

A F F I R M A T I O N V O T E

R E S P O N S E S H E E T

RELEASED TO THE PDR

12/27/90 : *g*
date initial

TO: SAMUEL J. CHILK, SECRETARY OF THE COMMISSION
FROM: COMMISSIONER CURTISS
SUBJECT: SECY-90-387 - TRANSMITTAL OF REVISED PART 20

APPROVED ^x w/comments DISAPPROVED _____ ABSTAIN _____

NOT PARTICIPATING _____ REQUEST DISCUSSION _____

COMMENTS:

I approve the revised 10 CFR Part 20 package as reflected in SECY-90-387 except that the Commission's decision reflected in the November 20, 1990 SRM on implementation by Agreement States needs to be added. I have attached a proposed insert for the Statement of Considerations to address this issue. I also have attached conforming changes to the congressional letters and public announcement on this issue, as well as a few editorial changes.

9101020295 901207
PDR COMMS NRCC
CORRESPONDENCE PDR

John R. Letin
SIGNATURE

RELEASE VOTE

December 7, 1990

WITHHOLD VOTE

DATE

ENTERED ON "AS" YES No _____

RF02
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insert new paragraph on page 17 in "V. Implementation and Existing License Conditions":

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.

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 ~~and~~ 2.8 times higher than the earlier ICRP estimate. ~~The~~ Implications of ~~the~~ 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).

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 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, ~~were below an~~ ^{received} annual dose of ~~2 rems.~~ ^{less than 2 rems.} ~~Consequently,~~ ^{Consequently,} any immediate reduction in the occupational dose limits would result in only a small reduction in the population dose and in ~~the~~ ^{annual} 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 ~~estimate~~ ^{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 ~~7~~¹) 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).

necessary to fully implement the Commission's earlier decommissioning rulemakings

(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 is one aspect of the implementation of the Below Regulatory Concern policy. ~~by~~ NRC staff ^{are also} participating ⁱⁿ 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, *(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. Implementation and Existing License Conditions

Section 20.8 of the rule provides that NRC licensees must implement the Part 20 rule on or before January 1, 1993. Licensees that adopt 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 ^{OR APPLICANTS} 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.

insert on Agreement States 17

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.

~~1/28/89~~ 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.



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

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

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 implements the Federal radiation guidance issued by President Reagan in January 1987.

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. ^{→ Insert} The early ~~implementation date will allow new licensees or license renewals to adopt the new regulation without having to adopt the current Part 20 for only a short time.~~

The rule has been modified from a proposed rule published for public comment in January 1985. Over 800 public comments were received and considered in preparing the final rule. The rule is consistent with the recommendations of both the National Council on Radiation Protection and Measurements and the International Commission on Radiological Protection.

Sincerely,

Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

cc: Rep. Carlos J. Moorhead

(Similarly for other letters and announcements)

Insert for End of Second Paragraph of Letters

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 that all Agreement State licensees comply on or before January 1, 1994.