



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

IN RESPONSE, PLEASE
REFER TO: M901213B

December 19, 1990

OFFICE OF THE
SECRETARY

MEMORANDUM FOR: James M. Taylor
Executive Director for Operations

FROM: *A. Butler*
Samuel J. Chilk, Secretary

SUBJECT: STAFF REQUIREMENTS - AFFIRMATION/DISCUSSION
AND VOTE, 10:00 A.M., THURSDAY, DECEMBER 13,
1990, COMMISSIONERS' CONFERENCE ROOM, ONE
WHITE FLINT NORTH, ROCKVILLE, MARYLAND (OPEN
TO PUBLIC ATTENDANCE)

I. SECY-90-387 - Final Rule, Part 20 - Revised Standards for
Protection Against Radiation

The Commission, by a 4-0 vote, approved for publication in the Federal Register the revised 10 CFR Part 20 on Standards for Protection Against Radiation with the attached changes. This rule will become effective 30 days after publication. Licensees may, however, defer implementation of this rule until January 1, 1993.

Attachment:
As stated

cc: Chairman Carr
Commissioner Rogers
Commissioner Curtiss
Commissioner Remick
GPA
ACRS
✓ PDR - Advance
DCS - P1-24

9012280118 901219
PDR 10CFR
PT9.7 PDR

200010

For
11

ENCLOSURE A
FEDERAL REGISTER NOTICE

Enclosure A

americium, curium, and californium were found to be a factor of 2 higher than the ICRP-30 value so the ingestion ALIs are reduced by a factor of 2. Parameters applicable to inhalation ALIs and DACs are less affected than the ingestion ALIs as the transfer from the gastrointestinal (GI) tract to the blood for these radionuclides generally is ^{far} less significant than transfer from the lung to the blood. *by the new intestinal absorption factor*

C. ICRP 1987 Como Meeting

Following its 1987 meeting in Como, Italy, the ICRP issued a statement⁵ that reviewed the existing estimates of the biological risks of ionizing radiation and, in particular, the preliminary data from the reanalysis of the Hiroshima-Nagasaki atomic bomb followup studies. Reanalysis of these data indicated that the risks from gamma radiation are approximately a factor of 2 higher than previous estimates for the general population and are also higher, but by a smaller factor, for workers. The ICRP concluded in 1987 that this information alone was "not considered sufficient at that time to warrant a change in the dose limits for occupational exposure and, for the general population, the increase in risk indicated by the new data is not considered to require an immediate change in the recommended dose limits, following the reduction by the ICRP (in 1985) in the principal limit from 5 to 1 mSv in a year (from sources other than medical and natural background radiation)." The ICRP also noted that the potential higher risks indicated by the reanalysis of the atomic bomb data should not be a major consideration as the dose limits should not be of primary importance in controlling doses if the principle of keeping radiation exposures "as low as is reasonably achievable" is being practiced. This position has since been modified by the ICRP 1990 Statement (see Section II.I below).

D. Federal Radiation Protection Guidance on Occupational Exposure

On January 20, 1987, President Reagan approved revised guidance to Federal agencies for occupational radiation protection. This guidance, which was

⁵ International Commission on Radiological Protection, "Statement from the 1987 Como Meeting of the [ICRP]," *Health Physics*, 54(1): 125-132 (1988).

The latest report in this series is the 1988 report. The 1988 report⁷ 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 rads, 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. This would lead to an estimated risk of fatality of between $(0.7 \text{ to } 3.5) \times 10^{-4}$ health effects per rad 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 as estimated by the 1988 UNSCEAR report for low doses are between ~~0.7 to~~ 2.8 times higher than the earlier ICRP estimate. ~~The~~ Implications of ~~the~~ ^{an} increased risk are discussed in Section II.I.

1.8 times
lower to

- 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).

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

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-Emitters, (BEIR-IV)," National Research Council, National Academy Press, Washington, DC 20418 (1988).

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.

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 reevaluation 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 two to five times higher than the estimates in the 1980 BEIR-III report. The BEIR-V report gives the following factors as the principal reasons for this increase: (1) use of different dose-response and risk projection models, (2) revised estimates of the doses to the individual survivors of the atomic bombings in Japan, and (3) improved epidemiological data from additional years of followup studies since the BEIR-III¹ was completed in 1980.

report

The BEIR-V Committee uses the linear dose response model and the relative risk projection model to extrapolate the fatal tumor risk to future periods. The relative risk projection model assumes the risk to be proportional to the natural cancer incidence, which generally increases with age. Because of this dependence on 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. Estimates are given of the risk as a function of the time since the exposure occurred and the age and sex of the exposed person. The BEIR-V report, like the UNSCEAR-88 report, indicates that

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, DC 20418 (1990).

a reduction factor should be applied to the risk estimates derived from high doses and dose rates in order to apply them to low dose and low dose-rate situations. Although neither the BEIR-V report nor the UNSCEAR-88 report recommends a specific value for this factor, both reports indicate that this factor should be greater than 2 (larger reduction factors would give a lower risk per unit dose). Assuming a factor of 2 reduction in the risk estimates derived from high doses and high dose rates, BEIR-V would give a lifetime risk of a radiation-induced cancer fatality of about 4×10^{-4} fatal cancers/rem (0.04 per sievert) for workers and 5×10^{-4} per rem (0.05 per sievert) for the general population, the higher value for the public being associated with the higher sensitivity and the longer period of elevated risk associated with the younger ages present in the general population. The value of 5×10^{-4} is three times as large as the recommended value in the 1980 BEIR-III report and four times as large as the estimate in the 1977 ICRP-26¹ report (see Section II.F).

The BEIR-V report also summarized the data on the frequency of severe mental retardation found in the children of Hiroshima and Nagasaki atomic bomb survivors. These children were exposed in utero at gestational ages of 8-15 weeks and the risk of severe mental retardation during this period is about 4×10^{-3} per rem ~~with less of a risk at other gestational ages~~ with a possible threshold for the effect in the range of 20 to 40 rem. The risk of severe retardation was less during other gestational ages; there was no evidence of increased risk in survivors exposed earlier than 8 weeks or later than 26 weeks after conception.

The estimates of genetic effects to the offspring of irradiated individuals remained similar to those in the 1972 BEIR-I and 1980 BEIR-III reports. As radiation-induced inherited abnormalities have not been observed directly in humans, estimates of genetic effects have been based primarily upon experimental studies with mice. These studies suggest that it would take a dose of about 100 rads to double the natural frequency of genetically transmitted diseases.

I. ICRP 1990 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 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 ICRP dose limit for long-term exposure of members of the general public would remain equivalent to the level adopted in this revision of Part 20, 0.1 rem per year.

The Nuclear Regulatory Commission does not believe that additional reductions in the dose limits are urgently required by the latest radiation risk estimates.

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 and also below the ^{limits recommended} ~~changes being considered~~ by the ICRP. For example, in 1987 about 97 percent of the workers in nuclear power plants, industrial radiography, reactor fuel fabrication, and radioisotope manufacturing, four of the industries having the highest ^{potential} for occupational radiation exposures, ^{received} ~~were below an~~ annual dose ^{less than} of 2 rems, ^{which is the occupational limit recommended by the ICRP.} ~~so that an immediate reduction in~~

Maintaining Exposures.

the occupational dose limits would result in only a small reduction in the population dose and in the potential health impact. Although the risk per unit dose is higher than previously thought, individual annual exposures averaged over a lifetime in the highest exposed groups in the working population appear to be about 2-3 rems per year (50-60% of the 5-rem annual limit). Therefore, a factor of 2 increase in the risk per unit dose would result in estimated potential risks associated with actual lifetime exposures that are comparable to the previous risk estimate applied to an assumed lifetime exposure of 5 rems per year.

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 the uranium fuel cycle, doses from radioactive effluents from fuel cycle facilities are already much less than the 0.1 rem per year standard in the revised Part 20. The 0.1 rem per year remains as the level recommended by the ICRP for protection of the general public.

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 the promulgation of the proposed dose limits, rather than deferring the dose reductions that are already associated with the revised Part 20 rule. The Commission will carefully review the final recommendations of the International Commission on Radiological Protection, the comments of the scientific community and others on these recommendations, and the ICRP response to these comments. In addition, the Commission staff 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 U.S. Committee on Radiation Research and Policy Coordination and any inter-agency task force convened by the Environmental Protection Agency to consider revised Federal radiation guidance. Any future reductions in the dose limits by the Commission would be the subject of a future rulemaking proceeding.

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 Section ^{VI} 4) 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 27522). This policy statement establishes the framework for the Commission to formulate rules and licensing decisions to exempt certain practices involving small quantities of radioactive materials from some or all regulatory controls. The BRC policy statement sets forth criteria for protection of both individuals (individual dose criteria) and population groups (a collective dose criterion).

and are necessary to fully implement the Commission's earlier rulemaking on General Requirements for Decommissioning Nuclear Facilities (53 FR 24618, June 27, 1988).

(2) Limits for decommissioning of nuclear facilities and for residual radioactive contamination. This is being actively pursued by the NRC staff by developing criteria for residual contamination of soils and structures, which ^{are} one aspect of the implementation of the Below Regulatory Concern policy ~~and by~~ ^{The} NRC staff ^{is also participating in} participation on an EPA Interagency Task Force on Residual Radioactivity.

(3) Limits and calculational procedures for dealing with the "hot particle" issue (small particles found in nuclear reactors that, because of their high activity and 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" was published in the July 31, 1990 Federal Register (55 FR 31113). The NCRP report, together with a forthcoming ICRP report on the biological effects of skin irradiation and other technical analyses, will be considered in a future rulemaking to set limits for skin irradiation.

(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). If this proposal is adopted as a final rule, it would modify both the existing Part 20 and this revision.

(5) Publication of a separate rule for large irradiators. A new Part 36 is being proposed for public comment. The detailed requirements for irradiators presently in the revised Part 20 (§ 20.603) will eventually be deleted and replaced by the provisions incorporated in the new Part 36.

There are also additional areas where the scientific basis is not yet resolved sufficiently to justify a change from current practice. These two areas require better scientific consensus on the appropriate position: (1) The need for and impact of a lifetime cumulative dose limit of 1 rem per year of age and (2) quality

factors, especially for neutrons, low-energy beta-emitters, and high-energy gamma photons. These issues will be reconsidered as consensus positions are reached by the scientific community.

IV. Need for Additional Regulatory Guidance

The Commission recognizes that the incorporation of many new concepts into Part 20 will require additional guidance and explanation on their application to practical problems in radiation protection. The Commission also notes the desirability of having such additional guidance available at the same time that the final rule is issued in effective form. However, it was impractical, both for reasons of scheduling and availability of resources, for these guides to be developed concurrently with Part 20. Some of the regulatory guides being developed or revised to assist in the implementation of the revised Part 20 are:

- (1) Content of Radiation Protection Programs at Nuclear Power Plants;
- (2) Interpretation of Bioassay Measurements (Draft Regulatory Guide 8.9, Revision 1),
- (3) Criteria and Procedures for Summation of Internal and External Occupational Doses,
- (4) Acceptable Criteria for Planned Special Exposures and for Satisfying Documentation Requirements;
- (5) Methods and Parameters for Calculating the Dose to the Embryo/Fetus;
- (6) Instructions for Recording and Reporting Occupational Radiation Exposures (includes NRC Forms 4 and 5).

The Commission has instructed the staff to have these and other draft guides published for public comment early in 1991^x and published in final form by December 31, 1991.

Applicants seeking new licenses and holders of existing licenses filing for renewal after the effective date also have the option of complying with either the revised Part 20 or with the previous version of Part 20. Until January 1, 1993,

V. Implementation and Existing License Conditions

Section 20.8 of the rule provides that NRC licensees must implement the revised Part 20 rule on or before January 1, 1993. ~~Licensees that adapt the provisions of this rule prior to the required implementation date are required to notify the NRC.~~ Early implementation may benefit applicants for new licenses or license renewals as they could avoid having to adopt and implement one version of Part 20 for only a short period of time prior to the required implementation date of this revision. ~~Licensees choosing early implementation must adopt the entire revised Part 20.~~ Compliance will be required with the version of 10 CFR Part 20 codified in the Code of Federal Regulations on January 1, 1991 until January 1, 1993, or until the licensee notifies the Commission of early implementation of the revised Part 20.

License conditions and reactor technical specifications may contain citations to portions of the existing 10 CFR Part 20. After adoption of the revised Part 20 by the licensee or after January 1, 1993, the applicable section of the revised Part 20 that corresponds to the same topic should be used in place of any section of the Part 20 in effect on or before January 1, 1991 that is cited in the technical specifications or license conditions. When there is no corresponding section in the revised Part 20 to these cited provisions, the current license condition based on the Part 20 in effect on or before January 1, 1991 shall remain in force until there is a technical specification change, or license amendment or renewal. If a license condition or technical specification exempted a licensee from a provision of Part 20, it will be assumed to also exempt the licensee from the applicable provision of the revised Part 20. If the license condition or technical specification is more restrictive than the revised Part 20, it shall remain in force until it is modified by a technical specification change or license amendment or renewal.

The NRC will issue a regulatory guide that provides the section and paragraph identifiers in the revised Part 20 and the corresponding sections or paragraphs in the earlier Part 20. This document will ^{be} issued shortly after ~~the~~ publication of this rule and will enable licensees to locate sections of the revised Part 20 that correspond to sections of the earlier Part 20 cited in license conditions and technical specifications.

[Add new paragraph from next page here]

Licensees (or applicants) that adopt the provisions of this rule prior to the required implementation date are required to notify the NRC and to adopt Part 20 in its entirety.

NRC Agreement States each have regulations compatible with the existing 10 CFR Part 20. Agreement States normally amend their regulations to preserve compatibility within three years after NRC issues final rules. In the Commission's view, it is desirable to minimize the period when different radiation standards and methods of determining doses are in effect across the nation. The States and the public have had extensive advance knowledge of the planned revision of Part 20. Consequently, it is the Commission's view that the Agreement States must proceed as quickly as possible to conform to Part 20 and should require that all Agreement State licensees comply on or before January 1, 1994. The States are encouraged to provide the flexibility for early adoption should licensees so choose. As just discussed, the Commission has provided about two years from publication of the final rule before all NRC licensees must comply. Agreement States may also wish to provide additional time for their licensees to comply to facilitate transition and the Commission would have no objection so long as compliance is required by January 1, 1994.

[Insert this new paragraph on previous page]

Comment: 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 sources 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's 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 from the dose from either facility alone.

The definition of "natural background" has been replaced by "background radiation," which ~~includes natural background, global fallout, and radon not associated with licensed material.~~ ^{means radiation from cosmic sources, naturally occurring radioactive materials, including radon, and global fallout as it exists in the environment from the testing of nuclear devices.} This clarifies sources of radiation and radionuclides that can be excluded from evaluations of the dose from licensed activities. ^{except as a decay product of source or special nuclear material}

Comment: Differentiation of limits for long-term operation and for shorter-term transient operation. A number of commenters noted that ICRP-26 described the 0.1 rem (1 mSv) per year value as intended to be an average goal for long-term operation but that 0.5 rem (5 mSv) was intended as the primary annual dose limit for members of the public. Some commenters suggested that a lifetime dose limit be established for members of the public.

Response: As noted above in Section II.A., the ICRP has modified its interpretation in the ICRP statement issued following their 1985 Paris meeting,² so that the primary standard is 1 mSv (0.1 rem) per year. This clarification of ICRP philosophy is reflected in Part 20 by the change of the 0.1 rem per year value from a "reference level" in the proposed rule to a primary limit in the final rule.

Final Rule: It should be emphasized that the 0.1 rem per year limit in Part 20 is not intended to be applied as a long-term average goal: it is an annual limit. As a matter of practicality, long-term (or lifetime) dose limits for members of the public cannot be implemented unless each year's dose is kept within the long-term goal. Doses to individuals in the general public are not usually monitored directly (locations rather than individuals in the offsite environment are monitored). As individuals may change residency and there is no reporting or tracking system, lifetime doses to specific individuals in the general population are very difficult to determine.

The 0.5 rem per year limit is available only upon specific application to and approval by the Commission (see § 20.301(c)). A 0.5-rem value has been retained in order to apply to transient situations and to alleviate the immediate need to redesign or reshield existing facilities that were designed to meet the former 0.5-rem limit. 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. *Such facilities may include, for example, hospitals with existing teletherapy machines that were designed, constructed, and installed to comply with a 0.5 rem annual dose limit.*

The Commission is aware that some categories of licensees, such as uranium mills and in situ uranium mining facilities, may experience difficulties in determining compliance 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 for protection of members of the general public that are different from those in Appendix B, Table 2, if the licensee can demonstrate that the physicochemical properties of the effluent justify such modification and the revised value is approved by the NRC. 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 provision permits (upon NRC approval) the use of concentration limits for members of the general public that better represent actual exposure conditions. This is similar to the allowance for use of ² modified derived air concentrations (with Commission approval) in § 20.204(c)(~~X~~). [^] X

In both situations, licensees would be permitted to propose radionuclide concentration limits for their facility that reflect actual properties of the effluents rather than use the generic concentration-to-dose assumptions associated with Appendix B values. These adjustments tailor the concentration limits to specific conditions, provide the same limitation of dose, and do not permit any greater risk even though the adjusted concentration limits (for members of the general public or for workers) may be higher than the Appendix B generic values.

in accordance with 10 CFR 20.302(b)(1).

Use of this provision, applied to the percentage of radionuclide equilibrium existing in radioactive decay chains, 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, and (3) procedures to control doses to be ALARA. These options used singularly or in combination coupled with process or operational modifications of these facilities is expected to provide sufficient flexibility to enable most uranium recovery facilities to comply with the provisions of the revised 10 CFR Part 20.

Section 20.303 [Reserved].

The former 0.1-rem "Reference Level" and the EPA Standard for Nuclear Power Operations that were in this section in the proposed rule are included as primary limits for members of the public in § 20.301 of the final rule.

Many of the commenters who supported a generic BRC concept did not agree with the numerical value (0.001 rem per year) proposed for the cutoff, believing it to be too low. An explanation for this opinion was that if 0.001 rem represented an insignificant level of risk, then all larger doses might be perceived as representing "significant" levels of risk. A value of 0.010 rem was noted by several commenters as being a more suitable value and still represented an inconsequential risk.

(BRC)

Response: The Commission agrees that "Below Regulatory Concern" levels would be useful and has issued ^a policy statement^a on the application of the concept of ^{BRC} below regulatory concern with regard to waste disposal ("Radioactive Waste Below Regulatory Concern," ~~Federal Register of August 20, 1985~~ 51 FR 30839) and a general policy statement on ^{BRC} below regulatory concern^a ~~announced on June 27, 1990, and was subsequently published in the Federal Register on~~ July 3, 1990 (55 FR 27522). The general policy statement establishes the framework for the Commission to formulate rules and licensing decisions to exempt certain practices involving small quantities of radioactive materials from some or all regulatory controls. The BRC policy statement sets forth criteria for protection of both individuals (individual dose criteria) and population groups (a collective dose criterion).

In order to ensure that any computational changes reflect the policy that evolves from the effort to develop generic BRC policy, the Commission removed the threshold for truncating collective doses (§ 20.304) from Part 20 and has included such a threshold in the generic BRC policy statement. This deletion is also consistent with comments that noted that this section described a method for calculating a quantity (collective dose) that was not required to be calculated by Part 20 and comments that such details of calculations would be better in a regulatory guide rather than in a regulation.

Comment: NRC should permit a health professional to certify physical capability to use a respirator rather than requiring a physician to perform each required certification. The proposed rule requires that a physician annually certify a worker's physical suitability for using a respirator. This should be broadened to permit any qualified health professional, acting under a physician's orders, to perform the actual certification rather than requiring a doctor to do this.

Response: As noted in the previous response, the decision on the physical ability of an individual to wear a respirator is a subjective judgment that, in the Commission's opinion, requires the decisionmaker to have a medical degree. The Commission notes that this annual certification could easily be included in an annual physical checkup.

Comment: The selection of respirator protection factors based upon "average concentrations" and not "peak airborne concentrations" is an improvement. The proposed rule, unlike the previous Part 20, permitted protection factors to be applied to the time-averaged air concentration rather than the peak air concentration.

Response: Despite some favorable comments on this change, the Commission has determined that the use of the average airborne concentration may not provide an adequate margin for health protection and, in the final rule, has reverted to the use of the anticipated peak concentration.

Final Rule: The proposed rule has been modified to require a respiratory protection program when respiratory protection devices are being used to limit intakes, whether or not credit is taken for respiratory protection 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. Such a determination should only be reached after careful consideration of the trade-off between calculated reductions in total dose based on ALARA evaluations and increased internal doses resulting from alternative procedures that do not minimize internal exposures.

Comment: Unnecessary restrictions on research. One commenter thought that the requirement to secure small quantities of radioactive materials when they are not in use would interfere with university research.

Response: The Commission believes that locking radiotracer laboratories when they are not being used is a small nuisance compared to the consequences of unauthorized access to or theft of the radioactive materials, which could result in contamination of unrestricted areas or exposure of individuals, as well as having to report a loss of licensed material to the NRC.

Subpart J--Precautionary Procedures

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 on 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 a 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 ~~requiring~~^{ing} replacement.

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

Final Rule: The final rule has been modified to explicitly list "decay-in-storage" as an authorized form of disposal. Section 20.1002 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.

Section 20.1003 Disposal by Release into Sanitary Sewerage.

Comment: 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: In the final rule, the Commission has modified 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 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 as flakes of metallic foil containing americium-241,} Such materials may accumulate in the sewer system, in the sewer treatment plants, and in the sewer sludge. X

Final Rule: The final rule permits disposal into sanitary sewers of: (1) radionuclides in soluble form or (2) radionuclides in readily dispersible biological material, provided that the limits in Appendix B, Table 3, on the

Comment: 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. This exemption is in the current Part 20.

Section 20.1004 Treatment or Disposal by Incineration.

Comment: 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 commenters 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 the revised Part 20 because the acceptability of incineration as a disposal option, except for exempted quantities of radioactive materials, must be determined on a site-specific basis considering (1) incinerator design, ~~to safely dispose of hazardous materials,~~ ^{isotopic composition and activity} (2) the variable ~~nature~~ ^{nature} of the material to be burned, ~~both in terms of isotopic composition and activity,~~ ^{potential human exposure to effluents, which may require} and (3) ~~because many of these incinerators can be located in urban areas,~~ ^{special calculational methods may be required to assess doses to people located near these facilities,} because of complex meteorologic conditions and other factors.

Final Rule: Disposal by incineration still requires specific approval by the Commission (or Agreement State) whether done only for wastes from the licensed facility or whether done for wastes received from other licensees.

X | Section ² 20.1106 Records of Individual Monitoring Results.

Comment: 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 II.D) contains a recommendation that cumulative dose records be maintained and provided to the worker.

Comment: The proposed rule does not require recording annual doses as listed in the 1987 Federal occupational guidance.

Response: "Annual dose" is specified in the guidance and is the same as the annual deep-dose equivalent for external doses. However, "annual dose" is not required to be recorded by the revised Part 20 for internal doses. This is consistent with an exception 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."

Paragraph 20.1106(b) -- See discussion under § 20.1204.

Insert from next page

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. ~~The Safe Drinking Water Act was not intended to control effluents and, although radionuclide concentrations at downstream water supplies are routinely calculated as part of licensing evaluations, the licensee must meet the Part 20 concentration limits at the effluent release point, not at the drinking water intake after dilution occurs.~~

Appendix A

Comment: 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 Part 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 (PFs) 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.

Comment: 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 requirement for standby rescuers to be available when using supplied-air suits. These were felt to be unneeded considering that, if the air flow failed, the person could withstand a small exposure to the airborne radionuclides while exiting the area after removing the protective hood.

Insert for Page 94:

"Any exemption that could have a significant impact on the environment would be evaluated in accordance with the Commission's requirements in 10 CFR Part 51 under the National Environmental Policy Act. Regarding EPA's comment on controlling radionuclides under the Safe Drinking Water Act, the Commission will ensure that potential impacts on water resources and drinking water supply systems are considered in evaluations of proposed exemptions, such as alternative liquid effluent concentration limits. Where appropriate, NRC will coordinate with EPA to ensure that drinking water supplies are appropriately protected by any proposed exemptions."

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. These requirements were in § 20.311 of the existing 10 CFR Part 20. Because these requirements are relatively recent, they were not modified in the Part 20 revision. The Commission is considering revisions to the manifest requirements in a rulemaking separate from the Part 20 rulemaking.]

Appendix G

In accordance with the implementation schedule above, licensees will remain subject to the version of Supplement IV of the NRC Enforcement Policy in Appendix C in existence prior to January 1, 1991. The conforming amendments to Appendix C of 10 CFR Part 2 in today's notice would only apply after January 1, 1993, or if the licensee implements the revised part 20 before that date.

No comments on Appendix G were received.

These conforming amendments are to be implemented in accordance with the schedule for implementing the revised Part 20 as reflected in §20.8.

VII. Conforming Amendments

Accompanying the revised rule are amendments to other parts of Chapter I that update citations to 10 CFR Part 20 that are found in these other regulations. ^{TP}Two amendments are particularly important as they go beyond updating cross-reference citations. One amendment to Appendix C to 10 CFR Part 2 updates and modifies the examples of the severity levels associated with violations of 10 CFR Part 20. ~~Because Appendix C relates to the administrative policy of the Commission and because the listed violations are used as examples of different severity levels and are not all inclusive,~~ ^{on the conforming changes to Appendix C of 10 CFR Part 2} The Commission does not believe that solicitation of public comment ^{they} is required before ~~these~~ are issued in final form.

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. (These comments are discussed with regard to § 20.1106.) Part 19 has been revised to require licensees to advise each worker at least annually of the worker's dose recorded pursuant to § 20.1106.

VIII. Finding of No Significant Environmental Impact: Availability

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 that this rule is not a major Federal action significantly affecting the quality of the human environment and therefore an environmental impact statement is not required. The revised 10 CFR Part 20 changes the level for protection of the general public from an implicit limit of 0.5 rem 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 higher or lower than present concentration limits; and some are similar to the present limits.

Insert from next page 1

and existing ALARA programs

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~~ ^{new HP} to 10 CFR Part 20, there are other regulations that govern allowable doses to members of the public and that remain unchanged by the ~~changes~~ ^{revisions} to Part 20.

These other regulations include Appendix I to 10 CFR Part 50, 10 CFR Part 560 ^X and ~~in CFR Part 61~~, the EPA's ~~generally applicable~~ environmental standards in 40 CFR Part 190 ^{191, and 192} and the National Emission Standards for Hazardous Air Pollutants (NESHAP) in 40 CFR Part 61 Subpart I. These standards set limits or design objectives (Appendix I) for releases of radioactive material to the general environment that are generally more restrictive than the dose limits in ^{final} Part 20. ^X Consequently, since these more restrictive standards remained essentially

Insert for Page 101:

NRC (and Agreement State) licensees have implemented radiation protection measures that keep radiation exposures and radioactive effluents as low as reasonably achievable (ALARA) in accordance with existing provisions of 10 CFR 20.1(c) and comparable State provisions. These measures, whether established by rule, license, or good management practice, have been particularly successful in minimizing effluents to the general environment and exposures to members of the public and radiation workers. The final Part 20 rule will make such ALARA programs mandatory as a part of licensee radiation protection programs.

X unchanged by the Part 20 revision^s, the level of public protection and the associated environmental impact are not changed appreciably from those associated with existing practice under the current ~~rule~~, and the aforementioned regulations.

Part 20

The environmental assessment and finding of no significant impact on which this determination is based are available for inspection at the NRC Public Document Room, 2120 L Street NW (Lower-Level), Washington, DC 20555. Single copies of the environmental assessment and finding of no significant impact are available from Harold T. Peterson, Jr., Nuclear Regulatory Commission, NL/S-139, Washington, DC 20555, Telephone: (301)492-3640.

IX. Paperwork Reduction Act Statement

This final 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 in this final rule have not been reviewed by the Office of Management and Budget (OMB), but will be submitted by NRC for approval by OMB. These information collection requirements will not become effective until approved by OMB. The OMB approval will be published in the Federal Register.

Public reporting burden for this collection of information is estimated to average 33 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Information and Records Management Branch (MNBB 7714), U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOF-3019 (3150-0014, 3150-0044, 3150-0005, and 3150-0006), Office of Management and Budget, Washington, DC 20503.

X. Revised Regulatory Analysis

The Commission has issued a final regulatory analysis for this regulation. This revised analysis was based on the draft regulatory analysis as modified to account for the changes from the proposed rule resulting from public comments on both the proposed rule and the staff's revised rule in SECY-88-315 and supplemental papers. Copies of both the draft and final regulatory analysis are available for inspection and copying for a fee in the NRC Public Document Room. (See Address.)

XI. Final Regulatory Flexibility Analysis

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission has prepared a regulatory flexibility analysis that indicated 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 of which a comparable number are assumed to be small entities.) The types of small entities that would be affected by this rule include physicians, small hospitals, small laboratories, industrial applications in small industries, radiographers, and well loggers.

Copies of the draft and final regulatory analysis are available for inspection and copying, for a fee, in the NRC Public Document Room. (See Address.)

XII. Backfit Analysis

A final backfit analysis has been prepared for this rule and may be examined and copied for a fee in the Commission's Public Document Room (see Address). For the reasons stated in this backfit analysis, the Commission believes that the reductions in allowable dose limits that are embodied in the revised Part 20 ^{tributary} constitute ₁ substantial increases in the protection of public

the Commission has concluded that the revisions to Part 20, as applied to nuclear power reactors, provide a substantial increase in overall protection of public health and safety both for workers and for members of the general public. The Commission's conclusion rests on both quantitative and qualitative grounds.

health and safety. Although current practice, including the philosophy of keeping radiation exposures as low as is reasonably achievable (ALARA), generally has kept radiation exposures well below the existing limits, the reductions in the allowable dose limits ensure that such doses will also remain low in the future.

~~In addition to the quantifiable safety benefits occurring from dose reductions and other improvements in the revised Part 20, there are several qualitative factors that support ~~issuing~~ the Part 20 revisions. One of the main qualitative factors is that it is necessary to revise the 30-year-old existing Part 20 to ensure that the NRC regulations reflect the current state of radiation protection science. Any future revisions in dose limits recommended by ICRP or NCRP would undoubtedly be based upon the 1977 ICRP and 1987 NCRP recommendations and, therefore, would be more easily incorporated into the framework of the revised Part 20 than in the framework of the current Part 20. Other qualitative factors include: maintaining consistency with international radiation protection ^{programs} ~~standards~~, keeping the radiation protection requirements consistent with current risk assessment methodologies, and having the NRC's standards conform to Federal radiation protection guidance.~~

the Commission's conclusion that

provide a substantial increase in protection.

~~Based upon the conclusions in the final backfit analysis, the revised Part 20 provides a substantial increase in public health and safety compared to current standards, including a determination that, when the quantitative and qualitative safety benefits of the revision are considered, the costs of implementing the revised Part 20 are justified, the Commission finds that the requirements of the "Backfit Rule" (§ 50.109) are satisfied and that the Part 20 revision should be issued as final rule.~~

(next to reports these thoughts)

The Commission is adopting the final rule based ^{in part} on the conclusions 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 the rule. The Commission notes, however, that, even had the analysis not concluded that the revised Part 20 provides a substantial increase in the overall 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 substantial increase in protection and cost justification standards do not apply to a redefinition of adequate protection.

~~12/15~~ Additional Views of Commissioner Curtiss
With Respect to Backfit:

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:

- 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 characteristics 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.

~~Implementation date: I would have preferred a common implementation date of January 1, 1994 for both NRC and Agreement State licensees to allow adequate time for all licensees to implement the revised Part 20 on the same schedule.~~

~~XIII~~

~~XIV.~~ List of Subjects

Part 20 - Byproduct material, licensed material, nuclear materials, nuclear power plants and reactors, occupational safety and health, packaging and containers, penalty, radiation protection, reporting and recordkeeping requirements, special nuclear material, source material, waste treatment and disposal.

Parts 2, 19, 20, 31, 32, 34, 35, 39, 40, 50, and 61 - Radiation protection.

Under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the following amendments to 10 CFR Parts 2, 19, 20, 31, 32, 34, 35, 39, 40, 50, and 61 are published as a document subject to codification.

"Background radiation" means radiation from cosmic sources; naturally occurring radioactive materials, including radon, ~~in concentrations or levels commonly found in structures or the environment~~; and global fallout as it ~~comes~~ ^{exists} only in the environment from the testing of nuclear explosive devices. "Background radiation" does not include radiation from source, byproduct, or special nuclear materials regulated by the Commission.

except as a ^{decay} daughter product of source or special nuclear material

"Bioassay" (radiobioassay) means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement (in vivo counting) or by analysis and evaluation of materials excreted or removed from the human body.

"Byproduct material" means --

(1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or utilizing special nuclear material; and

(2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition.

"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-time: for Class D (Days) of less than 10 days, for Class W (Weeks) from 10 to 100 days, and for Class 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.

"Very high radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in 1 hour at 1 meter from a radiation source or from any surface that the radiation penetrates. [Note: At very high doses received at high dose rates, units of absorbed dose (e.g., rads and grays) are appropriate, rather than units of dose equivalent (e.g., rems and sieverts).]

"Week" means 7 consecutive days starting on Sunday.

"Weighting factor," w_T , for an organ or tissue (T) is the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

ORGAN DOSE WEIGHTING FACTORS	
Organ or Tissue	w_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30 ^a
Whole Body	1.00 ^b

^a 0.30 results from 0.06 for each of 5 ~~remainder~~ "remainder" organs (excluding the skin and the lens of the eye) that receive the highest doses.

^b For the purpose of weighting the external whole body dose (for adding it to the internal dose), a single weighting factor, $w_T = 1.0$, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

(c) Any existing license condition or technical specification that is more restrictive than this part remains in force until there is a technical specification change, license amendment, or license renewal.

(d) If a license condition or technical specification exempts a licensee from a provision of Part 20 in effect on or before January 1, 1991, it also exempts the licensee from the corresponding provision of this part.

(e) If ^{a license condition cites} ~~any condition in this part corresponds to the provisions of Part 20~~ in effect prior to January 1, 1991, ^{which does not correspond with any provisions of this part, the} ~~condition based on Part 20 in effect on or before January 1, 1991, remains in force~~ until ~~either~~ there is a technical specification change, license amendment, or license renewal that modifies or removes this condition.

§ 20.9 Reporting, recording, and application requirements: OMB approval.

(a) The Nuclear Regulatory Commission will submit the information collection requirements contained in this part to the Office of Management and Budget for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). The information collection requirements in this part will not become effective until OMB clearance is obtained.

(b) The information collection requirements contained in this part appear in §§ 20.101, 20.202, 20.204, 20.206, 20.301, 20.501, 20.601, 20.603, 20.703, 20.901, 20.902, 20.904, 20.906, 20.1002, 20.1004, 20.1006, 20.1102, 20.1103, 20.1104, 20.1105, 20.1106, 20.1107, 20.1108, 20.1109, 20.1110, 20.1201, 20.1202, 20.1203, 20.1204, 20.1206, ~~and~~ Appendix F, and NRC form 4 and form 5.

SUBPART B--RADIATION PROTECTION PROGRAMS

§ 20.101 Radiation protection programs.

(a) Each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of this part. (See § 20.1102 for recordkeeping requirements relating to these programs.)

(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 that 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: *el X*

- (a) Control of access;
- (b) Limitation of exposure times;
- (c) Use of respiratory protection equipment; or
- (d) Other controls.

§ 20.703 Use of individual respiratory protection equipment.

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

(1) The licensee shall use only respiratory protection 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).

The value 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 by either inhalation or ingestion or both, or when the individual is exposed to both internal and external irradiation (see § 20.202). When an individual is exposed to radioactive materials which fall under several of the translocation classifications (i.e., Class D, Class W, or Class Y) of the same radionuclide, the exposure may be evaluated as if it were a mixture of different 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 radioisotopes. For this reason, values are given for Class D, W, and Y compounds, even for very short-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 of § 20.302. The concentration values given in Columns 1 and 2 of Table 2 are equivalent to the radionuclide concentrations which, if inhaled or ingested continuously over the course of a year, would produce a total effective dose equivalent of 0.05 rem (50 millirem or 0.5 millisieverts)

Consideration of non-stochastic limits has not been included in deriving the air and water effluent concentration limits because non-stochastic effects are presumed not to occur at the dose levels established for individual members of the public. For radionuclides, where the non-stochastic limit was governing in deriving the occupational DAC, the stochastic ALI was used in deriving the corresponding airborne effluent limit in Table 2. For this reason, the DAC and airborne effluent limits are not always proportional as they were the previous Appendix B.

in

X

ENCLOSURE D
FINAL ENVIRONMENTAL ASSESSMENT

Enclosure D

The regulations provide limits for planned special exposures. Under the current regulations a worker could exceed a 5 rems/y dose if an occupational exposure history was on file, in which case the worker could receive up to 12 rems/y. The revised regulation allows for planned special exposures exceeding the annual limits by an increment equal to the annual dose limit during any one year. No more than five times the annual limit may be permitted during a worker's lifetime. These new criteria may have an affect on some licensee's operation, but the data in Table 4 indicates that the impact is not likely to be significant.

The revisions include an explicit requirement to include the "as low as reasonably achievable" (ALARA) concept in radiation protection programs. The ALARA concept is not new. Although not an explicit general regulatory requirement heretofore, the NRC's regulatory practice has included this basic concept in a number of regulatory programs (e.g., effluent technical specifications discussed previously). As a result, most, if not all, licensees currently have ALARA programs whose functions generally cover those listed in Section 20.102.

3. Concentration and Effluent Limits

A significant change occurs in the summation of both external and internal dose for a member of the public and the restriction of that dose to 0.1 rems/yr. The summation of the external and internal doses has required new derived limits in air and water to be calculated based on the 0.1 rem allowed dose. The revised effluent concentration limits are based upon an annual effective dose equivalent of 50 millirem in each release pathway (air and water).

The MPC changes, nevertheless, will have little environmental impact. This is a result of the de facto limitation on doses ~~due~~ to members of the public arising from the more restrictive requirements in 10 CFR Part 50, Appendix I, and 40 CFR Part 190.

19
licensee implementation
of ALARA measures in accordance with 10 CFR 20.1(c) and

ENCLOSURE F
LETTER TO CONGRESSIONAL COMMITTEES

Enclosure F

The Honorable Bob Graham, Chairman
Subcommittee on Nuclear Regulation
Committee on Environment and Public Works
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

Enclosed for the information of the Subcommittee are copies of a public announcement and a final rule revising the Commission's regulations for protection against radiation in 10 CFR Part 20. This rule is the foundation of NRC's radiation protection regulatory framework and implements the Federal radiation guidance issued by President Reagan in January 1987. NRC considers its completion as a significant accomplishment in its mission to protect the public health and safety and the environment.

The rule will become effective 30 days after issuance in the Federal Register, but licensees will have until January 1, 1993 to come into compliance. Early implementation may be beneficial to applicants for new licenses or renewal of existing licenses so that they will not have to commit to and implement the existing 10 CFR Part 20 for only a short period of time before the revised Part 20 would replace it. Consequently, flexibility for early implementation has been provided. ~~In addition, it is the Commission's view that the Agreement States must proceed as quickly as possible to conform to Part 20 and should require their licensees to comply on or before January 1, 1994.~~ ^{to}

F12

The rule has been modified from a proposed rule published for public comment in January 1986. Over 800 public comments were received and considered in preparing the final rule. The rule is consistent with ~~most of~~ the recommendations of both the National Council on Radiation Protection and Measurements and the International Commission on Radiological Protection. ^{general}

Members of the NRC staff would be pleased to brief you and members of your subcommittee and staff on this revised regulation.

is also asking

Sincerely,

Kenneth M. Carr

cc: Senator Alan K. Simpson

ENCLOSURE G
PRESS RELEASE

Enclosure G



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
Office of Governmental and Public Affairs
Washington, D.C. 20555

No. 90-156
Tel. 301/492-0240

FOR IMMEDIATE RELEASE
(Thursday, December 13, 1990)

NUCLEAR REGULATORY COMMISSION AMENDS RADIATION
PROTECTION REQUIREMENTS

The Nuclear Regulatory Commission is amending its regulations governing protection against radiation to provide for a substantial increase in the overall protection of the public health and safety.

The new requirements are based on those that were proposed for public comment in January 1986. They incorporate Federal guidance for radiation protection of workers in the nuclear industry issued by the President in 1987 and recommendations of the International Commission on Radiological Protection (ICRP) and the National Council on Radiation Protection and Measurements (NCRP).

Some highlights of the new requirements are:

- Annual radiation exposures to individual members of the public from NRC-licensed activities are lowered to a limit of 0.1 rem per year, compared with the previous limit of 0.5 rem per year.
- The sum of internal and external doses to radiation workers is limited to 5 rem per year;
- NRC licensees are required to implement programs to ensure that all radiation doses are kept as low as is reasonably achievable. Most licensees already have such programs in place;
- A standard is established for protection of the embryo or fetus of female radiation workers which limits the exposure to 0.5 rem over the duration of the pregnancy, if the worker tells her employer about her pregnancy; and
- Concentration limits for specific radioactive materials releasable to air and water have been updated to reflect new dose limits, dosimetry, and metabolic data. Some decrease, some increase, and others remain the same.

The revised requirements reflect the first complete revision of the NRC's radiation protection requirements since they were established in 1960.

The revised Part 20 and conforming amendments to Parts 19, 32, 34, 39, 50 and 70 of the NRC regulations will become effective 30 days after publication in the Federal Register. Licensees will have until January 1, 1993, to come into compliance. Early implementation may be beneficial to applicants for new licenses or renewal of existing licenses so they will not have to commit to and implement the existing 10 CFR Part 20 for only a short period of time before the revised Part 20 would replace it. Consequently, flexibility for early implementation has been provided. The Commission is also asking the Agreement States to proceed as quickly as possible to conform to Part 20 and require their licensees to comply on or before January 1, 1994.

The NRC staff is developing guidance documents that will provide more details on the methods of implementing the new rule.

#