April 12, 2002

COMMISSION VOTING RECORD

DECISION ITEM: SECY-01-0148

TITLE: PROCESSES FOR REVISION OF 10 CFR PART 20 REGARDING ADOPTION OF ICRP RECOMMENDATIONS ON OCCUPATIONAL DOSE LIMITS AND DOSIMETRIC MODELS AND PARAMETERS

The Commission (with Chairman Meserve and Commissioners Dicus, Diaz, and Merrifield agreeing) approved Option 3 (in part) of subject paper as recorded in the Staff Requirements Memorandum (SRM) of April 12, 2002. Commissioner McGaffigan approved Option 2c.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

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Annette L. Vietti-Cook
Secretary of the Commission

Attachments:
1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
EDO
PDR

VOTING SUMMARY - SECY-01-0148

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE	
CHRM. MESERVE	X				X		11/13/01
COMR. DICUS	X	X			X		10/27/01
COMR. DIAZ	X	X			X		11/7/01
COMR. McGAFFIGAN		X			X		4/8/02
COMR. MERRIFIELD	X				X		11/5/01

COMMENT RESOLUTION

In their vote sheets, Chairman Meserve and Commissioners Dicus, Diaz, and Merrifield approved the staff's recommendation (Option 3) in part, and provided some additional comments. Commissioner McGaffigan approved Option 2c. Subsequently, the comments of the Commission were incorporated into the guidance to staff as reflected in the SRM issued on April 12, 2002.

Commissioner Comments on SECY-01-0148

Chairman Meserve

SECY-01-0148 proposes three options for revising 10 CFR Part 20 to consider updated ICRP recommendations on occupational dose limits and dosimetric models and parameters. I approve the staff's recommendation (Option 3) in part.

I agree with the thoughtful vote of Commissioner Dicus to the effect that this is not the time to prepare for an imminent rulemaking. The fact that major revisions to update dosimetric methods and to reassess the health risk from low levels of radiation are underway and will be completed within the next several years shows that this is not the time to accommodate the soon-to-be-superceded ICRP 1991 recommendations. I also agree that, under the circumstances, there is little need to develop a communication plan or to forge ahead with the development of a technical information base (Items (i) and (iii) of Option 3). On the other hand, the staff should monitor the ongoing efforts and should continue to work with other Federal agencies on revisions to the Presidential Guidance (Items (ii) and (iv) of Option 3). In the meantime, staff should also continue to grant licensee requests to use the ICRP revised internal dosimetry models on a case-by-case basis.

Commissioner Dicus

After throughly reviewing the staff's advantages and disadvantages for potentially updating 10 CFR Part 20 to incorporate the most recent revisions recommended by the International Commission on Radiological Protection (ICRP), I agree with Option 3, in part, to not initiate a rulemaking at this time. However, for the reasons I have outlined below, I also disapprove, in part, the staff's proposed Option 3 which I believe would also require significant resources to complete, and instead propose an alternative modification to Option 3.

First, I would note that in the responses to my questions of August 29, 2001, the staff correctly points out that in 1999, only 26 occupationally-exposed NRC-licensed workers (out of a total 129,951 monitored individuals) received an annual TEDE in excess of 20 mSv (2 rem). This figure represents a decrease from 1,422 in 1989 (of 109,990 monitored workers that year). In addition, the average measurable TEDE also decreased from (0.36 rem to 0.25 rem) for this same time period along with a 2½-fold decrease in collective dose. Although there are other changes that arose from ICRP 60 other than the recommendations for a limit on the effective dose received by an occupational worker of 20 mSv (2 rem) per year, averaged over 5 years so as to not exceed 100 mSv (10 rem) in 5 years, it is clearly evident that the 1991 revisions to 10 CFR Part 20, with the inclusion of the ALARA principle, were able to effectively reduce the occupational dose to workers, without the need for additional changes to the regulations.

The Commission continues to not only monitor the work of the ICRP, but also has allowed licensees, upon request and identified need, to adopt the most recent revisions of ICRP 60, 66 and 68-72 which contain updated models and newer biokinetic parameters for calculation of exposure from radioactive materials. In particular, I reference SECY-99-077, in which the Commission approved the staff's request to issue an exemption to an NRC licensee using the new internal dosimetry models as described in ICRP 68. The SRM to SECY-99-077 also allowed the staff to approve, on a case-by-case basis, the granting of other such exemptions,

when requested by licensees, for the use of the newer ICRP methodologies. The SRM goes on to state that only if a "significant number of exemption requests were received" (emphasis added) should the staff recommend to the Commission a consideration of rulemaking of 10 CFR Part 20. During the past three years, I note that only four such exemptions have been granted by the staff, reaffirming my position that relatively few NRC licensees have the type and quantity of radioactive materials on hand which would warrant a request to use the newer internal dosimetry models of the ICRP.

As noted in the most recent meeting of the ICRP in September 2001, the ICRP acknowledges that the methodology it recommended in ICRP 60 covers many diverse topics, resulting in an overall system, which while very comprehensive, is also very complex. In order to resolve many of the more difficult issues presented by these most recent recommendations, the ICRP has initiated a new set of initiatives which they believe will be a genuine attempt to simplify the existing system of radiation protection to one that is more coherent and more easily explainable. The ICRP revised recommendations are planned to be completed in the next 3 to 5 years. This coincides well with the Radiation Effects Research Foundation's (RERF) revisions to the DS86 dosimetry system that was used in the health assessments of the A-Bomb survivors as well as the National Research Council's re-assessment of the health risks associated with exposures to low-levels of ionizing radiation (BEIR VII) which are expected to be completed within the next 2 to 3 years. I believe that these international and national reassessments must be completed before the NRC begins a path forward in an outreach program for potentially revising 10 CFR Part 20.

In addition, one cornerstone of the U.S. Federal Radiation Protection System, the Presidential Radiation Protection Guidance for Federal agencies, is now in the process of being revised and only last week was routed for interagency review. As the staff points out, this will be one of the items of discussion at the next meeting of the Federal Guidance Subcommittee of the Interagency Steering Committee on Radiation Standards (ISCORS). Because this Federal guidance (issued in 1960 and 1961) would eliminate the 5 mSv (500 millirem) annual public dose limit, along with reference to severely outdated dosimetry methodology (i.e., ICRP 2), I believe that it is more important to use our limited staff resources on finalizing this revision to the Federal Guidance, rather than to initiate a communication plan [Item (i) of Option 3 in SECY-01-0148] to gather views on the need for, and implications of, proposed changes to 10 CFR Part 20. As stated in SECY-01-0148 (Option 3, Item ii), staff is already spending resources on interagency coordination of this, as well as many other radiation protection issues, including the development of a White Paper which would analyze the economic and regulatory implication regarding the adoption of ICRP 60/66/68 (see memorandum dated October 11, 2001 from John Craig, OEDO, to Commissioner Assistants). Once the Commission is able to review this interagency White Paper, which may take 1 to 2 years to develop, I believe that the Commission will be in a much better position to provide the staff guidance for a path forward, with the added benefit of also having additional finalized technical information at hand, such as the RERF and BEIR VII studies.

Because of all these ongoing efforts, and the fact that any proposed change to the current regulations would likely: (1) provide little to no added safety benefit to the general public (i.e., the doses received would most likely not be lower with any change in regulation); (2) be immediately outdated with newer ICRP revisions which are planned to be presented in the near term (i.e., 5-years); and (3) be extremely costly and time-consuming for both Federal and State agencies, as well as licensees; it is my view that the NRC should not forge ahead with a communication plan [item (1) of Option 3 in SECY-01-0148] or the development of a technical

information base [item (iv) of Option 3], but wait until the recommendations of these international bodies converge in the next three to five years. Knowledge and uncertainty about radiation health effects are not exclusively the domains of any individual country and radiation health effects is an international science. Once any final recommendations from these scientific bodies have been made available for review, and if, the NRC decides to revise its regulations, we can then consider all the new and updated information provided -- not only from the ICRP, but from RERF, BEIR VII, and from other Federal agencies via the White Paper on economic and regulatory implications. With the plethora of new scientific information available to all of us in the near term, I believe it is advisable to obtain all the facts and information that we can before a decision is made to proceed with any proposed communications plan for *possible* rulemaking changes to 10 CFR Part 20.

Commissioner Diaz

I approve staff's Option 3, in part, to "not conduct a rulemaking at this time, but initiate a pro-active effort to elicit a better understanding of significant issue and concerns." I see no advantage to conducting a rulemaking to revise Part 20 to either incorporate the recommendations in ICRP Publication 60 or the ICRP dosimetric models and related parameters in ICRP Publications 66 and 68-72. I strongly believe that the agency should not expend resources on rulemakings that would not result in improved protection of public health and safety. It makes much more sense to evaluate the need for revising Part 20 when we have the benefit of the outcomes of the multiple national and international activities underway or planned in the radiation protection area, including those outlined in the SECY. Any future evaluation should then very carefully consider whether the outcomes or recommendations are in the nation's best interest, i.e., adoption or implementation would improve protection of the public from NRC-licensed activities. In the meantime, I continue to support the SRM on SECY-99-077NRC which directed staff to approve, on a case-by-case basis, the limited number of exemption requests that allow licensees to use the dosimetric models in ICRP reports.

Regarding the specific components of Option 3, I agree with Items (ii) and (iv) so that NRC is prepared to evaluate any new information in a timely manner. However, I disapprove Items (i) and (iii) and agree with Commissioners Merrifield and Dicus that, at this time, it is premature for staff to develop a communication plan or to begin development of software and staff expertise on current ICRP recommendations.

Commissioner McGaffigan

I fundamentally disagree with the staff and my colleagues on whether the Commission should move to incorporate into Part 20 the ICRP 60 recommendations on occupational dose limits and the ICRP dosimetric models and related parameters in ICRP 60 and later publications.

I proceed from a different starting point, namely that literally all other nations with significant commercial nuclear programs have adopted ICRP 60's recommendations. Indeed, at the April 1999 first review conference of the parties to the Convention on Nuclear Safety, the summary report stated: "The Radiation Protection System recommended in ICRP 60 is already applied or is planned to be applied by all countries." The United States was not represented at that conference because of delays in the Senate advice and consent process, or there would have had to have been an exception to that statement.

In my view, when the United States is an outlier among nuclear nations, as we were until recently on the use of potassium iodide as a supplementary protective action in radiological emergencies, we should take action to remedy the situation unless we have very good reasons not to.

The staff and my fellow Commissioners offer various reasons for not conforming to the international consensus on ICRP 60, which they find compelling and which I do not.

First, they argue that there are a lot of studies underway and things may change. I would note that there will always be more studies coming on the risks of radiation. I personally can not imagine that the results of these studies will be so compelling that all the other nations will raise their occupational dose limit from the ICRP 60 recommended 10 rem effective dose equivalent over 5 years and no more than 5 rem in any one year. According to ICRP 60, the estimate of annual risk of fatal cancer for workers is 4x10-4/rem. At our current Part 20 occupational dose limit of 5 rem/year, that equates to a 2x10-3 risk of fatal cancer per year for a worker at the limit. Over a 30 year career, receiving 5 rem/year would equate to a six percent additional risk of fatal cancer. I do not believe that we have many occupations in our society where such a risk is acceptable. Moreover, the current 5 rem occupational limit was based on ICRP 26's lower fatal cancer risk estimate of 1.25x10-4/rem. So it was thought at the time to equate to a 6.25x10-4 risk of fatal cancer per year, three times lower than what we now believe to be true. To ensure that risk from occupational radiation exposure is limited to approximately the same level as was intended when the 5 rem limit was adopted, we need to adopt the ICRP 60 limit.

But that brings us to a second argument, that few if any workers are or will be exposed to more than 2 rem per year because of the as low as reasonably achievable (ALARA) principle which we have embraced in Part 20. I strongly support the ALARA principle, but according to NUREG-0713, volume 22, "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities 2000," 335 individuals employed by NRC licensees received more than 2 rem of exposure in that calendar year. Only 23 of these were at commercial nuclear power facilities and 16 more were at Haddam Neck, a reactor in decommissioning, where major work was done in 2000 to remove reactor vessel internals. Most of the exposures were among industrial radiographers, at fuel fabrication facilities and at medical facilities. These numbers exclude Agreement State licensees and all those whom we do not regulate, for example workers at accelerators which produce the isotopes, like fluorine 18, used in PET scans. So there could well be a thousand or more workers who would directly benefit from adopting the ICRP 60 occupational dose limit, and many thousands more who would benefit from incremental dose reductions as licensees adopt procedural limits that provide regulatory margin.

That brings us to a third line of argument, that since EPA has the lead for federal radiation guidance, we should wait for them to act. EPA has shown precisely zero interest in revising the 1987 Presidential guidance on occupational exposures to radiation. Moreover, I would note that the Commission did not wait for EPA to revise the 1960 and 1961 Presidential radiation protection guidance on public dose (500 millirem per year) when the Commission revised Part 20 in 1991. Instead the Commission adopted the 100 millirem per year limit recommended by the ICRP. If we had waited for EPA, we would still be waiting. DOE similarly did not wait for EPA to amend the public dose limit, nor did the Conference of Radiation Control Program Directors (CRCPD). It would obviously be better if EPA were to take the lead and mandate the ICRP 60 occupational dose limit. That would clearly override our backfit rule, although I personally believe that adopting the lower occupational limit is an adequate protection backfit. I

do find EPA's lack of leadership in this area puzzling and troubling. While EPA stoutly defends scientifically indefensible limits for drinking water maximum contaminant levels (MCLs), which are often orders of magnitude below those recommended by the World Health Organization, and while it propounds new rules, such as its Yucca Mountain standard, which incorporates these broken MCLs and results in an effective standard of 200 microrem per year (the iodine 129 MCL), EPA can not find the time to deal with an occupational dose limit more than four orders of magnitude greater.

What would I do? I would proceed with Option 2c and adopt both the dosimetric models and related parameters and the occupational dose limits, as recommended by ICRP in a revised Part 20. Not all of the parameters would need to be reflected in the rule itself. Future Commissions would have more flexibility to keep pace with future ICRP revisions if many of the details were left to guidance documents. ICRP 60 and its successor publications are slowly creeping into our regulatory framework in a haphazard way via exemptions, via the proposed Part 71 transportation rule which we have just issued for comment, and via other processes such as the EPA Federal Guidance Reports. We pride ourselves on being a scientific leader. Yet our Part 20 reflects outdated parameters, for example on organ weighting factors, which both NCRP and ICRP have recommended be revised. We can not embrace ICRP only on decommissioning standards or on repository standards. We should embrace all of ICRP's recommendations as the best comprehensive set of rules available. Just as we budget funds to keep apace of IAEA's transportation standards, we should budget funds to periodically keep apace of ICRP's recommendations.

Commissioner Merrifield

I approve the staff recommendation of option 3 provided in SECY-01-0148 (Processes for revising 10 CFR Part 20 regarding adoption of the current ICRP recommendations and models) with further modifications. I substantially concur with Commissioner Dicus' well written vote on this topic. I do not believe rulemaking is appropriate at this time nor do I believe it is appropriate, necessarily, to develop a formal communication plan specifically for revising 10 CFR Part 20 to incorporate the most recent ICRP guidelines. Rather there are several important issues that should be further developed before proceeding to a rulemaking plan or even a communication plan. I believe that staff should continue to develop a more complete technical information base to better understand the impacts of alternative changes to Part 20; and therefore, I support the staff developing an internal, living list of milestones that should be completed before proposing a wholesale revision to Part 20.

In general, I fully support the staff's efforts to develop and use, where appropriate, the latest advances in scientific thinking. However, 10 CFR Part 20 is a fairly complex regulation that has a significant impact on a majority of our licensees. Therefore, changes to Part 20 must be carefully considered before a decision is made to implement new recommendations or models. I would contend that the current ICRP recommendations and methodologies are still under development for the reasons clearly outlined in Commissioner Dicus' vote. I believe that over the next two to five years, significant developments will occur in the area of radiation protection (i.e., potential revisions to the dosimetry system that was used in the health assessments of the atomic bomb survivors in Japan, a reassessment of the biological effects of ionizing radiation (BEIR VII), and potential revisions to reduce the complexity of ICRP 60). Therefore, I do not believe it would be appropriate, at this time, to enter into rulemaking or even detailed public communication on the necessity to adopt the most current ICRP guidelines.

In addition, adopting the current ICRP recommendations and methodology would not result in a meaningful increase in safety. Our current regulations coupled with the underlying principal of maintaining radiation exposures as low as reasonably achievable have resulted in real average exposures being well below the recommended limits in ICRP 60. Absent a meaningful safety improvement, the only other reason to modify Part 20 to the current ICRP guidelines is if it would make a significant reduction in unnecessary regulatory burden on our licensees. Based on the information submitted to date, I am convinced that a major change to Part 20 would result in a net overall increase in the regulatory burden on our licensees, at least in the short term. I recognize that in certain instances implementing a limited portion of current ICRP guidelines for a specific licensee may represent a significant reduction in unnecessary regulatory burden while maintaining the appropriate level of safety. In those few instances, the staff is correctly using the exemption provisions in our regulations to determine if the relief should be granted. If there are a number of exemptions requested and granted for the same regulation, I would have no objections to the staff proposing limited rulemaking to address the one area of concern without adopting ICRP 60 or other current ICRP guidelines in full.

Finally, I agree with Commissioner Dicus that it is important for the staff to work with the Environmental Protection Agency in updating the Presidential Radiation Protection Guidance for Federal agencies. These Presidential documents are well out of date and their revision over the next few years would establish a good foundation for revising NRC's Part 20 regulations. I recognize that revising these Presidential documents is not under NRC control and may prove difficult. But I believe the staff should closely work with EPA to develop acceptable revisions in the near term.