

DEC 17 1993

MEMORANDUM FOR: James M. Taylor, Executive Director for Operations

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

SUBJECT: RADIATION PROTECTION REQUIREMENTS; AMENDED DEFINITIONS AND CRITERIA

Enclosed for your signature is a proposed rule to be published in the Federal Register that amends 10 CFR Parts 19 and 20, "Radiation Protection Requirements; Amended Definitions and Criteria."

Backfit Analysis: The staff has determined that a backfit analysis is not required for this final rule because these amendments do not involve any provisions which would impose significant backfits as defined in 10 CFR 50.109(a)(1). However, in that deletion of "Controlled area" removes some flexibility from the rules, the statement of considerations specifically requests comment on the extent of the impact.

NRC Resource Burden: Completion of this proposed rulemaking is estimated to require 0.4 person-years of NRC staff time.

Notices: A notice to the Commission that the EDO has signed this proposed rule is enclosed for inclusion in the next Weekly Report to the Commission (Enclosure D). The appropriate Congressional committees will be notified (Enclosure C).

Coordination: The Offices of Administration, Nuclear Material Safety and Safeguards, Nuclear Reactor Regulation, Enforcement, State Programs, Information Resources Management, and Analysis and Evaluation of Operational Data, concur in these proposed amendments. The Office of the General Counsel has no legal objection. Resources to implement this rulemaking are included in the FY 1993-1997 Five-Year Plan, and no additional resources would be required for its implementation.

ORIGINAL SIGNED BY

Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

Enclosures: See page 2

RECORD NOTE: A draft copy of the proposed rule was sent to OIG for information on July 30, 1993.

[G:\RPHEB\ROECK\PT20-08\PT20-8_AKR]		*See previous concurrences						
Offc:	*RPHEB-DRA	*RPHEB-DRA	RPHEB-DRA	DD-DRA-RES	D-DRA-RES	DD-DRA-RES	*D:OE	*D:IRM
Name:	ARoecklein:rg	Dragonette	DCool	FCostanz	GMorris	CJHertemes	JLieberman	GCranford
Date:	9/2/93	9/2/93	12/19/93	11/11/93	12/14/93	11/15/93	9/3/93	8/5/93
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Offc:	*D:SP	*D:NRR	D:NMSS	*D:ADM	*GC	*D:AEOD	D:RES	
Name:	RBangart	TMurley	RBernero	PNarry	WParler	ELJordan	ESBeckjord	
Date:	9/7/93	9/2/93	10/29/93	8/10/93	12/09/93	8/16/93	12/17/93	
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Off:	*RPHEB:DRA	*RPHEB:DRA	RPHEB:DRA	DD:DRA:RES	D:DRA:RES	DD:RES	*D:OE	*D:IRM	
Name:	ARoecklein:rg	Dragonette	DCool	FCostanzo	BMorris	CJHestemec	JLieberman	GCranford	
Date:	9/2/93	9/2/93	12/14/93	12/11/93	12/11/93	12/15/93	9/3/93	8/5/93	
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Off:	*D:SP	*D:NRR	D:NMSS	*D:ADM	*GC	*D:AEOD	D:RES		
Name:	RBangart	TMurley	RBernero	PNorry	WParler	ELJordan	ESBeckjord		
Date:	9/7/93	9/2/93	/ /93	8/10/93	12/09/93	8/16/93	12/17/93		
	Telecon	Telecon		Memo	Meeting	Memo			
		w/DCool							

DOCUMENT NAME: AMENDMENTS TO 10 CFR PARTS 19 AND 20 TO DELETE CONTROLLED AREA, REVISE THE DEFINITION OF OCCUPATIONAL DOSE, AND TO REVISE CRITERIA ON WHEN RADIATION PROTECTION TRAINING IS REQUIRED

AUTHOR'S NAME: A. Roecklein

FILE NAME: G:\RPHEB\ROECK\PT20-08\PT20-8.AKR

DATE: July 2, 1993

REVISED 8/27/93 REWISED: 10/7/93 10/14/93, Pat Thompson
jw AM
10:00 am 11/16/93, Pat Thompson 11/19/93, Pat Thompson
12/1/93, Pat Thompson, 12/10/93, Doris Mendiola, 12/13/93 Pat T.

REVIEWERS:

ARoecklein 09/02/93

KDragonette 09/02/93

DCool Concurred in OGC changes 12/9/93

FCostanzi 12/16 ✓

BMorris 12/16 ✓

CJHeitemes *CJA*

JLieberman 09/03/93, E-Mail

GCranford 08/05/93, Memo

RBangart 09/07/93, Telecon

TMurley Telecon Congel/Morris 12/1/93

RBernero Paperiello-Meeting 10/29/93

PNorry 08/10/93, Memo

WParler 12/09/93, Meeting

EJordan 08/16/93, Memo

EBeckjord _____

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EX

PDR
AE80-1

ENCLOSURE A

Federal Register
Proposed Rule

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," (3) revise the definition of unrestricted area to be consistent with the deletion of controlled area, (4) revise the provision in 10 CFR Part 19 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). 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 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 can be limited for any reason (10 CFR 20.1003). The term "Restricted area" was retained in the revised standards 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 revised standard acknowledges the existence of controlled areas and currently is defined as an area "access to which is neither limited nor controlled by the licensee"

(10 CFR Part 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" to make this clear.

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.

"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 Part 20.1003) Through meetings with licensees to discuss the revised standards, 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 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. The Commission is separately considering revisions to Parts 20 and 35, whereby licensees who have administered radioactive materials to patients and released them in accordance with § 35.75 would be exempt from the provisions of § 20.1301 (a)(1) with regard to the radioactive material in the released

patient. 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. The suggestion that permission to expose a member of the public to a dose in excess of 100 mrem in a year, is created by that individual's location in a restricted area, 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 remainder of the definition of occupational dose would not be modified by this action, and maintains the description of both what is included and what is excluded in occupational dose for purposes of clarity.

The regulation entitled "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.

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 a member of the public who is potentially exposed to some radiation while visiting a facility or making deliveries, and, 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 (10 CFR 20.1301).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 activities, i.e., visiting a facility or making deliveries, were not assigned by the licensee or a licensee contractor. Under these conditions, the individual is a member of the public, and the

¹As discussed above, the Commission is separately considering revisions to Parts 20 and 35 to address cases whereby licensees have treated patients with radioactive material and released them under the provisions of § 35.75, and thus would not fall under the provision of § 20.1301 (a)(1) with regard to the radioactive material in the released patient.

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 the licensee or a contractor to the licensee and the individuals' assigned duties do involve the potential for exposure to radiation. Although the individual may not enter a restricted area and, whether this worker's dose exceeds 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. This training 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 provides information on the risks of exposure and methods for reducing exposure in keeping with the ALARA principle.

Prior to the 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.² Although it was the intent of the Commission that this provision remain in 10 CFR Part 20, the requirement was inadvertently omitted from the 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 licensee's obligation to notify an individual will be triggered if (and only if) the licensee's required report to NRC identifies that individual by name as having received an exposure to radiation and/or to radioactive material. The licensee's 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

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.)

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 indicate that public dose limits cannot be exceeded for members of the public even if they enter a restricted area.

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.

"Instructions to Workers," 10 CFR 19.12, 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.

"Reports to individuals of exceeding dose limits," 10 CFR 20.2205, 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.

Some licensees have already implemented the revised 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 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 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.³ 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 10 CFR 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 those who have already implemented the new regulations, are invited to comment on whether or not the proposed changes impose significant burden.

³ 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.)

Finding of No Significant Environmental Impact: Availability

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

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 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 Part 20.

For those reactor licensees who have already formally implemented the revised 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 to ensure that the Commission's intent to apply the dose limits of 10 CFR 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 receive an occupational dose and exceed the public dose limit. For this reason, the reference to a restricted area is being removed from the definition of occupational dose.

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 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 of 10 CFR 20.2205, "Reports to individuals of exceeding dose limits" is considered to be the restoration of a previous requirement. Paragraph 20.409(b) of Part 20 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 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 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. 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 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:

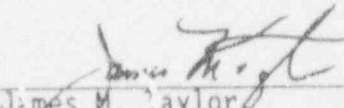
§ 20.2205 Reports to individuals of exceeding dose limits.

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.

* * * * *

Dated at Rockville, Maryland, this 19th day of January, 1994.

For the Nuclear Regulatory Commission.



James M. Taylor
Executive Director for Operations.

PDR
AF 50-1

ENCLOSURE B

Regulatory Analysis

REGULATORY ANALYSIS

RADIATION PROTECTION REQUIREMENTS; AMENDED DEFINITIONS AND CRITERIA

1. STATEMENT OF PROBLEM

The revised 10 CFR Part 20, Standards for Protection Against Radiation, published on May 21, 1991, defines a "Controlled area" as an area, access to which could be limited for any reason. The term "Restricted area" was retained in the revised standards for protection against radiation from the original regulation and 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." 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.

"Occupational dose" is defined as the dose received in a restricted area or in the course of employment in which the individual's assigned duties involve exposure to radiation and radioactive materials. Through meetings

with licensees to discuss the new 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 "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 the suggestion that such unintended permission 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 "Unrestricted area" in the new 10 CFR Part 20 designates an area, access to which is neither limited nor controlled by the licensee. This language was chosen to acknowledge "Controlled area" but does not clearly preclude the use of controlled area for radiation protection purposes.

Under the current Part 19 training (instruction) requirements, licensees might conclude that workers who never enter a restricted area, but nonetheless are exposed to radiation by virtue of their employment, require no training

concerning radiation protection. Conversely, members of the public who might infrequently enter a restricted area may receive extensive training whether or not they are exposed to any significant risk.

Prior to the 1991 revision, paragraph 20.409(b) of Part 20 provided that whenever a licensee is required to report to the Commission any exposure of an individual to radiation and/or radioactive material, the licensee must also notify that individual. In the development of the new 10 CFR Part 20, this requirement was inadvertently omitted.

2. PROPOSED SOLUTION

In the proposed revision of 10 CFR 20.1003, the definition of a "Controlled area" would be deleted from the rule. The Statement of Considerations makes it clear that a licensee has the option of controlling access to areas for reasons other than radiological protection. Likewise, the definition of "Occupational dose" would be changed to delete references to the "Restricted area," and make it clear that an individual is occupationally exposed if engaged in activities that involve exposure to radiation and/or to radioactive material. Further, NRC believes that the definition of "Restricted area" is sufficient to require licensees to limit access for purposes of radiation protection.

The definition of "Unrestricted area" would be revised to make it clear that for purposes of radiation protection, areas are either restricted or unrestricted.

Conforming changes would be necessary in the definitions of "Member of the public" and "Public dose." In addition, 10 CFR 20.1301(b), 20.1302(a), 20.1801 and 20.1802 would require minor conforming amendments.

A change would be made to 10 CFR 19.12 to ensure that training commensurate with the hazards present would be provided to all individuals who have the potential to be occupationally exposed.

The effect of these amendments would be to make clear that (1) individuals in the employ of a licensee, including contractors, whose assigned duties involve exposure to radiation and/or to radioactive material would be subject to occupational dose limits and associated protection requirements and (2) exposure of members of the public would be limited to the public dose limit, irrespective of their location or activity within the licensee's facility. In addition, the present system of restricted and unrestricted areas would be retained. Licensees would be free to establish control of access to certain areas for reasons other than radiological protection if they choose, but these areas would not be defined in the regulations.

The addition to 10 CFR Part 20 of § 20.2205, "Reports to individuals of exceeding dose limits" is considered to be a change to restore the Commission's intent. Paragraph 20.409(b) of the former Part 20, combined with

the definition of individual,¹ requires licensees to notify identified individual workers or members of the public, whenever a report to the NRC is required that identifies the individual. Although it was the Commission's intent that this requirement continue, it was inadvertently omitted from the new Part 20. Thus, the addition of § 20.2205 reflects a previous requirement and will add minimal burden to licensees. Few incidents of exposure in excess of the dose limits to the public occur and this provision requires mailing a copy of a report already generated for submittal to the NRC.

3. ALTERNATIVES

a - No Action

Licensees and Agreement States have advised the NRC that these definitions are misleading. Confusing definitions need to be addressed as soon as possible in order to facilitate the smooth and efficient implementation of the revised 10 CFR Part 20, which has a mandatory implementation date of January 1, 1994. The proposed changes would have no adverse impact on health and safety of workers or the public or result in significant costs to licensees. If no action is taken, some inspection and enforcement costs may result from efforts to correct inappropriate use of "Controlled area" and "Occupational dose," and the Commission's intent with respect to the issues described above would not be codified. Therefore the No Action alternative is not considered to be viable.

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 his exposure data.)

b - Regulatory Guidance

An alternative to No Action is to provide interpretation and clarification through the use of regulatory guides. However, the concerns and issues were identified in the process of providing guidance to licensees. In the case of "Controlled areas," numerous questions and answers have not provided a satisfactory solution for some licensees. In the case of the definition of "Occupational dose" and the application of training requirements, the concern lies with the wording of the regulation itself. The addition of the notification requirement needs to be in Part 20 where such a requirement would normally be expected. Thus, the alternative of using regulatory guides is not considered to be viable.

c - Changes to Regulation

The issues to be addressed stem directly from the definitions and specifications in 10 CFR Parts 19 and 20. Therefore, the more effective solution is modification of those sections by rulemaking.

4. IMPACT OF PROPOSED ACTION

a - Licensees

Smooth and efficient implementation of the revised 10 CFR Part 20 will be facilitated by these changes. Removing the term "Controlled area," revising the definition of "Unrestricted area," and clarifying the definition of occupational dose will have some, albeit relatively minor impact upon licensees.

Deleting the term "Controlled area" throughout the rule and revising the definition of "Unrestricted area" would not affect a licensee's option to

control access to any area for reasons other than radiation protection. Licensee procedures that have already been written, which include the provision for controlling access to unrestricted areas, for security reasons for example, will require no changes. If a licensee has written procedures that specify "Controlled areas" for radiation protection purposes, then those procedures may require revision irrespective of this proposed rulemaking. The proposed rule notes the option to request exemption from this proposed change and invites licensees to comment specifically on the extent of impact this change may cause.

The addition of 10 CFR 20.2205, "Reports to individuals of exceeding dose limits," reflects a previous requirement and will add no new significant burden to licensees. Few incidents of exposure in excess of the dose limits to the public occur, and this provision requires mailing a copy of a report already generated for submittal to the NRC.

Clarifying that the definition of "Occupational dose" applies to workers whose assigned duties involve exposure to radiation and/or radioactive material would have no impact on licensee procedures unless a licensee has interpreted the current rule as not requiring appropriate radiation protection training for workers exposed in unrestricted areas. If so, these procedures would need to be revised irrespective of this proposed rulemaking. Further, the proposed revision to § 19.12 would not require changes in licensee procedures for content and administration of training.

b - NRC Resources

It is estimated that 0.4 staff years of effort by NRC staff will be expended over the next 8 months to complete this rulemaking. It is noteworthy that significant staff time has been expended in responding to questions that have arisen regarding the issues addressed in this rulemaking, and questions continue to arise from licensees and other interested parties. In the absence of this rulemaking, considerable NRC resources may be spent correcting misapplication of the terms Controlled area and occupational dose, and related provisions.

PDR AE80-1

ENCLOSURE C

Congressional Letters

PDR
AE 80-1



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

The Honorable Richard H. Lehman, Chairman
Subcommittee on Energy and Mineral Resources
Committee on Natural Resources
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Enclosed for the information of the Subcommittee is a copy of a Notice of Proposed Rulemaking to be published in the Federal Register. The Nuclear Regulatory Commission is proposing to amend its regulations on radiation protection to delete the provision for controlled areas, to revise the definitions of occupational dose and unrestricted area, to clarify criteria that determine when radiation protection training is required, and to restore a notification requirement.

It has become apparent that these changes are needed as a result of numerous discussions with NRC and Agreement State licensees as they prepare to implement the new 10 CFR Part 20 and that these issues are best addressed by rulemaking. These changes will promote efficient implementation of the new rules, will have no adverse impact on health and safety of workers or the public, and are not expected to impose any significant burden on licensees.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:
Federal Register Notice

cc: Representative Barbara Vucanovich



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

The Honorable Joseph I. Lieberman, Chairman
Subcommittee on Clear Air and Nuclear Regulation
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

Enclosed for the information of the Subcommittee is a copy of a Notice of Proposed Rulemaking to be published in the Federal Register. The Nuclear Regulatory Commission is proposing to amend its regulations on radiation protection to delete the provision for controlled areas, to revise the definitions of occupational dose and unrestricted area, to clarify criteria that determine when radiation protection training is required, and to restore a notification requirement.

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Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:
Federal Register Notice

cc: Senator Alan K. Simpson



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20545-0001

The Honorable Philip R. Sharp, Chairman
Subcommittee on Energy and Power
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Enclosed for the information of the Subcommittee is a copy of a Notice of Proposed Rulemaking to be published in the Federal Register. The Nuclear Regulatory Commission is proposing to amend its regulations on radiation protection to delete the provision for controlled areas, to revise the definitions of occupational dose and unrestricted area, to clarify criteria that determine when radiation protection training is required, and to restore a notification requirement.

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Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:
Federal Register Notice

cc: Representative Michael Bilirakis

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Subcommittee on Energy and Mineral Resources
Committee on Natural Resources
United States House of Representatives
Washington, DC 20515

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Office of Congressional Affairs

Enclosure:
Federal Register Notice

cc: Representative Barbara Vucanovich

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*See previous concurrence.
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Offc: OCA
Name: DKRathbun
Date: / /93

OFFICIAL RECORD COPY

The Honorable Philip R. Sharp, Chairman
Subcommittee on Energy and Power
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

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Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:
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cc: Representative Michael Bilirakis

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*See previous concurrence.

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Offc: OCA
Name: DKRathbun
Date: / /93

OFFICIAL RECORD COPY

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Subcommittee on Clear Air and Nuclear Regulation
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

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Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:
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*See previous concurrence.

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Offc: OCA
Name: DKRathbun
Date: / /93

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ENCLOSURE D

Weekly Report

ENCLOSURE E

Draft Environmental Assessment and
Finding of No Significant Impact

PDR
AE 80-1

Draft Environmental Assessment and
Finding of No Significant Impact

on

Radiation Protection Requirements;
Amended Definitions and Criteria

Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission

I. Background

The revised 10 CFR Part 20, Standards for Protection Against Radiation, published on May 21, 1991, defines a "Controlled area" as an area, access to which could be limited for any reason and an "Unrestricted area" as an area access to which is neither limited nor controlled. The term "Restricted area" was retained in the revised standards for protection against radiation from the original regulation and 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." 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.

"Occupational dose" is defined as the dose received in a restricted area or in the course of employment in which the individual's assigned duties involve exposure to radiation and radioactive materials. Through meetings with licensees to discuss the new 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 "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 the suggestion that such unintended permission 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.

Under the current provisions of 10 CFR Part 19, workers who never enter a restricted area, but may be exposed to radiation or radioactive material by virtue of their employment, require no training concerning radiation protection.

Some licensees have interpreted the definition of occupational dose to mean that an individual is occupationally exposed only when in a restricted area. This, too, was not the Commission's intent. This problem has come to light now because of the focus by licensees on compliance with new requirements. By eliminating the phrase "in a restricted area" from the definition of occupational dose, the Commission's intent will be more clear. In addition, "radiation and/or radioactive material" should replace "radiation and radioactive material" to correct a technical error in the rule text. With these changes, occupational dose would then become dose received as a result of an individual's employment in which an individual's assigned duties involve exposure to radiation and/or radioactive material, as intended.

Paragraph 20.409(b) of Part 20, and the definition of "Individual"¹ require that whenever a licensee was required to report to the Commission any event involving exposure of an identified individual worker or member of the public to radiation and/or radioactive material, that individual would receive notification of the event at the same time. Although it was the intent of the Commission that this provision remain in Part 20, when the new 10 CFR Part 20 was developed, this requirement was inadvertently omitted from the new rule; therefore, the Part 20 provision for notifying individuals of exposures in excess of the dose limits should be restored.

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.)

II. The Proposed Action

In 10 CFR 20.1003, the definition of a "Controlled area" would be deleted as will further use of the term within the rule. Licensees would continue to have the option of controlling access to areas for reasons other than radiological protection.

The definition of "Unrestricted area" would be changed to make it clear that for radiation protection purposes, an area is either restricted or unrestricted.

The definition of "Occupational dose" would be changed to delete reference to restricted area and make it clear that an individual is occupationally exposed if his or her assigned duties involve exposure to radiation and/or to radioactive material, and changes to 10 CFR 19.12 would make it clear that all workers with the potential of being occupationally exposed must be appropriately trained in matters of radiation protection. The NRC believes that the definition of "Restricted area" is sufficient to limit access for purposes of radiation protection and that "Occupational dose" may be received outside "restricted areas."

Conforming changes would be necessary in the definitions of "member of the public" and "public dose." In 10 CFR 20.1301(b), 20.1302(a), 20.1801 and 20.1802 minor conforming amendments are also needed.

New Section 10 CFR 20.2205, "Reports to individuals of exceeding dose limits," would restore to Part 20 the Commission's intent that any 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 also receive notification of that exposure from the licensee if the report identifies the individual.

III. The Need for the Proposed Rule

Licensees and Agreement States have advised the NRC that these definitions need to be addressed in order to facilitate the smooth and efficient implementation of the revised 10 CFR Part 20. The proposed changes would have no adverse impact on health and safety of workers or the public.

The effect of these amendments would be to make clear that (1) individuals in the employ of a licensee, including contractors, whose assigned duties involve exposure to radiation and/or to radioactive materials would be subject to occupational dose limits and associated protection requirements and (2) exposures of members of the public would be limited to the public dose limit, irrespective of their location or activity within the licensee's facility. In addition, the present system of restricted and unrestricted areas would be retained. Licensees would be free to control access to certain areas for reasons other than radiological protection if they choose, but these areas would not be defined in the regulations.

Notification of identified individuals, including members of the public, of exposure incidents which are required to be reported to the NRC, represents a practice considered important by the Commission to protecting public health and safety.

IV. Environmental Impacts of the Proposed Action

Deleting the term "Controlled area" from the rule and revising the definition of "Unrestricted area" will have no environmental impact. Licensees may continue to control access to areas within their site boundaries for reasons such as security irrespective of whether the concept is defined in the rules. No additional lands or facilities or other natural resources would be affected as a result of the changes, and the releases of radiation and/or radioactive material would not be affected by the amendment.

With respect to "Occupational dose," making it clear that occupational dose and associated protection measures apply to workers would neither increase dose nor affect kinds or quantities of radiation or radioactive material released to the public. This change would make it clear that members of the public must be held to the prescribed public dose limit irrespective of where they may be and has the potential benefit of reducing public dose.

Clarifying the criteria for providing radiation protection training to workers engaged in licensed activities would also be considered to have no environmental impact, in that, it does not change the kind or amount of

training, but only clarifies the individuals to whom training must be provided.

Retaining the existing requirement to notify individuals of incidents involving exposure to radiation and/or radioactive material in excess of the dose limits, will not increase reporting burden appreciably. Few such incidents occur and although the public dose limit is now explicit and reduced to 100 mrem in a year, minimal resources will be expended in complying with this requirement.

V. Finding of No Significant Impact

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in 10 CFR Part 51, that the proposed amendments to 10 CFR Parts 19 and 20, associated with deleting the term "Controlled area," modifying the definitions of occupational dose and unrestricted area, clarifying the criteria for whom radiation protection training is required, and restoring a notification requirement if adopted, would not have a significant effect on the quality of the human environment and that an environmental impact statement is not required. This determination is based on the foregoing environmental assessment performed in accordance with the procedures and criteria in 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Function."

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Enclosure F
Approved for Publication

PDR
AE80-1

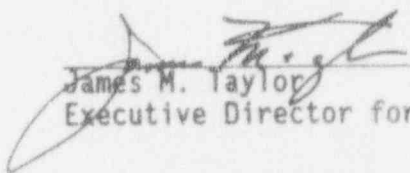
Approved For Publication

The Commission delegated to the EDO (10 CFR 1.31(c)) the authority to develop and promulgate rules as defined in the APA (5 U.S.C. 551 (4)) subject to the limitations in NRC Management Directive 9.17, Organization and Functions, Office of the Executive Director for Operations, paragraphs 0213, 038, 039, and 0310.

The proposed rule, entitled "Radiation Protection Requirements; Amended Definitions and Criteria," would amend Parts 19 and 20 by: (1) deleting the definition of "Controlled area" while making it clear that licensees have the option of establishing such areas for other than radiological purposes, (2) revising the definition of "Occupational dose" to delete reference to the "Restricted area" so that the occupational dose limit and associated provisions such as training and individual monitoring requirements apply to workers whose assigned duties involve exposure to radiation and so that members of the public cannot be permitted to exceed public dose limits, (3) revising the definition of "Unrestricted area" to make it clear that for radiation protection purposes, areas are either restricted or unrestricted, (4) revising § 19.12, "Instructions to Workers," so that training commensurate with the hazards present will be provided to persons occupationally exposed not just individuals who will be working in or frequenting any portion of a restricted area, and (5) restore a provision to Part 20 that whenever licensees are required to report exposures in excess of the dose limits of identified individual workers or members of the public to the NRC, then those individuals are to receive copies of the report.

This proposed rule does not constitute a significant question of policy, nor does it amend regulations contained in 10 CFR Parts 7, 8, or 9 Subpart C concerning matters of policy. I, therefore, find that this rule is within the scope of my rulemaking authority and am proceeding to issue it.

Date 1/19/88


James M. Taylor
Executive Director for Operations

Enclosure F



Copies to: Don C
Nick C
Bill M

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

PDR re u +
Comm paper
turned into this.
Not signed 2/4/94.
OE will send copy
when signed.

Looks ok to me

[Signature]

cc Alan
Steve

MEMORANDUM FOR:

- James Lieberman, Director
Office of Enforcement
- Ben B. Hayes, Director
Office of Investigations
- Robert M. Bernero, Director
Office of Nuclear Material Safety &
Safeguards
- Thomas E. Murley, Director
Office of Nuclear Reactor Regulation
- Thomas T. Martin, Regional Administrator
Region I
- Stewart D. Ebnetter, Regional Administrator
Region II
- John B. Martin, Regional Administrator
Region III
- James L. Milhoan, Regional Administrator
Region IV
- Bobby H. Faulkenberry, Regional Administrator
Region V

K800
2/4/94

FROM:

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards,
and Operations Support

SUBJECT:

ENFORCEMENT AND INVESTIGATION CONSIDERATIONS
FOR PART 20

Effective January 1, 1994, all licensees were to have implemented the revised Part 20. Based on past experience with other new requirements, some hospitals and many small licensees such as medical clinics or physician offices, radiographic or gauge licensees may not have implemented or have only partially implemented certain new requirements of the revised Part 20.

The staff anticipates that most noncompliances associated with implementing the revised Part 20 will involve failures to 1) establish procedures in the radiation protection program that incorporate the ALARA philosophy, 2) use the correct terminology (for example, total effective dose equivalent vs. whole body), and 3) demonstrate compliance with the dose limits for members of the public or the fetus. Assuming that the licensee is at least meeting the requirements of the old Part 20, there are few immediate safety implications of not implementing new requirements of the revised Part 20 for smaller licensees.

The NRC Enforcement Policy provides guidance for violations involving the failure to meet the revised Part 20 (See Supplement IV F through J). In cases where licensees are generally meeting the requirements of the old Part 20, violations of the revised Part 20 should normally be classified at a severity level IV or V. If appropriate corrective action is not taken, then the sanction should be escalated as provided in the Enforcement Policy. In addition, substantial noncompliance with the revised Part 20 should be considered for escalated action. Substantial noncompliance would include loss or release of materials; worker, public, or fetal exposures above the revised Part 20 limits; or a breakdown in the control of licensed activities which represents a significant lack of attention or carelessness in the health physics area (i.e., a programmatic breakdown in the protection of either workers or members of the public where the requirements of the old Part 20 or the new Part 20 are not generally being met).

In view of the extensive notice that has been provided to licensees on the requirements and the effective date of the new Part 20, licensees' failure to implement the new Part 20 could be considered willful. If there is evidence of willfulness, then the matter should be referred to OI as in the normal process. However, unless there is evidence of an affirmative deliberate decision not to implement the new Part 20, (i.e., more than if the licensee had notice of the new requirement but neglected to initiate or complete its implementation of the new Part 20) the case should be assigned a "low" priority for investigation.

This matter will be reconsidered after approximately six months of inspection experience. Should you have any questions on the guidance or on a particular situation where a different approach is warranted, please contact Mr. James Lieberman, Director, Office of Enforcement at 301-504-2741.

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety,
Safeguards, and Operations Support

Multiple Addresses

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