ACTION - Beckjord, RES

Cys: Taylor
Thompson
Blaha
Bernero, NMSS
Murley, NRR
Scroggins, OC
Wlahs, RES

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

OFFICE OF THE SECRETARY

October 13, 1989

MEMORANDUM FOR: James M. Taylor
Acting Executive Director for Operations

William C. Parler, General Counsel

Harold R. Denton, Director, GPA

FROM: Samuel J. Chilk, Secretary

SUBJECT: STAFF REQUIREMENTS - SECY-89-184 - PROPOSED COMMISSION POLICY STATEMENT ON EXEMPTIONS FROM REGULATORY CONTROL

This is to advise you the the Commission, with all Commissioners agreeing, has disapproved your recommendation on a proposed Commission Policy Statement on Exemption from Regulatory Control.

The Commission requested the staff to submit for Commission approval a final policy statement which incorporates the following elements:

A. BELOW REGULATORY CONTROL

The NRC will exempt from further regulatory control a practice that satisfies the criteria listed below.

B. INDIVIDUAL DOSE CRITERION

The average individual dose to typical individuals in the critical group should be less than 10 mrem/year for individual practices. An interim individual dose limit of 1 mrem/yr for exposures resulting from materials and products used by the general public should be established until the Commission gains more experience with the potential for individual exposures resulting from multiple practices. The staff should be clear and precise in defining an approach to distinguish which practices are subject to each of these dose limits. Dose will be considered in terms of effective dose equivalent.

Rec'd Off. EDO
Date 10-16-89
Time 7:30 A

C. ALARA

Collective doses resulting from exposure to a practice should be as low as reasonably achievable (ALARA). Annual collective doses less than or equal to 1000 person-rem will be deemed to satisfy the ALARA criterion. The calculation of collective dose does not need to consider individual doses less than or equal to 0.1 mrem/yr.

D. OTHER BRC EXEMPTIONS

The NRC may exempt practices that do not meet the individual dose criterion on a case-specific basis if the Commission determines that doses to the public are ALARA and regulatory control is not justified by further reductions in individual and collective doses.

The final policy statement should be written in terms understood by the average lay person and the discussions of the above criteria should be explained in the context of the risks that the ordinary individual faces in his or her everyday life. The policy statement should also be consistent with the following format:

1. INTRODUCTION

Describe the purpose of the BRC Policy; cite existing exemptions already codified in NRC's regulations and those of other Federal agencies; overview the content of the Policy Statement.

2. TERMS AND CONCEPTS

Define key terms and concepts used in the Policy Statement (e.g., practice, dose, risk, linear hypothesis, ALARA).

3. POLICY

Describe and justify the BRC criteria listed above (BRC, individual dose criterion, ALARA with the collective dose criterion and truncation level, and exemptions at higher doses). The rationale should clearly describe the unifying risk basis used in establishing the criteria.

4. IMPLEMENTATION

Describe how the BRC Policy will be implemented through rulemakings and licensing actions; describe opportunities for public comment through subsequent actions; identify the potential need, if any, for assessment of environmental impacts; provide guidance on how the NRC will consider applications for exemptions (e.g., would NRC develop a general rule for exempting consumer products or for specific products such as frying pans, jewelry, gas mantles, etc.); and describe how the NRC will review already exempted practices to ensure that the assumptions made were appropriate.

5. STANDARD FORMAT AND CONTENT

Describe, in general terms, the format and content of exemption applications that the NRC staff would find acceptable.

Additional comments are provided in the Commissioners' vote sheets.

The BRC Policy Statement should supersede the Commission's policy statement on consumer products dated March 8, 1965, because the BRC policy provides a consistent risk basis for exempting practices using radioactive materials from regulatory control.

~~(EDO)~~ (RES) (SECY Suspense: 11/30/89)

The General Counsel should examine the treatment of the issue of Agreement State compatibility under the Policy Statement, focusing on the question of whether we have the authority to require Agreement States to adopt criteria that are identical to those set forth in the Policy Statement (i.e., Agreement State BRC criteria can be neither less stringent nor more stringent than the criteria established by the Commission).

(OGC) (SECY Suspense: 11/30/89)

The Commission requested the staff to submit a plan, schedule, and resource requirements for the following activities:

a. Initiation of a systematic assessment of existing exemptions for radioactive materials in NRC's regulations. As the first step in the assessment, staff should identify existing exemptions and prepare a plan for evaluating them for conformance with the BRC policy.

b. Rulemaking activities, as appropriate, to ensure that codified exemptions are consistent with the BRC policy.

c. Development of a regulatory guidance to ensure that the BRC Policy is implemented consistently in licensing actions and future exemptions.

d. Proactive program for disseminating information on the BRC Policy to other Federal agencies, State and local authorities, Indian Tribal organizations, media, and the public. This program should include publication of an informative pamphlet on the BRC policy for widespread distribution to the general public in terms understood by the lay person.

e. Program for assuring that staff remains cognizant of ongoing health effects research about the nature and significance of risks at low doses and dose rates, as well as working with other responsible agencies to ensure that necessary research is being conducted and will provide useful results. Consideration should be given for the need to conduct appropriate health effects research, on a periodic basis, on the effectiveness of the implementation of the Commission's exemption policy.

RES
~~(EDO~~/GPA))

(SECY Suspense: 01/30/90)
(EDO Suspense: 01/16/90)

cc: Chairman Carr
Commissioner Roberts
Commissioner Rogers
Commissioner Curtiss
ACRS
ACNW
IG

EXEMPTIONS FROM REGULATION

CATEGORY	EXEMPTION	REFERENCE	EFFECTIVE	NUCLIDES	COMMENTS
CONSUMER PRODUCTS	Exempt Concentrations	30.14	1960		[A]
	Timepieces (watches & clocks)	30.15(a)(1)	1961	H-3	
			1967	Pm-147	
	Automobile Lock Illuminators	30.15(a)(2)	1962	H-3	
			1965	Pm-147	
	Balances of Precision	30.15(a)(3)	1964	H-3	
	Automobile Shift Quadrants	30.15(a)(4)	1966	H-3	
	Marine Compasses and Navigational Instruments	30.15(a)(5)	1966	H-3	
	Thermostat Dials and Pointers	30.15(a)(6)	1966	H-3	
	Electron Tubes	30.15(a)(8)	1966	H-3; Co-60	
				Ni-63; Kr-85	
				Cs-137; Pm-147	
	Ionizing Radiation Measuring Instruments	30.15(a)(9)	1970		[B]
	Spark Gap Irradiators	30.15(a)(10)	1978	Co-60	
	Synthetic Plastic Resins for Sand Consolidation in Oil Wells	30.16	1967	Sc-46	
	Exempt Quantities	30.18	1970		[C]
	Self Luminous Products (Class Exemption)	30.19	1969	H-3; Kr-85	
				Pm-147	
	Gas and Aerosol Detectors (Smoke Detectors) (Class Exemption)	30.20	1969		
	Chemical Mixtures, compounds, solutions, or alloys containing <0.05% source material	40.13(a)	1961	U,Th	
	Incandescent Gas Mantles	40.13(c)(1)(i)	1947	Th	
	Vacuum Tubes	40.13(c)(1)(ii)	1947	Th	
	Welding Rods	40.13(c)(1)(iii)	1961	Th	
	Electric Lamps for Illuminating Purposes	40.13(c)(1)(iv)	1966	Th	
	Germicidal Lamps, Sunlamps, and Outdoor or Industrial Lighting	40.13(c)(1)(v)	1966	Th	
	Rare Earth Metals and Compounds	40.13(c)(1)(vi)	1947	U,Th	
	Personnel Neutron Dosimeters	40.13(c)(1)(vii)	1977	Th	
	Glazed Ceramic Tableware	40.13(c)(2)(i)	1947	U,Th	
	Piezoelectric Ceramic	40.13(c)(2)(ii)	1970	U,Th	
	Glassware	40.13(c)(2)(iii)	1947	U,Th	
	Glass Enamel & Glass Enamel Frit	40.13(c)(2)(iv)	1964	U,Th	[K]

ENCLOSURE 4

EXEMPTIONS FROM REGULATION

CATEGORY	EXEMPTION	REFERENCE	EFFECTIVE	NUCLIDES	COMMENTS
CONSUMER PRODUCTS	Photographic Film, Negatives & Prints	40.13(c)(3)	1947	U,Th	
	Finished Tungsten or Magnesium-Thorium Alloy Products or Parts	40.13(c)(4)	1949	Th	
	Uranium Counterweights for Use in Aircraft, Rockets, Projectiles & Missiles	40.13(c)(5)	1960	U	
	Uranium as Shielding in Shipping Containers	40.13(c)(6)	1961	U	
	Thorium in Finished Optical Lenses	40.13(c)(7)	1963	Th	
	Thorium in Finished Aircraft Engine Parts	40.13(c)(8)	1967	Th	
	Uranium in Fire Detection Units	40.13(d)	1964	U	
DISPOSAL	Method for Obtaining Approval of Proposed Disposal Procedures	20.302	1957		[D] [I] [J]
	Disposal by Release into Sanitary Sewage Systems	20.303	1957		[E] [I]
	Exemption of Patient Excreta from Sewage Limits	20.303	1957		[I]
	Disposal of Specific Wastes	20.306	1981	H-3; C-14	[F]
DIRECT FACILITY EFFLUENTS	Radioactivity in Effluents to Unrestricted Areas	20.106(a)	1957		[G] [I]
	Radioactivity in Effluents to Unrestricted Areas	20.106(b)	1957		[I] [J]
	Technical Specifications on Effluents from Nuclear Power Plants	50.36a (Appdx I)	1970		[H]
	Releases of Radioactive Material from HLW Repository during Operation	60.111(a)	1983		
	Protection of the General Population from Releases of Radioactivity	61.41	1982		
	Criteria for Radioactive Materials in Effluents from an ISFSI or MRS	72.104	1980		

COMMENTS

[A] Isotope Concentrations listed in 30.70, Schedule A

[B] Exempt Quantities per 30.71, Schedule B

[C] Isotope Quantities listed in 30.71, Schedule B

[D] Section previously covered onsite disposal

[E] <10XAppdx C limits/day; or, <avg daily concentration of Appdx B, Table I, col2 limits; in any event <1 Ci/yr

[F] <0.05 µCi/gm liquid scintillation counting mediur[illegible] animal tissue) H-3 or C-14

[G] Average yearly concentrations up to limits in Appendix B, Table II

[H] Part 50, Appdx I provides dose design objectives; specific limits under 50.36(a) by case-by-case decision

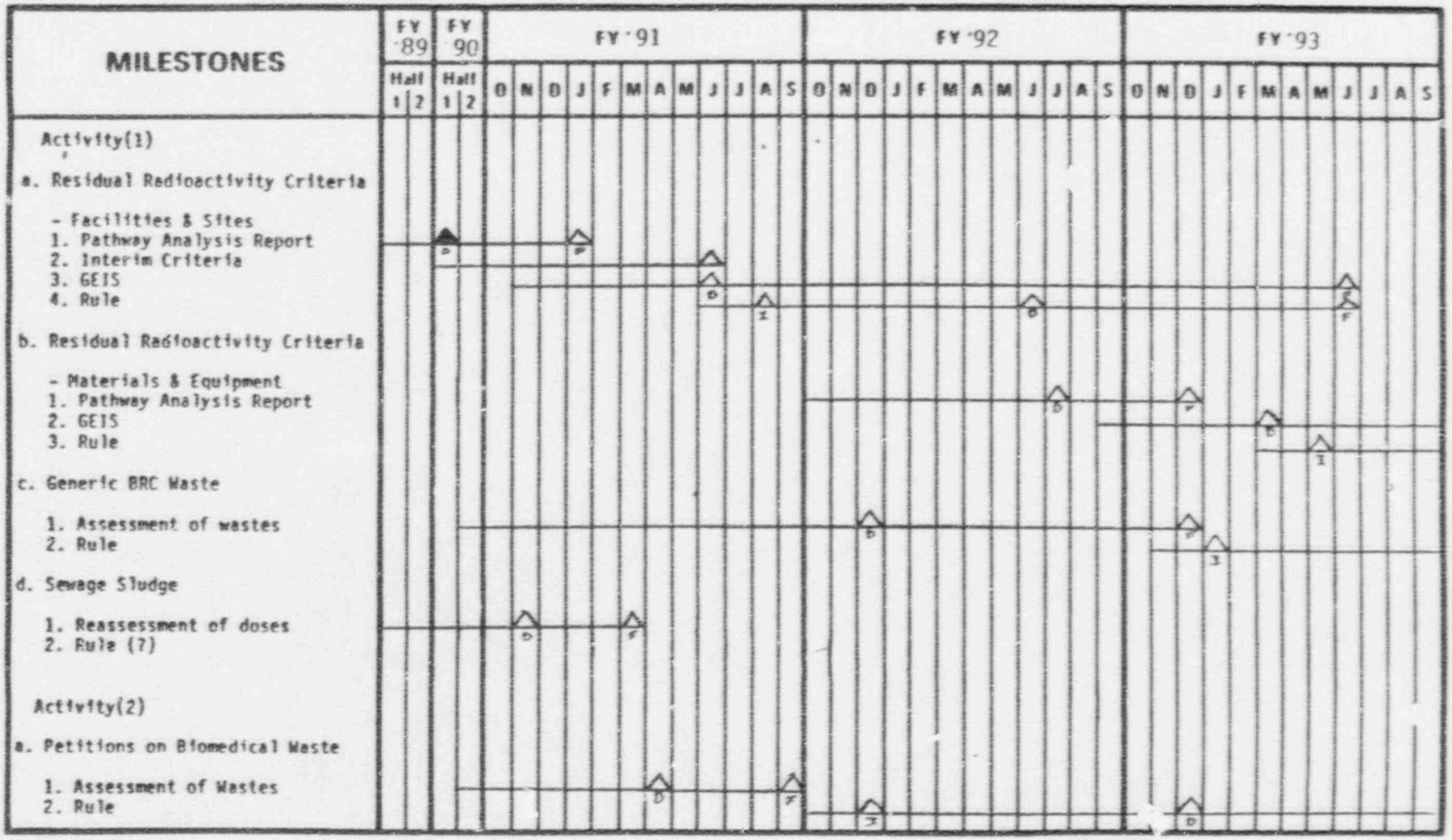
[I] Dates subject to verification

[J] Allows case specific exemptions

[K] This exemption was suspended in 1983 and amended in 1984 to exclude further distribution of the product.

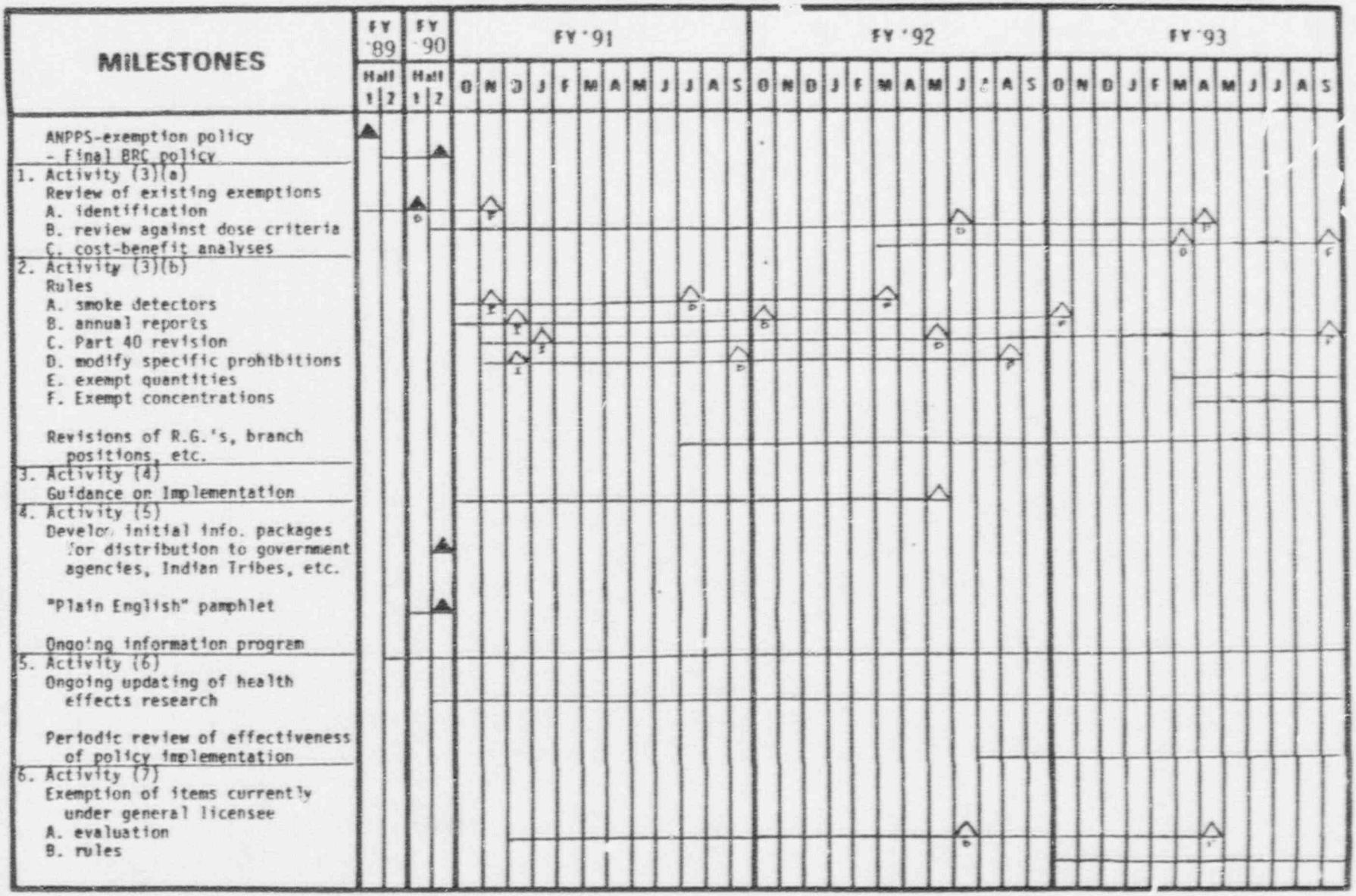
ENCLOSURE 4

ACTIVITIES PLANNED PRIOR TO BRC POLICY



Enclosure 5

ACTVITIES ADDRESSED IN RECENT SRM's



Enclosure 5

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), 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~~ are also included in accordance with

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

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. 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 (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 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 conducting 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 continous monitoring of the progress in radiobiology in the above examples, will provide scientifically valid and current information on the effects, if any, of the implomentation 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

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

Document Name:
STAFF ACTION PLAN/EDO CHANGES

Requestor's ID:
MENDIOLA

Author's Name:
Mattson, C.

Document Comments:
nrcres mendiola Cookie 4/5/90