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

OFFICE OF THE
SECRETARY

July 30, 1990

MEMORANDUM FOR: James M. Taylor
Executive Director for Operations

William C. Parler
General Counsel

FROM: Samuel J. Chilk, Secretary

SUBJECT: SECY-89-267/SECY-88-315/SECY-90-237 - REVISION OF 10 CFR PART 20 - STANDARDS FOR PROTECTION AGAINST RADIATION

This is to advise you that the Commission (with Chairman Carr and Commissioners Rogers, Curtiss, and Remick agreeing except as noted below) has approved the proposed revisions of 10 CFR Part 20 as presented in SECY-88-315, revised in SECY-89-267 and SECY-90-237, and subject to the modifications listed below.

Following staff completion of the following items the rule should be returned for final Commission review, affirmation and publication in the Federal Register. Publication of the new Part 20 should be accompanied by appropriate efforts to disseminate information about the rule to licensees, other Federal agencies, States, the Congress and the public.

(EDO/OGC) (SECY Suspense: 9/90)

1. The Commission (with Chairman Carr and Commissioners Rogers and Remick approving) has agreed that publication of the rule changes can be supported under the backfit rule as described below.

   The Federal Register Notice should incorporate the staff's summary of the revised backfit analysis based on a finding that the revisions to Part 20 provide for a substantial increase in safety. The analysis should conclude with the following paragraph:

   "The Commission is adopting the final rule based on the conclusion of this analysis that the rule provides for a substantial increase in the overall protection of the public health and safety and that the direct and indirect costs of its implementation are justified in terms of the quantitative and qualitative benefits associated with

NOTE: THIS SRM, THE SUBJECT SECY PAPER, AND THE VOTE SHEETS OF COMMISSIONERS CURTISS, REMICK, AND ROGERS WILL BE MADE PUBLICLY AVAILABLE WHEN THE FEDERAL REGISTER NOTICE IS PUBLISHED.

the rule. The Commission would note, however, that, even had the analysis not concluded that revised Part 20 provides a substantial increase in the overall protection of the public health and safety, it could have gone forward with the rule because the changes made to Part 20 also amount to a redefinition of the level of adequate protection and the backfit rule's cost justification standard does not apply to a redefinition of adequate protection."

Commissioner Curtiss believes that this rulemaking constitutes a redefinition of adequate protection. He believes that the Statement of Consideration and the backfit discussion should be modified as necessary to reflect this determination; he does not believe that the Commission should attempt to justify the revision as a substantial increase in the overall protection of the public health and safety. His comments on this are included in his vote sheet and are attached hereto.

2. The revision of Part 20 should become effective on January 1, 1992 and the staff should complete, to the maximum extent practicable, development of the necessary regulatory guidance documents by January 1, 1991. Early completion of the guidance, at least in draft form, should provide time for licensees to review and comment on the guidance and to develop and implement the measures necessary to comply with the new Part 20 by the effective date. In preparing regulatory guidance, the staff should ensure that it provides for the same flexibilities that have been incorporated into the rule, particularly in the areas of (1) determining compliance with the occupational dose limits involving internally deposited radionuclides and (2) establishing site-specific effluent limits in air and water considering physical and environmental characteristics that influence potential doses to members of the public. The language in the Statement of Consideration, the rule, and the guidance documents should clearly emphasize that these flexibilities apply only within an envelope of equivalent safety and protection (i.e., Part 20 provides flexibility in how the dose calculations are performed, but in all cases, unless specifically exempted, the dose limits in Sections 20.201 and 20.301 apply). The language in Enclosure 3, pages 2, 4, and 8 of SECY-89-267 should also be revised to ensure that flexibility is clearly and correctly reflected.

3. The discussion in the Statement of Consideration (pg. 13 of Enclosure 3 to SECY-88-315) allows licensees to make pen and ink changes to their licenses to reflect these revisions to Part 20. Language should be added to the rule itself in 10 CFR 20.8 to authorize the pen and ink changes.

4. The Statement of Consideration should be expanded to clarify the impact, if any, of the change in dose limits for members of the public from 500 to 100 millirem/yr when conforming the general license design standards in Parts 32 and 40 (see conforming amendment in Enclosure 5 to SECY-88-315 on pages 144 and 147). The staff should ensure that the conforming revisions are consistent with the current intent.

5. The Federal Register Notice should be updated as appropriate to reflect the Commission's recent decision on the Below Regulatory Concern Policy Statement.

6. Staff should clarify the purpose of the rule and the definition of natural background radiation in the Statement of Consideration and the rule, in regard to consideration of sources of radiation exposure that fall outside of the scope of Part 20 (e.g., fallout, NARM, x-rays) (pages 6 and 13 of Enclosure 4 of SECY-88-315).

7. The attached modifications should be considered for incorporation into the Federal Register Notice. Comments not incorporated should be identified within the final rulemaking package. In addition to the inserts provided in SECY-90-237, the notice should be reviewed to assure that no further changes are needed to reflect the national and international radiation protection developments that have occurred since the text was prepared (i.e. BEIR IV and V, UNSCEAR 1988, ICRP's 1990 recommendations, and NCRP's Report No. 106). Finally, the Notice should have a final quality control check, including use of Enclosure 6 of SECY-88-315, to be sure that issues raised in the Statement of Consideration are answered and that all significant changes between the proposed and final rules are discussed.

8. The Commission understands that the rationale for the staff's preferred risk coefficient of 5E-4 is that while 4E-4 remains a good working coefficient for occupational exposures, the greater susceptibility of fetuses and children makes 5E-4 a better number for the population as a whole. This should be made plain in the Statement accompanying the rule.

   On p. 5 of Enclosure A to SECY-90-237, the discussion notes that the range of fatal cancer risk from lower doses in UNSCEAR-88 (.7E-4 to 3.5E-4) is .6 to 5 times higher than the 1977 ICRP risk value of 1.25E-4. The correct relationship of 3.5 to 1.25 is about 3 times, not 5.

   Finally the second paragraph of the discussion of the 1990 ICRP recommendations should be revised to state the following:

   > "Until the final ICRP recommendations are published, and the need for further revisions in NRC standards established, the Commission believes it would be advisable to proceed with promulgation of the proposed dose limits, rather than deferring a reduction of the existing limits to a future rulemaking. The Commission plans to review the comments of the professional community and others on the ICRP recommendations and ICRP's response to them. In addition, the Commission will review the recommendations of other expert bodies, such as the National Council on Radiation Protection and Measurements, and participate in the deliberations of the Committee for Interagency Radiation Research and Policy Coordination on the need for further revision of the occupational radiation protection standards after the ICRP recommendations are published."

   The rule and the Statement of Consideration should be revised to incorporate the additional changes described in Enclosure A to SECY-90-237, as modified in the attached markings. (These changes partially implement items 3 and 7 listed above.)

The Commission commends the staff for its diligence and hard work in completing the revision of Part 20. Since the effort to revise Part 20 began in 1978, the staff has remained dedicated to completing the revisions in the interest of public health and safety.

cc: Chairman Carr
Commissioner Roberts
Commissioner Rogers
Commissioner Curtiss
Commissioner Remick
IG
ACRS
ACNW

Commissioner Curtiss' Comments on SECY-88-315:

I approve the revisions to 10 CFR Part 20 and related changes to other regulations as outlined in SECY-88-315 and SECY-89-267, subject to the modifications discussed below.

Backfit: I have examined the proposed Part 20 amendments from the standpoint of whether and, if so, how the backfit rule should apply to this particular rulemaking. The nature and effects of the proposed changes to Part 20 lead me to the conclusion that the proposed amendments, in essence, would redefine what is necessary for adequate protection of the public health and safety in the radiation protection area. Thus, while I believe that we should apply the backfit rule to this Part 20 rulemaking effort, I also believe that this rulemaking constitutes a redefinition of adequate protection as described in 10 CFR §50.109(a)(4)(iii) and that the usual backfit analysis and cost-benefit balancing are therefore not required in this instance.

On the question of whether such an approach would require this rule to be renoticed for further public comment, I have concluded that there was ample indication in the notice of proposed rulemaking that the Commission is rethinking its radiation protection standards across-the-board in this Part 20 rulemaking. Moreover, this initiative was explained in a manner that could logically be construed to encompass the approach to backfitting described above. Of particular importance, the notice of proposed rulemaking itself seems to indicate that the Commission is contemplating an action that would redefine what is necessary for adequate protection in the radiation protection area. For example, the notice states that:

> [T]he Nuclear Regulatory Commission (NRC) is proposing a major revision of its regulations in 10 CFR Part 20 which provide the requirements for the protection of individuals who are exposed . . . to ionizing radiation from routine activities . . . which are licensed by the NRC . . . . The intent of the revision is to improve NRC radiation protection standards by reflecting developments in the principles that underlie radiation protection and advances in related sciences that have occurred since the promulgation of 10 CFR Part 20 nearly thirty years ago . . . . The expected result of promulgating and implementing the proposed revised rule is an improved rule that provides better assurance of protection; establishes a clear health protection basis for limits and other regulatory actions taken to protect public health; applies to all licensees in a consistent manner; and reflects current information on health risk, dosimetry, and radiation protection practices and experiences.

51 Fed.Reg. 1092 (January 9, 1986).

With regard to existing Part 20 standards, the Commission noted that:

> [i]n promulgating these standards, the AEC emphasized "that the standards are subject to change with the development of new knowledge, with significant increase in the average exposure of the whole population to radiation and with further experience in the administration of the Commission's regulatory program." Consistent with this emphasis, the proposed revision reflects new knowledge, increased uses of radiation and generation of radiation sources, and experience gained during the past twenty years . . . . [Earlier] revisions [to the existing Part 20] have not kept the regulations in accord with more recent recommendations of scientific organizations . . . to improve overall protection and establish a clear health risk rationale . . . . [T]he central thrust of the revision [is] to ensure that radiation protection is adequate and defendable when judged by good protection practices and contemporary standards.

51 Fed.Reg. 1093, 1094 (citations omitted).

In discussing the benefits of the proposed rulemaking, the Commission indicated that:

> [t]he proposed revision to Part 20 includes numerous changes required to bring the radiation protection standards into accord with current defendable [sic] scientific knowledge, and to reflect contemporary scientific and philosophical approaches to protection against radiation . . . . The Commission anticipates that promulgating and implementing the proposed rule will result in a regulation that provides better assurance of protection, establishes a clear health protection basis for limits, applies to all licensees, including small entities, in a consistent manner, and reflects current information on health risk, dosimetry, and radiation protection practices and experiences.

51 Fed.Reg. 1120, 1122.

Consistent with all of these statements on the nature of the proposed changes to Part 20, a supplemental notice of proposed rulemaking that requested comments on a proposed backfit analysis indicated that:

> [T]his is the first complete revision of these regulations in over 25 years. This revision will bring the Commission's radiation protection standards into

accord with current recommendations of the International Commission on Radiological Protection (ICRP) . . . .

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The proposed revision to 10 CFR Part 20 [is] intended to:

a. Update the quarter-century-old 10 CFR Part 20 to incorporate advances in science and new concepts of radiation protection methodology and philosophy;

b. Implement pending Federal Radiation Guidance on occupational radiation protection;

c. Implement the principle current dose-limiting recommendations of the ICRP;

d. Incorporate the ICRP "effective dose equivalent" concept;

e. Update the limits on airborne radionuclide intakes, effluent releases and doses from inhaled or ingested radionuclides using up-to-date metabolic models and dose factors; and

f. Require that licensees have programs for keeping radiation exposures "as low as is reasonably achievable" (ALARA).

51 Fed. Reg. 30870, 30871 (August 29, 1986).

Overall, these various characterizations of the purpose, intent, and nature of the proposed changes to Part 20 lead to the conclusion that the Commission is, in fact, rethinking its radiation protection standards. For these reasons, I believe that the notice adequately describes the nature and substance of the proposed rule changes and that renoticing to further reflect a Commission judgment that the proposed changes constitute a redefinition of adequate protection is not necessary.

NUCLEAR REGULATORY COMMISSION

10 CFR PART 20

and 10 CFR Parts 2, 19, 30, 31, 32, 34, 39, 40, 50, 61, and 70

Standards for Protection Against Radiation

AGENCY: Nuclear Regulatory Commission

ACTION: Final rule

SUMMARY: The Nuclear Regulatory Commission (NRC) is revising its standards for protection against ionizing radiation. This action is necessary to incorporate updated scientific information and to reflect changes in the basic philosophy of radiation protection. The revision conforms the Commission's regulations to the Presidential Radiation Protection Guidance to Federal Agencies for Occupational Exposure and to recommendations of national and international radiation protection organizations. A proposed revision was published in 1986. The revised Part 20 incorporates changes suggested in the public comments, as appropriate. Amendments to other parts of 10 CFR Chapter I are also being issued that amend Part 19 and update citations to 10 CFR Part 20.

DATES: This is a final regulation that becomes effective January 1, ~~1991~~ 1992. However, public comments on the revisions to Appendix C of 10 CFR Part 2 may be submitted until [60 days after publication]. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received before this date.

ADDRESSES: Copies of documents relating to the January 9, 1986, proposed rule (51 FR 1092) or this document may be examined and

copied for a fee in the Commission's Public Document Room at 2120 L Street NW., Washington, DC. Public comments on the revision of Appendix C to 10 CFR Part 2, Rules of Practice for Domestic Licensing Proceedings, may be submitted to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch. Comments received may be examined and copied (for a fee) at the NRC Public Document Room, 2120 L Street, N.W., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Harold T. Peterson, Jr., Division of Regulatory Applications, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone (301) 492-3640.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Purpose of the Revision

The purpose of this revision of 10 CFR Part 20 is to modify the NRC's radiation protection standards to reflect developments in the principles and scientific knowledge that underlie radiation protection that have occurred since Part 20 was originally issued more than 30 years ago. These developments not only include updated scientific information on radionuclide uptake and metabolism, but also reflect changes in the basic philosophy of radiation protection. Incorporation of these changes will ensure that Part 20 continues to provide adequate protection of public health and safety.

It is also the purpose of this revision to implement recent Presidential Guidance on occupational radiation exposure (See Section II.E.) The (AEC) and the NRC have followed past Federal Radiation Protection Guidance and conformance with the guidance

(AEC) → Atomic Energy Commission

is viewed by the Commission as being necessary to ensure that all NRC licensees are using levels of protection comparable to those used by other Federal agencies.

The AEC and the NRC have generally followed the basic radiation protection recommendations of the International Commission on Radiological Protection (ICRP) and its U.S. counterpart, the National Council on Radiation Protection and Measurements (NCRP), in formulating basic radiation protection standards. In 1977, ICRP issued revised recommendations for a system of radiation dose limitation. This system, which was described in ICRP Publication 26[1], introduced a number of significant modifications to existing concepts and recommendations of the ICRP and the NCRP that are now being incorporated in the NRC regulations. In particular, this revision of Part 20 puts into practice recommendations from ICRP Publication 26 and subsequent ICRP publications. The Federal Radiation Protection Guidance signed by the President on January 20, 1987 is also based upon the ICRP 1977 recommendations in ICRP Publication 26.

In adopting the basic tenets of the ICRP system of dose limitation, the Nuclear Regulatory Commission ~~agrees with this judgment and notes~~ recognizes that, when application of the dose limits is combined with the principle of keeping all radiation exposures "as low as is reasonably achievable," the degree of protection could be significantly greater than from relying upon the dose limits alone.

B. Fundamental Radiation Protection Principles

The radiation protection standards in this part are based upon the assumptions that--

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1 Recommendations of the International Commission on Radiological Protection, January 13, 1977, ICRP Publication No.26, Annals of the ICRP, 1(3) (1977).

(a) Within the range of exposure conditions usually encountered in radiation work, there is a linear relationship, without threshold, between dose and probability of stochastic health effects (such as latent cancer and genetic effects);

(b) The severity of each type of stochastic health effect is independent of dose; and

(c) Non-stochastic (non-random) occurrences of radiation-induced health effects can be prevented by limiting exposures so that doses are below the thresholds for their induction.

The first assumption, the linear non-threshold dose-effect relationship, implies that the potential health risk is proportional to the dose received and that there is an incremental health risk associated with even very small doses, even radiation doses much smaller than received from naturally occurring radiation sources. These health risks, such as cancer, are termed stochastic because, for a given level of dose, not every person exposed would exhibit the effect. The second assumption means that when a stochastic effect is induced, the severity of the effect is not related to the radiation dose received. The third assumption implies that there are effects, termed nonstochastic effects, for which there is an apparent threshold; i.e., a dose level below which the effect is unlikely to occur. An example of a nonstochastic effect is the formation of radiation-induced cataracts of the eyes.

The above assumptions are necessary because it is generally impossible to determine whether or not there are any increases in the incidence of ~~ill health~~ health effects at very low doses and low dose rates, particularly in the range of doses to members of the general public resulting from NRC-licensed activities. It is firmly established, both from animal studies and human epidemiological studies (such as the radium dial painters, radiologists, and the atomic bomb survivors) that there are increased incidences of certain cancers associated with radiation exposure at high doses and high dose rates. However, whether these

effects occur at very low doses and, if they occur, whether their occurrence is linearly proportional to dose is not firmly established. In the absence of convincing evidence that there is a dose threshold, or that the linear assumption is unrealistic for extrapolating the observed risks at high doses to lower dose levels, the Commission believes that these assumptions remain appropriate for formulating radiation protection standards and planning radiation protection programs.

C. Background

Standards for radiation protection were originally issued by the former ~~Atomic Energy Commission~~ (AEC) in the late 1950's (22 FR 548; January 29, 1957.) These standards have been modified since that time by a series of amendments relating to specific issues; however, no complete revision of Part 20 has been made since the original standards were issued.

~~In 1980,~~ The NRC issued an Advance Notice of Proposed Rulemaking (ANPRM) in the Federal Register of March 20, 1980 (45 FR 18023). This ANPRM requested comments on possible topics that should be revised in a proposed revision of Part 20. The responses received to this announcement were considered in the formulation of the proposed revision.

During the development of this rule, early comments from licensees, labor unions, public interest groups, other Federal agencies and scientific organizations were solicited, discussed and considered in formulating the proposed rule. In addition, the NRC staff has benefited from its participation in several public meetings held by the Environmental Protection Agency (EPA) in connection with the guidance for occupational radiation exposure. The revised Part 20 and the Federal guidance on occupational exposure were developed in parallel and are both based primarily on the ICRP recommendations. The comments made

ed dose from neutrons (in rads or grays) to a dose equivalent (in rems or sieverts). The ICRP Statement recommended increasing the quality factor for high-energy neutrons by a factor of 2. The quality factor for fast neutrons, for example, would be increased from 10 to 20. This change has the effect of doubling the apparent biological risk of high-energy neutrons. For reasons explained in the discussion of quality factors (see the discussion on § 20.4), the NRC has not adopted this recommendation in this revision of Part 20.

B. ICRP 1987 Washington Meeting

The primary focus of the statement issued by the ICRP following the 1987 meeting in Washington[3] was ICRP Publication No. 48[4]. That publication discussed higher transfer factors for transport of certain transuranic elements across the intestinal walls. These higher fractional absorption factors have been incorporated in revisions to the ALIs and DACs in Appendix B of the final rule. The changes resulting from the use of these revised factors would not change either the ingestion or inhalation ALIs for plutonium in the oxide or nitrate forms, but would lower the ALIs for other compounds or mixtures by a factor of ten. The transfer factor for gut transfer of neptunium was found to be an order of magnitude lower than the value used in ICRP 30 and, consequently, the ingestion ALI can be increased by almost an order or magnitude. The transfer factor for americium, curium, and californium was found to be a factor of two higher than the ICRP 30 value so the ingestion ALIs are reduced by a factor of two. Parameters applicable to inhalation ALIs and DACs are less affected as the transfer from the

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3 International Commission on Radiological Protection, "ICRP Statement from 1987 Washington Meeting," Health Physics 53(3): 335-342 (1987).

4 International Commission on Radiological Protection, "The Metabolism of Plutonium and Related Elements," ICRP Publication No. 48, Annals of the ICRP 16(2/3) (1986).

It may also require modification of conditions designed to ensure compliance with the previous Part 20. A new section 20.8 has been added to indicate that the revised Part 20 will supersede any inconsistent or conflicting license conditions. Based on this section and

V. Conformance of License Conditions

The revision of 10 CFR Part 20 will necessitate modification of license conditions that cite or refer to sections of Part 20. In order to avoid the NRC having to issue the large number of license amendments that would be required merely to change citations, permission is granted to licensees to make handwritten changes to their licenses in order to conform them to the revised 10 CFR Part 20 sections. Such changes should be made only after the effective implementation date of the revised Part 20 rule of January 1, 1992.

The NRC will issue a document (NUREG) that provides the section and paragraph identifiers in the revised Part 20 and the corresponding sections or paragraphs in the existing Part 20. This document will be prepared and issued within a few months of the publication of this rule. These changes will be reviewed by NRC through the standard inspection process.

In cases where there may be a conflict or difference between the revised rule and a license condition, after January 1, 1992, the licensee shall comply with the revised Part 20 rule in lieu of the license condition.

VI. Summary of Public Comments and Changes from Proposed Rule

The purpose of this section is to respond to comments raised on the proposed rule and to explain and highlight the changes made to the proposed rule. This section presents, for each paragraph or section of the rule, the principal public comments on the proposed rule, an NRC staff response to the comments (where appropriate), and a summary of the principal changes that were made to the proposed rule. This section has been arranged so that it corresponds to the structure of the rule. Although it follows the format of the final rule, the following text is not intended to convey any additional requirement not already in the regulatory text. The text of revised Part 20 starts on page [FR to insert page number of start of regulatory text].

Subpart A -- General Provisions

§ 20.1 Purpose

Final Rule. A new sentence was added to convey the intent of the former § 20.9 in the proposed rule (which has been removed) that the regulations in Part 20 should not hinder a licensee's actions to protect health and safety in the event of an emergency. It is the Commission's intent that the regulations be observed to the extent practicable during emergencies, but that conformance with the regulations should not hinder any actions which have overriding priorities, such as lifesaving, protection of property, or maintaining confinement of radioactive materials.

In this regard, the Commission notes that the Federal guidance on occupational radiation protection states that those dose standards only apply to normal operating conditions. The Commission believes that the dose limits for normal operation should remain the primary guidelines in emergencies. However, the Commission also recognizes that, in a severe emergency, operations that do not conform to the regulations may have to be carried out to achieve the high priority tasks of worker, public and facility protection. The purpose of the addition to this section is to assure licensees that their first priority should be to carry out those actions which are necessary to protect workers and the public from radiation exposure, to prevent or limit the spread of radioactive contamination or release of radioactive materials to the environment, to perform lifesaving activities, and ~~any necessary operations~~ to preserve an adequate margin of safety. In evaluating any ensuing violations and their severity, the Commssion will consider on a case-by-case basis the existence of extenuating circumstances.

§ 20.2 Scope

Final Rule. The statement of scope remains essentially the same as in the proposed rule.

1. New Terms. The following definitions have been added since the publication of the proposed rule. These definitions have been added to clarify the meaning of the terms:

a. "Activity"
b. "Derived air concentration-hours" ("DAC-hours")
c. "Dosimetry processor"
d. "Entrance or access point"
e. "Generally-applicable environmental standard"
f. "Individual monitoring device"
g. "Quality factor"
h. "Sanitary sewerage"
i. "Total effective dose equivalent (TEDE)"
~~j. "Weighting factor"~~

2. Revised Definitions. The following definitions have been revised or modified from the definition used in the proposed rule:

a. "Absorbed dose"
b. "Annual limit on intake"
c. "Class"
d. "Committed dose equivalent"
e. "Committed effective dose equivalent"
f. "Derived air concentration"
g. "Dose equivalent"
h. "Effective dose equivalent"
i. "Embryo/fetus"
j. "Eye dose equivalent"
k. "Member of the public"
l. "Natural background"
m. "Non-stochastic"
n. "Person"
o. "Planned special exposure"
p. "Quarter"
q. "Survey"

reasonably achievable." This shift is to emphasize that the "ALARA" concept is intended to be an operating principle rather than an absolute minimization of exposures.

Any requirement for ALARA should include a lower bound. Many licensees felt that there should be a "floor" for ALARA efforts, dose levels below which further reductions are not necessary.

Response: The Commission agrees that there would be advantages to establishing such a "floor," below which efforts to further reduce doses would not be necessary. ~~This concept is currently being considered by the NRC staff.~~ (See discussion on § 20.304)

Compliance with "ALARA-based" standards should constitute being ALARA. Several commenters supported the statement in the proposed Part 20 (§ 20.102(b)) that compliance with EPA's 40 CFR Part 190 and with Appendix I to 10 CFR Part 50 should constitute de facto compliance with the requirement to keep LWR effluents ALARA. EPA comments did not support this view.

Response: Appendix I to 10 CFR Part 50 defines ALARA levels of radioactive materials in light-water-cooled reactor (LWRs) effluents. If the design objectives of Appendix I are met, it constitutes a demonstration that the effluents are ALARA and no additional effort is required to reduce the effluent levels.

Although the Environmental Protection Agency interprets 40 CFR Part 190 as an "ALARA-based" standard, it also believes that 40 CFR Part 190 constitutes an upper bound, not a lower bound,

39[14] and ICRP Publication No. 9[15] as well as the smaller area recommended in ICRP Publication No. 26.

Within the past several years there have been instances where very small (5-250 mm) particles of fuel or activated corrosion products have been discovered in reactor facilities, on workers or their clothing, and, in a few isolated cases, in worker's vehicles or homes. These particles are generally too large to pose a significant risk from inhalation, but are capable of producing intense beta-radiation doses over very small areas of the skin. The principal hazard appears to be skin ulceration if the particles remain localized on the skin surface. The primary uncertainty associated with evaluating the hazard of these small particles is determining the skin area or tissue volume to which the dose is to be computed (or even whether "dose" is the most appropriate indicator of the hazard). The NRC has requested the National Council on Radiation Protection and Measurements (NCRP) to look into the hot particle issue and make recommendations on how to evaluate the hazards associated with these particles.

Final Rule. This revision of Part 20 specifies an area of 1 cm^2 for skin dose evaluations. The "hot particle" issue is being addressed independently of the Part 20 rulemaking proceeding.

Effective dose equivalent for external exposure. The most prevalent comment concerning the effective dose equivalent is

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14 National Council on Radiation Protection and Measurements, "Basic Radiation Protection Criteria," NCRP Report No. 39 (January 15, 1971), page 79, paragraph 207.

15 International Commission on Radiological Protection, "Recommendations of the International Commission on Radiological Protection (adopted September 17, 1965)," ICRP Publication No. 9 (1966), page 6, paragraph 28.

parameters, there was concern regarding whether the more recent ICRP-30 parameters should be used, particularly when the value is to be compared with the intake limits in the existing Part 20.

Until the effective date of the revision, licensees must continue to demonstrate compliance with the intake limits of the present rule. Because the concentration limits, ALI's and DAC's in Appendix B of the revised Part 20 are based upon the effective dose equivalent, they should not be used until after the effective date of the rule. The NRC is planning to issue a Regulatory Guide that will address the use of bioassay measurements for determining compliance with Part 20. Appropriate parameters for calculating organ doses from radionuclide intakes that do not incorporate the w_T weighting factors can be found in ICRP-30 and its supplements. The effective dose equivalent can be used for purposes other than demonstrating compliance, such as environmental reports, prior to the effective date of the revision providing that it is clearly indicated as being an "effective dose equivalent."

§ 20.205 [deleted] Further Provisions -- Internal Exposure Involving Radionuclides with Very Long Effective Half-lives

Exemption for long-lived radionuclides and the use of the committed dose equivalent concept. The use of the concept of a "committed dose equivalent" drew numerous comments. This approach entails assigning to the year of intake, the future internal dose (the "committed dose equivalent" over 50 years) from radionuclides taken into the body during that year. The proposed rule (in § 20.205) allowed an exemption from the use of committed dose equivalents for several long-lived radionuclides.

commenters expressed concern that exposures during planned special exposures that did not result in doses to an individual in excess of the occupational annual dose limits would nevertheless have to be reported separately and subtracted from the individual's lifetime allotment for planned special exposures.

Response: The intent of the planned special exposure was that it would be used infrequently in circumstances where the elimination of the 5(N - 18) lifetime cumulative limit might create a severe handicap to the licensee's operations. Being able to switch doses between planned special exposures and routine dose limits would tend to encourage the use of planned special exposures as the licensee would have nothing to lose by using the planned special exposure. This is contrary to the Commission's intent that the planned special exposures be restricted to "special" situations. Once a licensee decides to conduct a planned special exposure, all of the unique limitations, reporting, and recordkeeping requirements are to apply, even if the doses actually received fall within the dose limits for routine operations.

Final Rule. The provisions of planned special exposures have been extended to include internal exposures, and the reporting times to the individuals involved has been changed to 30 days to allow sufficient time for analysis of internal dose.

§ 20.207 Occupational Dose Limits for Minors

Exposure of Minors. One commenter stated that minors should not be exposed to radiation because they do not meet the criteria for occupational radiation exposure. The commenter argued that minors are not trained regarding radiation protection, do not derive a benefit from employment and would require the preparation of a Form 4 if they were workers.

dose limits applicable to the general public (the recently-issued Federal guidance applied only to occupational radiation protection).

Response: Although ~~it believes that~~ it would be desirable to use Federal guidance as a basis for the revision of the limits for the public, the Commission believes that Part 20 needs to be based on a consistent set of principles and concepts rather than having its standards for workers using one dose limitation system and its standards for the general public using an entirely different (and outmoded) system. The fact that the latest Federal guidance does not address radiation exposure of the general public and the Commission's intent to address these limits were noted in the statement of considerations that accompanied the proposed rule (51 FR 1118, Section XXVIII).

Therefore, the Commission has chosen not to defer limits for the general public until EPA issues applicable guidance.

Facilities that are subject to other lower standards should not have to demonstrate compliance with the 0.1-rem limit ["reference level"]. Several commenters expressed concern that additional efforts would be required to demonstrate compliance with the proposed 0.1-rem "reference level." For licensees that were already subject to the 0.025-rem (25-millirem) limits of EPA's 40 CFR Part 190, this appeared to be an unnecessary burden.

Response: The concept that 0.1-rem represents a "Reference Level" has been eliminated and the 0.1-rem value represents the primary dose limit for protection of the public in the revised Part 20. This change from the proposed rule reflects the clarifications by the ICRP (see Section IIB.) regarding the usage of the 0.1-rem and 0.5-rem recommended dose levels. This change does not represent a major change from the proposed rule. Many commenters had indicated a belief that, because of the reporting and control requirements associated with the 0.1-rem "reference level," it already represented a de facto limit.

Demonstration of compliance with the limits in 40 CFP Part 190 or with the design objectives of Appendix I to 10 CFR Part 50 will be deemed to demonstrate compliance with the 0.1-rem dose limit for most licensed facilities. Power reactor licensees that comply with Appendix I may have to also demonstrate that they are also within the 0.025-rem limit in 40 CFR Part 190. Demonstration of compliance with the limits of 40 CFR Part 190 will be considered to demonstrate compliance with the 0.1-rem limit. For uranium mills, it will be necessary to show that the dose from radon and its daughters, when added to the dose calculated for 40 CFR Part 190 compliance, does not exceed 0.1 rem.

Inclusion of doses from other licensed or unlicensed radiation sources. Many commenters expressed an opinion that the dose should not be all inclusive and should not include fallout from nuclear weapons tests, transportation of radioactive material, or other source of radiation not under the control of the licensee.

Response: The new lower dose limit for members of the general public (which was described as a "reference level" in the proposed rule) applies only to doses from radiation and radioactive materials under the licensee's control. The EPA generally-applicable environmental radiation limit for nuclear power operations (40 CFR Part 190) does apply to the total dose from all sources within the uranium fuel cycle. However, in its practical implementation, the sources would have to be located within a few miles of each other for the combined dose contributions to be significantly different than the dose from either facility alone.

Differentiation of limits for long-term operation and for shorter term transient operation. A number of commenters noted

external monitoring requirements. The Commission acknowledges that, in some cases, particularly bioassay measurements of transuranic elements, it may not be feasible to actually confirm such levels by bioassay. However, the monitoring threshold is not a requirement on the capability of the measurement. Average airborne radionuclide concentrations and the expected time of exposure can be used to estimate radionuclide intakes and the need for bioassay or other monitoring methods.

The Commission intends to issue additional guidance on procedures to be used in estimating committed effective dose equivalents and deep-dose equivalents and guidance on when they have to be summed.

Evaluation of radionuclide intakes for respirator wearers. Several commenters mentioned that ~~a requirement to conduct~~ internal dose monitoring, such as bioassays, should not be required ~~when a result of wearing~~ respiratory protection devices. The rationale given by the commentors was that the requirement provides a negative incentive for using respirators and is, therefore, counter to ALARA operating practices.

Response: The requirement (in § 20.502(b)(3)) for bioassays for anyone using respiratory protection has been dropped. The Commission agrees that such a requirement might be a disincentive for using respirators as part of an ALARA effort. There is, however, a requirement (in § 20.703) for bioassays to be conducted, as appropriate, as part of a respiratory protection program. Whether bioassays are necessary for a particular individual will depend upon whether that individual could have exceeded 10% of the Annual Limit on Intake (ALI) or was exposed to airborne radionuclide concentrations in excess of the monitoring threshold. An evaluation of internal dose would be required if there were a potential for exceeding 10 percent of an Annual Limit on Intake (0.1 ALI), whether or not a respirator is worn.

[Note: Because the requirement for performing bioassays for a particular individual has been separated from the wearing of a respirator, the concentrations to be used for evaluating monitoring thresholds are those of the ambient atmosphere before credit is taken for respiratory protective factors. One of the purposes of such bioassays is to confirm the effectiveness of the respiratory protection being provided. If bioassay were made dependent upon the corrected air concentration (after dividing by the protection factor), it would be equivalent to assuming that the intended protection factor were correct without further verification.]

Subpart G -- Control of Exposure from External Sources in Restricted Areas

§§ 20.601, 20.602, and 20.603 Control of Access to High and Very High Radiation Areas

Inapplicability of requirements to nuclear power reactors. Many commenters indicated that the proposed requirements for control of entry into very high radiation areas could not be applied to nuclear power reactors because of the number and size of potential "very high radiation areas" and the physical inability to restrict access to these areas. Similarly, interlocks that can result in the withdrawal or cessation of the radiation source may be unworkable in nuclear power reactors. Several commenters proposed incorporating requirements for power reactors that are similar to reactor license conditions in reactor technical specifications. Response: The Commission recognizes that the detailed requirements applicable to large irradiators that were formerly in § 20.203(c)(6) would be better in a specific regulation dealing with these facilities rather than in Part 20.

Use item (5) under 9 in enclosure A to Secy 90-237 to update.

For this reason, ~~consideration is being given to the placement of these detailed requirements in a future part of Title 10 that may apply specifically to irradiators. At the time that such a specific rule is proposed, the Commission will consider transferring these requirements to that rule.~~ Update

Choice of Dose Rate Defining a "Very-high Radiation Area. Several commenters believed that the 500-rad per hour dose rate that defines a "very-high radiation area" was too high, noting the proximity of this value to the median lethal dose (LD_{50}) for acute radiation exposures. Alternative values, such as 1 rem per hour at 30 centimeters, were proposed.

Response: The seriousness of this dose rate was a factor in its adoption. The 500-rad per hour value appears in the previous 10 CFR 20.203(c)(6) as a criterion for additional access controls for irradiators (similar in scope to the requirements of § 20.603 in the final rule). However, the previous Part 20 did not use a unique designation such as the "very high radiation area" designation used in the proposed and revised rules.

Meaning of "direct surveillance". Several commenters thought that the term "direct surveillance" used in the proposed § 20.601 could be interpreted to require stationing an observer at the entrance to the "high" or "very high" radiation areas.

Response: The final rule permits "...continuous direct or electronic surveillance over a high radiation area that is capable of preventing unauthorized entry..." This removes the burden of having to station a person in or near a "radiation area," but requires interlocks or electronic locks so that the remotely located observer may prevent entry into the area when necessary.

§ 20.901 Caution Signs

Black should be permitted as an acceptable color for the radiation warning symbol. Several commenters requested that the color black should also be allowed to be used on signs and for stenciling packages. The fading of magenta inks in sunlight and the use of black for marking international shipments were cited as supporting this position.

Reponse: The Commission believes that the "magneta-on-yellow" color scheme has provided a visible and unique warning of possible radiation hazards. The fading of the magenta color can be remedied by replacing the sign at a relatively low cost. However, an exception to the color requirement has been made for certain high-temperature applications.

Final Rule. This section is the same as in the proposed rule.

§ 20.902 Posting Requirements

The terms "Caution" and "Danger" are not used consistently. Commenters noted that "Caution" or "Danger" could be used on signs for "Radiation Areas," "High Radiation Areas," and "Very High Radiation Areas" despite the considerable variation in the hazards that might exist in these different areas.

Response to Final Rule: The Commission agrees that the terms "Caution" and "Danger" should be used in a more consistent manner. The final rule permits only the term "Caution" to be used in "Radiation Areas." "Caution" or "Danger" may be used in "High Radiation Areas," since these cover the considerable range from 0.1 rem per hour to over 500 rads per hour. Only "Grave Danger" may be used in "Very High Radiation Areas." This should provide more emphasis to the use of "Danger," the importance of

intent of "in attendance" would be satisfied by a duty nurse at a nursing station, providing that the station was in sight of the entrance to the patient's room.

§ 20.904 Labeling Containers

There is no way to meet the requirement to label containers in some nuclear power plants or in hot cells. It is difficult to mark the detailed information on a container in some areas of a plant or in hot cells.

Response: Section 20.905 contains exceptions to the labeling requirements which take care of the problem noted by the commentor.

Note: For the purpose of this section, "Mixed Fission Products" and "Fission and Activation Products" may be regarded as radionuclides, provided that the total activity is also specified. Designations as to the process stream or location sampled or type of sample (e.g., "primary coolant") may also be helpful as an additional designation of the potential hazard.

§ 20.905 Exemptions to Labeling Requirements

The proposed rule deletes some prior exceptions to labeling. The proposed rule omits existing exemptions for packages containing only exempt quantities and those containing less than 10 mCi or less of tritium, I-125, C-14 and S-35.

Response: While these sources pose little external hazard from gamma radiation, the quantities could be a potential internal hazard if the package were ruptured and the contents were released. Consequently, some warning remains appropriate.

The proposed rule also omitted the existing exemption from labeling

for packages labelled for shipment in accord with DOT requirements.

Final Rule. This exemption has been restored because the Commission agrees that the DOT labeling is sufficient to denote the presence of radioactive materials and that quantities not requiring DOT labels would probably not warrant an NRC labelling requirement. (See § 20.905(d).)

§ 20.906 Procedures for Handling Packages

The requirement to monitor all packages is unnecessary. The requirement to monitor all incoming packages containing radioactive materials is unnecessary and in large installations creates a substantial monitoring burden.

Response: This requirement has been reevaluated and modified in order to reduce the burden.

Final Rule. Section 20.906 in the final rule requires incoming packages to be monitored when: (1) they are labelled as containing radioactive materials according to DOT regulations, or (2) when a package is damaged or leaking. The first provision would reinstate the exemption from monitoring for shipments of small quantities of radioactive materials that would not require DOT labelling.

The requirement to survey external surfaces of packages is unnecessary. Several commenters with extensive experience monitoring packages noted that external contamination was rarely if ever present and that wipe tests are time consuming both to make the smears and to count them.

Response: Experience in the shipment of multiple thousands of packages each year has been very good. However, potential

problems with leaking packages during transit warrant continued monitoring upon receipt to assure that leaking packages are found and reported. Appropriate action can then be taken to determine the extent of contamination in transport vehicles and storage areas in order to limit the consequences and avoid recurrence.

FINAL RULE: The requirement to monitor external surfaces of packages known to contain radioactive material have been retained.

The requirement to monitor packages within three hours is unwarranted. This requirement would be difficult to meet for several types of licensees, some of which do not have a full-time health physics staff person.

Response: Licensees receiving labelled packages of radioactive materials to which this requirement applies are expected to have available persons who are qualified to perform such monitoring. However, the person monitoring the package need not be a board-certified health physicist.

Final Rule. The three-hour period has been retained.

Update to reflect item 4. of SECY 90-234

Suhpart K -- Waste Disposal

§ 20.1001 General Requirements

Decay in storage as a disposal option. Many commenters noted favorably the addition of "decay in storage" as an allowed waste disposal option. Several commenters, however, did not believe that the option, as expressed in the proposed rule, was particularly helpful.

Response: Technically, the "decay in storage" option has always been available to a licensee as the license permitted possession of the radioactive materials and these materials naturally underwent radioactive decay. The option was formally included in the proposed and final rules because the list of

disposal options as exclusive and there have been questions as to whether this was allowed under the prior regulations. It should be noted that this option does not allow material that has "decayed in storage" to be released to unrestricted areas unless it meets the requirements of one of the other allowed forms of waste disposal in Part 20 or specific requirements given in NRC or Agreement State license conditions.

The NRC staff considered adding a separate "Disposal by Decay in Storage" option with specific criteria for unrestricted release of material after decay. These criteria are commonly included ~~in source and~~ byproduct material licenses. However, these criteria pertain to relatively short-lived radionuclides and would not have been applicable to other classes of licenses such as those to operate power reactors. Also, when evaluated for a specific licensed activity, it is possible to consider existing pathways of exposure and to establish specific criteria for decay.

Substantive change to language in SECY 89-207

General criteria in a rule would need to be sufficiently conservative to take into account all reasonably conceivable pathways, thereby reducing the applicable level from what would be permitted in a case-by-case evaluation.

Final Rule:

Identical to that in SECY 89-207

§ 20.1003 Disposal by Release into Sanitary Sewerage

Removal of Allowance for Disposal of "Dispersible Wastes." A number of commenters felt that the restriction of wastes released to sanitary sewers to soluble wastes would have an adverse impact on certain licensees that, under the previous rule, had disposed of "dispersible" but insoluble radioactive materials. In particular, the practice was mentioned of grinding up animal carcasses with subsequent sewer disposal of the ground residue. This practice is permitted by the previous

Part 20 but would not have been permitted under the proposed rule.

Response: The Commission has relaxed the conditions ~~in the proposed rule~~ for disposal of radioactive wastes into sanitary sewer systems so that "dispersible biological materials" may continue to be disposed of by release to sanitary sewers. This means of disposal is advantageous compared with other alternatives for disposal of this type of biological material.

The rationale for the reduction in the limits for sewer disposal is not explained. The concentration limits for radionuclides released to sanitary sewer systems in the proposed rule have been reduced by a factor of 10 from the former rule. This reduction did not appear to take into account the dilution afforded from multiple users of the sewer system. Commenters indicated that they thought that this reduction would increase the amount of material that would have to be disposed of via a low-level radioactive waste burial site and could result in increased radiation doses to workers having to package this material.

Response: The NRC has underway a study of the dose pathways associated with disposal of radioactive materials via sanitary sewers. This study will help clarify the potential for human exposure.

The assumption noted by many commenters that discharged into sanitary sewer systems are not ~~consumed~~ is not necessarily true, because water in large lake or river systems may be recycled. The dilution afforded by having multiple users of a sewer system can be offset in part because there can also be several users that discharge radioactive wastes into the same sewer system. The revised Part 20 rule allows a factor of 10 higher concentration limit for discharges into sanitary sewerage

than for other liquid effluent releases of radioactive materials.

The exemption on disposal of human excreta should be removed. Hospitals should have to comply with the same regulations as other licensees.

Response: Disposal into a sanitary sewer system (which was designed specifically to handle this type of waste) is the preferred method of disposal because of the other health considerations in handling human excreta in addition to radiation protection.

§ 20.1004 Treatment or Disposal by Incineration.

Relaxation of specific NRC authorization for incineration. A number of comments questioned the need for the existing requirement that incineration of radioactive materials requires specific prior NRC approval (except for small quantities of tritium and carbon-14 which are specifically exempted). These comments noted that the source of the released material (from an incinerator stack or from a fume hood vent) should not be the basis of requiring specific prior NRC approval of incineration while permitting general effluent releases.

Response: Relaxation of the prior approval requirement for incineration was considered in connection with the revision of Part 20. The requirement for prior NRC approval of incineration remains in revised Part 20 because (1) the suitability of incinerator design to safely dispose of hazardous materials and to provide adequate control over effluent activity levels; (2) the variable nature of the material to be burned in terms of isotopic composition and activity; and (3) human exposure to incinerator effluents, which may

special calculational methods may be required to ensure that doses to people located near these facilities are adequately assessed.

§ 20.1005 Disposal of Specific Wastes

There should be a definition of ALARA for solid wastes. Many commenters suggested the need for ALARA or exempt quantities of radioactive material in solid wastes so that very low-level solid wastes could be disposed of without regard to their radioactivity.

Response: The Commission agrees that such levels would be useful and has instituted a program to develop these levels.

§ 20.1007 Compliance with Environmental and Health Protection Regulations

Final rule. This section has a counterpart in the present Part 20 and in the proposed rule(§ 20.1005), that meeting Part 20 requirements does not remove the responsibility of licensees, when disposing of licensed radioactive materials, from meeting the requirements of applicable Federal, State, and local environmental protection regulations.

Final Rule. The warning in the final rule has been expanded to cover all methods of waste disposal. This section of the rule is advisory and it is not intended to imply that NRC will take enforcement action for violations of other environmental protection regulations issued under statutes other than the Atomic Energy Act.

insert 75-1

Response: The Commission agrees that such levels would be useful and has developed a policy statement regarding levels of dose and risk that can be used to determine that specific practices involve radiation hazards that are Below Regulatory Concern (BRC). The BRC policy statement provides a comprehensive policy that will establish a disciplined and consistent framework for all future Commission exemption decisions. The scope includes potential application to rulemaking or licensing actions for disposal of slightly contaminated solid radioactive wastes. The Commission is developing a program for implementing the BRC policy separate from this Part 20 rulemaking.

(Note that this rewrite does not commit to rulemaking on wastes and defers to the program being prepared by staff for Commission approval.)

Subpart L -- Records

Standardization of record retention requirements.

Final Rule. Records directly pertaining to doses received by individuals, ~~or~~ effluents released to the general environment, and waste disposal are to be kept until the "Commission terminates each pertinent license requiring the record." Other record retention requirements in this subpart generally have been modified to be for "three years after the record is made." This change is in conformance with the final rule published in effective form in the Federal Register of May 27, 1988 (53 FR 19240) on record retention requirements for other parts of the NRC regulations. This provides for consistent record retention requirements throughout Chapter I of Title 10 of the Code of Federal Regulations.

§ 20.1101 General Requirements

The units used in records should be limited to those commonly in use: the rad, the rem and the curie. Some commenters thought that the use of SI units (gray, sievert and becquerel) should not be allowed.

The Commission agrees that the use of "conventional units," the rad, rem, and curie, is preferable at this time. The F.R. Rule requires the use of these special units.

Response: See also the discussion of this topic under § 20.4 Units

§ 20.1102 Records of Radiation Protection Programs

Added implementation burden associated with requirements for formal radiation programs. A number of commenters thought that the requirement to have a formal ALARA program would result in substantial increased costs due to additional recordkeeping,

~~additional~~ procedural requirements, and ~~added~~ quality assurance requirements.

Response: As discussed under § 20.101, these provisions have been modified to ~~clearly place~~ require ALARA as one part of a licensee's radiation protection program. The adoption of requirements for licensees to have a formal radiation protection program was not intended to have large implementation costs. Much of the cost associated with this section in the proposed rule was a result of the ALARA documentation requirements. These recordkeeping requirements have been reduced in the final rule by deleting specific references to ALARA programs. ~~[illegible]~~ Specific records requirements will be developed by each licensee as part of the ALARA radiation protection program. Thus, specific reference to ALARA records is unnecessary in this section.

The recordkeeping burden for small licensees requires a commitment of resources that is not commensurate with the risk. (In Section XXXVI of the proposed rule (51 FR 1121-1122), NRC specifically requested comments on the magnitude of the impact of the proposed rule on small licensees and requested suggestions on how these impacts could be reduced.) Quite a few commenters expressed their belief that the proposed rule will require more extensive monitoring and recordkeeping efforts than were required by the existing Part 20. Several commenters suggested that the NRC explore possible exemptions or exclusions for academic licensees and other users of small quantities of licensed material. Other commenters expressed the view that the protection of public health for both the worker and the general public should be the same regardless of the size or economic resources of the licensee.

Response: Because of the changes ~~and~~ to reduce the recordkeeping burden discussed in response to the preceding comment and because the basic requirement in § 20.101 calls for effort "... commensurate with the scope and extent of licensed activities ...," the Commission has not made further exemptions or exclusions from the records required in this section for certain types of licensees.

§ 20.1104 Determination of Prior Occupational Dose

Medical and academic licensees would have difficulty in complying with the requirement to determine prior exposures. The transitory nature of personnel in these facilities would make meeting these requirements very costly. Doses to employees are small fractions of the limits, so ~~that~~ such costs would be difficult to justify.

Response: The requirement to determine dose received in the current year implements the annual dose limits. The requirement to attempt to obtain records of lifetime cumulative doses follows one of the provisions of the guidance to Federal agencies on occupational radiation protection. Determination of prior doses received during planned special exposures or doses in excess of the annual limits are required only for workers who will be used in planned special exposures. ~~Otherwise~~ Efforts to obtain prior exposure histories are only required for workers who are required to be monitored under § 20.502.

The recording of "fictitious" radiation doses should be avoided. The present and proposed rules state that, when information is not available regarding the dose received for a specific period, the licensee should assume that the dose received was at the dose limit. Several commenters thought that this was inappropriate. Some commenters mentioned that this practice might be non-conservative as it would tend to overestimate the dose used in any epidemiological studies of radiation effects, thereby resulting in an underestimate of the risk associated with a unit radiation dose.

Another commenter stated that there should be appropriate quarterly doses assumed to cover workers whose records have not yet been obtained from a former employer. This commenter suggested that a 0.5-rem dose per quarter could be assumed. [from p. 79]

Response and Final Rule: The final rule has been modified so that it does not require any assumed dose value to be recorded in case of incomplete prior dose his' ries. Only the lack of data must be recorded for periods where there is no information.

However, for the current year, where there are missing data, an assumption is to be made, for establishing administrative controls, that the portion of the dose limit remaining for the current year is reduced by 1.25 rems for each calendar quarter for which information is missing. The licensee must note the absence of this information on the employee's record, but should not enter the assumed dose value as part of the employee's permanent dose record.

~~There should be a quarterly dose limit to cover workers whose records have not been received from a former employer. A 0.5-rem dose might be appropriate for this purpose.~~ } moved to AS 7#

~~Response: As discussed above, the remaining allowable annual dose would be 5 rems less 1.25 rems times the number of quarters for which there are no prior data.~~ The values for other limits, such as shallow dose equivalent or eye dose equivalent, should be similarly ~~provided~~.

If data were missing for all four quarters (employment commenced late in the fourth calendar quarter), then a 0.5-rem dose limit would be applicable for the total effective dose equivalent limit. (This value is the § 20.502 monitoring threshold.)

§ 20.1105 Records of Planned Special Exposures

See discussion under § 20.1204.

§ 20.1106 Records of Individual Monitoring Results

NRC should not require reporting or recording of cumulative dose. A number of commenters noted that the ICRP system of dose limitation is based [as one of the principles] on controlling

annual doses. Consequently, they questioned the need for recording cumulative doses.

Response: Although the commenters are correct that there is no longer a cumulative dose restriction in Part 20 (such as the former 5(N - 18) formula), the Federal Guidance on Occupational Exposure (See Section IID.) contains a recommendation that cumulative dose records be maintained and provided to the worker. ~~§ 20.1106(b) too discussion under § 20.1204.~~

The recordkeeping requirement in the proposed § 20.1106(d)(2) would require that all records begin at the beginning of a calendar year. This would create an unnecessary hardship on dosimeter processors as they could not stagger the dosimeter changeover schedules to provide a more uniform workload distribution.

Response and Final Rule: The term "year" replaces the term "calendar year" in § 20.3 and permits the licensee to define the year to begin anytime in January. A licensee may change the starting date, provided that the change is made at the beginning of the year and provided that no day is omitted and no day is included twice in consecutive years.

The requirement in § 20.1106(e) for each licensee to keep a copy of the dosimeter processor's accreditation certificate creates an undue burden on commercial processors. Commercial dosimeter processors would have to print and distribute thousands of their certificates so that each user had a copy.

Response: The proposed rule contained a requirement for the licensee to maintain a copy of the dosimetry processing accreditation certificate issued to the processor providing dosimetry services to the licensee. This requirement, which was in the proposed dosimetry accreditation rule, was considered

The problem of dual employment is more of a problem when the employee has not confided in the employer. The licensee is required to ascertain the employment and dose record for the current year for new employees (§ 20.1104). If the employee deliberately falsifies this information, the licensee would not know of concurrent employment and the licensee would not be penalized for combined doses from both employers that exceeded the dose limits. If a current employee takes on additional outside radiation work without informing the employer, again, the employer should not be penalized. It should be noted that, under the new reporting requirements in § 20.1206, individual dose records will be required to be submitted to the NRC for all workers for those categories of licensees formerly subject to § 20.407, including nuclear power reactors licensees. These records may provide a means of detecting some "moonlighting" employees.

Edit after determining the use of NRC Form 5 and S.S. #

Final Rule. Section 20.1106 has been modified in order to separate the requirement for keeping a record from the format of the record. A clarification has been added that the dose information on an embryo/fetus be kept with the mother's dose record ~~and coded by the mother's Social Security Account Number.~~

§ 20.1107 Records of Dose to Individual Members of the Public

Reporting requirements for exceeding "Reference Levels." The proposed rule contained requirements for reporting exposures in excess of the "Reference Levels" for doses to members of the general public. Many commenters thought that this was excessive because this was not an actual regulatory limit.

Response: The 100-millirem per year "Reference Level" for doses to members of the general public has become the actual limit so that the associated recording and reporting requirements now pertain to a bona fide regulatory dose limit.

Final Rule. Section 20.1107 has been broadened in scope from "effluents" to pertain to records of all estimates of doses received by individual members of the public. This shift in emphasis does not imply any lessening of requirements for keeping adequate records of effluents released to unrestricted areas.

§ 20.1108 Records of Waste Disposal

Final Rule. Section 20.1108 is unchanged from the proposed rule.

§ 20.1109 Records of Testing Entry Control Devices for Very High Radiation Areas.

Final Rule. Section 20.1109 contains an addition to the proposed rule for keeping records of tests of entry control devices for very high radiation areas. This addition is based upon a requirement in § 20.203(c)(6) of present Part 20.

§ 20.1110 Form of Records

NRC should allow computerized recordkeeping systems to handle records. A few licensees suggested that NRC allow "electronic" recordkeeping systems and provide guidance for their use.

Response: The Commission agrees that there is great value in the use of "electronic media." There are a growing number of licensees that are using computer information networks for retaining and transmitting radiation dose histories and other worker-related information among different facilities.

specified period, such as 7 days, should be permitted before a "lost" source would have to be reported to the NRC.

Response: The rule contains two notification requirements: the one for immediate notification only pertains to those sources that could produce substantial exposures. The second notification requirement pertains to sources that exceed 10 times the activity levels in Appendix C and that are still missing at that time. This provides a "grace period" of 30 days for reporting the loss of most sources.

§ 20.1202 Notification of Incidents

The requirements for immediate notification of NRC are too low. Some commenters thought that the doses associated with the requirements for immediate reporting to NRC (five times the respective annual limits) would not produce any discernible harmful effects to the individual to warrant immediate reporting.

Response: Doses of the order of 25 rems (5 times the 5-rem annual dose limit) can produce discernible biological effects in the form of chromosome aberrations and changes in the white blood cell populations. Although the majority of these effects are temporary, they could be discerned. However, irrespective of the potential for discernible effects, doses at these levels represent a major breakdown on the licensee's control over the radioactive material, and the Commission believes that it is important that NRC be promptly notified so that it can take actions, if necessary, to limit further consequences.

Final Rule. The final rule ~~perpetuates~~ retains the previous reporting requirement.

There is no requirement for reporting doses in excess of the limit for the embryo-fetus. There is no requirement for reporting doses that exceed the limit for protection of the embryo/fetus in § 20.208.

Response: A requirement has been added to the final rule in (See § 20.1203(a)(iii)).

The identifiers required in § 20.1203(b)(2) for the embryo-fetus should be those of the mother. As the fetus has no date-of-birth and no social security account number, those of the mother should be used.

Response and Final Rule: A footnote to this effect has been added to § 20.1203.

Reports of exceeding the 0.1-rem "reference level" should not be required. A number of commenters noted that the 0.1-rem "reference level" was not a limit and, therefore, exceeding it should not necessitate a report to the NRC.

Response: As a result of changes in the ICRP interpretation of the 0.1-rem level and the former 0.5-rem dose limit, the 0.1-rem level is now the recommended limit for exposure of the general public (individuals in unrestricted areas). Consequently, 0.1-rem is the primary limit applicable to members of the general public and reports are justified when it is exceeded.

Smaller licensees, such as nuclear medicine facilities, should be exempted from the reporting requirements of § 20.1203.

special exposures is shorter than the 30-day period usually allowed for similar reports.

Response: The reporting period of a planned special exposure has been increased from 15 days to 30 days to be more consistent with other reporting requirements.

Insert Ex Pg. 92

§ 20.1206 Reports of Individual Monitoring

Could the requirement for reporting of individual exposures be construed as an invasion of privacy? Some commenters believed that requiring the reporting of individual doses rather than a statistical summary might constitute an invasion of personal privacy.

Response: The Commission does not believe that submission of individual dose data constitutes an invasion of privacy. Such data has been reported to the NRC routinely in the termination reports for some time. Such information will be restricted, as it has in the past, to use by NRC officials, NRC contractors, or by qualified scientific investigators. Instructions on protecting this information appear in § 20.1106 (d).

protected in accordance with the Privacy Act and the routine uses will be

If the radiation exposure data is collected into a central repository, would the NRC be the proper place for it? One commenter felt that the radiation exposure data might be better maintained by an agency whose charter encompasses the analysis of the data for estimates of risk.

Response: Arguments might be made for other agencies having the lead role in the storage and analysis of this data; however, it is the NRC that has the statutory authority to require that this data be collected. Although the Part 20 recordkeeping requirements are intended primarily to fulfill

suggested that all licensees be required to submit an annual report to NRC on each monitored individual.

Response: The reporting of individual monitoring data will help track doses to individuals who are exposed at several facilities during any given year and whose total dose would be underreported by statistical reports prepared at each work site. Such information is only shown at the present time by analysis of the termination reports.

Licensees required to file both annual statistical summaries and termination reports with the NRC will, instead, submit annual dose reports to NRC for all workers for whom monitoring was required under § 20.502. A copy of the annual report to NRC could also be given to the individual worker in order to satisfy the revised reporting requirement in § 19.13 of 10 CFR Part 19. Although this may entail some additional burden to licensees, the use of "electronic media" for recordkeeping might in fact reduce overall costs. It is intended that large employers (such as nuclear power reactor licensees) would submit an electronic copy of their dose reports in a prescribed format to the NRC in lieu of paper copies of individual records.

The Commission has decided not to require pre-approval of planned special exposure. This is, in the Commission's view, consistent with the Federal guidance ~~as~~ and detailed requirements are prescribed in Part 20 for the use of planned special exposures.

§ 20.1301 Applications for Exemptions

NRC should make the issuance of exemptions a matter of public record. Several commenters felt that the issuance of any exemptions under this section should require public notice and

comment. The EPA stated that exemptions could adversely affect its ability to control radionuclides under the Safe Drinking Water Act.

Need to respond to EPA comment

Response: The NRC has issued few exemptions under this longstanding provision and has not exempted anyone from the dose limits for a worker or for a member of the public.

Appendix A

The protection factor for air-purifying respirators with particulate elements is too low. The listed protection factor for air-purifying respirators with particulate filters is 50, whereas both ANSI Z88.2 and the OSHA regulations in 29 CFR 134 use 100.

Response: The NRC never endorsed ANSI Z88.2-1980, whereas the OSHA regulations generally follow ANSI standards. The current NRC-allowed protection factors (PF) are based upon research conducted by the Los Alamos National Laboratory (LANL). These recommendations included a PF of 50 for full face respirators, based on experimental data on actual testing of personnel using respirators under carefully controlled conditions. In actual use, there is essentially no difference between a PF of 50 versus a PF of 100, so that there should be little or no real impact on field use of respirators or on operations at nuclear facilities that would result from using the higher protection factor.

Several respiratory equipment specifications in Appendix A should be applicable only for areas that are "immediately dangerous to life and health." Footnotes "h" and "i" contain specifications for air flow rates and flow calibration and a

Concentration limits for tritium omit chemical forms other than for tritiated water vapor.

Response: As there is expected to be no occupational intake via oral ingestion, and most of the organic forms are not volatile, different intake limits would apply to hydrogen gas (HT or T_2) and HTO. The HT or T2 gas is rapidly converted to HTO by exchange and oxidation so that specifying a submersion dose limit for HT would understate the actual radiological impact. Comparison with other derived limits for other chemical forms shows that the use of the concentration limits for HTO provides an adequate level of protection for most of the other chemical forms.

No concentration limits are listed for natural thorium. There are limits for natural uranium, but corresponding concentration limits for natural thorium are not given. The isotopic composition of thorium can vary somewhat with different ores and with different times after chemical separations.

Response: Use the thorium-232 value, or if a more precise value is desired, use the procedure for mixtures in Appendix B applied to the actual isotopic concentrations present.

The derived air concentrations for the general public are not always 0.1 times the occupational values.

Response: The limits for the general public are calculated solely from the stochastic risks. This differs from ICRP which would use a "capping" organ dose limit of 5 rems (0.1 x the non-stochastic limit of 50-rem) in deriving the organ dose limit for organs that are limited by the non-stochastic risk. The threshold for non-stochastic effects for the worker at 50 rems would also apply to a member of the public. Rather than applying a

factor of ten reduction, the limiting stochastic (effective) dose was used to calculate the concentration limits for the general public. Values are not based on the non-stochastic risk for members of the public, even if they were the basis for the calculation of the DACs and ALIs for the worker.

Appendix C

The reduction from 100 μCi to 0.001 mCi for thorium values will require posting of areas where thoriated-nickel machine parts are used.

Response: On the basis of specific activity considerations, the existing 100 μCi limit has been retained for long-lived radionuclides (half-lives longer than 10^9 years), such as thorium-232, which would require a considerable mass of material to produce the stated activity level.

Appendix E [Reserved]

Final Rule. The calculational guidelines and equations that appeared in Appendix E will be incorporated into a Regulatory Guide. This will make it easier to revise and clarify the calculational methods without having to resort to formal rulemaking. (Note: NRC routinely issues Regulatory Guides for public comment before making them final.)

Appendix F

Note: Appendix F is derived directly from requirements inserted by the Part 61 rulemaking proceeding on low-level radioactive waste disposal sites. Because these requirements

are relatively recent, they were not ~~substantially~~ modified in the Part 20 revision.

Appendix G

No comments on Appendix G were received.

VII. Conforming Amendments

Accompanying the revised rule are amendments to other parts of Chapter I which update citations to 10 CFR Part 20 that are found in these other regulations. Two amendments are particularly important as they go beyond updating cross-reference citations. One amendment to 10 CFR Part 2 updates and modifies the severity levels associated with violations of 10 CFR Part 20. Because these changes were not contained in the proposed Part 20, rule there has been no prior opportunity for public comment. Although these modifications are being issued in final form with the same effective date as the Part 20 rule, public comments may be submitted on these modifications to Part 2 (See the "Dates" and "Addresses" sections). If any public comments warrant revision of the Part 2, Appendix C, changes, a modified version will be published before the Part 20 effective date.

The second major change to other parts is the requirement to provide all workers with information on their radiation doses. This modification was made to conform to the 1987 Federal guidance on occupational radiation exposure. Formerly, Part 19 required licensees to furnish such a report at least annually upon the request of the worker. The change deletes the words "upon request." Public comment is not being solicited on this change as the comments were requested in the proposed rule (Section XXVII, 51 FR 1118) on the option of requiring reports to individual workers.

VIII. Environmental Assessment: Negative Declaration

The Commission 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 not to prepare an environmental impact statement for this revision of 10 CFR Part 20, because the Commission has concluded, on the basis of an environmental assessment, that promulgations of this revision of 10 CFR Part 20 as a final rule would not be a major Federal action significantly affecting the quality of the human environment.

The revised 10 CFR Part 20 changes the level for protection of the general public from an implicit limit of 0.5 rems per year to an explicit limit of 0.1 rem per year. There are also numerous changes in airborne and water radionuclide concentration limits. These changes result from changes in the models and parameters used to estimate the radiation dose associated with intake of a radionuclide. Some of the concentration limits for the general public in this revision are ~~new~~ higher or lower than present limits; some limits are similar to the present limits; ~~while other limits are changed upward or downward.~~

Despite the changes in the dose and concentration limits, the Commission believes that issuance of the final Part 20 rule will not have a major impact on the environment. The primary basis for this conclusion is that in addition to 10 CFR Part 20, there are other regulations that govern allowable doses to

members of the public and which remain unchanged by the changes to Part 20. These other regulations include Appendix I to 10 CFR Part 50, Part 60, Part 61 and the EPA's generally-applicable environmental standards in 40 CFR Parts 190, 191, 192 and ~~proposed 193~~, and the National Emission Standards for Hazardous Air Pollutants (NESHAPS) in 40 CFR Part 61 (radionuclides). These standards set limits or design objectives (Appendix I) for releases of radioactive material to the general environment which are generally more restrictive than the dose limits in Part 20. Consequently, since these more restrictive standards remained essentially unchanged by the Part 20 revision, the level of public protection and the associated environmental impact are not changed appreciably from those associated with the current rule and the aforenamed regulations.

This finding and the accompanying environmental assessment for the Part 20 revision may be examined and copied (for a fee) at the NRC Public Document Room (See ADDRESSES). Single copies of the assessment may be obtained from the NRC project manager (See FOR FURTHER INFORMATION CONTACT).

IX. Paperwork Reduction Act Statement

This rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C.

3501, et seq.). These information collection requirements were approved by the Office of Management and Budget, approval number 3150-0014.

X. Revised Regulatory Analysis

The Commission has prepared a final regulatory analysis for this regulation. This revised analysis was based on the draft regulatory analysis as modified to account for changes from the proposed rule and public comments ~~and the revised rule~~. Copies of both the draft and final Regulatory Analysis are available for review and copying (for a fee) in the Commission's Public Document Room. (See Addresses.)

XI. Regulatory Flexibility Certification

In accordance with Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission has prepared a regulatory flexibility analysis which indicated that the revised rule will apply to all NRC licensees. The NRC has approximately 7,500 licensees, approximately one quarter of which are classified as small entities. (Note: Agreement States, which implement comparable regulations under section 274 of the Atomic Energy Act of 1954, as amended, have about 16,000 licensees.) The types of small entities that would be affected by this rule

FROM DRAFT FINAL RULE — (This was pretty basic analysis)

include physicians, small hospitals, small laboratories, ~~industrial applications in~~ small industries, radiographers, and well loggers.

XII. Backfit Analysis

SUBSTITUTE REGULATORY ANALYSIS

The Commission has determined that the basic radiation protection standards in Part 20 are necessary to implement the 1987 revised Federal radiation protection guidance on occupational exposure. As provided for in Sec. 274(h) of the Atomic Energy Act, on January 20, 1987, the President has approved revised guidance to Federal agencies on the formulation of standards for occupational radiation exposure. Members of the NRC staff participated in an interagency working group that developed the recommendations for the President. The AEC and the NRC have considered Federal Guidance and have consistently implemented prior guidance in their regulations. While the Federal Guidance only addresses occupational exposure, failure to make similar conforming standards for the public would lead to confusion and problems in implementation. Consistency between the Federal Guidance and the NRC regulations is particularly important for Federal agencies that use source, byproduct, and special nuclear material under NRC license and are attempting to implement at the same time NRC regulations and the new Federal Guidance. Other agencies, such as DOT, are writing their regulations in terms consistent with the new dose

limitation system adopted in the new Federal Guidance. NRC regulations should be consistent with those of DOT and other Federal agencies.

The draft Backfit Analysis prepared for the Part 20 rule [Federal Register of August 29, 1986, 51 FR 30873] requested comment on whether § 50.109 should be suspended for this rulemaking because of other factors including the proposed issuance of Federal guidance on occupational exposure. This guidance, which was still in development when the draft backfit analysis was published, has since been approved by the President and issued in final form. There were 12 comments on the suspension of § 50.109 for this rulemaking; all were against suspending § 50.109. The principal reason cited for not suspending § 50.109 was maintaining the uniform application of the backfit rule to all regulations. The Commission believes that implementation of the Federal Guidance and ensuring uniform regulatory approach in various Federal agencies outweighs the considerations of maintaining uniform application of § 50.109.

The Commission believes that promulgation of the revised Part 20 is necessary and, consequently, the provisions of § 50.109 ("The Backfit Rule") are suspended. The Commission has the authority to suspend its regulations after opportunity has been provided for public comments as was done for this action.

20.302, 20.501, 20.502, 20.601(a) and (d), 20.602, 20.603, 20.701 - 20.704, 20.801, 20.802, 20.901(a), 20.902, 20.904, 20.906, 20.1001, 20.1002, 20.1003, 20.1004, 20.1005(b) - (d), 20.1006, 20.1101 - 20.1110, 20.1201 - 20.1206, and 20.1301 are issued under sec. 161b., 68 Stat. 948 (42 U.S.C. 2201(b)) and § 20.1106(d) is issued under the Privacy Act of 1974, Pub.L. 93-579, 5 U.S.C. 552a; and §§ 20.102(a)(2) and (4), 20.204(c), 20.206(g) and (h), 20.904(c)(4), 20.905(c) and (d), 20.1005(c), 20.1006(b) - (d), 20.1101 - 20.1103, 20.1104(b) - (d), 20.1105 - 20.1108, and 20.1201 - 20.1207 are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

SUBPART A - GENERAL PROVISIONS

§ 20.1 Purpose.

(a) The regulations in this part establish standards for protection against ionizing radiation resulting from activities conducted under licenses issued by the Nuclear Regulatory Commission. These regulations are issued under the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended.

(b) It is the purpose of the regulations in this part to control the receipt, possession, use, transfer, and disposal of licensed material by any licensee in such a manner that the total dose to an individual (including doses resulting from licensed and unlicensed radioactive material and to other radiation sources) does not exceed the standards for protection against radiation prescribed in the regulations in this part. However, nothing in this part shall be construed as limiting actions that may be necessary to protect health and safety.

Edit per No. 6 in SRM

other than natural background radiation

§ 20.2 Scope.

The regulations in this part apply to persons licensed by the Commission to receive, possess, use, or transfer byproduct, source, or special nuclear material or to operate a production or utilization facility under Parts 30 through 35, 39, 40, 50, 60, 61, 70, or 72 of this chapter. The limits in this part do not apply to doses due to natural

background, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, or to voluntary participation in medical research programs.

§ 20.3 Definitions.

As used in this part:

"Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the rad and the gray (Gy).

"Act" means the Atomic Energy Act of 1954 (42 U.S.C. 2011 et seq.), as amended.

"Activity" is the rate of disintegration (transformation), or decay of radioactive material.

The units of activity are the curie (Ci) and the becquerel (Bq).

"Adult" means an individual 18 or more years of age.

"Airborne radioactive material" means radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

"Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive materials, composed wholly or partly of licensed material, exist in concentrations--

(1) In excess of the derived air concentrations (DACs) specified in Appendix B, or

(2) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

"Class" (or "lung class" or "inhalation class") means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y which applies to a range of clearance half-times for D(Days) of less than 10 days, for W(Weeks) from 10 to 1[illegible]ys, and for Y(Years) of greater than 100 days.

"Collective dose" is the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

"Commission" means the Nuclear Regulatory Commission or its duly authorized representatives. ~~"NRC" means the Commission or its duly authorized representatives.~~ redundant — deleting "NRC"

"Committed dose equivalent" ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

"Committed effective dose equivalent" ($H_{E,50}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues which are irradiated and the committed dose equivalent to these organs or tissues ($H_{E,50} = \sum w_T H_{T,50}$).

"Controlled area" means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason.

"Declared pregnant woman" means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

"Deep dose equivalent" (H_d), which applies to external whole-body exposure, is the dose equivalent at a tissue depth of 1 cm (1000 mg/cm^2).

of locations under the control of persons possessing or using radioactive material. ~~These standards are set out in 40 CFR Parts 190, 191, and 192.~~

"Government agency" means any executive department, commission, independent establishment, corporation wholly or partly owned by the United States of America which is an instrumentality of the United States, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the Government.

"Gray" [See § 20.4]

"High radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour at 30 cm from the radiation source or from any surface which the radiation penetrates.

"Individual" means any human being.

"Individual monitoring" means:

(1) The assessment of dose equivalent by the use of devices designed to be worn by an individual;

(2) The assessment of committed effective dose equivalent by bioassay (see Bioassay) or by determination of the time-weighted air concentrations to which an individual has been exposed, i.e., DAC-hours; or

(3) The assessment of dose equivalent by the use of survey data.

"Individual Monitoring Devices" ("individual monitoring equipment") means devices designed to be worn by a single individual for the assessment of dose equivalent such as: film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, and personal ("lapel") air sampling devices.

"Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

"License" means a license issued under the regulations in Parts 30 through 35, 39, 40, 50, 60, 61, 70, or 72 of this chapter.

"Licensee" means the holder of a license.

"Licensed material" means source material, special nuclear material, or byproduct material received, possessed, used, or transferred under a general or specific license issued by the Commission.

"Limits" (Dose limits) means the permissible upper bounds of radiation doses.

"Lost or missing licensed material" means licensed material whose location is unknown. It includes material which has been shipped but has not reached its destination and whose location cannot be readily traced in the transportation system.

"Member of the public" means an individual in a controlled or unrestricted area. However, an individual is not a member of the public during any period in which the individual receives an occupational dose.

"Minor" means an individual less than 18 years of age.

"Monitoring" (radiation monitoring, radiation protection monitoring) means the measurement of radiation levels, concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses.

"Natural background" means naturally occurring cosmic and terrestrial radiation and radioactive material, but not including source, byproduct, or special nuclear material.

"Non-stochastic effect" means health effects, the severity of which varies with the dose, and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a non-stochastic effect.

"NRC" means the Nuclear Regulatory Commission or its duly authorized representatives.

"Occupational dose" means 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 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 natural background, as a patient from medical practices, from voluntary participation in medical research programs, or as a member of the general public.

"Person" means:

(1) Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency other than the Commission or the Department of Energy (except that the Department shall be considered a person within the meaning of the regulations in 10 CFR Chapter I to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the Commission under Section 202 of the Energy Reorganization Act of 1974 (88 Stat. 1244), the Uranium Mill Tailings Radiation Control Act of 1978 (92 Stat. 3021), and Section 3(b)(2) of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (99 Stat. 1842)), any State or any political subdivision of or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity; and

(2) Any legal successor, representative, agent, or agency of the foregoing.

"Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual dose limits.

"Public dose" means the dose received by a member of the public from exposure to radiation and to radioactive material released by a licensee, or to another source of radiation either within a licensee's controlled area or in unrestricted areas. It does not include occupational dose or

this part. (See § 20.1102 for recordkeeping requirements relating to these programs).

(b) The licensee shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to ensure that occupational doses and doses to members of the public are as low as is reasonably achievable (ALARA).

(c) The licensee shall periodically (at least annually) review the radiation protection program content and implementation.

SUBPART C - OCCUPATIONAL DOSE LIMITS

§ 20.201 Occupational dose limits for adults.

(a) The licensee shall control the occupational dose to individual adults, except for planned special exposures under § 20.206, to the following dose limits.

(1) An annual limit, which is the more limiting of--

(i) The total effective dose equivalent being equal to 5 rems (0.05 Sv); or

(ii) The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rems (0.5 Sv).

(2) The annual limits to the lens of the eye, to the skin, and to the extremities which are:

(i) An eye dose equivalent of 15 rems (0.15 Sv); and

(ii) A shallow dose equivalent of 50 rems (0.50 Sv) to the skin or to each of the extremities.

(b) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, must be subtracted from the limits for planned special exposures that the individual may receive during the current year (see § 20.206(e)(1)) and during the individual's lifetime (see § 20.206(e)(2)).

(c) The assigned deep dose equivalent and shallow dose equivalent must be for the part of the body receiving the highest exposure. The deep dose equivalent, eye dose equivalent and shallow dose equivalent may

be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

(d) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table 1 of Appendix B and may be used to determine the individual's dose (See § 20.1106) and to demonstrate compliance with the occupational dose limits.

(e) In addition to the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity (see footnote 3 of Appendix B).

(f) The licensee shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person (See § 20.1104(e)).

§ 20.202 Compliance with requirements for summation of external and internal doses.

(a) If the licensee is required to monitor under both §§ 20.502(a) and (b), the licensee shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee is required to monitor only under § 20.502(a) or only under § 20.502(b), then summation is not required to demonstrate compliance with the dose limits. The licensee may demonstrate compliance with the requirements for summation of external and internal doses by meeting ~~one of~~ the conditions specified in paragraphs (b), (c), and (d). (NOTE: The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.)

(b) Intake by inhalation. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

(1) The sum of the fractions of the inhalation ALI for each radionuclide; or

(2) The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000; or

(3) The sum of the calculated committed effective dose equivalents to all significantly irradiated[1] organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit.

(c) Intake by oral ingestion. If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable ALI, the licensee shall account for this intake and include it in demonstrating compliance with the limits.

(d) Intake through wounds or absorption through skin. The licensee shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. (NOTE: The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be further evaluated).

§ 20.203 Determination of external dose from airborne radioactive material.

Licensees shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, eye dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud (See Appendix B, footnotes 1 and 2). (NOTE: Airborne radioactivity measurements and DAC values should not be used as the primary means to assess the deep dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep dose equivalent to an individual should be based upon measurements using instruments or individual monitoring devices).

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1 An organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors, w_T, and the committed dose equivalent, H_{50}, per unit intake is greater than 10 percent of the maximum weighted value of H_{50} (i.e., $w_T H_{50,T}$) per unit intake for any organ or tissue.

(1) The sum of the ratios of the concentration ~~and~~ to the appropriate DAC value (e.g., D, W, Y) from Appendix B for each radionuclide in the mixture; or

(2) The ratio of the total concentration for all radionuclides in the mixture ~~divided by~~ to the most restrictive DAC value for any radionuclide in the mixture.

(f) If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture must be the most restrictive DAC of any radionuclide in the mixture.

(g) When a mixture of radionuclides in air exists, licensees may disregard certain radionuclides in the mixture if:

(1) The licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in § 20.201 and in complying with the monitoring requirements in § 20.502(b); and

(2) The concentration of any radionuclide disregarded is less than 10 percent of its DAC; and

(3) The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.

(h)(1) In order to calculate the committed effective dose equivalent, the licensee may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours results in a committed effective dose equivalent of 5 rems (0.05 Sv) for radionuclides which have their ALIs or DACs based on the committed effective dose equivalent.

(2) When the ALI (and the associated DAC) is determined by the nonstochastic organ dose limit of 50 rems (0.5 Sv), the intake of radionuclide that would result in a committed effective dose equivalent of 5 rems (0.05 Sv) (the stochastic ALI) is listed in parentheses in Table 1 of Appendix B. In this case, the licensee may, as a simplifying assumption, use the stochastic ALIs to determine committed effective dose equivalent. However, if the licensee uses the stochastic ALIs, the licensee must also demonstrate that the committed dose ~~equivalent~~ to any organ or tissue does not exceed 50 rems (0.5 Sv) in a year.

§ 20.205 [Reserved]

§ 20.206 Planned special exposures.

A licensee may authorize an adult worker to receive doses in excess of the limits specified in § 20.201 provided that each of the following conditions is satisfied:

(a) The licensee authorizes a planned special exposure only in an exceptional situation, when alternatives which might avoid the higher exposure are unavailable or impractical.

(b) The licensee (and employer, if the employer is not the licensee) specifically authorizes the planned special exposure, in writing, before the exposure occurs.

(c) Before a planned special exposure, the licensee ensures that the individuals involved are--

(1) Informed of the purpose of the planned operation;

(2) Informed of the estimated doses, and special radiation or other conditions that might be involved in performing the task; and

(3) Instructed in the measures to be taken to keep the dose, and other risks ~~ALARA~~ that may be present.

(d) Prior to permitting an individual to participate in a planned special exposure, the licensee ascertains the internal and external doses from all previous planned special exposures (as recorded in compliance with § 20.1104(b)) and all doses in excess of the annual limits received during the lifetime of the individual for each individual involved.

(e) Subject to § 20.201(b)(2), the licensee does not authorize a planned special exposure which would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed--

(1) The numerical values of any of the dose limits in § 20.201(a) in any year; and

(2) Five times the annual dose limits in § 20.201(a) during the individuals lifetime.

(f) The licensee maintains records of the conduct of a planned sperial exposure in accordance with § 20.1105, and submits a written report in accordance with § 20.1204.

(g) The licensee records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special expousures is not to be considered in controlling future occupational dose of the individual under § 20.201(a) but is to be included in evaluations required by § 20.206(d).

§ 20.207 Occupational dose limits for minors.

The annual occupational dose limits for minors are 10 percent of the annual dose limits specified for adult workers in § 20.201.

[N.B.: 0.5 Rem - NCRP #91 Recommd: 0.1 Rem/yr.]

§ 20.208 Dose to an embryo/fetus.

(a) The licensee shall ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). (For recordkeeping requirements, see § 20.1106)

(b) The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman which would satisfy the limit in paragraph (a) of this section.

(c) The dose to an embryo/fetus shall be taken as the sum of--

(1) The deep dose equivalent to the declared pregnant woman; and

(2) The committed effective dose equivalent assessed to the pregnant woman due to the intake of radionuclides, modified to take into account any established parameters that cause the dose to the embryo/fetus to be different from that of the declared pregnant woman.

(d) If the dose to the embryo/fetus is found to have exceeded 0.5 rem (5 mSv), or is within 0.05 rem (0.5 mSv) of this dose, by the time the woman declares the pregnancy to the licensee, the licensee shall be deemed to be in compliance with paragraph (a) of this section if the additional dose to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

SUBPART D - RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

§ 20.301 Dose limits for individual members of the public.

(a) Each licensee shall conduct operations so that--

(1) The total effective dose equivalent to individual members of the public from those operations does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contribution from the licensee's disposal of radioactive material into sanitary sewerage in accordance with § 20.1003; and

(2) The dose in any unrestricted area from external sources does not exceed 0.002 rem (0.02 mSv) in any one hour.

(b) If the licensee permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

(c) A licensee or license applicant may apply for prior NRC authorization for operating up to an annual dose to individual members of the public of 0.5 rem (5 mSv). The licensee or license applicant shall include the following information in this application:

(1) Demonstration of the need for and the expected duration of operations in excess of the limit in paragraph (a) of this section,

(2) The licensee's program to assess and control dose within the 0.5 rem (5 mSv) annual limit; and

(3) The procedures to be followed to maintain doses as low as is reasonably achievable.

(d) In addition to the requirements of this part, a licensee subject to the provisions of EPA's generally applicable environmental radiation standards shall comply with those standards.

(e) The Commission may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee may release in effluents in order to restrict the collective dose.

§ 20.302 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 and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the ~~annual~~ dose limits for individual members of the public in § 20.301.

(b) A licensee shall show compliance with the ~~annual~~ dose limits in § 20.301 by --

(1) Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from sources under the licensee's control does not exceed the annual dose limit; or

(2) Demonstrating that--

(i) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table 2 of Appendix B; and

(ii) If an individual were continually present in an unrestricted area, the dose from external sources would not exceed 0.002 rem (0.02 mSv) in any hour and 0.05 rem (0.5 mSv) in a year.

(c) Add new provision from Secy pg. 267

SUBPART E - [RESERVED]

SUBPART F - SURVEYS AND MONITORING

§ 20.501 General.

(a) Each licensee shall make or cause to be made, surveys that--

(1) May be necessary for the licensee to comply with the regulations in this part; and

(2) Are reasonable under the circumstances to evaluate:

(i) The extent of radiation levels; and

(ii) Concentrations or quantities of radioactive material; and

(iii) The potential radiological hazards that could be present.

(b) The licensee shall ensure that instruments and equipment used for quantitative radiation measurements (e.g., dose rate and effluent monitoring) are calibrated periodically for the radiation measured.

(c) All personnel dosimeters (except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to the extremities) that require processing to determine the radiation dose and that are utilized by licensees to comply with § 20.201, with other applicable provisions of this chapter, or with conditions specified in a license, must be processed and evaluated by a dosimetry processor--

(1) Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National ~~Bureau of~~ Institute of Standards and Technology; and

(2) Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximate the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

§ 20.502 Conditions requiring individual monitoring of external and internal occupational dose

Each licensee shall monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the

occupational dose limits of this part. As a minimum,

(a) Each licensee shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by--

(1) Adults likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of the limits in §20.201(a); and

(2) Minors and declared pregnant women likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of any of the applicable limits in §§ 20.207 or 20.208; and

(3) Individuals entering a high or very high radiation area.

(b) Each licensee shall monitor (see §20.204) the occupational intake of radioactive material by and assess the committed effective dose equivalent to--

(1) Adults likely to receive, in one year, an intake in excess of 10 percent of the applicable ALI(s) in Table 1, Columns 1 and 2, of Appendix B; and

(2) Minors and declared pregnant women likely to receive, in one year, a committed effective dose equivalent in excess of 0.05 rem (0.5 mSv).

SUBPART G - CONTROL OF EXPOSURE FROM EXTERNAL SOURCES IN RESTRICTED AREAS

§ 20.601 Control of access to high radiation areas.

(a) The licensee shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

(1) A control device which, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a dose of 0.1 rem (1 mSv) in 1 hour at 30 cm from the radiation source or from any surface which the radiation penetrates;

(2) A control device which energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; and/or

§ 20.603 Control of access to very high radiation areas - irradiators.

(a) Each area in which there may exist radiation levels in excess of 500 rads (5 grays) in 1 hour at 1 meter from a sealed radioactive source[2] that is used to irradiate materials must meet the following requirements.

(1) Each entrance or access point must be equipped with entry control devices which--

(i) Function automatically to prevent any individual from inadvertently entering the area when very high radiation levels exist; ~~and~~

(ii) Permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the sealed source, to be reduced below that at which it would be possible for an individual to receive a ~~dose in excess~~ of 0.1 rem (1 mSv) in one hour; and

(iii) Prevent operation of the source if the source would produce radiation levels in the area that could result in a ~~dose~~ to an individual in excess of 0.1 rem (1 mSv) in 1 hour.

(2) Additional control devices must be provided so that, upon failure of the entry control devices to function as required by paragraph (a)(1) of this section:

(i) The radiation level within the area, from the sealed source, is reduced below that at which it would be possible for an individual to receive a ~~dose in excess~~ of 0.1 rem (1 mSv) in one hour; and

(ii) Conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and make

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2 This section does not apply to radioactive sources that are used in teletherapy, in radiography, or in completely self-shielded irradiators ~~in~~ which ~~the~~ source ~~is~~ both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create high levels of radiation in an area that is accessible to any individual. This section also does not apply to sources from which the radiation is incidental to some other use nor to nuclear reactor generated radiation ~~other than radiation from byproduct, source, or special nuclear materials that are used in sealed sources in non self-shielded irradiators.~~

at least one other authorized individual, who is physically present, familiar with the activity, and prepared to render or summon assistance, aware of the failure of the entry control devices.

(3) The licensee shall provide control devices so that, upon failure or removal of physical radiation barriers other than the source's shielded storage container--

(i) The radiation level from the source is reduced below that at which it would be possible for an individual to receive a dose in excess of 0.1 rem (1 mSv) in one hour; and

(ii) Conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.

(4) When the shield for the stored source is a liquid, the licensee shall provide means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding.

(5) Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances, need not meet the requirements of paragraphs (a)(3) and (4) of this section.

(6) Each area must be equipped with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source can be put into operation and in sufficient time for any individual in the area to operate a clearly identified control device, which must be installed in the area and which can prevent the source from being put into operation.

(7) Each area must be controlled by use of such administrative procedures and such devices as are necessary to assure that the area is cleared of personnel prior to each use of the source.

(8) Each area must be checked by a radiation measurement to assure that prior to the first individual's entry into the area after any use of the source, the radiation level from the source in the area is below that at which it would be possible for an individual to receive a dose in excess of 0.1 rem (1 mSv) in one hour.

radiation levels before an individual can gain access to the area where such radiation sources are used.

(c) The entry control devices required by paragraphs (a) and (b) of this section must be established in such a way that no individual will be prevented from leaving the area.

SUBPART H - RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURE IN RESTRICTED AREAS

§ 20.701 Use of process or other engineering controls.

The licensee shall use, to the extent practicable, process or other engineering controls (e.g., containment or ventilation) to control the concentrations of radioactive material in air.

§ 20.702 Use of other controls.

When it is not practicable to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those which define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

(a) Control of access;

(b) Limitation of exposure times;

(c) Use of respiratory protective equipment; or

(d) Other controls.

§ 20.703 Use of individual respiratory protective equipment.

(a) If the licensee uses respiratory protective equipment to limit intakes pursuant to §20.702--

(1) The licensee shall use only respiratory protective equipment that is tested and certified or had certification extended by the National Institute for Occupational Safety and Health/Mine Safety and Health Administration (NIOSH/MSHA).

(2) If the licensee wishes to use equipment that has not been tested or certified by NIOSH/MSHA, has no had certification extended by NIOSH/MSHA, or for which there is no schedule for testing or certification, the licensee shall submit an application for authorized use of that equipment, including a demonstration by testing, or a demonstration on the basis of ~~reliable~~ test information from an independent party that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.

(3) The licensee shall implement and maintain a respiratory protection program that includes--

(i) Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate exposures;

(ii) Surveys and bioassays, as appropriate, to evaluate actual intakes;

(iii) Testing of respirators for operability immediately prior to each use;

(iv) Written procedures regarding selection, fitting, issuance, maintenance, and testing of respirators, including testing for operability immediately prior to each use; supervision and training of personnel; monitoring, including air sampling and bioassays; and recordkeeping; and

(v) Determination by a physician prior to initial fitting of respirators, and at least every 12 months thereafter, that the individual user is physically able to use the respiratory protective equipment.

(4) The licensee shall issue a written policy statement on respirator usage covering--

(i) The use of process or other engineering controls, instead of respirators;

(ii) The routine, nonroutine, and emergency use of respirators; and

(iii) The periods of respirator use and relief from respirator use.

(5) The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of

operating conditions, or any other conditions that might require such relief.

(6) The licensee shall use equipment within limitations for type and mode of use and shall provide proper visual, communication, and other special capabilities (such as adequate skin protection) when needed.

(b) In estimating exposure of individuals to airborne radioactive materials, the licensee may make allowance for respiratory protective equipment used to limit intakes pursuant to §20.702, provided that the following conditions, in addition to those in §20.703(a), are satisfied:

(1) The licensee selects respiratory protective equipment that provides a protection factor (see Appendix A) greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in Appendix B, Table I, Column 3. The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the ~~ambient~~ airborne concentration in air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than estimated, the corrected value must be used; if the exposure is later found to be less than estimated, the corrected value may be used.

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(2) The licensee shall obtain authorization from the Commission before assigning respiratory protection factors in excess of those specified in Appendix A. The Commission may authorize a licensee to use higher protection factors on receipt of an application that--

(i) Describes the situation for which a need exists for higher protection factors; and

(ii) Demonstrates that the respiratory protective equipment provides these higher protection factors under the proposed conditions of use.

(c) The licensee shall use as emergency devices only respiratory protective equipment that has been specifically certified or had certification extended for emergency use by NIOSH/MSHA.

(d) The licensee shall notify, in writing, the Director of the appropriate NRC Regional Office listed in Appendix D at least 30 days before the date that respiratory protective equipment is first used under the provisions of either §§ 20.703(a) or (b).

but not later than 3 hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

(d) The licensee shall immediately notify the final delivery carrier and, by telephone and telegram, mailgram, or facsimile, the Administrator of the appropriate NRC Regional Office listed in Appendix D when--

(1) Removable radioactive surface contamination exceeds the limits of § 71.87(i) of this chapter; or

(2) External radiation levels exceed the limits of § 71.47 of this chapter.

(e) Each licensee shall--

(1) Establish, maintain and retain written procedures for safely opening packages in which radioactive material is received; and

(2) Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

SUBPART K - WASTE DISPOSAL

§ 20.1001 General requirements.

(a) A licensee shall dispose of licensed material only--

(1) By transfer to an authorized recipient as provided in § 20.1006 or in the regulations in Parts 30, 40, 60, 61, 70, or 72 of this chapter; or

(2) By decay in storage; or

(3) By release in effluents within the limits in § 20.301; or

(4) As authorized under §§ 20.1002, 20.1003, 20.1004, or 20.1005.

(b) A person must be specifically licensed to receive waste containing licensed material from other persons for:

(1) Treatment prior to disposal; or

(2) Treatment or disposal by incineration; or

(3) Decay in storage; or

(4) Disposal at a land disposal facility licensed under Part 61 of this chapter; or

(5) Disposal at a geologic repository under Part 60 of this chapter.

§ 20.1002 Method for obtaining approval of proposed disposal procedures.

A licensee or applicant for a license may apply to the Commission for approval of proposed procedures, not otherwise authorized in the regulations in this chapter, to dispose of licensed material generated in the licensee's activities. Each application shall include:

(a) A description of the waste containing licensed material to be disposed of, including the physical and chemical properties important to risk evaluation, and the proposed manner and conditions of waste disposal; and

(b) An analysis and evaluation of pertinent information on the nature of the environment; and

(c) The nature and location of other potentially affected licensed and unlicensed facilities; and

(d) Methods to ensure that doses are maintained ALARA and within the dose limits in this part.

§ 20.1003 Disposal by release into sanitary sewerage.

(a) A licensee may discharge licensed material into sanitary sewerage if each of the following conditions is satisfied:

(1) The material is readily soluble (or is readily dispersible biological material) in water; and

(2) The quantity of licensed or other radioactive material that the licensee releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in Table 3 of Appendix B; and

(3) If more than one radionuclide is released, the following conditions must also be satisfied:

(i) The licensee shall determine the fraction obtained by dividing the actual monthly average concentration of each radionuclide released by

use language from Secy 90-237

the licensee into the sewer by the concentration of the radionuclide listed in Table 3 of Appendix B; and

(ii) The sum of the fractions for each radionuclide required by paragraph (a)(3)(i) of this section does not exceed unity; and

(4) The total quantity of licensed and other radioactive material that the licensee releases into the sanitary sewerage system in a year does not exceed 5 curies (185 GBq) of hydrogen-3, 1 curie (37 GBq) of carbon-14, and 1 curie (37 GBq) of all other radioactive materials combined.

(b) Excreta from individuals undergoing medical diagnosis or therapy with radioactive material is not subject to the limitations contained in paragraph (a) of this section.

§ 20.1004 Treatment or disposal by incineration.

A licensee may treat or dispose of licensed material by incineration only in the amounts and forms specified in § 20.1005, or as specifically approved by the Commission pursuant to § 20.1002.

§ 20.1005 Disposal of specific wastes.

(a) A licensee may dispose of the following licensed material as if it were not radioactive:

(1) 0.05 microcurie (1.85 kBq), or less, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting.

(2) 0.05 microcurie (1.85 kBq), or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.

(b) A licensee may not dispose of tissue under paragraph (a)(2) of this section in a manner that would permit its use either as food for humans or as animal feed.

(c) The licensee shall maintain records in accordance with § 20.1108.

§ 20.1006 Transfer for disposal and manifests.

(a) The requirements of this section and Appendix F are designed to control transfers of low-level radioactive waste intended for disposal at a land disposal facility (as defined in Part 61 of this chapter), establish a manifest tracking system, and supplement existing requirements concerning transfers and recordkeeping for those wastes.

(b) Each shipment of radioactive waste intended for disposal at a licensed land disposal facility must be accompanied by a shipment manifest as specified in Section I of Appendix F.

(c) Each shipment manifest must include a certification by the waste generator as specified in Section II of Appendix F.

(d) Each person involved in the transfer for disposal and disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in Section III of Appendix F.

§ 20.1007 Compliance with environmental and health protection regulations.

Nothing in this Subpart relieves the licensee from complying with other applicable Federal, State, and local regulations governing any other toxic or hazardous properties of materials which may be disposed of under this Subpart.

SUBPART L - RECORDS

§ 20.1101 General provisions.

(a) Each licensee shall use the units: curie, rad, rem, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this part.

(b) The licensee shall make a clear distinction among the quantities entered on the records required by this part (e.g., total effective dose equivalent, shallow dose equivalent, eye dose equivalent, deep dose equivalent, committed effective dose equivalent, etc.).

§20.1102 Records of radiation protection programs.

(a) Each licensee shall maintain records of the radiation protection program, including:

(1) The provisions of the program; and

(2) Audits and other reviews of program content and implementation.

(b) The licensee shall retain the records required by paragraph (a)(1) of this section until the Commission terminates each pertinent license requiring the record. The licensee shall retain the records required by paragraph (a)(2) of this section for three years.

§20.1103 Records of surveys.

(a) Each licensee shall maintain records showing the results of surveys and calibrations required by §§20.501 and 20.906(b). The licensee shall retain these records for three years after the record is made.

(b) The licensee shall retain each of the following records until the Commission terminates each pertinent license requiring the record:

(1) Records of the results of surveys to determine the dose from external sources and used, in the absence of individual monitoring data, in the assessment of individual dose equivalents; and

(2) Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and

(3) Records showing the results of air sampling, surveys, and bioassays required pursuant to § 20.703(a)(3)(i) and (ii); and

(4) Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

§ 20.1104 Determination of prior occupational dose.

(a) For each individual who may enter the licensee's restricted or controlled area ~~so that the individual~~ is likely to receive, in a year, an occupational dose requiring monitoring pursuant to § 20.502, the licensee shall--

(1) Determine the occupational radiation dose received during the current year; and

(2) Attempt to obtain the records of lifetime cumulative radiation dose.

(b) Prior to permitting an individual to participate in a planned special exposure, the licensee shall determine--

(1) The internal and external doses from all previous planned special exposures; and

(2) All doses in excess of the annual limits (including doses received during accidents and emergencies) received during the lifetime of the individual.

(c) In complying with the requirements of paragraph (a) of this section, a licensee may--

(1) Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual or from the individual's most recent previous employer that discloses the nature and the amount of any occupational dose that the individual may have received during the current year;

(2) Accept, as the record of lifetime cumulative radiation dose, an up-to-date NRC Form 4, or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer (if the individual is not employed by the licensee); and

(3) Obtain reports of the individual's dose equivalent(s) from the most recent employer for work involving radiation exposure, or the individual's current employer (if the individual is not employed by the licensee) by telephone, telegram, electronic media, or letter. The licensee shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

(d) The licensee shall record the exposure history, as required by paragraph (a) of this section, on NRC Form 4, or other clear and legible

record, of all the information required on that form.[4] The form or record must show each period in which the individual received occupational exposure to radiation or radioactive material and must be signed by the individual who received the exposure. For each period for which the licensee obtains reports, the licensee shall use the dose shown in the report in preparing NRC Form 4. For any period in which the licensee does not obtain a report, the licensee shall place a notation on NRC Form 4 indicating the periods of time for which data are not available.

(e) If the licensee is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee shall assume--

(1) In establishing administrative controls under § 20.201(f) for the current year, that the individual has received 1.25 rems (12.5 mSv) in each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

(2) That the individual is not available for planned special exposures.

(f) The licensee shall retain the records on NRC Form 4 or equivalent until the Commission terminates each pertinent license requiring this record. The licensee shall retain records used in preparing NRC Form 4 for three years after the record is made.

§ 20.1105 Records of planned special exposures.

(a) The licensee shall maintain records which describe, for each use of the provisions of § 20.206 for planned special exposures,

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4 Licensees are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed under the regulations in this part in effect before January 1, 1991. Further, occupational exposure histories obtained and recorded on NRC Form 4 before January 1, 1991 would not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

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(1) ~~Evaluations made pursuant to § 20.206(a) before the planned special exposure; and~~

(2) The name of the management official who authorized the planned special exposure and a copy of the signed authorization; and

(3) What actions were necessary; and

(4) Why the actions were necessary; and

(5) How doses were maintained ALARA; and

(6) What individual and collective doses were expected to result, and the doses actually received in the planned special exposure.

(b) The licensee shall retain the records until the Commission terminates each pertinent license requiring these records.

§ 20.1106 Records of individual monitoring results.

(a) Recordkeeping requirement. Each licensee shall maintain records of doses received by all individuals for whom monitoring was required pursuant to § 20.502, and records of doses received during planned special exposures, accidents and emergency conditions. These records[5] must include, when applicable:

(1) The deep dose equivalent to the whole body, eye dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities; and

(2) The estimated intake of the radionuclides (See § 20.202); and

(3) The committed effective dose equivalent assigned to the intake of radionuclides; and

(4) The specific information used to calculate the committed effective dose equivalent pursuant to § 20.204(c); and

(5) The total effective dose equivalent when required by § 20.202; and

(6) The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.

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5 Assessments of dose equivalent and records made using before January 1, 1991 need not be changed.

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(b) Recordkeeping frequency. The licensee shall make entries of the records specified in paragraph (a) of this section at least annually.

(c) Recordkeeping format. The licensee shall maintain the records specified in paragraph (a) of this section on NRC Form 5, in accordance with the instruction for NRC Form 5, or in clear and legible records containing all of the information required by NRC Form 5.

(d) Privacy protection. The records required under this section should be protected from public disclosure because of their personal privacy nature. These records are protected by most State privacy laws and, when transferred to the NRC, are protected by the Privacy Act of 1974, Pub.L. 93-579, 5 U.S.C. 552a, and the Commission's regulations in 10 CFR Part 9.

(e) The licensee shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman.

(f) The licensee shall retain each required form or record until the Commission terminates each pertinent license requiring the record.

§ 20.1107 Records of dose to individual members of the public.

(a) Each licensee shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public (See § 20.301).

(b) The licensee shall retain the records required by paragraph (a) of this section until the Commission terminates each pertinent license requiring the record.

§ 20.1108 Records of waste disposal.

(a) Each licensee shall maintain records of the disposal of licensed materials made under §§ 20.1002, 20.1003, 20.1004, 20.1005, Part 61, and disposal by burial in soil, authorized before January 28, 1981.[6]

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6 A previous § 20.304 permitted burial of small quantities of licensed materials in soil before January 28, 1981, without specific Commission authorization.

(b) The licensee shall retain the records required by paragraph (a) of this section until the Commission terminates each pertinent license requiring the record.

§ 20.1109 Records of testing entry control devices for very high radiation areas.

(a) Each licensee shall maintain records of tests made under § 20.603(a)(9) on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

(b) The licensee shall retain the records required by paragraph (a) of this section for three years after the record is made.

§ 20.1110 Form of records.

Each record required by this part must be legible throughout the specified retention period. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate and complete records during the required retention period. Records such as letters, drawings, or specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

SUBPART M - REPORTS

§ 20.1201 Reports of theft or loss of licensed material.

(a) Telephone reports.

(1) Each licensee shall report by telephone as follows:

(i) Immediately after its occurrence becomes known to the licensee, any lost, stolen, or missing licensed material in an aggregate quantity

accordance with the procedures described in § 50.73(b), (c), (d), (e), and (g) of this chapter and must include the information required in paragraph (b)(1) of this section, and

(ii) All other licensees shall make reports to the Administrator of the appropriate NRC Regional Office listed in Appendix D.

(c) A duplicate report is not required if the licensee is also required to submit a report pursuant to §§ 30.55(c), 40.64(c), 50.72, 50.73, 70.52, 73.27(b), 73.67(e)(3)(vi), 73.67(g)(3)(iii), 73.71, or 150.19(c) of this chapter.

(d) Subsequent to filing the written report, the licensee shall also report any additional, substantive information on the loss or theft within 30 days after the licensee learns of such information.

(e) The licensee shall prepare any report filed with the Commission pursuant to this section so that names of individuals who may have received exposure to radiation are stated in a separate and detachable part of the report.

§ 20.1202 Notification of incidents.

(a) Immediate notification. Notwithstanding any other requirements for notification, each licensee shall immediately report any event involving byproduct, source, or special nuclear material possessed by the licensee which may have caused or threatens to cause any of the following conditions:

(1) An individual to receive--

(i) A total effective dose equivalent of 25 rems (0.25 Sv) or more; or

(ii) An eye dose equivalent of 75 rems (0.75 Sv) or more; or

(iii) A shallow dose equivalent to the skin or extremities of 250 rads (2.5 Gy) or more; or

(2) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational annual limit on intake. (The provisions of this paragraph do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures); or

(3) A loss of one working week or more of the operation of any facilities affected; or

(4) Damage to property in excess of $200,000.

(b) Twenty-four hour notification. Each licensee shall, within 24 hours of discovery of the event, report any event involving loss of control of licensed material possessed by the licensee which may have caused, or threatens to cause, any of the following conditions:

(1) An individual to receive, in a period of 24 hours--

(i) A total effective dose equivalent exceeding 5 rems (0.05 Sv); or

(ii) An eye dose equivalent exceeding 15 rems (0.15 Sv); or

(iii) A shallow dose equivalent to the skin or extremities exceeding 50 rems (0.5 Sv); or

(2) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational annual limit of intake. (The provisions of this subparagraph do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures); or

(3) A loss of one day or more of the operation of any facilities affected; or

(4) Damage to property in excess of $2,000.

(c) The licensee shall prepare any report filed with the Commission pursuant to this section so that names of individuals who have received exposure to radiation or radioactive material are stated in a separate and detachable part of the report.

(d) Reports made by licensees in response to the requirements of this section must be made as follows:

(1) Licensees having an installed Emergency Notification System shall make the reports required by paragraphs (a) and (b) of this section to the NRC Operations Center in accordance with § 50.72; and

(2) All other licensees shall make the reports required by paragraphs (a) and (b) of this section by telephone to the NRC Operations Center[7] and by telegram, mailgram, or facsimile to the Administrator of the appropriate NRC Regional Office listed in Appendix D.

(i) Estimates of each individual's dose; and

(ii) The levels of radiation and concentrations of radioactive material involved; and

(iii) The cause of the elevated exposure, levels, or concentrations; and

(iv) Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, generally applicable environmental standards, and associated license conditions.

(2) Each report filed pursuant to paragraph (a) of this section must include for each individual[8] exposed: the name, social security account number, and date of birth. The report must be prepared so that this information is stated in a separate and detachable part of the report.

(c) For holders of an operating license for a nuclear power plant, the occurrences included in paragraph (a) of this section must be reported in accordance with the procedures described in §§ 50.73(b), (c), (d), (e), and (g) of this chapter and must also include the information required by paragraph (b) of this section. Occurrences reported in accordance with § 50.73 of this chapter need not be reported by a duplicate report under paragraph (a) of this section.

(d) All licensees, other than those holding an operating license for a nuclear power plant, who make reports under paragraph (a) of this section shall submit the report in writing to the U.S. Nuclear Regulatory Commission, Document Control Desk, Washington, DC 20555, with a copy to the appropriate NRC Regional Office listed in Appendix D.

§ 20.1204 Reports of planned special exposures.

The licensee shall submit a written report to the Administrator of the appropriate NRC Regional Office listed in Appendix D, within 30 days following any planned special exposure conducted in accordance with

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8 With respect to the limit for the embryo/fetus (§ 20.208), the identifiers should be those of the declared pregnant woman.

§ 20.206, informing the Commission that a planned special exposure was conducted, and indicating the date the planned special exposure occurred. This report shall contain the information required in § 20.2205.

§ 20.1205 [Reserved].

§ 20.1206 Reports of individual monitoring.

(a) This section applies to each person licensed by the Commission to--

(1) Operate a nuclear reactor designed to produce electrical or heat energy pursuant to § 50.21(b) or § 50.22 of this chapter or a testing facility as defined in § 50.2 of this chapter; or

(2) Possess or use byproduct material for purposes of radiography pursuant to Parts 30 and 34 of this chapter; or

(3) Possess or use at any one time, for purposes of fuel processing, fabricating, or reprocessing, special nuclear material in a quantity exceeding 5,000 grams of contained uranium-235, uranium-233, or plutonium, or any combination thereof pursuant to Part 70 of this chapter; or

(4) Possess high-level radioactive waste at a geologic repository operations area pursuant to Part 60 of this chapter; or

(5) Possess spent fuel in an independent spent fuel storage installation (ISFSI) pursuant to Part 72 of this chapter; or

(6) Receive radioactive waste from other persons for disposal under Part 61 of this chapter; or

(7) Possess or use at any time, for processing or manufacturing for distribution pursuant to Parts 30, 32, 33, or 35 of this chapter, byproduct material in quantities exceeding any one of the following quantities:

§ 20.1302 Additional requirements.

The Commission may, by rule, regulation, or order, impose requirements on a licensee, in addition to those established in the regulations in this part, as it deems appropriate or necessary to protect health or to minimize danger to life or property.

SUBPART O - ENFORCEMENT

§ 20.1401 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of--

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued under the requirements of those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under Section 234 of the Atomic Energy Act:

(1) For violations of--

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act specified in paragraph (a)(1) of this section;

(ii) Section 206 of the Energy Reorganization Act.

(iii) Any rule, regulation, or order issued under the requirements of the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section;

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

(c) Any person who willfully violates a provision of the Atomic Energy Act or regulation or order issued under the requirements of that Act may be guilty of a crime and, upon conviction, be punished by fine or imprisonment or both, as provided by law.

APPENDIX A

PROTECTION FACTORS FOR RESPIRATORS[a]

Description[b]	Modes[c]	Protection Factors[d] → Particulates only	Particulates, gases, & vapors[e]	Tested & Certified Equipment: National Institute for Occupational Safety and Health/Mine Safety/ and Health Administration tests for permissibility
I. AIR-PURIFYING RESPIRATORS[f]				
Facepiece, half-mask[g]	NP	10		30 CFR Part 11, Subpart K.
Facepiece, full	NP	50		
Facepiece, half-mask full, or hood	PP	1000		
II. ATMOSPHERE-SUPPLYING RESPIRATORS				
1. Air-line respirator				
Facepiece, half-mask	CF		1000	
Facepiece, half-mask	D		5	
Facepiece, full	CF		2000	
Facepiece, full	D		5	30 CFR Part 11, Subpart J.
Facepiece, full	PD		2000	
Hood	CF		h	
Suit	CF		i	j
2. Self-contained breathing apparatus (SCBA)				
Facepiece, full	D		50	
Facepiece, full	PD		10,000[k]	30 CFR Part 11, Subpart H.
Facepiece, full	RD		50	
Facepiece, full	RP		5,000[l]	
III. COMBINATION RESPIRATORS				
Any combination of air-purifying and atmosphere-supplying respirators		Protection factor for type and mode of operation as listed above		30 CFR Part 11, §11.63(b).

FOOTNOTES

a. For use in the selection of respiratory protective devices to be used only where the contaminants have been identified and the concentrations (or possible concentrations) are known.

b. Only for shaven faces and where nothing interferes with the seal of tight-fitting facepieces against the skin. (Hoods and suits are excepted.)

c. The mode symbols are defined as follows:

CF = continuous flow; D = demand; NP = negative pressure (i.e., negative phase during inhalation); PD = pressure demand (i.e., always positive pressure); PP = positive pressure; RD = demand, recirculating (closed circuit); RP = pressure demand, recirculating (closed circuit)

d. 1. The protection factor is a measure of the degree of protection afforded by a respirator, defined as the ratio of the concentration of airborne radioactive material outside the respiratory protective equipment to that inside the equipment (usually inside the facepiece) under conditions of use. It is applied to the ambient airborne concentration to estimate the concentrations inhaled by the wearer according to the following formula:

e. Excluding radioactive contaminants that present an absorption or submersion hazard. For tritium oxide, approximately one-third of the intake occurs by absorption through the skin so that an overall protection factor of less than 2 is appropriate when atmosphere-supplying respirators are used to protect against tritium oxide. If the protection factor for a device is 5, the effective protection factor for tritium is about 1.4; for devices with protection factors of 10, the effective factor for tritium oxide is about 1.7; and for devices with protection factors of 100 or more, the effective factor for tritium oxide is about 1.9. Air-purifying respirators are not suitable for protection against tritium oxide. See also footnote i concerning supplied-air suits.

f. Canisters and cartridges shall not be used beyond service-life limitations.

g. Under-chin type only. This type of respirator is not satisfactory for use where it might be possible (e.g., if an accident or emergency were to occur) for the ambient airborne concentrations to reach instantaneous values greater than 10 times the pertinent values in Table 1, Column 3 of Appendix B of this part. This type of respirator is not suitable for protection against plutonium or other high-toxicity materials. The mask is to be tested for fit prior to use, each time it is donned.

h. Equipment shall be operated in a manner that ensures that proper air flow-rates are maintained. A protection factor of no more than 1000

APPENDIX B

ANNUAL LIMITS OF INTAKE (ALIs) AND DERIVED AIR CONCENTRATIONS (DACs) OF RADIONUCLIDES FOR OCCUPATIONAL EXPOSURE; EFFLUENT CONCENTRATIONS; CONCENTRATIONS FOR RELEASE TO SEWERAGE

Introduction

For each radionuclide ~~in~~ Table 1 ~~listing is given~~ indicating the chemical form which is to be used for selecting the appropriate ALI or DAC value. The ALIs and DACs for inhalation are given for an aerosol with an activity median aerodynamic diameter of 1 μm and for three classes (D,W,Y) of radioactive material, which refer to their retention (approximately days, weeks or years) in the pulmonary region of the lung. This classification applies to a range of clearance half-times for D of less than 10 days, for W from 10 - 100 days, and for Y greater than 100 days. Table 2 provides appropriate effluent concentration limits for the same radionuclides in air and water. Table 3 provides similar limits on radionuclides in releases to sanitary sewers.

Notation

The values in Tables 1, 2, and 3 are presented in the computer "E" notation. In this notation a value of 6E-02 represents a value of 6×10^{-2} or 0.06, 6E+2 represents 6×10^{2} or 600, 6E+0 represents a value of 6×10^{0} or 6.

Use of the ALI listed first, the more limiting of the stochastic and non-stochastic ALIs, will ensure that non-stochastic effects are avoided and that stochastic effects are limited to an acceptably low level. If, in a particular situation involving a radionuclide for which the non-stochastic ALI is limiting, use of that non-stochastic ALI is considered unduly conservative, the licensee may use the stochastic ALI to determine committed effective dose equivalent. However, the licensee shall also ensure that the 50-rem committed dose equivalent limit for any organ or tissue is not exceeded. This is demonstrated if the sum of the fractions of the non-stochastic ALIs of all of the radionuclides that contribute to the committed dose equivalent to that organ or tissue does not exceed unity.

Note that the dose equivalents for extremities (hands and forearms, feet and lower legs), skin, and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.

A value of $w_T = 0.06$ is applicable to each of the five organs or tissues in the "remainder" category receiving the highest dose equivalents, and the dose equivalents of all other remaining tissues may be disregarded. The following parts of the GI tract - stomach, small intestine, upper large intestine, and lower large intestine - are to be treated as four separate organs.

The DAC values are derived limits intended to control chronic exposures. The relationship between DAC and ALI is given by:

$$\text{DAC} = \text{ALI in } \mu\text{Ci}/(2000 \text{ hours per year} \times 60 \text{ min per hour} \times 2 \times 10^4 \text{ ml per minute}) = [\text{ALI}/2.4 \times 10^9] \ \mu\text{Ci per ml}$$

where 2×10^4 ml is the volume of air breathed at work by "Reference Man" per minute under working conditions of "light work."

The DAC values relate to one of two modes of exposure: either the external submersion dose or the internal committed dose equivalents resulting from inhalation of radioactive materials. Derived air concentrations based upon submersion are for immersion in a semi-infinite cloud of uniform concentration and apply to each radionuclide separately. The dose contributions from any decay product (daughter) radionuclides not listed must be separately determined and added to the contribution from the listed parent radionuclide.

ALI and DAC values relate to exposure to the single radionuclide named and include an appropriate allowance for any daughter radionuclides produced in the body during the decay of the parent nuclide. However, intakes that include both parent and daughter radionuclides should be treated by the general method appropriate to mixtures.

The values of ALI and DAC do not apply directly when the individual both ingests and inhales a radionuclide, when the individual is exposed to a mixture of radionuclides, or when the individual is exposed to both internal and external irradiation (see § 20.202). When an individual is exposed to several translocation classifications, D, W, or Y, of the same radionuclide, the exposure may be treated as exposure to a mixture of radionuclides.

It should be noted that the classification of a compound as Class D, W, or Y is based on the chemical form of the compound and does not take

into account the radiological half-life of different radicisotopes. For this reason, values are given for Class D, W, and Y compounds, even for very sh t-lived radionuclides.

Table 2

The columns in Table 2 of this appendix captioned "Effluents", "Air" and "Water," are applicable to the assessment and control of dose to the public, particularly in the implementation of the provisions in § 20.302.

The air concentration values listed in Table 2, Column 1, were derived by one of two methods. For those radionuclides for which intake (committed effective dose equivalent) is limiting, the occupational stochastic inhalation ALI was divided by 2.4×10^9 (ml/year) x 300. The factor or 2.4×10^9, relating the inhalation ALI to the DAC, is explained above. The factor of 300 includes the following components: a factor of 50 - to relate the 5-rem annual occupational dose limit to the 0.1-rem limit for members of the public; a factor of 3 - to adjust for the difference in exposure time and inhalation rate between workers and members of the public; and a factor of 2 - to adjust the occupational values, which were derived for adults, so that they are applicable to other age groups.

For those radionuclides for which submersion (external dose) is limiting, the occupational DAC in Table 1, Column 3, was divided by 219. The factor of 219 is composed of a factor of 50, described above, and a factor of 4.38 relating occupational exposure for 2,000 hours per year to full-time exposure for 8,760 hours per year. Note that an additional factor of 2 for age considerations is not warranted in the submersion cases because the dose to internal organs from external radiation is not strongly dependent on the age of the receptor.

Atomic No.	Radionuclide	Class	Table 1 Occupational Values Col. 1- Oral Ingestion ALI (μCi)	Col. 2- Inhalation ALI (μCi)	Col. 3- DAC (μCi/ml)	Table 2 Effluent Concentrations Col. 1- Air (μCi/ml)	Col. 2- Water (μCi/ml)	Table 3 Release to Sewers Monthly Average (μCi/ml)
1	Hydrogen-3	Water, DAC includes skin absorption	8E+4	8E+4	2E-5	1E-7	1E-3	1E-2
4	Beryllium-7	W, all compounds except those given for Y	4E+4	2E+4	9E-6	3E-8	6E-4	6E-3
		Y, oxides, halides, and nitrates	-	2E+4	8E-6	3E-8	-	-
4	Beryllium-10	W, see ^{7}Be	1E+3 LLI wall (1E+3)	2E+2 -	6E-8 -	2E-10 -	- 2E-5	- 2E-4
		Y, see ^{7}Be	-	1E+1	6E-9	2E-11	-	-
6	Carbon-11[2]	Monoxide	-	1E+6	5E-4	2E-6	-	-
		Dioxide	-	6E+5	3E-4	9E-7	-	-
		Compounds	4E+5	4E+5	2E-4	6E-7	6E-3	6E-2
6	Carbon-14	Monoxide	-	2E+6	7E-4	2E-6	-	-
		Dioxide	-	2E+5	9E-5	3E-7	-	-
		Compounds	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4

FOOTNOTES:

[1]"Submersion" means that values given are for submersion in a hemispherical semi-infinite cloud of airborne material.

[2]These radionuclides have radiological half-lives less than 2 hours. The total effective dose equivalent received during operations with these radionuclides might include a significant contribution from external exposure. The DAC values for all radionuclides other than those designated Class "Submersion," are based upon the committed effective dose equivalent due to the intake of the radionuclide into the body and do NOT include potentially significant contributions to dose equivalent from external exposures. The licensee may substitute 1E-7 μCi/ml for the listed DAC to account for the submersion dose prospectively, but should use individual monitoring devices or other radiation measuring instruments that measure external exposure to demonstrate compliance with the limits. (See § 20.203.)

[3]For soluble mixtures of U-238, U-234, and U-235 in air, chemical toxicity may be the limiting factor (see § 20.201(e)). If the percent by weight (enrichment) of U-235 is not greater than 5, the concentration value for a 40-hour workweek is 0.2 milligrams uranium per cubic meter of air average. For any enrichment, the product of the average concentration and time of exposure during a 40-hour workweek shall not exceed 8E-3 (SA) μCi-hr/ml, where SA is the specific activity of the uranium inhaled. The specific activity for natural uranium is 6.77E-7 curies per gram U. The specific activity for other mixtures of U-238, U-235, and U-234, if not known, shall be:

$$SA = 3.6E\text{-}7 \text{ curies/gram U} \qquad \text{U-depleted}$$

$$SA = [0.4 + 0.38\,(\text{enrichment}) + 0.0034\,(\text{enrichment})^2]\ E\text{-}6 \qquad \text{enrichment} \geq 0.72$$

where enrichment is the percentage by weight of U-235, expressed as percent.

Revise to ensure Text footnote #1 Corresponds before footnote #2.

Radionuclide	Quantity (μCi)	Radionuclide	Quantity (μCi)
Krypton-79	1,000	Niobium-89	
Krypton-81	1,000	(122 min)	1,000
Krypton-83m	1,000	Niobium-90	100
Krypton-85m	1,000	Niobium-93m	10
Niobium-94	1	Silver-104	1,000
Niobium-95m	100	Silver-105	100
Niobium-85	100	Silver-106m	100
Niobium-96	100	Silver-106	1,000
Niobium-97	1,000	Silver-108m	1
Niobium-98	1,000	Silver-110m	10
Molybdenum-90	100	Silver-111	100
Molybdenum-93m	100	Silver-112	100
Molybdenum-93	10	Silver-115	1,000
Molybdenum-99	100	Cadmium-104	1,000
Molybdenum-101	1,000	Cadmium-107	1,000
Technetium-93m	1,000	Cadmium-109	1
Technetium-93	1,000	Cadmium-113m	0.1
Technetium-94m	1,000	Cadmium-113	100
Technetium-94	1,000	Cadmium-115m	10
Technetium-96m	1,000	Cadmium-115	100
Technetium-96	100	Cadmium-117m	1,000
Technetium-97m	100	Cadmium-117	1,000
Technetium-97	1,000	Indium-109	1,000
Technetium-98	10	Indium-110m	
Technetium-99m	1,000	(69.1m)	1,000
Technetium-99	100	Indium-110m	
Technetium-101	1,000	(4.9h)	1,000
Technetium-104	1,000	Indium-111	100
Ruthenium-94	1,000	Indium-112	1,000
Ruthenium-97	1,000	Indium-113m	1,000
Ruthenium-103	100	Indium-114m	10
Ruthenium-105	1,000	Indium-115m	1,000
Ruthenium-106	1	Indium-115	100
Rhodium-99m	1,000	Indium-116m	1,000
Rhodium-99	100	Indium-117m	1,000
Rhodium-100	100	Indium-117	1,000
Rhodium-101m	1,000	Indium-119m	1,000
Rhodium-101	10	Tin-110	100
Rhodium-102m	10	Tin-111	1,000
Rhodium-102	10	Tin-113	100
Rhodium-103m	1,000	Tin-117m	100
Rhodium-105	100	Tin-119m	100
Rhodium-106m	1,000	Tin-121m	100
Rhodium-107	1,000	Tin-121	1,000
Palladium-100	100	Tin-123m	1,000
Palladium-101	1,000	Tin-123	10
Palladium-103	100	Tin-125	10
Palladium-107	10	Tin-126	10

APPENDIX C (Continued)

APPENDIX D

UNITED STATES NUCLEAR REGULATORY COMMISSION REGIONAL OFFICES

	Address	Telephone (24 hours a day)
Region 1: Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont.	USNRC, 475 Allendale Road King of Prussia, PA 19406	(215)337-5000, (FTS) 346-5000.
Region II. Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, Puerto Rico, South Carolina, Tennessee, Virginia, Virgin Islands, and West Virginia.	USNRC, 101 Marietta Street Suite 2900 Atlanta, GA 30303	(404)~~221~~-4503, (FTS) ~~242~~-4503. 331 841
Region III: Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Ohio, and Wisconsin.	USNRC, 799 Roosevelt Road Glen Ellyn, IL 60137	(312)790-5500, (FTS) 388-5500.
Region IV: Arkansas, Colorado, Idaho, Kansas, Louisiana, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas, Utah, and Wyoming.	USNRC, 611 Ryan Plaza Drive Suite 1000 Arlington, TX 76011	(817)860-8100, (FTS) 728-8100.
Region IV: Field Office	USNRC, Region IV Uranium Recovery Field Office 730 Simms Street, Suite 100A P.O. Box 25325 Denver, CO 80225	(303)~~234-7232~~, (FTS) ~~234-7732~~. 236-2805 776-2805
Region V: Alaska, Arizona, California, Hawaii, Nevada, Oregon, Washington, and U.S. territories and possessions in the Pacific.	USNRC, 1450 Maria Lane Suite 210 Walnut Creek, CA 94596	(415)943-3700, (FTS) 463-3700.

update reg. I telephone #'s

APPENDIX E [RESERVED]

APPENDIX F

REQUIREMENTS FOR LOW LEVEL WASTE TRANSFER FOR DISPOSAL AT LAND DISPOSAL FACILITIES AND MANIFESTS

I. MANIFEST

The shipment manifest shall contain the name, address, and telephone number of the person generating the waste. The manifest shall also include the name, address, and telephone number or the name and EPA hazardous waste identification number of the person transporting the waste to the land disposal facility. The manifest must also indicate as completely as practicable: a physical description ~~of the waste~~, the volume, radionuclide identity and quantity, the total radioactivity, and the principal chemical form of the waste. The solidification agent must be specified. Waste containing more than 0.1% chelating agents by weight must be identified and the weight percentage of the chelating agent estimated. Wastes classified as Class A, Class B, or Class C in § 61.55 of this chapter must be clearly identified as such in the manifest. The total quantity of the radionuclides H-3, C-14, Tc-99 and I-129 must be shown. The manifest required by this paragraph may be shipping papers used to meet Department of Transportation or Environmental Protection Agency regulations or requirements of the receiver, provided all the required information is included. Copies of manifests required by this section may be legible carbon copies or legible photocopies.

4. Prepare shipping manifests to meet the requirements of section I and II of this appendix;

5. Forward a copy of the manifest to the intended recipient, at the time of shipment, or, deliver to a collector at the time the waste is collected, obtaining acknowledgement of receipt in the form of a signed copy of the manifest or equivalent documentation from the collector;

6. Include one copy of the manifest with the shipment;

7. Retain a copy of the manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material as required by Parts 30, 40, and 70 of this chapter; and,

8. For any shipments or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in this section. Conduct an investigation in accordance with paragraph E of this appendix.

B. Any waste collector licensee who handles only prepackaged waste shall:

1. Acknowledge receipt of the waste from the generator within one week of receipt by returning a signed copy of the manifest or equivalent documentation;

2. Prepare a new manifest to reflect consolidated shipments; the new manifest shall serve as a listing or index for the detailed generator manifests. Copies of the generator manifests shall be a part of the new manifest. The waste collector may prepare a new manifest without attaching the generator manifests, provided the new manifest contains for each package the information specified in section IX of this appendix. The collector licensee shall certify that nothing has been done to the waste which would invalidate the generator's certification;

3. Forward a copy of the new manifest to the land disposal facility operator at the time of shipment;

4. Include the new manifest with the shipment to the disposal site;

5. Retain a copy of the manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material as required by Parts 30, 40, and 70 of this chapter, and retain information from generator manifest until disposition is authorized by the Commission; and,

6. For any shipments or any part of a shipment for which acknowledgement of receipt is not received within the times set forth in this section, conduct an investigation in accordance with paragraph E of this section.

C. Any licensed waste processor who treats or repackages wastes shall:

1. Acknowledge receipt of the waste from the generator within one week of receipt by returning a signed copy of the manifest or equivalent documentation;

2. Prepare a new manifest that meets the requirements of sections II and III of this appendix. Preparation of the new manifest reflects that the processor is responsible for the waste;

3. Prepare all wastes so that the waste is classified according to § 61.55 and meets the waste characteristics requirements in § 61.56 of this chapter;

4. Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with §§ 61.55 and 61.57 of this chapter;

A. Severity I -- Violations involving for example:

1. Single radiation exposure of a worker in excess of 25 rems total effective dose equivalent, 75 rems to the lens of the eye, or 250 rads to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue;

2. Single radiation exposure of the embryo/fetus of a declared pregnant woman in excess of 2.5 rems total effective dose equivalent;

3. Single radiation exposure of a minor in excess of 2.5 rems total effective dose equivalent, 7.5 rems to the lens of the eye, or 25 rems to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue;

4. Annual exposure of a member of the public in excess of 2.5 rems total effective dose equivalent;

5. Release of radioactive material to an unrestricted area at concentrations in excess of 50 times the limits for members of the public in Appendix B of 10 CFR Part 20;

6. Disposal of licensed material in quantities or concentrations in excess of ten times the limits of 10 CFR 20.1003;

6. Release of radioactive material to an unrestricted area at concentrations in excess of 2 times the limits for members of the public in Table 2 of Appendix B of 10 CFR Part 20 (except when operation up to 0.5 rems a year has been approved by the Commission under § 20.301(c));

7. Failure to make a 24-hour notification required by 10 CFR 20.1202(b) or an immediate notification required by 10 CFR 20.1201(a)(1)(i);

8. Substantial potential for exposures or releases in excess of the applicable limits in 10 CFR Part 20 whether or not such exposure or release occurs (e.g., entry into high radiation areas, such as under reactor vessels or in the vicinity of exposed radiographic sources, without having performed an adequate survey; operation of a radiation facility with a non-functioning interlock system);

9. Improper disposal of licensed material not covered in Severity Levels I or II;

10. Release for unrestricted use of contaminated or radioactive material or equipment which poses a realistic potential for exposure of the public to levels or doses exceeding the annual dose limits for member of the public, or which reflects a programmatic (rather than an isolated) weakness in the radiation control program;

11. Conduct of licensee activities by a technically unqualified person; or

12. Significant failure to control licensed material.

D. Severity IV -- Violations involving for example:

1. ~~Exposures in excess of the limits of~~ Violations of requirements in 10 CFR 20.201, 20.207 or 20.208 not otherwise constituting Severity Level I, II or III violations.

2. Release of radioactive material to an unrestricted area at concentrations in excess of the limits for members of the public in Appendix B of 10 CFR Part 20 (except when operation up to 0.5 rems a year has been approved by the Commission under § 20.301(c));

3. A radiation dose rate in an unrestricted or controlled area in excess of 0.002 rem in any one hour (2 millirem/hour) or 50 millirem in a year;

4. Failure to maintain and implement radiation programs to keep radiation exposures as low as is reasonably achievable;

5. Doses to a member of the public in excess of any EPA generally applicable environmental radiation standards, such as 40 CFR Part 190;

6. Failure to make the 30-day notification required by 10 CFR 20.1201(a)(1)(ii) or 20.1203(a);

7. Failure to make a timely written report as required by 10 CFR 20.1201(b), 20.1204, or 20.1206.

8. Any other matter that has more than a minor safety, health, or environmental significance.

E. Severity V -- Violations that are of a minor safety, health, or environmental significance.

PART 19 - NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS

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

Authority: Sec. 161, 68 Stat 948, as amended (42 U.S.C. 2201); sec. 201, 88 Stat 1242, as amended (42 U.S.C.5481).

5 Section 19.3 is amended by revising paragraph (e) to read as follows:

§ 19.3 Definitions.

* * * * *

(e) "Restricted area" means an area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

6. In § 19.13 paragraph (d) is amended by changing the reference to "§20.405 and § 20.408" to read "§§20.1202, 20.1203, 20.1204 or 20.1206" and by revising paragraphs (b), (c) and (e) to read as follows:

calendar quarter doses associated with such activity or activities and the bases for these estimates. The submitted information must demonstrate that performance of this activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive in a year a dose in excess of 10 percent of the annual limits specified in § 20.201(a) of this chapter.

§ 32.61 [Amended].

18. In § 32.61(d), the reference to "§ 20.203(a)" is changed to read "§ 20.901(a)."

§ 32.71 [Amended].

19. In § 32.71(c)(2), the reference to "§ 20.203(a)(1)" is changed to read "§ 20.901(a)."

20. In § 32.71(e), the reference to "§ 20.301" is changed to read "§ 20.1001."

PART 34 - LICENSES FOR RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR RADIOGRAPHIC OPERATIONS

21 The authority citation for Part 34 continues to read as follows:

Authority: Sec. 161, 68 Stat 948, as amended (42 U.S.C. 2201); sec. 201, 88 Stat 1242, as amended (42 U.S.C.5481).

§ 34.29 [Amended].

22. In § 34.29(a), the reference to "§ 20.203(c) (2)(ii), (2)(iii), or (4)" is changed to read "§ 20.601(a)(2), (a)(3), or (b)."

§ 34.41 [Amended].

23. In § 34.41(a), the reference to "§ 20.203(c)(2)" is changed to read "§ 20.601(a)(1), (a)(2), or (a)(3)."

§ 34.42 [Amended].

24. In § 34.42, the reference to "§ 20.204(c)" is changed to read "§ 20.903" and the reference to "§ 20.203(b) and (c)(1)" is changed to read "§ 20.902(a) and (b)."

Insert [illegible] for Part 39-21

PART 39 - LICENSES AND RADIATION SAFETY REQUIREMENTS FOR WELL-LOGGING OPERATIONS

25. The authority citation for Part 39 continues to read as follows:

Authority: Sec. 161, 68 Stat 948, as amended (42 U.S.C. 2201); sec. 201, 88 Stat 1242, as amended (42 U.S.C.5481).

26. In § 39.15(a)(5)(iii)(B), the reference to "§ 20.203" is changed to read ""§ 20.901(a)."

releases of radioactive material in effluents and their resultant committed effective dose equivalents at small percentages of the values specified in § 20.301 of this chapter and in the operating license. At the same time, the licensee is permitted the flexibility of operation, compatible with considerations of health and safety, to assure that the public is provided a dependable source of power even under unusual operating conditions which may temporarily result in releases higher than such small percentages, but still within the committed effective dose equivalent values specified in § 20.301 of this chapter and the operating license. It is expected that in using this operational flexibility under unusual operating conditions, the licensee will exert its best efforts to keep levels of radioactive material in effluents as low as is reasonably achievable. The guides set out in Appendix I provide numerical guidance on limiting conditions for operation for light-water-cooled nuclear power reactors to meet the requirement that radioactive materials in effluents released to unrestricted areas be kept as low as is reasonably achievable.

37. In § 50.72 in paragraph (a), Footnote 1, the reference to "§ 20.205, § 20.403" is changed to read "§ 20.906, § 20.1202," and paragraphs (b)(2)(iv)(A) and (B) are revised to read as follows:

§ 50.72 Immediate notification requirements for operating nuclear power reactors.

* * * * *

(b) * * *

(2) * * *

PART 70 - DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

41. The authority citation for Part 70 continues to read as follows:

Authority: Sec. 161, 68 Stat 948, as amended (42 U.S.C. 2201); sec. 201, 88 Stat 1242, as amended (42 U.S.C.5481).

§ 70.51 [Amended].

42. In § 70.51(b)(6), the reference to "§ 20.401(c)" is changed to read "§ 20.1108."

Dated at Rockville, MD, this _____ day of _____ 1988.

For the Nuclear Regulatory Commission.

_____
Samuel J. Chilk,
Secretary of the Commission.

ENCLOSURE 3, RECOMMENDED REVISIONS TO FEDERAL REGISTER NOTICE

CHANGES TO ENCLOSURE 3 TO SECY-88-315, STATEMENT OF CONSIDERATIONS

Enclosure 3, bottom page 32, and top of page 33 in § 20.204, replace both paragraphs with:

Interim Dose Calculation Factors and Parameters. Because the existing Part 20 is based on ICRP-2[16] dosimetry and metabolic models and the revised Part 20 employs the ICRP-30[17] dose parameters, there was concern regarding whether the more recent ICRP-30 parameters should be used, particularly when the value is to be compared with the intake limits in the existing Part 20.

Until the effective date of the revision, licensees must continue to demonstrate compliance with the intake limits of the present rule. Because the concentration limits, ALIs and DACs in Appendix B of the revised Part 20 are based upon the effective dose equivalent, they should not be used until after the effective date of the rule. The NRC is planning to issue a Regulatory Guide that will address the use of bioassay measurements for determining compliance with Part 20. Appropriate parameters for calculating organ doses from radionuclide intakes that do not incorporate the w_T weighting factors can be found in ICRP-30 and its supplements. Dose factors for individual organs in Federal Guidance Report #11[18] are acceptable for use for occupational exposure. The effective dose equivalent factors in Federal ~~Radiation~~ Guidance Report # 11 do not employ the rounding method suggested in ICRP 30 and, for this reason, may be slightly different (10-20%) than the effective dose factors that correspond to the ALI's and DAC's in both the revised Part 20 and Report # 11. Licensees may use the effective dose factors in Report # 11 for compliance purposes, as these effective dose factors would be more restrictive (give slightly higher doses for the same intake) than dose factors computed using the ICRP 30 round-off procedure.

Effective dose factors should not be used for compliance determinations prior to the effective date of the rule. However, they can be used for purposes other than demonstrating compliance, such as environmental reports, prior to the effective date of this revision, providing that ~~it is~~ clearly indicated as being "effective dose equivalent."

these dose factors are

16 International Commission Radiological Protection, "Report of Committee II on Permissible Dose for Internal Radiation," ICRP Publication No. 2, (1959).

17 International Commission on Radiological Protection, "Limits for Intakes of Radionuclides by Workers," ICRP Publication No. 30, Annals of the ICRP; Vol. 2, No. 314 (1979).

18 Environmental Protection Agency, Federal Guidance Report No. 11, "Limiting Values of Radionuclide Intake and Air Concentration, and Dose Conversion Factors for Inhalation, Submersion and Ingestion." USEPA Report EPA-520/1-88-020 (September 1988).

Enclosure 3, page 49, Before second paragraph, beginning "Inclusion of doses from ...," insert:

The dose rate limit of 2 millirems in any one hour from §20.105(b)(1) of the present Part 20 was omitted in the proposed rule but has been reinstated in the revised rule. The reason for this is that this limit provides a more readily measurable quantity than the 100 millirem per year value and can be more easily verified by short-term measurements.

Enclosure 3, page 50, Add to last paragraph a new last sentence:

The 0.5 rem limit is intended to be applied primarily to temporary situations where operation of a facility, or the person's exposure to radiation and radioactive emissions, is not expected to result in doses above 0.1 rem over long periods of time. For design of new installations, the 0.1-rem limit should be used. However, existing facilities may apply for NRC approval to use the 0.5 rem-limit while more complete evaluation of the need for any additional modifications is performed.

Enclosure 3, page 50, Add following last paragraph:

The Commission is aware that some categories of licensees, such as uranium mill and in situ uranium mining facilities, may experience difficulties in ~~determining compliance~~ complying with the revised values in Appendix B, Table 2 for radionuclides such as radon-222.

Provision has been made for licensees to use air and water concentration limits or protection of members of the general public that are different from those in Appendix B, Table 2, if the licensee can demonstrate that the physio-chemical properties of the effluent justify such modification and the revised value is approved by the NRC. This provision permits the use of concentration limits for members of the general public that better represent actual exposure conditions. For example, uranium mill licensees could, under this provision, adjust the Table 2 value for radon with daughters to take into account the actual degree of equilibrium present in the environment. This is similar to the allowance for use of modified derived air concentrations (with Commission approval) in §20.204(c)(3) of the revised rule.

Use of this provision applied to the percentage of radionuclide equilibrium could provide a factor of 2 or 3 upward change in the appropriate air concentration limit. ~~In addition, the licensee can demonstrate compliance by calculating the dose to the nearest resident rather than meeting the air concentration limit at the site boundary. This should provide an additional factor of 2 or 3 allowance. Lastly,~~ If the 0.1 rem effective dose limit still cannot be met, the licensee can apply to NRC under §20.301(c) for permission to use a temporary 0.5 rem per year limit rather than the 0.1 rem per year limit. Section 20.301(c) of the revised rule requires that, in order to receive permission for use of this higher dose limit, the licensee has to specify (1) the need for and expected duration of the higher value, (2) their program to assess and

control doses, (3) procedures to control doses to be ALARA. These options used singularly or in combination with process or operational modifications of these facilities, are expected to provide sufficient flexibility to enable most uranium recovery facilities to comply with the provisions of the revised 10 CFR Part 20.

Enclosure 3, Page 63, §20.703 add to "Final Rule", Section at top of page after : "...factors."

Allowance has been made for use of respirators that do not provide protection factors that would keep exposures below the Derived Air Concentrations, if (and only if) such use would keep the total effective dose equivalent ALARA.

Enclosure 3, Page 72, first paragraph, line 6 - insert "meets the requirements of §35.92 'Decay-In-Storage' of 10 CFR Part 35," between "Part 20" and "or".

Enclosure 3, Page 72, second paragraph, lines 4 - 7, make third sentence read:

However, the provisions included in 10 CFR 35.92 and certain specific license conditions pertain to relatively short-lived radionuclides and are neither appropriate nor applicable to other classes of licenses, such as those issued under Part 50.

Enclosure 3, Page 72, insert the following before the section on §20.1003.

Final Rule. Section 20.1001 has been modified to incorporate the requirements that were in § 20.1002(b) of the proposed rule. These provisions require NRC licenses for persons who receive wastes containing licensed radioactive materials for treatment, for treatment or disposal by incineration, decay-in-storage, or disposal in facilities licensed under Part 60 or Part 61.

Enclosure 3, Page 73, At the end of the first "Response" add:

"The prohibition on disposal of insoluble materials via the sanitary sewer was intended to prevent disposal via sanitary sewers of material in which the radioactive material is primarily in an insoluble form. Such materials may accumulate in the sewer system, in the sewer treatment plants, and in the sewage sludge. [Addresses concerns that have been raised by licensees regarding the intent of the prohibition on disposal of insoluble materials via sewers.]

Enclosure 3, Page 75, Replace "Response" for §20.1005 with:

Response: The Commission agrees that such levels would be useful and has issued advance notices of proposed policy making (51 FR 30839, August 29, 1986 and 53 FR 49886, December 12, 1988) concerning the bases for developing and employing such levels.

Enclosure 3, page 100, last paragraph, add the following sentences after the sentence ending, "...occupational radiation exposure."

The radiation doses to be reported are those required to be recorded under §20.1106. These doses are listed in the 1987 Federal Guidance to be reported to the worker. "Annual dose" is also specified in the guidance and is used for external doses. However, "annual dose" is not required to be recorded by the revised Part 20 for internal doses. As noted in footnote 5 to the Federal Guidance (Federal Register of January 27, 1977; 52 FR 2832):

> "When these conditions on intake of radioactive materials have been satisfied [i.e., meeting the committed dose limits], it is not necessary to assess contributions from such intakes to annual doses in future years, and, as an operational procedure, such doses may be assigned to the year of intake for the purpose of assessing compliance."

CHANGES TO ENCLOSURE 4 OF SECY-88-315, REVISED RULE

Enclosure 4, page 9, "Commission" substitute for the definition, the following:

> "'Commission' means the Nuclear Regulatory Commission or its duly authorized representatives."

[restores tradition definition.]

Enclosure 4, page 12, "Generally-applicable Environmental Standards"

Delete last line of definition that reads: "These standards are set out in 40 CFR Parts 190, 191, and 192."

[Removal of this statement alleviates the need for rulemaking each time another EPA generally-applicable standard is issued.]

Enclosure 4, page 19, "Rem" - change first sentence to read:

> "'Rem' is the special unit of any of the quantities expressed as dose equivalent."

Enclosure 4, page 28, in §20.206, replace (c)(3) by:

"(3) Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present."

[Clarifies intent and removes apparent requirement for keeping other risks, not regulated by the NRC, "as low as is reasonably achievable."]

Enclosure 4, page 28, in §20.206, replace (d) by:

"(d) Prior to permitting an individual to participate in a planned special exposure, the licensee ascertains prior doses as required by § 20.1104(b)."

[Avoids duplicating the requirements in §20.1104(b) in this section.]

Enclosure 4, page 29, §20.208(c)(2), change to read:

"(2) the dose to the embryo/fetus from radionuclides in the embryo/fetus and in the declared pregnant woman."

[This change permits more accurate dose assessments of embryo/fetus dose to be used than the approximation that the embryo/fetus dose is the same as the dose to the mother.]

Enclosure 4, page 30, §20.301(a)(2):

Insert "from external sources" after "unrestricted area."

[Clarifies intent to exclude internal dose rates as they cannot be measured.]

Enclosure 4, page 31, §20.302 add a paragraph (c) as follows:

"(c) Upon approval from the Commission, the licensee may adjust the concentration values in Appendix B, Table 2, for members of the public, to take into account the actual physical and chemical characteristics of the effluents (e.g., aerosol size distribution, solubility, density, radioactive decay equilibrium, chemical form, ~~etc.~~)."

[This addition provides for the same degree of flexibility and improved precision of dose assessments for members of the public as is permitted for workers under §20.204(c)(3).]

ENCLOSURE A

RECOMMENDED CHANGES

[Changed wording in brackets or underscored]

1. MODIFY § 20.901 TO PERMIT THE USE OF BLACK AS AN ALTERNATE COLOR ON WARNING SIGNS (IN ADDITION TO MAGENTA AND PURPLE)

STATEMENT (Page 65 of Enclosure 3 to SECY-88-315)
Section 20.901 Caution Signs.

Comment: Black should be permitted as an acceptable color for the radiation warning symbol. Several commenters requested that the color black should also be allowed to be used on signs and for stenciling packages. The fading of magenta inks in sunlight and the use of black for marking international shipments were cited as supporting this position.

[Response: The Commission believes that, although the "magenta -on-yellow" color scheme has provided an unique warning of possible radiation hazards, black-on-yellow would also be acceptable. The fading of the magenta color as cited above may reduce the visibility of the sign with time. Because of the cost impacts if existing warning signs had to be replaced, the Commission is permitting the use of black in addition to continued approval of magenta and purple, rather than ~~as a~~ required replacement.

Final Rule. This section has been modified to add black as an acceptable color for the radiation warning symbol.]

MODIFY THE RULE (Page 42 of Enclosure 4 to SECY-88-315) AS FOLLOWS:

§ 20.901 Caution signs.

(a) Standard radiation symbol. Unless otherwise authorized by the Commission, the symbol prescribed by this part shall use the colors magenta, or purple, or black on a yellow background. The symbol prescribed by this part is the three-bladed design:

* * * * *

RADIATION SYMBOL

(1) Cross-hatched area is to be magenta, or purple, or black; and
(2) Background is to be yellow.

Paragraphs(b) and (c) are unchanged.

8. UPDATE STATEMENT TO ADD DISCUSSIONS OF BEIR & UNSCEAR REPORTS AND ICRP STATEMENT

MODIFY THE STATEMENT OF CONSIDERATIONS TO ADD IN SECTION II:

F. The 1988 Report of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR-88)[7].

The United Nations Scientific Committee on the Effects of Atomic Radiation has analyzed data on the sources and effects of atomic radiation and published a series of reports containing summaries of the sources of radiation, the doses received by workers and members of the general public from these sources, and an analysis of the potential health risks from exposure to ionizing radiation. The latest report in this series is the 1988 report. The 1988 report contains more recent information on the health risks of ionizing radiation determined from a reevaluation of the data on the survivors of the Hiroshima-Nagasaki atomic bombings. Based upon these data, the radiation risk at high doses and high dose rates is estimated to be 7.1×10^{-4} fatal health effects per rad (0.071 effects per gray). For estimating the risk from radiation doses below 100 rem, the UNSCEAR report recommended that a dose rate reduction factor be applied to account for the reduced effectiveness of lower doses and lower dose rates delivered over longer periods of time (dose protraction). A range of between 2 and 10 was recommended for the magnitude of the dose reduction factor.

This would lead to an estimated risk of fatality of between $(0.7 \text{ to } 3.5) \times 10^{-4}$ health effects per rem for low doses such as those encountered in routine occupational exposure and the even lower doses that might be received by members of the general public from ~~NRC (or Agreement State)~~ licensed activities.

The fatal cancer risk value associated with the 1977 ICRP recommendations[1], is 1.25×10^{-4} (the proposed Part 20 rule, 51 FR 1102, January 9, 1986) so that the risks per rem as estimated by the 1988-UNSCEAR report for low doses is between 0.6 to 5 times higher than the earlier ICRP estimate. The geometric mean of this range is about 1.7, about twice the earlier estimate associated with the 1977 ICRP report and the proposed Part 20. The implications of this increase are discussed in Section H below along with the results of the 1990 BEIR-V report.

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7 United Nations Scientific Committee on the Effects of Ionizing Radiation (UNSCEAR), "Sources, Effects and Risks of Ionzing Radiation," 1988 Report to the General Assembly, Sales Section, United Nations, N.Y. 10017 (1988).

G. The 1988 Report of the National Academy of Sciences' Committee on the Biological Effects of Ionizing Radiation (BEIR IV)[8]

The 1988 BEIR-IV report supplements the 1980 BEIR-III report by providing a more detailed analysis of the risks from internal alpha-emitting radionuclides to complement the emphasis of the BEIR-III report on gamma and beta radiation. Revised risk estimates are given for intakes of radon, radium, polonium, thorium, uranium, and ~~higher~~ transuranic elements (e.g., plutonium).

The radionuclide given the greatest emphasis in the BEIR-IV report is radon (radon-222), the gaseous decay product of radium-226. The radon dose conversion factor in the BEIR-IV report for exposure conditions representative of those of the general public is consistent with the value used to derive the airborne effluent concentration limit for radon-222 in Appendix B, Table 2 of the revised 10 CFR Part 20.

Revise to provide the magnitude of the radon dose conversion factors used in BEIR III and in Part 20.

H. The 1990 Report of the National Academy of Sciences' Committee on the Biological Effects of Ionizing Radiation (BEIR V)[9]

The BEIR-V report is another comprehensive re-evaluation of the health risks of radiation exposure based upon the revised dose estimates for the survivors of the atomic bombings of Hiroshima and Nagasaki. The BEIR-V report gives risk estimates for leukemia and non-leukemia (solid cancers) that are about three or four times higher than the estimates in the 1980 BEIR-III report. The BEIR V gives the following factors as the principal reasons for this increase: (1) use of different dose-response and risk projection models, (2) revised

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8 National Academy of Sciences-National Research Council, Committee on the Biological Effects of Ionizing Radiation, "Health Risks of Radon and other Internally Deposited Alpha-Emitter, (BEIR IV)," National Research Council, National Academy Press, Washington, D.C. 20418 (1988).

9 National Academy of Sciences-National Research Council, Committee on the Biological Effects of Ionizing Radiation, "Health Effects of Exposure to Low Levels of Ionizing Radiation, (BEIR V)," National Research Council, National Academy Press, Washington, D.C. 20418 (1990).

estimates of the doses to the individual survivors of the atomic bombings in Japan, and (3) additional years of followup studies since the BEIR-III was completed in 1980.

The primary projection model used in BEIR-V to extrapolate the cancer risk observed to date to future years uses a relative risk model in which the risk is assumed to be proportional to the natural cancer incidence. This results in the risk from radiation exposure being dependent upon both the time since the exposure occurred and the age of the person. Because of this dependence upon age, the relative risk model generally predicts higher future (lifetime) risks than the absolute risk model which employs a constant added risk per year with increasing age. Both the absolute and relative risk projection models had been used in the BEIR-I(1972) and BEIR-III reports, but until the BEIR-V report, the absolute model had been preferred.

Revised estimates of the doses to the survivors of the atomic bombings in Japan changes the cancer risk projections by about a factor of 3. However, estimates of thyroid cancer and genetic effects are derived from populations other than the Japanese atomic bomb survivors and are not affected by the dosimetry reevaluation.

Revise to describe BEIR V conclusions on genetic and developmental effects of radiation.

I. 1990 ICRP Recommendations

On June 22, 1990, the International Commission on Radiological Protection issued a press release indicating that it would issue revised recommendations for radiation protection based upon the newer studies of radiation risks (such as those described in Sections F, G, and H above). The press release indicated that the ICRP would recommend a reduction in the recommended occupational dose limit from an equivalent of 5 rems per year to an average of 2 rems per year with some allowance for year-to-year flexibility. The previous ICRP recommended dose limit for long-term exposure of members of the general public, which is equivalent to 0.1 rems per year, would remain at the ~~the~~ same level.

The Nuclear Regulatory Commission does not believe that additional reductions in the dose limits are urgently required by the latest risk estimates. Only a few individuals in either the work force or in the general public are exposed at or near the limits, and most of these will not be exposed at such levels over long periods of time. Due to the practice of ALARA ("as low as is reasonably achievable"), the average radiation dose to occupationally-exposed individuals is well below the limits in either the existing or revised Part 20, as well as the changes being contemplated by the ICRP. As a result of the

application of the ALARA philosophy to effluent release standards in Appendix I to 10 CFR Part 50 for nuclear power reactors and EPA's 40 CFR Part 190 for uranium fuel cycle, doses from effluents from fuel cycle facilities are generally much less than even the 0.1 rem per year standard in the revised Part 20.

However, because of the long-term implications of these recent higher estimates of the risk from ionizing radiation, the NRC has initiated studies to evaluate the need for and impacts of possible additional reductions in the occupational dose limits. With regard to possible future changes in the dose limits based on these revised risk estimates, the NRC is also carefully following the recommendations of advisory bodies such as the International Commission on Radiological Protection, the National Council on Radiation Protection and Measurements, and the U.S. Committee on Radiation Research and Policy Coordination, and any revised Federal Radiation Guidance that may be issued relative to radiation risks and standards.

9. Update Statement Section: III. [Issues Being Resolved Separately]

As noted in the above discussion, there are several areas where the Commission believes a better scientific consensus is needed before adopting values different from those in the present Part 20. There are also several areas where issues raised in the public comments (see following Section V) are being resolved in other NRC rulemaking proceedings because of either their scope, complexity, or timing. The following issues are being or will be resolved in other NRC rulemaking proceedings:

(1) Establishment of "Below Regulatory Concern (BRC)" levels ~~(related to de minimis levels and a negligible level of risk)~~. [On June 27, 1990, the Commission announced the issuance of a policy statement on "Below Regulatory Concern," which was subsequently published in the Federal Register on July 3, 1990 (55 FR XXXXX). This policy statement sets forth the basis for ~~future~~ Commission actions regarding rulemaking and licensing actions related to the use of this concept.] 27522

(2) Limits for decommissioning of nuclear facilities and for residual radioactive contamination. [This is being actively pursued by ~~both~~ the Commission staff which is developing criteria for residual contamination of soils and structures (as one aspect of the implementation of the Below Regulatory Concern Policy) and ~~is~~ participating on an EPA Interagency Task Force on Residual Radioactivity.] X X

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(3) Limits and calculational procedures for dealing with the "hot particle" issue (small particles found in nuclear reactors that, because of their small size, produce high localized doses to skin.) [The NRC notes that the National Council on Radiation Protection and Measurements (NCRP) has recently issued new recommendations regarding "hot particles" in NCRP Report No. 106, "Limit for Exposure to 'Hot Particles' On the Skin," December 31, 1989. A modified NRC enforcement policy statement with regard to the "hot particle issue" ~~is in the final stages of NRC review~~ and an Advance Notice of Proposed Rulemaking on this subject will be issued ~~later in 1990~~ in the near future].

(4) Modification of NRC incident notification requirements. [A modification of the incident notification requirements was issued for public comment on May 14, 1990 (55 FR 19890).]

[(5) Publication of a separate rule for large irradiators. A new Part 36 is undergoing Commission review prior to publication as a proposed rule for public comment. The detailed requirements for irradiators presently in the revised Part 20 (§ 20.603) will eventually be deleted in favor of the provisions incorporated in the new Part 36.]

* * * * *

10. ADD SECTION TO RULE REGARDING MODIFICATION OF TECHNICAL SPECIFICATIONS

[§ 20.8 Modifications of License Conditions and Technical Specifications

The requirements contained in this Part supercede and replace existing license conditions and technical specifications based upon earlier versions of this Part. After January 1, 1992, licensees shall comply with the applicable section of this Part in lieu of any corresponding conditions based upon the previous Part 20.]

Renumber existing § 20.8 as § 20.9.