

RULEMAKING ISSUE (Affirmation)

January 30, 2002

SECY-02-0021

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations /RA/

SUBJECT: FINAL RULE ON REVISION OF THE SKIN DOSE LIMIT, 10 CFR PART 20

PURPOSE:

To request Commission approval to publish a final rule in the Federal Register on a revision of the dose limit for the skin of the whole body and the extremities.

BACKGROUND:

In October 1998, the staff submitted a rulemaking plan (SECY-98-245) titled "Protection Against Discrete Radioactive Particle (DRP) Exposures (10 CFR Part 20)." The staff proposed establishing a constraint of 300 rad per 1 cm² as a program design guideline or action level to control doses from DRPs on or near the skin. The planned rule included a 1000 rem (10 Sv) limit that was intended to prevent an excessive number of high DRP doses. In the Staff Requirements Memorandum (SRM) SECY-98-245, dated December 23, 1998, the Commission directed the staff to proceed with the constraint but to establish the limit at 500 rem (5 Sv) to be consistent with draft recommendations from the National Council on Radiation Protection and Measurements (NCRP). Information from the nuclear power industry and NRC contractors received by the staff subsequent to public release of this rulemaking plan convinced the staff that, although the proposed constraint would accomplish the objective of controlling DRP doses to workers, the 500 rem (5 Sv) dose limit for DRPs would not achieve the objective of reducing worker whole-body dose associated with frequent monitoring for DRP contamination. In January 2000, the staff sent a memorandum to the Commission (COMSECY-00-0009), that recommended establishing a single, unified skin dose limit that would apply to any shallow-dose equivalent (SDE) to the skin regardless of the source or the geometry of the irradiation. The

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limit would be 50 rem (0.5 Sv) averaged over 10 square centimeters, which had been recommended for DRPs by the NCRP in Report No. 130, "Biological Effects and Exposure Limits for 'Hot Particles.'" In an SRM (Attachment 1), "Rulemaking on Discrete Radioactive Particle Dose Constraint," dated March 16, 2000, the Commission approved the staff recommendation and directed the staff to contract with the NCRP to provide technical justification for this regulatory action.

NCRP Statement No. 9, "Extension of the Skin Exposure Limit for Hot Particles to Other Sources of Skin Irradiation," was released in March 2001. In this statement, the NCRP recommended that the absorbed radiation dose to skin at a depth of 70 μm (7 mg/cm²) from any source of irradiation be limited to 0.5 Gy (50 rads) averaged over the most highly exposed 10 square centimeters of skin. The staff developed a proposed rule that would incorporate the NCRP recommendations. The Commission approved publication of the proposed rule for public comment. The rule was published in the Federal Register on July 12, 2001 (66FR36502). Nine letters of public comment were received, all supporting the proposed action, as discussed in the attached Federal Register notice of final rulemaking in the section entitled "Analysis of Public Comments and Staff Response" (Attachment 2). The attached Federal Register notice of final rulemaking would incorporate the NCRP recommendation in 10 CFR Part 20.

DISCUSSION:

With the installation at nuclear power plants in the mid and late 1980s of very sensitive portal monitors, it became apparent that some plants had large numbers of very small, highly radioactive particles, DRPs, that occasionally adhered to the skin and clothing of workers. Because of the nature of the principal radiation involved (beta particles), the extremely localized effects, and the lower risk of biological injury compared to nonlocalized effects, the NRC issued Information Notice (IN) No. 90-48, "Enforcement Policy for Hot Particle Exposures" (55 FR 31113; July 31, 1990). The IN addressed reporting and mitigation if a DRP dose exceeded the existing 50 rem over 1 cm² limit.

The small-area, non-uniform skin dose problem is not confined to DRPs at nuclear power plants, but is also to be found at some materials facilities, such as irradiator source and radiopharmaceutical manufacturers. In the latter case, the issue is point or very small area skin contaminations by high concentration liquids that from a dosimetric and biological point of view produce a skin dose distribution for which the current limit is also excessively conservative.

The current skin dose limit found at § 20.1201(a)(2)(ii) is "a shallow-dose equivalent of 50 rems (0.5 Sv) to the skin or to any extremity." SDE is currently defined in § 20.1003 as external exposure of the skin or an extremity taken as the dose equivalent at a tissue depth of 0.007 centimeters averaged over an area of 1 square centimeter. Thus, the dose limit is, in effect, 50 rem averaged over 1 square centimeter. Research results from studies performed at Brookhaven National Laboratory (BNL) and numerous other published reports made it clear that this limit was far too conservative for DRP and small area exposures and resulted in assigned doses that overstated the risk from such doses.

In the case of DRPs, power plant licensee efforts to avoid reaching the reporting threshold for doses of 50 rem to 1 square centimeter of skin result in frequent monitoring of workers for DRP

contamination. This results in workers receiving additional whole-body dose and its associated increased stochastic risk. The deterministic health effects, such as transient erythema, that might occur from a DRP exposure at the level of the current dose limit are considered by the NCRP as small compared to the increased external dose and stochastic risk from frequent monitoring.

In the case of small-area contaminations, doses at or near the current limit are considered as imposing little health risk to workers; visible but small and transient erythemas might occur. These overexposures can result in licensee citations and the possibility that a worker might not be permitted to work in a radiation area for the balance of the year. The efforts expended by reactor, and in some cases, materials licensees to avoid exceeding the current limit result in the use of multiple layers of protective clothing and other engineering controls that expose workers to nonradiological hazards, such as heat stress, and subsequent health and injury consequences now considered to be far greater than those associated with the skin doses being avoided.

A skin dose limit of 50 rem averaged over the most highly exposed 10 square centimeters constitutes a risk-informed solution to the DRP and small-area contamination cases discussed above. Licensees, in determining the skin dose, will be required to average a larger dose (up to 500 rem) to a small area, over a 10-square-centimeter area. This averaging of the dose will lead to recorded exposures that more appropriately reflect the risks associated with SDE to small areas of the skin. The higher dose limit will permit licensees to reduce monitoring of workers for DRP contamination and will permit reduced use of protective equipment to prevent small-area contaminations. This rule, in effect, provides a risk trade-off, that is, acceptance of an increased frequency of minor skin effects, such as transient erythema, in exchange for a reduction in whole-body exposure and avoidance of disrupting a worker's employment due to a low-risk skin exposure.

The averaging area of 10 square centimeters recommended by the NCRP covers both the case when a DRP is on the skin or a very small area of skin is contaminated, and the case when a DRP is on clothing and moving about. Experience has shown that such particles on clothing will expose an area on the order of 10 square centimeters or more. In the former case, averaging the very localized dose over 10 square centimeters results in an assigned dose value that more appropriately reflects the risk associated with a small area exposure. In the latter case, averaging a relatively uniform dose to the entire 10 square centimeters, results in a dose limit that is equivalent to the current 50 rem over 1 square centimeter. Thus, the effective limit decreases as the exposed skin area increases to 10 square centimeters, consistent with the expectation that the risk of an effect increases with increasing area of skin exposed to a given dose level.

As discussed in the Federal Register notice (Attachment 2), and the regulatory analysis (Attachment 3) for this final rule, the staff believes that revision of the skin dose limit, as recommended by the NCRP, is risk-informed, reduces unnecessary regulatory burden, and provides a substantial increase in worker safety. As discussed in Section XI. Backfit Analysis, of the Federal Register notice, this rule is considered to be a redefinition of the level of adequate protection. All of the public comments received on the proposed rule were supportive.

RESOURCES:

The resources required to finalize, publish, issue, and implement the final rulemaking include a total of 0.7 FTE for all offices in FY 2002. In addition, approximately \$10K may be needed for technical assistance in FY 2002, which is available in an existing contract supporting this effort.

COORDINATION:

The Office of the General Counsel has no legal objection to this paper. The Chief Financial Officer has reviewed this Commission paper for resource implications and has no objections. The Advisory Committee on Reactor Safeguards (ACRS) considered this final rule at its 488th meeting and decided not to review it. The ACRS stated that it had no objection to issuing the final rule for industry use. The CRGR reviewed the rule in Meeting No. 366 on December 18, 2001. Minutes of the meeting stated that the committee believes this rule change does not impose a backfit and should be approved.

RECOMMENDATION:

That the Commission:

1. Approve the notice of final rulemaking for publication (Attachment 2).
2. Certify that this rule will not have a negative economic impact on a substantial number of small entities in order to satisfy requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b)2.

Note:

- a. The rulemaking will be published in the Federal Register.
- b. This notice of final rulemaking includes a section titled IV. Enforcement that withdraws the Commission policy statement (55 FR 31113; July 31, 1990) entitled "Hot Particle Enforcement Policy," that was also provided as Information Notice No. 99-48.
- c. A final regulatory analysis and the environmental assessment will be available in the Public Document Room (Attachments 3 and 4).
- d. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification regarding economic impact on small entities and the basis for it, as required by the Regulatory Flexibility Act.
- e. Copies of the Federal Register notice of final rulemaking will be distributed to all affected Commission licensees and to commenters on the proposed rule. The notice will be sent to other interested parties upon request.
- f. A press release will be issued.
- g. The appropriate congressional committees will be informed.
- h. The NRC has determined that this action is not a major rule under the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) and has

confirmed this determination with OMB. This determination will be reflected in correspondence to the President of the Senate, the Speaker of the House, and the General Counsel of the General Accounting Office.

/RA/

William D. Travers
Executive Director
for Operations

Attachments:

1. Staff Requirements - COMSECY-00-0009, March 16, 2000
2. Federal Register Notice
3. Regulatory Analysis
4. Environmental Assessment

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ADAMS Package Accession Number: ML020090038
 Commission Paper Accession Number: ML020070327
 Attachment 1: ML012140168
 Attachment 2: ML020070546
 Attachment 3: ML020080096
 Attachment 4: ML020080136

*See previous concurrence

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