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

October 27, 1999

MEMORANDUM TO: Chairman Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield

FROM: William D. Travers William Travers
Executive Director for Operations

SUBJECT: RULEMAKING ON DISCRETE RADIOACTIVE PARTICLE DOSE CONSTRAINT

The purpose of this memorandum is to inform the Commission of a change in direction on the subject rulemaking that is needed as a result of new information obtained by the staff.

BACKGROUND:

In the early 1980s, health physicists noted increasing numbers of discrete radioactive particles (DRPs) on or near the skin of workers in nuclear power plants. These small (< 2 mm) particles have high specific activity (beta), and when on or very near the skin produce a very localized high dose to a small volume of skin tissue that may result in a transient break in the skin with little health consequence.

The existing Part 20 skin dose limit of 50 rem averaged over 1 cm^2 is intended to apply to relatively uniform dose to a larger area of skin, and was selected to prevent deterministic damage to the skin that might compromise skin function or appearance. Because this limit did not seem to apply to DRPs on or very near the skin, the NRC established an interim enforcement discretion policy in Information Notice No. 90-48, "Enforcement Policy for Hot Particle Exposures," that would require only reporting and mitigation if a DRP dose exceeded the existing "50 rem over 1-cm^2" limit, and enforcement action would be taken if the DRP beta emission exceeded 75 μCi-hrs (~300 rad). In order to avoid DRP doses greater than 50 rem and the resulting reporting requirement, licensees with DRP problems monitor workers frequently during the work shift, thus incurring additional external dose to the workers and the monitors.

In 1988 the staff contracted with Brookhaven National Laboratory (BNL) to study the health effects of DRPs on the skin and initiated a contract with the National Council on Radiation Protection and Measurement (NCRP) to develop guidance on controlling DRP doses. BNL provided definitive data on the probability of producing breaks in the skin from irradiation of the skin by DRPs in contact with the skin and that these effects did not pose any serious health

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provided definitive data on the probability of producing breaks in the skin from irradiation of the skin by DRPs in contact with the skin and that these effects did not pose any serious health problems to workers. Based on the BNL data, and similar experiments done by the Electric Power Research Institute (EPRI), the NCRP recommended a dose limiting guideline of 50 Rads averaged over ten square centimeters (or, 500 Rads averaged over one square centimeter). The BNL and NCRP work looked only at the nonuniform, highly concentrated dose to one square centimeter from DRPs in contact with the skin, and not at dose that would be delivered to the next nearest square centimeter.

In October 1998, the staff submitted a rulemaking plan (SECY-98-245) titled "Protection Against Discrete Radioactive Particle (DRP) Exposures (10 CFR Part 20)." The staff proposed establishing a "300 rad per 1 cm^2" constraint as a program design guideline or action level, and a "1000 rad per 1 cm^2" capping limit. The intent of the proposed amendments was to reduce the additional external dose incurred by workers in monitoring for DRPs during work shifts, and to reduce unnecessary burden by adopting more realistic thresholds for DRP dose control and reporting requirements. The staff requirements memorandum (SRM) dated December 23, 1998, directed the staff to proceed with rulemaking as proposed but to use 500 rad per 1 cm^2 as the capping dose limit to be consistent with NCRP recommendations. The staff began writing a proposed rule package; the draft FR Notice and Regulatory Analysis are already prepared consistent with the SRM.

DISCUSSION:

In March of 1999, several industry experts who had reviewed the now public rule plan and SRM, suggested that the planned action would not accomplish the intent of the proposed rulemaking. Because these experts were knowledgeable DRP dosimetry experts, and had served on the NCRP committee, the staff requested Dr. John Baum, the BNL researcher and NRC contractor to review their concerns. Dr. Baum concurred with their concerns and raised some additional issues. The NRC technical working group is in agreement that the following issues are valid and that they argue to a revision in staff plans:

- Of all DRP events, fewer than 10 percent are on (or near enough to) the skin to produce a unique, localized beta dose having no large area health implications. Most DRP events (>90%) are DRPs on clothing, or hair, or are far enough away from the skin (and most likely moving), so that the dose to the skin is more uniform, is spread over a larger area, and is more likely to be controlled by the existing 50-rem skin dose limit. This suggests that a reduction in monitoring frequency, and the associated external dose, cannot be realized with the existing skin dose limit.

- A revision to the VARSKIN code, which calculates dose to the skin, and new calculations performed by an NRC consultant, show that a DRP as close as 0.4 mm from the skin can deliver a concentrated DRP dose to a small volume of skin that is less than the proposed 500 rad to 1cm^2 DRP dose limit, and still deliver more than 50 rem to the next 1cm^2 area, thus exceeding the existing skin dose limit. This suggests that many of the DRP incidents where the particle remains fixed on the skin, would still be controlled by the existing skin dose limit and thus no reduction in monitoring would occur.

- An industry representative has observed that many licensees use 10-20 percent of any limit as an administrative guideline to avoid exceeding the limit. If the DRP dose limit were set at 500 rads over 1cm^2, the actual operating limit could be as low as 50-100 rad, thus losing the value of the 300-rad constraint to reduce the unnecessary monitoring dose.

The justification for proposing a 300 rad over 1cm^2 constraint, or action level, was in large part to reduce the additional external dose incurred by the plant staff from frequent monitoring to avoid having to report a DRP dose that exceeded the existing 50-rem 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 is in effect, and the constraint would only rarely be used. Little relief from monitoring dose would result from implementing the constraint.

For particles on the skin, it now appears that in some cases a DRP dose could be within the 300-rad DRP constraint and still exceed the existing 50-rem skin dose limit in the next annular square centimeter. For these reasons, it is likely that creating a DRP constraint of 300-rad would reduce monitoring for DRPs only slightly, if at all. Consequently the staff no longer believes that a DRP dose constraint is useful or justifiable, and the staff is considering several possible approaches to establishing an effective DRP dose limit. The staff is reviewing worker safety and health implications of the possible alternatives. The staff is considering whether there is justification for changing the area over which the existing skin dose limit is averaged and whether a single limit could apply to large area skin doses as well as DRP doses. The staff believes that the technical and regulatory issues can be resolved and a staff consensus reached so that recommendations can be made to the Commission for revised regulatory action. The staff will inform the Commission by December 22, 1999 of a revised schedule to complete the technical work and develop the rulemaking.

Attachments:
1. Rulemaking Plan
2. SRM

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RULEMAKING ISSUE

(NEGATIVE CONSENT)

October 23, 1998 SECY-98-245

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: RULEMAKING PLAN - PROTECTION AGAINST DISCRETE RADIOACTIVE PARTICLE (DRP) EXPOSURES (10 CFR PART 20)

PURPOSE:

To request Commission approval, by negative consent, for the staff to proceed with the development of the rulemaking described in the attached rulemaking plan for amending 10 CFR Part 20, "Standards for Protection Against Radiation". The staff action would include transmitting the attached rulemaking plan to the Agreement States for comment. This rulemaking would propose the use of a Discrete Radioactive Particle (DRP) Dose Constraint, or action level, of 300 rads as a program design objective to establish DRP survey and contamination control programs. The rulemaking would also add a DRP Dose Limit of 1000 rads intended to provide further assurance that extremely high DRP doses would not occur. These provisions would be intended to control the frequency and magnitude of doses to the skin of individual workers who are exposed to radiation from DRPs (sometimes known as "hot particles") on the skin.

BACKGROUND:

On May 21, 1991, the NRC revised 10 CFR Part 20, "Standards for Protection Against Radiation" (56 FR 23360). The rule established an occupational dose limit of 0.5 Sv (50 rems) shallow dose equivalent to the skin in 10 CFR 20.1201(a)(2)(ii). This limit is intended to prevent short term damage to relatively large areas of the skin that would affect skin function or appearance. When 10 CFR Part 20 was issued, there was a discussion in the supplemental information that provisions in 10 CFR 20.1201 were not intended to apply to skin irradiation by a DRP, and that there would be a future rulemaking to set limits for skin irradiation by DRPs.

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Attachment 1

DRPs are small, on the order of 1mm, beta emitting, and although highly radioactive, they produce a dose distribution that is both highly non-uniform and localized. The biological effects of a localized, non-uniform field on the skin are qualitatively different from, and are considered less severe than, the biological effects resulting from relatively uniform irradiation of large areas of the skin. DRP doses produce primarily small volume cell damage that results in cell killing rather than genetic changes that could become cancer. Only the biological effects of uniform irradiation of large areas of the skin were envisioned when the current skin dose limit in Part 20 was established. For these reasons, the current skin dose limit in Part 20 is not appropriate for the unique situation of DRP exposures.

The majority of DRP exposures are incurred by employees of power reactor licensees, but at least one case is recorded for a materials licensee manufacturing radiographic sources. Although more than 15,000 DRP contaminations have been recorded, only two DRP contamination cases have resulted in doses that exceeded the current skin dose limit of 50 rem in Part 20.

Licensees were informed that a modified enforcement policy would be used when a DRP exposure to the skin exceeded the skin dose limit in Part 20. The modified enforcement policy established an interim beta-dose criterion of 75 μCi-hrs ($\sim$ 300 rads) as recommended by NCRP and established severity levels of violations that are less than those used for exceeding other occupational limits. Information Notice (IN) No. 90-48, "Enforcement Policy for Hot Particle Exposures," was issued on August 2, 1990 (prior to the publication of the revised Part 20), to inform licensees of this policy, which would apply until a new limit for DRP exposures was established by rule.

Before rulemaking could proceed, the staff determined that additional research was needed to understand the incidence, persistence, and severity of skin effects that could result from exposure to DRPs and what levels of protection would be adequate. RES contracted with Brookhaven National Laboratory (BNL) to study the biological effects of DRP exposures on pig skin. The BNL research, published as NUREG/CR-6531, "Effects of Radioactive Hot particles on Pig Skin" (June 1997), provided the necessary technical basis for the staff to proceed with rulemaking.

The objectives of this rulemaking are:

- maintain the frequency of DRP exposure events at or below the current low level while reducing licensee reporting and monitoring burden,

- continue to prevent the occurrence of unusually large DRP exposures, and

- reduce the unproductive whole body dose (primarily for power reactors) that currently results from frequent monitoring of workers. Licensees monitor workers several times during each shift for DRP contamination to avoid exceeding the current 50 rem limit. Temporarily halting work for personnel to be surveyed results in extending the time to complete the job and thus an unproductive whole body dose (estimated by the power reactor industry to be 3-5 person-rems per outage).

DISCUSSION:

The rule plan describes three alternatives for rulemaking, along with the pros and cons for each. The following summarizes the main features of the alternatives:

1. Alternative 1 would make no change to Part 20 and continue to exercise enforcement discretion in cases of DRP exposure as discussed in IN 90-48.

2. Alternative 2 proposes a special limit of 3 Gy (300 rads) for DRP exposures to the skin.

3. Alternative 3 proposes a constraint, or action level, of 3 Gy (300 rads) as a program design objective and a 10 Gy (1000 rads) limit to control the frequency and magnitude of DRP exposures to the skin.

The attached rulemaking plan provides staff reasons for recommending alternative 3.

The constraint is intended to prevent frequent DRP doses above 3 Gy (300 rads) and the limit set at 1000 rads is expected to prevent unusually high DRP doses that could produce a persistent or severe break in the skin with permanent changes to the structure or appearance of the skin. The staff believes that a dose constraint set at 3 Gy (300 rads), which corresponds to about a 10 percent probability of a visible break in the skin, is an acceptable level of risk, is an easily measured quantity, and provides burden relief in terms of surveying and monitoring as compared to the 0.5 Sv (50 rem) skin dose limit, with no significant loss in worker health and safety. Furthermore, the preliminary regulatory analysis in the rule plan shows that Alternative 3 results in a significant reduction in burden for both licensees and the NRC, with a net positive impact on worker health and safety because of reduced unproductive dose. This approach is considered to be consistent with the Commission's directive to formulate risk informed and performance based regulations in that it takes into account the qualitatively and quantitatively less significant health effect involved, and compliance would depend on licensees and NRC judgement as to what constitutes an adequate program. For these and other reasons discussed in the rule plan, the staff recommends Alternative 3 as the way to control worker exposure to DRPs.

This action involves no resource adjustments to the NRC operating plan.

AGREEMENT STATE IMPLEMENTATION ISSUES:

The Office of State Programs has outlined the compatibility categories that would apply to the proposed changes in the attached rulemaking plan.

COORDINATION:

The Office of the General Counsel has no legal objection to the rulemaking plan. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objection. The Office of the Chief Information Officer has reviewed the rulemaking plan for information technology and information management implications and concurs in it. However, the plan suggests changes in information collection requirements that may require submission to the Office of Management and Budget at the same time the rule is forwarded to

the Federal Register for publication. The staff intends to coordinate this rule plan with the Agreement States even though the majority of licensees that are experiencing DRP exposures are power reactor licensees and are regulated by the NRC.

RECOMMENDATION:

Staff requests action within 10 days. Action will not be taken until the SRM is received. I consider this action to be within the delegated authority of the EDO. The staff action will include providing the draft Rulemaking Plan to the Agreement States for a 45-day comment period. If significant comments are received, I will provide the Commission with the staff's disposition of the Agreement State comments before I implement the rulemaking plan.

William D. Travers
Executive Director
for Operations

Attachment:
Rulemaking Plan

SECY NOTE: In the absence of instructions to the contrary, SECY will notify the staff on Tuesday, November 10, 1998 that the Commission, by negative consent, assents to the action proposed in this paper.

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RULEMAKING PLAN

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RULEMAKING PLAN - RESPONSE TO RES REQUEST FOR CONCURRENCE ON RULEMAKING PLAN:

PROTECTION AGAINST DISCRETE RADIOACTIVE PARTICLE EXPOSURES

Lead Office: Office of Nuclear Reactor Regulation

Staff Contact: Alan K. Roecklein, NRR

Concurrences:

C-Mail Paperiello 9/10/98
C. Paperiello, NMSS Date

Memo Treby - Roe
K. Cyr, OGC Date

see B. Shelton Memo 1/27/98
A. Galante, CIO Date

T. Heavey 1/29/98
J. Funches, CFO Date

See R. Bangart 4/3/98
R. Bangart, OSP Date

See R. DeMedico 9/11/98
J. Lieberman, OE Date

Shelton Memo 1/27/98
B. Shelton, OCIO Date

Approval:

William Travers 10/23/98
William D. Travers Date

RULEMAKING PLAN
10 CFR PART 20

PROTECTION AGAINST DISCRETE RADIOACTIVE PARTICLE (DRP) EXPOSURES

REGULATORY ISSUE

Should the NRC establish a limit or constraint to control doses to the skin of individual workers who are exposed to radiation from "discrete radioactive particles" on the skin?

BACKGROUND

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. 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, "hopping" from one surface to another. A unique aspect of DRPs on 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 the skin. Recently, the first reports of DRP exposures by a materials licensee were made when workers were exposed to DRPs while manufacturing radiographic sources.

Relative to the beta particle dose, it is usually the case that the gamma radiation associated with a beta-emitting DRP on the skin does not contribute significantly to the skin dose in the vicinity of the particle. Therefore, beta particles are in almost all cases the radiation of concern with regard to DRP exposures to the skin.

In the National Council on Radiation Protection and Measurements (NCRP) Report No. 106, "Limit for Exposure to 'Hot Particles' on the Skin" (1989), the definition of a DRP includes an upper limit on particle size of 1 mm in any dimension. However, more recent research suggests that there is little variation in the dose averaged over 1 cm^2 for particle sizes up to about 2 mm in any dimension. For the purpose of this rulemaking, a DRP will be considered to be a radioactive particle less than 2 mm in any dimension.

The principal stochastic risk associated with irradiation of the skin is non-melanoma skin cancer, i.e., basal cell and squamous cell skin cancers. The risk of skin cancer following irradiation of the skin by DRPs is less than when extended areas of the skin are irradiated 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 mutation. The NCRP, in NCRP Report No. 106, conservatively estimated the risk of skin cancer following a DRP exposure to be 7×10^{-7} Gy^{-1} (7×10^{-9} rad^{-1}), and the risk of skin cancer mortality to be about 1×10^{-9} Gy^{-1} (1×10^{-11} rad^{-1}),

assuming an irradiated skin area of 2 mm^2. This is negligible when compared to the lifetime risk of a radiation-induced cancer fatality of about 4×10^{-2} fatal cancers per Sv (4×10^{-4} rem^{-1}) for workers from uniform irradiation of the whole body. 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 less of a concern than the potential for deterministic effects.

In 1991, the NRC revised Part 20 and its occupational dose limit for the skin of the whole body to 0.5 Sv (50 rems) 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(a)(2)(ii) and is intended to prevent damage to relatively large areas of the skin 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. The Federal Register notice for the final rule stated that there would be a rulemaking to set limits for skin irradiation by discrete radioactive particles. This rulemaking plan responds to that commitment.

The staff recognized that the Part 20 skin dose limit is not appropriate for DRP exposures because the biological effects of a localized, non-uniform field on the skin are qualitatively different from the biological effects resulting from relatively uniform irradiation of large areas of the skin. Prior to the revision of 10 CFR Part 20, the NRC issued Information Notice No. 90-48, "Enforcement Policy for Hot Particle Exposures" (August 2, 1990), which stated 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 Part 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 Part 20.

Although a large number of DRP contaminations have occurred since 1985, very few events have resulted in doses that exceeded the current regulatory limits or associated reporting requirement for skin contamination in 10 CFR Part 20. The staff is unaware of any temporary or permanent biological effects to the skin of workers who have been exposed to DRPs, even though the dose to one worker's hand has been estimated, based on exposure rate measurements, to be about 5 Gy (500 rads).

Before rulemaking could proceed, the staff determined that additional research was needed. Despite studies by various researchers on the biological effects of DRPs on the skin of a human volunteer, monkeys, and pigs prior to 1991, the results were not adequate to form the technical basis necessary for rulemaking. The NRC contracted with Brookhaven National Laboratory (BNL) for research that would provide an adequate technical basis to understand the health risks presented by DRPs and define thresholds for the biological effects of concern. This research, completed in June 1997 and published as NUREG/CR-6531, "Effects of Radioactive Hot Particles on Pig Skin" (June 1997), provides the technical foundation necessary to go forward with this rulemaking. NUREG/CR-6531 was reviewed by numerous members of the NCRP and International Commission on Radiological Protection who are renowned in the fields of radiation biology and dosimetry, as well as by representatives of the nuclear power industry. Comments from these reviews were provided to BNL. BNL's research showed that for DRPs

on the skin, a visually detectable effect -- in this study, scab formation indicative of a break in the skin -- occurred approximately 10 percent of the time for doses of about 3 Gy (300 rads) at a tissue depth of 0.007 cm (7 mg/cm^2) averaged over an area of 1 cm^2. The breaks in the skin that did occur quickly healed with no residual biological effect. Based on this research and industry experience, DRP exposures to the skin at or even above 3 Gy (300 rads) are considered by the staff to present minimal health and safety significance to the exposed individual.

In a draft report being prepared by NCRP Scientific Committee 86 on Limits for Exposure to "Hot Particles", the NCRP recommends the equivalent of 500 rads, averaged over 1 square centimeter, DRP skin dose as a guideline. The NCRP also states:

> "This report addresses in considerable detail the consequences of hot particles on and near the skin.... Limits for exposures from hot particles are recommended. 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 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."

The NRC staff views the NCRP position as a useful guideline for establishing an "action" level at which licensees would review the effectiveness of their DRP monitoring program.

The staff was advised in a public meeting with NEI that, even though there is minimal health significance regarding DRP exposures to the skin, under the current enforcement policy as discussed in the next section, licensees conduct rigorous DRP exposure control programs that result in more frequent surveys and personnel monitoring (which increase the worker's whole-body dose) to avoid DRP exposures to the skin and to minimize the possibility of a reportable event. The industry position is that such control of DRP exposures to the skin is burdensome, increases whole-body dose, and is out of proportion to its health and safety significance.

To minimize the probability that exposures from DRPs would result in doses that exceed current NRC guidelines, licensees have increased the frequency of monitoring personnel working in areas with potential for DRP contamination, as well as the frequency of area monitoring for areas suspected of being potential sources of DRPs. The personnel monitoring frequency selected has been in the range of once every two hours to as high as more than once per hour. Such monitoring requires workers to leave their work areas and go to monitoring stations to be monitored, and then return to their work areas, and also requires the presence of one or more health physics technicians to supervise and assist in this monitoring. Industry has reported that this activity results in unproductive collective doses of the order of 3-5 person-rems per outage per site. Considering the almost invariably small to nonexistent deterministic effects that are being averted, this practice cannot be justified on ALARA grounds.

The selection of a dose constraint (goal) for DRP control of 300 rads is designed to relax the monitoring frequency to the point where the 3-5 person-rems currently incurred in DRP control programs will be significantly reduced. Providing a capping dose limit at 1000 rads would assure that unacceptably high DRP doses will be very unlikely.

The objectives of this rulemaking are to:

- maintain the frequency of DRP exposure events at the current low level while reducing licensee monitoring burden.
- continue to prevent the occurrence of unusually large DRP exposures.
- reduce the unproductive whole body dose estimated to be 3-5 person-rems per outage that currently results from frequent monitoring of workers.

EXISTING REGULATORY FRAMEWORK

As discussed above, the current skin dose limit in 10 CFR Part 20 is not appropriate for DRPs on the skin because the biological effects of a localized, nonuniform radiation field on the skin are qualitatively different from the biological effects resulting from relatively uniform irradiation of large areas of the skin. To address this issue, the NRC published IN 90-48 to inform licensees of the NRC's position that a modified enforcement policy would be used when a DRP exposure to the skin exceeded 0.5 Sv (50 rems), the skin dose limit in 10 CFR Part 20.

IN 90-48 explained that, for DRP exposures to the skin, the staff would use a beta emission criterion of 75 μCi-hrs (approximately 300 rads) and a skin dose criterion of 0.5 Sv (50 rems) for determining appropriate discretionary enforcement actions and appropriate severity levels. For a DRP exposure with the particle in contact with the skin, the NRC would issue a Notice of Violation if the time-integrated beta emission was greater than 75 μCi-hrs. The staff established numerical enforcement criteria (beta emission values or skin doses) for Severity Levels III, IV, and V but stated that enforcement at Severity Levels I and II would not be appropriate.

IN 90-48 stated that the enforcement policy did not change the limits of 10 CFR Part 20, the methods for determining compliance with those limits, or the notification and reporting requirements of 10 CFR Parts 19 and 20. In addition to the enforcement discretion related to the skin dose, IN 90-48 specified that enforcement discretion would be exercised in considering the severity levels for failures to notify and report. Furthermore, IN 90-48 explained that the NRC would use the information reported by licensees to assist the staff in addressing issues during the rulemaking process and to monitor licensees' programs to protect workers from DRP exposures.

ALTERNATIVES CONSIDERED

Three alternatives have been considered:

Alternative 1 - Make no change to Part 20 and continue to exercise enforcement discretion as discussed in IN 90-48.

Alternative 2 - Propose a special limit of 3 Gy (300 rads) for DRP exposures to the skin.

Alternative 3 - Propose a constraint of 3 Gy (300 rads) in § 20.1205, as a program design objective to control DRP exposures to the skin and a 10 Gy (1000 rads) limit in §20.1201 to prevent unacceptably large DRP doses to the skin.

Alternative 1 - Make no change to Part 20 and continue to exercise enforcement discretion as discussed IN 90-48.

This alternative would continue implementation of the statement of policy in IN 90-48 concerning the use of enforcement discretion for occupational doses to the skin from exposure to DRPs. The staff would continue to use a time integrated beta emission criterion of 75 μCi-hrs and a skin dose criterion of 0.5 Sv (50 rems) for determining appropriate discretionary enforcement actions and appropriate severity levels. The NRC would take enforcement action if the beta emission was greater than 75 μCi-hrs for a DRP exposure when the particle was in contact with the skin (including the hair).

Advantages

(1) This alternative would maintain the status quo. Over the past 10 years, all nuclear power plant licensees have implemented a DRP exposure control program designed to meet the interim criteria. Continuation of the policy on using enforcement discretion discussed in IN 90-48 would require no changes to these programs.

(2) By retaining IN 90-48, no staff resources would be needed to conduct a rulemaking.

Disadvantages

(1) IN 90-48 is a policy statement that does not specify any requirements to be established or implemented by licensees, but merely provides them with information. Therefore, the limits of 10 CFR Part 20, the methods for determining compliance with those limits, and the reporting and notification requirements of 10 CFR Parts 19 and 20 that are now in force would still apply.

(2) The Part 20 requirement that licensees report any DRP exposure that exceeds the skin dose limit of 0.5 Sv (50 rems) is burdensome without contributing significantly to worker health and safety. This burden derives from the fact that the majority of nuclear power

plant licensees incur significant costs, staff hours, and unproductive dose from frequent monitoring of workers for DRPs to minimize the occurrence of reportable events.

(3) The monitoring procedures that many licensees have in place to ensure that DRP exposures to the skin do not exceed the 0.5 Sv (50 rems) skin dose limit in Part 20 often require the worker to exit the work site for monitoring and then reenter or, to avoid delay in completing a task, require a health physics technician to enter a high radiation area to directly monitor the worker for DRPs. These procedures are estimated to add 3-5 person-rems to the collective occupational dose incurred in an outage and unnecessarily increase the whole body dose to the workers.

Alternative 2 - Propose a special limit of 3 Gy (300 rads) for DRP exposures to the skin.

This alternative would establish an occupational dose limit of 3 Gy (300 rads) for DRP exposures to the skin at a tissue depth of 0.007 cm (7 mg/cm^2) averaged over an area of 1 cm^2 based on the BNL research. A report would be required and a licensee would need to address corrective steps, as appropriate, according to §20.2203 (b)(iv), if the dose to the skin from a DRP exceeded 3 Gy (300 rads).

Part 20 would also be revised to include definitions for both "discrete radioactive particle" and "discrete radioactive particle dose." Also, the definition for "shallow-dose equivalent" would be revised to exclude an exposure received from a DRP, and conforming changes would be made to recordkeeping and reporting requirements.

Advantages

(1) This alternative would establish a more appropriate (risk informed) limit and reporting requirement for DRP exposures to the skin. Because there is minimal health and safety significance regarding DRP skin contamination events, the use of a special limit (based on the results of the BNL research) is reasonable and would be less restrictive than the current skin dose limit of 0.5 Sv (50 rems) in Part 20.

(2) To avoid exceeding the limit, licensees would continue operating to a lower administrative level that would most likely be higher than the current skin dose limit of 50 rems. Monitoring frequency could be reduced somewhat and the associated unproductive whole body dose would decrease.

(3) The current enforcement discretion policy, which is applied only to DRP skin doses but not to other dose limits, would not be necessary with a limit for skin irradiation by DRPs.

(4) This alternative would reduce the record keeping burden. Establishing a higher limit would reduce the number of overexposure events and, therefore, the number of related investigations and reports.

Disadvantages

(1) Exceeding a limit often results in revising procedures and training programs, reassigning or disciplining staff, work restrictions on the affected worker and public relations problems. This burden seems greatly disproportionate to the NRC staff compared to the minimal health affect that might occur from a 300 rad DRP dose.

(2) Licensees would need to change their operating procedures to implement the new limit.

(3) The rulemaking process would require NRC resources.

The ICRP, in its publication No. 60, stated that dose limits are not always appropriate. It further stated that regulatory agencies improperly apply dose limits even when the sources are partly or even totally beyond their control. Although licensees continue to take action to reduce the number of DRP events, such as filtration of reactor coolant, DRP exposures are not predictable in terms of frequency or severity and cannot be prevented operationally by surveys or other procedures. Without being able to predict exposure level and implement corresponding controls, the concept of a limit is not valid. In this case, ICRP recommends use of specified levels of dose that call for the initiation of a defined course of action, a procedure often called action or investigation level, an approach that the NRC has labeled a constraint.

This rulemaking addresses deterministic effects, small breaks in the skin, that increase both in probability of occurrence as well as in the severity of the effect as the dose increases. There is no obviously advantageous point at which to set a limit, and a limit in this case must be established by balancing the probability and severity of the effect. Minimizing the probability of an effect would result in setting a DRP dose limit that is very low, but results in much more significant health risks to the workers from additional external dose than the effect prevented. Increasing the dose limit to a level at which the expected biological effect would be unacceptable, a level that conforms to the generally accepted meaning of a dose limit based on preventing serious deterministic effects, would result in a DRP dose limit that is quite high, and one that would be too easily met with a minimal control program and increased risk of loss of control of DRPs. The ideal control point that maximizes worker safety, without undue burden on the licensee, is therefore above the point of lowest probability of a biological effect but below the point at which a dose limit would be established. For this reason, use of a dose limit at the 300 rad level would be inappropriate, and an alternative approach is desired.

Alternative 3 - Propose a constraint of 3 Gy (300 rads) in § 20.1205, as a program design objective to control DRP exposures to the skin, and a 10 Gy (1000 rads) limit in §20.1201 to prevent unacceptably large DRP doses to the skin.

This alternative would establish an occupational dose constraint of 3 Gy (300 rads) for DRP exposures to the skin at a tissue depth of 0.007 cm (7 mg/cm^2) averaged over an area of 1 cm^2. A report to the NRC would be required according to § 20.2203 within 30 days if the dose to the skin were measured or calculated to exceed 3 Gy (300 rads). DRP exposures in excess of 3 Gy (300 rads) would not be considered overexposures.

The report would describe the circumstances that led to the greater than 3 Gy (300 rads) dose, a description of the corrective steps the licensee had taken or proposed to take, as appropriate, to decrease chances that the constraint is again exceeded, a timetable for implementing the corrective actions, and the expected results. Records of the results of measurements and calculations needed to evaluate the DRP exposure to the skin of the worker would be required pursuant to the proposed 10 CFR 20.2106(a)(7).

In addition to the constraint of 3 Gy (300 rads) as a DRP program design objective, the NRC staff is proposing to add a DRP dose limit of 10 Gy (1000 rads) averaged over 1 square centimeter. The purpose of this limit is to establish the dose level at which observable prompt deterministic effects would be expected and to provide greater assurance that extremely high DRP doses (e.g. 3000 rads or more) will not occur that might cause breaks in the skin that would persist for weeks to months. Exceeding this dose limit may be considered an indication of a significant failure of the DRP contamination control program.

Using a 300 rad constraint or action level, and a 1000 rad limit, brackets the NCRP guideline equivalent of 500 rads averaged over one square centimeter. Comments would be specifically requested on the appropriateness of the 300 and 1000 rad values in view of the NCRP recommendation.

Part 20 would also be revised to include definitions for both "discrete radioactive particle" and "discrete radioactive particle dose." Also, the definition for "shallow-dose equivalent" would be revised to exclude an exposure received from a DRP.

Advantages

(1) Based on industry experience, a constraint with appropriate follow-up action as discussed will likely prevent very large exposures and will continue to minimize the frequency of lower DRP exposures.

(2) Adding a limit of 1000 rads would provide greater assurance that extremely large DRP skin doses would not occur.

This limit would impose a minimal burden on licensees because very few cases of exceeding the limit would be expected to occur. The highest documented DRP dose to date is about 520 rads. Notwithstanding the limit, however, it is expected that licensees would design their contamination control program to meet the 300 rads constraint, a sufficient margin to avoid exceeding the 1000 rad limit. Based on industry experience, surveys of the work area and once per shift monitoring of workers, considered adequate to assure compliance with the constraint, would also be adequate to prevent exceeding the limit. It should be noted that occasional, but infrequent, excedence of the constraint is expected but, in a well designed and implemented control program, dose levels would not be far above the constraint level, and almost always well below the limit.

(3) Licensees would design protection programs to the constraint level of 300 rads rather than the existing 50 rem skin dose limit. This would result in a significant reduction in the unproductive whole body dose estimated by industry to be 3-5 person-rems per outage caused by excessive monitoring.

(4) This alternative could provide guidance for possible follow-up medical evaluation. The statement of considerations will indicate that if a DRP exposure exceeds the constraint, licensees should consider having a physician look for a break in the skin. If a break in the skin occurs, it should be treated in the same manner as a physician would treat any open wound.

(5) Setting a constraint higher than the reporting requirement of 0.5 Sv (50 rems) to the skin would result in a reduced burden to licensees without a reduction in safety.

(6) This alternative would reduce the record keeping burden. Establishing a higher DRP dose level that would trigger a report would also reduce the number of related investigations and reports.

Disadvantages

(1) Licensees would need to specify corrective actions that might be needed if the constraint is exceeded and continue to ensure that their DRP exposure control programs are effective. NRC would need to inspect to assure that corrective actions are timely and appropriate.

(2) Licensees would need to change their operating procedures.

(3) The rulemaking process would require NRC resources.

DRP contamination differs from external radiation dose in several fundamental ways. DRP doses are unpredictable in that some workers may make many entries without incurring any skin contaminations, and others, taking the same precautions, may be exposed to a DRP on their first entry. The radionuclide composition of the DRP is also to some extent unpredictable, because DRPs may be fuel fragments or they may be fragments of activated material. The radioactive composition, and therefore the dose rate for a given level of activity, will vary substantially depending of the origin of the DRP and its history. Finally, and perhaps most importantly, the activity of the DRPs that contaminate personnel are unpredictable, with most being of low activity, but some having very high activities.

Because of the above considerations, exposure control in the traditional sense of predetermining the doses to be received by each individual and for each entry are not applicable to DRP exposures. Rather, DRP exposure control should be based on the design of a workplace survey and decontamination program for both areas and personnel that provides reasonable assurance that most personnel will not be exposed to DRPs, and that those who are unavoidably exposed to DRPs will receive doses that are within an acceptable level. The acceptable level must be a compromise between avoiding or minimizing the probability and severity of any deterministic effects, while at the same time avoiding the more hazardous

whole-body exposures that may be received during implementation of this program. The staff has reviewed this question in light of available operational and scientific data and has concluded that a design basis constraint of 300 rads per DRP exposure with a 1000 rad capping limit would serve as such a compromise. The expected deterministic effect at the proposed constraint dose level is a very small skin break that heals rapidly, without medical attention, and that occurs with a probability of about 10% of persons exposed at that level. The staff believes that this target could be achieved with minimal whole-body exposures from personnel monitoring, and therefore satisfies ALARA considerations. A lower dose level would result in rapidly increasing whole body exposures incurred in implementing the program, and a higher level is not necessary because it is believed that whole body doses that would be received to comply with the 300 rads level are already negligible.

It should be noted that the use of a 300 rads constraint as a design goal for DRP programs does not imply that DRP exposures to this level will become frequent. It is expected that exposures at these levels will still be very rare. However, the design basis of 300 rads means that the program will be established such that, should a DRP contamination occur, and should that contamination remain undetected for the entire interval between monitoring, the probability that the resulting dose will be less then 300 rads will be very high. The basis for program design to attain the goal of 300 rads will be site dependent, and will be based on the history of DRPs found at the site, their activities, and their radionuclide composition.

In order to experience a DRP dose that exceeded the 1000 rad limit, a licensees survey of the workplace would have to fail to detect the presence of an unusual highly radioactive DRP or fail to anticipate that opening a system could result in the release of such a particle. Another possible scenario that could result in exceeding the proposed limit would be for a DRP not to be detected by personnel monitoring procedures through two or more work shifts including leaving the restricted area. Such events would entail failure to perform adequate surveys as required by §20.1501 (failure to adequately evaluate workplace radiation hazards) or failure to control access to licensed material as required by §§ 20.1801 and 20.1802. Exceeding the 1000 rad limit would be a clear indication that a licensee had failed to comply with the survey and material control requirements.

<u>Related Issue</u> - Should DRP exposures to the skin be quantified as time-integrated activity such as beta emission in μCi-hrs, or as skin dose in rads.

In addition to choosing an alternative for rulemaking, a decision is needed on what unit should be used to express the constraint or dose limit. Either time-integrated beta activity or dose could be used when evaluating DRP exposures to the skin.

Knowing only the beta emission rate of a DRP particle and the exposure times (μCi-hrs) generally does not provide enough information to accurately evaluate the dose to the skin because assumptions must be made regarding the number of beta particles that actually interact with the skin, a quantity that will vary depending on the characteristics of the DRP (e.g., shape and self-absorption) and the back scatter media, and because the dose delivered is dependent on the energy of the beta particle.

On the other hand, the dose approach can more easily be evaluated in terms of the health and safety risk. In other words, the rad is more closely proportional to the potential skin damage than is μCi-hrs. Furthermore, there are methods to immediately estimate doses to the skin from exposure to a DRP in the work environment using relatively simple and inexpensive techniques (e.g., a hand-held ionization chamber). As a second consideration, because the NRC requirement for personnel exposure recordkeeping is specified in units of dose, the term "rad" would facilitate record keeping. For these reasons, the "rad" is a more meaningful way to quantify deterministic radiation effects to the skin from exposure to a DRP.

PRELIMINARY REGULATORY ANALYSIS

Background

During mid-1991, the Electric Power Research Institute (EPRI) surveyed the 109 then-operating nuclear power plants for information on their radiation protection programs to identify the impact of DRPs in terms of radiation exposures, physiological and psychological stress on workers, productivity, and costs. A total of 105 plants responded to the survey and the results were published in an EPRI Report, EPRI TR-104125, "Industry Experience with Discrete Radioactive Particles" (July 1994). As the EPRI report contains the only information that has been published on the impact of DRPs, it was used as the basis for this preliminary regulatory analysis.

Costs and Benefits of Alternatives

Alternative 1 - Make no change to Part 20 and continue to exercise enforcement discretion as discussed in IN 90-48

This is the no-action option (the status quo). The statement of considerations published with the revised 10 CFR Part 20 (May 21, 1991, 56 FR 23360) stated that the DRP issue would be resolved by rulemaking. This is the alternative that all the other alternatives are measured against to compare costs and benefits.

Alternative 2 - Propose a special limit of 3 Gy (300 rads) for DRP exposures to the skin

Alternative 3 - Propose a constraint of 3 Gy (300 rads), as a program design objective to control DRP exposures to the skin, and a 10 Gy (1000 rads) limit in §20.1201 to prevent unacceptably large DRP doses to the skin.

To determine the preferred alternative, the costs and benefits of alternatives 2 and 3, are each compared with alternative 1 (the status quo). About 100 power reactor licensees would be affected by the proposed changes and a few materials licensees. Based on EPRI Report TR-104125, the overall cost of operating a DRP exposure control program, in 1994 dollars, ranged from $200,000 to $2,000,000 annually per site. However, no further information was given regarding the distribution of plants across this range. Until such data are available, the staff can only express the overall costs and benefits of the alternatives relative to the range. During the course of this rulemaking, the staff will attempt to get additional recent DRP data from industry.

To minimize the possibility of a DRP dose that exceeds the current skin dose limit of 0.5 Sv (50 rems), the majority of licensees expend significant resources. Furthermore, these expenditures are often exacerbated because many licensees self-impose administrative limits that are lower than (e.g., as low as 10 percent of) the skin dose limit. Such expenditures are typically reflected in the use of more layers of protective clothing, additional DRP training, performance of special DRP surveys, and increased frequency of personnel monitoring. To keep skin doses below administrative levels in work areas where DRPs occur, many licensees monitor workers once per hour, or more frequently, over the course of an 8 to 10 hour work shift. This practice causes workers to repeatedly leave the work area, remove protective clothing, and then be monitored for DRP contamination before reentering the work area. These practices result in heat stress to workers because of the additional heavy clothing, increased time and manpower to do a job, increased whole body dose, and other physiological and psychological stresses (e.g., fear of contamination). To avoid delaying the completion of work, licensees sometimes have a health physics technician enter the work area to directly survey the workers. While this practice could result in a lower whole-body dose to the workers, the trade-off is likely to be a higher whole-body dose to the health physics technician. In recent discussions with an industry representative, the staff was informed that a soon to be published audit of several nuclear power plants shows that, during a typical outage (roughly two-thirds of the DRPs are discovered in areas associated with refueling outages), about 3-5 person-rems can be attributed to excessive programmatic controls simply to minimize DRP exposures to the skin.

With alternative 2 or 3, DRP exposures to the skin would be regulated by a dose value of 3 Gy (300 rads). The staff believes that a dose limit or constraint for DRPs that is greater than the current skin dose limit 0.5 Sv (50 rems) would significantly reduce burden with no reduction in workers safety because licensees would likely raise their administrative limits, and in turn reduce the frequency of surveys and monitoring for workers in DRP areas, which would reduce the number of dose records generated and maintained. Specifically, the staff believes that with alternative 2 or 3, licensees would likely monitor workers for DRP contamination only during their scheduled breaks, typically two or three times per shift, and therefore significantly fewer dose records would result and nonproductive dose to workers would be reduced. Licensees would realize a reduction in cost because they would be able to stop conducting activities that the NRC staff does not consider necessary for worker health and safety. Some additional small DRP exposures could occur, but it is unlikely that there would be an increase in the frequency of high DRP dose events.

The staff believes that, for the changes described above, the reduction in burden to licensees for alternatives 2 and 3 is similar when compared to alternative 1. Applying the cost data in EPRI Report TR-104125 to these changes, it is estimated that the cost of operating a DRP exposure control program could be reduced by as much as 20 percent, about $40,000 to $400,000 per plant-year. However, other operational costs of a licensee's DRP control program would be expected to remain constant because the staff believes that, with alternative 2 or 3, licensees would not significantly alter existing programmatic controls intended to contain DRPs within each nuclear power plant and prevent the DRPs from being inadvertently transported offsite.

EPRI Report TR-104125 stated that licensees discovered about 15,000 DRPs[1] over the reporting period. The percentage of DRPs involving a skin exposure was not indicated by the EPRI report, nor does published data exist on the number of DRPs discovered since the report was issued. Nonetheless, a review of the NRC's Radiation Exposure Information and Reporting System (REIRS) database and Nuclear Materials Events Database (NMED) indicates that very few events exceeded the skin dose limit, of 0.5 Sv (50 rems) in Part 20. With alternative 2 and 3 only one event in the REIRS database, a DRP exposure of about 5 Gy (500 rads) to the hand, would have exceeded the proposed dose limit (Alternative 2) or constraint (Alternative 3) of 3 Gy (300 rads). Based on available information, the staff believes that this trend should continue. Thus, alternative 2 or 3 would result in a substantial reduction in resources for both licensees and the NRC, with no expected impact on worker health and safety.

RECOMMENDED APPROACH

Based on the costs described above, as well as worker health and safety reasons, the staff believes that alternative 1 is not the preferred alternative. Furthermore, the staff believes that it is not appropriate to use a dose limit set at 300 rads to regulate DRP exposures to the skin (Alternative 2) because the detriment to the skin from a DRP exposure at that dose is not significant when compared with the debilitating biological effects normally avoided in setting limits for deterministic and stochastic risks.

With alternative 3, an occupational constraint would be established at 300 rads for the unique situation of DRP exposures to the skin. The staff believes that although a dose limit for controlling DRP exposures is warranted, a constraint provides adequate operational control needed for DRP exposures, given the relative minor health effects associated with them. However, the staff also believes that DRP exposures do merit certain actions by the licensee to control the frequency and magnitude of doses above the constraint: reporting the event to the NRC, corrective programmatic actions if needed in an effort to reduce the frequency of DRP exposures that exceed the constraint, and possible medical observation of the exposed individual to prevent infection. Enforcement action would be taken only if a licensee failed to report an actual or estimated skin dose from exposure to a DRP that had exceeded the constraint. A capping dose limit of 1000 rads set above the 300 rads constraint would provide further assurance that unacceptably high DRP doses to the skin would not occur.

Based on the preceding discussions, the staff recommends that a constraint value of 3 Gy (300 rads) at a tissue depth of 0.007 cm (7 mg/cm^2) averaged over an area of 1 cm^2 and a dose limit for DRP doses to the skin of 10 Gy (1000 rads) at a tissue depth of 0.007 cm (7mg/cm^2) averaged over an area of 1 cm^2, be adopted. The staff believes that selection of a dose value greater than 3 Gy (300 rads) is unwarranted because 3 Gy (300 rads) provides more than adequate burden relief for licensees and substantial protection for workers against the

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[1]The criteria for making the determination that a DRP had been discovered varied among licensees. For example, some licensees considered that a DRP had been discovered only when a specific activity was exceeded, regardless of where it was found. Some licensees made such a determination only when the DRP was involved with skin contamination regardless of the activity. And other licensees considered all DRPs found to have been discovered.

biological effects from DRP exposures, as well as the nonradiological health effects (e.g. scaring, industrial hazards associated with protection equipment.) A constraint of 3 Gy (300 rads) would establish an adequate level of protection to prevent large DRP skin doses that could result in persistent or severe breaks in the skin. A constraint of 3 Gy (300 rads) would also prevent a large number of exposures in excess of the constraint, which might suggest an inadequate level of programmatic control.

With Alternative 3, the staff believes that licensees who currently perform frequent surveys and personnel monitoring for individuals working in DRP areas could reduce the frequency of such actions with a net positive impact on worker health and safety because of reduced unproductive dose. However, the staff believes that licensees would not significantly alter other aspects of their programs, such as exit monitoring of individuals and equipment from plants, established to contain DRPs within each nuclear power plant and prevent the DRPs from being inadvertently transported offsite. The requirements contained in 10 CFR 20.1801 on the security of stored material and 10 CFR 20.1802 on the control of material not in storage would still apply to any DRP that leaves a restricted area.

SUGGESTED RULE LANGUAGE FOR 10 CFR PART 20

Subpart A--General Provisions

Section 20.1003, "Definitions," would be revised to include definitions for "DRP" and "DRP dose," and the definition for "shallow-dose equivalent" would be modified. The definitions would read as follows:

> Discrete radioactive particle (DRP) means a discrete radioactive fragment that is less than 2 mm in any dimension (also called a hot particle, flea, or speck).
>
> Discrete radioactive particle dose (DRP dose) means the dose averaged over the highest exposed 1 square centimeter of skin at a depth of 0.007 cm (7 mg/cm^2) resulting from a discrete radioactive particle.
>
> 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 cm (7 mg/cm^2) averaged over an area of 1 square centimeter. Shallow-dose equivalent does not include a discrete radioactive particle dose.

Subpart C--Occupational Dose Limits

Section 20.1201, Occupational dose limits for adults would be revised by adding (g), to read as follows:

> (g) The discrete radioactive particle dose to the skin from any discrete radioactive particle on the skin shall not exceed 1000 rads (10 Gy).

Section 20.1202, Compliance with requirements for summation of external and internal doses. The note following paragraph (a) would be revised to read as follows:

(NOTE: The dose equivalents for the lens of the eye, the skin, and the extremities, and the dose from a discrete radioactive particle exposure are not included in the summation, but are subject to separate limits or constraints.)

Section 20.1205 [Reserved]. This section would be titled "Constraint on discrete radioactive particle exposures" and would read as follows:

The constraint on the dose to the skin resulting from exposure to a discrete radioactive particle shall be 300 rads (3 Gy). This value is to be viewed as a program design objective. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall submit a report in accordance with § 20.2203.

Subpart F--Surveys and Monitoring

The survey requirements in § 20.1501, General, are adequate to require surveying for DRPs. Therefore, no changes are needed to § 20.1501.

Section 20.1502, Conditions requiring individual monitoring of external and internal occupational dose. This section would be revised and a new paragraph would be added to read as follows:

Each licensee shall monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits and constraints of this part. As a minimum--

* * * * *

(c) Each licensee shall implement a DRP individual monitoring program using the constraint in § 20.1205 as a design criterion whenever surveys indicate that the constraint in § 20.1205 could be exceeded.

Subpart L--Records

Section 20.2106, Records of individual monitoring results. This section would be revised to add a new paragraph as follows:

(a)(7) The specific information used to assess the dose from a discrete radioactive particle exposure to the skin pursuant to the constraint in § 20.1205 and the limit in § 20.1201.

Subpart M--Reports

Section 20.2203, Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits. This section would be revised to add a new paragraph as follows:

(a)(2)(vii) The constraint or limit for a discrete radioactive particle exposure; or

OGC LEGAL ANALYSIS

The proposed rulemaking revisions would address an issue which was identified for subsequent resolution in the Federal Register notice on the revised 10 CFR Part 20 rule published May 21, 1991 (56 Fed. Reg. 23360). The proposed establishment of a 3 Gy (300 rads) constraint level as a design objective of the radiation protection program, and adoption of a 10 Gy (1000 rads) occupational dose limit for worker exposures to discrete radioactive particles on the skin appear to be consistent with NCRP guidance, and with the research results produced by Brookhaven National Laboratory, published as NUREG/CR-6531. OGC has not identified any basis for a legal objection to the rulemaking plan. The rule does not require a backfit analysis because it is covered by the exclusion from the backfit rule for redefining what level of protection of public health and safety of the public should be regarded as adequate. §§ 50.109(a)(4)(iii), 72.62(b), and 76.76(a)(4)(iii). An environmental assessment must be prepared for this rule in compliance with 10 CFR § 51.21. There are new information collection requirements in this proposed rule, therefore in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), an analysis must be prepared and the information collection requirements must be submitted to the Office of Management and Budget for approval. The final rule must be evaluated for compliance with the Small Business Regulatory Enforcement Act of 1996.

BACKFIT ANALYSIS

A backfit analysis, as described in §§ 10 CFR 50.109, 72.62, and 76.76, "Backfitting," is not required for this rulemaking because the regulatory action involves redefining what level of protection to the public health and safety should be regarded as adequate. Specifically, this rulemaking would establish an adequate level of protection necessary to prevent large skin doses from DRP exposures that could result in a persistent break in the skin that, after healing, has permanent observable structural changes, e.g., dermal thinning or pigment changes. The quantities selected, a constraint set at 3 Gy (300 rads), and a capping limit set at 1000 rads, are believed to represent reasonable levels to trigger acceptable programmatic control of DRPs and permit levels of exposure that will not result in significant injury to the exposed worker. Adopting a constraint on the order of 3 Gy (300 rads) is likely to result in less reporting and should result in less frequent monitoring with a possible reduction in unproductive whole body dose to workers compared to the current 50 rem skin dose limit. Therefore, this rulemaking is covered by the exclusions in §§ 10 CFR 50.109(a)(4)(iii), 72.62(b) and 76.76(a)(4)(iii).

AGREEMENT STATE IMPLEMENTATION ISSUES

In accordance with the Adequacy and Compatibility Policy and Implementing Procedures approved by the Commission on June 30, 1997, the proposed modifications to 20.1003 and 20.1202 would be designated as Category A matters of compatibility. Therefore, an Agreement State should adopt program elements that are essentially identical to those of NRC to provide uniformity in the regulation of agreement material on a nationwide basis.

The addition of 20.1205, and proposed modifications to 20.2106 and 20.2203, would be designated as Category C matters of compatibility. As such, the Agreement States should adopt the essential objectives of the rule modification to avoid conflicts, duplications, gaps, or

other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis.

The proposed modification to 20.1502 has health and safety significance and Agreement States should adopt the essential objectives of this rule modification in order to maintain an adequate program. Therefore, these provisions are assigned to the "Health and Safety (H&S)" category.

No Agreement State implementation problems are expected because the majority of the licensees that are experiencing DRP exposures are power reactor licensees and are regulated by the NRC.

MAJOR RULE

This rulemaking will not be a major rule. It addresses a policy issue that is narrow in scope.

ASSESSMENT OF LIKELY IMPACTS ON NRC AND AGREEMENT STATE LICENSEES

This rulemaking would not result in any additional regulatory burden to NRC or Agreement State licensees.

SUPPORTING DOCUMENTS

A regulatory analysis, an environmental assessment, and an OMB information collection package will be provided for this rulemaking. The need for a regulatory guide to assist licensees with implementation of the final rule is unlikely. The decision to provide a regulatory guide will be based, in large part, on the public comments to the proposed rule and whether implementation can be adequately explained in the statement of considerations.

ISSUANCE BY EXECUTIVE DIRECTOR FOR OPERATIONS OR COMMISSION

The staff is recommending that the Commission issue this rulemaking because it involves a policy issue.

RESOURCES NEEDED TO COMPLETE RULEMAKING

FTE: 1.1 FTE (to develop proposed and final rules)

0.6 FTE (for other offices to provide technical input, review)

LEAD OFFICE AND STAFF WITHIN EACH OFFICE WHO WILL BE INVOLVED

Office	Staff-Level Working Group	Concurring Official
NRR	Alan K. Roecklein*	Samuel J. Collins
NMSS	Sami S. Sherbini	Carl J. Paperiello
OGC	Kathryn L. Winsberg	Karen D. Cyr
OE	R. Joseph DelMedico	James Lieberman

RES Stewart Schneider Ashok C. Thadani
*Project Manager

MANAGEMENT STEERING GROUP

Not needed for this rulemaking. This rulemaking should be straightforward and does not have the complexity or controversy that would require a management steering group.

PUBLIC PARTICIPATION

The rulemaking documents will be placed on the NRC's electronic bulletin board in addition to being published in the Federal Register.

SCHEDULE

Proposed rule to EDO	3 months after rule plan approval
Final rule to EDO	9 months after proposed rule published

The OMB clearance package will be submitted to OMB at the same time the proposed rule is forwarded to the Federal Register for publication.

Action: Collins, NRR

Cys: Travers
Miraglia
Knapp
Norry
Blaha
Shelton, CIO
Meyer, ADM
Lieberman, OE
Bangart, SP
Paperiello, NMSS
Schroll, SECY
Roecklein, NRR

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

SECRETARY

December 23, 1998

MEMORANDUM TO: William D. Travers
Executive Director for Operations

FROM: John C. Hoyle, Secretary

SUBJECT: STAFF REQUIREMENTS - SECY-98-245 - RULEMAKING PLAN - PROTECTION AGAINST DISCRETE RADIOACTIVE PARTICLE (DRP) EXPOSURES (10 CFR PART 20)

The Commission has approved the staff's proposal to develop a rulemaking to amend Part 20 to address discrete radioactive particles, including a 45-day comment period for the Agreement States. The Commission has agreed with the approach to include a constraint value of 300 rads, but disapproved the proposed dose limit of 1000 rads to the skin. The dose limit should be set at 500 rads to be consistent with the draft recommendations of the National Council on Radiation Protection and Measurements (NCRP). The staff should inform the Commission of the NCRP final recommendations.

199800205

The proposed and final rule should be provided to the Commission for review and approval. 199000178
(EDO suspense: ~~3/23/99~~ 9/30/99)

The proposed amendments to section 20.1201, "Occupational Dose Limits" should be assigned a compatibility category.

cc: Chairman Jackson
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
CIO
CFO
OCA
OIG
OPA
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR
DCS

Attachment 2

- An industry representative has observed that many licensees use 10-20 percent of any limit as an administrative guideline to avoid exceeding the limit. If the DRP dose limit were set at 500 rads over 1cm^2, the actual operating limit could be as low as 50-100 rad, thus losing the value of the 300-rad constraint to reduce the unnecessary monitoring dose.

The justification for proposing a 300 rad over 1cm^2 constraint, or action level, was in large part to reduce the additional external dose incurred by the plant staff from frequent monitoring to avoid having to report a DRP dose that exceeded the existing 50-rem 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 is in effect, and the constraint would only rarely be used. Little relief from monitoring dose would result from implementing the constraint.

For particles on the skin, it now appears that in some cases a DRP dose could be within the 300-rad DRP constraint and still exceed the existing 50-rem skin dose limit in the next annular square centimeter. For these reasons, it is likely that creating a DRP constraint of 300-rad would reduce monitoring for DRPs only slightly, if at all. Consequently the staff no longer believes that a DRP dose constraint is useful or justifiable, and the staff is considering several possible approaches to establishing an effective DRP dose limit. The staff is reviewing worker safety and health implications of the possible alternatives. The staff is considering whether there is justification for changing the area over which the existing skin dose limit is averaged and whether a single limit could apply to large area skin doses as well as DRP doses. The staff believes that the technical and regulatory issues can be resolved and a staff consensus reached so that recommendations can be made to the Commission for revised regulatory action. The staff will inform the Commission by December 22, 1999 of a revised schedule to complete the technical work and develop the rulemaking.

Attachments:
1. Rulemaking Plan
2. SRM

cc: SECY
OGC
OCA
OPA
CIO
CFO

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

September 23, 1999

MEMORANDUM TO: Samuel J. Collins, Director
Office of Nuclear Reactor Regulation

FROM: William F. Kane, Director
Office of Nuclear Material Safety and Safeguards

SUBJECT: NMSS CONCURRENCE ON NRR'S RULEMAKING ON DISCRETE RADIOACTIVE DOSE CONSTRAINT

We have reviewed the subject document and provide concurrence subject to the following changes.

1. The document should be revised to indicate more clearly that the intent of the proposed amendment to PART 20 was a) to improve worker safety by controlling the frequency and magnitude of doses to the skin of individual workers from exposure to DRPs and by reducing external doses and 2) to reduce unnecessary burden by adopting more realistic thresholds for worker dose control and reporting requirements.

2. The document should be revised to indicate that, based on new information, neither of the above goals would be met by a proposed rulemaking as currently envisioned. The document should explain more clearly how the new information affected the two goals.

3. The three recommendations should be revised to read: that the Commission approve the withdrawal of the rulemaking plan (SECY-98-245) from consideration and direct the staff to develop new recommendations to achieve the goals.

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Action: Collins, NRR

Cys: Travers
Miraglia
Knapp
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Paperiello, NMSS
Schroll, SECY
Roecklein, NRR

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

SECRETARY

December 23, 1998

MEMORANDUM TO: William D. Travers
Executive Director for Operations

FROM: John C. Hoyle, Secretary

SUBJECT: STAFF REQUIREMENTS - SECY-98-245 - RULEMAKING PLAN - PROTECTION AGAINST DISCRETE RADIOACTIVE PARTICLE (DRP) EXPOSURES (10 CFR PART 20)

The Commission has approved the staff's proposal to develop a rulemaking to amend Part 20 to address discrete radioactive particles, including a 45-day comment period for the Agreement States. The Commission has agreed with the approach to include a constraint value of 300 rads, but disapproved the proposed dose limit of 1000 rads to the skin. The dose limit should be set at 500 rads to be consistent with the draft recommendations of the National Council on Radiation Protection and Measurements (NCRP). The staff should inform the Commission of the NCRP final recommendations. 199800205

The proposed and final rule should be provided to the Commission for review and approval. 199000178
(EDO suspense: 3/23/99)

The proposed amendments to section 20.1201, "Occupational Dose Limits" should be assigned a compatibility category.

cc: Chairman Jackson
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
CIO
CFO
OCA
OIG
OPA
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR
DCS

Attachment 2