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DRAFT REGULATORY GUIDE

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PLANNED SPECIAL EXPOSURE

A. INTRODUCTION

This regulatory guide provides guidance on the conditions and prerequisites for permitting planned special exposure(s) (PSE(s)), as allowed by 10 CFR Part 20 including the associated specific monitoring and reporting requirements, and provides examples of acceptable means of satisfying these requirements.

In the revised 10CFR Part 20, "Standards for Protection Against Radiation," 10 CFR 20.1201(b) and 10 CFR 20.1206, provide the conditions and limits for planned special exposure of adult workers (i.e., radiation doses in addition to and accounted for separately from the doses received under the limits specified in 10 CFR 20.1201, "Occupational Dose Limits for Adults"). In addition, 10 CFR 20.2104(b) and 10 CFR 20.2104(c)(2) specify requirements for obtaining prior occupational dose information, and 10 CFR 20.2105, "Records of Planned Special Exposures," and 10 CFR 20.2106, "Records of Individual Monitoring Results," specify the requirements for exposure and monitoring records applicable to PSEs. The requirements for reporting PSEs appear in 10 CFR 20.2204.

The U.S. Nuclear Regulatory Commission (NRC) issues regulatory guides to describe to the public methods that the staff considers acceptable for use in implementing specific parts of the agency's regulations, to explain techniques that the staff uses in evaluating specific problems or postulated accidents, and to provide guidance to applicants. Regulatory guides are not substitutes for regulations and compliance with them is not required.

This regulatory guide contains information collection requirements covered by 10 CFR Part 20 that the Office of Management and Budget (OMB) approved under OMB control number 3150-0014. The NRC may neither conduct nor sponsor, and a person is not required to respond to, an information collection request or requirement unless the requesting document displays a currently valid OMB control number.

This regulatory guide is being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. It has not received final staff review or approval and does not represent an official NRC final staff position.

Public comments are being solicited on this draft guide (including any implementation schedule) and its associated regulatory analysis or value/impact statement. Comments should be accompanied by appropriate supporting data. Written comments may be submitted to the Rulemaking and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; submitted through the NRC's interactive rulemaking Web page at http://www.nrc.gov; or faxed to (301) 492-3446. Copies of comments received may be examined at the NRC's Public Document Room, 11555 Rockville Pike, Rockville, MD. Comments will be most helpful if received by March 11, 2010.

Electronic copies of this draft regulatory guide are available through the NRC's interactive rulemaking Web page (see above); the NRC's public Web site under Draft Regulatory Guides in the Regulatory Guides document collection of the NRC's Electronic Reading Room at http://www.nrc.gov/reading-rm/doc-collections/; and the NRC's Agencywide Documents Access and Management System (ADAMS) at http://www.nrc.gov/reading-rm/adams.html, under Accession No. ML091770345.

B. DISCUSSION

The regulations in 10 CFR 20.1206 restrict to those special situations that could result in a higher exposure than allowed by the normal limits of 10 CFR 20.1201 and that, if not provided for, could create a severe problem in the licensee's operations. Problems might include unscheduled facility shutdowns or high radiation levels that impede operations important to safety. Accordingly, a special set of limitations and reporting and recordkeeping requirements apply if licensees decide to use PSEs. Approval of PSEs for an adult worker must be in writing before the exposure occurs and, once it occurs, the exposure cannot be treated as a routine occupational exposure. Furthermore, minors are not allowed to participate in PSEs (see 10 CFR 20.1206(b)).

Efforts should be made to maintain the doses received during PSEs as low as reasonably achievable (ALARA). Methods for reducing the dose received by the individual authorized to perform the PSE should be considered while planning the activity. A more detailed discussion of reducing radiation doses appears in Regulatory Guide 8.8, "Information Relevant to Ensuring that Occupational Radiation Exposures at Nuclear Power Stations Will Be as Low as Is Reasonably Achievable," (Ref. 2).

In determining the amount of dose to assign to the PSE in advance of the exposures, licensees must be aware of the individual's current year exposure and lifetime PSE dose history to avoid unnecessary overexposure (see 10 CFR 20.2104, "Determination of Prior Occupational Dose").

C. REGULATORY POSITION

1. Use of Planned Special Exposures

a. The PSEs are to be used only under exceptional circumstances, not as a routine method of increasing dose limits applicable to routine exposures. However, licensees may consider the use of PSEs to permit workers who have critical skills and who are necessary for a particular job to receive an exposure in addition to the routine occupational exposure limit, provided the conditions in 10 CFR 20.1206 are met.

b. The rule does not require that participation in PSEs be voluntary on the part of the individual workers. However, licensees may establish a program of voluntary PSEs. Furthermore, individuals involved in a PSE must be informed prior to the PSE of the purpose, estimated doses, potential risks, and other conditions, as specified in 10 CFR 20.1206. In any case, licensees should consider the potential benefits of involving the worker in the planning and preparation for the PSE. The NRC believes that the health risk from these limited exposures is small and that the use of PSEs may be necessary for licensees to accomplish important tasks vital to continued safe operations. Regulatory Guide 8.29, "Instruction Concerning Risks from Occupational Radiation Exposure," (Ref. 3), discusses the issue of a worker accepting the risks associated with an assigned task.

c. Exposures in excess of the routine occupational dose limits received during accident or emergency situations that require immediate action to save human lives or to prevent the failure of equipment important to safety are not PSEs. However, all exposures in excess of the routine occupational dose limits received during accident and emergency situations must be determined and subtracted from the annual 50 mSv (5 rems) PSE limit and the 250 mSv (25 rems) allowed for lifetime PSEs (see 10 CFR 20.1201(b)). A PSE can be authorized if the conditions associated

2. Conditions for Use of Planned Special Exposures

The seven conditions listed in 10 CFR 20.1206 must be satisfied if a licensee authorizes an adult worker to receive a PSE. The list below summarizes these conditions.

(1) A PSE is reserved for an exceptional situation when alternatives are unavailable or impractical.

(2) The PSE is authorized in writing before the exposure occurs.

(3) Individuals involved are informed of the purpose, the estimated doses, and the associated potential risks, and are instructed in the measures to take to keep the dose ALARA.

(4) The licensee shall determine the doses from all previous PSEs and all doses in excess of the limits (including doses from accidents and emergencies) received during the lifetime of the individual.

(5) Dose from the PSE must be under the dose limit for 1 year and 5 times annual dose limits for a lifetime.

(6) Records shall be maintained of the details of the PSE and submitted to the NRC.

(7) The estimated dose from the PSE shall be recorded and the individuals who received the PSE should be informed of the dose within 30 days.

2.1 Exceptional Situation Exists

a. Licensees may authorize PSEs only for exceptional situations. The use of PSEs must be justified and well documented (see 10 CFR 20.2105). Licensees should not use PSEs as a routine method of increasing occupational exposure limits. The NRC staff will review the justification for the PSE when it examines the licensee's records of the PSE. To request an NRC review before initiating a PSE, the licensee may contact the appropriate regional office directly.

b. The following are examples of exceptional situations in which a PSE might be justified:

1. <u>The work is to be performed by one individual rather than several.</u> A source becomes disconnected during radiography. It may not be practical or feasible for the source to be recovered in two or three steps by different persons. Authorization for one person to receive up to 50 mSv (5 rems) total effective dose equivalent, in addition to his or her routine occupational exposure, may be reasonable for the recovery. The NRC regulations permit the licensee to use previously approved procedures in carrying out work under a PSE. For example, the licensee could have an approved generic procedure for source retrieval that, among other things, addresses all the administrative and recordkeeping requirements of 10 CFR 20.1206. Provided that the situation is exceptional and alternatives that might avoid higher exposures are unavailable or are impractical, an individual's exposure received during source retrieval may be considered a PSE. The licensee must meet all the conditions of 10 CFR 20.1206 and document the information required by 10 CFR 20.2105.

2. The use of dose-averting methods is not possible. Work must be performed on instrumentation in a high-radiation area where space is very limited and shielding or other dose-averting methods are not possible. It may be necessary to authorize a PSE to make the necessary repairs to the instrumentation.

3. The collective dose to personnel may be reduced. It may be more dose-effective to keep certain skilled workers on a particular job because they will be able to perform the job more rapidly than lesser skilled workers and thus reduce the overall dose to personnel. For example, if two persons can weld in a high-radiation area and collectively receive 120 mSv (12 rems) [60 mSv (6 rems) per person, 20 mSv (2 rems) under a PSE and 40 mSv (4 rems) of routine exposure)] while four less skilled workers would receive 160 mSv (16 rems) [40 mSv (4 rems)] per person of routine exposure], the collective dose would be reduced from 160 mSv to 120 mSv (16 rems to 12 rems) by using the two skilled workers. The PSEs are not intended to be used only as a routine collective dose reduction technique. However, reducing collective dose could contribute to the justification of a PSE.

2.2 Prior Written Authority Obtained

a. The licensee (and employer if the employer is not the licensee) must specifically authorize the PSE in writing before the exposure occurs (see 10 CFR 20.1206(b)). A contractor employer may authorize the use of PSEs by a licensee in advance to accommodate any urgent circumstances that may arise.

b. In planning for a PSE, the licensee is permitted to assign a portion of the dose due to routine exposure and the rest to the PSE. However, when the post exposure evaluation is made, the dose amount that the licensee planned to assign to a PSE should be recorded as a PSE. If the total dose received is less than the planned PSE, the actual dose received must be recorded as a PSE dose (see 10 CFR 20.2105(a)(6)). The intent of the regulation is that a PSE would be used infrequently. Once a licensee decides to authorize a PSE, all the unique limitations and reporting and recordkeeping requirements are to apply, even if the doses actually received fall within the dose limits for routine operations. For example, if a job planned with a PSE of 50 mSv (5 rems) and a routine dose of 20 mSv (2 rems) to an individual actually results in a dose of 40 mSv (4 rems), the entire 40 mSv (4 rems) dose must be recorded as a PSE dose (see 10 CFR 20.2105(a)(6)). If, before initiating a PSE, it is found that a PSE is not needed, and it is canceled, the resulting exposure can be recorded as routine.

c. The procedures for the radiation protection program should specify the management level of the person who may authorize a PSE. The responsible person should be at a sufficiently senior level to ensure worker protection and to judge the appropriateness of the PSE for the exceptional circumstances. This person would normally be the radiation safety officer, the radiation protection manager, or someone in the organization with equivalent qualifications.

2.3 Individual Informed and Instructed

a. Before authorizing a PSE, the licensee must ensure that the individuals involved are (1) informed of the purpose of the planned operation, (2) informed of the expected radiation levels, estimated doses, and associated risks or other conditions that may be involved in performing the task, and (3) instructed in measures to take to keep the dose ALARA, while considering other risks that may be present (see 10 CFR 20.1206(c)).

b. To ensure that the intent of the plan is realized, the workers who are to receive a PSE should be fully informed and aware of the circumstances under which the PSE was authorized. These workers should understand the importance of keeping their exposure ALARA. They should also understand the procedures and controls to be used in the particular PSE to keep their exposures ALARA. Licensees have an obligation to inform workers (before they receive a PSE) of the expected radiation levels, estimated doses, associated risks, or other significant conditions that might be involved in performing the task so that the individuals are aware of and understand the health and safety significance of the PSE. The authorization for the PSE should include this information.

2.4 Prior Doses Determined

a. According to 10 CFR 20.1206(d), before authorizing the PSE, the licensee must ensure that all previous PSEs and all doses in excess of the routine occupational limits in effect at the time of the exposures for the individual's lifetime have been determined from records for each individual who will participate in the PSE. The licensee must also determine the doses received during accidents and emergencies that exceed the routine occupational dose limits in effect at the time of the exposures (see 10 CFR 20.1206(d)) and must subtract those doses from the limits for PSEs (see 10 CFR 20.1201(b)). (Accident doses are doses resulting from an unexpected event involving exposure to radiation or radioactive material. Emergency doses are doses resulting from any immediate action taken in response to a situation or occurrence of a serious nature that develops suddenly and unexpectedly.)

b. If complete records (including the provisions of 10 CFR 20.2104) of the worker's current and previously accumulated occupational dose history, such as a completed NRC Form 4, are not available, the individual cannot be authorized to receive a PSE (see 10 CFR 20.2104(e)(2)). Regulatory Guide 8.7, "Instructions for Recording and Reporting Occupational Radiation Dose Data," (Ref. 4), provides guidance on records of occupational exposure.

2.5 Planned Special Exposures and Exposure Limits Determined

Under 10 CFR 20.1206, 20.1206(e)(1) and (2):

a. Individuals receiving PSEs can receive a maximum dose in 1 year of any or all of the following:

(1) 100 mSv (10 rems) total effective dose equivalent [50 mSv (5 rem) from routine operations and 50 mSv (5 rems) from PSEs]; or

(2) 1 Sv (100 rems) to any individual organ or tissue, including any deep-dose equivalent plus the committed dose equivalent for the organ or tissue [500 mSv (50 rems) from routine operations and 500 mSv (50 rems)]from PSEs; and

(3) 300 mSv (30 rems) dose equivalent to the eye [150 mSv (15 rems) from routine operations and 150 mSv (15 rems) from PSEs]; and

(4) 1 Sv (100 rems) to the skin or to any extremity [500 mSv (50rems) from routine operations and 500 mSv (50 rems) from PSEs].

b. Individuals can receive a lifetime dose from PSEs of any or all of the following:

(1) 250 mSv (25 rems) total effective dose equivalent; or 2.5 Sv (250 rems) to any individual organ or tissue, and

(2) 750 mSv (75 rems) to the eye, and

(3) 2.5 Sv (250 rems) to the skin or to any extremity.

2.6. Worker's Planned Special Exposure Dose Recorded and Worker Informed

a. The licensee must record its best estimate of the dose (dose of record) resulting from the PSE in each affected individual's record and inform the individual, in writing, of the dose within 30 days of the PSE (10 CFR 20.1206(g)). The 30-day time period for notifying the worker of the dose received is to allow sufficient time for the licensee to make its best estimate of internal and external exposures received as part of the PSE. The best estimate is understood to mean the dose of record as determined by accredited dosimetry, bioassay, air sampling, or other analyses, such as time and motion studies. If the intake of Class Y material (i.e., materials that remain in the body for time periods on the order of years) is being assessed, the licensee may delay the recording and reporting of the results of its assessments for periods of up to 7 months to allow for additional measurements necessary for the assessments (10 CFR 20.1204(d)). However, the internal dose reported within the 30 days may be identified as an initial best estimate pending completion of a final assessment, after which the actual dose assigned should be recorded and reported.

b. The dose from a PSE must be tracked separately from the routine occupational dose for the individual (see 10 CFR 20.1206(g)). Thus, a person may have an accumulated routine occupational dose of 30 mSv (3 rems) total effective dose equivalent for the year, receive a dose of 40 mSv (4 rems) total effective dose equivalent from a PSE, and still be able to receive up to 20 more mSv (2 rems) of routine occupational exposure for the year, even though the person has had a total dose of 70 mSv (7 rems) for the year. The dose from PSE is not to be considered in controlling the future occupational dose of the individual under 10 CFR 20.1201(a) but is to be included in evaluations required by 10 CFR 20.1206(d) and (e). The dose resulting from a PSE is to be included in the total for all PSEs for the individual, and it should be used in determining the dose balance remaining for future PSEs.

2.7 Records and Written Reports Maintained

a. The licensee must maintain records of the conduct of a PSE in accordance with 10 CFR 20.2105 and must submit a written report in accordance with 10 CFR 20.2204. In addition, 10 CFR 20.2106 requires that the records of doses received during PSEs be maintained for all individuals who participated in a PSE. These records should include all the information listed in 10 CFR 20.2105. The NRC has included its revised Form 5, along with guidance on its use, in Regulatory Guide 8.7.

b. A written report of the PSE, notifying the Administrator of the appropriate NRC Regional Office, is due within 30 days after the PSE has occurred. Any report filed under 10 CFR 20.2204 must contain the information in the records listed in 10 CFR 20.2105. The report allows the NRC to assess the actual frequency of PSEs and determine whether follow-up inspections may be warranted.

c. 10 CFR 2202(e) excludes immediate reporting of PSEs that are within dose limits, however additional reporting may be required if PSE limits are exceeded.

3. Internal and External Exposure Considerations

The sum of external and internal doses during the PSE should be maintained ALARA. Licensees should use the conditions specified in 10 CFR 20.1502, "Conditions Requiring Individual Monitoring of External and Internal Occupational Dose," to determine when monitoring is required.

4. Exposures of Minors and Declared Pregnant Women

The PSE provisions of 10 CFR 20.1206 do not apply to minors (see 10 CFR 20.1207, "Occupational Dose Limits for Minors") or to the embryo or fetus (10 CFR 20.1208, "Dose Equivalent to an Embryo/Fetus"). The rule permits a licensee to authorize only an adult worker to receive PSEs. In addition, the dose limits in 10 CFR 20.1208 would normally preclude a declared pregnant woman from receiving a PSE since the 10 CFR 20.1208 limits are more restrictive than the annual dose limits in 10 CFR 20.1201. In general, declared pregnant women should not be considered candidates for PSEs. However, the provisions of 10 CFR 20.1206 also apply to the dose limits for the lens of the eye, skin, and extremities. Therefore, in some situations, it may be possible for a declared pregnant woman to receive a PSE to her extremities (or skin or eyes) that would not exceed the dose limits to the embryo or fetus.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC's plans for using this draft regulatory guide. The NRC does not intend or approve any imposition or backfit in connection with its issuance.

The NRC has issued this draft guide to encourage public participation in its development. The NRC will consider all public comments received in development of the final guidance document. In some cases, applicants or licensees may propose an alternative or use a previously established acceptable alternative method for complying with specified portions of the NRC's regulations. Otherwise, the methods described in this guide will be used in evaluating compliance with the applicable regulations for license applications, license amendment applications, and amendment requests.

REGULATORY ANALYSIS

Statement of the Problem

The PSE is expected to be used on a very infrequent basis. Also, it is expected to be used when there is a very brief period of time available to perform needed planning for the associated event. Thus the guidance allows a licensee to perform a quick review and analysis of the requirements and methods acceptable to the NRC for managing the event. This revision is generated to align the guidance with the latest change to the regulations and to be current with other regulatory guidance.

Objective

The objective of this regulatory action is to update the guidance applicable to PSEs.

Alternative Approaches

The NRC staff considered the following alternative approaches:

Do not revise Regulatory Guide 8.35.
Revise Regulatory Guide 8.35.

Alternative 1: Do Not Revise Regulatory Guide 8.35

Under this alternative, the NRC would not revise the guidance, and the current guidance would be retained. If NRC does not take action, there would not be any changes in costs or benefit to the public, licensees or NRC. However, the "no-action" alternative would not address concerns with the current version of the regulatory guide. The NRC would continue to review each use of the PSE on a case-by-case basis without the benefit of guidance reflecting current understanding of the requirements. This alternative provides a baseline condition from which any other alternatives will be assessed.

Alternative 2: Revise Regulatory Guide 8.35

Under this alternative, the NRC would revise Regulatory Guide 8.35 taking into consideration the accumulated lessons learned since issue of revision 0.

One benefit of this action is that it would enhance the ability of the licensee to manage a PSE in accordance with the intent of the regulations.

The impact to the NRC would be the costs associated with preparing and issuing the regulatory guide revision. The impact to the public would be the voluntary costs associated with reviewing and providing comments to NRC during the public comment period. The value to NRC staff and its applicants would be the benefits associated with enhanced efficiency and effectiveness in using a common guidance document as the technical basis for records review and preparation and other interactions between the NRC and its regulated entities.

Conclusion

Based on this regulatory analysis, the NRC staff recommends revision of Regulatory Guide 8.35. The staff concludes that the proposed action will enhance the ability of the licensees to implement the associated regulations with a minimum of NRC staff interaction during the evolution of a PSE related event.

REFERENCES[1]

1. 10 CFR Part 20, "Standards for Protection Against Radiation," U.S. Nuclear Regulatory Commission, Washington, DC.

2. Regulatory Guide 8.8, "Information Relevant to Ensuring that Occupational Radiation Exposures at Nuclear Power Stations Will Be as Low as Is Reasonably Achievable," U.S. Nuclear Regulatory Commission, Washington, DC.

3. Regulatory Guide 8.29, "Instruction Concerning Risks from Occupational Radiation Exposure," U.S. Nuclear Regulatory Commission, Washington, DC.

4. Regulatory Guide 8.7, "Instructions for Recording and Reporting Occupational Radiation Dose Data," U.S. Nuclear Regulatory Commission, Washington, DC.

[1] Publicly available NRC published documents such as Regulations, Regulatory Guides, NUREGs, and Generic Letters listed herein are available electronically through the Electronic Reading room on the NRC's public Web site at: http://www.nrc.gov/reading-rm/doc-collections/. Copies are also available for inspection or copying for a fee from the NRC's Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD; the mailing address is USNRC PDR, Washington, DC 20555; telephone 301-415-4737 or (800) 397-4209; fax (301) 415-3548; and e-mail PDR.Resource@nrc.gov.