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10 CFR Parts 20, 32, 35, 36, and 39

RIN 3150–AF46

Minor Corrections, Clarifying Changes, and a Minor Policy Change

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to make minor corrections and clarifying changes to the NRC's 10 CFR Part 20, ''Standards for Protection Against Radiation.'' The final rule is also intended to conform other regulations with the Commission's 1991 revised radiation protection requirements. In addition, the final rule includes a minor policy change that raises the monitoring criteria for minors from 0.05 rem (0.5 mSv) to 0.1 rem (1 mSv) in a year and for declared pregnant women from 0.05 rem (0.5 mSv) to 0.1 rem (1 mSv) during their pregnancies. The 0.1 rem (1 mSv) in a year deep dose equivalent monitoring criterion is consistent with the public dose limit and represents a quantity more consistent with the measurement sensitivity of individual personnel dosimetry. Licensees are still required to ensure that the occupational dose limit of 0.5 rem (5 mSv) in a year is not exceeded for minors, that the dose limit of 0.5 rem (5 mSv) to an embryo/fetus due to occupational exposure of a declared pregnant woman is not exceeded during the course of the pregnancy, and that sufficient effort is made to ensure that substantial variations above a uniform monthly exposure rate for a declared pregnant woman are avoided. These changes to the threshold for monitoring exposures to radiation and radioactive material to demonstrate compliance with the limits do not change the occupational dose limits for minors or declared pregnant workers.

EFFECTIVE DATE: This regulation becomes effective on August 24, 1998.

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SUPPLEMENTARY INFORMATION:

I. Introduction

On May 21, 1991 (56 FR 23360), a final rule was published in the **Federal Register** that amended 10 CFR Part 20 to update the NRC's ''Standards for Protection Against Radiation.'' Subsequent amendments were published to (1) change the mandatory implementation to January 1, 1994, and make conforming changes to the text to reflect the new implementation date (57 FR 38588; August 26, 1992), (2) remove or modify provisions to reflect the new implementation date for NRC's revised ''Standards for Protection Against Radiation'' (58 FR 67657; December 22, 1993), and (3) restore provisions inadvertently removed or modified (59 FR 41641; August 15, 1994; and 60 FR 20183; April 25, 1995).

Since then, several inconsistencies have come to light. The Nuclear Regulatory Commission (NRC) is amending its regulations regarding standards for protection against radiation to make minor corrections and clarifying changes that will remove the inconsistencies and further facilitate implementation. This final rule also establishes conforming amendments to 10 CFR Parts 32, 35, 36, and 39. In addition, a minor policy change raises the monitoring criteria for minors from 0.05 rem (0.5 mSv) to 0.1 rem (1 mSv) in a year and for declared pregnant women from 0.05 rem (0.5 mSv) to 0.1 rem (1 mSv) during their pregnancies.

II. Background

On October 7, 1996, the NRC published a proposed rule for comment in the **Federal Register** (61 FR 52388) to amend 10 CFR Part 20 of its regulations to make minor corrections and clarifying changes regarding standards for protection against radiation; to conform other 10 CFR Parts with the Commission's revised radiation protection requirements; and to revise the deep dose equivalent monitoring criteria for minors from 0.05 rem (0.5 mSv) to 0.1 rem (1 mSv) in a year and for declared pregnant women from 0.05 rem (0.5 mSv) to 0.1 rem (1 mSv) during their pregnancies. The proposed rule noted that the monitoring criteria would not raise the dose limit for an embryo/fetus due to occupational dose to the declared pregnant woman or the dose limit for minors. Changing the criteria for monitoring does not, in any way, change the dose limits for declared pregnant women, for the embryo/fetus, or for minors. The 0.1 rem (1 mSv) in a year deep dose equivalent monitoring criterion is consistent with the public dose limit and represents a quantity more consistent with the measurement sensitivity of individual personnel dosimetry. The current criteria of 0.05 rem (0.5 mSv), if received uniformly in a year or throughout the gestation period, would result in an average monthly dose of less than 0.005 rem (0.05 mSv). The most routinely utilized individual monitoring devices cannot accurately measure doses below 0.01 rem (0.1 mSv), which is greater than the average monthly dose of 0.005 rem (0.05 mSv).

The public comment period closed on December 23, 1996. A discussion of the issues raised by public comment is covered in Section IV, below.

III. Summary of Final Rule

This final rule makes the following changes:

(1) In § 20.1003, ''Definitions,'' clarifying changes and minor corrections are made to the following:

(a) The definition of ''Declared pregnant woman'' is revised to specify that the written declaration of pregnancy is to be given to the licensee rather than the employer, unless the employer is also the licensee. This is necessary to ensure that the entity responsible for work assignments involving radiation exposure (the

licensee) is aware of the declaration of pregnancy to facilitate timely and appropriate protective action. The change also specifies that the declaration, as well as associated dose restrictions, remains in effect until it is withdrawn in writing or until the woman is no longer pregnant. The determination that a declared pregnant woman is no longer pregnant should be based on a discussion between the declared pregnant woman and the licensee.

(b) The definitions of ''High radiation area'' and ''Very high radiation area'' are revised to make it clear that these area designations exist solely to note radiation levels from sources external to an individual who may receive the dose.

(c) The definition of ''Individual monitoring devices'' is revised to correct the misuse of the term thermoluminescent to describe thermoluminescence dosimeters.

(d) The term ''Lens dose equivalent (LDE)'' replaces ''Eye dose equivalent'' (EDE) to avoid confusion between the initialisms for dose to the lens of the eye and effective dose equivalent (EDE). This should pose no procedural burden on licensees because the required NRC Forms 4 and 5 for records and reports were revised in August 1995 to reflect the new terminology, and these or their equivalent are required to be used by existing § 20.2104, § 20.2106(c), and § 20.2206(b).

(2) In § 20.1101(b), the word ''practicable'' is changed to ''practical'' to remove the basis for an incorrect perception among some licensees that, by using the word ''practicable'' in this section, the NRC is requiring licensees to use any dose averting technique that is capable of being used even if the technique is unproven or impractical.

(3) In §§ 20.1201(a)(2)(i) and (c); 20.1203; 20.2101; 20.2106(a)(1); and 20.2202(a)(1)(ii) and (b)(1)(ii), ''eye dose equivalent'' is replaced by ''lens dose equivalent'' as described above in the change to § 20.1003.

(4) In § 20.1206, Planned special exposures, paragraph (a) is revised to clarify what was intended by the term ''higher exposure'' used in the rule previously. The phrase applies to dose estimates performed prior to authorizing the planned special exposure (PSE). The new wording states that PSE's are authorized only in exceptional situations when alternatives that might avoid the dose estimated to result from the PSE are unavailable or impractical. Improved clarification will avoid possible misinterpretation of a PSE criterion.

(5) In § 20.1208(a), (c), (c)(2), and (d), the phrase ''dose to an embryo/fetus'' is changed to read ''dose equivalent to the embryo/fetus'' to make it clear that the dose limit specifically applies to the dose equivalent, which is the technically correct term to denote effect of dose to an organ.

(6) In § 20.1501(a)(2)(i), the phrase ''The extent of radiation levels; * * *'' is revised to read ''The magnitude and extent of radiation levels; * * *'' to clarify the intended meaning that surveys should evaluate both the area covering the dose field as well as the amount of dose in that area.

(7) In § 20.1501(a)(2)(iii), the phrase ''The potential radiological hazards that could be present'' is revised to read ''The potential radiological hazards'' in order to remove redundancy.

(8) In § 20.1502, the words ''from licensed and unlicensed radiation sources under the control of the licensee'' are added after ''exposure to radiation'' in paragraph (a) to improve clarity and to make it clear that, in determining whether or not monitoring is required, a licensee need not take into account sources of radiation not under its control. It should be noted that, although the criterion for monitoring includes only radiation from sources under the control of the licensee, occupational dose includes dose from licensed and unlicensed material, whether in the possession of the licensee or other person.

(9) In § 20.1502(a)(2) and (b)(2), monitoring requirements for minors and pregnant women are revised. In addition, for minors the dose limits referenced in paragraph (a)(2) apply for an entire year, while for a declared pregnant woman the dose limit referenced in paragraph (b)(2) applies only to the 9-month gestation period. These paragraphs are separated and revised accordingly to make this section consistent with § 20.1208 and technically correct. The criteria for monitoring the deep dose equivalent are changed for minors from 0.05 rem (0.5 mSv) to 0.1 rem (1 mSv) in a year and for declared pregnant women from 0.05 rem (0.5 mSv) to 0.1 rem (1 mSv) during their pregnancies. Changing the criteria for monitoring does not, in any way, change the dose limits for declared pregnant women, for the embryo/fetus, or for minors. This change constitutes a small licensee burden reduction while maintaining the current adequate level of protection of health and safety of minors and declared pregnant women. The 0.1 rem (1 mSv) in a year deep dose equivalent monitoring criterion is consistent with the public dose limit and represents a quantity more consistent with the measurement sensitivity of individual personnel dosimetry. This value also is consistent with the 100 mrem (1 mSv) training criterion in revised § 19.12 (60 FR 36038; July 13, 1995).

Licensees are still required to ensure that the occupational dose limits for minors in § 20.1207 are not exceeded, that the dose limit of 0.5 rem (5 mSv) to the embryo/fetus from occupational dose to the declared pregnant woman is not exceeded during the course of the pregnancy, and that sufficient effort is made to ensure that substantial variations above a uniform monthly exposure rate for a declared pregnant woman are avoided. All of the occupational dose limits in § 20.1201 continue to be applicable to the declared pregnant woman as long as the embryo/fetus dose limit is not exceeded. Note that the monitoring criteria for lens dose equivalent and shallow dose equivalent for skin and extremities continue to apply to determining the occupational exposure of declared pregnant women even though they are not applicable to the embryo/fetus.

(10) The proposed change to the posting requirement in § 20.1902(d), ''Posting of Airborne Radioactivity Area,'' has not been adopted because the Commission has determined that the benefit achieved from replacing signs to use more precise terminology is outweighed by the cost to the licensees to comply with the proposed change. This issue does not have any health and safety implications and was proposed only to make an acceptable term more precise.

(11) In § 20.1903, a new paragraph is added to exempt teletherapy rooms in a hospital from posting requirements as long as access is controlled by the licensee to prevent the exposure of workers, other patients, and members of the public to radiation. The purpose of this change is to bring the regulation into conformity with existing licensing practices which are intended to avoid the unwarranted and potentially unsettling effect that ''GRAVE DANGER, VERY HIGH RADIATION AREA'' signs may have on patients undergoing medical treatment.

(12) In § 20.1906(d), a revision requires licensees to notify the NRC Operations Center instead of an NRC Regional Office when, upon receiving and opening packages, radiation levels exceed regulatory limits. This provides for consistency by having all prompt notification requirements direct licensees to contact a single location. A conforming change also is made to the notification requirements in § 20.2202.

(13) In § 20.2101, a revision permits licensees to add the new SI units to the old (special) units of dose on records

required by this part. Each of the recorded dose quantities is to be recorded in the appropriate special unit and, if so desired, followed by the appropriate SI unit in parentheses.[1] The term ''eye dose equivalent'' is replaced by ''lens dose equivalent'' as discussed under the amendment to § 20.1003.

(14) In § 20.2106 (a)(2) and (a)(3), the references to ''body burden'' are removed because this term is obsolete. Section 20.2106(a)(4) is revised by adding a reference to § 20.1204(a), that requires licensees to take measurements of (1) concentrations of radioactive materials in air in work areas, or (2) quantities of radionuclides in the body, or (3) quantities of radionuclides excreted from the body, or (4) combinations of these measurements in order to determine internal dose when required by § 20.1502 to monitor internal dose. This, in effect, uses recorded concentrations of radioactive material in air, quantities of radioactive material determined to be in the body or excreta, or any combination of these that would be needed, for assessing the committed effective dose equivalent (CEDE). The NRC believes that this information is necessary to support the recorded results of the licensee's calculation of CEDE. Adding this reference would not impose any additional recordkeeping burden on licensees because they are required to obtain this information in order to calculate CEDE under § 20.1204.

(15) A revision to § 20.2202(d) results in the application of the same incident reporting requirements to all licensees. Previously, this section required that all licensees with an installed Emergency Notification System make reports to the NRC Operations Center, but all other licensees must submit both a telephone report to the NRC Operations Center and a telegram, mailgram, or facsimile to the Regional Office. This change now requires all licensees to report incidents by telephone to the NRC Operations Center to ensure consistency in the prompt notification requirements contained elsewhere in this part and results in a reduction in the information collection burden.

(16) In § 32.54(a), the reference to ''§ 20.203(a)'' is corrected to read ''§ 20.1901.''

(17) The proposed change has not been adopted in § 35.20 because this issue is being addressed as part of a major revision to 10 CFR Part 35.

(18) Safety precautions and survey requirements for restricted and unrestricted areas are specified in §§ 35.315, 35.415, 35.641, and 35.643. The proposed changes to §§ 35.315(a)(4) and 35.415(a)(4) have not been adopted because these issues are being addressed as part of a major revision to 10 CFR Part 35. Sections 35.641(a)(2)(i) and (a)(2)(ii) and 35.643(a) are revised to be consistent with the dose limits for occupationally exposed individuals and members of the public. Also, in § 35.643(a)(1), a misreference to § 20.1301(c) is corrected to read § 20.1301. The 0.5 rem (5 mSv) limit specified in § 20.1301(c) was never intended to be required under this section in Part 35. Rather, it was always the intent of the NRC to apply the 0.1 rem (1 mSv) limit in § 20.1301(a) to this section, with a provision for licensees to request the 0.5 rem (5 mSv) limit specified in § 20.1301(c).

(19) In § 36.23(g), posting requirements for a panoramic irradiator are revised to conform with posting requirements for high or very high radiation areas in § 20.1902. The previous posting requirements in Part 36 required a posting appropriate to a high radiation area only, which may not be appropriate for all panoramic irradiators.

(20) In § 39.33, ''Radiation detection instruments,'' a conforming change to paragraph (a) is made by replacing the term milliroentgens with the terms millisieverts (mSv) and millirem (mrem) to be consistent with revised Part 20 terminology. However, the NRC recognizes that most licensees may still use radiation detection instruments that measure radiation in units of roentgens. Measurements taken in roentgens may continue to be recorded in terms of the roentgen, provided that the measurements can be readily converted to rem for records required under 10 CFR Part 20.2101(a).

(21) In § 39.71(b), the reference to ''§ 20.3'' is corrected to read ''§ 20.1003.''

Appropriate conforming changes to regulatory guides such as 8.7, 8.13, 8.34, 8.35, and 8.36 are under consideration by the Commission.

One matter in the proposed rule was not adopted. The proposed rule would have changed the term ''Airborne radioactivity area'' to ''Airborne Radioactive Material Area'' because it is more precise language. While the Commission recognizes that the current language is somewhat imprecise, it has determined that the burden imposed on licensees to revise procedures and change signs would outweigh any benefits. In addition, the proposed change to this term does not constitute a health and safety improvement. The proposed conforming changes to §§ 20.1203 and 20.1902(d) also have not been adopted.

IV. Analysis of Public Comments and Staff Response

Four letters of public comment were received on the proposed rule. Comments were received from the Council on Radionuclides and Radiopharmaceuticals, Inc., the Nuclear Energy Institute, Commonwealth Edison Company, and the U.S. Department of Health and Human Services.

Several suggestions for additional changes in 10 CFR Part 20 were submitted and have been referred to the appropriate program offices for consideration. Comments specific to the scope of issues addressed by this rulemaking and the NRC staff's response are as follows:

One commenter observed that frequent minor changes to the regulations require licensees to make numerous changes to written procedures and training content, thus constituting a burden. It was observed by the commenter that the costs of revising procedures and training programs in response to a minor rulemaking such as this can range from $12,000.00 to $20,000.00 per licensee site in the nuclear power industry. In response to this comment, and others, the proposed change in terminology from ''Airborne radioactivity area'' to ''Airborne radioactive material area'' has been deleted in this final rule. Although supported by the comments, it was also criticized as a change having associated costs and little benefit. The NRC staff agrees that the costs outweigh the benefit and has removed this proposed change from the final rule. The regulatory analysis contained in Section VIII now reflects this adjustment in cost estimate and concludes that the benefits of improved clarity and consistency in NRC regulations remaining in this final rule will offset any remaining costs.

Similar comments regarding costs and limited benefit were received regarding the proposed change to lens dose equivalent (LDE), and one commenter suggested that NRC Forms 4 and 5 should be revised to use the new term, ''lens dose equivalent (LDE).'' The NRC staff believes any costs incurred by licensees to implement this change in terminology would be minimal since the required NRC Forms 4 and 5 have already been revised to reflect the new terminology and have been used by licensees since August 1995.

[1] Part 20 was implemented prior to the NRC's Statement of Policy on Conversion to the Metric System (61 FR 31169); therefore, in order to be consistent with the approach used in Part 20 in its presentation of dual units, this rule does not follow the NRC's metrication policy which supports presenting the SI units first, followed by the English (or special) units shown in brackets.

Several suggestions were received regarding the definition and meaning of total effective dose equivalent (TEDE) and effective dose equivalent (EDE). Revision of 10 CFR Part 20, based on the recent ICRP–60 publication, was recommended. These suggestions, though having merit, go far beyond the scope of this clarifying rulemaking and will be held for future consideration.

Several commenters agreed that the declaration of pregnancy must go to the licensee, rather than the employer, as the party responsible for taking timely protective action. Guidance was requested on how licensees could determine the duration of pregnancy and thus, how long dose restrictions would remain in effect. The Commission suggests that licensees establish an appropriate duration of restriction based on discussion with the declared pregnant worker. However, it is not the Commission's intent to require activities which might violate the individual's right to privacy.

One commenter suggested that an important reason for increasing the monitoring threshold for minors and declared pregnant women to 100 mrem (1 mSv) was the difficulty in measuring 50 mrem (0.5 mSv) in a year or during the gestation period. The NRC agrees and considered this in the adoption of the final rule change.

Another commenter observed that the change in the monitoring threshold for minors and declared pregnant women will reduce unnecessary burden on licensees while maintaining the current adequate level of protection of health and safety.

One commenter suggested that consistency with the public dose limit of 100 mrem (1 mSv) is not adequate justification for changing the monitoring criteria for minors and declared pregnant women. The NRC did not rely on consistency with the public dose limit as sole justification; however, it lends support to the underlying scientific basis to revise the criteria. Since the public dose limit of 100 mrem (1 mSv) is considered to be an acceptable level of risk for all members of the public, and the occupational dose limit for minors and the dose limit for the embryo-fetus of declared pregnant women is 500 mrem (5 mSv), monitoring for exposures of less than 100 mrem (1 mSv) does not provide an additional level of protection and is not necessary to comply with the dose limits. The final rule requires monitoring of minors and declared pregnant women when it is likely that they would receive over 100 mrem (1 mSv) in 1 year (or during the entire pregnancy).

V. Agreement State Compatibility

This rulemaking will be a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among State and Federal safety requirements. Four categories of compatibility (A through D), as well as a category identifying rules of Health and Safety significance (H&S), have been assigned to portions of this rule. Category A means the provisions affect a basic radiation protection standard or related definitions, signs, labels, or terms necessary for a common understanding of radiation protection that the State should adopt with (essentially) identical language. The NRC has assigned a Category A level of compatibility to the changes to the definitions Declared pregnant woman, High radiation area, Lens dose equivalent (LDE), and Very high radiation area in § 20.1003. Also included under the Category A level of compatibility are the changes to §§ 20.1201 and 20.1208.

Category B means the provisions affect a program element with significant direct transboundary implications that the State should adopt with essentially identical language. The NRC has assigned a Category B level of compatibility to the changes in § 32.54.

Category C means the provisions affect a program element, the essential objectives of which should be adopted by the State to avoid conflicts, duplications or gaps. The manner in which the essential objectives are addressed need not be the same as NRC provided the essential objectives are met. The NRC has assigned a Category C level of compatibility to the changes in §§ 20.1003 (Definition of Individual monitoring devices), 20.2101, 20.2106, 20.2202, 39.33, and 39.71.

Category D means the provisions are not required for purposes of compatibility; however, if adopted by the State, they should be compatible with NRC. The NRC has assigned a Category D level of compatibility to the changes in §§ 20.1101, 20.1206, 20.1501, 20.1502, 20.1903, 20.1906, 35.641, 35.643, and 36.23.

Category H&S means the provisions are not required for compatibility; however, they do have particular health and safety significance. The State should adopt the essential objectives of such provisions in order to maintain an adequate program. The Category H&S has been assigned to the changes in §§ 20.1101, 20.1501, 20.1502, 20.1906, and 36.23.

VI. Environmental Impact: Categorical Exclusion

The NRC has determined that this final rule is the type of action described in the categorical exclusion in 10 CFR 51.22(c)(2). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

VII. Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). These requirements were approved by the Office of Management and Budget, approval number 3150–0014, 3150–0001, 3150–0010, 3150–0158, and 3150–0130.

Because the rule will reduce existing information collection requirements by eliminating written incident reports and allowing licensees to submit incident reports by telephone, the public burden for this information collection is expected to be reduced by approximately 250 hours per year over the entire industry. This reduction includes the time required for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of this information collection, including suggestions for further reducing the burden, to the Information and Records Management Branch (T–6F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, or by Internet electronic mail at BJS1@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB–10202 (3150–0014), Office of Management and Budget, Washington, DC 20503.

Public Protection Notification

If a document used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

VIII. Regulatory Analysis

This final rule makes minor correcting and clarifying amendments to the requirements in 10 CFR Part 20 and conforms 10 CFR Parts 32, 35, 36, and 39 to 10 CFR Part 20. The final rule imposes one-time only, minor additional costs at a maximum of $12,000 per licensee site in the nuclear power industry for changing written procedures and possibly training associated with correcting and clarifying

several definitions and minor changes to requirements addressing standards for protection against radiation. It is expected that the cost for other classes of licensees may be substantially less. The NRC staff believes that the cost of revising procedures will be small and is offset by the benefits of improved clarity and consistency in the NRC's regulations.

The final amendments include a conforming change in 10 CFR Part 36 to make the posting requirements for a panoramic irradiator consistent with posting requirements in 10 CFR Part 20 for high or very high radiation areas. Licensees in compliance with the Part 20 posting requirements are also in compliance with Part 36 posting requirements; therefore, this is a conforming change to make the language in the two sections consistent, and no impact is expected to result from this action.

The final amendments also result in a minor reduction in burden to licensees by eliminating written incident reports and allowing licensees to submit incident reports by telephone. This change is consistent with the Paperwork Reduction Act of 1995.

The final requirements also waive posting requirements in teletherapy rooms in hospitals to remove the unsettling effects that the signs may have on patients. There would be no decrease in safety because the safety precautions in 10 CFR Part 35 are considered adequate to protect individuals from inadvertent exposure to radiation, and this change may have a beneficial effect on patients.

In addition, these final amendments change the deep dose equivalent monitoring requirements for minors and pregnant women from one-tenth of the applicable limit or 0.05 rem (0.5 mSv) to 0.1 rem (1 mSv) for the following reasons:

(1) The value is consistent with the 100 mrem (1 mSv) training criterion in the recently revised 10 CFR 19.12 (60 FR 36038; July 13, 1995).

(2) The value is consistent with the 0.1 rem (1 mSv) dose limit for members of the public in 10 CFR 20.1301(a). There is little benefit to require monitoring of workers who are expected to receive less dose than is permitted for members of the public.

No cost is associated with this rule change, and there may be some reduction in burden. However, any reduction is likely to be small because many factors impact the decision as to whether personal dosimeters will be worn and it is impossible to assess the extent of this burden reduction.

This discussion constitutes the regulatory analysis for this final rule.

IX. Backfit Analysis

The NRC has determined that the backfit rules in §§ 50.109, 72.62, and 76.76 do not apply to this final rule and, therefore, that a backfit analysis is not required for this final rule because these amendments do not involve any provision that would impose backfits as defined in §§ 50.109(a)(1), 72.62(a), and 76.76(a).

Small Business Regulatory Enforcement Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a ''major rule'' and has verified this determination with the Office of Information and Regulatory Affairs, Office of Management and Budget.

List of Subjects

10 CFR Part 20

Byproduct material, Criminal penalties, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Special nuclear material, Source material, Waste treatment and disposal.

10 CFR Part 32

Byproduct material, Criminal penalties, Labeling, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 35

Byproduct material, Criminal penalties, Drugs, Health facilities, Health professions, Medical devices, Nuclear materials, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 36

Byproduct material, Criminal penalties, Nuclear materials, Oil and gas exploration—well logging, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Source material, Special nuclear material.

10 CFR Part 39

Byproduct material, Criminal penalties, Nuclear materials, Oil and gas exploration—well logging, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Source material, Special nuclear material.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR Parts 20, 32, 35, 36, and 39.

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

1. The authority citation for Part 20 continues to read as follows:

Authority: Secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 953, 955, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236, 2297f), secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

2. In § 20.1003, the definition of *Eye dose equivalent* is removed. The definition of *Lens dose equivalent (LDE)* is added in alphabetical order, and the definitions of *Declared pregnant woman, High radiation area, Individual monitoring devices,* and *Very high radiation area* are revised to read as follows:

§ 20.1003 Definitions.

* * * * *

Declared pregnant woman means a woman who has voluntarily informed the licensee, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

* * * * *

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

* * * * *

Individual monitoring devices (individual monitoring equipment) means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescence dosimeters (TLDs), pocket ionization chambers, and personal (''lapel'') air sampling devices.

* * * * *

Lens dose equivalent (LDE) applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm^2).

* * * * *

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

* * * * *

3. In § 20.1101, paragraph (b) is revised to read as follows:

§ 20.1101 Radiation protection programs.

* * * * *

(b) The licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

* * * * *

4. In § 20.1201, paragraphs (a)(2)(i) and (c) are revised to read as follows:

§ 20.1201 Occupational dose limits for adults.

(a) * * *

(2) * * *

(i) A lens dose equivalent of 15 rems (0.15 Sv), and

* * * * *

(c) The assigned deep-dose equivalent and shallow-dose equivalent must be for the part of the body receiving the highest exposure. The deep-dose equivalent, lens dose equivalent, and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

* * * * *

5. In § 20.1203, the introductory text is revised to read as follows:

§ 20.1203 Determination of external dose from airborne radioactive material.

Licensees shall, when determining the dose from airborne radioactive material, include the contribution to the deep-dose equivalent, lens dose equivalent, and shallow-dose equivalent from external exposure to the radioactive cloud (see appendix B to part 20, footnotes 1 and 2).

* * * * *

6. In § 20.1206, paragraph (a) is revised to read as follows:

§ 20.1206 Planned special exposures.

* * * * *

(a) The licensee authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the dose estimated to result from the planned special exposure are unavailable or impractical.

* * * * *

7. In § 20.1208, the section heading, paragraph (a), the introductory text of paragraph (c), and paragraphs (c)(2) and (d) are revised to read as follows:

§ 20.1208 Dose equivalent to an embryo/fetus.

(a) The licensee shall ensure that the dose equivalent to the embryo/fetus during the entire pregnancy, due to the occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). (For recordkeeping requirements, see § 20.2106.)

* * * * *

(c) The dose equivalent to the embryo/fetus is the sum of—

* * * * *

(2) The dose equivalent to the embryo/fetus resulting from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

(d) If the dose equivalent to the embryo/fetus is found to have exceeded 0.5 rem (5 mSv), or is within 0.05 rem (0.5 mSv) of this dose, by the time the woman declares the pregnancy to the licensee, the licensee shall be deemed to be in compliance with paragraph (a) of this section if the additional dose equivalent to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

8. In § 20.1501, paragraphs (a)(2)(i) and (a)(2)(iii) are revised to read as follows:

§ 20.1501 General.

(a) * * *

(2) * * *

(i) The magnitude and extent of radiation levels; and

* * * * *

(iii) The potential radiological hazards.

* * * * *

9. In § 20.1502, paragraph (a)(3) is redesignated as (a)(4) and new paragraphs (a)(3) and (b)(3) are added; and the introductory text of paragraph (a) and paragraphs (a)(2), (b)(1), and (b)(2) are revised to read as follows:

§ 20.1502 Conditions requiring individual monitoring of external and internal occupational dose.

* * * * *

(a) Each licensee shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by—

* * * * *

(2) Minors likely to receive, in 1 year, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv);

(3) Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv);[2] and

* * * * *

(b) * * *

(1) Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI(s) in table 1, Columns 1 and 2, of appendix B to §§ 20.1001–20.2402;

(2) Minors likely to receive, in 1 year, a committed effective dose equivalent in excess of 0.1 rem (1 mSv); and

(3) Declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 0.1 rem (1 mSv).

10. In § 20.1903, a new paragraph (d) is added to read as follows:

§ 20.1903 Exceptions to posting requirements.

* * * * *

(d) Rooms in hospitals or clinics that are used for teletherapy are exempt from the requirement to post caution signs under § 20.1902 if—

(1) Access to the room is controlled pursuant to 10 CFR 35.615; and

(2) Personnel in attendance take necessary precautions to prevent the inadvertent exposure of workers, other patients, and members of the public to radiation in excess of the limits established in this part.

11. In § 20.1906, the introductory text of paragraph (d) is revised to read as follows:

§ 20.1906 Procedures for receiving and opening packages.

* * * * *

(d) The licensee shall immediately notify the final delivery carrier and the NRC Operations Center (301–816–5100), by telephone, when—

* * * * *

12. In § 20.2101, paragraph (b) is redesignated as paragraph (c), paragraph (c) is redesignated as paragraph (d) and revised, and a new paragraph (b) is added to read as follows:

[2] All of the occupational doses in § 20.1201 continue to be applicable to the declared pregnant worker as long as the embryo/fetus dose limit is not exceeded.

§ 20.2101 General provisions.

* * * * *

(b) In the records required by this part, the licensee may record quantities in SI units in parentheses following each of the units specified in paragraph (a) of this section. However, all quantities must be recorded as stated in paragraph (a) of this section.

* * * * *

(d) The licensee shall make a clear distinction among the quantities entered on the records required by this part (e.g., total effective dose equivalent, shallow-dose equivalent, lens dose equivalent, deep-dose equivalent, committed effective dose equivalent).

13. In § 20.2106, paragraphs (a)(1), (a)(2), (a)(3), and (a)(4) are revised to read as follows:

§ 20.2106 Records of individual monitoring results.

(a) * * *

(1) The deep-dose equivalent to the whole body, lens dose equivalent, shallow-dose equivalent to the skin, and shallow-dose equivalent to the extremities;

(2) The estimated intake of radionuclides (see § 20.1202);

(3) The committed effective dose equivalent assigned to the intake of radionuclides;

(4) The specific information used to assess the committed effective dose equivalent pursuant to § 20.1204(a) and (c), and when required by § 20.1502;

* * * * *

14. In § 20.2202, paragraphs (a)(1)(ii), (b)(1)(ii), and (d)(2) are revised to read as follows:

§ 20.2202 Notification of incidents.

(a) * * *

(1) * * *

(ii) A lens dose equivalent of 75 rems (0.75 Sv) or more; or

(b) * * *

(1) * * *

(ii) A lens dose equivalent exceeding 15 rems (0.15 Sv); or

(d) * * *

(2) All other licensees shall make the reports required by paragraphs (a) and (b) of this section by telephone to the NRC Operations Center (301) 816–5100.

* * * * *

PART 32—SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

15. The authority citation for Part 32 continues to read as follows:

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

§ 32.54 [Amended]

16. In § 32.54, paragraph (a) is amended by revising the reference to ''§ 20.203(a)'' to read ''§ 20.1901.''

PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

17. The authority citation for Part 35 continues to read as follows:

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

18. In § 35.641, paragraphs (a)(2)(i) and (a)(2)(ii) are revised to read as follows:

§ 35.641 Radiation surveys for teletherapy facilities.

(a) * * *

(2) * * *

(i) Radiation dose rates in restricted areas are not likely to cause any occupationally exposed individual to receive a dose in excess of the limits specified in § 20.1201 of this chapter; and

(ii) Radiation dose rates in controlled or unrestricted areas are not likely to cause any individual member of the public to receive a dose in excess of the limits specified in § 20.1301 of this chapter.

* * * * *

19. In § 35.643, paragraphs (a) introductory text and (a)(1) are revised to read as follows:

§ 35.643 Modification of teletherapy unit or room before beginning a treatment program.

(a) If the survey required by § 35.641 indicates that any individual member of the public is likely to receive a dose in excess of the limits specified in § 20.1301 of this chapter, the licensee shall, before beginning the treatment program:

(1) Either equip the unit with stops or add additional radiation shielding to ensure compliance with § 20.1301 of this chapter.

* * * * *

PART 36—LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

20. The authority citation for Part 36 continues to read as follows:

Authority: Secs. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

21. In § 36.23, paragraph (g) is revised to read as follows:

§ 36.23 Access control.

* * * * *

(g) Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator must be posted as required by 10 CFR 20.1902. Radiation postings for panoramic irradiators must comply with the posting requirements of 10 CFR 20.1902, except that signs may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

* * * * *

PART 39—LICENSES AND RADIATION SAFETY REQUIREMENTS FOR WELL LOGGING

22. The authority citation for Part 39 continues to read as follows:

Authority: Secs. 53, 57, 62, 63, 65, 69, 81, 82, 161, 182, 183, 188, 68 Stat. 929, 930, 932, 933, 934, 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

23. In § 39.33, paragraph (a) is revised to read as follows:

§ 39.33 Radiation detection instruments.

(a) The licensee shall keep a calibrated and operable radiation survey instrument capable of detecting beta and gamma radiation at each field station and temporary jobsite to make the radiation surveys required by this part and by part 20 of this chapter. To satisfy this requirement, the radiation survey instrument must be capable of measuring 0.001 mSv (0.1 mrem) per hour through at least 0.5 mSv (50 mrem) per hour.

* * * * *

§ 39.71 [Amended]

24. In § 39.71, paragraph (b) is amended by revising the reference to ''§ 20.3'' to read ''§ 20.1003.''

Dated at Rockville, Maryland, this 9th day of July 1998.

For the Nuclear Regulatory Commission.

L. Joseph Callan,

Executive Director for Operations.

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