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

OFFICE OF THE
SECRETARY

March 20, 2002

COMMISSION VOTING RECORD

DECISION ITEM: SECY-02-0021

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

The Commission (with all Commissioners agreeing) approved the subject paper as recorded in the Affirmation Session Staff Requirements Memorandum (SRM) of March 20, 2002.

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

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-02-0021

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. MESERVE	X				X	3/04/02
COMR. DICUS	X				X	2/28/02
COMR. DIAZ	X				X	2/28/02
COMR. McGAFFIGAN	X				X	3/08/02
COMR. MERRIFIELD	X				X	3/07/02

COMMENT RESOLUTION

In their vote sheets, all Commissioners approved the staff's recommendation and provided some additional comments or edits. Their votes were affirmed during a public meeting held on March 20, 2002. Subsequently, the comments of the Commission were noted in an Affirmation Session SRM issued on March 20, 2002.

Commissioner Comments on SECY-02-0021

Commissioner Diaz

The Summary in the draft Federal Register notice (FRN) states that the ". . .result of this rulemaking is to make the skin dose less restrictive . ." Because this is a public document, it needs to be made clear that this was not the overall objective of the rulemaking. The Summary, and other sections of the FRN, as appropriate, should be expanded to include a brief layman's explanation of why a less restrictive regulation that changes the definition and method of calculating the dose to the skin and extremities will not only provide adequate protection of workers, but be an improvement, e.g., the rulemaking would reduce the whole-body exposures and nonradiological health risks, such as heat stress, to workers.

Commissioner Merrifield

I appreciate the staff's considerable efforts on this rulemaking and support their recommendation. However, I agree with Commissioner Diaz that the staff should more clearly convey the objective of the rulemaking in the draft Federal Register notice. I also believe that enhancements should be made to the draft public announcement. While it may be clear to some stakeholders that the rulemaking is risk-informed, reduces unnecessary regulatory burden, and provides a substantial increase in worker safety, I do not believe that the public announcement conveys these attributes in a manner that would be clear to the overwhelming majority of our stakeholders.

AFFIRMATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: CHAIRMAN MESERVE

SUBJECT: **SECY-02-0021 - FINAL RULE ON REVISION OF THE SKIN DOSE LIMIT, 10 CFR PART 20**

Approved X w/edits Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

See attached edits.

SIGNATURE

March 4, 2002

DATE

Entered on "STARS" Yes ✓ No ____

In the late-1990s, a materials licensee reported that workers received DRP exposures while manufacturing radiographic sources. In addition to the DRP concern, several events have occurred involving contamination of very small areas (< 1.0 square centimeter) of skin, primarily in the handling of solutions of highly concentrated radiopharmaceuticals. Although, these contamination events produce relatively large doses to very small areas of skin, they are known to result in insignificant health detriments. Nevertheless, under existing provisions in NRC regulations, several of these contamination events resulted in overexposures, and subsequent enforcement actions, with the result that workers could not be assigned work in radiation areas for the balance of the year. These consequences 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 cancer). 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. In Report No. 106[1], "Limit for Exposure to "Hot Particles" on the Skin" (1989), the Congressionally chartered National Council on Radiation Protection and Measurements (NCRP) 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.

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[1]Copies of NCRP reports can be ordered by calling NCRP at 1-800-229-2652 or accessing the NCRP website www.ncrp.com.

Commission dated October 27,1999 (COMSECY-00-0009), the NRC staff explained why the constraint with a limit of 500 rads (5 Gy) would not accomplish this intended objective, and recommended further work to identify an effective regulatory approach. In an SRM dated March 16, 2000, the Commission directed the NRC staff to 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'." In that report 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 square centimeters of skin.

The averaging area of 10 square centimeters, recommended by the NCRP, is applicable to 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 square centimeters or more. In the former case, averaging the very localized dose over 10 square centimeters results in a dose value that more appropriately reflects the risk associated with exposure of a small area. 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 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. 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 that the NCRP 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," which 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 square centimeters 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 entitled "Analysis of Potential Radiobiological Effects Related to a Unified Skin Dose Limit," that was published in the June 2001 issue (pp. 537-543) of the peer-reviewed journal Health Physics[2]. In this paper, Dr. Baum estimated the probabilities and severity of both stochastic and deterministic effects for a wide range of exposure scenarios based on the research done by BNL and other research facilities, as well as information found in NCRP Report Nos. 106 and 130. Published data from experimental and epidemiological studies, as well as calculations of radial- and depth-dose distributions, show that skin exposures at the dose limit of 50 rem (0.5 Sv) of SDE averaged over 10 cm^2 could result in stochastic risks of $< 6.6 \times 10^{-10}$ rem^{-1} and $< 3.2 \times 10^{-7}$ rem^{-1} for fatal and nonfatal skin cancers respectively, confirming that stochastic risks at the proposed limit are small.

Given exposures at the proposed skin dose limit, that is, 50 rem (0.5 Sv) averaged over 10 square centimeters, Dr. Baum estimated that the worst-case deterministic effects are a 5-percent probability of erythema if all of the dose (500 rem) were delivered to an area of 2.5 square centimeters, and a 50-percent probability that measurable dermal thinning would be observable if all of the dose were delivered to an area of < 0.5 square centimeters. At this

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[2]For correspondence or reprints of this article contact J. W. Baum at Baum and Associates Inc., 317 Maple Ave., Patchogue, NY 11772.

dose, no acute cell killing or skin ulceration was predicted for DRPs 3 or more millimeters off the skin because the dose is distributed over too large an area. The worst case probability of producing a barely detectable scab as a result of acute cell killing was estimated to be 10 percent for ^{60}Co or activated fuel DRPs located about 0.4 mm off the skin. Additional discussion of implications of the health effects associated with the proposed unified skin dose limit can be found in the regulatory analysis developed for this rulemaking.

The NRC published a proposed rule in the Federal Register on July 12, 2001 (66 FR 36502). That rule proposed changing the method of calculating SDEs to the skin or the extremities by specifying in 10 CFR 20.1201(c) that the assigned SDE must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. Shortly after publishing the proposed rule, the NRC monitored a discussion of the rule that took place on a publicly accessible radiation protection bulletin board (RADSAFE). Comments were favorable regarding the intent and justification of the rule. However, radiation protection practitioners in the field raised several technical questions regarding implementation guidance. Although this exchange does not technically constitute public comment, the NRC staff has decided to note that parallel to this rulemaking, an effort is underway to contract for a major revision to the VARSKIN II computer code. This revision is expected to address calculations that will accommodate the new skin dose limit and address the technical questions raised in the RADSAFE discussion of the rule.

II. Analysis of Public Comments and Staff Response

The NRC received nine letters of public comment, all supporting the proposed rule. Mallinckrodt, a subsidiary of Tyco Healthcare, commented that ~~they are~~ it is in favor of the proposed revision of the skin dose limit and agrees with the NCRP's recommendations because the new

rule encompasses SDE from all sources into one limit. The Council on Radionuclides and Radiopharmaceuticals (CORAR), an association of NRC and Agreement State licensees that use unsealed sources of radioactive materials, fully supported the proposed rule. CORAR stated that the new limit would be more protective of workers, and more comparable to current annual limits for deep dose and lens of the eye dose, than the current limit, would establish a skin dose limit on a risk-informed basis, and would simplify the regulations.

CORAR requested clarification regarding the limit on deep-dose equivalent (DDE) to the extremities. No such limit exists. DDE, which § 20.1201(a)(1) limits to 5 rem in a year, is defined as applying to external whole-body exposure, and the whole body is defined as excluding the extremities. The SDE limit of 50 rems (0.50 Sv) averaged over 10 square centimeters is considered to adequately protect against any associated DDE to the less-radiosensitive deep tissues of the extremities.

CORAR noted that the NRC should allow licensees to estimate doses for the actual skin thickness involved, rather than a tissue depth of 0.007 cm as required. The NRC staff is not considering any changes to this requirement. For most areas of the body the specified depth defines the most radiosensitive tissue or leads to a conservative dose calculation if the sensitive tissue is deeper. Calculation of SDE at a depth of 0.007 cm is considered an important component of an acceptable radiation protection program, and will continue to be required to demonstrate compliance with the skin and extremity dose limits.

CORAR proposed that the NRC provide clarification of the limit in the event that multiple SDEs were delivered to the same skin area during the year. The NRC staff believes that the annual limit of 50 rems (0.50 Sv), modified by the requirement in § 20.1201(c) that the assigned SDE must be for the "...contiguous 10 square centimeters of skin receiving the highest exposure," makes it clear that multiple exposures to the same area during the record year would be additive for comparison to the limit. This interpretation is consistent with the

attributed to this monitoring. Workers are brought out of the workplace to be monitored, thereby incurring nonproductive exit-entry doses, or technicians enter the restricted area to monitor workers for DRPs. The new, less restrictive skin dose limit will eliminate the need to perform this DRP monitoring during work shifts for all but the highest activity DRPs[3], especially those having a high gamma component. The NRC believes that the possibility of some additional number of observable, transient deterministic effects, such as a small break in the skin, is justified by the reduction of the whole-body dose and stochastic risks associated with monitoring for DRPs.

The Radiation Exposure Information Reporting System (REIRS) database includes reports of nearly 15,000 individual DRP doses since 1990. Fewer than 10 have exceeded the current 50-rem (0.5-Sv) reporting limit. It is unlikely that this revision of the skin dose limit will result in any large increase in the number of DRP doses. The as-low-as-is-reasonably-achievable (ALARA) principle will continue to apply to any occupational doses, so the revised skin dose limit should not permit a large number of high DRP doses. It would be unacceptable for a licensee to permit large numbers of high DRP exposures on a continuing basis without attempting some mitigating procedures or engineering controls.

The Commission believes that the less restrictive limit on dose to small areas of skin might permit more observable, transient, deterministic effects, but nonetheless ~~this tradeoff~~ represents a substantial increase in worker protection because it will result in a less hazardous workplace and reduced whole-body occupational dose. This represents a shift in emphasis toward a risk-informed approach that would possibly permit more frequent deterministic effects in order to

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[3]For example, one recent event at a nuclear power plant involved a ^{60}Co DRP with an activity of about 75 mCi. The DDE estimated from this particle (had it been on the skin) was calculated to be about 10 rem/hr per mCi. For particles in this activity range, the DDE limit of 5 rem per year can be exceeded in less than 1 minute, and the new skin dose limit could be exceeded in even less time.

regulation essentially represents a continuation of current practice. The benefits of the rule are that it permits averaging doses to the skin over the most highly exposed 10 square centimeters, incorporates an NCRP recommendation for a less-restrictive skin dose limiting procedure, and permits reduced use of protective equipment known to expose workers to workplace stresses and unnecessary whole-body radiation dose.

XI. Backfit Analysis

Although the NRC has concluded that this amendment constitutes a reduction in unnecessary regulatory burden, the implementation of these changes will require revisions to licensee procedures, thereby constituting a potential backfit under 10 CFR 50.109(a)(1). Under § 50.109(a)(2), a backfit analysis is required unless the rule meets one of the exceptions listed in § 50.109(a)(4). This rule meets the exception at § 50.109(a)(4)(iii) in that it redefines the level of adequate protection embodied in the occupational dose limit for doses to the skin of the whole body and to the skin of the extremities. In addition, implementation of this rule is expected to ~~substantially~~ increase industrial safety for workers substantially. ~~see statement on page~~

Section III, Summary and Discussion of the Changes, discusses the changes to the definition of SDE and the provision for averaging SDE over the most highly exposed 10 square centimeters. This change raises the skin dose limit for DRPs on or near the skin and for small-area (< 1.0 square centimeter) contaminations. This change makes it possible for licensees to measure or calculate skin doses for comparison to the 50-rem (0.5-Sv) limit that, when averaged over 10 square centimeters, result in dose values that more appropriately reflect the risk associated with small area exposures according to the NCRP. The increased limit in the case of DRPs will eliminate the need to frequently monitor workers for DRP contamination during work shifts for all but the highest activity DRPs, especially those having a high gamma

AFFIRMATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER DICUS

SUBJECT: **SECY-02-0021 - FINAL RULE ON REVISION OF THE SKIN DOSE LIMIT, 10 CFR PART 20**

Approved X w/comment Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

See attached edits to Press Release and Federal Register Notice.

Greta Joy Dicus
SIGNATURE

February 28, 2002
DATE

Entered on "STARS" Yes X No ____

OPA

DRAFT

(Source: FINAL RULE)

NRC REVISES SKIN DOSE LIMITS FOR WORKERS AT NUCLEAR FACILITIES

The Nuclear Regulatory Commission is revising its regulations for dose limits to the skin of the whole body and extremities. ~~standards for protection against radiation. The~~ This changes ~~amend~~ the method used for calculating ~~determining~~ the amount of radiation to the skin that workers could potentially receive when conducting certain licensed activities.

The agency's final rule revises Part 20 of the Commission's regulations and is based on recent recommendations from the ~~Congressionally chartered~~ National Council on Radiation Protection and Measurements (NCRP Report No. 130 and Statement No. 9). It ~~responds to the need to~~ establishes a more risk-informed limits for potential doses received from small radioactive particles, sometimes known as "hot particles," which can result in ~~and~~ doses to very small areas on ~~of~~ the skin or clothing.

Publication of the proposed rule appeared in the *Federal Register* on July 12, requesting public comment. Nine letters were received, all supporting the proposed action.

Under the final rule, the dose to the skin will be averaged over the most highly exposed, ~~contiguous~~ 10 square centimeters instead of being averaged over one square centimeter, as is currently required. This change is based on scientific studies that demonstrate that risks from doses to small areas of the skin are less than risks to larger areas from the same dose.

Previously, rules required frequent monitoring of workers to detect hot particles and small area exposures that had insignificant health implications. To avoid exceeding the previous dose limit, multiple layers of protective clothing and cumbersome gloves were used that resulted in workers being subjected to non-radiological hazards, such as heat stress. Workers were also hampered by the excessive use of protective equipment and clothing, requiring them to spend more time completing a job in radiation areas. Additionally, small-area overexposures sometimes resulted in workers not being permitted to work in a radiation area for the balance of the year. These conservative efforts to prevent small, insignificant skin doses resulted in higher whole-body doses with ~~a~~ higher risk.

The health effects from small-area skin hot particle exposures, ~~doses~~ such as reddening of the skin, ~~which might occur from a hot particle exposure,~~ are considered by the NCRP to be very small as compared to the increased external ~~whole-body deep~~ doses ~~and~~ risk from frequent monitoring. ~~and work inefficiencies. To avoid exceeding the previous dose limit, protective clothing and cumbersome gloves were used that resulted in workers being subjected to non-radiological hazards, such as heat stress. Workers were also hampered by the excessive use of protective equipment and clothing, requiring them to spend more time~~

~~completing a job in radiation areas. Additionally, small-area overexposures sometimes resulted in workers not being permitted to work in a radiation area for the balance of the year~~.

The agency's revision of the skin dose limit establishes a ~~ruling establishes a uniform~~, risk-informed approach ~~skin dose limit~~ for all sources of shallow radiation exposures, including hot particles and small area skin contaminations. The rule also lessens physical stress and reduces whole-body doses to workers by reducing the frequency of monitoring for hot particles.

This rulemaking is expected to result in a decrease in the use of protective equipment used by nuclear power plant workers and others potentially exposed to skin contamination which will in turn ~~expected to~~ lead to a reduction in an external occupational dose to workers onsite. ~~and a substantial increase in worker industrial safety. It also is expected to result in a decrease in the use of protective equipment used by nuclear power plant workers and others potentially exposed to skin contamination, to prevent such contaminations.~~ This would be expected to result in an increase in worker safety, as well as a cost-effective reduction in unnecessary regulatory burden with little to no impact on worker safety.

For more information on the final rule contact Alan K. Roecklein, at 301-415-3883, or via e-mail at akr@nrc.gov

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In the late-1990s, a materials licensee reported that workers received DRP exposures while manufacturing radiographic sources. In addition to the DRP concern, several events have occurred involving contamination of very small areas (< 1.0 square centimeter) of skin, primarily in the handling of solutions of highly concentrated radiopharmaceuticals. Although these contamination events produce relatively large doses to very small areas of skin, they are known to result in insignificant health detriments. Nevertheless, under existing provisions in NRC regulations, several of these contamination events resulted in overexposures, and subsequent enforcement actions, with the result that workers could not be assigned work in radiation areas for the balance of the year. These consequences 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 cancer). 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. In Report No. 106, "Limit for Exposure to "Hot Particles" on the Skin" (1989), the Congressionally chartered National Council on Radiation Protection and Measurements (NCRP) 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.

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In 1991, the NRC revised Title 10, Part 20 of the Code of Federal Regulations 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 that might result from a lifetime exposure at the dose limit (56 FR 23360; May 21, 1991). This dose limit for the skin is specified 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 amendment to 10 CFR Part 20 responds, in part, to that commitment.

The existing Part 20 skin dose limit of 50 rem (0.5 Sv) averaged over 1 square centimeter was intended to apply to a relatively uniform dose to a larger area of skin than that usually exposed by DRPs with the objective of preventing deterministic damage to the skin. Because the NCRP considered this limit 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 31, 1990). That policy addressed reporting and mitigation if a DRP dose exceeded the existing limit of 50 rem (0.5 Sv) over 1 square centimeter, and stated that the NRC would take enforcement action for overexposures if the DRP beta emission exceeded 75 μCi-hrs (approximately 300-500 rads). To avoid DRP doses greater than 50 rem (0.5 Sv) and the resulting reporting requirement, licensees monitor workers for DRP contamination frequently during the work shift. This results in additional external dose either to the workers, who incur additional exposure time in exiting

Commission dated October 27,1999 (COMSECY-00-0009), the NRC staff explained why the constraint with a limit of 500 rads (5 Gy) would not accomplish this intended objective, and recommended further work to identify an effective regulatory approach. In an SRM dated March 16, 2000, the Commission directed the NRC staff to contract with the NCRP to provide additional technical support on this issue.

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The averaging area of 10 square centimeters, recommended by the NCRP, is applicable to 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 square centimeters or more. In the former case, averaging the very localized dose over 10 square centimeters results in a dose value that more appropriately reflects the risk associated with exposure of a small area. 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 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. This averaging area is also consistent with the skin dose limiting system adopted by the Department of Energy in 10 CFR Part 835.

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[2] For correspondence or reprints of this article contact J. W. Baum at Baum and Associates Inc., 317 Maple Ave., Patchogue, NY 11772.

rule encompasses SDE from all sources into one limit. The Council on Radionuclides and Radiopharmaceuticals (CORAR), an association of NRC and Agreement State licensees that use unsealed sources of radioactive materials, fully supported the proposed rule. CORAR stated that the new limit would be more protective of workers, and more comparable to current annual limits for deep dose and lens of the eye dose, would establish a skin dose limit on a risk-informed basis, and would simplify the regulations.

CORAR requested clarification regarding the limit on deep-dose equivalent (DDE) to the extremities. No such limit exists. DDE, which § 20.1201(a)(1) limits to 5 rem (50 mSv) in a year, is defined as applying to external whole-body exposure, and the whole body is defined as excluding the extremities. The SDE limit of 50 rems (0.50 Sv) averaged over 10 square centimeters is considered to adequately protect against any associated DDE to the less-radiosensitive deep tissues of the extremities.

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recommendations stated in NCRP Statement No. 9, "Extension of the Skin Dose Limit for Hot Particles to Other External Sources of Skin Irradiation" (March 30, 2001).

An individual commenter, a certified health physicist, noted the need to revise the whole-body limits specified in 10 CFR Part 20 to use Effective-dose equivalent (EDE) rather than Deep-dose equivalent (DDE). The commenter suggested that the risk associated with the DDE from a DRP at 1 centimeter was not comparable to the risk associated with DDE to the whole body. The NRC staff agrees that consideration should be given to adopting the EDE concept in its system of dose limitation. However, that issue is not relevant to the rule changes addressed in this final rule. The skin dose limit concerns only SDE, and the assertion that the associated DDE has minimal stochastic risk would be even more accurate if an EDE were used. The rule, as promulgated, is believed to reduce unnecessary regulatory burden, while providing increased worker protection. The NRC staff is separately addressing questions regarding EDE and the use of weighting factors for determining whole-body doses.

The Nuclear Energy Institute (NEI) solicited comments from its industry radiation protection members and submitted a letter of strong support for the rulemaking. NEI noted that the rule has a strong scientific basis, reflects NCRP recommendations that were based on replicated research studies, and incorporates a risk-based approach that will permit licensees to select protective measures that optimize worker safety. The commenter observed that the rule change is an easily implemented simplification that will permit reduction of external radiation exposure and result in an overall improvement in worker safety.

NEI noted that the rule would change the way licensees estimate the dose to the skin, but would not change existing dose reporting requirements and guidance. The NRC staff agrees that no changes in reporting requirements are needed to implement this final rule.

10 CFR 20.1201(c) is amended to specify that the assigned SDE must be the dose averaged over the 10 contiguous square centimeters of skin receiving the highest exposure.

~~Note that~~ Although the NCRP recommended limiting the dose from DRPs in the ear and on the eye, the NRC staff believes that these are special cases only with respect to measuring or calculating the dose, and that this revised skin dose limit, together with the existing limit for dose to the lens of the eye, is adequate to control DRP doses to these areas.

It is also important to note that previously it was considered relevant to distinguish between doses from DRPs that were on or off the skin. With this final rule, this distinction is only relevant to dosimetric considerations, and the proposed limit is independent of source or exposure geometry.

The NRC staff has elected to retain rem and Sievert as the units for the skin dose limit. According to data published in reports of the International Commission on Radiation Protection (ICRP), the unit for dose equivalent, rem (Sv), is acceptable for deterministic effects, especially at lower doses. The highest relative biological effectiveness (RBE) values for deterministic effects in the skin are all less than the Q values, or dose weighting factors that are used to convert dose in rads (Gy) to dose equivalent in rem (Sv). The use of dose equivalent in rem (Sv) units is conservative and has the advantage that all of the dose limits will be in the same units. In addition, regulations promulgated by the Department of Energy, use the rem and Sievert for SDE.

NCRP Statement No. 9 referred to NCRP Report No. 130 (1999) for guidance on good practices, and recommended that in addition to numerical limits, the exposed area of skin should be observed for 4 to 6 weeks whenever the DRP dose at a depth of 70 μm exceeds 10 rads (0.1 Gy) averaged over the most highly exposed 10 square centimeters of skin. The observational level of 10 rads (0.1 Gy) is well below the new limit of 50 rem (0.5 Sv), and is essentially equivalent to the current skin dose limit, at which no clinically significant effects have

Under the new rule, exposed areas of the skin that are less than 10 square centimeters are treated in a less restrictive manner. For example, a dose of 250 rem (2.5 Sv) to each of 2 square centimeters results in a 50-rem (0.5-Sv) SDE when averaged over 10 square centimeters. A dose as high as 500 rem (5.0 Sv) will be permitted to 1 square centimeter and will be recorded as 50 rem (0.5 Sv) when averaged over 10 square centimeters. This change effectively permits higher doses to small areas of skin than were formerly permitted by the regulations.

Although, as previously noted, the Commission is establishing a skin dose limit that in some source geometries is likely to permit more frequent occurrence of observable, though transient, deterministic effects, it is expected that the less restrictive limit will permit a reduction in the overly conservative use of protective clothing and other devices intended to prevent contamination and skin doses. As a result, workers should experience reduced exposure to nonradiological health hazards such as heat stress, and be subject to fewer industrial accidents caused by impaired motion. By reducing the overly conservative use of protective equipment, work should be performed more efficiently. Reduced time in the restricted area is expected, along with a concomitant reduction in whole-body dose and stochastic risks. The Commission intends this change to reduce overly conservative efforts to prevent skin contaminations thereby decreasing stress and reducing whole-body doses. Numerous studies of the impacts on worker efficiency and safety resulting from the use of protective clothing and equipment have been published in the journal, Health Physics, in Radiation Protection Management, and by the Electric Power Research Institute (EPRI). A recent discussion of this issue and specific references can be found in NUREG/CR-0041, "Manual of Respiratory Protection Against Airborne Radioactive Material" (January 2001).

A final geometry case of interest is the case of DRPs on or very near the skin, such that a relatively small volume of tissue receives a large dose, resulting in cell killing and possible observable breaks in the skin. Under the former dose limit, a DRP could deliver 50 rem (0.5 Sv) to an area of 1 square centimeter that when averaged over 1 square centimeter would yield a recorded dose of 50 rem (0.5 Sv). Under the new rule, the NCRP-recommended limit, a dose of 500 rem (5.0 Sv) delivered to 1 square centimeter, when averaged over 10 square centimeters, would yield a recorded dose of 50 rem (0.5 Sv). Thus, for DRPs on the skin, and other small area exposures, the rule change is in effect a tenfold relaxation of the former limit and may permit some increased number of observable, transient deterministic effects to the skin. This new limit would be approximately equivalent to the emission criterion of 75 μCi-hr that was used in the interim enforcement policy stated in IN 90-48. The worst case of 500 rem (5.0 Sv) to 1 square centimeter is estimated to result in a 50-percent chance of an observable but transient erythema, and a 15- to 20-percent chance of an observable break in the skin. NRC records include only one DRP dose that was calculated to exceed 500 rem (5.0 Sv), and no effects were observed in that case.

On the basis of extensive research performed at BNL and elsewhere, the NCRP stated in Report No. 130 that "if exposures are maintained below the recommended limits, few, if any, deterministic biological effects are expected to be observed, and those effects would be transient in nature. If effects from a hot-particle exposure are observed, the result is an easily treated medical condition involving an extraordinarily small stochastic risk. Such occurrences would be indicative of the need for improvement in radiation protection practices, but should not be compared in seriousness to exceeding whole-body exposure limits."

Reactor licensees currently monitor workers frequently during each work shift to prevent exceeding the interim 50 rem (0.5 Sv) reporting threshold for doses from DRPs. The industry estimates that up to 5 person-rem (0.05 person-Sv) of whole-body dose per outage could be

attributed to this monitoring. Workers are brought out of the workplace to be monitored, thereby incurring nonproductive exit-entry doses, or technicians enter the restricted area to monitor workers for DRPs. The new, less restrictive skin dose limit will eliminate the need to perform this DRP monitoring during work shifts for all but the highest activity DRPs[3], especially those having a high gamma component. The NRC believes that the possibility of some additional number of observable, transient deterministic effects, such as a small break in the skin, is justified by the reduction of the whole-body dose and stochastic risks associated with monitoring for DRPs.

NRC's ~~The~~ Radiation Exposure Information Reporting System (REIRS) database includes reports of nearly 15,000 individual DRP doses since 1990. Fewer than 10 have exceeded the current 50-rem (0.5-Sv) reporting limit. It is unlikely that this revision of the skin dose limit will result in any large increase in the number of DRP doses. The as-low-as-is-reasonably-achievable (ALARA) principle will continue to apply to any occupational doses, so the revised skin dose limit should not permit a large number of high DRP doses. It would be unacceptable for a licensee to permit large numbers of high DRP exposures on a continuing basis without attempting some mitigating procedures or engineering controls.

The Commission believes that the less restrictive limit on dose to small areas of skin might permit more observable, transient, deterministic effects, but this tradeoff represents a substantial increase in worker protection because it will result in a less hazardous workplace and reduced whole-body occupational dose. This represents a shift in emphasis toward a risk-informed approach that would possibly permit more frequent deterministic effects in order to

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[3]For example, one recent event at a nuclear power plant involved a ^{60}Co DRP with an activity of about 75 mCi. The DDE estimated from this particle (had it been on the skin) was calculated to be about 10 rem/hr per mCi. For particles in this activity range, the DDE limit of 5 rem per year can be exceeded in less than 1 minute, and the new skin dose limit could be exceeded in even less time.

AFFIRMATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER DIAZ

SUBJECT: **SECY-02-0021 - FINAL RULE ON REVISION OF THE SKIN DOSE LIMIT, 10 CFR PART 20**

Approved X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

The Summary in the draft Federal Register notice (FRN) states that the ". . .result of this rulemaking is to make the skin dose less restrictive . ." Because this is a public document, it needs to be made clear that this was not the overall objective of the rulemaking. The Summary, and other sections of the FRN, as appropriate, should be expanded to include a brief layman's explanation of why a less restrictive regulation that changes the definition and method of calculating the dose to the skin and extremities will not only provide adequate protection of workers, but be an improvement, e.g., the rulemaking would reduce the whole-body exposures and nonradiological health risks, such as heat stress, to workers.

SIGNATURE

Feb 28, 02

DATE

Entered on "STARS" Yes X No ____

AFFIRMATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MCGAFFIGAN

SUBJECT: **SECY-02-0021 - FINAL RULE ON REVISION OF THE SKIN DOSE LIMIT, 10 CFR PART 20**

Approved X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: I concur in the comments/edits of the Chairman, Commissioner Merrifield and Commissioner Diaz and offer a few additional edits to the FRN.

Edward McGaffigan Jr.

SIGNATURE

March 8, 2002

DATE

Entered on "STARS" Yes X No ____

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR PART 20

RIN 3150-AG25

Revision of the Skin Dose Limit

AGENCY: Nuclear Regulatory Commission

ACTION: Final rule

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations in 10 CFR Part 20 to change the definition and method of calculating Shallow-dose equivalents (SDEs) by specifying that the assigned SDE must be the dose averaged over the 10 square centimeters of skin receiving the highest exposure, rather than 1 square centimeter as stated in the existing regulation. A result of this rulemaking is to make the skin dose limit less restrictive when small areas of skin are irradiated and to address skin and extremity doses from all source geometries under a single limit. This change requires measuring or calculating SDEs from discrete radioactive particles (DRPs) on or off the skin, from very small areas (< 1.0 square centimeter) of skin contamination, and from any other source of SDE by averaging the measured or calculated dose over the most highly exposed, contiguous 10 square centimeters for comparison to the skin dose limit of 50 rem (0.5 Sv).

EFFECTIVE DATE: (Insert date 60 days from date of publication).

FOR FURTHER INFORMATION CONTACT: Alan K. Roecklein, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-3883; e-mail AKR@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

With the installation of very sensitive portal monitors in the mid- and late-1980s, 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, but the stochastic risk of inducing skin cancer due to a DRP exposure is negligible.

(From p.3 of Reg Analysis)

In the late-1990s, a materials licensee reported that workers received DRP exposures while manufacturing radiographic sources. In addition to the DRP concern, several events have occurred involving contamination of very small areas (< 1.0 square centimeter) of skin, primarily in the handling of solutions of highly concentrated radiopharmaceuticals. Although, these contamination events produce relatively large doses to very small areas of skin, they are known to result in insignificant overall health detriments. Nevertheless, under existing provisions in NRC regulations, several of these contamination events were defined as ~~resulted in~~ overexposures, and resulted in ~~subsequent~~ enforcement actions, with the result that workers could not be assigned work in radiation areas for the balance of the year. These consequences 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 cancer). 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. In Report No. 106[1], "Limit for Exposure to "Hot Particles" on the Skin" (1989), the Congressionally chartered National Council on Radiation Protection and Measurements (NCRP) 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.

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[1]Copies of NCRP reports can be ordered by calling NCRP at 1-800-229-2652 or accessing the NCRP website www.ncrp.com.

In 1991, the NRC revised Title 10, Part 20 of the Code of Federal Regulations 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 that might result from a lifetime exposure at the dose limit (56 FR 23360; May 21, 1991). This dose limit for the skin is specified 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~~ SDEs 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 amendment to 10 CFR Part 20 responds, in part, to that commitment.

The existing Part 20 skin dose limit of 50 rem (0.5 Sv) averaged over 1 square centimeter was intended to apply to a relatively uniform dose to a larger area of skin than that usually exposed by DRPs with the objective of preventing deterministic damage to the skin. Because the NCRP considered this limit 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 31, 1990). That policy addressed reporting and mitigation if a DRP dose exceeded the existing limit of 50 rem over 1 square centimeter, and stated that the NRC would take enforcement action for overexposures if the DRP beta emission exceeded 75 μCi-hrs (approximately 300-500 rads). To avoid DRP doses greater than 50 rem (0.5 Sv) and the resulting reporting requirement, licensees monitor workers for DRP contamination frequently during the work shift. This results in additional external dose either to the workers, who incur additional exposure time in exiting

and reentering the restricted area, or to the radiation protection staff, who must enter the restricted area to 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 that irradiation of the skin by DRPs in contact with or near the skin would produce breaks in the skin and demonstrated that these effects would be very unlikely to pose any serious health problems to workers. The BNL work examined the nonuniform, highly concentrated dose to 1 square centimeter from DRPs in contact with or near the skin, and not the dose that would be delivered to the adjacent skin tissue. This BNL data was supported by other reported studies and similar experiments performed by the Electric Power Research Institute (EPRI) as reported in EPRI TR-104781, "Skin Injuries From Discrete Radioactive Particles" (1994). Consequently, in Report No. 130, "Biological Effects and Exposure Limits for "Hot Particles" (1999), the NCRP recommended a dose-limiting guideline for DRPs of 50 rads (0.5 Gy) averaged over the most highly exposed 10 square centimeters.

In October 1998, the NRC staff submitted a rulemaking plan (SECY-98-245) entitled "Protection Against Discrete Radioactive Particle (DRP) Exposures (10 CFR Part 20)." In that plan the NRC staff proposed establishing a constraint of 300 rads (3 Gy) over 1 square centimeter as a program design guideline or action level, and a limit of 1000 rads (10 Gy) over 1 square centimeter for DRPs on or near the skin. The existing skin dose limit would have been retained for all other skin doses. The intent of that proposed amendment was to reduce the additional external dose incurred by workers in monitoring for DRP contamination during work shifts and to reduce unnecessary regulatory burden by adopting more realistic thresholds for DRP dose control and reporting requirements. In a staff requirements memorandum (SRM)

dated December 23, 1998, the Commission directed the NRC staff to proceed with rulemaking as proposed, but to use 500 rads (5 Gy) per 1 square centimeter as the dose limit to be consistent with the recommendations in NCRP Report No. 106.

In March 1999, several industry experts who had reviewed the publicly available rulemaking plan and SRM suggested that the planned action would not accomplish one of the intended objectives, that is, to reduce the frequency of worker monitoring. The industry concern argued against use of a DRP dose constraint with a 500-rem (5.0-Sv) limit, and supported use of the NCRP-recommended skin dose limit that is adopted in this rule. Specifically, the industry concern stated that, of all DRP events, fewer than 10 percent are on, or near enough to, the skin for the proposed constraint and limit to apply. Most DRP events (> 90 percent) are on clothing or hair, or are far enough away from the skin (and most likely moving) so that the dose to the skin is more uniform and spread over a larger area. In that case, the existing 50-rem (0.5-Sv) 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 square centimeter 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 irradiate 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 (COMSECY-00-0009), the NRC staff explained why the constraint with a limit of 500 rads (5 Gy) would not accomplish this intended objective, and recommended further work to identify an effective regulatory approach. In an SRM dated March 16, 2000, the Commission directed the NRC staff to 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'." In that report 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 square centimeters of skin.

The averaging area of 10 square centimeters, recommended by the NCRP, is applicable to 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 square centimeters or more. In the former case, averaging the very localized dose over 10 square centimeters results in a dose value that more appropriately reflects the risk associated with exposure of a small area. 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 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. 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 that the NCRP 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," which 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 square centimeters 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 entitled "Analysis of Potential Radiobiological Effects Related to a Unified Skin Dose Limit," that was published in the June 2001 issue (pp. 537-543) of the peer-reviewed journal Health Physics[2]. In this paper, Dr. Baum estimated the probabilities and severity of both stochastic and deterministic effects for a wide range of exposure scenarios based on the research done by BNL and other research facilities, as well as information found in NCRP Report Nos. 106 and 130. Published data from experimental and epidemiological studies, as well as calculations of radial- and depth-dose distributions, show that skin exposures at the dose limit of 50 rem (0.5 Sv) of SDE averaged over 10 cm^2 could result in stochastic risks of $< 6.6 \times 10^{-10}$ rem^{-1} and $< 3.2 \times 10^{-7}$ rem^{-1} for fatal and nonfatal skin cancers respectively, confirming that stochastic risks at the proposed limit are small.

Given exposures at the proposed skin dose limit, that is, 50 rem (0.5 Sv) averaged over 10 square centimeters, Dr. Baum estimated that the worst-case deterministic effects are a 5-percent probability of erythema if all of the dose (500 rem) were delivered to an area of 2.5 square centimeters, and a 50-percent probability that measurable dermal thinning would be observable if all of the dose were delivered to an area of < 0.5 square centimeters. At this

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[2]For correspondence or reprints of this article contact J. W. Baum at Baum and Associates Inc., 317 Maple Ave., Patchogue, NY 11772.

AFFIRMATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MERRIFIELD

SUBJECT: **SECY-02-0021 - FINAL RULE ON REVISION OF THE SKIN DOSE LIMIT, 10 CFR PART 20**

Approved X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

See attached comments.

SIGNATURE

3/7/02
DATE

Entered on "STARS" Yes ✓ No _____

Commissioner Merrifield's Comments on SECY-02-0021

I appreciate the staff's considerable efforts on this rulemaking and support their recommendation. However, I agree with Commissioner Diaz that the staff should more clearly convey the objective of the rulemaking in the draft Federal Register notice. I also believe that enhancements should be made to the draft public announcement. While it may be clear to some stakeholders that the rulemaking is risk-informed, reduces unnecessary regulatory burden, and provides a substantial increase in worker safety, I do not believe that the public announcement conveys these attributes in a manner that would be clear to the overwhelming majority of our stakeholders.