

**RULEMAKING ISSUE**  
(Notation Vote)

May 30, 2001

SECY-01-0096

FOR: The Commissioners

FROM: William D. Travers  
Executive Director for Operations

SUBJECT: PROPOSED RULE ON REVISION OF THE SKIN DOSE LIMIT

PURPOSE:

To request Commission approval to publish a proposed rule in the Federal Register on a revision of the dose limit on 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 cm<sup>2</sup> 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, December 23, 1998, the Commission directed the staff to proceed with the constraint but to establish the limit at 500 rem 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 dose limit for DRPs would not achieve the intended objective of reducing worker whole-body dose associated with frequent monitoring for DRP contamination.

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## The Commissioners

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 limit would be 50 rem (0.5 Sv) averaged over 10 square centimeters, that 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 evaluate the use of the DRP limit as an acceptable limit for all skin doses.

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  $\mu\text{m}$  (7 mg/cm<sup>2</sup>) from any source of irradiation be limited to 0.5 Gy (50 rads) averaged over the most highly exposed 10 cm<sup>2</sup> of skin. The attached Federal Register notice of proposed 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 the existing skin dose limit was considered by the NCRP to be overly conservative for the highly localized dose distribution resulting from DRPs on the skin, the NRC issued Information Notice No. 90-48, "Enforcement Policy for Hot Particle Exposures" (55 FR 31113; July 1990). The IN addressed reporting and mitigation if a DRP dose exceeded the existing 50 rem over 1 cm<sup>2</sup> 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 later 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 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.

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In the case of DRPs, power plant licensee efforts to avoid reporting doses of 50 rem to 1 square centimeter of skin result in frequent monitoring of workers for DRP contamination at the cost of unproductive 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 considered to be far greater than those associated with the skin doses being avoided.

The proposed 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, would be permitted to average a larger dose (up to 500 rem) to 1 square centimeter, over a 10-square-centimeter area. This averaging of the dose would lead to recorded exposures that more appropriately reflect the risks associated with SDE to small areas of the skin. The higher dose limit would permit licensees to reduce monitoring of workers for DRP contamination and would permit reduced use of protective equipment to prevent small-area contaminations. This rule, in effect, provides a risk trade-off, that is, to accept an increased frequency of minor skin effects such as transient erythema, for a reduction in whole-body exposure and an avoidance of disrupting a workers employment because of a low risk skin exposure.

The averaging area of 10 cm<sup>2</sup>, recommended by the NCRP would permit treating 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 cm<sup>2</sup> or more. In the former case, averaging the very localized dose over 10 cm<sup>2</sup> results in an assigned dose value that more appropriately reflects the risk associated with a small area exposure. In the latter case, averaging relatively uniform dose to the entire 10 cm<sup>2</sup>, results in a dose limit that is equivalent to the current 50 rem over 1 cm<sup>2</sup>. Thus the effective limit decreases as the exposed skin area increases to 10 cm<sup>2</sup>, consistent with the belief 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 proposed rule, the staff believes that revision of the skin dose limit, as recommended by the NCRP, is risk informed, will reduce unnecessary regulatory burden, and will provide a substantial increase in worker safety.

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## RESOURCES

The resources required to finalize, publish, issue and implement the proposed rulemaking include a total of 1.0 FTE for all offices in FY 2001 and approximately \$100K dollars in contract support combined for FY 2001 and FY 2002. The estimated contract dollars to be spent primarily in FY 2001 are budgeted. An additional, small funding increment (\$25K) may be necessary in FY 2002 for assistance in resolving public comment. Resources would be reprogrammed in accordance with the office of Nuclear Reactor Regulation's PBPM process if needed. We estimate that completion of the final rule including resolution of public comment will require a total of 0.7 FTE in FY 2001 and 2002, which is included in the budget for these years.

## 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 Committee To Review Generic Requirements (CRGR) has agreed to delay CRGR review of the proposed rule until public comments have been resolved and the final rule is prepared.

## RECOMMENDATION:

That the Commission:

1. Approve the notice of proposed rulemaking for publication (Attachment 2).
2. Certify that this rule, if promulgated, 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:

1. The rulemaking will be published in the Federal Register with a 75-day public comment period.
2. A draft regulatory analysis will be available in the Public Document Room (Attachment 3).
3. 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.
4. Copies of the Federal Register notice of proposed rulemaking will be distributed to all affected Commission licensees. The notice will be sent to other interested parties upon request.

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5. A press release will be issued.
6. The appropriate congressional committees will be informed.

***/RA by Carl J. Paperiello Acting for/***

William D. Travers  
Executive Director  
for Operations

Attachments:

1. SRM (COMSECY-00-0009) dated 03/16/00
2. Federal Register Notice
3. Regulatory Analysis
4. Environmental Assessment

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5. A press release will be issued.
6. The appropriate congressional committees will be informed.

**/RA by Carl J. Paperiello Acting for/**

William D. Travers  
Executive Director  
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**Package AN: ML011440059**  
**SRM dtd 03/16/00: ML003693145**  
**SECY Paper: ML011440161**  
**Federal Register Notice: ML011440208**  
**Reg. Analysis: ML011440300**  
**Envir. Assessment: ML011440282**

Attachments:

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\*See previous concurrence

DOCUMENT NAME:O:\NRR\DRIP\PERB\RGE\BRS\ROECKLE\PROPOSED SKIN DOSE LIMIT\COMMISSION PAPER.WPD

<b>OFC</b>	*RGEB:DRIP	*Tech. Ed.	*RGEB:DRIP	E	*RGEB:DRIP	*D:PMAS
<b>NAME</b>	ARoecklein:ayw	BCalure	MMalloy		WBeckner	KOliver for JSilber
<b>DATE</b>	03/06/01	03/06/01	04/09/01		04/09/01	05/17/01
<b>OFC</b>	*OCIO	*CFO	*D:DIPM		*D:DRIP	ADRIP
<b>NAME</b>	BShelton	KFitch for JFunches	BBoger		DMatthews	RBorchardt
<b>DATE</b>	04/01/01	05/17/01	04/28/01		04/18/01	/ /01
<b>OFC</b>	*D:OE	*D:NMSS	*OGC		*ADM	*D:STP
<b>NAME</b>	FCongel	MVirgilio	STreby for JGray		MLesar	PLohaus
<b>DATE</b>	05/07/01	05/18/01	05/24/01		04/25/01	05/03/01
<b>OFC</b>	D:NRR	OEDO				
<b>NAME</b>	SCollins	WTravers/CJP for				
<b>DATE</b>	5/25/01	5/30/01				

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