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Department of Energy

10 CFR Part 835
Occupational Radiation Protection; Final
Rule

DEPARTMENT OF ENERGY

10 CFR Part 835

[Docket No.: EH-RM-96-835]

RIN 1901-AA59

Occupational Radiation Protection

AGENCY: Department of Energy.

ACTION: Final rule.

SUMMARY: The Department of Energy (DOE) is amending its primary standards for occupational radiation protection. This final rule is the culmination of a systematic analysis to identify the elements of a comprehensive radiation protection program and determine those elements of such a program that should be codified as DOE continues its transition from a system of contractually-based nuclear safety standards to regulatory-based requirements. The final rule codifies requirements previously established in DOE's contractually-based standards, clarifies certain issues identified during implementation of programs to ensure compliance with the original rule, and corrects minor errors.

EFFECTIVE DATE: The amendments to this regulation become effective on December 4, 1998.

FOR FURTHER INFORMATION CONTACT: Dr. Joel Rabovsky, U.S. Department of Energy, Office of Worker Protection Programs and Hazards Management, EH-52, 19901 Germantown Road, Germantown, MD 20874, (301) 903-2135.

SUPPLEMENTARY INFORMATION:

- I. Background
- II. Discussion of Significant Changes
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- IV. Review Under the Regulatory Flexibility Act
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I. Background

On December 14, 1993, DOE published a final rule, 10 CFR part 835, "Occupational Radiation Protection" (58 FR 65458), which established regulatory requirements consistent with the "Radiation Protection Guidance to Federal Agencies for Occupational Exposure" (52 FR 2822) (Guidance to Federal Agencies), as well as guidance issued by authoritative organizations, including the National Council on Radiation Protection and Measurements

(NCRP) and the International Commission on Radiological Protection (ICRP). Many of the codified requirements were previously established in DOE Order 5480.11, "Radiation Protection for Occupational Workers." In addition, DOE codified in 10 CFR part 835 the "as low as is reasonably achievable" (ALARA) process as the primary means of maintaining occupational radiation doses below regulatory limits.

As a result of an initiative to eliminate redundant and unnecessarily stringent requirements, DOE conducted a systematic analysis to identify the elements of a comprehensive radiation protection program and determine those elements of such a program that should be codified as DOE continues its transition from a system of contractually-based nuclear safety standards to regulatory-based requirements. The systematic analysis included an evaluation of DOE's objectives for occupational radiation protection programs, including structured analyses of existing standards for similar programs, operational occurrences within the DOE complex, and provisions in the original rule. The analysis also included reviews of the requirements in DOE Notice 441.1, "Radiological Protection for DOE Activities," (extended by DOE N 441.2 and 441.3) and the provisions of the "DOE Radiological Control Manual" (Manual). DOE proposed to codify requirements in use within the DOE complex to ensure that worker health and safety programs would continue to be maintained at a level commensurate with workplace hazards. DOE also considered approaches used by national and international radiation protection organizations and experience throughout the DOE complex in achieving compliance with 10 CFR part 835. The systematic analysis is documented in a report entitled, "Development of the 1996 Proposed Amendment to 10 CFR part 835, Occupational Radiation Protection," (regulatory development document, November 1996) which may be viewed in the DOE Freedom of Information Reading Room at Room 1E-190, 1000 Independence Avenue, SW, Washington, DC, 20585, (202) 586-6020.

On December 23, 1996, DOE published a Notice of Proposed Rulemaking that would amend 10 CFR part 835 by:

1. Modifying the scope to explicitly exclude radioactive material transportation and certain activities conducted on foreign soil;

2. Adding requirements for area posting and sealed radioactive source control;

3. Adding a removable surface contamination value for tritium, to be used to identify the need for area posting and imposition of certain radioactive material controls;

4. Expanding and clarifying provisions of the rule to address emergent radiation protection issues;

5. Deleting certain provisions, as appropriate, to eliminate redundant and excessively stringent regulatory requirements; and

6. Clarifying and correcting minor errors.

As discussed in this Notice of Final Rulemaking, the final rule was developed in consideration of the extensive input received during two public hearings and through written and electronic public comments.

The schedule for achieving compliance with the amendments to 10 CFR part 835 is as follows. The final rule will become effective 30 days following publication in the **Federal Register**. As provided at § 835.101(g)(3), updated radiation protection programs (RPPs) must be submitted to DOE within 180 days following the effective date of the final rule. Changes that do not decrease the effectiveness of the RPP may be implemented prior to DOE approval. Changes that decrease the effectiveness of the RPP require DOE approval prior to implementation. As provided at § 835.101(i), an update of the RPP shall be considered approved 180 days after its initial submission unless rejected by DOE at an earlier date. The final rule, at § 835.101(f), requires full compliance with the regulatory changes within 180 days of RPP approval except for radiobioassay program accreditation required under § 835.402(d). Because of the breadth of the joint DOE/DOE-contractor effort needed to accomplish radiobioassay program accreditation, at § 835.101(f) DOE has established January 1, 2002 as the compliance date for the radiobioassay program accreditation requirements.

II. Discussion of Significant Changes

The discussion of the significant changes to 10 CFR part 835 and the response to public comments is organized according to subpart. When there was more than one significant change in a subpart the significant changes are generally listed in order of section. The topic addressed by each significant change is listed. In many cases, inclusion of a change to the provisions in one subpart or section required changes to other subparts or

sections of the regulation either for internal consistency or to resolve a public comment. For example a number of changes to the provisions of the rule required concomitant changes to the definitions or recordkeeping requirements. Accordingly, the discussion of a change may reference other subparts in addition to the one in which the primary change was made. This organization of the discussion of the significant changes to 10 CFR part 835 and the response to public comments was chosen to more clearly explain the changes and how DOE responded to the public comments.

A. General Provisions, Subpart A

1. Nuclear Explosive and Weapon Surety Program

Proposed Amendment

DOE proposed to revise the Nuclear Explosive and Weapon Surety Program exclusion at § 835.1(b)(3) to clearly indicate that the exclusion applies only to the extent that compliance with 10 CFR part 835 would compromise the effectiveness of activities essential to prevention of an accidental or unauthorized detonation. This action was initiated to ensure that radiation protection programs are implemented that do not compromise the overriding goal of preventing such incidents.

Summary of Public Comments and Disposition

DOE received comments indicating that this exclusion should also be extended to address the provisions of CG-TSS-S2, "Transportation Safeguards System Classification and Unclassified Controlled Information Guide (Supplement)," which states that "The fact that a specific SST (Safe Secure Trailer)/SSR (Safe Secure Railcar) is loaded or empty is CNSI (controlled nuclear safeguards information)." The commenters believe that certain posting and labeling provisions of 10 CFR part 835 would provide indication of the loaded or empty status of affected vehicles, contrary to the referenced guidance. DOE believes that the existing exclusion already provides the flexibility needed for implementation of programs consistent with CG-TSS-S2. Indeed, the situation presented by the commenters is exactly the type of condition for which the exclusion is intended.

Final Rule

After further consideration, DOE has determined that the proposed clarification is not needed. Ruling 1995-1 makes it clear that the existing language recognizes "the paramount

importance of preventing accidental or unauthorized nuclear detonations and ensuring that the requirements in (part 835) do not come into conflict with any activities necessary to prevent such detonation. However, [the language is] not intended to relieve the person responsible for a DOE nuclear facility or a DOE activity from complying with the requirements in (part 835) to the extent they do not interfere with the conduct of activities undertaken to prevent an accidental or unauthorized detonation." (61 FR 4212, February 5, 1996.)

2. Radioactive Material Transportation Proposed Amendment

DOE standards for packaging and transporting radioactive material are addressed in DOE Orders. DOE Orders 460.1A, "Packaging and Transportation Safety," and 460.2, "Departmental Materials Transportation and Packaging Management," provide DOE requirements for packaging and transportation of radioactive material. Requirements for radioactive material transported under DOE's national security mission are provided in DOE Order 5610.12, "Packaging and Off-site Transportation of Nuclear Components and Special Assemblies Associated with the Nuclear Explosive and Weapon Safety Program," and DOE Order 5610.14, "Transportation Safeguards System Program Operations." The requirements of these Orders are consistent with Department of Transportation (DOT) regulatory requirements and provide the framework for ensuring transportation safety. Certain provisions of 10 CFR part 835 complement these transportation safety directives by ensuring that individuals are afforded an adequate level of radiation protection while preparing radioactive materials for transportation and taking possession of radioactive material from transportation.

Although the absence of provisions pertaining to radioactive material transportation was addressed in the preamble for the original Rulemaking (58 FR 65465), DOE did not explicitly exclude radioactive material transportation from the scope of 10 CFR part 835. Consistent with its original intent as expressed in the preamble of the final rule, DOE proposed an exclusion at § 835.1(b)(4) for radioactive material transportation conducted in accordance with applicable DOE Orders. DOE also proposed a definition of "radioactive material transportation" at § 835.2(a) to clarify the distinction between the process of transporting radioactive materials, which would be excluded from 10 CFR part 835, and

those activities leading to or resulting from radioactive material transportation, which would be subject to 10 CFR part 835. The proposed definition included a specified threshold (specific activity) consistent with DOT requirements at 49 CFR 171-179.

Summary of Public Comments and Disposition

Public comments supported DOE's intent to exclude radioactive material transportation, but indicated that the proposed approach did not clearly establish the interface between 10 CFR part 835 and applicable transportation requirements. Other comments indicated that the term "specific activity" in the proposed § 835.2(a) definition of the term "radioactive material transportation" could be misconstrued, potentially resulting in non-compliant conditions.

Final Rule

The final rule clearly establishes the interface between the occupational radiation protection and transportation requirements. This approach makes it clear that 10 CFR part 835 does not apply to the radioactive material transportation, which is defined to be movement of radioactive material that is subject to DOE Orders or DOT regulations. The definition of radioactive material transportation is independent of the geographical location of the material being transported (i.e., inside or outside of the area controlled by DOE) and also independent of the radiological characteristics (e.g., specific activity) of the material in question. As a result of this revised approach, DOE has not included the term "specific activity" in the § 835.2(a) definition of the term "radioactive material transportation."

3. DOE Activities Conducted on Foreign Soil

Proposed Amendment

DOE proposed to add an exclusion at § 835.1(b)(5) for DOE activities conducted on foreign soil and under requirements agreed to between the foreign government and the United States. DOE proposed this exclusion in recognition of the primacy of foreign governments' occupational radiation protection requirements.

Summary of Public Comments and Disposition

Several commenters indicated that the development and approval of agreements with foreign governments may require action by the State Department and that DOE contractors could not take independent actions to

ensure that appropriate agreements have been reached. However, DOE activities, including those performed on foreign soil, are conducted under the cognizance of the responsible DOE Program Office and these offices are responsible for ensuring that such agreements are in effect before authorizing the conduct of the activities. The only action required of the DOE contractor will be to ensure that the DOE Program Office has established, or verified the establishment of, the appropriate agreements. Also, the activity is not excluded unless there are occupational radiation protection requirements agreed upon.

Final Rule

The final rule includes the exclusion for DOE activities conducted on foreign soil at § 835.1(b)(5).

4. Applicability of Occupational Dose Received From Excluded Activities

Proposed Amendment

At §§ 835.1(c), 835.202(a), and 835.202(b), DOE proposed changes to clarify the requirements for accounting for occupational doses received from non-DOE activities. The proposed amendment indicated that, even though certain activities are excluded from the scope of the rule at § 835.1(b), an individual's occupational dose resulting from excluded activities would be applied toward determination of compliance with the occupational dose limits established in subpart C of 10 CFR part 835. This is necessary to ensure that an individual's annual aggregate occupational dose is maintained below the limits specified in the Federal Guidance. This would include occupational doses received from activities licensed by the Nuclear Regulatory Commission (NRC) and its agreement states, activities conducted under the authority of the Director, Naval Nuclear Propulsion Program, activities conducted under the Nuclear Explosive and Weapon Surety Program, radioactive material transportation activities, and activities conducted under the auspices of foreign governments. However, radiation doses received from background radiation, as a patient for the purposes of medical diagnosis or therapy, and from participation as a subject in medical research programs are not considered occupational doses and would not be considered in determining compliance with the occupational dose limits. Furthermore, occupational dose received as a result of authorized emergency exposures and planned special exposures, although

occupational in nature, would not be considered in determining compliance with the dose limits established at § 835.202(a).

Summary of Public Comments and Disposition

Commenters generally supported this clarification of DOE policy.

Final Rule

The final rule adopts the proposed clarification that all occupational doses, other than doses resulting from authorized emergency exposures and planned special exposures, shall be considered in determining compliance with the limits set forth in §§ 835.202, and 835.207. Section § 835.206, Limits for the embryo/fetus, was included in this provision for consistency and completeness. Because § 835.1302 establishes the appropriate criteria for authorizing exposures under emergency conditions, DOE has instituted an editorial change to reference this section. Procedures for handling doses resulting from authorized emergency exposures and planned special exposures are discussed in Section II.C of this Notice of Final Rulemaking, "Limitation of Individual Doses."

5. Definitions

DOE proposed to add, revise, or remove the definitions of a number of terms that appear at § 835.2(a) and (b) as follows:

a. Adding definitions of the terms "accountable sealed radioactive source," "derived air concentration-hour," "occupational dose," "radioactive material area," "radioactive material transportation," "radiological control technician," "real time air monitoring," "respiratory protective device," "sealed radioactive source," "source leak test," and "week."

b. Revising the definitions of the terms "airborne radioactive material or airborne radioactivity," "airborne radioactivity area," "contamination area," "controlled area," "DOE activity," "high contamination area," "member of the public," "monitoring," "radiological area," "year," "committed dose equivalent," "cumulative total effective dose equivalent," "effective dose equivalent," "external dose or exposure," "internal dose or exposure," "quality factor," "total effective dose equivalent," and "weighting factor."

c. Removing the definitions of the terms "ambient air," "continuous air monitor," "collective dose," and "occupational exposure."

The effects of these proposed changes, significant public comments on these proposed changes, and any resulting

changes are discussed in this Notice of Final Rulemaking as these terms appear in the final rule.

6. Intervals Between Required Activities Proposed Rule

DOE proposed to revise the required intervals for internal audits, instrument and equipment calibration and maintenance, and radiation safety retraining from the specified number of years to the equivalent number of months. This change was proposed to eliminate any confusion resulting from the § 835.2(a) definition of the term "year," which specifically defined the year in terms necessary to ensure compliance with the subpart C dose limits.

Summary of Public Comments and Disposition

DOE received a number of comments indicating that the required intervals appeared to be somewhat arbitrary and should therefore include some degree of flexibility to accommodate operational and scheduling needs. DOE agrees with these observations.

Final Rule

DOE has included a provision at § 835.3(e) that will allow a 30 day automatic extension in the required time interval to accommodate operational and scheduling constraints. The extension is considered to be automatic in that there is no requirement to obtain DOE or other approval for the extension. This provision addresses the requirements of §§ 835.102, 835.901, and 835.1202 for internal audits, radiation safety training, and sealed radioactive source inventories and leak tests, respectively. Because of the varying lengths of the calendar months, DOE has not provided a definition of the term "month." DOE expects that those entities responsible for ensuring compliance with 10 CFR part 835 will undertake those measures necessary to perform the required activities within the prescribed time frame (i.e., if a sealed radioactive source is leak tested on January 15, DOE would expect the subsequent leak test to be performed on or before July 15 of the same year). When operational or scheduling considerations preclude adherence to that schedule, then one may consider utilization of the 30 day extension (i.e., the leak test could be performed no later than August 14 of the same year).

7. Radiological Units

Proposed Amendment

DOE proposed to delete the § 835.4 prohibition on use of the international (SI) radiological units. The international system of radiological units is commonly used for calculational and reference purposes. As proposed, § 835.4 would continue to require the use of the special radiological units in required records. Consistent with its historical endorsement of the special units and in recognition of the capabilities of many commercially-available instruments in use throughout the DOE complex, DOE also proposed to specifically allow for use of subunits and multiples of the unit "roentgen."

Summary of Public Comments and Disposition

Although some comments indicated that DOE should proceed toward use of the SI units for required records, DOE believes that considerations of consistency with records required by the NRC and its agreement states override the impetus toward use of SI units.

Final Rule

As proposed, § 835.4 of the final rule allows the use of the international system of units for calculations or reference purposes. Records required by 10 CFR part 835 will continue to be maintained using the special radiological units of curie, rad, roentgen, and rem.

B. Management and Administrative Requirements, Subpart B

1. Documented Radiation Protection Programs

Proposed Rule

Paragraph 835.101(g) of the original rule requires that those entities subject to the requirements of 10 CFR part 835 submit an update of the documented radiation protection program (RPP) within 180 days of the effective date of any regulatory modifications. DOE proposed to establish provisions at § 835.101(f) requiring compliance with amendments to 10 CFR part 835 no later than 180 days following approval of the updated RPP, except for the provisions of § 835.402(d) for radiobioassay program accreditation. Because of the extent of the joint DOE/DOE contractor effort necessary to complete the radiobioassay program accreditations, DOE proposed a compliance date of January 1, 2000 for this provision. DOE also proposed to delete outdated provisions codified at § 835.101 (f) and (g).

Summary of Public Comments and Disposition

Several commenters indicated that DOE's proposed compliance date of January 1, 2000 for radiobioassay program accreditation may be inappropriate due to the lack of experience in implementing the accreditation program. Other comments indicated that DOE delays in implementing the program might result in a state of non-compliance for DOE-contractors. DOE agrees that more time may be necessary to complete the required program accreditations.

Final Rule

DOE has codified the proposed 180 day period for achieving compliance with the amendments to 10 CFR part 835, except for the radiobioassay program accreditation requirements of § 835.402(d). DOE has extended the date for compliance with the radiobioassay program accreditation requirements until January 1, 2002 to accommodate the planned schedule to complete program accreditations throughout the DOE complex. DOE expects this extension to provide ample time for completion of the program accreditations. Should significant delays occur in performing the program accreditations, DOE could exercise appropriate enforcement discretion. These changes will not affect the compliance status of personnel dosimetry programs currently accredited, or excepted from accreditation, under the existing Department of Energy Laboratory Accreditation Program (DOELAP) standards.

DOE has deleted the outdated provisions of § 835.101 (f) and (g) as proposed.

2. Education and Training of Cognizant Individuals

Proposed Amendment

To address a number of shortcomings in its provisions for training radiological control technicians identified during its systematic analysis, DOE proposed to codify a definition of "radiological control technician" at § 835.2(a). DOE also solicited comments on four alternative approaches that were discussed in the preamble of the Notice of Proposed Rulemaking.

Summary of Public Comments and Disposition

Public comments indicated that DOE's proposed definition of the term "radiological control technician" did not adequately describe the roles and responsibilities of individuals filling

this position. DOE received comments endorsing each of the proposed alternative approaches, with the majority of the comments endorsing Alternative Approach 4 as discussed in the preamble of DOE's Notice of Proposed Rulemaking.

Final Rule

To satisfy its programmatic objectives for occupational radiation protection programs, DOE has codified an approach consistent with that discussed as Alternative Approach 4 in its Notice of Proposed Rulemaking. Under this approach, DOE has eliminated the specific requirements for radiological control technician training from subpart J of 10 CFR part 835 and added at § 835.103 a requirement for all individuals responsible for ensuring compliance with the rule to have the appropriate education, training, and skills. This approach provides the flexibility necessary to address the wide range of individuals involved in developing and implementing measures necessary for ensuring compliance with 10 CFR part 835, including cognizant managers, supervisors, auditors, engineers, clerks, and technicians.

3. Written Procedures

Proposed Rule

In its Notice of Proposed Rulemaking, DOE noted that the existing rule did not establish requirements for written procedures that consistently addressed the hazards associated with the specified activity. DOE believes that, due to the wide variation of radiological activities and their associated hazards conducted at DOE facilities, requiring written procedures for specific types of activities may divert resources from active management of higher-hazard activities to administrative control of lower-hazard activities. DOE discussed two alternative approaches in its Notice of Proposed Rulemaking. Alternative Approach 1 would eliminate most or all of the requirements for written procedures and leave the determination of the need for written procedures to the cognizant DOE Program Office. Alternative Approach 2 would eliminate most or all of the existing requirements for written procedures in favor of a general requirement that written procedures be developed and implemented commensurate with the radiological hazards created by the activity and consistent with the education, training, and skills of the affected individuals.

Summary of Public Comments and Disposition

Public comments overwhelmingly favored Alternative Approach 2. Commenters indicated that this approach would provide for an appropriate level of radiological safety while providing the flexibility needed to address the wide range of DOE activities. DOE agrees with the public comments.

Final Rule

DOE has established a requirement at § 835.104 consistent with that described as Alternative Approach 2 in its Notice of Proposed Rulemaking. As a result of this change, DOE has deleted specific requirements for written procedures from §§ 835.501(d), 835.1001(a), 835.1001(b), 835.1003(a), 835.1101(c), and 835.1102(c)(3) (formerly 835.404(d)). In addition, proposed requirements for written procedures at §§ 835.405(f) and 835.1201(a) were omitted from the final rule.

DOE's adoption of this approach is not intended to imply a global requirement that written procedures be developed and implemented to address all of the requirements of 10 CFR part 835. In evaluating the need for written procedures addressing any particular provision of 10 CFR part 835, consideration must be given to the nature and extent of the radiological hazards, the complexity of the measures necessary to achieve compliance, and the education, training and skills of the individuals who must implement those measures. Under such a regimen, a low hazard activity employing a stable staff of highly educated and skilled workers having an advanced knowledge of radiation protection principles and practices could have fewer and less detailed procedures than a higher hazard activity employing a transient force of workers with less knowledge of radiation protection principles and practices. The adequacy of the written procedures is ultimately determined by the appropriate implementation of the necessary compliance measures by the affected individuals.

Because the scope of subpart B of 10 CFR part 835 has been expanded, DOE has changed the title of this subpart to "Management and Administrative Requirements."

C. Limitation of Individual Doses, Subpart C

1. Summing of Internal and External Doses

Proposed Amendment

DOE proposed to revise § 835.203(a) to provide flexibility in requirements for summing of individual internal and

external dose equivalents to determine the total effective dose equivalent. As proposed, § 835.203(a) would require summing only when the individual was monitored in accordance with § 835.402 (that is, when the individual's dose was likely to exceed the mandatory individual monitoring thresholds) or when the individual's dose exceeded the mandatory monitoring thresholds, regardless of a priori expectations.

DOE also proposed to delete § 835.203(c) because this provision is redundant with provisions included in the § 835.2(b) definition of the term "weighting factor."

Summary of Public Comments and Disposition

DOE received comments indicating that all monitored individual internal and external doses should be summed to determine the total effective dose equivalent. Commenters noted that these data were available and could be important in future dose reconstruction or litigation efforts. DOE agrees with these comments. Although DOE is concerned about the administrative burden associated with the need to sum trivial internal and external doses, DOE has provided ample flexibility for ameliorating such burdens through codification of the individual monitoring thresholds provided at § 835.402.

Final Rule

DOE has omitted the proposed change from § 835.203(a), but deleted the second sentence of § 835.203(a) because this sentence is redundant with provisions included in the definition of the term "effective dose equivalent" at § 835.2(b). DOE has deleted § 835.203(c), as proposed.

2. Planned Special Exposures

Proposed Amendment

DOE proposed changes to the 10 CFR part 835 requirements for conducting planned special exposures in excess of the dose limits established at § 835.202. The proposed changes included:

- a. Changing the § 835.204(a)(1) reference from § 835.202(a)(1) to § 835.202(a) to indicate that all of the § 835.202 dose limits apply.
- b. Revising § 835.204(c) to indicate that doses resulting from planned special exposures may exceed the numerical values established at § 835.202(a) without actually exceeding the occupational dose limits.
- c. Clarifying documentation requirements for planned special exposures at § 835.204(d).

DOE also solicited comments on the possibility of deleting the provisions for planned special exposures because

these provisions have not been used to date.

Summary of Public Comments and Disposition

Commenters generally supported the proposed changes to the provisions for planned special exposures. Many commenters indicated that the provisions for planned special exposures should be retained to provide the maximum practical degree of flexibility.

Final Rule

Consistent with the comments received, DOE has retained the provisions for planned special exposures, with the proposed revisions, in the final rule.

3. Radiation Dose Limits

Proposed Amendment

DOE proposed editorial changes to § 835.207 and the heading of that section to clarify that the dose limits for minors apply to doses resulting from occupational exposure only. DOE also proposed to add deterministic dose limits for minors consistent with the Federal Guidance. Non-occupational exposure of minors is subject to the dose limits established at § 835.208 for members of the public entering a controlled area. DOE also proposed changes to § 835.208 to clarify that the member of the public dose limit applies to members of the public in the controlled area only. DOE proposed to revise the definition of "member of the public" at § 835.2(a) to clearly distinguish members of the public from temporary or transient workers or visiting scientists who could receive occupational doses.

DOE proposed to revise the definition of "cumulative total effective dose equivalent" (CTEDE) at § 835.2(b) to include all total effective dose equivalent (TEDE) values, where available, from January 1, 1989, whether or not the dose was received at that DOE site or facility.

Summary of Public Comments and Disposition

Several commenters questioned DOE's proposed approach to controlling doses to minors, pointing out that a minor could possibly receive 0.1 rem in a year occupational dose and 0.1 rem in a year as a member of the public. Although this scenario is possible, the resulting maximum dose is well below the most recent recommendations of scientific bodies for exposures that do not occur repeatedly.

DOE did not receive any substantive comments on the proposed change to the definition of the term "cumulative total effective dose equivalent."

Final Rule

DOE has adopted the changes, essentially as proposed. DOE has also made editorial changes to §§ 835.207 and 835.208 for clarity. These changes include omitting, in § 835.207, the proposed occupational dose limit for minors of 10% of the § 835.202(a)(2) limit. This limit is redundant because the 0.1 rem total effective dose equivalent limit for minors is always more restrictive.

4. Exposures to Airborne Radionuclides

Proposed Amendment

DOE proposed to delete § 835.209(b) because of redundancy with other rule requirements for inhalation exposures and external exposures from airborne radionuclides.

Summary of Public Comments and Disposition

DOE did not receive any substantive comments on the proposed deletion.

Final Rule

DOE has deleted § 835.209(b) and redesignated § 835.209(c) as § 835.209(b). In addition, DOE has initiated an editorial change by deleting the word "representative" from § 835.209(c)(3) (redesignated as § 835.209(b)(3)). This word was redundant with the remaining requirement that the internal dose estimate based upon air concentration values must be as or more accurate than that based upon bioassay results.

D. Monitoring of Individuals and Areas, Subpart E

1. General Requirements for Area and Individual Monitoring

Proposed Amendment

In reviewing the requirements of 10 CFR part 835, DOE noted that the terms "monitoring" and "survey" were not used consistent with the definitions provided at § 835.2(a). DOE proposed changes to the definition of the term "monitoring" at § 835.2(a) to clearly establish that "monitoring" involves measurement of radiological conditions and the subsequent use of the results of these measurements to evaluate potential and actual exposures to ionizing radiation. As proposed, the term "survey," would be more directly related to the assessment of workplace or material radiological conditions through direct measurement, assessment, or calculation for the

purposes of hazards assessment. DOE proposed changes throughout the rule to ensure consistent application of these terms.

DOE proposed to clarify the requirements of §§ 835.401(c) and 835.703(d) by making the calibration requirements apply to both "instruments" and "equipment." This clarification is consistent with current field practice with regard to equipment, such as an air sampler, that, although incorporated into or associated with instrumentation systems, does not have any instrumentation.

Summary of Public Comments and Disposition

DOE received a number of comments supporting its attempt to clarify the "monitoring" and "surveying" terminology. However, comments indicated that the usage of these terms remained inconsistent.

With regard to the proposed § 835.401(c) requirements for calibration and maintenance of instruments and equipment, DOE received a number of comments indicating that the required one year calibration frequency was overly stringent given the reliability of many modern instruments, particularly certain fixed monitors. Other commenters indicated that the term "equipment" could conceivably be extended to include vehicles, calculators, and other equipment routinely used in the course of area monitoring.

Commenters indicated that the use of the undefined term "workplace" in this subpart could result in confusion regarding the scope of the requirements. Commenters also indicated that the use of the term "area monitoring" at § 835.401(b) seemed to imply that stationary area monitors were required under certain conditions.

Final Rule

DOE has determined that, for regulatory purposes as established in 10 CFR part 835, there is no substantive difference between the uses of the terms "monitoring" and "survey." Therefore, in the final rule DOE has revised the definition of the term "monitoring" and deleted the term "survey," replacing this term with "monitoring" (as modified) throughout the rule. DOE has also deleted the undefined terms "sampling" and "measurements" in favor of the defined term "monitoring."

DOE has deleted the term "workplace" from subpart E of 10 CFR part 835, instead adopting a performance-oriented approach of "monitoring of individuals and areas." In a related editorial change, DOE has

deleted the term "area monitoring" from proposed § 835.401(b) and redesignated the remaining text as § 835.401(a)(6) to eliminate any connotation regarding requirements for stationary radiation monitors. DOE has also substituted the defined term "individual" for the undefined term "personnel" in this provision.

In response to comments on DOE's requirements for calibration and maintenance of instruments and equipment, DOE has revised these requirements (at redesignated § 835.401(b)(1)) such that calibration and maintenance will be required "periodically" on an "established frequency." This change is consistent with NRC requirements at 10 CFR 20.1501 and provides flexibility for acceptance of recommendations provided in various consensus standards accepted by the instrument calibration community and used within the DOE complex. DOE will provide guidance regarding measures for establishing appropriate maintenance and calibration frequencies and proper application of these requirements to "equipment" used for monitoring.

As used in 10 CFR part 835, instruments and equipment used for monitoring includes devices used for both area monitoring (e.g., portable and installed radiation, contamination, and airborne radioactivity sampling and monitoring devices) and individual monitoring devices (e.g., thermoluminescent dosimeters, pocket ion chambers, track etch dosimeters, and electronic dosimeters). Note that the calibration of personnel dosimeters that are required under § 835.402 is addressed by the DOELAP for personnel dosimetry.

2. Individual Monitoring and Dose Determination

Proposed Amendment

DOE proposed several changes to the existing requirements for monitoring individual radiation doses. The proposed changes included:

a. Clarifying the requirements for external and internal dose monitoring programs at § 835.402(b) and (d) by providing that such programs must be capable of demonstrating compliance with all of the individual dose equivalent limits in subpart C. This approach is consistent with DOE's previously established requirements for records required under § 835.701(a).

b. Revising the monitoring requirements for minors at § 835.402(a)(3) and (c)(3) to expressly state that these requirements apply to occupationally exposed minors only.

Minors who are not occupationally exposed are subject to the member of the public monitoring requirements found at § 835.402(a)(4) and (c)(4).

c. Deleting from § 835.402(c)(1) the monitoring threshold based on organ and tissue committed dose equivalent. The monitoring threshold based upon committed effective dose equivalent obviates the need for this threshold because, through application of the weighting factors defined at § 835.2(b), the committed effective dose equivalent always provides a more restrictive basis for individual monitoring.

d. Changing § 835.402(a)(1)(i) to require individual monitoring on the basis of deep dose equivalent rather than effective dose equivalent because deep dose equivalent is the parameter actually monitored by existing dosimetry programs.

e. Removing provisions at § 835.402(a)(1)(iv) for measuring deep dose equivalent from external sources to any organ or tissue other than the lens of the eye because any doses meeting this condition are adequately addressed by § 835.402(a)(1)(i).

f. Clarifying § 835.402(a)(4) and (c)(4) to indicate that these provisions apply to members of the public inside the controlled area only.

Summary of Public Comments and Disposition

Commenters indicated that the proposed § 835.402(a)(1)(i) requirement for monitoring of deep dose equivalent, as worded, would challenge the capabilities of modern dosimetry systems. While the technical basis for the comments was not clear, reflection on these comments revealed that the wording in the proposed rule could suggest the basis for initiating monitoring was the highest dose received by any portion of the whole body. Furthermore, although deep dose equivalent is the quantity most commonly measured, effective dose equivalent is the appropriate criterion upon which the mandatory individual monitoring threshold should be based because the corresponding occupational dose limits are stated in terms of effective dose equivalent.

Final Rule

DOE agrees with the public comments regarding the proposed change to § 835.402(a)(1)(i). The language in the original version of 10 CFR part 835 has been retained. DOE has included the other proposed changes in the final rule.

3. Program Accreditation Proposed Amendment

DOE proposed a number of enhancements and additions to the existing requirements for the DOELAP. These proposed changes included:

a. Amending § 835.402(b) to indicate that, except as discussed below, personnel dosimetry programs must be either accredited under the DOELAP or excepted from accreditation under that program.

b. Amending § 835.402(d) to require radiobioassay program accreditation or exception through the recently developed DOELAP for Radiobioassay. This proposed change was intended to ensure the integrity of radiobioassay programs and prevent recurrence of recent adverse events.

c. Revising § 835.402(b) and (d) to limit the scope of the DOELAP requirements to personnel dosimetry and radiobioassay programs implemented to ensure compliance with § 835.402 (i.e., monitoring when individual doses are likely to exceed the stated thresholds). In a related change, because § 835.401(b) addresses calibration of instruments and equipment used for monitoring and DOELAP for Personnel Dosimetry provides appropriate dosimetry system performance criteria, DOE proposed to delete the dosimeter calibration requirement from § 835.402(b).

d. Adding § 835.402(e) to require that external dosimetry and bioassay programs conform to the most recent revisions of the DOELAP technical standards or be subject to review and approval of the Secretarial Officer responsible for environment, safety, and health matters (currently the Assistant Secretary for Environment, Safety and Health). For those programs that are not accredited or excepted from the accreditation program, this provision would also allow this same officer to provide approval if the programs demonstrate performance equivalent to those accredited under the DOELAP. This provision would ensure that, to the extent practical, DOE radiation protection programs will reflect the latest advances in the sciences of external and internal dosimetry. To prevent the automatic loss of accreditation status as a result of changes to the DOELAP technical standards, the DOELAP technical standards provide that changes in the standards become effective only during the ensuing accreditation cycle.

Summary of Public Comments and Disposition

Several commenters suggested that all individual dose measurements be performed under an accredited dosimetry program in order to maintain credibility of all monitoring data. However, DOE does not believe that is appropriate to impose regulatory accreditation requirements on monitoring programs that are not required by regulation. Existing regulatory provisions at § 835.402(a) and (c) require individual monitoring for all individuals likely to receive a dose equivalent exceeding the specified thresholds. As part of a comprehensive radiation protection program, measures used to identify these individuals should include comprehensive, documented area monitoring and could include, if management so chooses, individual monitoring. Section 835.401 establishes minimum requirements for performing such monitoring, including requirements for calibration and maintenance of instruments and equipment used to perform the monitoring. As required by §§ 835.701(a) and 835.703, the monitoring results must be documented.

Several commenters recommended that DOE revise the rule to permit DOE facilities to procure the services of dosimetry processors who are accredited by the National Voluntary Laboratory Accreditation Program (NVLAP) administered through the National Institute of Standards and Technology, as an alternative to accreditation under the DOELAP for personnel dosimetry. These comments noted the NRC's regulations require licensees to use dosimetry processors with NVLAP accreditation. They argued that permitting NVLAP accreditation in lieu of DOELAP accreditation, would maximize private sector competition for DOE contracts. DOE has not accepted the commenters' recommendations because NVLAP accreditation does not meet DOE's requirement for an external dose monitoring program. DOELAP accreditation covers both the facility's and the processor's quality assurance program, whereas NVLAP only deals with the dosimetry processor. The commenter's reference to the NRC's use of NVLAP accreditation for dosimetry processors ignores the fact that NRC has the resources to perform frequent on-site inspections of a facility's dosimetry program. In the absence of such resources at DOE facilities, DOE relies upon the DOELAP accreditation to ensure that a facility's personnel dosimetry program provides accurate results.

DOE received comments on its proposal to require DOELAP accreditation, exception from accreditation under DOELAP, or DOELAP equivalency, for radiobioassay programs that would satisfy the internal dose monitoring program requirement in the rule. The commenters argued that it would be premature to impose this requirement because DOE has not completed the process for developing accreditation standards for radiobioassay programs. As discussed in connection with § 835.101, concerning the effective date of the rule, DOE has responded to these concerns by extending the deadline for complying with this provision to January 1, 2002. In any event, § 835.402(d) provides for Secretarial Officer approval of radiobioassay programs that are not accredited under DOELAP.

Several commenters objected to proposed § 835.402(e), which would have required Secretarial Officer approval of personnel dosimetry and radiobioassay programs that do not comply with the latest edition of DOE's technical standards governing program accreditation. They argued that incorporation by reference of the technical standards was inappropriate because the requirements in the technical standards had not been proposed for public comment in a rulemaking. In light of these comments, DOE has deleted the reference to DOE's technical standards for accreditation in the regulatory text of the final rule. DOE does not intend to codify the accreditation standards through this rulemaking. DOE technical standards are guidance documents to assist contractors in implementing regulatory requirements. As a matter of policy (DOE P 450.2A, May 15, 1996), DOE routinely seeks public comments on guidance documents issued to implement environment, safety and health requirements at DOE sites. On April 24, 1997, DOE published a notice of availability of draft guides and technical standards for the Occupational Radiation Protection Program (62 FR 19940). At that time, DOE invited public comment on draft technical standard, "Department of Energy Laboratory Accreditation Program Administration," which includes requirements for personnel dosimetry and radiobioassay program accreditation. The revised regulatory provisions will accomplish DOE's purpose of providing that programs which DOE accredits, or excepts from accreditation, under DOELAP will satisfy the requirements in this rule for programs that are implemented to demonstrate

compliance with § 835.402(a) and (c). Accreditation under DOELAP will obviate the need for contractors to secure approval of the Assistant Secretary for Environment, Safety and Health.

Final Rule

In the final rule DOE has revised § 835.402(b) and (d) to provide that contractors may demonstrate the adequacy of external and internal dose monitoring programs, respectively, by submitting their programs to the Secretarial Officer responsible for environment, safety and health for approval in lieu of accreditation or exception from accreditation under the DOELAP. Alternative programs will be approved if their performance is demonstrated to be substantially equivalent to that of accredited programs. This change makes unnecessary, and DOE has deleted, proposed § 835.402(e), which would have required Secretarial Officer approval of programs not complying with the latest edition of the technical standards for DOELAP accreditation.

DOE has adopted the other changes as proposed, with minor editorial corrections.

4. Air Monitoring

Proposed Amendment

DOE proposed to revise the § 835.403(a)(1) air sampling requirement to be based on potential individual exposures in derived air concentration (DAC)-hours in a year rather than a percentage of the annual limit on intake (ALI) because the values provided in appendices A and C of 10 CFR part 835 are listed as DACs. DOE proposed to add § 835.403(a)(2) to require that air sampling be performed when respiratory protective devices are prescribed to protect individuals from exposure to airborne radionuclides. DOE also proposed an editorial change to delete § 835.403(b), eliminating redundancy with § 835.401(b).

To enhance air monitoring programs, DOE proposed to provide more practical and technically accurate criteria at § 835.403 for the use of real-time air monitors based on potential releases that would exceed a defined threshold exposure levels of 40 DAC-hours in a week. In a related change, DOE proposed to replace the term "continuous air monitor" with the term "real-time air monitor" with supporting changes to the definitions provided at § 835.2(a). DOE also proposed to add a definition of the term "week" at § 835.2(a).

Summary of Public Comments and Disposition

DOE received a number of comments indicating that the proposed revision of the requirements for real-time air monitoring was unclear and did not acknowledge the actual capabilities of available monitors. Other commenters indicated that the proposed definition of the term "week," based upon a period beginning on Monday, might cause unnecessary changes in existing schedules for real-time air monitor filter changes. Several commenters indicated that the proposed provisions for air sampling when respiratory protective devices are prescribed could be construed to mean that an air sample must be taken each time an individual enters an area wearing a respiratory protective device.

DOE received comments indicating that the existing criterion based upon the percentage of an ALI was more appropriate for prospective establishment of air monitoring programs. DAC-hours are related to the fraction of an ALI in a consistent and fixed manner; therefore, potential exposures in units of DAC-hours are an appropriate basis for prospectively determining the need for air sampling.

Final Rule

As suggested through public comments, DOE clarified the mandatory airborne radioactivity monitoring criteria in the final rule. Section 835.403(a) of the final rule requires the implementation of air sampling programs in areas in which an individual is expected to be exposed in excess of 40 DAC-hours in a year. The final rule clarifies that airborne radioactivity monitoring during use of respiratory protective equipment is required "as necessary" to characterize the hazard. This provision is consistent with requirements imposed by both the NRC and the Occupational Safety and Health Administration (OSHA) (see 10 CFR 20.1703(a)(3), "Use of individual respiratory protection equipment," and 29 CFR part 1910, "Occupational Safety and Health Standards," § 1910.134(d)(1)(iii), respectively).

The § 835.403(b) criterion for real-time air monitoring is based upon the need to alert potentially exposed individuals of the need for action to reduce or terminate exposures to airborne radioactive material. This approach provides more flexibility for implementation on a site-and facility-specific basis, taking into account realistic event scenarios, source terms, and instrument capabilities. This requirement acknowledges the wide

variety of configurations and hazards associated with DOE activities and the limitations of currently available real-time air monitoring equipment. DOE's implementing guidance provides an acceptable approach for achieving compliance with this provision. The restructuring of the requirements for real-time air monitoring rendered proposed § 835.403(c) redundant; DOE has therefore deleted this provision.

In support of the revised provisions, § 835.2(a) provides definitions for the terms "derived air concentration-hour (DAC-hour)," "real-time air monitoring," "respiratory protective device," and "week" which are used at § 835.403. In consideration of public comments, DOE has revised the proposed definition of the term "week" to omit a mandatory starting day. In addition, DOE has deleted the definitions of "ambient air" and "continuous air monitor" because these terms are no longer used in 10 CFR part 835.

5. Contamination Monitoring

In consideration of public comments received, DOE has revised the § 835.404 requirements for contamination monitoring and control and moved these requirements to § 835.1102. The proposed changes, public comments, and final rule provisions are discussed in full in Section II.J of this Notice of Final Rulemaking.

6. Receipt of Packages of Radioactive Material

Proposed Amendment

DOE proposed to add requirements at § 835.405 for surveys of packages of radioactive material received from radioactive material transportation to ensure adequate protection is provided to individuals, including warehouse and office workers, who may be exposed to these materials. The proposed provisions included requirements for taking possession of radioactive material packages from transport and performing surveys of these packages. At § 835.405(d), DOE proposed to establish requirements for completion of the necessary surveys within three hours of receipt of the package (if received during working hours) or within three hours of the beginning of the following working day (if received after working hours). The proposed requirements are similar to NRC requirements at 10 CFR 20.1906.

Summary of Public Comments and Disposition

Several commenters suggested that the time provision included in the proposed amendment was unnecessarily

stringent. During evaluation and resolution of these comments, DOE determined that the nature of many of its sites and facilities and the stringency of the requirements for radioactive material transportation indicate that this observation is accurate.

Final Rule

In deference to the comments received and in recognition of the variety of sites and facilities subject to 10 CFR part 835, DOE has extended the time required for monitoring packages received from radioactive material transportation to 8 hours after the beginning of the working day following the receipt of the package. In practice, the actual interval may also be constrained by the requirements for individual monitoring and radiation safety training at §§ 835.402 and 835.901 respectively, and by the ALARA requirements at § 835.101.

As used in § 835.405, a "working day" is considered to be the interval of time within each 24 hour period during which the building or area in which the received package is stored is routinely occupied or available for operations other than emergency activities. For example, if the received package is stored in a warehouse awaiting the required monitoring and that warehouse is occupied or accessible to shipping and receiving personnel, then the working day is that period of time within each 24 hour period during which the shipping and receiving personnel are scheduled to be working or to have ready access to the warehouse. The working day does not include periods during which shipping and receiving personnel would have to return to work on a non-scheduled basis to address emergent issues requiring their attendance.

E. Entry Control Program, Subpart F

Proposed Amendment

DOE proposed more detailed provisions for written work authorizations at § 835.501(e) to address operational occurrences throughout the DOE complex. DOE also proposed to revise § 835.502 to add measures for control of access to high radiation areas. The proposed control measures were consistent with those previously established in the Manual and included requirements for use of a supplemental dosimetry device and appropriate area surveys.

Summary of Public Comments and Disposition

Commenters expressed concern that the proposed § 835.501(e) entry control

requirements were inappropriate for relatively minor hazards present in areas such as radiation areas. With regard to the proposed high radiation area access control requirements, commenters also indicated that devices capable of rendering an immediate indication of an individual's integrated dose resulting from neutron radiation are not commercially available. Several commenters also indicated that the proposed § 835.502(c) requirements for control of access to very high radiation areas could be taken to mean that the required controls must be impenetrable. DOE agrees that these issues require clarification.

Final Rule

Regarding low-hazard radiological areas, the final rule provides significant flexibility for implementation of access controls on a facility-and hazard-specific basis. The written authorizations required by § 835.501(d) must specify radiation protection measures consistent with existing and potential hazards. DOE does not intend for this provision to establish a global requirement for the development and implementation of radiological work permits to address all entries into radiological areas. The written authorization may take the form of generally applicable procedures, as appropriate. Guidance on the use of written authorizations will be published in DOE's Radiological Control Standard. As a result of the deletion of specific requirements for written procedures (discussed in Section II.B.3 of this Notice of Final Rulemaking), DOE has redesignated proposed § 835.501(e) as § 835.501(d) in the final rule.

To address the unavailability of devices capable of providing an immediate indication of an individual's dose resulting from exposure to neutron radiation in a high radiation area, § 835.502(a)(2) allows for supplemental dosimeters or other means of immediately estimating or measuring the individuals' integrated doses during the area entry. The other means may include knowledge of the area exposure rates combined with tracking of individual access times. Consistent with the existing definition of the terms "high radiation area" and "very high radiation area," DOE has revised the proposed requirements to indicate that the required devices and measures must be capable of estimating the affected individual's deep dose equivalent, rather than the dose equivalent. DOE also provided an editorial correction at § 835.502(b)(2), substituting the defined term "individuals" for the undefined term "personnel."

In response to public comments, DOE has clarified § 835.502(c) to indicate that the additional controls required for very high radiation areas need to be sufficient to prevent "unauthorized or inadvertent" entries rather than to prohibit entry into the area.

F. Posting and Labeling, Subpart G

1. Controlled Area and Radiological Area Posting Requirements

Proposed Amendment

DOE proposed several changes to clarify and simplify requirements for area hazard posting and to provide additional flexibility in implementing these requirements. In acknowledgment of the differing hazards and controls associated with removable and fixed radioactive contamination, DOE proposed to revise the § 835.2(a) definitions of "contamination area" and "high contamination area" to be based upon removable surface contamination levels only and to clearly establish these areas based on accessibility rather than the general reference to "working areas" which appeared at § 835.601(a). DOE proposed a similar change to the § 835.2(a) definition of the term "airborne radioactivity area." DOE also proposed to move the controlled area maximum dose expectation from the § 835.2(a) "controlled area" definition to the § 835.602(a) controlled area posting provision.

Because radiological area terms are defined at § 835.2(a), DOE proposed to remove redundant definitions imbedded in the posting provisions at § 835.603. DOE also proposed to delete the requirement for DOE approval of warning signs from § 835.601(b) because acceptable signs are described in DOE's implementing guidance and DOE did not intend to establish a formal process for approval of radiological postings and labels. In addition, DOE proposed to expand its provision at § 835.601(e) (redesignated as § 835.601(d) in the proposed amendment) allowing modification of postings and labels to accommodate special considerations of DOE activities involving private residences to also include private businesses.

Consistent with NRC requirements published at 10 CFR 20.1902, DOE proposed to amend § 835.603(b), (d), and (f) to allow use of the words "Caution" or "Danger" on postings for high radiation, high contamination, and airborne radioactivity areas, respectively. This proposed change would accommodate the wide range of radiological conditions that may be present in these areas to provide some degree of flexibility in their posting.

Proposed § 835.604(a) would create an exception from posting requirements for periods of less than 8 continuous hours as long as the radiological area is placed under continuous observation and control of a person able to implement the required access and exposure control measures. This exception would cover temporary conditions or activities such as maintenance, repair or cleanup activities so long as the absence of posting is kept to within the prescribed time and the prescribed control measures are implemented.

DOE also proposed to add § 835.604(b) and (c) delineating specific exceptions from the radiological area posting requirements of § 835.603, recognizing that compensatory measures may be implemented that would obviate the need for area posting. The proposed exceptions are similar to those established by the NRC at 10 CFR 20.1903.

Summary of Public Comments and Disposition

DOE received several comments indicating that the proposed definition of the term "airborne radioactivity area" should include an exposure-based criterion (i.e., based upon potential individual exposures in term of dose, percentage of an ALI, or DAC-hours) instead of, or in addition to, the existing criterion based upon the absolute airborne radioactivity concentration. DOE agrees that this issue requires clarification.

Some commenters expressed support for the current 10 CFR part 835 posting provisions based upon the identification of "working areas." However, the term "working areas" is not defined and DOE does not believe that posting of only "working areas" provides adequate protection of individuals approaching or entering radiological areas in which there is no work in progress. The commenters did not provide any evidence that such a practice would provide for adequate protection.

DOE received a number of comments on the proposed allowance for the use of "Caution" or "Danger" on certain radiological hazard warning signs. Commenters indicated that the terms "Caution" and "Danger" are not interchangeable and that the term "Danger" generally carries a connotation of greater hazard than "Caution." While DOE agrees with these observations, DOE believes that, in the continuum of possible radiological conditions associated with DOE activities, the threshold at which "Danger" becomes more appropriate than "Caution" most likely lies somewhere within those conditions

described in the § 835.2(a) definitions of "airborne radioactivity area," "high radiation area," and "high contamination area." Furthermore, individual protective actions required for entry into these areas are dependent upon the radiological area title, not the "Caution" or "Danger" heading. DOE believes that the demarcation between those conditions requiring "Caution" and "Danger" headings is best left to the discretion of those responsible for individual DOE activities to ensure that activity-specific conditions are addressed. Therefore, DOE believes that it is appropriate to allow flexibility in the use of the "Caution" and "Danger" headings for posting of high radiation, high contamination, and airborne radioactivity areas.

Some commenters indicated that provisions for alternative measures for DOE activities conducted at private residences and businesses should be extended to DOE activities conducted on state- and Federally-owned lands. However, DOE does not believe that considerations of individual property rights and property value impacts extend to DOE activities conducted on state and Federal lands. Furthermore, the great majority of DOE activities are conducted at state- and Federally-owned sites. Such an exception would negate the specific posting requirements for essentially all DOE activities.

Commenters generally supported DOE's proposed exceptions to the radiological posting requirements. However, comments indicated that the proposed § 835.604(c) exception for packages received from radioactive material transportation should not apply to damaged packages. DOE agrees that this issue requires specific attention.

Final Rule

DOE has revised the § 835.2(a) definition of the term "airborne radioactivity area" such that posting and control of these areas will be required when the airborne radioactivity concentration exceeds the DAC values provided in appendix A or C of 10 CFR part 835 or when an individual present in the area without a respiratory protective device could be exposed to airborne radioactive material in excess of 12 DAC-hours in a week. This definition is similar to that provided by the NRC at 10 CFR 20.1003.

DOE has codified the changes to the radiological hazard posting requirements as proposed. In the final rule, DOE has deleted § 835.601(a) to eliminate redundancy. As a result, § 835.601(b)—(d) have been redesignated as § 835.601(a)—(c), respectively. The § 835.604 radiological

area posting exceptions do not apply to the radiological area entry control requirements established at §§ 835.501 and 835.502 or to the radiation safety training requirements at § 835.901. In response to public comments, DOE has restricted the scope of the posting exception for packages received from radioactive material transportation to those packages received in a non-degraded condition.

2. Radioactive Material Area Posting Proposed Amendment

To ensure that individuals entering controlled areas but not entering radiological areas are adequately protected, DOE proposed requirements for posting of radioactive material areas similar to the existing requirements of DOE N 441.1 (extended by DOE N 441.2 and DOE N 441.3). The proposed posting requirements were based on quantities of radioactive materials that exceeded 10 times the threshold values proposed in appendix E of 10 CFR part 835 and were similar to NRC requirements at 10 CFR 20.1902. DOE proposed to define "radioactive material area" and include this term in the definition of "radiological area" at § 835.2(a) and establish requirements for posting radioactive material areas at § 835.603(g). DOE also proposed exceptions to the radioactive material area posting requirements at § 835.604(b).

Summary of Public Comments and Disposition

DOE received numerous comments on these proposed requirements. The major issues included: (1) The threshold values (based on ten times the activity levels provided in proposed appendix E of 10 CFR part 835) which would require posting of radioactive material areas were overly restrictive; (2) the hazards present in a radioactive material area, as defined, did not warrant the imposition of specific entry controls and radiation safety training programs required for radiological areas; (3) posting of radioactive material areas should not be required when the radioactive material consists solely of activated structures or installed components; and (4) there is no apparent difference between the hazards in a controlled area and a radioactive material area, as defined at § 835.2(a).

DOE agrees that: (1) The proposed appendix E values, as a basis for defining a radioactive materials area, were somewhat restrictive; (2) posting of radioactive material areas should not be required when the material solely consists of structures or installed

components which have been activated; and (3) the hazards present in a radioactive material area, as defined, are not always significantly different than the hazards in a controlled area and would not always warrant imposition of the entry controls required for the defined radiological areas.

Final Rule

DOE recognizes the fact that the radiological conditions expected in radioactive material areas, as proposed, are less hazardous than those present in radiological areas as defined in the original rule. Accordingly, a less restrictive approach to radiological protection is warranted. In the final rule, DOE has omitted the term "radioactive material area" from the § 835.2(a) definition of "radiological area." Therefore, radioactive material areas will not be subject to the specific entry control provisions of § 835.501. As a result of the codification of hazard-based radiation safety training requirements at § 835.901 (discussed in Section II.H. of this Notice of Final Rulemaking), applicability of the radiation safety training requirements for entry into radioactive material areas will be subject to an evaluation of the activities to be performed in the area and the degree of actual or potential exposure to radiological hazards.

Section 835.603(g) of the final rule requires posting of radioactive material areas at the entry points to accessible areas where there exist items or containers of radioactive material in excess of the revised appendix E values as published, rather than ten times the appendix E values, as proposed. The basis for the revised appendix E values is discussed in detail in Section II.K of this Notice of Final Rulemaking. Because of the minimal hazards present in radioactive material areas, DOE has omitted the allowance for the use of the "Danger" heading from the § 835.603(g) requirement for posting of radioactive material areas.

DOE has included proposed exceptions to the radioactive material area posting requirement at § 835.604. In response to the comments received, DOE has included another posting exception for areas in which the radioactive material consists solely of structures or installed components which have been activated, such as activation by exposure to neutron radiation or radiation incident to operation of a particle accelerator. DOE expects that this exception will most commonly be applied to building and shielding structures associated with nuclear reactors and particle accelerators. Note that these structures

and components are not excepted from the radiological area posting requirements.

Because the term "radioactive material area" has been deleted from the § 835.2(a) definition of the term "radiological area," DOE has revised the heading of § 835.603 and the provisions of § 835.602(a) to reflect the inclusion of the radioactive material area posting requirements in subpart G of 10 CFR part 835.

3. Radioactive Material Labeling Proposed Amendment

To augment and clarify existing requirements, DOE proposed to add requirements for labeling items and containers of radioactive materials at § 835.605, with appropriate exceptions being proposed at § 835.606. These proposed provisions are similar to those in the Manual and consistent with requirements imposed by the NRC at 10 CFR 20.1904 and 20.1905.

Summary of Public Comments and Disposition

DOE received comments indicating that, because the proposed labeling provisions were based upon the proposed appendix E total activity values, they were not adequate to ensure proper labeling of items having removable contamination exceeding the 10 CFR part 835 appendix D surface radioactivity values. However, even though labeling of contaminated items is not explicitly required by the rule, adequate controls are established under §§ 835.1101 and 835.1102 which will require that either labeling or equivalent measures be implemented to inform individuals of the contamination hazard.

DOE also received comments on the proposed exceptions from the labeling requirements. Commenters indicated that exceptions should also be provided for nuclear weapons and their components, for inaccessible radioactive material, and for activated building components. DOE agrees with these comments.

Final Rule

DOE has codified the proposed requirements for labeling with minor editorial changes. Section 835.605 requires labeling of radioactive items and containers of radioactive materials. Section 835.606 provides an exception from the labeling requirements for items and containers having a total activity of less than $\frac{1}{10}$ of the appendix E values rather than at the proposed appendix E values because DOE has reevaluated the appendix E values to address concerns regarding the stringency of the proposed

requirements for accountable sealed radioactive sources (see discussion in Section II.K. of this Notice of Final Rulemaking). Because §§ 835.1101 and 835.1102 establish appropriate requirements for control of contaminated material and equipment, DOE has not included specific requirements for labeling of contaminated items in this subpart.

In response to the comments received, DOE has revised the radioactive material labeling exceptions proposed at § 835.606 to include nuclear weapons and their components and inaccessible radioactive material. In addition, the exception from the § 835.601 design and color specifications for labels applied to sealed radioactive sources, proposed at § 835.1201(b), has been codified at § 835.606(b).

G. Records and Reports, Subparts H and I

Proposed Amendment

DOE proposed a number of changes to its requirements for records demonstrating compliance with 10 CFR part 835. The proposed changes included:

1. Revising §§ 835.203(a) and 835.702(b) to provide that, when monitoring is performed, but not required by § 835.402, internal and external doses must be summed and records must be maintained only if the doses determined by the non-mandatory monitoring exceed the thresholds of § 835.402. This proposed change was intended to reduce the burden of recordkeeping consistent with the recommendations in the Guidance to Federal Agencies.

2. Deleting the words "caused by contamination on the skin" from § 835.702(b) to ensure consistency with the referenced requirements at § 835.205.

3. Revising § 835.702(c)(1) to provide that records must be sufficient to demonstrate compliance with all of the subpart C dose limits. This provision is consistent with § 835.701(a).

4. Deleting the requirement at § 835.702(c)(4)(iii) to record the estimated intake associated with internal dose assessments. This change was necessary because determination of the individual dose equivalent resulting from intakes of certain radionuclides, such as tritium, does not require determination of the estimated intake.

5. Revising § 835.702(d) and (e) such that acceptance of written estimates of an individual's prior occupational dose is based upon an inability to obtain formal records, rather than the absence of those records. DOE also proposed to

revise § 835.702(d) consistent with the previously discussed clarification of the components of occupational dose and to reference DOE Orders for authorizing emergency exposures. DOE further proposed to revise § 835.702(e) to indicate that efforts to obtain records of prior years doses were necessary only for those individuals monitored in accordance with § 835.402.

6. Technical and editorial changes to clarify the recordkeeping provisions and to ensure consistency with other changes included in subparts J and M. DOE also proposed to revise § 835.704(d) to require documentation of revocations of declarations of pregnancy.

7. Because some individuals may not have social security numbers, DOE proposed to revise § 835.801(a) to allow for use of another unique identification number in reports associated with such individuals.

Summary of Public Comments and Disposition

DOE received a number of comments indicating that the results of all individual monitoring that is performed should be recorded. DOE agrees that this approach has merit. Furthermore, DOE has provided adequate flexibility under the individual monitoring requirements of § 835.402 to eliminate any onerous administrative burdens resulting from records of trivial doses.

DOE received comments indicating that the term "accident" was not clearly defined, resulting in uncertainty about the proper application of the individual monitoring records requirement of § 835.702(a).

DOE received comments suggesting that the proposed change to § 835.702(e) was not needed because, in the absence of a cumulative dose limit, written estimates would not serve any substantive purpose. DOE agrees with this observation.

Final Rule

DOE has revised § 835.702(a) to delete reference to accidents and to specify that records be maintained to document unplanned doses exceeding the monitoring thresholds of § 835.402.

In consideration of the comments received, DOE has not included the proposed changes to § 835.702(b) in the final rule.

Consistent with the changes to § 835.1302 discussed in Section II.L. of this Notice of Final Rulemaking, DOE has revised § 835.702(d) to reference the emergency exposure authorization measures included in that section.

DOE has also not included in the final rule the proposed change to § 835.702(e)

allowing written estimates of prior years doses. DOE has included the remaining changes with minor editorial corrections to enhance clarity.

DOE's review of 10 CFR part 835 revealed the fact that § 835.702(c)(2) inappropriately invoked the requirements of certain DOE Orders. The applicability of these Orders is established through DOE contractual processes. DOE has revised the text to delete this invocation of DOE Orders.

Consistent with changes discussed elsewhere in this Notice of Final Rulemaking, DOE has revised the heading of § 835.703 and language at § 835.703(a) and (e) to eliminate the use of the term "workplace" and to reference those subparts of the rule (subparts E and L) that establish monitoring requirements.

Because individuals generally do not record the results of contamination monitoring upon exiting contamination and high contamination areas and there is little perceived value in maintaining such records, DOE has clarified § 835.703(a) to permit such a practice. In consideration of comments on the specificity of the proposed § 835.703(c) recordkeeping provisions, DOE has not included the second portion of proposed § 835.703(c) regarding informational content of these records in the final rule. DOE has revised the recordkeeping requirements of § 835.703(d) consistent with the changes made to § 835.401.

In recognition of the need to record the estimated date of conception for a declared pregnant worker (in order to determine compliance with the applicable dose limit for the embryo/fetus), DOE has clearly stated this as a requirement at § 835.704(d). Also, consistent with the changes made at § 835.401, DOE has deleted the term "workplace" from § 835.704(e).

H. Radiation Safety Training, Subpart J

1. Training Course Content and Administration

Proposed Amendment

When 10 CFR part 835 was originally developed, the detailed radiation safety training requirements provided in the Manual obviated the need to specify minimum training course content in the rule. Because the Manual is no longer mandatory, DOE proposed to specify minimum training course content at § 835.901(b). Also at § 835.901(b), DOE proposed requirements that would allow more liberal acceptance of an individual's previous radiation safety training.

DOE proposed to further consolidate and simplify its requirements for

radiation safety training. Under the proposed amendment, the level of training required would be based upon the areas entered by the individual unescorted, the activities performed, and the likely doses, rather than the individual's classification as a member of the public, general employee, or radiological worker. Implementation of this hierarchical approach to training would result in the appropriate level of radiation safety training for general employees, with a higher level of training required for radiological workers. This approach is consistent with field experience and feedback from DOE operating contractors and is similar to the approach previously taken by DOE in DOE Order 5480.11 and currently taken by the NRC in 10 CFR part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations." DOE proposed to eliminate the examination requirement for individuals who are not permitted unescorted access to radiological areas and who do not perform unescorted assignments as a radiological worker. DOE also proposed to provide specific requirements at § 835.901(f) for individuals who may act as escorts of individuals who have not completed required training.

Summary of Public Comments and Disposition

Public comments generally endorsed DOE's proposed hierarchical approach to radiation safety training. However, some commenters were concerned that the proposed approach, which would require an individual to complete radiation safety training prior to being occupationally exposed to radiation, would needlessly penalize those facilities that conduct training inside the controlled area or in other areas in which trivial occupational exposures may occur. However, as proposed, § 835.901(c) (§ 835.901(b) in the proposed rule) requires training to the extent appropriate to the individual's degree of exposure to potential radiological hazards. Under the circumstances described, the "extent appropriate" may be minimal (perhaps a briefing on appropriate alarm responses).

Comments indicated that the proposed § 835.901(b)(3) requirement to provide training on "measures implemented at the facility to minimize exposures" was inappropriate, as there is no requirement to "minimize exposures." Other comments indicated that it was unnecessary for the required training to be appropriate to "anticipated and actual" work assignments; training appropriate to the

individual's work assignments should be sufficient. DOE agrees with these observations.

DOE received comments indicating that the existing § 835.2(a) definition of the term "radiological worker" was overly restrictive and unclear due to its inclusion of individuals who operate radiation producing devices. Commenters indicated that this inclusion could require extensive training and testing of individuals who operate devices emitting nominal amounts of radiation or those who operate devices such as televisions and computer monitors. However, consumer devices that emit nominal amounts of radiation are clearly excluded from the scope of 10 CFR part 835 under the provisions of 835.1(b)(6) and the related § 835.2(a) definition of "background." Although the proposed provisions of § 835.901(d) (see § 835.901(b) in the final rule) would require training and testing of individuals who operate other radiation producing devices, the provisions of § 835.901(c) (see § 835.901(b) in the proposed rule) would only require that such training be appropriate to the extent of the individual's potential exposure to radiological hazards.

Although many commenters favored DOE's proposed relaxation of the examination requirements, other commenters indicated that an examination should be required for all forms of training to ensure that the student has an understanding of the material presented. DOE agrees that examinations are useful tools for assessing the retention of information by the student. However, as stated in DOE's Notice of Proposed Rulemaking, the radiological hazards present in those portions of controlled areas which are outside of radiological areas are so minimal that the information needed prior to entry does not warrant a regulatory requirement for an examination. However, the absence of this regulatory requirement does not preclude DOE's operating entities from administering an examination.

Several commenters indicated that DOE's proposed requirements for use of escorts in lieu of training were unclear because of the use of the phrase "where an escort is required." These commenters correctly pointed out that the proposed § 835.901(c) and (d) would permit, but would not explicitly require, the use of escorts.

Other commenters were concerned that the retraining requirements of proposed § 835.901(g) might require individuals to complete the full introductory radiation safety training

course every 24 months. DOE agrees that this issue requires clarification.

Final Rule

As proposed, DOE has reformatted subpart J into one section in the final rule, codifying an approach similar to that previously published in the Manual and eliminating redundancy. DOE has omitted proposed § 835.901(a) from the final rule because that paragraph would not establish any substantive requirements. DOE has also eliminated the examination requirement for individuals who are not permitted unescorted access to radiological areas and who do not perform unescorted assignments as a radiological worker, as proposed. Although not a regulatory requirement, DOE contractors may still choose to administer examinations or to undertake other means of assessing individual understanding, such as interactive classroom discussions.

DOE has included at § 835.901(c) (§ 835.901(b) in the proposed amendment) a requirement for training to be provided to the extent appropriate to the individual's work assignment. DOE has also included at § 835.901(c)(3) (proposed § 835.901(b)(3)) a requirement that the training address measures used to "manage doses and maintain doses ALARA," rather than "minimize" doses. This modification makes clear the distinction between maintaining doses well below the dose limits using the ALARA process and maintaining doses well below the dose limits by minimizing doses regardless of other considerations.

DOE has established requirements applicable to instances in which escorts are used, rather than required, in lieu of training at revised § 835.901(d) (§ 835.901(f) in the proposed amendment).

With regard to the requirements for biennial retraining, DOE has eliminated the use of the undefined term "retraining." Section 835.901(e) of the final rule requires affected individuals to complete the required training at least every 24 months. Like the initial training, this follow-on training is for individuals subject to the requirements of § 835.901(a) and (b), and is subject to the provisions of § 835.901(c). Thus, the content and scheduling (prior to the end of the two year time interval) of such training needs to incorporate considerations of the individual's prior training, work assignments, and degree of exposure to radiological hazards, as well as significant changes to radiation protection policies and procedures that affect the individual.

2. Radiological Control Technician Training [§ 835.903]

DOE also proposed changes to the 10 CFR part 835 requirements for training of radiological control technicians. These changes are discussed in detail in Section II.B.3. of this Notice of Final Rulemaking.

I. Design and Control, Subpart K

Proposed Amendment

Experience in implementing programs to ensure compliance with 10 CFR part 835 revealed that the design objectives currently included at § 835.1002(b) and (c) may not be practical in developing certain modifications to existing facilities. Therefore, DOE proposed to delete § 835.1002(b) and (c). DOE also proposed to move the remaining requirements in paragraphs (a) and (d) of § 835.1002 to § 835.1001.

The design criteria established at § 835.1003(a) did not include all of the occupational dose limits of § 835.202, e.g. the lens of the eye dose limit established at § 835.202(a)(3). This omission implied that the design of new facilities or modification of existing facilities could include design features that would result in doses exceeding the lens of the eye dose equivalent limit of 15 rem established at § 835.202. DOE proposed to correct this omission by including all applicable occupational dose limits established at § 835.202 in this section.

Summary of Public Comments and Disposition

Comments indicated that the phrase "as low as is reasonably achievable" at § 835.1001(a) could be construed to have a meaning that differed from "ALARA" as defined at § 835.2(a).

Many commenters stated that DOE should retain the numerical design objectives provided at § 835.1002. Although achievement of the numerical design objectives may not be practical in some cases (particularly for minor modifications of existing facilities), the design objectives are important components of the ALARA process. Public comments suggested that elimination of the numerical design objectives could result in confusion over when to apply quantitative design objectives and the appropriate magnitude of those objectives. Comments also indicated that § 835.1003(b) did not establish any substantive requirements beyond those established in subpart E of 10 CFR part 835.

DOE agrees with these observations.

Final Rule

At § 835.1001(a), DOE has substituted "ALARA" for "as low as is reasonably achievable."

Because procedural requirements are a type of administrative control, DOE has deleted the term "procedural requirements" from § 835.1001 and deleted the term "procedures" from § 835.1003 to eliminate redundancy. For consistency, DOE has revised the heading of § 835.1003 to read "Workplace Controls."

Because the use of quantitative design objectives plays a significant role in the ALARA process as it applies to facility design, DOE has chosen to defer this critical change until more experience is gained through implementation of these regulatory provisions. DOE has accepted the public comments and has retained the numerical design objectives of § 835.1002; however, DOE has retained the proposed editorial change at § 835.1002 (proposed § 835.1001(c)) substituting the term "existing facilities" for the term "old facilities." DOE will address its concerns with the application of these requirements through enhanced guidance for achieving compliance. DOE has included in the final rule the proposed change related to the lens of the eye dose limit. In consideration of public comments, DOE has also deleted § 835.1003(b) from the final rule.

J. Radioactive Contamination Control, Subpart L

Proposed Amendment

Consistent with the changes to the § 835.2(a) definitions of the terms "contamination area" and "high contamination area," DOE proposed changes to the § 835.404 requirements for areas having only fixed contamination exceeding the appendix D total surface radioactivity values.

DOE proposed several changes to appendix D of 10 CFR part 835, which provides mandatory surface radioactivity values for contamination control. DOE proposed to add the word "alpha" after the values for uranium isotopes in appendix D to clarify the applicability of these values. DOE also proposed to add to appendix D of 10 CFR part 835 a contamination control value of 10,000 disintegrations per minute per 100 square centimeters for surfaces contaminated with tritium and Footnote 6 to explain the use of this value. The surface contamination value would be used to determine the applicability of the § 835.603 contamination hazard posting provisions and the §§ 835.404 and 835.1101 contamination control

provisions. DOE has prepared an Environmental Assessment, available at DOE's Freedom of Information Reading Room at the address provided above, that addresses this change in detail.

DOE also proposed to move the existing requirements of § 835.1101(d) to § 835.703(c) to consolidate recordkeeping requirements and to add a new requirement for removal of radioactive material labels from released materials and equipment at § 835.1101(d).

Summary of Public Comments and Disposition

Public comments were generally supportive of DOE's proposed changes to the requirements for control of radioactive contamination. Public comments also indicated that the recordkeeping requirements of proposed § 835.703(c) were overly prescriptive in comparison to related requirements of the rule. Public comments also indicated that a literal reading of § 835.404(f) would indicate that the performance of individual contamination monitoring by someone other than the individual exiting a contamination or high contamination area (i.e., individual frisking by radiological control technicians) would be contrary to 10 CFR part 835. DOE agrees with these observations.

Comments indicated that the related requirements of §§ 835.404 and 835.1101 were confusing and possibly contradicting. The existing provisions of § 835.404 establish requirements for control of areas contaminated by radioactive material; the provisions of § 835.1101 establish similar requirements for materials and equipment contaminated by radioactive materials. Upon reexamination of these requirements in light of the comments received, DOE believes that there is opportunity for simplification and clarification of the rule.

Final Rule

DOE has combined and simplified the requirements of §§ 835.404 and 835.1101 in the final rule as follows:

a. Although the provisions of § 835.404 were specifically related to controlling the spread of contamination, they were located in subpart E, which was entitled "Monitoring in the Workplace." Therefore, DOE has moved these requirements, with revisions discussed below, to subpart L.

b. Although the title of subpart L indicates that the subject matter is related to "Releases of Materials and Equipment from Radiological Areas," the requirements are more specifically related to retention and control of

contaminated materials in radiological areas. Therefore, DOE has retitled subpart L, "Radioactive Contamination Control."

c. DOE has clarified and simplified the structure of § 835.1101(a).

d. DOE has retained paragraphs 835.1101(b) and (c) with minor editorial clarifications. Consistent with the discussion in Section II.B.3 of this Notice of Final Rulemaking regarding written procedures, DOE has omitted the requirement for written procedures (formerly § 835.1101(c)(3)).

e. Because the existing requirements of § 835.404(a) established no substantive requirements, DOE has omitted this paragraph from the final rule.

f. DOE has redesignated paragraph 835.404(b) as § 835.1102(a) in the final rule.

g. DOE has edited paragraph 835.404(c) and redesignated it as § 835.1102(b) in the final rule. DOE has omitted the provision related to posting of contamination hazards (formerly § 835.404(c)(1)) because this provision is redundant with § 835.603(e) and (f).

h. DOE has edited paragraph 835.404(d) and redesignated it as § 835.1102(c) in the final rule. Consistent with the discussion in Section II.B.3 of this Notice of Final Rulemaking regarding written procedures, DOE has omitted the requirement for written procedures (formerly § 835.404(d)(5)).

i. Because of the changes to the § 835.2(a) definitions of "contamination area" and "high contamination area" discussed above, the areas discussed at § 835.404(d) (i.e., those having fixed contamination at levels exceeding the appendix D total contamination values, but removable contamination levels below the appendix D removable contamination values) would no longer be considered radiological areas. This renders the provisions of § 835.404(e) redundant; therefore, DOE has omitted these requirements from the final rule.

j. DOE has clarified § 835.404(f) and redesignated it as § 835.1102(d).

k. DOE has revised the language at § 835.404(g) for clarity and redesignated it as § 835.1102(e).

DOE has reconsidered its proposal to add § 835.1101(d) establishing requirements for removal of radioactive material labels from released materials and equipment. Although DOE considers materials and equipment meeting the requirements of § 835.1101(a) to be appropriate for release from radiological areas, such materials and equipment are not necessarily "non-radioactive" and conditions may arise under which

retention of the radioactive material labels is appropriate. DOE has therefore omitted this provision from the final rule.

As before, the requirements of § 835.1101 address release of materials and equipment from radiological areas to controlled areas. DOE requirements for release of materials and equipment from its control are addressed in DOE environmental protection standards.

K. Control of Sealed Radioactive Sources, Subpart M

Proposed Amendment

DOE proposed to add subpart M to 10 CFR part 835 to establish requirements for control of sealed radioactive sources. These requirements would supersede similar requirements established in DOE Notice 5400.9, "Sealed Radioactive Source Accountability" (extended through DOE Notice 5400.13 and superseded by DOE N 441.1 through DOE N 441.3). DOE proposed to add the terms "accountable sealed radioactive source," "sealed radioactive source," and "source leak test" at § 835.2(a) and to add recordkeeping requirements at § 835.704(f). DOE also proposed to add appendix E to 10 CFR part 835 to establish threshold values for sealed radioactive source accountability, radioactive material labeling, and radioactive material area posting.

Summary of Public Comments and Disposition

Although many commenters supported DOE's efforts to codify requirements for sealed radioactive source control, several commenters indicated that the accountability threshold values proposed for inclusion in appendix E of 10 CFR part 835 were overly restrictive. Commenters also indicated that the definition of "sealed radioactive source" was too broad to allow for exclusion of certain items, such as reactor fuel elements, that are not commonly produced or used as sealed radioactive sources. In addition, several commenters indicated that DOE's proposed minimum activity requiring performance of periodic leak tests (0.005 microcuries) was overly restrictive.

Commenters indicated that inaccessible sources should be excepted from the requirements for leak testing and inventory. Such a measure would obviate the need to disassemble facility components and instruments for the purpose of performing the inventories and leak tests. Commenters also indicated that common contamination control measures are capable of minimizing, but perhaps not preventing,

the spread of contamination as would be required by proposed § 835.1202(e).

DOE agrees with these observations.

Final Rule

In response to public comments, DOE has revised the § 835.2(a) definition of the term "sealed radioactive source" to exclude reactor fuel elements, nuclear explosive devices, and radioisotope thermoelectric generators. DOE has included the definitions of "accountable sealed radioactive source" and "source leak test" at § 835.2(a) as proposed. DOE has revised § 835.1202(d) to provide an exception from leak testing and inventory for sealed radioactive sources that are inaccessible. DOE has also revised § 835.1202(e) to indicate that the required contamination control measures must "minimize" the spread of contamination.

DOE has revised the proposed appendix E values. DOE determined the appendix E values in the final rule as follows: For each radionuclide, DOE considered two scenarios: (1) the activity quantity resulting in a deep dose equivalent from external radiation of 0.1 rem (0.001 sievert) assuming an individual was irradiated for a period of 12 hours per day at a distance of 1 meter from the source for 365 days; and (2) the activity quantity resulting in a committed effective dose equivalent of 0.1 rem (0.001 sievert) assuming an instantaneous intake of 0.001% of the material by an individual. DOE compared the activity quantities for the deep dose equivalent and the committed effective dose equivalent and selected the more restrictive value as the basis for the accountability threshold value. DOE selected the value of 0.1 rem as the basis for the revised appendix E values for consistency with DOE's mandatory threshold for monitoring of general employee dose (see § 835.402) and dose limit for members of the public in controlled areas (see § 835.208). DOE also assumed more realistic values for the exposure time and intake factor and eliminated the arbitrary 300 microcurie activity cap. The basis for the appendix E values is discussed in more detail in a technical basis document available in DOE's Freedom of Information Reading Room at the address provided above.

Because all of the revised appendix E values are greater than 0.005 microcuries, DOE has deleted this threshold from the requirements for sealed radioactive source leak tests (proposed § 835.1202(b)). DOE has also omitted the proposed requirement for written procedures from the final rule. For details on this omission, see Section II.B.3 of this Notice of Final Rulemaking. Finally, because DOE's

reevaluation of the appendix E values resulted in significant increases in all of the accountability threshold values, DOE has codified a general requirement at § 835.1201 for all radioactive sources (both accountable and non-accountable) to be used, handled, and stored in a manner commensurate with the radiological hazards created by the operation involving the sources. DOE will provide implementing guidance to discuss acceptable methods for achieving compliance with this provision.

The basis for the control of sealed radioactive sources is a hierarchy of increasing radiological controls based upon the maximum credible dose consequence resulting from the loss of a source. The maximum credible dose consequence should not be considered to be a release criterion. Under the requirements of 10 CFR part 835, some degree of radiological control is required for all sealed radioactive sources, regardless of their activity. This hierarchy of controls reduces the likelihood of losing a sealed radioactive source. Thus the approach to sealed radioactive source control is analogous to that taken in nuclear safety. As the potential consequences of a credible incident increase, additional controls are imposed to reduce the probability that the incident will occur and mitigate the consequences of that incident.

For the lowest activity sealed radioactive sources, a minimal level of radiological control is required based upon the hazards associated with the operations involving the sources. More specific actions are not considered necessary and are therefore not specified.

For sealed radioactive sources whose loss could result in a maximum credible dose consequence of 0.1 rem or more in a year, additional controls are imposed. The requirement for semi-annual inventories reduces the possibility of losing the source and, by triggering investigative action, mitigates the consequences of a lost source. The requirement for semi-annual leak testing provides a means of monitoring the integrity of the source and likewise triggers action to mitigate the consequences of a leaking source.

L. Accident and Emergency Exposures, Subpart N

Proposed Amendment

DOE proposed to correct § 835.1301(a), (b), and (d) by deleting references to § 835.205, which provides no dose limits. Consistent with changes to § 835.204, DOE proposed to revise § 835.1301(a) to indicate that doses

resulting from accident and emergency exposures may exceed the numerical values established at § 835.202(a) without violating the occupational dose limits. Both accident and emergency doses are considered occupational doses and are included in a general employee's occupational dose record, but emergency doses are explicitly excluded from consideration in determining compliance with the occupational dose limits at § 835.202(a).

DOE proposed to delete § 835.1302(d) because these provisions are adequately addressed in related DOE Orders and emergency management guides.

DOE clarified § 835.1304 by substituting the defined term "individual" for the term "personnel" which eliminates any confusion regarding the coverage of the personal nuclear accident dosimetry provisions. DOE also proposed to remove the reference to "all personnel" to provide flexibility in implementing the personal nuclear accident dosimetry provisions.

Summary of Public Comments and Disposition

Regarding accident and emergency exposures, public comments indicated that DOE had failed to clearly define the terms "accident" and "emergency," resulting in uncertainty about the proper application of these provisions.

Comments regarding the proposed approach basing personal nuclear accident dosimetry requirements on the need for nuclear criticality alarms indicated that this approach would be impractical due to the vagueness of the referenced requirements for these alarms.

DOE agrees with these observations.

Final Rule

DOE has included the proposed changes into the final rule.

Consistent with the clarification of the requirements for accounting for occupational doses, including doses resulting from authorized planned special exposures and emergency exposures, DOE has deleted the term "accident" from § 835.1301(a). This deletion results from DOE's recognition that, except for doses resulting from planned special exposures and authorized emergency exposures, all doses in excess of the regulatory limits may be considered to be "accidents." Under such circumstances, DOE believes that provisions allowing affected individuals to return to work without further detailed review subverts the intent of the § 835.202 occupational dose limits. DOE believes that it is most appropriate for this section to address doses resulting from authorized

emergency exposures. Despite this change, DOE recognizes the fact that issues of individual work rights and DOE liability may arise as a result of "accidental" exposures exceeding the regulatory dose limits. Mechanisms for addressing doses resulting from accidents, and authorizations to return affected individuals to work, exist within the exemption process established in 10 CFR part 820.

In response to public comments, DOE revised the text in § 835.1301(c) and (d) to eliminate the terms "emergency" and "accident" and specify that the notification and resumption provisions apply when doses were received in excess of the limits of § 835.202, except those doses received in accordance with § 835.204.

As discussed above with regard to § 835.702(c)(2), DOE found that § 835.1301(e) inappropriately invoked the requirements of DOE Orders. The applicability of these Orders is established through DOE contractual processes. Therefore, DOE has deleted this provision.

To resolve issues related to requirements for personal nuclear accident dosimetry, DOE has revised the requirement to simply indicate that the nuclear accident dosimetry system must include personal nuclear accident dosimeters. This approach will allow for flexible implementation on a site-and facility-specific basis.

M. Use of Appendices

Proposed Amendment

DOE proposed to clarify the application of the data presented in the appendices of 10 CFR part 835 by adding introductory text to each appendix referencing those sections of the rule requiring use of the appendix. DOE also proposed to delete the absorption factor (f1) values and the related footnote (footnote 5) from appendix A of 10 CFR part 835 because absorption factors and alternative absorption factors are neither used nor referenced in the rule. DOE determined that 10 CFR part 835 established no substantive requirements for use of the data presented in appendix B, and therefore proposed to delete appendix B.

DOE's review of exemption requests concerning occupational exposure to ²²⁰Rn and ²²²Rn and their daughter products revealed that DAC values for these radioisotopes are inappropriately referenced in both appendices A and C. Exposure to these radionuclides results in a lung dose and therefore, the air immersion DACs in appendix C are inappropriate. Accordingly, DOE

proposed to delete the air immersion DAC values for 220Rn and 222Rn from appendix C.

Experience in implementing programs that ensure compliance with 10 CFR part 835 has proven that the exposure conditions used to determine the appendix C DAC values (immersion in a semi-infinite cloud) often differ from those at DOE facilities (i.e., exposure in relatively small enclosures). Use of the appendix C DAC values under these conditions can result in the overestimation of individual doses. Therefore, DOE proposed to revise appendix C, note b., to allow modification of the DAC values to compensate for immersion in a cloud of finite dimensions and to provide instructions for determining the DAC of a mixture of radionuclides.

Summary of Public Comments and Disposition

Although several commenters suggested that the data in appendix B were useful and should be retained, the correlation of chemical form to lung retention class is available directly from Table 3 of Federal Guidance Report Number 11, "Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion."

Commenters favored DOE's proposal to allow for modification of the appendix C values. However, contrary to the information provided in appendix C, note b., these values were calculated based upon an exposure of 2000 hours per year, and not based upon a continuous exposure.

Final Rule

DOE has included the proposed changes in the final rule with minor editorial corrections. For consistency with the existing provisions associated with appendix C of 10 CFR part 835, DOE has included a note with appendix A of 10 CFR part 835 that will allow use of the sum of the fractions rule when there exists a mixture of radionuclides in the area of interest. DOE has also revised appendix C, note b., to reflect the 2000 hour per year exposure basis of the values.

Consistent with terminology used throughout the rule and in DOE's guidance documents, DOE has also retitled the table in appendix D of 10 CFR part 835 "Surface Contamination Values."

N. Corrections and Clarifications

Proposed Amendment

DOE proposed numerous editorial corrections and technical clarifications

that do not change the requirements of the rule or the measures necessary to ensure regulatory compliance. The proposed changes included:

1. Correction of the definitions of "airborne radioactive material", and "year" (§ 835.2(a)) and "external dose or exposure," and "quality factor" (§ 835.2(b));
2. Clarification of the application of the mean quality factors for neutrons provided at § 835.2(b);
3. Deletion of § 835.2(d) because the convention stated in that paragraph for the use of singular, plural, masculine, and feminine terms is not used in part 835;
4. Revision of the requirements of § 835.102 for clarity;
5. Change of the heading of § 835.202 to "Occupational dose limits for general employees" to accurately reflect the content of that section;
6. Deletion from § 835.203(a) and the § 835.2(b) definition of "total effective dose equivalent" the provision related to substitution of deep dose equivalent for effective dose equivalent from external exposure. This provision is redundant with the revised definition of "effective dose equivalent" proposed at § 835.2(b).

Summary of Public Comments and Disposition

DOE received no substantive comments on these changes.

Final Rule

DOE has included the proposed changes in the final rule.

III. Review Under the National Environmental Policy Act

DOE has reviewed the promulgation of this amendment to 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 (40 CFR parts 1500–1508). DOE has completed an Environmental Assessment and on the basis of that information has issued a Finding of No Significant Impact (FONSI) for this amendment. The FONSI and the Environmental Assessment update the FONSI and Environmental Assessment issued when the proposed amendment was published for public comment and reflect changes in the final rule made in response to public comments. 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.

IV. Review Under Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601–612, requires that an agency prepare an initial regulatory flexibility analysis and publish it at the time of publication of general notice of rulemaking for the rule. This requirement does not apply if the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. 5 U.S.C. 605(b).

Today's action amends DOE's regulations governing programs established at DOE facilities to protect individuals from ionizing radiation resulting from DOE activities. The contractors who manage and operate DOE facilities are responsible for implementing the occupational radiation protection program. DOE has considered whether management and operating (M&O) contractors are "small businesses," as that term is defined by the Regulatory Flexibility Act (5 U.S.C. 601(3)). The Regulatory Flexibility Act's definition incorporates the definition of "small business concern" in the Small Business Act, which the Small Business Administration (SBA) has developed through size standards in 13 CFR part 121. Small businesses are business concerns which, together with their affiliates, have no more than 500 to 1500 employees, varying by SIC category, and annual receipts of between \$0.5 million to \$25 million, again varying by SIC category—Title 13 CFR part 121. DOE's M&O contractors exceed the SBA's size standards for small businesses. In addition, it is noted that M&O contractors are reimbursed through their contracts with DOE for the costs of complying with DOE occupational radiation protection requirements. They will not, therefore, be adversely impacted by the requirements in the rule. For these reasons, DOE certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

V. Review Under Executive Order 12866

Today's regulatory action has been determined not to be a "significant regulatory action" under Executive Order 12866, "Regulatory Planning and Review," (58 FR 51735, October 4, 1993). Accordingly, today's action was not subject to review under the Executive Order by the Office of Information and Regulatory Affairs

within the Office of Management and Budget.

VI. Review Under Executive Order 12612

Executive Order 12612, 52 FR 41685 (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 final rule would not have a substantial direct effect on the institutional interests or traditional functions of States.

VII. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, "Civil Justice Reform," 61 FR 4729 (February 7, 1996), imposes on Executive agencies the general duty to adhere to the following requirements:

(1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction. With regard to the review required by section 3(a), section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that the amendments to 10 CFR part 835 meet the relevant standards of Executive Order 12988.

VIII. Review Under Paperwork Reduction Act

DOE submitted the proposed collections of information in this rule to the Office of Management and Budget for review under section 3507(d) of the Paperwork Reduction Act of 1995 (42 U.S.C. 3507(d)), and, by separate notice on May 26, 1998, invited public comment on DOE's statement of need and estimates of the burden of the collection of information in 10 CFR part 835 (63 FR 28495). The information that DOE management and operating contractors are required to produce, maintain and report is necessary to permit the Department and its contractors to manage and oversee health and safety programs that control worker exposure to radiation. DOE estimates that the total annual burden of the collection of information requirements to be 50,000 hours for the approximately 50 contractors subject to the rule.

The Office of Management and Budget has approved the collections of information in 10 CFR part 835 and assigned to the part OMB Number 1910-5105. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number (5 CFR 1320.5(b)).

IX. Review Under the Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (the Act), Pub.L. 104-4 on March 22, 1995, codified at 2 U.S.C. 1501-1571, requires each Federal agency, to the extent permitted by law, to prepare a written assessment of the effects of any Federal mandate in a proposed or final agency rule that may result in the expenditure by State, local, and tribal governments, in the aggregate or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. Section 204(a) of the Act, codified at 2 U.S.C. 1534(a), requires the Federal agency to develop an effective process to permit timely input by elected officers (or their designees) of State, local, and tribal governments on proposals containing "significant Federal intergovernmental mandates." Section 203(a) of the Act, codified at 2 U.S.C. 1533(a), provides that before establishing any regulatory requirements that might significantly or uniquely affect small governments, the agency shall have developed a plan that, among other things, provides for notice to potentially affected small governments, if any, and enables officials of affected small governments to provide meaningful and timely input

in the development of regulatory proposals containing significant intergovernmental Federal mandates.

The final rule published today does not contain any Federal mandate that would result in any expenditure by State, local or tribal government. The provisions of 10 CFR part 835 apply only to activities conducted by or for DOE. Therefore, the requirements of Title II of the Unfunded Mandates Reform Act of 1995 do not apply.

X. Review Under Small Business Regulatory Enforcement Fairness Act of 1996

As required by 5 U.S.C. 801, DOE will report to Congress promulgation of this rule prior to its effective date. The report will state that it has been determined that the rule is not a "major rule" as defined by 5 U.S.C. 804(2).

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 recordkeeping requirements, Safety during emergencies, Training.

Issued in Washington, DC, on October 29, 1998.

Peter N. Brush,

Acting Assistant Secretary, Environment, Safety and Health.

For the reasons set forth in the preamble, Title 10, Code of Federal Regulations, part 835 is amended as set forth below:

PART 835—OCCUPATIONAL RADIATION PROTECTION

1. The authority citation for part 835 continues to read as follows:

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

Subpart A—General Provisions

2. Section 835.1 is amended by revising the introductory text of paragraph (b) and paragraph (b)(3), redesignating paragraph (b)(4) as (b)(6), and by adding paragraphs (b)(4), (b)(5), and (c) as follows:

§ 835.1 Scope.

* * * * *

(b) *Exclusion.* Except as discussed in paragraph (c) of this section, the requirements in this part do not apply to:

* * * * *

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

(4) Radioactive material transportation as defined in this part;

(5) DOE activities conducted outside the United States on territory under the jurisdiction of a foreign government to the extent governed by occupational radiation protection requirements agreed to between the United States and the cognizant government; or

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

(c) Occupational doses received as a result of excluded activities and radioactive material transportation, as listed in paragraphs (b)(1) through (b)(5) of this section, shall be considered when determining compliance with the occupational dose limits at §§ 835.202 and 835.207, and with the limits for the embryo/fetus at § 835.206. Occupational doses resulting from authorized emergency exposures and planned special exposures shall not be considered when determining compliance with the dose limits at §§ 835.202 and 835.207.

3. At § 835.2, paragraph (a) is amended by removing definitions of the terms "ambient air", "continuous air monitor", "DOE activities", "occupational exposure", "representative", and "survey"; by adding in alphabetical order, definitions for the terms "accountable sealed radioactive source", "derived air concentration-hour", "DOE activity", "occupational dose", "radioactive material area", "radioactive material transportation", "real-time air monitoring", "respiratory protective device", "sealed radioactive source", "source leak test", and "week"; and revising the definitions of the terms "airborne radioactive material or airborne radioactivity", "airborne radioactivity area", "contamination area", "controlled area", "declared pregnant worker", "general employee", "high contamination area", "member of the public", "monitoring", "radiological area", and "year" to read as follows. At § 835.2, paragraph (b), the definition of "collective dose" is removed, the definition of "dose" is added, and the definitions of the terms "cumulative total effective dose equivalent", "effective dose equivalent", "external dose or exposure", "quality factor", "total effective dose equivalent", and "weighting factor" are revised as follows. Paragraph (d) of § 835.2 is removed.

§ 835.2 Definitions.

(a) As used in this part:

Accountable sealed radioactive source means a sealed radioactive source having a half-life equal to or greater than 30 days and an isotopic activity equal to or greater than the corresponding value provided in appendix E of this part.

Airborne radioactive material or airborne radioactivity means radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

Airborne radioactivity area means any area, accessible to individuals, where:

(1) The concentration of airborne radioactivity, above natural background, exceeds or is likely to exceed the derived air concentration (DAC) values listed in appendix A or appendix C of this part; or

(2) An individual present in the area without respiratory protection could receive an intake exceeding 12 DAC-hours in a week.

Contamination area means any area, accessible to individuals, where removable surface contamination levels exceed or are likely to exceed the removable surface contamination values specified in appendix D of this part, but do not exceed 100 times those values.

Controlled area means any area to which access is managed by or for DOE to protect individuals from exposure to radiation and/or radioactive material.

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 dose limits to the embryo/fetus as provided at § 835.206. This declaration may be revoked, in writing, at any time by the declared pregnant worker.

Derived air concentration-hour (DAC-hour) means the product of the concentration of radioactive material in air (expressed as a fraction or multiple of the DAC for each radionuclide) and the time of exposure to that radionuclide, in hours.

DOE activity means an activity taken for or by DOE in a DOE operation or facility 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 or multiple DOE sites.

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

High contamination area means any area, accessible to individuals, where removable surface contamination levels exceed or are likely to exceed 100 times the removable surface contamination values specified in appendix D of this part.

Member of the public means an individual who is not a general employee. An individual is not a "member of the public" during any period in which the individual receives an occupational dose.

Monitoring means the measurement of radiation levels, airborne radioactivity concentrations, radioactive contamination levels, quantities of radioactive material, or individual doses and the use of the results of these measurements to evaluate radiological hazards or potential and actual doses resulting from exposures to ionizing radiation.

Occupational dose means an individual's ionizing radiation dose (external and internal) as a result of that individual's work assignment. Occupational dose does not include doses received as a medical patient or doses resulting from background radiation or participation as a subject in medical research programs.

Radioactive material area means any area within a controlled area, accessible to individuals, in which items or containers of radioactive material exist and the total activity of radioactive material exceeds the applicable values provided in appendix E of this part.

Radioactive material transportation means the movement of radioactive material by aircraft, rail, vessel, or highway vehicle when such movement is subject to Department of Transportation regulations or DOE Orders that govern such movements. Radioactive material transportation does not include preparation of material or packagings for transportation, monitoring required by this part, storage of material awaiting transportation, or application of markings and labels required for transportation.

Radiological area means any area within a controlled area defined in this section as a "radiation area," "high radiation area," "very high radiation

area," "contamination area," "high contamination area," or "airborne radioactivity area."

* * * * *

Real-time air monitoring means measurement of the concentrations or quantities of airborne radioactive materials on a continuous basis.

* * * * *

Respiratory protective device means an apparatus, such as a respirator, worn by an individual for the purpose of reducing the individual's intake of airborne radioactive materials.

Sealed radioactive source means a radioactive source manufactured, obtained, or retained for the purpose of utilizing the emitted radiation. The sealed radioactive source consists of a known or estimated quantity of radioactive material contained within a sealed capsule, sealed between layer(s) of non-radioactive material, or firmly fixed to a non-radioactive surface by electroplating or other means intended to prevent leakage or escape of the radioactive material. Sealed radioactive sources do not include reactor fuel elements, nuclear explosive devices, and radioisotope thermoelectric generators.

Source leak test means a test to determine if a sealed radioactive source is leaking radioactive material.

* * * * *

Week means a period of seven consecutive days.

Year means the period of time beginning on or near January 1 and ending on or near December 31 of that same year used to determine compliance with the provisions of this part. The starting and ending 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) * * *

Cumulative total effective dose equivalent means the sum of all total effective dose equivalent values recorded for an individual, where available, for each year occupational dose was received, beginning January 1, 1989.

* * * * *

Dose is a general term for absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent as defined in this part.

* * * * *

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, $H_E = \sum w_T H_T$. It includes the dose from radiation sources internal and/or external to the body. For purposes of compliance with this part, deep dose equivalent to the whole body may be used as effective dose equivalent for external exposures. 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 outside the body (i.e., "external sources").

* * * * *

Quality factor (Q) means the 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.

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

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 0.1 rem (0.001 sievert). Where neutron energy falls between listed values, the more restrictive mean quality factor shall be used.]

Neutron energy (MeV)	Mean quality factor	Neutron flux density ($\text{cm}^{-2}\text{s}^{-1}$)
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

QUALITY FACTORS FOR NEUTRONS—Continued

[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 0.1 rem (0.001 sievert). Where neutron energy falls between listed values, the more restrictive mean quality factor shall be used.]

Neutron energy (MeV)	Mean quality factor	Neutron flux density ($\text{cm}^{-2}\text{s}^{-1}$)
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

* * * * *

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).

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 (H_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 ORGANS AND 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, excluding the skin and lens of the eye, 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.

(c) * * *

4. Section 835.3 is amended by adding paragraph (e) as follows:

§ 835.3 General Rule

* * * * *

(e) For those activities that are required by §§ 835.102, 835.901(e), 835.1202 (a), and 835.1202(b), the time interval to conduct these activities may be extended by a period not to exceed 30 days to accommodate scheduling needs.

§ 835.4 [Amended]

5. Section 835.4 is amended by adding "roentgen," after "rad," in the first sentence and removing the last sentence.

Subpart B—Management and Administrative Requirements

6. The heading of subpart B is revised to read as set forth above.

6a. Section 835.101 is amended by revising paragraph (f) to read as follows, removing paragraph (g), and redesignating paragraphs (h), (i), and (j) as (g), (h), and (i) respectively; in paragraph (d), the reference to "§ 835.101(i)" is changed to "§ 835.101(h)".

§ 835.101 Radiation protection programs.

* * * * *

(f) The RPP shall include plans, schedules, and other measures for achieving compliance with regulations of this part. Unless otherwise specified in this part, compliance with amendments to this part shall be achieved no later than 180 days following approval of the revised RPP by DOE. Compliance with the requirements of § 835.402(d) for radiobioassay program accreditation shall be achieved no later than January 1, 2002.

* * * * *

7. Section 835.102 is revised to read as follows:

§ 835.102 Internal audits.

Internal audits of the radiation protection program, including examination of program content and implementation, shall be conducted through a process that ensures that all functional elements are reviewed no less frequently than every 36 months.

8. Section 835.103 is added as follows:

§ 835.103 Education, training and skills.

Individuals responsible for developing and implementing measures necessary for ensuring compliance with the requirements of this part shall have the appropriate education, training, and skills to discharge these responsibilities.

9. Section 835.104 is added as follows:

§ 835.104 Written procedures.

Written procedures shall be developed and implemented as necessary to ensure compliance with this part, commensurate with the radiological hazards created by the activity and consistent with the education, training, and skills of the individuals exposed to those hazards.

10. Section 835.202 is amended by revising the section heading, revising the introductory text of paragraph (a), and revising paragraphs (b) and (c) to read as follows:

§ 835.202 Occupational dose limits for general employees.

(a) Except for planned special exposures conducted consistent with § 835.204 and emergency exposures authorized in accordance with § 835.1302, the occupational dose received by general employees shall be controlled such that the following limits are not exceeded in a year:

* * * * *

(b) All occupational doses received during the current year, except doses resulting from planned special exposures conducted in compliance with § 835.204 and emergency exposures authorized in accordance with § 835.1302, shall be included when demonstrating compliance with §§ 835.202(a) and 835.207.

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

11. Section 835.203 is amended by revising the section heading and paragraph (a) to read as follows and by removing paragraph (c):

§ 835.203 Combining internal and external dose equivalents.

(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.

* * * * *

12. Section 835.204 is amended by revising paragraphs (a)(1), (a)(3), (c)(1), (c)(2) and (d) to read as follows:

§ 835.204 Planned special exposures.

(a) * * *

(1) The planned special exposure is considered only in an exceptional situation when alternatives that might prevent a radiological worker from

exceeding the limits in § 835.202(a) are unavailable or impractical;

* * * * *

(3) Joint written approval is received from the appropriate DOE Headquarters program office and the Secretarial Officer responsible for environment, safety and health matters.

* * * * *

(c) * * *

(1) In a year, the numerical values of the dose limits established at § 835.202(a); and

(2) Over the individual's lifetime, five times the numerical values of the dose limits established at § 835.202(a).

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

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

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

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

* * * * *

13. Section 835.207 is revised to read as follows:

§ 835.207 Occupational dose limits for minors.

The dose equivalent limits for minors occupationally exposed to radiation and/or radioactive materials at a DOE activity are 0.1 rem (0.001 sievert) total effective dose equivalent in a year and 10% of the occupational dose limits specified at § 835.202(a)(3) and (a)(4).

14. Section 835.208 is revised to read as follows:

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

The total effective dose equivalent limit for members of the public exposed to radiation and/or radioactive material during access to a controlled area is 0.1 rem (0.001 sievert) in a year.

§ 835.209 [Amended]

15. Section 835.209 is amended by changing the first "to" to "of" in paragraph (a), removing paragraph (b), redesignating paragraph (c) as (b), and removing the word "representative" from (b)(3).

Subpart E—Monitoring of Individuals and Areas

16. The heading of Subpart E is revised to read as set forth above.

16a. Section 835.401 is amended by removing paragraph (b), redesignating

paragraph (c) as (b), revising paragraphs (a), introductory text, (a)(2), (a)(4), (a)(5), (a)(6), and revising in newly redesignated paragraph (b), the introductory text, and (b)(1) to read as follows:

§ 835.401 General requirements.

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

- (1) * * *
- (2) Document radiological conditions;
- (3) * * *
- (4) Detect the gradual buildup of radioactive material;
- (5) Verify the effectiveness of engineering and process controls in containing radioactive material and reducing radiation exposure; and
- (6) Identify and control potential sources of individual exposure to radiation and/or radioactive material.

(b) Instruments and equipment used for monitoring shall be:

- (1) Periodically maintained and calibrated on an established frequency;

* * * * *

17. Section 835.402 is revised to read as follows:

§ 835.402 Individual monitoring.

(a) For the purpose of monitoring individual exposures to external radiation, personnel dosimeters 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;

(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 limit at § 835.206(a);

(3) Occupationally exposed minors likely to receive a dose in excess of 50 percent of the applicable limits at § 835.207 in a year from external sources;

(4) Members of the public entering a controlled area likely to receive a dose in excess of 50 percent of the limit at § 835.208 in a year from external sources; and

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

(b) External dose monitoring programs implemented to demonstrate compliance with § 835.402(a) shall be adequate to demonstrate compliance with the dose limits established in subpart C of this part and shall be:

(1) Accredited, or excepted from accreditation, in accordance with the DOE Laboratory Accreditation Program for Personnel Dosimetry; or

(2) Determined by the Secretarial Officer responsible for environment, safety and health matters to have performance substantially equivalent to that of programs accredited under the DOE Laboratory Accreditation Program for Personnel Dosimetry.

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

(1) Radiological workers who, under typical conditions, are likely to receive a committed effective dose equivalent of 0.1 rem (0.001 sievert) or more from all occupational radionuclide intakes in a year;

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

(3) Occupationally exposed minors who are likely to receive a dose in excess of 50 percent of the applicable limit stated at § 835.207 from all radionuclide intakes in a year; or

(4) Members of the public entering a controlled area likely to receive a dose in excess of 50 percent of the limit stated at § 835.208 from all radionuclide intakes in a year.

(d) Internal dose monitoring programs implemented to demonstrate compliance with § 835.402(c) shall be adequate to demonstrate compliance with the dose limits established in subpart C of this part and shall be:

(1) Accredited, or excepted from accreditation, in accordance with the DOE Laboratory Accreditation Program for Radiobioassay; or,

(2) Determined by the Secretarial Officer responsible for environment, safety and health matters to have performance substantially equivalent to that of programs accredited under the DOE Laboratory Accreditation Program for Radiobioassay.

18. Section 835.403 is revised to read as follows:

§ 835.403 Air monitoring.

(a) Monitoring of airborne radioactivity shall be performed:

(1) Where an individual is likely to receive an exposure of 40 or more DAC-hours in a year; or

(2) As necessary to characterize the airborne radioactivity hazard where respiratory protective devices for protection against airborne radionuclides have been prescribed.

(b) Real-time air monitoring shall be performed as necessary to detect and

provide warning of airborne radioactivity concentrations that warrant immediate action to terminate inhalation of airborne radioactive material.

§ 835.404 [Reserved]

19. Section 835.404 is removed and reserved.

20. Section 835.405 is added to subpart E to read as follows:

§ 835.405 Receipt of packages containing radioactive material.

(a) If packages containing quantities of radioactive material in excess of a Type A quantity (as defined at 10 CFR 71.4) are expected to be received from radioactive material transportation, arrangements shall be made to either:

(1) Take possession of the package when the carrier offers it for delivery; or

(2) Receive notification as soon as practicable after arrival of the package at the carrier's terminal and to take possession of the package expeditiously after receiving such notification.

(b) Upon receipt from radioactive material transportation, external surfaces of packages known to contain radioactive material shall be monitored if the package:

(1) Is labeled with a Radioactive White I, Yellow II, or Yellow III label (as specified at 49 CFR 172.403 and 172.436-440); or

(2) Has been transported as low specific activity material (as defined at 10 CFR 71.4) on an exclusive use vehicle (as defined at 10 CFR 71.4); or

(3) Has evidence of degradation, such as packages that are crushed, wet, or damaged.

(c) The monitoring required by paragraph (b) of this section shall include:

(1) Measurements of removable contamination levels, unless the package contains only special form (as defined at 10 CFR 71.4) or gaseous radioactive material; and

(2) Measurements of the radiation levels, unless the package contains less than a Type A quantity (as defined at 10 CFR 71.4) of radioactive material.

(d) The monitoring required by paragraph (b) of this section shall be completed as soon as practicable following receipt of the package, but not later than 8 hours after the beginning of the working day following receipt of the package.

Subpart F—Entry Control Program

21. Section 835.501 is amended by revising paragraph (d) as follows:

§ 835.501 Radiological areas.

* * * * *

(d) Written authorizations shall be required to control entry into and perform work within radiological areas. These authorizations shall specify radiation protection measures commensurate with the existing and potential hazards.

22. At § 835.502, paragraphs (a), (b), and (c) are redesignated as paragraphs (b), (c), and (d) respectively; the paragraph heading of redesignated paragraph (b) is revised; a new paragraph (a) is added and redesignated paragraphs (b)(2) and (c) are revised as follows:

§ 835.502 High and very high radiation areas.

(a) The following measures shall be implemented for each entry into a high radiation area:

(1) The area shall be monitored as necessary during access to determine the exposure rates to which the individuals are exposed; and

(2) Each individual shall be monitored by a supplemental dosimetry device or other means capable of providing an immediate estimate of the individual's integrated deep dose equivalent during the entry.

(b) *Physical controls.* * * *

(1) * * *

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

* * * * *

(c) *Very high radiation areas.* In addition to the above requirements, additional measures shall be implemented to ensure individuals are not able to gain unauthorized or inadvertent access to very high radiation areas.

Subpart G—Posting and Labeling

23. Section 835.601 is revised to read as follows:

§ 835.601 General requirements.

(a) Except as otherwise provided in this subpart, postings and labels required by this subpart shall include the standard radiation warning trefoil in black or magenta imposed upon a yellow background.

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

(c) The posting and labeling requirements in this subpart may be modified to reflect the special considerations of DOE activities conducted at private residences or businesses. Such modifications shall provide the same level of protection to

individuals as the existing provisions in this subpart.

24. Section 835.602 is amended by revising paragraph (a) to read as follows:

§ 835.602 Controlled areas.

(a) Each access point to a controlled area (as defined at § 835.2) shall be posted whenever radiological areas or radioactive material areas exist in the area. Individuals who enter only controlled areas without entering radiological areas or radioactive material areas are not expected to receive a total effective dose equivalent of more than 0.1 rem (0.001 sievert) in a year.

* * * * *

25. Section 835.603 is revised to read as follows:

§ 835.603 Radiological areas and radioactive material areas.

Each access point to radiological areas and radioactive material areas (as defined at § 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 each radiation area.

(b) *High radiation area.* The words "Caution, High Radiation Area" or "Danger, High Radiation Area" shall be posted at each high radiation area.

(c) *Very high radiation area.* The words "Grave Danger, Very High Radiation Area" shall be posted at each very high radiation area.

(d) *Airborne radioactivity area.* The words "Caution, Airborne Radioactivity Area" or "Danger, Airborne Radioactivity Area" shall be posted at each airborne radioactivity area.

(e) *Contamination area.* The words "Caution, Contamination Area" shall be posted at each contamination area.

(f) *High contamination area.* The words "Caution, High Contamination Area" or "Danger, High Contamination Area" shall be posted at each high contamination area.

(g) *Radioactive material area.* The words "Caution, Radioactive Material(s)" shall be posted at each radioactive material area.

26. Section 835.604 is added to subpart G to read as follows:

§ 835.604 Exceptions to posting requirements.

(a) Areas may be excepted from the posting requirements of § 835.603 for periods of less than 8 continuous hours when placed under continuous observation and control of an individual knowledgeable of, and empowered to implement, required access and exposure control measures.

(b) Areas may be excepted from the radioactive material area posting requirements of § 835.603(g) when:

(1) Posted in accordance with §§ 835.603(a) through (f); or

(2) Each item or container of radioactive material is labeled in accordance with this subpart such that individuals entering the area are made aware of the hazard; or

(3) The radioactive material of concern consists solely of structures or installed components which have been activated (i.e., such as by being exposed to neutron radiation or particles produced by an accelerator).

(c) Areas containing only packages received from radioactive material transportation labeled and in non-degraded condition need not be posted in accordance with § 835.603 until the packages are monitored in accordance with § 835.405.

27. Section 835.605 is added to subpart G to read as follows:

§ 835.605 Labeling items and containers.

Except as provided at § 835.606, each item or container of radioactive material shall bear a durable, clearly visible label bearing the standard radiation warning trefoil and the words "Caution, Radioactive Material" or "Danger, Radioactive Material." The label shall also provide sufficient information to permit individuals handling, using, or working in the vicinity of the items or containers to take precautions to avoid or control exposures.

28. Section 835.606 is added to subpart G to read as follows:

§ 835.606 Exceptions to labeling requirements.

(a) Items and containers may be excepted from the radioactive material labeling requirements of § 835.605 when:

(1) Used, handled, or stored in areas posted and controlled in accordance with this subpart and sufficient information is provided to permit individuals to take precautions to avoid or control exposures; or

(2) The quantity of radioactive material is less than one tenth of the values specified in appendix E of this part; or

(3) Packaged, labeled, and marked in accordance with the regulations of the Department of Transportation or DOE Orders governing radioactive material transportation; or

(4) Inaccessible, or accessible only to individuals authorized to handle or use them, or to work in the vicinity; or

(5) Installed in manufacturing, process, or other equipment, such as reactor components, piping, and tanks; or

(6) The radioactive material consists solely of nuclear weapons or their components.

(b) Radioactive material labels applied to sealed radioactive sources may be excepted from the color specifications of § 835.601(a).

Subpart H—Records

29. In § 835.702, paragraphs (a), (b), (c), (d), and (e) are revised to read as follows:

§ 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 to document doses received during planned special exposures, unplanned doses exceeding the monitoring thresholds of § 835.402, and authorized emergency exposures.

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

(c) The records required by this section shall:

- (1) Be sufficient to evaluate compliance with subpart C of this part;
- (2) Be sufficient to provide dose information necessary to complete reports required by subpart I of this part;
- (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 information 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) 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.

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

(d) Documentation of all occupational doses received during the current year, except for doses resulting from planned special exposures conducted in compliance with § 835.204 and emergency exposures authorized in accordance with § 835.1302(d), shall be obtained to demonstrate compliance with § 835.202(a). If complete records documenting previous occupational dose during the year cannot be obtained, a written estimate signed by the individual may be accepted to demonstrate compliance.

(e) For radiological workers whose occupational dose is monitored in accordance with § 835.402, reasonable efforts shall be made to obtain complete records of prior years occupational internal and external doses.

* * * * *

30. In § 835.703, paragraphs (a), (b), (c), and (d) are revised to read as follows:

§ 835.703 Other monitoring records.

* * * * *

(a) Results of monitoring for radiation and radioactive material as required by subparts E and L of this part, except for monitoring required by § 835.1102(d);

(b) Results of monitoring used to determine individual occupational dose from external and internal sources;

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

(d) Results of maintenance and calibration performed on instruments and equipment as required by § 835.401(b).

31. Section 835.704, paragraph (a) is amended by removing the reference to ", 835.902, and 835.903"; paragraphs (d) and (e) are revised and a new paragraph (f) is added as follows:

§ 835.704 Administrative records.

* * * * *

(d) Written declarations of pregnancy, including the estimated date of conception, and revocations of declarations of pregnancy shall be maintained.

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

(f) Records shall be maintained as necessary to demonstrate compliance with the requirements of §§ 835.1201 and 835.1202 for sealed radioactive

source control, inventory, and source leak tests.

Subpart I—Reports to Individuals

32. Section 835.801, paragraph (a) is revised to read as follows:

§ 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, employee number, or other unique identification number.

* * * * *

Subpart J—Radiation Safety Training

33. In subpart J, § 835.901 is revised to read as follows:

§ 835.901 Radiation safety training.

(a) Each individual shall complete radiation safety training on the topics established at § 835.901(c) commensurate with the hazards in the area and the required controls:

(1) Before being permitted unescorted access to controlled areas; and

(2) Before receiving occupational dose during access to controlled areas at a DOE site or facility.

(b) Each individual shall demonstrate knowledge of the radiation safety training topics established at § 835.901(c), commensurate with the hazards in the area and required controls, by successful completion of an examination and performance demonstrations:

(1) Before being permitted unescorted access to radiological areas; and

(2) Before performing unescorted assignments as a radiological worker.

(c) Radiation safety training shall include the following topics, to the extent appropriate to each individual's prior training, work assignments, and degree of exposure to potential radiological hazards:

(1) Risks of exposure to radiation and radioactive materials, including prenatal radiation exposure;

(2) Basic radiological fundamentals and radiation protection concepts;

(3) Physical design features, administrative controls, limits, policies, procedures, alarms, and other measures implemented at the facility to manage doses and maintain doses ALARA, including both routine and emergency actions;

(4) Individual rights and responsibilities as related to

implementation of the facility radiation protection program;

(5) Individual responsibilities for implementing ALARA measures required by § 835.101; and

(6) Individual exposure reports that may be requested in accordance with § 835.801.

(d) When an escort is used in lieu of training in accordance with paragraph (a) or (b) of this section, the escort shall:

(1) Have completed radiation safety training, examinations, and performance demonstrations required for entry to the area and performance of the work; and

(2) Ensure that all escorted individuals comply with the documented radiation protection program.

(e) Radiation safety training shall be provided to individuals when there is a significant change to radiation protection policies and procedures that may affect the individual and at intervals not to exceed 24 months. Such training provided for individuals subject to the requirements of § 835.901(b)(1) and (b)(2) shall include successful completion of an examination.

§§ 835.902 and 835.903 [Removed and Reserved]

34. Sections 835.902 and 835.903 of subpart J are removed and reserved.

Subpart K—Design and Control

35. In Subpart K, section 835.1002 is amended by changing the word "old" to "existing", and section 835.1001 is revised to read as follows:

§ 835.1001 Design and control.

(a) Measures shall be taken to maintain radiation exposure in controlled areas ALARA through physical design features and administrative control. The primary methods used shall be physical design features (e.g., confinement, ventilation, remote handling, and shielding). Administrative controls shall be employed only as supplemental methods to control radiation exposure.

(b) For specific activities where use of physical design features is demonstrated to be impractical, administrative controls shall be used to maintain radiation exposures ALARA.

36. Section 835.1003 is revised to read as follows:

§ 835.1003 Workplace controls.

During routine operations, the combination of physical design features and administrative controls shall provide that:

(a) The anticipated occupational dose to general employees shall not exceed the limits established at § 835.202; and

(b) The ALARA process is utilized for personnel exposures to ionizing radiation.

Subpart L—Radioactive Contamination Control

37. The heading of subpart L is revised to read as set forth above.

37a. Section 835.1101 is revised and § 835.1102 is added to read as follows:

§ 835.1101 Control of material and equipment.

(a) Except as provided in paragraphs (b) and (c) of this section, material and equipment in contamination areas, high contamination areas, and airborne radioactivity areas shall not be released to a controlled area if:

(1) Removable surface contamination levels on accessible surfaces exceed the removable surface contamination values specified in appendix D of this part; or

(2) Prior use suggests that the removable surface contamination levels on inaccessible surfaces are likely to exceed the removable surface contamination values specified in appendix D of this part.

(b) Material and equipment exceeding the removable surface contamination values specified in appendix D of 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 is performed and appropriate controls for the movement are established and exercised.

(c) Material and equipment with fixed contamination levels that exceed the total contamination values specified in appendix D of this part may be released for use in controlled areas outside of radiological areas only under the following conditions:

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

(2) The material or equipment is routinely monitored and clearly marked or labeled to alert personnel of the contaminated status.

§ 835.1102 Control of areas.

(a) 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.

(b) Any area in which contamination levels exceed the values specified in appendix D of this part shall be controlled in a manner commensurate with the physical and chemical characteristics of the contaminant, the

radionuclides present, and the fixed and removable surface contamination levels.

(c) Areas accessible to individuals where the measured total surface contamination levels exceed, but the removable surface contamination levels are less than, corresponding surface contamination values specified in appendix D of this part, shall be controlled as follows when located outside of radiological areas:

(1) The area shall be routinely monitored to ensure the removable surface contamination level remains below the removable surface contamination values specified in appendix D of this part; and

(2) The area shall be conspicuously marked to warn individuals of the contaminated status.

(d) Individuals exiting contamination, high contamination, or airborne radioactivity areas shall be monitored, as appropriate, for the presence of surface contamination.

(e) Protective clothing shall be required for entry to areas in which removable contamination exists at levels exceeding the removable surface contamination values specified in appendix D of this part.

38. Subpart M is added, consisting of §§ 835.1201 and 835.1202, to read as follows:

Subpart M—Sealed Radioactive Source Control

§ 835.1201 Sealed radioactive source control.

Sealed radioactive sources shall be used, handled, and stored in a manner commensurate with the hazards associated with operations involving the sources.

§ 835.1202 Accountable sealed radioactive sources.

(a) Each accountable sealed radioactive source shall be inventoried at intervals not to exceed six months. This inventory shall:

(1) Establish the physical location of each accountable sealed radioactive source;

(2) Verify the presence and adequacy of associated postings and labels; and

(3) Establish the adequacy of storage locations, containers, and devices.

(b) Except for sealed radioactive sources consisting solely of gaseous radioactive material or tritium, each accountable sealed radioactive source shall be subject to a source leak test upon receipt, when damage is suspected, and at intervals not to exceed six months. Source leak tests shall be capable of detecting radioactive material leakage equal to or exceeding 0.005 microcurie.

(c) Notwithstanding the requirements of paragraph (b) of this section, an accountable sealed radioactive source is not subject to periodic source leak testing if that source has been removed from service. Such sources shall be stored in a controlled location, subject to periodic inventory as required by paragraph (a) of this section, and subject to source leak testing prior to being returned to service.

(d) Notwithstanding the requirements of paragraphs (a) and (b) of this section, an accountable sealed radioactive source is not subject to periodic inventory and source leak testing if that source is located in an area that is unsafe for human entry or otherwise inaccessible.

(e) An accountable sealed radioactive source found to be leaking radioactive material shall be controlled in a manner that minimizes the spread of radioactive contamination.

Subpart N—Emergency Exposure Situations

39. In § 835.1301, paragraphs (a), introductory text, (b), (c), and (d) are revised to read as follows:

§ 835.1301 General provisions.

(a) A general employee whose occupational dose has exceeded the numerical value of any of the limits specified in § 835.202 as a result of an authorized emergency exposure may be permitted to return to work in radiological areas during the current year providing that all of the following conditions are met:

* * * * *

(b) All doses exceeding the limits specified in § 835.202 shall be recorded in the affected individual's occupational dose record.

(c) When the conditions under which a dose was received in excess of the limits specified in § 835.202, except those received in accordance with § 835.204, have been eliminated, operating management shall notify the Head of the responsible DOE field organization.

(d) Operations after a dose was received in excess of the limits specified in § 835.202, except those received in accordance with § 835.204, may be resumed only with the approval of DOE.

40. Section 835.1302 is revised in paragraphs (b), (c), and (d) as follows:

§ 835.1302 Emergency exposure situations.

* * * * *

(b) Operating management shall weigh actual and potential risks against the benefits to be gained.

(c) No individual shall be required to perform a rescue action that might involve substantial personal risk.

(d) Each individual authorized to perform emergency actions likely to result in occupational doses exceeding the values of the limits provided at § 835.202(a) shall be trained in accordance with § 835.901(b) and briefed beforehand on the known or anticipated hazards to which the individual will be subjected.

* * * * *

41. At § 835.1304, paragraphs (a) and (b)(1), the word "personnel" is revised to read "individuals" and paragraph (b)(4) is revised as follows:

§ 835.1304 Nuclear accident dosimetry.

* * * * *

(b) * * *

(4) Personal nuclear accident dosimeters.

42. Appendix A of Part 835 is amended by removing footnote 5 from the Footnotes for Appendix A and, adding the following two paragraphs at the beginning of the introductory text:

Appendix A to Part 835—Derived Air Concentrations (DAC) for Controlling Radiation Exposure to Workers at DOE Facilities

The data presented in appendix A are to be used for controlling individual internal doses in accordance with § 835.209, identifying the need for air monitoring in accordance with § 835.403, and identifying the need for posting of airborne radioactivity areas in accordance with § 835.603(d).

The DAC values are given for individual radionuclides. For known mixtures of radionuclides, determine the sum of the ratio of the observed concentration of a particular radionuclide and its corresponding DAC for all radionuclides in the mixture. If this sum exceeds unity (1), then the DAC has been exceeded. For unknown radionuclides, the most restrictive DAC (lowest value) for those isotopes not known to be absent shall be used.

* * * * *

Appendix B—[Removed and Reserved]

43. Appendix B to Part 835 is removed and reserved.

44. Appendix C to Part 835 is amended by removing the entries for the radionuclides Rn-220 and Rn-222 and their corresponding half-lives and air immersion DACs from the table and revising the introductory text preceding the table as follows:

Appendix C to Part 835—Derived Air Concentration (DAC) for Workers From a Contaminated Atmospheric Cloud

* * * * *

a. The data presented in appendix C are to be used for controlling occupational exposures in accordance with § 835.209,

identifying the need for air monitoring in accordance with § 835.403, and identifying the need for posting of airborne radioactivity areas in accordance with § 835.603(d).

b. The air immersion DAC values shown in this appendix are based on a stochastic dose 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 $\mu\text{Ci}/\text{ml}$; 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 DACs listed in this appendix may be modified to allow for submersion in a cloud of finite dimensions.

c. 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.

d. 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.

e. The DAC values are given for individual radionuclides. For known mixtures of radionuclides, determine the sum of the ratio of the observed concentration of a particular

radionuclide and its corresponding DAC for all radionuclides in the mixture. If this sum exceeds unity (1), then the DAC has been exceeded. For unknown radionuclides, the most restrictive DAC (lowest value) for those isotopes not known to be absent shall be used.

* * * * *

45. Appendix D to part 835 is revised as follows:

Appendix D to Part 835—Surface Contamination Values

The data presented in appendix D are to be used in identifying the need for posting of

contamination and high contamination areas in accordance with § 835.603(e) and (f) and identifying the need for surface contamination monitoring and control in accordance with §§ 835.1101 and 835.1102.

SURFACE CONTAMINATION VALUES¹ IN DPM/100 CM²

Radionuclide	Removable ^{2,4}	Total (Fixed + Removable) ^{2,3}
U-nat, U-235, U-238, and associated decay products	⁷ 1,000	⁷ 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 and tritiated compounds ⁶	10,000	N/A

¹ The values in this appendix, with the exception noted in footnote 5, apply to radioactive contamination deposited on, but not incorporated into the interior or matrix 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 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 cm² is less than three times the value specified. For purposes of averaging, any square meter of surface shall be considered to be above the surface contamination value if: (1) From measurements of a representative number of sections it is determined that the average contamination level exceeds the applicable value; or (2) it is determined that the sum of the activity of all isolated spots or particles in any 100 cm² area exceeds three times the applicable value.

⁴ The amount of removable radioactive material per 100 cm² 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 cm² is determined, the activity per unit area shall be based on the actual area and the entire surface shall be wiped. 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.

⁶ Tritium contamination may diffuse into the volume or matrix of materials. Evaluation of surface contamination shall consider the extent to which such contamination may migrate to the surface in order to ensure the surface contamination value provided in this appendix is not exceeded. Once this contamination migrates to the surface, it may be removable, not fixed; therefore, a "Total" value does not apply.

⁷ (alpha)

46. Appendix E to Part 835 is added as follows:

Appendix E to Part 835—Values for Establishing Sealed Radioactive Source Accountability and Radioactive Material Posting and Labeling Requirements

The data presented in this appendix E are to be used for identifying accountable sealed radioactive sources as defined at § 835.2(a), establishing the need for radioactive material area posting in accordance with § 835.603(g), and establishing the need for radioactive material labeling in accordance with § 835.605.

Note: The data are listed in alphabetical order by nuclide.

Nuclide	Activity (μCi)	Nuclide	Activity (μCi)	Nuclide	Activity (μCi)
Ac-227	1.5E+00	H-3	1.6E+08	Re-184m	1.5E+02
Ag-105	2.1E+06	Hf-172	3.1E+04	Re-186m	2.8E+05
Ag-108m	1.8E+01	Hf-175	1.8E+06	Rh-101	2.5E+05
Ag-110m	2.2E+01	Hf-178m	4.1E+03	Rh-102	8.3E+04
Al-26	1.6E+01	Hf-181	3.5E+02	Rh-102m	2.1E+05
Am-241	2.3E+01	Hf-182	3.0E+03	Ru-103	4.4E+02
Am-242m	2.4E+01	Hg-194	3.5E+04	Ru-106	2.1E+04
Am-243	2.3E+01	Hg-203	4.9E+02	S-35	4.0E+06
As-73	5.4E+02	Ho-166m	2.2E+01	Sb-124	9.1E+01
Au-195	4.8E+02	I-125	3.5E+02	Sb-125	6.8E+01
Ba-133	5.2E+01	I-129	1.8E+02	Sc-46	6.2E+01
Be-10	2.8E+04	In-114m	7.8E+02	Se-75	6.4E+01
Be-7	3.2E+03	Ir-192	1.4E+02	Se-79	1.0E+06
Bi-207	1.7E+01	Ir-192m	2.6E+04	Si-32	9.9E+03
Bi-208	1.5E+01	Ir-194m	2.7E+01	Sm-145	9.1E+05
Bi-210m	1.3E+03	K-40	2.8E+02	Sm-146	1.2E+02
Bk-247	1.7E+01	La-137	1.1E+05	Sm-151	2.5E+05
Bk-249	7.2E+03	Lu-173	4.4E+05	Sn-113	3.1E+02
C-14	4.8E+06	Lu-174	2.5E+05	Sn-119m	3.3E+02
Ca-41	7.4E+06	Lu-174m	3.9E+05	Sn-121m	8.7E+05
Ca-45	1.5E+06	Lu-177m	5.8E+01	Sn-123	1.3E+04
Cd-109	1.6E+02	Md-258	6.0E+02	Sn-126	1.8E+02
Cd-113m	6.5E+03	Mn-53	2.0E+07	Sr-85	1.2E+02

Nuclide	Activity (μ Ci)	Nuclide	Activity (μ Ci)	Nuclide	Activity (μ Ci)
Cd-115m	1.0E+04	Mn-54	6.5E+01	Sr-89	2.4E+05
Ce-139	2.4E+02	Mo-93	7.7E+01	Sr-90	7.7E+03
Ce-141	2.4E+03	Na-22	1.9E+01	Ta-179	1.5E+06
Ce-144	1.5E+03	Nb-91	7.0E+01	Ta-182	7.3E+01
Cf-248	2.0E+02	Nb-91m	3.6E+02	Tb-157	2.5E+03
Cf-249	1.7E+01	Nb-92	1.8E+01	Tb-158	3.9E+04
Cf-250	3.8E+01	Nb-93m	4.4E+02	Tb-160	1.2E+02
Cf-251	1.7E+01	Nb-94	2.3E+01	Tc-95m	1.3E+02
Cf-252	6.4E+01	Nb-95	3.4E+02	Tc-97	8.1E+01
Cf-254	3.4E+01	Ni-59	7.5E+06	Tc-97m	3.6E+02
Cl-36	4.6E+05	Ni-63	3.2E+06	Tc-98	2.5E+01
Cm-241	6.8E+04	Np-235	1.2E+02	Tc-99	6.8E+06
Cm-242	5.8E+02	Np-236	2.2E+01	Te-121m	1.9E+02
Cm-243	3.3E+01	Np-237	1.9E+01	Te-123m	2.8E+02
Cm-244	4.0E+01	Os-185	1.4E+02	Te-125m	4.4E+02
Cm-245	2.2E+01	Os-194	1.5E+04	Te-127m	8.0E+02
Cm-246	2.2E+01	Pa-231	7.8E+00	Te-129m	2.3E+03
Cm-247	2.4E+01	Pb-202	1.0E+05	Th-228	2.9E+01
Cm-248	6.0E+00	Pb-205	9.1E+01	Th-229	4.7E+00
Cm-250	1.1E+00	Pb-210	9.2E+01	Th-230	3.1E+01
Co-56	4.0E+01	Pd-107	7.8E+05	Th-232	6.1E+00
Co-57	2.3E+02	Pm-143	1.3E+02	Ti-44	1.6E+02
Co-58	1.4E+02	Pm-144	2.9E+01	Ti-204	2.2E+04
Co-60	1.8E+01	Pm-145	2.6E+02	Tm-170	8.4E+03
Cs-134	2.7E+01	Pm-146	4.5E+01	Tm-171	2.8E+04
Cs-135	2.2E+06	Pm-147	2.5E+05	U-232	1.5E+01
Cs-137	6.0E+01	Pm-148m	1.1E+02	U-233	7.4E+01
Dy-159	4.1E+06	Po-209	6.3E+03	U-234	7.5E+01
Es-254	6.3E+01	Po-210	1.1E+03	U-235	6.7E+01
Es-255	4.6E+04	Pt-193	4.4E+07	U-236	8.0E+01
Eu-148	7.0E+05	Pu-236	6.9E+01	U-238	8.4E+01
Eu-149	5.3E+06	Pu-237	3.3E+02	V-49	2.9E+07
Eu-152	3.1E+01	Pu-238	2.5E+01	W-181	1.1E+03
Eu-154	3.1E+01	Pu-239	2.3E+01	W-185	3.9E+06
Eu-155	3.7E+02	Pu-240	2.3E+01	W-188	6.4E+04
Fe-55	3.7E+06	Pu-241	1.2E+03	Y-88	3.4E+01
Fe-59	2.0E+02	Pu-242	2.4E+01	Y-91	5.0E+04
Fe-60	1.3E+04	Pu-244	2.5E+01	Yb-169	5.5E+02
Fm-257	4.3E+02	Ra-226	1.2E+03	Zn-65	1.1E+02
Gd-146	2.6E+05	Ra-228	2.1E+03	Zr-88	1.2E+02
Gd-148	3.0E+01	Rb-83	9.2E+01	Zr-93	3.1E+04
Gd-151	1.1E+06	Rb-84	2.0E+02	Zr-95	2.0E+02
Gd-153	2.1E+02	Re-183	5.4E+02		
Ge-68	5.7E+02	Re-184	2.6E+02		

Any alpha emitting radionuclide not listed above and mixtures of alpha emitters of unknown composition have a value of 10 microcuries.

Any radionuclide other than alpha emitting radionuclides not listed above and mixtures of beta emitters of unknown composition have a value of 100 microcuries.

Note: Where there is involved a combination of radionuclides in known amounts, derive the value for the combination as follows: determine, for each radionuclide in the combination, the ratio between the quantity present in the combination and the value otherwise established for the specific radionuclide

when not in combination. If the sum of such ratios for all radionuclides in the combination exceeds unity (1), then the accountability criterion has been exceeded.

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