MAY 20, 1985

C O R R E C T I O N N O T I C E

TO ALL HOLDERS OF

SECY-85-147 - PROPOSED REVISION TO 10 CFR PART 20,
"STANDARDS FOR PROTECTION AGAINST RADIATION"
(COMMISSION ACTION ITEM)

THE ATTACHED PAGES SHOULD BE INCLUDED IN ENCLOSURE 10 (PART III) OF SECY-85-147.

ATTACHMENTS:
AS STATED

SECRETARIAT

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

JAN 31 1984

MEMORANDUM FOR: Robert B. Minogue, Director
Office of Nuclear Regulatory Research

FROM: John G. Davis, Director
Office of Nuclear Material Safety and Safeguards

SUBJECT: PROPOSED REVISION OF 10 CFR PART 20 - STANDARDS FOR PROTECTION AGAINST RADIATION

This refers to your January 25, 1984 memorandum with the same subject. The Office of Nuclear Material Safety and Safeguards concurs in submitting the revision of 10 CFR Part 20 to the Commission for publication as a proposed rule.

John G. Davis, Director
Office of Nuclear Material
Safety and Safeguards

cc: Mr. Denton
Mr. DeYoung

Mills

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

March 27, 1985

MEMORANDUM FOR: Robert B. Minogue, Director
Office of Nuclear Regulatory Research

FROM: James P. Murray
Acting Executive Legal Director

SUBJECT: PROPOSED REVISION OF 10 CFR PART 20

The Office of the Executive Legal Director has no legal objection to the subject revision.

James P. Murray
Acting Executive Legal Director

JUL 11 1984

MEMORANDUM FOR: Harold R. Denton, Director
Office of Nuclear Reactor Regulation

FROM: William A. Mills, Chief
Health Effects Branch
Division of Radiation Programs
and Earth Sciences, RES

SUBJECT: PROPOSED REVISION OF 10 CFR PART 20

The purpose of this memorandum is to provide you with my views and those of the Branch's drafting group related to your June 5, 1984 memorandum to Victor Stello concerning CRGR's review of the proposed revision of 10 CFR Part 20. The drafting group has tried to be open and responsive to all comments received during development and review of the revision, including the concerns raised by certain individual NRR staff members and now presented in the enclosures to your memorandum. However, since many of the comments were only informally discussed and we did not receive copies of some of the NRR staff memoranda until after the CRGR review, I believe a written response to comments of the individual NRR staff members is warranted.

The initial draft revision of 10 CFR Part 20 was prepared in 1981 using EPA (SECY-81-232) and Commission (July 24, 1981 letter to EPA) guidance, with input and advice from senior scientists from all impacted offices. Throughout the drafting process, the drafting group had numerous formal and informal discussions with NRR staff regarding the various provisions, especially those impacting on reactor licensing and operations.

Following distribution of the draft revision for the initial Office level review, the drafting group and NRR staff had a series of meetings (June 9 and July 5, 7, 12, 14 and 19, 1983) to discuss the proposed revision page-by-page. At each meeting, NRR staff members presented their questions and comments, with many NRR suggestions adopted on the spot. However, some comments were continuously overtoned with an attitude of "if it ain't broke, don't fix it" and, therefore, were not commensurate with the thrust of the effort to provide the Commission with a viable alternative to the present Part 20 consistent with ICRP recommendations in Publication 26. At the conclusion of this series of meetings, the drafting group had no reason to believe that any NRR staff had not been provided an opportunity to directly voice any concerns about the revision.

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On September 13, 1983, a meeting of senior managers from NRR, NMSS and RES was held to resolve remaining issues raised by NRR and NMSS concerning the proposed revision. Prior to this meeting, NRR and NMSS had identified certain issues they wanted resolved before the rulemaking proceeded. A copy of a Memorandum For Files, dated October 3, 1983, that summarizes these issues and the resolution of those issues reached during that meeting is enclosed (Enclosure 1). All of the changes agreed upon by the senior managers were incorporated into the rulemaking "package." Some of the required modifications were major, such as deletion of the de minimis provision, deletion of the proposed dose limit for the embryo/fetus of a declared (voluntary) pregnant woman, provision for further exposure following overexposure, changes in the application of the reference level, and expansion of Appendix B to include reference level concentrations in air and water and discharges into sanitary sewerage. The view of the managers was that, if the requested changes were made, they felt that the rule was ready for CRGR consideration. Questions of implementation cost and complexities and of the benefit of a revision were not issues requiring further consideration prior to CRGR review. I note that during CRGR meetings these questions required considerable attention.

In view of the history of development of this revision, we are somewhat dismayed by the continued opposition of certain members of NRR to the proposed revision of Part 20; opposition based on suppositions and a priori views. We believe all staff members have been given every opportunity to present their comments to the Part 20 drafting group and during Office and CRGR reviews, and we believe that the issues have been appropriately considered.

Nevertheless, enclosed are our responses to the comments contained in the memoranda from Willis to Congel, dated September 1, 1983, (Enclosure 2) and from Cleveland to Denton, dated June 5, 1984, (Enclosure 3). Note that the memorandum and enclosures from Willis to Congel dated September 1, 1983 predate the above mentioned senior management meeting held on September 13, 1983.

We have also addressed Mr. Willis' comments on the EPA guidance, which were similar to his comments on the Part 20 revision. Our response to his comments on the EPA guidance is included as Enclosure 4. It is important to recognize that EPA is developing revised guidance for Federal agencies on occupational radiation protection which will also be based on ICRP-26. Since the NRC and its predecessor, the AEC, have as a matter of policy considered such guidance as binding and conformed our regulations accordingly, we have developed the Part 20 revision in close coordination with EPA.

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It is our opinion that an overall revision of Part 20 is needed and timely and that the proposed revision should be published for public comment. By copy of this memo and enclosures to V. Stello we are making our responses to the NRR staff comments available to the CRGR. Should you have any questions or further comments, please let me know how we can be helpful.

Original Signed by:

William A. Mills, Chief
Health Effects Branch
Division of Radiation Programs
and Earth Sciences, RES

Enclosures:
1. 10/3/83 Memorandum For Files
2. Part 20 Drafting Group's Response to 9/1/83 Memorandum from Willis to Congel
3. Part 20 Drafting Group's Response to 5/5/84 Memorandum from Cleveland to Denton
4. Part 20 Drafting Group's Response to Comments in 4/20/84 Memorandum from Willis to Cleveland RE: Draft Radiation Protection Guidance

cc: V. Stello, EDO

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

OCT 3 1983

MEMORANDUM FOR: Files*

FROM: W. A. Mills, Chief, HEB/RES

SUBJECT: PROPOSED REVISION OF 10 CFR PART 20

On September 13, 1983 representatives of RES, NMSS, and NRR met with the RES group drafting the proposed revision of 10 CFR Part 20. The purpose of the meeting was to discuss and to obtain direction on issues raised by NRR and NMSS concerning the proposed revision (Enclosure 1).

Attendees at the meeting included:

R. E. Cunningham, NMSS
R. J. Mattson, NRR
D. R. Muller, NRR
F. Congel, NRR
R. B. Minogue, RES
F. J. Arsenault, RES
W. A. Mills, RES
R. E. Baker, RES
W. S. Cool, RES
D. S. Flack, RES

After discussions, consensus was reached on the following directions among R. B. Minogue, R. E. Cunningham, and R. J. Mattson as the principal representatives of their respective offices.

The issues raised and the guidance given to the drafting group on the issues are summarized below:

Issue #1: Should the revised Part 20 include a de minimis provision and how should this be applied?

Direction for Issue #1: There was agreement that a de minimis provision that truncated consideration of collective dose would definitely have merit as far as saving millions of dollars in costs related to calculating and controlling the effects of licensed activities over all time, etc., and is to be retained. On the other hand, concern was voiced over the possible abuse in applying the provision for "de minimis" individual exposure (1 mrem/yr) to activities such as waste disposal and the use of radioactive material in consumer products. The conclusion reached was that the provision should apply only to disposal of

*Draft copies of this memorandum were distributed to all attendees for review and comment. Comments received from R. E. Cunningham were incorporated into this final copy.

Enclosure 1

waste from approved, licensed operations and involve prior NRC review and approval of this use of the provision. The consensus was also that the provision should not apply to consumer products because of potential abuse. In addition, guidance was given that the provision should not apply to LWR waste stream effluents, since the value to regulate them had been set, and had been demonstrated to be cost-effective, during a previous ALARA rulemaking. In summary, direction was given to the drafting group to keep the provision pertaining to collective dose and to set bounds on the application of the de minimis provision: to maintain some control over its application to waste disposal; to consider increasing the de minimis value used in operations under NRC control; to deny its application to consumer products and LWR waste stream effluents; and to build constraints into the provision which would allow the NRC, if desired, to look over the considerations used in determining that other actions, including waste disposal, could be performed under this provision.

Issue #2: Should the combined external and internal occupational exposure be limited to 5 rems/year?

Direction for Issue #2: The 5 rems/year occupational limit is consistent with the limit accepted by the international community. The consensus was that application of this limit shall apply to the sum of the internal and external exposures. It is anticipated that summing internal and external exposures would not result in undue administrative burdens because summation would only be required for demonstrating compliance when an individual is occupationally exposed at levels exceeding both 10% of the (external) deep dose equivalent and 30% of the (internal) annual limit of intake (ALI) of radioactive material. In summary, the 5 rem occupational limit applicable to the sum of the internal and external exposures would remain as presented in the proposed revision.

Issue #3: Should a provision for planned special exposures be included, and is the provision as presently worded either too stringent or subject to abuse?

Direction for Issue #3: The consensus was that the provision for planned special exposures: is consistent with ICRP 26; is not too stringent so as to prevent its use in necessary situations; and, yet, is stringent enough to prevent its abuse. Therefore, no changes in this provision were proposed at the meeting, although Dr. Congel was to supply suggestions which might enhance flexibility in use.

Issue #4: Should the limit for members of the general public be 500 mrem/yr or 100 mrem/yr, and how should these limits apply to operations licensed by the NRC?

Direction for Issue #4:

The general consensus was that the limit for members of the public from all sources should be 500 mrem/yr. However, several practical problems with application of this limit were noted:

(a) The ability of licensees to account for all significant contributions of dose to individual members of the public under the 500 mrem/year limit.

(b) The ability of most material licensees to undertake the modeling and dose calculations necessary to demonstrate compliance with the 500 mrem/year limit.

(c) With the present structure of the rule, the need to make a determination in issuing licenses that the applicant does in fact have the capability of making assessments in (b) above and the economic burden this implies.

(d) The problem of the "second guessing" syndrome appearing between the licensee and inspectors regarding the accuracy of calculations and assessments if the 100 mrem per year reference level is exceeded.

With these issues in mind, the drafting group was directed to reword this section of the proposed rule to more clearly reflect the following:

(a) The limit for members of the public from all sources is 500 mrem/year.

(b) A licensee shall be assumed to meet the 500 mrem/year limit if it controls exposure to members of the public to doses within a 100 mrem/year reference level from its own operations.

(c) A licensee may apply to the NRC for prior authorization of operations which may result in public exposures greater than the 100 mrem/year reference level. Such applications shall include the licensee's program which assesses and controls dose within the 500 mrem/year limit; shall demonstrate a clear need to operate in excess of the reference level; and shall be supported by an explanation to do so in terms of ALARA requirements.

Issue #5: Should any restriction be placed on the worker whose dose has exceeded the quarterly or annual limit?

Direction for Issue #5: The consensus of the office representatives was that the proposed provision to allow workers who have exceeded their quarterly limits to receive an additional 300 mrem/quarter for the remainder of the calender year was not acceptable. It was felt that the additional 300 mrem/quarter: 1) would penalize the worker by contributing to his potential unemployability; and 2) would not help at all to assure employability of those workers who are most likely to

receive the higher exposures because of the nature of their job. Allowing greater than 300 mrem/quarter additional exposure was not felt to increase the health risk of the worker significantly. Consideration was given to discounting exposures from isolated incidents, but it was felt that defining isolated incidents would present a problem. After further discussion of resetting the limits after over-exposures, the direction to the drafting group was to remove all constraints on limiting additional exposures to overexposed workers in order to protect their employability and to couple this action with a strong enforcement policy which penalizes the licensee, rather than the worker, in cases of occupational overexposures.

Issue #6: Should the dose to the embryo/fetus be restricted by specific dose limits for either the pregnant woman or the embryo/fetus per se?

Direction for Issue #6: The drafting group was directed to drop the dose limit for the declared pregnant woman from its proposed revision, and defer to EPA's development of Federal Guides on this topic. Discussion of this point should be included in the Statement of Considerations.

Issue #7: Should the ICRP-26 methodology be adopted for inclusion in the revision of Part 20?

Direction for Issue #7: The consensus was that the proposed revision should include the ICRP-26 methodology. However, concern was expressed over the ability of many licensees to apply the ALI and DAC occupational values listed in Appendix B to demonstrate compliance with the limits for unrestricted areas. Therefore, the drafting group was directed to expand Appendix B to include concentration values applicable to unrestricted areas.

William A. Mills

William A. Mills, Chief
Health Effects Branch
Office of Nuclear Regulatory Research

PART 20 DRAFTING GROUP'S RESPONSE TO COMMENTS
IN 9/1/83 MEMORANDUM FROM C. WILLIS TO F. CONGEL

ENCLOSURE 1 OF INCOMING MEMORANDUM

General Comments:

"The proposed new Part 20 raises a multitude of issues. Many of these appear to have the potential for major programmatic and economic impact without concommitant benefits. Generally, regulations should not be changed unless a net benefit is foreseen. Even where the reasons for a change appear compelling, an evaluation of the potential impacts should be provided as a basis for the Commission's decision.

"The proposed evaluation is deficient in that it fails to address many important potential impacts, it contains many misleading or erroneous statements and it is not in sufficient depth. The following list identifies key issues for which evaluation should be provided before the proposal goes to the Commission. These issues are discussed briefly in Enclosure 2."

Response to General Comments:

The overall revision of 10 CFR Part 20 is a major policy matter and we agree that a number of important issues are addressed. For this reason, it is important that the entire rulemaking package be transmitted to the EDO and Commission for their consideration. Both the EDO (SECY-81-232) and the Commission (July 24, 1981 letter to EPA) have already recognized the merits of adopting the system of dose calculation in ICRP Publication 26.

The revision offers the potential for establishing a scientifically sound and explicit health protection basis for not only the Part 20 standards, but also other NRC regulatory actions, including licensing decisions affecting nuclear power plants. The revision would permit control of licensed operations on the basis of the regulation itself, as opposed to technical specifications imposed on the licensees in a non-uniform manner.

The economic impact has been assessed, not only in two contract efforts, but by a number of licensees and industrial groups. The cost estimates presented in the staff paper and its enclosures have been reviewed by the Office of Resource Management's Cost Analysis Group (CAG) and, with only minor changes, have been accepted. The potential benefits have been discussed in the Commission paper, the draft Statement of Consideration, and the presentations to the CRGR. We believe that they well justify the potential cost of the revision. Identification and suggested corrections of allegedly misleading and erroneous statements are welcomed.

ENCLOSURE 2

Specific Comment 1:

"In view of the lack of potential benefit and past overwhelmingly negative responses, is it worthwhile to publish the proposed rule for comment?"

Response to Specific Comment 1:

We disagree that the proposed revision lacks potential benefit. An unusual amount of effort has been made to assess the potential benefits and costs, including many contacts with representatives of licensees, unions, and other interested people and views by ACRS, CAG, and CRGR. An independent assessment of the benefits and cost of the draft revision was presented by Paul E. Ruhter at the 1984 meeting of the Health Physics Society in New Orleans (Addendum 1). Mr. Ruhter is convinced that the benefits far outweigh the costs.

We also disagree that past response has been overwhelmingly negative. On the contrary, the response of representatives of licensees and the very large number of other interested people with whom we have discussed the revision has been very favorable. The comment might be in reference to the responses to the draft guidance to Federal agencies on occupational exposure published by EPA in January 1981. The draft revision of Part 20 has been developed in light of those responses and the hearings that were held jointly by EPA-OSHA-NRC and in parallel with EPA's revision of the guidance. The approach that is being taken is greatly different from the guidance proposed in 1981, and we do not believe that the generalization is valid or that the proposed revision of Part 20 will receive comparable criticism.

We are convinced that the revision is needed as a viable alternative to the present Part 20, that its use by the NRC is cost beneficial, and that early publication as a proposed rule is in the public interest.

Specific Comment 2:

"With so little to be gained, why accept the inevitable problems, confusion and cost of working with a completely new regulation?"

Response to Specific Comment 2:

As noted in our response to Comment 1, we consider the benefits of the proposed revision to outweigh the costs. The rulemaking package clearly identifies the principal benefits (Supplementary Information, pp. 71-74) of the proposed revision (Addendum 2). In addition, the three CRGR presentations of Part 20 included handouts and subsequent lengthy discussions of the benefits of the proposed revision, improvements in safety features and workers' protection, and areas of economic benefits of the proposed revision. At the May 30, 1984 CRGR meeting we described our "guesstimates" of the ratio of the annual cost of the revision per unit of occupational dose reduction and it is very reasonable.

We recognize that there are new terms and definitions, and that new text will raise concerns about complexity and questions of interpretation. This is because adoption of a new system of protection that is based explicitly on health risks associated with the dose limits requires some changes in the "way of doing things" by those who license, inspect or operate. However, we would

expect this situation to be short term and subsequently mitigated by education through comments, hearings, and general training before the date of effective implementation. Our experience to date would indicate that once the terms are understood the use of the system appears less complex and, therefore, less ominous.

Specific Comment 3:

"Is it responsible regulatory practice to drastically change requirements to partially follow ICRP recommendations?"

Response to Specific Comment 3:

We are convinced that it is responsible regulatory practice to update the requirements in Part 20 to reflect updated recommendations by such authoritative organizations as ICRP and NCRP. That does not mean, however, that an effective regulation should embody every detailed aspect of the recommendations of those organizations. Some aspects are not amenable to regulatory structure and these organizations recognize that national authorities must tailor the recommendations to their specific circumstances. Other aspects provide more flexibility in the management of individual worker's exposure than we deemed necessary (such as the ICRP recommendation that two times the basic annual dose limit be permitted during a single planned special exposure event) and are constrained in the proposed revision of Part 20. On the other hand, we believe that it would not be responsible action for NRC to maintain status quo and fail to implement, in general, the international system of dose limitation recommended by ICRP in Publications 26 and 30. Other countries (Canada, UK, the Netherlands, etc.) have already implemented these recommendations, or are moving in that direction. In the U.S., as well, adoption of the system appears certain sooner or later.

Specific Comment 4:

"Should limits be changed to make them a bit more nearly proportional to decade-old risk estimates, considering that biological risk estimates change so frequently?"

Response to Specific Comment 4:

The system of dose limitation that would be implemented permits change to reflect significant changes in risk estimates. Such changes are not frequent, as indicated in the comment. Further, according to a "Report of Foreign Travel - May 11-26, 1984", by Mr. R. E. Cunningham, ICRP Committee 1 has recently made an extensive review of scientific literature and has proposed to the main Commission the following statement:

> The Commission continued its review of epidemiological surveys and related reports which claim either an excessive or a decreased risk of irradiation at low doses, in relation to current cancer risk estimates presently used by ICRP for the purpose of radiation protection. On the basis of these reviews and discussions, it was concluded that no changes in current cancer risk estimates are required at the present time.

We believe that the risk coefficients presently provided by expert bodies are sufficiently consistent and well established so that changes in the proposed revision will not be a troublesome problem.

Specific Comment 5:

"Should the regulations show so little regard for a technically overexposed worker? Should one be thrown out of work for exceeding an arbitrary limit?"

Response to Specific Comment 5:

The provision (proposed §20.201(c)) regarding further exposure of an individual following exposure in excess of the limits was changed following the Office level meeting on September 13, 1983 (see enclosed Memorandum For Files dated 10/3/1983), subsequent to Mr. Willis' comments, to alleviate this perception. The Supplementary Information in the rulemaking package clearly states now that "The Commission believes that for those individuals who do exceed the annual dose limits, the regulations should not present a potential for adversely affecting an individual's availability for continued employment within the basic dose limits, provided that there is no medical advice to the contrary and the individual chooses to do so."

Specific Comment 6:

"Do we want to promote sexual discrimination in the name of "safety?"

Response to Specific Comment 6:

This comment appears to be addressed to a proposed limit on the dose to the embryo/fetus due to occupational exposure of a declared pregnant woman, a provision that was incorporated in earlier drafts of the revised Part 20.

This former provision could certainly not have promoted "sexual discrimination" because the provision depended on voluntary declaration of pregnancy by the employee. In the absence of a declaration, the licensee would have been expected to provide to the employee all entitlements and protection as provided to any other employee.

As a result of discussion during the Office level meeting on September 13, 1983, the provision was removed from the draft revision so this comment is no longer applicable. However, there is discussion of the provision in the Statement of Consideration, and comment on the issue is specifically invited. During the CRGR review on May 30, 1984, we were instructed to include the text of the provision in the Statement of Consideration in order to permit more meaningful review and comment on the issue.

ENCLOSURE 2 OF INCOMING MEMORANDUM

Response to Background Comment:

Three major points are raised in this section, namely that the proposed revision of Part 20: (1) differs from the ICRP recommendations in some provisions; (2) adopts the ICRP limits for internal emitters; and (3) limits

the combined internal and external exposure.

As clearly stated in the Commission paper, the proposed revision is consistent, in principle, with most of the recommendations on radiation protection of the ICRP, as set forth in ICRP Publications 26, 30 and 32. It is also noted that the revision differs, in some respects, from the ICRP recommendations. The differences are necessary to translate the recommendations in ICRP publications into practical regulatory requirements. (See response to preceding comment #3 of incoming Enclosure 1.)

We have considered the point regarding the ICRP-recommended system of dose limitation for internal emitters to have been resolved by the Commission's consideration of SECY-81-232 and the letter to EPA dated July 24, 1981. Those documents recommended that EPA adopt the ICRP system of dose limitation and directed the staff to consider the ICRP recommendations in the development of the revision of Part 20.

The use of the weighted sum of the internal and external dose as a regulatory limit was raised as an issue at the Office level meeting on 9/13/83 (see Memorandum for Files dated 10/3/83). The consensus of the Office representatives was that a system based explicity on total health risk has merit and, therefore, the limit shall apply to the sum of the internal and external doses. This summing should not result in undue administrative burdens because summation would only be required for demonstrating compliance when an individual is occupationally exposed at levels exceeding both 10% of the (external) deep dose equivalent and 30% of the (internal) annual limit of intake (ALI) of radioactive material. Any effect of the requirement is expected to be relevant only for workers in uranium milling, conversion, and fuel fabrication, and, potentially, some workers in radiopharmaceutical manufacturing or in hospital preparation of radioactive medicinals.

We recognize that there are inherent inaccuracies in estimating both internal dose and external dose. However, these inaccuracies do not constitute a reason for neglecting the assessment and recording of the best estimates of both components of the dose and, when applicable, their sum. Recognizing difficulties in measurement of internal dose, the proposed §20.202(b) specifies alternative ways of demonstrating compliance with the limits. Conversion from estimates of intake (already required under the existing Part 20) can be made readily to committed effective dose equivalent (using the instructions provided with revised NRC Form 5) with no disruption of operations.

While acknowledging the correctness of the comment that "nothing in the present system prevents the use of combined internal and external doses in risk estimates", the present Part 20 does not require it, and is not structured in a way as to encourage summation. Most often, compliance with limits on intake (current §20.103) is demonstrated by air sampling and records of MPC-hours of exposure. However, these are seldom recorded in an individual's records. Indeed, the dose record is likely to show only overexposures and the results of routine bioassays, which are seldom translated to dose.

Response to "Publication for Comment Not Justified" Comments (Page 2)

At this stage of the Part 20 rulemaking we consider publication of the proposed regulation to be in the public interest. Public comments can be both instructive and constructive for the Commission in making its decision on the merits of this risk-based alternative and, ultimately, result in an improved final rule if so adopted. The drafting group has already had the benefit of many comments and discussions which served as a valuable resource in preparing the proposed revision. These comments and discussions provided useful views, particularly in regard to technical and administrative problems foreseen in implementing the revision, enhancing its viability and probable acceptance.

We have no reason to expect the overwhelmingly negative responses received by EPA following publication of the draft guidance to Federal agencies on occupational exposure on January 23, 1981. The draft revision of Part 20 has been developed in the light of those comments and the hearings that were held jointly by EPA-OSHA-NRC and in parallel with EPA's revision of the guidance. EPA's present approach is greatly different from the guidance proposed in 1981 and generally consistent with the proposed revision of Part 20.

Additional comments on publication and expected responses are addressed in the Response to Specific Comment 1 in Enclosure 1 of the incoming memorandum.

Response to "The Value of Completely Re-Writing the Rule is Not Established" Comments (Pages 3-5)

The present Part 20 is a combination of the original rule and approximately 100 amendments that have been added in a piecemeal fashion over nearly thirty years. As a result, we believe the entire regulation requires rewriting to correct deficiencies, ambiguities, etc. The proposed revision provides a uniform integrated approach to the radiation protection standards, which can serve as a consistent and contemporary basis for regulatory actions. The draft Supplementary Information, Regulatory Analysis and Environmental Assessment address, in detail, the alternatives to rewriting the regulation and the reasons for not adopting these alternative actions.

Our discussions with representatives of many licensees and other interested persons indicate that many ambiguities in the present regulations have been removed in many places, reducing the opportunity for misinterpretations in licensing and inspection. Experience gained by our discussions with hourly union workers showed us that once people attempt to understand the new terminology and basic concepts in the proposed rule, they can understand the proposed revision and the rationale behind the radiation protection standards better than they understand the present Part 20 and its bases. We have attempted to correct ambiguous provisions and resolve existing problems, not to create new problems. The draft revision of Part 20 is not intended to serve as a training document, although we have attempted to incorporate the bases for the changes to the extent that it was feasible to do so. This was one of the relatively few directives given the drafting group by the middle-management steering group at the outset of the work. Most reviewers have appreciated this extra effort to help the readers understand the regulations.

The proposed revision has received extensive, detailed review by many individuals and numerous review groups. Contrary to the comment offered by NRR staff, all of the Appendix B values have been checked. A number of the values were questioned by reviewers, but all were found to be matters of rounding from the data provided by ORNL, in Bq/m^3 with two significant numbers, to the single digit values in uCi/ml we chose for Appendix B. The reviewers were making the comparison against data in ICRP-30, which were presented in one significant figure and contained a number of printing errors (corrected in Part 3 of the publication).

With respect to the need for implementing license amendments, we would hope that in time the NRC will find it reasonable to remove some of the license conditions or technical specifications that have been considered necessary beyond the coverage of the present Part 20. By proposing a relatively long period for comment following publication of the proposed rule, we believe there will be little need for early amendment of the revised Part 20.

Response to "Benefits From Changing the Requirements of Part 20 Not Established" Comments (Pages 5-7)

The issue of the benefits of the proposed revision has already been responded to (See Response to Specific Comments 1 & 2 in Enclosure 1 of the incoming memorandum). Therefore, this response is limited to those specific benefits addressed in this particular section of incoming Enclosure 2.

The ALARA issue is addressed in detail in the response to "The ALARA Requirement is Unjustified and, Without Criteria, is Poor Regulatory Practice" comments.

We do not believe that the statement that "conversion to the ICRP-recommended limits will allow comparison of theoretical risks to radiation workers with risks in other occupations" is misleading. While it might not meet all of the desirable criteria of comparison between risks to workers, it does offer some perspective. The present 10 CFR Part 20 and all of the Statement of Considerations that have been published in association with the nearly 100 amendments that have been made never have stated a numerical value for the risk associated with exposure within the limits. Prior to publication of ICRP 26 this was true of the recommendations put forth by ICRP and NCRP. NRC's regulatory limits have not been keyed into any level of risk. However, in the nearly thirty years since Part 20 was originally published there have been data developed and greatly expanded on the risk of developing various types of cancer and other radiation effects. Particularly important has been the identification of many radiation-induced solid tumors, which are now recognized to be more important than leukemia, previously considered to be the controlling risk. The system of dose limitation that would be implemented in the revision is contemporary and employs weighting factors to relate dose to each of the organs and tissues of the body to dose to the whole body, with the (stochastic) limit on this "effective" dose equivalent set at a level of risk chosen as the average of so-called "safe" industries. The (non-stochastic) "capping dose" limit to any organ or tissue, imposed after careful consideration (not arbitrarily), ensures that health effects other than cancer and genetic damage, such as cataract and reduced thyroid function, will not occur.

We believe that workers and members of the public will be well able to understand the risk estimates associated with exposure at the limits, and will be able to get a much better perspective of those risks by being able to compare them to their own experiences in life, including risks of auto accidents, risks of food additives, and risks in their work place. We consider this a very significant benefit in the instruction of the worker and a positive step forward in building understanding and perspective in the public on radiation matters.

We believe that the comment on our claiming as a benefit that the revision would permit a consistent regulatory basis for all licensees is particularly addressed at the proposed extension of very high radiation area controls to all licensees rather than present application to irradiators only. Our expectation of a benefit is much broader, but does include benefit of added protection in such areas. Our broader expectations of benefit relates to the many license conditions and technical specifications that have been used to deal with areas in which the present Part 20 is deficient in providing the basic standards of protection against radiation. These licensing actions, which are not uniformly applied to all types of licensees (or even to licensees within a given type), constitute much of the actual regulatory control of licensees and much of the administrative and economic burden because they can be more restrictive than Part 20 requires. The revision of Part 20 would permit re-evaluation, and perhaps some relaxation in these licensing provisions. An example is the technical specification requiring operation of the liquid rad waste systems at very low doses for off-site dose projections.

The NRR comment appears to attribute only to the planned special exposure provision our view that the proposed revision provides increased flexibility in the use of workers. A number of other features add to the ability of a licensee to use a worker within the dose limits. For example, in the present Part 20 there are certain precautionary procedures, such as the limitation to 40 MPC-hours in seven consecutive days when respiratory protective equipment is used, that greatly reduce short term intakes and reduce utilization of workers unnecessarily. That precautionary procedure has been removed because the wearing of respirators may not be in the best interest of the worker, if the expected intake is not significant. As a second example, under the proposed revision the licensee may permit any individual (adult) to receive up to 3 rems per quarter (and 5 rems per year) without obtaining the complete occupational exposure history of the individual and maintaining the individual's status under the present 5(N-18) dose-averaging formula. As a third example, the licensee may control on the basis of real dose to individuals, rather than on the basis of the concentrations of radioactive material that may be present and standard man assumptions. Licensees would not be required to assess real dose, but would have the option to control on that basis or on the basis of assessed intake, as in the present regulation. Thus, we believe the revision offers operational flexibility to the licensee without increasing any potential health risk to the worker exposed.

Response to "The Cost Estimates Appear Unrealistically Low" Comments (Pages 7-9)

The earlier value/impact report, which was the source of NRR staff comments, has been replaced in the rulemaking package by an updated version of the report

by Jack Faucett Associates and S. Cohen and Associates, entitled "Cost of Compliance with Occupational Exposure Revisions to 10 CFR Part 20." Our cost estimates were reviewed by the Office of Resource Management's Cost Analysis Group (CAG) and suggested changes incorporated. The major change was the addition of an estimate of the total cost of implementing the revision at a fixed discount rate.

The economic impact of the revision has also been evaluated by a number of licensees and industrial groups. As expected, there is a wide range of anticipated costs among utilities, depending on their current health physics program costs and costs they would charge to the proposed revision, but some of which they would incur anyway--such as training programs.

Mr. Willis points out that "a contested licensing action associated with the Part 20 revision could force an extended outage costing 100 million dollars at a single plant." We recognize the potential for licensing hearings, but are of the opinion that it is equally likely, if not more so, that such a hearing would be requested to challenge NRC for not updating its regulations. Some NRR and NMSS staff members have expressed concern about going into licensing hearings in which they might be called upon to testify about license conditions and technical specifications that go beyond present Part 20 requirements.

As noted earlier, the proposed revision of Part 20 could provide substantial economic benefits. A quantitative risk basis for radiation protection limits could be used to provide some relief from present requirements for licensees to meet dose levels well below levels required by health considerations. While it is not possible to accurately estimate the savings which might be realized through less restrictive technical specifications, licensing conditions, or commitments made during the licensing process, the savings could be tens of millions of dollars annually. However, such substantial savings would be realized only if a review and revision of the current staff requirements imposed on applicants and licensees are performed in the context of the proposed revision of the Part 20 rule and its system of dose limitation based on health risk decisions.

Response to "The Documentation is Misleading in Regard to the Scientific Bases for the New Limits" Comments (Pages 9-11)

We do not consider the statements in the Commission paper and Statement of Consideration that there is new knowledge and substantive scientific support for the new limits and requirements to be misleading. There have been nearly thirty years of research on the biological effects of radiation since Part 20 was first published and information was by-in-large limited to recognition of leukemia and bone tumors (radium induced). The extensive and intensive research program conducted has resulted in much better understanding of the behavior and the effects of radiation and radionuclides in the body. These studies have resulted in better dosimetric models and improved calculations, as Mr. Willis acknowledges.

We also believe that the statement by Mr. Willis that "Biological risks from low levels of radiation are not as high as previously supposed" is wrong. The biological risks based on the most recent studies of exposed populations are

significantly higher than limited types of risks recognized when Part 20 was made effective. The principal reason is that the risk of development of solid tumors (as opposed to leukemia) appears to persist longer (most likely for the lifetime of the individual). The number of excess solid cancers in the population of Japanese exposed to the atomic bombs continues to increase with age.

The ICRP system of dose limitation and the weighting factors were discussed earlier. To repeat briefly, the weighting factors are based on the biological data available and are based on the assessment of risk of developing cancer or significant genetic damage due to dose to each organ and tissue. We agree that you would not expect to "see" evidence of biological damage at the dose levels normally encountered in occupational exposure because the limits were set to achieve that goal. However, that does not mean that there is no damage, but rather that any increased incidence is sufficiently small, as to be indistinguishable from cancers or other effects that occur without radiation exposure.

ICRP has very recently reconsidered the available epidemiological and related information and concluded that no changes in the current cancer risk estimates, as used in its Publication 26, are warranted at this time.

Response to "The Commission Paper is Misleading in Implying that Basing Limits on ICRP-26 is Important to Risk Estimates" Comments (Pages 11-12)

We agree that the present Part 20 in no way constrains the NRC against estimating risk or even using risk to health as a consideration in decision-making. However, the present Part 20 does not address risk, as such, nor does it require (or permit) summation of external and internal dose, consider dose to organs other than the organs of reference (critical organs), or have any of a number of other features that we consider benefits and that can be directly related to health risk. We do not agree that the ICRP-26 methodology can be used under the present Part 20; the lack of a risk basis that reflects differences in organ sensitivities makes Part 20 incompatible with ICRP Publication 26. For example, licensees would not be allowed to calculate effective dose equivalent or to use the less restrictive intake limits that derive from that concept in some cases.

As noted above, ICRP reviewed the most recent literature on risk estimates this year (1984) and concluded that no changes are warranted. The proposed limits are based on the risk estimates, except as constrained to avoid the non-stochastic effects, a constraint which we consider necessary and desirable. It is highly unlikely that the risk estimates will change enough in the near future to pose any problem with changing limits.

We disagree that "no one has seriously suggested that risk is proportional to dose commitment." The concept of committed dose is not new, having been embodied in the recommendations in ICRP Publication 2 and those of NCRP. We have presented a rather detailed discussion of the committed dose concept in the Commission paper and in the draft Statement of Consideration. It is certainly incorrect to imply that risk from internal emitters is limited to one year and that the retained body burden does not continue to contribute to

overall risk. This is particularly true for long lived alpha-emitting radionuclides and it is generally accepted by the expert scientific community that linearity is the likely true dose-response relationship for these radionuclides. Operationally, it is conservative, in that it charges to the year of intake the whole dose that would be calculated to result if the individual lived for 50 years after an intake. However, this conservatism is balanced against the inherent weakness of controlling on the basis of annual dose where the individual might not be aware of the commitment to dose in future years and where the licensee must maintain rather extensive and burdensome records to account each year for the dose delivered from radioactive material taken into the body in all previous years. We believe the adoption of the conservative committed dose concept is simpler, less burdensome, and morally correct since it fully accounts for the overall risk to the worker resulting from a significant intake.

We do not argue that risks do not change with age, or that the risk that would be assigned in the year of intake might be greater than that actually received later in life (or perhaps not at all). However, the statement that "the genetic risk is relatively small for people under age 20" is wrong. Genetic risk is proportional to the expected number of offspring and would be somewnat higher at age 16 than at age 20, or any subsequent age. The statement is most incorrect in regard to exposure of women because they are born with a fixed number of ova that begin to decrease with onset of menstruation. The values in Appendix B, Table 2, which are applicable to the assessment and control of dose to the public, were adjusted by an additional factor of 2 from the occupational values, so that they are applicable to other age groups--including the young. These values will be used until more definitive values related to age, sex and race are available and changes are warranted. While differences in metabolic parameters, etc. must be carefully assessed in determining regulatory values, descrimination on the basis of age, sex, or race must also be avoided in setting limits.

Response to "The ALARA Requirement is Unjustified and, Without Criteria, is Poor Regulatory Practice" Comments (Pages 12-13)

Mr. Willis has indicated his belief that the proposed requirement for inclusion of ALARA considerations in the licensee's radiation protection program is "unjustified", "one major ratchet", and may lead to increased exposures (see pages 5, 12, and 13 of Enclosure 2 to his 9/01/83 memorandum). We agree that ALARA can be, and often is, used by regulators as a means of ratcheting licensees; but, we disagree that our inclusion of the concept has this effect. On the contrary, we believe that we have placed ALARA in the proper use as it relates to worker and public protection. Many licensees, such as power reactor licensees and medical licensees, are already committed for one reason or another (including regulatory pressure), to more detailed and specific ALARA programs than would be called for under the revision.

We are convinced of the need to include those involved in management decisions in the establishment and review of procedures for maintaining exposures ALARA. This involvement offers one of the greatest opportunities for dose reduction because cost savings can accompany such decisions in some instances. It is difficult to assess the potential dose reduction that might result from the

requirement for ALARA. However, if there is only a 5% reduction in man-rems in the licensed facilities not already required by technical specifications or license conditions to have ALARA programs, there could be over 1,000 man-rems saved per year.

We do not believe that the proposed ALARA provision will lead to any shift from licensed to unlicensed materials, to diversion from real radiation control measures to paperwork, or to distributing doses more widely to avoid levels that might attract regulatory attention. The undesired results noted in the NRR comment would, in our view, come about by use of the requirements in a way not intended by the regulation, which provides considerable leeway to the licensee and perhaps less to the ratcheting-oriented regulators. We note that, at the outset NRR advised the Part 20 drafting group that the only change NRR really wanted was to change the wording regarding ALARA from "should" to "shall."

We also do not agree with the comment that "if we cannot define what is 'reasonable,' we should not establish the requirements." ALARA will vary on a case-by-case basis and should be implemented as a philosophy in making decisions on radiation protection, rather than as quantitative requirements imposed upon the broad range of licensed activities to which Part 20 applies.

Response to "Overexposures" Comments (Pages 13-15)

The response to Specific Comment #5 in Enclosure 1 of the incoming memorandum discusses changes in the overexposure provision that make additional discussion of this issue unnecessary.

Response to "Pregnant Women" Comments (Pages 16-18)

The response to Specific Comment #6 in Enclosure 1 of the incoming memorandum discusses changes in the rulemaking package that make additional discussion of this issue unnecessary. However, it should be noted that even though the Commission does currently operate under a policy of informed consent, it stated in its July 24, 1981 letter to EPA that "the Commission believes that the lower ICRP exposure limit should apply." EPA is currently updating the guidance to Federal regulatory agencies regarding occupational radiation exposure that was established by Presidential memorandum and Federal Radiation Council Report No. 1 on May 13, 1960. The latest draft of the revised guidance includes a statement that the dose equivalent to an unborn child as a result of occupational exposure of a woman declared or known to be pregnant should not exceed 0.5 rem, and in addition, positive efforts to control dose equivalents to the unborn to less than 0.2 rem in any month are encouraged. We recognize the authority of EPA to develop recommendations in this area, and, following approval by the President of any recommendations as Federal guidance, NRC will implement that guidance in a revision of 10 CFR Part 20.

The "biological realities" of the importance of protecting the embryo/fetus have been documented, most recently in a May 1984 paper by Otake and Shull, which was published in the British Journal of Radiology. The published data demonstrate an increase in mental retardation from in utero radiation during the 8th to 15th week of gestation.

Response to Comments on "No Evident Justification for 'Very High Radiation Area' Requirements" (Pages 18-19)

The revised requirements for very high radiation areas have been simplified to the degree considered consistent with achieving positive assurance that individuals will not be inadvertently exposed at very high dose rates which present an immediate threat of lethality in any type of licensed facility. There should be additional control measures for all areas in which radiation levels might exist such that an individual could receive a lethal dose in a very short period of time. Only those licensees who use sealed radioactive sources to irradiate materials are required by the present Part 20 to use such additional controls. However, very high radiation levels are not limited to irradiator facilities, but are present in areas of nuclear power plants, some industrial radiography operations (primarily fixed installations), medical teletherapy installations, etc. There have been at least three events where workers in nuclear power plants, while overexposed, could have received lethal doses under slightly different circumstances. (On two occasions, shift supervisors have entered the area under the reactor vessel when thimbles were exposed; on another, workers failed to recognize a large pipe used for fuel transfer and were near the pipe when a "hot" element passed.) While the provisions in the present §20.203(c)(6) have been modified somewhat to permit application to all types of licensees, we believe that the requirements in the revision will be more effective in preventing such instances and the accompanying overexposures.

Response to "Should the Regulatory Limits be on the Weighted Sum of the Internal and External Dose?" Comments (Pages 20-21)

This question is raised in paragraph 2, page 2, and on pages 20 and 21, of Enclosure 2 to Mr. Willis' memorandum. It was also raised as an issue at the Office level meeting on 9/13/83 (see Memorandum for Files dated 10/3/83). The consensus of the Office representatives was that the limit shall apply to the sum of the internal and external exposures.

It is anticipated that summing internal and external exposures would not result in undue administrative burdens because summation would only be required for demonstrating compliance when an individual is occupationally exposed at levels exceeding both 10% of the (external) deep dose equivalent and 30% of the (internal) annual limit of intake (ALI) of radioactive material. The requirement for summation is estimated, in the absence of good data on the extent of exposure to radioactive materials, to impact the workers in uranium milling, conversion, and fuel fabrication, and, potentially, some workers in radiopharmaceutical manufacturing or in hospital preparation of radioactive medicinals. The total number of workers involved is estimated to exceed 10,000.

We recognize that there are inherent inaccuracies in estimation of internal dose, as there are in the comparable estimation of external dose. They do not constitute a reason for neglecting the assessment and recording of both components of the dose, and when assessed, to sum them. It is true that it is not possible to actually measure internal (or external) dose. This is

recognized in the draft revision and the proposed §20.202(b) specifies alternative ways of demonstrating compliance with the limits. Conversions from estimates of intake (already required under the present Part 20) to committed effective dose equivalent can be readily made (using the instructions provided on revised NRC Form 5 which is included in the notice of proposed rulemaking) with no disruption of operations.

While "nothing in the present system prevents the use of combined internal and external doses in risk estimates," it does not require it, and it is not structured in such a way as to permit or encourage summation. In our observation of licensed operations, compliance with the limits on intake (present §20.103) is demonstrated by air sampling and records of MPC-hours of exposure. However, these are seldom recorded in an individual's record. Indeed, the dose record is likely to show only overexposures and the results of routine bioassays, which are seldom translated to dose.

Response to "Non-Radiological Risks Should be Recognized" Comments (Pages 21-23)

These comments raise a valid point on the desirability of balancing risks from radiation exposure with other risks that might be involved. A very good example of this is the use of respiratory protective equipment to reduce the intake of radioactive material. There is considerable stress associated with the use of some of these devices (increased breathing resistance, as well as heat discomfort, clumsiness, movement limitations, communication problems, etc.) that are hazards of their own right, and increase the amount of time or effort that must be expended in the radiation area in order to accomplish a given task. The proposed revision includes changes, such as deletion of the recuirement in the present §20.103(b)(2) that limits individual intake to 40 MPC-hours in any seven days when using respiratory protective devices, that are intended to put internal dose into better perspective with external dose and in clear recognition of the non-radiation problems mentioned above. We believe that the proposed revision is an improvement in this respect, and that we have done about all we can in this area at this time. We would welcome any specific examples or language which would further this intention.

There is a powerful psychological differentiation by workers (and by many NRC staff members) between external dose and dose received from radioactive material taken into their bodies. This bias rejects the basis of the calculations and chooses respiratory protection, with its associated difficulties, often resulting in higher external doses. For example, a task that can be done in three hours without respiratory protection might require four hours with such protection. If the work conditions involved air concentrations ten times MPC and an external dose rate of one rem/hour, this use of respir tory protection could cost an extra 0.925 man-rem in addition to the stress of respirator use. (One MPC-hour is equivalent to 2.5 mrem. Three hours of intake at ten times MPC, without respiratory protection, would be equivalent to 75 mrems. Even if the respirator is 100% efficient, the external dose of 1 rem for the additional hour would outweigh the internal dose that might be saved.)

Part of this comment addresses the basis (ICRP Publication 27, "Problems Involved In Developing an Index of Harm") used to select the level of risk to which the recommended limits would be targeted. It is recognized that accidental deaths are not directly comparable to potential cancer fatalities or to genetic defects expressed in the first two generations of offspring. We understand that ICRP is considering other bases for selecting the level of risk. However, changing the bases would not necessarily change the system of dose limitation, and is unlikely to result in significant change in the level of risk selected because of the many non-technical elements that are inevitably part of a decision regarding acceptability.

Concerns about unjustified exclusion of people from radiation work (such as overexposed workers and pregnant women) are addressed in other responses.

Response to "Other Important Issues for Which Evaluation is Needed" (Page 23)

Issue 1: "Should detailed requirements, such as 'reference levels' for radiation protection be established by regulation? Should the requirements be the same for a nuclear power plant, a hospital and a one-man instrument shop?"

Response to Issue 1:

The reference level provision was raised and resolved at the Office level meeting 9/13/83 (see Memorandum For Files dated October 3, 1983), subsequent to Mr. Willis' memorandum of 9/1/83. The reference level of dose to the public was proposed as a tool to accomplish several purposes. First, the limit for members of the public from all sources is 0.5 rem/year. However, it is impractical, if not impossible, to determine precisely an actual dose because of possible multiple sources, complex problems involving dosimetry, incomplete information concerning water and food intake, habits, spatial and temporal considerations, and other confounding factors. Therefore, a licensee shall be assumed to meet the 0.5 rem/year limit if the licensee controls exposure to members of the public to doses within 0.1 rem/year from the licensee's own operations. Second, the proposed requirement for reporting when the reference level is exceeded (proposed §20.1205) will identify those licensees who are making the more significant contributions to public dose and permit consideration of those operations for additional control. Further, the reference level would implement the ICRP recommendation that life-long dose to the individual member of the public be limited to 0.1 rem/year.

Issue 2: "Why eliminate the 5(N-18) provision which tends to shift exposure to older workers where theoretically it is less harmful?"

Response to Issue 2:

By memorandum of November 30, 1978, Chilk to Gossick, the staff was directed to develop for Commission-review and approval a revision of Part 20 to eliminate the use of the 5(N-18) formula. Commission paper SECY-78-415A responded to that directive. The notice of proposed rulemaking, published February 20, 1979 (44 FR 10388), indicated that the

action was based on assessment of the need for the dose-averaging formula, which allows a worker to receive up to 12 rems per year, and the desire of the Commission to reduce the risks of occupational radiation doses in Commission-licensed activities. The proposed rulemaking was not carried forward to effective rulemaking, but rather combined with the overall revision of Part 20.

Other than the NRC, the drafting group is not aware of any domestic or international organization which still permits the use of the 5(N-18) dose-averaging formula. Both the NCRP and ICRP agree that the use of the formula should not be permitted.

Issue 3: "Should requirements for elaborate environmental dose calculations be included in Part 20? It would seem more appropriate to address such requirements to those specific facilities where there may be a need."

Response to Issue 3:

First, note that the revision of Part 20 would not require elaborate environmental dose calculations. Licensees may continue to operate on the basis of the concentrations of radioactive material released in air and water effluents to unrestricted areas, as most licensees do at this time. The values listed in Appendix B, Table 2, are calculated to meet the reference level, rather than the 0.5 rem/year limit, or equivalent organ or tissue dose, targeted in the current Appendix B, Table II. The licensee would be provided the option to control releases on the basis of real dose, and, if so, might then have to make environmental assessments in order to assure that the dose to members of the public from all sources and pathways does not exceed 0.5 rem/year. We believe that the few licensees who would choose this option are already operating in a comparable manner under procedures specifically approved in the license. This is only one example of our efforts in the revision of Part 20 to make the limits, and the optional methods of demonstrating compliance, uniformly applicable and available to all licensees.

Issue 4: "What is the value and impact of dramatically changing the limits for certain nuclides? The changed thorium limit may be the most important aspect of the ICRP-based regulations; it might effectively preclude the consideration of thorium as a nuclear fuel in the USA."

Response to Issue 4:

An important value in changing the limits for certain nuclides is that the NRC's regulatory values will reflect defensible, widely accepted, contemporary scientific knowledge. It is recognized that a large portion of the cost impact of the revision derives from the more restrictive ALIs and DACs for uranium. Little cost was assigned to the greater reduction (about a factor of 60) in the value for thorium, primarily because of the limited use of thorium at this time. No attempt has been made to assess the cost or industrial impacts of potential future uses of a given nuclide. The values for thorium have been larger than calculations based on dose limits would have indicated for many years. The listings for

thorium in ICRP Publication 2 (1959) are footnoted as "Provisional values", arbitrarily listed a factor of ten higher than would be suggested by calculations based upon evidence even then available. The footnote further states that "the possibility that further evidence may require lower values and to urge especially that exposure levels for these radionuclides be kept as low as is operationally possible." The additional factor of 5 or 6 (from the 10 of the provisional values to the 60 that would relate to the values in the revision) applies to uranium and other alpha emitters, as well as thorium.

Addenda:

1. Ruhter, Paul E., "The Effect of Revised 10 CFR 20 on Power Reactor Health Physics, June 5, 1984.

2. Supplementary Information, pp.71-74.

EG&G Idaho, Inc.

P.O. BOX 1625, IDAHO FALLS, IDAHO 83415

Dear Mr. Mills:

Enclosed is a copy of the paper presented at the 29th Annual Health Physics Society meeting which you requested. Thank you for your interest. If you have any questions, please give me a call.

Sincerely,

Paul E. Ruhter

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cc: File

Enclosure 2 / Addendum 1

THE EFFECT OF REVISED 10 CFR 20 ON POWER REACTOR HEALTH PHYSICS

Paul E. Ruhter
EG&G Idaho, Inc.

Presented at
29th Annual Meeting
HEALTH PHYSICS SOCIETY
New Orleans, Louisiana
June 5, 1984

THE EFFECT OF REVISED 10 CFR 20 ON POWER REACTOR HEALTH PHYSICS

P. E. Ruhter
EG&G Idaho, Inc.

A major revision to 10 CFR 20 has been prepared by the Nuclear Regulatory Commission (NRC). Although it has not yet been published for public comment, it has been released informally to industrial sources for review and comment. Changes are being made on the draft, which was available in early-1982, and where those changes are significant, they will be discussed.

A casual glance at the proposed revision immediately reveals that it is substantially longer than the current regulation. The current regulation was written with the philosophy of identifying those minimum items which would be essential to preventing serious exposures to workers or significant loss of control of radioactive materials. The details of a radiation protection program were left up to the experienced professionals to determine, and were covered as a part of the licensing process for each specific plant. The proposed revision to 10 CFR 20 provides considerably more detail. In fact, it effectively is a reasonable guideline for the procedures which would constitute an acceptable radiological controls program. From the standpoint of one who believes that our society should be moving toward fewer, more efficient laws and regulations which permit a person to exercise reasonable and prudent judement, this abundance of detail would seem objectionable.

However, the NRC has the same problem in hiring personnel that the nuclear power industry has; every new hire does not have 20 years experience. The current regulations are clear if one knows what they mean. Unfortunately not all power plant health

physicists nor all NRC inspectors have the years of experience require to exercise reasonable and prudent judgment. As a power plant health physicist, you do not operate in a vacuum, but must frequently interact with the NRC during preoperational approvals or during inspections and audits. Although one may have the experience to understand what the current regulations were intended to mean, the NRC personnel with whom one interacts may have a differing opinion which leads to long discussions and inefficiencies. Although the proposed revision to 10 CFR 20 is much more detailed, the detail is in those areas which are generally accepted as being routine requirements for a radiological controls program and should not be the subject of misunderstandings or long discussions. Examples will be provided below. This paper is intended to identify the effect this proposed revision will have on health physics at nuclear power plants and to provide background for reviewing the proposal when it is published for comment.

The most controversial aspect of the proposed revision deals with how the bookkeeping will be done on internal exposures from long-lived isotopes such as uranium and plutonium. The proposed revision incorporates the methodology of ICRP 26 and 30, particularly with respect to determining 50-year committed doses. In those cases where the long-lived isotopes make this impractical, a 'further provision' has been included which permits, with certain limitation, assigning only the annual dose to a given year rather than the 50 year committed dose. Since a nuclear power plant seldom is concerned about internal uptakes of plutonium or uranium, this controversial area has essentially no effect on power reactor health physics and will therefore not be discussed in any more detail.

Improvements Over Current 10 CFR 20

The definitions for the various radiologically controlled areas in the proposed revision are substantially improved over

the current definitions. The definition for Radiation Area serves as a good example.

Current Definition- Radiation Area

Any area, accessible to personnel, in which there exists radiation, originating in whole or in part within licensed material, at such level that a major portion of the body could receive in any one hour a dose in excess of 5 millrems, or in any 5 consecutive days a dose in excess of 100 millrems.

Although we may all understand this definition, several areas are unclear and have been the subject of long discussions held personally with NRC inspectors. The phrase 'in whole or in part within licensed material' looms as potentially significant, but what does 'in part' mean? The phrase 'a major portion of the body' is reasonably clear, but how is it applied in the field by a technician with a survey meter trying to determine how to post a hot spot? Although 5 mrems per hour is clear, what dose rate is equal to 100 millirems in 5 consecutive days? Most health physicists 'know' that this means 100 mrem in 40 hours or 2.5 mrem/hr. However there is an official interpretation by NRC that this means 100 mrem in 120 hours or 0.8 mrem/hr. At TMI, radiation areas were posted at 0.8 mrem/hr because of this interpretation.

The proposed definition is much clearer.

Proposed Definition

An area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem in one hour at 30 cm from the radiation source or from any surface which the radiation penetrates.

This definition omits the legalese 'in whole or in part'. It states unambiguously that the dose rate for a radiation area is 5 mrem/hour and it provides a distance at which the dose rate shall be measured. This definition as well as the other 'area' definitions are clearer and therefore more effective. The definitions are equivalent to how most power plants have implemented them, but are stated in a much clearer fashion. The effect will be more consistent implementation of the regulations.

The proposed revision uses the ICRP nomenclature of Derived Air Concentration (DAC) instead of Maximum Permissible Concentration (MPC). The definition for Airborne Radioactivity Area is the same except that the average air activity has been raised from 25% MPC to 30% or 12 DAC-hours in 1 week. A comparison of proposed DACs and current MPCs is presented in the table below. A few isotopes have been selected that are typical of those encountered at a power reactor. The DACs are equal to or greater than current MPCs. The increase for noble gases is about a factor of 10 as shown for Kr-85. This is due to the correction of errors in the calculation that derived MPCs.

COMPARISON OF AIR CONCENTRATIONS

	Current MPC	Proposed DAC
H-3	5×10^{-6}	2×10^{-5}
Co-60	9×10^{-9}	1×10^{-8}
Kr-85	1×10^{-5}	1×10^{-4}
Sr-90	1×10^{-9}	2×10^{-9}
I-131	9×10^{-9}	2×10^{-8}
Cs-137	1×10^{-8}	6×10^{-8}
	(s) 6×10^{-9}	

The DACs are listed by solubility classes of D (days), W (weeks), and Y (years) instead of the more nebulous soluble and insoluble. The table of DACs in the proposed revision gives considerable information to aid in determining which class is appropriate.

There is a new definition included in the proposed revision--Very High Radiation Area. Although the definition is new, this area designation and the access controls are included in the current 10 CFR 20 albeit buried in paragraph 20.203.(c)(6) and have probably escaped detection by all but those with a fine-toothed comb. The access controls are applicable primarily to facilities with large irradiation sources and have little effect on power reactors. However, by including the definitions for a Very High Radiation Area (500 rads in 1 hour at 1 meter), it is less likely to be overlooked. The access controls in the proposed revision are the same as those specified in the current 10 CFR 20. The proposed revision correctly reminds us that dose in this range should be recorded as rads since the quality or modifying factors at these dose rates are not well understood. This could be a recordkeeping nuisance but is not a practical problem since exposures at this rate do not occur routinely!

The proposed revision clears up some signficiant gray areas. For example, the current 10 CFR 20 identifies acceptable dose rates in 'unrestricted areas' and identifies restricted areas as those areas access to which is controlled for radiological purposes. Most power reactors have an area known as the 'owner-controlled area' that is not actually a restricted area but is also not an unrestricted area. The acceptable dose rates in this gray area (the owner-controlled area) are ambiguous. The proposed revision clarifies this by defining restricted area and controlled area as follows:

Restricted Area

An area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials.

Controlled Area

An area, access to which is limited by the licensee for any reason.

The proposed revision provides reasonable guidance concerning the exposures permitted to occupational workers or the public who might be in these areas without limiting dose rates. This is very sensible since it is exposure to people that should actually be controlled, not just dose rates in air. In this manner, the proposed revision has eliminated a potentially gray area and by placing the limit on the proper parameter has given the licensee more flexibility in conducting his activities providing the exposure to people is properly controlled.

The proposed revision provides clear guidance in several areas which have the possibility of being 'gotchas', i.e. circumstances beyond reasonable control which create potential noncompliance situation. A good example is the paragraph which specifies dose limits for the embryo/fetus. The limits are the same as presently covered by Regulatory Guide 8.13, however the proposed revision provides more definitive direction about how to handle the pregnant person situation.

One potentially sticky situation deals with how to calculate the dose to the embryo/fetus if the pregnant worker receives an uptake of internal emitters. A literature search provides very little guidance on how to calculate the dose to the fetus. However the proposed revision states that the dose assigned to the embryo/fetus should be twice that assigned to the pregnant worker unless a more appropriate value can be substantiated. This makes

the health physicist's job much easier should he ever encounter this situation. The second 'gotcha' deals with how to handle the situation where the pregnant worker finally identifies that she is pregnant but has already received more than 0.5 rem since becoming pregnant. The current guidance would suggest this to be a noncompliance situation from a regulatory standpoint, yet would be essentially beyond the health physicist's control. Yet this is a likely scenario involving a pregnant worker who continues to work while trying to decide whether to tell her employer that she is pregnant. The proposed revision states that you would not be charged with an overexposure providing her exposure during the remainder of her pregnancy did not exceed 50 mrem. This is a reasonable and workable requirement.

Note: Recent discussions with NRC personnel indicate that the limits for the embryo/fetus will be eliminated from the public comment version. I personally believe that to be a mistake since handling it as a Regulatory Guide matter does not place the proper emphasis on it.

Potential Problem Areas in Proposed Revision

Although the proposed revision has eliminated many of the problems of the current 10 CFR 20, it is not without fault. An example is provided by the limits placed on exposure to members of the public.

Dose Limits for Members of the Public

The licensee shall constrain exposure of any individual member of the public from sources under the licensee's control so that the total dose from all sources and operations, licensed and unlicensed, except for natural background and medical diagnosis and therapy, does not exceed 0.5 rem per year.

The phrase 'licensed and unlicensed' makes the licensee responsible for the sins of his neighbors. This phrase indicates that the health physicist must be aware of what radiological exposures the public is receiving from sources other than his own plant and adjust the releases from his plant accordingly if the exposures were approaching 0.5 rem per year. Experience has shown it is very prudent to be aware of the 'other' sources of radioactivity in the environment around a power plant, be they natural background, fallout, or a nearby radioisotope user. But having to potentially shut down to accommodate the releases from facilities beyond ones control is unreasonable. However, this will not generally be a practical problem since exposures to the public from power reactors is typically less than 0.001 rem. The proposed revision also states that if a power plant is in compliance with the EPA guidelines of 40 CFR 190, "Environmental Radiation Protection Standards for Nuclear Power Operations", then the effluents would be considered ALARA.

Another area in the proposed revision which appears unreasonable is the specification of conversion factors for photons of differing energies. The proposed revision specifies a factor of 1 for all energies except those from 35 kev to 150 kev for which the conversion factor is specified as 1.5. This is a potential inspection/audit trap with no redeeming benefit. A properly calibrated dosimetry system accommodates the correct conversion factor implicitly, although doing the background research to prove this to the inquiring inspector would be inefficiently time consuming. With the current direction which NRC is taking in requiring NVLAP approved dosimetry processors, the inclusion of the conversion factor appears unnecessary.

NOTE: Recent discussions with NRC personnel have indicated this will be corrected in the public comment version.

The proposed revision has incorporated the methodology and terminology of ICRP 26 and 30. This will require an adjustment

in the terminology health physicists use while discussing personnel dosimetry since there will be many more terms than 'internal dose', 'external dose', 'extremity dose' and 'skin dose'. The new terms include *absorbed dose, dose equivalent, deep dose equivalent, committed dose equivalent, effective dose equivalent, committed effective dose equivalent, shallow dose equivalent,* etc. Although reasonably clear after a small amount of study, the use of these terms with lay people, such as operations and maintenance personnel and even the boss, will undoubtedly add some confusion for awhile. While some may consider this additional job security, others will view it as a nuisance. It is fortunate that the proposed revision does not also try to convert to SI units!

The proposed revision has an expanded section of definitions. The definitions for these dosimetry terms are generally clear with one exception. Effective dose equivalent is defined as

> *The sum of the products of the weighting factors applicable to each of the body organs or tissues which are irradiated and the annual dose equivalent to the organ or tissue (T) from an intake of radioactive material.*

The use of the term 'annual dose equivalent' with reference to the intake of radioactive material is confusing. The other definitions associated with internal dose refer to committed dose equivalent as a 50-year dose. The usage throughout the proposed revision of the term 'effective dose equivalent' appears to mean 50-year committed dose. As discussed at the beginning of this paper, there are provisions for assigning to the individuals' records only the dose actually received during that year from long-lived isotopes. However, the use of the term 'annual' raises a question about whether the intent is to apply this procedure to other isotopes. Omitting the word 'annual' in the definition for Effective Dose Equivalent or replacing it with 'committed' would clear up the confusion.

Major Additions to the Regulations

As discussed thus far, much of the proposed revision looks very much like the current 10 CFR 20 with minor changes which have been substantive improvements. There have also been some major additions.

The proposed revision has added a section on De Minimus levels for doses to individual members of the public. As stated, the levels are limited in scope but at least it is a start in this sensitive area. De Minimus levels are defined as 0.001 rem in a year to any individual, while 0.0001 rem or less in a year may be omitted in making collective dose estimates as long as the sum total of De Minimus is less than 0.001 rem in a year. This should help simplify the dose calculations for annual environmental impact reports.

The requirement for and the elements of an ALARA program have been added to the proposed revision. Briefly these elements are:

1. A radiation protection program including ALARA is required.

2. Management or designee must examine and verify the program features and records, and investigation levels below the limits must be established.

3. Licensee shall review circumstances which cause doses in excess of investigation levels.

4. Records must be maintained of ALARA actions.

This addition places in the regulations what previously was essentially a part of a Regulatory Guide. This will effect a power reactor health physics program only if these elements have not been included. However, the requirements allow considerable flexibility in implementation.

The incorporation of ICRP 26 and 30 has caused the occupational dose limits to appear different. The following summarizes the proposed revision.

Occupational Dose Limits for Adults

1. Annual limit is the more limiting of:

   - The sum of the (external) deep dose equivalent to the whole body and the (internal) committed effective dose being equal to 5 rems; or

   - The sum of the deep dose equivalent and the committed dose equivalent being equal to 50 rems to an organ or tissue other than the eye.

2. The annual dose equivalent limit to the lens of the eye is 15 rems.

3. The annual dose equivalent limit to the skin and to each of the extremities is 50 rems (applies to DE averaged over 10 cm^2 in region of highest exposure).

4. The deep dose equivalent component of the annual effective dose equivalent... shall not exceed 3 rems in any calendar quarter.

The limits for effective whole body exposure, both internal and external, is 5 rem in a year with the external component limited to 3 rem in a quarter. This is essentially a reduction from the current external exposure limits, but should have little effect since few workers receive exposure greater than 5 rem in a year. The proposed limits also include internal and external where the current 10 CFR 20 has separate limits for each. Although this is a significant reduction, this should have no practical effect

since internal exposures at power reactors are normally not detectable or seldom significant. These changes bring the US regulations more in line with international recommendations and actual practice.

The proposed revision also states the area of skin over which skin exposures should be averaged. This will end that perpetual debate for NRC licensees.

The current 10 CFR 20 has the 5(N-18) rule which provided some flexibility for unusual exposure requirements that occasionally crop up at a power reactor. This rule has been eliminated by the proposed revision but has been replaced with provisions for 'Planned Special Exposures" which are explained as follows:

Planned Special Exposure

1. Permits receiving a dose equal to the annual limits in addition to normal occupational exposures.

2. Lifetime limit for PSE's and overexposures of 5 times the annual limits.

The special exposure must be planned in advance with appropriate records. The total exposure from PSEs and overexposures is limited to the values in item 2. This provision retains the flexibility to conduct an exposure intensive job with exposure in excess of the annual limits. Although current experiences indicate the option may not be frequently used, it is desirable and necessary, particularly in an emergency situation, to have this flexibility. The knowledge of the biological effects of radiation indicates that the proposed exposure limits should not be treated rigidly and that this flexibility does not significantly increase the risk to workers.

Another addition to the proposed revision is the requirement to report to the NRC and the individual worker his occupational exposures on an annual basis. This is a significant change from the current practice of reporting only when the employee terminates. As a trade off, the annual statistical report and the termination report have been eliminated. The effect of this change will be to require the reporting of more information to the NRC but on a regular basis rather than on the non-regular basis of whenever terminations occur. This latter was a significant continual work load at TMI and would be very significant at the end of outages at routinely operating plants. The proposed revision should permit a more organized approach to reporting this information to the NRC.

The addition of the report to the individual worker on an annual basis will be an increase in reporting. However, the benefits of making the worker more aware of and knowledgeable about his own personal exposure should outweigh the impact of preparing the individual reports. The degree to which records are computerized and 'termination reports' are prepared by the computer should permit an annual letter to be generated fairly easily.

The proposed revision addresses respiratory protection programs in a more direct manner than the current 10 CFR 20. Currently 10 CFR 20.103 states that the respiratory protection program must comply with Regulatory Guide 8.15 which directs one to be in compliance with NUREG-0041, "Manual of Respiratory Protection Against Airborne Radioactive Materials". The proposed revision incorporates the requirements of the NUREG-0041 in a broad sense directly into the regulations by identifying the elements that must exist to have a satisfactory program. To avoid the bulk of NUREG-0041, the proposed revision requires, among other things, that the licensee have "written procedures regarding selection, fitting, issuance, maintenance, and testing of respirators; supervision and training of personnel; and recordkeeping". This requirement covers about everything. Although specific requirements

as to what should be in these written procedures is not included, one could suspect that NUREG-0041 would be used as guidance for the reviewer. Because of the current emphasis on respiratory protection, these procedures should be in general existence and this particular requirement should have very little effect.

Several other changes should be noted in the area of respiratory protection. The current guidance in NUREG-0041 states that th the respirator should be selected such that the anticipated peak concentration does not exceed MPC by the Protection Factor of the respirator. Although this may sound great on paper, it is not a practical criteria because of the difficulty in anticipating the peak concentration and then being able to prove it afterwards. The proposed revision relates the Protection Factor and the DAC to the average concentration of airborne radioactive material. This is a more reasonable requirement.

The current time requirement for respiratory physical exam is one year, with no allowance for overrun of this period. The proposed revision requires certification by a physician every 9-15 months. This allows some leeway to accommodate training schedules, peak loads, and other interferring factors that always arise.

The proposed revision specifically requires testing of respirators for operability immediately prior to each use. Although this is a reasonable requirement considering worker protection, it is not universal practice to do so in the power reactor industry. This will require incorporating such a test into the routine use of respiratory equipment.

The financial effect of the revision to 10 CFR 20 has been estimated by L. F. Booth and F. L. Bronson in their paper "Dosimetry and Recordkeeping Implications of the Proposed Revisions to 10 CFR 20". The estimates were about $500,000 initial costs and about $250,000 additional operating costs annually. Much of this cost

is in the recordkeeping portion of the program where many utilities are currently upgrading their systems for improved operability reasons. Consequently some of these costs may not be incurred solely because of the proposed revision. The costs will vary from one plant to the next depending on the degree of computerization and the flexibility of the software used to conduct the record-keeping. For reference, a health physics program with 50 people will typically have an annual budget in the range of $2-3 million dollars, where many utility health physics programs have annual budgets approaching $10 million. Although the estimated costs of the proposed revision are significant, they would not generally have a major impact on the budgets.

Summary

On the balance, the proposed revision would appear to have a beneficial effect on power reactor health physics. This occurs because of clearer requirements which permit more flexibility where years of experience has shown this to be desirable. Many of the rigid requirements have been replaced by more reasonable options. The revision will require more reporting and recordkeeping but in many cases the new reports and records are more sensible than the current ones which are being deleted.

As an example of the "flexibility-where-appropriate" philosophy which the NRC has appeared to use in developing the proposed revision, consider the way internal exposures should be reported. The current 10 CFR 20 establishes the limits for internal uptake in terms of MPC-hou Consequently, even though the internal exposure may be calculated in terms of rem, it gets converted to and reported in units of MPC-hours. The proposed revision states that compliance with the limits may be demonstrated by using the fraction of the Annual Limit of Intake, or the fraction of DACs inhaled during the year, or the committed effective dose equivalent (any of the above) in conjunction with the fraction of the deep dose equivalent limit. Consequently the internal dose may be kept in the most convenient and appropriate terms--a much more reasonable approach.

Although a significant improvement over the current 10 CFR 20, the proposed revision still has rough edges. Proper attention by power reactor health physicists during their review of the version published for public comment will aid in eliminating those remaining rough edges. Look for it later this year and give it the benefit of your experiences.

TABLE 5. PRINCIPAL BENEFITS FROM PROPOSED REVISION OF 10 CFR PART 20

CONCERN WITH PRESENT PART 20	PROPOSED PART 20 REVISION	BENEFITS OF REVISION
1. Many Values In Appendix B Do Not Reflect Current Knowledge.	° Revises and expands Appendix B to reflect contemporary knowledge of dosimetry and biology.	° Derived values will reflect ICRP risk based system and make use of contemporary knowledge.
° Present MPCs can cause underestimates of doses by a factor of 6 for most alpha emitters and 60 for thorium.		° Air concentrations are based on a lung model which permits adjustment for the particle sizes of aerosols.
° "Soluble" and "insoluble" designations in Part 20 and many other bases were abandoned by health physicists many years ago.		° Values are presented for various compounds.
		° Coverage of radionuclides has been increased from 260 to 757.
		° Of the radionuclides where comparisons can be made, about 65% of the new values are less restrictive, about 8% are unchanged, and about 27% are more restrictive.
2. 5(N-18) Dose-Averaging Formula Permits Workers to Receive 12 Rems per Year from External Sources.	° Deletes 5(N-18) and adopts 5 rems per year and 3 rems per quarter dose limits.	° Annual and Lifetime doses to individuals receiving highest exposures will be reduced.
° Several hundred workers each year receive doses of 5 rems or more.	° Provides "planned special exposures" for necessary and unavoidable activities.	° Risks to radiation workers receiving highest exposures will be more comparable to those in safe industries.

TABLE 5. (Continued)

CONCERN WITH PRESENT PART 20	PROPOSED PART 20 REVISION	BENEFITS OF REVISION
° Potential risk could be substantial (3-10%) from 50 years external exposures at 5 rems per year and additional dose from internal exposures.		° Provides substantial flexibility for licensee to manage justifiable exposures beyond selected annual dose limits.
		° Provides for readily monitored records of use.
3. Dose Limits for Internal and External Doses are Independent.	° Establishes 5 rems annual limit for sum of external and internal doses.	° Effective dose equivalents limits from combined external and internal exposures are related to individual risk.
° Risks from dose limits to various organs are unequal.	° Adopts ICRP "effective dose equivalent" which adjusts doses to various organs to whole body dose equivalent based on risk.	° Limits for various organ doses reflect comparable risks.
		° Dose weighting factors based on quantified risk of radiation-induced health effects are consistent with Commission policies on use of quantitative risk.
		° Workers and public can understand risk base which is more rational than present dose limit selection.
		° Doses to workers subjected to both external and internal exposures will be reduced.
4. No Requirements for Formal Radiation Protection Program or for ALARA.	° Requires written radiation protection program with ALARA provisions.	° Ensures adequate radiation protection program and ALARA efforts by all licensees.

TABLE 5. (Continued)

CONCERN WITH PRESENT PART 20	PROPOSED PART 20 REVISION	BENEFITS OF REVISION
° Uneven requirements among types of licenses brought about mostly through licensing actions other than Part 20.	° Requires management commitment and participation. ° Requires selection of investigation levels for doses to workers below dose limits.	° Would reduce doses to workers. ° Provides basis for more effective ALARA efforts with reliance on licensee's judgment. ° Provides regulatory requirements for enforcement actions.
5. Limits Treated As Sharp Line of Demarcation Between Acceptable and Unacceptable. ° De Facto limits are established by licensing actions.	° Emphasizes ALARA and provides reference levels to permit graded scale of action as limits are approached.	° Actions are taken to reduce exposures before dose limits are exceeded and to review exposures when they are substantial. ° Would reduce doses to workers and public without resorting to other regulatory means.
6. Staff Cannot Obtain Dose Data on Specific Workers until they Terminate Employment. ° Data on annual doses to workers are inadequate for regulatory purposes. ° No reports are made of internal doses. ° Workers are not required to be informed of annual or accumulated doses without request.	° Requires reporting of annual doses to worker and to NRC by Social Security Number. ° Eliminates present "annual statistical summary" report. ° Eliminates present "termination" report.	° Would provide worker dose histories in real time. ° Improved data base would permit NRC to better assess adequacy of radiation protection efforts and regulations. ° Would permit evaluation of transient worker annual doses.
7. Presents No Clear Dose Limits for Members of the Public.	° Establishes 500 mrem/yr effective dose equivalent (external and internal sources).	° Dose limits for public would include possible multiple sources and multiple exposure modes.

TABLE 5. (Continued)

CONCERN WITH PRESENT PART 20	PROPOSED PART 20 REVISION	BENEFITS OF REVISION
• NRC can require de facto limits without compromising Part 20.	• Establishes reference levels for action below limits.	• Would provide clearly identified limits and graded actions would result in individual doses less than 100 mrem per year. • Facilitates use of estimates of health risk as a fundamental determinant in decision-making and in any reform of nuclear regulation and licensing.
8. Present Part 20 Provides No Constraint on Collective Dose Evaluations. • Can result in unwarranted expenditures of resource for incremental risks which are trifles.	• Provides constraint on collective dose evaluations to omit doses less than 0.1 mrem per year to individuals.	• Would save considerable resources. • Would provide perspective in judgments. • Would eliminate consideration of health risks which are trifles.

THE PART 20 DRAFTING GROUP'S RESPONSE TO THE 6/5/84
MEMORANDUM FROM R. CLEVELAND TO H. DENTON

Comment 1:

"...First, I believe much of the difficulty in considering the merits of the proposal stems from a lack of clarity as to what is needed to be done (i.e., what is broken?). Without a clear indication of the objectives to be accomplished..."

Response to Comment 1:

The rulemaking package clearly identifies the major concerns (Supplementary Information, pp. 71-74) with the present Part 20 and the purpose (Commission paper, pp. 2-3) and principal benefits (Supplementary Information, pp. 71-74) of the proposed revision. In addition, the three CRGR presentations on Part 20 included handouts, with subsequent lengthy discussions, of lists of deficiencies with the present Part 20, benefits of the proposed revision, improvements in safety features and workers' protection, and areas of economic benefits of the proposed revision.

Comment 2:

"...doesn't properly consider a basic principle for a regulation: Keep it simple."

Response to Comment 2:

We recognize that the proposed major change in the Part 20 regulation is viewed by many as being difficult to understand. This is because adoption of a system of protection that is based explicitly on health risks associated with the dose limits is new and requires some changes in the "way of doing things" by those who license, inspect or operate. However, we would expect this situation to be short term and subsequently mitigated by education through comments, hearings, and general training before the date of effective implementation. Our experience to date would indicate that much of the perceived complexity of the proposed revision is caused by the introduction of some new terms which are needed to communicate accurately and effectively the newer system proposed. Once the terms are understood the use of the system appears less complex and, therefore, less ominous. In addition, discussions with IE personnel have assured us that the regulation is not so complex as to be difficult to either implement or enforce.

The draft revision has been modified to help users understand not only what is required, but also the rationale for the requirement, and to simplify its implementation by allowing greater flexibility in choosing alternative compliance methods. We believe this will be helpful to those licensees who handle only small quantities of radioactive materials.

ENCLOSURE 3

Comment 3:

"...the contention that the ICRP 26 methodologies are 'state-of-the-art' and scientifically supportable appears open to some challenge."

Response to Comment 3:

The "state-of-the-art" reflected in ICRP Publication 26 methodologies are not seriously challenged by knowledgeable scientists and many practitioners of radiation protection. In its July 24, 1981 letter to EPA on its proposed "Federal Radiation Protection Guidance for Occupational Exposure," the Commission noted that recommendations in ICRP Publication 26 were "logical and self-consistent, and appear to be based on the best scientific information available." We believe that the ICRP-26 system remains defensible and know of no serious challenge to its bases.

Recently, Committee 1 of the ICRP completed reviewing epidemiological surveys and related reports and concluded that no changes in the cancer risk estimates used by ICRP in radiation protection were warranted at the present time.

Comment 4

"...I find the new Appendix B impressive in its detail and absurd in its recital of distinctions without differences. For example, the two sets of entries of Antimony-116 have only one pair of values which are different (not counting the three unexplained omissions of entries for Class W), 4X10(-7) versus 5X10(-7)."

Response to Comment 4:

Antimony-116 is only one example of a radionuclide that requires several entries in Appendix B because there are multiple lung clearance classes appropriate to the radionuclide. These lung clearance classes are based on the chemical and physical form of the radioactive material. If values of DACs, ALIs, and reference level air concentrations are not given for each appropriate lung clearance class, questions would be raised about the proper control levels for the omitted classes of radionuclides. As noted, there may be small differences in the DAC values whenever a radionuclide has a radioactive half life which is shorter than its translocation time. These differences become even more obscure when the values are rounded to one significant figure, as in the Appendix B entries.

The "unexplained omissions" refer to the dashes in the columns for the ALIs for oral intake, the reference level concentration for water, and the monthly average concentrations for releases to sewerage. These values are <u>not</u> related to lung clearance class, and, therefore, there is only one set of values for each radionuclide. As a matter of format, and convenience, these oral intake values are presented in the first line, which also happens to contain values for one of the inhalation classes. Other reviewers have not found either the format or the listed values confusing.

Comment 5:

"...this massive change in Part 20 conveys a false message to the public that our present radiation protection program is not adequate and that radiation hazards are in need of even more stringent control."

Response to Comment 5:

The rulemaking package for Part 20 is written to convey to the public that the NRC intends to base its standards on the best scientific knowledge, the latest in radiation protection philosophy and practices, and experience gained during the nearly thirty years since promulgation of the original Part 20. The proposed revision could lead to adjustments in both directions -- more stringent control, where outdated data have led to routine underestimates of doses, or less stringent control and more flexibility, where present regulatory practices have gone beyond those justified by the current regulation. The comment appears to reflect personal perception rather than being misleading.

PART 20 DRAFTING GROUP'S RESPONSE TO COMMENTS
IN 4/20/84 MEMORANDUM FROM WILLIS TO CLEVELAND
RE EPA DRAFT RADIATION PROTECTION GUIDANCE

General Comment:

"Glen Sjoblum's April 13, 1984 letter requesting comments on the subject draft guidance allows little time, so my comments must be brief. I recommend that the NRC comment that this guidance should not be issued because:

1. Existing guidance is resulting in an adequate level of protection.

2. The new guidance will not provide any improvement in health and safety.

3. Implementing the new guidance will be costly; 100 million dollars present worth seems a minimum estimate."

Response to General Comment:

The three basic comments are similar to NRR staff comments made on the proposed revision of Part 20, and have been addressed in the responses of the drafting group to comments on the Part 20 revision. The Part 20 revision has been developed in parallel with the draft EPA guidance and would be compatible with it.

Specific Comment 1:

"Recommendation 1, requiring 'overall benefit' before occupational exposure is permitted, should be dropped because the agencies generally are neither qualified nor empowered to make such judgements. Treating this recommendation with benign neglect makes something of a farce of the entire process."

Response to Specific Comment 1:

The recommendation being addressed, "There should not be any occupational exposure of workers to ionizing radiation without the expectation of an overall benefit...", is not new. It is a restatement of the basic principle expressed in the Federal Radiation Council Report No. 1, signed by President Eisenhower on May 13, 1960. Agencies, including the NRC, do make such value judgements and they are within their authorities to do so in protecting public health. In some instances, the judgements have been made by the Congress.

Specific Comment 2:

"Recommendation 2, requiring the agencies to switch to ICRP-26 methodology, should be dropped because implementation would be quite costly, and because it offers no health and safety benefit. Moreover, the 'new' system is not supported by solid, scientific evidence."

ENCLOSURE 2

Response to Specific Comment 2:

We disagree with this contention. We have addressed the potential costs, the benefits of implementation, and the scientific merits of the ICRP-26 system of dose limitation in considerable detail in response to comparable comments on the overall revision of Part 20.

Specific Comment 3:

"Recommendation 3, requiring the agencies to control radioactive material so as to avoid uptake, as far as is reasonably achievable, should be dropped because it is technically absurd. Zero uptakes are not attainable or verifiable, so such regulations would be unenforceable as well as unbeneficial. This recommendation would also impose impracticable limits or the uptake of certain important long-lived nuclides."

Response to Specific Comment 3:

We agree with this comment and have expressed it to EPA with respect to several drafts of the updated guidance. See paragraph four of the enclosed letter dated May 3, 1984, from Mills to Sjoblom, transmitting coordinated NRC staff comments to EPA (Addendum 1). A more recent draft of the EPA guidance, transmitted June 20, 1984, has modified the wording somewhat, and specifically recognizes the need to balance external exposure with efforts to control intake. It reads:

> 3. As the primary means for limiting internal exposure to radionuclides, agencies should require that radioactive materials be controlled so as to avoid intake, to the extent reasonably achievable, considering concomitant external exposure.

Specific Comment 4:

"Recommendation 6, which requires special protection of an unborn child, should be dropped because it is not needed and because it imposes de facto sex descrimination."

Response to Specific Comment 4:

We disagree with dropping this EPA recommendation in toto. However, we are concerned that the wording "or known" in the EPA recommendation may result in problems, such as interpreting known by whom. The key words are underlined in the following quotation from the latest EPA draft transmitted June 20, 1984.

> ...The total dose equivalent to an unborn child as a result of occupational exposure of a woman declared or known to be pregnant should be maintained as low as reasonably achievable, and in any case should not exceed an RPG of 0.5 rem. In addition, positive efforts to control dose equivalent to the unborn to less than 0.5 rem in any month are encouraged.

Earlier drafts of the proposed revision of 10 CFR Part 20 avoided such problems by requiring licensees to limit the occupational exposure of only those employees who had voluntarily declared their pregnancy to the licensee. In the

absence of such a declaration, the licensee would be expected to maintain doses to a pregnant woman as low as is reasonably achievable and within the limits, as for any other employee.

Additional comments on the issue of protection for an embryo/fetus are in our response to comments on the revision of Part 20. We note that during internal review of this issue one of the reasons for deleting the proposed dose limit for the embryo/fetus from the revision was the belief that EPA should address the issue because of the broader application of Federal guidance.

Specific Comment 5:

"Recommendation 8, requiring 'state of the art monitoring methods,' should be dropped because honest implementation would be extremely costly and would provide no significant benefit. In that instruments serve their intended purpose, the agencies should not require their replacement merely because something better is available."

Response to Specific Comment 5:

The referenced sentence in Recommendation 8 of the draft EPA guidance transmitted April 13, 1984 reads --

> ...The types, accuracy, and state of the art of monitoring methods and procedures utilized should be periodically reviewed to ensure that appropriate techniques are being competently applied.

That wording has subsequently been changed so the comment is no longer an issue. The comparable sentence in the draft guidance transmitted June 20, 1984, reads --

> ...The types and accuracy of monitoring methods and procedures utilized should be periodically reviewed to assure that appropriate techniques are being competently applied.

Addendum:

1. Letter from Mills (NRC) to Sjoblom (EPA), May 3, 1984

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

MAY 3 1984

Mr. Glen L. Sjoblom, Director
Office of Radiation Programs
U.S. Environmental Protection Agency

Dear Mr. Sjoblom:

Subject: Radiation Protection Guidance to Federal Agencies for Occupational Exposure (4-09-84)

Thanks for your letter of April 13, 1984 enclosing a draft Memorandum to the President dated April 9, 1984 containing revised Federal Guidance (Radiation Protection Guides) for occupational exposures to ionizing radiation. I was pleased to see that we have progressed to the point that we have something to review that goes beyond the recommendations themselves.

Regarding the preface material or preamble, I believe that this requires a substantial rewrite before it is ready to go to the Federal agencies for formal review and comment. I suggest that after a background section describing how the guidance was developed (draft pgs. 3-5) attention be directed to why changes are being made in the 1960 RPG's for radiation workers. This could be done in a recommendation-by-recommendation comparison format--but need not go into details which can better be explained in the background document (will there be a revised one?) or in readily available referenced material.

The lengthy discussion of "net benefit", justification, "optimization" and "ALARA" is overplayed and should be deleted or severly shortened to a clear point. I suggest deletion because, as I have noted before, I believe that the wording of Recommendations 1 and 2 in the 1960 Federal Guides is most satisfactory and that no change in language is necessary.

I remain troubled by some of the wording in the Recommendations and the text continues to project an intent of unnecessary rigidity in implementation of these recommendations by Federal agencies. Phrases such as "avoid any uptake" (why uptake rather than intake), "continued...exposure at (the RPG) would not provide an acceptable level of protection and should be avoided," and "publicly note or specify situations in which exceeding the RPG's has been authorized" are not reducible to reasonable regulatory requirements and can be easily interpreted in a most restrictive way. I expressed my view on this matter as well as other concerns in earlier letters (12/9/83 to Guimond, 1/5/83 and to 4/583 Richardson). I trust that ORP has considered my comments and suggestions in drafting the latest draft but remains unconvinced. For your information and possible reconsideration I am enclosing a copy of my December 9, 1983 letter to R. Guimond.

Enclosure 4/ Addendum 1

I assume from your letter that the guidance will not be reproposed for public comment and that Federal agencies will be sent a final draft for formal review and comment before the Administrator sends his recommendations to the President for approval. In view of this perceived procedure, I suggest that the interagency working group be provided an opportunity to meet with you as a group to receive EPA's response to our comments and to go over what ORP views as the package likely to be sent to our respective agencies for review and concurrence.

Enclosed are some selected specific comments from an ad hoc review which we hope will permit an improve draft.

William A. Mills, Ph.D.
Chief, Health Effects Branch
Division of Radiation Programs and
and Earth Sciences
Office of Nuclear Regulatory Research

Enclosures:
As stated

cc: Mr. Robert E. Alexander, NRC
Mr. Lewis Andrews, NASA
Ms. Joanna M. Becker, NRC
CDR Tom Bell, DOD
Mr. Elmer H. Eisenhower, DOC
Dr. Aurel Goodwin, MSHA
Mr. Charles Gordon, OSHA
Mr. Richard Rawl, DOT
Dr. Marvin Rosenstein, HHS
Dr. Warren K. Sinclair, NCRP
Mr. Allan C. Tapert, CRCPD
Mr. Edward J. Vallario, DOE
Dr. Sheldon Weiner, OSHA

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

DEC 9 1983

Mr. Richard J. Guimond
Director, Criteria and
Standards Division (ANR-460)
U.S. Environmental Protection Agency
401 M. Street, S.W.
Washington, D.C. 20460

Dear Mr. Guimond:

I offer a few comments for your consideration regarding the September draft of recommendations for Federal Radiation Protection Guidance for Occupational Exposure sent to me by memorandum, dated November 10, 1983. These are my personal comments and, thus, have not been coordinated with my colleagues in the NRC. A NRC staff review will be made on the total package when we receive it. I assume this package will include a copy of the Federal Register Notice and other related documents the working group should consider in providing its recommendations.

I believe that the draft has come a long way as an expression of consensus. I am looking forward to reviewing the preamble that explains how we arrive at our conclusions.

Rec. 1. In the second sentence change "may" to "should" or delete the sentence. "May" means giving permission for such activities through Federal guides; whereas, "should" implies encouraging such activities when the Federal guides are conformed with. I believe the latter is the working group's intent.

Rec. 2. Delete the wording "...establish the upper limits of..." and replace with "...apply as guides for limiting...". I don't believe the word "limit" is suitable for guidance, and "upper" implies that lower limits may be warranted. I believe the working group has rejected the idea of lower limits and accepted lower levels of administrative controls as additional requirements instead.

A working group in NEA has opted for the inclusion of partial body external exposure in the definition of effective dose equivalent. An example of when this inclusion is important arises in the situation of the head and neck being exposed when a lead apron is used. The definition of H_{eff} is amenable to this situation and I suggest "footnote (1)" be changed accordingly.

Add a sentence after the period in the second sentence to make clearer the meaning of H_i to read: "H_i is the dose equivalent received in a year from both residual and new intakes during the year." Since H_i has a different meaning than used by the ICRP it

is desirable to use a symbol such as $H_{a,}$ to designate this annual dose equivalent for organ weighted intakes.

I am still opposed to the general use of annual dose equivalent for internal depositions in the summation of doses that is intended to be a surrogate for the total health risk to the exposed worker. I believe the use of committed dose equivalent is more straight forward, technically and administratively. Certainly, the worker is more likely to understand the meaning of risk ipvolved with his retention of long-lived materials.

Rec. 3. Delete the lead sentence--it is redundant with the first sentence in the following paragraph that follows.

Reword the first sentence in the second paragraph to read: "If an agency concludes that it is not practical to avoid intakes, it should require that the control of exposures to radioactive materials be designed, operated and maintained such that any expected committed effective dose equivalent will not exceed 5 rems, and the committed dose equivalent to any organ or tissue will not exceed 50 rems from any intakes in a given year."

Question: How does ORP see this requirement handled when the agency also expects some external exposure to occur? Are the two types of exposures to be treated separately?

Reword the last sentence to read: "When design, operating, and maintain controls are not effective in meeting the above numerical guides for committed effective dose equivalent or committed dose equivalent to any organ or tissue, annual dose equivalents..."

Rec. 4.: Reword second sentence to read: "However, it should be general practice to maintain expected and actual doses from radiation to levels below the RPGs...agencies should encourage the establishment of radiation protection programs that include ALARA considerations."
Federal guides should not advocate the establishment of goals for limiting exposures through agency requirements--it leads to "de facto" ALARA limits (likely to be based on erroneous optimization assumptions) which de-emphasize the dose limits established.

Rec. 6: What is the meaning of "known", and by whom must it be known? Ambiguous.

Rec. 7: Make the following changes in the second sentence: add "...the principles and recommendations set forth..."; and delete "and operating procedures which implement this guidance." The limited operating procedures given can hardly be considered adequate to implement the guidance, plus implementation of the guidance is the responsibility of the responsible agencies.

Rec. 8: In the last sentence delete "lifetime". This could be a very troublesome recommendation for NRC to implement. It would require that every licensee be held accountable for recording lifetime doses--a requirement of verification that would be an impossible imposition in the transfer of records. Without a centralized national registry for all radiation workers this cannot be done.

Footnote 5. Change "limits" to "requirements".

Rec. 10: Reword to read: "Agencies should not adopt procedures that would result in doses exceeding the RPGs except for emergencies or unusual circumstances that merit such action. In making exceptions the responsible federal agency should carefully consider the above recommendation and, as necessary, procedures for public awareness."

Note 3: Would not ICRP-32 be used for uranium mill workers?

Note 4: What is "general guidance established herein"--the non-numerical recommendation?

Note 5: Reword the second sentence to read: "The handling of such cases is the responsibility of the Federal agency having the necessary legislative authority." Federal guides cannot assign responsibility to the private sector.

Note 6: Reword to read: "...exposure to workers in underground uranium mines..."

Happy Holidays to ORP.

Sincerely,

Bill

William A. Mills, Chief
Health Effects Branch
Office of Nuclear Regulatory Research

cc: Members of Working Group

ENCLOSURE 2

SPECIFIC COMMENTS ON EPA DRAFT GUIDANCE ON OCCUPATIONAL EXPOSURES (4-09-84)

p. 8. EPA should make it clear that neither quantified justification nor optimization will be required. Here (3rd last line) and in several other locations e.g., p. 10, 11, it is stated that the primary objective is to minimize the total harm. This is incorrect. The objective is to maximize benefit and/or minimize total cost (including deteriment).

p. 10. The term "may" throughout the paper should be reserved to indicate permissive actions.

To minimize collective and cumulative doses are generally contradictory actions.

p. 12. It is not clear that there is a legal base for agencies to protect the unborn without loss of job security or ecomcmic penalty to women workers.

p. 13. The term "uptake" ratherthan "intake" appears here and elsewhere. This is a major change from previous drafts and should receive full review and resolution prior to proceeding with the guidance.

p. 15. Recommendation 1 should make it clear that demonstration of a quantified net benefit is not required.

Recommendation 2 uses annual dose while Recommendation 3 (p. 16) uses the committed dose. The relationship between these two, and the order of precedence, is unclear. This ambiguity should be eliminated. Further the definition of effective dose equivalent is inconsistent with the definition of that term by the ICRP. If the guidance is to be written as recommending annual dose, (see comment on this subject in previous comments to EPA dated December 9, 1983) then a new name and abbreviation should be used to void confusion.

The definition of H_{wb} states that it is from external irradiation. This could also be internal, e.g., from tritium. (Also see p. 17 line 2.)

p. 16. The judgement that "continued annual exposure of an individual at this level for substantial portions of his or her lifetime would not provide an acceptable level of protection and should be avoided" does not appear to be warranted. It is ambigious and does not recognize the possible need for some skilled individuals to perform in high-exposure environments. The acceptability should be left to the judgment of the individual so long as it is within the legal limits. Such judgements by EPA in Recommendation 2 (p. 16) invite litigation.

p. 16. Avoiding" all uptake" as in Recommendation 3, is obviously impossible. Avoiding exposures to the extent practicable is ALARA. In Recommendation 3, with respect to monitoring, we would suggest the substitution of "...on a continuing basis..." with the words "with sufficient frequency".

p. 17. The admonition for agencies to establish measures by which management can assess ALARA efforts should be left to the agencies and deleted from Recommendation 4. Limiting individual and collective dose are usually contrary results. Since there are no collective dose limit as requirements, we believe that the emphasis should be on limiting individual doses.

Clearly, some lines or words must be missing in Recommendation 6 or we would permit the unborn to receive higher doses than are received by workers.

p. 18. The phrase..."or known to be pregnant"... in Recommendation 6 makes this guidance least ambiguous, e.g., known by whom?, and perhaps impossible to implement.

What is a "positive effort" when used as an admonition?

Workers cannot be expected to "avoid and minimize exposure" except in the most general way. The administration is only a "motherhood" statement in Recommendation 7.

Recommendation 8 would require that state of the art monitoring systems be used. We do not believe that it is appropriate for Federal guidance to specify continuous upgrading of monitoring systems simply because a newer instrument is developed. The phrase "and state of the art of" should therefore be deleted.

It is impossible for agencies to provide the lifetime dose records to workers as suggested in Recommendation 8.

The first sentence of Recommendation 9 is too long and is confusing. This statement should be revised into two sentences which clearly present the intent of the recommendation.

The notes provided to clarify application of the recommendations use the annual limit on intake (ALI), derived air concentration (DAC), and metabolic models developed by the ICRP. However, in Recommendation 3, the term "uptake" is used rather than "intake". This change in terminology is inappropriate and would require modification of all calculations currently based upon the intake. We recommend that "intake" be used.

Previous suggestions by W. A. Mills should be reconsidered by EPA. Few changes have been made to accomodate them.