

AA38-2
Central files only

August 26, 1986

MEMORANDUM FOR: Samuel S. Chilk,
Secretary to the Commission

FROM: Victor Stello, Jr.
Executive Director for Operations

SUBJECT: STAFF REQUIREMENTS--SECY-86-48/48A "BACKFIT ANALYSIS FOR
PROPOSED REVISION OF 10 CFR PART 20"

As indicated by your Memorandum of July 18, 1986 on this subject, the Commission approved publication of a draft backfit analysis for Part 20 in the Federal Register. The revised draft backfit analysis incorporating Commissioners' changes and additional comments is provided as a notice for transmission to the Federal Register (Enclosure 1). Enclosure 2 is a marked-up copy of the notice showing where changes have been made from the version in SECY-86-48A.

Enclosure 3 is a separate notice to be transmitted to the Federal Register along with the draft backfit analysis notice. This notice extends the public comment period on the proposed Part 20 revisions to be concurrent with the comment period for the draft backfit analysis. This extension is consistent with Note No. 3 on page 5 of SECY-86-48A.

Original signed by
Victor Stello

Victor Stello, Jr.
Executive Director for Operations

Enclosures:

1. FRN
2. Mark-up
3. FRN Extension Notice

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NOTE: "Paragraph bottom of Page 11 modified by CRGR staff to conform to order of requirements in the 'Backfit Rule,' §50.109" HTP

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NUCLEAR REGULATORY COMMISSION
PARTS 19, 20, 30, 31, 32, 34, 40, 50, 61, AND 70 :

STANDARDS FOR PROTECTION AGAINST RADIATION; AVAILABILITY OF
SUPPLEMENTAL INFORMATION

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule; availability of supplemental information.

SUMMARY: On January 9, 1986, the Nuclear Regulatory Commission published for public comment a proposed revision of its radiation protection standards, 10 CFR Part 20. If implemented, that rule would require changes in the radiation protection procedures at nuclear power reactors and other NRC-licensed activities. Section 50.109 of the Commission's regulations requires that a backfit analysis be prepared for proposed NRC regulations that require changes to operating procedures for nuclear power reactor facilities licensed by the Commission under 10 CFR Part 50. This notice provides such an analysis for the proposed revision of 10 CFR Part 20 and solicits public comment on it.

DATES: Comments on this backfit analysis must be submitted in writing on or before October 31, 1986. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments filed on or before this date. The comment period for the proposed Part 20 revision is being extended to this same date, thereby providing more than 60 days of concurrent comment period.

ADDRESSES: Submit written comments or any other information concerning this matter to the Secretary of the Commission, U.S. Nuclear Regulatory

Commission, Washington, DC 20555, Attention: Docketing and Service Branch. Copies of the proposed revision of 10 CFR Part 20 and the accompanying Regulatory Analysis that supports this Backfit Analysis may be examined, and copied for a fee, at the Commission's Public Document Room at 1717 H Street, NW, Washington, DC. Single copies of these documents may be obtained from the person indicated under the "FOR FURTHER INFORMATION CONTACT" heading.

FOR FURTHER INFORMATION CONTACT: Robert E. Alexander, Division of Regulatory Applications, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Telephone (301) 443-7976.

SUPPLEMENTARY INFORMATION:

I. BACKGROUND

A. Part 20 Revision

The Commission's primary standards governing radiation protection requirements for its licensees are given in 10 CFR Part 20. The original Part 20 was issued on January 29, 1957 (22 FR 548). Although about 100 amendments to 10 CFR Part 20 have been made since that time, this is the first complete revision of these regulations in over 25 years. This revision will bring the Commission's radiation protection standards into accord with current recommendations of the International Commission on Radiological Protection (ICRP). The revision is also consistent with "Radiation Protection Guidance to Federal Agencies for Occupational Exposure," which has been prepared for the signature of the President under the leadership of the Environmental Protection Agency.

On March 30, 1980, the Commission published an Advance Notice of Proposed Rulemaking (45 FR 18023) announcing its initiation of a rulemaking proceeding for the purpose of updating its radiation protection standards. The notice described in detail the elements being considered for incorporation into the proposed rule and solicited public comment

thereon. About 70 responses were received in response to this notice. In addition, numerous meetings were held between the cognizant NRC staff members preparing the revision and groups associated with States, unions, the nuclear industry, licensees, public interest groups, radiation protection organizations, and other Federal agencies. On December 20, 1985, the Commission published a proposed revision of Part 20 in the Federal Register (50 FR 51992). A corrected version was published in the Federal Register on January 9, 1986 (51 FR 1092). There is an ongoing public comment period on the proposed rule.

B. The Backfit Rule

On September 20, 1985, the Commission published a final rule (50 FR 38097), commonly called the "backfit rule" (10 CFR 50.109), which sets forth requirements on imposing new or amended requirements on nuclear power reactor facilities licensed by the Commission under 10 CFR Part 50. This regulation sets forth the following requirements, among others:

1. (§50.109(a)(2)) "The Commission shall require a systematic and documented analysis pursuant to paragraph (c) of this section for backfits which it seeks to impose."
2. (§50.109(a)(3)) "The Commission shall require the backfitting of a facility only when it determines, based upon the analysis described in paragraph (c) of this section, that there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that facility are justified in view of the increased protection."

In order to reach this determination, §50.109(c) sets forth certain factors that are to be considered in the backfit analysis. These factors and the accompanying analyses are presented in Section II of this notice.

II. DRAFT BACKFIT ANALYSIS

The proposed revision to 10 CFR Part 20 is not anticipated to require physical modification to nuclear power reactors (or other licensed facilities). However, the definition of a "backfit" in §50.109(a)(1) includes the modification of or addition to the procedures or organization required to design, construct or operate a nuclear power reactor facility. Even though the Part 20 rule is applicable to all NRC licensees and therefore is broader in scope than the "Backfit Rule," it would result in the need for revisions in the operating procedures dealing with radiation protection at nuclear power reactor facilities licensed under 10 CFR Part 50 and, consequently, a backfit analysis is to be performed for power reactor facilities.

Paragraph 50.109(c) requires consideration of the priority and scheduling of the action under consideration in light of other regulatory activities. Implementation of the proposed revision of 10 CFR Part 20 should not significantly affect any other backfits or safety-related activities. In order to minimize the impact of the retraining and revisions of procedures, the proposed implementation period of the Part 20 revision extends over a five-year period. Therefore the changes required to implement the Part 20 revision would not conflict with and do not need to be further prioritized with respect to other activities at nuclear power plants.

Paragraph 50.109(c) of the backfit rule also sets forth certain factors which are to be considered in the backfit analysis. These factors and how the proposed Part 20 revision relates to each are summarized below. These summary statements are based on the Regulatory Analysis which describes the anticipated benefits and anticipated costs that would be associated with the implementation of the proposed revision, were it to be adopted. This Regulatory Analysis is the primary source of the estimates of the benefits and the impacts described in this draft backfit analysis and is incorporated as part of this draft backfit analysis. Copies of the Regulatory Analysis are available for inspection in the

Public Document room (see "ADDRESSES") and single copies are available from the NRC staff contact.

1. Statement of Specific Objectives to be Achieved

The proposed revision of 10 CFR Part 20 is intended to:

- a. Update the quarter-century-old 10 CFR Part 20 to incorporate advances in science and new concepts of radiation protection methodology and philosophy;
- b. Implement pending Federal Radiation Guidance on occupational radiation protection;
- c. Implement the principal current dose-limiting recommendations of the ICRP;
- d. Incorporate the ICRP "effective dose equivalent" concept;
- e. Update the limits on airborne radionuclide intakes, effluent releases and doses from inhaled or ingested radionuclides using up-to-date metabolic models and dose factors; and
- f. Require that licensees have programs for keeping radiation exposures "as low as is reasonably achievable" (ALARA).

2. General Description of the Actions to be Required of the Licensee or Applicant

The principal new or additional actions that would be required of licensees by the proposed 10 CFR Part 20 revisions are to:

- a. Sum, under some circumstances, the estimated dose from radionuclides external to the body and from radionuclides deposited in the body;

- b. If not previously done, provide documentation of programs for keeping exposures "as low as is reasonably achievable";
 - c. Provide increased protection for the embryo/fetus when female workers declare themselves pregnant; .
 - d. Employ the latest ICRP limits on airborne radionuclide intakes, effluent releases and doses from inhaled or ingested radionuclides; and
 - e. Modify training guides, operating procedures, and manuals to incorporate the new concepts and requirements and provide retraining of employees on these concepts and their implementation.
3. Change in the Risk to the Public from Accidental Off-Site Release of Radioactive Material

10 CFR Part 20 generally applies only to normal off-site releases of radioactive material, so there would be no direct impact on risks associated with accidental releases of radioactive materials.

4. Potential Impact on Radiological Exposure of Facility Employees

The principal impact of the revision would be to assure significantly better and more up-to-date worker protection. The added protection results from the following:

- a. The limit for annual worker doses would be 5 rems (effective whole-body dose) per year. Workers are permitted to receive 12 rems per year (3 rems per quarter) under the current Part 20 providing that the worker's average dose does not exceed 5 rems per year. Between 200 and 400 workers receive more than 5 rems per year under the existing rule. The Part 20 revision would provide for Planned Special Exposures which would allow worker

doses to exceed 5 rems per year, but only under very stringently controlled conditions.

- b. The worker dose limit for extremities would be reduced from 75 to 50 rems per year.
- c. A limit would be placed on the dose to the embryo/fetus. There is currently no specific limit in the NRC regulations to protect the embryo/fetus.
- d. Allowable intakes of radionuclides would be based upon the latest radiobiological, metabolic, and dosimetric data. For a number of radionuclides the intake limits would be lowered.
- e. Doses would be limited by considering both internal and external radiation doses added together rather than evaluating them separately as allowed by the present rule.
- f. Dose limits would be expressed as the sum of organ doses weighted by the comparative biological risk of the organ. These limits would therefore be based on a better characterization of the predicted biological effect on the body organs.
- g. More effort would be required of some licensees to formulate and implement programs to keep worker exposures "as low as is reasonably achievable" (ALARA).

5. Installation and Continuing Costs, Including the Cost of Facility Downtime or the Cost of Construction Delays

There should be little or no costs associated with facility downtime or construction delays. The Part 20 changes apply primarily to operational procedures and should cause only minor revisions, if any, in facility design or in shielding. The initial and annual costs associated with various provisions in the revision are

discussed and analyzed in the Regulatory Analysis and are summarized in the notice of proposed rulemaking (51 FR 1121). The total estimated costs for all affected licensees are \$33 million for initial implementation and \$7.8 million additional costs per year thereafter. Of these amounts, a \$13.1 million initial cost and \$2.5 million annual cost are estimated to apply to nuclear power reactors. These costs may be reduced as a result of the five-year implementation period mentioned in the proposed revision.

6. Potential Safety Impact of Changes in Plant or Operational Complexity, Including Relationships to Proposed and Existing Regulatory Requirements

Any safety impacts and changes in plant complexity would be negligible, since the proposed rule should not entail changes in plant design. Some of the proposed changes could increase operational complexity. However, once the new procedures are fully implemented they are expected to become routine.

The impact of modifying operating procedures, manuals, and records would be minimized by a five-year implementation period during which licensees may develop the necessary new procedures, manuals, and records and convert to the new system at any time most convenient to the licensee.

7. The Estimated Resource Burden on the NRC and the Availability of These Resources

Costs to the NRC would primarily be associated with the preparation of new regulatory guides for implementing the new procedures and revising existing regulatory guides, branch technical positions, and inspection procedures to reflect the Part 20 revisions. It has been estimated that this effort would consist of 5 to 7 new regulatory guides requiring 0.2 staff-years per guide or 1 to 1.4 staff-years total and approximately \$350K of technical support effort. At least seven existing regulatory guides would require revision, resulting in an additional staff-year of effort. It is estimated that

approximately one staff-year would be required in both the Office of Nuclear Material Safety and Safeguards (NMSS) and the Office of Nuclear Reactor Regulation (NRR) to modify license conditions and technical specifications to comply with the proposed revision.

The largest impact in NRC would be in the Office of Inspection and Enforcement and the NRC Regional Offices to revise inspection procedures and to train inspectors on the new regulations and procedures. It is estimated that this would require about 5 staff-years total. Once the new procedures are in place, there should not be any significant resource expenditures above current levels.

These impacts would be spread over the 5-year implementation period. For this reason and the fact that the impact would be distributed over several NRC offices, the Part 20 implementation should not have a major impact on NRC programs.

8. Potential Impact of Differences in Facility Type, Design, or Age on the Relevancy and Practicality of the Proposed Action

Since the proposed revisions principally affect operating procedures rather than facility physical design, there would be no significant impact from differences in facility type, design or age.

9. Are the Proposed Revisions Interim or Final and if Interim, What is the Justification for Imposing Them on an Interim Basis

The proposed rule, with modifications, is intended to be issued as a final rule.

Other Factors

The Environmental Protection Agency, in cooperation with NRC and other Federal Agencies, has prepared revised Federal guidance on radiation protection for workers. This guidance, if approved by the President,

would greatly influence the formulation of occupational radiation protection standards. The proposed Part 20 modifications would implement the new guidance. If the Part 20 revision is not adopted, NRC regulations would not be consistent with the new Federal guidance and the regulations of other Federal agencies.

Conclusion

The proposed revisions will provide improved public health protection by virtue of:

- ° Limiting routine annual occupational doses to 5 rems and deleting the present 5(N-18) formula option which allows doses up to 12 rems per year;
- ° Imposing a limit on radiation doses to the embryo-fetus. (No specific limit exists in the present Part 20 for the embryo-fetus);
- ° Updating the radionuclide intake limits based upon current scientific data, including substantially lower limits for several radionuclides such as uranium. (Part 20 now relies upon more than 25-year-old methodology and information);
- ° Providing limits for the combined doses from both internal and external radiation sources. (The current Part 20 permits the evaluations to be done separately);
- ° Incorporating the "effective dose" concept whereby organ doses are weighted by their relative health risk and summed to give a risk-equivalent dose. (The current Part 20 uses the "critical organ" concept and does not consider doses to organs other than the critical organ in setting allowable limits on radionuclide intake); and
- ° Requiring licensees to develop and implement a program and procedures for keeping radiation exposures "as low as is reasonably

achievable" or "ALARA." (Except for LWR effluent releases subject to Appendix 1 of 10 CFR Part 50, the present regulations exhort the licensee to keep radiation exposures "ALARA", but do not make this a requirement.)

In spite of these expected improvements, the Commission's analysis does not show unequivocally that the direct and indirect costs of implementation are justified in view of the increased protection. However, the Commission believes that there are additional relevant and material factors not amenable to quantitative cost comparisons and having significant bearing on this issue, including:

- ° Incorporation of updated Presidential guidance on radiation protection;
- ° Consistency with international standards, particularly with regard to international commerce.
- ° Updating the technical basis for the Part 20 limits; and
- ° Consistency of the methods and technical approaches for radiation protection regulations and those for current risk assessment methodologies.

Because of the public health improvements and the additional qualitative factors bearing on the issue described above, the Commission believes that the rule should be promulgated even though it may not provide a substantial increase in the overall protection of the public health and safety for the common defense and security. In addition, the Commission has tentatively concluded, pending consideration of public comments, that when all factors, qualitative as well as quantitative, are taken into consideration, the benefits to be derived from the proposed revision of Part 20 justify the direct and indirect costs of its implementation. However, this decision and the Commission's decision regarding the

cost-benefit balancing and conformance of the proposed Part 20 revision to the "Backfit Rule" are tentative pending receipt of public comments on these issues.

III. REQUEST FOR COMMENTS

The Commission solicits public comment on:

- (1) The draft Backfit Analysis for the proposed revision of Part 20;
- (2) Whether the Commission has adequately implemented §50.109 as it applies to the proposed Part 20 revision;
- (3) Whether the proposed revision of 10 CFR Part 20 would provide a substantial increase in the overall protection of public health and safety that will justify the direct and indirect costs of implementing this rule; and
- (4) Whether, because of other factors which support the proposed Part 20 revision, the application of Section 50.109(a)(3) should be suspended for this rulemaking if it is found that the proposed amendments do not meet the criteria in that section.

In addition to the above questions, Commissioner Bernthal also would like comments on the following two issues:

1. In regard to the Backfit Analysis, comment is solicited on whether criteria for Commission suspension of the "substantial increase" threshold should be developed and made subject to rulemaking.
2. Comment is also solicited on whether the Backfit Rule, given its evident defects and limitations in such cases, should continue to be applied at all to Commission rulemaking per se.

IV. ADDITIONAL COMMENTS OF THE NRC COMMISSIONERS

Commissioner Roberts' Views

Commissioner Roberts disapproved the proposed revision to Part 20 because the backfit analysis could not demonstrate that the changes would provide a "substantial" reduction in the radiation dose received by workers and members of the public.

Commissioner Asselstine's Views

I approve the publication of this Backfit Analysis for the purpose of obtaining public comment on the adequacy of the Commission's compliance with its Backfit Rule. The NRC staff has written that it "...does not believe that the Part 20 revision will provide a 'substantial' change in the radiation doses received by workers and members of the public." (See SECY-86-48A, page 2, "Backfit Analysis for Proposed Revision of 10 CFR Part 20" dated May 19, 1986.) The Commission's Backfit Rule (10 CFR 50.109) requires a two prong test to be met before the Commission can promulgate a new or revised regulation such as the Part 20 proposed revisions. One of the required tests contained in 10 CFR 50.109 (a)(3) is that any revision to the Commission's regulations affecting Part 50 licensees must provide "...a substantial increase in the overall protection of the public health and safety..." Given the above conclusion of the staff that this threshold is not met in the proposed revision to Part 20, the Commission is here asking the public whether the application of the threshold standard in 10 CFR 50.109(a)(3) should be suspended for the Part 20 revisions. I would particularly appreciate receiving comments from those that believe the threshold standard should be suspended as to why the Part 20 rulemaking deserves special treatment under the Backfit Rule. In addition, I would appreciate comments on whether the Commission should develop criteria governing when the Commission will or will not apply the threshold standards of 10 CFR 50.109(a)(3) and whether such criteria should be subjected to rulemaking.

Commissioner Bernthal's Views

The public should be aware of the fact that the Commission has for nearly a year attempted to adapt the Backfit Rule to all rulemaking, even rulemaking that has nothing to do with powerplant hardware and the original intent of the Backfit Rule. This rulemaking and the accompanying analysis illustrates the difficulty. When applied to human-factors and certain other rulemaking, the Backfit Rule continues to exact NRC resources wholly disproportionate to any conceivable benefit to the public.

The record already shows cases where the Commission has been forced to sidestep a strict reading of the cost-benefit requirements of the Backfit Rule, when it nevertheless finds broad agreement that a rulemaking is in the public interest (e.g. in the case of conversion of non-power reactors from HEU [Highly Enriched Uranium] to LEU [Low Enriched Uranium]).

I therefore believe the public may wish to comment directly on the question of whether the Commission should continue its attempts to apply the Backfit Rule to all rulemaking, or whether the Rule should be revoked as it applies to rulemaking activity per se.

Alternatively, the public may wish to consider whether the Commission should amend the Backfit Rule to indicate explicitly that non-monetary benefits may be weighed by the Commission in the cost-benefit balance, when such considerations are found by the Commission to be in the public interest.

Dated at Washington, DC this ____ day of _____, 1986.

For the Nuclear Regulatory Commission.

Samuel S. Chilk,
Secretary of the Commission.

CHANGES FROM ENCLOSURE 2 AA38-2
OF SECY-86-48A [7590-01]

NUCLEAR REGULATORY COMMISSION
PARTS 19, 20, 30, 31, 32, 34, 40, 50, 61, AND 70 :

STANDARDS FOR PROTECTION AGAINST RADIATION; AVAILABILITY OF
SUPPLEMENTAL INFORMATION

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule; availability of supplemental information.

SUMMARY: On January 9, 1986, the Nuclear Regulatory Commission published for public comment a proposed revision of its radiation protection standards, 10 CFR Part 20. If implemented, that rule would require changes in the radiation protection procedures at nuclear power reactors and other NRC-licensed activities. Section 50.109 of the Commission's regulations requires that a backfit analysis be prepared for proposed NRC regulations that require changes to operating procedures for nuclear power reactor facilities licensed by the Commission under 10 CFR Part 50. This notice provides such an analysis for the proposed revision of 10 CFR Part 20 and solicits public comment on it.

DATES: Comments on this backfit analysis must be submitted in writing on or before October 31, 1986. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments filed on or before this date. The comment period for the proposed Part 20 revision is being extended to this same date, thereby providing more than 60 days of concurrent comment period.

ADDRESSES: Submit written comments or any other information concerning this matter to the Secretary of the Commission, U.S. Nuclear Regulatory

Commission, Washington, DC 20555, Attention: Docketing and Service Branch. Copies of the proposed revision of 10 CFR Part 20 and the accompanying Regulatory Analysis that supports this Backfit Analysis may be examined, and copied for a fee, at the Commission's Public Document Room at 1717 H Street, NW, Washington, DC. Single copies of these documents may be obtained from the person indicated under the "FOR FURTHER INFORMATION CONTACT" heading.

FOR FURTHER INFORMATION CONTACT: Robert E. Alexander, Division of Regulatory Applications, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Telephone (301) 443-7976.

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SUPPLEMENTARY INFORMATION:

I. BACKGROUND

A. Part 20 Revision

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Paragraph 50.109(c) requires consideration of the priority and scheduling of the action under consideration in light of other regulatory activities. Implementation of the proposed revision of 10 CFR Part 20 should not significantly affect any other backfits or safety-related activities. In order to minimize the impact of the retraining and revisions of procedures, the proposed implementation period of the Part 20 revision extends over a five-year period. Therefore the changes required to implement the Part 20 revision would not conflict with and do not need to be further prioritized with respect to other activities at nuclear power plants.

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- b. Implement pending Federal Radiation Guidance on occupational radiation protection;
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The principal new or additional actions that would be required of licensees by the proposed 10 CFR Part 20 revisions are to:

- a. Sum, under some circumstances, the estimated dose from radionuclides external to the body and from radionuclides deposited in the body;

- b. If not previously done, provide documentation of programs for keeping exposures "as low as is reasonably achievable";
- c. Provide increased protection for the embryo/fetus when female workers declare themselves pregnant;
- d. Employ the latest ICRP limits on airborne radionuclide intakes, effluent releases and doses from inhaled or ingested radionuclides; and
- e. Modify training guides, operating procedures, and manuals to incorporate the new concepts and requirements and provide retraining of employees on these concepts and their implementation.

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10 CFR Part 20 generally applies only to normal off-site releases of radioactive material, so there would be no direct impact on risks associated with accidental releases of radioactive materials.

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The impact of modifying operating procedures, manuals, and records would be minimized by a five-year implementation period during which licensees may develop the necessary new procedures, manuals, and records and convert to the new system at any time most convenient to the licensee.

7. The Estimated Resource Burden on the NRC and the Availability of These Resources

Costs to the NRC would primarily be associated with the preparation of new regulatory guides for implementing the new procedures and revising existing regulatory guides, branch technical positions, and inspection procedures to reflect the Part 20 revisions. It has been estimated that this effort would consist of 5 to 7 new regulatory guides requiring 0.2 staff-years per guide or 1 to 1.4 staff-years total and approximately \$350K of technical support effort. At least seven existing regulatory guides would require revision, resulting in an additional staff-year of effort. It is estimated that

approximately one staff-year would be required in both the Office of Nuclear Material Safety and Safeguards (NMSS) and the Office of Nuclear Reactor Regulation (NRR) to modify license conditions and technical specifications to comply with the proposed revision.

The largest impact in NRC would be in the Office of Inspection and Enforcement and the NRC Regional Offices to revise inspection procedures and to train inspectors on the new regulations and procedures. It is estimated that this would require about 5 staff-years total. Once the new procedures are in place, there should not be any significant resource expenditures above current levels.

These impacts would be spread over the 5-year implementation period. For this reason and the fact that the impact would be distributed over several NRC offices, the Part 20 implementation should not have a major impact on NRC programs.

8. Potential Impact of Differences in Facility Type, Design, or Age on the Relevancy and Practicality of the Proposed Action

Since the proposed revisions principally affect operating procedures rather than facility physical design, there would be no significant impact from differences in facility type, design or age.

9. Are the Proposed Revisions Interim or Final and if Interim, What is the Justification for Imposing Them on an Interim Basis

The proposed rule, with modifications, is intended to be issued as a final rule.

Other Factors

The Environmental Protection Agency, in cooperation with NRC and other Federal Agencies, has prepared revised Federal guidance on radiation protection for workers. This guidance, if approved by the President,

would greatly influence the formulation of occupational radiation protection standards. The proposed Part 20 modifications would implement the new guidance. If the Part 20 revision is not adopted, NRC regulations would not be consistent with the new Federal guidance and the regulations of other Federal agencies.

Conclusion

The proposed revisions will provide improved public health protection by virtue of:

- ° Limiting routine annual occupational doses to 5 rems and deleting the present 5(N-18) formula option which allows doses up to 12 rems per year;
- ° Imposing a limit on radiation doses to the embryo-fetus. (No specific limit exists in the present Part 20 for the embryo-fetus);
- ° Updating the radionuclide intake limits based upon current scientific data, including substantially lower limits for several radionuclides such as uranium. (Part 20 now relies upon more than 25-year-old methodology and information);
- ° Providing limits for the combined doses from both internal and external radiation sources. (The current Part 20 permits the evaluations to be done separately);
- ° Incorporating the "effective dose" concept whereby organ doses are weighted by their relative health risk and summed to give a risk-equivalent dose. (The current Part 20 uses the "critical organ" concept and does not consider doses to organs other than the critical organ in setting allowable limits on radionuclide intake); and
- ° Requiring licensees to develop and implement a program and procedures for keeping radiation exposures "as low as is reasonably

achievable" or "ALARA." (Except for LWR effluent releases subject to Appendix I of 10 CFR Part 50, the present regulations exhort the licensee to keep radiation exposures "ALARA", but do not make this a requirement.)

In spite of these expected improvements, the Commission's analysis does not show unequivocally that the direct and indirect costs of implementation are justified in view of the increased protection. However, the Commission believes that there are additional relevant and material factors not amenable to quantitative cost comparisons and having significant bearing on this issue, including:

- ° Incorporation of updated Presidential guidance on radiation protection;
- ° Consistency with international standards, particularly with regard to international commerce.
- ° Updating the technical basis for the Part 20 limits; and
- ° Consistency of the methods and technical approaches for radiation protection regulations and those for current risk assessment methodologies.

Because of the public health improvements and the additional qualitative factors bearing on the issue described above, the Commission believes that the rule should be promulgated even though it may not provide a substantial increase in the overall protection of the public health and safety for the common defense and security. In addition, the Commission has tentatively concluded, pending consideration of public comments, that when all factors, qualitative as well as quantitative, are taken into consideration, the benefits to be derived from the proposed revision of Part 20 justify the direct and indirect costs of its implementation.

However, this decision and the Commission's decision regarding the

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order

AA38-2

[7590-01]

cost-benefit balancing and conformance of the proposed Part 20 revision to the "Backfit Rule" are tentative pending receipt of public comments on these issues.

1st paragraph of 7/18/86 SRM on SECY-86481

III. REQUEST FOR COMMENTS

The Commission solicits public comment on:

- (1) The draft Backfit Analysis for the proposed revision of Part 20;
- (2) Whether the Commission has adequately implemented §50.109 as it applies to the proposed Part 20 revision;
- (3) Whether the proposed revision of 10 CFR Part 20 would provide a substantial increase in the overall protection of public health and safety that will justify the direct and indirect costs of implementing this rule; and
- (4) Whether, because of other factors which support the proposed Part 20 revision, the application of Section 50.109(a)(3) should be suspended for this rulemaking if it is found that the proposed amendments do not meet the criteria in that section.

In addition to the above questions, Commissioner Bernthal also would like comments on the following two issues:

2nd paragraph of 7/18/86 SRM on SECY-86481 484

1. In regard^{[5]-de} to the Backfit Analysis, comment is solicited on whether criteria for Commission suspension of the "substantial increase" threshold should be developed and made subject to rulemaking.
2. Comment is also solicited on whether the Backfit Rule, given its evident defects and limitations in such cases, should continue to be applied at all to Commission rulemaking per se.

IV. ADDITIONAL COMMENTS OF THE NRC COMMISSIONERS

Commissioner Roberts' Views

Paragraph 5 of 7/18/86
SRM

Commissioner Roberts disapproved the proposed revision to Part 20 because the backfit analysis could not demonstrate that the changes would provide a "substantial" reduction in the radiation dose received by workers and members of the public.

Commissioner Asselstine's Views

Enclosure to 7/18/86 SRM
ON SECY-86/48-48A

I approve the publication of this Backfit Analysis for the purpose of obtaining public comment on the adequacy of the Commission's compliance with its Backfit Rule. The NRC staff has written that it "...does not believe that the Part 20 revision will provide a 'substantial' change in the radiation doses received by workers and members of the public." (See SECY-86-48A, page 2, "Backfit Analysis for Proposed Revision of 10 CFR Part 20" dated May 19, 1986.) The Commission's Backfit Rule (10 CFR 50.109) requires a two prong test to be met before the Commission can promulgate a new or revised regulation such as the Part 20 proposed revisions. One of the required tests contained in 10 CFR 50.109 (a)(3) is that any revision to the Commission's regulations affecting Part 50 licensees must provide "...a substantial increase in the overall protection of the public health and safety..." Given the above conclusion of the staff that this threshold is not met in the proposed revision to Part 20, the Commission is here asking the public whether the application of the threshold standard in 10 CFR 50.109(a)(3) should be suspended for the Part 20 revisions. I would particularly appreciate receiving comments from those that believe the threshold standard should be suspended as to why the Part 20 rulemaking deserves special treatment under the Backfit Rule. In addition, I would appreciate comments on whether the Commission should develop criteria governing when the Commission will or will not apply the threshold standards of 10 CFR 50.109(a)(3) and whether such criteria should be subjected to rulemaking.

Commissioner Bernthal's Views*Commissioner Bernthal's views
transmitted from SECY to EDO*

The public should be aware of the fact that the Commission has for nearly a year attempted to adapt the Backfit Rule to all rulemaking, even rulemaking that has nothing to do with powerplant hardware and the original intent of the Backfit Rule. This rulemaking and the accompanying analysis illustrates the difficulty. When applied to human-factors and certain other rulemaking, the Backfit Rule continues to exact NRC resources wholly disproportionate to any conceivable benefit to the public.

The record already shows cases where the Commission has been forced to sidestep a strict reading of the cost-benefit requirements of the Backfit Rule, when it nevertheless finds broad agreement that a rulemaking is in the public interest (e.g. in the case of conversion of non-power reactors from HEU [Highly Enriched Uranium] to LEU [Low Enriched Uranium]).

I therefore believe the public may wish to comment directly on the question of whether the Commission should continue its attempts to apply the Backfit Rule to all rulemaking, or whether the Rule should be revoked as it applies to rulemaking activity per se.

Alternatively, the public may wish to consider whether the Commission should amend the Backfit Rule to indicate explicitly that non-monetary benefits may be weighed by the Commission in the cost-benefit balance, when such considerations are found by the Commission to be in the public interest.

Dated at Washington, DC this ____ day of _____, 1986.

For the Nuclear Regulatory Commission.

Samuel S. Chilk,
Secretary of the Commission.

NUCLEAR REGULATORY COMMISSION
PARTS 19, 20, 30, 31, 32, 34, 40, 50, 61 and 70

STANDARDS FOR PROTECTION AGAINST RADIATION;
EXTENSION OF COMMENT PERIOD

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule; extension of comment period.

SUMMARY: On January 9, 1986, the Nuclear Regulatory Commission published for public comment a proposed revision of its radiation protection standards, 10 CFR Part 20. This Notice extends the comment period from September 12, 1986 to October 31, 1986 in order to be coincident with the comment period for the draft backfit analysis for this proposed rulemaking that is being published elsewhere in this issue.

DATE: Comments on the proposed revision must be submitted in writing on or before October 31, 1986. Comments received after this date will be considered if it is practical to do so, but assurance of this consideration cannot be given except as to comments filed on or before this date. The comment period on the proposed backfit analysis for this rule also ends on this date.

ADDRESSES: Submit written comments or any other information concerning this matter to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch. Copies of the proposed revision of 10 CFR Part 20 and the accompanying regulatory analysis that support this backfit analysis may be examined and copied for a fee at the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. Single copies of these documents may be obtained from the person indicated under the "FOR FURTHER INFORMATION CONTACT" heading.

FOR FURTHER INFORMATION CONTACT: Robert E. Alexander, Division of Regulatory Applications, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone (301) 443-7976.

SUPPLEMENTARY INFORMATION: The Nuclear Regulatory Commission is proposing to revise its regulations pertaining to radiation protection standards. The proposed revision was published in the Federal Register on January 9, 1986 (51 FR 1092). In that document (51 FR 1122), the Commission indicated that it was publishing the proposed Part 20 revision without waiting for the preparation of a backfit analysis in accordance with §50.109 of 10 CFR Part 50. The Commission noted that such an analysis could be prepared and, if necessary, public comment on the backfit analysis could be obtained at a later date. A draft backfit analysis is published elsewhere in this issue of the Federal Register. The change in the comment period on the proposed Part 20 revision, extending it to October 31, 1986, is coincident with the comment period on the draft backfit analysis and will provide at least 60 days of concurrent comment period for both documents.

Dated Washington, D.C. this day of , 1986.

For the Nuclear Regulatory Commission.

Samuel S. Chilk,
Secretary of the Commission.