

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM
QUESTIONNAIRE

Name of State: **Kentucky**
Reporting Period: **June 16, 2012 to July 25, 2016**

Note: If there has been no change in the response to a specific question since the last IMPEP questionnaire, the State or Region may copy the previous answer, if appropriate.

A. GENERAL

1. Please prepare a summary of the status of the State's or Region's actions taken in response to each of the open recommendations from previous IMPEP reviews.

[Recommendation 1.](#)

The MRB directed that a recommendation be made for the Radiation Health Branch to perform a self-assessment to determine the effectiveness of its oversight of the inspection program. The results of this self-assessment would be discussed at the next periodic meeting.

Status:

The Program has taken action on this recommendation. The program conducted a self-assessment to determine the effectiveness of its oversight of the inspection program in November 2012, a copy of which was shared with the Commission. As a result of this self-assessment, changes were made to four existing policies and a new policy was created to ensure that oversight and continuity of the inspection program is maintained. The new and revised policies include the following:

INSPECTION AND ENFORCEMENT MANUAL

<u>Policy Number</u>	<u>Title</u>	<u>Revision Date</u>
Title 200, Section 201	Inspection Frequency and Announcement of Inspections	7/2014

¹ Estimated burden per response to comply with this voluntary collection request: 53 hours. Forward comments regarding burden estimate to the Records Management Branch (T-5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to the Paperwork Reduction Project (3150-0183), Office of Management and Budget, Washington, DC 20503. If an information collection does not display a currently valid OMB control number, NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

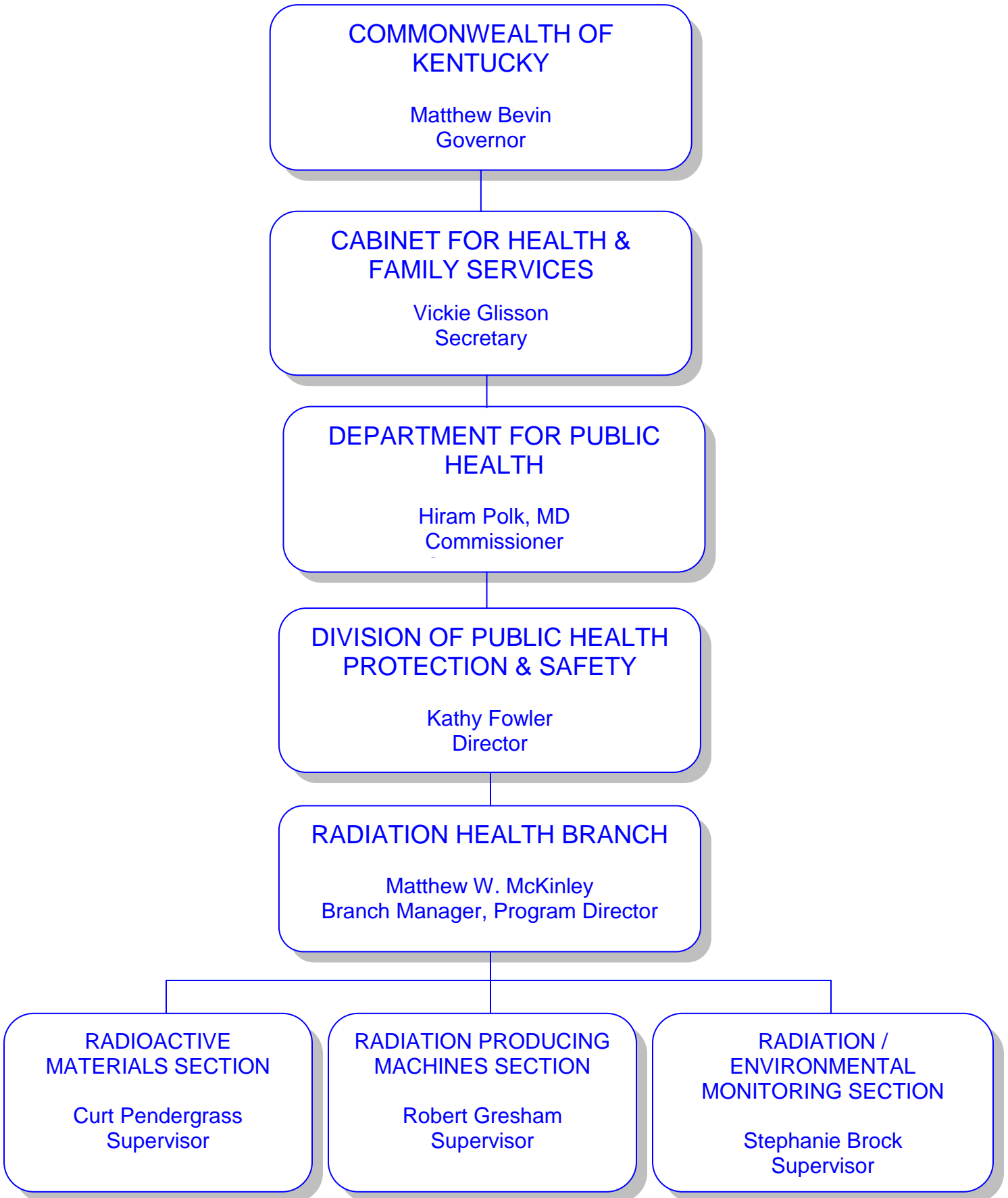
ADMINISTRATIVE MANUAL

<u>Policy Number</u>	<u>Title</u>	<u>Revision Date</u>
Title 200, Section 213	Continuity of Operations Plan (COOP) for Specific License Inspection Program	1/2013 (new)
Title 300, Section 301	Assignment of RAM Inspections	12/2012
Title 300, Section 302	License Tracking Management System Database Maintenance and Statistical Reporting	12/2012
Title 400, Section 415	Reciprocity	5/2013

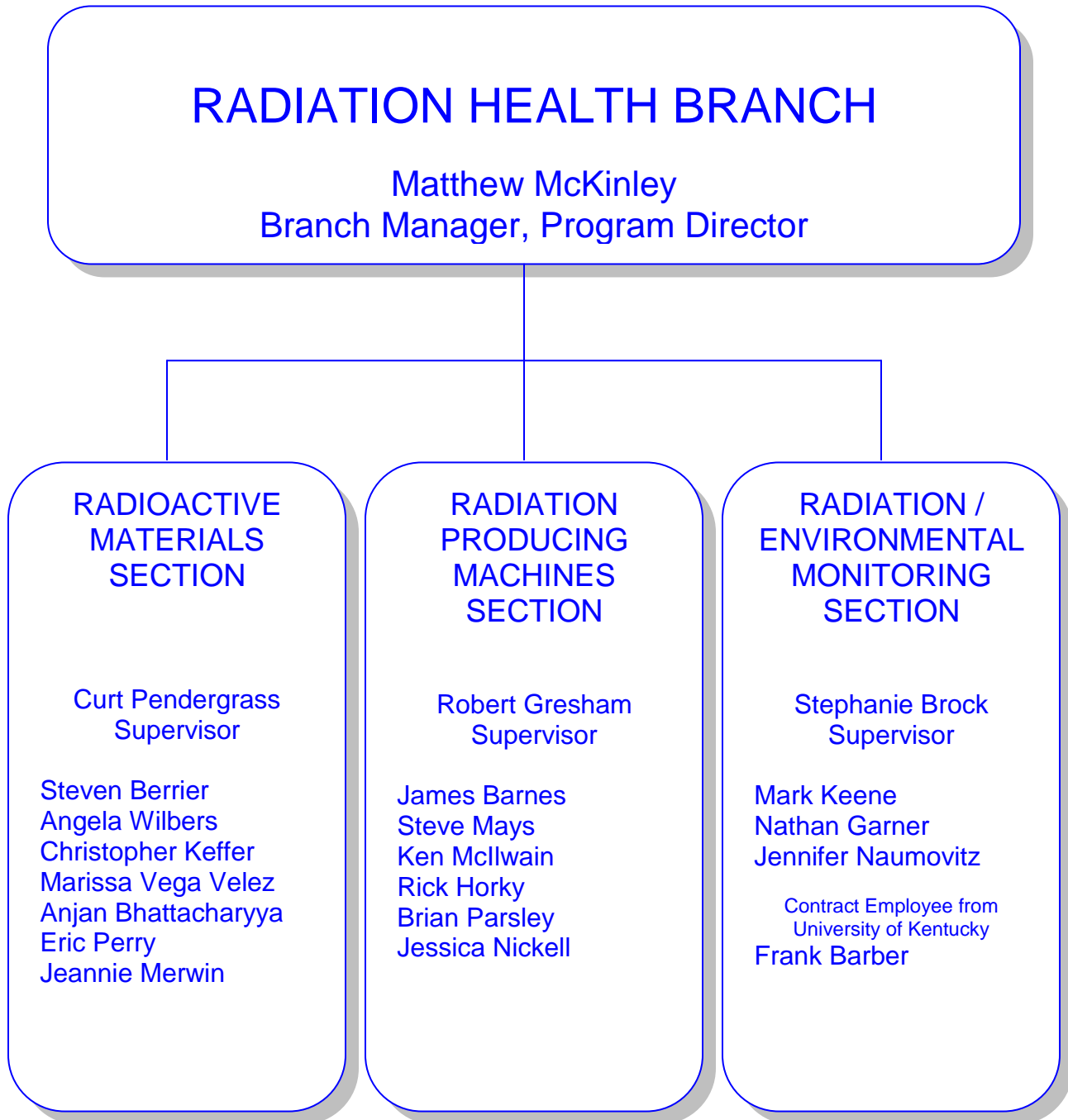
Changes called for in the self-assessment and the revised policies and procedures have been implemented and the program feels this recommendation has been satisfactorily addressed.

COMMON PERFORMANCE INDICATORS

- I. Technical Staffing and Training
2. Please provide the following organization charts, including names and positions:
 - (a) A chart showing positions from the Governor down to the Radiation Control Program Director;

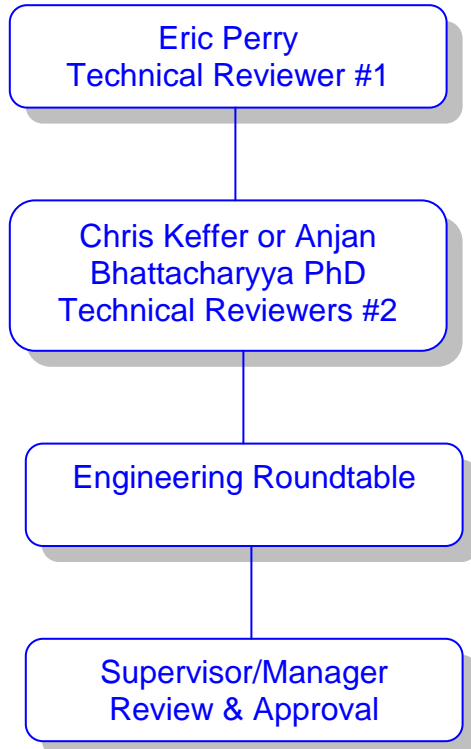


(b) A chart showing positions of current radiation control program including management; and

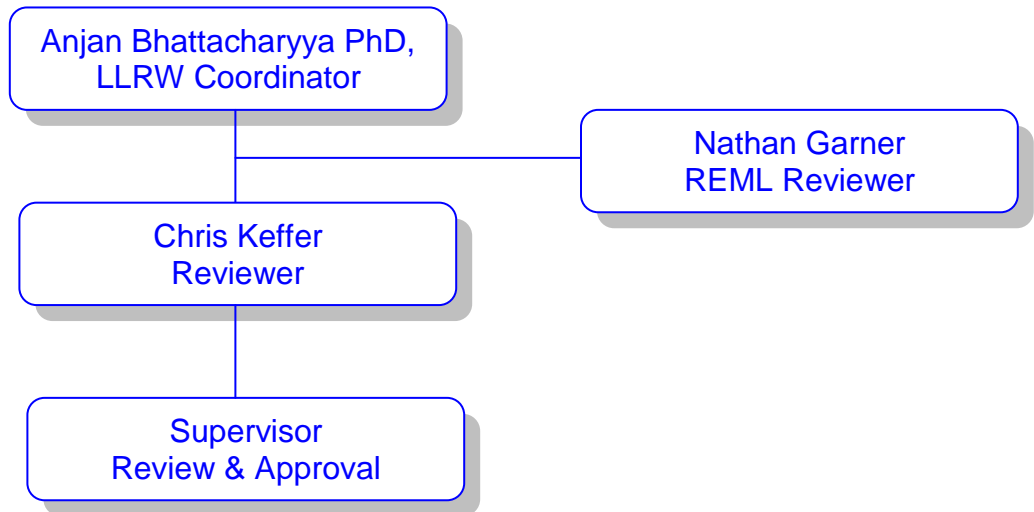


- (c) Equivalent charts for sealed source and device evaluation, low-level radioactive waste and uranium recovery programs, if applicable.

SS&D evaluation is conducted in accordance with the Radioactive Materials Section (RMS) "Policy for the Review of an Application for a Sealed Source and Device Certificate" which calls for two technical reviews by qualified staff followed by an "Engineering Roundtable" and final Supervisor/Manager approval.



The low level radioactive waste program is led by the LLRW Coordinator with review by qualified staff together with input from the Radiation Environmental Monitoring Laboratory (REML).



Kentucky does not have a uranium recovery program.

3. Please provide a staffing plan, or complete a listing using the suggested format below, of the professional (technical) full-time equivalents (FTE) applied to the radioactive materials program by individual. Include the name, position, and, for Agreement States, the fraction of time spent in the following areas: administration, materials licensing & compliance, emergency response, low-level radioactive waste, uranium recovery, other. If these regulatory responsibilities are divided between offices, the table should be consolidated to include all personnel contributing to the radioactive materials program. Include all vacancies and identify all senior personnel assigned to monitor work of junior personnel. If consultants were used to carry out the program's radioactive materials responsibilities, include their efforts. The table heading should be:

<u>Name</u>	<u>Position</u>	<u>Area of Effort</u>	<u>FTE%</u>
Matthew McKinley	RCPD	Administration	2%
		Materials Lic. & Comp.	0%
		Emergency Response	10%
		LLRW	0%
		Other	8%
		Total	20%
Curt Pendergrass	Supervisor	Administration	75%
		Materials Lic. & Comp.	10%
		Emergency Response	10%
		LLRW	2.5%
		Other	2.5%
		Total	100%
Steven Berrier (returned from Active duty 12/2/13)	RH Spec. III	Administration	35%
		Materials Lic. & Comp.	30%
		Emergency Response	0%
		LLRW	0%
		Other (GLs)	35%
		Total	100%
Angela Wilbers	RH Spec. III	Administration	35%
		Materials Lic. & Comp.	55%
		Emergency Response	5%
		LLRW	0%
		Other (Training, NSTS)	5%
		Total	100%
Michele Greenwell (left state employment On 7/15/13)	RH Spec. III	Administration	45%
		Materials Lic. & Comp.	35%
		Emergency Response	0%
		LLRW	0%
		Other (Training, Brachy Com)	20%
		Total	100%

Marissa Vega Velez	RH Spec. III	Administration	35%
		Materials Lic. & Comp.	35%
		Emergency Response	0%
		LLW	0%
		Other (I&A, Reg Review)	30%
		Total	100%
Christopher Keffer	RH Spec. III	Administration	20%
		Materials Lic. & Comp.	50%
		Emergency Response	5%
		LLRW	5%
		Other (IT & Database Mgmt)	20%
		Total	100%
Eric Perry (started work On 7/1/12)	RH Spec. II	Administration	35%
		Materials Lic. & Comp.	35%
		Emergency Response	5%
		LLRW	0%
		Other (Reciprocity, SS&D, escorts)	25%
		Total	100.00%
Anjan Bhattacharyya (started work On 7/1/12)	RH Spec. II	Administration	35%
		Materials Lic. & Comp.	35%
		Emergency Response	5%
		LLRW reporting & MFDS	20%
		Other (LLRW, Hot Loads)	5%
		Total	100%
Maria Jeanie Merwin (started work On 12/1/13)	RH Spec. II	Administration	35%
		Materials Lic. & Comp.	35%
		Emergency Response	5%
		LLW	0%
		Other (Archives)	25%
		Total	100%

FTE % for Matthew McKinley is an estimated average of time spent on radioactive materials responsibilities since becoming the RCPD in May, 2011.

4. Please provide a listing of all new professional personnel hired since the last review, indicate the degree(s) they received, if applicable, and additional training and years of experience in health physics, or other disciplines, as appropriate.

<u>Name</u>	<u>Hire Date</u>	<u>Degree(s) received</u>	<u>Years of Experience</u>
Eric Perry	7/1/12	N/A	6 years, US Navy Nuclear Power Program MM1, EWS, QA Officer
Anjan Bhattacharyya	7/1/12	M.S. Chemistry Ph.D. Biochemistry	20 years academic & biomedical research, 8 years RSO & RAM licensee
Maria Jeanie Merwin	12/1/13	B.S.	Certified Nuclear Medicine Technologist with over 22 years' of nuclear medicine experience

5. Please list all professional staff who have not yet met the qualification requirements for a license reviewer or materials inspector. For each, list the courses or equivalent training/experience they need and a tentative schedule for completion of these requirements.

All five senior staff members have fully met the qualification requirements in at least one modality with either an industrial or medical emphasis. Of the two staff members hired in July 2012, Mr. Perry and Dr. Bhattacharyya, both have fully qualified on the industrial tract and are currently cross-training as medical tract license reviewers and inspectors through the documented on the job and didactic training process outlined in the "RMS Staff Qualification and Training" program. Both should complete their training in the next two years in order to become fully qualified medical license reviewers and inspectors and hopefully advance to Radiation Health Specialist III. Ms. Merwin is currently completing her medical licensing and inspecting qualifications with only brachytherapy and gamma knife left to complete and she has begun her initial industrial tract cross-training. She should complete her medical tract training in the next year. All staff members are required to qualify simultaneously as license reviewers and inspectors in all modalities.

6. Identify any changes to your qualification and training procedure that occurred during the review period.

The "RMS Staff Qualification and Training Program" was revised in March 2016 to encompass refresher training requirements and to reflect revisions of NRC sponsored courses added to the core and specialized training curriculum. Requirements for qualification as an Incident Investigator and Sealed and Source Device Reviewer clarified.

7. Please identify the technical staff that left your program during the review period.

Mary Michele Greenwell left the program on July 15, 2013 to assume the job as the Radiation Safety Office for the VA Medical Center in Louisville, KY.

Steven Berrier did not leave the program, but he was deployed on active duty with the National Guard on May 16, 2011 and returned to state government from active duty on 12/2/13.

8. List any vacant positions in your program, the length of time each position has been vacant, and a brief summary of efforts to fill the vacancy.

There are currently no vacancies in the Radioactive Materials Section. RHB was informed that when former employee Melvin Goodfriend retired in March 2012 that his position would not be refilled.

9. For Agreement States, does your program have an oversight board or committee which provides direction to the program and is composed of licensees and/or members of the public? If so, please describe the procedures used to avoid any potential conflict of interest.

The Radiation Health Branch is currently in discussions with upper Cabinet level administrators regarding the formation of a Medical Advisory Board composed of Program administration and professionals in the private sector. This Medical Advisory Board would encompass both radioactive materials and radiation producing machines. Several current medical RSOs, AMPs, and physician authorized users have been approached about possibly serving on this board and all have responded favorably. Discussions on how to establish the board, appoint its members, develop its mission and by-laws, etc. are in their early stages of development but the hope is to have the board established in the next two years.

II. Status of Materials Inspection Program

10. Please identify individual licensees or categories of licensees the State is inspecting less frequently than called for in NRC's Inspection Manual Chapter (IMC) 2800 and explain the reason for the difference. The list only needs to include the following information: licensee name, license number, your inspection interval, and rationale for the difference.

All licensees are inspected in accordance with the RMS policy "RAM Inspection Frequency and Announcement of Inspections". No licensees or groups of licensees are inspected less frequently than called for in NRC Inspection Manual Chapter 2800. Up until January 1, 2012, some licensee groups were inspected more frequently than specified in the IMC 2800 such as Private Practice Medical, Broad Medical, Broad Academic, Radiopharmacies, Portable Gauge users and Manufacturers and Distributors of Industrial Gauges. The increased frequency was due historically to the observation of previous program personnel that, for these particular groups, reducing the time between inspections resulted in fewer and less significant violations. In recent years, program compliance is these licensee groups relative to others has not significantly differed based on increased inspection frequency so the decision was made to adopt the inspection frequency called for in IMC 2800 for all KY licensees starting on January 1, 2012 to make better use of available manpower and resources while still providing adequate licensee oversight.

With the revision of 902 KAR 100:012, Section 3. "Inspection Fee" in July 2015, RMS is now able to charge licensee's \$500 for reduced interval inspections to ensure ongoing public health and safety based on any of the following conditions being met:

- (a) Willful neglect or careless disregard that has, or could lead to, a threat to public health and safety;
- (b) Failure to take appropriate and timely action to correct documented violations of statutes, regulations, or conditions of the license or permit;
- (c) A substantiated violation that indicates a lack of management oversight or that the radiation safety officer is not adequately performing duties; or
- (d) Repeated violations from the previous inspection.

The cost of a routine interval inspections are covered in the annual licensing renewal fee.

No charges for reduced interval inspections have been levied to date but several licensees have been placed on reduced intervals. Notably among them is Wayne County Hospital, license no. 202-215-24, for operating over a year and a half with no RSO or physician Authorized Users without notifying RHB, for knowingly submitting inaccurate information and for multiple repeat violations. The licensee's inspection interval has been reduced from five to years to three years with the next inspection due date being 1/14/2019.

The other notable reduced inspection interval licensee is Taylor Regional Hospital, license no. 202-160-25, for failure to implement its own written procedures to provide high confidence that manual brachytherapy prostate implants were in accordance with the treatment plan and the written directive. Specifically, the licensee did not perform post-implant CTs on all patients implanted with brachytherapy sources and for those patients that did have post-implant CTs, did not perform dosimetric evaluations to determine if the administered dose was in accordance with that called for by the treatment plan and written directive. Furthermore, on several patients where post-implant CTs and dosimetric evaluations were performed, the licensee failed to recognize and failed to report multiple medical events. The licensee has suspended its brachytherapy program and will resubmit all brachytherapy policies and procedures to RHB for review and approval before commencing those licensed activities. If approval is granted, the licensee will be inspected by RHB soon after reinstating its manual brachytherapy program.

In addition escalated enforcement action by RHB, Wayne County Hospital and Taylor Regional Medical Center are both currently being investigated by the Cabinet's Office of the Inspector General.

11. Please provide the number of routine inspections of Priority 1, 2, and 3 licensees, as defined in IMC 2800 and the number of initial inspections that were completed during each year of the review period.

Date		Priority 1	Priority 2	Priority 3	Initial	Yearly Total
6/16/2012	12/31/2012	1	3	9	6	19
1/1/2013	12/31/2013	12	6	10	7	35
1/1/2014	12/31/2014	11	20	24	10	65
1/1/2015	12/31/2015	10	8	29	11	58
1/1/2016	To Date	2	4	5	8	19
Priority Totals		36	41	77	42	
Total Priority 1-3 & Initial Inspections for the reporting period						196

12. Please submit a table, or a computer printout, that identifies inspections of Priority 1, 2, and 3 licensees and initial inspections that were conducted overdue.

At a minimum, the list should include the following information for each inspection that was conducted overdue during the review period:

- (1) Licensee Name
- (2) License Number
- (3) Priority (IMC 2800)
- (4) Last inspection date or license issuance date, if initial inspection
- (5) Date Due
- (6) Date Performed
- (7) Amount of Time Overdue
- (8) Date inspection findings issued

Priority 1, 2 and 3 and initial Inspections performed overdue for reporting period of June 16, 2012 to July 8, 2016 sorted by actual inspection date.

Licensee	License Number	Disc. Code	Prior-ity	Initial Inspection	Date of Last Inspection	Inspection Due Date	Inspection Date	No. Days Overdue	Date Of Findings
¹ GEORGE R. CHANEY, M.D.	202-230	25	3	NO	6/23/2008	6/23/2011	6/21/2012	90	7/17/2012
² SIEMENS MEDICAL SOLUTIONS	201-776	60	5	YES	N/A	3/17/2015	2/8/2016	328	2/23/2016
³ NORTON HOSPITAL, INC. (DBA NORTON HOSPITAL BROWNSBORO	202-396	25	3	NO	3/3/2011	3/2/2014	5/12/2016	802	7/8/2016

¹ Licensee was known to be overdue for inspection at the beginning of this IMPEP reporting period.

² Facility originally applied for a new license on 7/29/2013 but RHB terminated the application on 6/13/2014 after repeated attempts to acquire additional information went unanswered. At that time, a termination date of 6/13/2014 was entered in the license inspection tracking database. The company reapplied for a new license less than a month later on 7/3/2014 at which time RHB reissued the same license number to the company for the application. When the license was finally granted on 9/17/14 the termination date was not removed from the license tracking database as it should have been thus preventing the initial inspection due date from automatically populating in the database. When the mistake was finally noted in January 2016 and the termination date removed, the licensee became overdue for inspection.

³ License was amended on 9/29/2011 to add I-131 but the discipline code in license inspection tracking database was not changed from -24 (priority 5) to -25 (priority 3) as required until 2016 when the mistake was noted and at which time the licensee became overdue for inspection. A separate computer database created over twenty years ago is still being used to actually track and create new licenses and make amendments to existing licenses as well as generate inspection findings (e.g. Notice of Compliance, Notice of Violation, Return to Compliance) and for accounting purposes all done outside of the License Tracking Management System created in 2012. Hopefully one of these days the Program will have a single computer database that both tracks license actions and inspections and generates required documents which will alleviate problems such as this. Progress is being made in those efforts on the accounting and x-ray machines producing fronts but radioactive materials has yet to be addressed.

13. Please submit a table or computer printout that identifies any Priority 1, 2, and 3 licensees-and initial inspections that are currently overdue, per IMC 2800. At a minimum, the list should include the same information for each overdue inspection provided for Question 12 plus your action plan for completing the inspection. Also include your plan for completing the overdue inspections.

There are no priority 1, 2 or 3 inspections or initial inspections currently overdue. Below is the tabulated data for priority 1, 2, 3 and initial inspections that were conducted overdue during this IMPEP reporting period.

IMPEP Data Report

PCO = number of Priority 1, 2, and 3 inspections completed overdue during the review period

PU = number of Priority 1, 2, and 3 inspections overdue at the time of the review

PC = number of Priority 1, 2, and 3 inspections completed on time during the review period

ICO = number of Priority 1, 2, and 3 inspections completed overdue during the review period

IU = number of Priority 1, 2, and 3 inspections overdue at the time of the review

IC = number of Priority 1, 2, and 3 inspections completed on time during the review period

$$\% = 100 \frac{\text{PCO} + \text{PU} + \text{ICO} + \text{IU}}{\text{PCO} + \text{PU} + \text{ICO} + \text{IU} + \text{PC} + \text{IC}}$$

	On Time	Overdue	Overdue on Arrival		Term	Value
Priority 1	11	0	0		PCO	2
Priority 2	27	0	0		PU	0
Priority 3	60	2	0		PC	98
Priority total	98	2	0		ICO	1
Initial	40	1	0		IU	0
Total	138	3	0		IC	40

$$\% = 100 \frac{3}{141}$$

$$\% = 2.12766$$

14. Please provide the number of reciprocity licensees that were candidates for inspection per year as described in IMC 1220 and indicate the number of reciprocity inspections of candidate licensees that were completed each year during the review period.

Year	Priority 1			Priority 2			Priority 3			Other			Total Priority 1,2,3		
	Eligible Candidates	Inspected	%	Eligible Candidates	Inspected	%	Eligible Candidates	Inspected	%	Eligible Candidates	Inspected	%	Eligible Candidates	Inspected	%
2012	7	2	29	5	0	0	3	0	0	52	1	2	15	2	13%
2013	3	1	33	4	0	0	5	2	40	52	0	0.000	13	3	23.077
2014	8	3	37.5	7	1	14.29%	4	0	0	52	0	0	19	4	21.05%
2015	9	4	44.44%	6	1	16.67%	5	0	0	48	2	4.17%	20	5	25.00%
2016	1	0	0	4	1	25.00%	4	0	0				9	1	11.11%

A self-assessment of the reciprocity program was conducted on 6/13/2016 and reciprocity inspection percentages recalculated based on this self-assessment. Percentages presented above reflect the revised reciprocity results based on the findings of this self-assessment. A copy of the self-assessment is included at the end of this questionnaire.

III. Technical Quality of Inspections

15. What, if any, changes were made to your written inspection procedures during the reporting period?

RHB continues to make improvements of all inspection procedures and revise its inspection report forms as required. In this review period several inspection forms were revised including medical diagnostic imaging, therapeutic unsealed WD directive required, brachytherapy, and radiopharmacy inspection forms. In addition, irradiator, gamma knife, gauge manufacturer and industrial radiography inspection report forms were revised to incorporate the requirements of 902 KAR 100:037. "Physical protection of category 1 and category 2 quantities of radioactive material" (effective 2/5/16). A new inspection report form cover sheet was adopted to capture initial and pre-licensing inspections as well as routine inspections and reactive investigation inspections. In addition, space was provided on the inspection cover page to capture a reduction in inspection interval and the reasoning behind that reduction. Also, a block was added to the second page of the inspection report form cover sheet for recording any significant NMED reportable events that occurred since the time of the last inspection. If there were significant NMED reportable events, the inspector is to attach a copy of those NMED reports. If NMED reportable events have occurred since the last inspection, the inspector is to verify those corrective actions have been implemented. These changes to the inspection report cover pages were improvements made as a result of the previous IMPEP review.

16. Prepare a table showing the number and types of supervisory accompaniments made during the review period. Include:

<u>Inspector</u>	<u>Supervisor</u>	<u>License Category</u>	<u>Date</u>
<u>2016</u>			
Marissa Vega Velez	Curt Pendergrass	Baptist Health Paducah (therapeutic unsealed WD required, manual brachytherapy, HDR, routine)	1/14/16
Anjan Bhattacharyya	Curt Pendergrass	Ohio County Hospital (diagnostic imaging, routine)	1/15/16
Eric Perry	Curt Pendergrass	National Inspection Services (radiographer, routine)	7/6/16
<u>2015</u>			
Anjan Bhattacharyya	Curt Pendergrass	Mistras Group (radiographer, routine)	1/12/15
Eric Perry	Curt Pendergrass	Applied Technical Services (radiographer, routine)	11/18/15
Angela Wilbers	Curt Pendergrass	University of Kentucky Medical Broad Scope	9/17/15

Jeannie Merwin	Curt Pendergrass	University of Louisville Medical Broad Scope	6/26/15
Marissa Vega Velez	Curt Pendergrass	Cardinal Health 414 LLC (PET cyclotron, routine)	3/4/15
Christopher Keffer	Curt Pendergrass	JanX Integrity Testing (radiographer, routine)	7/7/15
Steven Berrier	Did not lead any specific license inspections in all of 2015. Not accompanied.		

2014

Jeannie Merwin	Curt Pendergrass	Central Cardiology Associates (diagnostic Imaging, routine)	10/29/14
Angela Wilbers	Curt Pendergrass	Kings Daughter Medical Center (therapeutic unsealed WD required, manual brachy- therapy, routine)	10/23/14
Christopher Keffer	Curt Pendergrass	Maxey Flats Disposal Site (routine & joint RHB & DEP/EEC annual review Low level radioactive waste disposal site)	7/2/14
Anjan Bhattacharyya	Curt Pendergrass	Dow Corning Inc. (Portable gauge, routine)	6/5/14
		Reclamation Services (Portable gauge, routine)	2/14/14
Eric Perry	Curt Pendergrass	Western Kentucky University (routine Type B Academic Broad scope)	6/4/14
Marissa Vega Velez	Curt Pendergrass	21 st Century/Louisville Radiation Oncology (HDR, therapeutic unsealed WD required, routine)	3/25/14
		Baptist Health Madisonville (Therapeutic unsealed WD Required, Manual Brachy- Therapy, routine)	1/13/14
Steven Berrier	Did not lead any specific license inspections in all of 2014. Not accompanied.		

2013

Chris Keffer	Curt Pendergrass	Mistras Group, Inc. (industrial radiographer)	12/26/13
Angela Wilbers	Curt Pendergrass	Cumberland Clinic PLLC (diagnostic imaging, reactive inspection)	12/17/13
Eric Perry	Curt Pendergrass	Rood and Riddle Equine Hospital	11/19/13
Marissa Vega Velez	Curt Pendergrass	Baptist Health Paducah (therapeutic, WD required, HDR, routine inspection)	11/13/13
		Daves and Kelly (service provider, routine)	7/18/13
Michele Greenwell	Curt Pendergrass	University of Kentucky Good Samaritan Hospital (therapeutic WD required routine)	6/13/13
Anjan Bhattacharyya	Curt Pendergrass	Dummer Surveying and Engineering Services, Inc. (portable gauge, routine)	6/12/13
Steven Berrier	Did not lead any specific license inspections in all of 2013. Not accompanied.		

2012

Eric Perry	Curt Pendergrass	Roof Resources (portable gauge, routine)	12/26/12
Michele Greenwell	Curt Pendergrass	Saint Joseph Lexington (therapeutic, manual brachytherapy, routine)	12/19/12
Anjan Bhattacharyya	Curt Pendergrass	Cumberland Valley Engineering (portable gauge routine)	11/13/12
Chris Keffer	Curt Pendergrass	Team Industrial Services (radiographer, ICs)	6/1/12
Marissa Vega Velez	Curt Pendergrass	Gregg Laboratories (portable gauge reactive)	4/19/12
Angela Shryock	Curt Pendergrass	University of Louisville (broad scope academic)	3/7/12
Mel Goodfriend	Curt Pendergrass	Sud-Chemie (M&D)	1/10/12
Steven Berrier	Did not return from active duty until 12/2/13 and did not conduct any specific license inspections. Not accompanied.		

17. Describe or provide an update on your instrumentation, methods of calibration and laboratory capabilities. Are all instruments properly calibrated at the present time? Were there sufficient calibrated instruments available throughout the review period?

New equipment purchased during the review period:

Instrument	Qty	Calibration Frequency	Performance Check
Ludlum 2241-3	2	Annually and after any repair.	Prior to each use.
SEI Radiation Alert Inspectors	4	Annually and after any repair.	Prior to each use.
Thermo RadEye SPRD	20	Annually and after any repair.	Prior to each use.
Thermo RadEye G	18	Annually and after any repair	Prior to each use

The Radiation Environmental Monitoring Laboratory is part of the Radiation Health Branch and is therefore under the direct authority of the RCPD. Radio-analytical equipment used by the laboratory includes 5 Gas-Flow Proportional Counters, 4 Liquid Scintillation Counters, 5 HPGe Gamma Detectors, 3 ISOCs Gamma Detectors and 16 Alpha Chambers. Sample preparation capabilities include drying, grinding, sifting, furnace ashing, acid leaching, acid digesting, U separation, Pu separation, Y-90 separation, Tc-99 separation, distillation (H-3) and C-14 preparation. REML has recently added analysis for Ra-226 and Ra-228 detection in soils and liquids.

All Radiation Health Branch equipment that requires calibration is calibrated according to manufacturer's specifications. In the case of the handheld and field instruments, calibration of all in-use equipment is completed at least annually. In most cases, the equipment is shipped back to the manufacturer for calibration; however, some equipment is calibrated by local calibration vendors.

All equipment currently in use is properly calibrated and performance checks are completed prior to each use. A sufficient number of calibrated instruments have been available throughout the review period.

IV. Technical Quality of Licensing Actions

18. How many specific radioactive material licenses does the Program regulate at this time?

Kentucky Radioactive Materials Section regulates 364 specific radioactive material licenses including 19 subject to 902 KAR 100:037. "Physical protection of category 1 and category 2 quantities of radioactive material".

19. Please identify any major, unusual, or complex licenses which were issued, received a major amendment, were terminated, decommissioned, submitted a bankruptcy notification or renewed in this period.

Licensing statistics for this review period are shown below.

2016 License Actions IMPEP Summary Report					
License Action		Number Requested	Number Complete	Number Pending	Average Age of Complete and Pending Amendments
Amendment	A	586	577	9	44.15 Days
Tech. Amendment	TA	523	511	12	98.25% Complete
New	N	46	42	4	
Amend. In Entirety	AE	109	88	21	
Transfer of Control	TC	60	56	4	
Terminate	T	112	111	1	
Renewal	R	1471	1471	0	
Total License Actions		2907	2856	51	

A total of 111 licenses were terminated during this review period and 42 new licenses were granted. The majority of the terminated licenses were fixed and portable gauge facilities, many associated with the downturn in the economy especially in the coal industry in KY. The holders of fixed gauge licenses for several coal preparation plants including Alpha Natural Resources, James River Coal, Arch Coal, Peabody/Patriot Coal and JW Resources all submitted bankruptcy notifications during this review period. RHB is working with these licensees to ensure all licensed materials are controlled and secure and pending proper disposition and termination and where requested, assisting with transfer of control of those licenses to other entities which will use these licensed materials as intended. In addition, several smaller diagnostic imaging clinics terminated their licenses during this review period in large part due to the consolidation occurring in the medical field. Berea College and Kentucky State University both terminated their specific licenses during this review period. KY specific licenses expire on an annual basis which accounts for the high number of renewals during this review period.

Of the licenses granted during this review period, North Wind, Inc. (license no. 201-785-15) granted 5/7/15 and Transport Logistics International (license no. 201-770-92) granted 11/5/13 were two of the more complex. The North Wind license authorizes the possession and use of licensed materials for the purpose of decommissioning, decontamination, reclamation and site restoration and associated surveys and sampling. The licensee has yet to conduct any licensed activities in KY. The Transport Logistics International license was originally granted for the storage and washing and recertification of Type 48 and 12B cylinders and for chemical processing of UF6 and related compounds. Subsequent amendments have expanded the scope of the license to include surface preparation of empty Type 48 cylinders, cutting of Type 48 and Type 30 cylinders for disposal as well as repair and storage of a variety of shipping containers including Trushield, GNS-16, and BU-D. The most recent amendment involved replacement of defective Hunt valves in full Type 48G cylinders and cryogenic sampling of UF6 from full Type 48G cylinders.

The Maxey Flats Disposal Site (MFDS) operated under specific license no. 206-002-03 granted to the Superfund Branch of the Division of Waste Management, Department of Environmental Protection, of the Energy and Environment Cabinet entered into the final closure period (FCP) pursuant to CERCLA requirements stipulated in Civil Action No. 95-58 during this review period.

Planning began in earnest in September 2012 with submission of the trench stabilization report to EPA, selection of the design contractors in June 2013 along with submission of the initial final closure period remedial design work plan to EPA. Before entering FCP, the licensee submitted a revised Radiation Protection Program with revised policies and procedures along with a revised health and safety plan (HASP) as part of an Amendment in Entirety of the MFDS license. The licensee has submitted monthly FCP progress reports to RHB starting in June 2012 and RHB has provided review and comments. Sump abandonment and high point removal was completed in December 2014 and the FCP Construction Management Work Plan approved by EPA in January 2015. The construction of the final cap is scheduled to be completed in the fall of 2016. The ICP Work Plan including the Performance Standards Verification Plan, Health and Safety Plan, and Sampling Analysis Data Evaluation Plans is currently being reviewed by RHB.

Corhart Refractories, Inc. (KYRAM license # 204-027-92) requested termination of their license on 02/14/05. Decontamination and decommissioning activities were completed by the private contractor and the Final Status Survey submitted for RHB review and data verification in 2011. RMS staff were on hand continually throughout this process conducting confirmatory surveys of materials and debris prior to leaving the site for disposal and recycling. REML analyzed air and soil samples taken during the remediation phase. RMS and REML jointly conducted gamma walk over surveys of the entire site following remediation and conducted in-situ observational counting (ISOCs) using HPGe and subsequent analysis for residual activities. The licensee's consultant, Chase Environmental Group, submitted a copy of the Final Status Survey Report to RHB on February 17, 2012. RHB reviewed the FSSR as did the RHB consultant, URS, Inc. On January 24, 2013 the Corhart Refractories license was terminated.

20. Discuss any variances in licensing policies and procedures or exemptions from the regulations granted during the review period.

Ictal Brain Imaging Single Positron Emission Computed Tomography (IBI-SPECT) exemption was developed on 7/31/10 and requirements thoroughly documented by RHB at the behest of several medical licensees. IBI-SPECT exemptions were granted to three facilities during this review period. They are the University of Louisville broad scope medical license (no. 202-029-22), Norton Hospital (license no. 202-031-26) and Norton Hospital Brownsboro (license no. 202-396-25). For the facilities granted this exemption, a condition was added to the license detailing the requirements for utilization of this exemption including end of year reporting requirements to RHB. The IBI-SPECT license condition is as follows:

THE LICENSEE SHALL COMPLY WITH THE EXEMPTION REQUIREMENTS DESCRIBED IN THE RADIATION HEALTH BRANCH LETTER DATED JULY 31, 2010 ENTITLED "UNIQUE NEEDS OF SEIZURE DISORDER PATIENTS REQUIRING MEDICAL UNIT MONITORING FOR RADIOPHARMACEUTICAL INJECTION PRIOR TO TOMOGRAPHIC (SPECT) ICTAL BRAIN IMAGING (IBI)". REGARDLESS OF THE INITIAL GRANTING DATE OF THE EXEMPTION, THE LICENSEE MUST SUBMIT AN AMENDMENT REQUEST TO EITHER EXTEND THE EXEMPTION FOR ANOTHER YEAR OR A REQUEST TO RESCIND THE EXEMPTION ALONG WITH THE FOLLOWING INFORMATION BY JANUARY 15TH :

- A. THE NUMBER OF SPECT IBI PROCEDURES ORDERED IN THE PREVIOUS CALENDAR YEAR.
- B. THE NUMBER OF SPECT IBI PROCEDURES WHERE THE PATIENT RECEIVED THE RADIOPHARMACEUTICAL INJECTION.

C. THE NUMBER OF SPECT IBI PROCEDURES WHERE THE RADIOPHARMACEUTICAL WAS TAKEN TO THE MEDICAL UNIT AND NOT USED.

21. What, if any, changes were made in your written licensing procedures (new procedures, updates, policy memoranda, etc.) during the reporting period?

The following administrative policies and procedures were updated during this review period.

INSPECTION AND ENFORCEMENT MANUAL

<u>Policy Number</u>	<u>Title</u>	<u>Revision Date</u>
Title 200, Section 201	Inspection Frequency and Announcement of Inspections	7/2014
Title 300, Section 301	Enforcement Actions	12/2013
Title 300, Section 301	Enforcement Actions, Appendix A	7/2016

ADMINISTRATIVE MANUAL

<u>Policy Number</u>	<u>Title</u>	<u>Revision Date</u>
Title 200, Section 211	Financial Assurance	6/2012
Title 200, Section 212	Peer Review of License Actions by RMS Staff	3/2013
Title 200, Section 213	Continuity of Operations Plan (COOP) for Specific License Inspection Program	1/2013
Title 200, Section 214	Policy for Review of an Application for a Sealed Source and Device Certificate	1/2013
Title 300, Section 301	Assignment of RAM Inspections	12/2012
Title 300, Section 302	License Tracking Management System Database Maintenance and Statistical Reporting	12/2012
Title 400, Section 415	Reciprocity	5/2013
Title 400, Section 421	Conduct of Escorts of Radioactive Materials Shipments	4/2014
Title 600, Section 601	NRC Training for RMS Staff	6/2016
Title 600, Section 602	RMS Staff Qualification and Training	3/2016
Title 600, Section 603	General License Collateral Duty Procedure	12/2012

License templates for industrial and medical licenses were updated to ensure all licenses included conditions specifying a physical address records location, prohibition against transfer of license control without RHB written permission, requirements for RAM transportation and where appropriate, maintaining possession limits below levels requiring decommissioning financial assurance, maintaining aggregated possession limits below 902 KAR 100:037 thresholds. The following guides and forms were updated or adopted during this review period.

Revised Licensing Guides

- Kentucky License Guide for Portable Gauging Devices, Revised 6/2013
- Kentucky License Guide for Industrial Radiography, Revised 8/2013
- Kentucky Medical License Guide, Revised 7/2015
- Kentucky License Guide for Well Logging Operations, draft under review

Revised Forms

- Kentucky Weekly Radiography Schedule, Revised 2/2012

- Kentucky Reciprocity Location Report, Revised 6/2013
- Kentucky Radioactive Materials License Fee Schedule, Revised 7/2015
- RPS-12, Transfer of Control, Revised 1/2015

New Forms

- RPS-526, Small Entity Certification, July 2015

22. Identify by licensee name and license number any renewal applications that have been pending for one year or more. Please indicate why these reviews have been delayed and describe your action plan to reduce the backlog.

No license renewal applications have been pending for more than a year but numerous licenses are overdue for a timely renewal or amendment in entirety as it is referred to in KY regulation. Amendments in entirety are required every five, seven or ten years depending on the license category (program code). Efforts have been underway during this review period to work through the pending backlog of licensees requiring a comprehensive renewal. The Program has been sending out 5-10 requests per quarter based on number of pending license actions to licensees due for comprehensive renewal during this review period starting with the industrial licensees. To date, 34 industrial licensees are due for an amendment in entirety and of those, 9 have submitted applications that are currently under review. Letters requesting amendments in entirety of medical licensees were begun being sent out in 2015. Currently 34 medical licensees are due for an amendment in entirety and of those, 11 have submitted applications pending review. To date, a total of 88 amendments in entirety have been processed during this review period with a total of 21 applications submitted pending review.

During this review period a total of 46 new license applications were submitted and of those, 42 have been granted. At present, 4 applications for new specific licenses are pending with one of those having been submitted over one year ago. The applicant, 21st Century Oncology of Kentucky (DBA Danville Radiation Therapy) was given thirty days to provide the information requested by the reviewer or face termination of their application on 7/6/16 after multiple attempts to acquire needed additional information have gone unanswered over the past year. The table below is listing of new license applications pending review.

New License Applicant	Tentative License Number	Application Receipt Date	Currently Under Review
21 st Century Oncology of Kentucky (DBA Danville Radiation Therapy)	202-442-25	5/7/15	Yes
Phoenix Process Equipment Company	201-801-60	5/16/16	No
Vector Engineers, Inc.	201-802-51	6/17/16	No
Osram Sylvania	201-803-91	6/27/16	No

V. Technical Quality of Incident and Allegation Activities

23. For Agreement States, please provide a list of any reportable incidents not previously submitted to NRC (See Procedure SA-300, *Reporting Material Events*, for additional guidance, OMB clearance number 3150-0178). The list should be in the following

format:

<u>Licensee Name</u>	<u>License #</u>	<u>Date of Incident/Report</u>	<u>Type of Incident</u>
----------------------	------------------	--------------------------------	-------------------------

All reportable incidents occurring during the review period have been previously submitted to the NRC.

24. Identify any changes to your procedures for responding to incidents and allegations that occurred during the period of this review.

All RMS staff attended the NMED and SA-300 training workshop conducted jointly on-site by the NRC and INEL in September 2015 in Frankfort, KY. The NMED access database installed on the shared network server to which all RMS staff have access, was recently updated in June 2016 to NMED 9.0 after its release. All staff are required to make entries into the local NMED database for any incident or allegation for which they are directly involved. In addition, staff are required to inform the Supervisor and the Incidents and Allegations (I&A) Coordinator of any and all incidents and allegations. The I&A Coordinator is responsible for maintaining a file on all incidents and allegations, responsible for checking the local NMED database entries to ensure they are complete and accurate and responsible for uploading appropriate reportable events in the local NMED to INL. NMED has been adopted as the official method of tracking all incidents and allegations in RMS regardless of whether or not they are reportable.

The NRC Fax Cover Sheet for reporting to the NRC Ops Center was revised in December 2012 and the Incident & Allegation Report Form was revised in April 2015 incorporating all of the information in SA-300, Table 4. The 10 CFR -902 KAR reporting requirement cross reference table was updated in April 2015 to include EA-05-090 IC and EA-07-300 Finger Printing security order reporting requirements but needs to be revised again to include reporting requirements of recently adopted 902 KAR 100:037, "Physical protection of category 1 and category 2 quantities of radioactive material". All staff have been instructed in the use of these new forms and cross reference table and they are routinely shared with licensees to aid in reporting. The staff use the RMS Outlook calendar to prompt follow-up on all open NMED events.

C. NON-COMMON PERFORMANCE INDICATORS

I. Compatibility Requirements

25. Please list all currently effective legislation that affects the radiation control program. Denote any legislation that was enacted or amended during the review period.

Current Effective Legislation for the Radiation Health Branch is listed below:

Kentucky Revised Statutes (KRS) 13B.170, 194A.050, 211.090, 211.842 to 211.852, 211.859, 211.990 (4), and KRS 211.861 to 211.869.

Regulations for radioactive material are located in Administrative 902 Kentucky Administrative Regulations (KAR) Chapter 100 (see <http://www.lrc.ky.gov/kar/TITLE902.HTM>).

Twelve parts of 902 KAR 100 were amended and published in their final form on June 3, 2011, November 16, 2011 and December 7, 2011. Of those 12 parts, the NRC identified minor issues with eight of them (<http://pbadupws.nrc.gov/docs/ML1203/ML120390169.pdf> and <http://pbadupws.nrc.gov/docs/ML1223/ML12234A559.pdf>). RHB agreed with these comments

and those parts were revised and resubmitted to the Cabinet for review in October 2012. Those eight parts were returned to RHB three times by the Cabinet during this review period for various reasons beyond our control. In addition to those 8 parts, RHB also revised 902 KAR 100:012. Fee schedule. to make our fees more in line with those charged by neighboring agreement states and the NRC. After the last resubmission in July, 2014, the revised regulations were finally adopted in February 2015. In addition, RHB submitted a brand new 902 KAR 100:037, “Physical protection of category 1 and category 2 quantities of radioactive material” which adopts 10 CFR 37 by reference for Cabinet review on 9/11/15. The new 902 KAR 100:037 regulation was adopted on 2/5/16. The revised regulations submitted and adopted are as follows:

Initial Submission Date	Final Adoption Date	Title	State Section
6/3/11	2/5/15	Definitions for 902 KAR Chapter 100	902 KAR 100:010
11/16/11	2/5/15	Standards for protection against radiation	902 KAR 100:019
11/16/11	2/5/15	Decommissioning and financial surety	902 KAR 100:042
6/3/11	2/5/15	Specific licenses to manufacture, assemble, repair, or distribute products	902 KAR 100:058
6/3/11	2/5/15	Transportation of radioactive material	902 KAR 100:070
6/3/11	2/5/15	Use of radionuclides in the health arts	902 KAR 100:072
11/16/11	2/5/15	Industrial radiography	902 KAR 100:100
12/7/11	2/5/15	Wire line service operations	902 KAR 100:142
11/17/14	2/26/15	Fee schedule	902 KAR 100:012
9/11/15	2/5/16	Physical protection of category 1 and category 2 quantities of radioactive material	902 KAR 100:037

These regulation changes corresponded to the following RATS-IDs:

- RATS ID # 1998-5
- RATS ID # 2000-1
- RATS ID # 2000-2
- RATS ID # 2002-1
- RATS ID # 2003-1
- RATS ID # 2004-1
- RATS ID # 2005-1
- RATS ID # 2005-2
- RATS ID # 2006-1
- RATS ID # 2013-1

We believe that adoption of these revisions satisfies the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-200.

Given the success of adopting 10 CFR 37 by reference in 902 KAR 100:037 and with the encouragement of senior management, RHB has decided to take the approach of adopting other parts of 10 CFR by reference in 902 KAR 100 in hopes of making Kentucky’s regulation “ever green”. The recent hiring of a full-time regulation writer by the Dept. for Public Health has been extremely helpful in these efforts. The following are stand-alone parts of 902 KAR 100 that are being revised to adopt specific tables from 10 CFR by reference. These revised regulations are scheduled for review by the Administrative Regulation Review Subcommittee on 7/14/16.

Initial Submission Date	Final Adoption Date	Title	State Section
11/5/15	TBD	Quantities of radioactive material requiring labeling (10 CFR 20 Appendix C)	902 KAR 100:030
11/5/15	TBD	Exempt quantities (10 CFR 20 Appendix C)	902 KAR 100:080
11/5/15	TBD	Exempt concentrations (10 CFR 30.70 Schedule A)	902 KAR 100:085

The next step in the “ever green” process is to begin adopting whole parts of 10 CFR by reference in compatible parts of 902 KAR 100. The plan is to start with the following parts of 902 KAR 100 since they have the fewest references to other parts:

- 902 KAR 100:070. Transportation of radioactive material (10 CFR 71)
- 902 KAR 100:100. Industrial radiography. (10 CFR 34)
- 902 KAR 100:142. Wire line service operations. (10 CFR 39)

In the midst of this process, RHB has been charged with promulgating new regulations for Technologically Enhanced Naturally Occurring Radioactive Materials (TENORM) following the discovery in February 2016 that out-of-state TENORM wastes resulting from oil and gas exploration production had been disposed of in several KY landfills from July 2015 to January 2016. This disposal of out-of-state TENORM was a direct violation of the Central Midwest Interstate Low-Level Radioactive Waste Compact and KRS 211.863. 211.863 “Control of commerce of low-level radioactive waste in and out of Kentucky -- Prohibitions – Exemption”. RHB staff are now working with others in the EEC Division of Waste Management and Division of Oil and Gas along representatives of private industry and public interest groups on the KY Oil and Gas Working Group to develop new TENORM regulations. A status report to the KY legislature is due in December 2016.

26. Are your regulations subject to a "Sunset" or equivalent law? If so, explain and include the next expiration date for your regulations.

Our regulations are not subject to a “sunset law”

27. Please review and verify that the information in the enclosed State Regulation Status (SRS) sheet is correct. For those regulations that have not been adopted by the State, explain why they were not adopted, and discuss actions being taken to adopt them. If legally binding requirements were used in lieu of regulations and they have not been reviewed by NRC for compatibility, please describe their use.

The provided SRS information appears to be correct. According to the SRS, there are comments on 5 RATS IDs (1996-1, 1997-5, 1998-5, 2001-1, 2002-2) encompassing 9 parts of KY regulations for which there are outstanding compatibility comments. One of these amendments, RATS ID # 2001-1, was partially addressed by issuing license conditions to the affected M&D licensee. Those were recently amended to include reporting requirements which were originally omitted. In addition, KY has not yet submitted proposed amendments encompassing 11 RATS IDs which are past their adoption due date (2007-1, 2007-2, 2007-3,

2008-1, 2009-1, 2011-1, 2011-2, 2012-1, 2012-2, 2012-3, 2012-4). As previously discussed, the plan is to adopt compatible parts of 10 CFR by reference to rectify these compatibility deficiencies.

28. If you have not adopted all amendments within three years from the date of NRC rule promulgation, briefly describe your State's procedures for amending regulations in order to maintain compatibility with the NRC, showing the normal length of time anticipated to complete each step.

Our process for amending regulations includes the following steps:

Drafting the regulation(s) IAW NRC compatibility requirements	3 months
NRC review of proposed regulation	2 months
Cabinet review and approval	6 months
File with Legislative Research Commission (LRC)	1 month
Regulation published by LRC	0.5 months
Prepare for public hearing	0.5 months
Public hearing period	1 month
Administrative Regulation Subcommittee review	1 month
Health & Welfare Committee review	1 month
Finalization of Kentucky Administrative Regulation	1 month
NRC review of final regulation	<u>2 months</u>
Total	19 months

II. Sealed Source and Device (SS&D) Evaluation Program

29. Prepare a table listing new and amended (including transfers to inactive status) SS&D registrations of sources and devices issued during the review period. The table heading should be:

Kentucky has only one Manufacturer and Distributor of industrial gauging devices, Ronan Engineering, Inc. (license no. 201-260-95 & 201-267-95). During the reporting period, no new registries for any Ronan devices were approved. During the reporting period, two existing registries were amended and discussions are currently ongoing between RHB and the NRC regarding the wording of the leak testing requirements for the RLL-1.

SS&D Registry Number	Manufacturer, Distributor or Custom User	Product Type or Use	Date Issued	Type of Action
KY-576-D-115-S	Ronan GS-400 Series	Gamma Gauge	3/28/13	Amendment
KY-576-D-115-S	Ronan SA-1	Gamma Gauge	8/16/13	Amendment
KY-576-D-113-B	Ronan RLL-1	Gamma Gauge	5/30/2002	Discussions ongoing with NRC regarding leak tests of bundled sources

30. Please include information on the following questions in Section A, as they apply to the SS&D Program:

Technical Staffing and Training - Questions 2-9
Technical Quality of Licensing Actions - Questions 18-22
Technical Quality of Incident and Allegation Activities - Questions 23-24

The Radiation Health Specialists III who was primarily responsible for SS&D reviews during this review period, Chris Keffer, has met all the requirements specified in the RMS Staff Training and Qualification program for a SS&D reviewer including attending the NRC's SS&D Workshop in Columbus, OH in 2012 and again in Covington, KY in 2014. Mr. Keffer has successfully completed 3 weeks of NRC health physics training including Introductory Health Physics course (H-117) and Basic Health Physics course (H-122) but has yet to complete the Health Physics Technology course (H-201) or the newly revised Fundamental Health Physics course (H-123) which may now be substituted for H-201. Mr. Keffer spent approximately 40 hours on SS&D review during this review period. In addition to Mr. Keffer, RHB hired another gentlemen, Eric Perry, who is a veteran of the US Navy nuclear power program where he attained the rank of Machinist Mate First Class and where he served as Engineering Watch Supervisor and Quality Assurance officer. He has taken several engineering related courses at the University of Kentucky with hopes of eventually pursuing a BS degree in Mechanical Engineering. Mr. Perry also attended the SS&D Workshop in 2014 and he has completed his qualifications as a SS&D reviewer. Mr. Perry has assumed the role of lead SS&D technical reviewer for RHB with Chris Keffer serving as the second technical reviewer. Dr. Anjan Bhattacharyya, who also attended the SS&D Workshop in Covington, KY is serving as the alternate technical reviewer. In addition, the Supervisor of the Radioactive Materials Section will serve as the final SS&D reviewer since he also meets all the requirements for an SS&D reviewer including attendance at the 2014 SS&D Workshop. In addition, the "Policy for the Review of an Application for a Sealed Source and Device Certificate" was revised in January 2013 and is now being used for the review process.

III. Low-level Radioactive Waste Disposal Program

31. Please include information on the following questions in Section A, as they apply to the Low-Level Radioactive Waste Disposal Program:

Technical Staffing and Training - Questions 2-9
Status of Materials Inspection Program - Questions 10-14
Technical Quality of Inspections - Questions 15-17
Technical Quality of Licensing Actions - Questions 18-22
Technical Quality of Incident and Allegation Activities - Questions 23-24

Information on the LLRW program is incorporated in the responses to the above questions on the program and is not separate from the radioactive materials program.

IV. Uranium Recovery Program

32. Please include information on the following questions in Section A, as they apply to the Uranium Recovery Program:

Technical Staffing and Training - Questions 2-9

Status of Materials Inspection Program - Questions 10-14

Technical Quality of Inspections - Questions 15-17

Technical Quality of Licensing Actions - Questions 18-22

Technical Quality of Incident and Allegation Activities - Questions 23-24

[Kentucky does not have a uranium recovery program](#)

Cabinet for Health & Family Services
Department for Public Health
Radiation Health Branch

Reciprocity Program

Self-Assessment

Eric Perry, Reciprocity Coordinator

6/13/2016

Executive Summary:

The effectiveness and compatibility of the reciprocity inspection program was assessed by the Radioactive Materials Section Supervisor (RMS Supervisor) and the Reciprocity Coordinator (Coordinator) due to the identification of a difference in priority classification for service provider licensees. Certain Service Provider licensees require more frequent inspection than others depending on the quantity (activity) of the byproduct material contained in the device. In addition to service provider licensees, several other modalities were also incorrectly prioritized. These modalities were licensees that use sealed sources to perform process diagnostics, and that package and remove low level waste from licensed facilities for final disposal.

The reciprocity program had not previously differentiated between service provider licensees based on device activity and therefore did not correctly prioritize inspection of these licensees appropriately. Additionally a few licensees perform process diagnostics using sealed sources which the program had equated to portable gauges and had assigned a lower priority to the removal of low level waste. This misprioritization of licensees resulted in the reciprocity inspection program not meeting the goal of inspecting 20 percent of all eligible high priority licensees for each calendar year. In 2012 13% of all high priority licensees were inspected. For 2013, 2014 and 2015 the program exceeded its goal with 23%, 21% and 29% inspected respectively.

Based on this information the Coordinator working with the RMS Supervisor have identified and reprioritized the inspection of certain licensees, conducted a self-assessment of the reciprocity program and will be conducting training for the inspection staff on this issue and all corrective actions.

The Coordinator and RMS Supervisor have concluded that overall the reciprocity inspection program is adequate to protect public health and safety and is compatible with the U.S. Nuclear Regulatory Commission's (NRC) program for reciprocal recognition.

Background:

Article VII of the agreement between the Commonwealth of Kentucky (Commonwealth) and the U.S. Nuclear Regulatory Commission (NRC) require the Commonwealth acting through the Cabinet for Health and Family Services, Department for Public Health, Radiation Health Branch (the Cabinet) to develop appropriate rules, regulations and procedures for granting reciprocal recognition to licensees of the NRC and other agreement states. 902 KAR 100:065 "Reciprocal Recognition" contains the Cabinet's administrative regulations which authorize reciprocal recognition of licensees of NRC and other agreement states. Administrative Policy Title 400 section 415 "Reciprocity" revised June of 2014 provides the staff with guidance on granting reciprocal recognition as required by part 065.

Licensees that conduct licensed activities under reciprocal recognition are subject to the same health, safety and security inspections as licensees that are specifically licensed by the Cabinet. The Cabinet's policy requires 20% of all eligible candidates that are high priority inspections be inspected each calendar year. To be considered a high priority inspection the licensee must be assigned a priority code of 1, 2 or 3 meaning that the licensee would be inspected at intervals of 1, 2 or 3 years respectively. These codes are assigned based on the risk associated with licensed activities and typically the Cabinet assigns priority codes in the same manner as NRC; meaning a licensee that is assigned a priority code of 1 by the Cabinet would also be assigned a priority code of 1 by NRC. Eligibility is determined in accordance with the Cabinet's policy and depends on the licensee's performance and when they were inspected last.

Summary of Issue:

While attempting to determine the appropriate priority code of a licensee that applied for reciprocal recognition the reciprocity coordinator noted that the NRC's inspection manual chapter 2800 contained two listings for licensees that service devices containing byproduct material; one for devices which contain 100 Curies or less (NRC program code 03225) and devices that contain greater than 100 Curies (NRC program code 03226). Licensees that service devices containing 100 Curies or less of byproduct material are assigned a priority code of 5 by NRC; which is consistent with the Cabinet's program. Licensees that service devices that contain more than 100 Curies of byproduct material are assigned a priority code of 2 by NRC; however, the Cabinet failed to distinguish these service providers from those that service devices which contain lower quantities of byproduct material. In effect the Cabinet assigned one discipline/program code (60) to all licensees which perform servicing of devices containing byproduct material.

Further review revealed that the Cabinet had also incorrectly prioritized licensees that use Industrial Diagnostic Systems which contain sealed sources (NRC program code 03311). The Cabinet had considered these as similar to portable gauging devices and prioritized them in a similar manner. Also licensees that package and prepare low level waste for shipment at the customer's facility were assigned a priority code of 5 instead of a priority code of 3 as would be consistent with NRC's program.

This caused the Cabinet to incorrectly identify and prioritize licensees conducting activities under reciprocal recognition for inspection. From 2012 through 2015 there were ten licensees that should have been assigned a priority code of 1, 2 or 3 and included in the eligible candidates for high priority inspections. When these licensees are added to the total number of eligible high priority candidates for 2012 calendar years the reduced percentage of licensees inspected falls below the 20 percent goal stated in the Cabinet's policy administering the reciprocal recognition program.

Root Cause Analysis:

The root cause of this failure is that the Cabinet has no active licensees that are authorized to perform the above activities. As the Cabinet has no similar licensees with which to compare these out of state licensees; the Cabinet attempted to categorize them using its existing discipline codes and failed to recognize that the Cabinet's discipline codes were not a complete representation of NRC program codes for the use of byproduct material.

An additional root cause is that many of these licensees are authorized to perform multiple activities of varying risk to public health and safety while they may only perform relatively low risk activities within the Commonwealth. Additionally the authorized use statements vary greatly between different agreement states and NRC regions.

Corrective Action:

Short term corrective actions include a review of all licensees granted reciprocal recognition to identify all licensees that perform activities that are described above and assign the correct priority codes. All end of year inspection totals were recalculated using this increased number of eligible licensees. This will also ensure that all eligible licensees are considered for inspection in the 2016 calendar year. Training will also be conducted for all staff on this self-assessment and the underlying issue.

Long term corrective actions include coordinating with information technology services to create new discipline codes for these types of licensees, periodic reviews (at least annually) of the Cabinets discipline codes and NRC program codes contained in IMC-2800 to ensure the Cabinet is prioritizing inspections of reciprocal licensees in the same manner as NRC. This review will include both the Reciprocity Coordinator and the RMS Supervisor. Administrative policies will be revised at the RMS Supervisor's discretion to provide further guidance on this issue and to require approval from the RMS Supervisor for the assignment of certain discipline codes when licensees are granted reciprocal recognition. Consideration will be given to licensees that are authorized multiple activities or authorized to perform activities that the Cabinet has never issued a specific license authorizing similar activities.

Conclusion:

The Cabinet has concluded that its program for granting reciprocal recognition is adequate to protect public health and safety and is compatible with the NRC's program and meets the requirements of Article VII of the agreement. Additionally in the course identifying the full scope of this issue the Cabinet

assisted NRC staff in potentially improving the NRC's reciprocal recognition program as well. The Cabinet remains committed to providing the appropriate level of regulatory oversight for all licensed activities performed within the Commonwealth. Implementing the corrective actions described above will ensure that the Cabinet's resources are utilized in the best manner to ensure that licensed activities are conducted in a manner that is safe and meets all Cabinet requirements.

Year	Priority 1			Priority 2			Priority 3			Other			Total Priority 1,2,3		
	Eligible Candidates	Inspected	%	Eligible Candidates	Inspected	%	Eligible Candidates	Inspected	%	Eligible Candidates	Inspected	%	Eligible Candidates	Inspected	%
2012	7	2	29	5	0	0	3	0	0	52	1	2	15	2	13%
2013	3	1	33	4	0	0	5	2	40	52	0	0.000	13	3	23.07692
2014	8	3	37.5	7	1	14.29%	4	0	0	52	0	0	19	4	21.05%
2015	9	4	44.44%	6	1	16.67%	5	0	0	48	2	4.17%	20	5	25.00%
2016 To date	1	0	0	4	1	25.00%	4	0	0				9	1	11.11%