Frequently Asked Questions (FAQs) Regarding Radium-226 Overview

The questions and responses which follow have been developed by the staff of the U.S. Nuclear Regulatory Commission (NRC) to increase the knowledge and awareness by members of the public who may possess certain sources of radium-226 or may be considering such possession in the future. The FAQs are based primarily on recent additions to NRC regulations. Because Agreement States, in many cases, have a long regulatory history with radium-226 using regulations which may differ somewhat in content from those of the NRC, and changes to the Agreement State regulations may be needed as a matter of compatibility, no attempt has been made herein to cite these differences. Occasional reference is made herein to Agreement State programs for convenience only, i.e., it is not meant to represent a complete discussion of such programs. For information specific to your situation, please contact the appropriate NRC region (http://www.nrc.gov/about-nrc/locations.html) or Agreement State office (http://nrc-stp.ornl.gov/). For convenience and ease of use, the FAQs have been divided into the following six categories:

- A. Background and History
- B. Source Manufacturing
- C. Overview of Licensing Requirements
- D. Radium Disposal
- E. Regulation of Timepieces
- F. Regulation of Gauges, Dials and Other Items Containing Radium

A. Background and History

A.1 What is radium-226 (Ra-226)?

Ra-226 is a radioactive substance found in nature. Pierre and Marie Curie discovered radium in 1898 while conducting research with uranium ore. Ra-226 is produced by the radioactive decay of uranium-238. Radioactive decay occurs because certain atoms are unstable and need to release energy in an attempt to become stable. When Ra-226 decays, it releases energy in the form of particles and rays. This energy, called "radiation," cannot be detected by our senses. Special instrumentation is needed to perform this detection task. The intensity of radiation from radioactive materials decreases over time. The time required for the intensity to decrease by one-half is referred to as the "half-life" a. [as noted in the footer, the reader is prompted by a symbol (a) for a reference to the definition of certain technical terms.] The half-life of Ra-226 is 1600 years.

A.2 How is Ra-226 commonly used?

Ra-226 has been used in numerous applications following its discovery over 100 years ago. At the beginning of the 20th Century, radium was a popular additive in consumer products such as toothpaste, hair creams, and even food items due to its supposed beneficial health properties. Such products soon fell out of vogue, and were prohibited by authorities in many countries because of the potential health effects. Ra-226 was used until the late 1960s/early 1970s in self-luminous paints for watches, aircraft switches, clocks, and instrument dials. Because of its gamma emission properties, Ra-226 was also used in various industrial applications such as radiation monitoring instrument calibration facilities, industrial radiography cameras, oil well logging instrumentation, and many others.

Ra-226 was used in numerous medical applications during the 20th Century as well. It was used in sealed and unsealed sources for cancer therapy applications. Ra-226 was fashioned into various sizes and types of sealed sources, many of which were called "needles" because of their shape. Radium needles and other forms were implanted into cancerous tumors to arrest the cancerous growth. In unsealed form, Ra-226 has been used as a source of radon-222 for inhalation therapy.

Most uses of Ra-226 have been replaced by other radioactive materials or radiationgenerating devices which are more efficient or effective.

A.3 I've heard about discrete sources of radium. What does this mean?

The NRC definition of "discrete" source is "a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities." Until the Energy Policy Act of 2005 (EPAct), "discrete" source had never been defined in the NRC's regulations. However, the language of the EPAct required that the NRC work with appropriate Federal agencies to establish a definition for discrete sources and the means by which to regulate them. As a result of an interagency meeting and in response to public comment on the proposed rule language, "discrete" source was defined, as noted above.

A.4 Why is the NRC now regulating Ra-226?

The Energy Policy Act amended the Atomic Energy Act (the principal source of NRC's regulatory authority) to add discrete sources of Ra-226 to the existing definition of "byproduct material," thereby giving NRC the authority to regulate such sources.

A.5 Why is it important to regulate Ra-226?

To promote consistency in the manner in which certain radioactive materials were regulated by its Member States (including the U.S.), the International Atomic Energy Agency (IAEA) initiated the development of a document which would serve as the international framework for the safe and secure management and control of sources. This effort was begun in 1998. Following the 9/11/2001 terrorist events, the security aspect of the source management and control effort was increased. As a result of this effort, the "Code of Conduct for the Safety and Security of Radioactive Sources," was published in final form by the IAEA in January 2004. The United States has provided a commitment to implement the provisions of the Code of Conduct via letter from the Department of State to the IAEA. The IAEA Code of Conduct contains a list of 16 radionuclides which are considered to be dangerous when present above certain quantity thresholds and which could be used for malevolent purposes. This list includes Ra-226 (the 15 other radionuclides on the list were already regulated by the NRC). For these reasons, Ra-226 should be regulated consistently throughout the United States. Although many States in the U.S. had previously regulated Ra-226, the NRC lacked comprehensive authority to regulate radium and provide leadership in this area until the EPAct was signed into law in August of 2005.

A.6 I've heard that there are security concerns about radium sources; how is the international community responding to these concerns?

As discussed in Question A.5, the IAEA Code of Conduct contains a list of 16 radionuclides which are considered to be dangerous when present above certain quantity thresholds and which could be used for malevolent purposes. Malevolent uses considered by the IAEA include incorporation of sources in a Radiological Dispersal Device (RDD, or "dirty bomb") or in a Radiological Exposure Device (RED). In an RDD, radioactive material is spread over a land area or within a building by an explosive device in an attempt to expose individuals to harmful levels of radiation. In the case of an RED, an unshielded source is placed in a public area and unsuspecting individuals are exposed to its intense radiation. Dangerous sources require special management and security measures and controls to ensure that they are not used for such malevolent purposes. The IAEA's Member States are implementing such measures and controls pursuant to the Code of Conduct.

In the U.S., Ra-226 sources having a radioactivity content equal to or exceeding 37,000 megabecquerels (equivalent to 1.0 Curie**n**) are subject to these special IAEA Code of Conduct measures/controls which, in addition to the new licensing requirements, are applicable to all radium sources.

Based on these concerns, the NRC, in consultation with other Federal agencies, the Organization of Agreement States (OAS) and Conference of Radiation Control Program Directors (CRCPD), and other stakeholders, developed a regulatory framework for discrete sources of Ra-226.

B. Source Manufacturing

B.1 I've heard that Ra-226 was discovered over 100 years ago and that in the early part of the 20th Century, it was used in a number of consumer products. What types of products were produced and are they currently available?

As noted in the response to FAQ A.2, radium was initially thought to be an elixir, and was added to a number of consumer products and even certain foods. Although these practices waned, there were other non-food products introduced such as radium emanator jars, revigators (radium clay urns), radium water jars, radon generators, radium salt baths and healing pads. These products are no longer manufactured; however, some of them remain of interest as collectors' items or for other purposes. Not all of the items advertised at the time as containing radium actually contained processed radium; rather, refined uranium or unprocessed uranium ore (from which radium originates) was incorporated in them, thereby resulting in a very small quantity of radium actually present. Those items which contain processed radium are now subject to the general license requirements of the NRC's regulations or comparable Agreement State regulations.

B.2 Are Ra-226 sources currently being manufactured, or is the concern regarding their safe and secure management based on those manufactured several decades in the past?

Ra-226 has generally been replaced by other radioactive materials. Although a limited number of sealed source and device authorizations are still active, we have no

information that suggests these authorizations are being used to manufacture Ra-226 sources. Thus, the focus of the regulatory management effort is on sources that were manufactured in the past and the degree to which they are being safely and securely managed at this time.

C. Overview of Licensing Requirements

C.1 I possess several sealed sources of Ra-226. Now that this material is becoming more consistently regulated, what are my responsibilities for these sources?

The actions you need to take depend on the particular sources you possess. Ra-226 sources and the materials or devices containing them are either generally licensed or specifically licensed unless an exemption has been provided by the NRC or an Agreement State. If you need more information to determine the licensing status of your sources or determine if they may be exempt from regulation, please contact your regulatory agency. More information about license types is found in FAQ C.2-C.4.

C.2 What is a general license?

A general license is an authorization from an Agreement State or the NRC to possess limited quantities of radioactive material under certain conditions. An application does not need to be filed with the regulatory agency, nor is a document issued for a general license. General licensing is described in the NRC's regulations at 10 CFR 30.31(b) and the comparable Agreement State regulations.

Certain products containing radium subject to general licensing are identified in 10 CFR 31.12 and include antiquities (items originally intended for public use such as radium emanator jars, radium salt baths, and revigators (radium clay urns) which were originally made available in the late 19th and early 20th centuries), certain luminous products (timepieces and dials/gauges), and small sources used for instrument calibration, static elimination, and as lightning arrestors.

C.3 What is a specific license?

When an individual proposes to possess more radioactive material than is allowed by a general license (e.g., more than 100 of certain luminous items) or proposes to undertake activities beyond the scope of a general license, a specific license is required. Specific licenses require an application to be filed with either an Agreement State or an NRC Regional Office (depending on where the individual will be licensed to possess the material), and after review, a license may be issued. The license holder is subject to an inspection process, and, as noted in the response to <u>FAQ C.9</u>, fees may also be assessed. Requirements for the content of an application to the NRC for a specific license are found in <u>10 CFR 30.32</u>.

C.4 Are certain Ra-226 sources exempt from licensing?

Yes. There are currently two categories of sources exempt from licensing under NRC regulations. The first of these, contained in 10 CFR 30.15(a)(1)(viii), relates to intact timepieces containing a quantity up to 0.037 megabecquerel (1 μCi) of Ra-226 per timepiece which were manufactured prior to November 30, 2007. Such timepieces are

exempt from regulatory requirements, i.e., no license (either general or specific) is required to possess them.

The second category, contained in 10 CFR 30.20, relates to radium-containing smoke alarms and includes gas and aerosol detectors manufactured or distributed before November 30, 2007 in accordance with a specific license issued by a State under comparable provisions to 10 CFR 32.26 authorizing distribution to persons exempt from regulatory requirements. The NRC has no plans at this time to add an exempt concentration or exempt quantity of radium-226 to its regulations.

C.5 How is the military affected by the new requirements of the EPAct?

In the Statement of Considerations for the rulemaking "Requirements for Expanded Definition of Byproduct Material" (the NARM rule, *Federal Register citation* 72 FR 55864), the Commission determined that certain discrete sources of radium-226 under control of the military do not constitute "commercial use" under the EPAct, and are, therefore, outside the Commission's jurisdiction. This determination recognizes a difference between military operational and commercial uses of these sources and devices.

The term "military operational use" includes what is traditionally understood as the military's primary mission for national defense, including warfare, combat, and battlefield missions, and training for battlefield missions. Radium used, or available for use, for these purposes would not be subject to the requirements of the EPAct or the NARM rule. If the material is intended for use in military operations, it is not subject to the requirements of the NARM rule, notwithstanding the fact that it was originally produced by a commercial supplier. In addition, "military operational" material includes material still under the control of the military; i.e., in storage, or material that may be subject to decontamination and disposal. Other military possession and use of Ra-226, including medical or research activities conducted by the Department of Defense, or use in a manner similar to a commercial activity; e.g., military museums, are subject to NRC's regulatory authority.

C.6 I had previously used radium needles in my medical practice for cancer therapy, but switched to other radiation sources many years ago. The needles have been in storage since that time. Do these sources now require licensing?

Based on the general description of the sources you possess, they may need to be specifically licensed by your regulatory agency that may elect to perform an inspection of the sources and the facility where the material had been stored. If you have no desire to apply for a license to keep the sources, the regulatory authority can provide information and support relative to the disposition of these sources (for further information, see FAQs <u>D.1</u> and <u>D.4</u>).

C.7 I own an instrument calibrator which contains a 10 mCi Ra-226 source. I have possessed this equipment for a very long time, and, as far as I know, it has never been licensed (the State where I reside does not have a regulatory program for radium). To the best of my knowledge, the manufacturer of the calibrator is no longer in business and the equipment is not listed in the Sealed Source and Device Registry maintained by the NRC. What do I need to do in order to have this calibrator licensed?

You will need to obtain a license for possession of a device containing a sealed source. 10 CFR 30.32(g) specifies the information that you need to provide in order to obtain such a license for possession of a device containing a sealed source.

Paragraph 30.32(g)(3) addresses situations such as yours.

Under 10 CFR 30.32(g)(3), sources or devices containing naturally occurring or accelerator-produced radioactive material manufactured prior to November 30, 2007 that are not registered with the Commission under 10 CFR 32.210 or with an Agreement State, and for which the applicant is unable to provide all categories of information specified in 10 CFR 32.210(c), the applicant must provide all available information identified in 10 CFR 32.210(c) concerning the source, and, if applicable, the device. Also, the applicant must supply sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

Submission of the above information regarding your calibration device to either the NRC or Agreement State (as appropriate) should enable this issue to be resolved. Note that Section 32.210 contains the regulatory requirements for registering sources and devices with the NRC.

C.8 I possess a small Ra-226 calibration source (3 μ Ci) which I use to make sure my radiation detection instruments are operating properly. Do I need to apply to the NRC for a license to continue possessing this calibration source?

Calibration sources of the type you possess are subject to the general licensing provisions of $\underline{10~CFR~31.8}$. This regulation authorizes the possession, at any one time and one location, of calibration and reference sources containing Ra-226 in quantities up to 5 μ Ci. There are certain other requirements in this section of the regulations with which you should become familiar if you wish to continue possessing the source. If you posses calibration and reference sources containing Ra-226 in quantities that are greater than 5 μ Ci, then the source(s) must be specifically licensed. Specific licenses are discussed in question C.8.

C.9 What actions should I take if the NRC contacts me requesting information about the antique radium products that I possess?

The specific actions to be taken will, of course, depend on the nature of the request from the NRC. In general, such requests will concern the radium-containing materials or items that you possess and the nature of the activities associated with them. In accordance with the NRC regulations, you will be given 30 calendar days to respond (or other time specified in the request). If you cannot respond within the specified time, you may request an extension in writing. The extension should contain a justification for the additional time, so that the NRC can determine whether to grant the extension.

C.10 Is there a fee associated with an NRC license for possessing radium sources?

A fee may be needed for possession depending upon the type of license that is required. There are no fees for possession under the general license in 10 CFR 31.12. However, if you possess Ra-226 sources or devices that require a specific license, you would be subject to licensing fees. Therefore, if you possess Ra-226 sources or materials/objects containing radium which exceed the criteria contained in the general licensing requirements in the NRC regulations, you would be subject to fee requirements. For example, if you possess more than 100 luminous radium products at a given location (see 10 CFR 31.12(a)(4)), you would be subject to specific licensing requirements and a fee for possession and use would need to be paid to the NRC. You should also be aware that if you possess a gauge containing radium pursuant to 10 CFR 31.5 and the device is required to be registered with the NRC's General License Tracking System, a fee would be assessed in this case as well [10 CFR 31.5(c)(13)(i)].

If the nature of your activities includes manufacturing, repair, assembly, disassembly, or importation of radium-bearing materials or objects, a specific license would be required in most instances. A notable exception is contained in the general license regulations in 10 CFR 31.12(d), which allow disassembly and repair of timepieces without a specific license. Fees for specific licenses are dependent on the nature of the activity and the quantity of radium possessed; however, in all cases, application fees and annual fees are assessed.

Note: Application fees for specific licenses and registration fees change. These changes are published annually and may be obtained by contacting fees@nrc.gov [http://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0238/]. Agreement States may have a different fee structure; the regulating office can provide you that information.

C.11 I own a small mineral collection. Included in my collection are a number of pieces of uranium ore and items which I understand contain uranium, such as the glazing on ceramic tableware. Someone told me that the ore contains radium. Because the NRC is now regulating radium, does this mean that I need to obtain a license for either the ore or the tableware?

No. The radium that may be present in the glazing as a result of the radioactive decay of the uranium is not a discrete source. Thus, the regulatory status of these items is not impacted by the Energy Policy Act. Unrefined and unprocessed ore is exempt from requirements for a license under Section 40.13(b) and ceramic tableware is exempt under Section 40.13(c)(2)(i).

D. Radium Disposal

D.1 How are Ra-226 sources disposed of?

All radioactive sources should be properly disposed of when they are no longer useful for their radioactive properties. The NRC and Agreement State regulations authorize a number of different mechanisms for waste disposal; however, the mechanisms most relevant to discrete generally or specifically licensed radium sources are either transferring to another licensee, or disposal at a licensed radioactive waste disposal facility. The requirements for disposal do not apply to products whose end users are

exempt from licensing, such as watches and certain smoke detectors. In addition to these regulations, certain low-level radioactive wastes are authorized to be disposed of in hazardous waste disposal sites pursuant to Subtitle C of the Resource Conservation and Recovery Act (RCRA). Generally, disposal of radium sources in RCRA hazardous waste sites is very limited. The EPAct very specifically states that the disposal of these sources does not fall under the Low-Level Waste Policy Act.

D.2 What actions should be taken if a source of Ra-226 is found and it is not apparent who owns it?

The term "orphan source" is often used to describe radioactive sources whose ownership is unknown. The person discovering an orphan source of Ra-226 or other radioactive source should contact his or her local law enforcement authority or fire department, who will make an initial response to assess the situation and then involve State/Federal authorities as needed. The ultimate authority at the Federal level for orphan source disposition rests with the radiological division of the U.S. Environmental Protection Agency (contact information at http://www.epa.gov/radiation/contact.html).

D.3 A Ra-226 source is found and the licensed owner of the source has been determined; however, the licensed owner does not have the resources to dispose of the material. What happens to the source then?

If the source was licensed by a State, the State may work through the Conference of Radiation Control Program Directors (CRCPD) under its Orphan Radioactive Material Disposition Program, to determine if source collection and disposal can be accomplished [for further information, see www.crcpd.org/orphans.asp]. Additionally, regulatory agencies can work through the U.S. Department of Energy under their Offsite Source Recovery Project to accomplish source collection and disposal when the owner lacks the resources to do so [for further information see http://osrp.lanl.gov/].

D.4 An existing licensee wants to dispose of a radium source that it is authorized to possess under an NRC or Agreement State license. How is this accomplished?

In such a case, the licensee would be expected to pay the source disposal costs. There are a few disposal options available at this time. The licensee should contact a waste site operator for specific disposal requirements and/or variance requests prior to packaging the material for disposal. Hazardous waste sites regulated under Subtitle C of the Resource Conservation and Recovery Act could potentially accept such sources for disposal.

D.5 My facility used several small sealed radium sources while it was in operation. The facility has been torn down and demolished. The radium sources have been co-mingled with the building rubble and soil. I'm making arrangements to have the rubble sent to a disposal facility which accepts diffuse sources of radium. Does this situation fall under NRC's jurisdiction?

Yes. Discrete sources of radium retain their identity as discrete sources even when comingled with soil and building rubble. Any discrete source created for a commercial use retains that identity throughout the source lifetime. "Discrete" radium need not be encapsulated; for example, the contaminated soil associated with the radioactive rubble

is also defined as discrete. Disposal requirements applicable to such sources are the same as those cited in response to FAQ D.4.

E. Regulation of Timepieces

E.1 I possess an antique timepiece. How do I know if it contains Ra-226, and if so, is there anything that I need to do?

If your watch was manufactured prior to 1960 and it is self-luminous (glows in the dark), the watch is likely to contain a Ra-226-impregnated compound on the hands as well as on the hour points on the face perimeter. However, the self-luminosity may, in some cases, be due to a chemical compound. A quick way to differentiate these two forms of luminosity is to keep the timepiece in a dark area for 24 hours and determine after that time whether it continues to glow in the dark. If it does, the source of the luminosity in the timepiece is probably Ra-226. Radium watches sometimes have the letter "R" or "Ra" printed on the watch face near the number 6. If the watch contains radium, you may be subject to the general license requirements of the NRC or the Agreement State in which you live, depending on the quantity of radium in the watch (less than 1 μ Ci is exempt) and whether the timepiece is intact. Self-luminous watches manufactured after 1970 are likely to contain small quantities of radioactive material other than Ra-226.

E.2 If the timepieces that I possess contain Ra-226 but are intact, are they still regulated?

Possibly. Any individual intact timepiece containing less than 0.037 megabecquerel (1.0 microcurie) of radioactivity is exempt from regulatory requirements (10 CFR 30.15(a)(1)(viii)). However, if the timepiece contains more than this amount of Ra-226, it will be subject to the general licensing requirements in 10 CFR 31.12(a)(2) or State equivalent.

E.3 The NRC regulations for general licensing refer to "intact timepieces." What does this mean?

A timepiece is considered "intact" if the crystal is not broken and all luminous components (e.g. hands, dials and bezels) are in placement as initially designed.

E.4 How can I find out how much Ra-226 is present in the timepieces that I possess so that I can determine if my continued possession of them is an exempt activity or is subject to general licensing requirements?

If you have a limited number of timepieces of concern, it is possible that you may be able to have the Ra-226 analysis performed by your State Health Department or a commercial laboratory, but may have to assume the associated testing costs. The principal method for accurately determining the quantity of Ra-226 present in any given material is by way of a testing procedure called gamma spectral analysis. After you receive the results of the analysis, you will then have to decide what to do with any timepieces containing more than the 0.037 megabecquerel (1.0 microcurie) limit for exempt products (30.15(a)(1)(viii)). You may either: (1) retain the timepieces and be subject to general licensing requirements or (2) properly transfer or dispose of them.

E.5 The watches containing Ra-226 that I possess are not in good condition. The hands and dial portions are chipped and some of the luminous material may have sloughed off. Is this a cause for concern, and if so, what should I do?

If your watches were in this condition when you took possession of them, there may be no basis for a concern. However, you may wish to contact your local (e.g., city or county) health department and explain the situation, particularly if you have "tinkered" with any of the watches and believe that additional material may have sloughed off as a result. You may also contact your regulatory agency (NRC or Agreement State) if the local department is unable to assist you.

E.6 I am a collector of antique watches. There are several hundred watch hands and dials in my collection. Do I need a specific license for this?

No, you do not need a specific license. The NRC regulations or equivalent Agreement State regulations allow possession of an unlimited number of non-intact (disassembled) timepiece hands and dials at any one location and time under a general license.

E.7 I operate a watch repair shop and work on watches and clocks of all ages and types. Some of these are self-luminous. Do I need a license to repair the self-luminous ones because they may contain radium?

Your possession of radium-containing watches and clocks for repair purposes, though only temporary, is subject to the general license provisions for self-luminous products containing Ra-226 contained in NRC regulations (10 CFR 31.12) or equivalent Agreement State regulations.

- F. Regulation of Gauges, Dials and Other Items Containing Radium
- F.1 I am a collector of antique gauges and dials from old military vehicles, boats, and airplanes. Do I need a license for this?

Gauges and dials of this type were typically self-luminous because of radium-bearing compounds added to hands, pointers, and key read-out points on the gauge or dial. The activity in which you engage would be subject to the general license requirements of the NRC and equivalent Agreement State regulations. There is a limit of 100 of these items that you may possess under a general license. However, note that a general license does not allow you to manufacture, assemble, disassemble, repair, or import such products. If you desire to perform any of these activities, a specific license from the NRC or Agreement State will be required.

F.2 The NRC regulations refer to general license requirements for "small radium sources". What is meant by "small" – can you give me its dimensions in terms of inches?

In this instance, "small radium source" refers to the level of radioactivity of the source, not to its physical size. A small radium source is defined in 10 CFR 31.12(a)(5) as containing an amount of radioactivity of 0.037 megabecquerels (equivalent to 1.0 microcurie) or less. Sources of this type have been used as operational check sources for radiation measuring instruments, educational demonstration equipment (e.g., cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static

eliminators, and other approved uses. Such sources may be possessed under a general license; however, if the source strength exceeds 0.037 megabecquerels (1.0 microcurie), a specific license will be required.

F.3 The NRC regulations for general licensing refer to "no more than 100 items [other than timepieces and luminous items installed in air, marine, or land vehicles]....used or stored at the same location at any one time." What is meant by the term "same location?"

In this context, "same location" refers to a single building where up to 100 Ra-226 sources may be safely used or stored at any one time under a general license. This requirement is designed to minimize the potential likelihood of a significant radiation exposure to an individual. The use or storage of a greater number of sources in the same location would require a specific license.