POLICY ISSUE
NOTATION VOTE

August 2, 2001 SECY-01-0148

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

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

PURPOSE:

To inform the Commission of staff recommendations on a process for revising 10 CFR Part 20 regarding adoption of the occupational dose limits and dosimetric models and related parameters recommended by the International Commission on Radiological Protection (ICRP).

SUMMARY:

The last major revision of 10 CFR Part 20, published in the Federal Register in 1991, was based on ICRP Publications 26 (1977) and 30 (1978). Since that time, the ICRP has made major revisions to its basic radiation protection recommendations, and these were published in ICRP Publication 60 (1990). The ICRP 60 recommendations superceded those in ICRP Publication 26. In addition, ICRP published a series of reports, following publication of ICRP 60, that described revised internal dosimetry models, and these have superceded many, but not all of the models described in ICRP Publication 30 and earlier publications.

The Nuclear Regulatory Commission (NRC) has not formally adopted either the recommendations in ICRP 60, nor any of the revised internal dosimetry models. Some licensees have, however, requested exemption from certain sections of 10 CFR Part 20 that

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thereby allows them to use the ICRP revised internal dosimetry models in their licensed activities, and these requests have been granted on a case-by-case basis. Similar exemption applications have been made to implement some aspects of the ICRP recommendations in the conduct of external dose assessments, but none have been granted to date.

This paper discusses the merits and disadvantages of NRC's possible adoption of the recommendations in ICRP 60 and the dosimetry models in subsequent ICRP publications, either together or separately. That is, the recommendations in ICRP 60 may be adopted without adoption of the dosimetry models, the models may be adopted without the ICRP 60 recommendations, or both models and recommendations may be adopted. The paper suggests that there is currently little to be gained from adoption of the recommendations in ICRP 60, but that there are sound reasons for adopting the revised dosimetry models. The paper recommends that the agency develop the necessary tools and expertise in this area, possibly in cooperation with other Federal agencies, in preparation for eventual adoption of the revised internal dosimetry models in the near future. Although none of the Federal agencies have adopted the ICRP 60 recommendations to date, many, including the NRC, Department of Energy (DOE), and Environmental Protection Agency (EPA) are using the revised internal dosimetry models in some of their activities. Coordination amongst these agencies regarding ICRP recommendations and Federal guidance is being accomplished through the Interagency Steering Committee on Radiation Standards (ISCORS) and its subcommittees.

BACKGROUND:

The U.S. Nuclear Regulatory Commission's (NRC's) last major revision of the standards for protection against radiation, 10 CFR Part 20, was published in the Federal Register in May 1991. The purpose of that revision was to implement the 1987 Presidential Radiation Protection Guidance for Occupational Exposure (52 FR 2822, January, 27, 1987) and adopt the basic tenets of the ICRP system of dose limitation, as described in ICRP Publication No. 26 (1977).

Concurrent with the Part 20 revision, ICRP was developing a new series of recommendations that were published in 1991 as Publication 60. Because of the timing, NRC adopted only some of the ICRP 60 recommendations into Part 20. As stated in the Statements of Considerations (SOC) for the final rule, the Part 20 revision included the ICRP 60 recommendation to reduce the annual dose limit for members of the general public from 500 mrem (5 mSv) to 100 mrem (1 mSv). However, as also noted in the SOC, NRC did not adopt into Part 20 the new occupational dose limit recommendation of 2 rem/year (20 mSv) contained in ICRP 60. NRC believed that a reduction from 5 rem (50 mSv) was not urgently required because the average annual radiation dose to occupational workers in 1987 was already well below 2 rem (20 mSv) because of the practice of maintaining radiation exposures as low as is reasonably achievable.

The 1991 revision to Part 20 included the dosimetry methodology and parameters of ICRP Publication 30. Subsequent to issuance of Part 20 in 1991, ICRP issued publications 66 and 68-72 which contained updated models and related parameters for calculation of exposure from radioactive materials. Part 20 has not been revised to incorporate these more recent models and parameters.

DISCUSSION:

There has been discussion recently with regard to a potential need for revising Part 20. In considering whether, and how, to proceed, it is useful to consider several factors which might affect any decision-making. These factors include the rationale for considering revisions to Part 20, other national and international activities that are ongoing which could impact on the potential revisions, and the nature and extent of any rulemaking process that would take place to revise Part 20. These factors are discussed below and then three options are described with regard to how the Commission might proceed.

Rationale for considering potential revision to Part 20

Although the revised Part 20 has been used successfully for 10 years, there have been some issues that have arisen because of the differences between Part 20 and the dosimetry approaches and occupational limits reflected in ICRP Publications 60, 66, and 68-72. These issues include:

1) licensee requests to use different dosimetric methods in both external and internal dose assessments. Currently, such requests must be considered on a case-specific basis as exemptions. With regard to external exposures, there has been a request from a group of power reactor licensees for exemptions from Part 20 methodology for assessing external dose. In addition, there have been fuel cycle and materials license amendments granted to use more recent ICRP methodology for internal dosimetry. On April 21, 1999 (SRM-SECY-99-077), the Commission approved the staff's granting of exemptions on a case-by-case basis based on the precedent set by the Commission's decision in the OSRAM, Inc. exemption request (SECY-99-077). Although the total number of such licensing cases to date has been limited, the staff has been receiving frequent informal contacts from both NRC and Agreement State licensees inquiring as to how to go about using the newer ICRP internal and external dosimetry methods in their licensing activities. It would be beneficial if NRC's regulatory process had more flexibility to handle such situations rather than having to rely on the exemption process.

2) enforcement issues in cases where licensees exceed, or potentially exceed, dose limits even though it is known that in some cases the Part 20 methods for assessing internal and external dose are overly conservative. In addition, the ICRP Publication 60 models are less limited, in terms of the ability to adjust input parameters to account for the physical properties of the radioactive aerosol.

3) the proposed Part 71 rulemaking includes a dose-based approach based on ICRP 66 and 68-72; and

4) general areas of non-alignment between the NRC and the international community, including the differences in occupational exposure limits. Questions have arisen as to if and when the U.S. would align certain of its exposure limits, as well as its dosimetric approaches, with other nations.

5) some Federal agencies are currently using the revised dosimetry models in some of their activities. For example, the EPA is using the risk coefficients listed in Federal Guidance Report 13, which were derived on the basis of the new ICRP models, in all risk assessments for activities conducted under Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), and DOE has approved the use of the new ICRP models at some of its operations. In both cases, the models are used without adoption or use of any part of the ICRP 60 recommendations.

To ameliorate this situation, the Commission could consider it appropriate to revise Part 20. A rulemaking of this nature would be significant and the Commission would have to consider various factors, both with regard to the rulemaking process itself and with regard to other activities ongoing both in the U.S. and in the international community, before proceeding.

Current National/International Activities in the Radiation Protection Arena

Four major efforts are underway, both in the U.S. and internationally, to update dosimetric methods and reassess the health risk from low levels of ionizing radiation. These are discussed briefly below; additional background materials regarding these activities are presented in Attachment 1.

1) Revision of the DS86 dosimetry system

The 1991 ICRP recommendations were partly based on the receipt of new information from the on-going health assessments of the A-bomb survivors in Japan and the adoption of a new dosimetry system for the A-bomb survivors [dosimetry system-1986 (DS86)]. However, it has been suggested that there are inadequacies in the DS86 dosimetry system. Preliminary investigation indicates that there are discrepancies between the DS86 calculation of neutron flux at certain distances from the bomb hypocenter and the measured values from materials activated by thermal neutrons. These discrepancies are most pronounced at distances of more than 1000 meters from the hypocenter, in Hiroshima, where most of the survivors in the Life Span Study are located.

In response to the concerns regarding DS86, the U.S. Department of Energy and the National Research Council's Committee on Dosimetry for the Radiation Effects Research Foundation (RERF) are coordinating and supervising a revision of DS86. The new dosimetry system, DS02, will incorporate revisions of both neutron and gamma source terms. A final RERF report containing a re-analysis of Japanese cancer morbidity and mortality data could be published in 2003.

2) Reassessment of health risk from ionizing radiation - BEIR VII

In September 1998, the National Research Council was awarded a 3-year grant to conduct a comprehensive reassessment of the health risk resulting from exposures to low levels of ionizing radiation. This reassessment (BEIR VII) will include a review of data that might affect the shape of the dose-response curve at low doses, in particular, evidence for thresholds in dose-response relationships and the influence of adaptive response and radiation hormesis on radiation dose-response.

In September 2000, U.S. Environmental Protection Agency requested a 2-year extension of the BEIR VII study to provide the BEIR VII committee with the opportunity to review the final DS02 report and reanalyze the Japanese health effects data, if necessary. Assuming both reports are completed on schedule, the final BEIR VII report should be published in late 2003.

3) Revision of ICRP Publication 60

The system of radiological protection set out in ICRP Publication 60 was developed over 30 years. ICRP has acknowledged that the current system is complex and difficult to explain and, consequently, is attempting to develop a new system that is more coherent and less confusing. A proposed system considers establishing protective action levels, i.e., levels of dose above which additional protective actions could be required. The protective action levels would replace both worker and public dose limits. The new controllable dose concept will be debated by the ICRP, as well as at the mid-term (2002) and full (2004) meetings of the International Radiation Protection Association. The ICRP would like to finalize its new recommendations before 2005.

4) Department of Energy (DOE) analyses

The DOE is adapting a computer code, originally developed by the United Kingdom's National Radiation Protection Board (NRPB) so that the code will conform to DOE's requirements for implementation of the latest bioassay models and methods recommended by ICRP. Such a code would also be needed by NRC and its licensees to implement these models on anything other than a very limited case-by-case basis involving those licensees with the technical capabilities necessary to implement these complex models without such support.

The Nature and Extent of a Part 20 rulemaking process

10 CFR Part 20 contains NRC's basic safety standards for protection of the public and workers against radiation, as well as appendices which contain radionuclide concentrations based on specific dosimetry methods. Typical rulemaking efforts at NRC involve a period of at least 18 months. Given the basic nature of the requirements in Part 20, a rulemaking revising Part 20 would need to include a substantial effort to obtain stakeholder input, including possibly an ANPR or an issues paper for comment, one or more stakeholder meetings, and a potentially large number of comment letters for resolution. In addition, there would be issues related to backfit requirements which were difficult to resolve in the 1991 revision to Part 20. Thus, it is anticipated that the rulemaking process (including the ANPR, rulemaking plan, and stakeholder meeting process, as well as the proposed and final rule process) for revising Part 20 would require both significant resources and an extended time frame of 3 or more years to complete.

Options for proceeding

Based on the above, the staff has developed and evaluated the options listed below.

Option 1 - No action; maintain status quo. In this option, NRC would not conduct a rulemaking to revise Part 20 at this time, and would instead defer any effort in this area to wait for more clarity in models and recommendations at some later time, probably after completion of the DS02, BEIR VII, and DOE studies in late 2003. Under this option, NRC would retain the current occupational dose limits in Part 20. With regard to dosimetry methods, NRC would continue the current practice of review of exemption requests that allow licensees to use current ICRP dosimetric models in performing dose and risk assessments. With regard to dose-based rulemakings, NRC would review appropriate use of ICRP dosimetric models on a case-by-case basis.

Option 2 - Conduct a rulemaking to revise Part 20 at this time. This option could take one of the following approaches:

Option 2a - Revise Part 20 to delete sections that are used to assess radiation exposure and place them in Regulatory Guidance documents, however, do not formally adopt revised dosimetric models and related parameters into Part 20 and make no change in Part 20 regarding the occupational dose limits.

Option 2b - Revise Part 20 to formally adopt the newer dosimetric models and related parameters, and issue guidance on the use of these models, but do not change the occupational dose limits in Part 20.

Option 2c - Revise Part 20 to adopt both the dosimetric models and related parameters and the occupational dose limits, as recommended by ICRP, and issue guidance on the application of the ICRP recommendations and use of the new models.

Option 3 - Do not conduct rulemaking at this time, but initiate a pro-active effort to elicit a better understanding of significant issues and concerns. This option would not involve the extensive resource effort involved in a rulemaking under Option 2, but it would begin a process to put NRC in a better position to react to completion of the DS02, BEIR VII, and DOE studies in 2003 than the status quo approach of Option 1. It is anticipated that Option 3 would include the following:

i) Preparation of a communication plan (based on use of information exchange processes (meetings, conferences, etc.) already in place) to gather views on basic issues from stakeholders, including the States, and other scientific organizations, on broad issues such as the need for and implications of a change, resources involved in current and potential requirements, etc. Separate stakeholder meetings are not proposed at this time.

ii) Work with other Federal agencies to ensure a coherent approach within the U.S. in radiation protection standards and dosimetric models. To that end, the NRC will continue working with other Federal agencies through ISCORS to

coordinate adoption of the revised dosimetric models and possible revisions to the Presidential Guidance in this area.

iii) Development of a technical information base to provide a better understanding of analytical impacts of possible alternative changes to Part 20. As part of this effort, NRC could begin developing software and staff expertise necessary to implement current ICRP recommendations and models, as well as future guidance that ICRP may publish. Where feasible, this effort could incorporate, and/or augment, existing work in other organizations such as the DOE analyses and other work noted above.

iv) Monitoring the work of the ICRP as it develops its revision to ICRP Publication 60. This phase of Option 3 would be further clarified as the above activities proceed.

The staff notes that there have been several exemption requests concerning current methodology for calculating external deep-dose equivalents and will evaluate the need to revise Part 20 to address this issue separately from the ongoing efforts related to ICRP recommendations.

A detailed discussion of the options, including advantages and disadvantages of each, as well as a consideration of how the options would impact the four performance goals of the Strategic Plan in NUREG-1614, is contained in Attachment 2 and summarized here.

With regard to the Performance Goal of maintaining safety and protecting the environment, the staff does not believe that there are any safety issues which need to be addressed. Both the occupational and public doses are, with the exception of certain incidents, well within current dose limits, and the recommendations in ICRP Publication 60. Thus, the staff does not believe that any of the three options would have an impact on maintaining safety or protecting the environment, and therefore there is not a significant difference in proceeding with any of the options with regard to this important performance goal.

With regard to the Performance Goals of making NRC activities and decisions more effective and efficient and reducing unnecessary regulatory burden, there are aspects of the current situation, discussed above, that need addressing. The status quo approach of Option 1 would not tend towards accomplishing these goals because it would continue to require case-specific determinations, result in some over/underestimations, and not be compatible with other nations. Option 2 would begin a rulemaking process towards these goals, however it could actually cause a net decrease in effectiveness and efficiency and an increase in burden in that it would involve expending extensive resources on a rulemaking effort whose results might need to be modified pending completion of the major national/international studies noted above. In particular, there could be potential confusion and duplication of effort if NRC were to seek to include results from major new studies (such as DS02, BEIR VII, and the DOE study) in the late stages of an Option 2 rulemaking process or directly after such a rulemaking was complete. A significant concern regarding Options 2b and 2c is that these options would lead to the NRC adopting rules that would not be in conformance with current Presidential Guidance. Such an action would create the difficult and undesirable situation in which Federal agencies within the U.S. did not use consistent criteria and methods in regulating the use of

radiation and radioactive materials. The current Presidential Guidance on occupational exposure was issued in 1987. It specifies 5 rem/yr as the occupational dose limit on effective dose equivalent and uses the tissue weighting factors of ICRP 26 and 30. ICRP-60 includes more tissues and different tissue weighting factors. Although NRC is not required to follow this guidance, other federal agencies are required to do so. Therefore, if NRC were to adopt Options 2b or 2c, a situation could develop where workers engaged in the same types of activities would be held to different dose limits depending on which agency has jurisdiction over the activity. Such a situation would undermine the public's, and worker's, confidence in regulatory agencies, and changes in dose limits should therefore be coordinated with other federal agencies. There is currently no stated intent to revise the existing Presidential Guidance on occupational radiation exposure or the endorsement of ICRP-26 dosimetry methodology, but NRC is coordinating discussions on this and other matters with the other federal agencies through the Interagency Steering Committee on Radiation Standards (ISCORS). In addition, the staff does not currently have an adequate information base, including consideration of possible impacts on the reactor safety goals, to conduct a major rulemaking to revise Part 20 that would engender substantial stakeholder concern and involvement. Finally, under Option 2c there may be issues with regard to the backfit regulations of Parts 50.109 and 70.76 (for power reactor and fuel cycle facility licensees, respectively) as to whether the increased regulatory requirements are justified by commensurate substantial increase in worker safety. Option 3 would provide NRC with a better basis for moving forward with plans for achieving these performance goals than the status quo approach of Option 1. Option 3 is also a more appropriate use of resources and, therefore, a better option for the accomplishing the performance goals of effectiveness, efficiency, and regulatory burden than Option 2.

With regard to the Performance Goal of increasing public confidence, Option 1 does not lead towards any increase. While some aspects of Option 2 may provide an increase in public confidence (due to consistency in dose modeling, lowered occupational dose limits, etc), there could also be a net decrease in public confidence because the amount of radioactivity allowed to be released and still meet dose limits could increase for some radionuclides under the new modeling. Also, because Option 2 would involve a major effort for a rulemaking that has minimal health or safety benefit, it is counterproductive to NRC's current effort to make its regulations more risk-informed and thus could cause confusion and instability in the regulatory process and a decrease in public confidence. Lowering the occupational dose limit from 5 rem/yr to 2 rem/yr would have very little health and safety impact because the current exposure levels of nearly all workers in the U.S., with very few exceptions, are already considerably below 2 rem/yr. This is a result of the application of ALARA within the existing regulatory framework. This, coupled with a possible revision downward of the radiation risk coefficients as a result of the DS02 dosimetry reassessment, with a possible consequent raising of the dose limit by ICRP, would create a very negative impact on public perception. Option 3 would allow NRC to seek additional views on issues, further develop our technical knowledge base, put NRC in a position to incorporate in a systematic way results of major

studies, and monitor efforts to revise ICRP 60. Option 3 would also allow NRC to monitor activities of other agencies in this area and incorporate their findings. In this regard, the staff notes that there is no current effort to modify the 1987 Federal occupational guidance.

Recommendation

Based on the above, and on the discussion in Attachment 2, the staff recommends Option 3. If the Commission agrees with the staff's recommendation, the staff will move forward to further develop Option 3 and will provide the Commission with a status report and communication plan within 6 months of the Staff Requirements Memorandum.

RESOURCES

No additional resources would be required to maintain the status quo as presented in Option 1 because resources to review activities on a case-by-case basis are included in the current budget. Under Option 2, rulemaking priorities would need to be adjusted to accommodate revision of Part 20 at this time, and such adjustment could delay lower priority rulemaking activities. The staff notes that the last major revision of Part 20 was a very resource and time intensive effort that spanned a period of 12 years, between 1979 and 1991, and resulted in the expenditure of resources that were substantially higher than the minimum identified here. Also, amendment of one significant aspect of Part 20, i.e., establishment of criteria for license termination in Subpart E, required significant staff effort over more than 5 years. Based on this experience, the staff has identified a minimum of 12 FTE and $1,000,000 in contract support over a 3-year period to develop the rule, prepare the regulatory analyses, develop technical bases for implementation, respond to public comments, and conduct public workshops associated with Option 2. To implement Option 3, staff estimates that no additional resources would be required to develop a communications plan, but that resources would be required to develop a technical information base to provide a better understanding of the impact of alternative changes to Part 20. Several federal agencies, such as DOE and EPA, are developing some of this technical information base, and other organizations, such as governmental and private organizations in other countries, are engaged in similar activities. It may therefore only be necessary that NRC adapt these tools to its own needs, train its staff in their use, and develop guidance documents. Based on this approach, it is estimated that the NRC resources would be about 2 FTE and $300K. Development of a communications plan, designed to gather views from stakeholders on the basic issues, could be achieved through meetings and interchanges that are scheduled to take place as part of currently budgeted activities. Additional resources for the technical development phase of Option 3 would be addressed through the PBPM process.

COORDINATION:

This paper has been coordinated with the Office of the General Counsel, which has no legal objection. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objection.

/RA by William F. Kane Acting For/

William D. Travers
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Attachments
1. Additional Background Materials
2. Analysis of options

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ADAMS PACKAGE ACCESSION NO. ML011580363

File Name: (G:\\Part20\icrp60-commpaper-1.wpd **)** *See Previous Concurrence

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