



UNITED STATES  
**NUCLEAR REGULATORY COMMISSION**  
WASHINGTON, D.C. 20555-0001

December 27, 2016

K. David Walter, Director  
Office of Radiation Control  
State Department of Public Health  
201 Monroe Street  
P.O. Box 303017  
Montgomery, AL 36130-3017

Dear Mr. Walter:

We have reviewed the final revisions to the Alabama regulations 420-3-26-.01 and 420-3-26-.02, received by our office on November 19, 2016. These regulations were reviewed by comparison to the equivalent U.S. Nuclear Regulatory Commission (NRC) rules and the requirements of Regulation Amendment Tracking System Identification Numbers (RATS ID) 2007-1, 2007-3, 2012-4, and 2013-2; as identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with David Turberville on December 22, 2016.

As a result of our review, we have two comments that stand from the NRC letter dated August 19, 2016 and one new comment that has been identified in the enclosure. Please note that we have limited our review to regulations required for compatibility and/or health and safety. We have determined that if these regulations are revised, incorporating our comments and without other significant change, they would meet the compatibility and health and safety categories established in the Office of Nuclear Material Safety and Safeguards (NMSS) Procedure SA-200, "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements."

We request that when you revise your regulations to address our comments, a copy of the "as published" regulations be provided to us for review. As requested in NMSS Procedure SA-201, "Review of State Regulatory Requirements," please highlight the location of any changes made by Alabama, in response to our comments, and provide a copy to Division of Material Safety, State, Tribal, and Rulemaking Programs, NMSS. 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 NMSS State Communication Portal: <https://scp.nrc.gov/rulemaking.html>.

D. Walter

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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 Michelle Beardsley, State Regulation Review Coordinator, at (267) 884-2305 ([Michelle.Beardsley@nrc.gov](mailto:Michelle.Beardsley@nrc.gov)) or Monica Ford at (610) 337-5214 ([Monica.Ford@nrc.gov](mailto:Monica.Ford@nrc.gov)).

Sincerely,

*/RA/*

***PMichalak for PHenderson***

Pamela J. Henderson, Deputy Director  
Division of Material Safety, State, Tribal  
and Rulemaking Programs  
Office of Nuclear Material Safety  
and Safeguards

Enclosures:

1. Compatibility Comments
2. Alabama SRS Data Sheet

D. Walter

-2-

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Sincerely,

Pamela J. Henderson, Deputy Director  
Division of Material Safety, State, Tribal  
and Rulemaking Programs  
Office of Nuclear Material Safety  
and Safeguards

Enclosures:

1. Compatibility Comments
2. Alabama SRS Data Sheet

DISTRIBUTION: SP[05]  
DIR RF (17-10)  
MFord, RSAO  
AL File

OFFICE	RI	ASPB	OGC	ASPB:BC	MSTR:DD
NAME	MFord	MBeardsley	MSegarnick	PMichalak	PMichalak for PHenderson
DATE	12/22/16	12/22/16	12/22/16	12/27/16	12/27/16

**ML16333A166**

**OFFICIAL RECORD COPY**

**Package ML16314D996**

**COMPATIBILITY COMMENTS ON ALABAMA FINAL REGULATIONS**

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	420-3-26-.02(10)(t)	32.72	2007-1 2007-3	B	<p><b>Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35.</b></p> <p>AL omits an equivalent regulation to 10 CFR 32.72(b)(3). AL needs to add an equivalent regulation to 10 CFR 32.72(b)(3) to 420-3-26-.2(10)(t) to meet the requirements of a compatibility category B designation.</p> <p>AL omits “no later than 30 days after the date that the licensee allows, under paragraphs 420-3-26-.02(10)(t)(2)(ii)(I) and (III), the individual to work as an authorized nuclear pharmacist” from the end of 420-3-26-.02(10)(t)(5)(v).</p> <p>AL needs to make the above changes in order to meet the compatibility category B designation assigned to 10 CFR 32.72.</p> <p><b>COMMENT STANDS FROM NRC LETTER DATED AUGUST 19, 2016</b></p> <p><b>Note:</b> AL provided a rationale for not addressing this comment in their submitted comment resolution document (ML16314D996).</p> <p>As written, AL’s proposed regulations are not essentially identical to NRC’s and as such, cause inconsistency and have transboundary implications. They do not meet the Compatibility Category B designation assigned to 32.72. For example, AL’s proposal to omit the equivalent regulation to 10 CFR 32.72(b)(3) would allow AL to issue license conditions that are less restrictive, which is inconsistent and not essentially identical for</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					compatibility category B designation. Similarly, AL's proposal for the equivalent regulation to 10 CFR 32.72(b)(5) is more restrictive, which is also not essentially identical for compatibility category B designation.
2	420-3-26-.07(45)	35.100	2007-3	H&S	<p><b>Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required</b></p> <p>AL lists the wrong references in 420-3-26-.07(45)(b). AL needs to correct this provision to say "...an authorized user and who meets the requirements specified in 420-3-26-.07(51) or 420-3-26-.07(56) and 420-3-26-.07(51)(c)(1)(ii)(VII), or an individual ..."</p> <p>AL needs to make the above change in order to meet the category H&amp;S designation assigned to 10 CFR 35.100.</p> <p><b>AL did not address comments pertaining to 420-3-26-.07 in this rule making. AL will address this comment at a later date.</b></p> <p><b>COMMENT STANDS FROM NRC LETTER DATED AUGUST 19, 2016.</b></p>
3	420-3-26-.02(3)	40.13	2013-2	B	<p><b>Unimportant quantities of source material</b></p> <p>AL omits the word "delivers" from 420-3-26-.02(3)(a).</p> <p>AL needs to remove 420-3-26-.02(3)(c)2.(ii) from its regulations.</p> <p>AL needs to add a regulation</p>

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
				<p>equivalent to 10 CFR 40.13(c)(2)(ii) "Piezoelectric ceramic containing not more than 2 percent by weight source material" to 420-3-26-.02(3)(c)2.</p> <p>AL needs to remove 420-3-26-.02(3)(c)8. from its regulations.</p> <p>AL needs to add a regulation equivalent to 10 CFR 40.13(c)(9) "The exemptions in this paragraph (c) do not authorize the manufacture of any of the products described." to 420-3-26-.02(3)(c).</p> <p>AL lists the incorrect reference in 420-3-26-.02(3)(c)10.(ii). AL needs to reference Section "40.52" instead of Section "40.42."</p> <p>AL needs to make the above changes in order to meet the Compatibility Category B designation assigned to 10 CFR 40.13 (except 10 CFR 40.13(c)(5)(iv) which is a compatibility category NRC).</p>

**STATE REGULATION STATUS**

State: Alabama

Tracking Ticket Number: 17-10

Date: 12/27/2016

[ 4 amendment(s) reviewed identified by a \* at the beginning of the equivalent NRC requirement.]

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
1991-1	Safety Requirements for Radiographic Equipment Part 34 55 FR 843 <b>(Superceded by 1997-5)</b>	01/10/1994	Final	No Comments 04/02/1994	Alabama has adopted Final Regulations equivalent to RATS ID 1997-5
1991-2	ASNT Certification of Radiographers Part 34 56 FR 11504 <b>(Superceded by 1997-5)</b>	none	Not Required	Not Required	Alabama has adopted Final Regulations equivalent to RATS ID 1997-5
1991-3	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;	01/01/1994	Final	No Comments 11/19/1997	
1991-4	Notification of Incidents Parts 20, 30, 31, 34, 39, 40 and 70 56 FR 64980	10/15/1994	Final	No Comments 04/02/1994	
1992-1	Quality Management Program and Misadministrations Part 35 56 FR 34104 <b>(Superceded by 2002-2)</b>	01/27/1995	Final	No Comments 04/02/1994	Alabama has adopted Final Regulations equivalent to RATS ID 2002-2

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
1992-2	Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions Parts 30 and 35 57 FR 45566	none	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility
1993-1	Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites] Parts 30 and 40 58 FR 39628	10/25/1996	Final	No Comments 06/05/1998	
1993-2	Licensing and Radiation Safety Requirements for Irradiators Part 36 58 FR 7715	07/01/1996	Final	No Comments 06/05/1998	
1993-3	Definition of Land Disposal and Waste Site QA Program Part 61 58 FR 33886	07/22/1996	Not Applicable <sup>i</sup>	Not Applicable	Alabama does not have any licensees subject to these regulations. (See SECY-95-112)
1994-1	Self-Guarantee as an Additional Financial Mechanism Parts 30, 40 and 70 58 FR 68726; 59 FR 1618	none	Final	No Comments 06/05/1998	These regulation changes are not required to be adopted for purposes of Compatibility.
1994-2	Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards Part 40 59 FR 28220	07/01/1997	Not Applicable	Not Applicable	Alabama does not have authority to regulate this material under its Agreement



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1994-3	Timeliness in Decommissioning Material Facilities Parts 30, 40 and 70 59 FR 36026	08/15/1997	Final	No Comments 06/05/1998	
1995-1	Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use Parts 30, 32 and 35 59 FR 61767; 59 FR 65243; 60 FR 322	01/01/1998	Final	No Comments 06/05/1998	
1995-2	Frequency of Medical Examinations for Use of Respiratory Protection Equipment Part 20 60 FR 7900	03/13/1998	Final	No Comments 06/05/1998	
1995-3	Low-Level Waste Shipment Manifest Information and Reporting Parts 20 and 61 60 FR 15649; 60 FR 25983	03/01/1998	Final	No Comments 06/05/1998	
1995-4	Performance Requirements for Radiography Equipment Part 34 60 FR 28323 <b>(Superceded by 1997-5)</b>	06/30/1998	Not Required	Not required	Alabama has adopted Final Regulations equivalent to RATS ID 1997-5
1995-5	Radiation Protection Requirements: Amended Definitions and Criteria Parts 19 and 20 60 FR 36038	08/14/1998	Final	No Comments 06/05/1998	

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1995-6	Clarification of Decommissioning Funding Requirements Parts 30, 40 and 70 60 FR 38235	11/24/1998	Final	No Comments 06/05/1998	
1995-7	Medical Administration of Radiation and Radioactive Materials Parts 20 and 35 60 FR 48623 <b>(Superceded by 2002-2 and 2005-2)</b>	10/20/1998	Final	No Comments 08/29/2000	Alabama has adopted Final Regulations equivalent to RATS IDs 2002-2 and 2005-2
1996-1	Compatibility with the International Atomic Energy Agency Part 71 60 FR 50248; 61 FR 28724 <b>(Superceded by 2004-1)</b>	04/01/1999	Final	No Comments 08/29/2000	Alabama has not yet adopted RATS ID 2004-1 in final.
1996-2	One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses Parts 30, 40 and 70 61 FR 1109	02/15/1999	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility
1996-3	Termination or Transfer of Licensed Activities: Record keeping Requirements Parts 20, 30, 40, 61 and 70 61 FR 24669	06/17/1999	Final	No Comments 08/29/2000	
1997-1	Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act Part 20 61 FR 65120	01/9/2000	Final	No Comments 08/29/2000	

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1997-2	Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State Part 150 62 FR 1662	02/27/2000	Final	No Comments 08/29/2000	
1997-3	Criteria for the Release of Individuals Administered Radioactive Material Parts 20 and 35 62 FR 4120	05/29/2000	Final	No Comments 08/29/2000	
1997-4	Fissile Material Shipments and Exemptions Part 71 62 FR 5907 <b>(Superceded by 2004-1)</b>	02/10/2000	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility. (See STP-97-078)
1997-5	Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations Parts 30, 34, 71 and 150 62 FR 28947	06/27/2000	Final	No Comments 08/29/2000	
1997-6	Radiological Criteria for License Termination Parts 20, 30, 40 and 70 62 FR 39057	08/20/2000	Final	No Comments 08/29/2000	
1997-7	Exempt Distribution of a Radioactive Drug Containing One Micro curie of Carbon-14 Urea Part 30 62 FR 63634	01/02/2001	Final	No Comments 06/05/1998	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
1998-1	Deliberate Misconduct by Unlicensed Persons Parts 30, 40, 61, 70, 71 and 150 63 FR 1890; 63 FR 13773	02/12/2001	Final	No Comments 10/01/2001	
1998-2	Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees Parts 30, 40 and 70 63 FR 29535	07/01/2001	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility
1998-3	License Term for Medical Use Licenses Part 35 63 FR 31604 <b>(Superceded by 2002-2)</b>	07/10/2001	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility. (See STP-98-074) Alabama has adopted Final Regulations equivalent to RATS IDs 2002-2.
1998-4	Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations Part 34 63 FR 37059	07/09/2001	Final	No Comments 08/29/2000	
1998-5	Minor Corrections, Clarifying Changes, and a Minor Policy Change Parts 20, 32, 35, 36 and 39 63 FR 39477; 63 FR 45393	10/26/2001	Final	No Comments 08/29/2000	
1998-6	Transfer for Disposal and Manifests: Minor Technical Conforming Amendment Part 20 63 FR 50127	11/20/2001	Final	No Comments 08/29/2000	

<b>RATS ID</b>	<b>NRC Chronology Identification</b>	<b>Date Due for State Adoption</b>	<b>Incoming Letter</b>	<b>Outgoing Package</b>	<b>Notes</b>
1999-1	Radiological Criteria for License Termination of Uranium Recovery Facilities Part 40 64 FR 17506	06/11/2002	Not Applicable	Not Applicable	Alabama does not have authority to regulate this material under its Agreement
1999-2	Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information Part 31 64 FR 42269	10/04/2002	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility
1999-3	Respiratory Protection and Controls to Restrict Internal Exposure Part 20 64 FR 54543; 64 FR 55524	02/02/2003	Final ML021090092	No Comments 04/25/2002 ML021160517	
2000-1	Energy Compensation Sources for Well Logging and Other Regulatory Clarifications Part 39 65 FR 20337	05/17/2003	Final ML062000076	No Comments 08/10/2006 ML062220014	
2000-2	New Dosimetry Technology Parts 34, 36 and 39 65 FR 63750	01/08/2004	Final ML062000076	No Comments 08/10/2006 ML062220014	
2001-1	Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material Parts 30, 31 and 32 65 FR 79162	02/16/2004	Final ML062000076	No Comments 08/10/2006 ML062220014	

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2002-1	Revision of the Skin Dose Limit Part 20 67 FR 16298	04/05/2005	Final ML052940420	No Comments 11/08/2005 ML053120389	
2002-2	Medical Use of Byproduct Material Parts 20, 32 and 35 67 FR 20249	10/24/2005	Final ML062000076	No Comments 08/10/2006 ML062220014	
2003-1	Financial Assurance for Materials Licensees Parts 30, 40 and 70 68 FR 57327	12/03/2006	Final ML062000076	No Comments 08/10/2006 ML062220014	
2004-1	Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments Part 71 69 FR 3697	10/01/2007	Final ML14293A397  Revised Final ML16203A187	Comments 12/16/2014 ML14290A377  No Comments 08/19/2016 ML16203A174	
2005-1	Security Requirements for Portable Gauges Containing Byproduct Material Part 30 70 FR 2001	07/11/2008	Final ML13176A135  License Condition ML081960176	No Comments 09/18/2013 ML13176A123  Comments 07/28/2008 ML082100083	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
2005-2	Medical Use of Byproduct Material - Recognition of Specialty Boards Part 35 70 FR 16336; 71 FR 1926	04/29/2008	Final ML062000076	No Comments 08/10/2006 ML062220014	
2005-3	Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090) 70 FR 72128	12/01/2005	License Condition ML052570218	No Comments 09/15/2005 ML052620319	
2006-1	Minor Amendments Parts 20, 30, 32, 35, 40 and 70 71 FR 15005	03/27/2009	Final ML13176A135	Comments 09/18/2013 ML13176A123	
2006-2	National Source Tracking System - Serialization Requirements Part 32 with reference to Part 20 Appendix E 71 FR 65685	02/06/2007	Final ML13176A135	Comments 09/18/2013 ML13176A123	
2006-3	National Source Tracking System Part 20 71 FR 65685, 72 FR 59162	01/31/2009	Final ML13176A135  License Condition ML082820556	No Comments 09/18/2013 ML13176A123  No Comments 10/21/2008 ML082820596	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
*2007-1	Medical Use of Byproduct Material - Minor Corrections and Clarifications Parts 32 and 35 72 FR 45147, 54207	10/29/2010	Final ML14293A397  Revised Final ML16203A187  Revised Final ML16314E173	Comments 12/16/2014 ML14290A377  Comments 08/19/2016 ML16203A174  Comment 12/27/2016 ML16314D996	
2007-2	Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements Parts 30, 31, 32 and 150 72 FR 58473	12/17/2010	Final ML14293A397  Revised Final ML16203A187	Comments 12/16/2014 ML14290A377  No Comments 08/19/2016 ML16203A174	
*2007-3	Requirements for Expanded Definition of Byproduct Material Parts 20, 30, 31, 32, 33, 35, 61 and 150 72 FR 55864	11/30/2010	Final ML14293A397  Revised Final ML16203A187  Revised Final ML16314E173	Comments 12/16/2014 ML14290A377  Comments 08/19/2016 ML16203A174  Comments 12/27/2016 ML16314D996	



RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
2007-4	Order Imposing Fingerprinting Requirements and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Material NRC Order EA-07-305 72 FR 70901	06/05/2008	License Condition ML081090443	No Comments 05/01/2008 ML081220314	
2008-1	Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent Parts 19 and 20 72 FR 68043	02/15/2011	Final ML13176A135	No Comments 09/18/2013 ML13176A123	
2009-1	Medical Use of Byproduct Material – Authorized User Clarification Part 35 74 FR 33901	09/28/2012	Final ML14293A397	No Comments 12/16/2014 ML14290A377	
2011-1	Decommissioning Planning Parts 20, 30, 40 and 70 76 FR 35512	12/17/2015	Final ML14293A397	No Comments 12/16/2014 ML14290A377	
2011-2	Licenses, Certifications, and Approvals for Materials Licensees Parts 30, 36, 39, 40, 70 and 150 76 FR 56951	11/14/2014	Final ML15127A281	No Comments 06/11/2015 ML15127A276	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
2012-1	Change of Compatibility of Parts 31.5 and 31.6 (See RATS ID: 2001-1 for Rule text) 77 FR 3640	01/25/2015	Final ML15127A281  Revised Final ML16203A187	Comments 06/11/2015 ML15127A276  No Comments 08/19/2016 ML16203A174	
2012-2	Advance Notification to Native American Tribes of Transportation of Certain Types of Nuclear Waste Part 71 77 FR 34194	08/10/2015	Final ML16076A374  Revised Final ML16203A187	Comments 04/22/2016 ML16076A369  No Comments 08/19/2016 ML16203A174	
2012-3	Technical Corrections Parts 30, 34, 40 and 71 77 FR 39899	08/06/2015	Final ML14293A397  Revised Final ML16203A187	Comments 12/16/2014 ML14290A377  Comments 08/19/2016 ML16203A174	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
*2012-4	Requirements for Distribution of Byproduct Material Parts 30, 31, 32, 40 and 70 77 FR 43666	10/23/2015	Final ML14293A397  Revised Final ML16203A187  Revised Final ML16314E173	Comments 12/16/2014 ML14290A377  Comments 08/19/2016 ML16203A174  No Comments 12/27/2016 ML16314D996	
2013-1	Physical Protection of Byproduct Material Parts 20, 30, 32, 33, 34, 35, 36, 37, 39 and 71 78 FR 16922	03/19/2016	Proposed ML15252A268  Final ML15323A029  Revised Final ML16203A187	Comments 10/15/2015 ML15252A240  Comment 12/16/2015 ML15323A030  No Comments 08/19/2016 ML16203A174	Comment is regarding 30.13
*2013-2	Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions Parts 30, 40 and 70 78 FR 32310	08/27/2016	Proposed ML16203A187  Final ML16314E173	No Comments 08/19/2016 ML16203A174  Comment 12/27/2016 ML16314D996	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
2015-1	Domestic Licensing of Special Nuclear Material – Written Reports and Clarifying Amendments Part 70 79 FR 57721, 80 FR 143	01/26/2018			
2015-2	Safeguards Information - Modified Handling Categorization, Change for Materials Facilities Parts 30, 37, 73 and 150 79 FR 58664, 80 FR 3865	01/28/2018			
2015-3	Revisions to Transportation Safety Requirements and Harmonization with International Atomic Energy Agency Transportation Requirements Part 71 80 FR 33987	07/13/2018			
2015-4	Miscellaneous Corrections, Parts 37 and 40 80 FR 45841	09/02/2018			
2015-5	Miscellaneous Corrections, Parts 19, 20, 30, 32, 37, 40, 61, 70, 71 and 150 80 FR 74974	12/31/2018			