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

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MEMORANDUM FOR: Robert M. Bernero, Director, NMSS
Thomas E. Murley, Director, NRR
Eric S. Beckjord, Director, RES
Thomas T. Martin, Regional Administrator, RI
Stewart D. Ebneter, Regional Administrator, RII
A. Bert Davis, Regional Administrator, RIII
Robert D. Martin, Regional Administrator, RIV
John B. Martin, Regional Administrator, RV

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: GUIDANCE ON FEDERAL REGISTER NOTIFICATION OF RULEMAKINGS AND LICENSING ACTIONS WHICH EXEMPT MATERIAL FROM REGULATORY CONTROL

The purpose of this memorandum is to provide interim guidance in light of the Commission's policy statement on "Below Regulatory Concern (BRC)", on Federal Register notification of rulemakings and licensing actions involving exemption decisions. The BRC policy statement states that opportunity for public comment will be provided through noticing in the Federal Register, for rulemakings and any new licensing actions involving the exemption of small quantities of radioactive materials from regulatory control where generic exemption provisions have not already been established. The statement permits the continued use of existing generic exemption provisions that do not require a Federal Register Notice until the generic exemption has been reviewed for consistency with the BRC policy. Licensing actions taken in accordance with such provisions may continue to be issued without such notice, unless notice is otherwise required (for example, Part 51 may require notice).

I have included as enclosures to this memorandum, interim guidance on how to proceed with exemption decisions in the near term. In preparing these enclosures, the staff has taken a broad look at existing exemption provisions and has identified all those which could be relevant to the BRC policy. Enclosure 1 provides guidance for NRR actions and Enclosure 2 provides guidance for NMSS and regional actions. Federal Register Notices required for regional actions should be prepared by the region following existing guidance. If you have any questions on this matter, please contact Lemoine J. Cunningham for NRR questions (492-1086) or John Hickey for NMSS questions (492-3425).

James M. Taylor
Executive Director for Operations

Enclosures:
As stated

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ENCLOSURE 6

NRR GUIDELINES FOR PUBLIC NOTICE OF LICENSING ACTIONS RELATED TO THE BRC POLICY

POWER AND NON-POWER REACTOR LICENSEES
CONTACT: L. J. Cunningham, NRR, 492-1086

1. The following licensing actions do not need to be noticed in the Federal Register, unless there is a previously existing requirement for such notice; such as a Sholly Notice or 10 CFR 51:

   a. Authorizations based on regulations or guidance issued after June 27, 1990, if the regulations or guidance do not themselves require notice and were developed in accordance with the BRC policy and noticed for comment in the Federal Register.

   b. Authorizations in accordance with provisions of 10 CFR Section 20.303, 20.306, 30.15(a), 30.18, and 30.20.

   c. Onsite burials in non-Agreement States approved pursuant to 10 CFR Section 20.302.

   d. Authorizations to release equipment or facilities for unrestricted use in accordance with the guidelines in Regulatory Guide 1.86, NRC Circular 81-07, Information Notice 85-92 or environmental lower limits of detection (LLD's) contained in NUREG-0472.

   e. Approvals of incineration pursuant to 10 CFR Section 20.305, if the ash is disposed as non-BRC radioactive waste, transferred to a licensed person, or contains non-detectable radioactivity.

2. The following licensing actions must be noticed in the Federal Register, with at least a 30-day comment period.

   a. Any action not covered by No. 1 which uses the BRC policy as justification for approval.

   b. Any exemption authorization involving transfer of radioactive material to unregulated status, not covered by 1(b) above, where a dose analysis is performed, and the projected doses exceed the BRC criteria.

   c. Any 20.302 off-site burial.*

   d. Any authorization for incineration which allows disposal of ash which contains detectable levels of radioactivity as BRC waste.

   e. Any NRR approval letter, license amendment or change in Technical Specifications that requires notice in the Federal Register (Sholly Notice).

*Note that actions under 20.302 do not remove material from regulatory control unless specifically so stated; thus 20.302 approvals may not be subject to BRC policy.

NMSS GUIDELINES FOR PUBLIC NOTICE OF LICENSING ACTIONS RELATED TO THE BRC POLICY

FUEL CYCLE AND MATERIAL LICENSEES
CONTACT: John Hickey, NMSS, 492-3425

1. The following licensing actions do not need to be noticed in the Federal Register, unless there is a previously existing requirement for such notice:

   a. Authorizations based on regulations or guidance issued after June 27, 1990, if the regulations or guidance do not themselves require notice and were developed in accordance with the BRC policy and noticed for comment in the Federal Register.

   b. Authorizations in accordance with provisions of 10 CFR Section 20.303, 20.306, 30.14, 30.15(a), 30.16, 30.18, 30.19, 30.20, 31.7, 31.11(f), 35.92, 39.47, 39.49, 39.77, 40.13, 40.22(b), and 40.25(e).

   c. Onsite burials approved pursuant to 10 CFR Section 20.302, in accordance with Policy and Guidance Directive FC 86-10, dated October 9, 1986, or the Federal Register notice entitled "Disposal or Onsite Storage of Thorium or Uranium Wastes," 46 FR 52061, October 23, 1981.*

   d. Authorizations to release equipment or facilities for unrestricted use in accordance with the guidelines in Policy and Guidance Directives FC 83-3, dated March 7, 1983, and FC 83-23, dated November 3, 1983.

   e. Authorizations to dispose of waste which has been held for decay to non-detectable radiation levels.

   f. Approvals of incineration pursuant to 10 CFR Section 20.305, if the ash is disposed as non-BRC radioactive waste, transferred to a licensed person, or contains non-detectable radioactivity.

2. The following licensing actions, including renewals, must be noticed in the Federal Register, with at least a 30-day comment period.

   a. Any action not covered by No. 1 which uses the BRC policy as justification for approval.

   b. Any exemption authorization involving transfer of radioactive material to unregulated status, not covered by 1(b) above, where a dose analysis is performed, and the projected doses exceed the BRC criteria.

   c. Any 20.302 off-site burial or any burial which is not in accordance with Policy and Guidance Directive FC 86-10 or 46 FR 52061.*

   d. Any authorization for incineration which allows disposal of ash which contains detectable levels of radioactivity as BRC waste.

   e. Any authorization to distribute a new type of consumer product on a license-exempt basis which has not been previously authorized.

*Note that actions under 20.302 do not remove materials from regulatory control unless specifically so stated; thus 20.302 approvals may not be subject to BRC policy.

For: The Commissioners

From: James M. Taylor, Executive Director for Operations

Subject: STAFF ACTION PLAN FOR IMPLEMENTATION OF BELOW REGULATORY CONCERN POLICY

Purpose: To inform the Commission of the staff action plan ~~for~~ the implementation of the Below Regulatory Concern Policy (BRC) Statement. This plan was originally requested in the Staff Requirements Memorandum (SRM) of October 13, 1989, concerning the subject policy (Enclosure 1). The need for such a plan was reiterated in the (revised) SRM of June 28, 1990 (Enclosure 2). The Commission also requested an addition to the plan concerning some generally licensed products in an SRM of August 13, 1990 (Enclosure 3).

Summary: This paper presents resource estimates and projected schedules for activities related to implementation of the subject policy as requested by the Commission. It also describes the activities that have been initiated in these areas. The staff intends to proceed with the activities outlined in this action plan unless directed otherwise by the Commission. The resources known at this time to be necessary to implement this plan are included in the latest revision of the Five-Year Plan. Additional resource needs identified as a result of the studies (3(a) and 7(a) below) conducted under the plan will be included in future revisions of the Five-Year Plan.

Background: The Commission has recently published the policy statement on below regulatory concern (previously referred to as the exemption policy). The SRM of October 13, 1989, directed the staff to prepare an action plan to accomplish certain activities involved in implementing that policy. This plan covers: (1) those activities identified by the Commission ~~at that time~~ (items (3) through (6) below); (2) previously initiated activities which also relate to implementing the policy (items (1) and (2) below);

in October

Contact:
C. R. Mattsen, RES
492-3638

and (3) consistent with the SRM of August 13, 1990, consideration of exemptions of certain generally licensed devices (item 7).

To restate, the activities covered by this plan are:

(1) Rulemaking and associated tasks currently planned or in progress that fall within the framework of the policy;

(2) Evaluation of and action on petitions for rulemaking to establish or modify exemption levels;

(3) (a) A systematic assessment of existing exemptions in the regulations for conformance with the policy, and

(b) Revision of those regulations identified in the systematic assessment that require modification to be consistent with the policy;

(4) Development of guidance on consistent implementation of the policy in licensing actions and rulemaking;

(5) Development of a program of information dissemination concerning the policy and its implementation;

(6) Development of a program to ensure that necessary health effects research is conducted and the results used to monitor the effectiveness of policy implementation; and

(7) (a) Evaluation of five identified generally licensed devices for possible exemption under the policy, and

(b) Rulemaking as appropriate to exempt these devices.

Discussion

Activity (1) includes: (a) development of interim guidance and rulemaking on residual radioactivity criteria for the release to unrestricted use of facilities and sites (decommissioning); (b) development of residual radioactivity criteria for equipment and materials (recycling); (c) contractor study and eventual generic rulemaking for BRC waste (in accordance with the December 2, 1986, advance notice of proposed rulemaking); and (d) evaluation of potential doses from reconcentration of radionuclides in sewage sludge to provide input to a reconsideration of sewage limits.

Activity (2) includes plans to evaluate and respond to anticipated petitions for rulemaking to exempt waste streams from regulatory control. Two such petitions from Rockefeller Institute and one from the University of Utah related to biomedical wastes have been received. A petition that had been anticipated from NUMARC, requesting exemption of certain reactor waste streams, now is not expected in the foreseeable future.

Activity (3)(a), the systematic assessment of existing exemptions, involves two steps. The first step, identification of existing exemptions in the regulations, is essentially complete. The list of exemptions is included as Enclosure 4. The list includes only those exemptions contained in the regulations to which the policy statement could be applicable; that is, those that involve release of radioactive material from regulatory control in some manner. Some exemptions are not written explicitly as exemptions from specific regulations, rather they are requirements pertaining to releases of radioactive material. All such regulations are included in Enclosure 4 for completeness. However, based on some preliminary considerations, certain of these will not need to be reevaluated in order to assure consistency of the regulations. For example, as noted in Enclosure 4, three of the cited paragraphs, §§ 20.302, 20.106(b), and 50.36a, allow for case specific exemptions and do not contain specific criteria which are deemed inconsistent with the policy.

In addition, certain of these regulations; namely, §§ 20.106(a) (which governs effluents to air and water) and 20.303 (which governs releases into sanitary sewage systems) are intended to ensure compliance with the overall dose limit and not to generically define as low as is reasonably achievable (ALARA) releases. Other effluent release limits either incorporate ALARA considerations generically or are otherwise lower than the overall dose limit because of generally applicable environmental standards of the EPA. In all cases, effluent limits provide an upper bound on controlled releases to which ALARA measures are to be applied by individual licensees. A revision of the overall limits for effluents presently contained in §§ 20.106 and 20.303 is included in the overall revision of 10 CFR Part 20 which has been approved by the Commission and is undergoing detailed revisions in wording by the staff. (This rulemaking would also add to 10 CFR Part 20 the requirement that ALARA be applied by all individual licensees.) Because these limits are so broad in their application, it is probably not practical nor desirable to attempt to apply ALARA generically as would be done for the more practice-specific regulations which were the focus of the policy statement.

However, as noted above, activity (1) includes a reevaluation of potential doses associated with sewage limits (§ 20.303).

A contractor study was initiated in 1987 and is scheduled for completion by early 1991 (as shown in Enclosure 5). The staff will consider whether further modifications to § 20.303 are appropriate at that time.

Another regulation governing effluents, Part 50, Appendix I, was developed as a generic ALARA regulation. Although technology may be somewhat improved since the original analysis, no major flaw has appeared in the original basis for these ALARA criteria. Therefore, the staff does not believe that these criteria should be reexamined further.

The second step to be undertaken is to systematically assess the doses for each exemption. This task will be accomplished with contractor assistance. In those cases where the exemption results in doses that exceed the individual and/or collective dose criteria of the policy, a cost-benefit analysis will be performed to determine whether the doses resulting from the exemption are ALARA. After these dose estimates and subsequent analyses are completed, the staff will be in a position to determine which exemption regulations are candidates for revision in order to achieve consistency with the policy. Examination of the principal literature on previous estimates of doses from specific exemptions has been initiated. Existing dose estimates, if judged adequate, could be the basis for determining that the dose criteria of the policy are unlikely to be exceeded. Also, existing analyses may provide at least a partial basis for decisions on whether ALARA is met for exemptions exceeding the dose criteria. However, for consistency, dose estimation should be conducted as uniformly as practical with a consistent, up-to-date model and modeling assumptions. As indicated in Enclosure 5, the preliminary schedule for completion of the assessment of existing exemptions is September 1992, however, this depends on the number and complexity of the ALARA analyses needed.

Activity (3)(b) will involve the rulemaking actions necessary to revise exemptions for consistency with the policy statement. The number and extent of these rulemaking actions cannot be precisely determined until the systematic assessment has been completed. However, preliminary reviews suggest that at least six rulemakings are likely to be needed. The effort necessary to conduct these rulemakings is included in the staff's resource estimate. Any other rulemaking actions determined to be necessary as a result of the systematic assessment will require additional resources in the period 1993 and beyond. The order of the six rulemakings discussed below is not meant as an indication of their priorities.

One rulemaking that has been identified by the preliminary review as a candidate for conforming the regulations to the policy would be reducing the specific individual dose criterion in 10 CFR § 32.28 applicable to gas and aerosol detectors (smoke detectors) from 5 mrem/year to 1 mrem/year. The 5 mrem/year criterion was part of the initial rulemaking for smoke detectors in 1969 and was compatible with the developing industry's practice for the quantities of Am-241 used per detector at the time. As a result of advancements in the design of smoke detectors and the issuance in 1977 of the internationally accepted Nuclear Energy Agency (NEA) smoke detector standard with its recommended limit of 1 microcurie of Am-241 per detector, manufacturers are generally making smoke detectors which meet the 1 mrem/year criterion. Given the present situation, an ALARA analysis would not support the continued use of a 5 mrem/year criterion. Thus a rather straightforward rulemaking would make this regulation consistent with the interim criterion for practices involving widespread distribution of materials in the policy statement. It would preclude unnecessary doses in the future and would be consistent with the international regulatory community.

The second rulemaking that would appear to be necessary to conform the regulations to the policy is a revision of 10 CFR Part 40, "Domestic Licensing of Source Material," to update the requirements and to improve tracking of exemptions by the Commission. The staff has been aware for a number of years that such a rulemaking is desirable. In addition to updating the requirements for the source material exemptions, revision of the rule would appear to be critical to the ability of the Commission to monitor the effectiveness of the policy and maintain total exposures from multiple sources within the appropriate limit. A rulemaking to revise 10 CFR Part 40 may involve revamping the regulation to make it more consistent with the approach taken in 10 CFR Part 30 for the regulation of byproduct material and consider other aspects of source material licensing beyond the exemptions. Concerning the source material exemptions in Part 40, requirements similar to those applicable to the distribution of materials and products exempt from licensing under Part 30, such as quality assurance, may be considered. Better controls and information on distribution of source materials to unrestricted use may be especially important to the Commission's stated intent to control "multiple" exposures since the consumer products previously estimated to produce the greatest collective exposures contain source material. Before initiating this rulemaking, a preliminary research and cost effectiveness study would be conducted to determine the most effective approach.

A third potential rulemaking that may be necessary to achieve consistency of the regulations with the policy statement would be modifications of references to an outright prohibition of the use of radioactive material in food, beverages, cosmetics, drugs, toys, adornments, or otherwise designed for ingestion, inhalation, or application to the human body. Some part of this prohibition appears at least four places in the regulations (§§ 30.14, 30.19, 32.11(c), and 32.18(b)). Although this may be a relatively simple rulemaking, it may also be controversial and raise public opposition. Also, other agencies such as the Food and Drug Administration and the Consumer Product Safety Commission may have a regulatory interest in such modifications.

Additionally, a rulemaking which should be seriously considered would be to resume annual reporting of quantities of materials and products distributed to exempt persons. Such a requirement would be in keeping with the Commission's stated intent that it will maintain cognizance over the types of exemptions granted and the quantities of material distributed under exemptions. Since 1983, reports have been required only every 5 years without the requirement to break the data down by years. This has made it difficult for the staff to maintain a clear picture of distribution trends of materials and products to exempt persons. Information of this type will be important if the NRC is to keep current on the amount of materials being released to unrestricted use and to carry out the stated intent to ensure that the exposures of the public from all sources controlled by the NRC do not exceed 100 mrem/yr. Keeping up with information on the distribution of materials on an annual basis will also be important in achieving an effective continuing public information program.

In addition to these four rulemakings, the staff believes that two rulemakings to revise the exempt quantities and exempt concentration tables of 10 CFR Part 30 will be necessary after completion of the assessment and calculation of doses based upon updated models and scientific information. However, these and other amendments and revisions to specific exemption regulations can only be initiated after completion of the review and assessment of the respective individual exemptions for consistency with the policy statement.

In addition to rule changes, there are other documents, such as regulatory guides, standard review plans, and possibly branch positions that may also need revision because of inconsistencies either with the policy itself or with the amendments made to the regulations. The staff has not yet identified all the specific revisions that might be needed and thus cannot estimate at this time what level of effort will be necessary. A somewhat lower priority will be given to these tasks. Those revisions that reflect changes to existing

regulations governing exemptions or any new guidance needed for new exemptions would be initiated after the associated rulemaking is well underway. One document that has been identified is Standard Review Plan 11.6, "Method for Obtaining Approval of Proposed Disposal Procedures," which is presently under development by NRR. This SRP addresses requests for approval under § 20.302 to dispose of licensed material in a manner not otherwise authorized in the regulations. Since NMSS, NRR, the Regional offices, and the Agreement States can authorize these disposals, a formal review plan with uniform criteria is needed in order to provide a consistent approach in staff evaluations. One issue to be resolved is whether BRC criteria are applicable to actions taken under § 20.302 which do not remove materials from regulatory control. This issue, and others related to § 20.302 disposals, is the subject of a separate Commission paper being prepared by the staff.

The remaining three areas of effort that were specifically requested by the Commission in the October 13, 1989, SRM (activities (4) through (6)) are relatively straightforward. Resource estimates for these activities do not depend to any extent on the outcome of the systematic assessment and associated rulemaking tasks.

For activity (4), the development of guidance for the staff to ensure consistent implementation of the policy, a task force approach has been used, involving knowledgeable staff from the various offices whose work will need to incorporate the policy. Guidance was distributed on July 30, 1990, describing when Federal Register notification of rulemakings and licensing actions is necessary (Enclosure 6). Other guidance will be developed on an "as needed" basis as issues are identified. As distinct from the development of Regulatory Guides associated with specific regulations, activity (4) is to develop generic guidance on BRC issues; e.g., criteria for defining a practice.

In regard to activity (5) concerning information dissemination, GPA has prepared and is distributing the "plain English" pamphlet on exemptions. In addition to that and other planned information dissemination, the staff has been and will continue to be responding to many letters of inquiry, including a large number of Congressional requests. Besides the written documents, the staff is actively presenting and explaining the policy in various technical, professional, and public forums. Furthermore, the staff will maintain cognizance of efforts involved in a Committee on Interagency Radiation Research

and Policy Coordination (CIRRPC) initiative to develop a national policy on education of the public regarding the risks from radiation.

In regard to activity (6), concerning health effects research, there are currently several initiatives underway. These include examination of effects from high-LET radiation for incorporation into NUREG/CR-4214 and confirmatory research on effects of hot particles on the skin. In addition, the NRC staff participates formally in several authoritative committees and panels such as the CIRRPC Science Panel. There are also other ongoing activities, such as attending professional meetings and symposia and keeping informed about other involved agencies' activities, through which the staff currently keeps abreast of and encourages appropriate health effects research. The task called for in this plan is to review, maintain, and possibly augment the ongoing program to assure staff cognizance of health effects research and ensure that necessary research is conducted. In addition, this information will be utilized in evaluating the implementation of the BRC policy. The staff recognizes, in view of the invaluable potential information on human health effects arising from the accident at Chernobyl and the dramatic advances in molecular and cellular biology in the last 15 years, the need to maintain cognizance of the field and to reflect the new information in NRC's regulatory program. The importance of these events is described below.

The health effects from the Chernobyl release could be expected to provide information on the health effects of interest to the NRC. However, the Soviets appear to have limited economic resources and thus plan only limited national support to gather health effects data. The US-USSR Joint Coordinating Committee for Civilian Nuclear Reactor Safety is currently preparing research protocols for work with the Soviets.

In regard to the need for evaluating the advances in biology, the staff is aware that a significant reduction in the uncertainties associated with risk coefficients might be achieved with a better understanding of the basic processes of radiation carcinogenesis and mutagenesis through studies on radiation effects at the molecular and cellular levels. Of course, the Departments of Energy and Health and Human Services have the major responsibility for health effects research. However, it is important that expertise in contemporary radiobiology be maintained within the staff to properly advise the Commission on and take advantage of advances in this science.

To this end, a research program is now underway assessing the utility of such studies to NRC programs and will be a catalyst for future cooperative research efforts in this area.

A scientifically valid research program that could detect or measure health effects, if any, due to BRC levels of radiation is not considered feasible. However, the effectiveness of the BRC policy can be evaluated with a periodic review of the dose estimates from the aggregate of all the actual BRC practices that have been approved by the Commission. The frequency of the periodic evaluation of the aggregated doses will reflect the number and kinds of BRC practices that the Commission approves and that are implemented. As a result, if the number of approved BRC practices grows significantly over the next several years, additional resources will be included in updates of the Five-Year Plan to assure a comprehensive and valid monitoring program.

In regard to activity (7)(a), the evaluation of certain generally licensed devices for possible exemption under the policy statement, the analyses necessary are essentially the same as for the reevaluation of existing exemptions. Five devices were identified by the staff in SECY-90-175 as candidates for exemption: (i) static eliminators containing krypton-85; (ii) beta backscatter devices; (iii) gas chromatographs containing nickel-63; (iv) x-ray fluorescence analyzers containing cadmium-109 and iron-55, but excluding those containing curium-244 and americium-241; and (v) certain calibration and reference sources having small activities. Dose estimates will be made for comparison with the BRC criteria, and if necessary cost/benefit analyses will also be done. Because the work to be done on this task is the same as that for the reevaluation of existing exemptions and because of the importance of using a consistent approach, activities (3)(a) and (7)(a) will be carried out in combination with the assistance of a contractor.

Presuming that the above assessment indicates that certain generally licensed devices should be exempted under the BRC policy, appropriate rulemakings (activity (7)(b)) will be initiated in FY 1993 as shown in Enclosure 5. As many as five separate rulemakings may eventually be undertaken. Resource estimates for these rulemakings will be included in the next update of the Five-Year Plan if the evaluations demonstrate that exemptions are indeed appropriate.

Resources: The FY 1991-1995 Five-Year Plan includes resources to carry out all of the known activities described above. The FTE resources by Office for these activities are shown below:

	FY 91	FY 92	FY 93	FY 94	FY 95
RES FTE	7.0*	7.0	7.0	7.0	7.0
NMSS FTE	1.0	1.0	1.0	1.0	1.0
GPA FTE	1.9	1.6	1.4	0.3	0.3
ADM FTE	0.2	0.2	0.2	0.2	0.2
TOTAL	10.1	9.8	9.6	8.5	8.5

* Include[illegible] erhire positions.

The above resource estimates generally represent minimum requirements which could be higher depending on the difficulty of the specific tasks identified. In addition to the NRC staff resources, an additional $0.5 million per year in contractor assistance has been included in the Five-Year Plan for the dose evaluations and the cost-benefit analyses of activities (3)(a) and (7)(a). However, the total cost of these activities cannot be determined at this time. The actual cost of the dose assessments will depend on the extent that existing information can show consistency with the policy without extensive reevaluation. The total cost for the cost-benefit analyses and environmental assessments or impact statements will depend on the number of exemptions (and potential exemptions) with doses exceeding the criteria, on the complexities associated with the specific exemptions involved, and on the depth of the analysis necessary to determine consistency with the policy statement. Based upon previous experience, a full scope Environmental Impact Statement, if necessary for one of the more difficult exemptions, could cost $2 million. However, reexamination of some of the consumer products on a cost-benefit basis could be relatively simple in some cases and considerably less costly.

In addition, the above estimates include resources for development of the rules described above but do not include resources for associated licensing and inspection activities. Resource

For: The Commissioners

From: James M. Taylor, Executive Director for Operations

Subject: STAFF ACTION PLAN FOR IMPLEMENTATION OF BELOW REGULATORY CONCERN POLICY

Purpose: To inform the Commission of the staff action plan for the implementation of the Below Regulatory Concern Policy (BRC) Statement. This plan was originally requested in the Staff Requirements Memorandum (SRM) of October 13, 1989, concerning the subject policy (Enclosure 1). The need for such a plan was reiterated in the (revised) SRM of June 28, 1990 (Enclosure 2). The Commission also requested an addition to the plan concerning some generally licensed products in an SRM of August 13, 1990 (Enclosure 3).

Summary: This paper presents resource estimates and projected schedules for activities related to implementation of the subject policy as requested by the Commission. It also describes the activities that have been initiated in these areas. The staff intends to proceed with the activities outlined in this action plan unless directed otherwise by the Commission. The resources known at this time to be necessary to implement this plan are included in the latest revision of the Five-Year Plan. Additional resource needs identified as a result of the studies (3(a) and 7(a) below) conducted under the plan will be included in future revisions of the Five-Year Plan.

Background: The Commission has recently published the policy statement on below regulatory concern (previously referred to as the exemption policy). The SRM of October 13, 1989, directed the staff to prepare an action plan to accomplish certain activities involved in implementing that policy. This plan covers those activities identified by the Commission at that time (items (3) through (6) below) and previously initiated activities which also relate to implementing the policy (items (1) and (2) below); ~~and plans to consider for exemption certain devices now generally licensed (item 7). The SRM of August 13, 1990, concerning the general license study (Enclosure 3) requested~~

(1) and (3) coordinated with

Contact:
C. R. Mattsen, RES
492-3638

~~the staff to incorporate plans to~~ consider exemptions of certain generally licensed devices ~~into this overall plan for implementing the BRC policy~~ (item 7).

To restate) The activities covered by this plan are:

(1) Rulemaking and associated tasks currently planned or in progress that fall within the framework of the policy;

(2) Evaluation of and action on petitions for rulemaking to establish or modify exemption levels;

(3) (a) A systematic assessment of existing exemptions in the regulations for conformance with the policy, and

(b) Revision of those regulations identified in the systematic assessment that require modification to be consistent with the policy;

(4) Development of guidance on consistent implementation of the policy in licensing actions and rulemaking;

(5) Development of a program of information dissemination concerning the policy and its implementation;

(6) Development of a program to ensure that necessary health effects research is conducted and the results used to monitor the effectiveness of policy implementation; and

(7) (a) Evaluation of five identified generally licensed devices for possible exemption under the policy, and

(b) Rulemaking as appropriate to exempt these devices.

Discussion: Activity (1) includes: (a) development of interim guidance and rulemaking on residual radioactivity criteria for the release to unrestricted use of facilities and sites (decommissioning); (b) development of residual radioactivity criteria for equipment and materials (recycling); (c) contractor study and eventual generic rulemaking for BRC waste (in accordance with the December 2, 1986, advance notice of proposed rulemaking), and (d) evaluation of potential doses from reconcentration of radionuclides in sewage sludge to provide input to a reconsideration of sewage limits.

Activity (2) includes plans to evaluate and respond to anticipated petitions for rulemaking to exempt waste streams from regulatory control. Two such petitions from Rockefeller Institute and one from the University of Utah related to biomedical wastes have been received. A petition that had been anticipated from NUMARC, requesting exemption of certain reactor waste streams, now is not expected in the foreseeable future.

Activity (3)(a), the systematic assessment of existing exemptions, involves two steps. The first step, identification of existing exemptions in the regulations, is essentially complete. The list of exemptions is included as Enclosure 4. The list includes only those exemptions contained in the regulations to which the policy statement could be applicable; that is, those that involve release of radioactive material from regulatory control in some manner. Some exemptions are not written explicitly as exemptions from specific regulations, rather they are requirements pertaining to releases of radioactive material. All such regulations are included in Enclosure 4 for completeness. However, based on some preliminary considerations, certain of these will not need to be reevaluated in order to assure consistency of the regulations. For example, as noted in Enclosure 4, three of the cited paragraphs, §§ 20.302, 20.106(b), and 50.36a, allow for case specific exemptions and do not contain specific criteria which ~~could be~~ deemed inconsistent with the policy.

In addition, certain of these regulations; namely, §§ 20.106(a) (which governs effluents to air and water) and 20.303 (which governs releases into sanitary sewage systems) are intended to ensure compliance with the overall dose limit and not to generically define as low as is reasonably achievable (ALARA) releases. Other effluent release limits either incorporate ALARA considerations generically or are otherwise lower than the overall dose limit because of generally applicable environmental standards of the EPA. In all cases, effluent limits provide an upper bound on controlled releases to which ALARA measures are to be applied by individual licensees. A revision of the overall limits for effluents presently contained in §§ 20.106 and 20.303 is included in the overall revision of 10 CFR Part 20 which has been approved by the Commission and is undergoing detailed revisions in wording by the staff. (This rulemaking would also add to 10 CFR Part 20 the requirement that ALARA be applied by all individual licensees.) Because these limits are so broad in their application, it is probably not practical nor desirable to attempt to apply ALARA generically as would be done for the more practice-specific regulations which were the focus of the policy statement.

However, as noted above, activity (1) includes a reevaluation of potential doses associated with sewage limits (§ 20.303).

A contractor study was initiated in 1987 and is scheduled for completion by early 1991 (as shown in Enclosure 5). The staff will consider whether further modifications to § 20.303 are appropriate at that time.

Another regulation governing effluents, Part 50, Appendix I, was developed as a generic ALARA regulation. Although technology may be somewhat improved since the original analysis, no major flaw has appeared in the original basis for these ALARA criteria. Therefore, the staff does not believe that these criteria should be reexamined further.

The second step to be undertaken is to systematically assess the doses for each exemption. This task will be accomplished with contractor assistance. In those cases where the exemption results in doses that exceed the individual and/or collective dose criteria of the policy, a cost-benefit analysis will be performed to determine whether the doses resulting from the exemption are ALARA. After these dose estimates and subsequent analyses are completed, the staff will be in a position to determine which exemption regulations are candidates for revision in order to achieve consistency with the policy. Examination of the principal literature on previous estimates of doses from specific exemptions has been initiated. Existing dose estimates, if judged adequate, could be the basis for determining that the dose criteria of the policy are unlikely to be exceeded. Also, existing analyses may provide at least a partial basis for decisions on whether ALARA is met for exemptions exceeding the dose criteria. However, for consistency, dose estimation should be conducted as uniformly as practical with a consistent, up-to-date model and modeling assumptions. As indicated in Enclosure 5, the preliminary schedule for completion of the assessment of existing exemptions is September 1993; however, this depends on the number and complexity of the ALARA analyses needed.

Activity (3)(b) will involve the rulemaking actions necessary to revise exemptions for consistency with the policy statement. The number and extent of these rulemaking actions cannot be precisely determined until the systematic assessment has been completed. However, preliminary reviews suggest that at least six rulemakings are likely to be needed. The effort necessary to conduct these rulemakings is included in the staff's resource estimate. Any other rulemaking actions determined to be necessary as a result of the systematic assessment will require additional resources in the period 1993 and beyond. The order of the six rulemakings discussed below is not meant as an indication of their priorities.

One rulemaking that has been identified by the preliminary review as a candidate for conforming the regulations to the policy would be reducing the specific individual dose criterion in 10 CFR § 32.28 applicable to gas and aerosol detectors (smoke detectors) from 5 mrem/year to 1 mrem/year. The 5 mrem/year criterion was part of the initial rulemaking for smoke detectors in 1969 and was compatible with the developing industry's practice for the quantities of Am-241 used per detector at the time. As a result of advancements in the design of smoke detectors and the issuance in 1977 of the internationally accepted Nuclear Energy Agency (NEA) smoke detector standard with its recommended limit of 1 microcurie of Am-241 per detector, manufacturers are generally making smoke detectors which meet the 1 mrem/year criterion. Given the present situation, an ALARA analysis would not support the continued use of a 5 mrem/year criterion. Thus a rather straightforward rulemaking would make this regulation consistent with the interim criterion for practices involving widespread distribution of materials in the policy statement. It would preclude unnecessary ~~increases in~~ doses in the future and would ~~also~~ be ~~generally more~~ consistent with the international regulatory community.

The second rulemaking that would appear to be necessary to conform the regulations to the policy is a revision of 10 CFR Part 40, "Domestic Licensing of Source Material," to ~~upgrade~~ the ~~safety~~ requirements and to improve tracking of exemptions by the Commission. The staff has been aware for a number of years that such a rulemaking is desirable. In addition to updating the ~~safety~~ requirements for the source material exemptions, revision of the rule would appear to be critical to the ability of the Commission to monitor the effectiveness of the policy and maintain total exposures from multiple sources within the appropriate limit. A rulemaking to revise 10 CFR Part 40 ~~would probably~~ involve revamping the regulation to make it more consistent with the approach taken in 10 CFR Part 30 for the regulation of byproduct material and ~~should~~ reconsider other aspects of source material licensing beyond the exemptions. Concerning the source material exemptions in Part 40, requirements similar to those applicable to the distribution of materials and products exempt from licensing under Part 30, such as quality assurance, ~~should~~ be considered. Better controls and information on distribution of source materials to unrestricted use may be especially important to the Commission's stated intent to control "multiple" exposures since the consumer products previously estimated to produce the greatest collective exposures contain source material. Before initiating this rulemaking, a preliminary research and cost effectiveness study would be conducted to determine the most effective approach.

A third potential rulemaking that may be necessary to achieve consistency of the regulations with the policy statement would be modifications of references to an outright prohibition of the use of radioactive material in food, beverages, cosmetics, drugs, toys, adornments, or otherwise designed for ingestion, inhalation, or application to the human body. Some part of this prohibition appears at least four places in the regulations (§§ 30.14, 30.19, 32.11(c), and 32.18(b)). Although this may be a relatively simple rulemaking, it may also be controversial and raise public opposition. Also, other agencies such as the Food and Drug Administration and the Consumer Product Safety Commission may have a regulatory interest in such modifications.

Additionally, a rulemaking which should be seriously considered would be to resume annual reporting of quantities of materials and products distributed to exempt persons. Such a requirement would be in keeping with the Commission's stated intent that it will maintain cognizance over the types of exemptions granted and the quantities of material distributed under exemptions. Since 1983, reports have been required only every 5 years without the requirement to break the data down by years. This has made it difficult for the staff to maintain a clear picture of distribution trends of materials and products to exempt persons. Information of this type will be important if the NRC is to keep current on the amount of materials being released to unrestricted use and to carry out the stated intent to ensure that the exposures of the public from all sources controlled by the NRC do not exceed 100 mrem/yr. Keeping up with information on the distribution of materials on an annual basis will also be important in achieving an effective continuing public information program.

In addition to these four rulemakings, the staff believes that two rulemakings to revise the exempt quantities and exempt concentration tables of 10 CFR Part 30 will be necessary after completion of the assessment and calculation of doses based upon updated models and scientific information. However, these and other amendments and revisions to specific exemption regulations can only be initiated after completion of the review and assessment of the respective individual exemptions for consistency with the policy statement.

In addition to rule changes, there are other documents, such as regulatory guides, standard review plans, and possibly branch positions that may also need revision because of inconsistencies either with the policy itself or with the amendments made to the regulations. The staff has not yet identified all the specific revisions that might be needed and thus cannot estimate at this time what level of effort will be necessary. A somewhat lower priority will be given to these tasks. Those revisions that reflect changes to existing

regulations governing exemptions or any new guidance needed for new exemptions would be initiated after the associated rulemaking is well underway. One document that has been identified is Standard Review Plan 11.6, "Method for Obtaining Approval of Proposed Disposal Procedures," which is presently under development by NRR. This SRP addresses requests for approval under § 20.302 to dispose of licensed material in a manner not otherwise authorized in the regulations. Since NMSS, NRR, the Regional offices, within NRC, and the Agreement States can authorize these disposals, a formal review plan with uniform criteria is needed in order to provide a consistent agency approach in staff evaluations. One issue to be resolved is whether BRC criteria are applicable to actions taken under § 20.302 which do not relieve licensees from possible future requirements, i.e., some actions under § 20.302 do not remove materials from regulatory control. A plan to deal with this issue, and others related to § 20.302 disposals, is the subject of a separate Commission paper being prepared by the staff.

The remaining three areas of effort of the four that were specifically requested by the Commission in the October 13, 1989, SRM (activities (4) through (6)) are relatively straightforward. Resource estimates for these activities do not depend to any extent on the outcome of the systematic assessment and associated rulemaking tasks.

For activity (4), the development of guidance for the staff to ensure consistent implementation of the policy, a task force approach has been used, involving knowledgeable staff from the various offices whose work will need to incorporate the policy. A Federal Register notification of rulemakings and licensing actions was distributed on July 30, 1990 (Enclosure 6). Other guidance will be developed in a similar manner. As distinct from the development of Regulatory Guides associated with specific regulations, activity (4) is to develop generic guidance on BRC issues, e.g., criteria for defining a practice.

In regard to activity (5) concerning information dissemination, GPA has prepared and is distributing the "plain English" pamphlet on exemptions. In addition to that and other planned information dissemination, the staff has been and will continue to be responding to many letters of inquiry, including a large number of Congressional requests. Besides the written documents, the staff is actively presenting and explaining the policy in various technical, professional, and public forums. This requires travel funds in addition to the staff time and effort. Furthermore, the staff will maintain cognizance of efforts involved in a Committee on Interagency Radiation

Research and Policy Coordination (CIRRPC) initiative to develop a national policy on education of the public regarding the risks from radiation.

In regard to activity (t), concerning health effects research, there are currently several initiatives underway. These include examination of effects from high-LET radiation for incorporation into NUREG/CR-4214 and confirmatory research on effects of hot particles on the skin. In addition, the NRC staff participates formally in several authoritative committees and panels such as the CIRRPC Science Panel. There are also other ongoing activities, such as attending professional meetings and symposia and keeping informed about other involved agencies' activities, through which the staff currently keeps abreast of and encourages appropriate health effects research. The task called for in this plan is to review, maintain, and possibly augment the ongoing program to assure staff cognizance of health effects research and ensure that necessary research is conducted. In addition, this information will be utilized in evaluating the implementation of the BRC policy. The staff recognizes, in view of the invaluable potential information on human health effects arising from the accident at Chernobyl and the dramatic advances in molecular and cellular biology in the last 15 years, the need to maintain cognizance of the field and to reflect the new information in NRC's regulatory program. The importance of these events is described below.

The health effects from the Chernobyl release could be expected to provide information on the health effects of ~~concern~~ to the NRC, ~~although only in the long term.~~ The Soviets ~~are willing to provide the opportunity~~ to gather health effects data. ~~However, they~~ appear to have limited economic resources and thus plan only limited national support ~~for this research~~. The US-USSR Joint Coordinating Committee for Civilian Nuclear Reactor Safety is currently preparing research protocols for work with the Soviets.

In regard to the need for evaluating the advances in biology, the staff is aware that a significant reduction in the uncertainties associated with risk coefficients might be achieved with a better understanding of the basic processes of radiation carcinogenesis and mutagenesis through studies on radiation effects at the molecular and cellular levels. Of course, the Departments of Energy and Health and Human Services have the major responsibility for health effects research. However, it is important that expertise in contemporary radiobiology be maintained within the staff to properly advise the Commission on and take advantage of advances in this science.

To this end, a research program is now underway assessing the utility of such studies to NRC programs and will be a catalyst for future cooperative research efforts in this area.

~~The infeasibility of producing~~ A scientifically valid research program that could measure health effects, if any, due to BRC levels of radiation ~~precludes direct, periodic monitoring of the health effects resulting from implementation of the BRC policy.~~ However, the effectiveness of the BRC policy can be evaluated with a periodic review of the dose estimates from the aggregate of all the actual BRC practices that have been approved by the Commission. ~~The results of this periodic, aggregated evaluation coupled with continuous monitoring of the progress in radiobiology in the above examples, will provide scientifically valid and current information on the effects, if any, of the implementation of the BRC policy on health.~~ The frequency of the periodic evaluation of the aggregated doses ~~should depend on~~ the number and kinds of BRC practices that the Commission approves and that are implemented. If the number of approved BRC practices grows significantly, ~~the requirement for~~ additional resources ~~could be expected, either in the form of contractor or staff support, or both.~~

In regard to activity (7)(a), the evaluation of certain generally licensed devices for possible exemption under the policy statement, the analyses necessary are essentially the same as for the reevaluation of existing exemptions. Five devices were identified by the staff in SECY-90-175 as candidates for exemption: (i) static eliminators containing krypton-85; (ii) beta backscatter devices; (iii) gas chromatographs containing nickel-63; (iv) x-ray fluorescence analyzers containing cadmium-109 and iron-55, but excluding those containing curium-244 and americium-241; and (v) certain calibration and reference sources having small activities. Dose estimates will be made for comparison with the BRC criteria, and if necessary cost/benefit analyses will also be done. Because the work to be done on this task is the same as that for the reevaluation of existing exemptions and because of the importance of using a consistent approach, activities (3)(a) and (7)(a) will be carried out in combination with the assistance of a contractor.

Presuming that the above assessment indicates that certain generally licensed devices should be exempted under the BRC policy, appropriate rulemakings (activity (7)(b)) will be initiated in FY 1993 as shown in Enclosure 5. As many as five separate rulemakings may eventually be undertaken. Resource estimates for these rulemakings will be included in the next update of the Five-Year Plan if the evaluations demonstrate that exemptions are indeed appropriate.

Resources: The FY 1991-1995 Five-Year Plan includes resources to carry out all of the known activities described above. The FTE resources by Office for these activities are shown below:

	FY 91	FY 92	FY 93	FY 94	FY 95
RES FTE	7.0*	7.0	7.0	7.0	7.0
NMSS FTE	1.0	1.0	1.0	1.0	1.0
GPA FTE	1.9	1.6	1.4	0.3	0.3
ADM FTE	0.2	0.2	0.2	0.2	0.2
TOTAL	10.1	9.8	9.6	8.5	8.5

* Includes 2 overhire positions.

The above resource estimates generally represent minimum requirements which could be higher depending on the difficulty of the specific tasks identified. In addition to the NRC staff resources, an additional $0.5 million per year in contractor assistance has been included in the Five-Year Plan for the dose evaluations and the cost-benefit analyses of activities (3)(a) and (7)(a). However, the total cost of these activities cannot be determined at this time. The actual cost of the dose assessments will depend on the ~~availability of expertise and on the~~ extent that existing information can show consistency with the policy without extensive reevaluation. The total cost for the cost-benefit analyses and environmental assessments or impact statements will depend on the number of exemptions (and potential exemptions) with doses exceeding the criteria, on the complexities associated with the specific exemptions involved, and on the depth of the analysis necessary to determine consistency with the policy statement. Based upon previous experience, a full-blown Environmental Impact Statement, if necessary for one of the more difficult exemptions, could cost $2 million. However, reexamination of some of the consumer products on a cost-benefit basis could be relatively simple in some cases and considerably less costly.

In addition, these estimates include resources for development of the rules described above but do not include resources for associated licensing and inspection activities. Resource

to continue level funding

Insert to Page ii

The FY 1991-1995 Five-Year Plan increased resources previously allocated to BRC and now includes the resources known to be needed to carry out the activities described in this plan. Specifically, I have approved two overage positions for RES in FY 1991. Starting in FY 1992, I have reprogrammed two FTEs from the RES high-level waste program and have authorized one additional FTE for RES BRC activities. Also, I have authorized the Director, RES, to begin the hiring process for these FTEs, since a shortage of qualified experienced personnel may make it difficult to carry out this plan according to the proposed schedules.

9/13/90

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Fax to: Don Cool, RES

From: Karen Olive, OC

requirements for these activities will be estimated in the regulatory analysis for each rule in accordance with standard procedure and cannot be foreseen in sufficient detail at this time to provide useful estimates.

As noted above, additional resources may also be needed: (1) as a result of the systematic assessment of existing exemptions, (2) if rulemakings are deemed appropriate for exempting certain generally licensed products, or (3) if a large number of documents such as regulatory guides, SRP's, branch positions are determined to need revision.

The FY 1991-1995 Five-Year Plan that was recently submitted to the Commission includes resources known to be needed to carry out the activities described in this plan. ~~For 1991,~~ one new FTE had been previously authorized for BRC, and RES ~~is to be~~ allowed two FTE's as overage positions, ~~Starting in 1992, two FTE's per year will be reprogrammed from the high level waste program plus one additional FTE authorized to RES for BRC,~~ (a total of three additional FTE's per year.) ~~Since a shortage of qualified experienced personnel may make it difficult to carry out this plan according to the proposed schedules as well as meet other responsibilities, I have authorized the Director, RES, to begin hiring an additional three FTE's for BRC work.~~

Some details of the assignments and specific tasks will have to be determined as the program proceeds and the results of the systematic assessment of existing exemptions and the evaluation of generally licensed devices become available. The staff will prepare a summary ~~of these assessments~~ for Commission review when this effort is completed and the recommendations regarding rulemaking and regulatory guidance revisions are available.

Coordination: GPA has concurred in this staff plan. The Office of the General Counsel has no legal objection.

Recommendations: That the Commission note that:

1) The staff plans to proceed with the implementation of this plan unless otherwise directed by the Commission.

2) The resources necessary to implement known activities of this plan have been included in the FY 1991 - 1995 Five-Year Plan.

James M. Taylor
Executive Director
for Operations

Enclosures:
1. SRM dated 10/13/89
2. SRM dated 6/28/90
3. SRM dated 8/13/90
4. List of Exemptions
5. Schedules
6. Guidance on Federal Register Notification dated 7/30/90

Distribution: STAFF ACTION PLAN/EDO CHANGES
RPHEB R/F - Cool
Subject File
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ESBeckjord
CJHeltemes
BMMorris
FACostanzi
RMeck
CMattsen

*See previous concurrences

Offc:	RPHEB:RES*	RPHEB:RES*	RPHEB:RES*	DD:DRA:RES*	D:DRA:RES*	DD/GIR:RES*	D:RES*
Name:	Mattsen:dm:sy	Meck	DCool	Costanzi:	BMMorris	CJHeltemes	ESBeckjord
Date:	4/19/90	4/19/90	4/19/90	4/30/90	5/01/90	5/10/90	6/01/90

Offc:	OGC*	NRR*	NMSS*	GPA*	EDO
Name:	WParler	TMurley	RBernero	HDenton	JTaylor
Date:	3/20/90	3/19/90	3/27/90	4/06/901	9/ /90

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