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 The ICRP 60 recommendations superceded those in ICRP Publication 26.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a series of reports, following publication of ICRP 60, that described revised internal dosimetry models, and these have superceded many, but not all of the models described in ICRP Publication 30 and earlier publications.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

CONTACTS: Sami S. Sherbini, NMSS/IMNS
(301) 415-7853

E. Vincent Holahan, RES/DRAA
(301) 415-8715

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
Executive Director
for Operations

Attachments
1. Additional Background Materials
2. Analysis of options

ADDITIONAL BACKGROUND MATERIALS

Major Revision of Part 20 in 1991 and ICRP 60

The last major revision of 10 CFR Part 20 was published in the Federal Register in May 1991. The purpose of the 1991 revision was to implement the 1987 Presidential guidance on occupational radiation exposure and to adopt the basic tenets of the ICRP system of dose limitation described in ICRP Publication 26, "Recommendations of the International Commission on Radiological Protection," published in 1977. The internal dosimetry aspects of the revised Part 20, such as the models and parameters used to calculate internal doses and to estimate intake limits, were based on a companion ICRP report, namely Publication 30, "Limits for Intakes of Radionuclides by Workers." Publication 30, which was published in 1978, was basically the application of the recommendations in Report 26 to the field of internal dosimetry.

Nearly coincidentally with publication of the revised Part 20 in the Federal Register in 1991, ICRP published Publication 60, "1990 Recommendations of the International Commission on Radiological Protection." The guidance in Publication 60 superceded the guidance provided in Publication 26, and the changes introduced in Publication 60 are discussed later in this attachment. Subsequently, the ICRP issued a series of publications dealing with various aspects of internal dose assessment, mainly the biological models that describe the routes of intake of radioactive materials into the body and its movement and elimination from the body. This series of reports substantially revised the models used to calculate internal doses, and also introduced age-dependence into the dose estimates. Most countries of the world, with the major exception of the United States, plan to adopt most or all of the recommendations in Publication 60 and use the internal dosimetry models and dose coefficients described in a series of ICRP publications.

Changes in Recommendations Between Publications 26 and 60

The main changes in the recommendations in ICRP Publication 60 from those in ICRP Publication 26, and hence from the bases of the current Part 20, are the following:

- The limit on the effective dose equivalent was lowered from 5 rem per year to a five-year average of 2 rem (20 mSv) per year, with the dose in any given year not to exceed 5 rem (50 mSv).
- The annual dose limit for members of the public was reduced from 500 mrem (5 mSv) in ICRP 26 to 100 mrem (1 mSv) in ICRP 60. This change has already been incorporated in Part 20.
- Part 20 limits exposure to an embryo/fetus during the gestation period to 500 mrem (5 mSv). ICRP 60 recommends 200 mrem (2 mSv) from external exposure and 1/20 of an Annual Limit on Intake (ALI) from internal exposure, or about a total of 450 mrem (4.5 mSv) for the gestation period.
- The dose limits for individual organs were eliminated, except for the skin and the lens of the eye, which were retained.
- Many of the quantities used in radiation protection were renamed, although most retained their original definitions with only subtle changes. For example, the dose equivalent was renamed the equivalent dose; the effective dose equivalent was renamed the effective dose; the quality factor used to convert dose to dose equivalent was renamed the radiation weighting factor; the organ weighting

factor was renamed the tissue weighting factor; and similar other name changes were made.

- The tissue weighting factors were changed both in magnitude for individual organs, and also in the number of organs specifically assigned weighting factors. In ICRP 26, six individual organs and tissues are given specific weighting factors, and five remainder organs share a weighting factor. In ICRP 60, 12 individual organs and tissues are given specific weighting factors, and the remainder organs include 10 named organs. The weighting factors for some organs and tissues changed significantly.
- The cancer mortality risk in ICRP 26 is 1.25×10^{-2} Sv^{-1} and applies to both sexes and all ages. The cancer mortality risk in ICRP 60 is 4×10^{-2} Sv^{-1} for adult workers and 5×10^{-2} Sv^{-1} for the general population.
- The risk of hereditary effects in ICRP 26 is 4×10^{-3} Sv^{-1}, and is 8×10^{-3} Sv^{-1} in ICRP 60 for the adult worker and 1.3×10^{-2} Sv^{-1} for the general population.
- ICRP 26 did not explicitly consider non-fatal cancers in its overall risk, whereas this was considered in the overall risk in ICRP 60. The risk of nonfatal cancer in ICRP 60 for workers is 8×10^{-3} Sv^{-1} and 1×10^{-2} Sv^{-1} for the general population.
- The total risk, including fatal and non-fatal cancer and hereditary effects in ICRP Publication 60 is 5.6×10^{-2} Sv^{-1} for adult workers and 7.3×10^{-2} Sv^{-1} for the general population.
- Although the dependence of a dose on age was not introduced explicitly in ICRP 60, it was introduced in subsequent reports.
- Although the default size for inhaled radioactive particulates was not changed in ICRP 60, it was changed to 5 µm for occupational exposures in subsequent reports. It remained unchanged at 1 µm for members of the general public.

Components of the ICRP 60 System of Radiological Protection

The system of radiation protection recommended in ICRP 60 and subsequent publications can be divided, for convenience, into two components: the dose limitation component and the dose assessment component. The dose limitation component is that part of the recommendations that establishes dose limits for the various exposed groups, such as workers, members of the public, minors, and pregnant workers, and also requires that these doses be maintained as low as is reasonably achievable (ALARA). This part of the system is based on current estimates of radiation risk per unit exposure. Obtaining this risk value involves several assessments and value judgements based mostly on epidemiological studies of exposed populations. These include estimates of the doses received by each member of the exposed population considered in the epidemiological studies (e.g., the DS86 dosimetry for the Japanese survivors); the models used to extrapolate the epidemiological data for cancer incidence and mortality as observed in an exposed population most of whose members are still alive, to a lifetime risk (e.g., use of the absolute or relative risk extrapolation models); transfer of the risk values from the exposed population to other, different populations (e.g., from risks for the Japanese population to risks to other populations); and allowances to account for the observation that low dose and dose rate exposures to penetrating radiation are less effective in inducing radiation injury than the high dose and dose rate exposures on which the Japanese A-bomb survivor data is based (e.g., use of the dose and dose rate effectiveness factor).

The dose assessment component is largely independent of the risks and dose limits established, and is the component that addresses the methods by which external and internal doses are assessed or estimated under different exposure conditions. These assessments use

a combination of instrumentation and mathematical models to estimate the external and internal doses received by workers and members of the general public. There have been substantial developments in this area since publication of Part 20 in 1991. These developments represent an increased understanding of the behavior of radioactive materials in the body, and also improved instrumentation for measuring external radiation fields and internally deposited radioactive materials, as well as much more sophisticated computational capabilities that permit even modestly equipped licensees to run complex mathematical dose calculations. Most of these models apply to internal dosimetry, and were described in the series of ICRP publications starting from Publication 56 in 1989 to ICRP Publication 72 in 1996. Developments in this area are expected to continue indefinitely. Parallel developments also occurred in the methods used to assess external doses, mainly by the use of tissue weighting factors for external exposures in a manner similar to that used for internal exposures, and by the use of multiple dosimetry to obtain better estimates of the effective dose from external exposures than is possible using a single dosimeter.

The two components noted above, namely dose limitation and dose assessment, are not completely independent. Tissue weighting factors are an important link between the two components. The tissue weighting factors are based on cancer mortality, account for years of life lost, and account for genetic and hereditary disorders. Changes in these factors will result in changes in the assessed effective doses. However, because they are based on relative rather than absolute risks, even a major change in the overall radiation risk coefficient need not necessarily lead to a change in the tissue weighting factors, and these factors are therefore much more robust than the absolute risk values.

Current Developments that May Affect Radiation Protection Practices

There are currently several major efforts underway that may have a significant impact on the dose limits recommended by national and international radiation protection advisory groups. These efforts include the following:

- A reassessment of the dosimetry for the survivors of Hiroshima and Nagasaki. Data now available suggest that the last such dosimetry assessment, called DS86, should be revised, and the new assessment, to be called DS02, is expected to be completed and published in 2002. A change in dosimetry may result in a change in the risk coefficients. This effort is critical because our knowledge of the radiation risk factors comes almost entirely from data on the Japanese survivors.
- The National Research Council was awarded a three-year grant in 1998 to conduct a reassessment of the health effect of low levels of ionizing radiation. The last such assessment, known as BEIR V (Committee on the Biological Effects of Ionizing Radiation) was published in 1990, and the new report will be BEIR VII. Because of the importance of the DS02 dosimetry in this type of reassessment, it is expected that the BEIR VII committee will not complete its work until mid- to late-2003
- The ICRP is also considering a complete review of its current recommendations, and the revised recommendations may differ substantially from the current ones. Because it is likely that ICRP will await completion of DS02 and publication of BEIR VII, the ICRP may publish revised recommendations in 2005 if not later.

Convention on Nuclear Safety

The Convention on Nuclear Safety was adopted on June 17, 1994, by a Diplomatic Conference convened by the International Atomic Energy Agency. By April 12, 1999, 50 states had ratified the Convention. The U.S. ratified the Convention on April 9, 1999. Under Article 15 of the Convention "each Contracting Party shall take the appropriate steps to ensure that in all operational states the radiation exposure to the workers and the public caused by a nuclear installation shall be kept as low as reasonably achievable and that no individual shall be exposed to radiation doses which exceed prescribed national dose limits." During the first review meeting of the Contracting parties, April 12-23, 1999, it was observed that "the ALARA principle (As Low As Reasonably Achievable) is implemented in all countries with regard to doses and releases. The Radiation Protection System recommended in ICRP 60 is already applied or is planned to be applied in all countries." The three elements of the radiation protection system being justification of a practice, optimization of protection and limitation of exposure and risk.

Although U.S. regulatory requirements are generally consistent with the recommendations of the ICRP, there are constraints that limit the extent to which the U.S. regulations coincide with the ICRP recommendations. One important consideration is the desire for regulatory stability; revising the regulations to reflect every new ICRP position would impose a serious burden on the licensees without a commensurate benefit. Furthermore, for nuclear power reactors, new requirements are constrained by the "backfit rule" (10 CFR Part 50.109) which in essence, requires that any increase in regulatory requirements be justified by a commensurate improvement in safety. Consequently, U.S. regulations often are based on older (rather than the most recent) recommendations of the ICRP.

It should also be noted that radiation protection rules promulgated by Federal agencies generally follow Presidential Guidance, which specifies the general outlines of the radiation protection system recommended for protecting workers and the general public against the hazards of radiation exposure. The Presidential Guidance has not been revised by EPA to reflect the ICRP 60 recommendations, and at this date there have been no recommendations to revise the guidance. To ensure coherence within the U.S. in formulating and implementing radiation protection regulations, it is important that the Presidential Guidance be revised prior to Federal agencies adopting new ICRP recommendations. To this end, the Federal agencies are discussing, and will continue to discuss, the possibility of changing the guidance, or parts of it, through ISCORS.

Attachment 2

Analysis of Options

To assist the Commission, the staff has evaluated the following options for Commission consideration. The following paragraphs include an evaluation of the options, including consideration of how the options would impact the four performance goals of the Strategic Plan in NUREG-1614.

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.

Advantages:

1) Public and occupational health is already adequately protected by Part 20. The ICRP Publication 60 recommendation for the public dose limit is already codified in Part 20, and lowering the occupational dose limit would not substantially increase worker protection (most workers' annual doses are < 2 rems (<20 mSv)).
2) The risk coefficient for cancer mortality used in the current regulations may require no change if, after completion of DS02 and BEIR VII, the cancer risk coefficients revert back toward those contained in ICRP Publication 26.
3) An regulatory framework already exists under which licensees can request license amendments to use the new dosimetric models and dose coefficients that may yield lower committed effective dose equivalents.
4) Revisions to other dose-based regulations, e.g., the Part 71 revision, could refer to Publications 66 and 68-72, as appropriate.
5) Resources would not need to be diverted from other activities to conduct a rulemaking at this time.

Disadvantages:

1) NRC regulations would continue to not be compatible with other nations that are adopting the 1990 recommendations and subsequent changes in dosimetric modeling.
2) NRC would continue to have to review licensee requests for use of new dosimetric methods in dose assessments on a case-specific basis as exemptions. Although the number of licensing cases proposing to use the ICRP dosimetry has been very limited, there have been 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.
3) Not adopting the newer dosimetric models can result in: (1) overestimation of committed effective dose equivalent to some nuclear fuel cycle workers, (2) overestimation of exposure to children and infants to some nuclear reactor effluents (e.g., Sr-90 and

Cs-137), (3) underestimation of thyroid exposure to radio iodine, and (4) potential 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.

4) Using ICRP Publications 66 and 68-72 for new regulations may result in values in Appendix B, Part 20 being derived from both new and old systems. For example, if Appendix B were to be revised to include the unrestricted release of slightly contaminated solid materials based on newer models and dose coefficients, there would be inconsistency with other values in Appendix B, which are based on older models and dose coefficients.
5) Taking no action would ignore the issues related to a potential need to revise Part 20 and would also not lead toward developing a formalized plan under which NRC could seek to gain further insights on potential approaches to revising Part 20 and impacts associated with those approaches.

NRC's performance goals. Option 1 would continue to achieve the goal of maintaining public health and safety because public and worker protection would be unaffected. This option would tend to decrease public confidence because there may be some confusion and concern because NRC's approach differs from other countries, because there are some over/under estimations in particular cases, and because there can be potential enforcement issues. This option would not make NRC's activities and decisions more effective and efficient nor reduce unnecessary regulatory burden because it would continue to require case-specific determinations, result in some over/underestimations, and not be compatible with other nations.

Cost of Option 1. No NRC, Agreement State, or licensee cost related to a rulemaking or other back-fit is associated with this option.

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

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.

Examples of sections that may be revised or moved to guidance documents are:

1. Remove §20.1003, Table of organ dose weighting factors.
2. Remove Table 1004(B).1-Quality Factors and Absorbed Dose Equivalencies
3. Remove Table 1004(B).2-Mean Quality Factors, Q, and Fluence per Unit Dose Equivalent for Monoenergetic Neutrons.
4. Remove Appendix B.
5. Revise §20.1003 definitions to be consistent with Publication 60.

Advantages:

1) There would continue to be protection of public and occupational health for the reasons noted in advantage #1 for Option 1
2) It would be easier to adopt future recommendations on new dosimetric models and related parameters by revising guidance instead of Part 20.

3) Having the dose assessment provisions in guidance rather than regulations would allow greater flexibility in using appropriate methodology.

Disadvantages:

1) There would still be incompatibility with international recommendations and a need for case-specific review of dosimetry as described in disadvantages #1 and #2 of Option 1.
2) Resources to carry out a rulemaking could be substantial and the related costs for NRC and the Agreement State costs may not be justifiable considering that there would not be an increase in public health and safety and that the increase in efficiency and reduction in burden would likely be minimal.

NRC's performance goals. Option 2a would continue to achieve the goal of maintaining public health and safety because public and worker protection would be unaffected. This option may not achieve a goal of increased public confidence because there may still be some confusion as to why NRC's occupational exposure criteria differ from other countries and also concern as to why rule requirements are being eliminated. This option would tend to make NRC's activities and decisions more effective and efficient, and reduce unnecessary regulatory burden, compared to Option 1 because it would allow for more flexibility under the regulations in handling case-specific dose assessments. However, Option 2a could involve an extensive rulemaking process to revise Part 20 which may not be commensurate with the benefit realized and whose results might need to be modified pending completion of major national/international studies.

Option 2b: Revise Part 20 to formally adopt the newer dosimetric models and related parameters, but do not change the occupational dose limits in Part 20.

Advantages:

1) Part 20 would be revised to provide consistency with new ICRP methodologies.
2) Licensees could use the new dosimetric models without obtaining case-by-case approval from NRC.
3) Permitting the use of the models and related parameters in Publications 66, and 68-72 would: (1) reduce the internal dose to some nuclear fuel cycle workers (e.g., exposure to U, Th, and Pu), (2) reduce the internal dose to children and infants exposed to some nuclear reactor effluents (e.g., Sr-90 and Cs-137), and (3) increase the internal dose to children exposed to radio iodine, radium, and technicum.
4) There would be consistency between Part 20 and with other recent dose-based regulations being developed, e.g., the Part 71 revision.
5) Permitting the newer dosimetric methods in Part 20 will enable the U.S. and other countries to harmonize the development of technical bases for dose-based radiation standards.

Disadvantages:

1) Substantial resources for a complete revision of Part 20, Appendix B would be required to incorporate new models and dose coefficients. Whether these resources are justified is not clear as a majority of the dose coefficients in Publication Nos. 68-72 are similar to those in Publication 30 (when differences are apparent, slightly more dose coefficients

have increased relative to ICRP Publication 30 compared to those that have decreased). In addition, a majority of occupational workers exposed to ionizing radiation are exposed externally, not internally, and thus, permitting new methodologies for calculating internal dose may not have any impact on these workers. Finally, ICRP is considering changing the dose coefficients by 1.5 to 2 fold in its next set of recommendations.

2) NRC would need to revise Part 20 again if ICRP made additional recommendations based on new information or new data. Revising policy and procedures to reflect every new ICRP position would impose a significant burden without commensurate benefit.

NRC's performance goals Option 2b would continue to achieve the goal of maintaining public health and safety because public and worker protection would be unaffected. However 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 as a result of application of ALARA within the existing regulatory framework. This option may provide some increase in public confidence due to consistency in dose modeling between NRC and other nations, however there could also be a decrease in public confidence because the amount of radioactivity allowed to be released and still meet dose limits would increase for some radionuclides under the new modeling. Also, there could be concern as to why NRC occupational dose limits would differ from the 1987 Presidential Guidance and other U.S. federal agencies, who are required to follow the Presidential Guidance, or if dose models were to be changed again after completion of DS02 and BEIR VII. This option would contribute to the goals of making NRC's activities and decisions more effective and efficient, and reducing unnecessary regulatory burden, more than Option 1 because it would allow for greater consistency in dose assessments and rulemakings on dose-based regulations, both internally and with other nations. However, Option 2b could involve an extensive rulemaking process to revise Part 20 which may not be commensurate with the benefit realized and whose results might need to be modified pending completion of major national/international studies.

Option 2c: Revise Part 20 to adopt both the dosimetric models and related parameters and the occupational dose limits, as recommended by ICRP.

Advantages

1) Advantages with regard to consistency with ICRP methodologies, removing need for case-specific reviews, and consistency of bases amongst NRC dose-based regulations, would be similar to those of advantages #1 - 5 of Option 2b.
2) The occupational dose limit in §20.1201 would conform to the 1990 recommendations of the ICRP.

Disadvantages

1) Disadvantages with regard to expenditure of resources to incorporate ICRP methodologies into Part 20, whether this expenditure would be cost-effective, and whether Part 20 would have to be revised again when further revisions to the ICRP methodologies are made, would be similar to Disadvantages #1 and 2 of Option 2b.
2) Reducing the occupational dose limit would suggest that the current occupational dose limit is not adequately protective.

3) Changing the Part 20 limits for occupational dose may not be cost effective. Further, exposure to workers who are currently receiving doses in excess of 2 rems (20 mSv) may not be easily reduced without extensive modifications of equipment or procedures, such as steam generation, maintenance, and refueling in nuclear power plants.
4) There may be issues with regard to the backfit regulations of Part 50.109 as to whether the increased regulatory requirements for nuclear power reactors are justified by commensurate substantial increase in worker safety.
5) The staff may need to evaluate whether there would be an impact on the reactor safety goals because the current safety goals are based on the mortality risks whereas the new recommendations consider total detriment.

NRC performance goals Option 2c would continue to achieve the goal of maintaining public health and safety. Although Option 2c would result in lower occupational dose limits, the net effect of the lower limits would be small, as noted for Option 2b, because most licensees are already in compliance with these lower levels and because this change may not be cost effective. Thus, Option 2c is not considered to provide significant added public and worker protection compared to the other options. This option may provide some increase in public confidence due to consistency in dose modeling and a lowering of occupational dose limits, however there could also be a decrease in public confidence because the amount of radioactivity allowed to be released and still meet dose limits would increase for some radionuclides under the new modeling. Also, there could be some concern as to the adequacy of current occupational exposure standards if NRC is considering new standards and consistency with the 1987 Presidential Guidance used by other federal agencies. This option could tend to make NRC's activities and decisions more effective and efficient, while decreasing unnecessary regulatory burden, compared to other options because it would allow for more consistency in dose assessments and related rulemakings with other nations. However, Option 2c could involve an extensive rulemaking process to revise Part 20 which may not be cost-effective and whose results might need to be modified pending completion of major national/international studies.

Costs for Option 2. The costs for Options 2a, 2b, and 2c would be similar and involve approximately 12 FTE over 3 years to develop a final rule. Contract support for rulemaking development, development of technical bases for implementation, and support for an estimated 4 public meetings and/or workshops, is estimated to be about $1,000,000. There would be some variation amongst the suboptions for specific actions such as guidance development, revisions to Appendix B of Part 20, etc. These costs would the similar to those discussed under Option 3 below, but NRC may have to bear a much greater share of the costs, compared to the costs under Option 3, because of the need to accelerate the development of such a technical base to keep pace with rulemaking activities.

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. Option 3 would first involve preparation of a communication plan (based on use of information exchange processes already in place) to gather views from stakeholders and scientific organizations on basic issues such as the need for and implications of a change, resources involved in current and potential requirements, etc. Option 3

would also involve developing a technical information base to provide a better understanding of impacts of 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. Subsequently, Option 3 would involve NRC monitoring work on the revision to ICRP Publication 60. This phase of Option 3 would be further clarified as the above activities proceed.

Advantages

1) Advantages with regard to maintenance of public and occupational health and safety, existence of a regulatory framework for case-specific reviews of licensee amendments, and development of dose-based regulations are similar to advantages #1-4 of Option 1.
2) This option would begin a process to put NRC in a position to react to completion of the DS02 and BEIR VII by gathering further information from stakeholders and other scientific organizations on such issues as need for and implications of a change, resources involved in current and potential requirements, etc.
3) This option would begin a process of consideration of revision of Part 20 while not committing substantial resources at this time to a rulemaking that may not be cost-effective and that may need revision soon after its completion to incorporate various national/international studies.

Disadvantages

1) Disadvantages with regard to inconsistency of standards and models with other nations and between 10 CFR Parts and need for case-specific reviews would be similar to disadvantages #1-4 of Option 1. However tempering these disadvantages is that a process for considering revision would have begun and also that the current burden for case-specific reviews is not great.
2) Consideration would have to be given to reactor safety goals as noted in disadvantage #5 of Option 2c.

NRC performance goals Option 3 would continue to achieve the goal of maintaining public health and safety because public and worker protection would be unaffected. While there may be some confusion as to why NRC's approach differs from other countries under this option, the long-term communications program for considering a re-assessment of Part 20 may tend to increase public confidence. This option would not, in the short-term, make NRC's activities and decisions more effective and efficient nor reduce unnecessary regulatory burden because it would continue to require case-specific determinations and not be compatible with other nations; however this impact is tempered by the fact that the burdens associated with this are not considered significant and because this option would avoid the commitment of substantial resources to an extensive rulemaking process to revise Part 20 which may not be cost-effective and whose results might need to be modified pending completion of major national/international studies.

Costs for Option 3. There would not be costs for this option for conducting rulemaking to revise Part 20 or for potential back-fits. Costs related to development and implementation of a communication plan would be minor and would be borne within existing budgets. Resources would be required to develop a technical information base for Option 3 that is needed 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 $300 K. 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. Eventual costs for initiating extensive potential rulemaking related actions after completion of DS02 and BEIR VII and during completion of ICRP 60 revisions would be estimated and included in the planning for later budgets.