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RULEMAKING ISSUE

July 5, 1990

(NEGATIVE CONSENT)

SECY-90-237

For:

The Commissioners

From:

James M. Taylor, Executive Director for Operations

Subject:

MINOR REVISIONS TO 10 CFR PART 20 REVISION AND PREAMBLE

Purpose:

To get Commission approval on clarifications and additions

to the final revised Part 20.

Category:

Although the changes are relatively minor they relate to a major policy issue.

Summary:

Several areas where modifications to the Part 20 rule in SECY-88-315 and SECY-89-267 are desirable or needed have been identified. Enclosure A to this paper provides suggested text for these changes. Approval of this text or suggested changes can be noted in the Staff Requirement Memorandum (SRM) on SECY-88-315 and SECY-89-267. Other suggested changes where major new text was not required (e.g., word deletions or insertions) will be implemented as directed in the SRM. As per standard procedure, a marked-up copy of the final statement and rule which shows all of the changes from the version in SECY-88-315 will be provided with the final Federal Register notice to the Office of the Secretary.

None of these changes is believed to generate an impact on either the NRC, the environment, or on licensed activities that would warrant any modification to the MRC implementation resource estimates, the environmental assessment, or the regulatory analysis provided in SECY-88-315.

The most significant change is permitting the use of "black" in addition to "magenta" or "purple" on a yellow background for the radiation warning symbol on signs, placards, and labels.

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NOTE: TO BE MADE PUBLICLY AVAILABLE WHEN THE FINAL SRM IS MADE AVAILABLE

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The change of the radiation warning symbol color is a permissive rather than a required change, so that there is no requirement for licensees to change and no significant economic impact associated with this change. The rationale for this addition is in the suggested text for modifying the preamble (See item # 1 in Enclosure A).

James M. Taylor executive Director for Operations

Enclosure A : Recommended Changes

SECY NOTE:

In the absence of instructions to the contrary, SECY will notify the staff through the SRM on Part 20 (SECY-88-315 and SECY-89-267), that the Commission, by negative consent, assents to the action proposed in this paper. The comments on the draft SRM on SECY-88-315 and SECY-89-267 will be due by COB Monday, July 16, 1990.

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ENCLOSURE A

RECOMMENDED CHANGES

[Changed wording in brackets or underscored]

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

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

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

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

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

MODIFY THE RULE (Page 42 of Enclosure 4 to SECY-88-315) AS FOLLOWS: § 20.901 Caution signs.

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

RADIATION SYMBOL

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

Paragraphs(b) and (c) are unchanged.

2. DELETE INCORPORATION OF REFERENCE TO OSHA RESPIRATORY PROTECTION STANDARDS in § 20.704

The staff believes that this provision is similar in nature to the generic incorporation of EPA generally-applicable environmental standards and that the same type of arguments as raised by Commissioner Curtiss in his votesheet on that change provide sufficient justification for deleting this cross-reference to the OSHA standards.

STATEMENT: (Pages 63-64 of Enclosure 3 to SECY-88-315)

Under § 20.704 (page 63 of Enclosure 3 to SECY-88-315), "Final Rule" delete all but the first sentence.

RULE:

Under § 20.704 (page 41 of Enclosure 4 to SECY-88-315), delete paragraph (a) and remove paragraph designation from (b). Redesignate subparagraphs (1) and (2) under (b) to be (a) and (b).

3. REDESIGNATE APPLICABILITY OF EPA STANDARDS TO APPLY SOLELY TO 40 CFR Part 190 AND NOT A GENERIC ENDORSEMENT OF ANY EPA GENERALLY-APPLICABLE ENVIRONMENTAL RADIATION STANDARD

STATEMENT: No modification required.

RULE: In § 20.301(d) insert the words "in 40 CFR Part 190" between the first "standards" and "shall" to read:

"...a licensee subject to the provisions of EPA generallyapplicable environmental radiation standards in 40 CFR Part 190 shall comply with those standards,"

This returns to the wording in the proposed rule.

4. MODIFY § 20.906 TO CLARIFY "PACKAGE" SURVEY REQUIREMENT FOR SEALED SOURCES

Modify § 20.906 by inserting an exemption in a new paragraph (f) to remove the inadvertent requirement for well-loggers and radiographers having to perform smear tests on the transportation packages everytime they move their source to and from a work site. This requirement resulted from the removal in the proposed rule of exemptions in the current Part 20 that included exempting "special form [sealed] sources" from the package opening procedures. Staff does not believe that going back to the full exemption for sealed sources is desirable because of the possibility that a source can become dislodged from its shield or broken (in which case there may be a contamination as well as an external radiation problem). The proposed partial reinstatment does not require the contamination check as source breakage is more likely to be known if an event occurs in a licensee-owned or operated vehicle than in general commerce.

Note that the proposed change is a relaxation of the requirement in the proposed rule or in SECY-88-315, but is still more stringent than the present Part 20.

STATEMENT: (Pages 70-71 of Enclosure 3 to SECY-88-315)

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

Response: Experience in the shipment of thousands of packages each year has been very good. However, potential problems with leaking packages during transit warrant continued monitoring upon receipt to ensure that leaking packages are found and reported. Appropriate action can then be taken to determine the extent of contamination in transport vehicles and storage areas in order to limit the consequences and avoid recurrence. [However, an exemption from the contamination survey requirement has been provided for special form (sealed) sources that are being moved to and from work sites in licensee owned or operated vehicles. This partially restores a total exemption from the package surveys in the existing Part 20 (§ 20.205 (b)(iii)) for all special form sources. The Commission believes that restoring this exemption will not result in any additional hazard and notes that an external radiation survey of the source package is still required. The primary purpose of this external survey is to ensure that the source is still properly secured and shielded after transporting it.]

CHANGES TO RULE: (Page 46 of Enclosure 3 to SECY-88-315)

§ 20.906 Procedures for receiving and opening packages.

[(f) Licensees transferring special form sources in licensee-owned or licensee-operated vehicles to and from a work site are exempt from the contamination monitoring requirements of (b), but are not exempt from the survey requirement in (b) for measuring radiation levels which is required to ensure that the source is still properly lodged in its shield.]

5. MODIFY § 20.206 (Page 28 of Enclosure 4 to SECY-88-315) to conform more closely to the definition of "planned special exposures" by removing "in excess of" and replacing with "in addition to and accounted for separately from the doses received under § 20.201 ..."

The definition of "Planned Special Exposure" from § 20.3 (page 14 of Enclosure 4 to SECY-88-315) is:

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

STATEMENT: No Change

RULE:

§ 20.206 Planned special exposures

A licensee may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under § 20.201 provided that each of the following conditions is satisfied--

* * * * *

6. MODIFY § 20.1003 (a) (3) (i) by two additions in order to improve specificity and clarity:

STATEMENT: No change required.

RULE: (Pages 47-48 of Enclosure 4 to SECY-88-315)

§ 20.1003 Disposal by release into sanitary sewerage.

(a)

* * * * *

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

(i) The licensee shall determine the fraction of the limit in Table 3 of Appendix B represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide listed in Table 3 of Appendix B; and

* * * * *

7. MODIFY THE STATEMENT (Encl. 3 to SECY-88-315) page 73 for § 20.1003 to stress the prohibition against disposal of insoluble materials into sanitary sewer systems.

After "Response" add:

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 average monthly concentrations and the limits in § 20.1003 (a)(4) on the total activity released annually are met. The revised rule no longer permits the disposal of non-biological insoluble materials because of potential reconcentration of these materials in the sanitary sewer system, sewage treatment plants, and sewage sludge. Accordingly, there are no values listed in Table 3 of Appendix B for insoluble materials.

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

MODIFY THE STATEMENT OF CONSIDERATIONS TO ADD IN SECTION 11:

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

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

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

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

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

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

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 intake of radon, radium, polonium, thorium, uranium, and higher transuranic elements (e.g., plutonium).

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

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

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 nonleukemia (solid cancers) that are about three or four
times higher than the estimates in the 1980 BEIR-III
report. The BEIR V gives the following factors as the
principal reasons for this increase: (1) use of different
dose-response and risk projection models. (2) revised

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

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

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

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

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

1990 ICRP Recommendations

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

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

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

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

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

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

- (1) Establishment of "Below Regulatory Concern (BRC)"
 levels (related to de minimis levels and a negligible level of risk). [On June 27, 1990, the Commission announced the issuance of a policy statement on "Below Regulatory Concern," which was subsequently published in the Federal Register on July 3, 1990 (55 FR XXXXX). This policy statement sets forth the basis for future Commission actions regarding rulemaking and licensing actions related to the use of this concept.]
 - (2) Limits for decommissioning of nuclear facilities and for residual radioactive contamination. [This is being actively pursued by both the Commission staff which is developing criteria for residual contamination of soils and structures (as one aspect of the implementation of the Below Regulatory Concern Policy) and as participating 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 small size, produce high localized doses to skin.) [The NRC notes that the National Council on Radiation Protection and Measurements (NCRP) has recently issued new recommendations regarding "hot particles" in NCRP Report No. 106, "Limit for Exposure to 'Hot Particles' On the Skin," December 31, 1989. A modified NRC enforcement policy statement with regard to the "hot particle issue" is in the final stages of NRC review and an Advance Notice of Proposed Rulemaking on this subject will be issued later in 1990].
- (4) Modification of NRC incident notification requirements. [A modification of the incident notification requirements was issued for public comment on May 14, 1990 (55 FR 19890).]
- [(5) Publication of a separate rule for large irradiators. A new Part 36 is undergoing Commission review prior to publication as a proposed rule for public comment. The detailed requirements for irradiators presently in the revised Part 20 (§ 20.603) will eventually be deleted in favor of the provisions incorporated in the new Part 36.]

10. ADD SECTION TO RULE REGARDING MODIFICATION OF TECHNICAL SPECIFICATIONS

[§ 20.8 Modifications of License Conditions and Technical Specifications

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

Renumber existing § 20.8 as § 20.9.