April 3, 2006

Kirksey Whatley, Director Alabama Office of Radiation Control PO Box 303017 Montgomery AL 36130-3017

Dear Mr. Whatley:

We have reviewed the proposed changes to the Alabama regulations in the Alabama Radiological Health Rules 420-3-26-.07, "Use of Radionuclides in the Healing Arts," received by our office on February 15, 2006. These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) rules in 10 CFR Parts 20, 32 and 35 and the requirements of the two amendments identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with David Walter on April 3, 2006.

As a result of our review, we have nine 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 Alabama 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 Alabama 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.

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 Alabama 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: <u>http://www.hsrd.ornl.gov/nrc/rulemaking.htm</u>.

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 Mr. Osiris Siurano at 301-415-2307 or by e-mail at osp@nrc.gov.

Sincerely,

\RA By KNSchneider For\

Dennis K. Rathbun, Deputy Director Office of State and Tribal Programs

Enclosures: As stated Kirksey Whatley, Director Alabama Office of Radiation Control PO Box 303017 Montgomery AL 36130-3017

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COMPATIBILITY COMMENTS ON ALABAMA PROPOSED REGULATIONS

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	420-3-26- .07(2)(d)	§35.2	2002-2	В	Definition: Authorized medical physicist Alabama has incorrect references to 420-3-2607(27) and (29) regarding the requirements of the authorized medical physicist. The correct references are in the State sections 420-3-2607(27) and (30). Alabama needs to correct the references in 420-3-26.07(2)(d) to meet the compatibility category B
2	420-3-26- .07(2)(d)	§35.2	2002-2	В	assigned to 10 CFR 35.2. Definition: Authorized medical physicist The State regulation requires that the individual must meet the requirements in (27) or (30), and other requirements. Requirements in (27) and (30) should be inclusive (i.e., and) and exclusive (i.e., or) for the other requirements. Alabama needs to correct this to meet the compatibility category B assigned to 10 CFR 35.2.
3	420-3-26- .07(2)(e)	§35.2	2002-2	В	Definition: Authorized nuclear pharmacist Alabama has incorrect references to 420-3-2607(28) and (29) regarding the requirements of the authorized nuclear pharmacist. The correct references are in State sections 420- 3-2607(27) and (30). Alabama needs to correct the references in 420-3-26.07(2)(e) to meet the compatibility category B assigned to 10 CFR 35.2.

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
4	420-3-26- .07(2)(e)	§35.2	2002-2	В	Definition: Authorized nuclear pharmacist
					The State regulation requires that the individual must meet the requirements in (28) or (30), and other requirements. Requirements in (28) and (30) should be inclusive (i.e., and) and exclusive (i.e., or) for the other requirements.
					Alabama needs to correct this to meet the compatibility category B assigned to 10 CFR 35.2.
5	420-3-26-	§35.2	2002-2	С	Definition: Prescribed dosage
	.07(2)(bb)				Alabama has incorrect references to 420-3-2607(2)(bb), which are not equivalent to §35.100 and §35.200. The correct State sections equivalent to §35.100 and §35.200 are 420-3-2607(45) and (48).
					Alabama needs to correct the references in 420-3-2607(2)(bb) to meet the compatibility category C assigned to 10 CFR 35.2.
6	420-3-26- .07(2)(ee)	§35.2	2005-2	В	Definition: Radiation Safety Officer
	.01(2)(00)				Alabama has incorrect references to 420-3-2607(27) and (29) regarding the requirements of the radiation safety officer. The correct references are in State sections 420-3-2607(27) and (30).
					Alabama needs to correct the references in 420-3-2607(27) and (29) to meet the compatibility category B assigned to this definition.
7	420-3-26- .07(2)(ee)	§35.2	2005-2	В	Definition: Radiation Safety Officer
	(_)(00)				The State regulation requires that the individual must meet the requirements in (26) or (30). These requirements should be inclusive (i.e., and).
					Alabama needs to correct this to meet the compatibility category B assigned to this definition.

STA	TE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
8	420-3-26- .07(26)	§35.50	2002-2	В	Training for Radiation Safety Officer
					Alabama incorrectly referenced 420- 3-2607(51)(a) regarding the rule under which a specialty board's certification process is recognized in 420-3-2607(26)(c)(1). The correct reference should be to State section 420-3-2607(27)(a).
					Alabama needs to correct the references in 420-3-26-07(26)(c)(1) to meet the compatibility category B assigned to 10 CFR 35.50.
9	420-3-26- .07(48)	§35.200	2002-2	H&S	Use of Unsealed Byproduct Material for Imaging and Localization Studies for Which a Written Directive is not Required
					The State regulation requires that radioactive material for imaging and localization studies be prepared by an authorized nuclear pharmacist or physician who meets the requirements in 420-3-2607(51). The state did not include 420-3-26- .07(56) as an exclusive (i.e., or) requirement that this individual may also meet.
					Alabama needs to revise 420-3-26- .07(48) to meet the compatibility category H&S assigned to 10 CFR 35.200.

STATE REGULATION STATUS

State: Alabama

[2 amendments reviewed are identified by a i at the beginning of each equivalent NRC regulation]			Tracking Ticket Number: 6-53 Date: April 3, 2006				
NRC Chronology Identification	FR Notice (Date Due for State Implementation)	RATS ID	Proposed (P) / Final (F) ¹ Rule / License Condition (LC) ML # ⁴	NRC Review / Y, N ² / Date / ML # ⁴	Final State Regulation ¹ (Effective Date)		
Safety Requirements for Radiographic Equipment-Part 34	55 FR 843; (1/10/94)	1991-1	F	N 4/2/94	4/22/94		
ANT 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	F	N 11/19/97	12/21/93		
Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70	56 FR 64980; (10/15/94)	1991-4	F	N 4/2/94	4/22/94		
Quality Management Program and Misadministrations-Part 35	56 FR 34104; (1/27/95)	1992-1	F	N 4/2/94	12/18/96		
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	F	N 6/5/98	3/18/98		
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715; (7/1/96)	1993-2	F	N 6/5/98	3/18/98		
Definition of Land Disposal and Waste Site QA Program-Part 61	58 FR 33886; (7/22/96)	1993-3			Not Applicable SECY-95-112⁴		
Self-Guarantee as an Additional Financial Mechanism-Parts 30, 40, 70	58 FR 68726; 59 FR 1618 (none)	1994-1	F	N 6/5/98	3/18/98		
Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards- Part 40	59 FR 28220; (7/1/97)	1994-2			Not Applicable to AL		
Timeliness in Decommissioning Material Facilities-Parts 30, 40, 70	59 FR 36026; (8/15/97)	1994-3	F	N 6/5/98	3/18/98		
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 6/5/98	3/18/98		
Frequency of Medical Examinations for Use of Respiratory Protection Equipment- Part 20	60 FR 7900; (3/13/98)	1995-2	F	N 6/5/98	3/18/98		
Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649; 60 FR 25983 (3/1/98)	1995-3	F	N 6/5/98	3/18/98		
Performance Requirements for Radiography Equipment-Part 34	60 FR 28323; (6/30/98)	1995-4	F		Superceded by		

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					62 FR 28948 due 6/27/00
Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038; (8/14/98)	1995-5	F	N 6/5/98	3/18/98
Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70	60 FR 38235; (11/24/98)	1995-6	F	N 6/5/98	3/18/98
Medical Administration of Radiation and Radioactive Materials-Parts 20, 35	60 FR 48623; (10/20/98)	1995-7	F	N 8/29/00	5/25/00
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	N 8/29/00	5/25/00
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: Record keeping Requirements-Parts 20, 30, 40, 61, 70	61 FR 24669; (6/17/99)	1996-3	F	N 8/29/00	5/25/00
Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act-Part 20	61 FR 65120; (1/9/00)	1997-1	F	N 8/29/00	5/25/00
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	N 8/29/00	5/25/00
Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35	62 FR 4120; (5/29/00)	1997-3	F	N 8/29/00	5/25/00
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	N 8/29/00	5/25/00
Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39057; (8/20/00)	1997-6	F	N 8/29/00	5/25/00
Exempt Distribution of a Radioactive Drug Containing One Micro curie of Carbon-14 Urea- Part 30	62 FR 63634; (1/02/01)	1997-7	F	N 6/5/98	3/18/98
Deliberate Misconduct by Unlicenced Persons-Parts 30, 40, 61, 70, 71, 150	63 FR 1890; 63 FR 13773 (2/12/01)	1998-1	F	N 10/1/01	8/16/01
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
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	F	N 8/29/00	5/25/00

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Minor Corrections, Clarifying Changes, and a Minor Policy Change-Parts 20, 35, 36	63 FR 39477; 63 FR 45393 (10/26/01)	1998-5	F	N 8/29/00	5/25/00
Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127; (11/20/01)	1998-6	F	N 8/29/00	5/25/00
Radiological Criteria for License Termination of Uranium Recovery Facilities-Part 40	64 FR 17506; (6/11/02)	1999-1			Not Applicable to AL
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 ML021090092	N 4/25/02 ML021160517	4/17/05
Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1	P ML050130295	N 08/1/05 ML052160098	
New Dosimetry Technology-Parts 34, 36, 39	65 FR 63750; (1/8/04)	2000-2			
Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material - Parts 30, 31, 32	65 FR 79162; (2/16/04)	2001-1	P ML050130295	Y 08/1/05 ML052160098	
Revision of the Skin Dose Limit -Part 20	67 FR 16298; (4/5/05)	2002-1	F ML052940420	N 11/8/05 ML053120389	4/17/05
i Medical Use of Byproduct Material-Parts 20, 32, and 35	67 FR 20249; (10/24/05)	2002-2	P ML060540346	Y 4/3/06 ML060960005	
Financial Assurance for Materials Licensees – Parts 30, 40, 70	68 FR 57327; (12/3/06)	2003-1			
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			
i Medical Use of Byproduct Material - Recognition of Specialty Boards - Part 35	70 FR 16336; 71 FR 1926 (4/29/08)	2005-2	P ML060540346	Y 4/3/06 ML060960005	
Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090) ⁶	70 FR 72128; (12/1/05)	2005-3	LC ML052570218	N 09/15/05 ML052620319	

- 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 the regulation. See: "Final Policy Statement on Adequacy and Compatibility of Agreement State Programs," III.1.Time From For Adoption of Compatible State Regulations, p. 6, SECY-95-112, May 3, 1995.
- 5. ADAMS ML Number.
- 6. By letter dated September 2, 2005, from Paul H. Lohaus, Director, Office of State and Tribal Programs, Agreement States were given 90 days to issue legally binding requirements satisfying the requirements of NRC Order EA-05-090.