

Adequacy and Compatibility of Agreement State Programs

***Directive
5.9***

**Volume 5, Governmental Relations and Public Affairs
Adequacy and Compatibility of Agreement State Programs
Directive 5.9**

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U. S. Nuclear Regulatory Commission

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Policy (5.9-01)

It is the policy of the U.S. Nuclear Regulatory Commission to evaluate Agreement State programs established pursuant to Section 274 of the Atomic Energy Act of 1954, as amended, to ensure they are adequate to protect public health and safety and compatible with NRC's regulatory program.

Objectives (5.9-02)

- To establish the process NRC staff will follow to determine when a proposed or final Commission regulation or program element should be adopted as a legally binding requirement by an Agreement State and whether adoption is required for the purpose of compatibility or health and safety as set out in the Commission's Policy Statement on Adequacy and Compatibility of Agreement State Programs. (021)
- To identify Commission regulations and program elements that must be implemented as legally binding requirements by an Agreement State to maintain a program that is adequate to protect public health and safety and compatible with NRC's regulatory program. (022)
- To describe how NRC staff should apply provisions of the policy statement to current and future Agreement State regulations and program elements. (023)

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**Organizational Responsibilities and
Delegations of Authority**

(5.9-03)

**Deputy Executive Director for Regulatory
Programs (DEDR)**

(031)

As delegated by the Executive Director for Operations, oversees the program to evaluate adequacy and compatibility of Agreement State programs.

Director, Office of State Programs (OSP)

(032)

- Reviews the adequacy and compatibility of Agreement State programs through the Integrated Materials Performance Evaluation Program (Management Directive 5.6, "Integrated Materials Performance Evaluation Program [IMPEP]). (a)
- Reviews, evaluates, and determines, in coordination with other NRC offices, those NRC program elements that an Agreement State should adopt for compatibility or adequacy. (b)
- Assists in the review, evaluation, and determination of those NRC regulations that an Agreement State should adopt as legally binding requirements for the purpose of compatibility or health and safety. (c)
- Coordinates the review of Agreement State regulations and program elements with other NRC offices. (d)

Office of the General Counsel (OGC)

(033)

- Assists in the review, evaluation, and determination of those NRC program elements and regulations that an Agreement State should adopt for the purpose of compatibility or health and safety. (a)
- Advises staff on findings regarding the adequacy and compatibility of Agreement State regulations and program elements. (b)

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**Director, Office of Nuclear Material Safety and
Safeguards (NMSS)**
(034)

- Reviews, evaluates, and determines, in coordination with other NRC offices, those NRC regulations that an Agreement State should adopt as legally binding requirements for the purpose of compatibility or health and safety. (a)
- Assists in the review, evaluation, and determination of those NRC program elements that an Agreement State should adopt for the purpose of compatibility or health and safety. (b)

**Director, Office for Analysis and Evaluation of
Operational Data (AEOD)**
(035)

Assists in the review, evaluation, and determination of those NRC program elements and regulations that an Agreement State should adopt for the purpose of compatibility or health and safety.

Regional Administrators
(036)

Assist in the review, evaluation, and determination of those NRC program elements and regulations that an Agreement State should adopt for the purpose of compatibility or health and safety.

Applicability
(5.9-04)

The policy and guidance in this directive and handbook apply to all NRC employees who are responsible for and participate in the review and evaluation of Agreement State regulatory programs or who are involved in development and promulgation of NRC regulations or program elements for byproduct, source, and special nuclear materials.

Handbook
(5.9-05)

Handbook 5.9 describes the criteria and the process that will be used to determine the compatibility and health and safety components of NRC regulations and program elements that an Agreement State should adopt for an adequate and compatible program.

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References

(5.9-06)

Atomic Energy Act of 1954, as amended (42 U.S.C. 2011 et seq.).

Code of Federal Regulations, Title 10.

Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)."

—6.3, "The Rulemaking Process," and its handbook, NUREG/BR-0053, "NRC Regulations Handbook."

NRC "Statement of Principle and Policy for the Agreement State Program; Policy Statement on Adequacy and Compatibility of Agreement State Programs," 62 FR 46517, September 3, 1997.

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5.9***

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Part I

Introduction

Overview (A)

The Commission's Policy Statement on Adequacy and Compatibility of Agreement State Programs sets forth the approach that the Commission will use to determine those program elements that should be adopted by an Agreement State to maintain an adequate and compatible program. This handbook describes the specific criteria and process that will be used to identify the compatibility categories of those NRC program elements that should be adopted by an Agreement State for purposes of compatibility, as well as for identifying those program elements that have a particular health and safety significance. It further describes how NRC staff is to apply the provisions of the policy statement to current and future Agreement State program elements for purposes of compatibility. However, the overall determination of adequacy and compatibility for an Agreement State is made pursuant to Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)."

Policy Statement on Adequacy and Compatibility of Agreement State Programs (B)

An Agreement State radiation control program is compatible with the Commission's regulatory program when the State program does not create conflicts, duplications, gaps, or other conditions that jeopardize an orderly pattern in the regulation of agreement material (source, byproduct, and small quantities of special nuclear material as identified by Section 274b. of the Atomic Energy Act, as amended) on a nationwide basis. Compatibility focuses primarily on the potential effects of State action or inaction either on the regulation of agreement material on a nationwide basis or on other jurisdictions. The concept of compatibility does not directly address matters of health and safety within a particular Agreement State; such matters are addressed directly under adequacy. However, many program elements for compatibility may affect public health and safety; therefore, they also

Policy Statement on Adequacy and Compatibility of Agreement State Programs (B) (continued)

may be considered program elements for adequacy. Further, basic radiation protection standards and program elements with transboundary implications, although important for health and safety within the State, should be uniform nationwide for compatibility purposes. (1)

An Agreement State radiation control program is adequate to protect public health and safety if administration of the program provides reasonable assurance of protection of public health and safety in regulating the use of agreement material. The level of protection afforded by the program elements of NRC's materials regulatory program is presumed to be that which is adequate to provide a reasonable assurance of protection of public health and safety. A subset of one of the five elements identified to help provide such reasonable assurance is legally binding requirements addressing protection of public health and safety within the State. (2)

On the basis of the policy statement, NRC program elements (including regulations) can be placed into four compatibility categories. In addition, NRC program elements also can be identified as having particular health and safety significance or as being reserved solely to the NRC. These are summarized below. (3)

Compatibility Category A (a)

NRC program elements in Category A are those that are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. The program elements adopted by an Agreement State should be essentially identical to those of NRC to provide uniformity in the regulation of agreement material on a nationwide basis.

Compatibility Category B (b)

NRC program elements in Category B are those that apply to activities that have direct and significant transboundary implications. An Agreement State should adopt program elements essentially identical to those of NRC.

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**Policy Statement on Adequacy and Compatibility of
Agreement State Programs (B) (continued)**

Compatibility Category C (c)

NRC program elements in Category C are those that do not meet the criteria of Category A or B, but the essential objectives of which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis. An Agreement State should adopt the essential objectives of the NRC program elements.

Compatibility Category D (d)

NRC program elements in Category D are those that do not meet any of the criteria of Category A, B, or C, above, and, thus, do not need to be adopted by Agreement States for purposes of compatibility.

Health and Safety (e)

These are NRC program elements that are not required for compatibility (i.e., Category D), but that have been identified as having a particular health and safety role (i.e., adequacy) in the regulation of agreement material within the State. Although not required for compatibility, the State should adopt program elements in this category, based on those of NRC, that embody the essential objectives of the NRC program elements because of particular health and safety considerations.

Areas of Exclusive NRC Regulatory Authority (f)

These are NRC program elements that address areas of regulation that cannot be relinquished to Agreement States pursuant to the AEA or provisions of Title 10 of the *Code of Federal Regulations*. These program elements are designated "NRC" and should not be adopted by Agreement States.

Part II

Categorization Criteria

Compatibility Category A* (A)

To be included in Category A, an NRC program element is to be generally applicable and is to be a dose limit or a related concentration or release limit or a scientific term, definition, sign, or label that is necessary to understand basic radiation protection principles (basic radiation protection standard). Basic radiation protection standards do not include constraints or other limits below the level associated with "adequate protection" that take into account permissible balancing considerations, such as economic cost, and other factors. (1)

Examples include, but are not necessarily limited to: (2)

- Public dose limits (e.g., 10 CFR 20.1301) plus any regulation that relates directly to these dose limits (a)
- Concentration and release limits (b)
- Occupational dose limits (e.g., 10 CFR 20.1201) plus any regulation that directly relates to these dose limits (c)
- Dose limits in 10 CFR 61.41 (d)
- Radiation symbol (e)
- Caution signs and labels (f)
- Scientific terms (e.g., conventional and Systeme Internationale units, definitions of types of radioactive material) (g)
- Definitions needed for common understanding (e.g., restricted area, year, stochastic) (h)

* Many program elements for compatibility may affect public health and safety; therefore, they also may be considered program elements for adequacy.

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Compatibility Category B* (B)

To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. (1)

Examples include, but are not necessarily limited to: (2)

- Transportation requirements (e.g., low level radioactive waste manifests, packaging requirements) (a)
- Requirements for approval of products that are distributed nationwide (e.g., sealed sources and devices) (b)
- Definitions of products (e.g., sources and devices) that licensees routinely transport in multiple jurisdictions (c)
- Content and format of sealed source and device registration certificates. (d)

Compatibility Category C* (C)

To be included in Category C, an NRC program element is to be one, the essential objective(s) of which an Agreement State should adopt to avoid conflicts, duplications, or gaps in the regulation of agreement material on a nationwide basis and that, if not adopted, would result in an undesirable consequence. Definitions of "conflict," "duplication," and "gap" are included in the Glossary of this handbook. (1)

Examples of undesirable consequences include, but are not necessarily limited to: (2)

- Exposure to an individual in a different jurisdiction in excess of the basic radiation protection standards established for compatibility in Category A (a)
- Undue burden on interstate commerce (e.g., additional record-keeping or training requirements) (b)
- Preclusion of an effective review or evaluation by the Commission and Agreement State programs for agreement material with respect to protection of public health and safety (c)
- Preclusion of a practice in the national interest (d)

• Many program elements for compatibility may affect public health and safety; therefore, they also may be considered program elements for adequacy.

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Compatibility Category C* (C) (continued)

- Absence or impairment of effective communication (e)
- Lack of minimum level of safety for agreement material—containing products distributed nationwide (f)
- Disruption of the regulation of agreement material on a nationwide basis (g)

Examples of program elements in this category include, but are not necessarily limited to: (3)

- Reports of lost or stolen agreement material or mis-administrations (a)
- Radiation surveys for industrial radiographers and well loggers (b)
- Documents and records required at temporary job sites (c)

Compatibility Category D (D)

NRC program elements that do not meet any of the criteria of Category A, B, or C, above, are Category D and are not required for compatibility purposes.

Health and Safety (E)

An NRC program element that is not required for compatibility and could result directly (i.e., two or fewer failures**) in an exposure to an individual in excess of the basic radiation protection standards in Category A if its essential objectives were not adopted by an Agreement State is identified as having particular health and safety significance. (1)

Examples of such program elements include, but are not necessarily limited to: (2)

- Requirement for irradiator interlocks (a)
- Safety checks for medical teletherapy facilities (b)

* Many program elements for compatibility may affect public health and safety; therefore, they also may be considered program elements for adequacy.

** The concept embodied by "two or fewer failures" is that if the essential objectives of the program element were not adopted and implemented, then an event could occur that would not have taken place were the essential objectives adopted. This alone, or in conjunction with, at most, one other event, could result in exposure of an individual in excess of limits set by basic radiation protection standards.

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Health and Safety (E) (continued)

- Package opening procedures. (c)

**Exclusive NRC Regulatory
Authority (F)**

The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the AEA or the provisions of Title 10 of the *Code of Federal Regulations*. (1)

Examples include, but are not necessarily limited to: (2)

- Issuance of licenses for production and utilization facilities (a)
- Regulation of activities in federal offshore waters (b)
- Issuance of licenses for distribution to exempt persons (c)

Although an Agreement State may not adopt program elements reserved to NRC, it may wish to inform its licensees of certain requirements via a mechanism that is consistent with the particular State's administrative procedure laws, but does not confer regulatory authority on the State. (3)

Examples include, but are not necessarily limited to: (4)

- Agreement State licensee submission to the Commission of nuclear material transfer reports pursuant to 10 CFR 150.16 (a)
- Agreement State licensee compliance with safeguards agreement between the United States and the International Atomic Energy Agency pursuant to 10 CFR 150.17a and 10 CFR Part 75 (b)
- Agreement State licensee submission to the Commission of tritium reports pursuant to 10 CFR 150.19 (c)

Part III

Categorization Process for NRC Program Elements

The protocol to be used to assign a compatibility category to NRC program elements or to identify a program element as having particular health and safety significance is diagramed in the flow chart in the exhibit of this handbook. The basis of the flow chart is a series of questions that are listed below. Each program element is tested by asking the series of questions below in the order given. The answers to these questions determine the compatibility category for each NRC program element or identify it as having particular health and safety significance.

Question (1)—Do the essential objectives of the program element address a regulatory area reserved solely to the authority of the NRC? If the response to the question is “yes”, the compatibility category is “NRC.” If the response to the question is “no,” then proceed to Question (2). (A)

Question (2)—Do the essential objectives of the program element address or define a basic radiation protection standard as defined by the Policy Statement or is it a definition, term, sign, or symbol needed for a common understanding of radiation protection principles? If the response to this question is “yes”, the compatibility category is “A.” If the response to the question is “no”, then proceed to Question (3). (B)

Question (3)—Do the essential objectives of the program element address or define an issue that has a significant, direct transboundary implication? If the response to this question is “yes”, the compatibility category is “B.” If the response to the question is “no”, then proceed to Question (4). (C)

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Question (4)—Would the absence of the essential objectives of the program element from an Agreement State program create a conflict or gap? If the response to this question is “yes”, the compatibility category is “C”. If the response to the question is “no”, then the compatibility category is “D” and proceed to Question (5) to determine whether the program element should be identified as having particular health and safety significance. (D)

Question (5)—Would the absence of the essential objectives of the program element from an agreement state program create a situation that could directly result in exposure to an individual in excess of the basic radiation protection standards found in compatibility category A? If the response to this question is “yes”, the program element is not required for purposes of compatibility, but is identified as having particular health and safety significance. (E)

Part IV

Applicability to NRC Program Elements

Current NRC Program Elements (A)

The compatibility category and identification of particular health and safety significance for current Commission program elements that are applicable to the regulation of agreement materials are found in the Office of State Programs (OSP) Internal Procedure B.7 (Revision 1), "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements." This procedure will be updated periodically as final rules are published.

Future NRC Regulations and Other Program Elements (B)

The compatibility category or identification of particular health and safety significance of a proposed rule is to be suggested at the time the rulemaking plan is formulated and is to be coordinated with the Agreement States according to Management Directive 6.3, "The Rulemaking Process." Staff are to use this handbook to determine the compatibility category or to identify particular health and safety significance for each draft rulemaking plan. OSP Internal Procedure B.7 will be revised to incorporate the results of these determinations after the final rule or program element is adopted.

Part V

Applicability to Agreement State Program Elements

Current Agreement State Program Elements (A)

Regulations (1)

NRC regulations that had not been required for compatibility according to the Office of State Programs (OSP) Internal Procedure B.7, "Criteria for Compatibility Determinations," but, pursuant to the Policy Statement on Adequacy and Compatibility of Agreement State Programs, are included in compatibility Categories A, B, or C or are identified as having health and safety significance should be adopted by the States with an effective date within 3 years of the effective date of the policy statement and implementing procedures. (a)

NRC regulations that had been required for compatibility according to OSP Internal Procedure B.7, but will not be required under the policy statement do not require any action by the States. (b)

In addition to the foregoing, if an Agreement State's regulations had been evaluated using OSP Internal Procedure B.7 and NRC's program review procedures before the effective date of the policy statement and found: (c)

- To be compatible, then no further action is required by the State except in the special circumstance where the compatibility category now requires the State to be essentially identical (e.g., a change from Division 2 to Category B) and the State regulation is not so deemed, then the State should conform the regulation as expeditiously as possible, but not later than 3 years after the policy's effective date (i)

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Current Agreement State Program Elements (A) (continued)

Regulations (1) (continued)

- To be not compatible, then the regulation deemed not compatible should be changed to conform to the policy as expeditiously as possible, but not later than 3 years after the policy's effective date (ii)
- Not to have adopted a regulation previously required for compatibility and still required by compatibility Category A, B, or C or identified as having health and safety significance, then the regulation should be adopted as expeditiously as possible, but not later than 3 years after the policy's effective date or other date set by the Commission (iii)

Program Elements (2)

Program elements other than regulations had not been identified previously for purposes of compatibility or for having health and safety significance. Such program elements now identified under the policy statement should be adopted and implemented by the States within 6 months of the effective date of the policy statement and implementing procedures. If, due to other factors, an Agreement State cannot adopt and implement such a program element within the 6-month timeframe, then the State and the Commission will agree upon a mutually acceptable timetable for adoption and implementation.

**Future Agreement State Program
Elements (B)**

General (1)

Any changes to Agreement State program elements after the effective date of the policy statement should conform to the policy and implementing procedures set out in this handbook.

Future Regulations (2)

Proposed and final Agreement State regulations for agreement materials that will be submitted to the NRC will be reviewed in accordance with guidance provided in OSP Internal Procedures, D.7, "Reviewing State Regulations," and B.7 (Revision 1), "Compatibility

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**Future Agreement State Program
Elements (B) (continued)**

Future Regulations (2) (continued)

Categories and Health and Safety Identification for NRC Regulations and Other Program Elements.” Results of the evaluation will be transmitted to the State in accordance with OSP internal procedures. Note: The overall determination of the adequacy and compatibility of individual Agreement State programs will be made in accordance with Management Directive (MD) 5.6, “Integrated Materials Performance Evaluation Program (IMPEP).”

Future New or Changed Program Elements (3)

NRC staff will review the adoption and implementation of any new or revised (non-regulation) program element by an Agreement State in accordance with the review procedures set out in MD 5.6 at the time of the next regularly scheduled review.

**Evaluation of Applications for Agreement
State Status (C)**

NRC staff will apply the compatibility and health and safety categorization criteria and process in this handbook when reviewing the regulations and program elements contained in applications for Agreement State status submitted after the September 3, 1997, effective date of the policy statement.

Part VI

Additional Implementing Issues

Use of Management Directive 5.9 (A)

The overall determination of adequacy and compatibility of individual Agreement State programs will be made in accordance with Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." However, for IMPEP reviews, the review teams will use this handbook to assess the status of the State's program elements with regard to those that should be adopted for compatibility or for health and safety reasons. Specific Agreement State regulations will be assessed as they are submitted by the State and a summary report will be provided to the IMPEP review team at the time of the State's next program review.

Essential Objectives (B)

The essential objective of each NRC program element in compatibility Category C or identified as having particular health and safety significance should be adopted by the Agreement State. The term "essential objective" is defined in the Glossary to this handbook. (1)

For those NRC program elements in compatibility Category C, adoption of the essential objective(s) by an Agreement State means that the State is compatible with regard to that program element. (2)

For those NRC program elements identified as having particular health and safety significance, adoption of the essential objective(s) by an Agreement State means that the State is providing a level of protection equivalent to NRC with respect to that program element. A State has the latitude to adopt essential objectives that are more stringent. (3)

Essentially Identical (C)

Program elements in compatibility Categories A and B adopted by Agreement States should be essentially identical. The term "essentially identical" is defined in the Glossary to this handbook. If a requirement adopted by an Agreement State differs in any significant respect from that of the NRC, the State should explain how the requirements are essentially identical. An example of a substitution that would not be considered significant would be use of the term "deterministic" in place of the term "nonstochastic." In this case, the former term is one commonly accepted in the international radiation protection community. Similarly, the use of Systeme Internationale (SI) units rather than conventional units would be deemed essentially identical. Further, the adoption by States of more recent technical information (e.g., with regard to reference man) would be viewed as being essentially identical. Finally, changes to reflect increased scope of State authority (e.g., use of the term "radioactive material" in place of the term "byproduct material") or wording needed to conform to State administrative procedures (e.g., use of State agency name in place of "Commission") would not be considered significantly different.

Legally Binding Requirements (D)

Where appropriate, Agreement States should adopt program elements in compatibility Categories A, B, and C or those identified as having particular health and safety significance and applicable to all licensees in the form of a rule or other generic legally binding requirement in a manner consistent with the State's administrative laws. The use of generic requirements will help to avoid inconsistency and confusion that may result from the imposition of individual requirements on a case-by-case basis. (1)

Further, requirements applicable to more than a few licensees also should be adopted in the form of a generic requirement. However, since the appropriate approach to such issues will depend on the types and numbers of licensees involved, the State's approach will be reviewed on a case-by-case basis. (2)

The mechanism used by the State should be legally binding on the licensee(s) and enforceable as law. Examples of such legally binding requirements may include license conditions (including licensee commitments referenced in "tie-down" conditions), orders or other mechanisms determined by the State to be legally binding and enforceable. The State has the responsibility of demonstrating that requirements adopted other than by regulation are legally binding. (3)

Timeframes for Adoption (E)

Commission regulations that should be adopted by an Agreement State for purposes of compatibility or health and safety should be adopted in a timeframe such that the effective date of the State requirement is not later than 3 years after the effective date of NRC's final rule (September 3, 1997). Certain circumstances (e.g., adoption of a basic radiation protection standard or other rule that will have significant impact on the regulation of agreement material on a nationwide basis, such as the low-level radioactive waste manifest) may warrant that the effective dates for both NRC licensees and Agreement State licensees be the same. In some cases, and with sufficient justification, health and safety considerations may warrant adoption by the States in less than the recommended 3-year (or 6-month) timeframe. (1)

Program elements, other than regulations or equivalent legally binding requirements, that have been designated as necessary for maintenance of an adequate and compatible program should be adopted and implemented by the Agreement States within 6 months of such designation by NRC. If, due to other factors, an Agreement State cannot adopt and implement such a program element within the 6-month timeframe, then the State and the Commission will agree upon a mutually acceptable timetable for adoption and implementation. (2)

Glossary

Conflict. The essential objectives of regulations or program elements are different and an undesirable consequence is likely to result in another jurisdiction or in the regulation of agreement material on a nationwide basis.

Duplication. Identical regulations or program elements apply to the same material at the same time. Note: this definition applies primarily to review of Agreement State regulations.

Essential objective (of a regulation or program element). The action that is to be achieved, modified, or prevented by implementing and following the regulation or program element. In some instances, the essential objective may be a numerical value (e.g., restriction of exposures to a maximum value) or it may be a more general goal (e.g., access control to a restricted area).

Essentially identical. The interpretation of the text must be the same regardless of the version (NRC or Agreement State) that is read.

Gap. The essential objectives of NRC regulations or program elements are absent from the Agreement State program and an undesirable consequence is likely to result in another jurisdiction or in the regulation of agreement materials on a nationwide basis.

Practice. A use, procedure, or activity associated with the application, possession, use, storage, or disposal of agreement material. The term "practice" is used in a broad and encompassing manner in the Policy Statement on Adequacy and Compatibility of Agreement State Programs. The term encompasses both general activities involving use of radioactive materials such as industrial and medical uses and specific activities within a practice such as industrial radiography and brachytherapy.

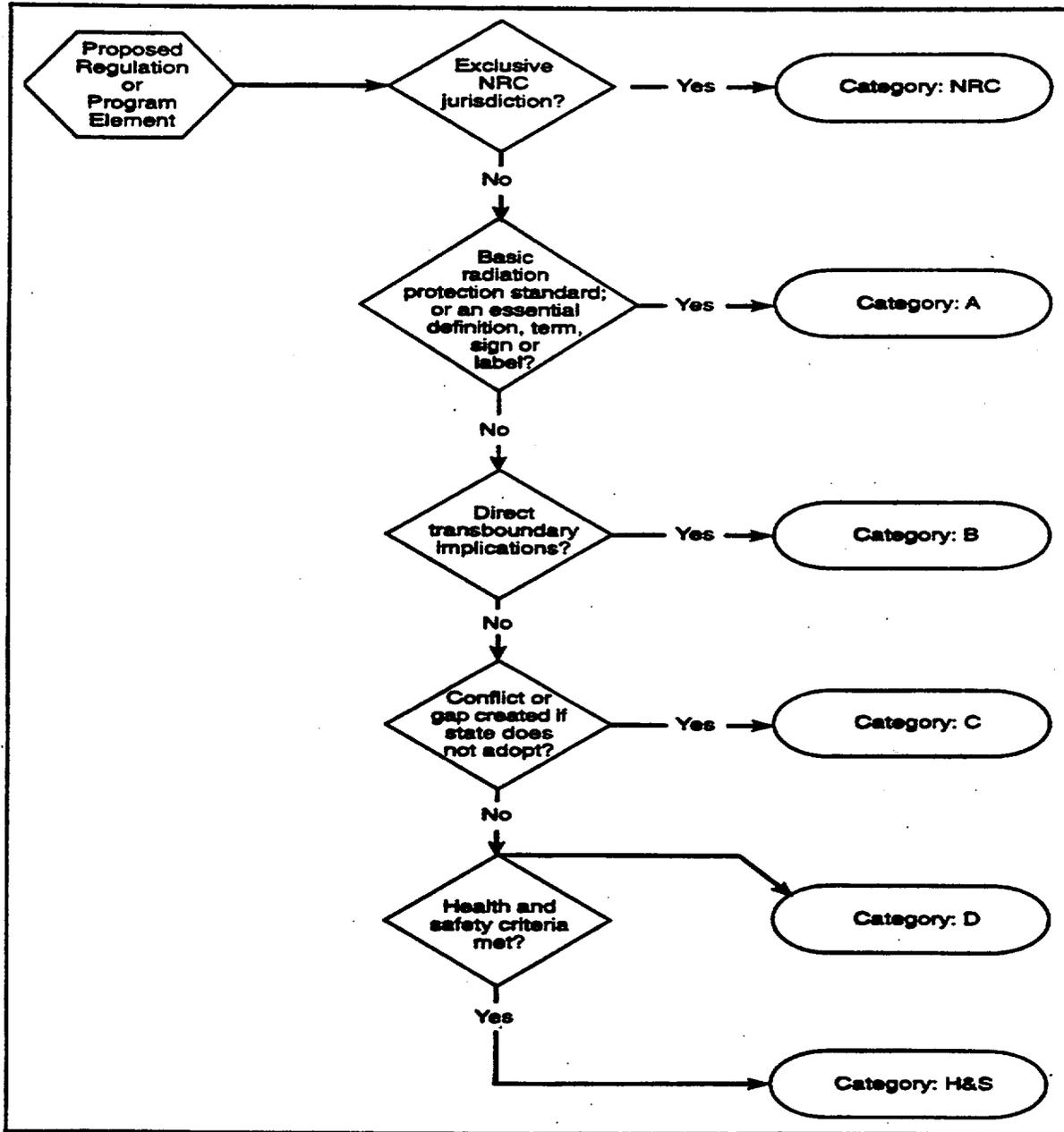
Glossary (continued)

Program element. Any component or function of a radiation control regulatory program, including regulations and/or other legally binding requirements imposed on regulated persons, that contributes to implementation of that program.

Transboundary. Across jurisdictional boundaries within the United States. It does not mean between the United States and other nations.

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Exhibit
Flow Chart



QUESTION 42.

Under the agreement state policy, radiation control programs should be based on a common regulatory philosophy including the common use of definitions and standards. "They should be not only effective and cooperatively implemented by NRC and the Agreement States, but also should provide uniformity and consistency in program areas having national significance."

Do the NRC, Tennessee and the other agreement states have common definitions for such words as "waste," "disposal," "effluent," "byproduct material," "transfer," and "release limits"? Please provide those definitions.

ANSWER.

NRC regulations include definitions of the terms "byproduct material", "waste", and "disposal," for application in particular contexts. Those definitions are:

[10 CFR 150.3(c)] Byproduct material means: (1) Any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material; and (2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition.

[10 CFR 61.2] Waste means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level waste has the same meaning as in the Low-Level Radioactive Waste Policy Act, that is, radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in Section 11e.(2) of the Atomic Energy Act (uranium or thorium tailings and waste).

[10 CFR 61.2] Disposal means the isolation of radioactive wastes from the biosphere inhabited by man and containing his food chains by emplacement in a land disposal facility.

Under the implementing procedures for the Policy Statement on Adequacy and Compatibility of Agreement State Programs, Agreement States should adopt definitions for "byproduct material" and "waste" that are essentially identical to those of NRC and adopt a definition for "disposal" that meets the essential objectives of the NRC's definition.

All States have adopted a compatible definition for 11e.(1) byproduct material as set forth in 10 CFR 150.3(c). Six States do not include the definition of 11e.(2) byproduct material as set out in paragraph (2) of 10 CFR 150.3(c) -- the definition of "11e.(2) byproduct material." These six States, however, do not have regulatory authority over 11e.(2) byproduct material under their Agreements. All States, except two which have not adopted a definition of waste, have adopted

a compatible definition of waste. All States, except eleven which have not adopted a definition of disposal, have a compatible definition of disposal.

The terms "effluent", "transfer", and "release limits" are not defined in NRC regulations and are therefore not covered in the implementing procedures.

QUESTION 43.

This policy, under the authority of Section 274 (j)(1) of the Atomic Energy Act, requires that the NRC must consider suspending or terminating its agreement with agreement states if their release standards are not compatible with the NRC's and the other agreement states. Please describe the release standards for solid material containing byproduct material of the other agreement states and answer the following questions:

ANSWER.

We asked each Agreement State for information on the criteria and regulatory approach they use to control the release of solid material containing very low levels of surface and/or volumetric radioactive material. Their responses indicate that, although the approaches vary, the States' practices with respect to the release of solid material provide reasonable assurance of adequate protection of public health and safety. However, some responses appear to indicate that there is a need for clarification, particularly with respect to the need for some States to differentiate between the decommissioning rule for release of land, buildings and structures that are on sites at the time of license termination, and the release of materials for unrestricted use. We plan to communicate with the Agreement States to clarify their practices. We are aware that two other States (Washington and New York) have also received recent requests from their licenses to authorize releases of large volumes of slightly contaminated material.

The criteria utilized by States, generally applied on a case-by-case basis, include use of levels that are indistinguishable from background, use of guidelines similar or equivalent to RG 1.86,

and use of dose-based analyses. While the variation in State approaches does not represent a health and safety issue, there may be a benefit in establishing a consistent national approach. If an Agreement State promulgates requirements that are inconsistent with the compatibility designation assigned to an existing NRC rule, NRC would likely find the state's action "not compatible" under the Integrated Materials Performance Evaluation Program (IMPEP). Such a finding could result in NRC consideration of suspending or terminating its agreement with the Agreement State. Before taking such action, however, a number of steps would first be implemented. These steps would include: correspondence with the State requesting action to effect adoption of a compatible standard; a follow-up meeting at a senior management level to discuss the need to adopt a compatible standard and understand the State's basis for not adopting a compatible standard; a follow-up IMPEP review; or placement of the State's program on heightened oversight, or probation. In most cases, NRC expects that such measures, short of suspension or termination of an agreement, would effect the change necessary to achieve a compatible State standard.

- (a) Is it possible for any agreement state to set a completely different standard for the release of solid material containing byproduct material? Please explain and provide any supporting documentation.

ANSWER.

In the current situation where NRC has not established a "basic radiation protection standard" applicable to all licensees for the release of solid material, Agreement States have the flexibility to establish standards, criteria or individual limits on a case-by-case basis. Generally, an

Agreement State may set a different standard from other Agreement States where: (1) NRC has not established a specific requirement, (2) the State has an adequate supporting health and safety basis; (3) the requirement does not preclude a practice that is in the national interest and is otherwise generally compatible with the Commission's program; and (4) the Agreement State continues to provide reasonable assurance of adequate protection of public health and safety.

- (b) Is it possible for any or all other states to ban the import of MSC nickel released under the Tennessee license from entering their states? Please explain and provide any supporting documentation.

ANSWER.

If the nickel continues to contain detectable levels of AEA material, it is conceivable that another Agreement State, based on its authority stemming from its Agreement with NRC, could attempt to assert regulatory authority over the material and prohibit the entry into that State. As the Policy Statement indicates, a State may impose regulatory requirements for material covered by its agreement as long as it, among other things, "does not preclude a practice in the national interest without an adequate health and safety or environmental basis related to radiation protection." Given the NRC's ongoing efforts to explore the need for consistency in this area, it is premature for the Commission to conclude that the practice in question (i.e., MSC's release of nickel) qualifies as a "practice in the national interest" warranting the

Commission's intervention against State actions seeking to preclude the entry of such material into their State. We note, however, that it is likely that a State's attempt to ban the import of the material would raise a host of practical implementation problems associated with the identification of the material.

It is possible that States may have authority outside the Agreement State context to ban import of MSC nickel. We have not analyzed the extent of State authority in this regard.

- (c) Would such actions by other states in response to Tennessee's setting of a standard for the unrestricted release of byproduct material "create conflicts, duplications, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis"? If the answer is in the negative, please explain why different state standards for release "create conflicts, duplications, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis."

ANSWER.

As stated in the response to Question 41(b), NRC's policy statement on adequacy and compatibility of Agreement State programs indicates that where NRC has not established a specific standard, Agreement States have the flexibility to establish their own requirements, or to develop and apply a criterion or limit applicable to a specific case, provided that the States continue to provide reasonable assurance of protection of public health and safety and that their

activities are in a broad sense compatible with the Commission's program. (62 FR 46525.) (Also see response to Question 43(b)). It can be expected that such flexibility will result in some differences between NRC and Agreement State programs, particularly where no general NRC standard exists. In addition, as explained in more detail in response to Question 43(b), the NRC will raise compatibility concerns with Agreement States if a State's regulatory action precludes a practice in the national interest. At this time, it is premature for the NRC to determine whether the State's effort to ban an import would raise a compatibility concern.

QUESTION 44.

The agreement state policy also requires that "Regulations and regulatory decisions should be based on assessments of the best available information from affected and interested individuals and organizations, as well as on the best available knowledge from research and operational experience.... The public should have an opportunity for early involvement in significant regulatory program decisions." (Subsection C (1).)

By everyone's evaluation, the unrestricted release of 6,000 tons of byproduct material into interstate commerce is a "significant regulatory program decision." The public received no notice or the opportunity to comment on the MSC license amendment. Is this in keeping with the policy statement cited above? Please explain.

ANSWER.

Generally, NRC imposes no specific requirements on Agreement States to employ any particular public notice or hearing procedures for particular licensing actions. (For mill tailings, the requirements in Section 274o of the AEA require the Agreement State to provide for an opportunity, after public notice, for written comments and a public hearing, along with several other procedural and legal review requirements). In most cases, the Agreement States follow administrative procedures dictated by the administrative laws applicable to all regulatory agencies in that state. In light of this, NRC has not generally imposed its own procedures on

the Agreement States. However, if NRC identifies adequacy problems in an Agreement State program that can be linked to procedures in the State, NRC will raise the issue with the State.

In this particular case, Tennessee staff has informed NRC staff that the MSC licensing action was reviewed and issued in accordance with Tennessee State administrative procedures. We believe that Tennessee could assert that this action is not a "significant regulatory program decision" since it addresses, for only one licensee in one specific license, the criteria that will be applied to the release of material containing very low levels of radioactive material.

In the case of NRC licensees, licensing actions involving the issuances of licenses or license amendments, including those addressing releases, would be subject to an opportunity for a hearing. Also, additional information may be provided through supporting environmental analysis for the licensing actions. However, as stated above, NRC does not require Agreement States to adopt the same procedures and, as such, differences in approach are inevitable. Specific opportunities for public participation vary among the States.

QUESTION 45. Under this policy the agreement states are required to provide the NRC with information about their regulations and license conditions. When and how did the NRC receive information concerning the MSC license amendment?

ANSWER.

When approving a new agreement, NRC reviews a State's program including regulations, licensing and inspection procedures, and other program implementation documentation to determine that the State's program is adequate to protect public health and safety and compatible with NRC's program. After an agreement is effective, as discussed in response to Question 3, NRC reviews each Agreement State program under the Integrated Materials Performance Evaluation Program (IMPEP) for continued adequacy and compatibility. As part of each review, under the common performance indicator "Technical Quality of Licensing Actions," a State is asked to identify any major, unusual or complex licenses which were issued or amended. This listing is used by the review team to identify licensing actions to review during the on-site review. The State is also asked to identify any changes made in written licensing procedures during the review period. Tennessee's last IMPEP review was conducted in 1996, and at that time, the Tennessee program was found to be adequate and compatible. The next IMPEP for Tennessee is scheduled for August 2000.

In the late March (1999) time frame, NRC staff received a press inquiry regarding the MSC licensing action. In response, NRC staff contacted Tennessee staff to obtain information on the MSC license. Subsequently, NRC staff also requested information from Tennessee on the licensing action in connection with activities of the Release of Solid Material Working Group in

QUESTION 45.(A). (continued)

-2-

order to develop background information on Agreement State activities. Staff is not aware of any specific notification by Tennessee staff to NRC that Tennessee had issued the license amendment. However, staff on the NRC Release of Solid Materials Working Group were informally contacted by Tennessee staff during Tennessee's review of the amendment request to discuss whether work being done by the Working Group could be of assistance to Tennessee. NRC staff indicated the work was in progress and the results were not yet available.

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U.S. House of Representatives
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, DC 20515-6115

October 25, 1999

JAMES E. DERDERIAN, CHIEF OF STAFF

The Honorable Greta Dicus
Chairman
Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, Maryland 20852

Dear Chairman Dicus:

We are writing to inform the Nuclear Regulatory Commission (NRC) of an unprecedented act taken by one of the Commission's agreement states to license the release of a large volume of products containing radioactive byproduct material into interstate commerce. We are asking for an immediate investigation of the license and an expeditious response to the undersigned to the attached questions so that we may further review its legality. This is particularly significant because the Department of Energy (DOE) - from whom this contaminated material emanated - and nuclear reactor plants undergoing decommissioning would like to release hundreds of thousands of tons of contaminated byproduct material into interstate commerce over the next several years. This has never been allowed before.

In March of this year -- without public notice or comment -- the State of Tennessee approved a license amendment which purported to authorize Manufacturing Sciences Corporation (MSC), a wholly owned subsidiary of BNFL, Incorporated, to release into general interstate commerce 6,000 tons of nickel metal volumetrically contaminated with technetium, a radioactive material that is a byproduct of the process of producing or utilizing special nuclear material. The nickel is a product of the operations of the gaseous diffusion plant at the Oak Ridge nuclear weapons facility operated by the DOE. The license amendment would authorize for the first time since the passage of the Atomic Energy Act the totally unrestricted transfer or sale by a radioactive waste processing company of massive and continuing amounts of radioactive byproduct material without any labeling or use restriction requirements. It also marks the first time that licensed material has been allowed to be released into interstate commerce without a license from the NRC itself.

MSC's plan is to sell the nickel as scrap without notice as to its radioactive properties. As such, it would be incorporated into steel and other nickel-containing products sold for general

use. Such a release appears to violate numerous NRC regulations which were developed specifically to prohibit the uncontrolled release by radioactive byproduct material into general commerce. These regulations implement a decades-long and still-existing policy of the Atomic Energy Commission and its successors to keep radioactive byproduct material out of the hands of the general public for safety and national security reasons. Additionally, such releases have been vehemently opposed by the American public for some time. In fact, as the NRC itself recognized, in 1992, Congress ordered the NRC in the Energy Policy Act to halt its attempt to set a "below regulatory concern" standard for the unrestricted release of such materials after a public uproar. (See 64 Fed. Reg. 35094.)

It also appears that the NRC regulations forbid states from taking such an action on their own. Agreement states, which do license some restricted uses of byproduct material, have been specifically banned since their creation from licensing the unrestricted release of byproduct material. (See 10 CFR 30.3; 10 CFR 150.15.) Tennessee is an agreement state of the NRC under the provisions of Section 274 (b) of the Atomic Energy Act. Its agreement with the NRC incorporates the ban against licensing the unrestricted release of byproduct material. Article III; Agreement between Atomic Energy Commission and the State of Tennessee, Aug. 21, 1965. As described in more detail in the attached staff memorandum, we have found no subsequent statutory or regulatory authority for Tennessee to issue the MSC license amendment.

Since the enactment of the Atomic Energy Act in 1946, the NRC has banned the release of radioactive byproduct material into interstate commerce without a specific license from the NRC. Byproduct material is defined in the Act and the NRC regulations as radioactive material (except special nuclear material) that is a byproduct of the process of producing or utilizing special nuclear material. (See 42 U.S.C. 2014 (e).) The NRC's regulations governing these licenses for release are detailed and extremely restrictive. They require, for example, that byproduct be contained in a product only because its radioactive properties are necessary to the product, not as a contaminant of the product. Each product to be licensed is identified by name and has its own standards. Extensive warning labels are required before transfer from an NRC licensee to a non-licensee is allowed for both individual products and bulk transfers. (See 10 CFR Parts 30-35.)

The reason for these tight controls was clearly stated by the NRC in 1962, when it issued its agreement state regulations prohibiting those states from regulating the use of byproduct material that would go into general commerce.

The uncontrolled distribution of atomic materials in products designed for distribution to the general public, such as consumer type devices, and the ultimate uncontrolled release of these material into the environment, involve questions of national policy which have not yet been resolved." ("Exemptions and Continued Regulatory Authority in Agreement States under Section 274," 27 Fed. Reg. 1351, Feb. 14, 1962.) (Emphasis added.)

In brief, the NRC intended to know -- and control -- exactly who was using byproduct material.

To date, those national policy issues identified in 1962 have not been resolved in favor of broader releases. All attempts by the NRC to set national standards for additional unrestricted releases by regulation have been met with significant opposition from the public. Nor has the NRC changed its regulations governing agreement states to allow the states, such as Tennessee to assume the responsibilities for licensing the release of byproduct material into general commerce.

The regulations not only cover MSC, the initial transferor of byproduct material into interstate commerce, but also every subsequent possessor or purchaser who is using byproduct material for commercial purposes. A specific license to manufacture, process, produce, package, repackage, or transfer any quantity of byproduct material for commercial distribution to persons exempt from licensing is required. This would cover all the scrap dealers, steel mills and any other manufactures or distributors of commodities and products that contain the contaminated nickel. Those parties are required to label their products with its radioactive content prior to distribution, demonstrate that the byproduct material will not be released to the environment, and undergo a variety of other prohibitions prior to sale. (*See* 10 CFR 32.14 (a)(6).) The license also requires a commitment from the licensee that the material will not be applied to a human being, that it is identified as radioactive, that it is not incorporated into any product intended for commercial distribution, and that it be labeled "Radioactive Material – Not for Human Use – Introduction Into Foods, Beverages, Cosmetics, Drugs, or Medicinals or Into Products Manufactured for Commercial Distribution is Prohibited – Exempt Quantities Should Not be Combined." (*See* 10 CFR 32.18-19.)

This regulatory structure is completely in keeping with the policy to keep all byproduct material out of the hands of the general public that pervades the NRC's rules, even in the restricted release areas in which agreement states are authorized to regulate. For example, agreement states regulate the use of byproduct material in devices designed for certain enumerated industrial processes. But the NRC requires that each device be labeled, tracked, tested for leakage, returned only to the manufacturer for repair and that it be disposed of only by returning it to the manufacturer or other person licensed to receive it. These devices specifically cannot be abandoned or exported. (*See* 10 CFR Part 31.)

Even the Commission's Regulatory Guide 1.86 (Termination of Operating Licenses for Nuclear Reactors), which -- although there are questions as to its legitimacy discussed in more detail in the attached memorandum -- many point to as the basis for the release of contaminated metal, is limited to nuclear plant operating licenses which remain under the control of the NRC. The NRC itself must approve the release of all such equipment and scrap under this guidance document.

As a result of the staff's review of the Atomic Energy Act and the NRC's extensive regulations governing the unrestricted release of byproduct material, we are at a loss to determine

under what authority Tennessee issued this license amendment. There are strong indications, however, that the NRC and Tennessee are taking the position none of these stringent regulations apply to MSC, but that its unrestricted release of byproduct material into commerce is some alternate form of “waste disposal” or “effluent” release from an operating nuclear facility that the state can regulate under Part 20 of the NRC’s regulations. (Regulatory Guide 1.86 is based on this interpretation.)

This theory is not supported by the law or NRC’s own regulations. First, the Part 20 regulations control exposure to ionizing radiation resulting from “routine” activities conducted under licenses issued by the NRC, not exposures resulting from the uncontrolled use of radioactive material in commercial products by non-licensees. (See 56 Fed. Reg. 23390, May 21, 1991.) Second, in the Atomic Energy Act and throughout the NRC’s regulations, “disposal” is defined as “isolation” of radioactive materials. Unrestricted release does not appear to promote “isolation.” (See, e.g., 42 U.S.C. 2021b (7).) Although 10 CFR 20.2002 allows a licensee to obtain a license for an alternate forms of “disposal,” there is no evidence that free release is an alternate form of disposal. Indeed, when Congress amended the Atomic Energy Act to require the NRC to identify “methods for the disposal of low-level radioactive waste other than shallow land burial, and establish and publish technical guidance regarding licensing of facilities that use such methods,” Congress listed those technical requirements as “site suitability, site design, facility operation, disposal site closure, and environmental monitoring, as necessary to meet the performance objectives established by the Commission for a licensed low-level radioactive waste disposal facility.” (42 U.S.C. 2021h (emphasis added).) Free release cannot meet any of these technical requirements, and every single one of the alternate methods identified by the NRC involved isolation of the radioactive material. (“Licensing of Alternative Methods of Disposal of Low-Level Radioactive Waste,” NUREG-1241, December 1986.)

Finally, it is difficult to view the release of tons of nickel metal as bearing any similarity to gaseous and liquid effluents or “readily soluble” solids allowed to be emitted into the environment from an operating facility under the Part 20 regulations. (See e.g., 10 CFR 20.2003.) Part 20 sets exposure limits for plant workers and an effective annual dose for members of the public deemed to be continuously at the boundaries of the plant for a year when effluents leave the plant. In publishing its proposed Part 20 revisions in 1985, the NRC described the public dose as being received in the following manner:

If effluents containing radionuclides are released, external exposures occur directly from the passing plumes, from radionuclides in the environs, or from radionuclides taken into the body by inhalation or by ingestion of water or locally produced foodstuffs. (50 Fed. Reg. 51992, 52011.) (Emphasis added.)

This bears no relationship to contaminated products being deliberately transferred to the public through the normal stream of commerce.

The NRC, in its recent issues paper issued as a first step to another attempt to set a rule to allow the unrestricted release of certain byproduct material into interstate commerce, says its purpose is only to provide “consistency” for solid material releases with the allowable gaseous and liquid effluent release provisions. (See 64 Fed. Reg. 35090.) Not only does the NRC already have a regulation for the release as sewage of small amounts of “readily soluble” solids, it has yet to explain how a product deliberately created by a licensee for transfer is an “effluent” resulting from its “routine” operations that will leave the boundary in some sort of natural movement.

Even were the NRC somehow to determine that the State of Tennessee did have authority to issue this license, then we also must ask whether the Commission, under the provision in 42 U.S.C. 2021 (g) and (j), should begin consideration of proceedings to suspend all or part of its agreement with Tennessee because the state has acted in a manner incompatible with the NRC’s “Statement of Principles and Policy for the Agreement State Program Policy Statement on Adequacy and Compatibility of Agreement State Programs” (hereafter cited as “Agreement State Policy”). That policy and the implementing Directive 5.9 set identical release limits as a program element that must be implemented as one of the legally binding requirements for an Agreement State to maintain a program that is compatible with NRC’s regulatory program.” (State Agreement Policy; Directive 5.9, Objectives.) The directive states that “concentration and release standards” are a Category A program element, for which it is mandatory that the states adopt identical standards. NRC has already admitted in its issues paper that it has no standard. Therefore, Tennessee has set its own separate release standards for contaminated nickel.

Compatibility is defined as “program elements necessary to meet a larger nationwide interest in radiation protection generally limited to areas of regulation involving radiation protection standards and activities with significant transboundary implications.” (“Agreement State Policy,” Subsection III (B).) State radiation control programs are compatible only when they do “not create conflicts, duplications, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis.” (“Compatibility,” Subsection III (E).) To achieve compatibility, state standards for release limits “should be essentially identical to those of the Commission.” (“Agreement State Policy,” Subsection III (E) (A).)

Because the NRC has set no release standard for volumetrically contaminated materials and is in the process of beginning a rulemaking to establish that release standard, Tennessee cannot establish a standard in an individual license amendment and maintain compatibility. If it is allowed to do so, other states are free to set more or less restrictive standards, resulting in regulatory chaos. The Agreement State Policy also requires that the public have “opportunity for early involvement in significant regulatory program decisions” and that “radiation control programs should be based on a common regulatory philosophy including the common use of definitions and standards.” This is clearly a “significant regulatory program decision” done without any public involvement.

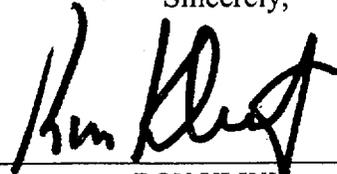
The Honorable Greta Dicus
Page 6

We are seeking to determine whether the NRC is carrying out its statutory responsibilities pursuant to its established regulations. To that end, we ask that you respond to this letter and the attached questions by Monday, November 15, 1999. We also ask that this letter and attached memorandum and questions be placed into the public record of the Commission's consideration of this matter. Please have your staff contact Edith Holleman, Minority Counsel, at (202) 226-3400 if you have any questions.

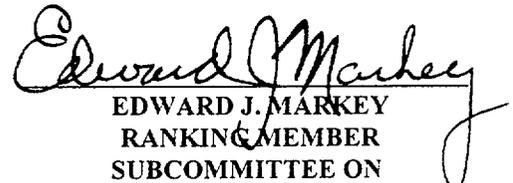
Sincerely,



JOHN D. DINGELL
RANKING MEMBER
COMMITTEE ON COMMERCE



RON KLINK
RANKING MEMBER
SUBCOMMITTEE ON OVERSIGHT
AND INVESTIGATIONS



EDWARD J. MARKEY
RANKING MEMBER
SUBCOMMITTEE ON
TELECOMMUNICATIONS, TRADE,
AND CONSUMER PROTECTION

Attachments

**REQUESTS AND QUESTIONS
FOR THE NUCLEAR REGULATORY COMMISSION**

1. Please provide a copy of the complete agreement between the Nuclear Regulatory Commission (NRC) and the State of Tennessee issued pursuant to Section 274 (b) of the Atomic Energy Act, including any amendments issued subsequent to the original 1965 amendment.
2. Please provide a copy of the complete license issued by the State of Tennessee to Manufacturing Sciences Corporation (MSC), including any amendments issued subsequent to the original 1965 amendment.
3. In 1962, when the NRC first promulgated its regulations setting out agreement states' authority to regulate some aspects of byproduct material use and disposal, the Commission reserved for itself – and denied to the states – the authority to license, or exempt from licensing, the transfer of possession or control over any “equipment, device, commodity or other product containing source, byproduct or special nuclear material that could be “distribut[ed] to the general public.” (10 CFR 150.15.) The reason was clearly stated:

The uncontrolled distribution of atomic materials in products designed for distribution to the general public, such as consumer type devices and the ultimate uncontrolled release of these materials into the environment, involve questions of national policy which have not yet been resolved. It is for this reason that the Commission is retaining control over such products. (21 Fed. Reg. 1351, Feb. 14, 1962.)

Does the NRC still retain control over such products and the “ultimate” uncontrolled release of those materials? If the answer is in the negative, please explain and provide supporting documentation.

4. Have the questions of national policy referred to in the 1962 *Federal Register* notice been resolved? Please provide copies of any documents that support a statement of resolution.
5. In 1969, the term “general public” was deleted from 10 CFR 150.15. The rewritten section prohibited transfer of byproduct material to “all other persons exempted” from an NRC license. Did this change reduce or expand the number of persons and/or products covered by the prohibition? Please explain and provide supporting documentation.
6. Byproduct material is defined by statute as “radioactive material (except special nuclear material) that is a byproduct of the process of producing or utilizing special nuclear material.” (42 U.S.C. 2014(e).) Under 10 CFR 30.71, technetium-99 is listed as a byproduct material. Since January 1, 1999, has the NRC removed technetium-99 from

the byproduct material list? If the answer is in the affirmative, please provide supporting documentation.

7. The Department of Energy has 6,000 tons of nickel barrier from its gaseous diffusion plant in Oak Ridge, Tennessee, which contains technetium-99. This contaminated material resulted from the uranium enrichment process undertaken at this plant. Is the technetium a "byproduct of the process of producing or utilizing special nuclear material"? If not, please describe what it is and provide any documentation supporting a different definition.
8. MSC intends to melt the nickel barrier, remove some, but not all, of the technetium-99, and sell the resulting product to whomever wishes to purchase it. Is this nickel a product containing byproduct material as defined by 42 U.S.C. 2014(e) and 10 CFR 30.71?
9. In its contract with BNFL, the Department of Energy has described the contaminated nickel as "process equipment" that may be recycled and released as scrap metal by MSC, an NRC-licensed facility. (See East Tennessee Technology Part (ETTP) Three-Building Decontamination and Decommissioning (D&D) and Recycle Project Contract, August 25, 1997, Attachment A, pp. 23, 33-34.) Please explain why recycling and release as scrap metal does not constitute the "transfer" of a product containing byproduct material to exempt persons does not require a license from the NRC under Part 30.3. Please provide supporting documentation.
10. Is it the NRC's understanding that the nickel contaminated with technetium-99 which will be released by MSC into interstate commerce without any restrictions on use may find its way into a host of consumer products, such as tableware, orthodontic braces, caps for baby food jars, cans used for food and beverages, automobiles, intrauterine devices, hip replacement devices, and all other products that incorporate steel and/or of various types?
11. As of January 1, 1999, by regulation (published in 10 CFR 150.1 *et seq.*), the NRC has prohibited agreement states from exempting persons from the Commission's licensing and regulatory requirements in 10 CFR Parts 30-40 who carry out the following activity: "The transfer of possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material or byproduct material whose subsequent possession, use, transfer and disposal by all other persons are exempted from licensing and regulatory requirements of the Commission under Parts 30 and 40 of this chapter." (10 CFR 150.15.) That prohibition is repeated in 10 CFR 30.3. Has there been any regulatory revision of this prohibition since January 1, 1999? Please provide copies of any such revisions.
12. Article III of the agreement between the NRC and the State of Tennessee incorporates the prohibition cited in 10 CFR 150.15 and 10 CFR 30.3 as a limitation on the State's authority. Has there been any revision of Article III that now allows the State of

Tennessee to exempt persons from the Commission's licensing and regulatory requirements under Parts 30 and 40 who are undertaking the activities listed in 10 CFR 150.15? Please provide copies of any such revisions.

13. The MSC nickel containing the byproduct material appears to be one or more of the following: "equipment, device, commodity, or other product containing source material or byproduct material." (10 CFR 150.15.) Please describe which of the above categories are applicable to the MSC nickel. If it is the NRC's position that none applies, please explain and provide supporting documentation.
14. Under its license amendment, the State of Tennessee has permitted MSC to transfer "possession or control" of metal containing technetium-99 to anyone who wishes to purchase or otherwise use it. Are those persons "exempt from the licensing and regulatory requirements of the Commission under Parts 30 . . . of this chapter"? If they are, under what authority does Tennessee issue such a license? If the answer is in the negative, please explain and provide documentation.
15. The transfer of byproduct material by NRC licensees to exempt persons is prohibited in 10 CFR 150.15 and 10 CFR 30.3 without certain licenses from the NRC itself. Is it the NRC's position that the sale or transfer of byproduct material by MSC to exempt persons is not covered by these regulations? If so, please explain and provide supporting documentation.
16. NRC regulations in 10 CFR 30.14 (c) and (c) requires that anyone introducing any concentration of byproduct material into a "product or material" must have a "specific license issued by an agreement State, the Commission, or the Atomic Energy Commission expressly authorizing such introduction." Persons who put the material in a product "knowing or having reason to know" it will be transferred to exempt persons have a specific prohibition. This appears to cover both MSC and any subsequent purchaser of the MSC nickel who plans to incorporate it into another product or commodity, such as a carload of nickel scrap or steel or nickel products. How does the NRC or the State of Tennessee plan to determine that each one of these processors and manufacturers has a "specific license" to incorporate this material into their products? Please explain and provide supporting documentation.
17. 10 CFR 30.14 further limits the introduction of byproduct material in less than exempt concentrations into both industrial and consumer products to those applications in which the byproduct material is used for its radioactive purposes. This can only be done by a holder of an NRC or agreement state license. The byproduct material released by MSC will be inserted into many products by numerous persons. Will it be released only for applications in which it will be used for its radioactive purposes by licensees with "express authorization" in their license to do so? If not, please explain why these regulations do not apply and provide supporting documentation.

18. The specific license requirements for the introduction of byproduct material into a product or material – even in exempt concentrations – and the transfer of ownership or possession to an exempt person are governed by 10 CFR 32.11. These requirements are numerous and specifically provide that the material not be incorporated into any product designed for application to a human being. Are these regulations applicable to persons obtaining byproduct material from MSC? If they are not applicable to persons who obtain byproduct material from MSC, please explain why and provide documentation.
19. 10 CFR 30.11 specifically prohibits the introduction of byproduct material into other products that are designed “for application to a human being.” Some of the potential uses for the nickel containing byproduct material are earrings, orthodontic braces, hip replacement devices and intra-uterine devices. Are these products designed for application to a human being? If not, please explain why not and provide supporting documentation.
20. 10 CFR 32.18 establishes the requirements for obtaining a license to release byproduct material in exempt quantities for commercial distribution to a person without a license. Does MSC’s license amendment allow it to release byproduct material in exempt quantities for commercial distribution to a person without a license? If the answer is in the affirmative, please explain and provide supporting documentation.
21. According to 10 CFR 32.18, prior to transfer from a licensee to a person exempt from licensing, the byproduct material must be in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources or similar substances, be identified as radioactive and to be used for its radioactive properties, cannot be incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution.
 - (a) Will the MSC nickel containing byproduct material be in one of the above forms? If so, state which one and provide documentation of that form.
 - (b) Will the MSC byproduct material be identified as radioactive? If the answer is in the affirmative, please provide documentation of the labeling requirements or other methods of identification. If the answer is in the negative, please explain why this material is not required to be identified as radioactive and provide supporting documentation.
 - (c) Will the MSC byproduct material be used for its radioactive properties? If the answer is in the affirmative, please provide documentation of that use. If the answer is in the negative, please explain why this material is not required to be used for its radioactive properties and provide supporting documentation.

(d) Will the MSC byproduct material be incorporated into a commodity intended for commercial distribution? If the answer is in the negative, please explain and provide supporting documentation.

22. Under 10 CFR 32.18-.19, the applicant must submit, and the NRC approve, prototype labels and brochures for each container of byproduct material which include the following statements: (a) the material is exempt from licensing; (b) the label will bear these specific words: "Radioactive Material -- Not for Human Use -- Introduction Into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or Into Products Manufactured for Commercial Distribution is Prohibited -- Exempt Quantities Should Not be Combined"; and (c) set forth appropriate additional radiation safety precautions and instructions about handling, use, storage, and disposal of the radioactive material.

Does the MSC license amendment permitting release of the DOE nickel contaminated with byproduct material mandate any of these labeling requirements? Please explain your response and provide supporting documentation.

23. As described in the MSC license amendment, does the 6,000 tons of nickel containing byproduct material to be transferred by MSC contain in total more or less than the exempt quantity of technetium listed in 10 CFR 30.71? Please explain and provide supporting documentation.
24. 10 CFR 32.19 requires that no more than 10 individual packages containing exempt quantities of byproduct material shall be contained in an outer package or sold or transferred in a single transaction to an exempt person. Does MSC's license to transfer byproduct material contain that restriction? If not, please explain and provide supporting documentation.
25. Is NRC Regulatory Guide 1.86 -- which the NRC is using to release surface-contaminated metal from decommissioned nuclear power plants -- a regulation under the Administrative Procedure Act? What force of law does it have? Please explain and provide supporting documentation.
26. Regulatory Guide 1.86 cites no statutory or regulatory authority for its implementation, but in its recent issue paper, the NRC stated that Regulatory Guide 1.86 was compliant with the case-by-case reviews for alternative disposal provided for under the Part 20 regulations. (See 64 Fed. Reg. 35090, 35092, 35095, June 30, 1999.) In the Atomic Energy Act and in the NRC's implementing regulations, "disposal" is defined as "isolation" of a radioactive waste. (See e.g., 42 U.S.C. 2021h; 10 CFR 61.2; 62.2; and 110.2.)

Please explain under what authority the NRC classified the unrestricted release of byproduct material into interstate commerce as "disposal" providing "isolation" of

radioactive waste under the above-cited statute and regulations. Provide supporting documentation.

27. Is the MSC facility an NRC licensee undergoing decommissioning?
28. In 1986, the Congress ordered the NRC to “identify methods of the disposal of low-level radioactive waste other than shallow land burial, and establish and publish technical guidance regarding licensing” of those facilities. Technical requirements for those methods are outlined in the statute. They include “site suitability, site design, facility operation, disposal site closure, and environmental monitoring, as necessary to meet the performance objectives established by the Commission for a licensed low-level radioactive waste disposal facility.” (42 U.S.C. 2021h.) (Emphasis added.)

Please explain how the unrestricted release of byproduct material into interstate commerce as an alternative method of disposal meets the “performance objectives established by the Commission for a licensed low-level radioactive waste disposal facility” and provide supporting documentation.

29. The resulting NRC report on alternative methods of disposal was published in December 1986. Entitled “Licensing of Alternative Methods of Disposal of Low-Level Radioactive Waste”(NUREG-1241), the study began by stating that all “siting, design, operations, closure, and the monitoring criteria” of Subpart D (Technical Requirements for Land Disposal Facilities) of 10 CFR 61 (Licensing Requirements for Land Disposal of Radioactive Waste) should apply. Subpart D limits off-site releases of radioactive material to those which is released “to the general environment in ground water, surface water, air, soil, plants, or animals.” (See 10 CFR 61.41.)

Please explain how the unrestricted release of byproduct material into interstate commerce is an alternative method of disposal limiting off-site release of radioactive material to those contained “in ground water, surface water, air, soil, plants, or animals.” Provide supporting documentation.

30. 10 CFR 20.2002 allows the NRC only to license alternative forms of “waste disposal.” Please explain how unrestricted release qualifies as an alternative form of waste disposal, based on definition in the statute, regulations and NRC report cited in the previous questions. Provide supporting documentation.
31. The 1986 alternate method report reported on five types: below-ground vaults, above-ground vaults, earth-mounded concrete bunkers, mined cavities and augured holes and specifically refers to Subpart D, 10 CFR 61. Please explain how unrestricted release of byproduct material into interstate commerce compares with the criteria applied to these listed alternate methods of disposal and provide supporting documentation.

32. 10 CFR Part 20 covers all persons licensed by the Commission to “receive, possess, use, transfer, or dispose of byproduct . . . material . . . under Parts 30 through 35.” (10 CFR 20.1002.) Is there any other section in Part 20 that exempts MSC from the requirements of Parts 30-35? If the answer is in the affirmative, please explain and provide supporting documentation.
33. 10 CFR 20.1302 allows for some radioactive material from the normal operations of a licensee to be released in gaseous and liquid effluents. At the boundary of the licensee’s restricted area, these releases must meet certain standards. Effluent is most commonly defined as “waste material (as smoke, liquid industrial refuse, or sewage) discharged into the environment especially when serving as a pollutant.” Does the NRC or the State of Tennessee have a different definition of “effluent” that would include products or commodities sold into interstate commerce? Please explain and provide supporting documentation.
34. In its recent issues paper, the NRC stated that although Part 20 provided for the release of air and liquid effluents from licensees’ operations, it was “inconsistent” because it did not have a standard for a release of solid material, presumably as an effluent.

Please explain how 6,000 tons of nickel to be sold into interstate commerce can be defined as a solid “effluent” emanating from a licensee’s normal operations and released for natural dispersion at the boundary of the licensee’s restricted area similar to the gaseous and liquid effluents. Provide supporting documentation.

35. In the same issues paper, the NRC stated that Part 20 does not have a provision for the release of solid material. This does not appear to be accurate, as 10 CFR 20.2003 allows for the disposal by release of “licensed material” into sewerage if it is “readily soluble” in water.

Please state whether this provision allows solid material to be released under certain conditions and provide supporting documentation.

36. Please explain how, under Part 20, MSC would release its solid byproduct material at the boundary of its restricted area and how it will carry out the other provisions requiring monitoring of those releases for persons “continuously present” at the boundary of the licensee’s restricted area. Provide supporting documentation.
37. In its contract with BNFL, the Department of Energy has described the contaminated nickel as “process equipment” that may be recycled and released as scrap metal by MSC, an NRC-licensed facility. (See East Tennessee Technology Plant (ETTP) Three-Building Decontamination and Decommissioning (D&D) and Recycle Project Contract, August 25, 1997, Attachment A, pp. 23, 33-34.) Please explain how recycling and release as scrap metal qualifies as the disposal of waste. Provide supporting documentation.

38. Since 1992, has the NRC promulgated through the regulatory process under the Administrative Procedure Act an unrestricted release standard for solid material of any type that contains byproduct material in any form? If the answer is in the affirmative, please provide supporting documentation.
39. Based on the above response, has the NRC established a legally binding release standard for solid material of any type containing byproduct material in any other process? Please explain and provide supporting documentation.
40. If there are such release standards, under what statutory and/or regulatory authority did the NRC issue them?
41. Section 274(j)(1) of the Atomic Energy Act allows the Commission to terminate or suspend all or part of its agreement with a state if it finds that the state's program is not compliant with the statute. Section 274 (g) requires that radiation standards be "coordinated and compatible." (See 42 U.S.C. 2021 (g) and (j)(1).) In September of 1997, the NRC adopted its "Statement of Principles and Policy for the Agreement State Program Policy Statement on Adequacy and Compatibility of Agreement State Programs." It was published in the *Federal Register* after extensive public comment. (See 62 Fed. Reg. 46517, Sept. 3, 1997.)

Specifically, compatibility is defined in the policy as "program elements necessary to meet a larger nationwide interest in radiation protection generally limited to areas of regulation involving radiation protection standards and activities with significant transboundary implications." (See "The Commission Policy," Subsection III (B).) State radiation control programs are compatible only when they do "not create conflicts, duplications, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis." (See "Compatibility," Subsection III (E).) State standards for release limits "should be essentially identical to those of the Commission, unless Federal statutes provide the State authority to adopt different standards." (See "Basic Radiation Protection Standards," Subsection III (E) (A).)

Several years ago the NRC attempted to establish a level of byproduct contamination "below regulatory concern" that would allow the release of solid byproduct material. In 1992, Congress ordered the NRC to halt that rulemaking. In June of this year, the NRC published in the *Federal Register* an issue paper on the release of solid materials at licensed facilities. In that paper, the Commission states that it "has no specific regulatory requirements regarding release of solid material," and that it wants "to establish a regulatory framework more consistent with existing NRC requirements on air and liquid releases."

(a) Are those accurate statements as of this date?

(b) How does the State of Tennessee have an "essentially identical" standard to one promulgated by the NRC for the release of solid material containing byproduct material when there is no standard? Please explain and provide supporting documentation.

42. Under the agreement state policy, radiation control programs should be based on a common regulatory philosophy including the common use of definitions and standards. "They should be not only effective and cooperatively implemented by NRC and the Agreement States, but also should provide uniformity and consistency in program areas having national significance."

Do the NRC, Tennessee and the other agreement states have common definitions for such words as "waste," "disposal," "effluent," "byproduct material," "transfer" and "release limits"? Please provide those definitions

43. This policy, under the authority of Section 274 (j)(1) of the Atomic Energy Act, requires that the NRC must consider suspending or terminating its agreement with agreement states if their release standards are not compatible with the NRC's and the other agreement states. Please describe the release standards for solid material containing byproduct material of the other agreement states and answer the following questions:

(a) Is it possible for any agreement state to set a completely different standard for the release of solid material containing byproduct material? Please explain and provide any supporting documentation.

(b) Is it possible for any or all other states to ban the import of MSC nickel released under the Tennessee license from entering their states? Please explain and provide any supporting documentation.

(c) Would such actions by other states in response to Tennessee's setting of a standard for the unrestricted release of byproduct material "create conflicts, duplications, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis"? If the answer is in the negative, please explain why different state standards for release "create conflicts, duplications, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis."

44. The agreement state policy also requires that "Regulations and regulatory decisions should be based on assessments of the best available information from affected and interested individuals and organizations, as well as on the best available knowledge from research and operational experience. . . . The public should have an opportunity for early involvement in significant regulatory program decisions." (Subsection C (1) .)

By everyone's evaluation, the unrestricted release of 6,000 tons of byproduct material into interstate commerce is a "significant regulatory program decision." The public received no notice or the opportunity to comment on the MSC license amendment. Is this in keeping with the policy statement cited above? Please explain.

45. Under this policy the agreement states are required to provide the NRC with information about their regulations and license conditions. When and how did the NRC receive information concerning the MSC license amendment?

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October 25, 1999

M E M O R A N D U M

JAMES E. DERDERIAN, CHIEF OF STAFF

TO: The Honorable John D. Dingell, Ranking Member
Committee on Commerce

The Honorable Ron Klink, Ranking Member
Subcommittee on Oversight and Investigations

The Honorable Edward Markey, Ranking Member
Subcommittee on Telecommunications, Trade, and Consumer Protection

FROM: Commerce Committee Democratic Staff

SUBJECT: Tennessee's Lack of Authority under Section 274 (b) of the Atomic Energy Act to
License the Unrestricted Release of Radioactive Byproduct Material

Summary

In March of 1999, the State of Tennessee approved a license amendment for Manufacturing Sciences Corporation (MSC) permitted the unrestricted sale of 6,000 of nickel metal contaminated with technitium, a radioactive byproduct of the process of producing or utilizing special nuclear material. The contaminated nickel resulted from the uranium enrichment process carried out at the Oak Ridge gaseous diffusion plant by the Department of Energy (DOE). MSC believes that it has a process that will reduce the amount of byproduct contamination in the nickel, but it cannot eliminate it.

Agreement states of the Nuclear Regulatory Commission (NRC) are prohibited from licensing the unrestricted release for general use of any quantities of radioactive byproduct material by the Commission's regulations as published in 10 CFR 150.15 and 10 CFR Parts 30. These regulations are completely in keeping with the policies set long ago by the Atomic Energy Act, the Congress, and the Nuclear Regulatory Commission to tightly control the use of byproduct material and keep it out of interstate commerce except by specific NRC license.

Since the NRC first promulgated its regulations in 1962 setting out agreement states' authority to regulate some aspects of byproduct material use and disposal, the Commission has reserved for itself -- and denied to the states -- the authority to license, or exempt from licensing, the transfer of possession or control over any "equipment, device, commodity or other product containing source, byproduct or special nuclear material that could be "distribut[ed] to the general public." (10 CFR 30.3.) The reason was clearly stated:

The uncontrolled distribution of atomic materials in products designed for distribution to the general public, such as consumer type devices and the ultimate uncontrolled release of these materials into the environment, involve questions of national policy which have not yet been resolved. It is for this reason that the Commission is retaining control over such products. (21 Fed. Reg. 1351, Feb. 14, 1962.¹)

The resulting rule specifically imposed Commission licensing requirements on the following activity:

The transfer of possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material, intended for use by the general public. (10 CFR Part 150.15 (a)(6) (1962 version).)

Those national policy questions have not been settled to this day, and the regulations remain basically as they were first written with some clarifying changes that expanded further the NRC's control. Tennessee's agreement with the NRC incorporates the ban against state licensing of the release of byproduct material to exempt purposes. Article III, Agreement between Atomic Energy Commission and the State of Tennessee, Aug. 21, 1965.

In 1969, the Commission deleted "for use by the general public" because of difficulties in definition. It was replaced by "all other exempted persons," an even broader definition of prohibited transferees. Currently, persons in agreement states are not exempt from the Commission's licensing or regulatory requirements for the following activities:

¹The prior history of the Atomic Energy Commission's and the NRC's refusal to allow any other party to transfer byproduct material to exempt persons is well discussed in 21 Fed. Reg. 16 (Jan 11, 1956); 23 Fed Reg. 8428 (Oct. 31, 1958); 26 Fed. Reg. 7886 (Aug. 2, 1961; and 26 Fed. Reg. 9174-76 (Sept. 29, 1961)). The last of these published prior to the 1962 rule prohibiting state control over byproduct material sales and transfers to exempt persons stated that the Commission needed to consider "whether continued Federal control over such products is needed to assure that appropriate limits are maintained on the total quantity of atomic energy material entering into our general environment." It determined that such control was necessary, a ruling that has not been revoked.

(a)(6) The transfer of possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material or byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from licensing and regulatory requirements (10 CFR Part 150.15.) (Emphasis added)

In 1992, the Commission attempted to set standards of contamination that would be "below regulatory concern" and, therefore, allow the unrestricted release of the contaminated material. As the NRC recognized, there was such tremendous public opposition that the Congress ordered in the Energy Policy Act of 1992 that the rulemaking be halted. (*See* 64 Fed. Reg. 35094.)

In short, it appears that Tennessee cannot license MSC transfer a commodity or product (nickel) containing byproduct material (technetium) to a person exempt from NRC or agreement state licensing authority without a specific license to do so from the NRC itself. Under these regulations, MSC is therefore barred from selling the nickel to a scrap dealer, for example, or a mini-mill, or any other party without an NRC license. The Commission may obtain an injunction to prevent such a violation, and there are criminal penalties for "willful violations" of these regulations. (*See* 10 CFR 30.63-64.)

The NRC's regulations for a license to release any quantity of byproduct material to unlicensed recipient are extensive and strict as described in more detail below. The most important restriction is that the byproduct material must be used for its radioactive qualities. There are specific requirements for each device incorporating byproduct material. Warning labeling requirements are often required. For licensees who sell individual, otherwise exempt quantities byproduct material in a bulk form, such as in processed chemical elements, to exempt persons, the byproduct material must be used for its "radioactive properties" and cannot be incorporated into any "commodity . . . intended for commercial distribution." Each exempt quantity must contain a label stating that it is radioactive, not for human use or to be introduced into "Products Manufactured for Commercial Distribution." (*See* 10 CFR 30.18 and 32.18-19.)

The MSC license on its face violates these regulations. The byproduct material in the bulk nickel is not being used for its radioactive properties; it is a contaminant that cannot be removed. And, MSC's publicly stated intent is to sell this contaminated bulk nickel specifically for its incorporation into products manufactured for commercial distribution, some of which will be designed for human use and application, and others which will contain food and beverages. All of these actions are in direct violation of the NRC's regulations.

NRC's Licensing and Labeling Requirements

NRC's licenses for the unrestricted release of byproduct material are governed by the very stringent regulations in 10 CFR Parts 30-35. These regulations govern the actions of both the

NRC and its agreement states. From their initial publication, Part 30-35 regulations have concentrated on establishing exempt products, product specifications, requirements for testing and labeling and restrictions on use for products available to the public consumer. (See 27 Fed. Reg. 1351.) This has not changed to the present time. Except for specifically identified devices produced under a separate NRC license, (see, e.g, 10 CFR Part 31), almost all transfers of byproduct material into general commerce are banned without a license from the NRC itself.

For any owner or possessor of a product containing byproduct material to be exempt from the licensing requirements for the transfer of byproduct material under Part 30, that material in the product to be transferred must be in concentrations less than specified and “introduced into the product or material by a licensee holding a specific license issued by an agreement State, the Commission or the Atomic Energy Commission expressly authorizing such introduction.” (See 10 CFR 30.14.) Moreover, this exemption specifically does not authorize “for purposes of commercial distribution the production, packaging, repackaging, or transfer or byproduct material or the incorporation of byproduct material into products intended for commercial distribution.” And no person may transfer materials in certain individual quantities (which we believe the nickel will meet) “knowing or having reason to believe that such quantities of byproduct material will be transferred to persons exempt . . . except in accordance with a license issued under [Sec.] 32.18 . . . which license states that the byproduct material may be transferred by the licensee to persons exempt. . . .” (See 10 CFR 30.18.)

It does not appear that MSC can meet any of these requirements. Byproduct material was not introduced into its product by a licensee with specific authorization to do so, but was the actual result of the process of producing or utilizing special nuclear material. It is intending that its product be commercially distributed, and it knows that the byproduct material will be transferred to persons exempt, *i.e.*, scrap dealers, steel mills, manufacturers and, ultimately, the general public. Therefore, MSC requires a specific license under 10 CFR 32.18 to transfer its material to exempt persons.

However, there is no evidence that MSC has a license for the release of this material to exempt persons under 10 CFR 32.18. This part contains several requirements that MSC cannot meet:

(1) The byproduct material cannot be contained in any commodity designed for application to a human being. *We know that some of the potential uses of the nickel are for devices that are applied to human beings, such as orthodontic braces and intra-uterine devices.*

(2) The byproduct material must be in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources or similar substances, “identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for

commercial distribution.” (Emphasis added.) *The MSC byproduct nickel does not meet any of these requirements. It will not be in the proper form; it will not be identified as radioactive; it will not be used for its radioactive properties; and it will be incorporated into a commodity intended for commercial distribution.*

(3) The applicant must submit, and the NRC approve prototype labels and brochures for each container which include the following statements: (a) the material is exempt from licensing; (b) the label will bear these specific words: “Radioactive Material -- Not for Human Use -- Introduction Into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or Into Products Manufactured for Commercial Distribution is Prohibited -- Exempt Quantities Should Not be Combined”; and (c) set forth appropriate additional radiation safety precautions and instructions about handling, use, storage, and disposal of the radioactive material. (See 10 CFR 32.18-19.) *Again, MSC's license from Tennessee includes none of these labeling requirements, although its product is intended for commercial distribution and its use in steel containers for food and beverages is anticipated.*

Part 32 also includes provisions for specific licenses to manufacture certain items containing byproduct material, such as self-luminous devices, radioactive drugs, gas and aerosol detectors and certain consumer products listed in 10 CFR 30.15.

Therefore, it appears all persons who add byproduct material – no matter how much or how little – to a product intended for unrestricted use by exempt persons are subject to the NRC’s licensing requirements. This provision appears to include not only MSC, but anyone who ultimately uses DOE’s contaminated nickel to manufacture commercial products.

It appears then that both individually and when read as a whole, the NRC’s regulations ban all unrestricted transfers of any amount of byproduct material from a licensee to persons exempt from licensing without a specific license from the NRC itself. Those specific licenses are narrow and require many additional steps to be taken to protect the ultimate consumer.

Unrestricted Release of Byproduct Material as a Form of “Waste Disposal” or “Effluent Release” from the “Routine Activities” of an NRC Licensee

It appears more and more likely that both the NRC and Tennessee are attempting to avoid the stringent licensing restrictions of Parts 30-35 by determining that MSC’s sale of nickel contaminated with technetium is a form of “waste disposal” under 10 CFR Part 20 (Standards for Protection against Radiation), Subpart K (Waste Disposal) or, in the alternative, is a solid “effluent” emitted during the plant’s operations to the nearby public similar to gaseous and liquid effluents released into unrestricted areas by the plant. (See, e.g, 10 CFR 20.1302.)

When the major rewriting of Part 20 was begun in 1986, its stated purpose was to “provide the requirements for the protection of individuals who are exposed, both within and without of the workplace, to ionizing radiation from routine activities (normal operations) which are licensed by the NRC.” (See 51 Fed. Reg. 1092, Jan. 9, 1989.) (Emphasis added.) It set worker exposures, public exposure limits from gaseous and liquid effluents released from the licensee’s boundaries into unrestricted areas, and waste disposal. Part 20 governs all licensees, including those under Parts 30-35. It did not govern the deliberate production and/or release of radioactive material into interstate commerce for general use nor supersede those regulations. Not a single mention of such a purpose is made in the hundred-plus pages of the proposed rule.

Nonetheless, the NRC’s recent issue paper, which it has published as a precedent to a rulemaking that would allow the unrestricted release of radioactively contaminated materials into interstate commerce, indicates that it is only proposing another “radiation protection” standard under 10 CFR Part 20 that set a release standard from a licensed facility for solid effluents similar to those for gaseous and liquid effluents. (See 64 CFR 35090, June 30, 1999.) If so, this will mark the first time in environmental history that tons of processed metal ingots are referred to as “effluent.”²

There are numerous statutory and regulatory hurdles to these interpretations that require the acceptance of extremely creative legal theories and some leaps of legal faith. Additionally, the contaminated nickel is not a waste resulting from MSC’s “routine activities.” MSC’s waste is whatever contaminants it manages to remove from DOE’s nickel by its own clean-up process. As is stated in the BNFL contract with the Department of Energy, MSC is to take DOE’s contaminated waste nickel, process it and attempt to get a license to sell it. (See East Tennessee Technology Part (ETTP) Three-Building Decontamination and Decommissioning (D&D) and Recycle Project Contract, August 25, 1997, Attachment A (hereafter “BNFL Contract, Attachment A”), pp. 22-3, 33, 37.)

Unrestricted Release of Byproduct Material as “Waste Disposal”

As stated above, Part 20 of NRC’s regulations do not contemplate that a company that processes and partially cleans radioactively contaminated materials for unrestricted sale into interstate commerce is “disposing” of waste generated in its routine operations. The contract between BNFL and the Department of Energy does not describe the nickel resulting from the melting and processing of the barriers used in enrichment as waste. It describes it as “process equipment” which it is encouraged to recycle to “promote waste minimization.” “Disposal” is described as another “dispositioning option.” MSC will produce other wastes resulting from the use of its clean-up technology in its routine licensed operations. The Energy Department’s

²According to Webster’s Dictionary, “effluent” comes from the “effluvium”, the Latin word for the act of flowing out. It is defined as “waste material (as smoke, liquid industrial refuse, or sewage) discharged into the environment esp. when serving as a pollutant.”

contract with BNFL describes these wastes in detail. They include “[a]ll radiological and chemical wastes generated as a result of metal processing beyond the primary melt.” (See BNFL Contract, Attachment A, pp. 22-3, 33, 37.)

Low-level radioactive wastes are to be disposed of pursuant to 10 CFR Part 20. The Atomic Energy Act defines *disposal* as:

“the permanent *isolation* of low-level radioactive waste pursuant to the requirements established by the Nuclear Regulatory Commission under applicable laws, or by an Agreement state if such *isolation* occurs in such agreement State.” (42 U.S.C. 2021b (7) .) (Emphasis added.)

10 CFR 61 (Licensing Requirements for Land Disposal of Radioactive Waste), defines disposal as:

“... [T]he *isolation* of radioactive wastes from the biosphere inhabited by man and containing his food chains by emplacement in a land disposal site.” (10 CFR 61.2.) (Emphasis added.)

Elsewhere in the NRC regulations, disposal has similar meanings. It is defined as: “the *permanent isolation* of low-level radioactive waste pursuant to requirements established by the Nuclear Regulatory Commission under applicable laws, or by an Agreement State if such isolation occurs in this Agreement State. (10 CFR 62.2.) (Emphasis added.); and “*permanent isolation* of radioactive material from the surrounding environment” (10 CFR 110.2.). (Emphasis added.)

10 CFR Part 20, Subpart K (Waste Disposal) does not contain a new, more expansive definition of disposal but further reinforces the standard definition of isolation. Subpart K’s specified methods of disposal allow licensees to dispose of radioactive waste by 1) transfer to an authorized recipient; 2) decay in storage; 3) release in liquid and gaseous effluents under NRC; release into sanitary sewers for small amounts of “readily soluble” material under certain limited condition; and treatment or disposal by incineration -- again under restrictive circumstances. An authorized recipient is defined as someone “specifically licensed to receive waste containing licensed material” for treatment prior to disposal; treatment or disposal by incineration; decay in storage or disposal. (See 10 CFR 20.2001-2005.)

Clearly, what Tennessee contemplated in the MSC license amendment was not “isolation” of any sort. Nor does Part 20 exempt licenses from the requirements of Parts 30-35 concerning release of byproduct material for use by exempt persons. (See 10 CFR 20.1002 (Scope).)

10 CFR 20.2002 (“Method for obtaining approval of proposed disposal procedures”) does allow licensees to apply to use a method of disposal of radioactive waste not otherwise specified

-- and some incineration methods must be authorized under Part 20 (*see* 10 CFR 20.2004), but again it does not change the statutory definition of "disposal" as "*permanent isolation.*" This section was not set up as a loophole for the commercial release of byproduct material.

The NRC has been studying alternative disposal methods since at least 1981. These have included mined cavity disposal, below-ground vaults, above-ground vaults, earth-mounted concrete bunkers, deep-well injection and hydrofraction, among others. In 1986, Congress ordered the NRC to "identify methods of the disposal of low-level radioactive waste other than shallow land burial, and establish and publish technical guidance regarding licensing" of those facilities. Technical requirements that such facilities must meet include "site suitability, site design, facility operation, disposal site closure, and environmental monitoring, as necessary to meet the performance objectives established by the Commission for a licensed low-level radioactive waste disposal facility." (42 U.S.C. 2021h.) (Emphasis added.)

Those alternative methods of disposal were identified in December of 1986 in a publication entitled "Licensing of Alternative Methods of Disposal of Low-Level Radioactive Waste," NUREG-1241. The study began by stating that all "siting, design, operations, closure, and the monitoring criteria of Subpart D (Technical Requirements for Land Disposal Facilities) of 10 CFR 61 (Licensing Requirements for Land Disposal of Radioactive Waste) should apply. Off-site releases of radioactive material are limited to those which is released "to the general environment in ground water, surface water, air, soil, plants, or animals." (10 CFR 61.41.) Once again, unrestricted release into interstate commerce for commercial use is not sanctioned.

The NRC's Regulatory Guide 1.86, under which it has been releasing metals and other materials that are surface-contaminated into interstate commerce, is alleged to be issued under the authority of 10 CFR 20.2002. Based on the above statutory provisions, regulations and guidance, that appears to be an improper use of that section. 10 CFR 20.2002 requires that the "proposed manner and conditions of waste disposal" be described. It does not provide that the waste so disposed of is exempted from disposal requirements and thus miraculously avoids the licensing requirements for release of byproduct material to exempt persons.

The NRC can exempt its licensees from the requirements of Part 20 "if it determines the exemption is authorized by law and would not result in undue hazard to life or property." (10 CFR 20.2301.) It does not appear that this provision has been used or this determination has been made. The steel industry, for example, was not allowed to address potential damage to its property from this release. It has indicated that the inclusion of a steady stream of even slightly contaminated metals into their steel plants can accumulate to the point where their entire facilities are contaminated. The clean up and the subsequent loss of confidence of their customers could cost them billions of dollars.

Unrestricted Release of Byproduct Material as a "Solid Material Effluent"

In its issues paper entitled "Release of Solid Materials at Licensed Facilities," published on June 30, 1999 (64 Fed. Reg. 35090), the NRC takes the intriguing position that it needed to repair the Part 20 regulatory "inconsistencies" because it does not provide for the release of "solid materials" as it does for gaseous and liquid effluents generated from the normal operations of a licensee. "Effluent" is most commonly defined as "waste material (as smoke, liquid industrial refuse, or sewage) discharged into the environment especially when serving as a pollutant." (Webster's Dictionary.) Part 20 does not revise this common meaning. The gaseous and liquid effluents allowed for release in Part 20, are those that are released as a pollutant from an operating facility off-site into the nearby environment.

It does not appear that the NRC desires to be so consistent with these regulations that it plans to also provide for the release of "solid effluents" into the nearby environment to sit there waiting for dissipation through some as-yet-undefined natural process.

An even closer reading of Part 20 uncovers that there already is a provision for the disposal of certain small amounts of solid waste into the environment – just as there is for certain small amounts of gaseous and liquid waste – and no need for a change to achieve "consistency." 10 CFR 20.2003 allows the release of "readily soluble" licensed material into sanitary sewers if it does not exceed certain amounts. For some reason, this provision does not satisfy the NRC.

It appears that both individually and in their entirety, the NRC's regulations ban all unrestricted transfers of any amount of byproduct material from a licensee to persons exempt from licensing without a specific license from the NRC itself. Additionally, we have found nothing in the regulations that indicate that "disposal" of byproduct material is to be interpreted so broadly that unrestricted release into commerce is accepted form of "disposal."

Tennessee's Lack of Compatibility with NRC Regulations and Standards

It also appears that the State of Tennessee is taking actions incompatible with the NRC's regulations and standards that require the NRC to consider suspending or terminating its agreement with Tennessee.

In September of 1997, the NRC adopted its "Statement of Principles and Policy for the Agreement State Program Policy Statement on Adequacy and Compatibility of Agreement State Programs," hereafter "Agreement State Policy." It was published in the *Federal Register* after extensive public comment "to assure adequate protection of public health and safety." (See 62 Fed. Reg. 46517, Sept. 3, 1997.)

This policy requires that the NRC must consider suspending or terminating its agreement with the State of Tennessee because one of the three elements in Tennessee's program that must be compatible with the NRC's and the other Agreement States' program is not. The incompatibility results from the establishment by the State of Tennessee of radiation protection standards for the release of solid material volumetrically contaminated with technitium, a byproduct material. The NRC has not promulgated any regulations for such releases. This compatibility is required by Section 274j(1) of the Atomic Energy Act and cited at length in the policy statement. (See "Comment Summary," Subsection III (A).)

Specifically, compatibility is defined as "program elements necessary to meet a larger nationwide interest in radiation protection generally limited to areas of regulation involving radiation protection standards and activities with significant transboundary implications." (See "The Commission Policy," Subsection III (B).) State radiation control programs are compatible only when they do "not create conflicts, duplications, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis." (See "Compatibility," Subsection III (E).) State standards for release limits "should be essentially identical to those of the Commission, unless Federal statutes provide the State authority to adopt different standards." (See "Basic Radiation Protection Standards," Subsection III (E) (A).) Since the NRC has set no release standard in this area and is in the process of beginning a rulemaking to consider those release standards, Tennessee cannot establish a standard in an individual license amendment.

Additionally, the Agreement States are required to provide a level of protection in its program elements, including standards, that "should be equivalent to, or greater than, the level provided by the NRC program." However, under the compatibility requirement, matters of health and safety are not to be considered. Those come under a different category. (See NRC, "Transmittal of Directive 5.9, Adequacy and Compatibility of Agreement State Programs.")

One of the objectives of Directive 5.9 was to "identify Commission regulations and program elements that must be implemented as legally binding requirements by an Agreement State to maintain a program that is . . . compatible with NRC's regulatory program. (See Directive 5.9, Objectives.)

One of the principles that pervades this statement is that "Regulations and regulatory decisions should be based on assessments of the best available information from affected and interested individuals and organizations, as well as on the best available knowledge from research and operational experience. . . . The public should have an opportunity for early involvement in significant regulatory program decisions." (Subsection C (1).) (Emphasis added.) Additionally, NRC and the agreement states have the responsibility to ensure that consistent and compatible radiation control programs are administered. Such radiation control programs should be based on a common regulatory philosophy including the common use of definitions and standards. They should be not only effective and cooperatively implemented by NRC and the

Agreement States, but also should provide uniformity and consistency in program areas having national significance.

Such areas include those affecting interstate commerce . . . (Subsection C(4).)
(Emphasis added.)

During the public comment period for this policy, one state specifically commented that it did not believe that Section 274 of the Atomic Energy Act required compatibility of programs or program elements except for requirements under the Uranium Mill Tailings Radiation Act. The policy specifically rejected that comment, stating that:

It is the Commission's view that, pursuant to Section 274, an Agreement State's program should be compatible with the NRC's program for the duration of the Agreement for the following reasons:

Subsection 274(g) authorizes and directs the Commission to cooperate with the States in the formulation of radiation protection standards "to assure that the State and Commission programs for the protection against hazards of radiation will be coordinated and compatible . . .

Subsection 274(j)(1) calls on the Commission to suspend or terminate an Agreement State's program if "the state has not complied with one or more of the requirements" of the Section 274. The Commission believes that this phrase "one or more of the requirement," encompasses all requirements of Section 274, including the requirement for compatibility. ("Policy Statement, III. Policy Statement on Adequacy and Compatibility of Agreement State Programs," Subsection A.)

A second principle is that the NRC expects the Agreement states to "provide it with early and substantive involvement in the development of new Suggested State Regulations. NRC and Agreement States will keep each other informed about their individual regulatory requirements (e.g., regulations or license conditions)." ("Policy State, II. Statement of Principles and Policy for the Agreement State Program," Subsection J.) NRC staff told Committee staff that they were totally unaware of Tennessee's actions until they received a letter from Reps. Dingell and Klink in August.

Nonetheless, in March of this year, without public notice or input, Tennessee, an NRC agreement state, established its own standard for the unrestricted release of metal contaminated with two radioactive isotopes, uranium and technetium-99.

The Commission apparently thought this to be a "program area having national significance" in the past as it attempted previously to set a national standard, but it failed because of widespread public opposition. As a result, neither the NRC nor any of its agreement states

have attempted to license on-going releases of such material. In fact, the NRC just began the pre-rulemaking process again by conducting public hearings to discuss setting a standard.