# QUESTIONNAIRE FOR FILING PROPOSED RULES AND REGULATIONS WITH THE ARKANSAS LEGISLATIVE COUNCIL AND JOINT INTERIM COMMITTEE

D	EPARTMENT/AGENCY	Arkansas I	Departn	nent of Health	L	RECE	VED
D	IVISION	Health Sys	tems L	icensing and	Regulation		
D	IVISION DIRECTOR	Renee Mal	lory			FEB 07	2012
C	ONTACT PERSON	Robert Bre				BUREA	U OF
<b>A</b> ]	DDRESS	4815 West Little Rock			LE	GISLATIVE	
Pl	HONE NO. 661-2297	FAX NO	O. <u>(</u>	582-2357	_ E-MAIL	robert.brech@	arkansas.gov
N.	AME OF PRESENTER A	T COMMI	TTEE	MEETING	Renee M	<b>I</b> allory	
PI	RESENTER E-MAIL	renee.mallo					
			INST	RUCTIONS			
C. D.	Please answer each ques necessary.  If you have a method of a Title of this Rule" below. Submit two (2) copies of front of two (2) copies of Donna K. Day Administrativ. Arkansas Leg Bureau of Leg Room 315, St. Little Rock, A	indexing you this question the proposition of the p	ur rule onnaire ed rule view S uncil search	es, please give and financia and require	e the propos al impact sta d document	ed citation afte stement attache s. Mail or deliv	r "Short ed to the ver to:
	What is the short title of the		Propo		to the Arka	nsas Rules and I	
2.	What is the subject of the	proposed rul	le?	radioactive Nuclear Reg	material lice gulatory Con	gulations to estal nsing fees at 159 nmission's annua ration fees in ac	% of the U.S. al rate and to
	Is this rule required to com If yes, please provide the f		regulat	ion, and/or sta	_		No 🛚
4.	Was this rule filed under the Procedure Act?			··	Administrativ	⁄e Yes □	No 🖂
	If yes, what is the effective	date of the	emerge	ency rule?	-N/A-		
	When does the emergency	rule expire?	•		-N/A-		<del></del>

	Will this emergency rule be promulgated under the permanent provisions of the Administrative Procedure Act?	f Yes 🔲	No 🖾
5.	Is this a new rule?	Yes 🗌	No 🖂
	If yes, please provide a brief summary explaining the regulation.		
<u>-N</u>	/A-		
		<b></b>	<b>5</b>
	Does this repeal an existing rule? If yes, a copy of the repealed rule is to be included with your completed que replaced with a new rule, please provide a summary of the rule giving an exrule does.	Yes estionnaire. xplanation o	No ⊠ If it is being f what the
<u>-N</u>	/A-		
	Is this an amendment to an existing rule? If yes, please attach a mark-up showing the changes in the existing rule and substantive changes. Note: The summary should explain what the ame mark-up copy should be clearly labeled "mark-up."	Yes ⊠ I a summary ndment doe	No ☐ of the s, and the
6.	Cite the state law that grants the authority for this proposed rule?		
٨؞	If codified, please give Arkansas Code citation. It 596 of the 88th General Assembly gave the Arkansas Board of Health auth	omigation to	atablish
rac	lioactive material license fees. Ark. Code Ann. §20-21-201 et seq. is the aut	thority for lic	ensing and
fee	es.	<del></del>	
Th Co	What is the purpose of this proposed rule? Why is it necessary? the Revisions will establish radioactive material license fees at 15% of the U.S. immission's comparable annual fees. The Revisions will document the currence accordance with Statue.	S. Nuclear R ent x-ray regi	egulatory stration fees
8.	Please provide the address where this rule is publicly accessible in electron required by Arkansas Code § 25-19-108(b).	ic form via t	he Internet as
wv	ww.healthy.arkansas.gov "Rules and Regs" link; www.sos.arkansas.gov "A	dministrativ	e Rules" link
9.	Will a public hearing be held on this proposed rule?	Yes 🔀	No 🗌
	If yes, please complete the following:		
	Date: March 8, 2012		
	Time: 10:00 a.m.  Central Office Auditorium  Arkansas Department of Health  4815 West Markham Street  Place: Little Rock, Arkansas		
10			
10.	. When does the public comment period expire for permanent promulgation? (Must provide a date.)  March 8, 201	2	<u> </u>
11	. What is the proposed effective date of this proposed rule? (Must provide a date.)  July 1, 2012	·	_
12	. Do you expect this rule to be controversial?	Yes 🔀	No 🗌
If	yes, please explain. Some radioactive material licensees may oppose the	e increase in	their current

license fees althoug ADH has worked with the Arkansas Hospital Association, the Arkansas Medical Society and the Department of Higher Education and none are opposed to these revisions.

13. Please give the names of persons, groups, or organizations that you expect to comment on these rules? Please provide their position (for or against) if known.

Private Practice Nuclear Medicine Licensees — Against

Industrial Gauge Licensees == Against

## FINANCIAL IMPACT STATEMENT

### PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT	Health					
DIVISION	Health Systems	s Licensing	and regulatio	n		
PERSON COMPLETING THIS STATEME			Γ Bernard (E	Bernie) Bevill		
TELEPHONE NO.	661-2301	FAX NO.	661-2236	EMAIL:	bernard.bevill@a	arkansas.gov
	To comply with Act 1104 of 1995, please complete the following Financial Impact Statement and file two copies with the questionnaire and proposed rules.					
SHORT TITLE OF	THIS RULE			the Arkansas l onizing Radia	Rules and Regulation	tions for
1. Does this proposed	d, amended, or i	repealed rul	e have a finar	ncial impact?	Yes 🛚	No 🗌
2. Does this proposed If yes, please attack Economic Development SEE ATTACHMENT	th a copy of the pment Commiss	economic ir	npact stateme	ent required to		No □ Arkansas
If you believe that prohibited, please	the development explain.		-		•	oe cost
No administrative cos	t to agency. Unl	cnown how	individual lic	ensees will be	affected.	_ <del></del>
<ol> <li>If the purpose of this rule is to implement a federal rule or regulation, please give the incremental cost for implementing the rule. Please indicate if the cost provided is the cost of the program.</li> <li>Current Fiscal Year</li> </ol> RECEIVEDNext Fiscal Year						
General Revenue Federal Funds Cash Funds Special Revenue Other (Identify) Total		FEB (	)7 <b>2012</b> EAU OF	General Revolution Federal Funds Cash Funds Special Reve Other (Identi Total	enue	
5. What is the total estimated cost by fiscal year to any party subject to the proposed, amended, or repealed rule? Identify the party subject to the proposed rule and explain how they are affected.  Current Fiscal Year  \$ 0						
6. What is the total extremely the program or grace Current Fiscal Year \$\ 0			to the agency	to implement  Next Fiscal  0		the cost of

### **ECONOMIC IMPACT STATEMENT** OF PROPOSED RULES OR REGULATIONS

EO 05-04: Regulatory Flexibility

RECEIVED

Department: 'Health'

Contact Person: 'Bernard (Bernie) Bevill'

Contact Phone: 501-661-2301

Division: Center for Health Protection

Date: February 2, 2012

Contact Email: bernard.bevill@arkansas.gov FEB 07 2012

BUREAU OF Title or Subject: Proposed Revisions to the Arkansas Rules and Regulations for Control of Sources of Ionizing Radiation

LEGISLATIVE RESEARCE

#### Benefits of the Proposed Rule or Regulation

Explain the need for the proposed change(s). Did any complaints motivate you to pursue regulatory action? If so, please explain the nature of such complaints.

Act 596 of the 88th General Assembly gave the Arkansas Board of Health authorization to establish radioactive material license fees not to exceed 25% of the U.S. Nuclear Regulatory Commission's (NRC) comparable annual fees. The Department's PROPOSED fees are 15% of the NRC annual fees. These regulations are NOT the result of complaints.

- What are the top three benefits of the proposed rule or regulation?
  - 1. Increased Department fees will provide the Radioactive Materials Licensing program fianancial stability through at least FY18.
  - 2. Arkansas Radioactive Material Licensees will pay substantially less annual licensing fees in comparision to those required to be paid if inspections were conducted by the NRC and fees will stay within the State of Arkansas as opposed to being paid to the federal government.
  - 3. Arkansas Radioactive Material Licensees will continue to be able to work with local radiation regulators who are responsive to their needs. .
- 3. What, in your estimation, would be the consequence of taking no action, thereby maintaining the status quo? Without the increase of the Arkansas Radioactive Material licensee fees, the State will be faced with the possibility of no longer being able to meet requirements for being an Agreement State with NRC. If this occurred the NRC would begin to regulate the use and possession of radioactive material in the State of Arkansas at a substantially higher cost to the Arkansas licensees.
- Describe market-based alternatives or voluntary standards that were considered in place of the proposed 4. regulation and state the reason(s) for not selecting those alternatives. -N/A-

#### Impact of Proposed Rule or Regulation

- 5. Estimate the cost to state government of collecting information, completing paperwork, filling, recordkeeping, auditing and inspecting associated with this new rule or regulation. No additional administrative cost to state government.
- What types of small businesses will be required to comply with the proposed rule or regulation? Please 6. estimate the number of small businesses affected.
  - Small nuclear cardiology medical practices, small engineering testing firms using portable nuclear gauges, small industrial plants using permanent nuclear gauges and small industrial radiography companies using large radioactives sources. The Department of Health estimates that approximately 60 of its 228 radioactive material licensees may be affected as small business entities but has no way of knwoing a true number.
- 7. Does the proposed regulation create barriers to entry? If so, please describe those barriers and why those barriers are necessary. NO
- Explain the additional requirements with which small business owners will have to comply and estimate the costs associated with compliance.
  - There are no additional requirements for small business owner to complywith in these proposed revisions other than an increased licensing fee..
- 9. State whether the proposed regulation contains different requirements for different sized entities, and explain why this is, or is not, necessary. Radioactive material license fees are based upon the category of use of licensed material and are not based on the business size.
- Describe your understanding of the ability of small business owners to implement changes required by the proposed regulation.

Most small businesses will pay the increased feesas as part of doing business. Some will evaluate the need to use radioactive material and may determine that radioactive devices are not required in their business model and will dispose of the radioactive material resulting in the termination of their license while continuing their business without radioactive material.

- 11. How does this rule or regulation compare to similar rules and regulations in other states or the federal government?
  - The proposed Arkansas Radioactive Material fees will be 15% of the U.S. Nuclear Regulatory Commission's (NRC) compariable annual fees

12. Provide a summary of the input your agency has received from small business or small business advocates about the proposed rule or regulation.

The Departmentt has discussed the proposed fee increase with the Arkansas Medical Society, the Arkansas Hospital Association and the Arkansas Department of Higher Education. None of these organizations are opposed.

# ARKANSAS DEPARTMENT OF HEALTH' RECEIVED RADIATION CONTROL'S PROPOSED REGULATION FEB 07 2017

BUREAU OF LEGISLATIVE RESEARCH

RH - 58 of the attached proposed revisions to Rules and Regulations for Control of Sources of Ionizing Radiation

SUMMARY

Places language in the regulations for fee X-ray registrants' certification. The language does not change the current fee.

RH-103 of the attached proposed revisions to Rules and Regulations for Control of Sources of Ionizing Radiation

Places language in the regulations for radioactive material license fees and reflects increases in these fees for radioactive material licensees.

#### Explanation

The Department regulates and licenses the possession and use of radioactive material in the State. The regulatory oversight of radioactive material is performed as an Agreement State with the U.S. Nuclear Regulatory Commission (NRC). Under this agreement the NRC accepts State licensing in lieu of federal oversight which would include charging substantially more for fees and conducting inspections. Licensing fees are used to cover the majority of the cost of the program. Currently fees generated are at  $1/6^{th}$  of what it costs to operate the Program. Act 596 of 2011 authorized the Arkansas State Board of Health to establish radioactive material license fees not to exceed 25% of the NRC's comparable fees. Revised language proposes radioactive material fees at 15% of the NRC's fees which results in an additional \$297,555 to current licensees. If the State were no longer able to maintain its agreement with the NRC and the NRC provided oversite, the total cost for current licensed providers would be \$1.98 million. These proposed revisions have been discussed with the Arkansas Medical Society, Arkansas Hospital Association and the Department of Higher Education and none are opposed to the revision.

# RULES AND REGULATIONS FOR CONTROL OF SOURCES OF IONIZING RADIATION FEE CHANGES DRAFT 01-10-12 RECEIVED

FEB 07 2012

RH-58. Registration Fees.

BUREAU OF LEGISLATIVE RESEARCH

In accordance with Act 796 of 1995 Codified as the Arkansas Code of 1987 Annotated, §20-21-217, annual fees for registration shall be paid. Nonpayment of fees shall result in escalated enforcement action and/or revocation of registration.

In accordance with the Arkansas Code Annotated §20-21-217, X-ray Registration Fees are as follows:

- a. All X-ray units, \$65.00 per tube up to a maximum of \$260.00
- b. Vendor services providing radiation equipment services or radiation safety services, or both, \$65.00

#### RH-103. License Fees.

In accordance with Act 796 of 1995 Act 596 of 2011 - Codified in the Arkansas Code Annotated §20-21-217, annual fees for licensing shall be paid.

Nonpayment of fees shall result in escalated enforcement action and/or revocation of license.

The following Radioactive Material Fees are based upon 15% of the U.S. Nuclear Regulatory Commission's Federal Fiscal Year 2012 annual fees found in 10 CFR 171.16.

#### The Radioactive Material Fees are as follows:

<u>CATEGORY</u>	CODE	<u>FEE</u>
A. Academic R&D	03620	<b>\$1,215.00</b>
B. Academic Broad Scope	<u>01120</u>	<u>\$2,115.00</u>
C. Accelerator Produced		
<u>Radionuclides</u>	<u>03210</u>	<u>\$2,280.00</u>
D. Blood Irradiators	<u>03510</u>	\$1,305.00

# RULES AND REGULATIONS FOR CONTROL OF SOURCES OF IONIZING RADIATION FEE CHANGES DRAFT 01-10-12

### RH-103. (Cont'd)

The Radioactive Material Fees are as follows:				
<u>C</u> .	ATEGORY	CODE	FEE	
	Consultant Services	<u>03225</u>	<u>\$2,145.00</u>	
<u>F.</u>		<u>02210</u>	<u>\$1,260.00</u>	
	Gamma Knife	02310	<u>\$2,625.00</u>	
	Gas Chromatographs	<u>03123</u>	<u>\$720.00</u>	
<u>I.</u>	High Dose Rate Remote		71 2000	
_	<u>Afterloader</u>	02230	<u>\$1,260.00</u>	
<u>J.</u>		02410	\$720.00 62.055.00	
	Industrial Radiography Instrument Calibration	03310 03221;03222	\$3,855.00 \$720.00	
	Irradiators - Activity	<u>U3221;U3222</u>	<u>\$720.00</u>	
47.44	≥ 10,000 Curies	03521	\$20,625.00	
N.	Irradiators – Activity	OSSER, Inc.	<u> </u>	
	< 10,000 Curies	03511	\$2,280.00	
<u>O.</u>	Manufacturing			
	& Distributing	03214	\$1,770.00	
<u>P.</u>	Measuring Systems			
	Analytical Devices	03122	<u>\$720.00</u>	
	Measuring Systems	is		
	Fixed Gauge	<u>03120</u>	<u>\$720.00</u>	
<u>R.</u>	Measuring Systems	MONTH CONTRACTOR OF THE CONTRA		
~	Portable Gauge	03121	<u>\$720.00</u>	
	Medical Broad Scope	<u>02110</u>	<u>\$6,810.00</u>	
<b>T.</b>	Medical Facility	00101	01 070 00	
ΙT	No Written Directive Required Medical Facility	02121	<u>\$1,260.00</u>	
<u>v.</u>	Written Directive Required	02120	\$1,260.00	
$\mathbf{v}$	Medical Private Practice	02120 02200; 02201	\$1,260.00 \$1,260.00	
	Medical Therapy	<u>02240</u>	\$1,260.00 \$1,260.00	
	Mobile Medical Services	02231	\$1,260.00	
	Nuclear Pharmacy	02500	\$2,430.00	
	Well Logging		<del>34,155155</del>	
_	Including Tracers	03110; 03111; 03112	\$1,500.00	
AA		02400	\$720.00	
$\overline{\mathbf{B}}$	<del>-</del>			
	Material (non-NORM)			
	<b>Decommissioning</b>		<u>\$5,000.00</u>	

# RULES AND REGULATIONS FOR CONTROL OF SOURCES OF IONIZING RADIATION FEE CHANGES DRAFT 01-10-12

### RH-103. (Cont'd)

### The Accelerator Fees are as follows:

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m 49		
Parti	cle accelerator, medical, non-hospit	10000
	\$450.00 for first unit. \$300.00 for	each auditional u
3 <i>4</i> 3		
iviea	cal, therapy, non-hospital unit	Section 1
<i>(</i> 2)	6250 00 C 54	
(i)	\$250.00 for first unit.	1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1
(ii)	\$175.00 for each additional unit.	

#### The General Licensed Device Fees are as follows:

i	Certain measuring, gauging, and controlling devices	\$720.00
ii.	Generally licensed gas chromatographs	\$720.00
iii.	Static elimination devices	\$125.00
iv.	Source material devices.	. \$500.00
v.	Devices containing depleted uranium	\$500.00
vi.	Public safety devices containing radioactive material.	\$25.00
vii.	All other general license registrations other than	<u> </u>
	those specified above	\$300.00

# RULES AND REGULATIONS FOR CONTROL OF SOURCES OF IONIZING RADIATION FEE CHANGES DRAFT 01-10-12

viii.	Portable & Fixed Gauges	. \$1,125.00

#### RH-103. (Cont'd)

OTHER FEES:	
	•
	_f : *.

- 1. Naturally Occurring Radioactive Material (NORM) License \$2,500.00
- 2. Naturally Occurring Radioactive Material (NORM) Site General License \$500.00
- 3. Arkansas State Board of Health Rules and Regulations for Control
  of Sources of Ionizing Radiation 0.00 for first copy
  30.00 for each additional copy
- 4. Amendment to existing license . . . . 50.00 per amendment

#### RECIPROCITY FEES

<u>7.</u>

<u> 1.</u>	Naturally Occurring Radioactive Material		
	(NORM) Decommissioning \$2	,500.00	<u>)</u>
	日本の大学 (大学 ) 「大学 (大学 ) 「大学 ) 「		_
<u>2.</u>	Other Radioactive Material (non-NORM) Decommission	oning	\$5,000.00
<u>3.</u>	Radiography, Field	\$3,8	<u> </u>
<u>4.</u>	i. Well logging with Sealed Sources Only	\$1	<u>,500.00</u>
	ii. Well logging Tracer Studies	\$1	<u>,500.00</u>
<u>5.</u>	Nuclear gauge	\$7	20.00
6.	Consultant.	\$2	145.00

Gas Chromatograph/Lead Painter Analyzers......

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