

Arkansas Department of Health

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Governor Sarah Huckabee Sanders
Renee Mallory, RN, BSN, Interim Secretary of Health
Jennifer Dillaha, MD, Director

May 10, 2023

Theresa V. Clark, Deputy Director
Division of Materials Safety, Security, State and Tribal Programs
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
T8-E18
Washington, D.C. 20555-0001

Dear Ms. Clark:

Enclosed is a copy of proposed revisions to the Arkansas State Board of Health's <u>Rules for Control of Sources of Ionizing Radiation</u>, effective December 20, 2021. At the earliest, these "July 2023" proposed revisions will be made available for public comment on approximately September 1, 2023, with a request for comments by approximately October 1, 2023. We request NRC's comments by June 12, 2023, if possible. The proposed rules are identified by line-in/line-out text and by a right-sided border.

The following RATS IDs are addressed:

RATS ID	Title	State Section
2019-2	Organizational Changes and Conforming Amendments	Section 4
2020-1	Individual Monitoring Devices	Sections 3, 8
2020-2	Social Security Number Fraud Prevention	Section 9
2020-3	Miscellaneous Corrections	Sections 2, 3, 4, 9
2021-1	Miscellaneous Corrections	Sections 2, 3, 9, 12
2021-2	Miscellaneous Corrections	Section 12
2022-1*	Miscellaneous Corrections	Not applicable
2022-2*	Miscellaneous Corrections	Not applicable

^{*}not required for compatibility

We believe that adoption of these revisions satisfies the compatibility and health and safety categories established in the Office of Nuclear Material Safety and Safeguards (NMSS) Procedure SA-200. Attached are cross-references for the RATS IDs listed above.

Note that language addressing RATS ID 2018-1 is included in the attached rule draft (in blue), but this RATS ID has already been reviewed by the NRC as part of the proposed rule package submittal dated June 9, 2021. RATS ID 2018-1 was not able to continue in the rulemaking process with other RATS IDs in 2021. No changes have been made to 2018-1 reviewed language – except for two minor revisions in paragraphs designated as Compatibility Category D, language inserted due to RATS 2021-1, and as noted in Appendix A.

Also, note that some changes reflecting removal of the word "regulation" and replacing with "rule" are included in the attached rule draft, but the NRC in letter dated March 24, 2022, determined these changes due to the implementation of Arkansas Act 315 of 2019 do not need a compatibility review.

Please review Appendix A containing proposed revisions to sections not in conjunction with a RATS ID.

Additionally enclosed, as Appendix B, is the Department's response to two comments received from the NRC in letter dated October 25, 2017.

If you have any questions, please contact me at (501) 661-2301 [Bernard.Bevill@arkansas.gov] or Angela Minden of my staff at (501) 661-2528 [Angela.Minden@arkansas.gov].

Sincerely,

Bernard (Bernie) Bevill, Section Chief Radiation Control Section Arkansas Department of Health

Enclosures: As stated

BB:AM

Organizational Changes and Conforming Amendments 10 CFR Parts 1, 2, 37, 40, 50, 51, 52, 55, 71, 72, 73, 74, 100, 140, and 150 (84 FR 65639, Published November 29, 2019 and 84 FR 66561, Published December 5, 2019)

RATS ID: 2019-2

Effective Date: December 30, 2019 Date Due for State Adoption: December 30, 2022 ARKANSAS CROSS REFERENCE

Change to NRC Section	Title	State Section	Comp. Category	Notes
§ 37.7(a)	Communications	RH-11007.	D	NA
§ 40.64(a) & (b)(2)	Reports	NA	NRC	
§ 71.1	Communications and Records	RH-3003.	D	NA
§ 71.17(c)(3)	General License: NRC approved package	RH-3301.c.3.	В	
§ 71.95	Reports	RH-3508.	D	NA
§ 71.101	Quality Assurance requirements	RH-3600.	С	No change needed in RH- 3600.c. – already says Department.
§ 150.16	Submission to Commission of nuclear material transaction reports	NA	NRC	
§ 150.17	Submission to Commission of nuclear material transaction reports	NA	NRC	

Individual Monitoring Devices 10 CFR Parts 34, 36, and 39 (85 FR 15347, Published March 18, 2020)

RATS ID: 2020-1

Effective Date: June 16, 2020

Date Due for State Adoption: June 16, 2023 ARKANSAS CROSS REFERENCE

Change to NRC Section	Title	State Section	Comp. Category	Notes
§ 34.47	Personnel monitoring	RH-1802.f.1. RH-1802.f.1.C. RH-1802.f.4. RH-1802.f.5.	С	Revised all of paragraph f. Also revised incorrect reference in RH-1301.a. [§ 20.1501(d), H&S] Revised RH-1803.f. (no NRC equivalent)
§ 34.83	Records of personnel monitoring	RH-1800.d.11.C.	С	
§ 36.55	Personnel monitoring	RH-7055.	H&S	
§ 39.65	Personnel monitoring devices	RH-1965.	С	

Social Security Number Fraud Prevention 10 CFR Parts 9 and 35 2 33527 Published June 2, 2020 and 85 FR 44

(85 FR 33527, Published June 2, 2020 and 85 FR 44685) RATS ID: 2020-2

Effective Date: August 17, 2020
Date Due for State Adoption: August 17, 2023
ARKANSAS CROSS REFERENCE

Change to NRC Section	Title	State Section	Comp. Category	Notes
§ 35.3045(g)(1) (ii)	Report and notification of a medical event	RH-8703.	С	There is no NRC equivalent to RH-8703. NRC instead addresses the reports (records) within § 35.3045.
				Section had been included as part of RATS 2018-1.
				No change. Licensee's decision as to which identifying # they want to include in the report they are retaining and providing to the referring physician. Report to NRC/AS does not contain the patient name or other identifier.
§ 35.3047(f)(1) (ii)	Report and notification of a dose to an embryo/fetus or a nursing child	RH-8704.	С	There is no NRC equivalent to RH-8704. NRC instead addresses the reports (records) within § 35.3047.
				No change. Licensee's decision as to which identifying # they want to include in the report they are retaining and providing to the referring physician. Report to NRC/AS does not contain names or other patient identifiers.

Miscellaneous Corrections

10 CFR Parts 1, 2, 19, 20, 21, 30, 34, 35, 40, 50, 51, 52, 60, 61, 62, 63, 70, 71, 72, 73, 74, 75, 76, 110, and 140 85 FR 65656

RATS ID: 2020-3

Effective Date: November 16, 2020 Date Due for State Adoption: November 16, 2023

ARKANSAS CROSS REFERENCE

Revised 06/2022 to add reviewer notes for reports/notifications provisions

Change to NRC Section	· · · · · · · · · · · · · · · · · · ·		•	Notes
§ 19.8(b)	Information collection requirements: OMB approval	NA	D	
§ 20.1906(d)			H&S	Revising other paragraphs in RH-1307 as well
§ 20.2201(a)(2) (ii)	Reports of theft or loss of licensed material	RH-1501.a.2.	С	No change needed
§ 20.2202(d)(2)	Notification of incidents	RH-1502.c.	С	No change needed
Appendix D to Part 20	United States Nuclear Regulatory Commission Offices	NA	D	
§ 30.50(c)(1)	Reporting requirements	RH-601.c.1.	С	No change needed
§ 34.8(b)	Information collection requirements: OMB approval	NA	D	
§ 35.390(a)(1)	Training for use of unsealed byproduct material for which a written directive is required	RH-8560.a.1.	В	Already reviewed as part of RATS 2018-1
§ 35.490	Training for use of manual brachytherapy sources	RH-8610.a.1. RH-8610.b.2.	В	Already reviewed as part of RATS 2018-1

Change to NRC Section	Title	State Section	Comp. Category	Notes
§ 35.690	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	RH-8660.a.1. RH-8660.b.2.	В	Already reviewed as part of RATS 2018-1
§ 40.8(b)	Information collection requirements: OMB approval	NA	D	
§ 40.31(g)(1)	Application for specific licenses	NA	D	
§ 40.60(c)(1)	Reporting requirements	RH-601.c.1.	С	No change needed
§40.67(c) and (d)	Requirement for advance notice for importation of natural uranium from countries that are not party to the Convention on the Physical Protection of Nuclear Material.	NA	NRC	
§ 61.8(c)	Information collection requirements: OMB approval	NA	D	
§ 61.32(a)	Facility information and verification	NA	D	
§ 70.8(c)(1)	Information collection requirements: OMB approval	NA	D	
§ 70.21(g)(1)	Filing	NA	NRC	
§ 70.50(c)(1)	Reporting requirements	RH-601.c.1.	С	No change needed
§ 70.52(a)	Reports of accidental criticality	NA	NRC	
§ 71.97(c)(3)(i)	Advance notification of shipment of irradiated reactor fuel and nuclear waste	RH-3509.c.3.A.	В	No changed needed; was revised during RATS 2018-3
Appendix A to Part 71, Table A-1	A1 and A2 Values for Radionuclides Exempt Material Activity Concentrations and Exempt Consignment Activity Limits for Radionuclides	Table A-1 of Appendix A to Section 4	[B]	

Miscellaneous Corrections

10 CFR Parts 2, 11, 20, 25, 32, 35, 37, 50, 52,55, 70, 72, 73, 95, and 110 86 FR 43397/Published August 9, 2021 and 86 FR 47209/Published August 24, 2021 corrected version

RATS ID: 2021-1

Effective Date: September 8, 2021 Date Due for State Adoption: September 8, 2024

ARKANSAS CROSS REFERENCE

Change to NRC Section	Title	State Section	Comp. Category	Notes
§ 20.2207(h) Remove	Reports of transactions involving nationally tracked sources	RH-1513.h.	 [formerly B]	
§ 32.15(d)	Quality assurance, prohibition of transfer and labeling	NA	NRC	
§ 35.50(c)(3)	Training for Radiation Safety Officer and Associate Radiation Safety Officer	RH- 8315.c.3.	В	Change already reviewed as part of RATS 2018-1
§ 35.55(a)(1)	Training for authorized nuclear pharmacist	RH- 8317.a.1.	В	Language added into section previously reviewed as part of RATS 2018-1
§ 35.57(b)(2)	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist	RH- 8318.b.2.	В	Language added into section previously reviewed as part of RATS 2018-1
§ 37.27(c)(1)	Requirements for criminal history record checks of individuals granted unescorted access to category 1 or category 2 quantities of radioactive material	RH- 11027.c.1.	В	No change needed – in current rule
§ 70.22(g)(3)	Contents of application	NA	NRC	
§ 70.32(a)(9) (i)(B) and (C)	Conditions of licenses	RH- 409.g.1.B. and C.	H&S	No change needed – in current rule

Miscellaneous Corrections 10 CFR Parts 9, 37, 40, 50, 51, 52, 55, 71, 73, and 110 (86 FR 67839, Published November 30, 2021) RATS ID: 2021-2

Effective Date: December 30, 2021 Date Due for State Adoption: December 30, 2024

ARKANSAS CROSS REFERENCE

Change to NRC Section	Title	State Section	Comp. Category	Notes
Appendix A to Part 37	Category 1 and Category 2 Radioactive Materials	Appendix A to Section 12	В	Inserted revised formula
§ 40.23	General license for carriers of transient shipments of natural uranium other than in the form of ore or ore residue.	NA	NRC	
§ 40.66	Requirements for advance notice of export shipments of natural uranium.	NA	NRC	
§ 40.67	Requirement for advance notice for importation of natural uranium from countries that are not party to the Convention on the Physical Protection of Nuclear Material.	NA	NRC	
§ 71.4	Definitions	RH-3100 (NA)	D	

APPENDIX A

SECTIONS FOR REVIEW – NOT IN CONJUNCTION WITH A RATS ID*

AR SECTION	TITLE	NRC SECTION	CATEGORY	NOTES
RH-301.a.1.	Exempt concentrations.	30.14(a)	В	
RH-301.b.1.	Certain items containing radioactive material.	30.15(a)	В	
RH-401.a.2.C	Small quantities of source material.	40.22(b)(3)	В	See SA-201, Appendix A, Section I – Differences That Are Not Significant, references to other rules for reader convenience (transportation and "additional requirements"); to match other GL's; Language in RH-751 is equivalent to 20.2302 (Comp D), and SSR includes at C.20c. (A.7). See email dated 8/26/22.
RH-401.c.5. and c.6.	Certain industrial products or devices.	40.25(e) (no equivalent to c.6.	С	See SA-201, Appendix A, Section I – Differences That Are Not
С.б.		- references to Part 40 provisions like in 40.22(b)(3))		Significant, references to other rules for reader convenience; to match other GL's and Table C-8 of Appendix C of NUREG-1556, vol. 16, rev. 1. RH-1400. (20.2001) is a requirement in RH-401.c.4.C. (SSR's C.21e.iv.(3)). RH-1216. is 20.1402 equivalent. 20.2001 and 20.1402

				are Comp C. See email dated 8/16/22.
RH-402.e.	Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.	31.2	D	Not required for compatibility.
RH-402.f.5.	Luminous safety devices in aircraft.	31.2	D	Not required for compatibility.
RH-402.g.5.	Calibration and reference sources.	31.8(c), 31.2 70.19(c)	D, D C	Not required for compatibility. Limiting RH-409. to those provisions required for the GL, includes 70.32(a)(9) which is H&S. Utilizing Table C-9 of Appendix C of NUREG-1556, vol. 16, rev. 1.
RH-402.i.4.	Ice detection devices.	31.2	D	Not required for compatibility.
RH-402.j.2.	Products containing radium-226.	31.12(b)	С	This GL is not exempt from RH-600.c.
RH-402.j.5.	Products containing radium-226.	31.2	D	Not required for compatibility.
RH-402.k.7.	Use of radioactive material for certain in vitro clinical or laboratory testing.	31.2	D	Not required for compatibility.
RH-402.n.	Incidentally produced radioactive material generated by the operation of a particle accelerator.	No equivalent		GL is for medical accelerator facilities (except proton accelerator – would be SL).
RH-5002.c.	Purpose and Scope. Production of radioactive material.	No equivalent		References RH-402.n.
RH-405.l.1.B.ii., iii., and v. RH-405.l.2.E.vi.	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use under Section 9, "Use of Radionuclides in the Healing Arts."	32.72(a)(2)(ii), (iii), and (v) 32.72(b)(5)(vi)	В	Provisions to reflect Arkansas Board of Pharmacy rules regarding pharmacy permitting and pharmacist licensing.

				32.72(b)(5)(vi) is explained in 58 FR 33396.
RH-409.g.1.	Bankruptcy notification.	30.34(h)(1) 70.32(a)(9)(i)	H&S H&S	Notification to be required of RH-402.g.2. general licensees.
RH-750.a.2. and b.2.	Reciprocal Recognition of Licenses.	31.6	С	
RH-1300.c.	Surveys.	20.1501(c)	H&S	Defining "periodically."
RH-1915.a.3.	Agreement with Well Owner or Operator.	39.15(a)(3)	С	Correcting a reference.
RH-1915.b.	Agreement with Well Owner or Operator.	39.15(b)	С	
RH-1961.e.	Training.	39.61(e)	В	RH-1992. to be deleted.
RH-8500.d.	Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive Is Not Required.	35.100(d)	H&S	
RH-8634.f. preamble	Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.	35.615(f) preamble	H&S	
RH-8801.d.1.E.	Reports and Notifications of a Dose to an Embryo/Fetus or a Nursing Child.	35.3407(d)(1)(v)	С	

^{*}Some Compatibility D regulations have been included as an aid to the reviewer, not as a request to review.

APPENDIX B

RESPONSE TO COMMENTS DATED OCTOBER 25, 2017 – REGARDING NRC'S REVIEW OF "JANUARY 2017 PACKAGE" FINAL REGULATIONS SUBMITTED SEPTEMBER 20, 2017

AR S	ECTION	NRC SECTION	RATS ID	CATEGORY	TITLE	RESPONSE
4	RH-3600.a.	71.101(a)	2015-3	С	Quality assurance requirements - Purpose	The sentence in question needs to remain, with the newly revised wording as indicated, in order to explain who is responsible for the design, fabrication, testing, and modification of packaging requirements listed in the first sentence of RH-3600.a. Explaining in paragraph RH-3600.a., "Purpose," what entities are governed by the NRC also provides clarity to RH-3602.b. and c. where "certificate holder" and "applicant for a CoC" are used. The proposed wording meets the intent of SA-200 and MD 5.9 (concerning the description of Compatibility Category C) and the "Criteria for Comparing Regulations and Identifying Differences" document available on the Regulation Toolbox – Resources webpage

AR SECTION		NRC SECTION	RATS ID	CATEGORY	TITLE	RESPONSE
						(concerning the incorporation of supplementary/parenthetical information).
7	RH-600.a.2.	40.61(a)(2)	2015-4	С	Records	See revised language at RH-600.a.2.