atomic Energy Act;

(2) Activities conducted under the authority of the Director, Naval Nuclear Propulsion Program, as described in Pub. L. 98–525;

(3) Activities conducted under the Nuclear Explosives and Weapons Safety Program relating to the prevention of accidental or unauthorized nuclear detonations; or

(4) Background radiation, radiation doses received as a patient for the purposes of medical diagnosis or therapy, or radiation doses received from voluntary participation in medical research programs.

§ 835.2 Definitions.

(a) As used in this part:

Airborne radioactive material or airborne radioactivity means radioactive material in any chemical or physical form that is dissolved, mixed, suspended, or otherwise entrained in air.

Airborne radioactivity area means any area where the measured concentration of airborne radioactivity, above natural background, exceeds or is likely to exceed 10 percent of the derived air concentration (DAC) values listed in appendix A or appendix C of this part.

ALARA means "As Low As is Reasonably Achievable," which is the approach to radiation protection to manage and control exposures (both individual and collective) to the work force and to the general public to as low as is reasonable, taking into account social, technical, economic, practical, and public policy considerations. As used in this part, ALARA is not a dose limit but a process which has the objective of attaining doses as far below the applicable limits of this part as is reasonably achievable.

Ambient air means the general air in the area of interest (e.g., the general room atmosphere), as distinct from a specific stream or volume of air that may have different properties.

Annual limit on intake (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man (ICRP Publication 23) that would result in a committed effective dose equivalent of 5 rems (0.05 sievert) or a committed dose equivalent of 50 rems (0.5 sievert) to any individual organ or tissue. ALI values for intake by ingestion and inhalation of selected radionuclides are based on Table 1 of the U.S. Environmental Protection Agency's Federal Guidance Report No. 11, *Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion,* published September 1988. This document is available from the National Technical Information Service, Springfield, VA.

Background means radiation from:

(i) Naturally occurring radioactive materials which have not been technologically enhanced;

(ii) Cosmic sources;

(iii) Global fallout as it exists in the environment (such as from the testing of nuclear explosive devices);

(iv) Radon and its progeny in concentrations or levels existing in buildings or the environment which have not been elevated as a result of current or prior activities; and

(v) Consumer products containing nominal amounts of radioactive material or producing nominal amounts of radiation.

Bioassay means the determination of kinds, quantities, or concentrations, and, in some cases, locations of radioactive material in the human body, whether by direct measurement or by analysis, and evaluation of radioactive materials excreted or removed from the human body.

Calibration means to adjust and/or determine either:

(i) The response or reading of an instrument relative to a standard (e.g., primary, secondary, or tertiary) or to a series of conventionally true values; or

(ii) The strength of a radiation source relative to a standard (e.g., primary, secondary, or tertiary) or conventionally true value.

Contamination area means any area where contamination levels are greater than the values specified in appendix D of this part, but less than or equal to 100 times those levels.

Continuous air monitor (CAM) means an instrument that continuously samples and measures the levels of airborne radioactive materials on a "real-time" basis and has alarm capabilities at preset levels.

Contractor means any entity under contract with the Department of Energy with the responsibility to perform activities at a DOE site or facility.

Controlled area means any area to which access is managed in order to protect individuals from exposure to radiation and/or radioactive material. Individuals who enter only the controlled area without entering radiological areas are not expected to receive a total effective dose equivalent of more than 100 mrem (0.001 sievert) in a year.

Declared pregnant worker means a woman who has voluntarily declared to her employer, in writing, her pregnancy for the purpose of being subject to the occupational exposure limits to the embryo/fetus as provided in § 835.206. This declaration may be revoked, in writing, at any time by the declared pregnant worker.

Derived air concentration (DAC) means, for the radionuclides listed in appendix A of this part, the airborne concentration that equals the ALI divided by the volume of air breathed by an average worker for a working year of 2000 hours (assuming a breathing volume of 2400 m^3). For the radionuclides listed in appendix C of this part, the air immersion DACs were calculated for a continuous, non-shielded exposure via immersion in a semi-infinite atmospheric cloud. The value is based upon the derived airborne concentration found in Table 1 of the U.S. Environmental Protection Agency's Federal Guidance Report No. 11, *Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion,* published September 1988. This document is available from the National Technical Information Service, Springfield, VA.

DOE activities means an activity taken for or by the DOE that has the potential to result in the occupational exposure of

an individual to radiation or radioactive material. The activity may be, but is not limited to, design, construction, operation, or decommissioning. To the extent appropriate, the activity may involve a single DOE facility or operation or a combination of facilities and operations, possibly including an entire site.

Entrance or access point means any location through which an individual could gain access to areas controlled for the purposes of radiation protection. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

General employee means an individual who is either a DOE or DOE contractor employee; an employee of a subcontractor to a DOE contractor; or a visitor who performs work for or in conjunction with DOE or utilizes DOE facilities.

High contamination area means any area where contamination levels are greater than 100 times the values specified in appendix D of this part.

High radiation area means any area, accessible to individuals, in which radiation levels could result in an individual receiving a deep dose equivalent in excess of 0.1 rem (0.001 sievert) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

Individual means any human being.

Member of the public means an individual who is not occupationally exposed to radiation or radioactive material. An individual is not a "member of the public" during any period in which the individual receives occupational exposure.

Minor means an individual less than 18 years of age.

Monitoring means actions intended to detect and quantify radiological conditions.

Nonstochastic effects means effects due to radiation exposure for which the severity varies with the dose and for which a threshold normally exists (e.g., radiation-induced opacities within the lens of the eye).

Occupational exposure means an individual's exposure to ionizing radiation (external and internal) as a result of that individual's work assignment. Occupational exposure does not include planned special exposures, exposure received as a medical patient, background radiation, or voluntary participation in medical research programs.

Person means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency, any State or political subdivision of, or any political entity within a State, any foreign government or nation or other entity, and any legal successor, representative, agent or agency of the foregoing; provided that person does not include the Department or the United States Nuclear Regulatory Commission.

Radiation means ionizing radiation: alpha particles, beta particles, gamma rays, X-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. Radiation as used in this part, does not include non-ionizing radiation, such as radio- or micro-waves, or visible, infrared, or ultraviolet light.

Radiation area means any area accessible to individuals in which radiation levels could result in an individual receiving a deep dose equivalent in excess of 0.005 rem (0.05 millisievert) in 1 hour at 30 centimeters from the source or from any surface that the radiation penetrates.

Radiological area means any area within a controlled area which must be posted as a "radiation area," "high radiation area," "very high radiation area," "contamination area," "high contamination area," or "airborne radioactivity area" in accordance with § 835.603.

Radiological worker means a general employee whose job assignment involves operation of radiation producing devices or working with radioactive materials, or who is likely to be routinely occupationally exposed above 0.1 rem (0.001 sievert) per year total effective dose equivalent.

Representative, as applied to the sampling of radioactive material, means sampling in such a manner that the sample closely approximates both the amount of activity and the physical and chemical properties of the material (e.g., particle size and solubility in the case of air sampling of the aerosol to which workers may be exposed).

Stochastic effects means malignant and hereditary diseases for which the probability of an effect occurring, rather than its severity, is regarded as a function of dose without a threshold for radiation protection purposes.

Survey means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. When appropriate, such an evaluation includes a physical survey of the location of radioactive material and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present.

Very high radiation area means any area accessible to individuals in which radiation levels could result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in one hour at 1 meter from a radiation source or from any surface that the radiation penetrates.

Year means the period of time beginning on or near January 1 used to determine compliance with the provisions of this part. The starting date of the year used to determine compliance may be changed provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

(b) As used in this part to describe various aspects of radiation dose:

Absorbed dose (D) means the energy absorbed by matter from ionizing radiation per unit mass of irradiated material at the place of interest in that material. The absorbed dose is expressed in units of rad (or gray) (1 rad = 0.01 gray).

Collective dose means the sum of the total effective dose equivalent values for all individuals in a specified population. Collective dose is expressed in units of person-rem (or person-sievert).

Committed dose equivalent ($H_{T,50}$) means the dose equivalent calculated to be received by a tissue or organ over a 50-year period after the intake of a radionuclide into the body. It does not include contributions from radiation sources external to the body. Committed dose equivalent is expressed in units of rem (or sievert).

Committed effective dose equivalent ($H_{E,50}$) means the sum of the committed dose equivalents to various tissues in the body ($H_{T,50}$), each multiplied by the appropriate weighting factor (w_T)—that is, $H_{E,50} = \Sigma w_T H_{T,50}$. Committed effective dose equivalent is expressed in units of rem (or sievert).

Cumulative total effective dose equivalent means the sum of the total effective dose equivalents recorded for an individual for each year of employment at a DOE or DOE contractor site or facility, effective January 1, 1989.

Deep dose equivalent means the dose equivalent derived from external radiation at a depth of 1 cm in tissue.

Dose equivalent (H) means the product of absorbed dose (D) in rad (or gray) in tissue, a quality factor (Q), and other modifying factors (N). Dose equivalent is expressed in units of rem (or sievert) (1 rem = 0.01 sievert).

Effective dose equivalent (H_E) means the summation of the products of the dose equivalent received by specified tissues of the body (H_T) and the appropriate weighting factor (w_T)—that

is, $H_E = \Sigma w_T H_T$. It includes the dose from radiation sources internal and/or external to the body. The effective dose equivalent is expressed in units of rem (or sievert).

External dose or exposure means that portion of the dose equivalent received from radiation sources (e.g., "external sources") outside the body.

Extremity means hands and arms below the elbow or feet and legs below the knee.

Internal dose or exposure means that portion of the dose equivalent received from radioactive material taken into the body (e.g., "internal sources").

Lens of the eye dose equivalent means the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 cm.

Quality factor means the principal modifying factor used to calculate the dose equivalent from the absorbed dose; the absorbed dose (expressed in rad or gray) is multiplied by the appropriate quality factor (Q).

(i) The quality factors to be used for determining dose equivalent in rem are shown below:

QUALITY FACTORS

Radiation type	Quality factor
X-rays, gamma rays, positrons, electrons (including tritium beta particles)	1
Neutrons, ≤ 10 keV	3
Neutrons, > 10 keV	10
Protons and singly-charged particles of unknown energy with rest mass greater than one atomic mass unit	10
Alpha particles and multiple-charged particles (and particles of unknown charge) of unknown energy	20

When spectral data are insufficient to identify the energy of the neutrons, a quality factor of 10 shall be used.

(ii) When spectral data are sufficient to identify the energy of the neutrons, the following mean quality factor values may be used:

QUALITY FACTORS FOR NEUTRONS

[Mean quality factors, $\bar{Q}$ (maximum value in a 30-cm dosimetry phantom), and values of neutron flux density that deliver in 40 hours, a maximum dose equivalent of 100 mrem (0.001 sievert).]

Neutron energy (MeV)	Mean quality factor	Neutron flux density ($cm^{-2}s^{-1}$)
2.5×10^{-8} thermal	2	680
1×10^{-7}	2	680
1×10^{-6}	2	560
1×10^{-5}	2	560
1×10^{-4}	2	580
1×10^{-3}	2	680
1×10^{-2}	2.5	700
1×10^{-1}	7.5	115
5×10^{-1}	11	27
1	11	19
2.5	9	20
5	8	16
7	7	17
10	6.5	17
14	7.5	12
20	8	11
40	7	10
60	5.5	11
1×10^{2}	4	14
2×10^{2}	3.5	13
3×10^{2}	3.5	11
4×10^{2}	3.5	10

Shallow dose equivalent means the dose equivalent deriving from external radiation at a depth of 0.007 cm in tissue.

Total effective dose equivalent (TEDE) means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures). For purposes of compliance with this part, deep dose equivalent to the whole body may be used as effective dose equivalent for external exposures.

Weighting factor (w_T) means the fraction of the overall health risk, resulting from uniform, whole body irradiation, attributable to specific tissue (T). The dose equivalent to tissue, T, is multiplied by the appropriate weighting factor to obtain the effective dose equivalent contribution from that tissue. The weighting factors are as follows:

WEIGHTING FACTORS FOR VARIOUS TISSUES

Organs or tissues, T	Weighting factor, w_T
Gonads	0.25
Breasts	0.15
Red bone marrow	0.12
Lungs	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder[1]	0.30
Whole body[2]	1.00

[1] "Remainder" means the five other organs or tissues with the highest dose (e.g., liver, kidney, spleen, thymus, adrenal, pancreas, stomach, small intestine, and upper large intestine). The weighting factor for each remaining organ or tissue is 0.06.

[2] For the case of uniform external irradiation of the whole body, a weighting factor (w_T) equal to 1 may be used in determination of the effective dose equivalent.

Whole body means, for the purposes of external exposure, head, trunk (including male gonads), arms above and including the elbow, or legs above and including the knee.

(c) Terms defined in the Atomic Energy Act and not defined in this part are used consistent with the meanings given in the Act.

(d) As used in this part, words in the singular also include the plural and words in the masculine gender also include the feminine and vice versa, as the case may be.

§ 835.3 General rule.

(a) No person or DOE personnel shall take or cause to be taken any action inconsistent with the requirements of:

(1) This part; or

(2) Any program, plan, schedule, or other process established by this part.

(b) With respect to a particular DOE activity, contractor management shall be responsible for compliance with the requirements of this part.

(c) Where there is no contractor for a DOE activity, DOE shall ensure implementation of and compliance with the requirements of this part.

(d) Nothing in this part shall be construed as limiting actions that may be necessary to protect health and safety.

§ 835.4 Radiological units.

Unless otherwise specified, the quantities used in the records required by this part shall be clearly indicated in special units of curie, rad, or rem, including multiples and subdivisions of these units. The SI units, becquerel (Bq), gray (Gy), and sievert (Sv), are only provided parenthetically in this part for reference with scientific standards. These SI units are not authorized for use in records required under this part.

Subpart B—Radiation Protection Programs

§ 835.101 Radiation protection programs.

(a) A DOE activity shall be conducted in compliance with a documented

radiation protection program (RPP) as approved by the DOE.

(b) The DOE may direct or make modifications to a RPP.

(c) The content of each RPP shall be commensurate with the nature of the activities performed and shall include formal plans and measures for applying the as low as reasonably achievable (ALARA) process to occupational exposure.

(d) The RPP shall specify the existing and/or anticipated operational tasks that are intended to be within the scope of the RPP. Except as provided in § 835.101(i), any task outside the scope of a RPP shall not be initiated until an update of the RPP is approved by DOE.

(e) The content of the RPP shall address, but shall not necessarily be limited to, each requirement in this part.

(f) The RPP shall include plans, schedules, and other measures for achieving compliance with regulations of this part. Compliance with this part shall be achieved no later than January 1, 1996.

(g) The RPP for an existing activity shall be submitted to DOE no later than January 1, 1995.

(h) An update of the RPP shall be submitted to DOE:

(1) Whenever a change or an addition to the RPP is made;

(2) Prior to the initiation of a task not within the scope of the RPP; or

(3) Within 180 days of the effective date of any modifications to this part.

(i) Changes, additions, or updates to the RPP may become effective without prior Department approval only if the changes do not decrease the effectiveness of the RPP and the RPP, as changed, continues to meet the requirements of this part. Proposed changes that decrease the effectiveness of the RPP shall not be implemented without submittal to and approval by the Department.

(j) An initial RPP or an update shall be considered approved 180 days after its submission unless rejected by DOE at an earlier date.

§ 835.102 Internal audits.

Internal audits of all functional elements of the radiation protection program shall be conducted no less frequently than every 3 years and shall include program content and implementation.

Subpart C—Standards for Internal and External Exposure

§ 835.201 [Reserved]

§ 835.202 Occupational exposure limits for general employees.

(a) The occupational exposure to general employees resulting from DOE activities, other than planned special exposures under § 835.204 and emergency exposure situations under § 835.1302, shall be controlled so the following annual limits are not exceeded:

(1) A total effective dose equivalent of 5 rems (0.05 sievert);

(2) The sum of the deep dose equivalent for external exposures and the committed dose equivalent to any organ or tissue other than the lens of the eye of 50 rems (0.5 sievert);

(3) A lens of the eye dose equivalent of 15 rems (0.15 sievert); and

(4) A shallow dose equivalent of 50 rems (0.5 sievert) to the skin or to any extremity.

(b) All occupational exposure received during the current year shall be included when demonstrating compliance with § 835.202(a).

(c) Exposures from background, therapeutic and diagnostic medical radiation, and voluntary participation in medical research programs shall not be included in dose records or in the assessment of compliance with the occupational exposure limits.

§ 835.203 Combining internal and external dose equivalents resulting from DOE activities.

(a) The total effective dose equivalent during a year shall be determined by summing the effective dose equivalent from external exposures and the committed effective dose equivalent from intakes during the year. For purposes of compliance with this part, deep dose equivalent to the whole body may be used as effective dose equivalent for external exposures.

(b) Determinations of the effective dose equivalent shall be made using the weighting factor values provided in § 835.2.

(c) For the case of uniform external irradiation of the whole body, a weighting factor (w_T) equal to 1 may be used in the determination of the effective dose equivalent.

§ 835.204 Planned special exposures.

(a) A planned special exposure may be authorized for a radiological worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in § 835.202(a), provided that each of the following conditions is satisfied:

(1) The planned special exposure is considered only in an exceptional situation when alternatives that might prevent a radiological worker from exceeding the limit in § 835.202(a)(1) are unavailable or impractical;

(2) The contractor management (and employer, if the employer is not the contractor) specifically requests the planned special exposure, in writing; and

(3) Joint written approval from the appropriate DOE Headquarters program office and the Assistant Secretary for Environment, Safety and Health is received.

(b) Prior to requesting an individual to participate in an authorized planned special exposure, the individual's dose from all previous planned special exposures and all doses in excess of the occupational dose limits shall be determined.

(c) An individual shall not receive a planned special exposure that, in addition to the doses determined in § 835.204(b), would result in a dose exceeding the following:

(1) A total effective dose equivalent of 5 rems (0.05 sievert) in the current year; and

(2) A cumulative total effective dose equivalent of 25 rems (0.25 sievert).

(d) Prior to a planned special exposure, written consent shall be obtained from each individual involved. Each individual shall be:

(1) Informed of the purpose of the planned operations and procedures to be used;

(2) Informed of the estimated doses and associated potential risks and specific radiological conditions and other hazards which might be involved in performing the task; and

(3) Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

(e) Records of the conduct of a planned special exposure shall be maintained and a written report submitted within 30 days after the planned special exposure to the approving organizations identified in § 835.204(a)(3).

(f) The dose from planned special exposures is not to be considered in controlling future occupational dose of the individual under § 835.202(a), but is to be included in records and reports required under this part.

§ 835.205 Determination of compliance for non-uniform exposure of the skin.

(a) Non-uniform exposures of the skin from X-rays, beta radiation, and/or radioactive material on the skin are to be assessed as specified in this section.

(b) For purposes of demonstrating compliance with § 835.202(a)(4), assessments shall be conducted as follows:

(1) *Area of skin irradiated is 100 cm² or more.* The non-uniform dose equivalent received during the year shall be averaged over the 100 cm² of the skin receiving the maximum dose, added to any uniform dose equivalent also received by the skin, and recorded as the shallow dose equivalent to any extremity or skin for the year.

(2) *Area of skin irradiated is 10 cm² or more, but is less than 100 cm².* The non-uniform dose equivalent (H) to the irradiated area received during the year shall be added to any uniform dose equivalent also received by the skin and recorded as the shallow dose equivalent to any extremity or skin for the year. H is the dose equivalent averaged over the 1 cm² of skin receiving the maximum absorbed dose, D, reduced by the fraction f, which is the irradiated area in cm² divided by 100 cm² (i.e., H=fD). In no case shall a value of f less than 0.1 be used.

(3) *Area of skin irradiated is less than 10 cm².* The non-uniform dose equivalent shall be averaged over the 1 cm² of skin receiving the maximum dose. This dose equivalent shall:

(i) Be recorded in the individual's occupational exposure history as a special entry; and

(ii) Not be added to any other shallow dose equivalent to any extremity or skin recorded as the dose equivalent for the year.

§ 835.206 Limits for the embryo/fetus.

(a) The dose equivalent limit for the embryo/fetus from the period of conception to birth, as a result of occupational exposure of a declared pregnant worker, is 0.5 rem (0.005 sievert).

(b) Substantial variation above a uniform exposure rate that would satisfy the limits provided in § 835.206(a) shall be avoided.

(c) If the dose equivalent to the embryo/fetus is determined to have already exceeded 0.5 rem (0.005 sievert) by the time a worker declares her pregnancy, the declared pregnant worker shall not be assigned to tasks where additional occupational exposure is likely during the remaining gestation period.

§ 835.207 Limits for minors.

Any minor exposed to radiation and/or radioactive material during direct on-site access at a DOE site or facility shall not exceed 0.1 rem (0.001 sievert) total effective dose equivalent in a year.

§ 835.208 Limits for members of the public entering a controlled area.

Any member of the public exposed to radiation and/or radioactive material during direct on-site access at a DOE site or facility shall not exceed 0.1 rem (0.001 sievert) total effective dose equivalent in a year.

§ 835.209 Concentrations of radioactive material in air.

(a) The derived air concentration (DAC) values given in appendices A and C to this part shall be used in the control of occupational exposures to airborne radioactive material.

(b) With regard to inhalation exposures and external exposures from airborne radionuclides, compliance with this part shall be demonstrated through conformity with § 835.101 and § 835.202 which establishes the applicable regulatory limits.

(c) The estimation of internal dose shall be based on bioassay data rather than air concentration values unless bioassay data are:

(1) unavailable;

(2) inadequate; or

(3) internal dose estimates based on representative air concentration values are demonstrated to be as or more accurate.

Subpart D—[Reserved]

Subpart E—Monitoring in the Workplace

§ 835.401 General requirements.

(a) Monitoring of individuals and areas shall be performed to:

(1) Demonstrate compliance with the regulations in this part;

(2) Document radiological conditions in the workplace;

(3) Detect changes in radiological conditions;

(4) Detect the gradual buildup of radioactive material in the workplace; and

(5) Verify the effectiveness of engineering and process controls in containing radioactive material and reducing radiation exposure.

(b) Area monitoring in the workplace shall be routinely performed, as necessary, to identify and control potential sources of personnel exposure to radiation and/or radioactive material.

(c) Instruments used for monitoring and contamination control shall be:

(1) Periodically maintained and calibrated on an established frequency of at least once per year;

(2) Appropriate for the type(s), levels, and energies of the radiation(s) encountered;

(3) Appropriate for existing environmental conditions; and

(4) Routinely tested for operability.

§ 835.402 Individual monitoring.

(a) For the purpose of monitoring individual exposures to external radiation, personnel dosimetry shall be provided to and used by:

(1) Radiological workers who, under typical conditions, are likely to receive one or more of the following:

(i) An effective dose equivalent to the whole body of 0.1 rem (0.001 sievert) or more in a year;

(ii) A shallow dose equivalent to the skin or to any extremity of 5 rems (0.05 sievert) or more in a year;

(iii) A lens of the eye dose equivalent of 1.5 rems (0.015 sievert) or more in a year;

(iv) A deep dose equivalent from external exposures to any organ or tissue other than the lens of the eye of 5 rems (0.05 sievert);

(2) Declared pregnant workers who are likely to receive from external sources a dose equivalent to the embryo/fetus in excess of 10 percent of the applicable limit in § 835.206;

(3) Minors and members of the public likely to receive, in 1 year, from external sources, a dose in excess of 50 percent of the applicable limits in § 835.207 or § 835.208, respectively; or

(4) Individuals entering a high or very high radiation area.

(b) Personnel external dosimetry programs shall be adequate to demonstrate compliance with § 835.202, including routine dosimeter calibration and conformance with the requirements of the DOE Laboratory Accreditation Program for Personnel Dosimetry.

(c) For the purpose of monitoring individual exposures to internal radiation, internal dose evaluation programs (including routine bioassay programs) shall be conducted for:

(1) Radiological workers who, under typical conditions, are likely to receive 0.1 rem (0.001 sievert) or more committed effective dose equivalent, and/or 5 rems (0.05 sievert) or more committed dose equivalent to any organ or tissue, from all occupational radionuclide intakes in a year;

(2) Declared pregnant workers likely to receive an intake resulting in a dose equivalent to the embryo/fetus in excess of 10 percent of the limit stated in § 835.206; or

(3) Minors and members of the public who are likely to receive, in 1 year, an intake resulting in a committed effective dose equivalent in excess of 50 percent of the limits stated in § 835.207 or § 835.208, respectively.

(d) Internal dose evaluation programs shall be adequate to demonstrate compliance with § 835.202.

§ 835.403 Area monitoring.

(a) Measurements of radioactivity concentrations in the ambient air of the workplace shall be performed as follows:

(1) Air sampling shall be performed in occupied areas where, under typical conditions, an individual is likely to receive an annual intake of 2 percent or more of the specified ALI values. For a given radionuclide and lung retention class, the ALI is the product of the DAC listed in appendix A of this part and the constant 2.4×10^9 ml. Samples shall be taken as necessary to detect and evaluate the level or concentration of airborne radioactive material at work locations.

(2) Real-time air monitoring, using continuous air monitors as defined in § 835.2, shall be performed in normally occupied areas where an individual is likely to be exposed to a concentration of airborne radioactivity exceeding 1 DAC as specified in appendix A of this part or where there is a need to alert potentially exposed individuals to unexpected increases in airborne radioactivity levels.

(3) For the airborne radioactive material that could be encountered, real-time air monitors shall have alarm capability and sufficient sensitivity to alert potentially exposed individuals that immediate action is necessary in order to minimize or terminate inhalation exposures.

(b) Monitoring of radiation in the workplace shall be performed using stationary (area) or portable radiation instruments, or a combination thereof. The instruments shall be readily available and shall be capable of measuring ambient radiation dose rates for the purpose of controlling radiation exposures.

§ 835.404 Radioactive contamination control and monitoring.

(a) Instruments and techniques used for radioactive contamination monitoring and control shall be adequate to ensure compliance with the requirements specified in this section.

(b) Appropriate controls shall be maintained and verified which prevent the inadvertent transfer of removable contamination to locations outside of radiological areas under normal operating conditions.

(c) Any area in which contamination levels exceed the values specified in appendix D of this part shall be:

(1) Posted in accordance with § 835.603; and

(2) Controlled in a manner commensurate with the physical and chemical characteristics of the contaminant, the radionuclides present, and the fixed and removable contamination levels.

(d) Areas with fixed contamination exceeding the total radioactivity values specified in appendix D of this part may be located outside of radiological areas provided the following conditions are met:

(1) Removable contamination levels are below the levels specified in appendix D of this part;

(2) Unrestricted access to the area is not likely to cause any individual to receive a total effective dose equivalent in excess of 0.1 rem (0.001 sievert) in a year;

(3) The area is routinely monitored;

(4) The area is clearly marked to alert personnel of the contaminated status;

(5) Appropriate administrative procedures are established and exercised to maintain control of these areas; and

(6) Dose rates do not exceed levels which would require posting in accordance with § 835.603.

(e) Entry control pursuant to § 835.501 and posting pursuant to § 835.603 are not required for areas with fixed contamination meeting the conditions of § 835.404(d).

(f) Appropriate monitoring to detect and prevent the spread of contamination shall be performed by individuals exiting radiological areas established to control removable contamination and/or airborne radioactivity.

(g) Protective clothing shall be required for entry to areas in which removable contamination exists at levels exceeding those specified in appendix D to this part.

Subpart F—Entry Control Program

§ 835.501 Radiological areas.

(a) Personnel entry control shall be maintained for each radiological area.

(b) The degree of control shall be commensurate with existing and potential radiological hazards within the area.

(c) One or more of the following methods shall be used to ensure control:

(1) Signs and barricades;

(2) Control devices on entrances;

(3) Conspicuous visual and/or audible alarms;

(4) Locked entrance ways; or

(5) Administrative controls.

(d) Administrative procedures shall be written as necessary to demonstrate compliance with the provisions of this section. These administrative procedures shall include actions essential to ensure the effectiveness and operability of barricades, devices, alarms, and locks. Authorizations shall be required to perform specific work within the area and shall include specific radiation protection measures.

(e) No control(s) shall be installed at any radiological area exit that would prevent rapid evacuation of personnel under emergency conditions.

§ 835.502 High and very high radiation areas.

(a) *High radiation areas.* One or more of the following features shall be used for each entrance or access point to a high radiation area where radiation levels exist such that an individual could exceed a deep dose equivalent to the whole body of 1 rem (0.01 sievert) in any one hour at 30 centimeters from the source or from any surface that the radiation penetrates:

(1) A control device that prevents entry to the area when high radiation levels exist or upon entry causes the radiation level to be reduced below that level defining a high radiation area;

(2) A device that functions automatically to prevent use or operation of the radiation source or field while personnel are in the area;

(3) A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry;

(4) Entryways that are locked. During periods when access to the area is required, positive control over each entry is maintained;

(5) Continuous direct or electronic surveillance that is capable of preventing unauthorized entry;

(6) A control device that will automatically generate audible and visual alarm signals to alert personnel in the area before use or operation of the radiation source and in sufficient time to permit evacuation of the area or activation of a secondary control device that will prevent use or operation of the source.

(b) *Very high radiation areas.* In addition to the above requirements, additional measures shall be implemented to ensure individuals are not able to gain access to very high radiation areas when dose rates are in excess of the posting requirements of § 835.603(c).

(c) No control(s) shall be established in a high or very high radiation area that would prevent rapid evacuation of personnel.

Subpart G—Posting and Labeling

§ 835.601 General requirements.

(a) Working areas that require posting because of the presence, or potential presence, of radiation and/or radioactive material are delineated in the

subsequent paragraphs of this section. Radioactive items or containers of radioactive materials, shall be individually labeled if adequate warning is not provided by control measures and required posting.

(b) DOE approved signs, labels, and radiation symbols shall be used to identify areas specified in this subpart.

(c) Required signs and labels shall have a yellow background. The radiation symbol shall be black or magenta.

(d) Signs required by this subpart shall be clear and conspicuously posted and may include radiological protection instructions.

(e) The posting requirements in this section may be modified to reflect the special considerations of DOE activities conducted at private residences. Such modifications shall provide the same level of protection to individuals as the existing provisions in this section.

§ 835.602 Controlled areas.

(a) Each access point to a controlled area (as defined in § 835.2) shall be posted, identifying it as a controlled area, whenever radioactive material and/or radiation fields which would require posting under § 835.603 may be present in the area.

(b) Signs used for this purpose may be selected by the contractor to avoid conflict with local security requirements.

§ 835.603 Radiological areas.

Each access point to a radiological area (as defined in § 835.2) shall be posted with conspicuous signs bearing the wording provided in this section.

(a) *Radiation Area.* The words "Caution, Radiation Area" shall be posted at any area accessible to individuals in which radiation levels could result in an individual receiving a deep dose equivalent in excess of 0.005 rem (0.05 millisievert) in 1 hour at 30 centimeters from the source or from any surface that the radiation penetrates.

(b) *High Radiation Area.* The words "Danger, High Radiation Area" shall be posted at any area accessible to individuals in which radiation levels could result in an individual receiving a deep dose equivalent in excess of 0.1 rem (0.001 sievert) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

(c) *Very High Radiation Area.* The words "Grave Danger, Very High Radiation Area" shall be posted at any area accessible to individuals in which radiation levels could result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in one hour at 1 meter from the radiation source or from any surface that the radiation penetrates.

(d) *Airborne Radioactivity Area.* The words "Caution, Airborne Radioactivity Area" shall be posted for any occupied area in which airborne radioactivity levels exceed, or are likely to exceed, 10 percent of the DAC value listed in appendix A or appendix C of this part.

(e) *Contamination Area.* The words "Caution, Contamination Area" shall be posted where contamination levels exceed values listed in appendix D of this part, but are less than or equal to 100 times those values.

(f) *High Contamination Area.* The words "Danger, High Contamination Area" shall be posted where contamination levels are greater than 100 times the values listed in appendix D of this part.

Subpart H—Records

§ 835.701 General provisions.

(a) Records shall be maintained to document compliance with this part and with radiation protection programs required by § 835.101.

(b) Unless otherwise specified in this subpart, records shall be retained until final disposition is authorized by DOE.

§ 835.702 Individual monitoring records.

(a) Records shall be maintained to document doses received by all individuals for whom monitoring was required pursuant to § 835.402 and doses received during planned special exposures, accidents, and emergency conditions.

(b) The results of individual external and internal dose measurements that are performed, but are not required by § 835.402, shall be recorded. Recording of the non-uniform shallow dose equivalent to the skin caused by contamination on the skin (see § 835.205) is not required if the dose is less than 2 percent of the limit specified for the skin in § 835.202(a)(4).

(c) The records required by this section shall:

(1) Be sufficient to evaluate compliance with § 835.202;

(2) Be sufficient to provide dose information necessary to complete reports required by subpart I of this part and by Departmental requirements for occurrence reporting and processing;

(3) Include the following quantities for external dose received during the year:

(i) The effective dose equivalent from external sources of radiation (deep dose equivalent may be used as effective dose equivalent for external exposure);

(ii) The lens of the eye dose equivalent;

(iii) The shallow dose equivalent to the skin; and

(iv) The shallow dose equivalent to the extremities.

(4) Include the following quantities for internal dose resulting from intakes received during the year:

(i) Committed effective dose equivalent;

(ii) Committed dose equivalent to any organ or tissue of concern; and

(iii) Estimated intake and identity of radionuclides.

(5) Include the following quantities for the summation of the external and internal dose:

(i) Total effective dose equivalent in a year;

(ii) For any organ or tissue assigned an internal dose during the year, the sum of the deep dose equivalent from external exposures and the committed dose equivalent to that organ or tissue; and

(iii) Cumulative total effective dose equivalent received from external and internal sources while employed at the site or facility, since January 1, 1989.

(6) Include the dose equivalent to the embryo/fetus of a declared pregnant worker.

(d) Documentation of all occupational exposure received during the current year shall be obtained when demonstrating compliance with § 835.202(a). In the absence of formal records of previous occupational exposure during the year, a written estimate signed by the individual may be accepted.

(e) Efforts shall be made to obtain records of prior years occupational internal and external exposure.

(f) The records specified in this section that are identified with a specific individual shall be readily available to that individual.

(g) Data necessary to allow future verification or reassessment of the recorded doses shall be recorded.

(h) All records required by this section shall be transferred to the DOE upon cessation of activities at the site that could cause exposure to individuals.

§ 835.703 Monitoring and workplace records.

The following information shall be documented and maintained:

(a) Results of surveys for radiation and radioactive material in the workplace as required by §§ 835.401, 835.403, and 835.404;

(b) Results of surveys, measurements, and calculations used to determine individual occupational exposure from external and internal sources;

(c) Results of surveys for the release of material and equipment as required by § 835.1101(d); and

(d) Results of maintenance and calibration performed on:

(1) Instruments used for area monitoring and contamination control as required by § 835.401; and

(2) Devices used for individual monitoring as required by §§ 835.401 and 835.402.

§ 835.704 Administrative records.

(a) Training records shall be maintained, as necessary, to demonstrate compliance with §§ 835.901, 835.902, and 835.903.

(b) Actions taken to maintain occupational exposures as low as reasonably achievable, including the actions required for this purpose by § 835.101, as well as facility design and control actions required by §§ 835.1001, 835.1002, and 835.1003, shall be documented.

(c) Records shall be maintained to document the results of internal audits and other reviews of program content and implementation.

(d) Written declarations of pregnancy shall be maintained.

(e) Changes in equipment, techniques, and procedures used for monitoring in the workplace shall be documented.

Subpart I—Reports to Individuals

§ 835.801 Reports to individuals.

(a) Radiation exposure data for individuals monitored in accordance with § 835.402 shall be reported as specified in this section. The information shall include the data required under § 835.702(c). Each notification and report shall be in writing and include: the DOE site or facility name, the name of the individual, and the individual's social security number or employee number.

(b) Upon the request from an individual terminating employment, records of exposure shall be provided to that individual as soon as the data are available, but not later than 90 days after termination. A written estimate of the radiation dose received by that employee based on available information shall be provided at the time of termination, if requested.

(c) Each DOE- or DOE-contractor-operated site or facility shall, on an annual basis, provide a radiation dose report to each individual monitored during the year at that site or facility in accordance with § 835.402.

(d) Detailed information concerning any individual's exposure shall be made available to the individual upon request of that individual, consistent with the provisions of the Privacy Act (5 U.S.C. 552a).

(e) When a DOE contractor is required to report to the Department, pursuant to Departmental requirements for occurrence reporting and processing, any exposure of an individual to radiation and/or radioactive material, or planned special exposure in accordance with § 835.204(e), the contractor shall also provide that individual with a report on his or her exposure data included therein. Such report shall be transmitted at a time not later than the transmittal to the Department.

Subpart J—Radiation Safety Training

§ 835.901 General employees.

(a) All general employees shall be trained in radiation safety prior to receiving occupational exposure during access to controlled areas at a DOE site or facility. Allowance may be made for previous DOE training on generic radiation safety topics (i.e., those not specific to a site or facility), provided the training was received at another DOE site or facility within the past 2 years. Documentation of the previous training shall clearly identify the individual's name, date of training, topics covered, and name of the certifying individual. The knowledge of radiation safety possessed by general employees shall be verified by examination.

(b) Retraining shall be provided when there is a significant change to radiation protection policies and procedures that affect general employees and shall be conducted at intervals not to exceed 2 years.

§ 835.902 Radiological workers.

Radiological worker training programs and retraining shall be established and conducted at intervals not to exceed 2 years to familiarize the worker with the fundamentals of radiation protection and the ALARA process. Training shall include both classroom and applied training. Training shall either precede assignment as a radiological worker or be concurrent with assignment as a radiological worker if the worker is accompanied by and under the direct supervision of a trained radiological worker. Radiological worker training not specific to a given site or facility may be waived provided that: This training has been received at another DOE site or facility within the past 2 years; there is provision of proof-of-training in the form of a certification document containing the individual's name, date of training, and specific topics covered; and an appropriate official has certified the training of the individual. The knowledge of radiation safety possessed by radiological workers shall be verified by examination prior to an unsupervised assignment. The training shall include procedures specific to an individual's job assignment. The level of training is to be commensurate with each worker's assignment.

§ 835.903 Radiological control technicians.

Training and retraining programs for radiological control technicians shall be established and conducted at intervals not to exceed 2 years to familiarize technicians with the fundamentals of radiation protection and the proper procedures for maintaining exposures ALARA. This program shall include both classroom and applied training. The training shall either precede performance of tasks assigned to radiological control technicians or be concurrent with such task assignments if the individual is accompanied by and under the direct supervision of a trained individual. The required level of knowledge of radiation safety possessed by radiological control technicians shall be verified by examination to include demonstration prior to any unsupervised work assignment. The training program shall include procedures specific to the site or facility where the technician is assigned. The level of training shall be commensurate with the technician's assignment. Allowance may be made for previous DOE training on generic radiation safety topics (i.e., those not specific to a site or facility), provided the training was received within the past 2 years. Documentation of the previous training shall clearly identify the individual's name, date of training, topics covered, and name of the certifying individual.

Subpart K—Design and Control

§ 835.1001 Design and control.

(a) Measures shall be taken to maintain radiation exposure in controlled areas as low as is reasonably achievable through facility and equipment design and administrative control. The primary methods used shall be physical design features (e.g., confinement, ventilation, remote handling, and shielding). Administrative controls and procedural requirements shall be employed only as supplemental methods to control radiation exposure.

(b) For specific activities where use of physical design features are demonstrated to be impractical, administrative controls and procedural requirements shall be used to maintain radiation exposures ALARA.

§ 835.1002 Facility design and modifications.

During the design of new facilities or modification of old facilities, the following objectives shall be adopted:

(a) Optimization methods shall be used to assure that occupational exposure is maintained ALARA in developing and justifying facility design and physical controls.

(b) The design objective for controlling personnel exposure from external sources of radiation in areas of continuous occupational occupancy (2000 hours per year) shall be to maintain exposure levels below an average of 0.5 mrem (5 microsieverts) per hour and as far below this average as is reasonably achievable. The design objectives for exposure rates for potential exposure to a radiological worker where occupancy differs from the above shall be ALARA and shall not exceed 20 percent of the applicable standards in § 835.202.

(c) Regarding the control of airborne radioactive material, the design objective shall be, under normal conditions, to avoid releases to the workplace atmosphere and in any situation, to control the inhalation of such material by workers to levels that are ALARA; confinement and ventilation shall normally be used.

(d) The design or modification of a facility and the selection of materials shall include features that facilitate operations, maintenance, decontamination, and decommissioning.

§ 835.1003 Control procedures.

(a) During routine operations, the combination of design features and administrative control procedures shall provide that:

(1) The anticipated magnitude of the total effective dose equivalent shall not exceed 5 rems (0.05 sievert) in a year;

(2) The anticipated magnitude of the committed dose equivalent to any organ or tissue, plus any deep dose equivalent from external exposure, shall not exceed 50 rems (0.5 sievert) in a year; and

(3) Exposure levels are as low as reasonably achievable.

(b) Compliance with the requirements in paragraph (a) of this section shall be demonstrated by appropriate monitoring pursuant to the provisions of subpart E of this part.

Subpart L—Releases of Materials and Equipment From Radiological Areas

§ 835.1101 Releases of materials and equipment from radiological areas.

The following requirements apply for the release of materials and equipment from radiological areas for use in controlled areas:

(a) In radiological areas established to control surface or airborne radioactive material, material and equipment shall be treated as radioactive material and shall not be released from radiological areas to controlled areas if either of the following conditions exist:

(1) Measurements of accessible surfaces show that either the total or removable contamination levels exceed the values specified in appendix D to this part; or

(2) Prior use suggests that the contamination levels on inaccessible surfaces are likely to exceed the values specified in appendix D to this part.

(b) Material and equipment exceeding the total or removable contamination levels specified in appendix D to this part may be conditionally released for movement on-site from one radiological area for immediate placement in another radiological area only if appropriate monitoring and control procedures are established and exercised.

(c) Material and equipment with fixed contamination levels that exceed the limits specified in appendix D to this part may be released for use in controlled areas outside of the radiological areas with the following provisions:

(1) Removable contamination levels are below the level specified in appendix D of this part; and

(2) Materials shall be routinely monitored, clearly labeled, or tagged to alert personnel of the contaminated status; appropriate administrative procedures shall be established and exercised to maintain control of these items.

(d) The records for release of material and equipment shall describe the property, date on which the release survey was performed, identity of the individual who performed the survey, type and identification number of the survey instrument used, and results of the survey.

Subpart M—[Reserved]

Subpart N—Accidents and Emergencies

§ 835.1301 General provisions.

(a) A general employee whose occupational exposure has exceeded any of the limits specified in §§ 835.202 or 835.205 may be permitted to return to work in radiological areas during the current year providing that all of the following conditions are met:

(1) Approval is first obtained from the contractor management and the Head of the responsible DOE field organization;

(2) The individual receives counseling from radiological protection and medical personnel regarding the consequences of receiving additional occupational exposure during the year; and

(3) The affected employee agrees to return to radiological work.

(b) All exposures exceeding the limits specified in §§ 835.202 or 835.205 shall be recorded in the affected individual's occupational exposure file and reported to the DOE in accordance with Departmental requirements for occurrence reporting and processing.

(c) When the conditions under which the emergency or accident exposures were received have been eliminated, operating management shall notify the Head of the responsible DOE field organization.

(d) Operations after an emergency or accidental exposure in excess of the limits specified in §§ 835.202 or 835.205 may be resumed only with the approval of the DOE.

(e) Occurrence reports to DOE regarding emergencies and/or accidents shall be prepared and submitted in accordance with Departmental requirements for occurrence reporting and processing.

§ 835.1302 Emergency exposure situations.

(a) The risk of injury to those individuals involved in rescue and recovery operations shall be minimized.

(b) Operating management shall weigh actual and potential risks to rescue and recover individuals against the benefits to be gained.

(c) Rescue action that might involve substantial personal risk shall be performed by volunteers.

(d) The dose limits for individuals performing these operations are as follows:

GUIDELINES FOR CONTROL OF EMERGENCY EXPOSURES

Dose limit [1] (whole body)	Activity performed	Conditions
5 rems	All	
10 rems	Protecting major property.	Where lower dose limit not practicable.
25 rems	Lifesaving or protection of large populations.	Where lower dose limit not practicable.

GUIDELINES FOR CONTROL OF EMERGENCY EXPOSURES—Continued

Dose limit[1] (whole body)	Activity performed	Conditions
>25 rems	Lifesaving or protection of large populations.	Only on a voluntary basis to personnel fully aware of the risks involved.

[1] The lens of the eye dose limit is three times the listed values. The shallow dose limit to the skin of the whole body and the extremities is ten times the listed values. These doses are in addition to and accounted for separately from the doses received under the limits in §§ 835.202 and 835.205.

(e) Each individual selected shall be trained in accordance with § 835.902 and briefed beforehand of the known or anticipated hazards to which the individual will be subjected.

§ 835.1303 [Reserved]

§ 835.1304 Nuclear accident dosimetry.

(a) Installations possessing sufficient quantities of fissile material to potentially constitute a critical mass, such that the excessive exposure of personnel to radiation from a nuclear accident is possible, shall provide nuclear accident dosimetry for those personnel.

(b) Nuclear accident dosimetry shall include the following:

(1) A method to conduct initial screening of personnel involved in a nuclear accident to determine whether significant exposures to radiation occurred;

(2) Methods and equipment for analysis of biological materials;

(3) A system of fixed nuclear accident dosimeter units; and

(4) Personal nuclear accident dosimeters worn by all personnel who enter locations in which installed criticality alarm systems are required.

Appendix A to Part 835—Derived Air Concentrations (DAC) for Controlling Radiation Exposure to Workers at DOE Facilities

The derived air concentrations (DAC) for limiting radiation exposures through inhalation of radionuclides by workers are listed in this appendix. The values are based on either a stochastic (committed effective dose equivalent) dose limit of 5 rems (0.05 Sv) or a nonstochastic (organ) dose limit of 50 rems (0.5 Sv) per year, whichever is more limiting.

Note: the 15 rems [0.15 Sv] dose limit for the lens of the eye does not appear as a critical organ dose limit.)

The columns in this appendix contain the following information: (1) Radionuclide; (2) inhaled air DAC for lung retention class D, W, and Y in units of μCi/ml; (3) inhaled air DAC for lung retention class D, W, and Y in units of Bq/m^3; and (4) an indication of whether or not the DAC for each class is controlled by the stochastic (effective dose equivalent) or nonstochastic (tissue) dose. The classes D, W, and Y have been established to describe the clearance of inhaled radionuclides from the lung. This classification refers to the approximate length of retention in the pulmonary region. Thus, the range of half-times for retention in the pulmonary region is less than 10 days for class D (days), from 10 to 100 days for class W (weeks), and greater than 100 days for class Y (years). The DACs are listed by radionuclide, in order of increasing atomic mass, and are based on the assumption that the particle size distribution of the inhaled material is unknown and an assumed particle size distribution of 1 μm is used. For situations where the particle size distribution is known to differ significantly from 1 μm, appropriate corrections can be made to both the estimated dose to workers and the DACs.

Radionuclide	Inhaled air-lung retention class[3] μCi/ml			Inhaled air-lung retention class[3] Bq/m^3			Stochastic or organ[1]
	D	W	Y	D	W	Y	(D/ W/ Y)
H-3 (Water)[2]	2.E−05	2.E−05	2.E−05	8.E+05	8.E+05	8.E+05	St/St/St
H-3 (Elemental)[2]	5.E−01	5.E−01	5.E−01	2.E+10	2.E+10	2.E+10	St/St/St
Be-7	–	9.E−06	8.E−06	–	3.E+05	3.E+05	/St/St
Be-10	–	6.E−08	6.E−09	–	2.E+03	2.E+02	/St/St
C-11 (Org)[2]	2.E−04	2.E−04	2.E−04	6.E+06	6.E+06	6.E+06	St/St/St
C-11 (CO)[2]	5.E−04	5.E−04	5.E−04	2.E+07	2.E+07	2.E+07	St/St/St
C-11 (CO_2)[2]	3.E−04	3.E−04	3.E−04	1.E+07	1.E+07	1.E+07	St/St/St
C-14 (Org)[2]	1.E−06	1.E−06	1.E−06	4.E+07	4.E+04	4.E+07	St/St/St
C-14 (CO)[2]	7.E−04	7.E−04	7.E−04	3.E+07	3.E+07	3.E+07	St/St/St
C-14 (CO_2)[2]	9.E−05	9.E−05	9.E−05	3.E+06	3.E+06	3.E+06	St/St/St
F-18	3.E−05	4.E−05	3.E−05	1.E+06	1.E+06	1.E+06	St/St/St
Na-22	3.E−07	–	–	1.E+04	–	–	St/ /
Na-24	2.E−06	–	–	8.E+04	–	–	St/ /
Mg-28	7.E−07	5.E−07	–	3.E+04	2.E+04	–	St/St/
Al-26	3.E−08	3.E−08	–	1.E+03	1.E+03	–	St/St/
Si-31	1.E−05	1.E−05	1.E−05	4.E+05	5.E+05	4.E+05	St/St/St
Si-32	1.E−07	5.E−08	2.E−09	4.E+03	2.E+03	8.E+01	St/St/St
P-32	4.E−07	2.E−07	–	1.E+04	6.E+03	–	St/St/
P-33	3.E−06	1.E−06	–	1.E+05	4.E+04	–	St/St/
S-35	7.E−06	9.E−07	–	3.E+05	3.E+04	–	St/St/
S-35 (Gas)	–	6.E−06	–	–	2.E+05	–	/St/
Cl-36	1.E−06	1.E−07	–	4.E+04	4.E+03	–	St/St/
Cl-38	2.E−05	2.E−05	–	6.E+05	7.E+05	–	St/St/
Cl-39	2.E−05	2.E−05	–	8.E+05	9.E+05	–	St/St/
K-40	2.E−07	–	–	6.E+03	–	–	St/ /
K-42	2.E−06	–	–	7.E+04	–	–	St/ /
K-43	4.E−06	–	–	1.E+05	–	–	St/ /
K-44	3.E−05	–	–	1.E+06	–	–	St/ /
K-45	5.E−05	–	–	2.E+06	–	–	St/ /
Ca-41	–	2.E−06	–	–	6.E+04	–	/E/
Ca-45	–	3.E−07	–	–	1.E+04	–	/St/

Radionuclide	Inhaled air-lung retention class [3] µCi/ml			Inhaled air-lung retention class [3] Bq/m [3]			Stochastic or organ [1]
	D	W	Y	D	W	Y	(D/ W/ Y)
Ca-47	–	4.E–07	–	–	1.E+04	–	/St/
Sc-43	–	–	1.E–05	–	–	4.E+05	/ /St
Sc-44m	–	–	3.E–07	–	–	1.E+04	/ /St
Sc-44	–	–	5.E–06	–	–	2.E+05	/ /St
Sc-46	–	–	1.E–07	–	–	4.E+03	/ /St
Sc-47	–	–	1.E–06	–	–	5.E+04	/ /St
Sc-48	–	–	6.E–07	–	–	2.E+04	/ /St
Sc-49	–	–	2.E–05	–	–	8.E+05	/ /St
Ti-44	5.E–09	1.E–08	2.E–09	2.E+02	4.E+02	9.E+01	St/St/St
Ti-45	1.E–05	1.E–05	1.E–05	4.E+05	5.E+05	5.E+05	St/St/St
V-47	4.E–05	4.E–05	–	1.E+06	1.E+06	–	St/St/
V-48	4.E–07	3.E–07	–	2.E+04	1.E+04	–	St/St/
V-49	1.E–05	7.E–06	–	5.E+05	3.E+05	–	BS/St/
Cr-48	5.E–06	3.E–06	3.E–06	2.E+05	1.E+05	1.E+05	St/St/St
Cr-49	3.E–05	4.E–05	4.E–05	1.E+06	2.E+06	1.E+06	St/St/St
Cr-51	2.E–05	1.E–05	8.E–06	7.E+05	4.E+05	3.E+05	St/St/St
Mn-51	2.E–05	2.E–05	–	8.E+05	9.E+05	–	St/St/
Mn-52m	4.E–05	4.E–05	–	1.E+06	2.E+06	–	St/St/
Mn-52	5.E–07	4.E–07	–	2.E+04	1.E+04	–	St/St/
Mn-53	5.E–06	5.E–06	–	2.E+05	2.E+05	–	BS/St/
Mn-54	4.E–07	3.E–07	–	1.E+04	1.E+04	–	St/St/
Mn-56	6.E–06	9.E–06	–	2.E+05	3.E+05	–	St/St/
Fe-52	1.E–06	1.E–06	–	5.E+04	4.E+04	–	St/St/
Fe-55	8.E–07	2.E–06	–	3.E+04	6.E+04	–	St/St/
Fe-59	1.E–07	2.E–07	–	5.E+03	8.E+03	–	St/St/
Fe-60	3.E–09	8.E–09	–	1.E+02	3.E+02	–	St/St/
Co-55	–	1.E–06	1.E–06	–	4.E+04	4.E+04	/St/St
Co-56	–	1.E–07	8.E–08	–	5.E+03	3.E+03	/St/St
Co-57	–	1.E–06	3.E–07	–	4.E+04	1.E+04	/St/St
Co-58m	–	4.E–05	3.E–05	–	1.E+06	1.E+06	/St/St
Co-58	–	5.E–07	3.E–07	–	2.E+04	1.E+04	/St/St
Co-60m	–	2.E–03	1.E–03	–	6.E+07	4.E+07	/St/St
Co-60	–	7.E–08	1.E–08	–	3.E+03	5.E+02	/St/St
Co-61	–	3.E–05	2.E–05	–	1.E+06	9.E+05	/St/St
Co-62m	–	7.E–05	7.E–05	–	3.E+06	2.E+06	/St/St
Ni-56 (Inorg)	8.E–07	5.E–07	–	3.E+04	2.E+04	–	St/St/
Ni-56 (Vapor)	–	5.E–07	–	–	2.E+04	–	/St/
Ni-57 (Inorg)	2.E–06	1.E–06	–	7.E+04	5.E+04	–	St/St/
Ni-57 (Vapor)	–	3.E–06	–	–	1.E+05	–	/St/
Ni-59 (Inorg)	2.E–06	3.E–06	–	6.E+04	1.E+05	–	St/St/
Ni-59 (Vapor)	–	8.E–07	–	–	3.E+04	–	/St/
Ni-63 (Inorg)	7.E–07	1.E–06	–	3.E+04	4.E+04	–	St/St/
Ni-63 (Vapor)	–	3.E–07	–	–	1.E+04	–	/St/
Ni-65 (Inorg)	1.E–05	1.E–05	–	4.E+05	5.E+05	–	St/St/
Ni-65 (Vapor)	–	7.E–06	–	–	3.E+05	–	/St/
Ni-66 (Inorg)	7.E–07	3.E–07	–	3.E+04	1.E+04	–	St/St/
Ni-66 (Vapor)	–	1.E–06	–	–	5.E+04	–	/St/
Cu-60	4.E–05	5.E–05	4.E–05	1.E+06	2.E+06	2.E+06	St/St/St
Cu-61	1.E–05	2.E–05	1.E–05	5.E+05	6.E+05	5.E+05	St/St/St
Cu-64	1.E–05	1.E–05	9.E–06	5.E+05	4.E+05	3.E+05	St/St/St
Cu-67	3.E–06	2.E–06	2.E–06	1.E+05	8.E+04	7.E+04	St/St/St
Zn-62	–	–	1.E–06	–	–	4.E+04	/ /St
Zn-63	–	–	3.E–05	–	–	1.E+06	/ /St
Zn-65	–	–	1.E–07	–	–	4.E+03	/ /St
Zn-69m	–	–	3.E–06	–	–	1.E+05	/ /St
Zn-69	–	–	6.E–05	–	–	2.E+06	/ /St
Zn-71m	–	–	7.E–06	–	–	3.E+05	/ /St
Zn-72	–	–	5.E–07	–	–	2.E+04	/ /St
Ga-65	7.E–05	8.E–05	–	3.E+06	3.E+06	–	St/St/
Ga-66	1.E–06	1.E–06	–	5.E+04	5.E+04	–	St/St/
Ga-67	6.E–06	4.E–06	–	2.E+05	2.E+05	–	St/St/
Ga-68	2.E–05	2.E–05	–	6.E+05	8.E+05	–	St/St/
Ga-70	7.E–05	8.E–05	–	3.E+06	3.E+06	–	St/St/
Ga-72	2.E–06	1.E–06	–	6.E+04	5.E+04	–	St/St/
Ga-73	6.E–06	6.E–06	–	2.E+05	2.E+05	–	St/St/
Ge-66	1.E–05	8.E–06	–	4.E+05	3.E+05	–	St/St/
Ge-67	4.E–05	4.E–05	–	1.E+06	2.E+06	–	St/St/
Ge-68	2.E–06	4.E–08	–	6.E+04	2.E+03	–	St/St/
Ge-69	6.E–06	3.E–06	–	2.E+05	1.E+05	–	St/St/
Ge-71	2.E–04	2.E–05	–	7.E+06	6.E+05	–	St/St/

Radionuclide	Inhaled air-lung retention class [3]			Inhaled air-lung retention class [3]			Stochastic or organ [1]
	μCi/ml			Bq/m [3]			
	D	W	Y	D	W	Y	(D/ W/ Y)
Ge-75	3.E−05	3.E−05	–	1.E+06	1.E+06	–	St/St/
Ge-77	4.E−06	2.E−06	–	2.E+05	9.E+04	–	St/St/
Ge-78	9.E−06	9.E−06	–	4.E+05	3.E+05	–	St/St/
As-69	–	5.E−05	–	–	2.E+06	–	/St/
As-70	–	2.E−05	–	–	8.E+05	–	/St/
As-71	–	2.E−06	–	–	7.E+04	–	/St/
As-72	–	6.E−07	–	–	2.E+04	–	/St/
As-73	–	7.E−07	–	–	3.E+04	–	/St/
As-74	–	3.E−07	–	–	1.E+04	–	/St/
As-76	–	6.E−07	–	–	2.E+04	–	/St/
As-77	–	2.E−06	–	–	8.E+04	–	/St/
As-78	–	9.E−06	–	–	3.E+05	–	/St/
Se-70	1.E−05	2.E−05	–	6.E+05	7.E+05	–	St/St/
Se-73m	6.E−05	6.E−05	–	2.E+06	2.E+06	–	St/St/
Se-73	6.E−06	7.E−06	–	2.E+05	2.E+05	–	St/St/
Se-75	3.E−07	3.E−07	–	1.E+04	9.E+03	–	St/St/
Se-79	3.E−07	2.E−07	–	1.E+04	9.E+03	–	St/St/
Se-81m	3.E−05	3.E−05	–	1.E+06	1.E+06	–	St/St/
Se-81	9.E−05	1.E−04	–	3.E+06	4.E+06	–	St/St/
Se-83	5.E−05	5.E−05	–	2.E+06	2.E+06	–	St/St/
Br-74m	1.E−05	2.E−05	–	6.E+05	6.E+05	–	St/St/
Br-74	3.E−05	3.E−05	–	1.E+06	1.E+06	–	St/St/
Br-75	2.E−05	2.E−05	–	7.E+05	8.E+05	–	St/St/
Br-76	2.E−06	2.E−06	–	7.E+04	7.E+04	–	St/St/
Br-77	1.E−05	8.E−06	–	4.E+05	3.E+05	–	St/St/
Br-80m	7.E−06	6.E−06	–	3.E+05	2.E+05	–	St/St/
Br-80	8.E−05	9.E−05	–	3.E+06	3.E+06	–	St/St/
Br-82	2.E−06	2.E−06	–	6.E+04	6.E+04	–	St/St/
Br-83	3.E−05	3.E−05	–	1.E+06	1.E+06	–	St/St/
Br-84	2.E−05	3.E−05	–	9.E+05	1.E+06	–	St/St/
Rb-79	5.E−05	–	–	2.E+06	–	–	St/ /
Rb-81m	1.E−04	–	–	5.E+06	–	–	St/ /
Rb-81	2.E−05	–	–	8.E+05	–	–	St/ /
Rb-82m	7.E−06	–	–	3.E+05	–	–	St/ /
Rb-83	4.E−07	–	–	2.E+04	–	–	St/ /
Rb-84	3.E−07	–	–	1.E+04	–	–	St/ /
Rb-86	3.E−07	–	–	1.E+04	–	–	St/ /
Rb-87	6.E−07	–	–	2.E+04	–	–	St/ /
Rb-88	3.E−05	–	–	1.E+06	–	–	St/ /
Rb-89	6.E−05	–	–	2.E+06	–	–	St/ /
Sr-80	5.E−06	–	5.E−06	2.E+05	–	2.E+05	St/ /St
Sr-81	3.E−05	–	3.E−05	1.E+06	–	1.E+06	St/ /St
Sr-83	3.E−06	–	2.E−06	1.E+05	–	5.E+04	St/ /St
Sr-85m	3.E−04	–	3.E−04	9.E+06	–	1.E+07	St/ /St
Sr-85	1.E−06	–	7.E−07	4.E+04	–	2.E+04	St/ /St
Sr-87m	5.E−05	–	6.E−05	2.E+06	–	2.E+06	St/ /St
Sr-89	3.E−07	–	6.E−08	1.E+04	–	2.E+03	St/ /St
Sr-90	8.E−09	–	2.E−09	3.E+02	–	6.E+01	BS/ /St
Sr-91	2.E−06	–	1.E−06	9.E+04	–	5.E+04	St/ /St
Sr-92	4.E−06	–	3.E−06	1.E+05	–	1.E+05	St/ /St
Y-86m	–	2.E−05	2.E−05	–	9.E+05	9.E+05	/St/St
Y-86	–	1.E−06	1.E−06	–	5.E+04	5.E+04	/St/St
Y-87	–	1.E−06	1.E−06	–	5.E+04	5.E+04	/St/St
Y-88	–	1.E−07	1.E−07	–	4.E+03	4.E+03	/St/St
Y-90m	–	5.E−06	5.E−06	–	2.E+05	2.E+05	/St/St
Y-90	–	3.E−07	2.E−07	–	1.E+04	9.E+03	/St/St
Y-91m	–	1.E−04	7.E−05	–	4.E+06	3.E+06	/St/St
Y-91	–	7.E−08	5.E−08	–	3.E+03	2.E+03	/St/St
Y-92	–	3.E−06	3.E−06	–	1.E+05	1.E+05	/St/St
Y-93	–	1.E−06	1.E−06	–	4.E+04	4.E+04	/St/St
Y-94	–	3.E−05	3.E−05	–	1.E+06	1.E+06	/St/St
Y-95	–	6.E−05	6.E−05	–	2.E+06	2.E+06	/St/St
Zr-86	2.E−06	1.E−06	1.E−06	6.E+04	4.E+04	4.E+04	St/St/St
Zr-88	9.E−08	2.E−07	1.E−07	3.E+03	7.E+03	5.E+03	St/St/St
Zr-89	2.E−06	1.E−06	1.E−06	5.E+04	4.E+04	4.E+04	St/St/St
Zr-93	3.E−09	1.E−08	2.E−08	1.E+02	4.E+02	9.E+02	BS/BS/BS
Zr-95	6.E−08	2.E−07	1.E−07	2.E+03	6.E+03	4.E+03	BS/St/St
Zr-97	8.E−07	6.E−07	5.E−07	3.E+04	2.E+04	2.E+04	St/St/St
Nb-88	–	1.E−04	9.E−05	–	4.E+06	3.E+06	/St/St
Nb-89 (66 min)	–	2.E−05	2.E−05	–	6.E+05	6.E+05	/St/St

Radionuclide	Inhaled air-lung retention class[3] µCi/ml			Inhaled air-lung retention class[3] Bq/m[3]			Stochastic or organ[1]
	D	W	Y	D	W	Y	(D/ W/ Y)
Nb-89 (122 min)	–	8.E–06	7.E–06	–	3.E+05	2.E+05	/St/St
Nb-90	–	1.E–06	1.E–06	–	4.E+04	4.E+04	/St/St
Nb-93m	–	5.E–07	7.E–08	–	2.E+04	3.E+03	/St/St
Nb-94	–	8.E–08	6.E–09	–	3.E+03	2.E+02	/St/St
Nb-95m	–	1.E–06	9.E–07	–	4.E+04	4.E+04	/St/St
Nb-95	–	5.E–07	5.E–07	–	2.E+04	2.E+04	/St/St
Nb-96	–	1.E–06	1.E–06	–	4.E+04	4.E+04	/St/St
Nb-97	–	3.E–05	3.E–05	–	1.E+06	1.E+06	/St/St
Nb-98	–	2.E–05	2.E–05	–	8.E+05	8.E+05	/St/St
Mo-90	3.E–06	–	2.E–06	1.E+05	–	7.E+04	St/ /St
Mo-93m	7.E–06	–	6.E–06	3.E+05	–	2.E+05	St/ /St
Mo-93	2.E–06	–	7.E–08	8.E+04	–	3.E+03	St/ /St
Mo-99	1.E–06	–	6.E–07	4.E+04	–	2.E+04	St/ /St
Mo-101	6.E–05	–	6.E–05	2.E+06	–	2.E+06	St/ /St
Tc-93m	7.E–05	1.E–04	–	2.E+06	5.E+06	–	St/St/
Tc-93	3.E–05	4.E–05	–	1.E+06	2.E+06	–	St/St/
Tc-94m	2.E–05	2.E–05	–	7.E+05	9.E+05	–	St/St/
Tc-94	8.E–06	1.E–05	–	3.E+05	4.E+05	–	St/St/
Tc-96m	1.E–04	1.E–04	–	4.E+06	4.E+06	–	St/St/
Tc-96	1.E–06	9.E–07	–	5.E+04	3.E+04	–	St/St/
Tc-97m	3.E–06	5.E–07	–	1.E+05	2.E+04	–	SW/St/
Tc-97	2.E–05	2.E–06	–	8.E+05	9.E+04	–	St/St/
Tc-98	7.E–07	1.E–07	–	3.E+04	5.E+03	–	St/St/
Tc-99m	6.E–05	1.E–04	–	2.E+06	4.E+06	–	St/St/
Tc-99	2.E–06	3.E–07	–	8.E+04	1.E+04	–	SW/St/
Tc-101	1.E–04	2.E–04	–	5.E+06	6.E+06	–	St/St/
Tc-104	3.E–05	4.E–05	–	1.E+06	1.E+06	–	St/St/
Ru-94	2.E–05	3.E–05	2.E–05	7.E+05	1.E+06	9.E+05	St/St/St
Ru-97	8.E–06	5.E–06	5.E–06	3.E+05	2.E+05	2.E+05	St/St/St
Ru-103	7.E–07	4.E–07	3.E–07	3.E+04	2.E+04	1.E+04	St/St/St
Ru-105	6.E–06	6.E–06	5.E–06	2.E+05	2.E+05	2.E+05	St/St/St
Ru-106	4.E–08	2.E–08	5.E–09	1.E+03	8.E+02	2.E+02	St/St/St
Rh-99m	2.E–05	3.E–05	3.E–05	9.E+05	1.E+06	1.E+06	St/St/St
Rh-99	1.E–06	9.E–07	8.E–07	5.E+04	3.E+04	3.E+04	St/St/St
Rh-100	2.E–06	2.E–06	2.E–06	8.E+04	6.E+04	6.E+04	St/St/St
Rh-101m	5.E–06	3.E–06	3.E–06	2.E+05	1.E+05	1.E+05	St/St/St
Rh-101	2.E–07	3.E–07	7.E–08	8.E+03	1.E+04	2.E+03	St/St/St
Rh-102m	2.E–07	2.E–07	5.E–08	8.E+03	6.E+03	2.E+03	St/St/St
Rh-102	4.E–08	7.E–08	2.E–08	1.E+03	3.E+03	9.E+02	St/St/St
Rh-103m	4.E–04	5.E–04	5.E–04	2.E+07	2.E+07	2.E+07	St/St/St
Rh-105	5.E–06	3.E–06	2.E–06	2.E+05	1.E+05	9.E+04	St/St/St
Rh-106m	1.E–05	1.E–05	1.E–05	4.E+05	6.E+05	5.E+05	St/St/St
Rh-107	1.E–04	1.E–04	1.E–04	4.E+06	4.E+06	4.E+06	St/St/St
Pd-100	6.E–07	5.E–07	6.E–07	2.E+04	2.E+04	2.E+04	St/St/St
Pd-101	1.E–05	1.E–05	1.E–05	5.E+05	5.E+05	5.E+05	St/St/St
Pd-103	3.E–06	2.E–06	1.E–06	1.E+05	7.E+04	5.E+04	St/St/St
Pd-107	9.E–06	3.E–06	2.E–07	3.E+05	1.E+05	6.E+03	K /St/St
Pd-109	3.E–06	2.E–06	2.E–06	1.E+05	8.E+04	7.E+04	St/St/St
Ag-102	8.E–05	9.E–05	8.E–05	3.E+06	3.E+06	3.E+06	St/St/St
Ag-103	4.E–05	6.E–05	5.E–05	2.E+06	2.E+06	2.E+06	St/St/St
Ag-104m	4.E–05	5.E–05	5.E–05	2.E+06	2.E+06	2.E+06	St/St/St
Ag-104	3.E–05	6.E–05	6.E–05	1.E+06	2.E+06	2.E+06	St/St/St
Ag-105	4.E–07	7.E–07	7.E–07	2.E+04	3.E+04	3.E+04	St/St/St
Ag-106m	3.E–07	4.E–07	4.E–07	1.E+04	1.E+04	1.E+04	St/St/St
Ag-106	7.E–05	8.E–05	8.E–05	3.E+06	3.E+06	3.E+06	St/St/St
Ag-108m	8.E–08	1.E–07	1.E–08	3.E+03	4.E+03	4.E+02	St/St/St
Ag-110m	6.E–08	8.E–08	4.E–08	2.E+03	3.E+03	1.E+03	St/St/St
Ag-111	7.E–07	4.E–07	4.E–07	2.E+04	1.E+04	1.E+04	L /St/St
Ag-112	3.E–06	4.E–06	4.E–06	1.E+05	2.E+05	1.E+05	St/St/St
Ag-115	4.E–05	4.E–05	3.E–05	1.E+06	1.E+06	1.E+06	St/St/St
Cd-104	3.E–05	5.E–05	5.E–05	1.E+06	2.E+06	2.E+06	St/St/St
Cd-107	2.E–05	2.E–05	2.E–05	8.E+05	9.E+05	8.E+05	St/St/St
Cd-109	1.E–08	5.E–08	5.E–08	5.E+02	2.E+03	2.E+03	K /K /St
Cd-113m	1.E–09	4.E–09	5.E–09	4.E+01	1.E+02	2.E+02	K /K /St
Cd-113	9.E–10	3.E–09	6.E–09	4.E+01	1.E+02	2.E+02	K /K /St
Cd-115m	2.E–08	5.E–08	6.E–08	8.E+02	2.E+03	2.E+03	K /St/St
Cd-115	6.E–07	5.E–07	6.E–07	2.E+04	2.E+04	2.E+04	St/St/St
Cd-117m	5.E–06	7.E–06	6.E–06	2.E+05	3.E+05	2.E+05	St/St/St
Cd-117	5.E–06	7.E–06	6.E–06	2.E+05	3.E+05	2.E+05	St/St/St
In-109	2.E–05	3.E–05	–	7.E+05	1.E+06	–	St/St/

Radionuclide	Inhaled air-lung retention class [3] µCi/ml			Inhaled air-lung retention class [3] Bq/m [3]			Stochastic or organ [1]
	D	W	Y	D	W	Y	(D/ W/ Y)
In-110 (69 min)	2.E−05	2.E−05	–	7.E+05	9.E+05	–	St/St/
In-110 (5 h)	7.E−06	8.E−06	–	3.E+05	3.E+05	–	St/St/
In-111	3.E−06	3.E−06	–	1.E+05	1.E+05	–	St/St/
In-112	3.E−04	3.E−04	–	1.E+07	1.E+07	–	St/St/
In-113m	6.E−05	8.E−05	–	2.E+06	3.E+06	–	St/St/
In-114m	3.E−08	4.E−08	–	1.E+03	2.E+03	–	St/St/
In-115m	2.E−05	2.E−05	–	7.E+05	7.E+05	–	St/St/
In-115	6.E−10	2.E−09	–	2.E+01	8.E+01	–	St/St/
In-116m	3.E−05	5.E−05	–	1.E+06	2.E+06	–	St/St/
In-117m	1.E−05	2.E−05	–	5.E+05	7.E+05	–	St/St/
In-117	7.E−05	9.E−05	–	3.E+06	3.E+06	–	St/St/
In-119m	5.E−05	6.E−05	–	2.E+06	2.E+06	–	St/St/
Sn-110	5.E−06	5.E−06	–	2.E+05	2.E+05	–	St/St/
Sn-111	9.E−05	1.E−04	–	4.E+06	4.E+06	–	St/St/
Sn-113	5.E−07	2.E−07	–	2.E+04	9.E+03	–	St/St/
Sn-117m	5.E−07	6.E−07	–	2.E+04	2.E+04	–	BS/St/
Sn-119m	1.E−06	4.E−07	–	4.E+04	1.E+04	–	St/St/
Sn-121m	4.E−07	2.E−07	–	1.E+04	9.E+03	–	St/St/
Sn-121	6.E−06	5.E−06	–	2.E+05	2.E+05	–	St/St/
Sn-123m	5.E−05	6.E−05	–	2.E+06	2.E+06	–	St/St/
Sn-123	3.E−07	7.E−08	–	1.E+04	3.E+03	–	St/St/
Sn-125	4.E−07	2.E−07	–	1.E+04	5.E+03	–	St/St/
Sn-126	2.E−08	3.E−08	–	9.E+02	1.E+03	–	St/St/
Sn-127	8.E−06	8.E−06	–	3.E+05	3.E+05	–	St/St/
Sn-128	1.E−05	1.E−05	–	4.E+05	6.E+05	–	St/St/
Sb-115	1.E−04	1.E−04	–	4.E+06	5.E+06	–	St/St/
Sb-116m	3.E−05	6.E−05	–	1.E+06	2.E+06	–	St/St/
Sb-116	1.E−04	1.E−04	–	4.E+06	5.E+06	–	St/St/
Sb-117	9.E−05	1.E−04	–	3.E+06	4.E+06	–	St/St/
Sb-118m	8.E−06	9.E−06	–	3.E+05	3.E+05	–	St/St/
Sb-119	2.E−05	1.E−05	–	7.E+05	4.E+05	–	St/St/
Sb-120 (16 min)	2.E−04	2.E−04	–	7.E+06	8.E+06	–	St/St/
Sb-120 (6 d)	9.E−07	6.E−07	–	3.E+04	2.E+04	–	St/St/
Sb-122	1.E−06	4.E−07	–	4.E+04	2.E+04	–	St/St/
Sb-124m	3.E−04	3.E−04	–	1.E+07	9.E+06	–	St/St/
Sb-124	4.E−07	1.E−07	–	1.E+04	4.E+03	–	St/St/
Sb-125	1.E−06	2.E−07	–	4.E+04	8.E+03	–	St/St/
Sb-126m	8.E−05	8.E−05	–	3.E+06	3.E+06	–	St/St/
Sb-126	4.E−07	2.E−07	–	2.E+04	8.E+03	–	St/St/
Sb-127	9.E−07	4.E−07	–	3.E+04	1.E+04	–	St/St/
Sb-128 (9 h)	2.E−06	1.E−06	–	6.E+04	5.E+04	–	St/St/
Sb-128 (10 min)	2.E−04	2.E−04	–	6.E+06	7.E+06	–	St/St/
Sb-129	4.E−06	4.E−06	–	1.E+05	1.E+05	–	St/St/
Sb-130	3.E−05	3.E−05	–	1.E+06	1.E+06	–	St/St/
Sb-131	1.E−05	1.E−05	–	4.E+05	4.E+05	–	T /T /
Te-116	9.E−06	1.E−05	–	3.E+05	5.E+05	–	St/St/
Te-121m	8.E−08	2.E−07	–	3.E+03	6.E+03	–	BS/St/
Te-121	2.E−06	1.E−06	–	7.E+04	5.E+04	–	St/St/
Te-123m	9.E−08	2.E−07	–	3.E+03	8.E+03	–	BS/St/
Te-123	8.E−08	2.E−07	–	3.E+03	7.E+03	–	BS/BS/
Te-125m	2.E−07	3.E−07	–	7.E+03	1.E+04	–	BS/St/
Te-127m	1.E−07	1.E−07	–	4.E+03	4.E+03	–	BS/St/
Te-127	9.E−06	7.E−06	–	4.E+05	3.E+05	–	St/St/
Te-129m	3.E−07	1.E−07	–	1.E+04	4.E+03	–	St/St/
Te-129	3.E−05	3.E−05	–	1.E+06	1.E+06	–	St/St/
Te-131m	2.E−07	2.E−07	–	6.E+03	6.E+03	–	T /T /
Te-131	2.E−06	2.E−06	–	8.E+04	8.E+04	–	T /T /
Te-132	9.E−08	9.E−08	–	4.E+03	3.E+03	–	T /T /
Te-133m	2.E−06	2.E−06	–	8.E+04	8.E+04	–	T /T /
Te-133	9.E−06	9.E−06	–	4.E+05	4.E+05	–	T /T /
Te-134	1.E−05	1.E−05	–	4.E+05	4.E+05	–	T /T /
I-120m	9.E−06	–	–	3.E+05	–	–	St/ /
I-120	4.E−06	–	–	1.E+05	–	–	T / /
I-121	7.E−06	–	–	3.E+05	–	–	T / /
I-123	3.E−06	–	–	1.E+05	–	–	T / /
I-124	3.E−08	–	–	1.E+03	–	–	T / /
I-125	3.E−08	–	–	1.E+03	–	–	T / /
I-126	1.E−08	–	–	5.E+02	–	–	T / /
I-128	5.E−05	–	–	2.E+06	–	–	St/ /
I-129	4.E−09	–	–	1.E+02	–	–	T / /

Radionuclide	Inhaled air-lung retention class[3] µCi/ml			Inhaled air-lung retention class[3] Bq/m[3]			Stochastic or organ[1]
	D	W	Y	D	W	Y	(D/ W/ Y)
I-130	3.E−07	–	–	1.E+04	–	–	T / /
I-131	2.E−08	–	–	7.E+02	–	–	T / /
I-132m	4.E−06	–	–	1.E+05	–	–	T / /
I-132	3.E−06	–	–	1.E+05	–	–	T / /
I-133	1.E−07	–	–	4.E+03	–	–	T / /
I-134	2.E−05	–	–	7.E+05	–	–	E / /
I-135	7.E−07	–	–	2.E+04	–	–	T / /
Cs-125	6.E−05	–	–	2.E+06	–	–	St/ /
Cs-127	4.E−05	–	–	2.E+06	–	–	St/ /
Cs-129	1.E−05	–	–	5.E+05	–	–	St/ /
Cs-130	8.E−05	–	–	3.E+06	–	–	St/ /
Cs-131	1.E−05	–	–	5.E+05	–	–	St/ /
Cs-132	2.E−06	–	–	6.E+04	–	–	St/ /
Cs-134m	6.E−05	–	–	2.E+06	–	–	St/ /
Cs-134	4.E−08	–	–	2.E+03	–	–	St/ /
Cs-135m	8.E−05	–	–	3.E+06	–	–	St/ /
Cs-135	5.E−07	–	–	2.E+04	–	–	St/ /
Cs-136	3.E−07	–	–	1.E+04	–	–	St/ /
Cs-137	7.E−08	–	–	2.E+03	–	–	St/ /
Cs-138	2.E−05	–	–	9.E+05	–	–	St/ /
Ba-126	6.E−06	–	–	2.E+05	–	–	St/ /
Ba-128	7.E−07	–	–	3.E+04	–	–	St/ /
Ba-131m	6.E−04	–	–	2.E+07	–	–	St/ /
Ba-131	3.E−06	–	–	1.E+05	–	–	St/ /
Ba-133m	4.E−06	–	–	1.E+05	–	–	St/ /
Ba-133	3.E−07	–	–	1.E+04	–	–	St/ /
Ba-135m	5.E−06	–	–	2.E+05	–	–	St/ /
Ba-139	1.E−05	–	–	5.E+05	–	–	St/ /
Ba-140	6.E−07	–	–	2.E+04	–	–	St/ /
Ba-141	3.E−05	–	–	1.E+06	–	–	St/ /
Ba-142	6.E−05	–	–	2.E+06	–	–	St/ /
La-131	5.E−05	7.E−05	–	2.E+06	3.E+06	–	St/St/
La-132	4.E−06	5.E−06	–	2.E+05	2.E+05	–	St/St/
La-135	4.E−05	4.E−05	–	2.E+06	2.E+06	–	St/St/
La-137	3.E−08	1.E−07	–	1.E+03	4.E+03	–	L /E /
La-138	2.E−09	6.E−09	–	5.E+01	2.E+02	–	St/St/
La-140	6.E−07	5.E−07	–	2.E+04	2.E+04	–	St/St/
La-141	4.E−06	5.E−06	–	1.E+05	2.E+05	–	St/St/
La-142	9.E−06	1.E−05	–	4.E+05	5.E+05	–	St/St/
La-143	4.E−05	4.E−05	–	2.E+06	1.E+06	–	St/St/
Ce-134	–	3.E−07	3.E−07	–	1.E+04	1.E+04	/St/St
Ce-135	–	2.E−06	2.E−06	–	6.E+04	5.E+04	/St/St
Ce-137m	–	2.E−06	2.E−06	–	7.E+04	6.E+04	/St/St
Ce-137	–	6.E−05	5.E−05	–	2.E+06	2.E+06	/St/St
Ce-139	–	3.E−07	3.E−07	–	1.E+04	1.E+04	/St/St
Ce-141	–	3.E−07	2.E−07	–	1.E+04	9.E+03	/St/St
Ce-143	–	8.E−07	7.E−07	–	3.E+04	2.E+04	/St/St
Ce-144	–	1.E−08	6.E−09	–	4.E+02	2.E+02	/St/St
Pr-136	–	1.E−04	9.E−05	–	4.E+06	4.E+06	/St/St
Pr-137	–	6.E−05	6.E−05	–	2.E+06	2.E+06	/St/St
Pr-138m	–	2.E−05	2.E−05	–	8.E+05	7.E+05	/St/St
Pr-139	–	5.E−05	5.E−05	–	2.E+06	2.E+06	/St/St
Pr-142m	–	7.E−05	6.E−05	–	3.E+06	2.E+06	/St/St
Pr-142	–	8.E−07	8.E−07	–	3.E+04	3.E+04	/St/St
Pr-143	–	3.E−07	3.E−07	–	1.E+04	1.E+04	/St/St
Pr-144	–	5.E−05	5.E−05	–	2.E+06	2.E+06	/St/St
Pr-145	–	4.E−06	3.E−06	–	1.E+05	1.E+05	/St/St
Pr-147	–	8.E−05	8.E−05	–	3.E+06	3.E+06	/St/St
Nd-136	–	2.E−05	2.E−05	–	9.E+05	8.E+05	/St/St
Nd-138	–	3.E−06	2.E−06	–	1.E+05	8.E+04	/St/St
Nd-139m	–	7.E−06	6.E−06	–	3.E+05	2.E+05	/St/St
Nd-139	–	1.E−04	1.E−04	–	5.E+06	4.E+06	/St/St
Nd-141	–	3.E−04	3.E−04	–	1.E+07	9.E+06	/St/St
Nd-147	–	4.E−07	3.E−07	–	2.E+04	1.E+04	/St/St
Nd-149	–	1.E−05	1.E−05	–	4.E+05	4.E+05	/St/St
Nd-151	–	8.E−05	8.E−05	–	3.E+06	3.E+06	/St/St
Pm-141	–	8.E−05	7.E−05	–	3.E+06	3.E+06	/St/St
Pm-143	–	3.E−07	3.E−07	–	9.E+03	1.E+04	/St/St
Pm-144	–	5.E−08	5.E−08	–	2.E+03	2.E+03	/St/St
Pm-145	–	7.E−08	8.E−08	–	3.E+03	3.E+03	/BS/St

Radionuclide	Inhaled air-lung retention class [3] µCi/ml			Inhaled air-lung retention class [3] Bq/m [3]			Stochastic or organ [1]
	D	W	Y	D	W	Y	(D/ W/ Y)
Pm-146	–	2.E–08	2.E–08	–	8.E+02	7.E+02	/St/St
Pm-147	–	6.E–08	6.E–08	–	2.E+03	2.E+03	/BS/St
Pm-148m	–	1.E–07	1.E–07	–	5.E+03	5.E+03	/St/St
Pm-148	–	2.E–07	2.E–07	–	8.E+03	8.E+03	/St/St
Pm-149	–	8.E–07	8.E–07	–	3.E+04	3.E+04	/St/St
Pm-150	–	8.E–06	7.E–06	–	3.E+05	3.E+05	/St/St
Pm-151	–	2.E–06	1.E–06	–	6.E+04	5.E+04	/St/St
Sm-141m	–	4.E–05	–	–	2.E+06	–	/St/
Sm-141	–	7.E–05	–	–	3.E+06	–	/St/
Sm-142	–	1.E–05	–	–	4.E+05	–	/St/
Sm-145	–	2.E–07	–	–	8.E+03	–	/St/
Sm-146	–	1.E–11	–	–	6.E–01	–	/BS/
Sm-147	–	2.E–11	–	–	6.E–01	–	/BS/
Sm-151	–	4.E–08	–	–	2.E+03	–	/BS/
Sm-153	–	1.E–06	–	–	4.E+04	–	/St/
Sm-155	–	9.E–05	–	–	3.E+06	–	/St/
Sm-156	–	4.E–06	–	–	1.E+05	–	/St/
Eu-145	–	8.E–07	–	–	3.E+04	–	/St/
Eu-146	–	5.E–07	–	–	2.E+04	–	/St/
Eu-147	–	7.E–07	–	–	3.E+04	–	/St/
Eu-148	–	2.E–07	–	–	6.E+03	–	/St/
Eu-149	–	1.E–06	–	–	5.E+04	–	/St/
Eu-150 (12 h)	–	3.E–06	–	–	1.E+05	–	/St/
Eu-150 (34 yr)	–	8.E–09	–	–	3.E+02	–	/St/
Eu-152m	–	3.E–06	–	–	1.E+05	–	/St/
Eu-152	–	1.E–08	–	–	4.E+02	–	/St/
Eu-154	–	8.E–09	–	–	3.E+02	–	/St/
Eu-155	–	4.E–08	–	–	1.E+03	–	/BS/
Eu-156	–	2.E–07	–	–	7.E+03	–	/St/
Eu-157	–	2.E–06	–	–	7.E+04	–	/St/
Eu-158	–	2.E–05	–	–	9.E+05	–	/St/
Gd-145	7.E–05	7.E–05	–	2.E+06	3.E+06	–	St/St/
Gd-146	5.E–08	1.E–07	–	2.E+03	4.E+03	–	St/St/
Gd-147	2.E–06	2.E–06	–	6.E+04	5.E+04	–	St/St/
Gd-148	3.E–12	1.E–11	–	1.E–01	5.E–01	–	BS/BS/
Gd-149	9.E–07	1.E–06	–	3.E+04	4.E+04	–	St/St/
Gd-151	2.E–07	5.E–07	–	6.E+03	2.E+04	–	BS/St/
Gd-152	4.E–12	2.E–11	–	2.E–01	6.E–01	–	BS/BS/
Gd-153	6.E–08	3.E–07	–	2.E+03	9.E+03	–	BS/St/
Gd-159	3.E–06	2.E–06	–	1.E+05	9.E+04	–	St/St/
Tb-147	–	1.E–05	–	–	5.E+05	–	/St/
Tb-149	–	3.E–07	–	–	1.E+04	–	/St/
Tb-150	–	9.E–06	–	–	3.E+05	–	/St/
Tb-151	–	4.E–06	–	–	1.E+05	–	/St/
Tb-153	–	3.E–06	–	–	1.E+05	–	/St/
Tb-154	–	2.E–06	–	–	7.E+04	–	/St/
Tb-155	–	3.E–06	–	–	1.E+05	–	/St/
Tb-156m (24 h)	–	3.E–06	–	–	1.E+05	–	/St/
Tb-156m (5 h)	–	1.E–05	–	–	4.E+05	–	/St/
Tb-156	–	6.E–07	–	–	2.E+04	–	/St/
Tb-157	–	1.E–07	–	–	5.E+03	–	/BS/
Tb-158	–	8.E–09	–	–	3.E+02	–	/St/
Tb-160	–	1.E–07	–	–	4.E+03	–	/St/
Tb-161	–	7.E–07	–	–	2.E+04	–	/St/
Dy-155	–	1.E–05	–	–	4.E+05	–	/St/
Dy-157	–	3.E–05	–	–	1.E+06	–	/St/
Dy-159	–	1.E–06	–	–	4.E+04	–	/St/
Dy-165	–	2.E–05	–	–	7.E+05	–	/St/
Dy-166	–	3.E–07	–	–	1.E+04	–	/St/
Ho-155	–	7.E–05	–	–	2.E+06	–	/St/
Ho-157	–	6.E–04	–	–	2.E+07	–	/St/
Ho-159	–	4.E–04	–	–	2.E+07	–	/St/
Ho-161	–	2.E–04	–	–	7.E+06	–	/St/
Ho-162m	–	1.E–04	–	–	4.E+06	–	/St/
Ho-162	–	1.E–03	–	–	4.E+07	–	/St/
Ho-164m	–	1.E–04	–	–	5.E+06	–	/St/
Ho-164	–	3.E–04	–	–	1.E+07	–	/St/
Ho-166m	–	3.E–09	–	–	1.E+02	–	/St/
Ho-166	–	7.E–07	–	–	3.E+04	–	/St/
Ho-167	–	2.E–05	–	–	9.E+05	–	/St/

Radionuclide	Inhaled air-lung retention class [3] µCi/ml			Inhaled air-lung retention class [3] Bq/m [3]			Stochastic or organ [1]
	D	W	Y	D	W	Y	(D/ W/ Y)
Er-161	–	3.E−05	–	–	1.E+06	–	/St/
Er-165	–	8.E−05	–	–	3.E+06	–	/St/
Er-169	–	1.E−06	–	–	4.E+04	–	/St/
Er-171	–	4.E−06	–	–	2.E+05	–	/St/
Er-172	–	6.E−07	–	–	2.E+04	–	/St/
Tm-162	–	1.E−04	–	–	4.E+06	–	/St/
Tm-166	–	6.E−06	–	–	2.E+05	–	/St/
Tm-167	–	8.E−07	–	–	3.E+04	–	/St/
Tm-170	–	9.E−08	–	–	3.E+03	–	/St/
Tm-171	–	1.E−07	–	–	5.E+03	–	/BS/
Tm-172	–	5.E−07	–	–	2.E+04	–	/St/
Tm-173	–	5.E−06	–	–	2.E+05	–	/St/
Tm-175	–	1.E−04	–	–	4.E+06	–	/St/
Yb-162	–	1.E−04	1.E−04	–	5.E+06	4.E+06	/St/St
Yb-166	–	8.E−07	8.E−07	–	3.E+04	3.E+04	/St/St
Yb-167	–	3.E−04	3.E−04	–	1.E+07	1.E+07	/St/St
Yb-169	–	3.E−07	3.E−07	–	1.E+04	1.E+04	/St/St
Yb-175	–	1.E−06	1.E−06	–	5.E+04	5.E+04	/St/St
Yb-177	–	2.E−05	2.E−05	–	8.E+05	7.E+05	/St/St
Yb-178	–	2.E−05	1.E−05	–	6.E+05	6.E+05	/St/St
Lu-169	–	2.E−06	2.E−06	–	7.E+04	7.E+04	/St/St
Lu-170	–	9.E−07	8.E−07	–	3.E+04	3.E+04	/St/St
Lu-171	–	8.E−07	8.E−07	–	3.E+04	3.E+04	/St/St
Lu-172	–	5.E−07	5.E−07	–	2.E+04	2.E+04	/St/St
Lu-173	–	1.E−07	1.E−07	–	4.E+03	4.E+03	/BS/St
Lu-174m	–	1.E−07	9.E−08	–	4.E+03	3.E+03	/BS/St
Lu-174	–	5.E−08	7.E−08	–	2.E+03	2.E+03	/BS/St
Lu-176m	–	1.E−05	1.E−05	–	4.E+05	4.E+05	/St/St
Lu-176	–	2.E−09	3.E−09	–	7.E+01	1.E+02	/BS/St
Lu-177m	–	5.E−08	3.E−08	–	2.E+03	1.E+03	/BS/St
Lu-177	–	9.E−07	9.E−07	–	3.E+04	3.E+04	/St/St
Lu-178m	–	8.E−05	7.E−05	–	3.E+06	3.E+06	/St/St
Lu-178	–	5.E−05	5.E−05	–	2.E+06	2.E+06	/St/St
Lu-179	–	8.E−06	6.E−06	–	3.E+05	2.E+05	/St/St
Hf-170	2.E−06	2.E−06	–	9.E+04	7.E+04	–	St/St/
Hf-172	4.E−09	2.E−08	–	1.E+02	6.E+02	–	BS/BS/
Hf-173	5.E−06	5.E−06	–	2.E+05	2.E+05	–	St/St/
Hf-175	4.E−07	5.E−07	–	2.E+04	2.E+04	–	BS/St/
Hf-177m	2.E−05	4.E−05	–	9.E+05	1.E+06	–	St/St/
Hf-178m	6.E−10	2.E−09	–	2.E+01	8.E+01	–	BS/BS/
Hf-179m	1.E−07	3.E−07	–	5.E+03	9.E+03	–	BS/St/
Hf-180m	9.E−06	1.E−05	–	3.E+05	4.E+05	–	St/St/
Hf-181	7.E−08	2.E−07	–	3.E+03	7.E+03	–	BS/St/
Hf-182m	4.E−05	6.E−05	–	1.E+06	2.E+06	–	St/St/
Hf-182	3.E−10	1.E−09	–	1.E+01	5.E+01	–	BS/BS/
Hf-183	2.E−05	2.E−05	–	7.E+05	8.E+05	–	St/St/
Hf-184	3.E−06	3.E−06	–	1.E+05	1.E+05	–	St/St/
Ta-172	–	5.E−05	4.E−05	–	2.E+06	2.E+06	/St/St
Ta-173	–	8.E−06	7.E−06	–	3.E+05	3.E+05	/St/St
Ta-174	–	4.E−05	4.E−05	–	1.E+06	1.E+06	/St/St
Ta-175	–	7.E−06	6.E−06	–	3.E+05	2.E+05	/St/St
Ta-176	–	5.E−06	5.E−06	–	2.E+05	2.E+05	/St/St
Ta-177	–	8.E−06	7.E−06	–	3.E+05	3.E+05	/St/St
Ta-178	–	4.E−05	3.E−05	–	1.E+06	1.E+06	/St/St
Ta-179	–	2.E−06	4.E−07	–	8.E+04	1.E+04	/St/St
Ta-180m	–	3.E−05	2.E−05	–	1.E+06	9.E+05	/St/St
Ta-180	–	2.E−07	1.E−08	–	7.E+03	4.E+02	/St/St
Ta-182m	–	2.E−04	2.E−04	–	8.E+06	6.E+06	/St/St
Ta-182	–	1.E−07	6.E−08	–	5.E+03	2.E+03	/St/St
Ta-183	–	5.E−07	4.E−07	–	2.E+04	2.E+04	/St/St
Ta-184	–	2.E−06	2.E−06	–	8.E+04	7.E+04	/St/St
Ta-185	–	3.E−05	3.E−05	–	1.E+06	1.E+06	/St/St
Ta-186	–	1.E−04	9.E−05	–	4.E+06	3.E+06	/St/St
W-176	2.E−05	–	–	8.E+05	–	–	St/ /
W-177	4.E−05	–	–	1.E+06	–	–	St/ /
W-178	8.E−06	–	–	3.E+05	–	–	St/ /
W-179	7.E−04	–	–	3.E+07	–	–	St/ /
W-181	1.E−05	–	–	5.E+05	–	–	St/ /
W-185	3.E−06	–	–	1.E+05	–	–	St/ /
W-187	4.E−06	–	–	2.E+05	–	–	St/ /

Radionuclide	Inhaled air-lung retention class [3] µCi/ml			Inhaled air-lung retention class [3] Bq/m [3]			Stochastic or organ [1]
	D	W	Y	D	W	Y	(D/ W/ Y)
W-188	5.E−07	–	–	2.E+04	–	–	St/ /
Re-177	1.E−04	2.E−04	–	4.E+06	5.E+06	–	St/St/
Re-178	1.E−04	1.E−04	–	4.E+06	4.E+06	–	St/St/
Re-181	4.E−06	4.E−06	–	1.E+05	1.E+05	–	St/St/
Re-182 (64 h)	1.E−06	9.E−07	–	4.E+04	3.E+04	–	St/St/
Re-182 (12 h)	5.E−06	6.E−06	–	2.E+05	2.E+05	–	St/St/
Re-184m	1.E−06	2.E−07	–	5.E+04	7.E+03	–	St/St/
Re-184	2.E−06	6.E−07	–	6.E+04	2.E+04	–	St/St/
Re-186m	7.E−07	6.E−08	–	3.E+04	2.E+03	–	SW/St/
Re-186	1.E−06	7.E−07	–	5.E+04	3.E+04	–	St/St/
Re-187	3.E−04	4.E−05	–	1.E+07	2.E+06	–	SW/St/
Re-188m	6.E−05	6.E−05	–	2.E+06	2.E+06	–	St/St/
Re-188	1.E−06	1.E−06	–	4.E+04	4.E+04	–	St/St/
Re-189	2.E−06	2.E−06	–	8.E+04	7.E+04	–	St/St/
Os-180	2.E−04	2.E−04	2.E−04	6.E+06	8.E+06	7.E+06	St/St/St
Os-181	2.E−05	2.E−05	2.E−05	7.E+05	7.E+05	7.E+05	St/St/St
Os-182	2.E−06	2.E−06	2.E−06	9.E+04	7.E+04	6.E+04	St/St/St
Os-185	2.E−07	3.E−07	3.E−07	8.E+03	1.E+04	1.E+04	St/St/St
Os-189m	1.E−04	9.E−05	7.E−05	4.E+06	3.E+06	3.E+06	St/St/St
Os-191m	1.E−05	9.E−06	7.E−06	4.E+05	3.E+05	3.E+05	St/St/St
Os-191	9.E−07	7.E−07	6.E−07	3.E+04	3.E+04	2.E+04	St/St/St
Os-193	2.E−06	1.E−06	1.E−06	7.E+04	5.E+04	4.E+04	St/St/St
Os-194	2.E−08	2.E−08	3.E−09	7.E+02	9.E+02	1.E+02	St/St/St
Ir-182	6.E−05	6.E−05	5.E−05	2.E+06	2.E+06	2.E+06	St/St/St
Ir-184	1.E−05	1.E−05	1.E−05	4.E+05	5.E+05	4.E+05	St/St/St
Ir-185	5.E−06	5.E−06	4.E−06	2.E+05	2.E+05	2.E+05	St/St/St
Ir-186	3.E−06	3.E−06	2.E−06	1.E+05	1.E+05	9.E+04	St/St/St
Ir-187	1.E−05	1.E−05	1.E−05	5.E+05	5.E+05	4.E+05	St/St/St
Ir-188	2.E−06	2.E−06	1.E−06	7.E+04	6.E+04	5.E+04	St/St/St
Ir-189	2.E−06	2.E−06	2.E−06	7.E+04	6.E+04	6.E+04	St/St/St
Ir-190m	8.E−05	9.E−05	8.E−05	3.E+06	3.E+06	3.E+06	St/St/St
Ir-190	4.E−07	4.E−07	4.E−07	1.E+04	2.E+04	1.E+04	St/St/St
Ir-192m	4.E−08	9.E−08	6.E−09	1.E+03	3.E+03	2.E+02	St/St/St
Ir-192	1.E−07	2.E−07	9.E−08	4.E+03	6.E+03	3.E+03	St/St/St
Ir-194m	4.E−08	7.E−08	4.E−08	2.E+03	3.E+03	2.E+03	St/St/St
Ir-194	1.E−06	8.E−07	8.E−07	5.E+04	3.E+04	3.E+04	St/St/St
Ir-195m	1.E−05	1.E−05	9.E−06	4.E+05	4.E+05	3.E+05	St/St/St
Ir-195	2.E−05	2.E−05	2.E−05	6.E+05	8.E+05	7.E+05	St/St/St
Pt-186	2.E−05	–	–	6.E+05	–	–	St/ /
Pt-188	7.E−07	–	–	3.E+04	–	–	St/ /
Pt-189	1.E−05	–	–	4.E+05	–	–	St/ /
Pt-191	3.E−06	–	–	1.E+05	–	–	St/ /
Pt-193m	2.E−06	–	–	9.E+04	–	–	St/ /
Pt-193	1.E−05	–	–	4.E+05	–	–	St/ /
Pt-195m	2.E−06	–	–	7.E+04	–	–	St/ /
Pt-197m	2.E−05	–	–	7.E+05	–	–	St/ /
Pt-197	4.E−06	–	–	2.E+05	–	–	St/ /
Pt-199	6.E−05	–	–	2.E+06	–	–	St/ /
Pt-200	1.E−06	–	–	5.E+04	–	–	St/ /
Au-193	1.E−05	8.E−06	8.E−06	4.E+05	3.E+05	3.E+05	St/St/St
Au-194	3.E−06	2.E−06	2.E−06	1.E+05	9.E+04	8.E+04	St/St/St
Au-195	5.E−06	6.E−07	2.E−07	2.E+05	2.E+04	6.E+03	St/St/St
Au-198m	1.E−06	5.E−07	5.E−07	4.E+04	2.E+04	2.E+04	St/St/St
Au-198	2.E−06	7.E−07	7.E−07	6.E+04	3.E+04	3.E+04	St/St/St
Au-199	4.E−06	2.E−06	2.E−06	1.E+05	6.E+04	6.E+04	St/St/St
Au-200m	1.E−06	1.E−06	1.E−06	5.E+04	4.E+04	4.E+04	St/St/St
Au-200	3.E−05	3.E−05	3.E−05	1.E+06	1.E+06	1.E+06	St/St/St
Au-201	9.E−05	1.E−04	9.E−05	3.E+06	4.E+06	4.E+06	St/St/St
Hg-193m (Org)	6.E−06	–	–	2.E+05	–	–	St/ /
Hg-193m (Inorg)	4.E−06	3.E−06	–	1.E+05	1.E+05	–	St/St/
Hg-193m (Vapor)	–	4.E−06	–	–	1.E+05	–	/St/
Hg-193 (Org)	3.E−05	–	–	1.E+06	–	–	St/ /
Hg-193 (Inorg)	2.E−05	2.E−05	–	7.E+05	6.E+05	–	St/St/
Hg-193 (Vapor)	–	1.E−05	–	–	5.E+05	–	/St/
Hg-194 (Org)	1.E−08	–	–	4.E+02	–	–	St/ /
Hg-194 (Inorg)	2.E−08	5.E−08	–	7.E+02	2.E+03	–	St/St/
Hg-194 (Vapor)	–	1.E−08	–	–	5.E+02	–	/St/
Hg-195m (Org)	3.E−06	–	–	9.E+04	–	–	St/ /
Hg-195m (Inorg)	2.E−06	2.E−06	–	8.E+04	6.E+04	–	St/St/
Hg-195m (Vapor)	–	-2.E−06	–	–	6.E+04	–	/St/

Radionuclide	Inhaled air-lung retention class [3] µCi/ml			Inhaled air-lung retention class [3] Bq/m [3]			Stochastic or organ [1]
	D	W	Y	D	W	Y	(D/ W/ Y)
Hg-195 (Org)	2.E-05	–	–	7.E+05	–	–	St/ /
Hg-195 (Inorg)	1.E-05	1.E-05	–	5.E+05	5.E+05	–	St/St/
Hg-195 (Vapor)	–	1.E-05	–	–	5.E+05	–	/St/
Hg-197m (Org)	4.E-06	–	–	1.E+05	–	–	St/ /
Hg-197m (Inorg)	3.E-06	2.E-06	–	1.E+05	8.E+04	–	St/St/
Hg-197m (Vapor)	–	2.E-06	–	–	8.E+04	–	/St/
Hg-197 (Org)	6.E-06	–	–	2.E+05	–	–	St/ /
Hg-197 (Inorg)	5.E-06	4.E-06	–	2.E+05	1.E+05	–	St/St/
Hg-197 (Vapor)	–	3.E-05	–	–	1.E+05	–	/St/
Hg-199m (Org)	7.E-05	–	–	3.E+06	–	–	St/ /
Hg-199m (Inorg)	6.E-05	7.E-05	–	2.E+06	3.E+06	–	St/St/
Hg-199m (Vapor)	–	3.E-05	–	–	1.E+06	–	/St/
Hg-203 (Org)	3.E-07	–	–	1.E+04	–	–	St/ /
Hg-203 (Inorg)	5.E-07	5.E-07	–	2.E+04	2.E+04	–	St/St/
Hg-203 (Vapor)	–	3.E-07	–	–	1.E+04	–	/St/
Tl-194m	6.E-05	–	–	2.E+06	–	–	St/ /
Tl-194	3.E-04	–	–	9.E+06	–	–	St/ /
Tl-195	5.E-05	–	–	2.E+06	–	–	St/ /
Tl-197	5.E-05	–	–	2.E+06	–	–	St/ /
Tl-198m	2.E-05	–	–	9.E+05	–	–	St/ /
Tl-198	1.E-05	–	–	5.E+05	–	–	St/ /
Tl-199	3.E-05	–	–	1.E+06	–	–	St/ /
Tl-200	5.E-06	–	–	2.E+05	–	–	St/ /
Tl-201	9.E-06	–	–	3.E+05	–	–	St/ /
Tl-202	2.E-06	–	–	8.E+04	–	–	St/ /
Tl-204	9.E-07	–	–	3.E+04	–	–	St/ /
Pb-195m	8.E-05	–	–	3.E+06	–	–	St/ /
Pb-198	3.E-05	–	–	1.E+06	–	–	St/ /
Pb-199	3.E-05	–	–	1.E+06	–	–	St/ /
Pb-200	3.E-06	–	–	1.E+05	–	–	St/ /
Pb-201	9.E-06	–	–	3.E+05	–	–	St/ /
Pb-202m	1.E-05	–	–	4.E+05	–	–	St/ /
Pb-202	2.E-08	–	–	8.E+02	–	–	St/ /
Pb-203	4.E-06	–	–	2.E+05	–	–	St/ /
Pb-205	6.E-07	–	–	2.E+04	–	–	St/ /
Pb-209	2.E-05	–	–	9.E+05	–	–	St/ /
Pb-210	1.E-10	–	–	4.E+00	–	–	BS/ /
Pb-211	3.E-07	–	–	1.E+04	–	–	St/ /
Pb-212	1.E-08	–	–	5.E+02	–	–	St/ /
Pb-214	3.E-07	–	–	1.E+04	–	–	St/ /
Bi-200	3.E-05	4.E-05	–	1.E+06	2.E+06	–	St/St/
Bi-201	1.E-05	2.E-05	–	4.E+05	6.E+05	–	St/St/
Bi-202	2.E-05	3.E-05	–	6.E+05	1.E+06	–	St/St/
Bi-203	3.E-06	2.E-06	–	1.E+05	9.E+04	–	St/St/
Bi-205	1.E-06	5.E-07	–	4.E+04	2.E+04	–	St/St/
Bi-206	6.E-07	4.E-07	–	2.E+04	1.E+04	–	St/St/
Bi-207	7.E-07	2.E-07	–	3.E+04	5.E+03	–	St/St/
Bi-210m	2.E-09	3.E-10	–	7.E+01	1.E+01	–	K /St/
Bi-210	1.E-07	1.E-08	–	4.E+03	4.E+02	–	K /St/
Bi-212	1.E-07	1.E-07	–	4.E+03	4.E+03	–	St/St/
Bi-213	1.E-07	2.E-07	–	5.E+03	5.E+03	–	St/St/
Bi-214	3.E-07	4.E-07	–	1.E+04	1.E+04	–	St/St/
Po-203	3.E-05	4.E-05	–	1.E+06	1.E+06	–	St/St/
Po-205	2.E-05	3.E-05	–	6.E+05	1.E+06	–	St/St/
Po-207	1.E-05	1.E-05	–	4.E+05	4.E+05	–	St/St/
Po-210	3.E-10	3.E-10	–	1.E+01	1.E+01	–	E /St/
At-207	1.E-06	9.E-07	–	4.E+04	3.E+04	–	St/St/
At-211	3.E-08	2.E-08	–	1.E+03	8.E+02	–	St/St/
Rn-220	8.E-09 [4]	—[4]	—[4]	3.E+02 [4]	—[4]	—[4]	—[4]
Rn-222	3.E-08 [4]	—[4]	—[4]	1.E+03 [4]	—[4]	—[4]	—[4]
Fr-222	2.E-07	–	–	7.E+03	–	–	St/ /
Fr-223	3.E-07	–	–	1.E+04	–	–	St/ /
Ra-223	–	3.E-10	–	–	1.E+01	–	/St/
Ra-224	–	7.E-10	–	–	3.E+01	–	/St/
Ra-225	–	3.E-10	–	–	1.E+01	–	/St/
Ra-226	–	3.E-10	–	–	1.E+01	–	/St/
Ra-227	–	6.E-06	–	–	2.E+05	–	/BS/
Ra-228	–	5.E-10	–	–	2.E+01	–	/St/
Ac-224	1.E-08	2.E-08	2.E-08	4.E+02	8.E+02	7.E+02	BS/St/St
Ac-225	1.E-10	3.E-10	3.E-10	4.E+00	1.E+01	1.E+01	BS/St/St

Radionuclide	Inhaled air-lung retention class [3] µCi/ml			Inhaled air-lung retention class [3] Bq/m [3]			Stochastic or organ [1]
	D	W	Y	D	W	Y	(D/ W/ Y)
Ac-226	1.E−09	2.E−09	2.E−09	5.E+01	8.E+01	7.E+01	BS/St/St
Ac-227	2.E−13	7.E−13	2.E−12	7.E−03	3.E−02	6.E−02	BS/BS/St
Ac-228	4.E−09	2.E−08	2.E−08	2.E+02	6.E+02	7.E+02	BS/BS/St
Th-226	–	7.E−08	6.E−08	–	2.E+03	2.E+03	/St/St
Th-227	–	1.E−10	1.E−10	–	5.E+00	5.E+00	/St/St
Th-228	–	4.E−12	7.E−12	–	2.E−01	3.E−01	/BS/St
Th-229	–	4.E−13	1.E−12	–	1.E−02	4.E−02	/BS/BS
Th-230	–	3.E−12	7.E−12	–	9.E−02	2.E−01	/BS/BS
Th-231	–	3.E−06	3.E−06	–	1.E+05	1.E+05	/St/St
Th-232	–	5.E−13	1.E−12	–	2.E−02	4.E−02	/BS/BS
Th-234	–	9.E−08	6.E−08	–	3.E+03	2.E+03	/St/St
Pa-227	–	5.E−08	4.E−08	–	2.E+03	2.E+03	/St/St
Pa-228	–	5.E−09	5.E−09	–	2.E+02	2.E+02	/BS/St
Pa-230	–	2.E−09	1.E−09	–	7.E+01	5.E+01	/St/St
Pa-231	–	7.E−13	2.E−12	–	2.E−02	6.E−02	/BS/BS
Pa-232	–	9.E−09	2.E−08	–	3.E+02	9.E+02	/BS/BS
Pa-233	–	3.E−07	2.E−07	–	1.E+04	9.E+03	/St/St
Pa-234	–	3.E−06	3.E−06	–	1.E+05	1.E+05	/St/St
U-230	2.E−10	1.E−10	1.E−10	6.E+00	5.E+00	4.E+00	BS/St/St
U-231	3.E−06	2.E−06	2.E−06	1.E+05	9.E+04	7.E+04	St/St/St
U-232	9.E−11	2.E−10	3.E−12	3.E+00	6.E+00	1.E−01	BS/St/St
U-233	5.E−10	3.E−10	2.E−11	2.E+01	1.E+01	6.E−01	BS/St/St
U-234	5.E−10	3.E−10	2.E−11	2.E+01	1.E+01	6.E−01	BS/St/St
U-235	6.E−10	3.E−10	2.E−11	2.E+01	1.E+01	6.E−01	BS/St/St
U-236	6.E−10	3.E−10	2.E−11	2.E+01	1.E+01	6.E−01	BS/St/St
U-237	1.E−06	7.E−07	6.E−07	4.E+04	3.E+04	2.E+04	St/St/St
U-238	6.E−10	3.E−10	2.E−11	2.E+01	1.E+01	6.E−01	BS/St/St
U-239	8.E−05	7.E−05	6.E−05	3.E+06	3.E+06	2.E+06	St/St/St
U-240	2.E−06	1.E−06	1.E−06	6.E+04	4.E+04	4.E+04	St/St/St
Np-232	–	1.E−06 [5]	–	–	4.E+04 [5]	–	/BS/
Np-233	–	1.E−03 [5]	–	–	5.E+07 [5]	–	/St/
Np-234	–	1.E−06 [5]	–	–	4.E+04 [5]	–	/St/
Np-235	–	5.E−07 [5]	–	–	2.E+04 [5]	–	/BS/
Np-236 (1.E+05 yr)	–	1.E−11 [5]	–	–	4.E−01 [5]	–	/BS/
Np-236 (22 h)	–	2.E−08 [5]	–	–	6.E+02 [5]	–	/BS/
Np-237	–	2.E−12 [5]	–	–	9.E−02 [5]	–	/BS/
Np-238	–	4.E−08 [5]	–	–	1.E+03 [5]	–	/BS/
Np-239	–	1.E−06 [5]	–	–	4.E+04 [5]	–	/St/
Np-240	–	3.E−05 [5]	–	–	1.E+06 [5]	–	/St/
Pu-234	–	9.E−08 [5]	8.E−08 [5]	–	3.E+03 [5]	3.E+03 [5]	/St/St
Pu-235	–	1.E−03 [5]	1.E−03 [5]	–	5.E+07 [5]	4.E+07 [5]	/St/St
Pu-236	–	7.E−12 [5]	1.E−11 [5]	–	3.E−01 [5]	6.E−01 [5]	/BS/St
Pu-237	–	1.E−06 [5]	1.E−06 [5]	–	5.E+04 [5]	5.E+04 [5]	/St/St
Pu-238	–	3.E−12 [5]	7.E−12 [5]	–	9.E−02 [5]	3.E−01 [5]	/BS/BS
Pu-239	–	2.E−12 [5]	6.E−12 [5]	–	8.E−02 [5]	2.E−01 [5]	/BS/BS
Pu-240	–	2.E−12 [5]	6.E−12 [5]	–	8.E−02 [5]	2.E−01 [5]	/BS/BS
Pu-241	–	1.E−10 [5]	3.E−10 [5]	–	4.E+00 [5]	1.E+01 [5]	/BS/BS
Pu-242	–	2.E−12 [5]	6.E−12 [5]	–	9.E−02 [5]	2.E−01 [5]	/BS/BS
Pu-243	–	1.E−05 [5]	1.E−05 [5]	–	5.E+05 [5]	6.E+05 [5]	/St/St
Pu-244	–	2.E−12 [5]	6.E−12 [5]	–	9.E−02 [5]	2.E−01 [5]	/BS/BS
Pu-245	–	2.E−06 [5]	2.E−06 [5]	–	7.E+04 [5]	6.E+04 [5]	/St/St
Am-237	–	1.E−04 [5]	–	–	4.E+06 [5]	–	/St/
Am-238	–	1.E−06 [5]	–	–	4.E+04 [5]	–	/BS/
Am-239	–	5.E−06 [5]	–	–	2.E+05 [5]	–	/St/
Am-240	–	1.E−06 [5]	–	–	4.E+04 [5]	–	/St/
Am-241	–	2.E−12 [5]	–	–	8.E−02 [5]	–	/BS/
Am-242m	–	2.E−12 [5]	–	–	8.E−02 [5]	–	/BS/
Am-242	–	3.E−08 [5]	–	–	1.E+03 [5]	–	/BS/
Am-243	–	2.E−12 [5]	–	–	8.E−02 [5]	–	/BS/
Am-244m	–	2.E−06 [5]	–	–	6.E+04 [5]	–	/BS/
Am-244	–	7.E−08 [5]	–	–	3.E+03 [5]	–	/BS/
Am-245	–	3.E−05 [5]	–	–	1.E+06 [5]	–	/St/
Am-246m	–	7.E−05 [5]	–	–	3.E+06 [5]	–	/St/
Am-246	–	4.E−05 [5]	–	–	2.E+06 [5]	–	/St/
Cm-238	–	4.E−07 [5]	–	–	2.E+04 [5]	–	/St/
Cm-240	–	2.E−10 [5]	–	–	8.E+00 [5]	–	/BS/
Cm-241	–	9.E−09 [5]	–	–	4.E+02 [5]	–	/BS/
Cm-242	–	1.E−10 [5]	–	–	4.E+00 [5]	–	/BS/
Cm-243	–	3.E−12 [5]	–	–	1.E−01 [5]	–	/BS/
Cm-244	–	4.E−12 [5]	–	–	2.E−01 [5]	–	/BS/

Radionuclide	Inhaled air-lung retention class [3] µCi/ml			Inhaled air-lung retention class [3] Bq/m [3]			Stochastic or organ [1]
	D	W	Y	D	W	Y	(D/ W/ Y)
Cm-245	–	2.E–12 [5]	–	–	8.E–02 [5]	–	/BS/
Cm-246	–	2.E–12 [5]	–	–	8.E–02 [5]	–	/BS/
Cm-247	–	2.E–12 [5]	–	–	9.E–02 [5]	–	/BS/
Cm-248	–	6.E–13 [5]	–	–	2.E–02 [5]	–	/BS/
Cm-249	–	6.E–06 [5]	–	–	2.E+05 [5]	–	/BS/
Bk-245	–	5.E–07	–	–	2.E+04	–	/St/
Bk-246	–	1.E–06	–	–	5.E+04	–	/St/
Bk-247	–	2.E–12	–	–	8.E–02	–	/BS/
Bk-249	–	9.E–10	–	–	3.E+01	–	/BS/
Bk-250	–	2.E–07	–	–	7.E+03	–	/BS/
Cf-244	–	2.E–07 [5]	2.E–07 [5]	–	9.E+03 [5]	9.E+03 [5]	/St/St
Cf-246	–	4.E–09 [5]	4.E–09 [5]	–	2.E+02 [5]	1.E+02 [5]	/St/St
Cf-248	–	4.E–11 [5]	5.E–11 [5]	–	1.E+00 [5]	2.E+00 [5]	/BS/St
Cf-249	–	2.E–12 [5]	6.E–12 [5]	–	8.E–02 [5]	2.E–01 [5]	/BS/BS
Cf-250	–	5.E–12 [5]	1.E–11 [5]	–	2.E–01 [5]	4.E–01 [5]	/BS/St
Cf-251	–	2.E–12 [5]	5.E–12 [5]	–	8.E–02 [5]	2.E–01 [5]	/BS/BS
Cf-252	–	1.E–11 [5]	2.E–11 [5]	–	4.E–01 [5]	6.E–01 [5]	/BS/St
Cf-253	–	8.E–10 [5]	7.E–10 [5]	–	3.E+01 [5]	3.E+01 [5]	/St/St
Cf-254	–	9.E–12 [5]	7.E–12 [5]	–	3.E–01 [5]	3.E–01 [5]	/St/St
Es-250	–	3.E–07	–	–	1.E+04	–	/BS/
Es-251	–	4.E–07	–	–	2.E+04	–	/BS/
Es-253	–	6.E–10	–	–	2.E+01	–	/St/
Es-254m	–	4.E–09	–	–	2.E+02	–	/St/
Es-254	–	4.E–11	–	–	2.E+00	–	/BS/
Fm-252	–	6.E–09	–	–	2.E+02	–	/St/
Fm-253	–	4.E–09	–	–	2.E+02	–	/St/
Fm-254	–	4.E–08	–	–	2.E+03	–	/St/
Fm-255	–	9.E–09	–	–	3.E+02	–	/St/
Fm-257	–	1.E–10	–	–	4.E+00	–	/E /
Md-257	–	4.E–08	–	–	2.E+03	–	/St/
Md-258	–	1.E–10	–	–	4.E+00	–	/BS/

Footnotes for Appendix A

[1] A determination of whether the DACs are controlled by stochastic (St) or nonstochastic (organ) dose, or if they both give the same result (E), for each lung retention class, is given in this column. The key to the organ notation for nonstochastic dose is: BS=Bone surface, K=Kidney, L=Liver, SW=Stomach wall, and T=Thyroid. A blank indicates that no calculations were performed for the lung retention class shown.

[2] The ICRP identifies tritiated water and carbon as having immediate uptake and distribution; therefore no solubility classes are designated. For the purposes of this table, the DAC values are shown as being constant, independent of solubility class. For tritiated water, the inhalation DAC values allow for an additional 50% absorption through the skin, as described in ICRP Publication No. 30: Limits for Intakes of Radionuclides by Workers. For elemental tritium, the DAC values are based solely on consideration of the dose-equivalent rate to the tissues of the lung from inhaled tritium gas contained within the lung, without absorption in the tissues.

[3] A dash indicates no values given for this data category.

[4] These values are appropriate for protection from radon combined with its short-lived daughters and are based on information given in ICRP Publication 32: Limits for Inhalation of Radon Daughters by Workers and Federal Guidance Report No. 11: Limiting Values of Radionuclide Intake and Air Concentrations, and Dose Conversion Factors for Inhalation, Submersion, and Ingestion (EPA 520/1–88–020). The values given are for 100% equilibrium concentration conditions of the radon daughters with the parent. To allow for an actual measured equilibrium concentration or a demonstrated equilibrium concentration, the values given in this table should be multiplied by the ratio (100%/actual %) or (100%/demonstrated %), respectively. Alternatively, the DAC values for Rn-220 and Rn-222 may be replaced by 1 WL* and 1/3 WL*, respectively, for appropriate limiting of daughter concentrations. Because of the dosimetric considerations for radon, no f_1 or lung clearance values are listed.

*A "Working Level" (WL) is any combination of short-lived radon daughters, in one liter of air without regard to the degree of equilibrium, that will result in the ultimate emission of 1.3 E+05 MeV of alpha energy.

[5] For the calculations, f_1 values were obtained from ICRP Publication 48: The Metabolism of Plutonium and Related Elements. It is assumed that the effective dose equivalents for inhalation are unchanged even though the f_1 values have changed. This is because the contribution to organ dose from inhalation is dependent mainly on transfer from lung to blood when f_1 values are small. Also, the gastrointestinal tract dose would be unchanged because the fraction of activity passing through the tract is $(1.0 - f_1)$.

Appendix B to Part 835—Alternative Absorption Factors and Lung Retention Classes for Specific Compounds

Alternative absorption factors and lung retention classes for specific compounds are listed by element in this appendix for cross-referencing with the inhalation DACs in appendix A to this part. The data shown in this appendix are listed by element in alphabetical order.

Element/symbol	Atomic No.	Compound	f_1	Lung retention class
Actinium/Ac	89	Oxides, hydroxides	1.E–03	Y
		Halides, nitrates	1.E–03	W
		All others	1.E–03	D
Aluminum/Al	13	Oxides, hydroxides, carbides, halides, nitrates, elemental form.	1.E–02	W

Element/symbol	Atomic No.	Compound	f_1	Lung retention class
		All others	1.E−02	D
Americium/Am	95	All forms	1.E−03	W
Antimony/Sb	51	Oxides, hydroxides, halides, sulphides, sulphates, nitrates	1.E−01	D
		All others	1.E−02	W
Arsenic/As	33	All forms	5.E−01	W
Astatine/At	85	All (as a halide)	1.E+00	W or D; dependent upon associated element.
Barium/Ba	56	All forms	1.E−01	D
Berkelium/Bk	97	All forms	5.E−04	W
Beryllium/Be	4	Oxides, halides, nitrates	5.E−03	Y
		All others	5.E−03	W
Bismuth/Bi	83	All except nitrates	5.E−02	W
		Nitrates	5.E−02	D
Bromine/Br	35	Bromides	1.E+00	W or D; dependent upon associated element.
Cadmium/Cd	48	Oxides, hydroxides	5.E−02	Y
		Sulphates, halides	5.E−02	W
		All others	5.E−02	D
Calcium/Ca	20	All forms	3.E−01	W
Californium/Cf	98	Oxides, hydroxides	1.E−03	Y
		All others	1.E−03	W
Carbon/C	6	Oxides [1]	–	D
		Organic (C–11)	1.E+00	W
		Organic (C–14)	1.E+00	W
Cerium/Ce	58	Oxides, hydroxides, fluorides	3.E−04	Y
		All others	3.E−04	W
Cesium/Cs	55	All forms	1.E+00	D
Chlorine/Cl	17	Chloride	1.E+00	W or D; dependent upon associated element.
Chromium/Cr	24	Oxides, hydroxides	1.E−01	Y
		Halides, nitrates	1.E−01	W
		All others	1.E−01	D
		Ingestion [2]		
		Trivalent	1.E−02	—
		Hexavalent	1.E−01	—
Cobalt/Co	27	Oxides, hydroxides, halides, nitrates	5.E−02	Y
		All others	5.E−02	W
		Ingestion only [2]	3.E−01	—
Copper/Cu	29	Oxides, hydroxides	5.E−01	Y
		Sulphites, halides, nitrates	5.E−01	W
		All others	5.E−01	D
Curium/Cm	96	All forms	1.E−03	W
Dysprosium/Dy	66	All forms	3.E−04	W
Einsteinium/Es	99	All forms	5.E−04	W
Erbium/Er	68	All forms	3.E−04	W
Europium/Eu	63	All forms	1.E−03	W
Fermium/Fm	100	All forms	5.E−04	W
Fluorine/F	9	Fluoride	1.E+00	Y, W, or D; dependent upon associated element.
Francium/Fr	87	All forms	1.E+00	D
Gadolinium/Gd	64	Oxides, hydroxides, fluorides	3.E−04	W
		All others	3.E−04	D
Gallium/Ga	31	Oxides, hydroxides, carbides, halides, nitrates	1.E−03	W
		All others	1.E−03	D
Germanium/Ge	32	Oxides, sulphides, halides	1.E+00	W
		All others	1.E+00	D
Gold/Au	79	Oxides, hydroxides	1.E−01	Y
		Halides, nitrates	1.E−01	W
		All others	1.E−01	D
Hafnium/Hf	72	Oxides, hydroxides, halides, carbides, nitrates	2.E−03	W
		All others	2.E−03	D
Holmium/Ho	67	All forms	3.E−04	W
Hydrogen/H	1	Water, elemental	1.E+00	—
Indium/In	49	Oxides, hydroxides, halides	2.E−02	W
		All others	2.E−02	D
Iodine/I	53	All forms	1.E+00	D
Iridium/Ir	77	Oxides, hydroxides	1.E−02	Y
		Halides, nitrates, metallic form	1.E−02	W
		All others	1.E−02	D
Iron/Fe	26	Oxides, hydroxides, halides	1.E−01	W
		All others	1.E−01	D
Lanthanum/La	57	Oxides, hydroxides	1.E−03	W
		All others	1.E−03	D

Element/symbol	Atomic No.	Compound	f_1	Lung retention class
Lead/Pb	82	All forms	2.E−01	D
Lutetium/Lu	71	Oxides, hydroxides, fluorides	3.E−04	Y
		All others	3.E−04	W
Magnesium/Mg	12	Oxides, hydroxides, carbides, halides, nitrates	5.E−01	W
		All others	5.E−01	D
Manganese/Mn	25	Oxides, hydroxides, halides, nitrates	1.E−01	W
		All others	1.E−01	D
Mendelevium/Md	101	All forms	5.E−04	W
Mercury/Hg	80	Oxides, hydroxides, halides, nitrates, sulphites	2.E−02	W
		Sulphates, elemental form	2.E−02	D
		Organic forms	1.E+00	D
		Vapor[1]	–	D
Molybdenum/Mo	42	Oxides, hydroxides, MoS_2	5.E−02	Y
		All others	8.E−01	D
		Ingestion[2]		
		MoS_2	5.E−02	—
		All Others	8.E−01	—
Neodymium/Nd	60	Oxides, hydroxides, carbides, fluorides	3.E−04	W
		All others	3.E−04	Y
Neptunium/Np	93	All forms	1.E−03	W
Nickel/Ni	28	Oxides, hydroxides	5.E−02	W
		All others (vapor)[1]	–	D
Niobium/Nb	41	Oxides, hydroxides	1.E−02	Y
		All others	1.E−02	W
Osmium/Os	76	Oxides, hydroxides	1.E−02	Y
		Halides, nitrates	1.E−02	W
		All others	1.E−02	D
Palladium/Pd	46	Oxides, hydroxides	5.E−03	Y
		Nitrates	5.E−03	W
		All others	5.E−03	D
Phosphorus/P	15	Phosphates	8.E−01	W or D; dependent upon associated element.
Platinum/Pt	78	All forms	1.E−02	D
Plutonium/Pu	94	Oxides, hydroxides	1.E−05	Y
		Nitrates	1.E−04	W
		All other	1.E−03	W
		[Note: Use same values for ingestion]		
Polonium/Po	84	Oxides, hydroxides, nitrates	1.E−01	W
		All others	1.E−01	D
Potassium/K	19	All forms	1.E+00	D
Praseodymium/Pr	59	Oxides, hydroxides, carbides, fluorides	3.E−04	Y
		All others	3.E−04	W
Promethium/Pm	61	Oxides, hydroxides, carbides, fluorides	3.E−04	Y
		All others	3.E−04	W
Protactinium/Pa	91	Oxides, hydroxides	1.E−03	Y
		All others	1.E−03	W
Radium/Ra	88	All forms	2.E−01	W
Rhenium/Re	75	Oxides, hydroxides, halides, nitrates	8.E−01	W
		All others	8.E−01	D
Rhodium/Rh	45	Oxides, hydroxides	5.E−02	Y
		Halides	5.E−02	W
		All others	5.E−02	D
Rubidium/Rb	37	All forms	1.E+00	D
Ruthenium/Ru	44	Oxides, hydroxides	5.E−02	Y
		Halides	5.E−02	W
		All others	5.E−02	D
Samarium/Sm	62	All forms	3.E−04	W
Scandium/Sc	21	All forms	1.E−04	Y
Selenium/Se	34	Oxides, hydroxides, carbides	8.E−01	W
		All others	8.E−01	D
		Ingestion only[2]	5.E−02	—
Silicon/Si	14	Ceramic forms	1.E−02	Y
		Oxides, hydroxides, carbides, nitrates	1.E−02	W
		All others	1.E−02	D
Silver/Ag	47	Oxides, hydroxides	5.E−02	Y
		Nitrates, sulphides	5.E−02	W
		All others, elemental form	5.E−02	D
Sodium/Na	11	All forms	1.E+00	D
Strontium/Sr	38	$SrTiO_3$	1.E−02	Y
		All others (soluble)	3.E−01	D
Sulfur/S	16	All inorganic	8.E−01	D
		Elemental form	8.E−01	W
		Gases	1.E+00	D

Element/symbol	Atomic No.	Compound	f_1	Lung retention class
		Ingestion[2]		
		All inorganic	1.E−01	—
Tantalum/Ta	73	Oxides, hydroxides, halides, carbides, nitrates, nitrides	1.E−03	Y
		All others	1.E−03	W
Technetium/Tc	43	Oxides, hydroxides, halides, nitrates	8.E−01	W
		All others	8.E−01	D
Tellurium/Te	52	Oxides, hydroxides, nitrates	2.E−01	W
		All others	2.E−01	D
Terbium/Tb	65	All forms	3.E−04	W
Thallium/Tl	81	All forms	1.E+00	D
Thorium/Th	90	Oxides, hydroxides	2.E−04	Y
		All others	2.E−04	W
Thulium/Tm	69	All forms	3.E−04	W
Tin/Sn	50	Oxides, hydroxides, halides, nitrates, sulphides, $Sn_3(PO_4)_4$.	2.E−02	W
		All others	2.E−02	D
Titanium/Ti	22	$SrTiO_3$	1.E−02	Y
		Oxides, hydroxides, carbides, halides, nitrates	1.E−02	W
		All others	1.E−02	D
Tungsten/W	74	*Ingestion*[2]		
		Tungstic acid	1.E−02	—
		All others	3.E−01	—
Uranium/U	92	UO_2, U_3O_8	2.E−03	Y
		UO_3, tetravalent compounds	5.E−02	W
		UF_6, uranyl compounds	5.E−02	D
Vanadium/V	23	Oxides, hydroxides, carbides, halides	1.E−02	W
		All others	1.E−02	D
Ytterbium/Yb	70	Oxides, hydroxides, fluorides	3.E−04	Y
		All others	3.E−04	W
Yttrium/Y	39	Oxides, hydroxides	1.E−04	Y
		All others	1.E−04	W
Zinc/Zn	30	All forms	5.E−01	Y
Zirconium/Zr	40	Carbides	2.E−03	Y
		Oxides, hydroxides, halides, nitrates	2.E−03	W
		All others	2.E−03	D

[1] A dash indicates no data for the value shown.
[2] For ingestion, no lung retention classes are listed.

Appendix C to Part 835—Derived Air Concentration (DAC) for Workers From External Exposure During Immersion in a Contaminated Atmospheric Cloud

The air immersion DAC values shown in this appendix are based on a stochastic limit of 5 rems (0.05 Sv) per year or a nonstochastic (organ) dose limit of 50 rems (0.5 Sv) per year. Four columns of information are presented: (1) Radionuclide; (2) half-life in units of seconds (s), minutes (min), hours (h), days (d), or years (yr); (3) air immersion DAC in units of μCi/ml; and (4) air immersion DAC in units of Bq/m^3. The data are listed by radionuclide in order of increasing atomic mass. The air immersion DACs were calculated for a continuous, nonshielded exposure via immersion in a semi-infinite atmospheric cloud.

The DAC value for air immersion listed for a given radionuclide is determined either by a yearly limit on effective dose equivalent, which provides a limit on stochastic radiation effects, or by a limit on yearly dose equivalent to any organ, which provides a limit on nonstochastic radiation effects. For most of the radionuclides listed, the DAC value is determined by the yearly limit on effective dose equivalent. Thus, the few cases where the DAC value is determined by the yearly limit on shallow dose equivalent to the skin are indicated in the table by an appropriate footnote. Again, the DACs listed in this appendix account only for immersion in a semi-infinite cloud and do not account for inhalation or ingestion exposures.

Three classes of radionuclides are included in the air immersion DACs as described below.

(1) *Class 1.* The first class of radionuclides includes selected noble gases and short-lived activation products that occur in gaseous form. For these radionuclides, inhalation doses are negligible compared to the external dose from immersion in an atmospheric cloud.

(2) *Class 2.* The second class of radionuclides includes those for which a DAC value for inhalation has been calculated, but for which the DAC value for external exposure to a contaminated atmospheric cloud is more restrictive (i.e., results in a lower DAC value). These radionuclides generally have half-lives of a few hours or less, or are eliminated from the body following inhalation sufficiently rapidly to limit the inhalation dose.

(3) *Class 3.* The third class of radionuclides includes selected isotopes with relatively short half-lives. These radionuclides typically have half-lives that are less than 10 minutes, they do not occur as a decay product of a longer lived radionuclide, or they lack sufficient decay data to permit internal dose calculations. These radionuclides are also typified by a radioactive emission of highly intense, high-energy photons and rapid removal from the body following inhalation.

The DAC values are given for individual radionuclides. For known mixtures of radionuclides, the sum of the ratio of the observed concentration of a particular radionuclide and its corresponding DAC for all radionuclides in the mixture must not exceed 1.0. For unknown radionuclides, the most restrictive DAC (lowest value) for those isotopes not known to be absent shall be used.

Radionuclide	Half-Life	Air Immersion DAC	
		(μCi/ml)	(Bq/m^3)
C-11	20.48 min	4.E-06	1.E+05
N-13	9.97 min	4.E-06	1.E+05

Radionuclide	Half-Life	Air Immersion DAC	
		(μCi/ml)	(Bq/m³)
N–16	7.13 s	7.E–07	3.E+04
O–15	122.24 s	4.E–06	1.E+05
F–18[1]	109.74 min	4.E–06	1.E+05
Na–24[1]	15.00 h	9.E–07	3.E+04
Mg–27[2]	9.458 min	5.E–06	2.E+05
Al–28[2]	2.240 min	2.E–06	7.E+04
Cl–38[1]	37.21 min	3.E–06	1.E+05
Ar–37	35.02 d	3.E+00	1.E+11
Ar–39	269 yr	2.E–04[3]	7.E+06[3]
Ar–41	1.827 h	3.E–06	1.E+05
K–43[1]	22.6 h	5.E–06	2.E+05
Ca–49[2]	8.719 min	1.E–06	4.E+04
Sc–44[1]	3.927 h	2.E–06	7.E+04
Sc–46m[2]	18.72 s	5.E–05	2.E+06
Ti–45[1]	3.08 h	5.E–06	2.E+05
Ti–51[2]	5.752 min	1.E–05	4.E+05
V–52[2]	3.75 min	3.E–06	1.E+05
Cr–49[1]	42.09 min	5.E–06	2.E+05
Mn–52m[1]	21.4 min	2.E–06	7.E+04
Mn–56[1]	2.5785 h	2.E–06	7.E+04
Mn–57[2]	1.47 min	6.E–05	2.E+06
Co–60m[1]	10.47 min	1.E–03	4.E+07
Ni–57[1,4]	36.08 h	2.E–06	7.E+04
Ni–65[1,5]	2.520 h	8.E–06	3.E+05
Cu–61[1]	3.408 h	5.E–06	2.E+05
Cu–62[2]	9.74 min	5.E–06	2.E+05
Ga–66[1]	9.40 h	2.E–06	7.E+04
Ga–68[1]	68.0 min	5.E–06	2.E+05
Ga–72[1]	14.1 h	1.E–06	4.E+04
Se–73[1]	7.15 h	4.E–06	1.E+05
Br–77[1]	57.04 h	1.E–05[6]	4.E+05[6]
Br–80[1]	17.4 min	5.E–05	2.E+06
Br–82[1]	35.30 h	1.E–06	4.E+04
Br–84[1]	31.80 min	2.E–06	7.E+04
Br–85[2]	172 s	5.E–05	2.E+06
Kr–79	35.04 h	2.E–05	7.E+05
Kr–81	2.1E+05 yr	5.E–04	2.E+07
Kr–83m	1.83 h	5.E–02	2.E+09
Kr–85	10.72 yr	1.E–04[3]	4.E+06[3]
Kr–85m	4.48 h	3.E–05	1.E+06
Kr–87	76.3 min	5.E–06	2.E+05
Kr–88	2.84 h	2.E–06	7.E+04
Kr–89	3.16 min	2.E–06	7.E+04
Kr–90	32.32 s	3.E–06	1.E+05
Rb–81[1]	4.58 h	8.E–06	3.E+05
Rb–82[2]	1.25 min	2.E–06	7.E+04
Rb–88[1]	17.8 min	7.E–06	3.E+05
Rb–89[1]	15.44 min	2.E–06	7.E+04
Rb–90[2]	157 s	2.E–06	7.E+04
Rb–90m[2]	258 s	1.E–06	4.E+04
Sr–85m[1]	67.66 min	2.E–05	7.E+04
Sr–87m[1]	2.805 h	6.E–05	2.E+06
Sr–92[1]	2.71 h	3.E–06	1.E+05
Sr–93[2]	7.3 min	2.E–06	7.E+04
Y–86[1]	14.74 h	1.E–06	4.E+04
Y–90m[1]	3.19 h	5.E–06[6]	2.E+05[6]
Y–91m[1]	49.71 min	9.E–06	3.E+05
Nb–90[1]	14.60 h	1.E–07	4.E+03
Nb–94m[2]	6.26 min	9.E–04	3.E+07
Nb–97[1]	72.1 min	7.E–06	3.E+05
Nb–97m[1]	60 s	6.E–06	2.E+05
Mo–91[2]	15.9 min	4.E–06	1.E+05
Mo–101[1]	14.61 min	3.E–06	1.E+05
Tc–95[1]	20.0 h	5.E–06	2.E+05
Tc–96m[1]	51.5 min	1.E–04	4.E+06
Tc–99m[1]	6.02 h	3.E–05	1.E+06
Tc–101[1]	14.2 min	1.E–05	4.E+05
Ru–105[1]	4.44 h	5.E–06	2.E+05
Rh–105m[2]	45 s	1.E–04	4.E+06
Rh–106[2]	29.92 s	2.E–05	7.E+05
Ag–108[2]	2.37 min	2.E–04	7.E+06
Ag–109m[2]	39.6 s	1.E–03	4.E+07

Radionuclide	Half-Life	Air Immersion DAC	
		(μCi/ml)	(Bq/m³)
Ag-110[2]	24.57 s	9.E-05	3.E+06
Cd-111m[2]	48.7 min	1.E-05	4.E+05
Cd-117[1]	2.49 h	4.E-06	1.E+05
Cd-117m[1]	3.36 h	2.E-06	7.E+04
In-113m[1]	1.658 h	2.E-05	7.E+05
In-114[2]	71.9 s	1.E-04	4.E+06
In-116m[1]	54.15 min	2.E-06	7.E+04
In-117[1]	43.8 min	7.E-06	3.E+05
Sb-117[1]	2.80 h	3.E-05	1.E+06
Sb-126m[1]	19.0 min	3.E-06	1.E+05
Sb-129[1]	4.40 h	3.E-06	1.E+05
Te-133[1]	12.45 min	5.E-06	2.E+05
Te-133m[1]	55.4 min	2.E-06	7.E+04
Te-134[1]	41.8 min	5.E-06	2.E+05
I-122[2]	3.62 min	5.E-06	2.E+05
I-128[1]	24.99 min	5.E-05	2.E+06
I-132[1]	2.30 h	2.E-06	7.E+04
I-134[1]	52.6 min	1.E-06	4.E+04
I-135[1]	6.61 h	7.E-07[6]	3.E+04[6]
I-136[2]	83 s	1.E-06	4.E+04
Xe-122	20.1 h	8.E-05	3.E+06
Xe-123	2.14 h	7.E-06	3.E+05
Xe-125	16.8 h	2.E-05	7.E+05
Xe-127	36.406 d	1.E-05	4.E+05
Xe-129m	8.89 d	2.E-04	7.E+06
Xe-131m	11.84 d	5.E-04	2.E+07
Xe-133	5.245 d	1.E-04	4.E+06
Xe-133m	2.19 d	1.E-04	4.E+06
Xe-135	9.11 h	2.E-05	7.E+05
Xe-135m	15.36 min	1.E-05	4.E+05
Xe-137	3.83 min	2.E-05	7.E+05
Xe-138	14.13 min	4.E-06	1.E+05
Cs-126[2]	1.64 min	4.E-06	1.E+05
Cs-129[1]	32.06 h	1.E-05[6]	4.E+05[6]
Cs-138[1]	32.2 min	2.E-06	7.E+04
Cs-139[2]	9.40 min	1.E-05	4.E+05
Ba-137m[2]	2.552 min	7.E-06	3.E+05
Ba-141[1]	18.27 min	5.E-06	2.E+05
Ba-142[1]	10.70 min	5.E-06	2.E+05
La-142[1]	95.4 min	1.E-06	4.E+04
Pr-144m[2]	7.2 min	9.E-04	3.E+07
Nd-149[1]	1.73 h	1.E-05	4.E+05
Gd-162[2]	9.7 min	1.E-05	4.E+05
Td-162[2]	7.76 min	4.E-06	1.E+05
Dy-157[1]	8.06 h	1.E-05	4.E+05
Re-182m[1]	12.7 h	4.E-06	1.E+05
Os-190m[2]	9.9 min	3.E-06	1.E+05
Ir-190m[1]	3.2 h	8.E-05[6]	3.E+06[6]
Au-195m[2]	30.6 s	2.E-05	7.E+05
Tl-200[1]	26.1 h	3.E-06	1.E+05
Tl-207[2]	4.77 min	4.E-05[3]	1.E+06[3]
Tl-208[2]	3.053 min	1.E-06	4.E+04
Tl-209[2]	2.20 min	2.E-06	7.E+04
Tl-210[2]	1.30 min	1.E-06	4.E+04
Pb-204m[2]	66.9 min	2.E-06	7.E+04
Bi-211[2]	2.13 min	1.E-04	4.E+06
Po-211[2]	0.516 s	5.E-04	2.E+07
Rn-220	55.61 s	8.E-09[6]	3.E+02[6]
Rn-222	3.824 d	3.E-08[6]	1.E+03[6]
Th-233[2]	22.3 min	1.E-04	4.E+06
Pa-234[1]	6.70 h	2.E-06	7.E+04
Pa-234m[2]	1.17 min	4.E-05[3]	1.E+06[3]
U-239[1]	23.40 min	8.E-05[6]	3.E+06[6]
Np-240[1]	65 min	4.E-06	1.E+05
Np-240m[2]	7.4 min	1.E-05	4.E+05
Am-246[1]	25.0 min	4.E-06	1.E+05

[1] Committed effective dose equivalent from inhalation is calculated in ICRP Publication 30, but the DAC value for external exposure to a contaminated atmospheric cloud is more restrictive than the DAC value for inhalation.

[2] Committed effective dose equivalent from inhalation is not calculated in ICRP Publication 30, but DAC value for external exposure to contaminated cloud should be more restrictive than DAC value for inhalation due to relatively short half-life of radionuclide.

[3] DAC value is determined by limit on annual shallow dose equivalent to skin, rather than yearly limit on effective dose equivalent.

[4] DAC value applies to radionuclide in vapor form only; DAC value for inhalation is more restrictive for radionuclide in inorganic form.

[5] DAC value applies to radionuclide in inorganic or vapor form.
[6] DAC value for exposure to contaminated atmospheric cloud is the same as DAC value for inhalation.

Appendix D to Part 835—Surface Radioactivity Values

SURFACE RADIOACTIVITY VALUES;[1] IN DPM/100 CM[2]

Nuclide	Removable[2,4]	Total (Fixed + Removable)[2,3]
U-nat, U-235, U-238, and associated decay products	1,000	5,000
Transuranics, Ra-226, Ra-228, Th-230, Th-228, Pa-231, Ac-227, I-125, I-129	20	500
Th-nat, Th-232, Sr-90, Ra-223, Ra-224, U-232, I-126, I-131, I-133	200	1,000
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above.[5]	1,000	5,000
Tritium Organic Compounds; surfaces contaminated by HT, HTO, and metal tritide aerosols	[Reserved]	[Reserved]

[1] The values in this appendix apply to radioactive contamination deposited on, but not incorporated into the interior of, the contaminated item. Where surface contamination by both alpha- and beta-gamma-emitting nuclides exists, the limits established for alpha- and beta-gamma-emitting nuclides should apply independently.

[2] As used in this table, dpm (disintegrations per minute) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.

[3] The levels may be averaged over one square meter provided the maximum surface activity in any area of 100 cm^2 is less than three times the value specified. For purposes of averaging, any square meter of surface shall be considered to be above the activity guide G if: (1) From measurements of a representative number n of sections it is determined that $1/n \Sigma_n S_i \geq G$, where S_i is the dpm/100 cm^2 determined from measurement of section i; or (2) it is determined that the sum of the activity of all isolated spots or particles in any 100 cm^2 area exceeds 3G.

[4] The amount of removable radioactive material per 100 cm^2 of surface area should be determined by swiping the area with dry filter or soft absorbent paper, applying moderate pressure, and then assessing the amount of radioactive material on the swipe with an appropriate instrument of known efficiency. (Note—The use of dry material may not be appropriate for tritium.) When removable contamination on objects of surface area less than 100 cm^2 is determined, the activity per unit area should be based on the actual area and the entire surface should be wiped. Except for transuranics and Ra-228, Ac-227, Th-228, Th-230, Pa-231 and alpha emitters, it is not necessary to use swiping techniques to measure removable contamination levels if direct scan surveys indicate that the total residual surface contamination levels are within the limits for removable contamination.

[5] This category of radionuclides includes mixed fission products, including the Sr-90 which is present in them. It does not apply to Sr-90 which has been separated from the other fission products or mixtures where the Sr-90 has been enriched.

Appendix E to Part 835—[Reserved]

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December 14, 1993

Part V

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 16, et al.
Human Tissue Intended for Transplantation; Interim Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 1270

[Docket No. 93N–0453]

Human Tissue Intended for Transplantation

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim rule; opportunity for public comment.

SUMMARY: The Food and Drug Administration (FDA) is issuing an interim rule to require certain infectious disease testing, donor screening, and recordkeeping to help prevent the transmission of AIDS and hepatitis through human tissue used in transplantation. The regulations are effective upon publication. FDA is taking this action in response to growing concerns that some human tissue products are being offered for transplantation use without even the minimum donor testing and screening needed to protect recipients against human immunodeficiency virus (HIV) infection and hepatitis infection. The new regulations require all facilities engaged in procurement, processing, storage, or distribution of human tissues intended for transplant to ensure that minimum required infectious disease testing has been performed and that records documenting such testing for each tissue are available for inspection by FDA. The regulations also provide authority for the agency to conduct inspections of such facilities and to detain, recall, or destroy tissue for which appropriate documentation is not available.

DATES: *Effective Date:* The interim rule is effective December 14, 1993. *Comments:* Written comments by March 14, 1994.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Steven F. Falter, Center for Biologics Evaluation and Research (HFM–635), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION:

I. Background

There has been a growing concern about the risk of transmission of hepatitis or HIV-related disease through transplantation of human tissue. Many forms of human tissue are currently subject to Federal regulation. FDA has regulated blood and blood products for decades under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act (PHS Act). Further, the agency recently published a notice on the application of current statutory authorities to human somatic cell therapy and gene therapy products (58 FR 53248, October 14, 1993). Somatic cell therapy products are defined as autologous, allogenic, or xenogeneic cells that have been propagated, expanded, selected, pharmacologically treated, or otherwise altered in biological characteristics ex vivo to be administered to humans and applicable to the prevention, treatment, cure, diagnosis, or mitigation of disease or injuries. Gene therapy products are defined as products containing genetic material administered to modify or manipulate the expression of genetic material to alter the biological properties of living cells.

Other human tissues have been regulated by FDA on a case-by-case basis, as a public health need was identified. Tissues that the agency has already regulated under the Medical Device Amendments of 1976 (Pub. L. 94–295) include: Corneal lenticules (corneas used to correct rather than restore vision), dura mater allografts (brain membrane material), heart valve allografts, skin and bone products that are processed in ways other than to only reduce infectivity or preserve tissue integrity, and preserved umbilical cord vein grafts.

The National Organ Transplant Act of 1984 (Pub. L. 98–507, (42 U.S.C. 273 *et seq.*)), as amended, provides for Federal oversight of the organ transplant system. The Health Resources and Services Administration (HRSA) and the Health Care Financing Administration (HCFA) within the Department of Health and Human Services (DHHS) currently administer programs related to organ transplantation. In June 1991, DHHS published proposed rules governing performance standards for organ procurement organizations (56 FR 28513, June 21, 1991). The organ transplant system currently includes: Liver, heart, lung, kidney, and some pancreas transplants. Organ transplants are characterized by the fact that the organs receive oxygen and nutrients in the ultimate recipient through the original vascular structures.

Under 42 U.S.C. 274e, it is unlawful to buy or sell a human organ for use in transplantation. Transactions prohibited by this provision include: Sale of a human (including fetal) kidney, liver, heart, pancreas, bone marrow, cornea, eye, bone, skin, or any subpart. Human tissues that are subparts of the listed organs are included within the scope of the prohibition. Reasonable payments associated with removal, transportation, implantation, processing, preservation, quality control, and storage of an organ or with certain donor expenses are not prohibited.

The National Heart, Lung, and Blood Institute, within the National Institutes of Health of HHS, administers the contract for the National Marrow Donor Program, for which standards were established by the Transplant Amendments Act of 1990 (Pub. L. 101–616), and has published a related notice (58 FR 4961, February 7, 1991).

II. Human Tissue Banking

These various programs have, however, left one area of substantial activity without direct or active Federal oversight. Generally, this subject matter consists of musculoskeletal and integumentary materials that may be recovered from living or cadaveric donors. Specifically, these materials largely consist of bone, ligaments, tendons, fascia, cartilage, corneas, and skin that are used in the treatment of bond disease, orthopedic injuries, ligamentous and joint complaints, degenerative skeletal disease, blindness due to corneal opacification, and burn wounds. Tissue donation may be associated with organ procurement. In that event, a HCFA-certified organ procurement organization is likely to have interacted with the donor or the donor's family. Tissue banks may also recover tissue based on referrals of donor availability from other domestic sources, such as medical examiners' offices and hospitals. Medical examiners' offices and hospitals may also directly recover the tissue and send it elsewhere for processing and distribution. In addition, tissue may be recovered from foreign sources.

Currently, industry estimates are that over 280,000 patients annually receive bone, skin, or other integumentary transplants. Additionally, nearly 42,000 patients receive cornea transplants. Annual revenues for tissue banking generally may approach $100 million. Representatives of industry have noted the increasing commercialization of tissue banking.

In part based upon the absence of comprehensive national oversight, there has been concerted effort within the private sector to develop voluntary quality assurance programs. In 1976, the tissue banking industry established the American Association of Tissue Banks (AATB) to develop a voluntary

accreditation system for skin and orthopedic-related tissues. AATB's accreditation system evaluates tissue banks for compliance with a comprehensive set of standards through document review and site visits. The AATB currently has accredited over 50 U.S. skin and bone tissue banks out of an estimated 150 to 200 tissue banks. An estimated additional 50 banks are in the process of acquiring accreditation. The AATB standards cover acquisition, processing, preservation, storage, labeling, and distribution of tissue. Current acquisition standards include specific disease screening through testing for hepatitis B and C and HIV and review of medical histories for risk factors for disease transmission.

The Eye Bank Association of America (EBAA) was established in 1961 and today represents 109 eye bank organizations in the United States and Canada. Over 95 percent of the membership is accredited by EBAA. To become accredited, eye banks must meet voluntary medical standards and submit to a triennial site visit. EBAA works closely with the American Academy of Ophthalmology to revise and refine its medical standards. These standards include testing for hepatitis B and C and HIV. EBAA medical standards also require review of all available medical, coroner, and autopsy records for these diseases.

Additionally, because reports from the Centers for Disease Control and Prevention (CDC) that HIV had been transmitted through transplantation, the Public Health Service (PHS) has taken a number of actions. The Assistant Secretary for Health convened a Work Group to evaluate the need for and type of Federal oversight that should be developed over the entire array of human tissues. In its report issued and July 1, 1991, the Work Group concluded that the risk of infectious disease transmission was quite low, but it did recommend revision of PHS guidelines on donor screening, testing, and recordkeeping. Further, the Work Group noted that investigation into the needed level of mandatory oversight for tissue transplantation, apart from organ and bone marrow transplantation, should take place. The PHS Work Group recommended FDA evaluation of this question.

On March 17 of this year, the U.S. PHS announced the availability of the revised draft guideline on the prevention of transmission of HIV through transplantation of human tissues and organs (58 FR 14402, March 17, 1993).

III. Congressional Interest and Industry Support for Oversight

In 1992, Senator Simon introduced S. 2908, which would have required a mandatory floor of infectious disease controls and Federal certification of tissue banks that were in compliance with requirements. FDA participated in hearings on S. 2908 before the Senate Committee on Labor and Human Resources. While FDA opposed that particular resolution of tissue transplantation issues, the agency made a commitment to engage actively in investigation of the tissue banking industry and in the ongoing public debate on the appropriate role for Federal oversight. Senator Simon introduced S. 1702, which deals with human tissue regulation, on November 19, 1993.

A member of a national consortium of tissue banks testified at the 1992 hearing that the organization "supports Senator Simon's legislation because it believes that uniform national standards for the identification of donors, and the recovery, processing and distribution of tissue will provide needed assurance that tissue is safe and effective for all transplant recipients." (Senate Hearing on S. 2908, 102d Cong., 2d sess. 52 (Sept. 29, 1992).)

On October 15 of this year, Representative Wyden chaired a hearing before the Subcommittee on Regulation, Business Opportunities and Technology of the Committee on Small Business on appropriate oversight for tissue banking. At those hearings, representatives of industry advocated passage of legislation setting forth regulatory requirements for tissue banking.

The president of the AATB advocated "immediate compulsory registration of all tissue banks to determine the scope of tissue banking" and the "[establishment of] uniform donor selection requirements to ensure the lowest possible risk of disease transmission to patients." The chairperson of the EBAA noted that its accreditation system is voluntary and that "[a]bsent from this process is [an] enforcement mechanism to mandate closure of noncompliant entities and require universal participation." The chairperson further noted that, "[t]o truly provide for improved public safety, legislation and regulation must include a mechanism to either rapidly educate or close outlets within hospitals, clinics, and physician practices where standards for allografts addressed through accreditation and CDC guidelines often go unrecognized."

The national head of the American Red Cross Tissue Services testified that:

> The American Red Cross feels strongly that appropriate, enforceable federal standards are needed to ensure the continued safety of the people who depend upon human tissue to sustain or improve the quality of their lives and to foster continued public support for the collection and use of transplantable tissue * * *. We believe that safety and public support will be maintained if the Food and Drug Administration (FDA) (1) registers and licenses all tissue banks, whether they engage in procurement, processing, storage, or distribution; (2) establishes standard tissue-specific donor screening procedures; and (3) develops effective tracking procedures in order to identify the source of infection after transplant and to identify other recipients who may be at risk.

The president of the American Academy of Orthopaedic Surgeons similarly supported "legislation to provide uniform standards for tissue banking practices and processing in order to ensure the safety of our patients from the transmission of disease."

Representative Wyden introduced H.R. 3547 on November 19, 1993. This bill is substantially identical to S. 1702.

IV. Recent Developments

At the October 15 hearing, the Director of FDA's Center for Biologics Evaluation and Research noted the advent of commercialization and the development of promotional practices for human tissue materials. She testified that "[s]everal tissue bank directors have been solicited by individuals offering to sell tissue that originates from other countries. Generally, these contacts have been unwilling to declare the actual source of the tissue, to provide documentation as to the cause of death, the medical records of the donor, the results of donor screening and testing, or to furnish samples of donor serum for testing."

The manager of the Northwest Tissue Center in Seattle, Washington, stated that the tissue center had "received calls from brokers offering to send us tissue for processing from Russia, Eastern Europe, and Central and South America. This raises significant concerns about ensuring safety. If tissue is to be imported from outside the United States, very strict controls must be put in place to ensure the same standards of donor screening, testing, and tissue recovery, because of the potential for unknown diseases that might be transmitted."

The Director of Blood and Tissue Resources from the Department of Health for the State of New York testified concerning state regulation of tissue banking in New York. She noted that the New York program had found that tissues had been removed from donors for a variety of purposes despite

the fact that donor or family consent was totally absent and thus, donor medical histories were incomplete.

Representative Wyden submitted for the record a solicitation from a foreign tissue bank that noted that many tissues offered for use in the United States by the bank were recovered without aseptic precautions.

As a result of a number of similar allegations, the agency has initiated inquiries regarding possible supplying of human tissue materials intended for transplantation without appropriate infectious disease testing and medical screening. In a relatively brief period of time, the agency was able to ascertain, in a few isolated instances, the availability for importation and distribution of tissue materials that do not meet minimal screening standards for transmission of infectious disease. Agency investigators contacted several individuals who had offered to supply tissues from foreign sources. Two persons indicated immediate willingness to import tissues within weeks from donors from whom full medical histories and proper donor screening and testing had not been obtained. Both indicated that they had been engaged in past tissue sales for transplantation. Furthermore, the circumstances of alleged donation offered to agency investigators, without consent or notice to concerned relatives, would have precluded adequate evaluation of the donor's risk factors that would be relevant to minimize the potential for infectious disease transmission. Finally, the brief medical histories that were provided to agency investigators, limited to causes of death, indicated that tissue from these donors should not be accepted for transplantation use.

One purveyor provided-agency investigators with blood samples from a prospective donor-cadaver accompanied by documentation of previous infectious disease testing, including alleged testing for hepatitis B. On retesting by the Government, the sample was confirmed to be markedly positive for hepatitis B surface antigen. The purveyor admitted, when confronted with this fact, his awareness that testing facilities at the site of donation were inadequate and that previous donors had also tested positive for hepatitis.

These isolated instances demonstrate that donation has occurred, and continues to occur, when generally-accepted donor screening through medical history review is largely absent. The agency currently believes that these instances do not represent the predominant practice within the industry. Nonetheless, the traffic in tissue for transplantation without adequate testing or donor screening, whether domestic or imported, cannot be permitted to occur.

V. Legal Authority

Because the public health objective in regulating tissue entities in this interim rule is to prevent the transmission of communicable disease, FDA is developing these regulatory requirements under the legal authority of section 361 of the PHS Act (42 U.S.C. 264). This section authorizes the Secretary, DHHS (the Secretary), to make and enforce such regulations as judged necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or from State to State. Intrastate transactions may be regulated under authority of this provision, as appropriate. (*See State of Louisiana* versus *Mathews*, 427 F. Supp. 174 (E. D. La. 1977).)

Section 361 of the PHS Act also provides for such inspection and destruction of articles found to be so infected or contaminated as to be sources of dangerous infection to humans, and other measures, as may be deemed by the Secretary to be necessary. Section 361 of the PHS Act has been invoked by FDA to regulate various activities or articles. For example, FDA has invoked this authority to regulate conveyance sanitation, the source and use of potable water, and milk pasteurization. The agency has also acted under section 361 to prevent the transmission of communicable disease through shellfish, turtles, certain birds, and bristle brushes. (See 21 CFR parts 1240 and 1250.) FDA has also relied in part on this section in promulgating requirements to protect the blood supply.

Authority for the enforcement of section 361 of the PHS Act is provided for in part under section 368 of the PHS Act (42 U.S.C. 271). Under section 368(a) of the PHS Act any person who violates a regulation prescribed under section 361 of the PHS Act may be punished by imprisonment for up to 1 year (42 U.S.C. 271(a)). Individuals may also be punished for violating such a regulation by a fine of up to $100,000 if death has not resulted from the violation or up to $250,000 if death has resulted (18 U.S.C. 3559, 3571(b)). Organizations may be fined up to $200,000 per violation not resulting in death and $500,000 per violation resulting in death (18 U.S.C. 3559, 3571(c)). In addition, Federal district courts have jurisdiction to enjoin individuals and organizations from violating regulations implementing Section 361 of the PHS Act.

VI. Regulatory Program

A. Introduction

FDA is issuing this interim rule because of an immediate need to protect the public health from the transmission of HIV infection and hepatitis infection through transplantation of tissue from donors infected with or at risk of these diseases. The interim rule is not intended to serve as a long term regulatory program for assuring the safety or quality of human tissues used in transportation. In the near future, FDA intends to propose more extensive regulations regarding infectious disease control for tissues that would incorporate, but not be limited to, the elements described in this interim rule. FDA would then issue a final rule consolidating the interim rule and the subsequently proposed regulations and responding to comments both to the interim and proposed rules.

B. Scope

Section 1270.1 defines the scope of applicability of these regulations. In general, any establishment or person engaged in the recovery, processing, storage, or distribution of banked human tissues would be affected by the regulations. A definition of "banked human tissue" is provided in § 1270.3(b) of the interim rule. In essence, such tissue is tissue derived from a human body intended for administration to another human for medical purposes and procured, processed, stored, or distributed by methods not intended to change tissue structure or functional characteristics. Tissues that are processed or stored only in ways to prevent transmission of infectious disease and to preserve clinical usefulness would be covered by the regulation.

Tissues already regulated by FDA as drugs, biological products, or medical devices, and vascularized organs, semen, other reproductive tissue, human milk, and bone marrow would not be affected by the interim rule (see definition of "banked human tissue" in § 1270.3(b)). Tissues such as bone, ligaments, tendons, fascia, cartilage, corneas, and skin whose structure or functional characteristics have not been changed through processing or other techniques would be covered by the requirements of the regulations. Establishments such as transportation centers and other hospitals which may store tissue only for a short term pending scheduled surgery within the same facility but do not participate in

the recovery, processing, or distribution of tissue would not be regulated under these provisions. (See definition of "storage" in § 1270.3(h).)

C. Definitions

Section 1270.3 provides definitions for several of the terms used in the interim rule. The definitions will be discussed, as necessary, in the section of the interim rule in which the defined term appears.

D. Infectious Disease Testing and Donor Screening

Requirements for the laboratory tests to be performed and for the screening of donors to be conducted are specified in § 1270.5. In order for the laboratory test results to be reliable, it is important that the tests be properly performed. Section 1270.5(b) provides that the tests must be performed by laboratories appropriately certified under the Clinical Laboratories Improvement Act of 1988 (Pub. L. 100–578).

The purpose of the required laboratory tests is to help to establish a lack of infection with or exposure to Human Immunodeficiency Virus, Types 1 and 2, (HIV–1 and HIV–2), Hepatitis B, and Hepatitis C. The interim rule requires that a blood specimen obtained from the donor be used to perform the following required tests:

Human immunodeficiency virus-1 antibody (anti-HIV 1)
Human immunodeficiency virus-2 antibody (anti-HIV 2)
Hepatitis B surface antigen (HBsAg)
Hepatitis C virus antibody (anti-HCV)

HIV and Hepatitis B and C testing are essential to help protect against these serious and life-threatening diseases, which can be transmitted by all types of tissues. FDA recognizes that, depending on the types of tissue involved, other testing may be appropriate to assure that the tissue is safe for transplantation. Additional testing requirements may be included in the notice of proposed rulemaking which FDA intends to issue in the near future.

FDA is requiring in § 1270.5(e) that the process of determining suitable donors include identifying the donor and obtaining a relevant medical history to determine whether the donor has engaged in behaviors that place the donor at high risk for contracting AIDS or hepatitis and whether the donor has displayed signs or symptoms of these diseases. FDA is not specifying in these regulations what specific questions should be asked of the donor or the next-of-kin but only that such procedures be in place and in use by establishments which procure tissue. The future proposed rule may provide more specific requirements on obtaining an adequate medical history of the donor. When corneal retrieval is performed under authorization of a specific State or territorial law, § 1270.5(e) defines the relevant medical history as including all available medical, coroner, and autopsy records. This provision would apply to retrieval of corneas by medical examiners or coroners in certain States. FDA specifically requests comment on this definition of relevant medical history for corneal retrieval.

Section 1270.5 also contains requirements for the quarantining of tissue. Quarantining means identifying the tissue as not suitable for transplantation or holding the tissue in an area clearly identified as being for quarantine (see definition in 1270.3(i)). Banked human tissue must be quarantined unless it is accompanied by: (1) Records indicating negative test results for the required tests of the donor's blood and (2) records of the donor's medical history assuring freedom from risk factors or clinical evidence of HIV infection and hepatitis B and C. For donors that have been transfused within 48 hours of taking the blood sample, special quarantine provisions are set forth in § 1270.5(d) to help eliminate misleading test results.

This interim rule is effective immediately for tissues currently in storage. Thus, such tissues must either be immediately quarantined or have available the required documentation of donor testing and screening. FDA specifically solicits comment on the feasibility and burdensomeness of the immediate application of this rule to tissues currently in storage.

E. Written Procedures

Section 1270.7 requires that the testing and donor screening prescribed in § 1270.5 be performed in accordance with written procedures. The testing procedures must conform to the manufacturers' instructions for use in the package inserts for the required test kits. Such written procedures are intended to assure that testing and donor screening are adequate and consistently performed. The regulations also require that the personnel performing testing or donor selection have ready access to the appropriate written procedures. Any deviation from these written procedures must be recorded and justified. An establishment need not develop its own written procedures, but may adopt those in a manual prepared by another organization, as long as the procedures satisfy the requirements of the regulations.

F. Records

Sections 1270.9 and 1270.11 require the proper maintenance of records and identify specific records that must be kept. Under §§ 1270.9(a) and 1270.11(a), FDA requires that records be kept documenting the viral testing results for each donor and the interpretation of those results. The documentation must include identification of the person doing the work, and dates of data entries, and must be adequately detailed to provide a complete history of the testing.

Under § 1270.9(b), tissue must be quarantined until the required records documenting appropriate results from the infectious disease testing and donor screening accompany the tissue. Medical history records must be available either in English as the original record or in a verified translation into English, accompanied by the original record. Records on the destruction or other disposition of tissue unsuitable for transplantation must be maintained.

Under § 1270.9(c), all required records must be available for inspection by authorized FDA employees at any establishment or from an individual that recovers, processes, stores, or distributes banked human tissue. Photocopies, microfiches, microfilm, and retrieval from other locations by electronic means are permissible.

Because a person may be infected with HIV or viral hepatitis for several years before it becomes manifest, FDA believes that records must be retained for a sufficient period of time to assure that the records may be traced in the event a recipient displays evidence of infection that may be attributable to human tissue transplantation. FDA is requiring under § 1270.9(e) that records be retained for 10 years.

G. Inspections

Establishments that recover, process, store, or distribute banked human tissue will be subject to FDA inspection under § 1270.13. An establishment subject to inspection will be required to permit the FDA investigators conducting the inspection access to all facilities, equipment, processes, products, and records, as necessary to assure compliance with this interim rule. The FDA investigator will also be authorized to question any personnel involved in the performance of regulated activities. In most cases, FDA intends that routine inspections will not be announced by prior notice. At the beginning of the inspection, the FDA investigator will

provide to the most responsible person present at the establishment an FDA "Notice of Inspection." During the inspection the FDA investigator may copy records of the establishment as deemed necessary by the investigator, such as to document potential violations of the regulations. FDA recognizes the extreme sensitivity of information that would identify a human tissue donor or recipient. FDA investigators will be instructed to delete or obscure any donor or recipient identifying information from copied records unless such information is necessary for carrying out the investigator's duties.

At the end of the inspection, if potential significant violations of the regulations are found, the FDA investigator will issue to the most responsible person at the establishment a list of "Inspectional Observations," which will describe the observations of the investigator that may represent violations of the regulations. After the report of the investigator is reviewed, FDA may issue additional correspondence to the establishment describing the violations to the regulations and requesting appropriate follow-up action.

During the effective period of the interim rule, the agency intends to inspect a regulated establishment, either foreign or domestic, only when deemed necessary to ensure that human tissue is not infected with HIV or hepatitis B or C virus. Frequency of inspection after an initial inspection will depend on the extent of the violations found and will be at the agency's discretion. A more extensive discussion of FDA's inspection program will be described in the notice of proposed rulemaking to be published in the near future.

H. Recall and Destruction of Human Tissue

Section 361 of the PHS Act authorizes the Secretary to provide for such inspection and destruction of articles found to be so infected or contaminated as to be sources of dangerous infection to human beings and "other measures, as in [her] judgment may be necessary." FDA expects that in the majority of cases an establishment responsible for the distribution of human tissue for transplantation will voluntarily take appropriate measures when human tissue is found unsafe for use or is of questionable safety, and it will be unnecessary for FDA to order destruction of the human tissue. The procedures for recall and destruction in § 1270.15 of the regulations will be used only when the agency deems it necessary to ensure the continued safety of human tissue.

During the period of interim regulations, FDA intends to invoke § 1270.15 when there is a significant question as to the source of the tissue, the adequacy of the testing of the tissue, or the adequacy of donor selection. Such may be the case when the source of the tissue cannot be traced or when FDA has reason to believe the tissue donor may not have been adequately screened or tested. If, for example, the tissue is of foreign origin and FDA is unable to ascertain how the tissue was recovered, processed, stored, or distributed, recall and destruction orders may be issued. In the near future, FDA intends to propose that all establishments, foreign and domestic, involved in the recovery, processing, storage, and distribution of tissue intended for transplantation be registered with FDA. Thus FDA would be better able to ascertain the adequacy of the recovery, processing, storage, and distribution of tissue.

Section 1270.15 provides procedures under which FDA may order the recall or destruction of human tissue that has been collected or distributed in violation of the regulations. Under § 1270.15(a), FDA may issue to the person responsible for the distribution of the human tissue a written order that the product be recalled or destroyed, as appropriate. The written order will identify as specifically as practicable the human tissues that are affected, the grounds for issuing the order, and provide that, unless alternative arrangements are made, the human tissue must be recalled and/or destroyed within 5 working days of receipt of the order.

A written order to retain the tissue will also be provided to all persons in possession of the tissue in question. Authorized FDA employees may also take possession of the tissue and ultimately destroy the tissue.

Arrangements may be made with the FDA official issuing the order to hold the destruction order in abeyance and negotiate alternative arrangements for appropriate disposition of the human tissue. If the retention order is issued on the basis that FDA is unable to ascertain the adequacy of the testing of the tissue, the issue may be resolved by the distributor or other responsible person providing FDA with documentation showing that the tissue has been appropriately tested. If the order is based on testing deficiencies that fail to ensure adequately the suitability of the donor, additional or repeat testing of the donor samples may be possible that will clarify the suitability of the human tissue for transplantation. In other cases the human tissue may not be appropriate for use in transplantation but may be used for research purposes. If suitable arrangements cannot be made and there continues to be disagreement regarding the order, FDA will reaffirm in writing the order that the human tissue be recalled or destroyed.

If no agreement is reached, the recipient of the order may request a hearing under 21 CFR part 16 within 5 working days of the receipt of such an order. Any recall of human tissue will be monitored by FDA and destruction of human tissue will be under the supervision of a designated FDA official.

VII. Issuance of an Interim Rule; Immediate Effective Date

Under the provisions of the Administrative Procedure Act at 5 U.S.C. 553(b)(B) and FDA's administrative practices and procedures regulations at 21 CFR 10.40(e)(1), the Commissioner of Food and Drugs finds that use of prior notice and comment procedures for promulgating this interim rule is contrary to the public interest. In addition, the Commissioner finds good cause under 5 U.S.C. 553(d)(3) and 21 CFR 10.40(c)(4)(ii) for making this rule effective immediately upon publication. The agency believes that the unnecessary risk of transmission of HIV infection and hepatitis infection from shipment and transplantation of tissues derived from inadequately tested or screened donors justifies immediate action to protect the public health.

Tissue procurement, processing, storage, and distribution entities that follow generally accepted industry practices currently engage in such testing and screening and related recordkeeping. The agency is aware of no adequate justification for failure to perform such basic procedures related to prevention of these serious and life-threatening diseases. In light of the significant public health risk presented by the absence of procedures to prevent transmission of these diseases, the Commissioner finds good cause to make these regulatory requirements final and effective immediately.

Although this agency is publishing this regulation as an interim rule without an opportunity for prior notice and comment on a proposed rule, FDA is providing for comment on this interim rule. As previously discussed, the agency intends to promulgate a regulation encompassing additional infectious disease controls in the near future. Interested persons will have an opportunity to comment on all related issues in the context of that rulemaking.

VIII. Environmental Impact

The agency has determined under § 25.24(a)(10) (21 CFR 25.24(a)(10)) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, no environmental impact statement is required.

IX. Economic and Information Collection Impacts

A. Paperwork Reduction Act of 1980

This interim rule contains information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980. The title, description, and respondents of the information collections are shown below with an estimate of the annual recordkeeping and periodic reporting burden.

Title: Human Tissue Intended for Transplantation: 21 CFR part 1270.

Description: FDA is promulgating interim regulations to prevent the transmission of HIV disease and hepatitis B and C through the use of human tissue for transplantation. The interim regulations will provide for the inspection by FDA of tissue bank establishments engaged in recovery, processing, storage or distribution of banked human tissue. These facilities will be required to meet standards intended to assure appropriate screening and testing of human tissue donors, and to ensure that records are kept that document that the appropriate testing has been followed.

Description of Respondents: Businesses or other for-profit; nonprofit institutions; small businesses or organizations.

Recordkeeping

21 CFR section	No. of recordkeepers	Annual hours per recordkeeper	Recordkeeping hours
1270.7(b)	400	10	4,000
1270.9(a) & .11(a)	200	2.083	416
1270.11(b)	400	.5	200
Total Recordkeeping Hours:			4,616

No burden is being calculated for § 1270.11(c). With the rare exceptions noted in the preamble, FDA believes that all respondents obtain medical history of donors; these regulations add no additional requirements. There are approximately 400 establishments/persons affected by these regulations. Of these, 250 should already meet the requirements of this interim rule; 150 may not have written SOP's as required under 1270.7(a). In addition, approximately 200, although they have testing records, may not have all required information recorded. FDA is specifically requesting comments on the recordkeeping burden estimate.

As required by section 3504(h) of the Paperwork Reduction Act of 1980, FDA has submitted a copy of this proposed rule to OMB for its review of these information collection requirements. Other organizations and individuals desiring to submit comments regarding this burden estimate or any aspects of these information collection requirements including suggestions for reducing the burden, should direct them to FDA's Dockets Management Branch (address above) and to the Office of Information and Regulatory Affairs, OMB, rm. 3001, New Executive Office Bldg., 725 17th St. NW., Washington, DC 20503, Attn: Steve Semenuk.

B. Economic Impact

The agency has examined the economic impact of this interim rule and has determined that it does not require a regulatory flexibility analysis, as specified in the Regulatory Flexibility Act (Pub. L. 96–354). The only economic impact is related to the recordkeeping burdens described above. FDA believes that the costs of testing for infectious disease and the cost of screening donors has already been assumed by the tissue banking industry and this interim rule imposes no additional burdens. FDA believes there will be a one time burden of $48,000 for those tissue banks which prepare written procedures in accordance with the rules and an annual burden of $201,320 for preparing and keeping records which some regulated establishments may not currently consistently keep. FDA believes that the destruction of unsuitable tissue will be an infrequent occurrence and will be done only when necessary to prevent the transmission of communicable disease.

FDA certifies that the interim rule will not have a significant impact on a substantial number of small entities, as defined in the Regulatory Flexibility Act. Organizations and individuals desiring to submit comments regarding this economic burden estimate or any aspects of the economic effects of the interim rule, including suggestions for reducing the economic burden, should direct them to FDA's Dockets Management Branch (address above).

X. Request for Comments

Interested persons may, on or before March 14, 1994, submit to the Dockets Management Branch (address above) written comments regarding this interim rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 16

Administrative practices and procedures.

21 CFR 1270

Human tissue, Reporting and recordkeeping requirements.

Therefore, under the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR chapter I is amended as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

1. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: Secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 21 U.S.C. 41–50, 141–149, 467f, 679, 821, 1034; secs. 2, 351, 361 of the Public Health Service Act (42 U.S.C. 201, 262, 264); secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 28 U.S.C. 2112.

2. Section 16.1 is amended in paragraph (b)(2) by numerically adding

the entry "§ 1270.15(e)" to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

§ 1270.15(e), relating to the recall and destruction of banked human tissue.

3. New part 1270 is added to read as follows:

PART 1270—HUMAN TISSUE INTENDED FOR TRANSPLANTATION

Sec.

Authority: Secs. 215, 311, 361, 368 of the Public Health Service Act (42 U.S.C. 216, 243, 264, 271).

§ 1270.1 Scope.

(a) The regulations in this part apply to banked human tissue and to establishments or persons engaged in the recovery, processing, storage, or distribution of banked human tissue.

(b) Regulations in this chapter as they apply to drugs, biologics, devices or other FDA-regulated commodities do not apply to banked human tissue, except as specified in this part.

§ 1270.3 Definitions.

(a) *Act* for the purpose of this part means the Public Health Service Act, section 361 (42 U.S.C. 264).

(b) *Banked human tissue* means any tissue derived from a human body, which:

(1) Is intended for administration to another human for the diagnosis, cure, mitigation, treatment, or prevention of any condition or disease;

(2) Is recovered, processed, stored, or distributed by methods not intended to change tissue function or characteristics;

(3) Is not currently regulated as a human drug, biological product, or medical device;

(4) Excludes kidney, liver, heart, lung, pancreas, or any other vascularized human organ; and

(5) Excludes semen or other reproductive tissues, human milk, and bone marrow.

(c) *Vascularized* means containing the native vasculature which continues to carry blood after transplantation.

(d) *Donor* means a human being, living or dead, who is the source of tissue for transplantation.

(e) *Recovery* means the obtaining from a donor of tissue that is intended for use in human transplantation.

(f) *Processing* means any activity to prepare, preserve for storage, and/or remove from storage to assure the potency, quality and/or sterility of human tissue for transplantation.

(g) *Distribution* includes any transfer of human tissue from one establishment or individual to another establishment or individual (including importation), whether or not such transfer is entirely intrastate and whether or not possession of the tissue is taken.

(h) *Storage* means holding tissue in any facility other than the facility at which the tissue is to be implanted.

(i) *Quarantine* means the identification of banked human tissue as not suitable for transplantation or the holding of banked human tissue in an area clearly identified as being for quarantine.

§ 1270.5 Donor testing and screening.

(a) Donor blood specimens shall be tested for the following communicable disease serological markers by tests approved for such uses by the Food and Drug Administration:

(1) Human immunodeficiency virus-1 antibody (anti-HIV–1);

(2) Human immunodeficiency virus-2 antibody (anti-HIV–2);

(3) Hepatitis B surface antigen (HBsAg); and

(4) Hepatitis C virus antibody (anti-HCV).

(b) Such infectious disease testing shall be performed by a laboratory appropriately certified under the Clinical Laboratories Improvement Act of 1988 (CLIA).

(c) Banked human tissue shall be quarantined or accompanied by records indicating that the donor's blood has been tested and found negative in approved tests for anti-HIV–1, anti-HIV–2, HBsAg, and anti-HCV.

(d) Banked human tissue shall be quarantined from donors who, within 48 hours prior to taking the blood sample, have been transfused with four or more units of blood, blood components, colloids or crystalloids in adults, or any transfusions within 48 hours in children under 12 years of age, unless:

(1) A pretransfusion blood sample is available for infectious disease testing; or

(2) An adequate algorithm is used to ensure that there is not hemodilution sufficient to alter test results.

(e) Determination that a donor of banked human tissue intended for transplantation is suitable shall include ascertainment of the donor's identity and adequately completed and accurately recorded relevant medical history which assures freedom from risk factors for or clinical evidence of hepatitis B, hepatitis C, or HIV infection. For corneal retrieval which occurs under authorization of a specific State or territorial law the relevant medical history shall include all available medical, coroner, and autopsy records.

(f) Banked human tissue for transplantation shall be quarantined or accompanied by records of the donor's relevant medical history as defined in paragraph (e) of this section which assure freedom from risk factors for or clinical evidence of hepatitis B, hepatitis C, or HIV infection.

§ 1270.7 Written procedures.

(a) There shall be written procedures prepared and followed for all significant steps in the infectious disease testing process under § 1270.5 which shall conform to manufacturers' instructions for use contained in the package inserts for the required test kits. These procedures shall be readily available to the personnel in the area where the procedures are performed, unless impractical. Any deviation from the written procedures shall be recorded and justified.

(b) There shall be written procedures prepared and followed for all significant steps for determining the medical history of the donor as provided in § 1270.5. Such procedures shall be readily available to personnel who may perform the procedures. Any deviation from the written procedures shall be recorded and justified.

(c) In conformity with this section, any facility may use current standard written procedures such as those in a technical manual prepared by another organization, provided the procedures are consistent with and at least as stringent as the requirements of this part.

§ 1270.9 Records, general requirements.

(a) Records shall be maintained concurrently with the performance of each significant step required in this part in the performance of infectious disease screening and testing of donors of human tissue for transplantation. All records shall be accurate and indelible and legible. The records shall identify the person performing the work, the dates of the various entries, and shall be as detailed as necessary to provide a complete history of the work performed and to relate the records to the particular tissue involved.

(b) All banked human tissue shall be quarantined until:

(1) All infectious disease testing under § 1270.5 has been completed, reviewed by a responsible official, and found to be negative;

(2) Donor screening has been completed, reviewed by a responsible official, and determined to assure freedom from risk factors for or clinical evidence of hepatitis B, hepatitis C, or HIV infection; and

(3) Copies of the testing and screening records accompany the tissue.

(c) All records, or true copies of such records, required under this part shall be readily available for authorized inspection at any establishment or from any individual that recovers, processes, stores, or distributes banked human tissue. Records that can be immediately retrieved from another location by electronic means meet the requirements of this paragraph.

(d) Records required under this part may be retained electronically, or as original paper records, or as true copies such as photocopies, microfiche, or microfilm, in which case suitable reader and photocopying equipment shall be readily available.

(e) Records shall be retained for no less than 10 years.

§ 1270.11 Specific records.

Records shall be maintained which include:

(a) Results and interpretation of all required infectious disease tests and retests.

(b) The destruction or other disposition of unsuitable banked human tissue.

(c) Information on the identity and medical history of the donor, as required by § 1270.5(e) in English or, if in another language, accompanied by a verified translation.

§ 1270.13 Inspections.

(a) An establishment covered by regulations in this part shall permit authorized representatives of the Food and Drug Administration to make at any reasonable time such inspection of the establishment, its facilities, equipment, processes, products, and records as may be necessary in the judgment of such representatives to determine compliance with the provisions of this part. Inspections may be made with or without notice and will ordinarily be made during regular business hours.

(b) Frequency of inspection will be based upon the compliance history of the establishment and at the agency's discretion.

(c) The inspector shall call upon the acting head of the establishment and may question the personnel of the establishment as the inspector deems necessary.

(d) The inspector may review and copy any records required to be kept pursuant to part 1270.

(e) Ordinarily, records containing the name or other positive identification of donors or recipients of human tissue will not be copied unless the identification is suitably expurgated. However, such information may be copied if necessary, such as to document distribution of potentially infectious tissue.

§ 1270.15 Recall and destruction of banked human tissue.

(a) Upon a finding that banked human tissue may be in violation of the regulations in this part, an authorized Food and Drug Administration (FDA) representative may:

(1) Serve upon the person who distributed the tissue a written order that the tissue be recalled or destroyed, as appropriate, and upon persons in possession of the tissue that the tissue shall be retained until it is recalled by the distributor, destroyed, or disposed of as agreed by FDA, or the safety of the tissue is confirmed; and

(2) Take possession of and/or destroy the violative tissue.

(b) The written order will ordinarily provide that the human tissue be recalled or destroyed with 5 days from the date of receipt of the order and will recite with particularity the facts which justify the order.

(c) After receipt of an order under this part, the person in possession of the human tissue shall not distribute or dispose of the tissue in any manner except to recall and destroy it consistent with the provisions of the order, under the supervision of an authorized official of FDA.

(d) In lieu of paragraphs (b) and (c) of this section, other arrangements for assuring the proper disposition of the tissue may be agreed upon by the person receiving the written order and an authorized official of FDA. Such arrangements may include providing FDA with records or other written information that adequately assure that the tissue has been recovered, processed, stored, and distributed in conformance with this part.

(e) Within 5 days of receipt of a written order for recall or destruction of tissue (or within 5 days of the agency's possession of such tissue), the recipient of the written order or prior possessor of such tissue, may request a hearing on the matter in accordance with part 16 of this chapter.

Dated: December 8, 1993.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

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