Spring Gem, Sugar Giant, Sugar Lady, Summer Dragon, Summer Lady, Summer Sweet, Summer Zee, Supechfour (Amber Crest), Sweet Dream, Sweet Gem, Sweet Kay, Sweet September, Tra Zee, Vista, White Lady, Zee Lady, or 24–SB variety peaches unless:

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Dated: March 28, 2002.

A.J. Yates,

Administrator, Agricultural Marketing Service.

[FR Doc. 02–8140 Filed 4–3–02; 9:51 am]

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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 (i.e. more representative of actual health risks) 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). The Commission believes that although the less restrictive limit on dose to small areas of the skin might permit more frequent, transient, observable effects such as reddening of the skin, the change nevertheless represents a substantial increase in worker protection because reduced monitoring for DRPs will result in reduced external dose and reduced use of protective clothing will result in fewer industrial hazards in the workplace.

EFFECTIVE DATE: June 4, 2002.

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SUPPLEMENTARY INFORMATION:

I. Background

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

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

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

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 SDEs to very small areas of the skin. The final rule stated that there would be a rulemaking to set limits for skin irradiation by DRPs. This amendment to 10 CFR part 20 responds, in part, to that commitment.

The existing part 20 skin dose limit of 50 rem (0.5 Sv) averaged over 1 square centimeter was intended to apply to a relatively uniform dose to a larger area of skin than that usually exposed by DRPs with the objective of preventing deterministic damage to the skin. Because the NCRP considered this limit to be overly conservative for DRPs on or very near the skin, the NRC announced an interim enforcement discretion

policy in Information Notice (IN) 90–48, ''Enforcement Policy for Hot Particle Exposures'' (55 FR 31113; July 31, 1990). That policy addressed reporting and mitigation if a DRP dose exceeded the existing limit of 50 rem (0.5 Sv) over 1 square centimeter, and stated that the NRC would take enforcement action for overexposures if the DRP beta emission exceeded 75 μCi-hrs (approximately 300–500 rads). To avoid DRP doses greater than 50 rem (0.5 Sv) and the resulting reporting requirement, licensees monitor workers for DRP contamination frequently during the work shift. This results in additional external dose either to the workers, who incur additional exposure time in exiting and reentering the restricted area, or to the radiation protection staff, who must enter the restricted area to perform the monitoring.

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

In October 1998, the NRC staff submitted a rulemaking plan (SECY–98–245) entitled ''Protection Against Discrete Radioactive Particle (DRP) Exposures (10 CFR Part 20).'' In that plan the NRC staff proposed establishing a constraint of 300 rads (3 Gy) over 1 square centimeter as a program design guideline or action level, and a limit of 1000 rads (10 Gy) over 1 square centimeter for DRPs on or near the skin. The existing skin dose limit would have been retained for all other skin doses. The intent of that proposed amendment was to reduce the additional external dose incurred by workers in monitoring for DRP contamination during work shifts and to reduce unnecessary regulatory burden by adopting more realistic thresholds for DRP dose control and reporting requirements. In a staff requirements memorandum (SRM) dated December 23, 1998, the Commission directed the NRC staff to proceed with rulemaking as proposed, but to use 500 rads (5 Gy) per 1 square centimeter as the dose limit to be consistent with the recommendations in NCRP Report No. 106.

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

The justification for proposing a constraint, or action level, of 300 rads (3.0 Gy) over 1 square centimeter was in large part to reduce the additional external dose incurred by plant staff from frequent monitoring to avoid having to report a DRP dose that exceeded the existing 50-rem (0.5-Sv) skin dose limit. If more than 90 percent of DRPs are off the skin and irradiate a relatively large area, the existing skin dose limit would be controlling and the constraint would only rarely be used. The NRC staff concluded that little relief from monitoring dose would result from implementing the constraint and the 500-rad (5-Gy) limit. In a memorandum to the Commission dated October 27, 1999 (COMSECY–00–0009), the NRC staff explained why the constraint with a limit of 500 rads (5 Gy) would not accomplish this intended objective, and recommended further work to identify an effective regulatory approach. In an SRM dated March 16, 2000, the Commission directed the NRC staff to contract with the NCRP to provide additional technical support on this issue.

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

The averaging area of 10 square centimeters, recommended by the NCRP, is applicable to both the case when a DRP is on the skin or a very small area of skin is contaminated, and the case when a DRP is on clothing and moving about exposing an area on the order of 10 square centimeters or more. In the former case, averaging the very localized dose over 10 square centimeters results in a dose value that more appropriately reflects the risk associated with exposure of a small area. In the latter case, averaging a relatively uniform dose to the entire 10 square centimeters results in a dose limit that is equivalent to the current 50 rem over 1 square centimeter. Thus, the limit decreases as the exposed skin area increases to 10 square centimeters, consistent with the expectation that the risk of an effect increases with increasing area of skin exposed to a given dose level. This averaging area is also consistent with the skin dose limiting system adopted by the Department of Energy in 10 CFR part 835.

In an effort to find the least burdensome regulatory requirement for controlling DRP doses, as well as other skin doses, while maintaining an adequate level of worker protection, the NRC staff requested that the NCRP consider the advisability of applying its proposed limit for DRP exposures to all skin dose geometries. In March 2001, the NCRP published Statement No. 9, ''Extension of the Skin Exposure Limit for Hot Particles to Other Sources of Skin Irradiation,'' which can be found on the NCRP Website at *www.ncrp.com/statemnt.html*. In this statement, the NCRP recommended that the absorbed radiation dose to skin at a depth of 70 μm (7 mg/cm $_2$) from any source of irradiation be limited to 50 rads (0.5 Gy) averaged over the most highly exposed 10 square centimeters of skin.

Dr. John Baum, Ph.D., an NRC consultant, reviewed the health effects implications of the NCRP recommendation. Dr. Baum wrote a technical paper entitled ''Analysis of Potential Radiobiological Effects Related to a Unified Skin Dose Limit,'' that was published in the June 2001 issue (pp. 537–543) of the peer-reviewed journal *Health Physics*. 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) SDE averaged over 10 cm^2 could result in stochastic risks of $<6.6 \times 10^{-10}$ rem^{-1} and $<3.2 \times 10^{-7}$ rem^{-1} for fatal and nonfatal skin cancers respectively, confirming that stochastic risks at the proposed limit are small.

Given exposures at the proposed skin dose limit, that is, 50 rem (0.5 Sv) averaged over 10 square centimeters, Dr. Baum estimated that the worst-case deterministic effects are a 5-percent probability of erythema if all of the dose (500 rem) were delivered to an area of 2.5 square centimeters, and a 50-percent probability that measurable dermal thinning would be observable if all of the dose were delivered to an area of <0.5 square centimeters. At this 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 it is in favor of the proposed revision of the skin dose limit and agrees with the NCRP's recommendations because the new rule encompasses SDE from all sources into one limit. The Council on Radionuclides and Radiopharmaceuticals (CORAR), an association of NRC and Agreement State licensees that use unsealed sources of radioactive materials, fully supported the proposed rule. CORAR stated that the new limit would be more protective of workers, and more comparable to current annual limits for deep dose and lens of the eye dose than the current limit, would establish a skin dose limit on a risk-informed basis, and would simplify the regulations.

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

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.

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

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

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

NCRP Statement No. 9 referred to NCRP Report No. 130 (1999) for guidance on good practices, and recommended that in addition to numerical limits, the exposed area of skin should be observed for 4 to 6 weeks whenever the DRP dose at a depth of 70 μm exceeds 10 rads (0.1 Gy) averaged over the most highly exposed 10 square centimeters of skin. The observational level of 10 rads (0.1 Gy) is well below the new limit of 50 rem (0.5 Sv), and is essentially equivalent to the current skin dose limit, at which no clinically significant effects have 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, while it continues to provide adequate protection of workers, trades a higher risk of occurrence of temporary effects to the skin, such as reddening, for a reduction in the risk of whole-body dose and cancer, 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 that where DRPs are on or very near the skin, such that a relatively small volume of tissue receives a large dose, resulting in cell killing and possible observable breaks in the skin. Under the former dose limit, a DRP could deliver 50 rem (0.5 Sv) to an area of 1 square centimeter that when averaged over 1 square centimeter would yield a recorded dose of 50 rem (0.5 Sv). Under the new rule, the NCRP-recommended limit, a dose of 500 rem (5.0 Sv) delivered to 1 square centimeter, when averaged over 10 square centimeters, would yield a recorded dose of 50 rem (0.5 Sv). Thus, for DRPs on the skin, and other small area exposures, the rule change is in effect a tenfold relaxation of the former limit and may permit some increased number of observable, transient deterministic effects to the skin. This new limit would be approximately equivalent to the emission criterion of 75 μCi-hr that was used in the interim enforcement policy stated in IN 90–48. The worst case of 500 rem (5.0 Sv) to 1 square centimeter is estimated to result in a 50–percent chance of an observable but transient erythema, and a 15- to 20-percent chance of an observable break in the skin. NRC records include only one DRP dose that was calculated to exceed 500 rem (5.0 Sv), and no effects were observed in that case.

On the basis of extensive research performed at BNL and elsewhere, the NCRP stated in Report No. 130 that ''if (DRP) 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 (cancer) 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 other words, the NCRP concluded that skin dose from DRPs resulted in relatively insignificant health effects, and that it was more important to prevent whole body, external exposure that might cause cancer.

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, [1] especially those having a high gamma component. The NRC believes that the possibility of some additional number of observable, transient deterministic effects, such as a small break in the skin, is justified by the reduction of the whole-body dose and stochastic risks associated with monitoring for DRPs.

NRC's 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 nontheless represents a substantial increase in worker protection because reduced use of protective clothing will result in a less hazardous workplace and less frequent monitoring for DRP contamination will result in 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 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.

[1] 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.

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, Public Law 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 § 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 increase industrial safety for workers substantially.

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 (56 FR 23360; 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.

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 1st day of April, 2002.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. 02–8246 Filed 4–4–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 330, 331, 341, 346, 355, 358, 369, and 701

[Docket Nos. 98N–0337, 96N–0420, 95N–0259, and 90P–0201]

RIN 0910–AA79

Over-the-Counter Human Drugs; Labeling Requirements; Partial Delay of Compliance Dates

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; partial delay of compliance dates.

SUMMARY: The Food and Drug Administration (FDA) is providing a partial delay of the compliance dates for certain products subject to its final rule that established standardized format and content requirements for the labeling of over-the-counter (OTC) drug products (Drug Facts Rule). That final rule requires all OTC drug products to comply with new format and labeling requirements within prescribed implementation periods. The agency intends in a future issue of the **Federal Register** to propose an amendment to the Drug Facts Rule to modify the labeling requirements for ''convenience-size'' OTC drug products. This final rule