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

OCT 04 1993

MEMORANDUM FOR: Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

FROM: Patricia G. Norry, Director
Office of Administration

SUBJECT: OFFICE CONCURRENCE ON PROPOSED RULE PACKAGE ENTITLED "RADIATION PROTECTION REQUIREMENTS; AMENDED DEFINITIONS AND CRITERIA"

The Office of Administration concurs, subject to the comments provided, on the proposed rule that amends the Commission's regulations governing radiation protection. We have attached a marked copy of the proposed rule package that presents our comments.

When this document is forwarded for signature and publication, please have a member of your staff include a 3.5-inch diskette that contains a copy of the document in WordPerfect 5.0 or 5.1 as part of the transmittal package. The diskette will be forwarded to the Office of the Federal Register and the Government Printing Office for their use in typesetting the document.

To assist you in preparing the list of documents centrally relevant to this proposed rule that is required by the NRC's regulatory history procedures, you should place the designator "AE80-1" in the upper right-hand corner of each document concerning the rule that you forward to the Nuclear Documents System.

If you have any questions regarding our comments, please have a member of your staff contact Michael Harrison on 492-8208 or Michael T. Lesar on 492-7758 of the Division of Freedom of Information and Publications Services.

Patricia G. Norry, Director
Office of Administration

Attachment: As stated

PDR AE80-1

From: H. Hampton Newsome (HHN)
To: DAC, AKR, DAM2
Date: Tuesday, December 7, 1993 4:14 pm
Subject: OGC Comments on Part 20 PR

Please find attached OGC's proposed changes to the rulemaking package for Parts 19 and 20.

Files: P:\PT20OGC.COM

- Very little of legal consequence
- Mostly edits + few useful
- Most edits change Admin (Kesan) format for FR
- Several "wrong" changes, especially "computation" in definition of Occupational Dose

Used in Kesan 8/11

PDR AE80-1

[7590-01]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 19 and 20

RIN 3150-AE80-1

Radiation Protection Requirements; Amended Definitions and Criteria

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) proposes to amend its regulations concerning radiation protection requirements. The proposed rule would: (1) delete the definition of "Controlled area" to make it clear that any area to which access is restricted for the purpose of radiological protection is a restricted area as defined in the regulation, (2) revise the definition of "Occupational dose" to delete reference to the "Restricted area," and indicate which radiation doses are excluded for the purposes of computation of the occupational dose, (3) revise the definition of unrestricted area to be consistent with the deletion of controlled area, (4) revise the provision in 10 CFR Part 20 entitled "Instruction to Workers," so that radiation protection training will be provided to all persons with the potential to be occupationally exposed and (5) restore a provision to 10 CFR Part 20 to provide that whenever licensees are required to report exposures of

individual members of the public to the NRC, then those individuals are to receive copies of the report.

DATE: Comment period expires (60 days following publication in the Federal Register). Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Mail written comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

Deliver comments to: 11555 Rockville Pike, Rockville, Maryland between 7:45 am and 4:15 pm Federal workdays.

Copies of the regulatory analysis, the environmental assessment and finding of no significant impact, the supporting statement submitted to OMB, and comments received may be examined at: the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Alan K. Roecklein, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492-3740.

SUPPLEMENTARY INFORMATION:

Background

On May 21, 1991, (56 FR 23360) the NRC amended 10 CFR Part 20 to add its revised "Standards for Protection Against Radiation (10 CFR 20.1001 - 20.2402)

(hereinafter referred to as "revised standards"). Compliance will become mandatory for all licensees on January 1, 1994. Extensive discussion regarding interpretation and implementation of the new rules has ensued both within the NRC and Agreement State staffs and with licensees and other interested parties.

put in by Lesar

The revised standards ~~for protection against radiation~~ currently include a definition for the term "Controlled area." The term is defined to be "an area, outside of a restricted area~~,~~ but inside the site boundary, access to which ~~to which access could~~ can be limited for any reason." (10 CFR 20.1003). The term "Restricted area" was retained in the revised standards ~~for protection against radiation~~ from the original regulation, 10 CFR Part 20, and ~~is~~ defined as an area, "access to which is limited by the licensees~~,~~ for the purpose of protecting individuals against undue risks from exposure to radiation or radioactive materials...." (10 CFR 20.1003). Neither the revised standards themselves, nor the supplemental information provide a basis for deciding whether to designate a given area as a "Restricted area" or a "Controlled area." In discussions with licensees and Agreement States, the absence of such a clear delineation appears to be the cause of considerable uncertainty among a number of licensees regarding how to implement the revised standards in this regard. The NRC believes that this situation can be alleviated by eliminating the term "Controlled area" from the regulations. This change has the effect of returning the regulation to the former situation in which areas are either restricted or unrestricted for purposes of radiation protection. As has always been the case, licensees continue to have the option of controlling access to areas for reasons other than radiation protection.

Edits

The definition of "Unrestricted area" in the ~~new 10 CFR Part 20 was revised to~~ revised standards acknowledges the existence of controlled areas and ~~designates an~~ currently is defined as an area "access to which is neither limited nor controlled by the licensee." (10 CFR 20.1003). Deletion of the term "Controlled area" permits return to the former situation in which areas are either restricted or unrestricted for radiation protection purposes, and the Commission now proposes to revise the definition of "Unrestricted area" ~~would be revised~~ to make this clear.

~~The option to control access for reasons other than radiation protection continues to be available to licensees.~~ Under this proposal, licensees would continue to have the option to control access for reasons other than radiation protection. As before, the definitions of "restricted area" and of "unrestricted area" do not preclude the existence of areas in which access is limited for purposes other than protecting individuals against undue risks from exposure to radiation and (or) radioactive materials. ~~A fundamental principle present in the regulations is that a member of the public is subject to the limits for a member of the public (§ 20.1301 (a)(1)), irrespective of that individual's location. Thus, licensees must be able to ensure that a member of the public, if present in a restricted area, as well as any other area, will not exceed an exposure of 100 mrem/year.~~

"Occupational dose" is defined currently in the revised standards "as the dose received by an individual in a restricted area or in the course of employment in which the individual's assigned duties involve exposure to radiation and~~/or~~ to radioactive materials...." (10 CFR 20.1003). Through meetings with licensees to discuss the ~~new~~ revised standards ~~for protection against radiat~~ n, the Commission has become aware that this definition can be

interpreted to allow individuals who are members of the public to receive an "occupational dose" and exceed public dose limits if they enter restricted areas. This was not the intention of the Commission in ~~revising 10 CFR 20 and~~ promulgating the revised standards. A fundamental principle present in the regulations is that a member of the public is subject to the limits for a member of the public (§ 20.1301 (a)(1)), irrespective of that individual's location. Thus, licensees must be able to ensure that a member of the public, if present in a restricted area, as well as any other area, will not exceed an exposure of 100 mrem/year. T~~t~~he suggestion that ~~such unintended~~ permission to expose a member of the public to a dose in excess of 100 mrem/ year is created by that individual's location in a restricted area ~~is allowed~~ can be removed by a simple modification to the definition of occupational dose, specifically by eliminating reference to dose received in a restricted area. In addition, "radiation and/or radioactive material" should replace "radiation and radioactive material" to correct a technical error in the text of the rule. With these changes, it would become clear that occupational dose is dose received as a result of an individual's employment in which assigned duties involve exposure to radiation and/or radioactive material. These changes would also make it clear that the dose received by a member of the public cannot be permitted to exceed the public dose limit even if the individual is receiving a portion of that dose while in a restricted area. The definition of "occupational dose" is also being revised to clarify the computation of such doses. Through the addition of the phrase "The computation of" at the beginning of the second sentence of the definition, the Commission intends to clarify that in computing the occupational dose, one begins with the measured dose and then excludes, from that amount, doses received from background

determining?

radiation, as a patient from medical practices, from voluntary participation in medical research programs, or as a member of the general public.

The regulation entitled, ~~10 CFR 19.12,~~ "Instruction to Workers," 10 CFR 19.12 currently requires that all individuals working in or frequenting any portion of a restricted area be instructed in the health protection problems associated with exposure to radiation and in radiation protection procedures needed to minimize exposure. Under this provision, if a worker never enters a restricted area, he or she would require no radiation protection training. On the other hand, members of the public, such as delivery persons who might occasionally enter a restricted area, would be required to be trained even though the nature of their activities would perhaps not warrant such instruction. The proposed change to § 19.12 would make it clear that anyone in the course of their employment in which the individual's assigned duties involve the potential for exposure to radiation and/or radioactive material would have to be provided appropriate radiation protection training. ~~Another important reason for proposing this change is to ensure that workers have an opportunity to exercise informed consent if they are subject to occupational dose limits.~~

Concern about training requirements has been expressed for certain categories of workers and members of the public illustrated by the following cases. Case 1 involves ~~such as (1)~~ a member of the public who is potentially exposed to some radiation while visiting a facility or making deliveries, ~~and (2)~~ Case 2 a maintenance worker or contractor who is exposed to radiation while performing repairs or cleaning. In order to decide if training is required, and what type of training is appropriate, certain provisions of the rules must be considered.

First, after January 1, 1994, a member of the public cannot be permitted to receive more than 100 mrem in a year unless specifically approved by the Commission ~~(e.g., occupational doses to workers) (e.g. 20.1301(c)) (§ 20.1301(a)(1))~~. Second, training commensurate with the potential radiological health protection problems present would be required by the proposed 10 CFR 19.12 only for individuals whose assigned duties involve a potential for exposure to radiation and/or radioactive materials. In the first case above, the individual's ~~duties~~ activities, i.e., visiting a facility or making deliveries, were not assigned by the licensee or a licensee contractor~~, i.e., any person performing activities for a licensee~~. Under these conditions, the individual is a member of the public, and the licensee must ensure that exposures are less than 100 mrem in a year, and further must be as low as is reasonably achievable (ALARA). Doses to these individuals should be controlled by other measures that would be included in an ALARA program, such as shielding, escorting, removing radioactive sources during visits, and controlling stay-times. Therefore, the Commission believes training is not required. However, nothing in the rules prevents providing training to any individuals.

In the second case, the individual's activities, i.e., performing repairs or cleaning, are performed during the course of employment with ~~is in the employ of~~ the licensee or a contractor to the licensee and the individuals' assigned duties do involve the potential for exposure to radiation. Even ~~Although~~ ~~the~~ an individual ~~may not~~ is not likely to enter a restricted area ~~and, whether this worker's~~ or receive a dose exceeding 100 mrem in a year ~~or not~~, ~~if the worker has the potential to receive some occupational exposure,~~ training "commensurate with potential radiological

health protection problems present in the workplace" is required to ensure informed consent and control of exposure if the worker has the potential to receive some occupational exposure. This training ~~would not necessarily need~~ does not have to be extensive. The Commission believes that doses received by individual workers at a rate greater than the 1mSv (100 mrem) in a year public dose limit constitute a level of risk which requires training at least to a level which ~~permits not only informed consent on the part of those individuals, but also~~ provides information on the risks of exposure and methods for reducing exposure in keeping with the ALARA principle.

Prior to the ~~1991 revision~~ promulgation of the revised standards, paragraph 20.409(b) of Part 20 provided that whenever a licensee is required to report to the Commission any exposure of an identified individual worker or member of the public to radiation and/or radioactive material, the licensee must also notify that individual.[1] Although it was the intent of the Commission that this provision remain in 10 CFR Part 20, the requirement was inadvertently omitted from the ~~new rule~~ revised standards. Accordingly, ~~§~~ Section 20.2205 is added to clearly restore to 10 CFR Part 20 the intention that individual workers and individual members of the public are to be notified of exposures in excess of the dose limits that would require notifying the NRC. Under ~~§~~ Section 20.2205, the licensees' obligation to notify an individual will be triggered if (and only if) the licensees' required report to NRC identifies that individual by name as having received an exposure to radiation and/or to radioactive material. The licensee's

[1] See also 10 CFR 19.13(d) (When a licensee is required to report to the Commission any exposure of an individual to radiation or radioactive material, the licensee must also provide the individual a report on their exposure data.)

obligation to identify individuals in a required report to the NRC is as provided for in 10 CFR 20.2203.

Agreement States

The proposed amendments would apply to all NRC licensees and Agreement States (Definitions in 10 CFR Part 20 are Division I matters and are thus matters of compatibility). The proposed changes, with the exception of the addition of ~~§~~ Section 20.2205 and the revision of the definition of unrestricted area, were discussed in June 1993 with Agreement State representatives and the changes discussed were strongly supported. Agreement States have the opportunity to comment further on all of the proposed changes during the public comment period. The Agreement States cannot be expected to modify their regulations before the January 1, 1994, date. Some States will need as much as 3 years to conform to the changes. In the interim, States may wish to consider alternative methods to address the issues presented in this rulemaking.

A draft of the proposed amendments, with the exception of the addition of ~~§~~ Section 20.2205 and the revision of the definition of unrestricted area, was provided to the Agreement States prior to submitting the amendments for publication in the Federal Register. Several States submitted comments. One State suggested limiting public doses to "licensed" sources of radiation while another observed that keeping this provision general permitted the States to control exposure from Naturally Occurring and Accelerator Produced Radioactive Material (NARM) as well as byproduct material. The proposed rule is general and does not specify licensed sources. This approach is consistent with the

rule, as expressed in ~~§~~ Section 20.1001 to control doses from all sources of radiation that are under the control of the licensee.

Another State provided a revised definition of "Member of the Public" which would not rely on the definition of "Occupational dose" and would make clear that workers exposed to NARM are not members of the public. The intent here was to minimize the change to the definitions and still accomplish the needed clarifications of these issues. For that reason and because "Occupational dose" is defined as from "licensed or unlicensed" sources, this change is not made in the proposed rule.

Two States argued that the draft language restricting the training requirements in 10 CFR 19.12 to individuals involved "in licensed activities" and "in the licensee's facility" was too restrictive, and might prevent workers such as housekeeping staff and security staff from receiving minimal, but needed training. The language of the training requirement is more inclusive in this proposed rule.

One State proposed retaining in ~~§~~ Section 20.2104(a) a requirement to determine prior occupational dose if an individual enters the restricted area. The NRC staff believes that retaining only the words "is likely to receive, in a year, an occupational dose requiring monitoring," is sufficient to trigger a determination of prior dose. The State also suggested wording which would make licensees responsible for accounting for occupational exposure from nonlicensed activities. This is consistent with the Commission's position and the draft is revised accordingly.

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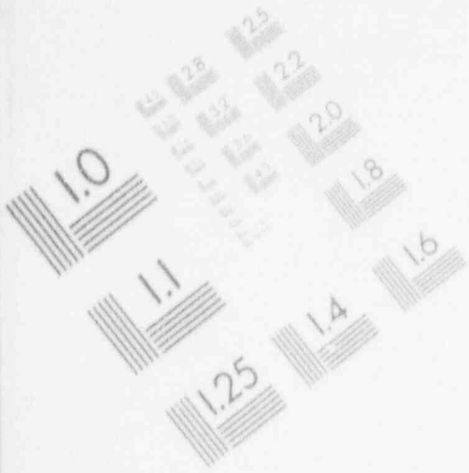

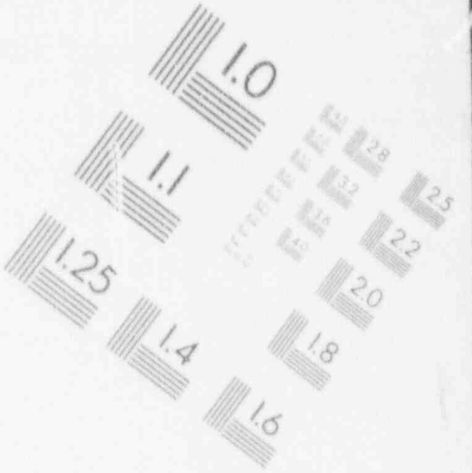

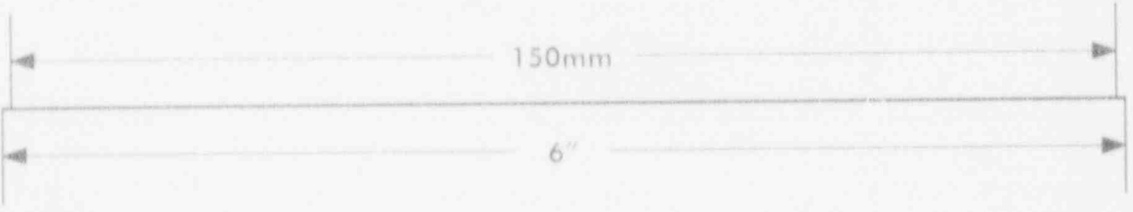

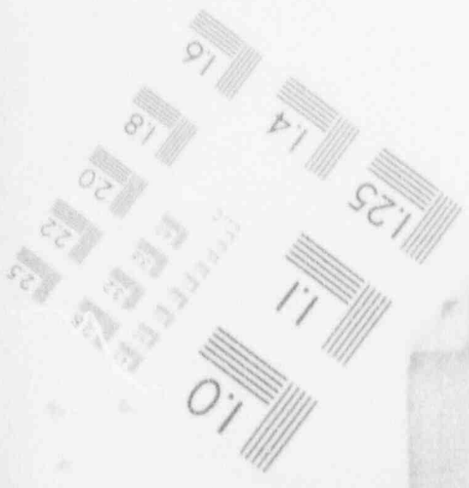

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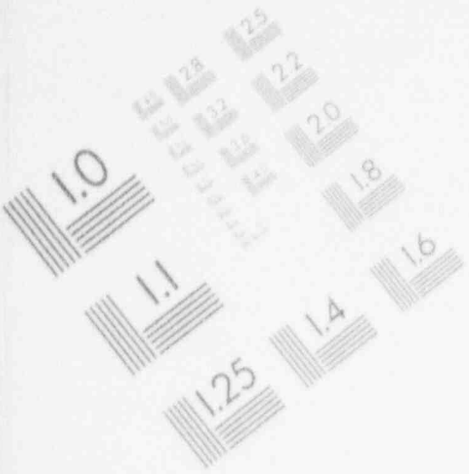

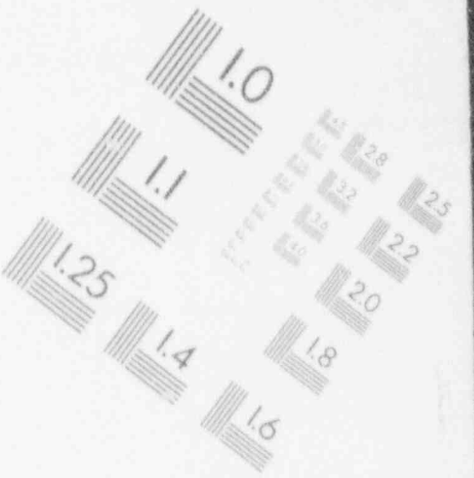

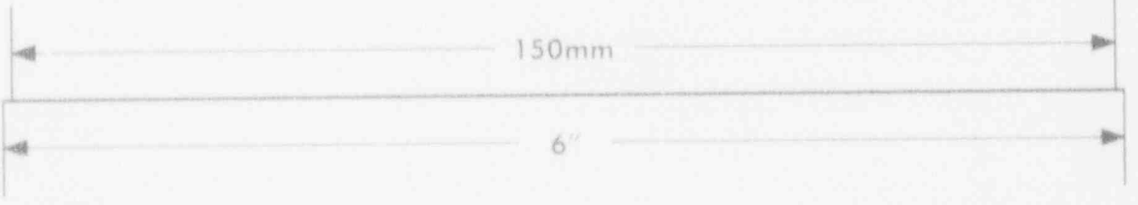

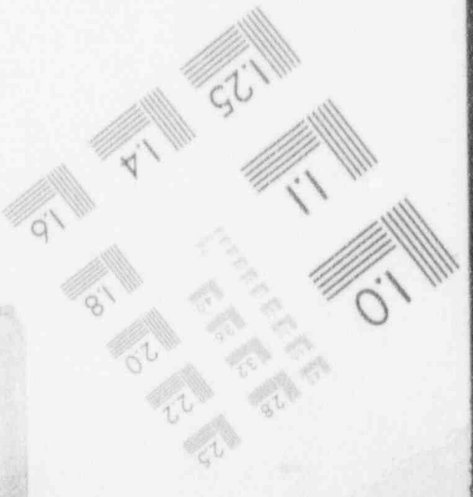

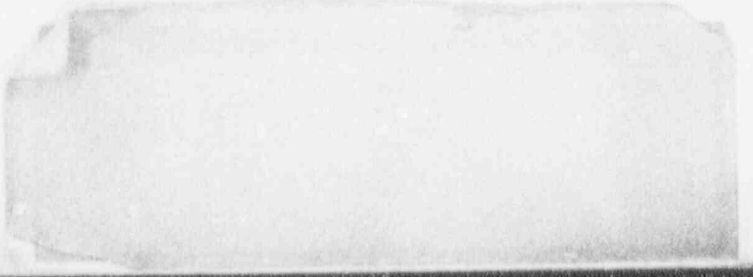

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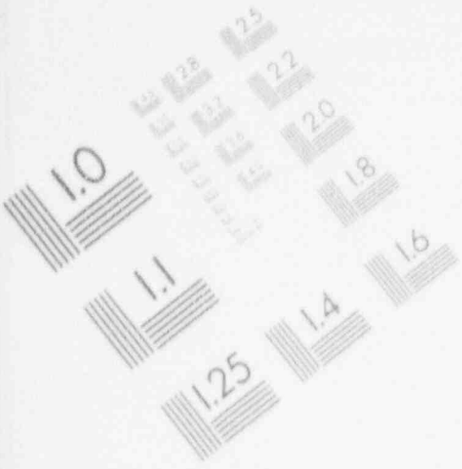

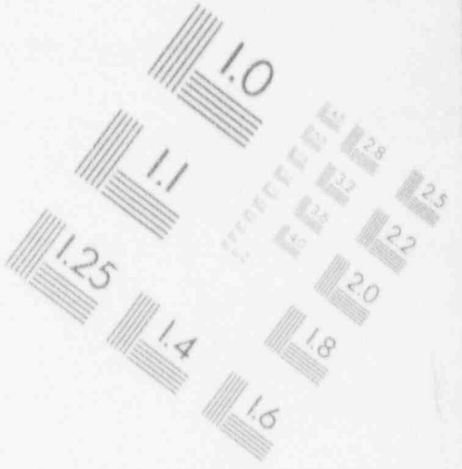

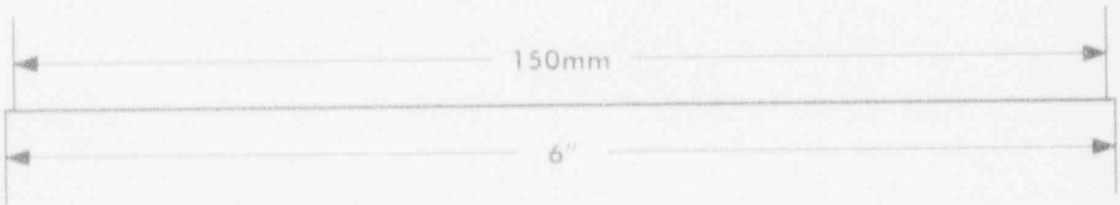

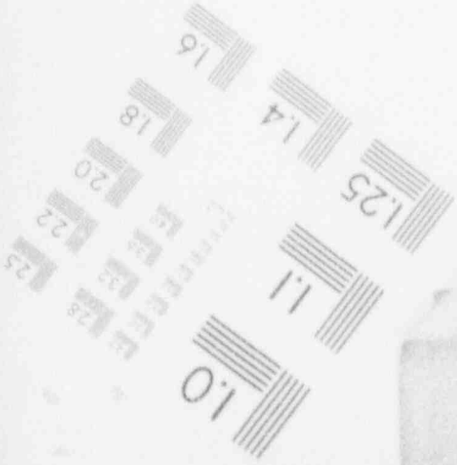

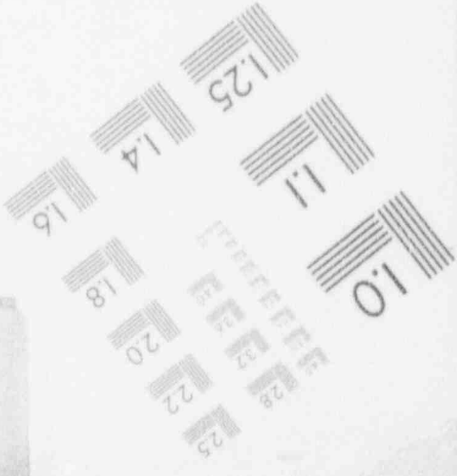

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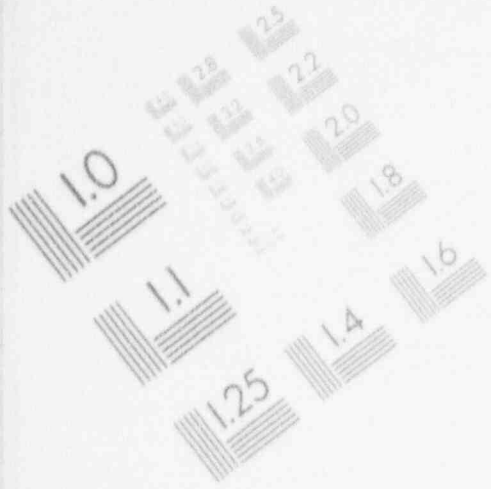

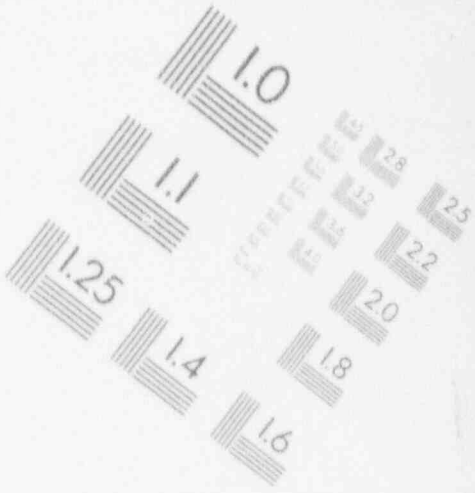

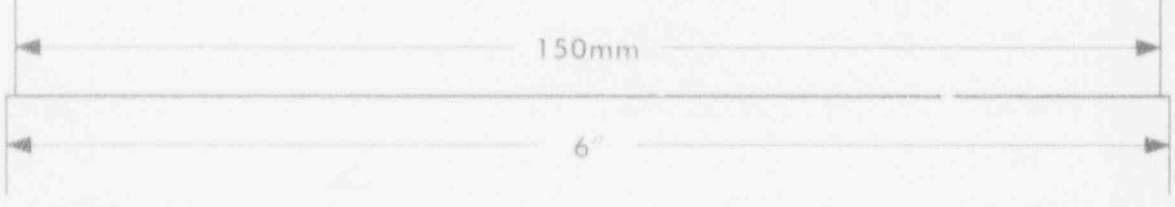

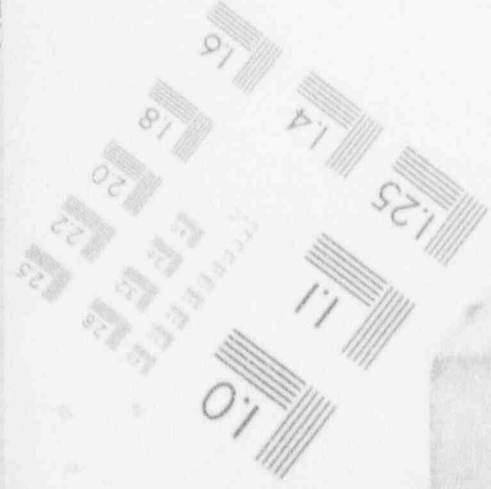

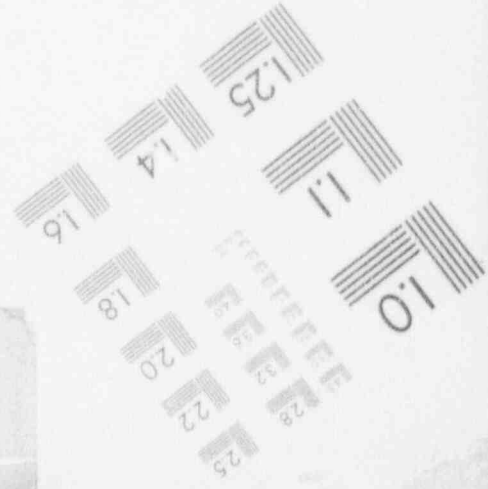

Description

The provision in 10 CFR Part 20 for a "Controlled area," its definition and its use in several other sections of Part 20 would be deleted. Licensees would continue to have the option to control access to areas for reasons other than radiation protection.

The proposed rulemaking would revise the definition of "Occupational dose" to delete reference to the "Restricted area" so that the occupational dose limit and its associated radiation protection provisions, such as training and individual monitoring requirements, would apply to an individual who in the course of employment has assigned duties involving exposure to radiation and/or to radioactive material. This change would also ~~prevent allowing members of the public to exceed public dose limits if they enter a restricted area~~ indicate that public dose limits cannot be exceeded for members of the public even if they enter restricted areas. The revised definition also adds the phrase "The computation of [illegible] the beginning of the second sentence in order to clarify the methodology for determining occupational doses.

The definition of "Unrestricted area" would be revised to make it clear that for the purposes of radiation protection, areas are either restricted or unrestricted and that access to unrestricted areas can be controlled for reasons other than radiation protection.

10 CFR 19.12, "Instructions to Workers," would be revised to make clear that training commensurate with the hazards present must be provided to all individuals who have the potential to be occupationally exposed rather than

just to individuals working in or frequenting any portion of a restricted area.

10 CFR 20.2205, "Reports to individuals of exceeding dose limits," is added to restore to Part 20 the Commission's intent that any identified individual, including members of the public, who receives an exposure in excess of the dose limits for which a report to the NRC is required, will receive notification of that exposure from the licensee.

Impact

The Commission believes that these proposed changes will have some, albeit relatively minor, impacts on licensees. The impacts associated with each of the changes are outlined below.

For the deletion of the definition of controlled area, the Commission believes that there will be little impact on most power reactor licensees. Although some confusion has surfaced associated with the intent of the terms "controlled area" and "occupational dose," these definitions have been discussed extensively with and by industry representatives, and the Commission believes that the proposed rule generally reflects current and planned practices of many reactor licensees. Licensees can continue to designate areas as controlled areas for purposes other than radiological protection, irrespective of whether the term appears in the rule or not.

~~However, this action would remove some flexibility from the regulations in that licensees would not be able to use controlled areas where dose rates exceed 2 mrem in an hour. Furthermore,~~ Some licensees have already implemented the revised ~~10 CFR Part 20~~ standards, and procedures have been

written which would require changes as a result of this proposed rulemaking if these procedures have employed the concept of controlling areas for radiological protection.

For those reactor licensees who have already formally implemented the revised ~~10 CFR 20~~ standards or who have a need for the additional flexibility afforded by the use of the concept of controlled area for purposes of radiological protection, the provisions for exemptions from the NRC's regulations provides an avenue of relief. The NRC currently believes that the elimination of the concept of "Controlled area" will have such a small impact on most power reactor licensees that it does not constitute a backfit as envisioned by 10 CFR 50.109. The action removes flexibility but does not directly impose new procedures. However, the NRC welcomes comments on whether this action does in fact constitute a backfit, the degree of burden imposed by the action, particularly for licensees who have already implemented the revised ~~10 CFR 20~~ standards, and on whether in the limited matter of "Controlled area," provisions for grandfathering should be provided in the final rule to avoid such burdens.

Revising the definition of "Unrestricted area" further makes clear the NRC's intent that for purposes of radiation protection, areas are either restricted or unrestricted. Some minor modifications to procedures and training may be necessitated by this change.

For the change involving the term occupational exposure, the Commission believes that some minor editorial modifications of procedures and training will be necessary. Occupational exposure was previously defined to include both presence in a restricted area and activities involving exposure to radiation and/or radioactive materials. Elimination of the reference to

restricted areas will not change the scope of applicability of the term occupational dose for most licensees' employees. Furthermore, this change as it relates to doses to members of the public, makes it clear that doses to members of the public must remain within the limits for members of the public, even if they are present within a restricted area. This distinction may result in some minor corrections to procedures and administrative control levels. However, it should be noted that licensees have controlled and continue to control the exposure of these individuals to small fractions of the public dose limit. Thus, there should be no significant change necessary in licensee activities.

The conforming change to 10 CFR Part 19 is minor and will affect only a small number of licensees and will have a negligible impact. For the modification of the training requirements to match the definition of occupational exposure, the Commission believes that licensees will need to make relatively minor modifications to training procedures to reflect the new definition. Training remains "commensurate with potential radiological health protection problems" and, thus, the scope of the training activities is not anticipated to require modification. The Commission also believes that any small incremental increase in burden of additional occupationally exposed individuals requiring training will be offset by the reduction in burden inherent in the fact that members of the public entering a restricted area will no longer be required to be trained in accordance with the provisions of 10 CFR Part 19.

The addition to 10 CFR Part 20 of a requirement to notify individual workers and individual members of the public of exposures in excess of the

dose limits is not considered to impose any additional burden on licensees,[2] The addition would make clear in 10 CFR Part 20, where such a requirement would normally be expected, that when existing reporting requirements would result in reporting exposure information on an identified individual member of the public to NRC, then the identified individual would receive a report on his or her exposure.

The impact of these proposed rule changes on materials licensees is considered to be minimal. The NRC believes that these changes will provide additional clarity when implementing the revised Part 20 and will not have an adverse impact on the health and safety of workers or the public. Removing the implied option to establish controlled areas for radiation protection purposes, and simplifying the definition and administration of occupational dose will require minimal changes in procedures and in some cases may even involve a net reduction in burden. Licensees continue to have the option to control access to areas for reasons other than radiological protection. Licensees who have already written procedures including provisions for controlled areas for radiation protection purposes would have the option to request exemptions. Materials licensees, particularly y those who have already implemented the new regulations, are invited to comment on whether or not the proposed changes impose significant burden.

Finding of No Significant Environmental Impact: Availability

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[2] See also 10 CFR 19.13(d) (When a licensee is required to report to the Commission any exposure of an individual to radiation or radioactive material, the licensee must also provide the individual a report on their exposure data.)

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

The option of establishing access control over an area owned by a licensee for reasons of security, for example, exists whether or not the term "Controlled area" is specifically defined in 10 CFR Part 20. The provision for controlled areas in the rule is not a requirement. Deleting the term "Controlled area" from the rule is not expected to result in a significant change in the number of areas to be controlled or in an increase in exposure to any member of the public. Public access to licensee owned facilities and land is expected to remain unchanged as a result of this amendment. No other environmental impact or benefit is associated with the "Controlled area" provision.

Changing the definition of "Occupational dose" to make it clear that individuals whose assigned duties involve exposure to radiation and radioactivity are subject to radiation protection procedures associated with occupational exposure and that members of the public cannot be permitted to receive doses that exceed public dose limits just by entering a restricted area is considered a benefit with no environmental impact. This change would have no effect on the type or quantity of material released into the environment and, if anything, would make it less likely for members of the public to be exposed to more than public dose limits.

Revising the definition of "Unrestricted area" to make it clear that for purposes of radiation protection, areas are either restricted or unrestricted, has no perceived environmental impact.

Amending the radiation protection training requirements to clarify that they apply to individuals who in the course of employment are potentially exposed to radiation and/or to radioactive material, regardless of whether they may or may not be within a restricted area, will result in no impact on the environment.

Adding ~~§~~ Section 20.2205 to Part 20, which would clearly restore the Commission's policy that individual workers and individual members of the public are notified, whenever NRC is notified, that they have been exposed to radiation or radioactive material in excess of the dose limits, will have no impact on the environment.

The environmental assessment and finding of no significant impact on which this determination is based are available for inspection at the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC. Single copies of the environmental assessment and finding of no significant impact are available from Alan K. Roecklein, U.S. NRC, 5650 Nicholson Lane, Rockville, MD 20852, (301) 492-3740.

Paperwork Reduction Act Statement

This proposed rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of

Management and Budget, approval numbers 3150-0044, 3150-0014, 3150-0005, and 3150-0006.

Regulatory Analysis

The NRC has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the NRC. The draft analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the draft analysis may be obtained from Alan K. Roecklein, U.S. NRC, 5650 Nicholson Lane, Rockville, MD 20852, (301) 492-3740.

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

Regulatory Flexibility Certification

Based upon the information available at this stage of the rulemaking proceeding and in accordance with the Regulatory Flexibility Act, 5 U.S.C. 605(b), the NRC certifies that, if promulgated, this rule will not have a significant economic impact upon a substantial number of small entities. The proposed amendments would apply to all NRC and Agreement State licensees. Because these amendments only clarify restore, and, conform existing requirements to the 1991 version of 10 CFR Part 20, they are considered to have no significant economic impact on any large or small entities.

However, the NRC is seeking comments and suggested modifications because of the widely differing conditions under which small licensees operate. Any small entity subject to this proposed regulation which determines that, because of its size, it is likely to bear a disproportionate adverse economic impact should notify the NRC of this in a comment that indicates --

(a) The licensee's size in terms of annual income or revenue, number of employees and, if the licensee is a treatment center, the number of beds and patients treated annually;

(b) How the proposed regulation would result in a significant economic burden upon the licensee as compared to that on a larger licensee;

(c) How the proposed regulations could be modified to take into account the licensee's differing needs or capabilities;

(d) The benefits that would be gained or the detriments that would be avoided by the licensee if the proposed regulation was modified as suggested by the commenter; and

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

Backfit Analysis

Because 10 CFR Parts 19 and 20 apply to all NRC licensees, any proposed changes to these parts must be evaluated to determine if these changes constitute backfitting for reactor licensees such that the provisions of 10 CFR 50.109, "Backfitting," apply. The following discussion addresses that evaluation.

The proposed rule consists of five changes: (1) deletion of the definition and use of the term "Controlled area," (2) deletion of the phrase "in a restricted area or" contained in the definition of occupational dose, (3) revising the definition of "Unrestricted area," (4) modification of the training requirement contained in 10 CFR 19.12, and (5) restoring a requirement that individuals ~~members~~ of the public be notified when they are identified in reports to NRC on exposures in excess of the limits.

The deletion of the definition of controlled area is a corrective change. The term was originally added with the 1991 revision of Part 20 to acknowledge the need for licensees to control access to areas for purposes other than radiation protection. The use of the term was not intended to be mandatory. Numerous questions from licensees regarding implementing Controlled areas have arisen. Since the staff believes that the use of a controlled area has no radiation protection function other than potential use in estimating the occupancy time for demonstrating compliance with the 100 mrem/year limit, it is being proposed that the term be deleted from 10 CFR Part 20.

For those reactor licensees who have already formally implemented the revised ~~10 CFR 20~~ standards or who have a need for the additional flexibility afforded by the use of the concept of controlled area for purposes of radiological protection, the provisions for exemptions from the NRC's regulations provide an avenue of relief. The NRC currently believes that the elimination of the concept of "Controlled area" will have such a small impact on most power reactor licensees that it does not constitute a backfit as envisioned by 10 CFR 50.109. The action removes flexibility but does not directly impose new procedures. However, the NRC welcomes comments on whether

this action does in fact constitute a backfit, the degree of burden imposed by the action, particularly for licensees who have already implemented the revised 10 CFR 20, and on whether in the limited matter of "Controlled area" provisions for grandfathering should be provided in the final rule to avoid such burdens. The deletion of the phrase "in a restricted area or," contained in the definition of occupational dose is ~~a clarifying change~~ to ensure that the Commission's intent to apply the dose limits of § 20.1301 to members of the public regardless of their physical location, is properly implemented. Currently, only workers are subject to the higher occupational dose limits and just because a member of the public is permitted entry into a restricted area does not mean that he or she should be allowed to receives an occupational dose and ~~is permitted to~~ exceed the public dose limit. For this reason, the reference to a restricted area is being removed from the definition of occupational dose. The revised definition also adds the phrase "the computation of" to the beginnning of the second sentence in order to clarify the methodology for determining occupational doses.

Revising the definition of "Unrestricted area," would make the current staff position clear that for purposes of radiation protection, areas are either restricted or unrestricted. This change is consistent with the former 10 CFR Part 20 and conforms to removing "Controlled area" from the rule.

The change to 10 CFR Part 19.12 will be consistent with the proposed revised definition of occupational exposure. Since occupational dose is to be based upon the individual's activities involving radiation and/or radioactive materials, rather than the location of the work (e.g., restricted area), a conforming change in Part 19 is needed to ensure that workers who receive an occupational dose are appropriately trained regardless of the physical

location where the work is performed. This is also needed so that members of the public, such as delivery persons, who occasionally enter a restricted area will not be required to receive occupational training merely because they entered a restricted area when their potential exposures do not exceed the 1 Msv (100 mrem) public dose limit and their activities, therefore, would not subject them to any significant risk.

The NRC staff believes that the impact of the ~~conforming~~ change to 10 CFR Part 19.12 is negligible for 10 CFR Part 50 licensees, given that the expected numbers of additional occupationally exposed individuals requiring training is small relative to the number of workers already receiving training at these facilities. The NRC staff also believes that these licensees have been providing training to these individuals, even though not specifically required by the regulations.

The addition to 10 CFR Part 20 of ~~§~~ Section 20.2205, "Reports to individuals of exceeding dose limits" is considered to be the restoration of a ~~previous requirement~~ ~~a clarifying change~~. Paragraph 20.409(b) of Part 20 ~~clearly~~ requires licensees to notify an individual worker or member of the public whenever a report to the NRC is required regarding an exposure of the identified individual. This requirement was inadvertently omitted from the ~~new Part 20~~ revised standards. Although few incidents occur that involved exposure of a member of the public in excess of dose limits, restoring this provision to Part 20 will ensure that licensees are aware of their obligation to notify the individual if, and when, they are required to submit a report to NRC of an occurrence that identifies that individual as having received an exposure.

The Commission believes that these proposed changes to 10 CFR Part 20 will have some albeit minor, impacts on reactor licensees. Licensees who have already implemented the ~~new Part 20~~ revised standards, or who have written procedures to do so, will need to revise those procedures to reflect the proposed changes if promulgated. Benefits such as simplifying the use of restricted and unrestricted area designation, making it clear that only workers can receive occupational dose, tying training requirements to the potential to receive occupational exposure and ensuring that overexposed individuals are notified, are considered by the Commission to far outweigh the impacts. However, these benefits are qualitative in nature, and are expressed in terms of reduced uncertainty in regulatory requirements, clarity of regulatory intent, and consistency of regulatory approach. Thus the NRC believes that the modifications proposed are not backfits. However, the NRC invites comments from affected licensees on whether these proposed changes impose significant burdens and whether or not the actions constitute a backfit.

List of Subjects

10 CFR Part 19

Criminal penalties, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Sex discrimination.

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 recordkeeping requirements, Source material, Special nuclear material, Waste treatment and disposal.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 553; the NRC is proposing to adopt the following amend to 10 CFR Parts 19 and 20.

PART 19 -- NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS: INSPECTION AND INVESTIGATION

1. The authority citation for Part 19 continues to read as follows:

AUTHORITY: Secs. 53, 63, 81, 103, 104, 161, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 955, as amended, secs. 234, 88 Stat. 444, as amended (42 U.S.C. 2073, 2093, 2111, 2133, 2134, 2201, 2236, 2282); secs. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841). Pub. L. 95-601, secs. 10, 92 Stat. 2951 (41 U.S.C. 5851).

2. Section 19.12 is revised to read as follows:

§ 19.12 Instructions to workers.

(a) All individuals who in the course of employment in which the individuals' assigned duties involve the potential for exposure to radiation and/or radioactive material shall be --

(1) Kept informed of the storage, transfer, or use of radiation and/or radioactive material;

(2) Instructed in the health protection problems associated with exposure to radiation and/or radioactive material, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

(3) Instructed in, and required to observe, to the extent within the workers control, the applicable provisions of Commission regulations and licenses for the protection of personnel from exposures to radiation and/or radioactive material;

(4) Instructed of their responsibility to report promptly to the licensee any condition which may lead to or cause a violation of Commission regulations and licenses or unnecessary exposure to radiation and/or radioactive material;

(5) Instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material; and

(6) Advised as to the radiation exposure reports which workers may request pursuant to § 19.13.

(b) The extent of these instructions must be commensurate with potential radiological health protection problems present in the workplace.

PART 20 -- STANDARDS FOR PROTECTION AGAINST RADIATION

3. 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, (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236, 2282); sec. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Sec. 20.408 also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161).

* * * * *

4. In § 20.1003, delete the definition "Controlled area."

5. In § 20.1003, the definitions of "Member of the public," "Occupational dose," "Public dose," and "Unrestricted area" are revised to read as follows:

§ 20.1003 Definitions

* * * * *

Member of the public means any individual except when that individual is receiving an occupational dose.

* * * * *

Occupational dose means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation and/or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. The computation of ~~O~~occupational dose does not include dose received from background radiation, as a patient from medical practices, from voluntary participation in medical research programs, or as a member of the public.

* * * * *

Add to 50c statement that 2nd sentence of definition is retained for clarity

Public dose means the dose received by a member of the public from exposure to radiation and/or radioactive material released by a licensee, or to any other source of radiation under the control of a licensee. It does not include occupational dose or doses received from background radiation, as a patient from medical practices, or from voluntary participation in medical research programs.

* * * * *

Unrestricted area means any area that is not a restricted area.

* * * * *

6. In § 20.1301 paragraph (b) is revised to read as follows:

§ 20.1301 Dose limits for individual members of the public.

* * * * *

(b) If the licensee permits members of the public to have access to ~~areas other than un~~restricted areas, the limits for members of the public continue to apply to those individuals.

* * * * *

7. In § 20.1302 paragraph (a) is revised to read as follows:

§ 20.1302 Compliance with dose limits for individual members of the public.

(a) The licensee shall make or cause to be made, as appropriate, surveys of radiation levels in unrestricted areas and radioactive materials in effluents released to unrestricted areas to demonstrate compliance with the dose limits for individual members of the public in § 20.1301.

* * * * *

8. Section 20.1801 is revised to read as follows:

§ 20.1801 Security of stored material.

The licensee shall secure from unauthorized removal or access licensed materials that are stored in unrestricted areas.

9. Section 20.1802 is revised to read as follows:

§ 20.1802 Control of material not in storage.

The licensee shall control and maintain constant surveillance of licensed material that is in an unrestricted area and that is not in storage.

10. In § 20.2104 the introductory text of paragraph (a) is revised to read as follows:

§ 20.2104 Determination of prior occupational dose.

(a) For each individual who is likely to receive, in a year, an occupational dose requiring monitoring pursuant to § 20.1502 the licensee shall -

* * * * *

11. Section § 20.2205 is added as follows:

§ 20.2205 Reports to individuals of exceeding dose limits.

When a licensee is required, pursuant to the provisions of §§ 20.2203, 20.2204, or 20.2206, to report to the Commission any exposure of an identified individual worker or member of the public to radiation or radioactive material, the licensee shall also provide to the individual, a written report on his or her exposure data included therein. This report must be transmitted at a time no later than the transmittal to the Commission.

PDR AE80-1

From: H. Hampton Newsome (HHN)
To: DAC, AKR, DAM2 BMM
Date: Tuesday, December 7, 1993 4:14 pm
Subject: OGC Comments on Part 20 PR

Please find attached OGC's proposed changes to the rulemaking package for Parts 19 and 20.

Files: P:\PT20OGC.COM

Don
I found the
Promise To Do
Something at
Dog Eared Pages -
Dog Eared. I had
promised S. Treby
to take appropriate
action but I
think it is
unwise to commit
now.
So I'll keep my
promise but not ready
to commit
action now.

PDR
AF80-1

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Files: P:\PT20OGC.COM

- Very little of legal consequence
- Mostly edits + few useful
- Most edits change Admin (Lisa) format for FR
- Several "wrong" changes, especially "computation" in definition of Occupational Dose

PDR
AE80-1

[7590-01]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 19 and 20

RIN 3150-AE80-1

Radiation Protection Requirements; Amended Definitions and Criteria

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) proposes to amend its regulations concerning radiation protection requirements. The proposed rule would: (1) delete the definition of "Controlled area" to make it clear that any area to which access is restricted for the purpose of radiological protection is a restricted area as defined in the regulation, (2) revise the definition of "Occupational dose" to delete reference to the "Restricted area," and indicate which radiation doses are excluded for the purposes of computation of the occupational dose, (3) revise the definition of unrestricted area to be consistent with the deletion of controlled area, (4) revise the provision in 10 CFR Part 20 entitled "Instruction to Workers," so that radiation protection training will be provided to all persons with the potential to be occupationally exposed and (5) restore a provision to 10 CFR Part 20 to provide that whenever licensees are required to report exposures of

No. Rotachang Summary only. Title changes 19, not 20. No. Admin (Losar) does that! No. Edit

Admin (Mike Losar) gets last shot at FR notice and sends it to FR in correct format.

individual members of the public to the NRC, then those individuals are to receive copies of the report.

DATE: Comment period expires (60 days following publication in the Federal Register). Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Mail written comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

Deliver comments to: 11555 Rockville Pike, Rockville, Maryland between 7:45 am and 4:15 pm Federal workdays.

Copies of the regulatory analysis, the environmental assessment and finding of no significant impact, the supporting statement submitted to OMB, and comments received may be examined at: the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Alan K. Roecklein, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492-3740.

SUPPLEMENTARY INFORMATION:

Background

On May 21, 1991, (56 FR 23360) the NRC amended 10 CFR Part 20 to add its revised "Standards for Protection Against Radiation (10 CFR 20.1001 - 20.2402)

(hereinafter referred to as "revised standards"). Compliance will become mandatory for all licensees on January 1, 1994. Extensive discussion regarding interpretation and implementation of the new rules has ensued both within the NRC and Agreement State staffs and with licensees and other interested parties.

The revised standards ~~for protection against radiation~~ currently include a definition for the term "Controlled area." The term is defined to be "an area, outside of a restricted area~~,~~ but inside the site boundary, access to which ~~to which access could~~ can be limited for any reason." (10 CFR 20.1003). The term "Restricted area" was retained in the revised standards ~~for protection against radiation~~ from the original regulation, 10 CFR Part 20, and ~~is~~ defined as an area, "access to which is limited by the licensees for the purpose of protecting individuals against undue risks from exposure to radiation or radioactive materials...." (10 CFR 20.1003). Neither the revised standards themselves, nor the supplemental information provide a basis for deciding whether to designate a given area as a "Restricted area" or a "Controlled area." In discussions with licensees and Agreement States, the absence of such a clear delineation appears to be the cause of considerable uncertainty among a number of licensees regarding how to implement the revised standards in this regard. The NRC believes that this situation can be alleviated by eliminating the term "Controlled area" from the regulations. This change has the effect of returning the regulation to the former situation in which areas are either restricted or unrestricted for purposes of radiation protection. As has always been the case, licensees continue to have the option of controlling access to areas for reasons other than radiation protection.

The definition of "Unrestricted area" in the ~~new 10 CFR Part 20 was revised to~~ revised standards acknowledges the existence of controlled areas and ~~designates an~~ currently is defined as an area "access to which is neither limited nor controlled by the licensee." (10 CFR 20.1003). Deletion of the term "Controlled area" permits return to the former situation in which areas are either restricted or unrestricted for radiation protection purposes, and the Commission now proposes to revise the definition of "Unrestricted area" ~~would be revised~~ to make this clear.

~~The option to control access for reasons other than radiation protection continues to be available to licensees.~~ Under this proposal, licensees would continue to have the option to control access for reasons other than radiation protection. As before, the definitions of "restricted area" and of "unrestricted area" do not preclude the existence of areas in which access is limited for purposes other than protecting individuals against undue risks from exposure to radiation and (or) radioactive materials. ~~A fundamental principle present in the regulations is that a member of the public is subject to the limits for a member of the public (§ 20.1301 (a)(1)), irrespective of that individual's location. Thus, licensees must be able to ensure that a member of the public, if present in a restricted area, as well as any other area, will not exceed an exposure of 100 mrem/year.~~

"Occupational dose" is defined currently in the revised standards "as the dose received by an individual in a restricted area or in the course of employment in which the individual's assigned duties involve exposure to radiation and~~/or~~ to radioactive materials....' (10 CFR 20.1003). Through meetings with licensees to discuss the ~~new~~ revised standards ~~for protection against radiation~~, the Commission has become aware that this definition can be

interpreted to allow individuals who are members of the public to receive an "occupational dose" and exceed public dose limits if they enter restricted areas. This was not the intention of the Commission in ~~revising 10 CFR 20 and~~ promulgating the revised standards. A fundamental principle present in the regulations is that a member of the public is subject to the limits for a member of the public (§ 20.1301 (a)(1)), irrespective of that individual's location. Thus, licensees must be able to ensure that a member of the public, if present in a restricted area, as well as any other area, will not exceed an exposure of 100 mrem/year. T~~t~~he suggestion that ~~such unintended~~ permission to expose a member of the public to a dose in excess of 100 mrem/ year is created by that individual's location in a restricted area ~~is allowed~~ can be removed by a simple modification to the definition of occupational dose, specifically by eliminating reference to dose received in a restricted area. In addition, "radiation and/or radioactive material" should replace "radiation and radioactive material" to correct a technical error in the text of the rule. With these changes, it would become clear that occupational dose is dose received as a result of an individual's employment in which assigned duties involve exposure to radiation and/or radioactive material. These changes would also make it clear that the dose received by a member of the public cannot be permitted to exceed the public dose limit even if the individual is receiving a portion of that dose while in a restricted area. The definition of "occupational dose" is also being revised to clarify the computation of such doses. Through the addition of the phrase "The computation of" at the beginning of the second sentence of the definition, the Commission intends to clarify that ~~in computing the~~ occupational dose, one begins with the measured dose and then excludes, from that amount, doses received from background

We will delete this OK to put back in!

OK

No! We don't compute the measured. That's useful!!

Deleting?

This adds nothing except invites more questions i.e. do we delete background only from computed occupational dose?

radiation, as a patient from medical practices, from voluntary participation in medical research programs, or as a member of the general public.

The regulation entitled, ~~10 CFR 19.12,~~ "Instruction to Workers," 10 CFR 19.12 currently requires that all individuals working in or frequenting any portion of a restricted area be instructed in the health protection problems associated with exposure to radiation and in radiation protection procedures needed to minimize exposure. Under this provision, if a worker never enters a restricted area, he or she would require no radiation protection training. On the other hand, members of the public, such as delivery persons who might occasionally enter a restricted area, would be required to be trained even though the nature of their activities would perhaps not warrant such instruction. The proposed change to § 19.12 would make it clear that anyone in the course of their employment in which the individual's assigned duties involve the potential for exposure to radiation and/or radioactive material would have to be provided appropriate radiation protection training. ~~Another important reason for proposing this change is to ensure that workers have an opportunity to exercise informed consent if they are subject to occupational dose limits.~~

Concern about training requirements has been expressed for certain categories of workers and members of the public illustrated by the following cases. Case 1 involves ~~such as (1)~~ a member of the public who is potentially exposed to ~~some~~ radiation while visiting a facility or making deliveries, ~~and (2)~~ Case 2 a maintenance worker or contractor who is exposed to radiation while performing repairs or cleaning. In order to decide if training is required, and what type of training is appropriate, certain provisions of the rules must be considered.

No! not relevant in context

First, after January 1, 1994, a member of the public cannot be permitted to receive more than 100 mrem in a year unless specifically approved by the Commission (e.g., occupational doses to workers) ~~(e.g. 20.1301(e)) (§ 20.1301(a)(1))~~. Second, training commensurate with the potential radiological health protection problems present would be required by the proposed 10 CFR 19.12 only for individuals whose assigned duties involve a potential for exposure to radiation and/or radioactive materials. In the first case above, the individual's ~~duties~~ activities, i.e., visiting a facility or making deliveries, were not assigned by the licensee or a licensee contractor~~, i.e., any person performing activities for a licensee~~. Under these conditions, the individual is a member of the public, and the licensee must ensure that exposures are less than 100 mrem in a year, and further must be as low as is reasonably achievable (ALARA). Doses to these individuals should be controlled by other measures that would be included in an ALARA program, such as shielding, escorting, removing radioactive sources during visits, and controlling stay-times. Therefore, the Commission believes training is not required. However, nothing in the rules prevents providing training to any individuals.

ok. useful addit

In the second case, the individual's activities, i.e., performing repairs or cleaning, are performed during the course of employment with ~~is in the employ of~~ the licensee or a contractor to the licensee and the individuals' assigned duties do involve the potential for exposure to radiation. Even ~~Although~~ ~~the~~ an individual ~~may not~~ is not likely to enter a restricted area ~~and, whether this worker's~~ or receive a dose exceeding 100 mrem in a year ~~or not~~, ~~if the worker has the potential to receive some occupational exposure,~~ training "commensurate with potential radiological

odds

No odds + not correct. They are likely to!!

health protection problems present in the workplace" is required to ensure informed consent and control of exposure if the worker has the potential to receive some occupational exposure. This training ~~would not necessarily need~~ does not have to be extensive. The Commission believes that doses received by individual workers at a rate greater than the 1mSv (100 mrem) in a year public dose limit constitute a level of risk which requires training at least to a level which ~~permits not only informed consent on the part of these individuals, but also~~ provides information on the risks of exposure and methods for reducing exposure in keeping with the ALARA principle.

Prior to the ~~1991 revision~~ promulgation of the revised standards, paragraph 20.409(b) of Part 20 provided that whenever a licensee is required to report to the Commission any exposure of an identified individual worker or member of the public to radiation and/or radioactive material, the licensee must also notify that individual.[1] Although it was the intent of the Commission that this provision remain in 10 CFR Part 20, the requirement was inadvertently omitted from the ~~new rule~~ revised standards. Accordingly, ~~§~~ Section 20.2205 is added to clearly restore to 10 CFR Part 20 the intention that individual workers and individual members of the public are to be notified of exposures in excess of the dose limits that would require notifying the NRC. Under ~~§~~ Section 20.2205, the licensees' obligation to notify an individual will be triggered if (and only if) the licensees' required report to NRC identifies that individual by name as having received an exposure to radiation and/or to radioactive material. The licensee's

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[1] See also 10 CFR 19.13(d) (When a licensee is required to report to the Commission any exposure of an individual to radiation or radioactive material, the licensee must also provide the individual a report on their exposure data.)

obligation to identify individuals in a required report to the NRC i as provided for in 10 CFR 20.2203.

Agreement States

The proposed amendments would apply to all NRC licensees and Agreement States (Definitions in 10 CFR Part 20 are Division I matters and are thus matters of compatibility). The proposed changes, with the exception of the addition of § Section 20.2205 and the revision of the definition of unrestricted area, were discussed in June 1993 with Agreement State representatives and the changes discussed were strongly supported. Agreement States have the opportunity to comment further on all of the proposed changes during the public comment period. The Agreement States cannot be expected to modify their regulations before the January 1, 1994, date. Some States will need as much as 3 years to conform to the changes. In the interim, States may wish to consider alternative methods to address the issues presented in this rulemaking.

A draft of the proposed amendments, with the exception of the addition of § Section 20.2205 and the revision of the definition of unrestricted area, was provided to the Agreement States prior to submitting the amendments for publication in the Federal Register. Several States submitted comments. One State suggested limiting public doses to "licensed" sources of radiation while another observed that keeping this provision general permitted the States to control exposure from Naturally Occurring and Accelerator Produced Radioactive Material (NARM) as well as byproduct material. The proposed rule is general and does not specify licensed sources. This approach is consistent with the

rule, as expressed in ~~§~~ Section 20.1001 to control doses from all sources of radiation that are under the control of the licensee.

Another State provided a revised definition of "Member of the Public" which would not rely on the definition of "Occupational dose" and would make clear that workers exposed to NARM are not members of the public. The intent here was to minimize the change to the definitions and still accomplish the needed clarifications of these issues. For that reason and because "Occupational dose" is defined as from "licensed or unlicensed" sources, this change is not made in the proposed rule.

Two States argued that the draft language restricting the training requirements in 10 CFR 19.12 to individuals involved "in licensed activities" and "in the licensee's facility" was too restrictive, and might prevent workers such as housekeeping staff and security staff from receiving minimal, but needed training. The language of the training requirement is more inclusive in this proposed rule.

One State proposed retaining in ~~§~~ Section 20.2104(a) a requirement to determine prior occupational dose if an individual enters the restricted area. The NRC staff believes that retaining only the words "is likely to receive, in a year, an occupational dose requiring monitoring," is sufficient to trigger a determination of prior dose. The State also suggested wording which would make licensees responsible for accounting for occupational exposure from nonlicensed activities. This is consistent with the Commission's position and the draft is revised accordingly.

Description

The provision in 10 CFR Part 20 for a "Controlled area," its definition and its use in several other sections of Part 20 would be deleted. Licensees would continue to have the option to control access to areas for reasons other than radiation protection.

The proposed rulemaking would revise the definition of "Occupational dose" to delete reference to the "Restricted area" so that the occupational dose limit and its associated radiation protection provisions, such as training and individual monitoring requirements, would apply to an individual who in the course of employment has assigned duties involving exposure to radiation and/or to radioactive material. This change would also ~~prevent allowing members of the public to exceed public dose limits if they enter a restricted area~~ indicate that public dose limits cannot be exceeded for members of the public even if they enter restricted areas. The revised definition also adds the phrase "The computation of" to the beginning of the second sentence in order to clarify the methodology for determining occupational doses.

The definition of "Unrestricted area" would be revised to make it clear that for the purposes of radiation protection, areas are either restricted or unrestricted and that access to unrestricted areas can be controlled for reasons other than radiation protection.

10 CFR 19.12, "Instructions to Workers," would be revised to make clear that training commensurate with the hazards present must be provided to all individuals who have the potential to be occupationally exposed rather than

just to individuals working in or frequenting any portion of a restricted area.

10 CFR 20.2205, "Reports to individuals of exceeding dose limits," is added to restore to Part 20 the Commission's intent that any identified individual, including members of the public, who receives an exposure in excess of the dose limits for which a report to the NRC is required, will receive notification of that exposure from the licensee.

Impact

The Commission believes that these proposed changes will have some, albeit relatively minor, impacts on licensees. The impacts associated with each of the changes are outlined below.

For the deletion of the definition of controlled area, the Commission believes that there will be little impact on most power reactor licensees. Although some confusion has surfaced associated with the intent of the terms "controlled area" and "occupational dose," these definitions have been discussed extensively with and by industry representatives, and the Commission believes that the proposed rule generally reflects current and planned practices of many reactor licensees. Licensees can continue to designate areas as controlled areas for purposes other than radiological protection, irrespective of whether the term appears in the rule or not.

~~However, this action would remove some flexibility from the regulations in that licensees would not be able to use controlled areas where dose rates exceed 2 mrem in an hour. Furthermore,~~ Some licensees have already implemented the revised ~~10 CFR Part 20~~ standards, and procedures have been

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written which would require changes as a result of this proposed rulemaking if these procedures have employed the concept of controlling areas for radiological protection.

For those reactor licensees who have already formally implemented the revised ~~10 CFR 20~~ standards or who have a need for the additional flexibility afforded by the use of the concept of controlled area for purposes of radiological protection, the provisions for exemptions from the NRC's regulations provides an avenue of relief. The NRC currently believes that the elimination of the concept of "Controlled area" will have such a small impact on most power reactor licensees that it does not constitute a backfit as envisioned by 10 CFR 50.109. The action removes flexibility but does not directly impose new procedures. However, the NRC welcomes comments on whether this action does in fact constitute a backfit, the degree of burden imposed by the action, particularly for licensees who have already implemented the revised ~~10 CFR 20~~ standards, and on whether in the limited matter of "Controlled area," provisions for grandfathering should be provided in the final rule to avoid such burdens.

Revising the definition of "Unrestricted area" further makes clear the NRC's intent that for purposes of radiation protection, areas are either restricted or unrestricted. Some minor modifications to procedures and training may be necessitated by this change.

For the change involving the term occupational exposure, the Commission believes that some minor editorial modifications of procedures and training will be necessary. Occupational exposure was previously defined to include both presence in a restricted area and activities involving exposure to radiation and/or radioactive materials. Elimination of the reference to

restricted areas will not change the scope of applicability of the term occupational dose for most licensees' employees. Furthermore, this change as it relates to doses to members of the public, makes it clear that doses to members of the public must remain within the limits for members of the public, even if they are present within a restricted area. This distinction may result in some minor corrections to procedures and administrative control levels. However, it should be noted that licensees have controlled and continue to control the exposure of these individuals to small fractions of the public dose limit. Thus, there should be no significant change necessary in licensee activities.

The conforming change to 10 CFR Part 19 is minor and will affect only a small number of licensees and will have a negligible impact. For the modification of the training requirements to match the definition of occupational exposure, the Commission believes that licensees will need to make relatively minor modifications to training procedures to reflect the new definition. Training remains "commensurate with potential radiological health protection problems" and, thus, the scope of the training activities is not anticipated to require modification. The Commission also believes that any small incremental increase in burden of additional occupationally exposed individuals requiring training will be offset by the reduction in burden inherent in the fact that members of the public entering a restricted area will no longer be required to be trained in accordance with the provisions of 10 CFR Part 19.

The addition to 10 CFR Part 20 of a requirement to notify individual workers and individual members of the public of exposures in excess of the

dose limits is not considered to impose any additional burden on licensees,[2] The addition would make clear in 10 CFR Part 20, where such a requirement would normally be expected, that when existing reporting requirements would result in reporting exposure information on an identified individual member of the public to NRC, then the identified individual would receive a report on his or her exposure.

The impact of these proposed rule changes on materials licensees is considered to be minimal. The NRC believes that these changes will provide additional clarity when implementing the revised Part 20 and will not have an adverse impact on the health and safety of workers or the public. Removing the implied option to establish controlled areas for radiation protection purposes, and simplifying the definition and administration of occupational dose will require minimal changes in procedures and in some cases may even involve a net reduction in burden. Licensees continue to have the option to control access to areas for reasons other than radiological protection. Licensees who have already written procedures including provisions for controlled areas for radiation protection purposes would have the option to request exemptions. Materials licensees, particularly y those who have already implemented the new regulations, are invited to comment on whether or not the proposed changes impose significant burden.

Finding of No Significant Environmental Impact: Availability

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[2] See also 10 CFR 19.13(d) (When a licensee is required to report to the Commission any exposure of an individual to radiation or radioactive material, the licensee must also provide the individual a report on their exposure data.)

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

The option of establishing access control over an area owned by a licensee for reasons of security, for example, exists whether or not the term "Controlled area" is specifically defined in 10 CFR Part 20. The provision for controlled areas in the rule is not a requirement. Deleting the term "Controlled area" from the rule is not expected to result in a significant change in the number of areas to be controlled or in an increase in exposure to any member of the public. Public access to licensee owned facilities and land is expected to remain unchanged as a result of this amendment. No other environmental impact or benefit is associated with the "Controlled area" provision.

Changing the definition of "Occupational dose" to make it clear that individuals whose assigned duties involve exposure to radiation and radioactivity are subject to radiation protection procedures associated with occupational exposure and that members of the public cannot be permitted to receive doses that exceed public dose limits just by entering a restricted area is considered a benefit with no environmental impact. This change would have no effect on the type or quantity of material released into the environment and, if anything, would make it less likely for members of the public to be exposed to more than public dose limits.

Revising the definition of "Unrestricted area" to make it clear that for purposes of radiation protection, areas are either restricted or unrestricted, has no perceived environmental impact.

Amending the radiation protection training requirements to clarify that they apply to individuals who in the course of employment are potentially exposed to radiation and/or to radioactive material, regardless of whether they may or may not be within a restricted area, will result in no impact on the environment.

Adding ~~§~~ Section 20.2205 to Part 20, which would clearly restore the Commission's policy that individual workers and individual members of the public are notified, whenever NRC is notified, that they have been exposed to radiation or radioactive material in excess of the dose limits, will have no impact on the environment.

The environmental assessment and finding of no significant impact on which this determination is based are available for inspection at the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC. Single copies of the environmental assessment and finding of no significant impact are available from Alan K. Roecklein, U.S. NRC, 5650 Nicholson Lane, Rockville, MD 20852, (301) 492-3740.

Paperwork Reduction Act Statement

This proposed rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of

Management and Budget, approval numbers 3150-0044, 3150-0014, 3150-0005, and 3150-0006.

Regulatory Analysis

The NRC has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the NRC. The draft analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the draft analysis may be obtained from Alan K. Roecklein, U.S. NRC, 5650 Nicholson Lane, Rockville, MD 20852, (301) 492-3740.

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

Regulatory Flexibility Certification

Based upon the information available at this stage of the rulemaking proceeding and in accordance with the Regulatory Flexibility Act, 5 U.S.C. 605(b), the NRC certifies that, if promulgated, this rule will not have a significant economic impact upon a substantial number of small entities. The proposed amendments would apply to all NRC and Agreement State licensees. Because these amendments only clarify restore, and, conform existing requirements to the 1991 version of 10 CFR Part 20, they are considered to have no significant economic impact on any large or small entities.

However, the NRC is seeking comments and suggested modifications because of the widely differing conditions under which small licensees operate. Any small entity subject to this proposed regulation which determines that, because of its size, it is likely to bear a disproportionate adverse economic impact should notify the NRC of this in a comment that indicates --

(a) The licensee's size in terms of annual income or revenue, number of employees and, if the licensee is a treatment center, the number of beds and patients treated annually;

(b) How the proposed regulation would result in a significant economic burden upon the licensee as compared to that on a larger licensee;

(c) How the proposed regulations could be modified to take into account the licensee's differing needs or capabilities;

(d) The benefits that would be gained or the detriments that would be avoided by the licensee if the proposed regulation was modified as suggested by the commenter; and

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

Backfit Analysis

Because 10 CFR Parts 19 and 20 apply to all NRC licensees, any proposed changes to these parts must be evaluated to determine if these changes constitute backfitting for reactor licensees such that the provisions of 10 CFR 50.109, "Backfitting," apply. The following discussion addresses that evaluation.

The proposed rule consists of five changes: (1) deletion of the definition and use of the term "Controlled area," (2) deletion of the phrase "in a restricted area or" contained in the definition of occupational dose, (3) revising the definition of "Unrestricted area," (4) modification of the training requirement contained in 10 CFR 19.12, and (5) restoring a requirement that individuals ~~s~~ members of the public be notified when they are identified in reports to NRC on exposures in excess of the limits.

The deletion of the definition of controlled area is a corrective change. The term was originally added with the 1991 revision of Part 20 to acknowledge the need for licensees to control access to areas for purposes other than radiation protection. The use of the term was not intended to be mandatory. Numerous questions from licensees regarding implementing Controlled areas have arisen. Since the staff believes that the use of a controlled area has no radiation protection function other than potential use in estimating the occupancy time for demonstrating compliance with the 100 mrem/year limit, it is being proposed that the term be deleted from 10 CFR Part 20.

For those reactor licensees who have already formally implemented the revised ~~10 CFR 20~~ standards or who have a need for the additional flexibility afforded by the use of the concept of controlled area for purposes of radiological protection, the provisions for exemptions from the NRC's regulations provide an avenue of relief. The NRC currently believes that the elimination of the concept of "Controlled area" will have such a small impact on most power reactor licensees that it does not constitute a backfit as envisioned by 10 CFR 50.109. The action removes flexibility but does not directly impose new procedures. However, the NRC welcomes comments on whether

this action does in fact constitute a backfit, the degree of burden imposed by the action, particularly for licensees who have already implemented the revised 10 CFR 20, and on whether in the limited matter of "Controlled area" provisions for grandfathering should be provided in the final rule to avoid such burdens. The deletion of the phrase "in a restricted area or," contained in the definition of occupational dose is ~~a clarifying change~~ to ensure that the Commission's intent to apply the dose limits of § 20.1301 to members of the public regardless of their physical location, is properly implemented. Currently, only workers are subject to the higher occupational dose limits and just because a member of the public is permitted entry into a restricted area does not mean that he or she should be allowed to receives an occupational dose and ~~is permitted to~~ exceed the public dose limit. For this reason, the reference to a restricted area is being removed from the definition of occupational dose. The revised definition also adds the phrase "the computation of" to the beginnning of the second sentence in order to clarify the methodology for determining occupational doses.

Revising the definition of "Unrestricted area," would make the current staff position clear that for purposes of radiation protection, areas are either restricted or unrestricted. This change is consistent with the former 10 CFR Part 20 and conforms to removing "Controlled area" from the rule.

The change to 10 CFR Part 19.12 will be consistent with the proposed revised definition of occupational exposure. Since occupational dose is to be based upon the individual's activities involving radiation and/or radioactive materials, rather than the location of the work (e.g., restricted area), a conforming change in Part 19 is needed to ensure that workers who receive an occupational dose are appropriately trained regardless of the physical

location where the work is performed. This is also needed so that members of the public, such as delivery persons, who occasionally enter a restricted area will not be required to receive occupational training merely because they entered a restricted area when their potential exposures do not exceed the 1 Msv (100 mrem) public dose limit and their activities, therefore, would not subject them to any significant risk.

The NRC staff believes that the impact of the ~~conforming~~ change to 10 CFR Part 19.12 is negligible for 10 CFR Part 50 licensees, given that the expected numbers of additional occupationally exposed individuals requiring training is small relative to the number of workers already receiving training at these facilities. The NRC staff also believes that these licensees have been providing training to these individuals, even though not specifically required by the regulations.

The addition to 10 CFR Part 20 of ~~§~~ Section 20.2205, "Reports to individuals of exceeding dose limits" is considered to be the restoration of a previous requirement~~a clarifying change~~. Paragraph 20.409(b) of Part 20 ~~clearly~~ requires licensees to notify an individual worker or member of the public whenever a report to the NRC is required regarding an exposure of the identified individual. This requirement was inadvertently omitted from the ~~new Part 20~~ revised standards. Although few incidents occur that involved exposure of a member of the public in excess of dose limits, restoring this provision to Part 20 will ensure that licensees are aware of their obligation to notify the individual if, and when, they are required to submit a report to NRC of an occurrence that identifies that individual as having received an exposure.

The Commission believes that these proposed changes to 10 CFR Part 20 will have some albeit minor, impacts on reactor licensees. Licensees who have already implemented the ~~new Part 20~~ revised standards, or who have written procedures to do so, will need to revise those procedures to reflect the proposed changes if promulgated. Benefits such as simplifying the use of restricted and unrestricted area designation, making it clear that only workers can receive occupational dose, tying training requirements to the potential to receive occupational exposure and ensuring that overexposed individuals are notified, are considered by the Commission to far outweigh the impacts. However, these benefits are qualitative in nature, and are expressed in terms of reduced uncertainty in regulatory requirements, clarity of regulatory intent, and consistency of regulatory approach. Thus the NRC believes that the modifications proposed are not backfits. However, the NRC invites comments from affected licensees on whether these proposed changes impose significant burdens and whether or not the actions constitute a backfit.

List of Subjects

10 CFR Part 19

Criminal penalties, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Sex discrimination.

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 recordkeeping requirements, Source material, Special nuclear material, Waste treatment and disposal.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 553; the NRC is proposing to adopt the following amend to 10 CFR Parts 19 and 20.

PART 19 -- NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS: INSPECTION AND INVESTIGATION

1. The authority citation for Part 19 continues to read as follows:

AUTHORITY: Secs. 53, 63, 81, 103, 104, 161, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 955, as amended, secs. 234, 88 Stat. 444, as amended (42 U.S.C. 2073, 2093, 2111, 2133, 2134, 2201, 2236, 2282); secs. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841). Pub. L. 95-601, secs. 10, 92 Stat. 2951 (41 U.S.C. 5851).

2. Section 19.12 is revised to read as follows:

§ 19.12 Instructions to workers.

(a) All individuals who in the course of employment in which the individuals' assigned duties involve the potential for exposure to radiation and/or radioactive material shall be --

(1) Kept informed of the storage, transfer, or use of radiation and/or radioactive material;

(2) Instructed in the health protection problems associated with exposure to radiation and/or radioactive material, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

(3) Instructed in, and required to observe, to the extent within the workers control, the applicable provisions of Commission regulations and licenses for the protection of personnel from exposures to radiation and/or radioactive material;

(4) Instructed of their responsibility to report promptly to the licensee any condition which may lead to or cause a violation of Commission regulations and licenses or unnecessary exposure to radiation and/or radioactive material;

(5) Instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material; and

(6) Advised as to the radiation exposure reports which workers may request pursuant to § 19.13.

(b) The extent of these instructions must be commensurate with potential radiological health protection problems present in the workplace.

PART 20 -- STANDARDS FOR PROTECTION AGAINST RADIATION

3. 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, (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236, 2282); sec. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Sec. 20.408 also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161).

* * * * *

4. In § 20.1003, delete the definition "Controlled area."

5. In § 20.1003, the definitions of "Member of the public," "Occupational dose," "Public dose," and "Unrestricted area" are revised to read as follows:

§ 20.1003 Definitions

* * * * *

Member of the public means any individual except when that individual is receiving an occupational dose.

* * * * *

Occupational dose means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation and/or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. The computation of ~~O~~occupational dose does not include dose received from background radiation, as a patient from medical practices, from voluntary participation in medical research programs, or as a member of the public.

* * * * *

Public dose means the dose received by a member of the public from exposure to radiation and/or radioactive material released by a licensee, or to any other source of radiation under the control of a licensee. It does not include occupational dose or doses received from background radiation, as a patient from medical practices, or from voluntary participation in medical research programs.

* * * * *

Unrestricted area means any area that is not a restricted area.

* * * * *

6. In § 20.1301 paragraph (b) is revised to read as follows:

§ 20.1301 Dose limits for individual members of the public.

* * * * *

(b) If the licensee permits members of the public to have access to ~~areas other than un~~restricted areas, the limits for members of the public continue to apply to those individuals.

* * * * *

7. In § 20.1302 paragraph (a) is revised to read as follows:

§ 20.1302 Compliance with dose limits for individual members of the public.

(a) The licensee shall make or cause to be made, as appropriate, surveys of radiation levels in unrestricted areas and radioactive materials in effluents released to unrestricted areas to demonstrate compliance with the dose limits for individual members of the public in § 20.1301.

* * * * *

8. Section 20.1801 is revised to read as follows:

§ 20.1801 Security of stored material.

The licensee shall secure from unauthorized removal or access licensed materials that are stored in unrestricted areas.

9. Section 20.1802 is revised to read as follows:

§ 20.1802 Control of material not in storage.

The licensee shall control and maintain constant surveillance of licensed material that is in an unrestricted area and that is not in storage.

10. In § 20.2104 the introductory text of paragraph (a) is revised to read as follows:

§ 20.2104 Determination of prior occupational dose.

(a) For each individual who is likely to receive, in a year, an occupational dose requiring monitoring pursuant to § 20.1502 the licensee shall -

* * * * *

11. Section § 20.2205 is added as follows:

§ 20.2205 Reports to individuals of exceeding dose limits.

When a licensee is required, pursuant to the provisions of §§ 20.2203, 20.2204, or 20.2206, to report to the Commission any exposure of an identified individual worker or member of the public to radiation or radioactive material, the licensee shall also provide to the individual, a written report on his or her exposure data included therein. This report must be transmitted at a time no later than the transmittal to the Commission.

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INSERT FOR PATIENT RELEASE FR:

In a companion rulemaking (58 FR -------; , 1993, if available) clarifying the agency's intent when revising 10 CFR Part 20, the following four provisions are being addressed: 1) deletion of the definition of "Controlled area," 2) revision of the definition of "Occupational dose," 3) clarifying the training requirements in 10 CFR Part 19, and 4) notifying individuals when exposure information is reported to NRC. The latter of these is indirectly related to this proposed rulemaking on patient release. The companion rulemaking would add a new 10 CFR 20.2205 to require that when licensees must inform NRC that exposures of individuals have exceeded the applicable limits, they must also notify the individual and provide a copy of the report to the individual. The subject individual may be either a worker or a member of the public. The general intent of the new 20.2205 is to ensure that individuals have the same information on their exposures that NRC has. Notifying individual members of the public was inadvertently deleted in the major revision of Part 20. Reports required to be submitted to NRC include exceeding the dose limits for members of the public in 10 CFR 20.1301.

The proposed rulemaking in this notice would exempt doses from patients released from a licensee's control in compliance with 10 CFR 35.75 from consideration in meeting the dose limits for members of the public in 10 CFR 20.1301. It is the Commission's intent that if a patient's release is found not to be in compliance with 10 CFR 35.75, the doses would no longer be exempt under section 20.1301 and the provisions of Part 20 would apply. Licensees would be expected to consider potential doses to members of the public under 20.1301 and make appropriate reports to NRC and to members of the public under the provisions of 20.2205, if adopted in final form. However, the Commission recognizes the unique situation when releasing patients. The noncompliance envisaged would be failure to do any evaluation under 35.75 or discovery of errors in the assumptions made in the licensee's evaluation on which release was determined to be in compliance with 35.75. To illustrate the latter, the licensee may discover an error in the residual activity estimated in the patient or may discover an error in the calculations. There is no expectation that the licensee would monitor the patient's activities or actual doses to members of the public after release of the patient; the release requirement is a prospective evaluation of likely doses. The licensee would be expected to notify the patient or patient's representative that doses exceeding those anticipated may have occurred. The licensee should then determine whether any additional individuals should be notified based on discussions with the patient or representative and on the magnitude of the potential exposures that may have occurred.

cc: Morris
Roecklein
Dragoette
Seal
File (Part 20/33

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PDR
AE80-1

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

October 8, 1993

NRC INFORMATION NOTICE NO. 93-80: IMPLEMENTATION OF THE REVISED 10 CFR PART 20

Addressees

All byproduct, source, and special nuclear material licensees.

Purpose

The U.S. Nuclear Regulatory Commission is issuing this information notice to emphasize the upcoming deadline for implementation of the revised 10 CFR Part 20 and to encourage licensees to prepare for the revised Part 20 immediately. PLEASE ENSURE THAT YOUR MANAGEMENT AND RADIATION SAFETY STAFF, SUCH AS RADIATION SAFETY OFFICER AND RADIATION SAFETY COMMITTEE MEMBERS, REVIEW THIS DOCUMENT. It is expected that licensees will review this information for applicability to their operation, distribute it to appropriate staff, and consider actions to prepare for, and incorporate, these changes. However, suggestions contained in this information notice are not new NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances

The revised Part 20, "Standards for Protection Against Radiation," becomes effective for all NRC licensees on January 1, 1994. In recent meetings NRC has held with byproduct material licensees, NRC has become aware that some licensees are not knowledgeable about and have done little, if anything, to prepare for the revised Part 20, even though the implementation date is less than 3 months away. On January 1, 1994, NRC will begin inspecting against and enforcing the regulations in the revised Part 20 for all licensees.

Discussion

Licensees who have not yet prepared to implement the revised Part 20 regulations are late. Licensees who are not even knowledgeable about the new regulations will have difficulty in meeting the January 1, 1994, implementation date and risk being out of compliance with the regulations once they become effective for all licensees. All NRC licensees should be taking action as soon as possible to develop procedures for implementing the revised Part 20.

The final rule for the revised Part 20 was published in the *Federal Register* on May 21, 1991 (56 FR 23360), with an original implementation date of January 1, 1993. Subsequently, the implementation date was extended to January 1, 1994 (57 FR 38588). Licensees were sent copies of the new regulations and were informed of the revised Part 20 in an information notice (IN 93-03). Licensees have had over 2 years to prepare for the new regulations.

The revised Part 20 makes fundamental changes in the standards for protection against radiation. These changes require corresponding changes in licensees' radiation protection programs. Licensees who are just now beginning to look at the new regulations and consider their impact are sorely behind in preparing for implementation. If licensees find themselves in this situation, NRC encourages them to immediately review the regulations, associated regulatory guides, and related guidance documents, and begin to prepare to implement the revised Part 20. Copies of the revised Part 20 and the regulatory guides may be obtained in accordance with the directions in Attachment 1.

This information notice requires no specific action nor written response. If you have any questions about the information in this notice, please contact one of the technical contacts listed below or the appropriate regional office.

Carl J. Paperiello

Carl J. Paperiello, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Technical contacts: Cynthia G. Jones, NMSS
(301) 504-2629
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Attachments:
1. Addresses for Obtaining Part 20 Documents
2. List of Recently Issued NMSS Information Notices
3. List of Recently Issued NRC Information Notices

ADDRESSES FOR OBTAINING REVISED 10 CFR PART 20 DOCUMENTS

OBTAINING THE REVISED 10 CFR PART 20

Title 10, Code of Federal Regulations (CFR), which contains the revised Part 20, may be obtained in bound form from the Government Printing Office (GPO), at the current GPO price. Information on prices may be obtained by contacting the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 371954, Pittsburgh, PA 15250-7954, or by telephoning GPO at (202) 783-3238. Be sure to request the volume that contains Parts 0 through 50 (Stock Number 869-019-00029-1).

OBTAINING REGULATORY GUIDES

Licensees are encouraged to review the applicable regulatory guides for assistance in the implementation of the revised Part 20. The regulatory guides that have been developed to assist with the implementation of the revised Part 20 include the following:

1. Regulatory Guide 8.7, Revision 1, "Instructions for Recording and Reporting Occupational Exposure Data"

2. Regulatory Guide 8.9, Revision 1, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program"

3. Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace"

4. Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Radiation Doses"

5. Regulatory Guide 8.35, "Planned Special Exposures"

6. Regulatory Guide 8.36, "Radiation Dose to the Embryo/Fetus"

7. Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities"

8. Regulatory Guide 10.8, Revision 2, Appendix X, "Guidance on Complying with New Part 20 Requirements"

Copies of issued regulatory guides may be purchased from the GPO at the current GPO price. Information on prices may be obtained by contacting the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, D.C. 20013-7082, or by telephoning (202) 512-2249 or (202) 512-2171.

OBTAINING OTHER REVISED PART 20 DOCUMENTS

NRC has issued six sets of questions and answers (Q&As) regarding implementation of the revised Part 20, and other sets are being developed. The Q&As may be obtained from NRC's Public Document Room at: Public Document Room, USNRC, Washington, D.C. 20555, or by telephoning (202) 634-3273. Ask for "the revised Part 20 question and answer sets" when requesting the documents. There is a fee for reproduction and mailing.

LIST OF RECENTLY ISSUED
NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
93-77	Human Errors that Result in Inadvertent Transfers of Special Nuclear Material at Fuel Cycle Facilities	10/04/93	All nuclear fuel cycle licensees.
93-73	Criminal Prosecution of Nuclear Suppliers for Wrongdoing	09/15/93	All NRC licensees.
93-69	Radiography Events at Operating Power Reactors	09/02/93	All holders of OLs or CPs for nuclear power reactors and all radiography licensees.
93-60	Reporting Fuel Cycle and Materials Events to the NRC Operations Center	08/04/93	All fuel cycle and materials licensees.
93-50	Extended Storage of Sealed Sources	07/08/93	All licensees authorized to possess sealed sources.
93-36	Notifications, Reports, and Records of Misadministrations	05/07/93	All U.S. Nuclear Regulatory Commission medical licensees.
93-31	Training of Nurses Responsible for the Care of Patients with Brachytherapy Implants	04/13/93	All U.S. Nuclear Regulatory Commission medical licensees.
93-30	NRC Requirements for Evaluation of Wipe Test Results; Calibration of Count Rate Survey Instruments	04/12/93	All U.S. Nuclear Regulatory Commission medical licensees.
93-19	Slab Hopper Bulging	03/17/93	All nuclear fuel cycle licensees.
93-18	Portable Moisture-Density Gauge User Responsibilities during Field Operations	03/10/93	All U.S. Nuclear Regulatory Commission licensees that possess moisture-density gauges.

LIST OF RECENTLY ISSUED
NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
93-79	Core Shroud Cracking at Beltline Region Welds in Boiling-Water Reactors	09/30/93	All holders of operating licenses or construction permits for boiling-water reactors (BWRs).
93-78	Inoperable Safety Systems At A Non-Power Reactor	10/04/93	All holders of OLs or CPs for test and research reactors.
93-77	Human Errors that Result in Inadvertent Transfers of Special Nuclear Material at Fuel Cycle Facilities	10/04/93	All nuclear fuel cycle licensees.
93-76	Inadequate Control of Paint and Cleaners for Safety-Related Equipment	09/21/93	All holders of OLs or CPs for nuclear power reactors.
93-75	Spurious Tripping of Low-Voltage Power Circuit Breakers with GE RMS-9 Digital Trip Units	09/17/93	All holders of OLs or CPs for nuclear power reactors.
93-74	High Temperatures Reduce Limitorque AC Motor Operator Torque	09/16/93	All holders of OLs or CPs for nuclear power reactors.
93-73	Criminal Prosecution of Nuclear Suppliers for Wrongdoing	09/15/93	All NRC licensees.
93-72	Observations from Recent Shutdown Risk and Outage Management Pilot Team Inspections	09/14/93	All holders of OLs or CPs for nuclear power reactors.
93-71	Fire at Chernobyl Unit 2	09/13/93	All holders of OLs or CPs for nuclear power reactors.

OL = Operating License
CP = Construction Permit