

U.S. NUCLEAR REGULATORY COMMISSION DIRECTIVE HANDBOOK (DH)

DH 5.9	ADEQUACY AND COMPATIBILITY OF <u>PROGRAM ELEMENTS FOR AGREEMENT STATE PROGRAMS</u>	DT-XX-XX
Volume 5	Governmental Relations and Public Affairs	
Approved By:	[Name and Title of Approving Official]	
Date Approved:	Month X, <u>20XX</u> [Date of Final Approval]	
Expiration Date:	Month X, <u>20XX</u> [Usually 5 years after Date Approved, Do Not Round to Nearest Work Day If Date Falls on Weekend or Holiday]	
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EXECUTIVE SUMMARY

Directive and Handbook 5.9 are being issued to establish the process NRC staff will follow to determine when a proposed or final program element is required for compatibility or health and safety, and to identify NRC program elements needed for compatibility or health and safety.

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I. INTRODUCTION

A. Overview

The U.S. Nuclear Regulatory Commission (NRC) Agreement State Program Policy Statement ~~on Adequacy and Compatibility of Agreement State Programs~~ sets forth the approach that the NRC will use to determine those program elements that must 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 must 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)."

B. Agreement State Policy Statement

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 NRC presumes that the implementation of the NRC's materials regulatory program elements affords a level of protection that provides a reasonable assurance of adequate protection of public health and safety. Legally binding requirements (i.e. regulations, license conditions, orders) can be used to implement these program elements within the State.
2. An Agreement State radiation control program is compatible with the NRC'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 may be considered program elements for adequacy. Further, basic radiation protection standards and program elements that cross jurisdictional boundaries, although important for health and safety within the State, should be uniform nationwide for compatibility purposes.
3. On the basis of the policy statement, NRC program elements (including regulations) can be placed into five compatibility categories (A, B, C, D, and NRC). In addition, NRC program elements can also be identified as having particular health and safety significance (H&S). These six categories (A, B, C, D, NRC, and H&S) form the basis for evaluating and classifying NRC program elements. These are summarized below.
 - (a) Compatibility Category 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.
 - (b) Compatibility Category B

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

(c) ~~Compatibility~~-Category C

NRC program elements in Category C ~~are include~~ those program elements that do not meet the criteria of Category A or B, but the essential objectives of which are important for an Agreement State ~~should adopt to have in order~~ 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 regulations and other program elements. The Agreement State program elements may be more restrictive than the NRC program elements provided that the essential objective is met, and the State requirements do not jeopardize an orderly pattern of regulation of the material nationwide.

(d) ~~Compatibility~~-Category D

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

(e) Health and Safety

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 must 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.

(f) Areas of Exclusive NRC Regulatory Authority

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 must not be adopted by Agreement States.

II. CATEGORIZATION CRITERIA

Many program elements for compatibility (categories A, B or C) may also affect public health and safety; therefore, they also may be considered program elements for adequacy.

A. Compatibility Category A¹

1. 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.
2. Examples include, but are not necessarily limited to:
 - (a) Public dose limits (e.g., 10 CFR 20.1301) plus any regulation that relates directly to these dose limits
 - (b) Concentration and release limits
 - (c) Occupational dose limits (e.g., 10 CFR 20.1201) plus any regulation that directly relates to these dose limits
 - (d) Dose limits in 10 CFR 61.41
 - (e) Radiation symbol
 - (f) Caution signs and labels
 - (g) Scientific terms (e.g., conventional and Systeme Internationale units, definitions of types of radioactive material)
 - (h) Definitions needed for common understanding (e.g., restricted area, year, stochastic)

C. Compatibility Category B²

1. 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~~ cross jurisdictional boundaries
2. Examples include, but are not necessarily limited to:
 - (a) Transportation requirements (e.g., low level radioactive waste manifests, packaging requirements)

¹~~Many program elements for compatibility may affect public health and safety; therefore, they also may be considered program elements for adequacy.~~

²~~Many program elements for compatibility may affect public health and safety; therefore, they also may be considered program elements for adequacy.~~

- (b) Requirements for criminal history records checks of individuals granted unescorted access to category 1 or category 2 quantities of radioactive material
- (c) Requirements for approval of products that are distributed nationwide (e.g., sealed sources and devices)
- (d) Definitions of products (e.g., sources and devices) that licensees routinely transport in multiple jurisdictions
- (e) Content and format of sealed source and device registration certificates.

D. Compatibility Category C³

1. 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~~ must implement in order to avoid conflicts, duplications, or gaps or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis. Such Agreement State Program elements shall embody the essential objective of the corresponding NRC program element and that, if not adopted/implemented, would result in an undesirable consequence. Definitions The essential objective(s) for a particular regulation may be found in the Statements of “conflict,” “duplication,” and “gap” are included in the Glossary of this handbook. Consideration published with the final rule in the Federal Register. For other program elements required for compatibility, the essential objectives may be found in the letter transmitting the requirement to the Agreement States.
2. Examples of undesirable consequences include, but are not necessarily limited to:
 - (a) Exposure to an individual in a different jurisdiction in excess of the basic radiation protection standards established for compatibility in Category A
 - (b) Undue burden on interstate commerce (e.g., additional record-keeping or training requirements)
 - (c) Preclusion of an effective review or evaluation by the NRC and Agreement State programs for agreement material with respect to protection of public health and safety and security
 - (d) Preclusion of a practice authorized by the AEA in the national interest
 - (e) Absence or impairment of effective communication (e.g., failure to report incidents to the NRC)

³ ~~Many program elements for compatibility may affect public health and safety; therefore, they also may be considered program elements for adequacy.~~

- (f) Lack of minimum level of safety for agreement material-containing products distributed nationwide
 - (g) Disruption of the regulation of agreement material on a nationwide basis
3. Examples of program elements in this category include, but are not necessarily limited to:
- (a) Reports of lost or stolen agreement material or ~~mis-administrations~~ medical events
 - (b) Radiation surveys for industrial radiographers and well loggers
 - (c) Documents and records required at temporary job sites
 - (d) License termination requirements

E. Compatibility Category D

NRC program elements that do not meet any of the criteria of Category A, B, or C, ~~above, or have~~ a particular health and safety role are Category D and are not required to be adopted for the purposes of compatibility.

F. Health and Safety

1. An NRC program element that is not required for compatibility and could result directly (i.e., two or fewer failures⁴) 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.
2. Examples of such program elements include, but are not necessarily limited to:
 - (a) Requirement for irradiator interlocks
 - (b) Safety checks for medical ~~teletherapy~~ gamma stereotactic radiosurgery facilities
 - (c) Package opening procedures.

G. Exclusive NRC Regulatory Authority

1. 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.

⁴ ~~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.~~

2. Examples include, but are not necessarily limited to:
 - (a) Issuance of licenses for production and utilization facilities
 - (b) Regulation of activities in federal offshore waters
 - (c) Issuance of licenses for distribution to exempt persons
3. Although an Agreement State may not adopt program elements reserved to NRC, it may wish to inform its licensees of certain requirements via [an appropriate](#) mechanism that is consistent with the particular State's administrative procedure laws, but does not confer regulatory authority on the State.
4. Examples include, but are not necessarily limited to:
 - (a) Agreement State licensee submission to the NRC of nuclear material transfer reports pursuant to 10 CFR 150.16
 - (b) 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
 - (c) Agreement State licensee submission to the NRC of tritium reports pursuant to 10 CFR 150.19

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 [illustrated](#) 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.

- A. 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).
- B. 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).

- C. Question (3): Do the essential objectives of the program element address or define an issue that ~~has a significant, direct transboundary implication?~~cross jurisdictional boundaries? 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).
- D. Question (4): Would the absence of the essential objectives of the program element from an Agreement State program create a conflict or gap? Would the addition of the essential objectives of the program element in the Agreement State program be duplicative? If the responses to these questions are “yes,” the ~~compatibility~~ category is “C.” If the responses to the questions are “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.
- E. 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: or category H&S. If the response to the question is “no,” then the program element should be identified as category “D.”

IV. APPLICABILITY TO NRC PROGRAM ELEMENTS

A. Current NRC Program Elements

The compatibility category and identification of particular health and safety significance for current NRC program elements that are applicable to the regulation of agreement materials are found in the Office of Nuclear Materials Safety and Safeguards (NMSS) State Agreement (SA) Procedure, “Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements – SA-200.”

B. Future NRC Regulations and Other Program Elements

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” and current NMSS Policy and Procedures.⁵ The NRC staff are to use this handbook to determine the compatibility category or to identify particular health and safety significance for each draft rulemaking plan.

⁵ <https://scp.nrc.gov/procedures.html>

The Standing Committee on Compatibility (Committee) will review proposed rules that are a matter of compatibility with the Agreement States and provide feedback to the Project Manager preparing the rulemaking package to amend the NRC regulations. The Commission Paper requesting publication of the proposed rule for comment should address the Committee's findings and any unresolved designations. The final rule should be provided to the Committee if there are any changes to compatibility designations, any new sections to the rule, and when there were unresolved compatibility designations with the proposed rule. Revisions to NRC program elements that are applicable to the regulation of agreement materials and matter of compatibility with the Agreement States should also be reviewed by the Committee.

V. APPLICABILITY TO AGREEMENT STATE PROGRAM ELEMENTS

B. ~~Current Agreement State Program Elements~~

~~1. Regulations~~

- ~~(a) 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.~~
- ~~(b) 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.~~
- ~~(c) 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:
 - ~~(i) 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.~~
 - ~~(ii) 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.~~~~

~~(iii) 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~~

~~2. Program Elements~~

~~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.~~

~~A. Future Agreement State Program Elements~~

3. General

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.

4. Future Regulations

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 [NMSS Procedures "Review of State Regulatory Requirements - SA-201"](#) and "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements - SA-200." Results of the evaluation will be transmitted to the State in accordance with ~~OSP~~[NMSS](#) 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)."~~

5. ~~Future~~ New or Changed Program Elements

The 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 MD 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)" at the time of the next regularly scheduled review.

B. Evaluation of Applications for Agreement State Status

The 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.

VI. ADDITIONAL IMPLEMENTING ISSUES

A. Use of Management Directive 5.9

The overall determination of adequacy and compatibility of individual Agreement State programs will be made in accordance with MD 5.6. 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 [the results of NRC's review are available](#) to the IMPEP review team at the time of the State's next program review.

B. Essential Objectives

1. The essential objective of each NRC program element in [compatibility](#) Category C or identified as having particular health and safety significance [must](#) be adopted by the Agreement State. ~~The term "essential objective" is defined in the Glossary of this handbook.~~
2. 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.
3. 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.

C. Essentially Identical

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 of 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.

D. Legally Binding Requirements

1. 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.
2. 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.
3. 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.

E. Timeframes for Adoption

1. The NRC regulations that should be adopted by an Agreement State for purposes of compatibility or health and safety should be adopted and implemented 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.
2. 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 NRC will agree upon a mutually acceptable timetable for adoption and implementation.

3. 4The Standing Committee on Compatibility will review the time frames for adoption for proposed regulations and program elements and provide feedback to the Project Manager. The Committee's finding for time frames for adoption should be addressed as detailed in Section IV.B. of this handbook.

F. Resolution of Compatibility Designation and Interpretive Issues

The Standing Committee on Compatibility should be consulted regarding any compatibility designation or interpretive issues involving regulations or program elements. Resolution of compatibility matters brought to the attention of the Committee should be documented in accordance with NRC policies and procedures.

VII. 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.

Cross Jurisdictional. A practice or licensed activity that is conducted in multiple jurisdictions and under separate regulatory authorities (Agreement State or NRC) within the United States. This does not include activities conducted between the United States and other nations.

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

Effective Date. The date the regulation or legally binding requirement can be enforced by the regulatory agency.

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.

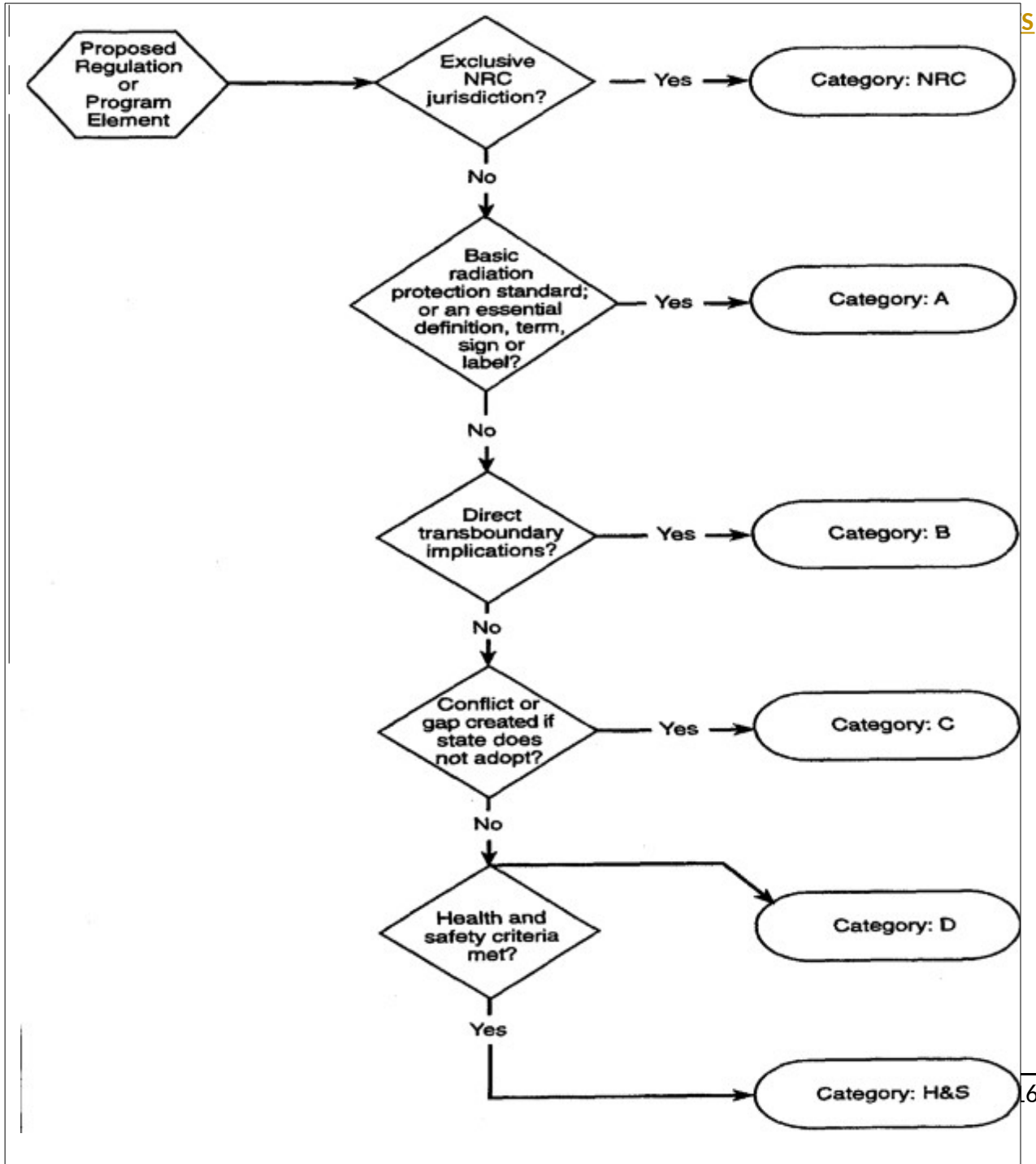
Program element. Any component or function of a radiation control regulatory program, including regulations and/or other legally binding requirements imposed on regulated persons; that contributes to implementation of that program.

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

Two or fewer failures. The concept embodied by “two or fewer failures” is that if the essential objective of the program element were not adopted or implemented, then an event could occur that would not have taken place if the essential objective was adopted. There is a higher probability that an event could occur, 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.

EXHIBIT

FLOW CHART 1



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EXHIBIT CHARACTERIZATION PROCESS FOR PROPOSED NRC REGULATIONS AND PROGRAM ELEMENTS

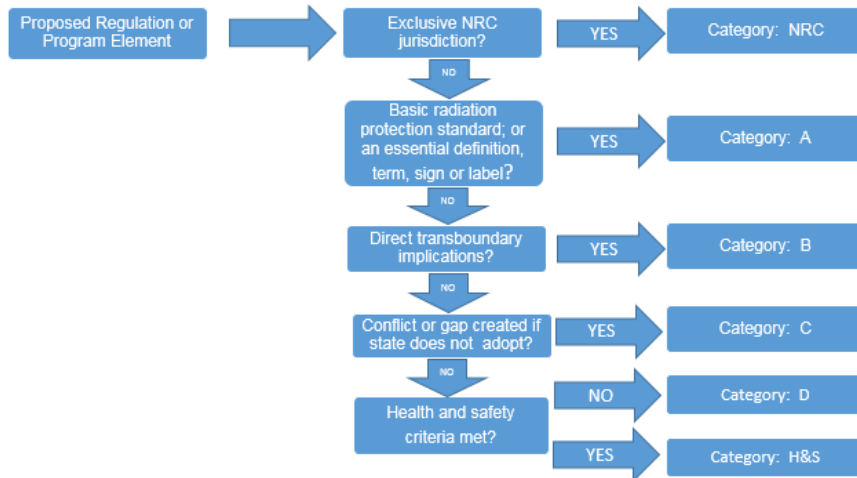


EXHIBIT CHARACTERIZATION PROCESS FOR PROPOSED NRC REGULATIONS AND PROGRAM ELEMENTS

