



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

March 12, 2015

Ms. Angela E. Leek, Chief
Bureau of Radiological Health
Iowa Department of Public Health
Lucas State Office Building
Des Moines, IA 50319-0075

Dear Ms. Leek:

We have reviewed the final revisions to the Iowa regulations in Iowa Administrative Code 641-45(136), received by our office on December 23, 2014. These regulations were reviewed by comparison to the equivalent U.S. Nuclear Regulatory Commission (NRC) rules in 10 CFR Part 34 provisions not associated with a specific RATS ID. This amendment has been noted in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with Radal Dahlin on March 10, 2015.

As a result of our review, we have 12 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. 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 Iowa, 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 Iowa 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 Web site:

<http://nrc-stp.ornl.gov/rulemaking.html>.

A. Leek

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If you have any questions regarding the review results, 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 (610) 337-6942 (Michelle.Beardsley@nrc.gov) or Jim Lynch at (630) 829-9661 (James.Lynch@nrc.gov).

Sincerely,

/RA Chris Einberg for/

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

Enclosures:

1. Compatability
2. Iowa SRS Data Sheet

A. Leek

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JLynch, RSAO
Iowa File

OFFICE	RIII	ASPB	OGC	ASPB	MSTR
NAME	JLynch	MBeardsley	MSpencer	CEingberg	PHenderson
DATE	2/23/15	2/23/15	3/10/15	2/12/15	3/12/15

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OFFICIAL RECORD COPY

Package ML14363A207

COMPATIBILITY COMMENTS ON IOWA FINAL REGULATIONS

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	45.1(2)	34.3	N/A	B	<p>Definitions: Radiographer's assistant</p> <p>Iowa's rule requires direct supervision by a radiographer trainer (instructor) rather than by a radiographer. This requirement is more restrictive than 34.3.</p> <p>Iowa needs to modify the definition to have the same supervision requirements as 34.3 in order to meet the Compatibility Category B designation assigned to 10 CFR 34.3.</p>
2	45.1(2)	34.3	N/A	B	<p>Definitions: Radiographic exposure device</p> <p>In its definition of "Radiographic Exposure Device" Iowa omits the phrase "(also called a camera, or a projector)". Iowa needs to insert this phrase after "Radiographic exposure device."</p> <p>In addition, Iowa needs to delete the term "e.g. camera" after the words "radiographic exposure".</p> <p>Iowa needs to make the above corrections to the definition of "Radiographic Exposure Device" in order to meet the Compatibility Category B designation assigned to 10 CFR 34.3.</p>
3	45.1(2)	34.3	N/A	B	<p>Definitions: Storage Container</p> <p>Iowa's rule uses the term "shield device" vs. "container" as stated in 34.3. Iowa also adds the term "transported" in the definition.</p> <p>Iowa needs to make the above corrections to the definition of "Storage Container" in order to meet the Compatibility Category B designation assigned to 10 CFR 34.3.</p>

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
4	45.3(3)	34.35	N/A	<p>Labeling, storage, and transportation</p> <p>Iowa's rule in 45.3(3)a(1) omits the asterisk and note stating that "Caution" may be changed to "Danger". As written, it appears to allow a label with the word "Danger" and nothing else.</p> <p>Iowa needs to add the asterisk and note, as noted above, in order to meet the Compatibility Category B designation assigned to 10 CFR 34.35.</p> <p>[Typographical comment: the word "black" is misspelled]</p>
5	45.3(6)c	34.41(a)	N/A	<p>Conducting industrial radiography operations</p> <p>Iowa uses the term "radiographer trainer" instead of "radiographer," as stated in 34.41(a).</p> <p>Iowa needs to use the same terminology as stated in 34.41(a) in order to meet the Compatibility Category B designation assigned to 10 CFR 34.41.</p>
6	45.1(10)	34.43(d)	N/A	<p>Training</p> <p>Iowa's rule omits annual refresher training for radiographers and radiographer's assistants as required in 34.43(d).</p> <p>Iowa needs to require annual refresher training for radiographers and radiographer's assistants in order to meet the Compatibility Category B designation assigned to 10 CFR 34.43.</p>
7	45.1(10)a	34.43(c)	N/A	<p>Training</p> <p>The Iowa rule is written differently and is missing a specific requirement to train radiographer's assistants in applicable DOT transportation</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					<p>regulations. The rule also adds a requirement for a “trainee status card.” It appears that the terms “radiographer’s assistant” and “trainee” are equivalent which can cause confusion as written.</p> <p>Iowa needs to add a specific requirement for radiographer assistants’ training in transportation regulations and clarify the terms regarding trainees and radiographer’s assistant as noted above, in order to meet the Compatibility Category B designation assigned to 10 CFR 34.43.</p>
8	45.3(6)	34.45(a)(7)	N/A	C	<p>Operating and emergency procedures</p> <p>Iowa’s rule does not meet the essential objectives of 34.45(a)(7) as it does not require procedures to include operability checks on radiography equipment, and inspection, maintenance and operability checks of survey instruments.</p> <p>Iowa needs to modify this rule to require licensees to have these procedures in order to meet the Compatibility Category C designation assigned to 10 CFR 34.45.</p>
9	45.1(13)	34.46	N/A	B	<p>Supervision of radiographer’s assistants</p> <p>Iowa’s rule requires direct supervision of radiographer’s assistants by a radiography instructor rather than a radiographer as required by 34.46.</p> <p>Iowa needs to modify the supervision requirement in order to meet the Compatibility Category B designation assigned to 10 CFR 34.46.</p>
10	45.3(7)	34.49	N/A	C	<p>Radiation Surveys</p> <p>Iowa’s rule contains an exemption from survey requirements for pipeline</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					<p>radiographic operations as required in 45.3(7)c(3). This does not meet the essential objectives of 34.49 as it is less restrictive.</p> <p>Iowa needs to eliminate this exemption in order to meet the Compatibility Category C designation assigned to 10 CFR 34.49.</p>
11	45.1(4)	34.63	N/A	C	<p>Records of receipt and transfer of sealed sources</p> <p>Iowa's rule is missing the requirement for maintaining records of receipt and transfer of "devices using DU for shielding." This does not meet the essential objectives of 34.63 as it is less restrictive.</p> <p>Iowa needs to add this requirement in order to meet the Compatibility Category C designation assigned to 10 CFR 34.63.</p>
12	45.1	34.79	N/A	C	<p>Records of training and certification</p> <p>Iowa's rule does not explicitly require records of annual refresher training or radiographer certification documents. This does not meet the essential objectives of 34.79 as it is less restrictive.</p> <p>Iowa needs to add these records requirements in order to meet the Compatibility Category C designation assigned to 10 CFR 34.79.</p>

STATE REGULATION STATUS

State: Iowa

Tracking Ticket Number: 14-75

Date: March 12, 2015

[1 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 (Superceded by 1997-5)	01/10/1994	Not Required	Not Required	Iowa has adopted Final Regulations equivalent to RATS ID: 1997-5.
1991-2	ASNT Certification of Radiographers Part 34 56 FR 11504 (Superceded by 1997-5)	none	Not Required	Not Required	Iowa 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 11/06/1997	
1991-4	Notification of Incidents Parts 20, 30, 31, 34, 39, 40, 70 56 FR 64980	10/15/1994	Final ML071970162	No Comments 09/24/2007 ML072670007	
1992-1	Quality Management Program and Misadministrations Part 35 56 FR 34104 (Superceded by 2002-2)	01/27/1995	Not Required	Not Required	Iowa 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, 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, 40 58 FR 39628	10/25/1996	Final ML071970162	No Comments 09/24/2007 ML072670007	
1993-2	Licensing and Radiation Safety Requirements for Irradiators Part 36 58 FR 7715	07/01/1996	Not Applicable ⁱ	Not Applicable	Iowa does not have any licensees subject to these regulations. (See SECY-95-112)
1993-3	Definition of Land Disposal and Waste Site QA Program Part 61 58 FR 33886	07/22/1996	Not Applicable	Not Applicable	Iowa does not have authority to regulate this material under its Agreement.
1994-1	Self-Guarantee as an Additional Financial Mechanism Parts 30, 40, 70 58 FR 68726; 59 FR 1618	none	Not Required	Not Required	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	Iowa does not have authority to regulate this material under its Agreement.
1994-3	Timeliness in Decommissioning Material Facilities Parts 30, 40, 70 59 FR 36026	08/15/1997	Final ML081790082	No Comments 07/07/2008 ML081890129	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
1995-1	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	01/01/1998	Final ML071970162	No Comments 09/24/2007 ML072670007	
1995-2	Frequency of Medical Examinations for Use of Respiratory Protection Equipment Part 20 60 FR 7900	03/13/1998	Final ML071970162	No Comments 09/24/2007 ML072670007	
1995-3	Low-Level Waste Shipment Manifest Information and Reporting Parts 20, 61 60 FR 15649; 60 FR 25983	03/01/1998	Final ML081790082	No Comments 07/07/2008 ML081890129	
1995-4	Performance Requirements for Radiography Equipment Part 34 60 FR 28323 (Superseded by 1997-5)	06/30/1998	Not Required	Not Required	Iowa has adopted Final Regulations equivalent to RATS ID: 1997-5.
1995-5	Radiation Protection Requirements: Amended Definitions and Criteria Parts 19, 20 60 FR 36038	08/14/1998	Final	No Comments 01/14/2000 ML003683660	
1995-6	Clarification of Decommissioning Funding Requirements Parts 30, 40, 70 60 FR 38235	11/24/1998	Final	No Comments 01/14/2000 ML003683660	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
1995-7	Medical Administration of Radiation and Radioactive Materials Parts 20, 35 60 FR 48623 (Superceded by 2002-2 and 2005-2)	10/20/1998	Final	No Comments 01/14/2000 ML003683660	Iowa 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 (Superceded by 2004-1)	04/01/1999	Final ML033640452	No Comments 02/04/2004 ML040360241	Iowa has adopted Final Regulations equivalent to RATS ID: 2004-1.
1996-2	One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses Parts 30, 40, 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, 70 61 FR 24669	06/17/1999	Final	No Comments 01/14/2000 ML003683660	
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 01/14/2000 ML003683660	
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 ML033640452	No Comments 02/04/2004 ML040360241	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
1997-3	Criteria for the Release of Individuals Administered Radioactive Material Parts 20, 35 62 FR 4120	05/29/2000	Final ML033640452	No Comments 02/04/2004 ML040360241	
1997-4	Fissile Material Shipments and Exemptions Part 71 62 FR 5907 (Superseded by 2004-1)	02/10/2000	Final ML033640452	No Comments 02/04/2004 ML040360241	These regulation changes are not required to be adopted for purposes of Compatibility. (See STP-97-078) Iowa has adopted Final Regulations equivalent to RATS ID: 2004-1.
1997-5	Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations Parts 30, 34, 71, 150 62 FR 28947	06/27/2000	Final ML050320039	No Comments 04/06/2005 ML050960431	
1997-6	Radiological Criteria for License Termination Parts 20, 30, 40, 70 62 FR 39057	08/20/2000	Final ML033640452	No Comments 02/04/2004 ML040360241	
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 01/14/2000 ML003683660	
1998-1	Deliberate Misconduct by Unlicensed Persons Parts 30, 40, 61, 70, 71, 150 63 FR 1890; 63 FR 13773	02/12/2001	Final ML033640452	No Comments 02/04/2004 ML040360241	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
1998-2	Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees Parts 30, 40, 70 63 FR 29535	07/01/2001	Final ML033640452	No Comments 2/04/2004 ML040360241	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 (Superseded by 2002-2)	07/10/2001	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility. (See STP-98-074) Iowa has adopted Final Regulations equivalent to RATS ID: 2002-2.
1998-4	Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations Part 34 63 FR 37059	07/09/2001	R ⁱⁱ ML003692594 Final ML14336A643	No Comments 03/21/2000 ML003694911 No Comments 01/07/2015 ML14328A559	
1998-5	Minor Corrections, Clarifying Changes, and a Minor Policy Change Parts 20, 32, 35, 36, 39 63 FR 39477; 63 FR 45393	10/26/2001	Final ML033640452	No Comments 2/04/04 ML040360241	
1998-6	Transfer for Disposal and Manifests: Minor Technical Conforming Amendment Part 20 63 FR 50127	11/20/2001	Final ML033640452	No Comments 02/04/2004 ML040360241	
1999-1	Radiological Criteria for License Termination of Uranium Recovery Facilities Part 40 64 FR 17506	06/11/2002	Not Applicable	Not Applicable	Iowa does not have authority to regulate this material under its Agreement.

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
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 ML033640452	No Comments 02/04/2004 ML040360241	
2000-1	Energy Compensation Sources for Well Logging and Other Regulatory Clarifications Part 39 65 FR 20337	05/17/2003	Final ML033640452	No Comments 02/04/2004 ML040360241	
2000-2	New Dosimetry Technology Parts 34, 36, 39 65 FR 63750	01/08/2004	Final ML033640452	No Comments 02/04/2004 ML040360241	
2001-1	Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material Parts 30, 31, 32 65 FR 79162	02/16/2004	Final ML13364A205	No Comments 02/20/2014 ML13364A196	
2002-1	Revision of the Skin Dose Limit Part 20 67 FR 16298	04/05/2005	Final ML033640452	No Comments 02/04/2004 ML040360241	
2002-2	Medical Use of Byproduct Material Parts 20, 32, 35 67 FR 20249	10/24/2005	Final ML081790082	No Comments 07/07/2008 ML081890129	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
2003-1	Financial Assurance for Materials Licensees Parts 30, 40, 70 68 FR 57327	12/03/2006	Final ML071970162	No Comments 09/24/2007 ML072670007	
2004-1	Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments Part 71 69 FR 3697	10/01/2007	Final ML071970162	No Comments 09/24/2007 ML072670007	
2005-1	Security Requirements for Portable Gauges Containing Byproduct Material Part 30 70 FR 2001	07/11/2008	Final ML071970162	No Comments 09/24/2007 ML072670007	
2005-2	Medical Use of Byproduct Material - Recognition of Specialty Boards Part 35 70 FR 16336; 71 FR 1926	04/29/2008	Final ML081790082	No Comments 07/07/2008 ML081890129	
2005-3	Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090) 70 FR 72128	12/01/2005	Proposed ML053550019 License Condition ML052520149	No Comments 01/19/2006 ML060200518 No Comments 09/14/2005 ML052570342	
2006-1	Minor Amendments Parts 20, 30, 32, 35, 40 and 70 71 FR 15005	03/27/2009	Final ML081790082	No Comments 07/07/2008 ML081890129	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
2006-2	National Source Tracking System - Serialization Requirements Part 32 with reference to Part 20 Appendix E 71 FR 65685	02/06/2007	Final ML071970162	No Comments 09/24/2007 ML072670007	
2006-3	National Source Tracking System Part 20 71 FR 65685, 72 FR 59162	01/31/2009	Final ML081790082	No Comments 07/07/2008 ML081890129	
2007-1	Medical Use of Byproduct Material - Minor Corrections and Clarifications Parts 32 and 35 72 FR 45147, 54207	10/29/2010	Final ML092170036	No Comments 09/16/2009 ML092310395	
2007-2	Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements Parts 30, 31, 32, 150 72 FR 58473	12/17/2010	Final ML092170036	No Comments 09/16/2009 ML092310395	
2007-3	Requirements for Expanded Definition of Byproduct Material Parts 20, 30, 31, 32, 33, 35, 61, 150 72 FR 55864	11/30/2010	Final ML102280251	No Comments 09/15/2010 ML102420351	
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 ML080310554	No Comments 02/13/2008 ML080440168	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Letter	Outgoing Package	Notes
2008-1	Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent Parts 19, 20 72 FR 68043	02/15/2011	Final ML102280251	No Comments 09/15/2010 ML102420351	
2009-1	Medical Use of Byproduct Material – Authorized User Clarification Part 35 74 FR 33901	09/28/2012	Final ML102280251	No Comments 09/15/2010 ML102420351	
2011-1	Decommissioning Planning Parts 20, 30, 40, 70 76 FR 35512	12/17/2015	Final ML14282A082	No Comments 11/7/2014 ML14281A780	
2011-2	Licenses, Certifications, and Approvals for Materials Licensees Parts 30, 36, 39, 40, 70, and 150 76 FR 56951	11/14/2014	Final ML13364A205	No Comments 02/20/2014 ML13364A196	
2012-1	Change of Compatibility of 10 CFR 31.5 and 31.6 (See RATS ID: 2001-1 for Rule text) 77 FR 3640	01/25/2015	Final ML13364A205	No Comments 02/20/2014 ML13364A196	
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 ML14175A525	No Comments 08/13/2014 ML14171A424	
2012-3	Technical Corrections Part 30, 34, 40 and 71 77 FR 39899	08/06/2015	Final ML14282A082	No Comments 11/7/2014 ML14281A780	

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 ML14282A082	No Comments 11/7/2014 ML14281A780	
2013-1	Physical Protection of Byproduct Material, 10 CFR Parts 20, 30, 32, 33, 34, 35, 36, 37, 39, and 71 78 FR 16922	03/19/2016	Final ML14175A525	No Comments 08/13/2014 ML14171A424	
2013-2	Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions, 10 CFR Parts 30, 40, and 70 78 FR 32310	08/27/2016	Final ML14282A082	No Comments 11/7/2014 ML14281A780	
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			
*N/A	10 CFR Part 34 provisions not associated with a specific RATS ID	N/A	Final ML14363A294	Comments 03/12/2015 ML14363A207	

ⁱ IMPEP Team: verify that Iowa does not have any licensees subject to these regulations during each review.

ⁱⁱ R stands for proposed changes to a final rule.