

RADIOACTIVE MATERIALS SECTION  
RADIATION HEALTH BRANCH  
Inspection and Enforcement Manual

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Title 200

Section 201

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RAM Inspection Frequency and Announcement of Inspections

I. Purpose and Objective

The purpose of this policy is to establish frequencies at which both specific licenses (201-, 202-, 203-, 204- & 206) and general licenses (401-) are to be inspected based upon their licensed activity. The objective is to designate frequencies in a uniform fashion and set intervals based on the possession and use of licensed material and the potential for adverse impacts to employee and public health and safety. It also establishes procedures regarding announced and unannounced inspections. This inspection policy is designed to be compatible with the inspection frequency mandated in the US Nuclear Regulatory Commission's Inspection Manual Chapter 2800 (<http://pbadupws.nrc.gov/docs/ML1028/ML102800160.pdf>). A table showing the NRC's Program Codes and RHB's corresponding Discipline Codes along with their respective inspection interval is shown at the end of this policy. All RHB inspection intervals were changed on January 1, 2012 to make them the same as the NRC's inspection frequencies including both specific and reciprocity licenses. Prior to January 1, 2012, KY policy required for more frequent inspections of several categories of specific licenses (shown in green in attached Table) in addition to more frequent inspections of reciprocity licensees.

II. Intervals and Frequency of Specific License Inspections

Licenses are assigned routine inspection intervals from 1 through 5 as contained in Appendix A of this policy. Initial inspections of specific licenses shall be conducted within twelve (12) months after material is received and/or operations under the license have begun or twelve (12) months after license issuance, even if no material has been received. All initial inspections appear as "past due" or yellow on the RMS License Tracking Management System (LTMS) at six (6) months after issuance of the license if not inspected and appear as "overdue" or red on the LTMS at twelve (12) months after issuance if not inspected. The RMS Supervisor will review the inspection status at the end of each month and make all RMS staff aware of any initial inspections that are past due or approaching their overdue date. If necessary, the Supervisor will assign initial inspections to qualified staff members to be completed in that month's time frame.

The inspection date should be advanced one (1) year after the initial inspection of a license that has not received material and the licensee requested to notify RHB when material is received or initiation of licensed operations. A telephone call should be made prior to the next inspection date to determine if material has been received. If it

has not, the date may be advanced another year. If material has been received, the inspection must be conducted within one (1) year of receipt of material.

Routine inspections of specific licenses in intervals 1 through 5 shall be conducted in years corresponding to their interval from the last inspection as indicated on the Inspections Due tab of the RMS License Tracking Management System (LTMS) database. The only exception would be in the case where the routine inspection interval has been reduced due to any of the reasons specified in Section IX. Appendix A-Inspection Intervals of this policy gives the routine inspection intervals for all specific licenses based on the discipline code assigned to the license.

### III. Assignment of Routine Inspection Intervals for Specific Licenses

When a new specific license is issued it shall be assigned a routine inspection interval based on the types, quantities and forms of radioactive material and the authorized use(s) in accordance with Appendix A-Inspection Intervals. If a license involves more than one type of use, the type associated with the most frequent interval shall be applied. The routine inspection interval shall be changed accordingly if an additional authorized use requiring a more frequent interval, is incorporated into the license after initial issuance. For example, a medical facility performing nuclear medicine procedures for imaging and therapy as well as manual brachytherapy (discipline code 26) that request and is granted the authority to possess and use high dose rate remote afterloaders HDR (discipline code 27), would go from a three (3) year inspection interval to a two (2) year inspection interval.

To achieve the goals of the inspection program and make efficient use of staff time and resources, routine inspections (other than initial inspections) may be scheduled within a window around their inspection due date. Routine inspections of specific licenses may vary from the due date by  $\pm 25$  percent. Routine inspections which have reached their next due date based on their inspection interval and have not yet been inspected are considered "past due" and show up as yellow on the RMS License Tracking Management System (LTMS). Inspections are not considered "overdue" until they exceed 25 percent of the inspection interval added on to the next inspection due date with one exception. Routine inspections with a five (5) year inspection interval, shall be inspected within one (1) year of their due date rather than 25% (one year and three months) before they are considered "overdue". Overdue inspections show up as red in the Inspections Due tab of the LTMS. Overdue routine inspections should be avoided at all costs and once overdue, should be given top priority over all other inspections and licensing matters. Inspections should be scheduled before their next inspection due date if RHB receives information that warrants an earlier inspection (e.g. allegation, NMED reportable event, etc.). Such inspections would not be considered routine inspections but rather classified as non-routine inspections, reactive inspections or investigations. The RMS Supervisor will be responsible for scheduling all non-routine reactive inspections and investigations. Typically, such inspections will be conducted by a team of qualified inspectors lead by the RMS Supervisor.

#### IV. Inspection of General Licenses

With the exception of reciprocity inspections, inspections of general licenses are not required on a routine basis. However, every attempt will be made to inspect all general licenses every five (5) years  $\pm$  25 percent, the same as for fixed and portable gauge specific licenses. The reason for this routine inspection interval is based on the fact that the vast majority of general licenses authorize the possession and use of gas chromatographs (GC) as well as fixed and portable gauging devices (e.g. XRF, IMS). These devices and the sealed sources they contain are designed to be inherently safe and pose little health and safety risk to their operators, other employees or members of the public. Inspections at intervals less than every 5 years shall be conducted to resolve allegations, complaints, or other indications of an unsafe practice, a case of non-compliance or when such an inspection is directly pertinent to an inspection involving a specific license. In addition, inspections of general licenses to support studies or for efficient use of time and travel in a particular area when inspecting specific licenses may be conducted. Next inspection due dates for all general licenses are tracked by the General License Coordinator as part of their collateral duty and not tracked in the LTMS.

#### V. Reciprocity Inspections

NRC or other Agreement State specific licensees operating under reciprocal recognition are granted a general license as provided in 902 KAR 100:065 (<http://www.lrc.state.ky.us/kar/902/100/050.htm>). Reciprocity licenses are assigned a corresponding discipline code based on their NRC and Agreement State license as described in Appendix A-Inspection Interval of this policy. The percentage of reciprocity licensees to be inspected are as follows:

Priority 1 – 3 – total of 20% of all eligible licensees inspected each year  
All Other Priorities – as time and resources allow

Eligibility is based on the reciprocity licensee not having been inspected in the previous calendar year or, if they were, the reciprocity licensee was subject to a significant, NMED reportable event somewhere in the US in the previous two (2) calendar years in accordance with the NRC's Inspection Manual Chapter 1220 (<http://www.nrc.gov/reading-rm/doc-collections/insp-manual/manual-chapter/mc1220.pdf>). If the latter is the case, the inspection report should make note of that NMED report number and findings.

The Reciprocity Coordinator is responsible for tracking all reciprocity inspections in the Reciprocity Access database maintained for each calendar year by the coordinator. Title 400, Section 415 "Reciprocity" addresses the inspection of Agreement State and NRC licensees operating in the Commonwealth of Kentucky in greater detail.

## VI. Pre-licensing Inspections of Specific Licenses

Pre-licensing inspections, when required, are to be conducted for all specific license applications in accordance with Administrative Policy Title 200, Section 212. Pre-licensing Guidance To Ensure Radioactive Materials Used As Intended, Rev. 02/2012.

## VII. Follow-up Inspections of Both Specific and General Licenses

Follow-up inspections should be performed when the following conditions exist:

1. The previous inspection resulted in a severity rating of I.
2. Numerous (4 or more) repeat items if a severity level II or III were identified.
3. When there is doubt, based on the judgment of the inspector, that the facility can continue to operate in compliance with regulations and license conditions.
4. After an investigation and based on the judgment of the investigator.

These inspections are to be coordinated with the RMS Supervisor and should generally be conducted within six (6) to twelve (12) months of the previous inspection.

## VIII. Extension of Inspection Frequency for Specific Licenses

The interval between inspections may NOT be extended beyond that specified by the inspection priority system specified in this policy on the basis of good licensee performance even where there is evidence of a well-managed and effective radiation safety program that shows a history of compliance. Inspections can only be reduced in frequency, never extended.

## IX. Reduction of Routine Inspection Frequency for Specific Licenses

The interval between routine inspections may be reduced on the basis of poor licensee or registrant performance. This action may be taken in response to any routine, field, or reactive inspection or investigation.

The final decision to reduce the routine inspection interval is made by the Radioactive Materials Section Supervisor; however, it is the responsibility of each radioactive materials inspector to recommend this action if any of the following conditions are met:

- The inspection is determined to be severity level I (one) or II (two).
- Any other escalated enforcement action is warranted in accordance with this policy.
- Any substantiated violation that indicates a lack of management oversight or that the RSO is not adequately performing duties.
- Any repeated violations from the previous inspection.

In accordance with 902 KAR 100:012, Section 3. Inspection Fee.

(<http://www.lrc.state.ky.us/kar/902/100/012.htm> )

- (1) The cost of a routine interval inspection shall be covered in the annual licensing renewal fee.
- (2) One (1) or more additional inspections shall be conducted to ensure ongoing public health and safety if any of the conditions established in paragraphs (a) through (d) exist:
  - (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.
- (3) The fee for each additional inspection shall be \$500.

(Note: A reactive inspection is not considered escalated enforcement. This is an important point since an additional \$500 fee is charged for additional inspections within an inspection cycle on the basis of escalated enforcement, not on the basis of an actual or potential incident or event or a unsubstantiated allegation.)

Other conditions may lead to a reduction of the routine inspection frequency at the discretion of the RMS Supervisor on a case by case basis.

Generally, the interval will be reduced to six (6) months from the date of the inspection for a Priority 1 licensee, one (1) year from the date of inspection for a Priority 2 licensee, two (2) years for a Priority 3 licensee and three (3) years from the date of the inspection for a Priority 5 licensee. If extenuating circumstances exist, the RMS Supervisor may adjust the interval as appropriate.

The licensee or registrant shall be notified in writing that their routine inspection interval has been reduced on the basis of poor licensee or registrant performance. The notification letter should also include:

- Indication of the normal, routine inspection interval,
- The reason for taking this action, and
- Indication of the reduced inspection interval

Notification of a licensee or registrant that their inspection interval has been reduced shall be sent certified and as a standard letter. The two otherwise identical letters shall be sent simultaneously to the same address.

When two otherwise identical letters are sent simultaneously (one certified and one standard), the intended recipient may be considered legally notified unless both letters are returned to the original sender undeliverable. The intended recipient need not sign for receipt on PS Form 3811 (certified mail card) in order to be considered legally notified.

A copy of all correspondence and receipts will be kept on file, along with other documents pertinent to the case.

X. Documentation of Change In Inspection Interval

To designate a reduced inspection priority for a specific licensee, the inspector should indicate a reduction in inspection interval on the inspection report cover page along with a brief note explaining the reason(s) for the reduction in interval and submit to the RMS Supervisor as part of the inspection report. This request for a reduction in inspection interval must be made at the time the latest inspection report is submitted. If approved by the RMS Supervisor, he/she will instruct the IT Coordinator to reduce the "next inspection date" in the LTMS. No change should be made in the discipline code determined "inspection interval" designation in the LTMS.

The Summary section below of the Inspection Report Form cover page is to be used for requesting the reduction in inspection interval and for assigning the next inspection due date.

**SUMMARY**

Announced \_\_\_\_\_ Unannounced \_\_\_\_\_ Priority \_\_\_\_\_

Number of Noncompliant Items \_\_\_\_\_ Severity Rating \_\_\_\_\_

Next Inspection Date: \_\_\_\_\_ ( ) Normal ( ) Reduced

Justification for reducing the routine inspection interval: \_\_\_\_\_

Violations \_\_\_\_\_

XI. Permanent Field Offices and Separate Use Locations of Specific Licenses

If the license authorizes licensed activities to be conducted from multiple field offices (satellite locations of use identified on the license), or at multiple use locations, at least ten (10) percent of the field offices/use locations should be inspected at the frequency specified in this policy for the type of license. Under no circumstances, should the same field offices or use locations be inspected repeatedly from one inspection to another. Emphasis should be given to rotating the inspection of various field offices and use locations to assess the licensee's entire program over several inspection cycles.

For mobile PET nuclear medicine imaging licenses which conduct licensed activities at multiple use locations, efforts should be made to contact the licensee for a schedule of sites where the licensed activities are to be conducted in the coming weeks and

unannounced inspections planned around that schedule. All attempts should be made to inspect the licensee at a different use location from one inspection to the next. For large portable gauge facilities with multiple storage locations, 10% of the different storage locations should be inspected each time in addition to the chosen records location.

## XII. Announced Inspections of Specific Licenses

Initial and pre-licensing inspections may be conducted on an announced basis. Routine specific license inspections may be announced with the approval of the RMS Supervisor in cases where the licensee is in a remote location and there is doubt if the licensee would be available in an unannounced situation. Routine inspections may be announced in cases where at least one previous attempt at an unannounced inspection was not successful. In cases where unannounced inspections have failed, refer to 902 KAR 100:015, Section 5. Routine inspections of Type A licenses of broad scope as defined in 902 KAR 100:052 should be announced given the nature and scope of such programs, the number of persons involved in the radiation safety program, and the extreme demand on the licensee's time. General license inspections may be conducted announced or unannounced at the discretion of the inspector and no RMS Supervisor pre-approval is required.

## XIII. Unannounced Inspections

Routine inspections of specific licensees should be conducted on an unannounced basis except as described in the previous paragraph.

## XIV. Other

Other type of inspections such as investigations will be conducted in a manner which would benefit the investigation.

## XV. Continuity of Operation (COOP) for Assignment of RAM Inspections

In the event the RMS Supervisor is unavailable at the end of the month when the monthly LTMS database reconciliation is performed and all RMS staff are made aware of what inspections are coming due in the new month, the IT Coordinator will make all the appropriate and necessary entries and updates to The Book and share those with the RMS staff. The RMS staff will then, in turn, plan their monthly inspections in accordance with the afore mentioned inspection guidelines to ensure that no inspection reaches the "overdue" status and preferably, all "past due" inspections are completed before the end of the month. If both the RMS Supervisor and IT Coordinator are unavailable at the end of the month to update the LTMS and share the updated Inspections Due workbook with the RMS staff, the staff will continue to use their copy of

the last month's Inspection Due table to plan and conduct their monthly inspections. RMS Staff have the ability to sort inspections by Inspection Due Date and should do so to ascertain which inspections are closest to reaching their "overdue date". All efforts will be made to ensure that no initial or routine inspection exceed its assigned inspection interval.



APPENDIX A  
Inspection Intervals

Description/Category Title	KY Discipline Code	NRC Program Code	KY Priority Code Prior to 1/1/12	Current KY & NRC Priority Code
Waste Disposal Burial Facility	01	3231	1	2
Waste Disposal Service Processing and/or Repackaging	02	3234/3236	2	2
Burial Facility Maintenance	03		2	
R & D (Non-Human)	04	2410	3	5
Industrial Radiography - Temporary & Fixed Sites	05	3310/3320	1	1
Industrial Radiography w/ Radium - Temporary & Fixed Sites	06	3320	1	1
Nuclear Laundry	07	3218	3	3
R & D (Human Use) Broad Type A, RSC Approved AUs	08	3610	3	3
Decontamination/Decommissioning of Material Facilities	15	3219/3900/ 11900/2220 00		3
Waste Disposal Service Prepackaged Only	16	3232		3
Waste Disposal Service Processing and/or Repackaging	17	3234		2
Broad Medical Institution	22	2110	1	2
In-Vitro Testing & Clinical Lab	23	2410	5	5
Nuc. Med. (Imaging Only) WD Not Required	24	2121/2201	3	5
Nuc. Med. (Imaging & Therapy) WD Required	25	2200	3	3
Nuc. Med. (Imaging, Therapy & Implant) WD Required	26	2120	3	3
Nuc. Med. (Implant Only) - Temporary (HDR) WD Required	27	2230	2	2
Diagnostic Medical Devices	28	2201	4	5
Mobile Nuc. Med. - WD Required	29	2231	2	2
Medical Therapy-Other Emerging Technology	30	2240	2	2
Teletherapy / Gamma Stereotactic Radiosurgery	31	2300/2310	2	2
Nuclear Pharmacy / Radiopharmacy	32	2500	1	2
Veterinary - Nonhuman Subjects	33	2400	5	5
Well Logger - Sealed Sources Only	40	3110/3111	3	3
Well Logger w/ Tracers	41	3112	3	3
Measuring Systems - Gas Chromatographs	50	3123	5	T-5yr
Measuring Systems Portable Gauges - Soil Density	51	3121	4	5
Measuring Systems Portable Gauges - Soil Density w/Radium	52	3121	4	5
Leak Testing Service Only	53	3220	5	T-5yr
Instrument Calibration Services	54	3221/3222	5	5
Instrument Calibration w/ Radium	55	3221/3222	5	5
Fixed Gauge Measuring Systems (mCi)	56	3120	5	5
Fixed Gauge Measuring Systems (Ci)	57	3120	5	5

Measuring Systems Analytical Instruments - XRF	58	3122	5	T-5 yr
Portable Gauge (Other than Soil Density)	59	3122	4	T-5 yr
Sealed Source Servicing ( $\leq 100$ Ci)	60	3225	4	5
Sealed Source Servicing ( $> 100$ Ci)	61	3225		2
Industrial Diagnostic Systems	62	3311		2
Waste Disposal Service Waste Pickup at customer facility (no permanent facility)	63	3232		3
Broad Academic	70	1100	2	3
Broad Academic w/Radium	71	1100	2	3
Broad Academic Type A	72	1100	2	3
Broad Academic Type B	73	1110	3	5
Broad Academic Type C	74	1120	5	5
Environmental Lab	81	2410	5	5
<b>Description/Category Title</b>	<b>KY Discipline Code</b>	<b>NRC Program Code</b>	<b>KY Priority Code Prior to 1/1/12</b>	<b>Current KY &amp; NRC Priority Code</b>
State Lab	82	2410	5	5
University	83	2410	5	5
College	84	2410	5	5
Lab - Commercial	85	2410	5	5
Other	90		3	3
Storage Only (Permanent Shutdown & Standby w/ No Operations)	91	3800/3810	3	3
Industry Use In Processing - Source Material $<150$ kg	92	11200	1	5
Distributor Medical Invitro - Generally Licensed	93	3244	3	5
Development Industrial Gauges	94			
Manufacturer and Distributor - Industrial Gauges	95	3214	3	5
Self-Shielded Gamma Irradiator ( $<10,000$ Ci)	96	3510	5	5
Self-Shielded Gamma Irradiator ( $>10,000$ Ci)	97	3520	3	5
Gamma Irradiator (Unshielded)	98	3511/3521	1	2
Increased Controls / RSRM		1000	H&S	H&S

	Not currently in use
	No corresponding NRC program code
	KY inspection interval changed on 1/1/12 to conform to NRC inspection interval
	New discipline codes implemented as a result of 7/1/15 revision of 902 KAR 100:012. Fees