April 15, 2010

Mr. Charles G. Vinson, Head
Radioactive Materials Section
Illinois Emergency Management Agency
Division of Nuclear Safety
1035 Outer Park Drive
Springfield, IL 62704

Dear Mr. Vinson:

We have reviewed the proposed changes to the Illinois regulations 32Ill. Administrative Code 32 Ill. Administrative Code Parts 310, 330, 331, 335, 340, and 346, received by our office on February 2, 2010. These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) rules in 10 CFR Parts 19, 20, 30, 31, 32, 33, 35, 36, 150, and the requirements of the five amendments identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with Steve Collins on April 9, 2010.

As a result of our review, we have eight 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 Illinois 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 Illinois 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 Federal and State Materials and Environmental Management Programs (FSME) 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 FSME Procedure SA-201, "Review of State Regulatory Requirements," please highlight the final changes, and provide a copy to Division of Materials Safety and State Agreements, FSME.

The SRS Data Sheet summarizes our knowledge of the status of other Illinois 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 FSME website: http://nrc-stp.ornl.gov/rulemaking.html.

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 Kathleen Schneider, State Regulation Review Coordinator at (301) 415-2320 (kathleen.schneider@nrc.gov) or Andrew Carrera at (301) 415-1078 (andrew.carrera@nrc.gov).

Sincerely,

/RA K.N. Schneider for/

Terrence Reis, Deputy Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

Enclosures:
As stated

[Concurrence Page]

Enclosures: As stated

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OFFICE	DILR		ASPB		OGC		ASPB:BC		MSSA:DD	
NAME	ACarrera		KSchneider		BJones		DWhite		TReis	
DATE	03/10/10		03/15/10		03/29/10		04/15/10		04/15/10	

COMPATIBILITY COMMENTS ON *Illinois* PROPOSED REGULATIONS

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	330.40	§30.15	2007-2	B	**Certain items containing byproduct material** Illinois' regulation omits the language "Ionization chamber smoke detectors containing not more than 1 microcurie (µCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires". Illinois needs to add the above language in order to meet the Compatibility Category B designation assigned to 10 CFR 30.15 (a)(7).
2	330.10	§30.4	2007-3	C	**Definition** Illinois regulation omits the definition of *Consortium.* Illinois needs to add the definition of "*Consortium* means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a Federal facility or a medical facility", in order to meet the Compatibility Category C designation assigned to 10 CFR 30.4.
3	330.220	§31.5 (b)(1) & (c)(13)	2007-3	B	**Certain detecting, measuring, gauging, or controlling devices and/or an ionizing atmosphere**. Illinois omits the registration requirement for devices containing at

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					least 370 megabecquerels (10 millicuries) of Cesium-137 and 37 megabecquerels (1 millicurie) of cobalt-60. Illinois needs to add the above requirements in order to meet the Compatibility Category B designation assigned to 10 CFR 31.5.
4	330.220	§31.12	2007-3	C	**General license for certain items and self-luminous products containing radium-226.** Illinois regulations 330.220 (h)(1)(B) and (E) use the equivalent of 1 millicurie to 0.037 megabecquerel. 0.037 megabecquerel is equivalent to 1 microcurie. Illinois needs to make the above adjustment in order to meet the Compatibility Category C designation assigned to 10 CFR 31.12.
5	330.260	§32.72 (a)(2)(i), (iii), (iv), (v), & (b)	2007-3	B	**Manufacture, preparation, or transfer for commercial distribution of radioactive drugs, containing byproduct material for medical use under Part 35.** Illinois regulation in 330.260 (c) omits the allowance of provision 10 CFR 32.72 (a)(2)(v) “A Positron Emission Tomography (PET) drug production facility registered with a State agency”. Illinois needs to make the above adjustment in order to meet the Compatibility Category B designation assigned to 10 CFR 32.72 (a)(2)(v).
6	335.3010	§35.100 (a) & (b)	2007-3	H&S	**Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.**

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					Illinois regulation in 335.3010 omits the allowance of provision 10 CFR 35.100 (a)(2) “A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements, or”. Illinois needs to make the above adjustment in order to meet the Compatibility Category H&S designation assigned to 10 CFR 35.100 (a)(2).
7	335.4010	§35.200 (a) & (b)	2007-3	H&S	**Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.** Illinois regulation in 335.4010 omits the allowance of provision 10 CFR 35.200 (a)(2) “A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements, or”. Illinois needs to make the above adjustment in order to meet the Compatibility Category H&S designation assigned to 10 CFR 35.200 (a)(2).
8	335.5010	§ 35.300 (a) & (b)	2007-3	H&S	**Use of unsealed byproduct material for which a written directive is required.** Illinois regulation in 335.5010 omits the allowance of provision 10 CFR 35.300 (a)(2) “A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements, or”. Illinois needs to make the above adjustment in order to meet the Compatibility Category H&S designation assigned to 10 CFR 35.300 (a)(2).

STATE REGULATION STATUS

State: Illinois
[5 amendment(s) reviewed is identified by a ★
at the beginning of the equivalent NRC requirement.]

Tracking Ticket Number: 10-8
Date: April 15, 2010

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1991-1	Safety Requirements for Radiographic Equipment Part 34 55 FR 843 (**Superceded by 1997-5)**	01/10/1994	Final ML051220064	No Comments 08/23/2005 ML052370399	Illinois 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	Final ML051220064	No Comments 08/23/2005 ML052370399	Illinois 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 ML052710117	No Comments 11/17/2005 ML053210292	
1991-4	Notification of Incidents Parts 20, 30, 31, 34, 39, 40, 70 56 FR 64980;	10/15/1994	Final ML051220064	No Comments 08/23/2005 ML052370399	
1992-1	Quality Management Program and Misadministrations Part 35 56 FR 34104 **(Superceded by 2002-2)**	01/27/1995	Final ML060970127	No Comments 05/30/2006 ML061510195	Illinois has adopted Final Regulations equivalent to RATS ID: 2002-2.
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	No Comments 08/21/2000	
1993-2	Licensing and Radiation Safety Requirements for Irradiators Part 36 58 FR 7715	07/01/1996	Final ML060250219	No Comments 03/07/2006 ML060660001	
1993-3	Definition of Land Disposal and Waste Site QA Program Part 61 58 FR 33886	07/22/1996	Not Applicable[1]	Not Applicable	Illinois does not have any licensees subject to these regulations. (See SECY-95-112)

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1994-1	Self-Guarantee as an Additional Financial Mechanism Parts 30, 40, 70 58 FR 68726; 59 FR 1618	none	Final	No Comments 08/21/2000	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[1]	Not Applicable	Illinois does not have any licensees subject to these regulations. (See SECY-95-112)
1994-3	Timeliness in Decommissioning Material Facilities Parts 30, 40, 70 59 FR 36026	08/15/1997	Final	No Comments 08/21/2000	
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 ML060970127	No Comments 05/30/2006 ML061510195	
1995-2	Frequency of Medical Examinations for Use of Respiratory Protection Equipment Part 20 60 FR 7900	03/13/1998	Not Applicable[1]	Not Applicable	Illinois does not have any licensees subject to these regulations. (See SECY-95-112)
1995-3	Low-Level Waste Shipment Manifest Information and Reporting Parts 20, 61 60 FR 15649; 60 FR 25983	03/01/1998	Final ML060250219	No Comments 03/07/2006 ML060660001	
1995-4	Performance Requirements for Radiography Equipment Part 34 60 FR 28323 **(Superceded by 1997-5)**	06/30/1998	Final ML051220064	No Comments 08/23/2005 ML052370399	Illinois 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 ML060250219	No Comments 03/07/2006 ML060660001	
1995-6	Clarification of Decommissioning Funding Requirements Parts 30, 40, 70 60 FR 38235	11/24/1998	Final ML051220062	No Comments 08/23/2005 ML052370399	
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 ML060970127	No Comments 05/30/2006 ML061510195	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
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 ML051220062	No Comments 08/23/2005 ML052370399	Illinois 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 08/21/2000	
1997-1	Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act Part 20 61 FR 65120	01/9/2000	Final ML060250219	No Comments 03/07/2006 ML060660001	
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 08/21/2000	
1997-3	Criteria for the Release of Individuals Administered Radioactive Material Parts 20, 35 62 FR 4120	05/29/2000	Final ML060970127	No Comments 05/30/2006 ML061510195	
1997-4	Fissile Material Shipments and Exemptions Part 71 62 FR 5907 **(Superceded by 2004-1)**	02/10/2000	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility. (See STP-97-078) Illinois 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 ML051220064	No Comments 08/23/2005 ML052370399	
1997-6	Radiological Criteria for License Termination Parts 20, 30, 40, 70 62 FR 39057	08/20/2000	Final ML051220062	No Comments 08/23/2005 ML052370399	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
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 05/26/2000	
1998-1	Deliberate Misconduct by Unlicensed Persons Parts 30, 40, 61, 70, 71, 150 63 FR 1890; 63 FR 13773	02/12/2001	Final ML060250219	No Comments 03/07/2006 ML060660001	
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	No Comments 08/21/2000	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 **(Superceded 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) Illinois 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	Final ML051220064	No Comments 08/23/2005 ML052370399	
1998-5	Minor Corrections, Clarifying Changes, and a Minor Policy Change Parts 20, 35, 36 63 FR 39477; 63 FR 45393	10/26/2001	Final ML060970127	No Comments 05/30/2006 ML061510195	
1998-6	Transfer for Disposal and Manifests: Minor Technical Conforming Amendment Part 20 63 FR 50127	11/20/2001	Final ML060250219	No Comments 03/07/2006 ML060660001	
1999-1	Radiological Criteria for License Termination of Uranium Recovery Facilities Part 40 64 FR 17506	06/11/2002	Not Applicable[1]	Not Applicable	Illinois does not have any licensees subject to these regulations. (See SECY-95-112)
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.

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1999-3	Respiratory Protection and Controls to Restrict Internal Exposure Part 20 64 FR 54543; 64 FR 55524	02/02/2003	Final ML060250219	No Comments 03/07/2006 ML060660001	
2000-1	Energy Compensation Sources for Well Logging and Other Regulatory Clarifications Part 39 65 FR 20337	05/17/2003	Final ML051220064	No Comments 08/23/2005 ML052370399	
2000-2	New Dosimetry Technology Parts 34, 36, 39 65 FR 63750	01/08/2004	Final ML060250219 Final ML051220064	No Comments 03/07/2006 ML060660001 (Part 36 only) No Comments 08/23/2005 ML052370399 (Parts 34 and 39 only)	
2001-1	Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material Parts 30, 31, 32 65 FR 79162	02/16/2004	Final ML060970127	Comments 05/30/2006 ML061510195	
2002-1	Revision of the Skin Dose Limit Part 20 67 FR 16298	04/05/2005	Final ML072920541	No Comments 11/09/2007 ML073120463	
2002-2	Medical Use of Byproduct Material Parts 20, 32, 35 67 FR 20249	10/24/2005	Final ML060970127	No Comments 05/30/2006 ML061510016	
2003-1	Financial Assurance for Materials Licensees Parts 30, 40, 70 68 FR 57327	12/03/2006	Final ML052710117	No Comments 11/17/2005 ML053210292	
2004-1	Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments Part 71 69 FR 3697	10/01/2007	Final ML061660148	No Comments 07/18/2006 ML061990338	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
2005-1	Security Requirements for Portable Gauges Containing Byproduct Material Part 30 70 FR 2001	07/11/2008	Final ML072920541	No Comments 11/09/2007 ML073120463	
2005-2	Medical Use of Byproduct Material - Recognition of Specialty Boards Part 35 70 FR 16336; 71 FR 1926	04/29/2008	Final ML082620058	No Comments 09/18/2008 ML082320963	
2005-3	Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090) 70 FR 72128	12/01/2005	License Condition ML052990499	No Comments 10/31/2005 ML053050005	
2006-1	Minor Amendments Parts 20, 30, 32, 35, 40 and 70 71 FR 15005	03/27/2009	Revised Final ML082620058	No Comments 09/18/2008 ML082320963	
2006-2	National Source Tracking System - Serialization Requirements Part 32 with reference to Part 20 Appendix E 71 FR 65685	02/06/2007	Final ML081700688	No Comments 07/07/2008 ML081840613	
2006-3	National Source Tracking System Part 20 71 FR 65685, 72 FR 59162	01/31/2009	Final ML081700688	No Comments 07/07/2008 ML081840613	
*2007-1	Medical Use of Byproduct Material - Minor Corrections and Clarifications Parts 32 and 35 72 FR 45147, 54207	10/29/2010	Proposed ML100470307	No Comments 04/15/2010 ML100760404	
*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	Proposed ML100470307	Comments 04/15/2010 ML100760404	
*2007-3	Requirements for Expanded Definition of Byproduct Material Parts 20, 30, 31, 32, 33, 35, 61, 150 72 FR 55864	11/30/2010	Proposed ML100470307	Comments 04/15/2010 ML100760404	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	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 ML080800070	No Comments 04/07/2008 ML080980514	
*2008-1	Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent Parts 19, 20 72 FR 68043	02/15/2011	Proposed ML100470307	No Comments 04/15/2010 ML100760404	
*2009-1	Medical Use of Byproduct Material – Authorized User Clarification Part 35 74 FR 33901	09/28/2012	Proposed ML100470307	No Comments 04/15/2010 ML100760404	

[1] IMPEP Team: verify that Illinois does not have any licensees subject to these regulations during each review.