UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

OFFICE OF THE
SECRETARY

June 22, 2001

COMMISSION VOTING RECORD

DECISION ITEM: SECY-01-0096

TITLE: PROPOSED RULE ON REVISION OF THE SKIN DOSE LIMIT

The Commission (with all Commissioners agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of June 22, 2001.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

A. L. Bates

Annette L. Vietti-Cook
Secretary of the Commission

Attachments:
1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
EDO
PDR

VOTING SUMMARY - SECY-01-0096

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. MESERVE	X				X	6/14/01
COMR. DICUS	X				X	6/21/01
COMR. DIAZ	X					6/18/01
COMR. McGAFFIGAN	X				X	6/15/01
COMR. MERRIFIELD	X				X	6/18/01

COMMENT RESOLUTION

In their vote sheets, all Commissioners approved the staff's recommendation and some provided additional comments. Subsequently, the comments of the Commission were incorporated into the guidance to staff as reflected in the SRM issued on June 22, 2001.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook
Secretary of the Commission

FROM: CHAIRMAN MESERVE

SUBJECT: SECY-01-0096 - PROPOSED RULE ON REVISION OF THE SKIN DOSE LIMIT

Approved X subject to edits **Disapproved** _____ **Abstain** _____

Not Participating _____ **Request Discussion** _____

COMMENTS:

See attached edits of the *Federal Register* notice.

SIGNATURE

June 14, 2001

DATE

Entered on "AS" Yes X **No** ____

The existing Part 20 skin dose limit of 50 rem (0.5 Sv) averaged over 1 cm^2 is intended to apply to a relatively uniform dose to a larger area of skin than that usually exposed by DRPs and was intended to prevent deterministic damage to the skin. Because this limit was considered by the NCRP to be overly conservative for DRPs on or very near the skin, the NRC announced an interim enforcement discretion policy in Information Notice (IN) 90-48, "Enforcement Policy for Hot Particle Exposures" (55 FR 31113; July 1990), that addressed reporting and mitigation if a DRP dose exceeded the existing 50 rem over 1 cm^2 limit, and enforcement action for overexposures would be taken if the DRP beta emission exceeded 75 μCi-hrs (300-500 rads). To avoid DRP doses greater than 50 rem (0.5 Sv) and the resulting reporting requirement, licensees monitor workers frequently during the work shift for DRP contamination, ~~thus incurring~~ additional external dose to the workers and to the radiation protection staff who perform the monitoring.

In 1988, the NRC contracted with Brookhaven National Laboratory (BNL) to study the health effects of DRPs on the skin and initiated a contract with the NCRP to develop guidance on controlling DRP doses. In NUREG/CR-6531, "Effects of Radioactive Hot Particles on Pig Skin," June 1997, BNL provided data on the probability of producing breaks in the skin from irradiation of the skin by DRPs in contact with or near the skin and demonstrated that these effects would not pose any serious health problems to workers. On the basis of the BNL data, and many other reported studies and similar experiments performed by the Electric Power Research Institute (EPRI) and reported on in EPRI TR-104781, "Skin Injuries From Discrete Radioactive Particles," (1994) the NCRP recommended in Report No. 130, "Biological Effects and Exposure Limits for "Hot-Particles," (1999) a dose-limiting guideline for DRPs of 50 rads (0.5 Gy) averaged over the most highly exposed 10 square centimeters. The BNL work only examined the nonuniform, highly concentrated dose to 1 square centimeter from DRPs in

In the former case, averaging the very localized dose over 10 cm^2 results in a 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^2, results in an dose limit that is equivalent to the current 50 rem over 1 cm^2. Thus the limit decreases as the exposed skin area increases to 10 cm^2, consistent with the expectation that the risk of an effect increases with increasing area of skin exposed to a given dose level. This averaging area is also consistent with the skin dose limiting system adopted by the Department of Energy in 10 CFR Part 835.

In an effort to find the least burdensome regulatory requirement for controlling DRP doses, as well as other skin doses, while maintaining an adequate level of worker protection, the NRC staff requested the NCRP to consider the advisability of applying its proposed limit for DRP exposures to all skin dose geometries. In March 2001, the NCRP published Statement No. 9, "Extension of the Skin Exposure Limit for Hot Particles to Other Sources of Skin Irradiation." The statement can be found on the NCRP website at www.ncrp.com/statemnt.html. In this statement, the NCRP recommended that the absorbed radiation dose to skin at a depth of 70 μm (7 mg/cm^2) from any source of irradiation be limited to 50 rads (0.5 Gy) averaged over the most highly exposed 10 cm^2 of skin.

Dr. John Baum,Ph.D., an NRC consultant, reviewed the health effects implications of the NCRP recommendation. Dr. Baum wrote a technical paper that ~~will be~~ was published in the June 2001 issue (pgs. 537-543) of the peer-reviewed journal, Health Physics, entitled "Analysis of Potential Radiobiological Effects Related to a Unified Skin Dose Limit." In this paper the probabilities and severity of both stochastic and deterministic risks were estimated by Dr. Baum for a wide range of exposure scenarios based on the research done at Brookhaven National Laboratory, at other research facilities, and on additional information found in NCRP Reports

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER DICUS

SUBJECT: **SECY-01-0096 - PROPOSED RULE ON REVISION OF THE SKIN DOSE LIMIT**

Approved __x__ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

I also concur with the Chairman's edits on the subject Federal Register notice and recommend several edits as attached.

Greta Joy Dicus
SIGNATURE

June 21, 2001
DATE

Entered on "STARS" Yes __x__ No ____

1 JUN 01 9:32

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gjd 6-21-01

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 Shallow-dose equivalent (H_s) is revised to read as follows:

§ 20.1003 Definitions

* * * * *

Shallow-dose equivalent (H_s), which applies to the external exposure of the skin or an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7mg/cm^2).

* * * * *

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER DIAZ

SUBJECT: **SECY-01-0096 - PROPOSED RULE ON REVISION OF THE SKIN DOSE LIMIT**

Approved X Disapproved ____ Abstain ____

Not Participating ____

COMMENTS:

SIGNATURE

6.18.01

DATE

Entered on "STARS" Yes ✓ No ____

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MCGAFFIGAN

SUBJECT: **SECY-01-0096 - PROPOSED RULE ON REVISION OF THE SKIN DOSE LIMIT**

Approved w/comment X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

I concur in the Chairman's edits to the Federal Register Notice, and recommend additional edits as attached.

Edward McGaffigan

SIGNATURE

June 15, 2001

DATE

Entered on "STARS" Yes X No ____

SUPPLEMENTARY INFORMATION:

I. Background

With the installation in the mid and late 1980s of very sensitive portal monitors, many nuclear power plants detected contamination of individuals and their clothing by small, usually microscopic, highly radioactive beta or beta-gamma emitting particles having relatively high specific activity. These particles, known as "discrete radioactive particles" (DRPs) and sometimes "hot particles," most commonly contain ^{60}Co or fission products. DRPs apparently become electrically charged as a result of radioactive decay and, therefore, tend to be fairly mobile. DRP movement in the workplace is unpredictable and thus worker contamination is difficult to control. A unique aspect of DRPs on or very near the skin is that very small amounts of tissue can be exposed to large, highly nonuniform doses. These intense localized irradiations may produce deterministic effects, such as reddening of the skin, transient breaks in the skin or necrosis of small areas of the skin.

In the late 1990s, reports of DRP exposures by a materials licensee were made when workers were exposed to DRPs while manufacturing radiographic sources. In addition to the DRP concern, several events have occurred involving very small areas (< 1. 0 square centimeters) of skin contamination, primarily in the handling of solutions of highly concentrated radiopharmaceuticals. These contamination events produce relatively large doses to very small areas of skin, resulting in an insignificant health detriment. Under existing provisions in NRC regulations, several of these contamination events have resulted in overexposures, as well as enforcement actions, with the result that workers could not be assigned work in radiation areas for the balance of the year. The consequences of these overexposures were not commensurate with the actual health detriment.

The principal stochastic risk associated with irradiation of the skin is non-melanoma skin cancer, that is, basal cell and squamous cell skin cancers. The risk of skin cancer following irradiation of the skin by DRPs, or from very small areas of contamination, is not comparable to irradiation of extended areas of the skin because of the very small number of cells involved and the greater potential for high local beta particle dose to kill cells rather than cause transformation to a precancerous stage. The Congressionally-chartered National Council on Radiation Protection and Measurements (NCRP) in Report No. 106, Limit for Exposure to "Hot Particles" on the Skin (1989), conservatively estimated the risk of skin cancer following a DRP dose of 50 rem (0.5 Sv) to an area of 2 mm^2 to be 7×10^{-7} Gy^{-1} (7×10^{-9} rad^{-1}), and the risk of skin cancer mortality to be about 1×10^{-9} Gy^{-1} (1×10^{-11} rad^{-1}). Because the risk of stochastic effects (i.e., cancer) from gamma and beta radiation from DRPs has been shown to be negligible for DRP exposures to the skin, induction of skin cancer is of less concern than the potential for deterministic effects.

In 1991, the NRC revised 10 CFR Part 20 and its occupational dose limit for the skin of the whole body to 50 rem (0.5 Sv) SDE per year to prevent deterministic effects (May 21, 1991; 56 FR 23360) that might result from a lifetime exposure at the dose limit. This dose limit for the skin is in 10 CFR 20.1201(a)(2)(ii) and is intended to prevent damage to areas of the skin that are large relative to areas exposed by DRPs, on the skin, and that could compromise skin function or appearance. The NRC noted in that rulemaking that certain issues "are being resolved in other rulemaking proceedings because of either their scope, complexity, or timing." One of the issues that was listed concerned limits and calculational procedures for dealing with the DRP issue. It was recognized that the current skin dose limit was overly conservative for DRP doses and SDE to very small areas of the skin. The final rule stated that there would be a rulemaking to set limits for skin irradiation by DRPs. This proposed amendment to Part 20 responds, in part, to that commitment.

skin dose limit would be applicable. This information suggested that a reduction in DRP monitoring frequency, and the associated external dose, could not be realized for most DRP exposures, because of the need to prevent exceeding the existing skin dose limit. Because the licensee may not know in advance whether the DRP is on the skin or moving the licensee would need to assume that the existing skin dose limit was applicable.

The justification for proposing a constraint, or action level, of 300 rads (3.0 Gy) over 1 cm^2 was in large part to reduce the additional external dose incurred by plant staff from frequent monitoring to avoid having to report a DRP dose that exceeded the existing 50-rem (0.5 Sv) skin dose limit. If more than 90 percent of DRPs are off the skin and irradiating a relatively large area, the existing skin dose limit would be controlling and the constraint would only rarely be used. The NRC staff concluded that little relief from monitoring dose would result from implementing the constraint and the 500 rad (5 Gy) limit. In a memorandum to the Commission dated October 27,1999 the staff explained why the constraint with a limit of 500 rad (5 Gy) would not accomplish this intended objective, and recommended further staff work to identify an effective regulatory approach. The Commission directed the staff to ~~consider other regulatory approaches~~ (COMSECY 00-0009) ~~March 16, 2000~~).

In an SRM dated March 16, 2000,

Contract with the NCRP to provide additional technical support on this issue.

In December 1999, the NCRP had published Report No. 130, "Biological Effects and Exposure Limits for 'Hot Particles." The NCRP recommended that the dose to skin at a depth of 70 μm (7 mg/cm^2) from hot particles on skin (including the ear), hair, or clothing be limited to no more than 50 rads (0.5 Gy) averaged over the most highly exposed 10 cm^2 of skin.

The averaging area of 10 cm^2, 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 exposing an area on the order of 10 cm^2 or more.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MERRIFIELD

SUBJECT: **SECY-01-0096 - PROPOSED RULE ON REVISION OF THE SKIN DOSE LIMIT**

Approved __X__ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

I concur with the Chairman's and Commissioner McGaffigan's comments and recommend the following changes to the attached draft Congressional letters.

SIGNATURE

June 18, 2001
DATE

Entered on "STARS" Yes ✓ No ____

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

should be addressed to Lieberman

The ~~Honorable George V. Voinovich~~, Chairman
Subcommittee on Clean Air, Wetlands,
Private Property and Nuclear Safety
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The Nuclear Regulatory Commission (NRC) intends to publish, in the Federal Register, the enclosed proposed amendment to the Commission's rules in 10 CFR Part 20, "Standards for Protection Against Radiation." This proposed rule would amend the NRC's regulations relating to occupational skin dose limits.

The proposed amendment would in effect raise the current skin dose limit for the special cases of dose to the skin from small radioactive particles, and from contamination to small areas of skin. Current knowledge on the effects of radiation on the skin, obtained in part through NRC-sponsored research at Brookhaven National Laboratory (BNL), indicates that the current skin dose limit, when applied to small area skin contaminations, adequately protect the skin from harmful effects of radiation exposure. However, these limits also have negative consequences to the worker that more than outweigh the benefits provided by this level of protection. The NRC intends to resolve this situation by raising the dose limit for small area skin contaminations to a level that is sufficient to avoid these negative consequences but at the same time keeps the risks of such exposures to levels that are not much higher than they are under the current rule. The negative impacts of the current rule that are to be avoided by the proposed amendment include a possible increase in whole body exposures that result from attempts to comply with the current limit, as well as possible disruption of a worker's employment as a radiation worker as a consequence of a small area skin exposure that exceeds the regulatory dose limit but that carries minimal health risks for the worker.

The intent of this amendment is to discourage licensees from using conservative measures to prevent small-area skin doses at the cost of incurring greater risk from external dose and occupational stress. The proposed rule would permit averaging these small area skin doses over 10 square centimeters rather than 1 square centimeter for comparison against the skin dose limit. This constitutes an increase in the limit for small area exposures that is expected to result in a substantial increase in worker protection and a cost-effective reduction in unnecessary regulatory burden. This approach was recommended by the National Council on

Radiation Protection and Measurements (NCRP) and is consistent with the regulations of the Department of Energy. The rulemaking is considered to be consistent with the Commission's intent to promulgate risk-informed regulations.

The Commission is issuing the proposed rule for public comments.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure: As stated

cc: ~~Senator Joseph I. Lieberman~~
Voinovich

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

should be addressed to Jim Jeffords

The ~~Honorable Bob~~ Smith, Chairman
Committee on Environmental and Public Works
United States Senate
Washington, DC 20510

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Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure: As stated

cc: ~~Senator Harry Reid~~
Bob Smith