November 4, 1997 SECY-97-262

FOR: The Commissioners

FROM: L. Joseph Callan, Executive Director for Operations /s/

SUBJECT: RULEMAKING PLAN - MINOR REVISION OF 10 CFR PART 72.106 TO CONFORM DOSE LIMITS TO 10 CFR PART 20 METHODOLOGY

PURPOSE:

To inform the Commission of the staff's rulemaking plan to amend 10 CFR 72.106(b) to adopt the dose limits and the dose calculational methodology used in 10 CFR Part 20 and to make a minor change to 10 CFR 72.104(a) to match 40 CFR 191.03(a).

BACKGROUND:

Part 72 contains dose limits for exposure to radiation during normal operations and during design basis accidents at any Independent Spent Fuel Storage Installation (ISFSI) or Monitored Retrieval Storage (MRS) Installation. These dose limits are based on the methodology of International Commission on Radiological Protection Publication Number 2 (ICRP-2, 1959). When Part 20 was revised in 1991, the dose calculational methodology in ICRP Publication Number 26 (ICRP-26, 1977) was used. As a result, the dose limits in Part 72 are based on a different methodology than the dose limits in Part 20.

DISCUSSION:

Section 72.106(b) currently specifies dose limits for the controlled area of each ISFSI or MRS site. These dose limits specify that any individual on or beyond the nearest boundary of the controlled area not receive a dose in excess of 5 rem to the whole body or any organ from a design basis accident. The staff plans to revise this 0.05 Sv (5 rem) limit to conform with the current dose calculational methodology used in Part 20. Under this approach, applicants would be required to use the more limiting dose, either the total effective dose equivalent of 0.05 Sv (5 rem) or the sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue (other than the lens of the eye) of 0.5 Sv (50 rem). Separate limits would apply to the lens of the eye, an eye dose equivalent of 0.15 Sv (15 rem), and to the skin or to any extremity, 0.5 Sv (50 rem). These organ dose limits are consistent with the occupational organ dose limits for radiation workers set forth in 10 CFR 20.1201. Using the

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ICRP-26 methodology would not result in an additional burden to licensees, and the ICRP-26 methodology would provide increased flexibility to licensees. In addition, the committed dose approach would allow the use of risk-based weighting factors to calculate organ doses. This would make § 72.106(b) consistent with Part 20.

Section 72.104(a) currently specifies that the dose from an effluent release and direct radiation to any real individual who is beyond the controlled area of an ISFSI or MRS site must not exceed 25 mrem to the whole body, 75 mrem to the thyroid, and 25 mrem to any other organ. This rulemaking plan does not propose to revise § 72.104(a) to incorporate ICRP-26 methodology because doing so would render this regulation incompatible with the Environmental Protection Agency's regulation at 40 CFR 191.03(a) which is applicable to ISFSI and MRS licensees. However, 10 CFR 72.104(a) would be modified to make it more consistent with 40 CFR 191.03(a) by inserting the word *critical* before the word *organ*. This administrative modification would not have an impact on NRC licensees, since they are already required to comply with the EPA requirements and the provision in 10 CFR 72.104(a) exists primarily as a reminder of this requirement.

This action involves no resource adjustments to the NRC Five-Year Plan.

COORDINATION:

The Office of the General Counsel has no legal objection to the rulemaking plan. The Office of the Chief Financial Officer concurs that there will be no resource impacts. The Office of the Chief Information Officer concurs that there will be no information technology or management impacts. The staff does not intend to coordinate this rule plan with the Agreement States because the licensing of ISFSIs and MRS installations is reserved to NRC by 10 CFR 72.8 and 10 CFR 150.15(a)(7).

RECOMMENDATION:

Unless directed otherwise by the Commission, the attached Rulemaking Plan will be implemented 10 days from the date of this paper.

L. Joseph Callan
Executive Director
for Operations

Enclosures:
1. Plan for Rulemaking
2. Regulatory Agenda Entry

occupational organ dose limits for radiation workers set forth in 10 CFR 20.1201. Using the ICRP-26 methodology would not result in an additional burden to licensees, and the ICRP-26 methodology would provide increased flexibility to licensees. In addition, the committed dose approach would allow the use of risk-based weighting factors to calculate organ doses. This would make § 72.106(b) consistent with Part 20.

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RULEMAKING PLAN

MINOR REVISION OF 10 CFR 72.106 TO CONFORM DOSE LIMITS TO 10 CFR 20 METHODOLOGY

Regulatory Issue

Section 72.106(b) establishes dose limits for a design basis accident at an independent spent fuel storage installation (ISFSI) or a monitored retrieval storage (MRS) installation. The dose limits currently in § 72.106(b) are based on the dose calculational methodology contained in International Commission on Radiological Protection Publication Number 2 (ICRP-2, 1959). The ICRP-2 methodology was subsequently revised in ICRP Publication Number 26 (ICRP-26, 1977), and was incorporated into 10 CFR Part 20 when Part 20 was revised in 1991.

The calculational methodology in the revised Part 20 no longer quantifies dose in terms of whole body dose and individual organ dose. Instead, the dose is quantified as a risk equivalent dose. In this manner, the doses absorbed by the whole body and the individual organs can be summed to a single quantity relating to risk. The dose to the whole body from penetrating radiation external to the body is now known as the deep dose equivalent (DDE). The dose to an individual organ or tissue over 50 years (a working lifetime) is now known as the committed dose equivalent (CDE). The dose from an intake of radioactive material to multiple organs is now known as the committed effective dose equivalent (CEDE). It is calculated by summing the products of the weighting factors (w_T) for each irradiated organ or tissue and the committed dose equivalent to each organ or tissue (CEDE = $\sum w_T CDE$). The total effective dose equivalent (TEDE) is obtained by adding the DDE for external dose and the CEDE for internal dose.

The ICRP-26 methodology was not incorporated into Part 72 at the time Part 20 was revised. Part 72 contains two regulations setting dose limits: § 72.104, which sets dose limits during normal operations and anticipated occurrences; and § 72.106, which sets dose limits for design basis accidents. The purpose of this proposed rulemaking plan is to revise § 72.106 to incorporate the ICRP-26 methodology. This action would make § 72.106 consistent with Part 20 and with the performance criteria in Part 60 for category 1 design basis events at a geologic repository operations area, [see 10 CFR 60.111(a) and 60.132(c)]. This action would also provide Part 72 licensees flexibility when performing design basis accident analyses because they will now be able to use organ weighting factors to calculate the dose to the maximally exposed organ. In addition, Part 72 licensees would no longer need to comply with one calculational methodology for their radiation protection programs (i.e., the revised Part 20 methodology) and another methodology for their design basis accident analyses.

This rulemaking plan does not propose to revise § 72.104(a) to incorporate ICRP-26 methodology because doing so would render this regulation incompatible with the Environmental Protection Agency's regulation at 40 CFR 191.03(a) which is applicable to ISFSI and MRS licensees. However, 40 CFR 191.03(a) phrases the standard in terms of dose limits to the whole body and any *critical organ*; whereas, § 72.104(a) phrases the standard in terms of dose limits to the whole body and any *organ*. The staff proposes to make § 72.104(a) more consistent with 40 CFR 191.03(a) by inserting the word *critical* before the word *organ*. *Critical organs* are described in ICRP-2 as the blood-forming organs, the gonads, and the lenses of the eyes.

How the Regulatory Problem Will be Addressed By Rulemaking

At present, § 72.106(b) Controlled area of an ISFSI or MRS provides:

(b) Any individual located on or beyond the nearest boundary of the controlled area shall not receive a dose greater than 5 rem to the whole body or any organ from any design basis accident. The minimum distance from the spent fuel or high-level radioactive waste handling and storage facilities to the nearest boundary of the controlled area shall be at least 100 meters.

This 0.05 Sv (5 rem) limit to the whole body or any organ would be modified to conform with the Part 20 dose limits and dose calculational methodology; namely, the more limiting of the total effective dose equivalent of 0.05 Sv (5 rem), or the sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue (other than the lens of the eye) of 0.5 Sv (50 rem). The modification would also include a separate dose limit for the lens of the eye of 0.15 Sv (15 rem); and for the skin or any extremity, a shallow dose equivalent of 0.5 Sv (50 rem). The use of separate dose limits for the eye, skin, and extremities would conform with the dose calculational methodology used in Part 20 and would ensure that no observable effects (e.g., induction of cataracts in the lens of the eye) would occur as a result of any accidental radiation exposure.

By using the 0.05 Sv (5 rem) TEDE, the expected probability of a design basis accident of no greater than 1×10^{-3} per year, and the estimated lifetime risk of 0.05 fatal cancers per Sv of exposure[(1)] to individuals in the general population, the lifetime risk of fatal cancer from an assumed 0.05 Sv (5 rem) exposure resulting from any design basis accident may be calculated: 0.05 Sv exposure $\times$ 1×10^{-3} per year $\times$ 0.05 fatal cancers per Sv exposure = 0.0000025 (i.e., 2.5×10^{-6}) per individual exposed per year.

Rulemaking Options

1. No action. Section 72.106(b) will continue to be inconsistent with Part 20. Part 72 licensees would demonstrate compliance with the dose limits in Part 20 using the 1977 dose calculational methodology of ICRP-26 for their radiation protection programs as required by §§ 72.24(e) and 72.44(d). Furthermore, Part 72 licensees will continue to use the 1959 dose calculational methodology of ICRP-2 and dose limits contained in the old Part 20 in addressing radiation dose from a design basis accident as required in § 72.106(b). Thus, licensees will not be able to take advantage of the flexibility provided by the dose calculational methodology used in Part 20 when performing design basis accident analyses because they would not be able to use organ weighting factors to calculate the dose to the maximally exposed organ. Also, design basis accident analyses for ISFSIs and MRS installations would continue to employ a different dose calculational methodology than design basis accident analyses for a geologic repository operations area.

2. Amendment of Regulations. Prepare a rulemaking to amend the dose limiting design objective in § 72.106(b) to be 5 rem TEDE. This is consistent with the intent of the existing rule, and updates the dose calculational methodology to that which is used for

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(1) National Council on Radiation Protection and Measurements, "Risk Estimates for Radiation Protection," NCRP Report No. 115, December 31, 1993.

demonstration of compliance with Part 20. Updating the dose calculational methodology also would increase the organ dose limit, CDE, from 5 rem to 50 rem, allow for the use of risk-based weighting factors for each organ or tissue to determine the 50 year CEDE, and provide licensees with additional flexibility in conducting and submitting design basis accident analyses to demonstrate compliance with the requirements in § 72.106(b). The suggested rule language follows:

> § 72.106 Controlled area of an ISFSI or MRS.
>
> (b) Any individual located on or beyond the nearest boundary of the controlled area shall not receive the more limiting of a total effective dose equivalent of 0.05 Sv (5 rem), or the sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue (other than the lens of the eye) of 0.5 Sv (50 rem). The eye dose equivalent shall not exceed 0.15 Sv (15 rem), and the shallow dose equivalent to skin or to any extremity shall not exceed 0.5 Sv (50 rem). The minimum distance from the spent fuel or high-level radioactive waste handling and storage facilities to the nearest boundary of the controlled area shall be at least 100 meters.

In addition, § 72.104(a) would be modified to more specifically match the language used by EPA in 40 CFR 191.03(a). This section of the EPA regulations requires all spent fuel licensees to meet dose limits of 25 mrem whole body, 75 mrem to the thyroid, and 25 mrem to any other *critical* organ, and is based on ICRP-2 methodology. Until the EPA regulations are changed, the newer ICRP-26 methodology used in Part 20 would not be adopted for § 72.104(a).

Preferred Options

The preferred option is alternative 2, rulemaking to amend § 72.106(b). The staff recommends proceeding with rulemaking to amend the dose limit for design basis accidents to be consistent with the dose calculational methodology in Part 20. In addition to the increased flexibility provided to licensees, this action would further the goal of conforming appropriate sections of Part 72 with the 1991 revision to Part 20. The staff also recommends that § 72.104(a) be modified to match the requirements in 40 CFR 191.03(a)

Office of General Counsel Legal Analysis

The proposed rulemaking revisions would conform the calculational methodology used in Part 72 design basis accident dose calculations to that used in 10 CFR Part 20. This revision is consistent with more current ICRP guidance. In addition, another minor correction will conform a section of Part 72 to the exact language of the EPA regulation after which it was patterned. OGC has not identified any basis for a legal objection to the rulemaking plan. The rule does not constitute a backfit under 10 CFR § 72.62, because it does not require a change to existing structures, systems, components, procedures, or organization. This is because the rule will not result in a more stringent outcome than the existing rule, and therefore current licensees who are in compliance with the existing rule will not be required to make any changes. New applicants and license renewal applications will be able to take advantage of some additional flexibility in the dose calculations that is afforded by the rule. No environmental assessment will be prepared for this rule which is corrective, or of a minor or non-policy nature consistent with the categorical exclusion in 10 CFR § 51.21(c)(2). There are no new information collection requirements in this proposed rule, therefore there are no issues involving the Paperwork Reduction Act of 1995. The final rule must be evaluated for compliance with the Small Business Regulatory Enforcement Act of 1996.

Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 72.62, does not apply to this rulemaking plan. A backfit analysis is not required, because these amendments do not involve any provisions that would impose backfits as defined in 10 CFR 72.62(a).

Current licensees would not need to take any action, because design basis accident analyses which are currently in place would still satisfy the rule. New license applicants or license renewal applicants would use the rule, which would allow some additional flexibility in dose calculations.

Agreement State Implementation Issues

Agreement States are not authorized to issue licenses under Part 72 at this time.

Major Rule

This is a minor rulemaking that would simply conform the dose limits and the dose calculational methodology used in § 72.106(b) to that used in Part 20 and conform § 72.104(a) to the exact terminology of 40 CFR 191.03(a).

Supporting Documents Needed

No new supporting documents would need to be developed by NRC. No environmental assessment or environmental impact statement would be required, as these amendments fall within the categorical exemption contained in § 51.22(c)(2), for amendments which are corrective or of minor or non-policy nature and do not substantially modify existing regulations.

Issuance by Executive Director for Operations or Commission

This rulemaking would not constitute any major policy change; rather, it would modify the dose limits in § 72.106(b) to be consistent with the dose limits and the dose calculational methodology in Part 20 and would modify § 72.104(a) to match the requirements in 40 CFR 191.03(a). For this reason, it falls within the authority delegated to the EDO to issue this rule in accordance with paragraph 0213 of Management Directive 9.17.

Resources Needed to Complete Rulemaking

The estimated resources to complete this rulemaking would be about 0.2 staff years. Approximately 70 percent of this effort would come from RES and about 30 percent divided among SFPO and OGC. While this estimate assumes no transfer of resources to the program office, the total effort would be the same if rulemaking were transferred to NMSS.

No contractor support funding is anticipated. No additional resources are anticipated to implement the rule. A copy of the rulemaking concurrence package will be forwarded to the Office of the Chief Financial Officer for coordination of resource issues per EDO Memorandum of June 14, 1991.

Staff Level Working Group

Mary L. Thomas, RES
Stacy L. Rosenberg, NMSS
F. I. Young, NMSS
Kathryn L. Winsberg, OGC
E. Neil Jensen, OGC

Concurring Official

Malcolm R. Knapp, RES
Carl J. Paperiello, NMSS
Stuart A. Treby, OGC

Management Steering Group

No steering group will be used on this rulemaking. The working group is identified above.

Public Participation

This rulemaking is a minor revision to conform to existing policy which does not warrant an enhanced public participation.

Schedule

Proposed Rule Published	3 months after EDO approval of Rulemaking Plan
Final Rule Published	6 months after proposed rule published