

Elements of the NARM rulemaking transition plan May '06 -NRC

- o **Transition plan goal** to ensure the orderly transition of regulatory authority over NARM nationwide. As authorized by the Energy Policy Act (EPAAct) of 2005, NRC issued a waiver to provide time to establish rules, allow states to establish 274b Agreements and to ensure an orderly transition of authority. It is in effect through August 7, 2009.
- o **Currently**, the draft proposed NARM rule is available, via NRC website, for early review while under Commission consideration. A public Commission briefing on this rule and other EPAAct items is scheduled for May 15. CRCPD and OAS will be represented. The NRC staff has worked closely with the Agreement and non-Agreement State representatives on the Task Force to develop a draft transition plan that addresses all potential transition scenarios, and is consistent with the language of the EPAAct. The proposed implementation strategy, upon which the transition plan is based, is described in the proposed rule FRIN.
- o **June-July 2006** For NRC budget planning purposes, NRC is considering sending a letter to Governors requesting response on intent of requesting authority for NARM. Two types of letters: 1) existing Agreement States; and 2) non-Agreement States.
- o **June- July 2006** NARM proposed rule issued for public comment and Draft Transition Plan coordinated with OAS and CRCPD.
- o **Fall 2006** Final Transition Plan provided to States prior to publication.
- o February 2007 NARM final rule published. Effective 60 days after publication.
- o February-April 2007 Final transition plan published.
- o February 2007-April 2007 [**date the transition plan is published**] **For EXISTING AGREEMENT STATES** That Intend to Continue to Regulate NARM, the Governor must Certify* on the Date the Transition Plan Is Published That the Current State Program Is Adequate for NARM and the State Intends to Regulate NARM.
- * **What is certification?** The Governor must certify by letter, as stated above, to the Chairman of NRC on the date of publication of the final transition plan. NRC will review the certification and determine if the waiver can be terminated immediately. (Energy Policy Act of 2005 allows NARM to be added to the 274b Agreement without amendment if the Governor certifies to the NRC on the date of publication of the final transition plan).

- o **Now August 2008* FOR NON-AGREEMENT STATES**, the Governor may either:
1) request to enter into an Agreement under 274b or; 2) notify the NRC that the State does not plan to request to enter into an Agreement at this time.

·By August 2008, allows NRC to ensure an orderly and phased transition of NARM licensees in non-Agreement States to NRC. This proposed approach will also allow NARM users in States for which waivers are being terminated sufficient time to submit a license application (within 1 year) or amendment to an existing NRC license (within 6 months).

- o **August 2009 FOR NON-AGREEMENT STATES IN THE PROCESS OF ENTERING AN AGREEMENT**, NRC is considering options to work with the State to ensure a smooth transition and avoid having NARM licensees subject to State, then NRC, then State regulation.. .i.e., the whiplash effect.
- o **FOR FEDERAL FACILITIES AND FEDERALLY RECOGNIZED INDIAN TRIBES**, THE RULE BECOMES EFFECTIVE 60 DAYS AFTER PUBLICATION AND NRC WOULD EXERT ITS AUTHORITY OVER NARM. Currently, it is staff's intent to allow such entities to continue to use NARM without an NRC issued license under certain conditions for a limited period of time to allow for applying and being granted appropriate licensing.

Non-Agreement States

(Example: Non-Agreement State with licensing or registration program for NARM)

Agency with Regulatory Authority over NARM after 8/7/09

Item	Isotope(s)	Non-agreement state	NRC	Agreement State
XRF	Co-57	No	Yes (GL)	Yes
Flood sources	Co-57	No	Yes (GL, SL)	Yes
Moisture density gauge	Ra-226	No	Yes (SL)	Yes
PET Radio-Pharmaceuticals	F- 18 (FDG)	No	Yes (SL)	Yes
Prostate Seeds	Pd-103	No	Yes (SL)	Yes
Medical imaging isotopes (gallium, thallium, indium)	Ga-68 Th-201 In-111	No	Yes (SL)	Yes
Radioactivity removal system (diffuse NORM)	Ra-226	No **	No	Yes

Bottom line: After 8/7/09, non-agreement states will have little to no regulatory authority over radioactive materials due to expansion of NRC authority. However, initial incident response role will likely remain with state.

* NRC may assume regulatory authority earlier than 8/7/09 if state does not intend to pursue agreement state status.

** Although non-agreement states will retain authority over diffuse NORM (ex: radioactivity removal systems), state law may require change to allow oversight of Ra-226 radwaste generated by removal systems.

Agreement state status allows state to issue specific license for radioactivity removal systems and require financial assurance to ensure proper disposal of waste. In addition, agreement state status ensures continued state oversight of materials covered by new definition of byproduct material.

Impact of Energy Policy Act (2005) on State Regulation of Radioactive Materials

Overview

- **Energy Policy Act of 2005 (EP Act)** expands definition of byproduct material to include:
Any discrete source of Ra-226
Any accelerator produced radioactive material
Any discrete source of NORM, other than source material, that poses a similar public health and safety threat as Ra-226
- EP Act requires NRC to provide a regulatory framework for licensing and regulating the additional byproduct material.
- NRC has issued waiver of byproduct material requirements until August 7, 2009 unless terminated sooner.
- After 8/7/09 (or earlier*), States no longer may assert regulatory authority over the newly covered byproduct materials, unless they are an Agreement State.

Impact

Agreement States

- Agreement States make no distinction between NARM and byproduct material (radioactive material).
- Proposed definition of 'discrete' developed by NRC/Agreement States/federal agencies.
- Compatibility designation of new definition of 'byproduct material' being discussed.
- Governor may have to recertify state radioactive material program as adequate for NARM.

Additional Information

- NRC SECY-06-0069 Proposed Rule: Requirements for expanded definition of byproduct material
<http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2006/secy2006-0069/2006-0069scy.html>
- May 15, 2006: NRC webcast on implementation of EP Act
<http://www.nrc.gov/public-involve/public-meetings/webcast-live.html>
- September 25-28, 2006: OAS annual meeting; Mobile, AL. Considerable discussion of energy policy act and agreement state/radioactive material issues. Good opportunity to obtain information on agreement states and process. Visit OAS web site at www.agreementstates.org
- Office of State and Tribal Programs web site at <http://nrc-stp.oml.gov/>
- Wisconsin application for agreement posted on ADAMS (access at <http://www.nrc.gov/reading-rm/adams/web-based.html>)

Search using key words: **Wisconsin agreement state final application**

Note: Application has been divided into multiple parts.

Overview of the 1997 Commission Policy Statement on Adequacy and Compatibility

On the basis of the policy statement and MD 5.9, 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.

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

Compatibility Category C - program elements 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, but may be more restrictive.

Compatibility Category D - program elements that do not meet any of the criteria of Category A, B, or C, and do not need to be adopted by Agreement States for purposes of compatibility.

Health and Safety - 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.

NRC (Areas of Exclusive NRC Regulatory Authority)- program elements that address areas of regulation that cannot be relinquished to Agreement States and should not be adopted by Agreement States.

- The Statements of Consideration for each new rule or rule amendment, proposed or adopted in final since 1997, has contained a section on Agreement State compatibility, which in accordance with MD 5.9, identifies the assigned compatibility level for each section of the proposed or final rule.
- MD 5.9 provides all regulations should be adopted by the State no later than three years after the effective date, unless a different time frame is specifically directed by the Commission.

Rule Adoption and IMPEP

STP procedures provides guidance for NRC staff review of Agreement State regulations and legal binding requirements (LBR) that are adopted to satisfy compatibility program elements and health and safety program elements.

Agreement States submit proposed and final regulations and other generic LBR to the NRC for review to ensure they satisfy the assigned compatibility, or health and safety designation associated with the equivalent Commission regulation.

NRC's review identifies all significant differences between the NRC and the Agreement State rules in sections designated as Compatibility Categories A, B, C and H&S using staff regulation review checklist based on the final NRC regulation.

Under IMPEP reviews, the status of an Agreement State's regulations is a major factor in the determination of compatibility of each Agreement State program. Also the status of program elements that are designated as H&S are a factor in the determination of adequacy.

For the new authority for NARM in the Energy Policy Act of 2005, STP expects the IMPEP teams to review the following:

- . Status of Materials Inspection Program .timeliness of NARM inspections
- . Technical Quality of Inspections .NARM inspect accomp~niments and WARM aspects of inspections.
- . Technical Quality of Licensing Actions .NARM licensing activities
- . Technical Quality of Incident and Allegation Activities .NARM reports to NJMED (compatibility C element), NARM incidents and allegations
- . Compatibility Requirements .status of regulations addressing NRC amendments and any new changes in State legislation affecting agreement material