Guide for Preparation of Radioactive Material Applications for Use of Sealed Sources in Gas Chromatography Devices and X-ray Fluorescence Analyzers

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I. INTRODUCTION

A. Purpose of Guide

This guide describes the information needed to evaluate an application for a specific license for receipt, possession, use and transfer of radioactive material in the form of sealed sources as contained in "bench top" gas chromatographs and x-ray fluorescence analyzers used in laboratory environments, and for portable x-ray fluorescence devices used in field environments at temporary job sites. Specific requirements for applicants who wish to perform certain maintenance and repair operations are addressed in Appendix A, and additional information which must be submitted for possession and use of portable devices is addressed in Appendix B. This guide also provides assistance to applicants and licensees in preparing applications for license amendments, license renewals and license terminations.

There is no single portion of the Kentucky Radioactive Materials Regulations which specifically addresses gas chromatographs and x-ray fluorescence analyzers. Therefore, this guide is intended to provide you with information that will clarify more general regulatory requirements and licensing policies as they apply to these devices. Licensing guides are issued to describe the methods acceptable to Radiation Control for implementing the Cabinet's regulations, to outline techniques used by the staff in evaluating specific problems, and to provide guidance to applicants. The information in this guide is not a substitute for training in radiation safety or for developing and implementing an effective radiation safety program. However, you should be aware that if your application references procedures in this guide, those procedures become a part of your licensing conditions and regulatory requirements.

After you are issued a license, you must conduct your program in accordance with (1) the statements, representations, and procedures contained in your application and other correspondence with Radiation Control, (2) the terms and conditions of the license, and (3) applicable regulations as discussed below. Therefore, all information you provide in your application must be clear, specific and accurate.

B. Applicable Regulations

In addition to the contents of this guide, applicants should refer to the requirements in the Cabinet's regulations listed below. The applicant should carefully read the regulations. This guide does not substitute for an understanding of the regulations. It is your responsibility as an applicant and licensee to have copies, read and abide by each regulation.

1. 902 KAR 100:010, "Definitions."
2. 902 KAR 100:012, "Fees."
3. 902 KAR 100:015, "General Requirements."
4. 902 KAR 100:019, "Standards for Protection Against Radiation."
5. 902 KAR 100:040, "General Provisions for Specific Licensees."
6. 902 KAR 100:060, "Leak Testing."
7. 902 KAR 100:070, "Transportation of Radioactive Material."

8. 902 KAR 100:165, "Notices, Reports and Instructions to Employees."

C. As Low as Reasonably Achievable (ALARA) Philosophy

Section 2 of 902 KAR 100:019 states that each licensee shall develop, document and implement a radiation protection program commensurate with the scope and extent of their activities and sufficient to ensure compliance with the provisions of 902 KAR 100:019. This must include the use, to the extent practicable, of procedures and controls based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are ALARA. This radiation protection program must be reviewed at least annually for the effectiveness of its implementation. Section 30 of 902 KAR 100:019 requires licensees to maintain records of the provisions of their radiation protection program until the license is terminated by the Cabinet. Records of audits and other reviews of program content and implementation must be retained for three (3) years after the record is made.

II. FEES

A fee is required for a radioactive material license, renewals and amendments. The applicant should refer to 902 KAR 100:012, "Fees", to determine the amount of fee that must accompany the application. No action will be taken on applications submitted without the proper fee. Checks should be made payable to the Kentucky State Treasurer, but should be mailed to this office with the application.

III. FILING AN APPLICATION

An application for a license should be filed on Form RPS-7, "Application for Radioactive Material License." Since the space provided on the form is limited, additional sheets should be attached as necessary to provide complete information. Each separate sheet submitted with the application should be identified and keyed to the item number on the application to which it refers. The information submitted must be of sufficient detail to enable the Cabinet to determine that the proposed equipment, facilities, procedures and controls are adequate to protect health and minimize danger to life and property. Submittal of insufficient information will result in delays in issuance of the license.

Two (2) copies of the application should be completed. The original application should be mailed to:

Radiation Health & Toxic Agents Branch
Department for Public Health
275 East Main Street
Mailstop HS1CA
Frankfort, Kentucky 40621

One (1) copy of the application with all information submitted should be retained by the applicant, since licensees are required to possess and use licensed material in

accordance with the statements and representations in the application, license conditions and Cabinet rules and regulations.

IV. CONTENTS OF AN APPLICATION

Item 1 – Applicant and Mailing Address: The applicant corporation or other legal entity should be specified by name and mailing address in Item 1. Individuals should be designated as the applicant only if they are acting in a private capacity and the use of radioactive material is not connected with their employment with a corporation or other legal entity.

The Cabinet shall issue a license only to an applicant who maintains an office in Kentucky at which copies of records are kept and from which licensed activities are directed. However, the applicant may maintain an out-of-state office for corporate radiation safety direction.

Item 2 – Street Address(es) Where Radioactive Material Will be Used: Specify each location of storage or use by the street address and city or other descriptive address (such as 5 miles east on Highway 10, Town, State) to allow easy locating of the facility. These sites may be different from the mailing address specified in Item 1. A post office box address is not acceptable. For portable devices, see Appendix B for additional requirements.

Item 3 – Telephone Number: Indicate the telephone number of the applicant.

Item 4 – Person to be Contacted: This individual should know your proposed program and be able to answer questions regarding the application. A change in the contact person requires notification to the Cabinet but is not considered an application for amendment; therefore, no fee is required.

Item 5 – Individual Users: The names and titles of individuals who will use (operate) and/or supervise the use of devices listed in the application must be listed in Item 5. If other individuals will use the "bench top" gas chromatography device or x-ray fluorescence analyzer under the supervision of an individual user who is listed in Item 5, their names do not need to be submitted. Such individuals, however, should not be permitted to perform any maintenance or repair operations.

Refer to Item 13 for training and experience requirements for individual users. Refer to Appendix A for requirements if you propose to perform maintenance and repair operations, and to Appendix B for additional requirements for users of portable devices.

Item 6 – Radiation Safety Officer (RSO): The RSO is expected to coordinate the safe use of the devices and ensure compliance with the Kentucky Administrative Regulations 902 KAR 100. The applicant should list the name of an individual user, supervisor, foreman, or other designated individual who will be responsible for the radiation safety program and has been assigned responsibilities for determining that:

(a) All radioactive materials, sealed sources, and devices in use and/or in the possession of the applicant are limited to those listed in the license and are being used for the purposes specified in the license.

(b) Only those individuals authorized by the license use or supervise use of the devices.

(c) Periodic leak tests for the sealed sources are conducted as required by the licensee.

This person must be qualified by training and experience to use the material for the purpose requested in such a manner as to protect health and minimize danger to life or property.

See Appendix B for additional RSO requirements for portable devices.

Item 7 – Licensed Material and Use of Radioactive Material.

(a) Identify the radioisotope that will be used in the gas chromatograph or x-ray fluorescence analyzer and indicate if it will be in the form of a sealed source, foil or plated source.

(b) Identify and manufacturer and model number of the foil source, plated source, or sealed source that will be used in the gas chromatograph or x-ray fluorescence analyzer.

(c) Specify the amount of radioactive material that will be in each foil source, plated source, or other sealed source.

(d) Identify the manufacturer and model number of the detector cell that will be used in the gas chromatograph or the manufacturer and model number of the x-ray fluorescence analyzer. Specify the purpose for which the gas chromatograph or x-ray fluorescence analyzer will be used.

(e) Provide a commitment to limit the number of source/device combinations such that you do not exceed the quantities of radioactive material that would require financial assurance for decommissioning. These limits are defined in 902 KAR 100:040, Section 15. With this commitment, you do not need to specify, in advance, a particular number of identical source/device combinations that you may wish to possess. Alternatively, specify the maximum number of identical source/device combinations you will possess at one time. Refer to Appendix D for further discussion on financial assurance and for recordkeeping requirements important for decommissioning.

(f) A facility in possession of "generally licensed" devices may elect to include these devices as part of its specific radioactive material license. To do so, simply include required information in the appropriate sections

of the application (or in an amendment request), and request termination of the general license. The advantages of "combining" the general and specific licenses include the elimination of the annual general license fee, and consistency of regulatory requirements for all devices. Note – in order to terminate the general license, all generally licensed devices must be included on the specific license.

The information specified above in Item 7(a) through (d) is available from the manufacturer of the device.

Items 8 & 9 – Radiation Detection Instruments & Calibration: You do not need a survey meter for routine use (i.e., normal operation for the intended purpose) of gas chromatographs or x-ray fluorescence analyzers (bench top or portable devices). If you propose to perform any maintenance or repair operations that involve removal of sources from the device or maintenance and repair of a device that involves the source, refer to Appendix A for additional requirements regarding survey meters.

Item 10 – Personnel Monitoring: You do not need to use personnel monitoring devices for routine use of bench top gas chromatographs or x-ray fluorescence analyzers.

If you propose to perform any maintenance or repair operations that involve removal of the source from the device or maintenance and repair operations that involve the source, refer to Appendix A for additional requirements regarding personnel monitoring.

If you will be using portable x-ray fluorescence analyzers, refer to Appendix B for additional requirements regarding personnel monitoring.

Item 11 – Facilities and Equipment.

The applicant's proposed equipment and facilities must be adequate to protect health and to minimize danger to life or property. Therefore, you should provide information about your equipment and facilities. If the device will be stored/used in a restricted area, the area should be accessible only to persons authorized to use the device and locked when an authorized person is not physically present. The room, laboratory or area cannot be considered a restricted areas if it is accessible to unauthorized persons.

If the licensed material is stored in an unrestricted area, it must be secured from unauthorized removal. Licensed material in use in an unrestricted area must be under the constant surveillance and immediate control of the license.

If the licensed material is a nickel-63 source as contained in a gas chromatograph device for which the manufacturer requires venting, describe how the device will be vented.

For portable devices, see Appendix B for additional requirements.

902 KAR 100:165, Section 2 requires the posting of certain documents, notices and forms, in order to be readily observable by employees. These postings are to include the regulations referenced in Section 2, and the license and operating procedures. Refer to the regulation for other posting requirements.

Item 12 – Radiation Protection Program.

The licensee is responsible for the conduct of the radiation safety program and all actions of the employees regarding the use of radioactive materials. The licensee should submit a description of the radiation safety program, covering the following items (Note – see Appendix B for additional requirements for portable devices).

12.1 Leak Testing – As a licensee you must test to determine whether or not there is any leakage from the radioactive source in the gas chromatograph or x-ray fluorescence analyzer. There are some source/device combinations that have leak-test intervals up to 3 years. Information on source/device combinations that have 3-year leak-test intervals may be obtained from suppliers and manufacturers. Unless a specific request for the 3-year leak-test interval is included in the application, a 6-month interval will be specified in the license.

Tests to determine leakage are not required for sources containing radioactive material in gaseous form, hydrogen-3 (tritium) and sources of beta or gamma emitting radioactive material with an activity of 100 microcuries or less.

If leak testing is required, submit the procedures for leak testing of the sources. If the supplier of the devices containing the radioactive sources will perform leak tests of the source in the applicant's facility, it is only necessary for the applicant to state this and to specify the frequency of the leak tests. If a consultant or commercial facility will take samples, evaluate them and report results to the licensee, specify the name, address and license number of the consultant or commercial facility. If the applicant plans to use a leak test kit, the name of the supplier, license number and the model number of the kit should be specified. Verify that a copy of the leak test instructions will be available, and state who will collect samples.

12.2 Transportation Procedures – Refer to Appendix B for requirements related to transportation of portable devices.

12.3 Emergency Procedures – Submit a copy of the emergency procedures that will be followed in the event of an accident, emergency, loss or theft involving the gas chromatograph or x-ray fluorescence analyzer. These procedures should list actions to be taken and persons to be contacted within the licensee's organization along with telephone numbers. Telephone number should also be included for the manufacturer and the Kentucky Radiation Control office:

(502) 564-3700 Normal working hours
(502) 564-7815 Other hours

Refer to Appendix B for additional requirements for portable devices.

REMINDER TO LICENSEE MANAGEMENT:

(a) In the event of an emergency involving the device(s), arrange for a survey to be conducted as soon as possible by a knowledgeable person using appropriate radiation detection instrumentation. (This person could be a licensee employee using a survey meter or a consultant.)

(b) Make necessary notifications to local authorities as well as to the Cabinet as required. Cabinet notification is required when devices containing radioactive material are lost or stolen, or when devices are damaged or involved in incidents that result in doses in excess of 902 KAR 100:019 limits.

(c) Timeliness of reports to the Cabinet need to be considered.

(d) Reporting requirements are found in 902 KAR 100:019, Sections 38, 39 and 40 and 902 KAR 100:040, Section 18.

12.4 Inventories

902 KAR 100:015, Section 8 provides that the Cabinet may incorporate, in any license, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material as it deems appropriate or necessary in order to, among other things, protect health or to minimize danger to life or property. The Cabinet requires that, periodically, licensees must account for all sealed sources and devices received and possessed under their licenses.

State that you will conduct inventories, at intervals not to exceed 6 months, to account for all radioactive sources and devices received and possessed under the license. You should maintain records of the inventories for at least 2 years from the date of the inventory. Your inventory records should include: the radionuclide and amount (in units of curies) of radioactive material in each source; the manufacturer's name, model number, and serial number of each device containing radioactive material; the location of each source and device; and the date of the inventory.

12.5 Annual Audit of Radiation Protection Program

Section 2 of 902 KAR 100:019 requires licensees: (1) to develop, document, and implement a radiation program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the regulations; (2) to use procedures and engineering controls to achieve occupational doses and doses to members of the public that are ALARA; and (3) to review, at least annually, the content and implementation of their radiation programs. Section 30 of 902

KAR 100:019 requires licensees to maintain records of the provisions of their radiation protection program until the Cabinet terminates the license. Licensees must also maintain records of audits and other reviews of program content and implementation for 3 years after the record is made.

The RSO needs to ensure that annual audits are conducted, but does not necessarily need to do it himself/herself. In fact, if the RSO is one of the authorized users, it may be beneficial for a qualified individual (e.g., radiation safety consultant or the corporate radiation safety officer) who is not associated with day-to-day operations to conduct the audit.

The audit should be sufficiently detailed to ensure that (1) the licensee is abiding by Cabinet regulations and the terms and conditions of the license (e.g., periodic leak tests, inventories, etc.), (2) the licensee's radiation protection program content and implementation achieve occupational doses and doses to members of the public that are ALARA; and (3) the licensee maintains all appropriate records with all appropriate information (e.g., records of personnel exposure, leak tests, inventory, training of users) sufficient to comply with Cabinet requirements. Appendix C describes an audit program that is acceptable to the Cabinet.

(a) Submit (1) the name and radiation safety qualifications of the individual who will conduct audits; (2) a description of the scope and extent of the audits; (3) a commitment to conduct audits at intervals not to exceed 12 months and to maintain records of the audits for at least 3 years after the record is made; (4) management's commitment to review the documented results of the audit promptly after the audit's completion; and (5) a commitment to take prompt action to correct deficiencies identified during audits, to inform all personnel (including those at other locations and those working under other licenses) of the deficiencies and the actions management expects its personnel to take to avoid similar deficiencies.

(b) In lieu of describing the scope and extent of the audits, you may state, "We will conduct audits as described in Appendix C of "Guide for Preparation of Radioactive Material Applications for the use of Sealed Sources in Gas Chromatographs and X-ray Fluorescence Analyzers," Revised 8/96.

12.6 Records

(a) Records required to be maintained in accordance with 902 KAR 100 or license conditions are to be maintained at one (1) central location. Usually this is the address specified in Item 1 of the application. If records will be maintained at a different location, the location must be specified. If more than one use/storage location is authorized by the license, records or

copies of records from these other locations must be forwarded, at least quarterly, to the central location for review by the Cabinet.

Item 13 – Training and Experience of Users:

If you do not propose to perform any maintenance or repair on the "bench top" gas chromatograph or x-ray fluorescence analyzer, no specific training and experience in the use and handling of radioactive materials is necessary for individuals who will use it or supervise its use. No specific training or experience is needed to perform leak tests using a leak test kit or to clean detector cells used in gas chromatography devices provided the source or foil is not removed from the detector cell.

If you propose to perform any operations that involve removal of sources from the device or maintenance and repair of a device that involves the source, only an authorized user who has received appropriate training may perform these operations. Refer to Appendix A.

If you propose to use portable x-ray fluorescence devices, refer to Appendix B for additional training requirements.

Item 14 – Waste Disposal: The applicant should describe the disposal method for sources containing radioactive material when use of the devices containing the radioactive material is discontinued. If the supplier will remove the devices and sources from the applicant's facility for disposal, this should be so stated in the application (i.e., return to manufacturer). If a person or company other than the supplier will remove the devices and sources from the applicant's facility for return to the supplier or transfer to an authorized recipient, the number of the NRC or Agreement State license which authorizes removal and disposal of the applicant's sources and devices should be provided.

Item 15 – Certification: If you are an individual applicant acting in a private capacity, you are required to sign the form. Otherwise, your application should be dated and signed by a representative of the corporation or legal entity who is authorized to sign official documents and to certify that the application contains information that is true and correct to the best of your knowledge and belief. Unsigned applications will be returned for proper signature.

You should also submit the names of any additional individuals authorized to sign on behalf of the licensee. This permits these individuals to sign correspondence sent to this office requesting license amendment or for responses submitted in regards to Inspection Letters. These individuals should be officers of the company or others with administrative authority in regards to matters of radiation safety.

V. AMENDMENTS TO LICENSE

After you are issued a license, you must conduct your program in accordance with (1) the statements, representations, and procedures contained in your application; (2) the terms and conditions of the license; and (3) the Cabinet's regulations as specified in 902 KAR 100.

It is your obligation to keep your license current. You should anticipate the needs for a license amendment insofar as possible. If any of the information provided in your application is to be modified or changed, including a change in RSO or authorized users, submit an application for a license amendment. In the meantime, you must comply with the terms and conditions of your license until it is actually amended. Cabinet regulations do not allow you to implement changes on the basis of a submission requesting an amendment to your license.

An application for a license amendment may be prepared either on the application form or in letter form and should be submitted to the address specified in Section III of this guide. Your application should identify your license by number and should clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page, and paragraph. For example, if you wish to change the radiation safety officer specified in Item 6, your application for a license amendment should specify the new RSO's name, training, and experience. The qualification of the new RSO individual should be equivalent to those specified in Item 6 of this guide.

You must send the appropriate fee for license amendment with your application. The Cabinet will not accept an application for filing or processing before the proper fee is paid in accordance with 902 KAR 100:012.

VI. RENEWAL OF LICENSE

An application for renewal of a license should be filed at least 30 days prior to the expiration date.

Renewal applications may be filed by completing the form sent by the Cabinet or in letter form. The renewal application should be signed and dated by a representative of the licensee's administrative management and should include the Kentucky Radioactive Material License Number. You must send the appropriate fee for license renewal with your application.

VII. TERMINATION OF A LICENSE

If you do not wish to renew your license, you must dispose of all licensed radioactive material you possess in a manner authorized by 902 KAR 100:021. Submit Form RPS-10 "Disposition of Radioactive Material," (See Attachment 1) or a letter indicating the manner in which you disposed of the radioactive material and send to the Kentucky Radiation Control office before the expiration date of your license with a request that the license be terminated. Include your Kentucky Radioactive Material License Number in the request. There is not fee assessed for terminating a license.

If you cannot dispose of all the licensed radioactive material in your possession before the expiration date, you must submit a request for license renewal, along with the renewal fee, for storage only of the radioactive material. The renewal is necessary to avoid violating Kentucky Administrative Radiation Regulations that do not allow you to possess radioactive material without a valid license.

APPENDIX A

EXTENDED MAINTENANCE

If you propose to perform any operations that involve removal of sources from the device or maintenance and repair of a device that involves the source, certain additional requirements described in this appendix must be met. Only those maintenance and repair operations which the device manufacturer authorizes to be performed by the device user will be approved. If the manufacturer provides specific instructions for such operations, you should submit those instructions and commit to following them. Requirements for "bench top" and portable devices are addressed separately. Item number from related items in Section IV, "Contents of An Application" of the licensing guide are referenced in parentheses in this appendix.

I. Maintenance and Repair of "Bench Top" Gas Chromatographs and/or X-ray Fluorescence Analyzers

If you propose to perform maintenance or repairs other than collection of leak test samples using a leak test kit, or cleaning of detector cells used in gas chromatographs (without removing the source or foil from the detector cell), the following should be addressed in your application:

1. Type of Work To Be Performed
   Describe the specific operations you wish to perform.

2. Training and Experience
   Provide the name of each authorized user who will perform the operations. Provide an outline of the instruction and training each authorized user above has received in the principles and practices of radiation safety, the use of radiation detection instruments, and the operations that will be performed, including actual practice in performing the operations. The amount of time spent on each topic in the training should be specified. Provide the name and affiliation of the person who provided the instruction and training and this person's qualifications to conduct the operations. For authorized users with previous experience performing the requested operations, provide a summary of this experience (Items 5 & 13 of the licensing guide).

3. Handling Procedures
   Submit your procedures for safe handling of the radioactive source. Your procedures should include, but not necessarily be limited to descriptions of any special protective measures taken to limit exposure of individuals, constant surveillance and/or secure storage of the source when removed from the device, labeling the source container if stored outside the device, and limiting of access to the area where maintenance is being performed. Verify that the manufacturer's instructions and recommendations for performing extended maintenance will be followed. If the manufacturer

provides written instructions for the proposed procedures, submit a copy with your request.

4. Radiation Detection Instruments & Calibration
You must have a survey meter that can measure the radiation levels to which personnel would be subjected to during proposed operations. List the type and ranges of survey instruments you will have available, state the frequency of calibration, and who will perform the calibrations. State how you will ensure that the survey instrument is working properly. For example, you can state that a survey instrument capable of measuring radiation levels between 0.1 millirem and 100 millirems per hour will be used to perform surveys and will be calibrated annually by the manufacturer. Alternatively, you can identify by name, address and license number an organization that is specifically licensed by NRC or an Agreement State to calibrate survey instruments for other licensees. In addition, you can state that, before each use of the instrument, you will check the response of the instrument with a dedicated check source that was supplied with the instrument, and commit that, if the instrument does not respond properly, you will not perform extended maintenance until the survey instrument is repaired and operable or until you obtain an operable instrument (Items 8 & 9 of the licensing guide).

5. Surveys
Describe how you will ensure that radiation levels in areas where extended maintenance will take place do not exceed 902 KAR 100:019 limits. For example, you can (1) commit to performing surveys with a survey instrument; (2) specify where and when surveys will be conducted during extended maintenance; and (3) commit to maintaining for three (3) years from the date of the survey, records of the survey (e.g., who performed the survey, date of the survey, instrument used, measured radiation levels correlated to location of those measurements), as required by 902 KAR 100:019.

6. Personnel Monitoring
902 KAR 100:019, Section 13 requires that personnel monitoring equipment be used by individuals entering restricted areas who receive, or are likely to receive a dose in excess of the (10) percent of the occupational dose limits described in Section 3 of that regulation. Your application should state that personnel will be provided with either film badges or thermoluminescent dosimeters (TLD's) for use while performing servicing operations, and state the frequency of exchange for personnel monitoring devices (not to exceed one (1) month for film badges or three (3) months for TLD's). State the name of the name and address of the supplier (Item 10 of the licensing guide).

Badges are to be worn on the trunk of the body. When not in use, badges are to be stored away from sources of radiation.

II. Maintenance and Repair of Portable X-ray Fluorescence Analyzers

Depending on the manufacturer and model of the device, the manufacturer may authorize the device user: (1) to remove the source holder from the device and return for exchange; (2) to exchange the source following the manufacturer's written instructions; or (3) may require that all such operations be performed only by the manufacturer. For any operations involving removal of the source from the source holder, you must submit the information described in Section I of this appendix.

APPENDIX D

ADDITIONAL REQUIREMENTS FOR USE OF PORTABLE X-RAY FLUORESCENCE ANALYZERS

If you propose to use portable x-ray fluorescence analyzers, certain additional information must be submitted relative to transport, storage, and security at temporary job sites. In addition, possession and use of certain devices (primarily those containing more than approximately ten (10) millicuries of Cobalt-57) require documented training by the device manufacturer, and a commitment to utilize personnel monitoring devices. Strictly for the purpose of clarity in this appendix, devices with approximately ten (10) millicuries of Cobalt-57, which are normally transported as "Limited Quantity-Instrument or Article" packages under USDOT regulations, will be referred to as "Limited Quantity" devices, whereas those devices with higher activity sources requiring additional documented training, etc., which are normally required to be transported as "Type A" packages, will be referred to as "Type A" devices. These terms are not recognized designations for these devices, and are used only for convenience in this appendix. If you are uncertain about the requirements (i.e., personnel monitoring, training and transportation) for the particular device(s) for which you are requesting authorization, contact the device manufacturer or this office for clarification. Specific information you are required to submit is addressed below. Item numbers from related items in Section IV, "Contents of An Application" of the licensing guide are referenced in parentheses in this appendix.

I. Street address(es) Where Radioactive Material Will Be Used

If you will conduct operations at temporary job sites, you should specify you are requesting authorization to do so at "temporary job sites throughout the Commonwealth of Kentucky." (Item 2 of the licensing guide).

II. Individual Users

Each person who will use the device independently at temporary job sites should be named as an authorized user on the license. Although other individuals may operate "limited quantity" devices under the supervision of an authorized user, an authorized user should be on-site to provide supervision. Use of such a device at a temporary job site at which an authorized user is not present is not considered supervised use.

In order for another individual who is not named as an authorized user on the license to operate a "Type A" device, that person must be under the direct supervision and <u>in the physical presence</u> of an authorized user. (Item 5 of the licensing guide).

III. Radiation Safety Officer (RSO)

In addition to the duties (a) through (c) listed in the licensing guide, the following additional duties should be listed related to use of portable devices:

(a) All users, when required, wear personnel monitoring equipment, such as film badges or thermoluminescent dosimeters (TLD's) and reports of personnel exposure are reviewed in a timely manner.

(b) Devices are properly secured against unauthorized removal at all times when they are not in use.

(c) Serves as a point of contact and ensures that proper authorities are notified promptly in case of an accident or damage to the device(s), fire or theft.

(d) Radioactive material is transported in accordance with all applicable DOT requirements. (Item 6 of the licensing guide).

IV. Personnel Monitoring

902 KAR 100:019, Section 13 requires that personnel monitoring equipment be used by individuals entering restricted areas who receive, or are likely to receive a dose in exceed of the ten (10) percent of the occupational dose limits described in Section 3 of that regulation.

Personnel monitoring devices are not required for routine use of "limited quantity" portable x-ray fluorescence analyzers.

If, however, you will be using "Type A" portable x-ray fluorescence analyzers, your application should state that personnel will be provided with and required to wear either film badges or thermoluminescent dosimeters (TLD's), and state the frequency of exchange for personnel monitoring devices (not to exceed one (1) month for film badges or three (3) months for TLD's. State the name and address of the supplier. (Item 10 of the licensing guide).

V. Facilities and Equipment

The applicant should provide a description of the means of storage of devices at his address, location of use, etc. when devices are not in actual use by the individuals listed in the application. Kentucky Administrative Regulation 902 KAR 100:019, Sections 21 and 22 require that licensed material stored in an unrestricted area be secured from unauthorized removal from the place of storage and that licensed material in an unrestricted area and not in storage be under the constant surveillance and immediate control of the license. A simple sketch of the storage area(s) showing relationship to actively occupied areas should be submitted. You should state that the device will be stored in a locked enclosure such as a store room, closet, etc., in a way that will prevent access by unauthorized persons. Indicate who will have access to the storage areas. Confirm that the storage location does not include residential quarters.

If the device will be kept at a temporary job site overnight, a description should be submitted of the means of storage to prevent unauthorized access.

When not in storage, the device must be physically watched by an authorized user at all times. It is not acceptable for a device to be left unattended on a job site or

in an unlocked vehicle during lunch or breaks, because the device would then be accessible to unauthorized persons. (Item 11 of the licensing guide).

VI. Transportation of Devices to Field Locations.
Transportation activities must be carried out in accordance with the requirements of 902 KAR 100:070 and U.S. Department of Transportation (DOT) regulations. (Refer to Attachment 2).

1. Transportation of "Limited Quantity" devices (as the term is used in this appendix) is subject to the same regulations described under item 2. below for "Type A" packages, except for those specific exceptions and requirements described in 49 CFR 173.142-425. These devices, when transported in the manufacturer's transport case, are excepted from the specification packaging, marking, labeling and, if not a hazardous substance or hazardous waste, the shipping paper and certification requirements described for "Type A" packages. The package must be certified as being acceptable for transportation by having a notice enclosed in or on the package, included with the packing list, or otherwise forwarded with the package. This notice must include the name of the consignor or consignee and the following statement: "This package conforms to the conditions and limitations specified in 49 CFR 173.424 for radioactive material, excepted package-instruments or articles, UN 2910." The applicant is responsible for being familiar with and complying with DOT requirements for transportation.

2. Transportation of "Type A" devices (as the term is used in this appendix) must be carried out in accordance with 902 KAR 100:070 and all applicable DOT regulations. It is your responsibility to become familiar with these regulations to help ensure safe transportation of radioactive materials. The applicable DOT regulations are outlined in 902 KAR 100:070, "Transportation of licensed material."

   Safety measures to be used in transporting the device in the applicant's vehicle must be described. The device must be fully secured in the vehicle and away from the passenger area. The device must be transported in packaging that has been certified by the U.S. Department of Transportation. Shipping papers are required to be carried with the device during transportation over public highways. The shipping papers must be carried in the passenger area of the transport vehicle. Carrying shipping papers in any other manner, such as in the transport case, will result in a cited violation during inspection.

   You must submit procedures for complying with applicable DOT regulations.

   Attachment 2 provides additional background information on transportation, and a sample shipping paper. The major areas in the DOT

regulations that are most relevant for transportation of typical portable devices that are shipped as Type A quantities are listed below:

1. Table of Hazardous Materials and Special Provisions 49 CFR 172.101

    a. 49 CFR 172.101 – Hazardous Materials Table [proper shipping name, hazard class, identification number]
    b. Table 2, Appendix 2, 49 CFR 172.101 – List of Hazardous Substances and Reportable Quantities [for radionuclides]

2. Shipping Papers 49 CFR 172.200

    a. 49 CFR 172.201 – General entries [on shipping papers]
    b. 49 CFR 172.202 – Description of hazardous material on shipping papers
    c. 49 CFR 172.203 – Additional description requirements
    d. 49 CFR 172.204 – Shipper's certification [if applicable]

3. Package Markings 49 CFR 172.300

    a. 49 CFR 172.301 – General marking requirements for non-bulk packaging
    b. 49 CFR 172.304 – Marking requirements
    c. 49 CFR 172.310 – Radioactive material [Type A or Type B]
    d. 49 CFR 172.324 – Hazardous substances in non-bulk packaging [designation of "reportable quantities" with the letters "RQ"]

4. Package Labeling 49 CFR 172.400

    a. 49 CFR 172.400(a) – General labeling requirements
    b. 49 CFR 172.403 – Radioactive materials [types and contents of labels]
    c. 49 CFR 172.406 – Placement of labels

5. Placarding of Vehicles 49 CFR 172.500

    a. 49 CFR 172.504 – General placarding requirements
    b. 49 CFR 172-516 – Visibility and display of placards
    c. 49 CFR 172.556 – RADIOACTIVE placard

6. Emergency Response Information – Subpart G

    a. 49 CFR 172.600 – Applicability and general requirements

b. 49 CFR 172-602 – Emergency response information
c. 49 CFR 172.604 – Emergency response telephone number

7. Training – Subpart H

a. 49 CFR 172.702 – Applicability and responsibility for training and testing
b. 49 CFR 172.704 – Training requirements (includes types of training, when it must be conducted, need for refresher training every 2 years, recordkeeping)

8. Carriage by Public Highway 49 CFR 177

a. 49 CFR 177.817 – Shipping paper [location of shipping papers during transport]
b. 49 CFR 177.842 – Class 7 (radioactive) material [includes requirement for blocking and bracing during transport]

VII. Operating and Emergency Procedures

It is necessary to submit operating and emergency procedures to the Cabinet for review. In addition to information required by Item 12.3 of the licensing guide, you will need to:

a. Commit to providing a copy of your operating and emergency procedures to all users of the device before they begin using it.

b. Commit to having a copy of your operating and emergency procedures at each job site. Procedure should be carried in the cab of the transport vehicle by the driver, rather than in the transport case.

Emergency procedures should include steps for workers to take in case of accidents involving damage or loss of the devices. Accidents during transport, as well as accidents at temporary job sites should be addressed. Submit a copy of your operating and emergency procedures for review. (Item 12.3 of the licensing guide).

An example of acceptable operating and emergency procedures is included below:

<u>Operating Procedures</u>

1. Before removing the device from its place of storage, check to make sure that the source is in the shielded, locked position. Check the transport case to ensure required labels and markings are legible, and that the lock is operable. Lock the transport case.

2. Sign the device out in a log book, stating the dates of use, names of the authorized users who will be responsible for the device, and the temporary job sites where the device will be used.

3. Never leave the device unattended while in your custody.

4. Follow the applicable DOT requirements when transporting the gauge (block and brace the device in the rear of the transport vehicle, away from passengers; carry shipping papers (if applicable) and emergency procedures in the passenger compartment; etc.).

5. Do not expose your fingers, hands, or any part of your body to the radiation beam. Make sure the source is locked in the shielded position after each measurement is made.

6. Always wear your assigned film badge or thermoluminescent dosimeter (TLD) when using the device (if applicable). Never wear another person's film badge or TLD. Never store your film badge or TLD near the device.

7. Always keep unauthorized persons away from the area where the device is being used.

8. Always maintain constant surveillance and immediate control of the device when it is not locked in storage.

9. When the device is not in use at temporary job sites, place the device in a secured storage location (e.g., locked in the trunk of a car or locked in a storage shed).

10. Return the device to its proper storage location at the end of the work shift.

11. When the device is returned to storage, indicate so on the source log.

<u>Emergency Procedures</u>

If the source cannot be returned to the shielded condition (i.e., shutter will not close, for example, as a result of being damaged) or if any other emergency or unusual situation arises (e.g., the device is struck or otherwise damaged, dropped, or if the transport vehicle is involved in an accident which may involve damage to the device):

1. Immediately secure the area around the device.

2. Prevent unauthorized persons from entering the secured area. Note: Emergency rescue, lifesaving and first aid efforts should not be delayed or hampered.

3. If heavy equipment is involved (e.g., device run over by vehicle), detain the equipment until it is determined that there is no contamination present.

4. Notify licensee management of the situation, calling company personnel in the order listed below:

NAME*	WORK PHONE*	HOME PHONE*
_____	_____	_____
_____	_____	_____
_____	_____	_____

*Fill in with (and update as needed) the names and telephone numbers of the Radiation Safety Officer (RSO) or other knowledgeable licensee staff to be contacted.

5. Follow the directions provided by the person contacted in step 4.

6. Notify Radiation Control at (502) 564-3700 normal working hours or (502) 564-7815 other hours, if required.

7. Manufacturer's phone number _____, if needed.

VIII. Training and Experience of Users

Training requirements for users of portable x-ray fluorescence analyzers differ, depending on whether a "Limited Quantity" device or a "Type A" device (as defined in this appendix) is authorized on the license. (Item 13 of the licensing guide.)

1. Users of "Limited Quantity" devices should, as a minimum, read and be familiar with the manufacturer's radiation safety and operating instructions, and receive training in safe operations of the device from an experienced authorized user. Completion of a radiation safety course by the manufacturer, where feasible, is recommended. Your application should describe training to be given to individuals who will operate the device.

2. Users of "Type A" devices must complete a training course or program approved by an Agreement State or the NRC. A certificate verifying training for each individual to be named as an authorized user must be included with the application. Completion of the manufacturer's training course will satisfy this requirement.

APPENDIX C

SAMPLE AUDIT PROGRAM

An audit is conducted, in part, to fulfill the requirements of 902 KAR 100:019, Section 2 for an annual review of the content and implementation of the licensee's radiation protection program. It should also identify program weaknesses and allow licensees to take early corrective actions (before Cabinet inspection). During an audit, the auditor needs to keep in mind not only the requirements of the Cabinet regulations, but also the licensee's commitments in its applications and other correspondence with the Cabinet. The auditor should also evaluate whether the licensee is maintaining exposures to workers and the general public as low as is reasonably achievable (ALARA) and, if not, make suggestions for improvement.

The form in this Appendix can be used to document the annual audit of the radiation protection program. Guidance follows on completing each section of the form. Note any deficiencies that were identified and the corrective actions taken (or to be taken) in Section 15.

Section 1. Audit History. Enter the date of the last audit, whether any deficiencies were identified, and where actions were taken to correct the deficiencies.

Section 2. Organization and Scope of Program. Describe the scope of licensed activities at the audited location. Check whether the Radiation Safety Officer (RSO) is the person identified in the license and fulfills the duties specified in the license. Evaluate management involvement with the radiation safety program, whether the RSO has sufficient time to perform his/her duties and whether the licensee has sufficient staff to handle the workload and maintain compliance with regulatory requirements. Verify that only persons authorized by the license use/supervise use of devices, or perform servicing operations (if applicable).

Section 3. Training and Instructions to Workers. Ensure that workers have received the training required by 902 KAR 100:165, Section 3. Be sure that, before being permitted to use or supervise the use of a device, the authorized user has received training (as approved by the Cabinet) and has a copy of, and training in, the licensee's operating and emergency (O/E) procedures; records should be maintained. By interview and/or observation of selected workers, ensure that each has a copy of the licensee's O/E procedures and can implement them properly.

Section 4. Facilities. Verify that the licensee's facilities are as described in the license documents.

Section 5. Materials. Verify that the license authorizes the radioactive source-device combinations that the licensee possesses. Verify that the licensee uses the source-device combinations in accordance with license provisions. Ensure that devices are maintained in accordance with licensee commitments.

Section 6. Leak Tests. Verify that all radioactive sources are tested for leakage at the prescribed frequency and in accordance with licensee commitments. Records of results should be maintained.

Section 7. Inventories. Verify that inventories are conducted at least once every six (6) months to account for all sealed sources; inventory records should be maintained.

Section 8. Radiation Surveys. Verify that the licensee has at least one (1) operable, calibrated survey instrument, if required, and that the instruments are calibrated in accordance with licensee commitments. Calibration records must be retained for three (3) years after the record is made. Check the radiation levels in the vicinity of authorized maintenance operations and immediately outside areas used for device storage are within regulatory limits. Verify that installation surveys are conducted, and records maintained.

Section 9. Receipt and Transfer of Radioactive Material (Includes Disposal). Verify that devices received from other (e.g., new devices) are in accordance with 902 KAR 100:019, Section 28. Ensure that device transfers are performed in accordance with 902 KAR 100:040, Section 12. Record of receipt, and transfer must be maintained in accordance with 902 KAR 100:040, Section 14.

Section 10. Transportation (portable devices only). Determine compliance with Department of Transportation (DOT) requirements. Verify that radioactive packages are prepared, marked, and labeled in accordance with 49 CFR Parts 172 and 173 requirements. Be sure that the licensee has records of performance testing of its special form sources and DOT-7A packages. Verify that shipping papers are prepared, contain all needed information, and are readily accessible during transport of Type A packages (49 CFR 172.200-204 and 177.718). Check that packages are blocked and braced (49 CFR 177.842).

Section 11. Personnel Radiation Protection. If required by the license, verify personnel dosimetry complies with 902 KAR 100:019, Section 12 and licensee commitments. Review personnel monitoring records; compare exposures of individuals doing similar work; determine reasons for significant differences in exposures. If any worker declared her pregnancy in writing, evaluate the licensee's compliance with 902 KAR 100:019, Section 9 and 36.

Section 12. Notification and Reports. Check on the licensee's compliance with the notification and reporting requirements in 902 KAR 100:019, Sections 38-40 and 902 KAR 100:040, Section 18.

Section 13. Posting. Check for compliance with the posting requirements of 902 KAR 100:165, Section 2.

Section 14. Recordkeeping for Decommissioning. Check to determine compliance with 902 KAR 100:040, Section 15(7).

Section 15. Problems or Deficiencies Noted: Recommendations. This section is self-explanatory.

NOTES FOR AUDITS OF GCs AND X-RAY FLUORESCENCE DEVICES

Note: All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit.

Audit Report No. _____ License No. _____

Licensee's name and mailing address:

_____
_____
_____

Audit of activities at (Address):

_____
_____
_____
_____

Contact at Audit Location _____
Telephone No. _____

Date of Last Audit of this Location _____

Date of This Audit _____

Summary of Findings and Action:

( ) No deficiencies
( ) Deficiencies
( ) Action on previous deficiencies

Recommendations:

Auditor: _____ Date_____
(Signature)

1. AUDIT HISTORY

A. Last audit of this location conducted _____

B. Problems/deficiencies identified during last two audits or two years, whichever is longer ( )Y ( ) N

C. Any previous problem/deficiency repeated or not corrected ( )Y ( ) N

Explain:

2. ORGANIZATION AND SCOPE OF PROGRAM

A. Senior licensee management appropriately involved with radiation safety program and/or RSO oversight ( )Y ( ) N

B. Radiation Safety Officer
(1) Authorized on license ( )Y ( ) N
(2) Fulfills duties as RSO (Appendix A of guide) ( )Y ( ) N

C. Use or supervision of use only by authorized individuals ( )Y ( ) N

3. TRAINING AND INSTRUCTIONS TO WORKERS

A. Instructions to workers (902 KAR 100:165, Section 3) ( )Y ( ) N

B. Authorized user training program – Before using gauge:
(1) User received training as described in license application ( )Y ( ) N

4. FACILITIES – as described in license application ( )Y ( ) N

5. MATERIALS

A. Isotopes, quantities, mfg's name and model no. of sources and devices; use as authorized on license ( )Y ( ) N

B. Extended maintenance (if applicable) ( )Y ( ) N
(1) Work requiring source in unshielded position by licensee in accordance with licensed procedures ( )Y ( ) N

6. LEAK TESTS (902 KAR 100:060 and license condition)

A. Leak tests performed as authorized by license (consultants, leak test kit, person performing) ( )Y ( ) N

B. Every 6 months or as authorized by license ( )Y ( ) N

C. Records with appropriate information maintained ( )Y ( ) N

7. INVENTORIES

A. Conducted at 6-month intervals ( )Y ( ) N

B. Records with appropriate information maintained ( )Y ( ) N

8. RADIATION SURVEYS (if applicable)

A. Calibrated and operable survey meter available, if required by license for extended maintenance ( )Y ( ) N

B. Surveys conducted during maintenance operations ( )Y ( ) N

C. Records maintained ( )Y ( ) N

9. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL (Includes Disposal)

A. Describe how new devices are received and by whom:

B. Transfer(s) between licensees (including disposal ( )Y ( ) N

C. Records of receipt/transfer maintained (902 KAR 100:040, Section 14) ( )Y ( ) N

10. TRANSPORTATION (portable device users only) (902 KAR 100:070 and 49 CFR 170-189)

A. Licensee shipments are:

(1) Delivered to common carrier ( )Y ( ) N
(2) Transported in licensee's private vehicle ( )Y ( ) N
(3) Both ( )Y ( ) N
(4) No shipments since last audit ( )Y ( ) N

B. Packages

(1) Authorized packages used ( )Y ( ) N
(2) Performance test records on file (Type A packages) ( )Y ( ) N
a. Special Form sources ( )Y ( ) N
b. DOT-7A packages ( )Y ( ) N
(3) Labels and markings as required, maintained in legible condition ( )Y ( ) N
(4) Closed and sealed during transport ( )Y ( ) N

C. Shipping Papers (Type A packages)

(1) Prepared and used ( )Y ( ) N
(2) Appropriate information included ( )Y ( ) N
(3) Readily accessible during transport along with emergency procedures ( )Y ( ) N

D. Vehicles

(1) Cargo blocked and braced ( )Y ( ) N

11. PERSONNEL RADIATION PROTECTION (if required)

A. ALARA incorporated into Radiation Protection Program (902 KAR 100:019, Section 2) ( )Y ( ) N

B. If required by license, external dosimetry provided and used ( )Y ( ) N
(1) Supplier _____ Frequency_____
(2) Supplier NVLAP-approved ( )Y ( ) N
(3) Dosimeters exchanged at required frequency ( )Y ( ) N

C. Reports
(1) Reviewed by _____ Frequency _____
(2) Auditor reviewed records for period _____ to _____
(3) Prior dose determined for new employees ( )Y ( ) N
(4) Maximum exposures _____
(5) Worker declared her pregnancy in writing during audit period (review records) ( )Y ( ) N
If yes, determine compliance with 902 KAR 100:019, Sections 9 and 34
(6) All records maintained of exposures, surveys, etc. ( )Y ( ) N

12. NOTIFICATION AND REPORTS (902 KAR 100:019, Sections 38-40; 902 KAR 100:040, Section 18)
A. License in compliance with notification/reports for:
(1) Theft or loss ( )Y ( ) N
(2) Incidents ( )Y ( ) N
(3) Overexposures, high radiation levels ( )Y ( ) N

13. POSTING (902 KAR 100:165, Section 2)
A. Notice to Employees ( )Y ( ) N
B. Regulations or appropriate notice ( )Y ( ) N
C. License or appropriate notice ( )Y ( ) N
D. Operating/emergency procedures ( )Y ( ) N

14. RECORDKEEPING FOR DECOMMISSIONING (if required) ( )Y ( ) N
(902 KAR 100:040, Section 15)

15. PROBLEMS OR DEFICIENCIES NOTED; RECOMMENDATIONS
Note: Briefly state (1) the requirements and (2) how and when violated. Provide recommendations for improvement.

Additional Remarks:

APPENDIX D
FINANCIAL ASSURANCE AND RECORDKEEPING FOR DECOMMISSIONING

Kentucky Administrative Regulation 902 KAR 100:040, Section 15 provides requirements for all licensees who must maintain records important to decommissioning and for certain licensees who must provide financial assurance for decommissioning.

Financial Assurance

The requirements for financial assurance are keyed to the types and quantities of radioactive material authorized on a license. Only a few sealed source licensees need to comply with the financial assurance provisions. In general, these licensees are large, nationwide companies that possess a very large number of devices under the terms of a single license. Most licenses do not specify the maximum number of devices that the licensee may possess (in order to allow the licensee flexibility in obtaining devices as needed without amending its license). As a result, these licenses contain a condition requiring the licensee to limit its possession of devices to quantities not requiring financial assurance for decommissioning.

Applicants for specific licenses authorizing possession and use of certain types an quantities of radioactive material must submit either a decommissioning funding plan or a certification that financial assurance for decommissioning has been provided in accordance with the requirements of 902 KAR 100:040, Section 15.

Typically, a gas chromatograph contains millicurie amounts of Nickel 63 or Hydrogen 3 in the form of sealed sources, while portable x-ray fluorescence analyzers contain millicurie amounts of Cobalt 57 or other radioactive materials. For sealed sources, 902 KAR 100:040, Section 15(4)(c) establishes a threshold of 10^{10} times the applicable quantities in 902 KAR 100:030, Section 1 and specifies the use of the "sum of the ratios" method to determine the thresholds if the applicant requests more than one radionuclide.

If a commitment to restrict the possession of radioactive material to quantities below the minimum level specified in 902 KAR 100:040, Section 15(4)(c) for establishing financial assurance for decommissioning is not provided, you must submit one of the following:

(1) certification that financial assurance for decommissioning has been provided in the amount of $75,000, or

(2) a decommissioning funding plan that contains a cost estimate for decommissioning
(generally to justify a cost less than $75,000) plus a certification that financial assurance has been provided in the amount equal to the cost estimate.

Recordkeeping Requirements

Licensees are required by 902 KAR 100:040, Section 15(7) to maintain records important for decommissioning. These records must include information related to spills, leaking sources, or other unusual incidents that involve the spread of contamination. The records must be maintained in the location identified in Item 12.10 until the license is terminated. If a licensee has not had events involving spills, leaking sources, or spread of contamination, there are no such records to maintain for decommissioning.

RPS-10
(1/04)

DISPOSITION OF RADIOACTIVE MATERIAL

Radiation Health & Toxic Agents Branch
Department for Health and Family Services
275 East Main Street
Mailstop HS1CA
Frankfort, KY 40621

1. Licensee Name _____

2. Address _____

_____

_____

3. Radioactive Material _____ 4. Expiration Date _____
License Number

5. Radioactive Material Disposition (Check Only One.)

❍ A. No radioactive material has been procured and/or processed by the licensee under this license.

❍ B. All radioactive material procured and/or possessed by the licensee has been transferred to the following licensee/supplier:

Name _____

Address _____

License Number _____

Date Transferred _____

❍ C. Radioactive material has been disposed of in the following manner. (Describe specific disposal procedures. Use reverse side of form if necessary.)

6. If unsealed sources or a leaking sealed source of radioactive material had been used, submit a copy of a radiation survey conducted to determine whether any contamination remains at location(s) authorized by license.

❍ Survey not required. (Explain.)

❍ Survey report attached.

7. This license is to be terminated. ❍ Yes ❍ No (If no, explain.)

8. Form must be signed and dated by person authorized to act on behalf of licensee.

_____ _____
Signature Date

_____
Typed/Printed Name and Title

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 40555

May 24, 1990

NRC INFORMATION NOTICE NO. 90-35: TRANSPORTATION OF TYPE A QUANTITIES OF NON-FISSILE RADIOACTIVE MATERIALS

Addressees: All U.S. Nuclear Regulatory Commission (NRC) Licensees.

Purpose:

This notice is provided to summarize and clarify the basic requirements of the U.S. Department of Transportation (DOT) Hazardous Materials Regulations (HMR) that are most frequently cited as deficiencies or violations during inspections of transportation activities of NRC licensees. Such deficiencies are most commonly noted during inspections of byproduct materials licensees, particularly when such licensees are first-time users of the regulations or those who package and deliver such packages to carriers only occasionally. However, the information here should be useful to any type of licensee who prepares and delivers radioactive material packages to carriers or transports packages in his own vehicle as a private carrier.

It is expected that addressees will review the information here for applicability to their licensed activities and consider actions, as appropriate, to avoid problems in transport of such materials. However, suggestions contained in this notice do not constitute any new requirements, and no written response is required.

Background:

In 1979, NRC incorporated into its own regulations (10 CFR Part 71) the DOT regulations contained in 49 CFR Parts 170 to 178. (See 10 CFR 71.5.)

This notice is an update of NRC IE Information Notice No. 82-47 (Ref. 1), bearing the same title, issued November 30, 1982, and a series of three articles which appeared in NRC NMSS Licensee Newsletter, during 1989. (Regs, 2, 3, 4.)

Discussion:

Special Form vs. Normal Form Determination

For transportation purposes, radioactive materials are classified either as “special form” or “normal form,” as defined in 49 CFR 173.403(s) and (z). Radioactive materials classified as “special form,” such as sealed sources, may be transported with fewer restrictions than other materials with equal radioactivity. However, sealed sources must meet the physical integrity requirements defined in 49 CFR 173.469. All other

radioactive materials are considered "normal form." For a particular shipping package specification, the activity limits for special form material usually are greater than those for normal form materials (49 CFR 173.435). That is, if the material is in special form, a greater quantity of material usually is permitted in the package.

Any licensee who ships or transports special form material, and declares it as such on shipping papers and package marking, must maintain documentation containing the results of the testing performed on the material or source, to demonstrate that it meets the special form requirements [49 CFR 173.476(a)]. This does not mean that each shipper or transporter must perform the tests, but that each must obtain and retain the test documentation. Each licensee should establish a file of such data for each special form design in its possession. It is usually necessary for the licensee to obtain this information from the source or device manufacturer.

Type A vs. Type B Package Determination

Normal form materials in quantities no greater than applicable A_2 limits (curies), specified in 49 CFR 173.435, may be shipped in a package called a "Type A" package (i.e., one which is expected to maintain its integrity only during normal conditions of transport). Similarly, a special form materials may be shipped in larger quantities up to the A_1 limit, in a Type A package. Shipment of materials in a single package in excess of these limits requires the use of the higher quality "Type B" package. (i.e., one which is expected to maintain its integrity during both normal and sever accident conditions of transport).

Examples of A_1 and A_2 limits (in curies) from 49 CFR 173.435 are as follows:

Radionuclide	A_1 (special form)	A_2 (normal form)
Am-141 (in AmBe sources)	20	0.008
Co-60	7	7
Cs-137	30	10
Ir-192	20	10
Mo-99	100	20

In some instances, qualification of the material as "special form" will have no bearing on the type of packaging required, relative to the activity of the material shipped. For example, in the case of shipment of less than seven curies of Co-60, Type A (rather than Type B) packaging may be used regardless of form (normal or special), because the Type A package limit prescribed in 49 CFR 173.435 is seven curies for both special form (the A_1 limit) and normal form (the A_2 limit). This contrasts with Cs-137, where any quantity exceeding 10 curies (the A_2 limit) in normal form requires Type B packaging, and as much as 30 curies (the A_1 limit in special form) are allowed in Type A packaging.

In any situation where the material is described on shipping papers and package marking as "Radioactive material, special form, n.o.s." (n.o.s. means "not otherwise specified"), the shipper is required to maintain the special form documentation prescribed by 49 CFR 173.476(a). To avoid this requirement, the shipper may elect to describe the material as "Radioactive material, n.o.s." However, this description may only be used if the special form material in the Type A package does not exceed the normal form limit (the A_2 limit).

DOT Specification 7A, Type a Packages

As indicated previously, normal form materials can be shipped in a "Type A" package, as long as the contained quantity does not exceed the A_2 limits (in curies) specified in 49 CFR 173.435. Similarly, special form materials that do not exceed the A_1 limits (which, for certain materials, may be higher than the A_2 limits) also may be shipped in a Type A package.

The usual Type A package specification is referred to as "DOT Specification 7A" in 49 CFR 173.415(a). This is a pure "performance" specification and is not based on any specific and detailed design specifications. For Specification 7A, DOT regulations require that each shipper of a Specification 7A package must maintain on file written documentation attesting to the results of the Specification 7A performance tests performed on the package design. Remember that a "shipper" also includes any NRC licensee transporting licensed material in his own vehicle, (i.e., a "shipper" acting as a "private carrier").

If the shipper of a Specification 7A package is not the original designer or user of that package, it is necessary for that shipper to obtain the test result data from the original supplier. Alternately, the shipper may perform the tests and document the results. The tests are described in 49 CFR 173.465-466. Type A packages also must meet the design requirements described in 49 CFR 173.411-412.

If a shipper makes any changes, to the packaging or its maximum authorized contents, from those described on the original test report furnished by another person, the shipper must perform and document a supplemental evaluation, addressing such changes, demonstrating that the package will continue to meet the appropriate performance requirements.

(Reference 5, a U.S. Department of Energy (DOE) evaluation document for Type A packaging, is a useful document which may be of value to shippers in the preparation of their DOT Specification 7A documentations.)

Labeling (Labels are for packages.)

Each package must be labeled with one of the three "RADIOACTIVE" labels described in 49 CFR 172.403. The three labels are referred to as RADIOACTIVE WHITE-I, RADIOACTIVE YELLOW-II, and RADIOACTIVE YELLOW-III. RADIOACTIVE WHITE-I is the lowest category label and RADIOACTIVE YELLOW-III is the highest. Labels must be affixed on each of two opposite sides of the package (49 CFR 172.406)

and must measure 4 inches on each side (49 CFR 172.407). DOT regulations display the formats of these labels in 49 CFR 172.436-440.

All labels include spaces for marking (1) the contents (the name of the radionuclide) and (2) the activity (in curies, millicuries, or microcuries). The YELLOW labels also include spaces for marking the Transport Index (TI). The TI is a number expressing the maximum radiation level in millirem per hour at 1 meter (3.3 feet) from the external surface of the package.

The appropriate label is selected based on the measured radiation levels anywhere on the external surface of the package and based on the package TI. A WHITE-I label may be used if the radiation level at any point on the surface of the package does not exceed 0.5 mrem/hr. A YELLOW-II label indicates that the surface rate does not exceed 50 mrem/hr and the TI does not exceed 1. Higher radiation levels require use of the YELLOW-III label. Pursuant to 49 CFR 173.441, package radiation levels are limited to 200 mrem/hr at the surface and 10 mrem/hr at 1 meter (i.e., a TI of 10).

Placarding (Placards are for vehicles.)

The outside of the transport vehicle must be placarded by the carrier on the front, rear, and each side with the RADIOACTIVE placard (identified in 49 CFR 172.556) only if any package in the vehicle bears the RADIOACTIVE YELLOW-III label. The licensee (shipper) is required to furnish the placards to a common or contract carrier at the time the packages are delivered to, (i.e., picked up by) that carrier. In the case of a licensee acting as a shipper/private carrier, obviously, the licensee must apply the placards. Vehicles are not required to be placarded when the shipment includes only WHITE-I or YELLOW-II packages. [Note: In the case of exclusive-use shipments of low specific activity (LSA) materials, the shipper must placard the vehicle, even though such LSA packages are exempted from labeling.]

DOT placard requirements should not be confused with the posting requirements of 10 CFR 20.203. Any temporary storage on a loading dock or transport vehicle at a licensee's facility must also comply with the applicable requirements of 10 CFR Part 20, as well as with other appropriate NRC regulations.

Labels and placards should be procured commercially. They are not obtainable from NRC.

Package Marking

The outside of each package must be marked with the following:

1. Applicable DOT Proper Shipping Name (see 49 CFR 172.101 List of Hazardous Materials); and "RQ," if a "reportable quantity" is present (see 49 CFR 172.101, Appendix Table 2, for radionuclide reportable quantities);

2. Identification Number (49 CFR 172.101);

3. Applicable DOT Specification, (e.g., "DOT-7A," "Type A");

4. Gross Weight [for packages in excess of 110 lbs (50 kilograms)];

5. The Marking "USA," if the package is destined for export;

6. The name and address of the consignee or consignor. (Both are recommended.)

Shipping Papers

A shipping paper is required for each transport of radioactive material from the confines of the licensee's facility, whether transported by the licensee in his own vehicles or delivered to a common carrier for transport. A properly certified shipping paper is an indicator of compliance with DOT regulations and is of prime importance to authorities in case of an accident, loss, or theft. It must include the information required by 49 CFR 172.202-203, including the following:

1. The applicable DOT proper shipping name from 49 CFR 172.101. (For sources that are shipped as special form, this will always be "Radioactive material, special form, n.o.s." For normal form materials, the shipping name will generally be "Radioactive material, n.o.s.")

2. The applicable Identification Number from 49 CFR 172.101. (For materials shipped as "Radioactive material special form, n.o.s.," this number is UN2974. For materials shipped as "Radioactive material, n.o.s.," this number is UN2982.)

3. For a radionuclide as a "hazardous substance" in a quantity exceeding the applicable "reportable quantity," the entry "RQ" shall immediately precede or follow the entries in 1 and 2, above.

4. The name of each radionuclide. (For example, "Co-60.")

5. A description of the physical and chemical form of the material. (For special form sources, this description is "SPECIAL FORM.")

6. The activity contained in each package, measured in curie units.

7. The category of label applied to each package ("RADIOACTIVE WHITE-I," "RADIOACTIVE YELLOW-II," OR "RADIOACTIVE YELLOW-III").

8. The transport index (radiation level at 1 meter) assigned to each package bearing YELLOW-II or YELLOW-III labels. (For packages destined for carriage on passenger-carrying aircraft, the maximum TI is 3 rather than 10.)

9. For shipments tendered to a common carrier, the appropriate signed shipper's certification (49 CFR 172.204). For shipments by aircraft, the additional statement as to acceptability for either passenger-carrying or cargo-only aircraft.

For shipments by passenger-carrying aircraft, the additional statement of intended use in research, medical diagnosis, or treatment must also be included.

10. An emergency response telephone number, for use in the event of an emergency involving the package.

When licensees transport sealed source packages in their own vehicles repetitively, a reusable type of shipping paper documentation may be used that is specific to each particular package configuration. Such documentation can take the form of laminated cards retained in the cab of the vehicle, thereby eliminating the need for preparing a new shipping paper document every time a shipment is made.

Shipping papers must be maintained in the vehicle, within the immediate reach of the driver restrained by the lap belt. Ordinarily, a glove compartment does not meet this requirement. [49 CFR 177.817(e) provides detailed information on accessibility of shipping papers within vehicles.]

Blocking, Bracing, and Securing of Packages

Licensees who transport packages in their own vehicles must provide for adequate blocking, bracing, or tie-down of the packages to prevent shifting or movement during normal transport. Licensees also are required to provide security measures adequate to prevent the unauthorized removal of materials from the place of storage during transport, pursuant to 10 CFR 20.207. This may involve locking the packages within an external, permanently-attached compartment of the vehicle, or within the cargo compartment, itself. In either case, it is necessary to remove the keys from the vehicle. (See Reference 6, Information Notice No. 87-31, for further information on blocking, bracing and securing of packages during transport.)

A Caution – Obtain a Copy of the Regulations !

This notice is for information and guidance. Reference 7, a review of DOT regulations on radioactive material transport, may also be useful to readers of this notice. Neither source should be considered as a substitute for the actual copy of the regulations. All licensees who package or transport radioactive packages are urged to avail themselves of up-to-date copies of the applicable NRC and DOT regulations. Copies of these regulations (i.e., Title 49 of the Code of Federal Regulations) can be obtained from Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402-9371, (202) 783-3238.

Future Regulatory Revision

This notice is based on the DOT and NRC regulations in effect at the time of issuance of this notice. Readers are advised that both NRC and DOT are currently in the midst of rulemaking actions to effect revisions to the regulations of the U.S. so as to incorporate the latest standards of the International Atomic Energy Agency in the 1985 edition (as supplemented) of its Safety Series No. 6, "Regulations for the Safe Transport of Radioactive Materials." (Ref. 8) The Notices of Proposed Rulemaking by each agency

are listed in References 9 and 10. It is estimated that final action on the regulatory requirements will be taken in late 1990 or early 1991.

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Attachments:
1. References
2. List of Recently Issued NMSS Information Notices
3. List of Recently Issued NRC Information Notices