

November 10, 2004

Steve Tarlton, P.E., Unit Leader  
Laboratory and Radiation Services Division  
Colorado Department of Public Health and Environment  
8100 Lowry Boulevard  
Denver, CO. 80230-6928

Dear Mr. Tarlton:

We have reviewed the proposed and final Colorado regulations contained in Parts 1,3,4,5,16, and 19. These rules were received by this office on August 30, 2004, with additional material arriving electronically on September 15, 2004. Our review and comments are in response to the State's request for Nuclear Regulatory Commission (NRC) evaluation of the changes to Colorado's radiation control rules that incorporated the amendments identified on the State's Regulation Status Data Sheet (SRS). These regulations were reviewed by comparison to the equivalent NRC rules in 10 CFR Parts 19, 20, 30, 32, 34, 35, 39, 61, 71, 150 and the requirements of the 14 amendments identified in the enclosed SRS. We discussed our review of the regulations with Ken Weaver on October 28, 2004.

As a result of our review, we have twelve comments and six editorial suggestions. Under our current procedure, a finding that a State regulation meets the compatibility and health and safety categories of the equivalent NRC regulation may only be made based on a review of the final State regulation. Please provide a final amended version of your rules showing the location of any changes made in response to our comments. If there are any comments which the State believes are in error, the State should identify the section of their regulations that meet the designated compatibility category. Please note that we have limited our review to regulations required for compatibility and/or health and safety, but have determined that if these regulations are adopted, incorporating our comments and without 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](#).

The SRS Data Sheet summarizes our knowledge of the status of other Colorado 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 of my staff at (301)415-2308 or JGZ@NRC.GOV.

Sincerely,

***IRA By K.N.Schneider For***

Josephine M. Piccone, Deputy Director  
Office of State and Tribal Programs

Enclosures:  
As stated

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***IRA By K.N.Schneider For***

Josephine M. Piccone, Deputy Director  
Office of State and Tribal Programs

Enclosures: As Stated

Distribution:

DIR RF[4-230,231,247] DCD (SP08) PDR (YES\_✓) VCampbell, RSAO TBrock, ASPO Colorado File

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DATE	11 /09/04*		11/09/04*		11/10/04*	

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**COMPATIBILITY COMMENTS ON COLORADO FINAL REGULATIONS**

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	Omitted	31.5(c)(8)(iii)	2001-1	B	<p><b>Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere</b></p> <p>The State omitted this provision.</p> <p>It needs to be adopted to meet Category B.</p>
2	Omitted	31.5(13)(iv)	2001-1	B	<p><b>Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere</b></p> <p>The State omitted this provision.</p> <p>It needs to be adopted to meet Category B.</p>
3	Omitted	32.51(a)(4)	2001-1	B	<p><b>Byproduct material contained in devices for use under §31.5; requirements for license to manufacture, or initially transfer.</b></p> <p>The State omitted this provision.</p> <p>It needs to be adopted to meet Category B.</p>
4	Omitted	20.1003 Pressure demand respirator	1999-3	B	<p><b>Definitions - Pressure demand respirator</b></p> <p>The State omitted the definition of Pressure demand respirator. There may be confusion with “demand respirator.”</p> <p>The definition needs to be adopted to meet Category B.</p>
5	4.24.1.3(4)	20.1703 Use of individual respiratory protection equipment	1999-3	H&S	<p><b>Use of Individual Respiratory Protection Equipment</b></p> <p>The State omitted from the list of procedures, item (vi) which is “inventory and control.”</p> <p>The State needs to adopt “inventory and control” to meet Category H&amp;S.</p>

6	4.24.1.3(4)	20.1703  Use of individual respiratory protection equipment	1999-3	H&S	<p><b>Use of Individual Respiratory Protection Equipment</b></p> <p>The State omitted paragraph (ix) re: limitations.</p> <p>The State needs to adopt paragraph (ix) to meet Category H&amp;S.</p>
7	RH 10.3.1.3	19.12(a)(3)	1995-5	C	<p><b>Instruction to Workers</b></p> <p>10 CFR 19.12(a) (3) states “Instruction in, and required to...”. The State substitutes the word “instructed” for “required.” Due to this substitution the States text does not mean the same thing as 19.12 (a) (3).</p> <p>The State needs to adopt the word, “required,” in lieu of “instructed” to meet the essential objective of Category C.</p>
8	RH 10.3.1.2, 4, and 6	19.12(a)	1995-5	C	<p><b>Instruction to Workers</b></p> <p>The State uses “or” instead of “and/or” in the NRC regulation. By having “and/or” the application is broader than only “or.”</p> <p>The State needs to replace “and/or” in the three paragraphs to meet the essential objectives of Category C.</p>

9	Part 4, Appendix G	Part 20, Appendix G  chelating agent	1995-3	B	<p><b>Requirements for Transfers of Low-Level Radioactive Waste for Disposal at Land Disposal Facilities and Manifests</b></p> <p>The State definition for “chelating agent” includes “gluconic acid” in addition to the same three families of acid in NRC’s definition (i.e., amine polycarboxylic, hydroxycarboxlic, and polycarboxylic). The separate treatment afforded “glucondic acid” may create the impression that it is somehow distinct from the polycarboxylic family which may cause confusion with licensees. The definition is also incorrect in Part 1.</p> <p>Although a similar comment was made in NRC’s June 20, 1997, letter to Mr. Quillin, the compatibility category is now “B” instead of the proposed “D” as cited in the letter.</p> <p>The State needs to delete “gluconic acid” in the definition of Appendix G and Part 1 to meet Category B.</p>
10	4.1	20.1003	1998-5	B	<p><b>Definition: Declared Pregnant Woman</b></p> <p>The State uses the phrase “or is confirmed to be no longer pregnant.” This phrase may cause some ambiguity in the interpretation of this regulation.</p> <p>The State needs to adopt language as found in 10 CFR 20.1003 to achieve compatibility.</p>

11	4.18	20.1502	1998-5	H&S	<p><b>Conditions requiring individual monitoring of external and internal occupational dose</b></p> <p>The State has omitted the clarification made in the footnote of paragraph a(3) that justifies the applicability of 10 CFR 20.1201 or equivalent State regulation as long as the dose to the fetus/embryo is not in excess of the limits of 10 CFR 20.1208 or equivalent State regulation.</p> <p>The State needs to adopt language similar to that found in Footnote 2 to 10 CFR 1502 to ensure applicability of the State's equivalent to 10 CFR 20.1201 in cases where the dose to the fetus/embryo is below the dose limits specified in 20.1208 or equivalent State regulation in order to meet compatibility.</p>
12	3.9.6	30.35	2003-1	<p>D-- paragraphs (c), (e), (f)</p> <p>H&amp;S-- paragraphs (a), (b), (d), and (g).</p>	<p><b>Financial assurance and recordkeeping for decommissioning</b></p> <p>In 3.9.6.2, the State references "Appendix A." The correct reference would be the State's "Schedule B."</p> <p>The State needs to correct this reference in order to meet compatibility.</p>

## EDITORIAL SUGGESTIONS

1. In Criterion 6(7) of Appendix A to Part 18, the State should insert a comma after the word “control” in the last sentence of the paragraph.
2. In the first sentence of Criterion 6A(3) of Appendix A of Part 18, the State should replace the word “report” with “request.”
3. The State omitted the clause in Paragraph a(2) of 10 CFR 35.33 that allows the report of a misadministration to be made to the patient’s responsible relative or guardian, when appropriate. The State’s current language for this requirement could be interpreted to allow reports of misadministrations to be made to the patient’s responsible relative or guardian; however, the State should adopt language to clearly state that the report may be made to the patient’s responsible relative or guardian to provide clarification to its licensees and physicians.
4. In the first sentence of 19.20.1, the State should remove the word “either” to alleviate any potential confusion in the requirement. The current placement of the word could lead the reader to believe that there is another option other than wearing a personal dosimeter.
5. In the second sentence of 19.20.1, the State should replace the word “accidental” with “accident.” The phrase “accidental dose” may be subject to a different interpretation than the phrase “accident dose” which appears in 10 CFR 36.
6. In Part 4, Appendix G, the State does not use the correct nomenclature, “Type A,” required by the U.S. Department of Transportation for packages. The State needs to change “type a” to “Type A”

## STATE REGULATION STATUS

**State: Colorado**

**[14 amendments reviewed is identified by a ★ at the beginning of the equivalent NRC regulation.]**

**Tracking Ticket Number: 4-230, 4-231, 4-247**

**Date: November 10, 2004**

<b>NRC Chronology Identification</b>	<b>FR Notice (Date Due for State Implementation)</b>	<b>RATS ID</b>	<b>Proposed (P) / Final (F)<sup>1</sup> Rule / ML #<sup>4</sup></b>	<b>NRC Review / Y, N<sup>2</sup> / Date / ML #<sup>4</sup></b>	<b>Final State Regulation<sup>1</sup> (Effective Date)</b>
Safety Requirements for Radiographic Equipment-Part 34	55 FR 843; (1/10/94)	1991-1	F	Y 5/29/97	6/30/94
ANT Certification of Radiographers-Part 34	56 FR 11504; (none)	1991-2			Not required <sup>3</sup>
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 8/18/97	1/1/94
Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70	56 FR 64980; (10/15/94)	1991-4	F	Y 5/29/97	11/1/94
Quality Management Program and Misadministrations-Part 35	56 FR 34104; (1/27/95)	1992-1			
Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions-Parts 30, 35	57 FR 45566; (none)	1992-2			Not required <sup>3</sup>
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 6/14/00	7/1/97
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715; (7/1/96)	1993-2	F	N 5/29/97	7/1/97
*Definition of Land Disposal and Waste Site QA Program-Part 61	58 FR 33886; (7/22/96)	1993-3	F ML042440167	N 11\10\04 ML043200010	7/1/97
Self-Guarantee as an Additional Financial Mechanism-Parts 30, 40, 70	58 FR 68726; 59 FR 1618 (none)	1994-1	F	N 6/14/00	7/1/97
*Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards-Part 40	59 FR 28220; (7/1/97)	1994-2	F ML042440167	N 11/10/04 ML043200010	12/30/97
Timeliness in Decommissioning Material Facilities-Parts 30, 40, 70	59 FR 36026; (8/15/97)	1994-3	F	N 6/14/00	7/1/97



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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 6/14/00	9/30/98
Frequency of Medical Examinations for Use of Respiratory Protection Equipment-Part 20	60 FR 7900; (3/13/98)	1995-2	F	N 6/14/01	1/1/98
*Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649; 60 FR 25983 (3/1/98)	1995-3	F ML042440167	Y 11/10/04 ML043200010	1/1/97
Performance Requirements for Radiography Equipment-Part 34	60 FR 28323; (6/30/98)	1995-4	F	N 6/14/00	3/30/98
*Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038; (8/14/98)	1995-5	F ML042440167	Y 11/10/04 ML043200010	3/30/98
*Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70	60 FR 38235; (11/24/98)	1995-6	F	N 11/10/04 ML043200010	
*Medical Administration of Radiation and Radioactive Materials-Parts 20, 35	60 FR 48623; (10/20/98)	1995-7	F ML042440167	N 11/10/04 ML043200010	
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 3/22/01	7/31/98
One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses-Parts 30, 40, 70	61 FR 1109; (none)	1996-2			Not required <sup>3</sup>
*Termination or Transfer of Licensed Activities: Record keeping Requirements-Parts 20, 30, 40, 61, 70	61 FR 24669; (6/17/99)	1996-3	F ML042440167	N 11/10/04 ML043200010	
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 8/8/00	12/30/99

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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 6/14/00	11/30/98
Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35	62 FR 4120; (5/29/00)	1997-3	F	N 6/14/00	3/30/98
Fissile Material Shipments and Exemptions-Part 71	62 FR 5907; (none)	1997-4	P	N 4/27/98	Not required <sup>3</sup>
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 8/8/00	5/30/00
Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39057; (8/20/00)	1997-6	F	N 7/13/99	5/19/99
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 6/14/00	9/30/98
Deliberate Misconduct by Unlicensed Persons-Parts 30, 40, 61, 70, 71, 150	63 FR 1890; 63 FR 13773 (2/12/01)	1998-1	F ML010380248	N 9/17/01 ML012630207	02/01/00
Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees- Parts 30, 40, 70	63 FR 29535; (none)	1998-2			Not required <sup>3</sup>
License Term for Medical Use Licenses-Part 35	63 FR 31604; (none)	1998-3			Not required <sup>3</sup>
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations-Part 34	63 FR 37059; (7/9/01)	1998-4	F	N 8/8/00	5/30/00
*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 ML042440167	Y 11/10/04 ML043200010	
*Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127; (11/20/01)	1998-6	F ML042440167	N 11/10/04 ML043200010	
Radiological Criteria for License Termination of Uranium Recovery Facilities-Part 40	64 FR 17506; (6/11/02)	1999-1	F ML020320440	N 3/28/02 ML020880468	11/20/01

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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 <sup>3</sup>
*Respiratory Protection and Controls to Restrict Internal Exposure-Part 20	64 FR 54543; 64 FR 55524 (2/2/03)	1999-3	F ML042440167	Y 11/10/04 ML043200010	
Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1			
*New Dosimetry Technology-Parts 34, 36, 39	65 FR 63750; (1/8/04)	2000-2	F ML042440167	N 11/10/04 ML043200010	
*Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material - Parts 30, 31, 32	65 FR 79162; (2/16/04)	2001-1	F ML042440167	Y 11/10/04 ML043200010	
*Revision of the Skin Dose Limit -Part 20	67 FR 16298; 4/5/05	2002-1	F ML042440167	N 11/10/04 ML043200010	
Medical Use of Byproduct Material-Parts 20, 32, and 35	67 FR 20249; 10/24/05	2002-2			
*Financial Assurance for Materials Licensees – Parts 30, 40, 70	68 FR 57327; (12/3/06)	2003-1	F ML042440167	Y 11/10/04 ML043200010	
Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments – Part 71	69 FR 3697; (10/01/07)	2004-1			

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. ADAMS ML Number.