July 5, 2001

MEMORANDUM TO: Michael T. Lesar, Chief
Rules and Directives Branch
Division of Administrative Services
Office of Administration

FROM: William D. Beckner, Acting Chief ***/RA/ Signed by W. Beckner***
Generic Issues, Environmental, Financial
and Rulemaking Branch
Division of Regulatory Improvement Programs
Office of Nuclear Reactor Regulation

SUBJECT: IMPLEMENTATION OF COMMISSION ACTION: PROPOSED RULE ON REVISION OF THE SKIN DOSE LIMIT (WITS NO.: 199000178)

By memorandum dated June 22, 2001, the Secretary of the Commission indicated that the Commission (with all Commissioners agreeing) has approved the publication of the proposed rule for public comment on Revision of the Skin Dose Limit set out in SECY-01-0096.

Please implement the Commission's action by arranging for publication of the attached proposed rule in the Federal Register.

Also, attached is a marked-up copy of those pages from the Federal Register notice showing Commission-requested changes for transmittal to the Office of the Secretary (SECY). We also noted the need for several additional editorial changes and have also included marked up pages to show those changes.

Also attached is a Congressional letter package for transmittal to the OCA.

In addition, attached is a copy of the Regulatory Analysis for transmittal to the PDR.

Please note that SECY should receive the Federal Register notice in sufficient time to allow for its transmittal to the Office of the Federal Register by no later than July 13, 2001.

Attachments:
1. FR Notice + 5 Copies & Diskette
2. Marked-up Pages of FR Notice
3. Congressional Letter Package
4. Marked-up Press Release
5. Regulatory Analysis

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ATTACHMENT 1

FEDERAL REGISTER NOTICE

[7590-01-P]

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. The regulatory analysis and the environmental assessment may be accessed via the NRC's Agencywide Documents Access and Management System (ADAMS) on the internet at http://www.nrc.gov/NRC/ADAMS/index.html.

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 an insignificant health detriment. Under existing provisions in NRC regulations, several of these contamination events have resulted in overexposures, as well as enforcement actions, with the result that workers could not be assigned work in radiation areas for the balance of the year. The consequences of these overexposures were not commensurate with the actual health detriment.

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

In 1991, the NRC revised 10 CFR Part 20 and its occupational dose limit for the skin of the whole body to 50 rem (0.5 Sv) SDE per year to prevent deterministic effects (56 FR 23360; May 21, 1991) 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 cm^2 is intended to apply to a relatively uniform dose to a larger area of skin than that usually exposed by DRPs and was intended to prevent deterministic damage to the skin. Because this limit was considered by the NCRP to be overly conservative for DRPs on or very near the skin, the NRC announced an interim enforcement discretion policy in Information Notice (IN) 90-48, "Enforcement Policy for Hot Particle Exposures" (55 FR 31113; July 31, 1990), that addressed reporting and mitigation if a DRP dose exceeded the existing 50 rem over 1 cm^2 limit, and enforcement action for overexposures would be taken if the DRP beta emission exceeded 75 μCi-hrs (300-500 rads). To avoid DRP doses greater than 50 rem (0.5 Sv) and the resulting reporting requirement, licensees monitor workers frequently during the work shift for DRP contamination. 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 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 cm^2 as a program design guideline or action level, and a limit of 1000 rads (10 Gy) per 1 cm^2 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 cm^2 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 cm^2 was in large part to reduce the additional external dose incurred by plant staff from frequent monitoring to avoid having to report a DRP dose that exceeded the existing 50-rem (0.5 Sv) skin dose limit. If more than 90 percent of DRPs are off the skin and irradiating a relatively large area, the existing skin dose limit would be controlling and the constraint would only rarely be used. The NRC staff concluded that little relief from monitoring dose would result from implementing the constraint and the 500 rad (5 Gy) limit. In a memorandum to the Commission dated October 27,1999 (COMSECY-00-0009) the staff explained why the constraint with a limit of 500 rads (5 Gy) would not accomplish this intended objective, and recommended further staff work to identify an effective regulatory approach. In an SRM dated March 16, 2000, the Commission directed the 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.” The NCRP recommended that the dose to skin at a depth of 70 μm (7 mg/cm^2) from hot particles on skin (including the ear), hair, or clothing be limited to no more than 50 rads (0.5 Gy) averaged over the most highly exposed 10 cm^2 of skin.

The averaging area of 10 cm^2, recommended by the NCRP, would permit treating both the case when a DRP is on the skin or a very small area of skin is contaminated, and the case when a DRP is on clothing and moving about exposing an area on the order of 10 cm^2 or more.

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

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

Dr. John Baum, Ph.D., an NRC consultant, reviewed the health effects implications of the NCRP recommendation. Dr. Baum wrote a technical paper that was published in the June 2001 issue (pp. 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 cm^2 could result in stochastic risks of < 3.3×10^{-7} fatal skin cancers and < 1.6×10^{-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 by Dr. Baum to be a 5 percent probability of erythema if all of the dose (500 rem) were delivered to an area of 2.5 cm^2, and a 50 percent probability that measurable dermal thinning would be observable if all of the dose were delivered to an area < 0.5 cm^2. 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 ^{60}Co or activated fuel DRPs located about 0.4 mm off the skin. A copy of this copyrighted article is available for viewing during the public comment period for this rulemaking at NRC's Public Document Room located in Rockville, MD.

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/cm^2), 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 rads (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 exposures, 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 μCi-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 DRPs[1], 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

[1]For 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 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.

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 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.

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 workers 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 workplace 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 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 a reduction in 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 mg/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.

ATTACHMENT 2

MARKED-UP PAGES OF FEDERAL REGISTER NOTICE

[7590-01-P]

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. The regulatory analysis and the environmental assessment may be accessed via the NRC's Agencywide Documents Access and Management System (ADAMS) on the internet at http://www.nrc.gov/NRC/ADAMS/index.html.

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 an insignificant health detriment. Under existing provisions in NRC regulations, several of these contamination events have resulted in overexposures, as well as enforcement actions, with the result that workers could not be assigned work in radiation areas for the balance of the year. The consequences of these overexposures were not commensurate with the actual health detriment.

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

In 1991, the NRC revised 10 CFR Part 20 and its occupational dose limit for the skin of the whole body to 50 rem (0.5 Sv) SDE per year to prevent deterministic effects (56 FR 23360; May 21, 1991) 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 cm^2 is intended to apply to a relatively uniform dose to a larger area of skin than that usually exposed by DRPs and was intended to prevent deterministic damage to the skin. Because this limit was considered by the NCRP to be overly conservative for DRPs on or very near the skin, the NRC announced an interim enforcement discretion policy in Information Notice (IN) 90-48, "Enforcement Policy for Hot Particle Exposures" (55 FR 31113; July 31, 1990), that addressed reporting and mitigation if a DRP dose exceeded the existing 50 rem over 1 cm^2 limit, and enforcement action for overexposures would be taken if the DRP beta emission exceeded 75 μCi-hrs (300-500 rads). To avoid DRP doses greater than 50 rem (0.5 Sv) and the resulting reporting requirement, licensees monitor workers frequently during the work shift for DRP contamination.~~, thus incurring~~ This results in additional external dose either to the workers, who incur additional exposure time in exiting and reentering the restricted area, or ~~and~~ to the radiation protection staff, who must enter the restricted are 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 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 cm^2 as a program design guideline or action level, and a limit of 1000 rads (10 Gy) per 1 cm^2 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 cm^2 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 cm^2 was in large part to reduce the additional external dose incurred by plant staff from frequent monitoring to avoid having to report a DRP dose that exceeded the existing 50-rem (0.5 Sv) skin dose limit. If more than 90 percent of DRPs are off the skin and irradiating a relatively large area, the existing skin dose limit would be controlling and the constraint would only rarely be used. The NRC staff concluded that little relief from monitoring dose would result from implementing the constraint and the 500 rad (5 Gy) limit. In a memorandum to the Commission dated October 27,1999 (COMSECY-00-0009) the staff explained why the constraint with a limit of 500 rads (5 Gy) would not accomplish this intended objective, and recommended further staff work to identify an effective regulatory approach. In an SRM dated March 16, 2000, the ~~The~~ Commission directed the staff to contract with the NCRP to provide additional technical support on this issue ~~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/cm^2) from hot particles on skin (including the ear), hair, or clothing be limited to no more than 50 rads (0.5 Gy) averaged over the most highly exposed 10 cm^2 of skin.

The averaging area of 10 cm^2, recommended by the NCRP, would permit treating both the case when a DRP is on the skin or a very small area of skin is contaminated, and the case when a DRP is on clothing and moving about exposing an area on the order of 10 cm^2 or more.

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

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

Dr. John Baum, Ph.D., an NRC consultant, reviewed the health effects implications of the NCRP recommendation. Dr. Baum wrote a technical paper that was ~~will be~~ published in the June 2001 issue (pp~~gs~~. 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 cm^2 could result in stochastic risks of < 3.3×10^{-7} fatal skin cancers and < 1.6×10^{-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 by Dr. Baum to be a 5 percent probability of erythema if all of the dose (500 rem) were delivered to an area of 2.5 cm^2, and a 50 percent probability that measurable dermal thinning would be observable if all of the dose were delivered to an area < 0.5 cm^2. 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 ^{60}Co or activated fuel DRPs located about 0.4 mm off the skin. A copy of this copyrighted article is available for viewing during the public comment period for this rulemaking at NRC's Public Document Room located in Rockville, MD.

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/cm^2), 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 rads (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 exposures, 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 μCi-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 DRPs[2], 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

[2]For 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 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.

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.

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 workers 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 workplace 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 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 a reduction in ~~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 mg/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

ATTACHMENT 3

CONGRESSIONAL LETTER PACKAGE

The Honorable Joseph I. Lieberman, Chairman
Subcommittee on Clean Air, Wetlands,
Private Property and Nuclear Safety
Committee on Environment and Public Works
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

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

The proposed amendment would in effect raise the current skin dose limit for the special cases of dose to the skin from small radioactive particles, and from contamination to small areas of skin. Current knowledge on the effects of radiation on the skin, obtained in part through NRC-sponsored research at Brookhaven National Laboratory (BNL), indicates that the current skin dose limit, when applied to small area skin contaminations, adequately protect the skin from harmful effects of radiation exposure. However, the monitoring to assure compliance serves to increase radiation exposure, which means that the negative consequences more than outweigh the benefits provided by this level of protection. The NRC intends to resolve this situation by raising the dose limit for small area skin contaminations to a level that is sufficient to avoid the negative consequences, but at the same time keeps the risks of such exposures to levels that are not much higher than they are under the current rule. The intent of this amendment is to discourage licensees from using conservative measures to prevent small-area skin doses at the cost of incurring greater risk from external dose and occupational stress.

The proposed rule would permit averaging of small area skin doses over 10 square centimeters rather than 1 square centimeter for judging compliance with the skin dose limit. This change expected to result in a substantial increase in worker protection and a cost-effective reduction in unnecessary regulatory burden. The approach was recommended by the National Council on Radiation Protection and Measurements (NCRP) and is consistent with the regulations of the Department of Energy. The rulemaking is considered to be consistent with the Commission's intent to promulgate risk-informed regulations.

The Commission is issuing the proposed rule for public comments.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure: *Federal Register* Notice

cc: Senator George V. Voinovich

The Honorable Joseph I. Lieberman, Chairman
Subcommittee on Clean Air, Wetlands,
Private Property and Nuclear Safety
Committee on Environment and Public Works
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The Honorable Harry Reid, Chairman
Subcommittee on Energy and Water Development
Committee on Appropriations
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

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Office of Congressional Affairs

Enclosure: *Federal Register* Notice

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Committee on Appropriations
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NAME	DRathbun	
DATE	/ /01	

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The Honorable Joe Barton, Chairman
Subcommittee on Energy and Air Quality
Committee on Energy and Commerce
United States House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

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

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Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure: *Federal Register* Notice

cc: Representative Rick Boucher

The Honorable Joe Barton, Chairman
Subcommittee on Energy and Air Quality
Committee on Energy and Commerce
United States House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

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

The proposed amendment would in effect raise the current skin dose limit for the special cases of dose to the skin from small radioactive particles, and from contamination to small areas of skin. Current knowledge on the effects of radiation on the skin, obtained in part through NRC-sponsored research at Brookhaven National Laboratory (BNL), indicates that the current skin dose limit, when applied to small area skin contaminations, adequately protect the skin from harmful effects of radiation exposure. However, the monitoring to assure compliance serves to increase radiation exposure, which means that the negative consequences more than outweigh the benefits provided by this level of protection. The NRC intends to resolve this situation by raising the dose limit for small area skin contaminations to a level that is sufficient to avoid the negative consequences, but at the same time keeps the risks of such exposures to levels that are not much higher than they are under the current rule. The intent of this amendment is to discourage licensees from using conservative measures to prevent small-area skin doses at the cost of incurring greater risk from external dose and occupational stress.

The proposed rule would permit averaging of small area skin doses over 10 square centimeters rather than 1 square centimeter for judging compliance with the skin dose limit. This change expected to result in a substantial increase in worker protection and a cost-effective reduction in unnecessary regulatory burden. The approach was recommended by the National Council on Radiation Protection and Measurements (NCRP) and is consistent with the regulations of the Department of Energy. The rulemaking is considered to be consistent with the Commission's intent to promulgate risk-informed regulations.

The Commission is issuing the proposed rule for public comments.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure: *Federal Register* Notice

cc: Representative Rick Boucher

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ATTACHMENT 4

PRESS RELEASE

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ATTACHMENT 5

REGULATORY ANALYSIS

REGULATORY ANALYSIS OF
REVISIONS TO 10 CFR 20

Unified Skin Dose Limit

March 26, 2001

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1. Statement of the Problem

Since 1985, many nuclear power plants have detected contamination of individuals and their clothing by small, usually microscopic, highly radioactive beta or beta-gamma emitting particles with relatively high specific activity (James, 1988; Kelly and Gustafson, 1994). These particles, known as "discrete radioactive particles" (DRPs) and sometimes as "hot particles," most commonly contain ^{60}Co from corrosion products or fission products from leaking fuel. A unique aspect of DRPs on or near the skin is that very small amounts of tissue can be exposed to very large, highly nonuniform doses. These intense local irradiations may produce deterministic effects such as reddening, ulceration, or necrosis of small areas of skin, but the stochastic risk of inducing skin cancer due to a DRP exposure is negligible. The skin cancer risk from a DRP dose at the proposed limit of 50 rem averaged over 10 cm^2 is estimated to be 4 orders of magnitude lower than the cancer risk associated with a whole-body dose of 5 rems.

In addition to power reactors, DRPs have been occasionally encountered at facilities that manufacture radioactive sources for calibration, medical devices, industrial gauges, and similar devices that contain radioactive materials. Highly localized skin contaminations are also encountered at facilities that manufacture or use high specific activity liquids, such as nuclear medicine, radio-pharmacies, and radio-pharmaceuticals manufacturers. Although not technically "DRPs", such localized contaminations share many of the key characteristics exhibited by DRPs, mainly highly localized intense radiation fields from small to nearly microscopic sources on the skin.

2. Background

Prior to the revision of 10 CFR 20, the NRC issued Information Notice (IN) No. 90-48, "Enforcement Policy for Hot Particle Exposures" (NRC, 1990) containing a Commission approved policy statement. This statement indicated that enforcement discretion would be used in cases involving occupational doses to the skin from exposure to DRPs that exceed the skin dose limit in 10 CFR 20. IN 90-48 further stated that the provisions of this enforcement policy would be followed by the NRC staff until a new limit applicable to DRP exposure cases was established by revising 10 CFR 20.

IN 90-48 explained that, for DRP exposures to the skin, the staff would use a beta emission criterion of 75 uCi-hr (approximately 300-500 rad) for a DRP on the skin and a skin dose criterion of 0.5 Sv (50 rem) for a DRP off the skin averaged over one cm^2 for determining appropriate discretionary enforcement actions and appropriate severity levels. IN 90-48 stated that the enforcement policy did not change the limits of 10 CFR 20, the methods for determining compliance with those limits, or the notification and reporting requirements of 10 CFR Parts 19 and 20. Thus, exposures above 0.5 Sv (50 rem) were still reportable.

In 1991, the NRC revised Part 20 and its occupational dose limit for the skin of the whole body or to any extremity to 0.5 Sv (50 rem) averaged over one cm^2 per year to prevent deterministic effects (May 21, 1991; 56 FR 23360). This dose limit for the skin is contained in 10 CFR 20.1201 (2) (ii) (CFR, 2000) and is intended to prevent damage to relatively large areas of the skin that could compromise skin function or appearance. The *Federal Register* notice for the final rule stated that there would be a rulemaking to set limits for skin irradiated by DRPs. This proposed rule responds to that commitment.

In 1989 the National Council on Radiation Protection and Measurements (NCRP) issued report No. 106, Limit for Exposure to "Hot Particles" (NCRP, 1989) on the Skin, in which it recommended *"(1) A limit for exposure to hot particles be based on ensuring that acute deep ulceration of the skin be prevented and that this be accomplished by a limit based on the time integral of the beta particles emitted due to the activity of the particle in contact with the skin, and (2) Exposure to the skin from a "point" particle or a particle of unknown size but less than 1 mm in diameter be limited to 10^{10} beta particles emitted from the radionuclides contained in the particle. For the case where 1 beta particle is emitted per disintegration, this limit may be expressed as 10 GBq-s or 75 uCi-hr. For a particle for which the self absorption can be measured or calculated, the limit can be increased by the ratio of the beta particles emitted by the radionuclides divided by the beta particles emitted from the surface of the particle. Alternatively, the limit can be expressed as 10^{10} beta particles emitted from the surface of the particle."*

These recommendations were based on consideration of both stochastic (cancer) and deep ulceration (nonstochastic) risk estimates. At the proposed limit, the skin cancer mortality risk estimates were considered insignificant (about a factor of 2.3×10^{-6} lower than the deep

ulceration risk) and orders of magnitude below the observed risks of mortality from accidents in safe industries. It was also recognized by the NCRP that when small areas of skin involved in DRP irradiation are irradiated sufficiently to cause erythema and lesions which give the appearance of dry desquamation, such effects are temporary, are confined to an area of a few square millimeters and were not considered to be severe nonstochastic effects. Ulceration, dermal thinning and pigment changes in such small areas were also not considered to be severe nonstochastic effects.

The NCRP recommendations were for particles on the skin. However, the Council indicated that the circumstances in which skin is irradiated by DRPs not directly on the skin required further study. They also indicated that "*Additional research is occurring presently and should be continued on both the biological effects of hot particles and the dosimetry of hot particles. Results from this ongoing work may well eventually provide sufficient new information to further support these recommendations or to require their review at a later time*."

Therefore, before rulemaking could proceed, the staff determined that additional research to study the effects of DRPs both on and off the skin was needed to provide adequate information to form the technical basis necessary for rulemaking. The NRC contracted with Brookhaven National Laboratory (BNL) for this research. The research was completed in June l997 and published as NUREG/CR-6531, "Effects of Radioactive Hot Particle on Pig Skin" (Kaurin, et. al., 1997). This work was reviewed and commented on by numerous members of the NCRP, the International Commission on Radiological Protection and representatives of the nuclear power industry. The results of this work and other recent studies were considered by the NCRP Scientific Committee 86 which published Report 130, Biological Effects and Exposure Limits for "Hot Particles", in 1999 (NCRP, 1999).

NCRP Report 130 provided an extensive review and summary of the scientific literature on biological effects and dosimetry related to DRP exposures to skin and other organs. In this review the Council discusses the problems of dosimetry for particles on clothing. In the working environment a DRP on clothing may move relative to a specific skin site, and may be at a variable distance from the skin. Both of these factors will result in a more homogenous dose to a larger area of skin. The anticipated movement of a particle on clothing, relative to the skin would also make it difficult to identify the most highly exposed 1 cm^2 of skin and to quantify the

exposure. Therefore, a limit was derived that would take account of a range of potential geometries specific to DRP exposure that will prevent deep ulceration. To achieve this goal, the Council recommended: "*The dose at a depth of 70 μm on skin (including ear), hair or clothing be limited to no more than 0.5 Gy averaged over the most highly exposed 10 cm^2 of skin."*

When applied to DRPs, this limit is mathematically equivalent to the 10^{10} beta particles or 75 uCi-hr [2,775 kBq-hr] limit recommended by NCRP in Report 106, which is the current enforcement discretion limit, and to a limit of 500 rad (5 Gy) averaged over 1 cm^2. The limit is below the dose at which the probability for acute lesions is 50 percent for all the particle energies studied and reviewed by the NCRP. At this limit, the risk of a stochastic effect (skin cancer mortality) was estimated as 1.1×10^{-7}. It was recognized by the NCRP that small transient effects may occur, "*However, if a biological effect were to result from a hot-particle exposure near or exceeding the recommended limit, the result is an easily treated medical condition still involving extremely small 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."*

In March of 2001 the NCRP issued Statement No. 9 which addresses "Extension of the Skin Dose Limit for Hot Particles to Other External Sources of Skin Irradiation." In this document, the NCRP points out that a single radioactive particle in random motion relative to the skin could produce a dose distribution nearly equivalent to that from either distributed contamination on the skin or an external beam that exposed the same area. The main difference is that the instantaneous dose rate to a small area of skin near the source would be higher for a moving DRP or a very small beam than for uniform contamination or a uniform beam delivering the same total dose over the same area. For this reason the NCRP indicated that "the absorbed dose in skin at a depth of 70 μm from any external source of irradiation be limited to 0.5 Gy (50 rad) averaged over the most highly exposed 10 cm^2 of skin."

To minimize the probability that exposures from DRPs would result in doses that exceed current NRC guidelines, licensees have reduced the number of potential sources of cobalt DRPs, and conduct rigorous DRP exposure control programs. These include more frequent surveys, e.g., once every two hours (which increase health physics technician exposures), and personnel

monitoring checks (which increase the worker's whole-body dose) to avoid DRP exposures to the skin and to minimize the possibility of a reportable event. Considering the almost nonexistent deterministic effects that are being averted, any measurable whole-body doses attributable to monitoring workers for DRP contamination would not be considered as low as reasonably achievable (ALARA) and should be avoided.

In addition, personnel contaminated by DRPs or high specific activity drops of liquid could in many cases exceed the current regulatory skin dose limit of 50 rem/yr averaged over 1 cm^2 before decontamination is completed successfully. Such personnel would be required by current NRC regulations to stop all work that may lead to any additional occupational exposure for the remainder of the calendar year. Such an action is unnecessary in view of the minimal risk from such contaminations, and may have severe consequences on the person's employment position, including in some cases loss of a job.

3. Objectives of this Rulemaking

The statement of consideration published with the revised 10 CFR Part 20 (56 FR 23360, 1991) stated that the DRP issue would be resolved by rulemaking. The objective of this rulemaking is to provide a risk-based skin dose limit for all sources of shallow dose equivalent including DRPs and small area contaminations that: (a) trades a higher risk of occurrence of deterministic effects to the skin for a reduction in the risk of whole-body stochastic effects, (b) reduces the unnecessary burden on licensees for reporting exposures which have insignificant health implications, (c) aids in avoiding unnecessary whole-body exposures and possible additional non-radiological health risks such as heat stress to workers, and (d) provides a common limit for shallow dose equivalent from all external sources of exposure to the skin.

4. Alternatives

Two alternatives are considered:

Alternative 1 - Make no change to Part 20.

This is the no-action option (the status quo). It is the alternative that is used for comparing costs and benefits with the recommended alternative two below.

Alternative 2 - Propose a shallow dose equivalent limit in Part 20.1201 for skin of 50 rem (0.5 Sv) averaged over the 10 square centimeters of skin receiving the highest exposure.

To determine the preferred alternative, the costs and benefits of each are evaluated and differences in net costs/yr and total costs discounted over a period of 20 years are estimated. An estimated 104 nuclear power units and a few materials licensees would be affected by the proposed changes. Information derived from two EPRI Reports (James, 1988; and Kelly & Gustafson, 1994), one joint EPRI/NEI report (ERS, 1997), NRC documents (Karagiannis and Hagemeyer, 2000; NRC, 1997); inspection reports in the NMED Database (NMED, 2001), and through personal contacts with several plants and knowledgeable individuals were used in arriving at the estimates below.

James (1988) surveyed sixty-one plants for incidence of DRPs. Nineteen of these reported finding fuel DRPs. Twenty-nine plants reported finding only activation DRPs. Kelly and Gustafson (1994) surveyed all nuclear utilities and nuclear power plants operating in 1991. Ninety-nine percent of the operating power reactors (71 sites/109 reactor units) responded to the survey. This is an exceptionally high participation rate and is indicative of the importance that utilities placed on collecting and documenting the industry's experience with DRPs. Of the 15,068 DRPs discovered during the period covered by this report only 0.2% involved both a skin contamination and a DRP of activity $\succ$ 1 uCi. Since 1991 plants have improved operations significantly. As a result only two or three plants are currently experiencing significant DRP problems.

5. Consequences

1) Routine area surveys of the workplace are conducted for DRPs and contamination during operations and shutdowns at nuclear power plants as part of a DRP and contamination-control program. The number of such surveys needed should not change under the new rule. These surveys are made to prevent spread or release of contamination and even particles well below the activity value of concern for the dose limit will continue to be searched for.

2) Following the discovery of DRPs during maintenance operations at a nuclear power plant, follow-up surveys are routinely employed to ensure that particles have been adequately controlled to prevent their spread to other locations, and to prevent workers from exceeding administrative and regulatory dose guidelines. The frequency, number and extent of these surveys are a function of particle activity, and plant and regulatory action levels.

With the proposed dose limit one could average the dose over an area of 10 cm^2 rather than the currently used 1 cm^2, leaving the skin dose limit of 50 rem/yr (0.5 Sv/yr) unchanged. For DRPs on the skin, this is mathematically equivalent to raising the current dose limit by a factor of 10, from 50 rem (0.5 Sv) averaged over the most highly exposed 1 cm^2 area of skin to 500 rem (5 Sv) averaged over the most highly exposed 1 cm^2 area of skin. The new dose limit would in effect be 50 rem (0.5 Sv) averaged over the most highly exposed 10 cm^2 of skin. This will make it reasonable to use longer working periods or "stay times" in those jobs likely to experience DRP or contamination problems, and yet not exceed the dose limit. These stay times are typically set at 2-3 hours under the current policy. Assuming the stay times are extended at least a factor of three, they will typically be more than six hours, which would essentially remove the need for a worker to leave a job to check for DRPs or contamination. Or, the number of times a surveyor will need to enter the area to check workers for DRPs will be fewer, and may be zero for most jobs. Thus, whole-body dose, added labor time, and costs should all be reduced significantly under the new regulation.

3) Protection from DRPs and contamination tends to increase the need for an extra layer of protective clothing. Any reduction of needs for protective clothing will also reduce the very important, related non-radiological hazards such as heat stress risks, and will increase the efficiency of workers. In addition, clothing is more often discarded as waste rather than washed if DRPs or contamination are present. However, under the new regulation, we expect costs for clothing, laundering and surveying to be reduced significantly since these costs are dictated primarily by contamination control needs. These will be less critical when dose from contamination can be averaged over 10 cm^2.

4) Nuclear Power Plant Jobs Likely to be Affected by DRPs:

a) During refueling operations at nuclear power plants, the reactor cavity is decontaminated. This operation is normally on the critical path and, for plants experiencing DRP problems, to avoid exceeding DRP administrative action levels, workers leave the work area to check for DRPs or contamination, This leads to additional external whole-body dose, labor costs and power costs. The frequency of these special checks is expected to decrease by about a factor of about three for the few plants that experience this problem under the new regulation. This will result in significant savings of whole-body dose and labor costs.

b) In nuclear power plants, work on the Residual Heat Removal (RHR) heat exchanger and valves is likely to result in DRP releases if the plant has had significant fuel failures, or problems with activated cobalt particles. Workers must leave the job periodically to check for DRPs or contamination in order to avoid exceeding the administrative action levels and limits. The new regulation is expected to require fewer such extra entries with resulting savings in both whole-body dose and labor costs.

c) In PWR plants, steam generator maintenance is sometimes a critical path job and is a significant source of DRPs and contamination for plants which have experienced significant fuel failures or activated cobalt particles. The extra time and whole-body dose caused by needed checks for DRPs or contamination

under the existing policy will be reduced under the new regulation. The reduction in extra entries is expected to yield significant dose and cost savings.

d) In PWR plants, maintenance of excore detectors is a potential source of DRPs and contamination. Workers are often required to leave the job to check for DRPs on their clothing thus causing extra whole-body dose, and labor costs. Since this job is often on the critical path, large additional costs can result from the extended outages. The need for these checks is expected to be less under the new regulation.

e) Refueling operations are generally on the critical path and are occasionally a source of DRP exposures. Delays due to the need for periodic checks for DRPs and contamination can lead to significant whole-body dose, labor and power costs. These extra costs are expected to be reduced under the new regulation.

f) Decontamination of the upper internal lift rigs is another potential source of DRPs and contamination. Workers must periodically leave the job to check for DRPs or contamination, leading to additional whole-body dose and labor costs. Fewer such entries are expected under the new regulation.

g) Decontamination of refueling equipment is an important source of DRPs and contamination for plants with significant fuel failures or activated cobalt problems. Workers must leave the job to check for contamination, thereby increasing their whole-body dose and time on the job. Under the new regulation fewer reentries will be needed, thus saving dose and labor costs.

5) DRP and contamination control training is needed to ensure workers are familiar with the characteristics, controls and measurement requirements. Under the new regulation the time spent on training is not expected to change significantly.

6) Administrative activities related to DRP activities and personal contamination incidents will be reduced due to fewer required reports and less probability of over-exposures.

7) To assess doses to workers exposed near the dose or administrative limit, or to evaluate the characteristics of DRPs, lab analyses are often required. Although only a few percent of exposures need these analyses, even fewer will be needed under the new regulation since shallow dose equivalent will be averaged over 10 cm^2 rather than over 1 cm^2 as required in the current regulation. For spots of highly concentrated activity or DRPs, this is an effective increase of about a factor of ten in dose permitted to the most highly exposed 1 cm^2 of skin. This will make it much less likely that a person will approach the limit and hence need a careful assessment.

8) First year NRC costs to implement the new regulation will be modest.

9) Licensees will incur minimal costs to change procedures, train workers, and implement the new regulations.

6. Value Impact Analysis

The value (benefit) and impact (cost) of the proposed changes are estimated in this section. These values represent the best estimated changes from the current baseline. From reportable events (NMED, 2001) and existing reports (Karagiannis & Hagemeyer, 2000), it is known that existing DRP rules as implemented are effective in protecting the licensee's employees from exposure to localized skin exposures. For example, during the period 1990-1999 only 11 skin and extremity exposures were reported in the NRC's Radiation Exposure Information and Reporting System (Karagiannis & Hagemeyer, 2000) that exceeded 500 rem averaged over 1 cm^2, and another 30 exceeded 50 rem averaged over 1 cm^2. However, these improvements have been made at considerable cost in dose and monetary units. After an extensive survey of 105 nuclear power plants Kelly and Gustfason (1994) indicated overall cost impacts of from $200,000 to $2,000,000 annually per site. The impacts most commonly cited as resulting from DRPs were:

- "*Increased whole body exposures due to increased stay time (i.e. increased radiological controls resulting in slower work progress).*
- *Increased time and manpower to do a job, thereby increasing costs.*

- *Heat stress due to additional heavy clothing requirements.*

- *Other physiological and psychological stresses on workers."*

The survey also concluded: "As an overall average among the responding sites, DRPs contributed to a 28% overall loss in productivity (28% increase in labor requirements). However, two sites reported an actual comparison, based on identical work, with and without DRP controls. Based on those scenarios alone, the sites experienced an estimated loss of 33%-55% in worker productivity due to DRP control measures."

"Fifty-four percent of the respondents indicated that the implementation of DRP control measures increases the whole body exposure of the individual radiation worker in specific DRP zones. Moreover, 38% indicated that there is an increase in total person-rem due to increased stay times in radiation fields in general."

"Additional DRP control measures can result in a physiological impact; existing utility documentation suggests that this is due primarily to heat stress as a result of the additional PCs (e.g.; double coveralls) and increased respiratory protection practices. Therefore, the magnitude of the impact is directly proportional to the DRP control measures implemented."

"Twenty-four percent of the respondents noted that critical path was affected (i.e.; longer outages). This was due to (and accompanied by) decreased worker efficiency."

"Two thirds of the respondents reported no impact from the implementation of IE Notice 90-48. The Notice reduced enforcement actions but not the requirement for treating exposures in excess of 10CFR20 exposure limits as overexposure. Thus, utilities either determined that the Notice did not provide significant enough relief to warrant change, or the current procedures were more conservative and, thus, more preferable. However, 28% reported some procedural changes incidental to the Notice."

These proposed changes in the application of the skin dose limits (i.e. averaging dose over 10 cm^2 instead of averaging over 1 cm^2) are a redefinition of acceptable DRP protection guidelines. They are an attempt to bring into better balance the risks due to whole-body exposures that cause stochastic risks, and localized skin exposures that lead to an increased possibility of skin effects. The deterministic risks in both alternatives are sufficiently small that there is no attempt to quantify added value or impact on employee health. The values and impacts of the changes are all related to potential whole-body dose saving or added cost in operating an effective radiation control program at licensee sites. In making the estimates, the following general assumptions were made

- The changes affect 104 power reactor licensees.

- Although some non-power-reactor licensees would be affected, their operations are not likely to be affected significantly by the changes. The costs and benefits to these licensees are small compared to those for the power plants and, therefore, are only considered qualitatively, and in section 7 on sensitivity analyses.

- Estimated labor cost is $150/hr for a power reactor licensee including all overhead and fringe benefit costs (NRC, 1997).

- NRC labor cost is estimated at $70/hr (NRC, 1997).

- Approximately 200,000 power reactor workers/yr are currently monitored for radiation exposure. About half the monitored workers are exposed and receive a measurable dose. Of those exposed to a measurable dose, all are potentially exposed to DRPs.

- The average plant has a remaining lifetime of 20 years.

- The impact and value of future doses and costs were discounted at 7%/yr using discrete (annual) discounting (NRC, 1997).

- The monetary value of dose avoided at nuclear power plants is estimated at approximately $10,000/person-rem collective dose based on recent nuclear power plant experience. Based on an October 2000 survey (Miller, 2001), valuations of dose avoided employed at U. S. nuclear power plants ranged from $5,000 /person-rem to $33,000/person-rem with a median value of $10,000/person-rem and an average of $12,682/person-rem. For these evaluations a value of $10,000/person-rem was employed. This value is significantly higher than the health effects value of $2,000/person-rem recommended in NUREG/BR-0184 (NRC, 1997). The difference is caused by high doses to maintenance workers. To avoid these worker doses approaching or exceeding dose limits, plants often hire extra workers for some high-dose jobs.

- Replacement power costs are $15,000/hr when critical path time is extended. This value depends on assumptions concerning plant capacity factors and was the approximate value that could be justified in 1993 (NRC, 1997).

These assumptions are made based on NRC data and on information obtained from industry experts on radiation protection, licensees, reports of the Electric Power Research Institute in Palo Alto, California and the Nuclear Energy Institute in Washington, D.C. The estimates and specific assumptions and rationale used are presented below item by item following the same sequential order as the discussion in Section 4. A summary of the overall values and impacts for nuclear power plants is presented at the end of this section. Alternate assumptions were used to test the sensitivity of results to the above values. Results from these analyses are summarized in Section 7 below.

6.1 Routine Surveys

Concerns over potential DRP or contamination exposures and spread of particles or contamination to clean areas leads to a need for additional routine area surveys beyond that which is necessary to prevent spread of DRP contamination. For this report it is assumed that approximately 4.9 hours/yr are spent doing surveys specifically for DRPs, or as supplements to normal contamination surveys because of the concerns for DRPs. On average these surveys are assumed to occur in radiation fields delivering 0.1 mSv/hr (10 mrem/hr) to the surveyors. It is assumed that all 104 nuclear power plant licensees do and will continue to do these surveys. The number of area surveys needed to prevent spread of contamination is assumed to remain constant under the new rule. The number of extra area surveys performed to prevent DRP contamination of workers will be reduced somewhat. Key specific assumptions in the analysis of this attribute are:

- 104 licensees at risk
- 4.9 hours survey time required/yr
- 10 mrem/hr average dose rate
- 100 percent of licensees need to do routine surveys each year
- 20 percent fewer routine surveys will be needed under new rule

With these assumptions the total current industry costs/yr would be

[(4.9 hr x 10 mrem/hr x $10/mrem) + (4.9 hr x $150/hr)]/licensee x (104) licensees = $127,400

Under the new rule, costs/yr are estimated at 80 percent of those for the current rule or

0.8 x $127,400 = $101,920

The net savings per year for all licensees combined under the new rule would be

$127,400 - $101,920 = $25,480

Assuming an average plant lifetime of 20 years, and employing a 7 percent discount rate for future doses and costs, the total discounted savings over 20 years would be $270,088 under the new rule. Annual dose savings of about 0.01 Sv (1 rem) are estimated.

6.2 Follow-up Surveys

This change will reduce the number of follow-up surveys required to meet plant and regulatory guidelines on exposure to DRPs. Plants currently employ follow-up surveys whenever they discover DRPs during routine or job-specific surveys. It is assumed that, on average, each year 1 percent of plants at risk (approximately 1) discover a significant number of particles that require follow-up surveys that are in addition to those surveys normally required for contamination control. It is assumed that the threshold activity for these additional surveys will increase a factor of two to ten, due to the larger area permitted for dose averaging, following implementation of the proposed regulation. Based on published distributions of activities typically found in particles at nuclear power plants, it is assumed that the higher dose reporting level will lead to the need for 34 percent fewer follow-up surveys. It is further assumed that these surveys currently require approximately 7 hours for technicians working in fields having average dose rates of about 0.1 mSv/hr (10 mrem/hr). Key specific assumptions in the analysis of this attribute are:

- 104 licensees at risk
- 7 hours survey time required/yr
- 10 mrem/hr average dose rate
- 1 percent of licensees need to do additional follow-up surveys each year
- 34 percent fewer follow-up surveys are needed under the proposed rule

With these assumptions the total current industry costs/yr would be

[(7 hr x10 mrem/hr x $10/mrem) + (7 hr x $150/hr)]/licensee x (0.01 x 104) licensees = $1,820.

Under the new rule, costs/yr are estimated at 66 percent of those for the current rule or

0.66 x $1,820 = $1,201

The net savings per year for all licensees combined under the new rule would be

$1,820 - $1,201 = $619.

Assuming an average plant lifetime of 20 years, and employing a 7 percent discount rate for future doses and costs, the total discounted savings during 20 years would be $6,559 under the new rule. Annual dose savings of about 0.25 mSv (25 mrem) are estimated.

6.3 Nuclear Power Plant Jobs Likely to be Affected by DRPs

The occurrences of DRP problems at nuclear power plants are related to work that breaches the primary system. Areas where DRPs and radioactive material contamination are found include fuel transfer pools, cask wash-down pits, steam generator cavities, fuel pits, reactor water clean-up rooms, and in laundry rooms. Jobs in which DRPs or contamination are likely to be found include work on control rod drives, the residual heat removal heat exchanger, cutting thermal shields, work on incore instrumentation spent fuel cleanup schedules, irradiated waste handling (fuel channel) and consolidation (shielding, compacting) projects. Several of these jobs are considered below:

a) Reactor Cavity Decontamination

Following each refueling, the reactor cavity is decontaminated. This operation is labor intensive, involves moderate dose rates (typically about 10 mrem/hr) and is normally on the critical path which leads to significant costs if operations are delayed. To ensure that workers do not exceed skin dose reporting thresholds, either workers must leave the work area to periodically check for DRPs or contamination, and/or additional health physics technicians must be assigned to monitor the workers clothing and work areas. If a plant is experiencing problems with DRPs, these activities can cause an additional collective whole-body dose of from a few mSv (few hundred mrem) to several cSv (several rem). These activities can also lead to extended outages with large costs for replacement power. In this analysis, it was assumed that 2 percent of the plants at risk experience such problems in a typical year, causing workers (including health physics technicians) to receive an average of 0.01 Sv (1 rem)/yr collective whole-body dose. Additional labor time for entries and exits for contamination checks

is estimated at 50 hours for operations personnel and 50 hours for health physics personnel. An additional 2 hours time is needed for job planning due to DRP and contamination concerns. The extra surveys and reentries cause a 15 hour longer outage, and replacement power costs of $15,000/hr are assumed.

Key specific assumptions in analysis of this attribute are:

- 104 licensees at risk
- 102 hours total labor time required/yr
- 100 hours spent in 10 mrem/hr average dose rate fields
- 2 percent of licensees experience this degree of need/yr
- Outage is extended by 15 hours
- 50 percent less costs will be incurred under the new rule
- Replacement power costs $15,000/hr

With these assumptions the total industry costs/yr for this attribute would be

[(100 hr x 10 mrem/hr x $10/mrem) + (102 hr x $150/hr) + (15 hr x $15,000/hr)]/licensee x (0.02 x 104) licensees = $520,624

Under the new rule, costs are estimated at 50 percent of those for the current rule or

0.50 x $520,624 = $260,312.

The net savings per year for all licensees combined under the new rule would be

$520,624 - $260,312 = $260,312.

Assuming an average plant lifetime of 20 years, and employing a 7 percent discount rate for future doses and costs, the total discounted savings over 20 years would be $2,759,307 under the new rule. Annual dose savings of about 10.4 mSv (1.04 rem) are estimated.

b) Residual Heat Removal

During maintenance on the residual heat removal system and valves, DRPs and contamination may be released. This problem has caused doses of about 1,000 mrem/outage at some PWR plants. For purposes of this analysis, it was assumed that 1 percent of plants may experience this type of problem in a typical year, leading to an average additional dose of about 6.5 mSv (650 mrem). This dose would be received during an additional 60 hours of maintenance worker time spent on the job due to DRP and contamination surveys and reentries, plus 5 hours health physics time for these surveys. It was assumed that no critical path time would be incurred, and that 50 percent less effort would be expended under the new rule.
Key specific assumptions in analysis of this attribute are:

- 69 licensees at risk
- 65 hours labor time required/yr
- 10 mrem/hr average dose rate
- 1 percent of licensees experience this degree of need/yr

- Outage is not extended
- 50 percent less costs will be incurred under the new rule

With these assumptions the total industry costs/yr for this attribute would be

[(65 hr x 10 mrem/hr x $10/mrem) + (65 hr x $150/hr)]/licensee x (0.01 x 69) licensees = $11,213.

Under the new rule, costs are estimated at 50 percent of those for the current rule or

0.50 x $11,213 = $5,606

The net savings per year for all licensees combined under the new rule would be

$11,213 - $5,606 = $5,606.

Assuming an average plant lifetime of 20 years, and employing a 7 percent discount rate for future doses and costs, the total discounted savings over 20 years would be $59,426 under the new rule. Annual dose savings of about 2.24 mSv (224 mrem) are estimated.

c) Steam Generator Maintenance

Steam generator maintenance is a major reoccurring job at nuclear power plants. These jobs have major potential for DRP and contamination exposures. The dose impact for steam generator activities involving DRPs is commonly due to elevated radiation fields adjacent to the steam generator platforms or nearby DRP survey areas. Some plants establish low dose personnel DRP survey areas away from the steam generator platforms, thereby requiring workers to move between the work platforms and the shielded survey area each time a DRP personnel survey is required. If significant quantities or activities of DRPs are encountered, these worker movements may occur on an hourly or even quarter-hour schedule. Typically workers receive from 100 to several hundred mrem extra exposure due to needed surveys and worker exits and reentries for DRP checks. Of the 69 PWR plants at risk, it was assumed that 1 percent have significant risk of DRP and contamination exposures It is estimated that special

surveys and worker exits and reentries for contamination checks require 50 hours worker time and 6 hours health physics technician time, in average dose rates of 0.1 mSv/hr (10 mrem/hr). Of the plants experiencing problems, half are assumed to be on critical path and result in approximately a 5 hr extension of the outage, at a cost for power of $15,000/hr.

Key specific assumptions in analysis of this attribute are:

- 69 licensees at risk
- 56 hours labor plus health physics time required/yr
- 10 mrem/hr average dose rate
- 1 percent of licensees experience this degree of need/yr
- Outage is extended by 5 hours for half of the plants affected
- 50 percent less costs will be incurred under the new rule
- Replacement power costs $15,000/hr

With these assumptions the total industry costs/yr for this attribute would be

[(56 hr x 10 mrem/ hr x $10/mrem) + (56 hr x $150/hr) + (0.5 x 5 hr x $15,000/hr)]/licensee x (0.01 x 69) licensees = $35,535

Under the new rule, costs are estimated at 50 percent of those for the current rule or

0.50 x $35,535 = $17,768.

The net savings per year for all licensees combined under the new rule would be

$35,535 - $17,768 = $17,768.

Assuming an average plant lifetime of 20 years, and employing a 7 percent discount rate for future doses and costs, the total discounted savings over 20 years would be $188,336 under the new rule. Annual dose savings of about 1.93 mSv (193 mrem) are estimated.

d) Excore Detector Maintenance

Maintenance of excore detectors in PWR plants can lead to significant exposures to DRP and need for special contamination control procedures. This job typically requires an additional whole-body exposure of about 1.9 mSv (190 mrem) due to an estimated 17 hours maintenance crew time and an estimated 2 hours health physics technician time for contamination checks and surveys in fields averaging 10 mrem/hr. These operations are typically on critical path and cause an estimated outage extension of about 5.75 hours at a cost of $15,000/hr.

Key specific assumptions in the analysis of this attribute are:

- 69 licensees at risk
- 19 hours labor plus health physics time required/yr
- 10 mrem/hr average dose rate
- 1 percent of licensees experience this degree of need/yr
- Outage is extended by 5.75 hours for the affected plants
- 50 percent less costs will be incurred under the new rule
- Replacement power costs $15,000/hr

With these assumptions the total industry costs/yr for this attribute would be

[(190 mrem x $10/mrem) + (19 hr x $150/hr) + (5.75 hr x $15,000/hr)]/licensee x (0.01 x 69) licensees = $62,790.

Under the new rule, costs are estimated at 50 percent of those for the current rule or

0. 5 x $62,790 = $31,395.

The net savings per year for all licensees combined under the new rule would be

$62,790 - $31,395 = $31,395.

Assuming an average plant lifetime of 20 years, and employing a 7 percent discount rate for future doses and costs, the total discounted savings over 20 years would be $332,787 under the new rule. Annual dose savings of about 0.66 mSv (66 mrem) are estimated.

e) Refueling Operations

Several steps in the refueling of a reactor can lead to release of DRPs and contamination. This item covers disassembly, cleaning and reassembly of the reactor vessel head, fuel leak testing through "sipping", and fuel shuffling and replacement. Since refueling is normally on the critical path, an average outage delay of 34 hours was assumed for plants experiencing DRP problems. The refueling operations were assumed to occur in average fields of 10 mrem/hr, and incur 32 Sv (3,200 mrem) collective dose during 300 person-hours of operator hours work and 20 hours of health physics technician hours work. Under the new rule, it was assumed that costs would be reduced by 50 percent due to fewer reentries and special surveys for DRPs and contamination.

Key specific assumptions in the analysis of this attribute are:

- 104 licensees at risk
- 320 hours labor time required/yr
- 10 mrem/hr average dose rate
- 1 percent of licensees experience this degree of need/yr
- Outage is extended by 34 hours for these plants
- 50 percent less costs will be incurred under the new rule
- Replacement power costs $15,000/hr

With these assumptions the total industry costs/yr for this attribute would be

[(320 hr x 10 mrem/hr x $10/mrem) + (320 hr x $150/hr) + (34 hr x $15,000/hr)]/licensee x (0.01 x 104) licensees = $613,600.

Under the new rule, costs are estimated at 50 percent of those for the current rule or

0.50 x $613,600 = $306,800.

The net savings per year for all licensees combined under the new rule would be

$613,300 - $306,800 = $306,800.

Assuming an average plant lifetime of 20 years, and employing a 7 percent discount rate for future doses and costs, the total discounted savings over 20 years would be $3,252,080 under the new rule. Annual dose savings of about 16.6 mSv (1,660 mrem) are estimated.

f) Upper Internal Lift Rig Decontamination

In plants experiencing DRP problems, decontamination of the upper internal lift rig after each refueling operation typically causes about 0.67 mSv (67 mrem) extra dose due to about 6.7 hours of operations personnel and health physics technician time spent doing special surveys and checks for DRPs and contamination in areas with average dose rates of 10 mrem/hr. It is

estimated that about 1 percent of plants at risk will experience DRP problems each year. For these plants it is estimated that a 50 percent reduction in the work requirements would be made for this job under the new rule. No reduction in work requirements or dose are assumed for the plants not experiencing DRP problems.

Key specific assumptions in the analysis of this attribute are:

- 104 licensees at risk
- 6.7 hours labor time required/yr
- 10 mrem/hr average dose rate
- 1 percent of licensees experience this degree of need/yr
- Outage is not extended
- 50 percent less costs will be incurred under the new rule

With these assumptions the total industry costs/yr for this attribute would be

[(6.7 hr x 10 mrem/hr x $10/mrem) + (6.7 hr x $150/hr)]/licensee x (0.01 x 104) licensees = $1,742.

Under the new rule, costs are estimated at 50 percent of those for the current rule or

0.50 x $1,742 = $871.

The net savings per year for all licensees combined under the new rule would be

$1,742 - $871 = $871.

Assuming an average plant lifetime of 20 years, and employing a 7 percent discount rate for future doses and costs, the total discounted savings over 20 years would be $9,233 under the new rule. Annual dose savings of about 0.35 mSv (35 mrem) are estimated.

g) Decontamination of Refueling Equipment

Post-outage decontamination of refueling equipment requires special zoning of the work area and frequent surveys by health physics technicians to ensure that DRPs and contamination are not released from the equipment and spread to other areas of the plant. It is estimated that plants at risk expend about 4 hours controlling the DRP problem and about 1 percent experience serious problems entailing about 80 hours of extra effort on the part of health physics technicians and decontamination workers. These jobs are not on the critical path. It is estimated that 50 percent less effort will be needed under the new rule due to the larger area over which dose may be averaged under the new rule.

Key specific assumptions in the analysis of this attribute are therefore:

- 104 licensees at risk
- 4 hours health physics and worker time is required/yr at half of the plants at risk, and 80 hours are required at 1 percent of the plants

- Costs will be reduced by 50 percent under the new rule

With these assumptions the total industry costs for this attribute would be

(4 hr x $150/hr)/licensee x (0.5 x 104) licensees/yr + (80 hr x $150/hr)/licensee x (0.01 x 104) licensee/yr = $31,200/yr + $12,480 = $43,680/yr.

Under the new rule, costs are estimated at 50 percent of those for the current rule or

0.50 x $43,680 = $21,840/yr.

The net savings per year for all licensees combined under the new rule would be

$43,680 - $21,840 = $21,840.

Assuming an average plant lifetime of 20 years, and employing a 7 percent discount rate for future doses and costs, the total discounted savings over 20 years would be $231,504 under the new rule. No dose savings are expected.

6.4 Protective Clothing Costs at Nuclear Power Plants

Based on an EPRI study of average industry costs for replacement, disposal, and extra monitoring of protective clothing at three nuclear power units experiencing DRP problems, it is estimated that typical additional costs are currently about $30,000/yr at such plants. It is further assumed that on average only 1 percent of U.S. plants are likely to need this level of control and cost each year. Under the new rule it is assumed fewer plants will need to incur these costs, and fewer costs will be incurred at those plants experiencing problems. It is assumed that net costs will be reduced by 34 percent under the new rule.

Key specific assumptions in the analysis of this attribute are:

- 104 licensees at risk
- 1 percent of licensees experience this degree of need/yr

- 34 percent less costs will be incurred under the new rule

With these assumptions the current total industry costs for this attribute are

0.01 x 104 plants x $30,000/plant-yr = $31,200/yr.

Under the new rule, costs are estimated at 66 percent of those for the current rule or

0.66 x $31,200 = $20,592/yr.

The net savings per year for all licensees combined under the new rule would be

$31,200-$20,592 = $10,608.

Assuming an average plant lifetime of 20 years, and employing a 7 percent discount rate for future doses and costs, the total discounted savings over 20 years would be $112,445 under the new rule.

6.5 DRP and Contamination Control Administrative Activities

Routine administrative activities will be reduced under the proposed rule due to fewer incidents needing to be investigated and reported on. Since very few incidents led to over exposures in the past, administrative efforts will more likely relate to the reduced number of incidents that will require reporting. Based on the change of a factor of ten in the area over which dose may be averaged, it is estimated that the number of reportable incidents should decrease by about 50 percent under the new rule. Other administrative costs related to initial implementation of this change are covered under item 18 below. In any year it is estimate that 5 percent of all plants at risk will need to perform administrative activities related to routine reporting of incidents and related follow-on actions. These activities will require an average of 50 hours of plant health physics and administrative time.

Key specific assumptions in the analysis of this attribute are therefore:

- 104 licensees at risk
- 50 hours administrative time required/yr for plants experiencing this need
- 5 percent of licensees experience this degree of need/yr
- Costs will be reduced by 50 percent under the new rule

With these assumptions the total current industry costs for this attribute would be

(50 hr x $150/hr)/licensee x (0.05 x 104) licensees/yr = $39,000/yr.

Under the new rule, costs are estimated at 50 percent of those for the current rule or

0.5 x $39,000 = $19,500/yr.

The net savings per year for all licensees combined under the new rule would be $39,000 - $19,500= $19,500.

Assuming an average plant lifetime of 20 years, and employing a 7 percent discount rate for future doses and costs, the total discounted savings over 20 years would be $206,700 under the new rule.

6.6 Lab Analyses of DRPs at Nuclear Power Plants

The number of DRPs needing analysis varies widely with the degree of problems experienced. Typically, only a few particles per year will need analysis, however, for some plants, many dozens may need analysis. It is estimated that 1 percent of plants will fall in the latter category and cause health physics technicians and analysts to spend about 12 hours per year on this effort. It is further estimated that the required efforts will be reduced by 10 percent under the new rule.

Key specific assumptions in the analysis of this attribute are therefore:

- 104 licensees at risk
- 12-hours health physics and analysts time are required/yr at affected plants

- 1 percent of plants at risk experience this degree of need/yr
- Costs will be reduced by 10 percent under the new rule

With these assumptions the current total industry costs for this attribute would be

(12 hr x $150/hr)/licensee x (0.01 x 104) licensees/yr = $1,872.

Under the new rule, costs are estimated at 90 percent of those for the current rule or

0.9 x $1,872 = $1,685/yr.

The net savings per year for all licensees combined under the new rule would be

$1,872 - $1,685 = $187.

Assuming an average plant lifetime of 20 years, and employing a 7 percent discount rate for future doses and costs, the total discounted savings during a 20-year period would be $1,984 under the new rule.

6.7 NRC Surveillance Costs

Average NRC surveillance and related training and reporting time currently spent on DRP and contamination control issues for all nuclear plants at risk is estimated at four hours per year per plant. Under the new rule, it is estimated that costs will be reduced by 50 percent due to fewer reports of exceeding the reporting requirement and somewhat less time spent on inspections and training related to these issues.

Key specific assumptions in the analysis of this attribute are therefore:

- 104 licensees at risk
- An average of 4-hour NRC staff time is required/yr/plant
- Costs will be reduced by 50 percent under the new rule

With these assumptions the total costs for this attribute would be

(4 hr x $70/hr)/licensee x 104 licensees/yr = $29,120/yr.

Under the new rule, costs are estimated at 50 percent of those for the current rule or

0.5 x $29,120 = $14,560/yr.

The net savings per year for all nuclear power plant licensees combined under the new rule would be

$29,120 - $14,560 = $14,560.

Assuming an average plant lifetime of 20 years, and employing a 7 percent discount rate for future doses and costs, the total discounted savings over 20 years would be $154,336 under the new rule.

6.8 NRC Costs to Implement

Costs to implement the new rule would include those related to dissemination of information to licensees, and training NRC inspectors. These are estimated at about $10,000 expended primarily in the first year. For convenience of comparison with other costs, using a 7 percent discount rate, this present value cost is expressed as an equivalent discounted annual cost of $944./yr.

6.9 Plant Costs to Implement

To implement the new rule, all plants will need to evaluate and revise policies and procedures, and train staff and workers. With the additional emphasis on reducing whole-body doses, avoiding use of unnecessary protective and respiratory equipment and minimizing risks from non-radiological factors such as heat stress, significant new training will be required. It is estimated that these activities will require an average of 80 staff and worker hours/plant to implement during the first year yielding present value costs of

104 plants x 80 hr/plant x $150/hr = $1,248,000.

Allocating this cost over 20 years and using a 7 percent discount rate for future costs yields $117,736/yr cost attributed to the new rule.

6.10 Total of Values and Impacts for Nuclear Power Plants

Table 1 shows a summary of the above value/impact analyses. Total savings/yr estimated for the above jobs and functions affected by DRPs equals to $588,376/yr. Total discounted savings estimated over 20 years for these jobs equals $6,236,785. These savings include an estimated collective dose saving per year of about 0.0427 person-Sv (4.27 person-rem). These values reflect only a portion of all jobs likely to be affected if a DRP problem is encountered at any given plant. Other DRP-related activities that have been identified and may result in additional dose and cost savings include: containment cavity drain line (filter suction) work, containment sump cleanout and inspection, dryer/separator pit work for boiling water reactors, spent fuel shuffle, transfer canal maintenance and decontamination in PWRs, spent fuel cask handling, loading, decontamination, cask washdown (decontamination) pit sump cleanout and inspection, control rod drive rebuilding, refuel floor area control activities, reactor head stand control zone work, reactor coolant pump platform work, reactor coolant pump seal decontamination/rebuild room work, residual heat removal pump room work, and primary side valve repair. Thus, although all of the jobs analyzed above will not be affected by a problem at any one plant, other jobs not included in the above estimates would likely be affected. Therefore, the overall estimate for jobs affected by DRPs and contamination at nuclear power plants is thought to be realistic or probably conservative (on the low side).

7. Value/Impacts on Other Licensees

Of the licensees who report to the NRC, about 92 percent of the reported workers with measurable doses were monitored by nuclear power facilities in 1999, where they received approximately 84 percent of the total collective dose (Karagiannis & Hagemeyer, 2000). Other NRC licensees received the remaining 16 percent of collective dose. In addition, approximately twice as many facilities are licensed to Agreement States as the number licensed by the NRC

(Karagiannis & Hagemeyer, 2000). Data from facilities licensed by agreement states are not included in the values above.

Little published information is available on the impacts of contamination and DRPs on non-nuclear-power and Agreement State licensees. To estimate likely impacts on these other licenses, it is assumed that the costs (except costs for replacement power) and impacts will be proportional to the respective collective doses. Omitting costs and savings of replacement power leaves annual cost savings of about $159,000 for nuclear power licensees. Assuming non-nuclear-power NRC licensees' savings are proportional to their collective doses relative to those for nuclear power plants, one can estimate these savings as 16 percent of $159,000 = $25,440/yr or $269,666 per 20 years. Also, Agreement State licensee benefits may contribute another estimated 32 percent of the non-power-replacement nuclear power plant savings, that is, $50,880/yr or $539,331 per 20 years. These values are also shown in Table 1. Including these estimates with those for nuclear power plants yields a total estimated benefit of $664,696/yr or $7,045,782 per 20 years with implementation of the new rule.

In addition, assuming the collective doses for other licensees are reduced in proportion to relative collective doses for nuclear power plants, the dose savings per year are estimated as 6.8 mSv/yr (0.68 rem/yr) for non-nuclear-power-plant NRC licensees, and 13.7 mSv/yr (1.37 rem/yr) for agreement state licensees. The actual values and impacts are likely to be less than these estimates, but not negative. The added flexibility afforded by the increase in area over which skin dose may be averaged (10 cm^2 under the new rule vs. 1 cm^2 under existing regulations) should permit more efficient work planning, less need for heavy gloves and in some cases extra protective clothing with resulting better utilization of the principal of ALARA and optimization of operations to reduce whole-body doses. In any case, the impacts on other licensees are expected to be smaller than those for nuclear-power-plant licensees, and possibly negligible.

8. Sensitivity Analyses

Values for some of the assumptions employed above are somewhat uncertain. To test the sensitivity of the results to assumptions made, values of the following were varied and values/impacts were recalculated and compared to the original (reference) results: (a)

replacement power costs, (b) dollar value of dose reduction ($/person-rem), (c) plant labor costs, and (c) NCR labor costs. Results are shown on Table 2 .

Replacement power costs were originally assumed to be $15,000/hr of extended outage. Since this value was more appropriate in 1993, an increase of 20 percent to $18,000/hr was assumed for this sensitivity test. Increased savings over original values of about $119,181/yr or $1,263,314 over a 20 year period are estimated for the increased value of replacement power. This is an increase in savings of about 17.9 percent.

Values of dose avoided were tested at $2,000/person-rem saved and $16,000/person-rem saved. The $2,000/person-rem value corresponds to the value recommended in the Regulatory Analysis Technical Evaluation Handbook (NRC, 1997) for health effects. The $16,000/person-rem value is 26 percent higher than the average employed at nuclear power plants in 2000. The $2,000/person-rem assumption caused a decrease in monetary savings of about 7.6 percent/yr, whereas the increase to $16,000/person-rem caused an estimated increase in savings of 5.7 percent/yr over values obtained with the reference assumptions.

The value of $150/hr recommended in the Regulatory Analysis Technical Evaluation Handbook (NRC, 1997) for plant labor costs was increased to $200/hr to test for sensitivity to this parameter. The results were estimated to increase monetary savings by $52,208/yr or 7.9 percent over the values obtained with the reference assumptions.

Assumed NRC labor costs were increased from $70/hr to $100/hr to test for sensitivity to this parameter. The results were estimated to increase monetary savings by $9,236/yr or 1.4 percent over the values obtained with the reference assumptions.

9. Decision Rationale

Of the two options considered, option two is preferable because it satisfies the following decision criteria and Agency goals:

9.1 Goal – Maintain worker and plant safety:

- the trades off of increased deterministic skin effects for reduced whole-body stochastic risk is based on comparative risks

- Retains assurance that large DRP skin doses that might cause significant health effects would not occur in large numbers through the limit of 50 rem (0.5 Sv) averaged over the highest exposed 10 cm^2 of skin

- Would reflect recommendations of the NCRP

- Provides a simplified, more easily understood regulatory approach than the existing enforcement policy

- Reduces the need for extra layers of protective clothing, which add to heat-stress for the workers, reduces worker efficiency, and adds additional whole-body dose

9.2 Goal – Reduce unnecessary burden:

- Reduces the frequency of job-related personnel-monitoring checks and surveys for DRPs and contamination, thereby reducing unnecessary whole-body doses that are incurred in attempts to avoid skin exposures due to DRPs and contamination and current reporting requirements

- Reduces the reporting burden on licensees because the reporting level is raised from 50 rem (0.5 Sv) averaged over 1 cm^2 to 50 rem (0.5 Sv) averaged over 10 cm^2 and few exposures are expected to exceed that level

- Would reduce and simplify the record keeping burden since the same exposure limit (50 rem (0.5 Sv) averaged over the highest exposed 10 cm^2) would apply for discrete particle exposures, contamination exposures and exposures to skin of the whole body

- Would provide greater planning and operations flexibility such as deciding to use or not use protective clothing based on considerations of other risks and the ALARA principal, thereby improving the efficiency and cost-effectiveness of licensee radiation protection programs

- Would reduce the number of related investigations and reports

- Responds in a positive way to the industry's petition for regulatory relief.

9.3 Goal – Increase public confidence:

- Would reflect the most recent recommendations of the NCRP and thereby ensure appropriate radiation protection practices

- Removes the interim enforcement policy, which was a temporary solution while more scientific data was developed

9.4 Goal – Increase NRC efficiency and effectiveness:

- Permits comparing all reported skin doses to a single limit

- Would reduce the number of related investigations and reports

10. References

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Table 1. Summary of Value/Impact Analyses.

Item	Savings/yr with New Rule	Disc. Savings Summed Over 20 yrs	Total Dose Savings/yr (person-rem)*
1. Routine Surveys	$25,480	$270,088	1.02
2. Follow-up Surveys	$619	$6,559	0.02
3. Reactor Cavity Decon	$260,312	$2,759,307	1.04
4. RHR Heat Ex. & Valves	$5,606	$59,426	0.22
5. Steam Gen. Main.	$17,768	$188,336	0.19
6. Excore Detector	$31,395	$332,787	0.07
7. Refueling	$306,800	$3,252,080	1.66
8. Upper Int. Lift Rig Decon	$871	$9,233	0.03
9. Decon of Refuel Equip	$21,840	$231,504	0.00
10. Prot. Clothing Costs	$10,608	$112,445	0.00
11. DRP Admin. Activities	$19,500	$206,700	0.00
12. Lab Analyses of DRPs	$187	$1,984	0.00
13. NRC Surveillance Costs	$14,560	$154,336	0.00
14. NRC Costs to Implement	($944)	($10,000)	0.00
15. Plant Costs to Implement	($117,736)	($1,248,000)	0.00
Nuclear Power Plant Totals:	$596,866	$6,326,785	4.27
Non-Power-Plant Licensees:	$25,440	$269,666	0.68
Agreement State Licensees:	$50,880	$539,331	1.37
Grand Totals:	$673,186	$7,135,782	6.31

*100 rem = 1 Sv

Table 2. Results of Sensitivity Analyses

Variable	Value	Benefit/yr	Benefit/20yr	Change/yr	Change/20yr	% change
(base case)		$664,696	$7,045,782	$0	$0	0.0
Power	$18,000/hr	$783,877	$8,309,096	$119,181	$1,263,314	17.9
$/person-rem*	$2,000	$614,189	$651,408	($50,507)	($535,374)	-7.6
$/person-rem*	$16,000	$702,577	$7,447,312	$37,881	$401,530	5.7
Plant Labor	$200/hr	$716,904	$7,599,182	$52,208	$553,400	7.9
NRC Labor	$100/hr	$673,932	$7,143,675	$9,236	$97,893	1.4

*$1,000/person-rem = $100,000/person-Sv