

NUCLEAR REGULATORY COMMISSION

10 CFR PART 20

RIN 3150-AG25

Revision of the Skin Dose Limit

AGENCY: Nuclear Regulatory Commission

ACTION: Proposed rule

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to delete a reference to averaging over 1 square centimeter from its definition of shallow-dose equivalent (SDE). In addition, the proposed rule would change the method of calculating SDEs by specifying that the assigned SDE must be the dose averaged over the 10 square centimeters of skin receiving the highest exposure. 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 would permit measuring or calculating SDEs from discrete radioactive particles (DRPs) on or off the skin, from very small areas (< 1.0 square centimeters) 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).

DATES: Submit comments by (insert date 75 days after publication in the Federal Register).

Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Submit comments to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff. Deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:30 a.m. and 4:15 p.m. on Federal workdays.

You may also provide comments via the NRC's interactive rulemaking Website at <http://ruleforum.llnl.gov>. This site provides the capability to upload comments as files (any format) if your Web browser supports that function. For information about the interactive rulemaking Website, contact Ms. Carol Gallagher, (301) 415-5905 (e-mail: CAG@nrc.gov).

Certain documents related to this rulemaking, including comments received, may be examined in the NRC Public Document Room, 11555 Rockville Pike, Rockville, Maryland. These same documents may be viewed and downloaded electronically via the rulemaking Website.

Obtain single copies of the environmental assessment and the regulatory analysis from 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.

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 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 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 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 mm² to be $7 \times 10^{-7} \text{ Gy}^{-1}$ ($7 \times 10^{-9} \text{ rad}^{-1}$), and the risk of skin cancer mortality to be about $1 \times 10^{-9} \text{ Gy}^{-1}$ ($1 \times 10^{-11} \text{ rad}^{-1}$). 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.

The existing Part 20 skin dose limit of 50 rem (0.5 Sv) averaged over 1 cm² 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 cm² limit, and enforcement action for overexposures would be taken if the DRP beta emission exceeded 75 μ Ci-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

contact with or near the skin and not the dose that would be delivered to the adjacent skin tissue.

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)." The NRC staff proposed establishing a constraint of 300 rads (3 Gy) over 1 cm² as a program design guideline or action level, and a limit of 1000 rads (10 Gy) per 1 cm² 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 DRPs 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 cm² as the dose limit to be consistent with the NCRP 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 of the proposed rulemaking, that is, to reduce the frequency of worker monitoring. The following industry concerns were raised arguing against use of a DRP dose constraint with a 500 rem (5.0 Sv) limit and supporting use of the NCRP recommended skin dose limit that is proposed in this rule: 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 DRPs on clothing, on hair, or are far enough away from the skin (and most likely moving) so that the dose to the skin is more uniform and is 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 cm² 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 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/cm²) 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 cm² of skin.

The averaging area of 10 cm², 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 cm² or more.

In the former case, averaging the very localized dose over 10 cm² 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 cm², results in an dose limit that is equivalent to the current 50 rem over 1 cm². Thus the limit decreases as the exposed skin area increases to 10 cm², 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/cm²) from any source of irradiation be limited to 50 rads (0.5 Gy) averaged over the most highly exposed 10 cm² 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 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

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 cm² could result in stochastic risks of $< 3.3 \times 10^{-7}$ fatal skin cancers and $< 1.6 \times 10^{-4}$ nonfatal skin cancers, confirming that stochastic risks at the proposed limit are small.

Given exposures at the proposed skin dose limit, i.e., 50 rem (0.5 Sv) averaged over 10 square centimeters, the worst case deterministic effects were estimated to be a 5 percent probability of erythema if all of the dose (500 rem) were delivered to an area of 2.5 cm², and a 50 percent probability that measurable dermal thinning would be observable if all of the dose were delivered to an area < 0.5 cm². At this dose, no acute cell killing or skin ulceration was predicted for DRPs 3 or more mm off of the skin because the dose is distributed over too large an area. The worst case probability of producing a barely detectable scab due to acute cell killing was estimated at 10 percent for ⁶⁰Co 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.

II. Summary and Discussion of the Proposed Changes

The Commission is proposing to amend § 20.1003, § 20.1201(a)(2)(ii), and § 20.1201(c).

Section 20. 1003 - Definitions.

In § 20.1003 Definitions, the definition of shallow-dose equivalent would be revised to delete the words “averaged over an area of 1 square centimeter.” The purpose of these words was to specify the area over which the dose to the skin was to be measured or calculated for comparison to the limit. The proposed revision to permit averaging over 10 square centimeters for measuring and recording SDE would be found in § 20.1201(c), along with other procedural requirements.

Section 20. 1201 - Occupational Dose Limits For Adults.

Section 20.1201, Occupational Dose Limits for Adults, would be changed in two places. Section 20.1201 (a)(2)(ii) would be changed to make it clear that the SDE limit of 50 rem (0.5 Sv) is the dose limit to the skin of any extremity as well as the skin of the whole body. The Commission believes that this specification makes it clear that the only dose limit for the extremities is a SDE limit on the dose delivered at a depth of 0.007 cm (7 mg/cm²), not a deep dose limit.

Section 20.1201(c) would be amended to specify that the assigned SDE must be the dose averaged over the 10 contiguous square centimeters of skin receiving the highest exposure. This is the significant change proposed in this rulemaking.

Note that the NCRP made recommendations regarding limiting 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 the proposed skin dose limit, and the existing limit for dose to the lens of the eye, are adequate to control DRP doses to these areas.

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

The NRC staff has elected to retain the units rem and Sievert for the skin dose limit. According to data published in reports of the International Commission on Radiation Protection, 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 units of rem (Sv) would be conservative and would have the advantage that all of the dose limits would be in the same units. The Department of Energy, in its regulations, uses the rem and Sievert for SDE.

NCRP Statement No. 9 referred to NCRP Report No. 130 (NCRP 1999) for guidance on good practices, and recommended that in addition to numerical limits, observation of the exposed area of skin should be performed for four to six weeks whenever the DRP dose at a depth of 70 μm exceeds 10 rad (0.1 Gy) averaged over the most highly exposed 10 cm^2 of skin. The observational level of 0.1 Gy is well below the proposed limit of 0.5 Gy, and is essentially equivalent to the current skin dose limit, at which no clinically significant effects have ever been reported. For those reasons the NRC is not proposing to incorporate the NCRP recommendation into the proposed rule.

The objective of the rulemaking is to establish a uniform, risk-informed skin dose limit for all sources of SDE, including DRPs, and small area contamination that: trades a higher risk of occurrence of deterministic effects to the skin for a reduction in the risk of whole-body

stochastic effects; allows licensees to reduce whole-body exposures and nonradiological health risks such as heat stress to workers subject to unnecessary DRP monitoring; and provides a common limit for SDE from all external sources of ionizing radiation. The proposed rule also reduces the unnecessary regulatory burden on licensees for reporting skin exposures that have insignificant health implications.

The current statement of the skin and extremity dose limit, along with the current definition of SDE, requires that skin doses be averaged over 1 square centimeter. The proposed rule would permit averaging the SDEs delivered to the 10 most highly exposed, and contiguous, square centimeters. It is important to discuss the consequences of this proposed change in the context of different source geometries.

In the case of large-area exposures of the skin from surface contamination or other external sources, areas on the order of 10 square centimeters or more would be likely to receive a relatively uniform dose. There is little difference to be expected in recorded doses from the current requirement that would attempt to identify the most highly exposed 1 square centimeter and the new approach that would sum the SDE to the 10 highest exposed, adjacent square centimeters and divide by 10. The recorded doses would be identical for the large-area (10 square centimeters or more) exposures that form the great majority of skin dose events.

Under the proposed rule, exposed areas of the skin less than 10 square centimeters would be treated in a less restrictive manner. For example, a dose of 250 rem (2.5 Sv) to each of 2 square centimeters would result in a 50-rem (0.5 Sv) SDE when averaged over 10 square centimeters. A dose as high as 500 rem (5.0 Sv) would be permitted to 1 square centimeter and would be recorded as 50 rem (0.5 Sv) when averaged over 10 square centimeters. This

change would effectively permit higher doses to small areas of skin than currently permitted by regulations.

Although as previously noted, the Commission is proposing 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 would permit a reduction in the 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 lead to a reduction in overly conservative efforts to prevent skin contaminations, that will result in decreased stress and lower 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 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 current 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 proposed 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 exposure the proposed rule change is in effect a tenfold relaxation of the current limit and might 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 μ Ci-hr in the interim enforcement policy stated in IN 90-48. The 500 rem (5.0 Sv) to 1 square centimeter (worst case) is estimated to result in a 50 percent chance of an observable but transient effect. 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 are currently monitoring workers frequently during each work shift to prevent exceeding the interim 50 rem (0.5 Sv) reporting threshold for doses from DRPs. Industry estimated that up to 5 person-rem (0.05 person-Sv) of whole-body dose per outage could be attributed to this monitoring. Workers are either brought out of the workplace to be monitored, incurring nonproductive exit-entry dose, or technicians enter the restricted area to monitor workers for DRPs. The proposed, less restrictive, skin dose limit would eliminate the need to perform this DRP monitoring during work shifts for all but the highest activity DRPs¹,

¹For example, one recent event at a nuclear power plant involved a CO-60 DRP with an activity of about 75 mCi. The deep dose equivalent estimated from this particle (had it been on

especially those having a high gamma component. The possibility of some additional number of observable deterministic effects, such as a small break in the skin, is considered by the NRC to be justified by the reduction of the whole-body dose and associated stochastic risks from 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 proposed 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 that 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 skin dose to small areas that might permit more observable, transient, deterministic effects will also result in a less hazardous workplace and reduced whole-body occupational dose. The Commission considers this tradeoff to represent a substantial increase in worker protection. This represents a shift in emphasis toward a risk-informed approach that would possibly permit more frequent deterministic effects in order to avoid the physical stress and whole-body doses associated with monitoring workers and the use of protective measures. The NRC is specifically soliciting comments on the acceptability of this approach.

the skin) was calculated to be about 10 rem/hr per mCi. For particles in this activity range, the deep-dose equivalent (DDE) limit of 5 rem per year can be exceeded in less than 1 minute. The proposed skin dose limit could be exceeded in even less time.

III. Issue of Compatibility for Agreement States

Under the “Policy Statement on Adequacy and Compatibility of Agreement State Programs”, which became effective on September 3, 1997 (62 FR 46517), NRC program elements, including regulations, are assigned compatibility categories. In addition, NRC program elements can also be identified as having particular health and safety significance or as being reserved solely to the NRC.

Compatibility Category A includes those program elements that are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. An Agreement State should adopt Category A program elements in an essentially identical manner in order to provide uniformity in the regulation of agreement material on a nationwide basis.

Compatibility Category B includes those program elements that apply to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner.

Compatibility Category C includes those program elements that do not meet the criteria of Category A or B but represent essential objectives that an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis. An Agreement State should adopt the essential objectives of the Category C program elements.

Compatibility Category D includes those program elements that do not meet any of the criteria of Category A, B, or C above and, thus, do not need to be adopted by Agreement States for purposes of compatibility.

Health and Safety (H&S) includes program elements that are not required for compatibility (i.e., Category D) but that have been identified as having a particular health and safety role (i.e., adequacy) in the regulation of agreement material within the State. Although not required for compatibility, the State should adopt program elements in this category that embody the essential objectives of the NRC program elements because of particular health and safety considerations.

Compatibility Category NRC includes those program elements that address areas of regulation that cannot be relinquished to Agreement States pursuant to the Atomic Energy Act (AEA) or provisions of Title 10 of the Code of Federal Regulations. These program elements should not be adopted by Agreement States.

The proposed modifications to §§20.1003 and 20.1201, which contain definitions and basic radiation protection standards that are necessary to understand radiation protection concepts, are designated as compatibility Category A. Therefore, the Agreement State program element should be essentially identical to NRC's in order to provide uniformity in skin dose determinations on a nationwide basis.

These proposed amendments were provided to the Agreement States via the NRC Technical Conferencing Forum. As of 5/24/01, only one comment had been received from the States.

IV. Plain Language

The Presidential memorandum dated June 1, 1998, entitled "Plain Language in Government Writing" directed that the Government's writing be in plain language. This memorandum was published on June 10, 1998 (63 FR 31883). The NRC requests comments on the proposed rule specifically with respect to the clarity and effectiveness of the language

used. Comments should be sent to the address listed under the ADDRESSES heading of the preamble.

V. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104-113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless using such a standard is inconsistent with applicable law or is otherwise impractical. In this proposed rule, the NRC is modifying its definition of Shallow-dose equivalent. This action does not constitute the establishment of a standard that contains generally applicable requirements.

VI. Environmental Assessment: Finding of No Significant Environmental Impact: Availability

The NRC has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51 that this rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required.

An environmental assessment has determined that the proposed amendment addresses technical and procedural improvements in the provisions for determining by measurement or by calculation the dose to the skin for comparison to the skin dose limit for the whole body or for the extremities. None of the impacts associated with this rulemaking have any effect on any

places or entities outside of a licensed site. An effect of this proposed rulemaking is expected to be a decrease in the use of protective equipment used by nuclear power plant worker and others potentially exposed to skin contamination, to prevent the skin contaminations. No changes are expected in licensee programs and procedures designed to mitigate the production and spread of DRPs in the workplace and to prevent the unauthorized release of radioactive materials off site. It is expected that there would be no change in radiation dose to any member of the public as a result of the revised regulation. The proposed amendment is expected to result in a reduction in external occupational dose to workers onsite.

The determination of this environmental assessment is that there will be no significant offsite impact to the public from this action. However, the general public should note that the NRC is seeking public participation. The NRC has also committed to complying with Executive Order (E.O.) 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income populations," dated February 11, 1994. The NRC evaluated environmental justice for this environmental assessment and has determined that there are no disproportionate high and adverse impacts on minority and low-income populations. In the letter and spirit of E.O. 12898, the NRC is requesting public comment on any environmental justice considerations or questions that the public thinks may be related to this proposed rule but somehow were not addressed. E.O. 12898 describes environmental justice as "identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations." Comments on any aspect of the environmental assessment, including environmental justice, may be submitted to the NRC as indicated under the ADDRESSES heading.

The NRC has sent a copy of the environmental assessment and this proposed rule to every State Liaison Officer and requested their comments on the environmental assessment.

The draft environmental assessment is available for inspection at the NRC's Public Document Room, One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland. Single copies of this document are available as indicated in the ADDRESSES heading.

VII. Paperwork Reduction Act Statement

This proposed rule would decrease the burden on licensees reporting under Section 20.2202(b)(iii) on DRP and other small area skin overexposures. The public burden for this information collection is estimated to average 40 hours per request. Fewer than 10 reports have been received by the NRC over the past 12 years. Because the burden for this information collection is insignificant, Office of Management and Budget (OMB) clearance is not required. Existing requirements were approved by the OMB, approval number 3150-0114.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

VIII. Regulatory Analysis

The NRC has prepared a regulatory analysis for the proposed amendment. The analysis examines the benefits and impacts considered by the NRC. The regulatory analysis is available for inspection in the NRC Public Document Room, One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland. Single copies of the analysis are available as indicated in the ADDRESSES heading.

The Commission requests public comment on the analysis. Comments on the analysis may be submitted to the NRC as indicated under the ADDRESSES heading.

IX. Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the NRC certifies that, if adopted, this proposed rule would not have a significant economic impact on a substantial number of small entities. The anticipated impact of the proposed changes would not be significant because the revised regulation basically represents a continuation of current practice. The benefit of the proposed rule is that it would permit averaging doses to the skin over the most highly exposed 10 square centimeters, incorporate an NCRP recommendation for a less restrictive skin dose limiting procedure, and permit reduced use of protective equipment known to expose workers to work place stresses and unnecessary whole body radiation dose.

The NRC is seeking public comment on the initial regulatory flexibility certification. The NRC is seeking comment particularly from small entities as defined under the NRC's size standards in 10 CFR 2.810 as to how the proposed regulations would affect them and how the regulations may be implemented or otherwise modified to impose less stringent requirements

on small entities while still adequately protecting the public health and safety. Any small entity subject to this regulation that determines that because of its size it is likely to bear a disproportionate adverse economic impact should offer comments that specifically discuss the following items:

(a) The licensee's size and how the proposed regulation would result in a significant economic burden or whether the resources necessary to implement this amendment could be more effectively used in other ways to optimize public health and safety, as compared to the economic burden on a larger licensee;

(b) How the proposed regulation could be modified to take into account the licensees' differing needs or capabilities;

(c) The benefits that would accrue, or the detriments that would be avoided, if the proposed regulation were modified as suggested by the licensee;

(d) How the proposed regulation, as modified, could more closely equalize the impact of NRC regulations or create more equal access to the benefits of Federal programs as opposed to providing special advantages to any individual or group; and

(e) How the proposed regulation, as modified, would still adequately protect the public health and safety.

The comments should be sent to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemaking and Adjudications Staff. Hand-deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:30 a.m. and 4:15 p.m. on Federal workdays.

X. Backfit Analysis

Although the NRC has concluded that the changes being proposed constitute 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 proposed rule meets one of the exceptions listed in § 50.109(a)(4). This proposed rule meets the exception at § 50.109(a)(4)(iii) in that it is redefining 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, the implementation of this proposed rule is expected to result in a substantial increase in worker industrial safety.

Section II, Summary and Discussion of the Proposed Changes, discusses the proposed changes to the definition of shallow-dose equivalent (SDE) and the provision for averaging SDE over the most highly exposed 10 square centimeters. This change would, in effect, raise the skin dose limit for discrete radioactive particles (DRPs) on or near the skin and for small-area ($< 1.0 \text{ cm}^2$) contaminations. This revision makes it possible for licensees to measure or calculate skin doses for comparison to the 50-rem (0.5 Sv) limit that when divided by 10, result in dose values according to NCRP that more appropriately reflect the risk associated with small area exposures. The increased limit in the case of DRPs will remove 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 component. This reduced monitoring will eliminate most of the whole body dose and stochastic risk associated with monitoring performed to avoid exceeding the current more restrictive skin dose limit. In addition, the relaxed skin dose limit,

based on NCRP recommendations, should make it clear that the consequences of transient skin contamination are less significant than the radiological and nonradiological risks incurred by workers as a result of licensee efforts to avoid skin contaminations. The overly conservative use of multiple layers of protective clothing and other devices worn to prevent skin contamination cause exposure to nonradiological hazards such as heat stress, as well as reducing worker efficiency estimated by industry to be as much as 15-25 percent which, in turn, increases whole-body dose. Licensees will be able to choose to use less protective gear at the cost of more frequent skin contamination, but with the benefit of less physical stress and reduced whole-body dose to workers.

In conclusion, the Commission believes that the proposed changes constitute a reduction in unnecessary regulatory burden that redefines the level of adequate protection and that should result in a substantial increase in worker safety. The proposed changes are therefore the type of change for which a backfit analysis is not required under § 50.109(a)(4)(iii).

List of Subjects in 10 CFR Part 20.

Byproduct material, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Penalty, Radiation protection, Reporting and recording requirements, Source material, Special nuclear material, Waste treatment and disposal.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 553; the NRC is proposing to adopt the following amendments to 10 CFR Part 20.

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 ($7\text{mg}/\text{cm}^2$).

* * * * *

3. In § 20.1201 the introductory text of paragraph (a)(2), and paragraphs (a)(2)(ii) and (c) are revised to read as follows:

§20.1201 Occupational Dose Limits for Adults

(a) * * *

(2) The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities, which are:

* * * * *

(ii) A shallow - dose equivalent of 50 rem (0.5 Sv) to the skin of the whole body or to the skin of any extremity.

* * * * *

(c) The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens dose equivalent, and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the

occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

* * * * *

Dated at Rockville, Maryland, this ____ day of _____, 2001.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,
Secretary of the Commission.