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

November 9, 1989

The Honorable Guy Vander Jagt
United States House of Representatives
Washington, DC 20515

Dear Congressman Vander Jagt:

I am responding to your letter of October 18, 1989, which asked us for our views on the matters pertaining to low-level radioactive waste disposal raised by your constituent, Mr. Eric Lewis. Mr. Lewis is one of several Michigan citizens who have conveyed their concerns on this subject to their Congressional representatives. Specifically, Mr. Lewis' concerns are directed at Nuclear Regulatory Commission (NRC) activities to exempt specific waste from further regulation if its radioactivity content is sufficiently low as to be "below regulatory concern (BRC)." The BRC terminology reflects a class of material described in P.L. 99-240, the Low-Level Radioactive Waste Policy Amendment Act of 1985.

In response to Mr. Lewis' concerns, I would first note that the Nuclear Regulatory Commission (NRC) has not published any proposed regulations which would allow disposal of low-level waste under the BRC provisions of P.L. 99-240. However, in 1986 we did issue a final policy (Enclosure 1, 51 FR 30839), which established the standards and procedures that will permit the NRC to act upon "BRC" rulemaking petitions in an expeditious manner, as called for in the Act.

The NRC has also initiated the development of a broadly applicable exemption policy. The policy would publicly express the principles and criteria that underlie Commission exemption decisions including those related to BRC waste disposal. The policy is intended to provide the public health and safety framework which would apply to the development of regulations, such as those which may allow disposal of very low-level radioactive waste at other than licensed low-level radioactive waste disposal sites. As a key step in this policy development effort, the Commission issued the advanced notice (Enclosure 2) in the Federal Register on December 12, 1988, and solicited public comment. The NRC received, and is continuing to receive, comment letters responding to this advance notice. Over 250 letters have been received to date. Many of these commenters have expressed views similar to those of Mr. Lewis. We understand the importance of these issues to concerned citizens and will be addressing them in the Commission's final exemption policy which we currently expect will be issued in late 1989 or early 1990.

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In closing, I want to assure you that we take our mandate to protect the health and safety of the public very seriously. As a result, the concern expressed by Mr. Lewis is one that we must carefully consider and address as we carry out our regulatory mission.

Sincerely,

James M. Taylor
Acting Executive Director
for Operations

Enclosures:
As stated

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Sincerely,

Original Signed By:
James M. Taylor

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Acting Executive Director
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Enclosures:
As stated

See next page for Distribution *See attached for previous concurrences.

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Appendix B to Part 2—General Statement of Policy and Procedures Concerning Petitions Pursuant to § 2.802 for Disposal of Radioactive Waste Streams Below Regulatory Concern:

I. Introduction and Purpose
II. Standards and Procedures
III. Agreement States
IV. Future Action

I. Introduction and Purpose

The Low-Level Radioactive Waste Policy Amendments Act of 1985 (the Act) (42 U.S.C. 2021b et seq.) was enacted January 15, 1986. Section 10 of the Act addresses disposal of wastes termed "below regulatory concern" that would not need to be subject to regulatory control to assure adequate protection of the public health and safety because of their radioactive content. The goal of this section of the Act is for the Commission to make practical and timely decisions to determine when wastes need not go to a licensed low-level waste disposal site. These decisions will be expressed through rulemaking. Alternative disposal would conserve space in the existing sites while new sites are established and reduce the costs of disposal. Rulemaking petitions may play a role in the national low-level waste strategy outlined by the Act. The Act provides that the Commission establish procedures for acting expeditiously on petitions to exempt specific radioactive waste streams from the Commission's regulations.

The purpose of this statement and accompanying implementation plan is to establish the standards and procedures that will permit the Commission to act upon rulemaking petitions in an expeditious manner as called for in the Act. This policy statement does not require petitioners to present all the information outlined or demonstrate that the decision criteria for expedited handling can be met, if such expedited handling is not wanted. For example, petitions requesting exemption of concentrations of radionuclides that might result in individual exposures higher than those recommended in the decision criteria may be submitted, but expedited handling cannot be assured.

Finally, this policy statement and accompanying implementation plan are intended to facilitate handling of rulemaking petitions for streams from multiple producers and do not apply to individual licensing actions on single producer waste. Individual licensees who seek approval for disposal of their uniques wastes may continue to submit their disposal plans under 10 CFR 20.302(a).

II. Standards and Procedures

The standards and procedures needed to handle petitions expeditiously fall into the following three categories: (1) Information petitioners should file in support of the petitions, (2) standards for assessing the adequacy of the proposals and providing petitioners insight on the decision criteria the Commission intends to use so that all relevant informational issues will be addressed in the petition, and (3) the internal NRC administrative procedures for handling the petitions. These three categories are addressed in the attached staff implementation plan. The staff plan was developed in response to Commission direction to provide detailed guidance on implementing the general approach outlined in this policy statement. Although staff may revise it from time to time as experience is gained in processing petitions, the plan outlines a reasonable basis for accomplishing the approach. Staff is to publish revisions as NUREG documents and notice the availability of the revisions in the Federal Register.

As a practical matter, the primary information for justifying and supporting petitions must be supplied by the petitioner if the Commission is to act in an expedited manner. If the petitioner wishes to assure expedited action, the supporting information should be complete enough so that Commission action is primarily limited to independent evaluation and administrative processing.

Decision criteria for judging whether to grant a petition involve the overall impacts of the proposed action, waste properties, and implementation of the proposed exemption. The following criteria address these areas. Petitions which demonstrate that these criteria are met should be suitable for expedited action.

1. Disposal and treatment of the wastes as specified in the petition will result in no significant impact on the quality of the human environment.

2. The maximum expected effective dose equivalent to an individual member of the public does not exceed a few millirem per year for normal operations and anticipated events.

3. The collective doses to the critical population and general population are small.

4. The potential radiological consequences of accidents or equipment malfunction involving the wastes and intrusion into disposal sites after loss of normal institutional controls are not significant.

5. The exemption will result in a significant reduction in societal costs.

6. The waste is compatible with the proposed treatment and disposal options.

7. The exemption is useful on a national scale, i.e., it is likely to be used by a category of licensees or at least a significant portion of a category.

8. The radiological properties of the waste stream have been characterized on a national basis, the variability has been projected, and the range of variation will not invalidate supporting analyses.

9. The waste characterization is based on data on real wastes.

10. The disposed form of the waste has negligible potential for recycle.

11. Licensees can establish effective, licensable, and inspectable programs for the waste prior to transfer to demonstrate compliance.

12. The offsite treatment or disposal medium (e.g., sanitary landfill) does not need to be controlled or monitored for radiation protection purposes.

13. The methods and procedures used to manage the wastes and to assess the impacts are no different from those that would be applied to the corresponding uncontaminated materials.

14. There are no regulatory or legal obstacles to use of the proposed treatment or disposal methods.

III. Agreement States

The Low-Level Radioactive Waste Policy Amendments Act of 1985 establishes a

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national system for dealing with low-level waste disposal. The system assigns to the States responsiblity for disposal capacity for low-level wastes not exceeding Class C wastes as defined in 10 CFR 61.55. Section 10 of the Act encourages a reduction in volume of such wastes subject to State responsibilitiy for disposal through the option of determining that certain wastes need not go to existing licensed disposal facilities or new sites licensed under 10 CFR Part 61 or equivalent State regulations. If radiological safety can be assured, such disposal would conserve space in the existing sites while new sites are developed, and would serve as an important adjunct to volume reduction efforts in meeting the waste volume allocation limits set forth in the Act. Thus, these rulemakings should aid the States in fulfilling their responsibilities under the Act. Equity also suggests that all waste generators be able to take advantage of below regulatory concern options as part of their waste management strategies. Generators in both Agreement and non-Agreement States will be competing for space in the existing sites and the concept should be applicable nationwide.

Agreement States will play an important role in ensuring that the system works on a national basis and that it remains equitable. States have been encouraging findings that certain wastes are below regulatory concern and do not have to go to low-level waste sites. The States have been voicing this view for a number of years through forums such as the Conference of Radiation Control Program Directors. Rulemakings granting petitons will be made a matter of compatibility for Agreement States. Consequently, rulemaking will be coordinated with the States.

IV. Future Action

The Commission will conduct a generic rulemaking on waste streams below regulatory concern based on a number of factors. The factors include public comments received on the statement, the number and types of petitons for rulemaking received, and how effective the statement is in enabling timely processing of petitions. A generic rulemaking is warranted to provide a more efficient and effective means of accomplishing the goals reflected in Section 10 of the Act. An advance notice of proposed rulemaking will be published within 90 days. Furthermore, the Commission may periodically review all rulemakings in order to assure that the relevant parameters have not changed significantly and may ask the petitioner to submit updated information to assist in the review. The Commission would also have to confirm that approved exemptions are consistent with any general standards issued by EPA.

Dated at Washington, DC this 25th day of August, 1986.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary to the Commission.

Editorial Note: The staff implementation plan will not appear in the Code of Federal Regulation.

Nuclear Regulatory Commission Staff Implementation of Nuclear Regulatory Commission Policy on Radioactive Waste Below Regulatory Concern

I. Introduction

Section 10 of the Low-Level Radioactive Waste Policy Amendments Act of 1985 requires the Nuclear Regulatory Commission (NRC) to develop standards and procedures for expeditious handling of petitions for rulemaking to exempt disposal of radioactive waste determined to be below regulatory concern. The Act also requires NRC to identify information petitioners should file. The Commission Policy Statement provides general guidance on how to meet the requirements of section 10 of the Act, outlines the overall approach to be followed, and lists decision criteria to be used. Implementation of the general approach and decision criteria of the Commission Policy Statement involves developing more detailed guidance and procedures. In accordance with Commission direction, the NRC staff has developed more detailed guidance and procedures for implementation of the Commission Policy Statement. This staff guidance and procedures cover: (1) Information petitioners should file in support of petitions to enable expedited processing, (2) discussion of the decision criteria, and (3) administrative procedures to be followed.

II. Information to Support Petitions

A. General

1. *10 CFR Part 2 requirements.* The codified information requirements for petitions for rulemaking are outlined in the Commission's regulations in 10 CFR 2.802(c). These regulations require the petitioner to identify the problem and propose solutions, to state the petitioner's grounds for and interest in the action, and to provide supporting information and rationale. As a practical matter, the information demonstrating that the radiological health and safety impacts are so low as to be below regulatory concern must be provided by the petitioner if the Commission is to act in an expedited manner. Petitions for rulemaking should therefore be submitted following the staff's supplemental guidance and procedures to assure expedited action.

2. *Environmental impacts.* Petitions must enable the Commission to make a finding of no significant impact on the quality of the human environment. Such Commission findings must be based on an Environmental Assessment that complies with 10 CFR 51.30 and must meet the requirements of 10 CFR 51.32. These requirements include addressing the need for the proposed action, identifying alternatives, and assessing the potential environmental impacts of the proposed action and alternatives. Consistent with 10 CFR 51.41, the petitioner should submit the information needed to meet these requirements and do so in a manner that permits independent evaluation by the Commission of the data and methodology used and the conclusions reached.

3. *Economic impact on small entities.* When a rulemaking action is likely to have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires that the impacts on these small entities must be specifically addressed. (The Commission's size standard for identifying a small entity is $3.5 million or less in annual receipts except for private practice physicians and educational institutions where the standard is $1 million or less in annual receipts for private practice physicians and 500 employees for educational institutions. See 50 FR 50214, December 9, 1985.) For any rulemaking, the Commission must either certify that the rule will not economically impact or will have no significant economic impacts on small entities, or present an analysis of alternatives to minimize the impacts. Because rulemakings on below regulatory concern should provide relief from requirements for all affected entities, satisfaction of this requirement should be straightforward but it must be addressed in any rulemaking. To facilitate expeditious preparation of the proposed rule responding to the petition, the petitioner should submit an evaluation of the estimated economic impacts on small entities. The evaluation should include estimates of the costs for small entities in terms of staff time and dollar costs. Any alternatives that could accomplish the objective of the petitioner's proposed rule while minimizing the economic impact on small entities should be presented. The evaluation should include an assessment of the incremental recordkeeping and reporting costs that would be associated with the petitioned rule change.

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complying with 10 CFR Part 61 waste classification requirements. Waste generators use generic scaling factors and factors established for their specific wastes through sophisticated analyses. The scaling factors are used to infer the presence and concentrations of many radionuclides based on measurement of only a few nuclides. The classification scheme in 10 CFR Part 61 has been in effect since December 1983. Considerable data and experience should be available to allow characterizing the radiological content and composition of the waste stream being addressed in the petition. The same principles outlined in 10 CFR 61.55(a)(8) may be applied, i.e., values based on direct measurements, indirect methods related to measurements, or material accountability.

5. *As low as is reasonably achievable (ALARA).* The Commission's ALARA requirement in 10 CFR 20.1(c) applies to efforts by licensees to maintain radiation exposures and releases of radioactive materials in effluents to unrestricted areas as low is reasonably achievable. 10 CFR Part 50, Appendix I, describes ALARA for radioactive materials in light water reactor effluents. Licensee compliance with 10 CFR 20.1(c) is a precondition to acceptance by NRC of any waste stream as exempt. Therefore, a description should be provided of reasonable procedures that waste generators would be expected to use to minimize radiation exposures resulting from the disposal of the exempt waste, e.g., removal of surface contamination. These procedures are assumed to apply prior to characterizing the waste to be exempted.

C. Waste Management Options

The management options that the Commission can deal with expeditiously are those described in NUREG/CR-3585. Onsite options include incineration and burial. Offsite options are municipal waste disposal facilities (sanitary landfills), municipal waste incinerators, hazardous disposal facilities, and hazardous waste incinerators. Pretreatment, e.g., shredding of otherwise potentially recyclable materials, is a potential adjunct to either onsite or offsite options. Combinations of these options can also be evaluated. For example, wastes may be incinerated on site and the ash shipped to a sanitary landfill. The favored disposal options should be identified and fully described. The petitioner should evaluate a full range of options. The practicality of the proposed option(s) should be presented. Waste compatibility discussed earlier is one aspect. The national availability and distribution of the option is another. Updates on national regulations and laws pertaining to the proposed option should be described and might have to be considered in selecting acceptable options.

D. Analyses

To support and justify the submittal, each petitioner should include analyses of the radiological impacts associated with handling, transport, and disposal of the specific wastes. Any incremental nonradiological impacts should be assessed. Also the petitioner should use the analyses to prepare and submit a detailed regulatory analysis with the petition.

1. *Radiological impacts.* The evaluation of radiological impacts should distinguish between expected and potential exporures and events. Impacts should be assessed for the expected concentrations and quantities of radionuclides. The petitioner should quantitatively evaluate the impacts from the proposed waste for each option requested. The petitioner should clearly relate the analytical findings to specific provisions in the recommended rule changes. For example, the basis for each recommended radionuclide limit should be clearly explained.

The radiological impacts included in NUREG/CR-3585 and in NRC's computer program (IMPACTS-BRC) cover exposures to workers and individual members of the public and cumulative population exposures. The program calculates both external direct gamma exposures and exposures from ingested or inhaled radionuclides. NRC's computer program can be used to calculate the expected radiological impacts from generator activities, transportation, treatment, disposal operations, and post-disposal inputs. The program can analyze a wide range of management options including onsite treatment and disposal by the generator, shipment to municipal waste management facilities, and shipment to hazardous waste management facilities. The program covers impacts beginning with initial handling and treatment by the generator through final disposal of all the radionuclides contained in the waste stream. Sequential treatment, sorting, and incineration onsite and at municipal and hazardous facilities can be assessed. Disposal of resulting ash and residue is included. Post-disposal impacts that can be calculated include releases due to intrusion, ground-water migration, erosion, and leachate accumulation. The program thus addresses both expected and potential post-disposal impacts.

The petitioner's analysis of transport impacts should be based on a reasonably expected spacial distribution of licensees and waste treatment and disposal facilities which will accept the wastes. The petitioner should address parameters such as average and extreme transport distances. The petitioner's analysis should address the basis for parameter selection and characterize the expected patterns (e.g., indicate how likely the extreme case may be). In addition, the petitioner's analysis should also address potential exposures from handling and transport accidents. The petitioner's analysis of accidents should include all assumptions, data, and results to facilitate review. The potential for shipment of the entire waste stream to one or a few facilities should be assessed. This scenario currently exists for 10 CFR 20.306 exempted liquid scintillation wastes and might result from very limited numbers of treatment facilities or decontamination services. The analysis of impacts for transport, handling, and disposal should include evaluation of this potential circumstance unless it can be clearly ruled out.

As suggested in Paragraph 89 on page 20 of ICRP Publication 46 [2]:

> Exception from regulation and requirements on these bases should not be used to make it possible to dispose of large quantities of radioactive material in diluted form, or in divided portions, causing widespread pollution which would eventually build up high dose levels by the addition of many small doses to individuals. Nor should they be used to exempt activities that, by isolation or treatment, have been made temporarily harmless but that imply large potential for release and could give rise to high individual doses or high collective doses.

The analysis of expected radiological impacts should clearly address:

—The maximum individual exposures.
—The critical group exposures
—The cumulative population exposures.

The maximum individual exposure evaluation should include exposures to all members of the public who may be exposed beginning with the initial handling at the generator's facility through post-closure. Both internal uptake and external exposures should be included. The individual may be a member of the general population (e.g., consumer of contaminated ground water) or a person receiving the exposure from his or her occupation. Anyone who may be exposed and is not a radiation worker should be considered a member of the public. For example, a worker at a sanitary landfill or a commercial trash truck driver would not be a radiation worker. However, occupational exposures to radiation workers should be evaluated and considered in the cost/benefit analysis of the incremental impacts between disposal at a licensed facility and the requested disposal options.

The total population exposures can be estimated and summed in two parts. One part is the smaller critical group (usually the occupationally exposed population) where potential exposures

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address whether changes in technical specifications or licenses may be needed.

F. Proposed Rule

The petition should include the text for the proposed rule (see 10 CFR 2.802(c)(1)). The proposed text should cover at least the following:

(1) The quantity and/or concentration limit for each radionuclide present (trace radionuclides could be lumped together with a total limit);

(2) A method to deal with radionuclide mixtures;

(3) The nonradiological specifications necessary to adequately define the waste; and

(4) The specific method(s) of exempt disposal.

If practicable, and if the supporting information indicates the need, the text should also address other features such as annual limits on each generator in terms of volume, mass, or total radioactivity, and administrative or procedural requirements including process controls, surveys, etc., that have been discussed. The text should not include the various dose limits used to justify the proposed radionuclide limits.

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III. Decision Criteria

The Commission policy statement establishes that the following criteria should be used by staff as guidelines for acting on a petition. Each criterion is repeated and staff views on implementation are discussed.

1. Disposal and treatment of the wastes as specified in the petition will result in no significant impact on the quality of the human environment.

Discussion: Unless this finding can be made during information submitted by the petitioner, the Commission must prepare an Environmental Impact Statement to more fully examine the proposed action, alternatives to the proposed action, and associated potential impacts of alternatives. Preparation would likely involve contractual support and would likely take 2 years or more to complete. The Commission could not act in the petition in an expedited manner.

2. The maximum expected effective dose equivalent to an individual member of the public does not exceed a few millirem per year for normal operations and anticipated events.

Discussion: The effective dose equivalent means the ICRP Publication 26 and 30 [3] sum of the dose from external exposure and the dose incurred from that year's intake of radionuclides. While a range of 1–10 millirem per year might be acceptable, a one millirem dose would facilitate expedited processing. Higher doses may require more extensive justification. Based on a mortality risk coefficient for induced cancer and hereditary effects of 2×10^{-4} per rem (ICRP Publication 26), radiation exposure at a level of millirem per year would result in an annual mortality risk of 2×10^{-7} (i.e., $2 \times^{-4}$ effects/rem $\times^{-3}$ rem/year).

The EPA is developing criteria for identifying low-level radioactive waste that may be below regulatory concern as part of that agency's development of general environmental standards for low-level waste disposal. The EPA published an Advance Notice of Proposed Rulemaking on August 31, 1983 (48 FR 39563) and currently hopes to publish proposed standards in early 1987. Other EPA standards that the doses can be compared to are the Clean Air Act radioactive release standard of 25 millirems per year in 40 CFR Part 61 and the uranium fuel cycle annual whole body limit of 25 millirems in 40 CFR 190.

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One millirem is very small when compared to naturally occurring background doses from cosmic and terrestrial sources. Background doses in the United States are typically in the 100–120 millirems per year range exclusive of the lung doses from radon. One millirem is also small when compared to the annual 500 millirem dose limit for individual members of the general public in Federal Radiation Council guidance.

An important feature is that doses of up to 1 millirem from the individual petition should minimize concerns over exposure to multiple exempted waste streams. ICRP Publication 46 addressed individual dose limits and other issues related to exemptions and stated, in paragraphs 83 and 84 on page 19:

> Many radiation exposures routinely encountered in radiation protection, particularly those received by members of the public, are very small by comparison with dose limits or natural background, and are well below dose levels at which the appearance of deleterious health effects has been demonstrated. In individual-related assessments, it is widely recognized that there are radiation doses that are so small that they involve risks that would be regarded as negligable by the exposed individuals. Studies of comparative risks experienced by the population in various activities appear to indicate that an annual probability of death of the order of 10^{-6} per year or less is not taken into account by individuals in their decisions as to actions that could influence their risks. Using rounded dose response factors for induced health effects, this level of risk corresponds to an annual dose of the order of 0.1 mSv (10 millirem).
>
> However, in most practical cases, the need for exemption rules arises in source-related assessment, to decide whether a source or waste stream should be subject to control. Consideration should be given to the need for any optimization of radiation protection and to the possibility that many practices and sources of the same kind could combine now or in the future so that their total effect may be significant, even though each source causes an annual individual dose equivalent below 0.1 mSv (10 millirem) to individuals in the critical group. This may involve assessments of dose commitments and of the collective dose per unit practice or source, in order to ensure that the individual dose requirement will not be exceeded now or in the future. It seems almost certain that the total annual dose to a single individual from exempted sources will be less than ten times the contribution from the exempted source giving the highest individual dose. This aspect could, therefore, be allowed for by reducing the annual individual dose exemption criterion from 0.1 to 0.01 mSv (10 to 1 millirem).

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The NRC staff recognizes that at times, human reactions are not so strictly governed by quantative considerations as the ICRP excerpt suggests. Nevertheless, the 10^{-6} per year value seems about as low as practicable, seems too low to justify significant concern, and so seems acceptable.

The United Kingdom's National Radiological Protection Board has issued generic guidance on de minimis dose levels (ASP-7, January 1985) [4] that has status similar to Federal Radiation Guidance issued by the President in this country. The Board identified effective dose equivalents of 5 millirem per year as insignificant when members of the public make their decisions. The 5 millirem limit represents the total dose contribution from all exempted practices. For individual practices, the Board divided by 10 (i.e., 0.5 millirem per year) to account for exposures from multiple practices. These limits are applied generically. Less conservatism under the well defined circumstances associated with specific waste streams and disposal options envisaged in this NRC statement seems justified. In a proposed policy statement dated May 6, 1985,[5] the Canadian Atomic Energy Control Board specifically addressed disposal of specific wastes that are of no regulatory concern. An individual does limit of 5 millirems per year was proposd for this limited application.

A maximum individual exposure of 1 millirem per year is also consistent with Appendix I to 10 CFR Part 50. Appendix I specifies design objective doses for operational light-water-cooled nuclear power reactor effluents. These design

expeditious action on the petitions. In addition, the Handbook notes general scheduling advice that proposed rules to grant petitions should be published in 6–12 months after acceptance and publication for comment. Proposed rules will be forwarded to the Commission on a 6-month schedule to the extent permitted by resource limits, the nature and extent of public comments, and internal Control of Rulemakings procedures. Rulemakings involving power reactors must be reviewed by the Committee on Review of Generic Requirements prior to publication. Proposed rules involving reactors will therefore be forwarded to the Commission on a 7-month schedule to the extent permitted by resources, comments, and approval procedures. In both cases, every effort will be made to publish proposed rules no later than 12 months after noticing for public comment.

Although the procedures in Part 11 of NUREG/BR–0053 include fast track processing, the nature of the anticipated petitions do not fully comply with the decision criteria to follow this alternative.

Some of the key features of the handling procedures include the following steps for complete and fully supported petitions.

1. Petitioners may confer on procedural matters with the staff before filing a petition for rulemaking. Requests to confer on procedural matters should be addressed to: The Director, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Chief, Rules and Procedures Branch.

2. Petitions should be addressed to: The Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch. In keeping with 10 CFR 2.802(f), petitioners will be promptly informed if the petition meets the threshold requirements for a petition for rulemaking in 10 CFR 2.802(c) and can be processed in accordance with this implementation plan. Ordinarily this determination will be made within 30 days after receipt of the petition.

3. Following this determination, the petition will be noticed in the Federal Register for a public comment period of at least 60 days.

4. The petitioner will be provided copies of all comments received, scheduling information, and periodic status reports.

The procedures in NUREG/BR–0053 also include the process for denial and withdrawal of petitions.

Footnotes:

[1] Copies of NUREG/BR–0053, NUREG/BR–0058 and NUREG/CR–3585 may be purchased through the U.S. Government Printing Office by calling (202) 275–2060 or by writing to the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20013–7082. Copies may also be purchased from the National Technical Information Service, U.S. Department of Commerce, 5185 Port Royal Road, Springfield, VA 22161. Copies are available for inspection and/or copying for a fee in the NRC Public Document Room, 1717 H Street, NW, Washington, DC 20555.

[2] ICRP Publication 46, "Radiation Protection Principles for the Disposal of Solid Radioactive Waste," adopted July 1985.

[3] ICRP Publication 26, "Recommendations of the International Commission on Radiological Protection," adopted January 17, 1977. ICRP Publication 30, "Limits for Intake of Radionuclides by Workers," adopted July 1978.

[4] Copies of the United Kingdom's document are available for inspection as enclosures to SECY–85–147A (relating to 10 CFR Part 20) dated July 25, 1985 in the Commission's Public Document Room, 1717 H Street NW, Washington, DC 20555. The United Kingdom documents are available for sale from: Her Majesty's Stationery Office, P.O. Box 569, London SE1 9NH, United Kingdom, as Advice document ASP–7 and a related technical report, "The Significance of Small Doses of Radiation to Members of the Public," NRPB–R175.

[5] Copies of the Canadian document are available for inspection as an enclosure to SECY–85–147A (relating to 10 CFR Part 20) dated July 25, 1985 in the Commission's Public Document Room, 1717 H Street NW, Washington, DC 20555. The Canadian document was issued as Consultative Document C–85, "The Basis for Exempting the Disposal of Certain Radioactive Materials from Licensing" by the Atomic Energy Control Board, P.O. Box 1046, Ottawa, Ontario, Canada, K1P 5S9.

[6] ICRP/85/C–03, "Statement from the 1985 Paris Meeting of the International Commission on Radiological Protect," 1985–04–26.

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NUCLEAR REGULATORY COMMISSION

10 CFR Ch. I

Policy Statement on Exemptions From Regulatory Control

AGENCY: Nuclear Regulatory Commission.

ACTIONS: Advance notice of proposed statement and meeting.

SUMMARY: The NRC is in the process of developing a broad policy on exemptions from regulatory control for practices whose health and safety impacts could be considered below regulatory concern. This policy statement would provide for more efficient and consistent regulatory actions in connection with exemptions from various specific Commission requirements. The Commission, in formulating this Advance Notice, is seeking public input on some specific

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questions which are key considerations in developing such a policy. The NRC staff will conduct a meeting to inform the public of its intentions, specifically to clarify and answer questions concerning the advance notice, and to hear preliminary views concerning a policy for exemptions with emphasis on the specific questions raised by the Commission.

DATES: Meeting to be held on January 12, 1989. Written comments should be submitted by January 30, 1989. Comments received after this date will be considered if it is practical to do so, but assurance of consideration can only be given as to comments received on or before this date.

ADDRESSES: Meeting will be held at the Holiday Inn, 8120 Wisconsin Avenue, Bethesda, MD 20814 (4 blocks north of the Bethesda Metro Station). Telephone: (301) 652-2000, 1-800-465-4329. Mail written comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch. Comments may be delivered to 11555 Rockville Pike, Rockville, MD between 7:30 a.m. and 4:15 p.m. weekdays. Copies of the comments received may be examined and copied for a fee at the NRC Public Document Room at 2120 L Street, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Catherine R. Mattsen, telephone (301) 492-3638, or William R. Lahs, telephone (301) 492-3774, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

SUPPLEMENTARY INFORMATION:

International Workshop

In addition to conducting this public meeting, the Commission has sought input from the international regulatory community through an international workshop on exemptions from regulatory control which was held October 17-19, 1988 in Washington, DC. The importance of such interaction stems from the fact that many existing and potential exemptions involve radioactive materials purposefully used in consumer products or introduced into various products or materials through the recycling of contaminated scrap, either of which may enter international trade. Even effluents and waste disposal can involve exposures to people in countries other than those from which the effluent or waste originated. This aspect is a significant issue in the European community. Thus, some degree of consistency internationally is desirable, since exemption decisions can affect populations outside each country's border. It is hoped that exchanges of ideas and information such as occurred at the international workshop will, besides providing one avenue of input to the Commission's actions, lead toward a greater degree of consistency in such exemptions worldwide. At the international workshop, the "Advance Notice of the Development of a Commission Policy on Exemptions from Regulatory Control for Practices Whose Public Health and Safety Impacts are Below Regulatory Concern", presented in this notice, was made available for discussion. The transcript of the international workshop which includes all the papers presented at the meeting may be examined and copied for a fee at the NRC Public Document Room at 2120 L Street, NW., Washington, DC.

Advance Notice of the Development of a Commission Policy

Introduction and Purpose

Over the last several years, the Commission has become increasingly aware of the need to provide a general policy on the appropriate criteria for release of radioactive materials from regulatory control. To address this need, the Commission is expanding upon its existing policy for protection of the public from radiation, currently expressed in existing regulations (Title 10, Code of Federal Regulations) and policy statements (30 FR 3462, Use of Byproduct Material and Source Material, dated March 16, 1965; 47 FR 57446, Licensing Requirements for Land Disposal of Radioactive Waste, dated December 27, 1982; and 51 FR 30839, General Statement of Policy and Procedures Concerning Petitions Pursuant to § 2.802 for Disposal of Radioactive Waste Streams Below Regulatory Concern, dated August 29, 1986). The expansion includes the development of an explicit policy on the exemption from regulatory control of practices whose public health and safety impacts are below regulatory concern. A practice is defined in this policy as an activity or a set or combination of a number of similar sets of coordinated and continuing activities aimed at a given purpose which involve the potential for radiation exposure. Under this policy, the definition of "practice" is a critical feature which will assure that the formulation of exemptions from regulatory control will not allow deliberate dilution of material or fractionation of a practice for the purpose of circumventing controls that would otherwise be applicable.

The purpose of this policy statement is to establish the basis upon which the Commission may initiate the development of appropriate regulations or make licensing decisions to exempt from regulatory control persons who receive, possess, use, transfer, own, or acquire certain radioactive material. This policy is directed principally toward rulemaking activities, but may be applied to license amendments or license applications involving the release of licensed radioactive material either to the environment or to persons who would be exempt from Commission regulations. It is important to emphasize that this policy does not assert an absence or threshold of risk but rather establishes a baseline where further government regulations to reduce risks is unwarranted.

The concept of regulatory exemptions is now new. For example, in 1960 and 1970, the Commission promulgated tables of exempt quantities and concentrations for radioactive material which a person, under certain circumstances, could recieve, possess, use, transfer, own, or acquire without a requirement for a license (25 FR 7875, August 17, 1960 and 35 FR 6426, April 22, 1970). Other exemptions allowing distribution of consumer products or other devices to the general public, or allowing releases of radioactive material to the environment, have been embodied in the Commission's regulations for some time. More recently, the Low Level Radioactive Waste Policy Amendments Act of 1985 directed the Commission to develop standards and procedures for expeditious handling of petitions to exempt from regulation the disposal of slightly contaminated radioactive waste material that the Commission determined to be below regulatory concern. The Commission responded to this legislation by issuing a policy statement on August 29, 1986 (51 FR 30839). That statement contained criteria which, if satisfactorily addressed in a petition for rulemaking, would allow the Commission to act expeditiously in proposing appropriate regulatory relief on a "practice-specific" basis consistent with the merits of the petition.

The Commission believes that these "practice-specific" exemptions should be encompassed within a broader NRC policy which defines levels of radiation risk below which specified practices would not require NRC regulation based on public health and safety interests. For such exemption practices, the Commission's regulatory involvement could therefore be essentially limited to licensing, inspection, and compliance activities associated with the transfer of

the radioactive material from a controlled to an exempt status.

The Commission recognizes that if a national policy on exemptions from regulatory control is to be effective, Agreement States will pay an important implementation role. In the past, States have been encouraging findings that certain wastes are below regulatory concern and the Commission believes that States will support an expansion of these views to all practices involving exempt distribution or release of radioactive material. The Commission intends that rulemakings codifying regulatory control exemptions will be made a matter of compatibility for Agreement States. Consequently, any rulemakings that evolve from this policy will be coordinated with the States.

Advisory and scientific bodies have offered diverse views to the Commission in anticipation of this Policy Statement. There is not clear consensus based on existing scientific evidence or research regarding the selection of numerical criteria for use in this Policy Statement. Further, the Commission is aware that there are differing views within the NRC staff on the selections of numerical criteria for BRC.

In the absence of a scientific consensus, it is the Commission's task to assess the diversity of views in establishing a responsible BRC policy. The authority and responsibility to make the final selection of criteria rests with the Commission. Criteria selected must: (1) Provide reasonable assurance that public health and safety will be protected, and (2) consistent with such assurance, permit practices in the public domain which involve the use of radioisotopes for which society perceives a demand.

It is recognized that there is a delicate balance here. Criteria can be set sufficiently restrictive such that there is absolute assurance that health and safety will always be protected, no matter what events might transpire. However, in doing so, the regulator may then place undue and unnecessary restrictions on practices which should be permitted because of otherwise reasonable social, economic, or industrial considerations. There is always the danger of over-regulation which results in effects that are felt in areas where the NRC does not have authority and responsibility. Moreover, the Atomic Energy Act does not require absolute assurances of safety in the use of radioactive material and licensed facilities.

The numerical criteria ultimately selected will have significant impact on nuclear regulation here in the United States and potentially in the international community. The values under consideration in this Policy Statement do not necessarily agree with those selected or under consideration by other countries. The Commission has carefully reviewed these alternate criteria, and does not find significant scientific evidence that would dictate preferential selection of any of those views over what is proposed in this Policy Statement.

Radiation Protection Principles

The Commission recognizes that three fundamental principles of radiation protection have historically guided the formulation of a system of dose limitation to protect workers and the public from the potentially harmful effects of radiation. They are: (1) Justification of the practice, which requires that there be some net benefit resulting from the use of radiation or radioactive materials, (2) dose limits, which define the upper boundary of adequate protection for a member of the public which should not be exceeded in the conduct of nuclear activities, and (3) ALARA, which requires that radiation dose be as low as is reasonably achievable, economic and social factors being taken into account. The term, ALARA, is an acronym for As Low As is Reasonably Achievable. The Commission is interested in assessing how these principles should be applied in establishing appropriate criteria for release of radioactive materials from regulatory control.

Because of the absence of observed health effects below 5 rem/year (50 mSv/year), scientific experts including the International Commission on Radiological Protection (ICRP) and the National Council on Radiation Protection and Measurements (NCRP) make the assumption that the frequency of occurrence of health effects per unit does at low dose levels is the same as at high doses (10 RAD (0.1 Gy)) where health effects have been observed and studied in humans and animals. This linear non-threshold hypothesis assumes that the risk of radiation induced effects (principally cancer) is linearly proportional to dose, no matter how small the dose might be. The coefficient used in the model as a basis for estimating statistical health risk is on the order of 2×10^{-4} risk of fatal cancer per person-rem of radiation dose (2×10^{-2} per SV). The Commission recognizes that it is a conservative model based upon data collected at relatively high doses and dose rates which is then extrapolated to the low dose and dose rate region where there are no statistically reliable epidemiological data available. Alternative hypotheses have been proposed and reevaluations of the data base at higher doses continue. The Commission believes that use of the linear non-threshold hypothesis allows the theoretical establishment of upper limits on the numbers of health effects that might occur at very low doses which are the subject of the exemption policy.

The risk of death to an individual, as calculated using the linear model, is shown in Table 1 for various defined levels of individual dose. A radiation exposure of 10 mrem per year (0.1 mSv per year) for a lifetime corresponds theoretically to an increase of 0.1% of the individual's annual risk of cancer death. The lifetime risk is based upon the further assumption that the exposure level is the same for each year of a 70-year lifetime.

In estimating the dose rates to members of the public that might arise through the use of various practices for which exemptions are being considered, the Commission has decided to apply the concept of the "effective dose equivalent." This concept, which is based on a comparison of the delayed mortality effects of ionizing radiation exposures, permits through use of weighting factors, the calculation of the whole body dose equivalent of partial body exposures. This approach was originally developed by the International Commission on Radiological Protection and was first expressed in its Publication 26 issued in 1977. Since that time, the concept has been reviewed and evaluated by radiation protection organizations throughout the world and has gained wide acceptance.

TABLE 1 [1]

Incremental annual dose	Incremental annual risk	Lifetime risk from continuing annual dose
100 mrem [2]	2×10^{-4}	1×10^{-3}
10 mrem [2]	2×10^{-5}	1×10^{-4}
1 mrem	2×10^{-6}	1×10^{-5}
0.1 mrem	2×10^{-7}	1×10^{-6}

[1] Risk coefficient of 2×10^{-4} per rem (2×10^{-2} per Sv) based upon publications of the ICRP.

[2] For purposes of comparison, the annual risk to an individual of dying from cancer from all sources in the U.S. is 1 in 500. The additional risk to an individual of dying from cancer when exposed to 10 mrem (0.1 mSv) is 2 in one million.

[3] Unless otherwise indicated, the expression of dose in mrem refers to the Total Effective Dose Equivalent. This term is the sum of the deep dose equivalent for sources external to the body and the committed effective dose equivalent for sources internal to the body.

The Commission recognizes that it is impossible to measure risk to individuals or populations directly, and,

that in most situations, it is impractical to measure annual doses to individuals at the low levels implied by exemption decisions. Typically, radioisotope concentrations or radiation levels from the material to be exempted are the actual measurements that can be made, and doses are then estimated by exposure pathway analysis combined with other types of assumptions related to the ways in which people might become exposed. Under such conditions, conservative assumptions are frequently used in modeling so that the actual dose is on the low side of the calculated dose. The Commission believes that this is the appropriate approach to be taken when determining if an exemption from regulatory controls is warranted.

Collective dose is the sum of the individual doses resulting from a practice or source of radiation exposure. By assigning collective dose a monetary value, it can be used in cost benefit and other quantitative analysis techniques. It is a factor to consider in balancing benefits and societal impact.

Considerations in Granting Exemptions From Regulatory Control

The following elements are being considered by the Commission as a basis for evaluating practices which are proposed to be exempt from regulatory control. These practices, if approved, would result in products containing low levels of radioactive material being distributed to the general public and radioactive effluents and solid waste being released to areas of the publicly-accessible environment.

• Justification—The Commission seeks comment on the extent to which exposures resulting from any practice should be justified. As lower levels of radiation exposure are projected, should lower levels of benefit be required for practice justification? In establishing its exemption policy, should the Commission exclude certain practices for which there appears to be no reasonable justification? In considering proposals for exemptions, should the Commission evaluate the social acceptability of practices? Should the Commission determine a practice to be unjustified if nonradioactive economical alternatives exist?

• Dose Limits and Criterion—Individual doses from practices exempted under this policy should not be allowed to exceed 100 mrem per year (1 mSv per year). This is the dose limit for members of the public specified in the final revision of 10 CFR Part 20, Standards for Protection Against Radiation. The dose limits in the final revision of 10 CFR Part 20 apply to all sources of radiation exposure under a licensee's control (natural background and medical exposures are excluded). Because of the small risks involved, a 10 mrem (0.1 mSv) individual dose criterion is proposed as the basis for exemption decisions based on simple analysis and judgements. The Commission specifically seeks comment on the need for establishing a collective dose limit in addition to an individual dose criterion. If such a collective dose criterion is needed, what is the basis for this need? If the Commission decides that a collective dose criterion is needed, what approaches allowing truncation of individual dose in calculation of collective dose or weighting factors for components of collective dose would be appropriate? What alternatives should be considered for assessing societal impact?

• ALARA—The ALARA principle generally applies to determining dose levels below which exemptions may be granted on a cost-benefit basis. However, it is the purpose of this policy to establish criteria which would, in effect, delineate achievement of ALARA without cost-benefit analysis.

Although it is possible to reasonably project what the dose will be from a practice, and then take this information into account in controlling regulated practices so that the dose limits are not exceeded, exemptions imply some degree of loss of control. The Commission believes that a key consideration in establishing a policy for exemptions, and subsequently in specific rulemaking or licensing decisions, is the question of whether individuals may experience radiation exposure approaching the limiting values through the cumulative effects of more than one practice, even though the exposures from each practice are only small fractions of the limit. The Commission specifically seeks comment on the issue. By appropriate choices of exemption criteria and through its evaluations of specific exemption proposals in implementing the policy, the Commission intends to assure that it is unlikely that any individual will experience exposures which exceed the 100 mrem per year (1 mSv per year) limit.

Principles of Exemption

A major consideration in exempting any practice from regulatory control hinges on the general question of whether or not application or continuation of regulatory controls are necessary and cost effective in reducing dose. To determine if exemption is appropriate, the Commission must determine if one of the following conditions is met:

1. The application or continuation of regulatory controls on the practice does not result in any significant reduction in the dose received by individuals within the critical group and by the exposed population or;

2. The costs of the regulatory controls that could be imposed for dose reduction are not balanced by the commensurate reduction in risk that could be realized.

For purposes of implementing its policy, the Commission recognizes that only under unusual circumstances would practices which cause radiation exposures approaching the 100 mrem per year (1 mSv per year) limit be considered as candidates for exemption. The Commission will consider such circumstances on a case specific basis using the general principles outlined in this policy statement. However, as the doses and attendant risks to members of the exposed population decrease, the need for regulatory controls decreases and the analysis needed to support a proposal for exemption can reasonably be somewhat simplified.

The Commission is evaluating the use of two numerical criteria in defining the region where ALARA has been achieved. They are: (a) A criterion for the maximum individual annual dose reasonably expected to be received as a result of the practice and (b) a measure of societal impact to the exposed population. These criteria are being considered to assure that, for a given exempted practice, no individual will be exposed to a significant risk and that the population as a whole does not suffer a significant impact.

If the individual doses from a practice under consideration for exemption are sufficiently small, the attendant risks will be small compared with other societal risks. The Commission believes that annual individual fatality risks below approximately 10^{-6} (one in 100,000) are of little concern to most members of society. Providing for some margin below this level, the Commission proposes 10 mrem (0.1 mSv) as the level of annual individual exposure. The incremental annual individual cancer fatality risk associated with an exposure level of 10 mrem per year (0.1 mSv per year) is about 2×10^{-6} (two in one million) as indicated in Table 1 and of the order of 0.1 percent (one in one thousand) of the overall risk of cancer death.

In evaluating the need for a collective dose criterion, the Commission recognizes that this criterion could be the limiting consideration for practices involving very small individual doses to very large numbers of people. It is also

recognized that in such cases the collective dose criterion would, in effect, apply the ALARA concept to individual doses less than the below regulatory concern level of 10 mrem per year to the individual. Conversely, where the collective dose criterion would not be limiting, it would serve no purpose. The Commission requests comments on this issue, including comments on what the magnitude of the collective dose criterion, if any, should be.

If the dose is less than the below regulatory concern criteria, then the risk from a practice would be considered to be ALARA without further analysis. The Commission stresses that adoption of the criteria should not be construed as a decision that smaller doses are necessary before a practice can be exempted, while doses above the criteria would preclude exemptions. On the contrary, the criteria simply represent a range of risk which the Commission believes is sufficiently small compared to other individual and societal risks that a cost benefit analysis is not required in order to make a decision regarding the acceptability of an exemption. Practices not meeting these criteria may be granted exemptions on a case-by-case basis in accordance with the principles embodied within this policy. To further emphasize the Commission's recognition that a rigid limitation on collective dose would be inappropriate, it notes that for some practices, such as use of smoke detectors, appreciable benefits can only be attained through extensive utilization and, hence, with a commensurate collective dose.

The Commission is aware that existing regulations of the Environmental Protection Agency establish criteria more restrictive than exemptions which could otherwise be granted under this proposed policy. With regard to its own regulations, the Commission will evaluate whether there are exemption criteria embodied therein for which modification, according to the principles of this policy, would be beneficial.

Exclusions From Exemptions

The Commission's March 18, 1965, notice on the Use of Byproduct Material and Source Material-Products Intended for use by General Public (Consumer Products) (30 FR 3462) provides the basis for the Commission's approval of the use of these materials in consumer products without regulatory control on the consumer-user. This is accomplished by case-by-case exemption of the possession and use of approved items from applicable licensing requirements. Approval of a proposed consumer product depends upon an assessment of exposures of persons to radiation as well as an evaluation of the usefulness of the product.

Certain practices involving radiation or radioactive materials have been judged by NRC to be socially unacceptable regardless of how trivial the resulting dose might be and, therefore, have been excluded from exemption. Excluded practices include, but are not limited to, the intentional introduction of radioactive material into toys and products intended for ingestion, inhalation or direct application to the skin (such as cosmetics).

In addition to socially unacceptable uses of radioactive materials, a question also arises regarding uses where there are clear economical alternatives, and no unique benefits exist from using radioactive material. Where risks are trivial, the regulatory prohibition of such uses could pose an unnecessary regulatory burden by interfering with the conduct of business.

The Commission seeks comments on whether practices should be categorically excluded based on the Commission's judgement regarding social acceptability or the existance of alternatives. An alternative to categorical exclusion could be a case specific determination based on a safety analysis.

Proposals for Exemption

A proposal for exemption must provide a basis upon which the Commission can determine if the basic conditions described above have been satisfied. In general, this means that the proposal should address the individual dose and societal impact resulting from the expected activities under the exemption, including the use of the radioactive materials, the pathways of exposure, the levels of activity, and the methods and constraints for assuring that the assumptions used to define a practice remain appropriate as the radioactive materials move from regulatory control to an exempt status.

If a proposal for exemption results in a rule containing generic requirements, a person applying to utilize the exemption would not need to address justification or ALARA. The Commission decision on such proposals will be based on the licensee's meeting the conditions specified in the rule. The promulgation of the rule would, under these circumstances, constitute a finding that the exempted practice is justified, and that ALARA considerations have been dealt with. This approach is consistent with past practice, e.g., consumer product rules in 10 CFR Part 30.

In evaluating proposals for exemption under this policy, the projected exposures to different components of the exposed population will be considered with regard to the potential that some individuals may receive doses near the 100 mrem per year (1 mSv per year) limit when doses from other practices are also taken into consideration. If exposures from multiple practices can occur which are significantly beyond the individual dose criterion (10 mrem per year (0.1 mSv per year)), the exemption will not be granted without further analysis. As experience is gained, this policy and its implementation will be reevaluated with regard to this issue to assure that the exposures to the public remain well below 100 mrem per year (1 mSv per year).

In addition to considerations of expected activities and pathways, the Commission recognizes that consideration must also be given to the potential for accidents and misuse of the radioactive materials involved in the practice. A proposal for exemption of a defined practice must therefore also address the potentials for accidents or misuse, and the consequences of these exceptional conditions in terms of individuals and collective dose.

Verification of Exemption Conditions

The Commission believes that the implementation of an exemption under this broad policy guidance must be accompanied by a suitable program to monitor and verify that the basic considerations under which an exemption was issued remain valid. In most cases, the products or materials comprising an exempted practice will move from regulatory control to the exempt status under a defined set of conditions and criteria. The monitoring and verification program must therefore be capable of providing the Commission with the appropriate assurance that the conditions for the exemption remain valid, and that they are being observed. The Commission will determine compliance with the specific conditions of an exemption through its established licensing and inspection program and will, from time to time, conduct studies as appropriate to assess the impact of an exempted practice or combinations of exempted practices.

Tentative Meeting Agenda

I. Introduction and Summary-NRC Staff

II. Discussion of Specific Questions-Brief NRC Staff summary and presentations or questions from scheduled participants.

A. Application of principle of justification including the questions:

1. As lower levels of radiation exposures are projected, should lower levels of benefit be required for justification of a practice which is a candidate for exemption?
2. In establishing exemption policy, should the Commission exclude certain practices for which there appears to be no reasonable justification?
3. In considering proposals for exemption, should the Commission evaluate social acceptability of the practice?
4. Should the Commission determine a practice to be unjustified if non-radiological economical alternatives exist?

B. Individual dose criterion for determining achievement of the "as low as reasonably achievable" (ALARA) principle in exemption decision-making:

1. Is the 10 mrem/year criterion proposed by the Commission appropriate?
2. Is the appropriateness of this number affected by the decision regarding whether a collective dose criterion should be used with the individual dose criterion?
3. Should the individual dose criterion be chosen on the basis of negligible risk as is done internationally (i.e., IAEA Safety Series No. 89) or can a somewhat higher number be used based on a Commission policy decision regarding a level of individual risk for which expenditure of resources is not warranted?
4. How important is international consistency in choosing an individual dose criterion?

C. Use of a collective dose criterion for determining achievement of the ALARA principle in exemption decision-making:

1. Is a collective dose criterion needed in addition to an individual dose criterion?
2. If so, what is the basis of that need?
3. If the Commission decides a collective dose criterion should be used, what should its magnitude be?
4. What alternative to a collective dose criterion should be considered for assessing societal impact?
5. In calculating collective dose, what approaches allowing truncation of individual doses or the use of weighting factors for components of collective dose are appropriate?

D. Approaches for assuring total exposures of individuals from multiple practices will not exceed the 100 mrem/year limit.

1. Is the approach of generally limiting individuals doses from each source or practice to a fraction of the overall limit appropriate?
2. Although most exempted sources would be expected to involve individual doses which are a small fraction of the overall limit, should flexibility be maintained by considering exemptions on a cost-benefit basis above 10 mrem/year?
3. Is the evaluation of collective dose important in considering the multiple exposure issue?
4. Will the application of justification of practices help to maintain a smaller number of sources making it easier to control overall exposures?
5. How important is monitoring to maintaining assurance that individual exposures do not exceed to the overall limit?

III. General Discussion/Question Period-Comments or questions by scheduled participants. Open to the floor as time permits.

Those members of the public who wish to participate by speaking at the meeting should notify one of the contacts listed above, so that they can be scheduled in the agenda.

Dated in Rockville, Maryland, this 2d day of December 1988.

Victor Stello, Jr.,

Executive Director for Operations.

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