RULEMAKING ISSUE
(Affirmation)

January 30, 2002 SECY-02-0021

FOR: The Commissioners

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

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

PURPOSE:

To request Commission approval to publish a final rule in the Federal Register on a revision of the dose limit for the skin of the whole body and the extremities.

BACKGROUND:

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 constraint of 300 rad per 1 cm^2 as a program design guideline or action level to control doses from DRPs on or near the skin. The planned rule included a 1000 rem (10 Sv) limit that was intended to prevent an excessive number of high DRP doses. In the Staff Requirements Memorandum (SRM) SECY-98-245, dated December 23, 1998, the Commission directed the staff to proceed with the constraint but to establish the limit at 500 rem (5 Sv) to be consistent with draft recommendations from the National Council on Radiation Protection and Measurements (NCRP). Information from the nuclear power industry and NRC contractors received by the staff subsequent to public release of this rulemaking plan convinced the staff that, although the proposed constraint would accomplish the objective of controlling DRP doses to workers, the 500 rem (5 Sv) dose limit for DRPs would not achieve the objective of reducing worker whole-body dose associated with frequent monitoring for DRP contamination. In January 2000, the staff sent a memorandum to the Commission (COMSECY-00-0009), that recommended establishing a single, unified skin dose limit that would apply to any shallow-dose equivalent (SDE) to the skin regardless of the source or the geometry of the irradiation. The

CONTACT:
Alan K. Roecklein
NRR/DRIP/RGEB
301-415-3883

limit would be 50 rem (0.5 Sv) averaged over 10 square centimeters, which had been recommended for DRPs by the NCRP in Report No. 130, "Biological Effects and Exposure Limits for 'Hot Particles.'" In an SRM (Attachment 1), "Rulemaking on Discrete Radioactive Particle Dose Constraint," dated March 16, 2000, the Commission approved the staff recommendation and directed the staff to contract with the NCRP to provide technical justification for this regulatory action.

NCRP Statement No. 9, "Extension of the Skin Exposure Limit for Hot Particles to Other Sources of Skin Irradiation," was released in March 2001. In this statement, the NCRP recommended that the absorbed radiation dose to skin at a depth of 70 Fm (7 mg/cm^2) from any source of irradiation be limited to 0.5 Gy (50 rads) averaged over the most highly exposed 10 square centimeters of skin. The staff developed a proposed rule that would incorporate the NCRP recommendations. The Commission approved publication of the proposed rule for public comment. The rule was published in the Federal Register on July 12, 2001 (66FR36502). Nine letters of public comment were received, all supporting the proposed action, as discussed in the attached Federal Register notice of final rulemaking in the section entitled "Analysis of Public Comments and Staff Response" (Attachment 2). The attached Federal Register notice of final rulemaking would incorporate the NCRP recommendation in 10 CFR Part 20.

DISCUSSION:

With the installation at nuclear power plants in the mid and late 1980s of very sensitive portal monitors, it became apparent that some plants had large numbers of very small, highly radioactive particles, DRPs, that occasionally adhered to the skin and clothing of workers. Because of the nature of the principal radiation involved (beta particles), the extremely localized effects, and the lower risk of biological injury compared to nonlocalized effects, the NRC issued Information Notice (IN) No. 90-48, "Enforcement Policy for Hot Particle Exposures"
(55 FR 31113; July 31, 1990). The IN addressed reporting and mitigation if a DRP dose exceeded the existing 50 rem over 1 cm^2 limit.

The small-area, non-uniform skin dose problem is not confined to DRPs at nuclear power plants, but is also to be found at some materials facilities, such as irradiator source and radiopharmaceutical manufacturers. In the latter case, the issue is point or very small area skin contaminations by high concentration liquids that from a dosimetric and biological point of view produce a skin dose distribution for which the current limit is also excessively conservative.

The current skin dose limit found at § 20.1201(a)(2)(ii) is ?a shallow-dose equivalent of 50 rems (0.5 Sv) to the skin or to any extremity." SDE is currently defined in § 20.1003 as external exposure of the skin or an extremity taken as the dose equivalent at a tissue depth of 0.007 centimeters averaged over an area of 1 square centimeter. Thus, the dose limit is, in effect,
50 rem averaged over 1 square centimeter. Research results from studies performed at Brookhaven National Laboratory (BNL) and numerous other published reports made it clear that this limit was far too conservative for DRP and small area exposures and resulted in assigned doses that overstated the risk from such doses.

In the case of DRPs, power plant licensee efforts to avoid reaching the reporting threshold for doses of 50 rem to 1 square centimeter of skin result in frequent monitoring of workers for DRP

contamination. This results in workers receiving additional whole-body dose and its associated increased stochastic risk. The deterministic health effects, such as transient erythema, that might occur from a DRP exposure at the level of the current dose limit are considered by the NCRP as small compared to the increased external dose and stochastic risk from frequent monitoring.

In the case of small-area contaminations, doses at or near the current limit are considered as imposing little health risk to workers; visible but small and transient erythemas might occur. These overexposures can result in licensee citations and the possibility that a worker might not be permitted to work in a radiation area for the balance of the year. The efforts expended by reactor, and in some cases, materials licensees to avoid exceeding the current limit result in the use of multiple layers of protective clothing and other engineering controls that expose workers to nonradiological hazards, such as heat stress, and subsequent health and injury consequences now considered to be far greater than those associated with the skin doses being avoided.

A skin dose limit of 50 rem averaged over the most highly exposed 10 square centimeters constitutes a risk-informed solution to the DRP and small-area contamination cases discussed above. Licensees, in determining the skin dose, will be required to average a larger dose (up to 500 rem) to a small area, over a 10-square-centimeter area. This averaging of the dose will lead to recorded exposures that more appropriately reflect the risks associated with SDE to small areas of the skin. The higher dose limit will permit licensees to reduce monitoring of workers for DRP contamination and will permit reduced use of protective equipment to prevent small-area contaminations. This rule, in effect, provides a risk trade-off, that is, acceptance of an increased frequency of minor skin effects, such as transient erythema, in exchange for a reduction in whole-body exposure and avoidance of disrupting a worker's employment due to a low-risk skin exposure.

The averaging area of 10 square centimeters recommended by the NCRP covers 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. Experience has shown that such particles on clothing will expose an area on the order of 10 square centimeters or more. In the former case, averaging the very localized dose over 10 square centimeters results in an assigned dose value that more appropriately reflects the risk associated with a small area exposure. In the latter case, averaging a relatively uniform dose to the entire 10 square centimeters, results in a dose limit that is equivalent to the current 50 rem over 1 square centimeter. Thus, the effective limit decreases as the exposed skin area increases to 10 square centimeters, consistent with the expectation that the risk of an effect increases with increasing area of skin exposed to a given dose level.

As discussed in the Federal Register notice (Attachment 2), and the regulatory analysis (Attachment 3) for this final rule, the staff believes that revision of the skin dose limit, as recommended by the NCRP, is risk-informed, reduces unnecessary regulatory burden, and provides a substantial increase in worker safety. As discussed in Section XI. Backfit Analysis, of the Federal Register notice, this rule is considered to be a redefinition of the level of adequate protection. All of the public comments received on the proposed rule were supportive.

RESOURCES:

The resources required to finalize, publish, issue, and implement the final rulemaking include a total of 0.7 FTE for all offices in FY 2002. In addition, approximately $10K may be needed for technical assistance in FY 2002, which is available in an existing contract supporting this effort.

COORDINATION:

The Office of the General Counsel has no legal objection to this paper. The Chief Financial Officer has reviewed this Commission paper for resource implications and has no objections. The Advisory Committee on Reactor Safeguards (ACRS) considered this final rule at its 488th meeting and decided not to review it. The ACRS stated that it had no objection to issuing the final rule for industry use. The CRGR reviewed the rule in Meeting No. 366 on December 18, 2001. Minutes of the meeting stated that the committee believes this rule change does not impose a backfit and should be approved.

RECOMMENDATION:

That the Commission:

1. Approve the notice of final rulemaking for publication (Attachment 2).

2. Certify that this rule will not have a negative economic impact on a substantial number of small entities in order to satisfy requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b)2.

   Note:

   a. The rulemaking will be published in the Federal Register.

   b. This notice of final rulemaking includes a section titled IV. Enforcement that withdraws the Commission policy statement (55 FR 31113; July 31, 1990) entitled “Hot Particle Enforcement Policy,” that was also provided as Information Notice No. 99-48.

   c. A final regulatory analysis and the environmental assessment will be available in the Public Document Room (Attachments 3 and 4).

   d. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification regarding economic impact on small entities and the basis for it, as required by the Regulatory Flexibility Act.

   e. Copies of the Federal Register notice of final rulemaking will be distributed to all affected Commission licensees and to commenters on the proposed rule. The notice will be sent to other interested parties upon request.

   f. A press release will be issued.

   g. The appropriate congressional committees will be informed.

   h. The NRC has determined that this action is not a major rule under the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) and has

confirmed this determination with OMB. This determination will be reflected in correspondence to the President of the Senate, the Speaker of the House, and the General Counsel of the General Accounting Office.

/RA/

William D. Travers
Executive Director
for Operations

Attachments:
1. Staff Requirements - COMSECY-00-0009, March 16, 2000
2. Federal Register Notice
3. Regulatory Analysis
4. Environmental Assessment

March 16, 2000

MEMORANDUM TO: William D. Travers
Executive Director for Operations

FROM: Annette L. Vietti-Cook, Secretary /s/

SUBJECT: STAFF REQUIREMENTS - COMSECY-00-0009 - RULEMAKING ON DISCRETE RADIOACTIVE PARTICLE DOSE CONSTRAINT

The Commission has approved the staff's recommendation to initiate rulemaking that would establish a single, unified skin dose limit that would apply to any shallow dose equivalent to the skin regardless of the source or geometry of the irradiation, as described in COMSECY-00-0009, subject to the following comments.

The staff should contract with the National Council on Radiation Protection and Measurements (NCRP) to provide technical justification for this regulatory action, by means other than a grant, to ensure that the needed technical support is completed in a timely manner. The proposed NCRP work should be completed within six months from the date of issuance of a contract, purchase order, or other appropriate method. There is no reason for the staff to develop and provide a formal rulemaking plan to the Commission. The staff should proceed to develop a proposed rule in parallel with the work that will be performed by NCRP. The staff should coordinate the draft proposed rule with the Agreement States before providing it to the Commission. The staff should consider discussing its rulemaking plans with State representatives at the May 2000 meeting of the Conference of Radiation Control Program Directors.

(EDO) (SECY Suspense: 6/15/01)

Before release of COMSECY-00-0009 to the public document room, the statement on page 2 regarding "authoritative recommendations from NCRP" should be revised to state:

> *"The staff believes that changing this fundamental definition of shallow dose equivalent would be strengthened with formal, authoritative recommendations from the NCRP."*

cc: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
CIO
CFO
OCA
OIG

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR PART 20

RIN 3150-AG25

Revision of the Skin Dose Limit

AGENCY: Nuclear Regulatory Commission

ACTION: Final rule

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

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

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

SUPPLEMENTARY INFORMATION:

I. Background

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

In the late-1990s, a materials licensee reported that workers received DRP exposures while manufacturing radiographic sources. In addition to the DRP concern, several events have occurred involving contamination of very small areas (< 1.0 square centimeter) of skin, primarily in the handling of solutions of highly concentrated radiopharmaceuticals. Although, these contamination events produce relatively large doses to very small areas of skin, they are known to result in insignificant health detriments. Nevertheless, under existing provisions in NRC regulations, several of these contamination events resulted in overexposures, and subsequent enforcement actions, with the result that workers could not be assigned work in radiation areas for the balance of the year. These consequences were not commensurate with the actual health detriment.

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

---

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

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

The existing Part 20 skin dose limit of 50 rem (0.5 Sv) averaged over 1 square centimeter was intended to apply to a relatively uniform dose to a larger area of skin than that usually exposed by DRPs with the objective of preventing deterministic damage to the skin. Because the NCRP considered this limit to be overly conservative for DRPs on or very near the skin, the NRC announced an interim enforcement discretion policy in Information Notice (IN) 90-48, "Enforcement Policy for Hot Particle Exposures" (55 FR 31113; July 31, 1990). That policy addressed reporting and mitigation if a DRP dose exceeded the existing limit of 50 rem over 1 square centimeter, and stated that the NRC would take enforcement action for overexposures if the DRP beta emission exceeded 75 FCi-hrs (approximately 300-500 rads). To avoid DRP doses greater than 50 rem (0.5 Sv) and the resulting reporting requirement, licensees monitor workers for DRP contamination frequently during the work shift. This results in additional external dose either to the workers, who incur additional exposure time in exiting

and reentering the restricted area, or to the radiation protection staff, who must enter the restricted area to perform the monitoring.

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

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

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

In March 1999, several industry experts who had reviewed the publicly available rulemaking plan and SRM suggested that the planned action would not accomplish one of the intended objectives, that is, to reduce the frequency of worker monitoring. The industry concern argued against use of a DRP dose constraint with a 500-rem (5.0-Sv) limit, and supported use of the NCRP-recommended skin dose limit that is adopted in this rule. Specifically, the industry concern stated that, of all DRP events, fewer than 10 percent are on, or near enough to, the skin for the proposed constraint and limit to apply. Most DRP events (> 90 percent) are on clothing or hair, or are far enough away from the skin (and most likely moving) so that the dose to the skin is more uniform and spread over a larger area. In that case, the existing 50-rem (0.5-Sv) skin dose limit would be applicable. This information suggested that a reduction in DRP monitoring frequency, and the associated external dose, could not be realized for most DRP exposures, because of the need to prevent exceeding the existing skin dose limit. Because the licensee may not know in advance whether the DRP is on the skin or moving, the licensee would need to assume that the existing skin dose limit was applicable.

The justification for proposing a constraint, or action level, of 300 rads (3.0 Gy) over 1 square centimeter was in large part to reduce the additional external dose incurred by plant staff from frequent monitoring to avoid having to report a DRP dose that exceeded the existing 50-rem (0.5-Sv) skin dose limit. If more than 90 percent of DRPs are off the skin and irradiate a relatively large area, the existing skin dose limit would be controlling and the constraint would only rarely be used. The NRC staff concluded that little relief from monitoring dose would result from implementing the constraint and the 500-rad (5-Gy) limit. In a memorandum to the

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

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

The averaging area of 10 square centimeters, recommended by the NCRP, is applicable to both the case when a DRP is on the skin or a very small area of skin is contaminated, and the case when a DRP is on clothing and moving about exposing an area on the order of 10 square centimeters or more. In the former case, averaging the very localized dose over 10 square centimeters results in a dose value that more appropriately reflects the risk associated with exposure of a small area. In the latter case, averaging a relatively uniform dose to the entire 10 square centimeters results in a dose limit that is equivalent to the current 50 rem over 1 square centimeter. Thus, the limit decreases as the exposed skin area increases to

10 square centimeters, consistent with the expectation that the risk of an effect increases with increasing area of skin exposed to a given dose level. This averaging area is also consistent with the skin dose limiting system adopted by the Department of Energy in 10 CFR Part 835.

In an effort to find the least burdensome regulatory requirement for controlling DRP doses, as well as other skin doses, while maintaining an adequate level of worker protection, the NRC staff requested that the NCRP consider the advisability of applying its proposed limit

for DRP exposures to all skin dose geometries. In March 2001, the NCRP published Statement No. 9, "Extension of the Skin Exposure Limit for Hot Particles to Other Sources of Skin Irradiation," which can be found on the NCRP Website at www.ncrp.com/statemnt.html. In this statement, the NCRP recommended that the absorbed radiation dose to skin at a depth of 70 Fm (7 mg/cm^2) from any source of irradiation be limited to 50 rads (0.5 Gy) averaged over the most highly exposed 10 square centimeters of skin.

Dr. John Baum, Ph.D., an NRC consultant, reviewed the health effects implications of the NCRP recommendation. Dr. Baum wrote a technical paper entitled "Analysis of Potential Radiobiological Effects Related to a Unified Skin Dose Limit," that was published in the June 2001 issue (pp. 537-543) of the peer-reviewed journal Health Physics[2]. In this paper, Dr. Baum estimated the probabilities and severity of both stochastic and deterministic effects for a wide range of exposure scenarios based on the research done by BNL and other research facilities, as well as information found in NCRP Report Nos. 106 and 130. Published data from experimental and epidemiological studies, as well as calculations of radial- and depth-dose distributions, show that skin exposures at the dose limit of 50 rem (0.5 Sv) of SDE averaged over 10 cm^2 could result in stochastic risks of < 6.6 x 10^{-10} rem^{-1} and < 3.2 x 10^{-7} rem^{-1} for fatal and nonfatal skin cancers respectively, confirming that stochastic risks at the proposed limit are small.

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

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

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

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

II. Analysis of Public Comments and Staff Response

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

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

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

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

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

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

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

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

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

Virginia Electric and Power Company (Dominion), Southern California Edison, Exelon Nuclear Generation Company, and the Tennessee Valley Authority (TVA) submitted letters referencing the NEI submittal and expressing strong agreement with NEI's comments and support for the rule. The Strategic Teaming and Resource Sharing (STARS) group of nuclear power plants also submitted comments supporting the proposed rule as published.

III. Summary and Discussion of the Changes

The Commission is amending § 20.1003, § 20.1201(a)(2)(ii), and § 20.1201(c), as follows.

Section 20. 1003 - Definitions.

In § 20.1003, "Definitions", the definition of SDE is 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 revision to require averaging over 10 square centimeters for measuring and recording SDE is found in § 20.1201(c), along with other procedural requirements.

Section 20. 1201 - Occupational Dose Limits For Adults.

10 CFR 20.1201, "Occupational Dose Limits for Adults," is changed in two places. 10 CFR 20.1201(a)(2)(ii) is changed to clarify 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 an SDE limit on the dose delivered at a depth of 0.007 cm (7 mg/cm^2), not a deep dose limit.

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

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

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

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

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

ever been reported. For those reasons, the NRC's final rule does not incorporate the NCRP recommendation for medical observation.

The objective of this 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 rule also reduces the unnecessary regulatory burden on licensees to report skin exposures that have insignificant health implications.

The former statement of the skin and extremity dose limit, along with the former definition of SDE, required that skin doses be averaged over 1 square centimeter. The new rule requires averaging the SDEs delivered to the most highly exposed, contiguous, 10 square centimeters. It is important to discuss the consequences of this 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 former requirement that would attempt to identify the most highly exposed 1 square centimeter and the new approach that would require averaging doses to the skin over the most highly exposed, adjacent 10 square centimeters. 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 new rule, exposed areas of the skin that are less than 10 square centimeters are treated in a less restrictive manner. For example, a dose of 250 rem (2.5 Sv) to each of 2 square centimeters results in a 50-rem (0.5-Sv) SDE when averaged over 10 square centimeters. A dose as high as 500 rem (5.0 Sv) will be permitted to 1 square centimeter and will be recorded as 50 rem (0.5 Sv) when averaged over 10 square centimeters. This change effectively permits higher doses to small areas of skin than were formerly permitted by the regulations.

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

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

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

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

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

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

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

---

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

avoid the physical stress and whole-body doses associated with monitoring workers and the use of protective measures. All of the public comments received on the proposed rule supported this tradeoff.

IV. Enforcement

On July 31, 1990 (55 FR 31113), the Commission published a policy statement entitled "Hot Particle Enforcement Policy," presenting criteria for enforcement discretion in cases that involve occupational skin dose due to radiation exposure from a hot particle. This policy was intended to be applicable until 10 CFR Part 20 was revised to include new limits applicable to these cases. Given that 10 CFR Part 20 is being revised, on the effective date of this rule, this policy will no longer be in effect.

V. 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 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 the NRC's in order to ensure uniformity in skin dose determinations on a nationwide basis.

The proposed amendments and compatibility determinations were provided to the States for review and comment. No comments were received objecting to the new rule or the compatibility determinations.

VI. 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 rule, the NRC is amending its definition of SDE. This action does not constitute the establishment of a standard that contains generally applicable requirements. The NRC is, however, adopting the recommendations of the NCRP regarding acceptable limits on radiation dose to the skin of occupationally exposed workers.

VII. 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

amendment is not 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 amendment addresses technical and procedural improvements in the provisions for measuring or calculating 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. This rulemaking is expected to decrease the need for use of protective equipment by nuclear power plant workers and others who are potentially exposed to skin contamination. No changes are expected in existing 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 will be no change in radiation dose to any member of the public as a result of the revised regulation. The 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. The NRC requested public comments and the views of the States on the environmental assessment for this rule. No comments were received that addressed changes to the environmental assessment.

The environmental assessment is available for inspection in the NRC's Public Document Room, One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland.

VIII. Paperwork Reduction Act Statement

This final rule decreases the burden on licensees reporting under Section 20.2202(b)(iii) on discrete radioactive particles and other small area skin overexposures. The burden reduction for this information collection is estimated to average 40 hours per report. Fewer than

10 reports have been received by the NRC over the past 12 years. Licensees must also revise policies and procedures for measuring discrete radioactive particles. The burden for these revisions is estimated to average .5 hours per power reactor licensee. Because the burden for these information collection changes is insignificant, Office of Management and Budget (OMB) clearance is not required. Existing requirements were approved by the Office of Management and Budget, approval number 3150-0014.

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.

IX. Regulatory Analysis

The NRC has prepared a regulatory analysis for this 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.

X. Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule will not have a significant economic impact on a substantial number of small entities. The anticipated impact of the changes will not be significant because the revised

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

XI. Backfit Analysis

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

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

component. This reduced monitoring will eliminate most of the whole-body dose and stochastic risk associated with monitoring to avoid exceeding the former, more restrictive skin dose limit. In addition, the relaxed skin dose limit, based on NCRP recommendations, should clarify that the consequences of transient skin contamination are less significant than the radiological and nonradiological risks that workers incur as a result of licensees' efforts to avoid skin contamination. 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 to 25 percent, which, in turn, increases whole-body dose. With the new rule 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.

The 1991 Federal Register Notice of final rulemaking on 10 CFR Part 20, (FR23360, May 21, 1991), made it clear that the skin dose limit would be addressed in subsequent rulemaking. The Commission also said that even had the 1991 changes, primarily to dose limits, not contributed to substantial increase in occupational health and safety, such changes would also amount to a redefinition of the level of adequate protection. This change in the skin and extremity dose limit will reduce worker exposure to external dose and the associated cancer risks, and reduce worker exposure to non-radiological hazards imposed by use of overly conservative protective equipment.

In conclusion, the Commission believes that this rule change constitutes a reduction in unnecessary regulatory burden, redefines the level of adequate protection, and should substantially increase worker safety. The changes, therefore, do not require a backfit analysis under § 50.109(a)(4)(iii).

XII. Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

XIII. 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. 552 and 553; the NRC is adopting 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 of the whole body or the skin of 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 _____, 2002.

For the Nuclear Regulatory Commission.

_____

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

REGULATORY ANALYSIS OF

REVISIONS TO 10 CFR 20

Unified Skin Dose Limit

October 2001

Prepared by:

Alan K. Roecklein, NRC

and

John W. Baum, PhD, CHP

Baum & Associates, Inc.

Radiation Safety Consultants

317 Maple Avenue

Patchogue, NY 11772

Table of Contents

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 FCi-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 (56 FR 23360; May 21, 1991). This dose limit for the skin is contained in 10 CFR 20.1201(a)(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 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’ on the Skin” (NCRP, 1989) 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 FCi-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 Particles 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 Fm 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 FCi-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 Fm 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, May 21, 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 regulatory 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 2 below.

Alternative 2 - Propose a shallow-dose equivalent limit in § 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); from inspection reports in the NMED Database (NMED, 2001), and through personal contacts with staff at several plants and knowledgeable individuals, was 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 ™ 1 FCi. 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 new dose limit one must average the dose over an area of 10 cm^2 rather than the formerly used 1 cm^2, leaving the skin dose limit of 50 rem/yr (0.5 Sv/yr) unchanged. For DRPs on the skin and other small area exposures, 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 is in effect 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 by 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, at 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 three for the few plants that will 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 higher 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 reduced 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, and increased 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 a lower 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 former 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 changes are estimated for NPPs 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 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 effects, and localized skin exposures that lead to an increased possibility of deterministic effects. The deterministic risks from DRP doses to small areas in both cases 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 Regulatory Analysis Guidelines clearly state that the $2,000/person-rem value relates only to health risks. Under the guidelines, other impacts such as labor cost considerations can and should be treated as additive elements in the NRC's value-impact analysis and this has been done in the Regulatory Analysis. We note that this change is cost-beneficial, even if the lower value of $2,000/person-rem were to be used.

- 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, and reports of the Electric Power Research Institute in Palo Alto, California and the Nuclear Energy Institute in Washington, D.C. The estimates, 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 new 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 former 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 and 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 extend an outage by 15 hours or longer, 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 former 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 former 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 recurring 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 hour 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 former 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 former 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 former 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 former 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 former 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 former 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 6.9 below. In any year it is estimated 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 former 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 former 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 hours 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 former 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 (Appendix A) 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 (Appendix A). 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 (d) NRC labor costs. Results are shown on Table 2 (Appendix B).

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 trade 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 regulatory 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 principle, 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 request 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

Code of Federal Regulations, Part 20 - Standards for protection against radiation, Office of the Federal Register, 56 FR 23360, National Archives and Records, U.S. Government Printing Office, Washington, May 21, 1991.

Code of Federal Regulations, Part 20 - Standards for protection against radiation, Office of the Federal Register, National Archives and Records, U.S. Government Printing Office, Washington, January 1, 2000 revision.

ERS Corp. Case Studies on the Radiological and Economic Impact of DRP, prepared for Electric Power Research Institute (EPRI), and Nuclear Energy Institute (NEI). ERS Corp., Anderson, SC, 1997.

Karagiannis, H. and D.A. Hagemeyer. Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities 1999, NUREG-0713, Vol. 21, 2000.

James, D. W. Problem Assessment of Discrete Radioactive Particles, EPRI Report NP-5969, Electric Power Research Institute, 1988.

Kaurin, D. G. L., Baum, J. W., Carsten, A. L. Archambeau, J. O., and Schaefer, C. W. Effects of Radioactive Hot Particles on Pig Skin. U.S. Nuclear Regulatory Commission; NUREG/CR-6531, 1997.

Kelly, J. J. and Gustafson, G. Industry Experience with Discrete Radioactive Particles, EPRI Report TR-104125, Electric Power Research Institute,1994.

Miller, David W., Personal communication, 2001.

National Council on Radiation Protection and Measurements. Limit for Exposure to "Hot Particles" on the Skin. Bethesda, Maryland: National Council on Radiation Protection and Measurements, NCRP Report No. 106; 1989.

National Council on Radiation Protection and Measurements. Biological Effects and Exposure Limits for “Hot Particles.” Bethesda, Maryland: National Council on Radiation Protection and Measurements, NCRP Report No. 130; 1999.

Nuclear Regulatory Commission. Regulatory Analysis Technical Evaluation Handbook, NUREG/BR-0184, 1997.

NRC Information Notice 90-48, ?Enforcement Policy for Hot Particle Exposures,” August 2, 1990.

NMED Search Results, http://nmed.inel.gov, January 30, 2001.

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

ENVIRONMENTAL ASSESSMENT

AND FINDING OF NO SIGNIFICANT IMPACT ON

AMENDMENTS OF 10 CFR PART 20, SECTIONS 20.1003 AND 20.1201

REVISION OF SKIN DOSE LIMIT

ALAN K. ROECKLEIN

OFFICE OF NUCLEAR REACTOR REGULATION

U.S. NUCLEAR REGULATORY COMMISSION

OCTOBER 2001

I. The Action

The Nuclear Regulatory Commission (NRC) is amending its regulations to revise its definition of Shallow-dose Equivalent (SDE) by removing the provision to average the dose over 1 square centimeter. In addition, the final rule amends § 20.1202(c) to specify that the assigned SDE must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The intent of this rulemaking is to address skin and extremity doses from all source geometries under a single occupational limit. This change would permit measuring SDEs from discrete radioactive particles (DRPs) on or off the skin, from very small areas (< 1.0 square centimeter) of skin contamination, and from any other source of SDE by averaging the measured or calculated dose over the most highly exposed 10 square centimeters for comparison to the skin dose limit of 50 rem (0.5 Sv).

By changing the area over which the dose must be averaged, the amendment focuses on methods of determining dose to the skin and to the extremities. In some skin dose geometries the changes would result in permitting licensees to average a measured or calculated dose to a very small area, over 10 square centimeters. This, in effect, would raise the limit on SDE to the skin by a factor of as much as 10. For exposed skin areas of about 2 cm^2, the current dose limit would be raised by a factor of 5. For exposed areas of 10 cm^2 or more, the current limit is, in effect, retained. Although this change is expected to permit a reduction in the overly conservative use of protective equipment to prevent skin

contamination, no impact is expected on any entity or area outside of licensed facilities. Occupational exposure to workers on site is expected to be reduced.

This environmental assessment was publicly available during the 75-day public comment period for the proposed rule, and was provided to all Agreement and Non-Agreement States. No comments were received on the environmental assessment.

II. Need for the Rulemaking Action

In the mid-1980s, nuclear power plants began to detect the presence of discrete radioactive particles (DRPs) or hot particles on the skin and clothing of workers. Until the NRC staff established a broad technical basis to support a rule, using National Council on Radiation Protection and Measurements (NCRP) recommendations in Report No. 106, "Limit for Exposure to 'Hot Particles' on the Skin" (1989), the NRC issued Information Notice (IN) No. 90-48, "Enforcement Policy for Hot Particle Exposures." This IN announced a Commission-approved enforcement discretion policy that addressed reporting and mitigation if licensees experienced DRP doses in excess of the current skin dose limit of 50 rem averaged over 1 square centimeter, and enforcement action if the DRP beta emission exceeded the NCRP guideline of 75 FCi-hrs. To avoid the need to report DRP doses in excess of the current limit, licensees are monitoring workers frequently during work shifts, thus incurring additional external dose and stochastic risk. NRC-funded research at Brookhaven National Laboratory (BNL) and numerous published research reports demonstrated that DRP doses resulted in observable but transient breaks in the skin that are of little health consequence. The NRC then funded the NCRP to make recommendations regarding appropriate skin dose limits. The NCRP, in Report No. 130, "Biological Effects and Exposures Limits for 'Hot Particles'" (1999), recommended a limit of 50 rem (0.5 Sv) of SDE averaged over the most highly exposed 10 square centimeters for DRPs on or near the skin, and later recommended that this limit would be acceptable for all doses to the skin.

A related problem occurred when several incidents at a radiopharmaceutical licensee resulted in small (< 1 square centimeter) area contaminations that exceeded the current SDE limit of 50 rem averaged over 1 square centimeter. Although these events resulted in no observable or significant deterministic health effects, citations had to be issued and workers were restricted from continuing work in radiation areas for the remainder of the year.

The intent of the rulemaking is to codify the NCRP recommendations; to reduce significantly the external whole body dose, and associated stochastic risk that results from monitoring for DRPs; to address all skin and extremity doses under one limit; and to de-emphasize the need to protect workers from skin contaminations by the use of protective clothing and other devices that increase the workers' risks from unnecessary whole body dose and non-radiological hazards such as heat stress. The rulemaking also withdraws the interim policy in Information Notice No. 90-48.

III. Alternatives Considered

The following alternatives have been considered.

Alternative 1: No Action

Taking no action would save NRC staff resources and would preclude the need for licensees to revise worker training programs and radiation protection procedures. However, no action would continue the need for licensees to monitor workers while in radiation and high radiation areas for DRP contamination that results in unneeded whole-body dose, and would leave the interim IN on enforcement policy in place. No action would also result in licensees continuing the unduly burdensome practice of requiring excessive protective clothing and other equipment to avoid skin contamination, when in fact the protective equipment may expose workers to more significant hazards than are being avoided. The no-action alternative would have no impact on the environment other than to continue exposing monitoring technicians and workers to unnecessary external dose and industrial stress.

Alternative 2: Separate DRP Dose Limit

Establishing a separate dose limit for DRPs on or near the skin of 50 rem averaged over 10 square centimeters would be a relatively straightforward effort that would provide relief from the need to monitor workers for DRP contamination and thus from the unnecessary additional external dose associated with that monitoring. The interim guidance provided in IN 90-48 could also be withdrawn. However, this approach would not resolve the occasional small area, non-DRP contamination incident that, although causing no significant health effect, must be treated as an overexposure, and might restrict workers from continuing their employment in radiation areas. Because this approach would not permit averaging SDEs to small areas from concentrated radioactive liquids over 10 square centimeters, licensees would not have an incentive to move in the direction of reduced use of protective clothing to protect against insignificant skin contamination and overexposed workers might be removed from working in radiation areas even though no serious health effects were incurred. Thus the current situation of exposing workers to non-radiological hazards such as heat stress, and the additional whole body dose incurred due to less efficient working conditions, would continue. Finally the NRC staff is not aware of a justification for not complying with the NCRP recommendation to apply the 10 square centimeter averaging concept to all skin dose situations.

The only alternative that would accomplish all of the stated objectives is to propose a single skin dose limit as recommended by the NCRP.

IV. Environmental Impacts of the Action and Alternatives

The environmental impacts of the preferred action, as well as the environmental impacts of the alternatives, are considered by the NRC staff to be negligible.

The amendment is focused entirely on technical and procedural methods of determining the occupational SDE to the skin and extremities in the work place. No change is contemplated in any of the required procedures that monitor for or prevent the release of radioactive material either through effluents or possible worker contamination. All of the impacts associated with

this rulemaking are worker-related, and onsite, with no effect on any place or entities outside of a licensed site. The net effect of this rulemaking is expected to be a decrease in the occupational whole-body dose to workers that results from monitoring for DRP contamination, and a reduction in the use of protective equipment that exposes workers to known non-radiological hazards. 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.

V. Finding of No Significant Environmental Impact

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 the amendments 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.

The Commission believes that these amendments result in benefits to workers, flexibility to licensees and would continue to adequately protect public health and safety. There will be no change in radiation exposure to the public or to the environment due to the changes made by the final rule.

VI. List of Agencies and Persons Consulted

Much of the technical information required for this rulemaking was obtained directly from technical experts both within and outside the NRC. The technical basis of health effects information, derives primarily from work performed at Brookhaven National Laboratory that was widely peer reviewed. Recommendations from the National Council on Radiation Protection and Measurements were endorsed and adopted by this rulemaking. Copies of the Environmental Assessment were provided to all Agreement and Non-Agreement States and no comments were received.