August 18, 2005

Ronnie Wascom, Administrator Emergency and Radiological Services Division Department of Environmental Quality 602 N. 5th, P.O. Box 4313 Baton Rouge, LA 70821-4313

Dear Mr. Wascom:

We have reviewed the proposed changes to the Louisiana Administrative Code, Title 33, Part XV, *Radiation Protection*, RP0034, RP0035, RP0036, RP0037, and RP0038, received by our office on April 11, 2005. These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) rules in 10 CFR Parts 20, 30, 31, 32, 35 and 36 and the requirements of the three amendments identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with Sharon Parker on May 26, 2005.

As a result of our review, we have five comments that have been identified in the enclosure. Please note that we have limited our review to regulations required for compatibility and/or health and safety. Under our current procedure, a finding that the Louisiana regulations meet the compatibility and health and safety categories of the equivalent NRC regulation may only be made based on a review of the final Louisiana regulations. However, we have determined that if your proposed regulations were adopted, incorporating our comments and without other significant change, they would meet the compatibility and health and safety categories established in the Office of State and Tribal Programs (STP) Procedure SA-200.

In addition, we reviewed the corrections to Louisiana Administrative Code, Title 33, Part XV, *Radiation Protection*, resulting from the NRC letters dated August 26, 2004, June 3, 2004, and July 31, 2003, as listed in the addendum to your April 11, 2005 letter. All of the changes noted in this addendum resolve our comments and these are closed. However we note that you indicated that the rest of the NRC comments, as listed in the addendum, will be addressed in a future rulemaking. In order to track the comments that still need to be addressed and for ease of future review, we have attached them to this letter.

As noted in the enclosure, two comments address Louisiana proposed regulations for generally licensed devices. Please note that we have a Petition For Rulemaking from the Organization of Agreement States (OAS) currently under review by NRC staff, and a request from OAS and the State of Florida to change the Compatibility Category assigned to sections of the GL rule. Staff is examining whether there may be need for additional guidance to Agreement States regarding the status of some Agreement State GL rules during the interim time the NRC will require to complete action on the Petition and request. We will correspond separately with you on this issue in the near future.

We request that when the proposed regulations are adopted and published as final regulations, a copy of the "as published" regulations be provided to us for review. As requested in STP Procedure SA-201, "Review of State Regulatory Requirements," please highlight the final changes and provide a copy to STP.

The SRS Data Sheet summarizes our knowledge of the status of other Louisiana regulations, as indicated. Please let us know if you note any inaccuracies, or have any comments on the information contained in the SRS Data Sheet. This letter, including the SRS Data Sheet, is posted on the STP website: http://www.hrsd.ornl.gov/nrc/rulemaking.htm.

If you have any questions regarding the comments, the compatibility and health and safety categories, or any of the NRC regulations used in the review, please contact me, or John Zabko at (301) 415-2308 or by e-mail at JGZ@NRC.GOV.

Sincerely,

\RA By K.N.Schneider For\

Dennis Rathbun, Deputy Director Office of State and Tribal Programs

Enclosures: As stated The SRS Data Sheet summarizes our knowledge of the status of other Louisiana regulations, as indicated. Please let us know if you note any inaccuracies, or have any comments on the information contained in the SRS Data Sheet. This letter, including the SRS Data Sheet, is posted on the STP website: http://www.hrsd.ornl.gov/nrc/rulemaking.htm.

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Sincerely,

\RA By K.N.Schneider For

Dennis Rathbun, Deputy Director Office of State and Tribal Programs

Enclosures: As stated

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LMcLean, RSAO, Kschneider, ASPO, BUSilton, Louisiana file Response to Incoming Document: ML051080512 DOCUMENT NAME:C:\NRC\Regs\LA Letter 5-115.wpd

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OFFICE	STP		STP		OGC		STP:DD	
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DATE	07/18/05*		07/19/05 *		08/15/05 *		08/18/05*	

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OFFICIAL RECORD COPY

COMMENTS ON PROPOSED LOUISIANA REGULATIONS AGAINST COMPATIBILITY AND HEALTH AND SAFETY CATEGORIES

ST	ATE SECTION	NRC Section	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	322 (D) (3)(d)	31.5(c) (4)	2001-1	В	Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere
					Louisiana has different record retention requirements for tests of the on-off mechanisms in section 322 (D) (3)(d). Section 10 CFR 31.5(c)(4) requires a three year retention.
					Louisiana needs to adopt a three year record retention time to meet the Compatibility Category B designation assigned to Section 10 CFR 31.5(c)(4).
2	322 (D) (3)(h)	31.5(c) (9)(ii)	2001-1	В	Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere
					Louisiana omitted the term "intermediate person" as added by this amendment.
					Louisiana needs to add the term "intermediate person" to to meet the Compatibility Category B designation assigned to Section 31.5(c)(9)(ii).
3	Title 33, Part XV§ 723	35.69	2002-2	H&S	Labeling of Vials and Syringes
					Louisiana does not cover all of the required elements of this section.
					Louisiana needs to adopt the essential objectives of the requirements for labeling of vials and syringes to meet the Category H&S designation assigned to Section 10 CFR 35.69.

ST	ATE SECTION	NRC Section	RATS ID CATEGORY		SUBJECT and COMMENTS
4	Title 33, Part XV§ 728	35.92	2002-2	H&S	Decay in Storage Louisiana does not limit the type of radioactive material that can be stored for decay as in 10CFR 35.92. Louisiana does not use the 120 day half life limit. Louisiana needs to adopt the essential objectives of the requirements for decay in storage to meet the Category H&S designation assigned to Section 10 CFR 35.92
5	None	35.400	2002-2	С	Use of sealed sources for manual brachytherapy Louisiana omitted Section 10 CFR 35.400. Louisiana needs to adopt Section 10 CFR 35.400 to meet the Compatibility Category C designation assigned to Section 10 CFR 35.400.

COMMENTS THAT REMAIN FROM PAST NRC LETTERS DATED JULY 31, 2003, JUNE 3 2004 AND AUGUST 26 2004.

STA [*]	TE TION	NRC Section	RATS ID	CATEGORY	SUBJECT and COMMENTS	STATE RESPONSE TO COMMENTS
1	442.A. 4.d & 442.A. 4.e	20.1703 (f)	1999-3	H&S	USE OF INDIVIDUAL RESPIRATORY PROTECTION Louisiana defines the minimum respiratory protection program expected of any licensee who assigns or permits the use of respirators to limit intake. Louisiana organization placed these provisions under the requirements for a written policy statement which does not achieve the same objective. Louisiana needs to adopt the essential objectives of the requirements for the licensee prior to assigning or permitting the use of respirators and not just a requirement for a written policy statement to meet the Category H&S designation assigned to Section 10 CFR 20.1703 (f).	Louisiana will address this comment in future rulemaking.
2	421	20.1301 (a) & (c)	2002-2	A	Dose limits for individual members of the public Louisiana Section 421.B allows access to be granted to members of the public to restricted areas. NRC Section 10 CFR 20.1301 states that access can only be granted to controlled areas. The words controlled and restricted cannot be used interchangeably. They are defined as two separate areas. Louisiana needs to change the wording of Section 421.B to reflect the difference between the controlled area and the restricted area to meet the Compatibility Category A designation assigned to Section 10 CFR 20.1003.	This comment will be corrected in future rulemaking.

STA [*] SEC	TE TION	NRC Section	RATS ID	CATEGORY	SUBJECT and COMMENTS	STATE RESPONSE TO COMMENTS
3	421	20.1301 (a) & (c)	2002-2	A	Dose limits for individual members of the public Louisiana omitted requirements of paragraph (c) of Part 20.1301 for members of the public visiting a person that cannot be released under 35.75 or equivalent Agreement State regulations. Louisiana needs to adopt requirements of paragraph (c) of Part 20.1301 to meet the Compatibility Category A designation assigned to Section 10 CFR 20.1003.	This comment will be corrected in future rulemaking.
4	102	35.2	2002-2	В	Definition: Authorized medical physicist Louisiana omitted the requirements of paragraph (1) of the definition of authorized medical physicist in 10 CFR 35.2, which defines the training and experience required for an authorized medical physicist. Louisiana needs to add a reference to the required training and experience for an authorized medical physicist to meet the Compatibility Category B designation assigned to this definition in Section 10 CFR 35.2.	This comment will be corrected in future rulemaking. This is part of amendment 2005-2, Agreement States have until April 29, 2008 to adopt these requirements

STA ⁻ SEC	TE TION	NRC Section	RATS ID	CATEGORY	SUBJECT and COMMENTS	STATE RESPONSE TO COMMENTS
5	102	35.2	2002-2	В	Definition: Authorized nuclear pharmacist Louisiana omitted the requirements of paragraph (1) of the definition of authorized nuclear pharmacist in Part 35.2, which defines the training and experience required for an authorized nuclear pharmacist. Louisiana needs to add a reference to the required training and experience for an authorized nuclear pharmacist to meet the Compatibility Category B designation assigned to this definition in Section 10 CFR 35.2.	This comment will be corrected in future rulemaking. This is part of amendment 2005-2, Agreement States have until April 29, 2008 to adopt these requirements
6	102	35.2	2002-2	В	Definition: Authorized user Louisiana omitted the requirements of paragraph (1) of the definition of authorized user in Part 35.2, which defines the training and experience required for an authorized user. Louisiana needs to add a reference to the required training and experience for an authorized user to meet the Compatibility Category B designation assigned to this definition in Section 10 CFR 35.2.	This comment will be corrected in future rulemaking. This is part of amendment 2005-2, Agreement States have until April 29, 2008 to adopt these requirements

STA ⁻ SEC	TE TION	NRC Section	RATS ID	CATEGORY	SUBJECT and COMMENTS	STATE RESPONSE TO COMMENTS
7	102	35.2	2002-2	В	Definition: Radiation Safety Officer Louisiana definition does not mention that the Radiation Safety Officer is required to be listed on the license as is found in the definition in Part 35.2. Louisiana needs to add language to the current definition to reflect that the radiation safety officer must be listed on the license to meet the Compatibility Category B designation assigned to this definition in Section 10 CFR 35.2.	This comment will be corrected in future rulemaking.
8	102	35.2	2002-2	В	Definition: Sealed Source Louisiana definition refers to a sealed source as any container of radioactive material constructed to prevent escape of material. The definition in 10 CFR 35.2 uses language that ensures the source is encased to prevent leakage and escape of material. Louisiana should revise their current definition to define that the source should be encased or encapsulated to prevent leakage or escape of material to meet the Compatibility Category B designation assigned to this definition in Section 10 CFR 35.2	This comment will be corrected in future rulemaking.

STA ^T	TE TION	NRC Section	RATS ID	CATEGORY	SUBJECT and COMMENTS	STATE RESPONSE TO COMMENTS
9	703	35.6	2002-2	С	Provisions for the protection of human research subjects Louisiana omitted the requirements of 10 CFR 35.6(b)(1) and (2) that require the licensee to obtain approval from an "Institutional Review Board" and the subject's "informed consent" prior to conducting federally conducted, funded, supported or regulated research activities. Louisiana needs to adopt the requirements requiring Institutional Review Board approval and patient informed consent research activities to meet the Compatibility Category C designation assigned to Section 10 CFR 35.6	This comment will be corrected in future rulemaking.
10	706 707	35.24	2002-2	D – paragraphs (a)(1), (a)(2), (a)(3), (c), (d), (e), (g), and (h) H & S- paragraph (b) and (f)	Authority and responsibilities for the radiation protection program Louisiana regulations do not require the radiation safety officer to agree in writing to assuming responsibility of the licensee's radiation protection program. The lack of this requirement may cause liability issues in the event of a violation or accident. Louisiana needs to add language to ensure that each licensee requires the radiation safety officer to assume responsibility of the radiation protection program in writing to meet the Category H&S designation assigned to Section 10 CFR 35.24.	This comment will be corrected in future rulemaking.

STA [*] SEC	TE TION	NRC Section	RATS ID	CATEGORY	SUBJECT and COMMENTS	STATE RESPONSE TO COMMENTS
11	763.O	35.59	2002-2	В	Recentness of training Louisiana requires training and experience to be acquired within five years of application. NRC regulations allow training to be acquired within seven years of application. Louisiana's regulations are more restrictive than those of the NRC. This could potentially have transboundary implications. Louisiana needs to adopt the requirements of Part 35,59 to meet compatibility.	This comment will be considered in future rulemaking.
12	736 737 742 743	35.310 35.315 35.410 35.415	2002-2	H&S	Safety instruction/Safety precautions Louisiana requires the radiation safety officer or the authorized user to be contacted in the event of the patient's or human research subject's death or medical emergency. NRC regulations require both the radiation safety officer or his/her designee and the authorized user to be contacted in the event of a death or medical emergency. Louisiana needs to change the language of their equivalent rule to ensure both the radiation safety officer or designee and the authorized user are contacted.	This comment will be corrected in future rulemaking.

STA ⁻ SEC	TE TION	NRC Section	RATS ID	CATEGORY	SUBJECT and COMMENTS	STATE RESPONSE TO COMMENTS
13	755	35.630	2002-2	H & S, except paragraph (c) is D	Louisiana's requirements for intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units do not require the licensee to use a comparable unit in reference to beam attenuators or collimators, as applicable, but does require the radionuclide to be the same as the source used at the licensee's facility. Louisiana needs to add additional language regarding the similarities in beam attenuators and collimators between units as found in 10 CFR 35.630(a)(2) to meet compatibility.	This comment will be corrected in future rulemaking.
14	757.A 759	35.642	2002-2	H & S, except paragraph (f) is D.	Periodic spot-checks for teletherapy units In Paragraph A.2.a of §757, Louisiana uses the term "constancy" instead of "accuracy." This may be an editorial error since similar language in other sections is correct; however, the error will cause compatibility issues.	This comment will be corrected in future rulemaking.

STA [*] SEC	TE TION	NRC Section	RATS ID	CATEGORY	SUBJECT and COMMENTS	STATE RESPONSE TO COMMENTS
15	757.A 759	35.642	2002-2	H & S, except paragraph (f) is D.	Periodic spot-checks for teletherapy units In Paragraph A.7.d of §757, Louisiana does not require the intercom system to be inspected during the safety-spot check. This may be an editorial error since similar language in other sections is correct; however, the error will cause compatibility issues. In Paragraph A.7.d of §757, Louisiana needs to add "intercom system" to the items inspected during the safety-spot check to meet compatibility.	This comment will be corrected in future rulemaking.

STATE REGULATION STATUS

State: Louisiana

[Three amendments reviewed are identified by a *

at the beginning of each equivalent NRC regulation.]

Date: August 18,

Tracking Ticket Number: 5-115 Date: August 18, 2005

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) / Final (F)¹ Rule / ML #⁵	NRC Review / Y, N² / Date /ML # ⁵	Final State Regulation ¹ (Effective Date)
Safety Requirements for Radiographic Equipment-Part 34	55 FR 843; (1/10/94)	1991-1			6/94
ASNT Certification of Radiographers-Part 34	56 FR 11504; (none)	1991-2			Not required ³
Standards for Protection Against Radiation-Part 20	56 FR 23360; 56 FR 61352; 57 FR 38588; 57 FR 57877; 58 FR 67657; 59 FR 41641; 60 FR 20183; (1/1/94)	1991-3	P	N 10/15/98	6/94
Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70	56 FR 64980; (10/15/94)	1991-4			6/94
Quality Management Program and Misadministrations-Part 35	56 FR 34104; (½7/95)	1992-1			11/98
Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions-Parts 30,35	57 FR 45566; (none)	1992-2			Not required ³
Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites]- Parts 30, 40	58 FR 39628; (10/25/96)	1993-1	P	N 4/4/97	
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715; (7/1/96)	1993-2			Not applicable SECY-95- 112⁴
Definition of Land Disposal and Waste Site QA Program-Part 61	58 FR 33886; (7/22/96)	1993-3	Р	N 4/4/97	Not applicable SECY-95-112 ⁴
Self-Guarantee as an Additional Financial Mechanism-Parts 30, 40, 70	58 FR 68726; 59 FR 1618; (none)	1994-1	F	N 1/6/99	Not required ³ 11/98
Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards-Part 40	59 FR 28220; (7/1/97)	1994-2			Not applicable SECY-95- 112⁴
Timeliness in Decommissioning Material Facilities-Parts 30, 40, 70	59 FR 36026; (8/15/97)	1994-3	F	N 1/6/99	11/98
Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use-Parts 30, 32, 35	59 FR 61767; 59 FR 65243; 60 FR 322; (1/1/98)	1995-1	F	N 1/6/99	11/98
Frequency of Medical Examinations for Use of Respiratory Protection Equipment- Part 20	60 FR 7900; (3/13/98)	1995-2	F	N 1/6/99	10/96
Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649; 60 FR 25983; (3/1/98)	1995-3	F	N 1/6/99	11/98

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) / Final (F)¹ Rule / ML #⁵	NRC Review / Y, N ² / Date /ML # ⁵	Final State Regulation ¹ (Effective Date)
Performance Requirements for Radiography Equipment-Part 34	60 FR 28323; (6/30/98)	1995-4	F	N 1/6/99	9/97
Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038; (8/14/98)	1995-5	F	N 1/6/99	11/98
Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70	60 FR 38235; (11/24/98)	1995-6	F	N 1/6/99	11/98
Medical Administration of Radiation and Radioactive Materials-Parts 20, 35	60 FR 48623; (10/20/98)	1995-7	F	N 1/6/99	11/98
10 CFR Part 71: Compatibility with the International Atomic Energy Agency-Part 71	60 FR 50248; 61 FR 28724; (4/1/99)	1996-1	F ML020280299	N 2/15/02 ML020460125	5/20/00
One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses-Parts 30, 40, 70	61 FR 1109; (none)	1996-2			Not required ³
Termination or Transfer of Licensed Activities: Recordkeeping Requirements-Parts 20, 30, 40, 61, 70	61 FR 24669; (6/17/99)	1996-3	Р	N 6/29/00	5/20/00
Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act-Part 20	61 FR 65120; (1/9/00)	1997-1	F ML011510385	N 11/15/01 ML013100191	
Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State-Part 150	62 FR 1662; (2/27/00)	1997-2	F ML011510385	N 11/15/01 ML013100191	
Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35	62 FR 4120; (5/29/00)	1997-3	F	N 1/6/99	11/98
Fissile Material Shipments and Exemptions-Part 71	62 FR 5907; (none)	1997-4			Not required ³
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations-Parts 30, 34, 71, 150	62 FR 28947; (6/27/00)	1997-5	F ML020280299	Y 2/15/02 ML020460125	8/20/01
Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39057; (8/20/00)	1997-6	F ML011510385	N 11/15/01 ML013100191	12/20/00
Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea- Part 30	62 FR 63634; (1/02/01)	1997-7	F	N 1/6/99	11/98
Deliberate Misconduct by Unlicensed Persons-Parts 30, 40, 61, 70, 71, 150	63 FR 1890; 63 FR 13773; (2/12/01)	1998-1	F ML011510385	N 11/15/01 ML013100191	12/20/00
Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees- Parts 30, 40, 70	63 FR 29535; (none)	1998-2			Not required ³

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) / Final (F)¹ Rule / ML #⁵	NRC Review / Y, N² / Date /ML # ⁵	Final State Regulation ¹ (Effective Date)
License Term for Medical Use Licenses-Part 35	63 FR 31604; (none)	1998-3			Not required ³
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations-Part 34	63 FR 37059; (7/9/01)	1998-4	P ML010460171	Y 4/13/01 ML011060084	
Minor Corrections, Clarifying Changes, and a Minor Policy Change-Parts 20	63 FR 39477; 63 FR 45393; (10/26/01)	1998-5	F ML011510385	Y 11/15/01 ML013100191	12/20/00
Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127; (11/20/01)	1998-6			
Radiological Criteria for License Termination of Uranium Recovery Facilities-Part 40	64 FR 17506; (6/11/02)	1999-1			
Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information-Part 31	64 FR 42269; (none)	1999-2			Not required ³
Respiratory Protection and Controls to Restrict Internal Exposure-Part 20	64 FR 54543; 64 FR 55524; (2/2/03)	1999-3	F ML041880305	N 8/26/04 ML042390322	
Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1	P ML041880305	Y 8/26/04 ML042390322	
New Dosimetry Technology-Parts 34, 36, 39	65 FR 63750; (1/8/04)	2000-2	F ML041880305	N 8/26/04 ML042390322	
★ Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material - Parts 30, 31, 32	65 FR 79162; (2/16/04)	2001-1	P ML051080512	Y 8/18/05 ML052310429	
★Revision of the Skin Dose Limit- Part 20	67 FR 16298; (4/5/05)	2002-1	P ML051080512	N 8/18/05 ML052310429	
★ Medical Use of Byproduct Material-Parts 20, 32, and 35	67 FR 20249;(10/24/05)	2002-2	P ML051080512	Y 8/18/05 ML052310429	
Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments – Part 71.	69 FR 3697; (10/01/07)	2004-1			
Security Requirements for Portable Gauges Containing Byproduct Material - Part 30	70 FR 2001; (7/11/08)	2005-1			

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) / Final (F)¹ Rule / ML #⁵	NRC Review / Y, N² / Date /ML # ⁵	Final State Regulation ¹ (Effective Date)
Medical Use of Byproduct Material - Recognition of Specialty Boards - Part 35	70 FR 16336; (4/29/08)	2005-2			

- 1. Or other generic Legally Binding Requirements.
- 2. (Y/N) Y means "Yes," there are comments in the review letter that the State needs to address. N means "No," there are no comments in the review letter.
- 3. Not required means these regulations are not required for purposes of compatibility.
- 4. A State need not adopt a specific regulation if the State has no licensees that would be subject to that regulation. See: "Final Policy Statement on Adequacy and Compatibility of Agreement State Programs," III.1. Time Frame for Adoption of Compatible State Regulations, p. 6, SECY-95-112, May 3, 1995.
- 5. ADAMS ML Number