

January 30, 2006

Aubrey Godwin, Director
Arizona Radiation Regulatory Agency
4814 South 40th Street
Phoenix, Arizona 85040

Dear Mr. Godwin:

We have reviewed the proposed changes to the Arizona regulations, New Part 35 in Articles 3 and 7 (corresponding to Regulatory Amendment 2002-2), received by our office on January 4, 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 one amendment identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with Dan Kuhl on the following dates: December 2, 2005; December 8, 2005; January 5, 2006; January 12, 2006; and January 13, 2006.

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 Arizona 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 Arizona 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" requirements 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 Arizona 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 Ashley Tull at (301) 415-5294 or by e-mail at amt1@nrc.gov.

Sincerely,

\RA By K.N. Schneider For

Dennis Rathbun, Deputy Director
Office of State and Tribal Programs

Enclosures:
As stated

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COMPATIBILITY COMMENTS ON ARIZONA PROPOSED REGULATIONS

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	12-1-311 (J) & 12-1-703 (C)(2)(a)	§32.72 (b)(1) & (b)(2)(i)-(ii)	2002-2	B	<p>Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35</p> <p>Arizona has omitted requirements for the manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use. §32.72 (b)(1), (b)(2)(i)-(ii) was not incorporated by reference in 12-1-311 (J) as stated in Rule Package RMP-0057 page 9 line 12 dated October 31, 2005.</p> <p>Arizona should incorporate §32.72 by reference in 12-1-311(J) to meet the Compatibility Category B designation assigned to §32.72(b)(1), (b)(2)(i)-(ii).</p>
2	12-1-311 (L) & 12-1-703 (C)(2)(b)	§32.74 (a)	2002-2	B	<p>Manufacture and distribution of sources or devices containing byproduct material for medical use</p> <p>Arizona has omitted requirements for the manufacture and distribution of sources or devices containing byproduct material for medical use. §32.74(a) was not incorporated by reference in 12-1-311(L) as stated in Rule Package RMP-0057 page 9 line 13 dated October 31, 2005.</p> <p>Arizona should incorporate §32.74 by reference in 12-1-311(L) to meet the Compatibility Category B designation assigned to §32.74(a).</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
3	12-1-704	§35.6	2002-2	C	<p>Provisions for the protection of human subjects</p> <p>Arizona does not distinguish between research that is conducted, funded, supported or regulated by an agency that has implemented the Federal Policy for the Protection of Human Subjects and an agency that has not.</p> <p>Arizona needs to include the phrase, “If the research is conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy of the Protection of Human Subjects (Federal Policy)”, in 12-1-704(B) to meet the compatibility category C designation assigned to §35.6(b).</p> <p>Arizona needs to include the phrase, “If the research will not be conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy”, in 12-1-704(c) to meet the Compatibility Category C designation assigned to §35.6(c).</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
4	12-1-720 (deleted/ revised) 12-1-438	§35.92	2002-2	H&S	<p>Decay-in-storage</p> <p>Arizona allows for waste to be disposed as ordinary trash when the radiation levels are “...less than two times background” in State section 12-1-438. §35.92 states that “the survey reading at the surface, with no interposed shielding, should not be distinguishable from background”. The essential objective will not be met as proposed by Arizona.</p> <p>Arizona needs to revise 12-1-438 to adopt the essential objectives for decay-in-storage to meet the Category H&S designation assigned to §35.92.</p>
5	12-1-721	§35.290	2002-2	B	<p>Training for imaging and localization studies</p> <p>Arizona’s proposed regulations inserted additional requirements in 12-1-721(B) that make the requirement more restrictive than §35.290.</p> <p>Arizona needs to delete 12-1-721(B) to meet to meet the Compatibility Category B designation assigned to §35.290.</p>

STATE REGULATION STATUS

State: ARIZONA

**[1 amendment reviewed identified by a i at
he beginning of the equivalent NRC requirement.]**

Tracking Ticket Number: 6-3

Date:1/30/06

<u>NRC Chronology Identification</u>	<u>FR Notice (Due Date for State Implementation)</u>	<u>RATS ID</u>	<u>Proposed (P) / Final (F)¹ Rule /License Condition (LC) /ML #⁵</u>	<u>NRC Review / Y, N² / Date / ML #⁵</u>	<u>Final State Regulation¹ (Effective Date)</u>
Safety Requirements for Radiographic Equipment-Part 34	55 FR 843; (1/10/94)	1991-1	F ML042180385	N 11/10/04 ML043200721	8/10/94
ASNT Certification of Radiographers-Part 34	56 FR 11504; (none)	1991-2	F ML042180385	N 11/10/04 ML043200721	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 P	N 9/22/97 N 10/5/00	8/10/94
Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70	56 FR 64980; (10/15/94)	1991-4	F ML042180385	N 11/10/04 ML043200721	6/13/97
Quality Management Program and Misadministrations-Part 35	56 FR 34104; (1/27/95)	1992-1	P	N 1/15/99	License Condition
Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions-Parts 30,35	57 FR 45566; (none)	1992-2	P	N 1/15/99	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			License Condition
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715; (7/1/96)	1993-2			Not applicable SECY-95-112 ⁴
Definition of Land Disposal and Waste Site QA Program-Part 61	58 FR 33886; (7/22/96)	1993-3			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			Not required ³
Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards-Part 40	59 FR 28220; (7/1/97)	1994-2			Not applicable to AZ
Timeliness in Decommissioning Material Facilities-Parts 30, 40, 70	59 FR 36026; (8/15/97)	1994-3	F	N 11/20/03 ML033240189	
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	P	N 1/15/99ML	
Frequency of Medical Examinations for Use of Respiratory Protection Equipment-Part 20	60 FR 7900; (3/13/98)	1995-2			License Condition
Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649;	1995-3	P	Y 10/5/00	

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	60 FR 25983; (3/1/98)				
Performance Requirements for Radiography Equipment-Part 34	60 FR 28323; (6/30/98)	1995-4	F ML042180385	N 11/10/04 ML043200721	
Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038; (8/14/98)	1995-5	F	N 11/20/03 ML033240189	
Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70	60 FR 38235; (11/24/98)	1995-6	F	N 11/20/03 ML033240189	
Medical Administration of Radiation and Radioactive Materials-Parts 20, 35	60 FR 48623; (10/20/98)	1995-7	P	N 10/5/00	
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 ML042180385	Y 11/10/04 ML043200721	
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	F	N 11/20/03 ML033240189	
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 11/20/03 ML033240189	
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 ML042180385	N 11/10/04 ML043200721	
Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35	62 FR 4120; (5/29/00)	1997-3	P	N 1/15/99	
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 ML042180385	N 11/10/04 ML043200721	
Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39057; (8/20/00)	1997-6	F ML032930364	N 11/06/03 ML033160544	
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 11/06/03 ML033160544	
Deliberate Misconduct by Unlicensed Persons-Parts 30, 40, 61, 70, 150	63 FR 1890; 63 FR 13773; (2/12/01)	1998-1	F ML042180385	N 11/10/04 ML043200721	
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	63 FR 37059; (7/9/01)	1998-4	F	N 11/10/04	

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Operations-Part 34			ML042180385	ML043200721	
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 11/20/03 ML033240189	
Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127; (11/20/01)	1998-6	F	N 11/20/03 ML033240189	
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 ML032930364	N11/06/03 ML033160544	
Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1	F ML032930364	N11/06/03 ML033160544	
New Dosimetry Technology-Parts 34, 36, 39	65 FR 63750; (1/8/04)	2000-2	F ML042180385	N 11/1/04 ML043200721	
Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material - Parts 30, 31, 32	65 FR 79162; (2/16/04)	2001-1	P ML052940213	Y 11/15/05 ML053190010	
Revision of the Skin Dose Limit -Part 20	67 FR 16298; 4/5/05	2002-1	P ML052940213	N 11/15/05 ML053190010	
i Medical Use of Byproduct Material-Parts 20, 32, and 35	67 FR 20249; 10/24/05	2002-2	P ML060050251	Y 1/30/06 ML060310539	
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	P ML 053050326	N 12/15/05 ML 053480043	
Medical Use of Byproduct Material - Recognition of Speciality Boards - Part 35	70 FR 16336; 71 FR 1926; (4/29/08)	2005-2			
Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090) ⁶	70 FR 72128; (12/1/05)	2005-3	LC ML052630048	N 9/21/2005 ML052640467	

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
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.

