

Kentucky Radiation Health Branch's Plan for Achieving and Maintaining Regulation Compatibility by Adopting 10 CFR by Reference into 902 KAR 100

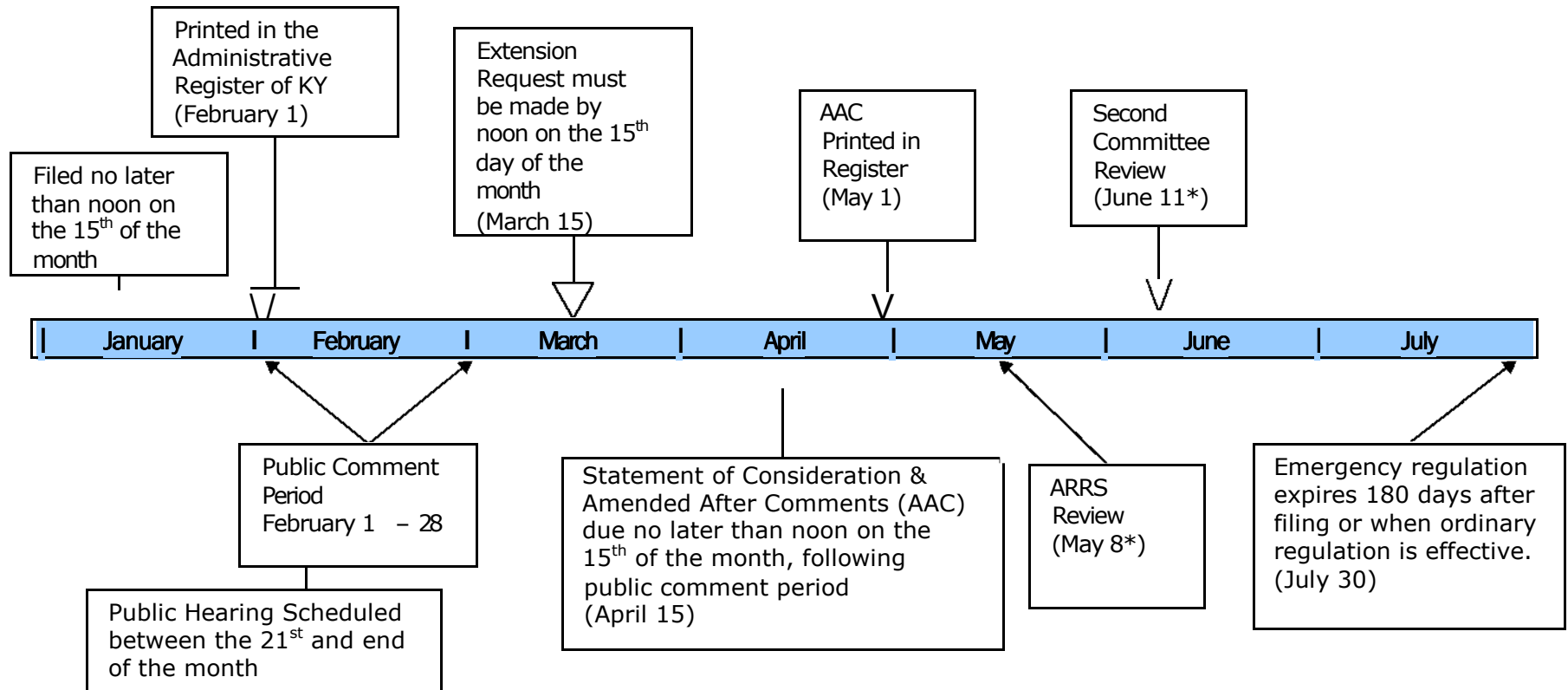
Background:

The KY Radiation Health Branch (RHB) has struggled for many years to maintain regulation compatibility with the U.S. Nuclear Regulatory Commission (NRC). The administrative regulation review and adoption process is a multi-step, multi-layered process involving many individuals between initial drafting by RHB staff, internal Department for Public Health (DPH) review and Commissioner approval followed by internal Cabinet for Health and Family Services (CHFS) review and Secretary approval. Once approved, the revised draft administrative regulation is filed with the Legislative Research Commission (LRC) by the 15th of the month. The administrative regulation promulgation process then proceeds as follows:

- A draft regulation is filed by the 15th of the month.
- It is printed in the Administrative Register of Kentucky (ARK) the 1st of the following month.
- A public hearing to receive comments is scheduled for the end of the month in which the regulation is published in the ARK.
- The public comment period ends at the end of the month in which the regulation was published in the ARK.
- If no comments are received, the regulation will be reviewed at the Administrative Regulation Review Subcommittee Meeting the 2nd Tuesday of the next month.
- If comments are received, a Statement of Consideration (consisting of comments and responses and changes, if applicable) is filed by the 15th of the next month or a 30-day extension period may be granted for substantial comments or changes.
- Once the Statement of Consideration is filed (with the amended regulation if changes were necessary), the regulation will be reviewed at the Administrative Regulation Review Subcommittee Meeting the 2nd Tuesday of the next month.
- If the regulation passes review, it will be reviewed by a second subcommittee the next month. For RHB regulations, this subcommittee is the Health and Welfare Subcommittee.
- If the regulation passes that review, it becomes effective upon adjournment of the second subcommittee meeting. If the regulation is not reviewed, it becomes effective 30 days from the date of the referral of the first subcommittee.

Administrative Regulation Promulgation Process

Sample Regulation Timeline



*Administrative Regulation Review Subcommittee (ARRS) REVIEW

ARRS typically held the 2nd Tuesday of each month at 10am.

ARRS ACTIONS:

1. Request deferral, must be approved by agency
2. Agree to staff or agency amendment
3. May not act to approve
4. May find regulation deficient

AGENCY ACTIONS:

1. May request deferral
2. May propose an amendment to be approved by ARRS
3. May agree to proposed amendment from ARRS
4. Agency may withdraw a regulation at any point in the process

*HEALTH & WELFARE SUBCOMMITTEE REVIEW

Typically held the 3rd Wednesday of each month.

- Second reviewing committee has 30 days from the date of referral to review the regulation

The second committee has the same powers as the ARRS
Regulation is placed on the agenda?

1. YES: It goes into effect on completion of the meeting
2. NO: It goes into effect at the end of the 30-day period

In addition to this lengthy process, RHB has faced the added challenge of finding staff with the training and expertise to draft regulations. Unlike the NRC and many agreement states, KY has never had the luxury of having staff dedicated to maintaining regulation compatibility. That has always been a task shared by the RHB staff and management who were already tasked with other duties such as licensing and inspecting.

What Changed:

In 2015, DPH for the first time in recent memory finally saw fit to hire a dedicated regulation reviewer, Ms. Laura Begin, who had previously worked in another cabinet, the Energy and Environment Cabinet (EEC). In EEC, Ms. Begin functioned as a dedicated regulation reviewer tasked primarily with keeping the EEC Department of Environmental Protection (DEP) regulations compatible with those of the U.S. Environmental Protection Agency. A major part of that compatibility effort involved adopting the EPA's 40 CFR by reference, a process referred to as making regulations "ever green". When Ms. Begin arrived in CHFS and began reviewing RHB's regulations and the many RATS IDs overdue for adoption (currently 12), she suggested this "evergreen" strategy to RHB and senior DPH and CHFS management. RHB had long been interested in pursuing this course, but was unable to gain the support of LRC. Now that the "evergreen" approach was a viable option, all were agreed that this would be best and most productive method of achieving and maintaining regulation compatibility with the NRC going forward.

Implementing the Plan:

With that aim in mind, RHB and Ms. Begin set forth to adopt the NRC's 10 CFR 37 by reference into a brand new 902 KAR 100:037. Physical protection of category 1 and category 2 quantities of radioactive material. After working with RHB to revise its 902 KAR 100:012. Fee Schedule. which became effective in February 2015, RHB and Ms. Begin began drafting a new Part 037 regulation. Over the next six months, the team developed a draft Part 037 which they was submitted for internal DPH and CHFS review. At the same time, RHB shared a copy of the draft Part 037 with the program's Regional Agreement State Officer for review and comments.

While 902 KAR 100:037 adopting 10 CFR 37 by reference was making its way through the internal review process, RHB and Ms. Begin turned their attention revising other parts of 902 KAR 100 to adopt 10 CFR by reference. With Part 037 being a brand new administrative regulation, there were not going to be an changes to make to an existing regulation. However, adopting 10 CFR parts into existing regulations would require deleting existing regulatory language, many pages in most case, and replacing those with reference to compatible parts of 10 CFR and calling out he exceptions where 10 CFR did not apply but rather directing the reader to the appropriate part of 902 KAR 100. The team adopted the strategy of converting the parts

of regulations that contained few or no references to other parts, and that would be free from significant exceptions, so we proceeded with revisions of stand-alone parts of 902 KAR which basically consist of tables of radionuclides, activities and activity concentration limits and revise those to incorporate corresponding parts of 10 CFR by reference. Those parts are:

Kentucky Administrative Regulation	Compatible Part of 10 CFR
902 KAR 100:030. Quantities of radioactive material requiring labeling	Adopting 10 CFR 30.71 Schedule B by reference.
902 KAR 100:080. Exempt quantities.	Adopting 10 CFR 30.70 Schedule A by reference.
902 KAR 100:085. Exempt concentrations.	Adopting 10 CFR 20 Appendix C by reference
902 KAR 100:090. Broad license limits.	Adopting 10 CFR 33.100, Schedule A by reference.

Making Progress:

As the team began its work on these four parts, the new 902 KAR 100:037 continued to make its way through the internal department and cabinet regulation review process after which there was a thirty day public comment period. After receiving no comments, the new Part 037 was filed with the LRC. On December, 9, 2015, the Administrative Regulation Review Subcommittee (ARRS) held a hearing at which time Part 037 was reviewed and discussed with RHB management and after receiving no objections, approved by the ARRS. The new regulation went before the Health and Welfare Subcommittee where it was reviewed and discussed with RHB management and after receiving no objections, approved. On February 5, 2016 the new 902 KAR 100:037 became effective in the Commonwealth of Kentucky. From start to finish, this first ever incorporation by reference regulation promulgation took almost exactly one year.

More Moving Through the Pipeline

After completing their internal DPH and CHFS review, Parts 030, 080 and 080 were signed by the Cabinet Secretary and filed with LRC on May 11, 2016. Unfortunately, Part 090 hit a snag was temporarily held up in the cabinet. The LRC had several questions for RHB regarding these proposed revisions which the staff were able to answer. As it turns out, by adopting compatible parts of 10 CFR in these three regulations, KY was correcting heretofore unrecognized mistakes and typographical errors in tables referenced in these regulations. On July 14, 2016 the revised Parts 030, 080 and 085 went before the ARRS where they were reviewed and discussed with RHB management and approved without changes. The three regulations are currently awaiting a hearing before the Health and Welfare Committee. If there are no unexpected delays, these three revised regulations should go final in August 2016.

While these three parts were making their way through the regulation review process, RHB has started work on adopting the following regulations by reference for the remainder of 2016:

Kentucky Administrative Regulation	Compatible Part of 10 CFR
902 KAR 100:070. Transportation of radioactive material.	Adopting 10 CFR 71 by reference
902 KAR 100:100. Industrial radiography.	Adopting 10 CFR 34 by reference
902 KAR 100:142. Wire line service operations.	Adopting 10 CFR 39 by reference

A Plan for the Future:

Moving forward, the plan is to tackle 3-4 regulations every six (6) months until all parts of 10 CFR have been adopted by reference with the exception of those parts of 902 KAR 100 that are currently being shared with the Radiation Producing Machines Section of RHB.

Spring 2017

Kentucky Administrative Regulation	Compatible Part of 10 CFR
902 KAR 100:050. General licenses.	Adopting 10 CFR 31 by reference
902 KAR 100:052. Broad scope licenses.	Adopting 10 CFR 33 by reference
902 KAR 100:058. Specific licenses to manufacture, assemble, repair, or distribute products.	Adopting 10 CFR 32 by reference

Fall 2017

Kentucky Administrative Regulation	Compatible Part of 10 CFR
902 KAR 100:040. General provisions for specific licenses.	Adopting 10 CFR 30 by reference
902 KAR 100:041. Quantities of radioactive materials requiring consideration of the need for an emergency plan.	Adopting 10 CFR 30, Appendix C by reference
902 KAR 100:042. Decommissioning and financial surety.	Adopting 10 CFR 30 by reference

As we complete the above regulation conversions, we will be concurrently preparing those parts that have a direct impact on other program areas. By the end of 2017 or the spring of 2018, we expect to push the remainder of our regulations into the pipeline for adoption. Our goal is to have all regulations either completed or in the pipeline toward completion by our scheduled periodic review in the summer of 2018

Current and Proposed Regulation Adoption by Reference Time Line

2015												2016												2017												2018																
J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J											
902 KAR 100:037																																																				
										902 KAR 100:030, 080, 085																																										
																		902 KAR 100:070, 090, 100, 142																																		
																								902 KAR 100:050, 052,058																												
																																				902 KAR 100:040, 041,042																