Assessment of Technical Issues and Feedback

Background:

In response to the Staff Requirements Memorandum (SRM) for SECY-08-0197, the staff has engaged stakeholders on a set of technical issues related to increasing alignment with international recommendations and standards. The set of issues was guided by the staff presentation in SECY-08-0197, and evolved somewhat during the stakeholder dialogue process. The issue topics discussed included use of a new methodology and terminology, occupational total effective dose, the occupational dose limit for the embryo/fetus of a declared pregnant female, and As Low As Reasonably Achievable (ALARA) planning. The issue of limits for the lens of the eye was added following the publication of the statement by the International Commission on Radiological Protection (ICRP) in April 2011. Additional topics were raised during the discussions, including use of the International System of units (SI) and reporting requirements for occupational exposure.

In the sections which follow, each issue area is presented, including a summary of the staff proposed position, the options initially proposed for discussion, the feedback and comments received from stakeholders, and the staff's conclusion on the direction to pursue for further development of the regulatory basis (previously referred to as technical basis) for a proposed rule.

Outline:

1) Methodology and Terminology

Summary of Staff Recommendation:

- Change radiation and tissue weighting factors to ICRP Publication 103.
- Adopt current metabolic (inhalation & ingestion) models.
- Revise Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20 Appendix B Annual Limits on Intake (ALI), Derived Air Concentrations (DAC), Effluent Concentrations, and Release to Sewer values based on new ICRP 103 dose coefficients when available.
- Adopt Total Effective Dose (TED) in place of Total Effective Dose Equivalent (TEDE), with flexibility in implementation period.
- Incorporate updates of methodology and terminology in revision of 10 CFR Part 50, Appendix I, and in other NRC CFR parts as revision opportunities become available.
- Consider best mechanisms for implementation to facilitate transition and minimize impacts.

Options Presented for Stakeholder Discussion:

- No Change – Use existing methodology and terminology.
- Update to ICRP 103 methodology and terminology.
- Allow use of either current or new terminology for effective dose.

Supporting Information:

The ICRP recommendations are supported by a series of documents that reflect scientific information on the intake, distribution, retention, and elimination of radioactive material from the body, and the calculation of dose in various organs and tissues. With each revision of the recommendations, there have been corresponding revisions to tissue weighting factors, radiation weighting factors, and the dose coefficients calculated for the intake and retention of radionuclides in the body.

The materials supporting the 1977 ICRP recommendations are contained in ICRP Publication 30. Supporting the 1990 ICRP recommendations, updated information was published in ICRP Publication 56 “Age-dependent Doses to Members of the Public from Intake of Radionuclides - Part 1, ” Publication 61, “Annual Limits on Intake of Radionuclides by Workers Based on the 1990 Recommendations”, Publication 67, “Age-dependent Doses to Members of the Public from Intake of Radionuclides - Part 2 Ingestion Dose Coefficients, ” Publication 68, “Dose Coefficients for Intakes of Radionuclides by Workers, ” Publication 69 “Age-dependent Doses to Members of the Public from Intake of Radionuclides - Part 3 Ingestion Dose Coefficients, ” Publication 71, “Age-dependent Doses to Members of the Public from Intake of Radionuclides - Part 4 Inhalation Dose Coefficients, ” Publication 72, “Age-dependent Doses to the Members of the Public from Intake of Radionuclides - Part 5 Compilation of Ingestion and Inhalation Coefficients, ” and Publication 74, “Conversion Coefficients for use in Radiological Protection against External Radiation.”

The ICRP is still in the process of preparing the updated dose conversion factors that are used to calculate doses from intakes of radioactive material and reflect the changes in Publication 103. These new dose coefficients will be compatible with the new tissue weighting factors, radiation weighting factors, updated nuclear decay data, and the updates of metabolic models.

The first report, for external exposure, is expected to be published in the next year. The calculations for Occupational Intake of Radionuclides will be published in a set of 5 publications, culminating in a completely revised set expected by the end of 2015. Dose conversion factors for members of the public are also under development, with publication expected in 2014.

10 CFR Part 20 uses the term TEDE to represent the summation of dose received from sources external to the body and the dose from the intake of radioactive materials. The term was actually created by the NRC staff for the NRC's 10 CFR Part 20 regulations, because at that time the ICRP used an entire phrase (the sum of the dose equivalent from sources external to the body, and the committed effective dose equivalent for the intake of radionuclides) to describe the summation of internal and external exposure. With the 1990 ICRP recommendations, there were some changes in the way that tissue and radiation quality factors were defined and used (moving from quality factors to radiation weighting factors), and there was a corresponding change in the terminology used, to Effective Dose (ED) or TED when additional emphasis was being added to make clear that the reference was to the summation of the contributions from external exposure, and from the intake of radioactive material. These terms are used in various ICRP publications.

10 CFR Part 20 defines the tissue weighting factors in the § 20.1003 definition of weighting factor W_T. The quality factors and absorbed dose equivalencies for different types of radiation are found in § 20.1004. An update to reflect the tissue weighting factors and radiation weighting factors from ICRP Publication 103 would amend these sections.

10 CFR Part 20, Appendix B, contains ALI and DAC values for occupational and public exposure via airborne or liquid pathways. These ALI values are generated using the tissue weighting factors, radiation quality factors, and radionuclide specific information to calculate a generic quantity of a radionuclide that would result in a dose of 5 rem (50 mSv) to a reference individual. The DAC values are similarly calculated to represent the concentration of material, in air, which, if breathed continuously for 2000 hours, would result in the intake of 1 ALI. These values are used by licensees as one acceptable method for demonstrating compliance with the dose limits of 10 CFR Part 20. These values have also been used in other portions of the regulations as trigger values for certain actions, such as reporting. If the methodologies are modified, NRC staff will need to review related NRC regulations, outside of 10 CFR Part 20, to determine the impact. The values in 10 CFR Part 20, Appendix B, would need to be amended to reflect the new tissue and radiation weighting factors.

A consistent use of updated tissue and radiation weighting factors will result in some changes to the calculated values of ALI and DAC. In some cases the ALI values will increase, indicating that a larger quantity of material corresponds to the dose limit. In other cases, the ALI values will decrease. Until all of the calculations have been completed, it is not possible to give complete details of the changes. The staff understands that the changes between the calculated values for the 1990 ICRP recommendations and the 2007 ICRP recommendations are not expected to be large. However, there are some more substantial differences between the 1977 ICRP recommendations, and the 2007 recommendations. One such change is ALI and DAC values for Uranium and Thorium, which will increase because the dose per unit intake of radionuclide is smaller than estimated in 1977. Because this change was present in the values calculated for the 1990 ICRP recommendations, many of the licensees impacted by this change have already requested amendments to their license to allow use of the newer information.

Stakeholder Views:

The discussion of methodology is the one area in which most of the stakeholders agreed that change was warranted. Many stakeholders expressed their general support for changes to reflect the more up-to-date modeling, and suggested that it was important to have the regulatory framework use the best available information. Furthermore, stakeholders suggested that the NRC wait for all the information to be available, and make the change all at once, rather than undertake a piecemeal approach, or some interim change, so that licensees would not have to make two or more sets of changes to their procedures and programs in a relatively short period of time.

While there was general support for changes, there were also some concerns expressed about using the newer factors and methodology. For example, the staff has had limited success in engaging some of the other public and environmental Non-governmental Organizations (NGO) stakeholders, in part because the discussions have focused on occupational exposure, rather than public or environmental exposure. These groups have, in other forums, raised concerns about the use of the effective dose concept and the use of the latest values if the use of these values would result in an increase in any of the calculated ALI or DAC values. Such changes are seen by these stakeholders as decreasing safety, irrespective of the fact that the underlying dose criteria remained unchanged.

The issue of changing terminology generated a mixed response, with many stakeholders agreeing that the terminology should be consistent with that used internationally and in the scientific literature. Stakeholders also recognized that the change in terminology, corresponding to a change in the methods for calculations, would be a logical and consistent move, and support a clear differentiation of when requirements were changed.

Stakeholders also identified some concerns with changing the terminology to that used in the 2007 ICRP recommendations. Stakeholders identified several issues, including the cost benefit associated with the changes. They noted that the change in terminology to TED from TEDE is not a significant change in the regulatory approach. Nevertheless, the training costs associated with the change could be significant, as well as difficult to explain. Furthermore, stakeholders noted that the necessary changes to computer programs and algorithms could be substantial, and urged the NRC to make sure that the changes are worth those costs.

Staff Analysis and Conclusions:

The starting point of the analysis is the present regulatory basis within the NRC regulatory framework. 10 CFR Part 20 is based upon the models and weighting factors available in the late 1970's. Other portions of the regulations, and in particular 10 CFR Part 50, Appendix I, are still based on the models and approach from the 1950's. Furthermore, there are some licensees who have been authorized to use the models and weighting factors from the 1990's by NRC approvals of licensee requests.

Relying upon a regulatory framework that relies upon scientific information from different dates raises issues. In particular, the oldest methodology from the 1950's does not readily lend itself to summation exposures from intakes of radioactive material with exposure received from sources external to the body. For the methodology from the 1970's, it is possible to sum

internal and external exposures. In each case, the changes in methodology and knowledge allow for a more accurate prediction of dose from an intake of radioactive material.

Changes to the modeling and weighting factors allow for a consistent, up-to-date assessment of exposures. For example, the August 1, 2007, letter from the Advisory Committee on Nuclear Waste and Materials to Chairman Klein, ACNWS-0266 (NRC's Agencywide Documents Access and Management System (ADAMS) Accession No. ML072120415), recommended that certain standard review plans in NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," be updated, including computer codes, methodologies, and parameter values cited in referenced regulatory guides, supporting NUREGs, and other documents. The August 1, 2007, letter describes a three step approach suggested by health physics staff in the Office of New Reactors (NRO) to address the weaknesses in NRC's dose methodologies and update them. The NRO staff suggested that the first step could update critical parameters such as dose conversion factors. The second step could then be the update of other important parameters such as shielding and biological accumulation factors. Finally, the third step could systematically review all dose methodologies used and comprehensively update all of them to ensure that a risk-informed approach is employed.

In the 1990 ICRP recommendations, the terminology was also changed from Effective Dose Equivalent to ED. This change was made to reflect the move from the quality factor approach to radiation effects weighting to the use of radiation weighting factors. While the staff recognizes the preference, from a regulatory stability standpoint, for retaining TEDE, the staff believes it is appropriate to change the terms to match the corresponding change in methodology and numerical values. From the standpoint of a retrospective review of records, a change in the terminology at the time of a change in methodology would facilitate identification of the approach used in generating the record.

The staff recognizes the concerns of some stakeholders that an amendment of the regulation would result in both increases and decreases in ALI values for compliance with the dose limit. A consistent implementation of the new methodology and weighting factors will result in some ALI values increasing, and others decreasing, based on our updated scientific basis. The staff believes that the changes should be made consistently, both up and down, so that the values represent a coherent set with the same scientific support.

The staff will also need to engage stakeholders on the dose which the ALI represents. Under the recommended set of options, the dose limit would be reduced to 2 rem (20 mSv). The revised ALI and DAC values would thus also have to be adjusted to correspond to the new dose limits. As part of this process, an examination will be needed on the impact of these changes to other portions of the NRC's regulations where ALI and DAC values are used as triggers for a regulatory action such as reporting. The staff will need to carefully examine all cross reference and uses of ALI and DAC values in regulations and guidance to develop a complete analysis of impacts.

The primary benefit in revising 10 CFR Part 20 to incorporate the recommendations and standards of ICRP 103 is that the demonstration of compliance would be based on the current scientific information. It is also important to ensure that the methodology and factors being used are a consistent set. For example, when the NRC approved licensee requests to use the methodology associated with the 1990 ICRP recommendations, one of the license conditions

was that the same methodology be used for the entire radiation protection program. This requirement was to avoid a possible situation in which results from different systems were "cherry picked" as advantageous for one reason or another.

The benefit of consistently moving to the updated methodology across the entire NRC radiation protection regulatory framework is greater than that seen for 10 CFR Part 20 alone. As noted previously, 10 CFR Part 50, Appendix I relies upon methodologies dating back to the 1950's. As a result, power reactor licensees must use entirely different approaches to demonstrating compliance with different portions of the regulations, which is both time consuming and difficult to explain. In that regard, a move to a consistent methodology should lead to an increase in public confidence and transparency.

The staff recognizes that the benefits of updated methodologies are not easily quantified. It is possible, however, to have quantitative measures of costs. There will, in fact, be substantial costs to update procedures, computer codes, training materials, and other documents to reflect the methodology and terminology.

These costs must be balanced against the benefits of improved accuracy and consistency, the value of being able to use a single approach rather than the different approaches currently required by the NRC regulations, and the value of terminology that represents the updated science which is used by many other nations.

It is possible that the staff will conclude that, despite the flexibility afforded by the Commission in attempting to demonstrate a "substantial increase in protection," that a positive demonstration of benefit cannot be made. The Commission's 1993 SRM also indicated that the staff could request that the Commission make an "exception" to the Backfit Rule. This type of request is discussed further in Section 10 with respect to "administrative exemption."

As the process moves forward, the staff will need to engage stakeholders to develop quantitative estimates of impacts, and examine areas in which flexibility in implementation can offset or mitigate those impacts. For example, it may be possible to allow a much longer transition period for the terminology to be implemented in training and documents.

The staff recommends that the regulatory framework be updated to reflect the new terminology and dose calculation methodologies, so as to align with the current scientific approach to estimating radiation exposure and risk. Further, the staff recommends that a rulemaking not be initiated to reflect these changes until all of the dose coefficients and other supporting information are available, so that a single, comprehensive, change can be made to the relevant paragraphs and appendices of 10 CFR Part 20. Changes to other portions of the NRC's regulations also need to be made to reflect the updated methodology and terminology. In particular, the staff recommends that this approach also be taken in a revision of 10 CFR Part 50, Appendix I.

Note that this recommendation relates only to the terms used to refer to dosimetry. The staff is not proposing that we adopt many of the words used internationally to describe the principles of radiation protection. For example, as described later in this package, the staff is recommending against the use of the term "constraint." This will be further described in Section 5 on ALARA planning.

The staff believes that this recommendation is consistent with Commission direction to consider revision of the safety criteria in 10 CFR Part 32 as part of its effort to develop the regulatory basis for possible revision of the NRC's radiation protection regulations, and Commission direction to provide an expanded proposed rule for 10 CFR Part 61 to consider the pros and cons of allowing licensees the flexibility to use ICRP dose methodologies in a site-specific performance assessment for the disposal of all radioactive waste (SRM-SECY-11-0129, SRM-COMWDM-11-002/COMGEA-11-002).

2) Limits for Occupational Total Effective Dose Equivalent

Summary of Staff Recommended Position:

- Change occupational dose limit to 2 rem (20 mSv).
- Develop provision to allow a licensee to apply for use of a dose limit up to 5 rem (50 mSv) in any one year, and 10 rem (100 mSv) over 5 years, upon application and approval.

Options Presented for Stakeholder Discussion:

1. No change.
2. ICRP max and average recommendation.
3. Single limit at 2 rem (20 mSv).

Supporting Information:

The area of greatest discussion, and controversy, is the area of possible changes to the mechanisms for controlling occupational exposure. This issue includes the occupational dose limits and the requirement to reduce exposures consistent with the ALARA principle. The discussion on ALARA is found in Enclosure 3, Section 5. There is a perception on the part of the international community, and some stakeholders, that alignment or lack thereof of the NRC regulations with the ICRP recommendations can be measured by whether the occupational dose limit is changed.

The current 10 CFR Part 20 occupational TEDE limit is 5 rem per year (50 mSv). The international recommendations have, since 1990, incorporated a lower limit of 10 rem (100 mSv) over a 5 year period, with a maximum of 5 rem (50 mSv) in any one year. International standards, such as those of the International Atomic Energy Agency (IAEA), have adopted these limits. The United States is now an outlier, because some variation of these limits is in place in most other nations. The trend internationally is to further simplify the limit to a single value of 2 rem (20 mSv), as evidenced in the draft Euratom Basic Safety Standards Directive in the European Union.

The selection of a recommended dose limit by ICRP in 1977 was based on a comparison of the radiation risk of fatal cancer with the average annual risk of accidental death in industries generally accepted as having a safe working environment. According to ICRP, such industries, at that time, could be defined as exhibiting an annual mortality risk of approximately one person in 10,000 from industrial accidents. The recommended limit was suggested to provide radiation workers with at least that level of protection. The selection of a 5 rem (50 mSv) value was based on an expectation that most individuals protected by such a limit would be unlikely to

exceed 1 rem (10 mSv) in a year. It was actually the radiation risk of 1 rem that corresponds numerically with the average annual accidental death rate in safe industries.

In 1990 ICRP reduced the recommended occupational dose limit in response to the changes in estimated radiation risk (see Enclosure 1). The recommended limit was expressed as an average and a maximum value in order to provide flexibility for possible implementation issues, while achieving an objective to restrict the cumulative occupational exposure to less than 100 rem (1 Sv). The 100 rem (1 Sv) level was selected from a range of possible options as a risk informed judgment that an aggregated risk of 5 percent from fatal cancer, serious nonfatal cancer, estimate of length of life lost from fatal cancer, and serious hereditary effects would be unacceptable. The ICRP also noted that the value was selected with the assumption that, with the application of sound radiation protection practices the limit would only rarely be approached.

In the United States, the majority of occupationally exposed individuals receive less than 2 rem (20 mSv) per year. However, a small percentage of individuals receive larger exposures, up to, and occasionally above the current limit of 5 rem (50 mSv). While the nuclear power community has been very successful in reducing individual exposures, such that only a very limited number of individuals exceed 2 rem (20 mSv) in a year, other segments of the regulated community, such as industrial radiography and various medically related activities have somewhat greater percentages of individuals above the levels recommended internationally. Stakeholder interactions lead the staff to believe that some of these individuals may be receiving doses close to the 5 rem (50 mSv) limit over multiple years, and thus there is the possibility that they may exceed the cumulative levels of exposure considered appropriate. Detailed information on these cumulative exposures is difficult to ascertain because some segments of the regulated community are not required to report occupational exposure.

The numerical value of the dose limit is also linked to other provisions of the regulations, including the basis for calculations for ALI values to demonstrate compliance with the limits (see Enclosure 3, Section 1), criteria for monitoring, and event reporting. If a change to the occupational dose limit is made, NRC staff will need to review the NRC regulations outside of 10 CFR Part 20 to determine if the basis for those requirements are either sufficiently independent of the occupational dose limit to remain unchanged or whether an adjustment should be made to conform with the regulations.

Stakeholder Views:

The issue of changes to occupational dose limits has been the single greatest point of concern and discussion in our interactions with stakeholders.

Almost all stakeholders objected to any change, saying it was not necessary, would impact the conduct of work and the delivery of medical care, could potentially impact compensation and legal claims, and was not scientifically supported. Some public stakeholder groups, however, supported a reduced occupational limit. A sampling of some of the salient points follows.

A change to the dose limits was adamantly opposed by most licensee groups. Medical licensees, for example, stated that a reduction in the occupational limit would result in an adverse impact to health care, both in the treatment of patients, and in the training of physicians and other medical professionals. As part of the discussions, these stakeholders indicated that the delivery of health care in the United States is different from other countries, in that there is a

greater use of radiation and radioactive materials in diagnosis and treatment of patients. Some medical licensees stated that reducing the occupational limit would result in an increase in non-compliance because medical professionals would remove their dosimetry badges when they approached the annual occupational limit. During the workshops there were a number of references to actions which would, in the opinion of the staff present, constitute non-compliance with the current regulations, although no specific allegations were made. It should be noted that changes (or not) to limits is not the solution of these potential non-compliance issues. This is an area which would have to be addressed by inspection and enforcement, irrespective of the final regulations adopted.

Stakeholders representing the medical community also mentioned the need for standards that are based on solid scientific evidence, instead of reducing the occupational limit without having the appropriate scientific basis to support that reduction. According to these comments, there are very limited opportunities for them to increase the cost of doing business without specific and very clear benefit both to those who are doing the work, as well as to the patients who are receiving those studies. Thus a change in the dose limit was viewed as an economic penalty on the providers of health care. Essentially, they indicated that a change in the occupational dose limit would have an impact on the practice of medicine, as the increased costs would force some medical practioners to abandon nuclear medicine, and there would then not be enough doctors available to perform the needed procedures.

One area of considerable discussion with the States, and with stakeholders in the medical area, was the use of effective dose for demonstrating compliance for external exposure. The Commission amended the definitions in 10 CFR 20.1003 and 10 CFR 50.2 (72 FR 68043; December 4, 2007), to clarify the definition of TEDE to mean the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures). The revised definition of TEDE allows a licensee to substitute “effective dose equivalent” for “deep dose equivalent” for external exposures. The December 4, 2007, rulemaking also made a conforming change to 10 CFR 20.1201(c) to clarify the determination of occupational radiation dose for adults. This rulemaking became effective on February 15, 2008 (72 FR 72233, December 20, 2007). The provision, or some variation thereof, has been adopted by many, but not all states. Medical stakeholders, particularly those involved in interventional radiology and cardiology, noted that a consistent recognition of effective dose, rather than a requirement to use the deep dose equivalent at the point of highest exposure, would greatly facilitate their ability to comply with the dose limits. In fact, one stakeholder noted that if a realistic estimate of effective dose was allowed, there would not be an issue with these medical fields complying with a dose limit of 2 rem (20 mSv).

Stakeholders representing industrial radiography, oil well logging, and gauging, including the International Source Suppliers and Producers Association, stated that their activities require that a higher occupational dose be received during the performance of those activities. To meet a lower limit, additional trained individuals would be needed to complete any particular job. In addition, some of these stakeholders stated that the higher activity of sources typically used by industrial radiographers and similar professions in the United States would make it difficult to operate within an annual occupational limit less than 5 rem (50 mSv). The staff is still seeking to understand how these ICRP recommendations have been implemented in other countries where the limit was reduced a number of years ago in response to the ICRP Publication 60 recommendations (see Enclosure 4).

The staff notes that the suggestion by stakeholders that the selection of an occupational dose limit should be related to the activities performed, and the size of the sources employed, is problematic. The staff asserts that the setting of a proper health and safety framework to provide adequate protection must be independent of the size of the sources that may be used. The recommendations of the ICRP and National Council on Radiation Protection and Measurements (NCRP), and the current NRC regulations, apply to all types of occupational exposures, and are intended to provide a consistent, adequate level of protection. The staff does not believe that the size of a source, or the various uses of radioactive materials, is a credible or appropriate argument to be made for changing, or not changing, the occupational dose limits.

Some stakeholders stated that changing the dose limits might open an opportunity for law suits because it might have the implication of saying we have been working unsafely all these years. Some stakeholders, such as portable gauge users, did not view the possible change in the occupational dose limit as having an impact in their operations. These types of licensees do not routinely see occupational exposures that would approach a 2 rem (20 mSv) per year level. Stakeholders were asked to go beyond the simple statement of opposition to a change in the dose limit, and provide perspectives on the relative impact of each of the options. In response, the stakeholders said that the use of an average and maximum value (Option 2) was particularly difficult because of the significant record keeping that would be needed to implement. For example, the NRC would need to return to the use of something equivalent to the previous versions of NRC Forms 4 and 5, in order to account for dose from previous years. While some nuclear utilities have protocols for sharing of individual occupational dose among the facilities, a requirement for accounting of doses across multiple years would exacerbate the problems of the transient worker groups that move from licensee to licensee, outage to outage in the reactor community.

Stakeholders also noted, as an argument against changing the dose limit, that Option 2 would make decisions on the basis for ALI and DAC calculations more difficult. The values in 10 CFR Part 20, Appendix B are intended to represent a level of intake of radioactive material, or airborne concentrations, that would be in compliance with the limits under standard conditions. If Option 2 were adopted, with an average and a maximum value of the occupational dose limit, then the values of ALI and DAC could be needed for both the average and maximum, complicating the Appendix B tables.

During the discussions with stakeholders, the stakeholders were asked to provide a rationale for why the existing limit should be seen as appropriate in light of the changes in radiation risk. Unfortunately, stakeholders did not provide any substantive suggestions. In fact, many stakeholders essentially dismissed the changes in radiation risk as either not relevant or non-existent. Nevertheless, these same stakeholders endorse the use of this same scientific information as the basis for making changes to tissue and radiation weighting factors.

Staff Analysis and Conclusions:

The staff has examined the need for a change in the occupational dose limit from several standpoints. First, is whether there is a scientific and risk informed basis that suggests that there should be adjustments in the radiation protection framework. As described in Enclosure 1, the NRC staff has concluded that there have been significant changes in radiation risk estimates, and the methodologies for recommending dose limits. These changes have been

developed by both national and international organizations. Given this information, the staff has concluded that there is a sufficient risk informed scientific basis to consider changes to the NRC's regulatory framework for occupational exposure. Such changes should logically reflect the risk implications of the limit, reflect a consistency in the rationale for occupational and public dose limits, and increase alignment with the ICRP recommendations, and the standards established in other nations.

Notwithstanding the above conclusion, the second question to be considered is whether the performance of licensees under the current NRC regulatory framework meets the more recent ICRP recommendations. The data available to the NRC staff indicates that the majority of individuals receiving occupational exposure are well within an annual average value of 2 rem (20 mSv). However, the data also indicate that there are small numbers of individuals who are receiving exposures greater than 2 rem (20 mSv) but less than 5 rem (50 mSv). Although data is not available, the statements made during the public workshops, by stakeholders in the industrial and medical sectors, lead to a conclusion that there may be individuals receiving exposures greater than 2 rem (20 mSv) every single year. Thus, there is the significant potential that their cumulative doses could legally reach the range which is not recommended.

The staff recognizes the strong viewpoints to keep the limit as it presently exists, and thus the staff carefully examined possible alternative methods to responding to the radiation risk information which would move in the direction of improving occupational protection while affording greater flexibility to licensees. Such an approach has, in fact, been suggested by a stakeholder in a formally docketed comment, and in discussions in some meetings with staff. The approach suggested was to strengthen the requirements for ALARA, in keeping with the ICRP recommendations, while leaving the occupational dose limit at its present value as the ultimate boundary for legal enforcement purposes.

An approach that puts an increased emphasis on ALARA planning, and some type of requirement for action if exposures were over some specified level, such as 2 rem (20 mSv) is, in fact, the approach currently utilized by the U.S. Department of Energy (DOE). The DOE regulations in 10 CFR Part 835, specify a 5 rem (50 mSv) limit for occupational exposure. The DOE also has in place an Administrative Control Level, as part of the required radiation protection program, set at 2 rem (20 mSv) per year. Approval for occupational exposures above the Administrative Control Level requires significant senior management approval before being allowed. Effectively, there are no occupational exposures greater than 2 rem (20 mSv) within the DOE system. Stakeholders similarly expressed the view that any secondary value would essentially become the limit. As described in Section 5, the staff carefully examined the possibility of establishing such a value as an alternative to a change in the dose limit, and concluded that the likely result would be a more prescriptive regulation that would be difficult for many smaller licensees to implement. Furthermore, the result would not ensure that exposures would be less than the suggested 2 rem (20 mSv) per year level.

External factors also have some impact on the trends in occupational dose performance by licensees. The trend to decreased individual exposure in the nuclear power reactor community is a result of a concerted effort to reduce exposures to ALARA. There is significant information sharing of best practices within this licensee community, and there are external factors such as industry ranking and insurance, which have provided a significant incentive to reduce exposures. As a result these licensees exhibit strong radiation control programs with detailed planning of activities that will incur radiation exposure. The approach used in these facilities is a

good example of the approach recommended by the ICRP for optimization of protection and the implementation of dose constraints, although those terms are not used.

Conversely, industrial licensees do not have the same type of culture of sharing of radiation protection best practices, and do not have external factors of comparative performance ranking across the industry that give an incentive to reduce exposures to ALARA. In fact, exposures are in many cases driven by the number of jobs. Further, many smaller licensees do not have radiation protection programs with the structure and planning approach typically utilized in large facilities, and do not have the resources available for striving to keep exposures well below the limits.

The staff believes that it is appropriate, and scientifically justified, to pursue changes to 10 CFR Part 20 to address occupational exposures that are near the current dose limit. Although recognizing the strong opposition by many stakeholders, the staff recommends that a reduction in the occupational TEDE limit to 2 rem (20 mSv) per year be explored in greater detail, including the mechanisms that would be available to provide some flexibility for licensees.

The staff believes that a provision, such as that currently in the regulations for planned special exposures, and the provision that allows licensees to apply for prior authorization to operate at a higher public dose limit (10 CFR 20.1301(d)), has the potential to mitigate some of the impacts of the reduced dose limit, and provide flexibility for implementation on a case by case basis. The staff recommends against stating the limit as an average and maximum value (as recommended by the ICRP) because of the significant record keeping and reporting that would be needed to implement such a regulation. Given the current distribution of occupational dose, most licensees would not need the flexibility for occupational doses above 2 rem. The staff does not, at this time, recommend significant prescriptive additions to the ALARA provisions of the regulations, as these would seem to present an expensive and uncertain mechanism to reducing the exposure of higher dose individuals (see Enclosure 3, Section 5).

The recommended approach provides a performance based approach to eliminating exposures which are above the internationally recommended values, and which present an increasingly significant risk when they are received over many years. The approach would increase alignment of the NRC regulations with the international recommendations, and with the standards that have been adopted by many other nations. The approach would foster a global consistency which facilitates the increasing trans-boundary movement of workers across national borders. Further, the approach is responsive to a suggestion in the Integrated Regulatory Review Service (IRRS) report of 2010. The IRRS mission which reviewed the NRC regulatory program for reactors, noted the ongoing NRC staff effort to consider possible changes to the NRC regulatory framework, and suggested that alignment be increased with international recommendations and standards[1]. The NRC staff would, in moving forward with this recommendation, seek to obtain specific feedback on impacts and implications, and be able to engage different stakeholder communities using draft language to develop the regulatory basis and regulatory analysis for a proposed rule.

[1] The IRRS is an international peer review conducted under the auspices of the IAEA and is designed to strengthen and enhance the effectiveness of the national regulatory infrastructure of a country. Consideration is given to both regulatory technical and policy issues, with comparisons against IAEA safety standards and where appropriate, good practices elsewhere. The U.S. NRC IRRS report can be found at ADAMS No. ML110630400.

During the March 27, 2012, conference call with representatives of State Radiation Control Program Directors, there was support for the staff's proposal. One State noted that there were small groups of licensees or registrants that were getting doses greater than the ICRP recommended dose limit. The State went on to support the new dose limit and work with the small group of licensees regarding compliance alternatives. Another State noted that the ICRP recommended average and maximum limits might not provide sufficient flexibility in the short term to accommodate licensee needs, but agreed that this was a topic that needed additional discussion as recommended by the NRC staff.

Note that the staff has not considered a lifetime limit, which is part of the underlying basis for ICRP's recommendations. The Commission has previously disapproved of a lifetime limit, as discussed in the FRN for the final rule for the 10 CFR Part 20 revision in 1991. A lifetime limit is also difficult to implement operationally, which is why annual limits have been used, both here and abroad. The complications of tracking individual exposure across more than one year, which was the case with the old 5(N-18) provision[2], have resulted in some countries, particularly in Europe, moving to a single limit of 2 rem (20 mSv). The same considerations argue against use of the NCRP's recommendation, which was 1 rem (10 mSv) times the age in years (as in a 100 year old person would have 100 rem (1 Sv)).

The costs associated with a reduction in the dose limit are anticipated to include changes in programs, procedures, monitoring, and record keeping. The staff recognizes that licensees may feel the need to modify their programs, even if exposures are already below the new dose limits, in order to provide assurance that the limit will not be exceeded. A discussion of factors associated with regulatory analysis and backfit provisions is provided in Enclosure 3, Section 10.

3) Occupational Limit for the Lens of the Eye

Summary of Staff Recommendation:

- Reduce limit to at least 5 rem (50 mSv) Lens Dose Equivalent (LDE) per year, and continue to develop regulatory basis.

Options Presented for Stakeholder Discussion:

1. No change, NRC limit would remain at 15 rem (150 mSv) per year.
2. ICRP recommendation of 2 rem (20 mSv) average over 5 years, with 5 rem (50 mSv) max in a year.
3. Single value of 5 rem (50 mSv) or 2 rem (20 mSv) per year.

[2] Prior to the 1991 revision of 10 CFR Part 20, the dose limit consisted of a quarterly limit of 3 rem (30 mSv), with an additional that the total occupational dose not exceed 5 rem (50 mSv) times the individuals age minus 18. So for an 18 year old individual the total occupational dose was not to exceed 5. For a 30 year old individual, the total occupational dose was not to exceed 60 rem. To demonstrate compliance, licenses therefore needed to have a record of the individual's total occupational dose. An annual limit, in contrast, does not require knowledge of occupational exposure from previous years, which greatly simplifies record keeping.

Supporting Information:

A statement by the ICRP in April 2011 recommended a reduction in the annual limit for the lens of the eye from 15 rem (150 mSv) to an average of 2 rem (20 mSv) per year with a maximum value of 5 rem (50 mSv). The recommendation was based on the compilation of scientific evidence that radiation induces cataracts at cumulative levels of approximately 50 rem (500 mSv), rather than the previously understood threshold of several hundred rem. The current NRC limit for the lens of the eye is 15 rem (150 mSv) per year.

Induction of a cataract is considered by the ICRP to be a "tissue reaction" effect with induction occurring at levels greater than the specified threshold value. For "tissue reactions," the severity of the effect is considered to be proportional to the accumulated dose above the threshold value. This model is in contrast to the model for cancer induction, which is modeled as a "stochastic" effect, where increasing the accumulated dose is assumed to result in a proportional increase in the probability of the effect. Evidence of a lower threshold for the induction of the effect is therefore evidence suggesting a reduction in the limit, in order to avoid accumulated doses which would cause the effect to occur.

The dose to the lens of the eye will be very close to the effective dose if there is not significant shielding to the body, or to the eyes. This is particularly true for gamma exposures, where the differences in the dose calculated at 0.007 cm (shallow dose equivalent), 0.3 cm (lens dose equivalent), and at 1 cm (deep dose equivalent) are not large. For other types of radiation, such as soft x-rays, beta particles, there is a more substantial difference that might need to be taken into account. So for many situations, such as industrial radiography, most reactor exposures, etc., a change to a value lower than the effective dose would mean that lens of the eye was the most restrictive requirement. Further, in these situations, it is not likely that a separate measurement of lens dose would be needed. Dosimetry processors today utilize algorithms to estimate lens dose based on the measured deep dose equivalent.

There are some situations where shielding comes into play. For example, when shielding is provided for the torso of the body, the dose to the lens of the eye will be the same as the deep dose measured above the shielding, but greater than the effective dose that would be calculated for the individual. This is particularly the case for interventional radiology and cardiology, where the routine use of leaded aprons results in the effective dose being much lower than the reading of a badge worn outside the apron. In this case, the lens dose would be an issue unless leaded glasses with side shields are used.

The IAEA had essentially completed the process for revising their Basic Safety Standards for Radiation Protection when the ICRP statement and recommendation became available. Member states of the IAEA were afforded an opportunity to comment on a change to incorporate the new recommendations. While a number of comments were provided to the IAEA that are similar to the comments raised by stakeholders during the NRC public comment period, the IAEA decided to move forward and incorporate the new recommended limit for the lens of the eye into the final version approved by the IAEA Board of Governors in September 2011.

Stakeholder Views:

The issue of possible changes for the limit on dose to the lens of the eye was not part of the early engagement process conducted by the staff. The ICRP made its new recommendation in April 2011. The topic was not a subject of discussion during the facilitated public workshops.

Stakeholder feedback to a solicitation of comments in the summer and fall of 2011 (76 FR 53847; August 30, 2011) provided a range of views. Several stakeholders agreed that the limit should be reduced from the present value. For example, an Agreement State supported the reduction in the LDE limit to 2 rem (20 mSv) per year, but noted that demonstration of compliance could be a problem if the LDE limit were to be less than the TEDE limit. Another stakeholder stated general support for aligning the NRC regulations to the ICRP recommendations, but did not provide specifics. One stakeholder even suggested that the change was overdue, because the increased incidence of cataracts has been known for some time.

Some comments received have been cautiously supportive of some change, but not the ICRP recommended values. A nuclear power licensee stated that a change to a single value of 5 rem (50 mSv) would be appropriate, and not entail significant costs. This same stakeholder indicated that the ICRP approach of an average and maximum value would be much more costly to implement, with the significant administrative costs to track and record the average dose over multiple years. Another commenter stated that a lens dose limit of 15 rem (150 mSv) per year is too high to provide a reasonable margin of safety. This commenter, however, also suggested that a lens dose limit of 2 rem (20 mSv) per year is overly cautious and may necessitate substantial changes in workflow, staff scheduling, increased costs, and other burdens.

Another commenter stated that the medical uses of radiation, particularly interventional radiology and cardiology, were the most likely to have significant exposure to the lens of the eye. Individuals in these fields commonly wear personal protective equipment, such as lead aprons, to shield the trunk of the body from the radiation field. The result is a dose to the lens of the eye which is greater than the calculated effective dose. The commenter went on to note that while these procedures are not under NRC jurisdiction, a move by States to modify their requirements would result in the States regulation of machine produced radiation in the same way as for byproduct material.

Other stakeholders did not support a change in the LDE limit from the current NRC requirement. For example one nuclear power licensee stated that the calculated LDE value rarely exceeds the TEDE dose estimate, and thus no change was necessary. This stakeholder further stated that the administrative control level established at their facility at 3 rem (30 mSv) had never been approached unless the administrative control level for TEDE of 1 rem (10 mSv) was also approached. Another stakeholder suggested that a low LDE limit could result in considerable follow up of monitoring measurements, which could detract from other ALARA efforts.

An Agreement State indicated that their operating experience did not justify a reduced dose limit. The State also indicated that a reduced limit might not be realistic for interventional medical personnel. The commenter stated that the imposition of reduced dose limits may result in certain individuals not consistently wearing lens of eye dosimeters to avoid recording exposure, resulting in an unmonitored dose.

Another commenter suggested that there was no scientifically convincing evidence that adults permitted a maximum of 15 rem (150 mSv) to the lens of the eye annually have any significantly increased evidence of cataracts. The commenter questioned the comparison of patients who have had radiation therapy or Computed Tomography (CT) scans to those who have not had them as an appropriate control group. According to this commenter, if exposure to other drugs, genetic differences and other possibly contributing factors are not considered, these comparisons are made more questionable. The commenter urged the NRC to compare patients who received radiation therapy with significant eye protection to those who did not, and patients who had CT scans with significant eye protection to those who did not, to determine any significant differences in cataract incidence.

Concerns were also raised about the comparability of the endpoint, specifically a cataract in the eye vs. the endpoint for effective dose limitation, which is morbidity and mortality from cancer. Contributing to these concerns is the fact that lens replacement for cataracts is a routine procedure, and a significant percentage of the population will experience cataracts as they age for reasons unrelated to occupational exposure. For example, a commenter from a nuclear power licensee suggested that changing the LDE dose limit appears to be out of alignment with the risk and severity for which the basis of the limit was established. According to the commenter, this would equate a deterministic endpoint of cataracts to that of a stochastic effect such as cancer. The commenter also believes that this recommendation requires further analysis based on the following concerns associated with this change: 1) The mechanism for radiation induced cataracts following low dose fractionated exposures is not well defined; 2) it is unclear how frequently radiation opacities might advance to visual impairment; 3) evidence is accumulating that both dose and latency play a role in developing conditions, but the latency period tends to be quite long and inversely related to dose; and 4) because cataract extraction rates are not well documented for occupational situations, it is difficult to judge the impact of radiation dose on the ability of the worker to perform his/her duties. The commenter said current limits for LDE were established at a period of time when cataracts were considered to be a more debilitating disease. The recommendation from the ICRP to lower the limit to the lens of the eye for cataracts does not appear to consider the current understanding of the severity, frequency of natural occurrence of cataracts, nor the actual impacts to an individual with cataracts.

Staff Analysis and Conclusions:

The staff has examined the stakeholder feedback, and the underlying technical and scientific issues. The staff believes there is an appropriate and scientifically justified basis to recommend that the impacts of a reduction in the dose limit for the lens of the eye to a single value of 5 rem (50 mSv) be explored in greater detail. The staff supports continued dialogue with stakeholders on the key issues to develop a regulatory basis for a proposed rulemaking.

Two key areas will need further discussion as part of the preparation of the regulatory basis for a proposed rulemaking. The first is the implications of establishing a value consistent with the limit for effective dose. The staff is aware that this issue will be particularly important to certain segments of the medical community, such as interventional radiology and interventional cardiology, where it is routine to provide shielding to the torso by the use of leaded aprons. These activities are not conducted under NRC jurisdiction, because they normally do not include exposure from byproduct material under the Atomic Energy Act. The staff would, under this

recommendation, work closely with the States through the Organization of Agreement States and the Conference of Radiation Control Program Directors to examine these impacts.

A second issue which requires further discussion is how the prevention of cataracts should be viewed in comparison with the potential induction of cancer. The staff plans to take into account comments which were received by the IAEA during the member state consultation, which included a number of concerns regarding the relative impact of cataracts vs. cancer.

The staff's recommended approach would not completely align the NRC's regulatory framework with the ICRP recommendations. The staff is not convinced, at this time that a reduction to 2 rem (20 mSv) is justified from a scientific and policy perspective. Depending upon the outcome of the continued discussions with stakeholders and the scientific community, the staff would continue to hold the possibility of a reduction to 2 rem, as one of the options analyzed in the preparation of the regulatory basis.

The costs associated with a reduction in the dose limit are anticipated to include changes in programs, procedures, monitoring, and record keeping. The staff recognizes that licensees may need to modify their programs, even if exposures are already below the new dose limits, in order to provide assurance that the limit will not be exceeded. A discussion of factors associated with regulatory analysis and backfit provisions is provided in Enclosure 3, Section 10.

4) Occupational Limit for the Embryo/Fetus

Summary of Staff Recommendation:

- Change requirement to 100 mrem (1 mSv) applicable over gestation period remaining after declaration.
- Explore implications of applying over entire gestation period.

Options Presented for Stakeholder Discussion:

1. No change, retain 500 mrem (5 mSv) over gestation period.
2. ICRP recommendation of 100 mrem (1 mSv) applied to period after declaration.
3. Some other single value.

Supporting Information:

The ICRP recommendations for the embryo or fetus of an occupationally exposed female are reflective of an approach whereby the protection afforded is generally consistent with the level of protection provided for a member of the public. With the 2007 ICRP recommendations, this protection takes the form of recommending that an embryo/fetus be limited to no more than a dose of 100 mrem (1 mSv) over the remaining pregnancy following notification of the licensee or employer by the female occupational worker. The ICRP recommendation does not include a requirement for a retrospective assessment of the dose received prior to the declaration. The recommendations of the NCRP have remained at 50 mrem (0.5 mSv) per month. The staff is aware that the NCRP is currently preparing a report on Health Effects of Radiation on the Gamete, Embryo, Fetus, and Nursing Infant.

The current requirements of 10 CFR Part 20 (as set forth in 10 CFR 20.1208) provide for a limit of 500 mrem (5 mSv) during the pregnancy. The limit becomes effective upon a formal declaration to the licensee, and any exposure prior to the declaration must be assessed to determine the allowable exposure for the remainder of the pregnancy (see 10 CFR 20.1208(d)).

The current limit in 10 CFR 20.1208 reflected an alignment with the older limit for members of the public (5 mSv or 500 mrem). The change in the public dose limit to 100 mrem (1 mSv) was not accompanied by a corresponding change in the limit for the embryo/fetus of a declared pregnant woman.

Note that the individual's right to choose whether or not to declare, and when to declare, is voluntary[3]. The licensee is under no obligation to apply the limit for the embryo/fetus if there has not been a declaration.

Stakeholder Views:

Feedback was mixed from stakeholders to possible changes in the provisions. Many licensees indicated that they had no problems complying with the present requirements. Furthermore, many stated that their response to a declaration of pregnancy was to accommodate the individual in such a way that there was essentially no exposure for the duration of the pregnancy. For some categories of licensees, such as industrial radiography, it was noted that the proportion of women in the field had been historically low, although this was changing. Thus, a revision to a limit as recommended by ICRP may not cause significant concerns.

Some types of licensees, for example in nuclear pharmacies, indicated that the routine annual exposures are reported to be on the order of several hundred mrem (several mSv). For these licensees, the existing requirements for the occupational exposure of an embryo/fetus do not pose an operational issue because normal activities do not pose the possibility of exceeding the dose to the embryo/fetus. These licensees indicated that a reduced limit of 100 mrem (1 mSv) could pose a potential impact, depending on when an individual chose to declare her pregnancy.

Some medical stakeholders expressed concerns that a regulatory change adopting the ICRP recommendation may require modifications to the design of their facilities. These stakeholders indicated that their facilities were designed using conservative assumptions and based on a 500 mrem (5 mSv) dose criterion. These stakeholders report that they have not seen any impacts with the 500 mrem (5 mSv) level, such as having their primary care physicians stop procedures because they are reaching the 500 mrem (5 mSv) limit.

In addition, some stakeholders have expressed the view that the 100 mrem (1 mSv) value should be applied to the entire pregnancy, just as the current requirements apply to the entire pregnancy, in order to assure adequate protection.

When asked about the impacts of the present system, where there is a retrospective assessment of dose to the estimated date of conception, licensees indicated that they have been able to provide any necessary accommodations, and that there have not been significant impacts. The requirement for a retrospective assessment is well understood, and the staff did not receive any comments which addressed the possible reduction in burden if the requirement

[3] See definition of "declared pregnant woman" in 10 CFR 20.1003.

for a retrospective analysis were removed. As noted above, the ICRP recommendation does not include a requirement for a retrospective assessment of dose received by the embryo/fetus prior to the declaration of the pregnancy.

One of the issues discussed was the potential for a variable degree of protection when the requirements are only applied after a formal declaration. For example, if an individual chooses to declare relatively late in the pregnancy, the ICRP recommendation could actually mean that a greater dose could be accumulated than would be allowed under the current NRC regulation. This is because the ICRP recommendation does not include a provision for retrospective assessment, and the recommended limit only applies to the remainder of the pregnancy. Conversely, a declaration early in the pregnancy could be more restrictive. A stakeholder noted that the current NRC requirements also contain a restriction (50 mrem (0.5 mSv) on the additional dose that can be received after declaration, if the retrospective assessment indicates that the exposure before declaration already exceeded the 500 mrem (5 mSv) limit for the pregnancy. In this situation, a change to the 100 mrem (1 mSv) ICRP recommendation, applied after declaration, would, according to the stakeholder, not seem to pose a substantial impact, and in fact would be less restrictive.

Several stakeholders indicated that a more restrictive limit could result in an increase in individuals choosing not to declare their pregnancy, in order to ensure their continued employment. This issue was raised specifically in the medical context, where it was stated that medical students, residents, etc. would not want to have any impacts on achieving their degree and requirements. Some stakeholders went so far as to suggest that the requirements could result in an inappropriate bias in the selection of female applicants. Statements were also made that there could be an increase in non-compliance, with individuals choosing not to wear proper dosimetry, etc. Other stakeholders noted that such decisions are always a personal decision, and expressed a view that it was important that the rule provide protection equivalent to that provided to any other member of the public.

Another issue raised was the limits of detection for routine monitoring dosimetry. For many typical thermo-luminescent dosimetry systems (TLD), the minimum detectable exposure is in the range of 10 mrem (0.1 mSv). If an individual declared early in her pregnancy, it would be a challenge to actually monitor her exposure with sufficient precision to ensure compliance. The staff recognizes that this may be an issue in some situations, but also notes that dosimetry methods are available which would allow for sufficient monitoring to ensure compliance with the rule. In particular, newer electronic systems are sensitive down to approximately 1 mrem (10 μSv). This issue needs continued evaluation if the staff moves forward to develop a regulatory basis.

Similar to the comments on the TEDE limit, some stakeholders stated that reducing the dose limits may result in law suits because such a reduction would imply that declared pregnant occupational workers have been exposed to unsafe levels of radiation.

Overall, stakeholders stated that they preferred to continue with the existing requirements, which they were familiar with, rather than changing the limit to the ICRP recommendation.

Staff Analysis and Conclusions:

The issue of the dose limit for the embryo/fetus poses both technical and policy issues. Both the present NRC regulatory requirements and the ICRP recommendations are triggered when an occupational worker declares her pregnancy.

A unique feature of both limits is that the actual dose that could be received by an embryo/fetus is not a fixed number. Irrespective of whether there is a requirement for a retrospective assessment or only application of a limit to the dose after the declaration of pregnancy, the total dose to an embryo/fetus is dependent upon the dose received before declaration. With the current formulation in 10 CFR 20.1208, if the dose already received exceeds 500 mrem (5 mSv), or is within 50 mrem (0.5 mSv) of that limit at the time of declaration, then the allowable exposure is restricted to an additional 50 mrem (0.5mSv). The approach recommended by the ICRP would allow 100 mrem (1 mSv) in the same situation.

In a situation in which the accumulated dose to an embryo/fetus is less than 400 mrem (4 mSv) prior to declaration, the current rule would allow for a dose up to a total of 500 mrem. The ICRP recommendation would limit the added dose to 100 mrem, irrespective of the previously accumulated dose. For this scenario, the ICRP recommendation is a more restrictive requirement.

The staff believes that it is appropriate, and scientifically justified, to recommend that a change in the dose limit for the embryo/fetus to 100 mrem (1 mSv) be explored in detail. Such an approach would align the regulatory requirements to the scientific information available that the embryo/fetus is more sensitive to radiation and align the NRC regulations to the ICRP recommendations. The present regulations are inconsistent at the present time because the limit for a member of the public is 100 mrem (1 mSv) but the limit for an embryo/fetus is 500 mrem (5 mSv).

The costs associated with a reduction in the dose limit are anticipated to include changes in programs, procedures, monitoring, and record keeping. The staff recognizes that licensees may modify their programs and facilities, even if exposures are already below the new dose limits, in order to provide assurance that the limit will not be exceeded. A discussion of factors associated with regulatory analysis and backfit provisions is provided in Enclosure 3, Section 10.

5) ALARA Planning

Summary of Staff Recommendation:

- Continue with existing general requirement for ALARA.
- Consider development of additional regulatory guidance, based on ICRP recommendations.

Options Presented for Stakeholder Discussion:

1. No change, existing ALARA requirements.
2. Add requirement for ALARA planning values as part of optimization of protection.
3. Specify a maximum value for ALARA planning.

Supporting Information:

The current 10 CFR Part 20 requires that licensees develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities. It also requires, to the extent practical, procedures and engineering controls to minimize occupational doses and doses to members of the public.

The ICRP, in Publication 103, emphasizes the optimization of protection, and organized its recommendations to focus on optimization in all exposure situations. It also recommended the use of "constraints" in planned exposure situations as a prospective tool in the planning of optimization.

Industry experience at nuclear power plants indicates that an effective implementation of ALARA is the best way to ensure compliance with the regulations, and further improve radiation protection. Exposures at civilian nuclear power plants are low because ALARA is emphasized and is part of the organizational culture. In fact, there are also external financial and public perception drivers, because the information on occupational and public exposures is publicly available, and is utilized by groups such as the Institute for Nuclear Power Operations and the American Nuclear Insurers as one of the rankings of the utilities and the plants. There are no similar internal or external set of drivers in the materials uses of radioactive material.

The NRC regulation at 10 CFR 20.1101(b) states that each NRC licensee "shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)." Thus the current 10 CFR Part 20 does not include an explicit requirement to plan activities to optimize radiation protection (ALARA planning), or to establish ALARA planning values as part of the radiation protection program. Although not required, ALARA planning is routinely found in commercial power reactor operations, but is not necessarily as commonplace in the programs of other types of licensees. The staff notes that enforcement citations in this area have not been made against the regulation. Instead, citations have been against specific license conditions, where such conditions exist.

The staff pursued discussion with stakeholders for several reasons. Fundamentally, the staff wished to determine if it is appropriate to provide the framework for ALARA in the regulations, rather than rely on a patchwork of license conditions, in order to foster a clear and consistent approach for all types of licensees. Such an approach could increase alignment with ICRP recommendations. Furthermore, this approach was seen as a possible alternative mechanism for reducing or eliminating the occurrence of occupational exposures that approach the dose limits.

Stakeholder Views:

Stakeholders were consistently opposed to the ICRP term "constraint." They were also consistently opposed to additional requirements for ALARA, with some indicating that it was difficult, or impossible to plan radiation protection. Stakeholders were also concerned that any numerical values would become de facto limits that must be met.

A power reactor stakeholder stated that every job in the plant is planned with an estimate of what that job is going to entail from a dose perspective, with goals which are somewhat less

than the estimate. According to this stakeholder, the collective radiation exposure has been on the decline in the United States for the last 15 - 20 years because of these ALARA techniques.

Another stakeholder stated that doses from portable gauges are extremely low, making it difficult to formalize constraints in their radiation protection programs. In this regard, most doses for portable gauge users are probably less than that which is minimally detectable. This stakeholder opposes the need for a constraint.

A commenter argued that the NRC should not adopt a wholesale approach to ALARA. This commenter argued that each radiation protection program should be reviewed individually to analyze the application of ALARA and of constraints.

An industrial radiography stakeholder stated that applying the ALARA concept has resulted in extra training and on-the-job observation. According to this commenter, the ALARA concept is very well received by employees. However, other industrial radiography stakeholders stated that it is difficult to plan ALARA activities and one went so far as to say that it was not possible to plan ALARA. The reasons cited are the unique environment of industrial radiography, where conditions and working areas are constantly changing, and the workload that must be accomplished to meet contractual obligations.

A number of industrial and medical stakeholders stated that any numerical values for planning radiation protection activities would become limits. They cited, as an example, the current requirement for a constraint on the airborne effluents of non-reactor facilities, where the requirement is to report if the effluent exceeds the value, and take corrective action to prevent recurrence. They indicated that this set of requirements made the constraint a limit because effluents had to be kept below the value.

A stakeholder representing a fuel fabricator reiterated that the current ALARA requirements are the effective way to reduce dose. According to this commenter, reducing the annual limit from 5 rem (50 mSv) to 2 rem (20 mSv) will not have any effect on managing the facilities' dose.

A stakeholder stated that the NRC's regulatory guides for ALARA requirements have been helpful for issues such as protecting pregnant occupational workers. The commenter recommended that the NRC develop an ALARA guideline which would provide licensees examples of how the ALARA program should be run. Therefore, this stakeholder recommends that the NRC issue such a regulatory guide rather than amending the NRC's regulations.

One stakeholder, in response to discussions about the occupational dose limits and ALARA, provided a proposal which would add requirements for ALARA planning, mandatory use of planning values, and reporting of situations in which the planning value was exceeded.

Staff Analysis and Conclusions:

The staff began the stakeholder outreach process with the possibility that strengthening ALARA could be an alternative approach to the reduction in the dose limits recommended by ICRP, particularly in the case of exposure of individuals approaching the dose limit. On several occasions, the staff outlined a possible approach where there could be explicit planning for ALARA as part of the radiation protection programs, a requirement that licensees establish and implement ALARA planning values for their activities, and a requirement that the maximum

acceptable ALARA planning value for individual occupational exposure be 2 rem (20 mSv). Licensees would need to translate the ALARA planning value into more specific, task or job planning, as appropriate for their activities. A similar proposal was made by one of the stakeholders.

Internationally, the discussion continues on the appropriate ways to incorporate the concept of constraints, or planning values, into regulatory programs. The IAEA has added a requirement to establish constraints as part of the International Basic Safety Standards. Similar requirements have been present in drafts of the European Directive that would update the European Basic Safety Standards. Notwithstanding these requirements, there continues to be discussion about how such provisions would be implemented and inspected.

The staff recognizes that any specification of a numerical value, as a planning value in ALARA programs, could become a de facto limit without careful specifications of the expectations of both the licensee and the regulator. During the stakeholder process it became clear that a great deal of work would be needed to construct language for regulations and guidance which might be acceptable.

The staff notes that ALARA cannot be a “one size fits all” requirement. Each licensed use presents its own set of hazards and opportunities for radiation protection, and licensees have a wide range of sophistication where it comes to the radiation protection program. The use of planning values, increased review of activities and circumstances causing exposure, and higher level management approval of any doses approaching or exceeding a planning value presupposes a relatively well established program and predictable working environments. While this is certainly the case in the nuclear power community, it is not the case for many industrial and other uses.

Further, the proposals discussed would not guarantee that individual occupational exposures greater than 2 rem (20 mSv) or some other planning value, would not continue. Unless the numerical value became a de facto limit, licensees would have the ability to justify continuing exposures on the basis of their analysis.

Thus, the staff has concluded that the ICRP recommendations, if implemented for ALARA planning, would result in a prescriptive set of requirements that could be difficult to implement for many licensees. Furthermore, the requirements would not guarantee the intended regulatory outcome of ensuring that higher occupational doses did not continue. There would also be the significant challenge to establish such a system and expectations across all of the Agreement States and NRC in a consistent, predictable and transparent manner. A major question would be the degree of compatibility that would be assigned, and the actions to be taken during inspection.

In light of these discussions, the staff believes that the international recommendations for ALARA should not be adopted as regulatory requirements and that it is more appropriate to propose that the limit be changed, as described in Enclosure 3, Section 2. With the existing requirements in 10 CFR Part 20, the NRC could develop additional guidance for improving ALARA implementation, which builds on existing industry experience as one way for licensees to continue to demonstrate compliance with the 10 CFR Part 20 ALARA requirements.

6) Protection of the Environment

Summary of Staff Recommendation:

- No change to current approach.

Options Presented for Stakeholder Discussion:

The topic of protection of the environment was not presented as a set of options during the stakeholder dialogue process. Nevertheless, the topic was discussed in a number of presentations made by NRC staff, and during the facilitated workshops.

Supporting Information:

In SRM-SECY-08-0197, the Commission agreed with the staff and the Advisory Committee on Reactor Safeguards (ACRS) that the current NRC regulatory framework continues to provide adequate protection of the health and safety of workers, the public, and the environment. The Commission also agreed with the ACRS that there is no evidence that the current set of radiation protection controls is not protective of the environment, and that the NRC should not develop separate radiation protection regulations for plant and animal species. The Commission directed the staff to continue to monitor international developments in this regard and keep the Commission informed.

The ICRP recommendations in Publication 103 discuss protection of the environment, and indicate the ongoing work to develop a framework in which to assess exposures in the environment to reference animals and plants. This activity is ongoing in the ICRP, and has been aimed primarily on the development of tools for dose assessment. The most recently published report is "Environmental Protection: Transfer Parameters for Reference Animals and Plants," ICRP Publication 114. The report focused on the approaches used to model the transfer of radionuclides through the environment, and detailed an approach to calculating generic radionuclide uptake into plants and animals, as part of ICRP's framework to assess dose impact of radioactivity on nonhuman species.

Stakeholder Views:

The topic was not initially presented as a formal topic of discussion with stakeholders, but some discussions did take place. Feedback generally affirmed the currently stated Commission position that additional regulatory standards were not necessary.

Staff Analysis and Conclusions:

The staff recommends that it continue to monitor, and interact with the various international organizations and efforts developing tools and methodologies for assessment of doses in the environment. The staff believes that such work could be useful to provide validated approaches that could be used within the existing regulatory structure in the United States under the National Environmental Policy Act. Thus the staff continues to believe that there is no need for additional standards, and does not plan to pursue the issue as part of its regulatory basis for a proposed rulemaking.

7) Units of Radiation Exposure and Dose

Summary of Staff Recommendation:

- Consider modification of 10 CFR Part 20 to reflect the current NRC metrification policy to list the dose units in SI first, with English in parenthesis.

Options Presented for Stakeholder Discussion:

The issue of units for radiation exposure and dose, specifically the use of the SI units was not one of the issues outlined for stakeholder discussion at the start of the outreach process. Nevertheless, the question was raised a number of times by various stakeholders.

Supporting Information:

On August 23, 1988, Congress passed the Omnibus Trade and Competitiveness Act (the Act), (19 U.S.C. 2901 et seq.), which amended the Metric Conversion Act of 1975 (15 U.S.C. 205a et seq.). Section 5164 of the Act (15 U.S.C. 205a) designates the metric system as the preferred system of weights and measures for United States trade and commerce. The Act also requires that all Federal agencies convert to the metric system of measurement in their procurements, grants, and other business-related activities by the end of fiscal year (FY) 1992, "except to the extent that such use is impractical or is likely to cause significant inefficiencies or loss of markets to United States firms, such as when foreign competitors are producing competing products in non-metric units"[4].

Executive Order (EO) 12770, "Metric Usage in Federal Government Programs," was signed by the President on July 25, 1991. Its purpose is "to implement the Congressional designation of the metric system of measurement as the preferred system of weights and measures for the United States trade and commerce." Further, the EO directs all executive branch departments and agencies "to take all appropriate measures within their authority to carry out the provisions of this order."

In 1985, the NCRP called for a gradual adoption of SI units in the United States over a 5-year transition period (NCRP, 1985). More recently, in 2008 the National Institute of Standards and Technology (NIST) discouraged the use of the curie, roentgen, rad and rem (NIST 2008). In February 2012, the Health Physics Society issued a final Position Statement on the "Exclusive Use of SI Units to Express Radiological Quantities (see http://hps.org/documents/SIunits_ps025-0.pdf) stating that "…the continued use of traditional units to express radiological quantities in the United States … can have significant repercussions with regard to effective response to radiation emergencies…."

In response to these actions, the NRC published a metrication policy statement for comment in the *Federal Register* on February 10, 1992 (57 FR 4891). A final policy statement was then published on October 7, 1992 (57 FR 46202), which also called for the NRC to assess the state of metric use by the licensed nuclear industry in the United States after 3 years to determine whether the policy should be modified. As a result, the staff contacted members of various industrial and standards groups to determine their view of the NRC policy. On September 27,

[4] 15 U.S.C. 205b(2).

1995 (60 FR 49928), the NRC published a request for public comment on its existing policy to learn if any modifications to the policy were needed. Following review of comments, the staff concluded that no changes to the Commission's metrication policy were needed.

A practical approach to using the metric system is one that is both consistent with the intent and direction of the Act and does not introduce safety concerns or result in an economic burden to licensees or applicants. This type of approach would result in the use of the metric system by those licensees and applicants for whom the use of the metric system presents no economic disadvantage and no safety detriment to the public.

The Commission's policy on metric system conversion remains as stated in the *Federal Register* (of October 7, 1992, 57 FR 46202), as updated by the Commission's policy statement of June 12, 1996. Pursuant to the 1992 policy, the NRC supports and encourages the use of the metric system of measurement by the licensed nuclear industry. In order to facilitate the use of the metric system by licensees and applicants, beginning January 7, 1993, the NRC began to publish the following documents in dual units: new regulations, major amendments to existing regulations, regulatory guides, NUREG-series documents, policy statements, information notices, generic letters, bulletins, and all written communications directed to the public[5]. The NRC policy further directs that documents specific to a licensee, such as inspection reports and docketed material dealing with a particular licensee, will be in the system of units employed by the licensee. Furthermore, all event reporting and emergency response communications between licensees, the NRC, and State and local authorities will be in the English system of measurement[6]. The Commission stated in its June 1996 policy statement that it does not intend to revisit this policy unless it is causing an undue burden or hardship (61 FR 31169, 31171, June 19, 1996).

Stakeholder Views:

In a number of the stakeholder interactions, representatives from various groups asked if the use of the SI units would be part of any revision to the NRC radiation protection regulatory framework. They stated that this was another factor in aligning the NRC's regulatory framework with the international recommendations. They also gave a number of areas in which SI units are seen as the primary units.

Some stakeholders, such as the Health Physics Society (HPS), have included this change both in comments during meetings and as a recommendation in written comments. They noted that the rest of the world uses the SI units exclusively. As noted above, the HPS issued a final Policy Statement in February 2012. Essentially all of the scientific literature uses SI units, having been adopted by the HPS and other scientific journals. Furthermore, these stakeholders stated that the differences in units can create issues of miscommunication.

Other stakeholders, such as those in the radio-pharmacy industry, noted that their business required the use of SI units because of the global movement of materials. These stakeholders suggested that it would be an advantage to be able to use SI units exclusively.

[5] 57 FR at 46203.

[6] 57 FR at 46204

Staff Analysis and Conclusions:

The use of SI units vs. the English system of measurement continues to be a point of dialogue. The staff recognizes the interest on the part of some stakeholders for a more uniform recognition of the SI units. However the staff also recognizes that there are significant issues in moving further towards alignment with the SI units. The same public communication and emergency response communication issues remain as they were in 1995. These issues were highlighted during the response to the Fukushima event, where there was confusion resulting from the use of different units.

Another significant factor will be interactions with other Federal agencies and the States. A move to increasing the use of the SI units would need to be in concert with a general move in that direction across the entire radiation protection community. Without such an agreement, it is not likely that such a change should be made. For example, one State noted that they did not support changing to SI units, and that their current practice of stating both units (SI in parenthesis) would continue. This matter would obviously need to be explored in detail with stakeholders if the Commission agrees that the staff should pursue this policy direction.

It is not clear, on the basis of stakeholder interactions to date, whether portions of the licensed community are now suggesting that there is burden or hardship issues which could warrant a re-examination of the current metrication policy. One suggestion was to simply reverse the ordering of the dual units from the existing format for 10 CFR Part 20, consistent with the current policy statement. The current 10 CFR Part 20 was issued before the metrication policy, and thus is formatted with the SI units in parenthesis. Other NRC regulations have instances in which the SI units are listed first, with the English units in parenthesis.

The staff recommends that discussions with stakeholders continue, to understand further the needs and implications of a change in the metrication policy. The results of the assessment would be provided to the Commission when the technical basis for rulemaking was completed.

8) Reporting of Occupational Exposure

Summary of Staff Recommendation:

- Explore with stakeholders the specific benefits and impacts of requiring additional categories of licensees to report occupational exposure.
- Work with Agreement States to identify possible methods to increase the availability of information to facilitate coordination.

Options Presented for Stakeholder Discussion:

The topic of reporting of occupational exposure was not part of the original list of topics included in the solicitation of stakeholder feedback.

Supporting Information:

Under the requirements of 10 CFR 20.2206(a), seven categories of licensees are required to provide reports each year of individual occupational exposure. These categories include nuclear power reactors pursuant to 10 CFR 50.21(b) or 10 CFR 50.22, industrial radiography

pursuant to 10 CFR Parts 30 and 34, fuel processing, fabrication and reprocessing pursuant to 10 CFR Part 70, high level radioactive waste pursuant to 10 CFR Parts 60 or 63, independent spent fuel storage installations pursuant to 10 CFR Part 72, radioactive waste under 10 CFR Part 61, and processing or manufacturing for distribution pursuant to 10 CFR Parts 30, 32, 33, or 35 for specified quantities of byproduct material. Licensees who are under jurisdiction of an Agreement State are required to report as required by that State, and are not under any requirement to report to the NRC.

During the stakeholder interactions, and the staff effort to develop estimates of possible impacts of possible changes, the lack of consistency in reporting of occupational exposure was identified. For example, at the present time there are no medical licensees that are required to report. As further discussed in Enclosure 4, this lack of information has made the development of realistic impact assessments difficult.

Information that is reported to the NRC is held in the Radiation Exposure Information Reporting System (REIRS). This data base can be analyzed in a variety of ways, and the NRC staff annually produces NUREG-0713, "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities." The report for calendar year 2010 is currently being finalized.

Information currently provided under the requirements is by individual, and is considered as Personally Identifiable Information. The REIRS database and access is properly controlled for such information.

Stakeholder Views:

During the staff's consultation with stakeholders, questions have arisen on the actual doses received by some categories of occupationally exposed workers. Because these groups do not have to report their exposures to the NRC, either because there is no requirement, or because they are a licensee of an Agreement State, it has been very difficult for the staff to develop estimates of the impact of various proposals. Some stakeholders have suggested that additional categories be required to report exposures. These statements were general statements of support, and did not provide specific advantages of reporting, other than noting that such reports would allow for more accurate assessments of impacts.

Other stakeholders have opposed possible requirements for reporting. Some of these stakeholders, for example portable gauge users, stated that there was no reason for their exposures to be reported because the doses received are very low. Other stakeholders oppose the possible requirements because of the added costs to provide such reports.

During the March 27, 2012, conference call with representatives of State Radiation Control Program Directors, there was support for the staff's proposal to explore the implications of reporting. State representatives agreed that an issue of concern is the total exposure an individual may be receiving while concurrently working at more than one facility.

Staff Analysis and Conclusions:

There are several potential benefits of reporting of occupational exposures for additional categories of licensees. The first benefit is the availability of data to assess the impact of

regulatory requirements on occupational radiation protection performance of licensees. The NRC staff has experienced difficulties in developing the information needed to accurately assess the current distribution of occupational doses for some segments of use, because reports are not required. This same type of information is also used to develop trends in exposures in response to various questions or events.

A second benefit is the availability of data to support possible inspections, where the presence of significant exposures, even within the limits, may result in a performance based evaluation of the radiation protection program. In addition, movement towards a national level database provides the opportunity to determine if individuals, who may work for multiple licensees across multiple jurisdictions, are approaching or exceed the occupational dose limit. At the present time there is no mechanism for gaining insights into this situation, except for individuals working within the nuclear power industry. A more unified reporting requirement and database could support inspection of licensees, and an understanding of trends that could be used in information notices and other generic communications to groups of licensees.

The NCRP Publication 160 indicates that there are individuals who exceed 5 rem (50 mSv) per year in a number of categories of exposure, but there is no specific analytical database to confirm these statements. If true, the NCRP information would point to compliance issues with the existing occupational exposure requirements.

The staff notes that an increase in the reporting would be consistent with international calls for dose registries.

Countering the potential benefits of reporting are the potential costs to report, and the effort that would be needed to integrate reports received from multiple jurisdictions. Under the present 10 CFR Part 20 requirements, the dose record for each person is provided to the database. Most of the submissions are now done electronically. For those categories of licensees who do not currently report, there would be the additional burden of providing the records of individual dose to the appropriate regulatory organization, either the NRC or the applicable Agreement State. These records are currently required to be maintained, but not reported. While the increment in cost to provide an electronic copy of their records to the regulatory agency is small, the aggregate cost across all individuals and additional licensees could be substantial. Additional costs would arise with respect to the sharing of information in a properly controlled manner so that an integrated set of data is available for assessment, or to provide the results of particular types of assessments to a regulatory organization to meet their specific needs or questions.

The staff believes that there is merit to adding to the categories of licensees that are required to provide annual reports of individual occupational exposure. However, there may be little reason for licensees using only small sources to provide such reports. While the simplest approach would be to simply require that the exposures that are monitored by licensees be reported, alternatives of how to specify the appropriate risk informed pool of licensed uses would need to be pursued. The staff is well aware that many individuals are routinely monitored who do not explicitly meet the requirements for monitoring. This monitoring is done as a good practice, to ensure that exposures are not somehow overlooked, and in many cases as part of guarding against liability issues.

At the present time, Agreement State licensees are not required to provide reports to the NRC, and there is no collaboration between the Agreement States and the NRC that would allow for the establishment of a national registry. In some cases, it appears that the Agreement States are not getting reports. Thus, the Agreement States are crucial in exploring the benefits, impacts, and any approach to increased reporting.

9) 10 CFR Part 50, Appendix I

Summary of Staff Recommendation:

The objective of the proposed revision is to align the dosimetry basis of 10 CFR Part 50, Appendix I regulations with 10 CFR Part 20 by incorporating current developments in radiation protection principles and advances in radiation dosimetry that have occurred since the issuance of ICRP Publication 2 over 50 years ago. This approach was consistent with the prior version of 10 CFR Part 20 up to 1991, but is no longer consistent with current 10 CFR Part 20. Accordingly, the staff recommends that up-to-date scientific methodology and terminology be applied in a consistent manner as opportunities are available to update other portions of the NRC's regulatory framework. Staff recommends that the concepts of effective dose, and the numerical values that support the 2007 ICRP recommendations, be used as the baseline of information supporting an update of the dosimetry basis of 10 CFR Part 50, Appendix I design objectives and guidance.

Options Presented by the Staff:

- No change, do not revise the dosimetry basis of 10 CFR Part 50, Appendix I design objectives and guidance, or
- Revise the dosimetry basis of 10 CFR Part 50, Appendix I and guidance to reflect an update of 10 CFR Part 20 based on the ICRP 2007 recommendations.

Supporting Information:

Since 10 CFR Part 50, Appendix I was promulgated in 1975, significant changes have occurred in radiation protection science and methodologies in calculating doses. The dosimetry basis utilized by 10 CFR Part 50, Appendix I was consistent with the version of 10 CFR Part 20 prior to 1991. As revised in 1991, 10 CFR Part 20 changed the methodology by implementing dosimetry concepts of ICRP Publication 26 and ICRP Publication 30. However, Appendix I and guidance documents (e.g., Regulatory Guide 1.109 and others) were not changed, and, therefore, are still based on ICRP Publication 2 dosimetry concepts.

Currently, the implementation of 10 CFR Part 50, Appendix I design objectives and ALARA provisions is well established and the power reactor industry has extensive operational experience in demonstrating compliance. The concern is that the use of an outdated dose calculation methodology, in expressing separate doses for the whole body and critical organs using ICRP 2 dosimetry, is inefficient for both licensees and the NRC. In anticipation of future nuclear power plant applications, the removal of inconsistencies between 10 CFR Part 20 and the dosimetry basis of 10 CFR Part 50, Appendix I design objectives would be an important modernization of the regulatory process and eliminate confusion in the current dual regulatory requirements.

The staff is recommending that the dosimetry basis of Part 50, Appendix I be aligned with the dosimetry concepts and dose calculation methods of ICRP 103. This alignment would be coordinated with the parallel update of 10 CFR Part 20. This approach provides the means to standardize the regulatory framework and avoid the need to calculate doses using two different methods. This option supersedes the staff's prior recommendation presented in SECY-08-0197. In that option, the staff had recommended that the dosimetry basis of 10 CFR Part 50, Appendix I requirements be aligned to that of the current 10 CFR Part 20 (based on ICRP 26 & 30) as a backup provision in modernizing Part 50, Appendix I. While Option 2 of SECY-08-0197 would be an improvement over the current situation, Option 2 of that paper is not recommended here since it would still leave the underlying dosimetry basis and dose calculation methodology of 10 CFR Part 50, Appendix I to an outdated dosimetry concept.

Over the past decade, there have been discussions with stakeholders and interested parties about updating the basis of 10 CFR Part 50, Appendix I design objectives and its supporting guidance documents to be consistent with the dose methodology used in 10 CFR Part 20. For example, issues have been raised in light of new applications for early site permits, design certifications, and combined construction permits and operating licenses submitted under 10 CFR Part 52.

Stakeholder Views:

The general preference with most stakeholders from the nuclear industry is the option to align the 10 CFR Part 50, Appendix I scientific information with the proposed alignment of 10 CFR Part 20. These stakeholders noted that because the current regulations provide adequate protection, any change to Appendix I should be consistent with any changes that are made to 10 CFR Part 20 as related to any regulatory alignment with the recommendations of ICRP Publication 103. A stakeholder stated that from a practical standpoint, most utilities that plan to build new plants would prefer a total alignment with 10 CFR Part 20, 10 CFR Part 50, and ICRP Publication 103. Another stakeholder noted that if the underpinnings of 10 CFR Part 50, Appendix I were to comply with ICRP Publication 103, it would probably align U.S. NRC regulations well with the international community.

A stakeholder from the nuclear industry stressed that updating the science is an opportunity, not the driver for the change and update to 10 CFR Part 50, Appendix I. Another stakeholder stated the advantage of revising 10 CFR Part 20 and 10 CFR Part 50, Appendix I at the same time, is that the NRC could address the revisions to its regulations in an "all in one" approach versus having to do it in two different rulemakings.

Other stakeholders questioned the potential change to 10 CFR Part 50, Appendix I, noting that 10 CFR 50.34a specifically states that the Appendix I numerical criteria and compliance with ALARA portion or elements or provisions of 10 CFR Part 50, Appendix I, are not a safety standard. These stakeholders further stated that it has, nevertheless, become a de facto standard for implementation. These stakeholders assert that these provisions are design criteria used for the review of systems for new reactors that are being licensed, but those same criteria are applied as limiting conditions of operation of operating plants. Thus, these stakeholders do not believe that a change should be made to 10 CFR Part 50, Appendix I.

Several questions were raised on options being considered by the staff. One stakeholder asked if the alignment and harmonization of 10 CFR Part 50, Appendix I, 40 CFR 190, and other

related rules with the ICRP guidance would cause reactor effluents to go down for current power plants. According to this commenter, if the answer to this question is no, then this is an intangible exercise, or an exercise to promote math and science. They indicated that they do not see any justification for this regulatory action unless it can be shown that reactor effluents have to go down to meet the new standards.

A stakeholder representing the nuclear power industry agreed with a revision of the regulatory guidance supporting 10 CFR Part 50, Appendix I (e.g. Regulatory Guides 1.21 and 1.109), which includes revising and importing all dose conversion factors and then evaluating assumptions that are equally important to dose, such as usage factors. Other stakeholders noted that they also support an expanded scope, which revises all of the parameters and dose conversion factors, updated with current state-of-the-art information, or whatever information is available in the literature, and then leaving intact basic environmental models, for example, atmospheric and aquatic dispersion. Some stakeholders stated that utilities with a large number of power plants versus a single entity with one or two power plants may have a greater benefit from revising the procedures and computer codes used in calculating doses to members of the public.

Staff Analysis and Conclusions:

The staff recommends a revision to the design objectives of 10 CFR Part 50, Appendix I and associated regulatory guidance for the purpose of making Appendix I and the associated guidance consistent with the dosimetry basis of 10 CFR Part 20. Under the staff's recommendation, the revised regulations and guidance would retain the current numerical design criteria of Appendix I, but would redefine the dose criteria as ED or TED to be consistent with new 10 CFR Part 20 definitions of doses and nomenclature – see discussion in Enclosure 3, Section 1 on proposed changes to 10 CFR Part 20 methodology and terminology. No changes are contemplated to 10 CFR 50.34a and 50.36a regulations as these requirements do not invoke dose criteria. The proposed revision offers several advantages as it provides an opportunity to integrate the guidance on technical issues associated with 10 CFR Part 50, Appendix I requirements with that of 10 CFR Part 20. Moreover, the proposed revision provides the means to standardize the regulatory basis, impart a common underpinning on the principles of optimization and limitation of doses, standardize dose calculation methodologies, and facilitate compliance with regulations and simplify reporting requirements.

If approved by the Commission, the staff would continue to develop the regulatory basis necessary for a revision of 10 CFR Part 50, Appendix I. This regulatory basis would utilize the approach recommended for the update of 10 CFR Part 20 for consistency, and is expected to include a number of issues that are not connected with the update of methodology and terminology, as discussed in Enclosure 3 of SECY-08-0197. Enclosure 3 of that SECY paper outlines ramifications on regulatory programs and potential impacts on stakeholders and members of the public that would need to be evaluated in the development of the regulatory basis. As part of the regulatory basis, the staff would consider updating key regulatory guides and determine whether other supporting documents require revision, and describe the advantages and limitations to NRC programs and licensees, as discussed in Enclosure 4 of SECY-08-0197. Enclosure 4 of that SECY paper presents a preliminary list of technical guidance documents (e.g., a generic letter, regulatory guides, and NUREGs) and computer codes that would need to be evaluated in assessing the need and extent of any revisions.

The staff will prepare a regulatory analysis addressing potential costs and benefits with respect to all affected classes of licensees and applicants. The evaluation would also assess the impacts on implementation of the Reactor Oversight Process. The regulatory analysis will be separate from consideration of backfitting and issue finality (discussed in Enclosure 3, Section 10 below).

A review of current regulations and requirements indicates that there are a number of regulatory and technical overarching issues that would need to be considered in defining the most effective course of action. The staff would address whether to initiate the revisions of 10 CFR Part 20 and 10 CFR Part 50, Appendix I as two parallel rulemaking efforts with the implementation of the revised rules being synchronized to a common implementation date when all regulatory conforming changes and revisions of implementing guidance would be completed. The staff recommends that this effort be initiated on a parallel track with that of 10 CFR Part 20 and managed under a separate rulemaking due to the unique challenges discussed in SECY-08-0197. For example, the staff recognizes the complexity of the proposed revision to guidance documents and ramifications on the implementation into the Reactor Oversight Process.

10) Backfit Analysis

Summary of Staff Recommendation:

- 10 CFR Part 20 applies to various licensees and applicants who are protected by various backfitting provisions, including issue finality provisions in 10 CFR Part 52.
- Some provisions could be considered as redefinitions of adequate protection.
- Other provisions would require assessment of benefits and impacts.
- Quantitative analysis will not be possible in many cases, and qualitative arguments will be important in the consideration of benefits.

Supporting Information:

10 CFR Part 20 is applicable to a wide range of licensees and applicants. Some of these licensees and applicants are protected by backfitting and issue finality provisions, in 10 CFR 50.109; 10 CFR §§ 52.39, 52.63, 52.83, 52.98, 52.145, 52.171; 10 CFR Part 52, Appendices A, B, C, and D, Section VIII; § 54.37; 10 CFR 70.72; 10 CFR 72.62; and 10 CFR 76.76. Thus, the development of a proposed rule will require assessment of each affected class or licensee or applicant under the applicable backfitting and issue finality provisions in 10 CFR Chapter I.

The revision of 10 CFR Part 20, published in May 1991, concluded that the final rule provided a substantial increase in overall protection of public health and safety for both workers and members of the public. The Commission's conclusion rested on both quantitative and qualitative grounds. It is likely that a similar situation will exist with this current set of considerations.

Staff Analysis and Conclusions:

While some of the specific provisions could be considered to be adequate protection, it is unlikely that the entire package could be considered as such – at least under the current NRC

regulatory framework.[7] The staff can prepare a backfit analysis with quantifiable costs, but some benefits are in many respects unquantifiable and will need to be expressed in qualitative terms, as the Commission suggested may be done in a 1993 SRM for SECY-93-086.

For the proposal to adopt updated methodology and terminology there are substantial costs to update procedures, computer codes, training materials, and other documents to reflect the methodology and terminology. These costs must be balanced against the benefits of improved accuracy and consistency, the value of being able to use a single approach rather than the different approaches currently required by regulations, and the value of terminology that represents the updated science and which is used by many other nations.

A benefit in updates to 10 CFR Part 20 are that the demonstration of compliance is based on the current scientific information, and that the regulatory requirements are aligned with the ongoing staff practice to recognize appropriate, up-to-date approaches. It is also important to ensure that the methodology and factors used in dose calculations are a consistent set. For example, when the staff granted requests to use the methodology associated with the 1990 ICRP recommendations, one of the provisions was that the same methodology be used for the entire radiation protection program. This was to avoid a possible situation in which results from different systems were “cherry picked” as advantageous for one reason or another.

The benefit of consistently moving to the updated methodology across the entire NRC radiation protection framework is greater than that seen for 10 CFR Part 20 alone. As noted previously, 10 CFR Part 50, Appendix I uses even more outdated methodologies. For example, reactor licensees currently perform dose calculations using two different methods, one for compliance with 10 CFR Part 20 regulations (based on ICRP 26 & 30) and for compliance with Part 50, Appendix I regulations (based on ICRP 2), with some overlap in demonstrating compliance with EPA regulations under 40 CFR 190 and as implemented in 10 CFR 20.1301(e). As a result, power reactor licensees use methods and a process that are different from the requirements of other parts of 10 CFR Chapter I, are time consuming, and are difficult to explain to the public. In that regard, a move to a consistent methodology should lead to an increase in public confidence and transparency.

The benefits of updated methodologies are not quantitative in nature. Public confidence, transparency, scientific accuracy, predictability of requirements are all qualitative in nature, as is the benefit of the NRC regulatory system using the same modeling and assessment approaches used elsewhere in the world. It is possible, however, to have quantitative measures of costs. There will, in fact, be substantial costs to update procedures, computer codes, training materials, and other documents to reflect the methodology and terminology.

These costs must be balanced against the benefits of improved accuracy and consistency, the value of being able to use a single approach rather than the different approaches currently required by regulations, and the value of terminology that represents the updated science and which is used throughout the world.

[7] If the Commission were to adopt the Near Term Task Force Recommendation 1, then it may be possible that a greater set of provisions in the 10 CFR Part 20 and 10 CFR Part 50, Appendix I rulemaking, or possibly the entire rulemaking, could be considered to be adequate protection.

It is possible that the staff will conclude that, despite the flexibility afforded by the Commission in using qualitative consideration to support a finding of a "substantial increase in protection," that the Commission will determine that such a finding cannot be made. In such an event, the Commission has several alternatives for moving forward to adopt the requirements. One possibility, discussed in the Commission's 1993 SRM, is that the Commission may make an "exception" (now termed an "administrative exemption") to the Backfit Rule. The Commission took this extremely rare action in its issuance of the Aircraft Impact Assessment Rule (74 FR 28112; July 9, 2009). However, another approach would be for the Commission to adopt amendments to the relevant backfitting requirements (including issue finality provisions in Part 52), which would specifically exclude the 10 CFR Part 20 and 10 CFR Part 50, Appendix I rulemaking from those backfitting provisions. The extent to which the modifications to 10 CFR Part 50, Appendix I are made applicable to existing power reactor licensees may also influence decisions regarding the approach to backfit.

The staff recommends moving forward to develop the regulatory basis for the recommended issues. As part of the discussion with stakeholders, the staff would develop the specific information necessary to prepare: (i) the documented evaluation supporting the adequate protection provisions, and (ii) the backfit analysis for those provisions which cannot reasonably be characterized as adequate protection, including the quantitative and qualitative factors to be considered in the determinations of a substantial increase in protection to public health and safety.