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NLS-139
H. Peterson

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

OFFICE OF THE
SECRETARY

November 14, 1989

MEMORANDUM FOR: Michael Weber
Maria Lopez-Otin
Gail Marcus
Susan Bilhorn
Janet Kotra

FROM: Jack Guttmann
Technical Coordinator, SECY

SUBJECT: COMMISSIONERS' ASSISTANTS MEETING - SECY-89-267 --- 10 CFR PART 20 REVISION: SUPPLEMENTAL INFORMATION

A Commissioners' Assistants meeting with staff on SECY-89-267 has been scheduled for 10:30 a.m., Monday, November 20, 1989, in the 18th floor Executive Conference Room, One White Flint North.

The purpose of this meeting is for staff to respond to questions from the Technical Assistants, some of which are attached.

Representing the staff will be:

- o Hal Peterson
- o Others

Attachment:
As Stated

cc: W. Parler (OGC - 15B-18)
H. Thompson (DEDO - 17G-21, X-21713)
J. Blaha (EDO - 17G-21, X-21703)
L. Roche (EDO - 17G-21, X-21729)
H. Peterson (NLS-139, X-23640)

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QUESTIONS ON DRAFT FINAL PART 20
FOR ASSISTANTS' MEETING ON NOVEMBER 20, 1989

1. What is the current status of the BEIR V report and the new ICRP guidance? How much are these efforts expected to alter current risk coefficients and approaches to radiation protection? Any impacts on Quality Factors for neutrons, beta particles, and high gamma? Any progress towards consensus on the 1 rem/yr cumulative dose limit? How would these developments impact Part 20?

2. What is the current status of efforts to develop and implement regulatory guides and alter existing guidance to support the new Part 20? What is the estimated level of resources for this effort? What guidance is being developed to describe acceptable ALARA programs for non-reactor facilities? Will these guides be in place by the time that Part 20 becomes effective?

3. When should Part 20 become effective [Assume that final Commission action is complete by 1/1/90]? Should licensees be allowed to phase into new Part 20 before it becomes effective?

4. What is the justification for decreasing the dose limit to the general public from 500 to 100 mr/yr? Is this reduction consistent with other recent NRC actions (e.g., BRC policy, Safety Goal)? Is this reduction expected to have a significant effect on licensed facilities, given that existing effluent standards (e.g., 40 CFR Part 190) are more stringent?

5. Should Part 20 require compliance with committed effective dose equivalent limits for design intakes of radionuclides, but only cite licensees for overexposures when indicated by actual uptakes (based on bioassay and measured whole-body doses)?

6. Does the elimination of the quarterly dose limits provide adequate protection for an unknown embryo/fetus? Is the admonition to licensees adequate? How does this compare with NCRP's recommendation that exposure of the embryo/fetus not exceed 50 mr/month [NCRP 91, pg. 30]?

7. What is the status of the national dose registery?

8. What is the status of NRC's assessment of radionuclide discharges to sewers? What is readily "dispersible biological material?" Are there limits imposed on such material? What is the health and safety basis for these limits? Is the same basis used in exempting human excreta?

9. Under what conditions would an individual receive a planned special exposure? Would adequate time be available to acquire exposure history information prior to approving the special exposure or should Part 20 require that employers acquire this information in advance for any employee that could reasonably receive a planned special exposure?

10. Is the reduction factor of 2 adequate to protect children and adolescents under the dose limits in Part 20? Do available age-dependent metabolic data confirm the adequacy of this reduction?

11. What is the basis for the chemical toxicity limit for uranium? How do the Appendix B limits for uranium compare with limits being established by EPA (e.g., 30 pCi/l in groundwater established in 40 CFR Part 192)? Is there a difference between NRC and EPA approaches to assessing risk associated with uranium in waterborne effluents?

12. Is the exemption to the non-stochastic ALI's provided in Appendix B (pg. 10 of Enclosure 5) viable? Please explain and provide an example.

13. Why is the NRC promulgating amendments to Part 2 that have not been noticed for public comment? Should these amendments be proposed (rather than published final) along with final Part 20?

14. How should the Commission address the requirements of 50.109 for final Part 20? Which requirements in final Part 20 "redefine adequate protection" as provided under 50.109(a)(4)(iii)? Which requirements are inherently linked with and necessary to implement the substantive requirements that redefine adequate protection? What other types of requirements are being promulgated?

NOT FOR RELEASE

RESPONSES TO QUESTIONS ON DRAFT FINAL PART 20
FOR COMMISSIONER'S ASSISTANTS MEETING ON NOVEMBER 20, 1989

1. Q. What is the current status of the BEIR V report and the new ICRP guidance? How much are these efforts expected to alter current risk coefficients and approaches to radiation protection? Any impacts on Quality Factors for neutrons, beta particles, and high [energy] gamma? Any progress towards consensus on the 1 rem/yr cumulative dose limit? How would these developments impact Part 20?

   A. The BEIR V Report is expected late this Fall (it was supposed to be out by now). The ICRP document is still in an initial draft stage. It is clear that the BEIR V (and UNSCEAR 88) reports indicate higher risks from low-LET (beta-gamma) radiation than previous evaluations of the risk. These changes are due to three factors: (1) evidence that supports a relative risk model for most solid tumors [this means that the expected cancer incidence becomes age-dependent and increases compared to the straight-line extrapolation of the "absolute risk model"], (2) more data has been accumulated on the Hiroshima-Nagasaki victims which indicates continuing elevated cancer risks for longer periods of time, and (3) revised dosimetry of the Hiroshima-Nagasaki exposures results in a higher risk assigned to the low-LET radiation.

   The higher risk estimates have led to the ICRP consideration of a lower long-term limit, but unlike the NCRP recommendation in NCRP 91 for a 1 rem x age cumulative worker dose limit, the ICRP is considering a shorter term cumulative limit of 10 rems over any 5 year period with a 5 rem in any one year cap. Staff discussions have taken place with a member of the ICRP (and the Chairman of NCRP Committee that produced NCRP 91) that cumulative dose limits are impractical to implement from a regulatory point of view and that the consequence of the ICRP action would likely be a 2 rem per year limit. The ICRP is retaining the 100 millirem per year limit for the "average" long-term exposure of any member of the public. This is implemented in the revised Part 20 as a straight 100 millirem per year dose limit.

   Based upon preliminary information it does not appear that any of the Quality Factors will depart from ICRP 26 values. However, the ICRP continues to use a Q of 20 for high-energy neutrons (greater than 0.5 MeV) whereas the revised Part 20 has not adopted this value (as discussed in the Statement of Considerations for § 20.4).

   As noted above, the ICRP does not appear willing to go along with the NRCP's 1 x age limit.

1. A. (cont) These revisions would affect the revised Part 20 only to the extent that the Commission chooses to adopt them. Most such revisions would be significant enough to warrant another round of public comment. Given the built-in delays for internal NRC reviews and office concurrence and the legally-mandated [Administative Procedures Act] external review process, this could add another two years to the issuance date.

2. Q. What is the current status of effort to develop and implement regulatory guides and alter existing guidance to support the new Part 20? What is the estimated level of resources for this effort? What guidance is being developed to describe acceptable ALARA programs for non-reactor facilities? Will these guides be in place by the time that Part 20 becomes effective?

A. The effort to develop the necessary guides is already underway. A contract has been signed to provide technical support to the staff First priority is on developing the nine new guides that have been identified (Enclosure 14 of SECY-88-315 plus one additional guide on reactor high/very high radiation areas). Second priority is on major revisions to existing guides. Last priority is on minor editorial revisions to change the Part 20 citations where appropriate. The latter will be handled by errata sheets for each of the ten guide divisions that instruct the reader to make pen and ink changes rather than having NRC republish each of these guides. The number of guides in each category is listed in Enclosure 14 to SECY-88-315.

The guidance on development of ALARA programs for materials licensees (excluding fuel cycle facilities) will be in two appendices to existing license application guides (R.G. 10.6 for sealed sources and radiography and R.G. 10.8 for medical licensees and unsealed sources) rather than a single new guide as indicated in Enclosure 14 to SECY-88-315.

The current schedule is to have the draft versions of the new guides available for issuance for public comment by August 1990. The final guides should be available by the following year, a few months ahead of the latest staff recommended implementation date (see Q #3).

3. Q. When should Part 20 become effective [Assume that final Commission action is complete by 1/1/90? Should licensees be allowed to phase into new Part 20 before it becomes effective?

A. The staff has revised its recommended implementation date to January 1, 1992 instead of January 1, 1991 to account for the delay in issuing Part 20 in final form (SECY-89-267, page 8, recommendation No. 3). The implementation is envisioned as a step function and does not permit a gradual phase-in. (See recommended addition to Statement of Considerations at page 1 of Enclosure 3 of SECY-89-267, August 29, 1989.) The elimination of a gradual phase-in was done to ensure uniformity in recorded and reported doses between different licensees by eliminating the possibility that there would be two different systems in place at the sane time.

4. Q. What is the justification for decreasing the dose limit to the general public from 500 to 100 mr/yr? Is this reduction consistent with other recent NRC actions (e.g., BRC policy, Safety Goal)? Is this reduction expected to have a significant effect on licensed facilities, given that existing effluent standards (e.g., 40 CFR Part 190) are more stringent?

A. The primary justification for reducing the public dose limits are the 1977 recommendations of the ICRP and the 1987 recommendations of the NCRP both of which recommend a 100 millirem per year long-term average dose limit from all sources and a 500 millirem cap in any one year. Part 20 applies the 100 millirem number per year rather than an average (see A # 1) and only to the dose from a licensed operation. (We believe that it is not practical to require our licensees to evaluate public dose contributions from other unregulated sources.)

The Part 20 limits provide an upper bound for health protection, the BRC (exemption) policy provides a lower bound for regulatory control so the two sets of limits are at opposite ends of the allowable operating range. The public dose limit is related to the BRC policy only in that the proposed exemption policy of 10 millirem maximum dose is an appropriately small faction of this dose limit.

The safety goal for acute fatalities is not comparable to the potential delayed effects from normal releases; the latent effects would be similar. Numerically, the safety goal of 0.1% of the fatal cancer incidence works out to be:

$$0.001 \times (198 \times 10^{-5} \text{ per year cancer fatality probability}) =$$

$$1.98 \times 10^{-6} \text{ per year.}$$

The Part 20 limit of 0.1 rem(100 millirem) per year has an estimated risk of:

$$0.1 \text{ rem/year} \times (5 \times 10^{-4} \text{ cancers/rem}) = 5 \times 10^{-5}.$$

One reason why there is an apparent difference between the two values is that the safety goal refers to the <u>average dose</u> to the 50-mile population whereas the Part 20 limit applies to the <u>maximum dose</u> to the nearest individual. The ratio of the 50-mile average dose to the maximum dose is typically 2×10^{-3} to 2×10^{-2}. Applying these values to the 0.1 rem maximum individual risk of 5×10^{-5} gives population averaged values of:

1×10^{-7} to 1×10^{-6} compared to the safety goal of 2×10^{-6} so that the values are more comparable than appears from their numerical magnitude.

4. Q. (Cont) The reduction in public dose limits is not expected to have any significant effect on licensees. Most facilities operate well below 100 millirem per year due to (1) the need to demonstrate compliance usually entails the use of lower internal "administrative limits"; (2) the application of the ALARA philosophy (such as Appendix I to 10 CFR Part 50); and (3) other standards (such as 40 CFR Part 190) that have lower values.

Two areas where the 100 millirem per year limit might have an impact are the shielding for irradiators and cobalt teletherapy rooms which were designed to limit doses in unrestricted areas to 500 millirem per year and uranium milling licensees where radon doses at a few sites may exceed the 100 millirem public limit (See SECY-89-267 Issue # 2.) There is a provision for licensees to come in for temporary relief (use of a 500 millirem limit) while studies of actual usage and occupancy are made to see if additional shielding is required.

5. Q. Should Part 20 require compliance with committed effective dose equivalent limits for design intakes of radionuclides, but only cite licensees for overexposures when indicated by actual uptakes (based upon bioassay and measured whole-body doses)?

A. Part 20 permits bioassay and whole-body counts (excretion and retention measurements) to be used in assessing doses for the purpose of compliance [Despite industry comments to the contrary. See § 20.204 (c).] However, the dose in all cases (from air sampling, excretion, or retention measurements) is evaluated using a dose factor that represents the committed future dose that will occur. For a discussion of the committed dose versus the annual dose see Enclosures 8 and 9 to SECY-88-315 and issue 1 in SECY-89-267.

6. Q. Does elimination of the quarterly dose limits provide adequate protection for an unknown embryo/fetus? Is the admonition to licensees adequate? How does this compare with NCRP's recommendation that exposure of the embryo/fetus not exceed 50 mr/month [NCRP 91 page 30]?

With the 5 rem/yr TEDE limit, the licensee is likely to establish quarterly "reference level " that are less than 1.25 rem per quarter. This would be less than the 1.25 rem per quarter limit and lower than the higher 3 rem/quarter limit. It is unlikely (but possible) that the fetus would be undetected for more than two months.

Staff believes that the admonition to licensees is sufficient given the legal restrictions on protection of fertile women. The NRC regulation in §20.208 has a requirement that the dose to the embryo/fetus be distributed fairly uniformly over the period of pregnancy. This would give an average dose of about

500 millirem/9 months $\approx$ 55 millirem per month.

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6. Q. (Cont) For all intent and purpose this is the same as the NCRP's 50 millirem/month. Use of the NCRP approach would mean a licensee that gave a embryo/fetus 49 millirem in one month and 51 millirem the next would have to be cited.

7. Q. What is the status of the national dose registry?

A. As noted in an information memorandum to the Commission dated August 23, 1989, the staff is waiting Commission approval of the revised Part 20. The new Part 20 reporting requirements would acquire data for the most highly exposed groups (those covered by the present §§ 20.407 and 20.408) including power reactor workers. The staff is currently working with representatives of licensed facilities and the National Cancer Institute to develop revised Forms 4 and 5 to be used for recordkeeping.

8. Q. What is the status of NRC's assessment of radionuclide discharges to sewers? What is readily "dispersible biological material?" Are there limits imposed on such material? What is the health and safety basis for these limits? Is the same basis used in exempting human excreta?

A. As of September 1989, the contractor had provided a draft report describing a dozen conservative scenarios characterizing potential exposures to radioactive materials that enter the sewer system. The review of this draft and the data acquistion phase of the project are ongoing RES staff tasks.

"Readily dispersible biological material" is essentially ground organic materials (e.g. rats). The original Part 20 sewer limits applied to materials that are "soluble or readily dispersible." As a result of several contamination incidents with cobalt-60 and americium-241 flakes, the proposed rule took out the "readily dispersible." Comments on the proposed rule noted that the preferred method of disposing of dead radioactive laboratory animals was to grind them up (in a device similar to a kitchen sink disposal) and that elimination of this option would be costly and could create a public health problem. Consequently, the "readily dispersible biological material" was added to permit this disposal but block the disposal of metallic flakes. Other than the Part 20 disposal restrictions there does not appear to be a restriction on such disposal. The basis for the limits in Table 3 of Appendix B is a TEDE of 0.5 rem. This is equal to the the upper bound for the public exposure and is a factor of 10 lower than the present Part 20 which uses the occupational concentration limits (5 rem/year whole body dose). In both cases it is believed that it would be highly unlikely that anyone would be exposed to such doses because the concentration limits are applied at the point of release to the sewer system and not at the point of water consumption. The new Part 20 restricts "sanitary sewers" to public sewers where dilution by wastewater, ground runoff and other sewers will occur.

8. A. (Cont) Human excreta are exempted because of the presence of other health hazards associated with the assay and storage of human faeces, not radiological conditions.

9. Q. Under what conditions would an individual receive a planned special exposure? Would adequate time be available to acquire exposure history information prior to approving the special exposure or should Part 20 require that employers acquire this information in advance for any employee that could reasonably receive a planned special exposure?

A. The guide detailing the conditions for receiving a planned special exposure (PSE) is under development. However, some of the conditions that could warrant a PSE are:

1. The necessity of performing a high-dose operation where the set-up conditions result in more dose to two workers than would be received by one worker.

2. The necessity for using a highly skilled worker (e.g. a pipefitter) who is near the dose limit

3. The need to permit continued employment of a worker who has been exposed above 5 rem.

It is envisioned that any licensee (primarily reactors) that intended to use PSE's would acquire the records beforehand. Since it might require up to 30 days to acquire the necessary records, it is unlikely that there would be enough time to acquire them at the time a PSE is being planned.

10. Q. Is the reduction factor of 2 [in the effluent release limits] adequate to protect children and adolescents under the dose limits in Part 20? Do available age-dependent metabolic data confirm the adequacy of this reduction?

A. We believe that the factor of two is adequate because the major health concern with radition exposure is the total lifetime exposure, not what the dose in one particular year is. For the protection of the public, the ICRP recommended limit is 0.1 rem per year as a lifetime average with a 0.5 rem limit for any one year. The revised Part 20 is more restrictive, using 0.1 rem as the limit for each year.

Another factor supporting the adequacy of this factor is that the major age-dependence occurs not in uptake but in organ size. With the application of the effective (risk-weighted) dose, the importance of many of the organs where there was an appreciable age difference (e.g., thyroid where the organ mass varies by an order of magnitude between an adult and a one-year-old child) is negated by a small risk factor (small w_T).

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11. Q. What is the basis for the chemical toxicity limit for uranium? How do the Appendix B limits for uranium compare with limits being established by EPA (e.g., 30 pCi/l in groundwater established in 40 CFR Part 192)? Is there a difference between NRC and EPA approaches to assessing risk associated with uranium in waterborne effluents?

A. The primary basis for the chemical toxicity for nantural and low-enrichment uranium is the toxic effects typical from heavy metals on the kidneys (nephretic effects).

Appendix B of the revised Part 20 contains a concentration limit for for natural uranium in liquid effluents of 3×10^{-7} uCi/ml. This works out to:

$$3 \times 10^{-7} \text{ uCi/ml } (10^3 \text{ ml/L})(10^6 \text{ pCi/uCi}) = 300 \text{ pCi/L},$$

a factor of 10 higher than the EPA 30 pCi/L value.

The EPA in their September 30, 1986, Federal Register notice (51 FR 34836) on drinking water maximum contaminant levels (MCL's) that form the basis for the groundwater protection levels showed the following calculation (51 FR 34843):

$$\frac{\text{(1 mg U/kg/day safe level for animals)(0.01 uptake by animals)(70 kg)}}{\text{(safety factor)(2 Liter/day water intake)(0.05 uptake by humans)}}$$

= 7 milligrams per liter/safety factor.

The EPA uses a specific activity factor of 40 pCi U/60 micrograms U; therefore, the estimated safe level for humans would be:

7 mg/L (1,000 ug/mg)(40 pCi/60 ug) = 4,666 pCi/L.

The difference between the magnitudes of NRC value of 300 pCi/L and the EPA's 30 pCi/L is that the NRC value contains a safety factor of about 10 (actually 4,666/300 or 15) and EPA states (51 FR 34836) that it uses a safety factor of 100 below the 4,700 pCi/L calculated from the animal data. Also the NRC value is an effluent limit whereas the EPA drinking water limit is applied to the tap side of a public drinking water supply and to the concentration in an aquifer.

12. Q. Is the exemption to the non-stochastic ALI's provided in Appendix B (page 10 of Enclosure 5) viable? Please explain and provide an example.

A. Yes, it is viable, but we don't expect it to be widely applied. For example, for iodine-131, the non-stochastic ALI (50 uCi) is limiting and the stochastic ALI is (200 uCi) (page 59 of Enclosure 5 to SECY-88-315). For estimating the committed effective dose equivalent from the thryoid for summation with those of other organs, the higher stochastic value may be used because it represents similar health consequences. For protecting the thyroid, however, the committed dose equivalent to the thyroid itself must also be assessed using the more limiting non-stochastic ALI value of 50 uCi = 50 rem.

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13. Q. Why is the NRC promulgating amendments to Part 2 that have not been noticed for public comment? Should these amendments be proposed (rather than published final) along with the final Part 20?

A. These amendments have to be published for comment rather than in final form as they represent substantive changes in the enforcement policy. However, the proposed nature of these changes is not discernible from reading the conforming amendments (Enclosure 5 to SECY-88-315) alone. It is clearly brought out in the accompanying statement of considerations part of the Federal Register notice (See page 1 "DATES" and page 100, Section VII. of Enclosure 3 to SECY-88-315.)

14. Q. How should the Commission address the requirements of 50.109 for final Part 20? Which requirements in the final Part 20 "redefine adequate protection" as provided under 50.109(a)(4)(iii)? Which requirements are inherently linked to and necessary to implement the substantive requirements that redefine adequate protection? What other types of requirements are being promulgated?

A. This topic will be addressed by OGC in the December 6, 1989 meeting.