

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF FEDERAL AND STATE MATERIALS
AND ENVIRONMENTAL MANAGEMENT PROGRAMS
WASHINGTON, D.C. 20555

July 27, 2009

NRC INFORMATION NOTICE 2009-12: EXEMPT DISTRIBUTION LICENSING
REQUIREMENTS FOR IRRADIATED
GEMSTONES

ADDRESSEES

All holders of NRC exempt distribution licenses authorized to distribute irradiated gemstones. Organizations associated with importing, distributing or selling irradiated gemstones or jewelry containing irradiated gemstones. All Radiation Control Program Directors and State Liaison Officers.

PURPOSE

The U.S. Nuclear Regulatory Commission is issuing this information notice (IN) to: 1) emphasize the NRC requirements governing the import into and initial distribution within the U.S. of irradiated gemstones containing byproduct material, and 2) emphasize that after the initial distribution of irradiated gemstones under an exempt distribution license, subsequent distributions (including export) are not subject to any other licensing or regulatory restriction.

It is expected that licensees, importers, and distributors will review this information and assure that they comply with applicable requirements. No specific action or written response is required.

DESCRIPTION OF CIRCUMSTANCES

Irradiated gemstones fall within the jurisdiction of the Nuclear Regulatory Commission (NRC or Commission) pursuant to the Atomic Energy Act of 1954, as amended, and the Energy Policy Act of 2005. The process of enhancing the gemstones' color through bombardment with either neutrons or electrons can induce radioactivity in the gemstones, making the gemstones slightly radioactive. The initial distribution of these gemstones within the U.S. is required to be by NRC licensed distributors pursuant to 10 CFR Parts 30 and 32. The initial distributors are required to conduct radiological surveys of each batch of gemstones to ensure that any residual radioactivity is below regulatory limits prior to being made available to the general public.

In a July 28, 1987, Commission Paper (SECY-87-186), NRC staff requested Commission direction on how to apply certain regulations in 10 CFR Parts 30 and 32 pertaining to the distribution of irradiated gemstones. In particular, the NRC staff had questions about how to apply 10 CFR 32.11, which establishes criteria for granting a specific NRC license to initially transfer certain products containing byproduct material; and 10 CFR 30.14, which grants an exemption from this license requirement to persons transferring products containing byproduct

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material not exceeding the concentrations listed in 10 CFR 30.70. The NRC staff also had questions regarding 10 CFR 32.11(c), which requires that an applicant who intends to introduce exempt quantities of byproduct material into products (or transfer such products) provide reasonable assurance that the product is not likely to be incorporated in any other product designed for application to a human being.

In a November 24, 1987, memorandum to staff (follow-up to SECY-87-186), the Commission directed the staff to issue interim exempt distribution licenses to distributors of irradiated gemstones, and to grant exemption to the requirements of 10 CFR 32.11(c), while developing a policy statement based on the level of risk. The conditions of the exempt distribution license required that the licensee meet other requirements of 10 CFR 32.11, 30.14, and 30.70.

On September 25, 1990, the NRC issued Information Notice No. 90-62, "Requirements for Import and Distribution of Neutron-Irradiated Gems," to remind U.S. distributors of gemstones, including importers, of long-standing NRC requirements in 10 CFR Part 30 governing U.S. distribution, and 10 CFR Part 110 governing the import (and distribution) of neutron-irradiated gems, and to provide information on the NRC's planned actions on unauthorized activities.

The NRC issued a number of exempt distribution licenses for irradiated gemstones in the late 1980s and early 1990s, but, by 2001, all had expired.

BACKGROUND

In August of 2005, the Energy Policy Act of 2005 expanded the definition of byproduct material to include material made radioactive in particle accelerators and produced, converted, or extracted for commercial, medical, or research activities. The NRC published its final rule on regulations implementing this expanded jurisdiction on October 1, 2007, with an effective date of November 30, 2007 (72 FRN 55864). Rulemaking for the expanded definition of byproduct material brought irradiated gemstones to the fore again because gemstones irradiated in particle accelerators are now under NRC jurisdiction.

In 2007, the NRC learned that there were gemstones on the market that were imported and distributed by a number of companies without an NRC distribution license. Accordingly, the NRC conducted selected surveys of the inventory in the market and held a public meeting with industry representatives and other stakeholders to gather more information. In the July 26, 2007, public meeting, NRC staff met with jewelers' industry representatives and other stakeholders to discuss the regulatory requirements for distribution of irradiated gemstones. In that meeting, industry representatives stated that they were concerned about significant interruption in providing certain gemstones to the market. At the same time, they expressed their commitment and willingness to cooperate with the NRC to ensure public health and safety and to prevent further unauthorized distribution. Subsequently, in November 2007, the NRC issued licenses to three organizations, and several other applications were pending before the NRC. In February 2008, the NRC issued a Fact Sheet, "Irradiated Gemstones," stating that it had no reason to believe that irradiated gemstones currently on the United States market are unsafe. However, the NRC is taking actions to ensure that from this point forward all irradiated gemstones will be distributed in compliance with NRC regulations.

DISCUSSION

NRC regulations provide exemptions from the requirements for an NRC license to persons who receive, possess, use, transfer, own or acquire byproduct material in exempt distribution products. These exemptions are set forth in 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material." See, e.g., 10 CFR 30.14, "Exempt concentrations," 10 CFR 30.18, "Exempt quantities." Exempt distribution products can include silicon chips, electron tubes, resins, check sources, carbon-14 urea capsules, gun-sights and smoke detectors. Such products are distributed by persons who have a specific NRC license authorizing such distribution to persons who would not require an NRC license.

Exemptions from licensing requirements are based primarily on the NRC's determination that the exempted classes of products or types of uses will not constitute an unreasonable risk to the common defense or security or to public health and safety. These exemptions do not apply to persons who manufacture, process, produce, incorporate byproduct material into, initially transfer for sale, or distribute products containing byproduct material.

Generally, distribution of byproduct material—including irradiated gemstones—to persons exempt from NRC regulations can only be made by persons who have a specific NRC license authorizing such distribution. After the initial distribution of the irradiated gemstones by an NRC-licensed distributor, the gemstones are no longer regulated. Therefore, subsequent distributors, jewelers, other retailers and consumers do not need to be licensed by the NRC.

Each NRC-licensed initial distributor of irradiated gemstones is required to ensure that its gemstones are tested and distributed in accordance with the specifications provided in its license application. Generally speaking, the licenses provide a safeguard against the possibility that gemstones reach the market too soon after irradiation. The initial distribution licensee must perform sophisticated surveys to verify that its gemstones meet NRC requirements. These specific licenses are issued by the Commission and are referred to as "exempt distribution" or "E" licenses. Persons authorized to initially transfer or distribute these products must also have a license authorizing the possession or use of radioactive material. If the distributor is in an Agreement State (one of thirty-six states that have entered into an agreement with the NRC to regulate certain classes of radioactive materials), the distributor must obtain its possession license from the Agreement State. Otherwise, NRC will issue the possession license.

The primary regulations applying to the distribution of irradiated gemstones are:

10 CFR 30.14 exempts from the requirements for a license persons to receive, possess, use, transfer, own, or acquire products or materials containing byproduct material provided that the byproduct material concentrations are not in excess of those specified in 10 CFR 30.70. 10 CFR 30.70 contains a table of exempt concentration levels.

10 CFR 32.11 describes the conditions and requirements necessary to obtain license approval for the introduction of byproduct material in exempt concentrations into products for transfer to individual not requiring a license. 10 CFR 32.11(c) requires that the license applicant provide reasonable assurance that the exempted product is not likely to be incorporated into any other product designed for application to a human being. If the NRC finds that these criteria are met, the NRC will issue an exempt distribution license.

10 CFR 32.12 establishes records and material transfer report requirements associated with the exempt distribution license licensed under section 32.11, and requires that material transfer reports, covering transfers made during the calendar year, be submitted to the NRC annually by January 31 of the following year.

10 CFR 110.27, "General license for imports," provides a general license to persons to import byproduct material if the importer is specifically licensed to possess the material.

Irradiated gemstones meeting the criteria in 10 CFR 30.14 may be distributed/transferred under an exempt distribution license as specified in 10 CFR 32.11, to others that are not required to have a license (e.g., wholesalers, retailers, and members of the public).

CONCLUSION

Initial distributors of irradiated gemstones must comply with the NRC's regulatory and licensing requirements. The NRC maintains the authority to take enforcement action against unauthorized distribution of irradiated gemstones that contain radiation induced byproduct material. The NRC is also providing verification of licenses to the U.S. Customs Service.

Importers can distribute irradiated gemstones under the following conditions:

1. The importer possesses a valid NRC or state license to possess the gemstones containing byproduct material and is authorized to distribute them under an NRC exempt distribution license; or
2. Gemstones containing byproduct material were previously distributed to U.S and foreign customers under the terms of a valid NRC exempt distribution license, and therefore, can subsequently be distributed (including re-import into the U.S.) without further regulatory control.

Therefore, importers and distributors of irradiated gemstones should consider taking steps to ensure that the irradiated gemstones have been distributed initially under an NRC exempt distribution license. Secondary and subsequent distributors and retailers do not need exempt distribution licenses. To help recipients of this IN comply with NRC import and exempt distribution regulations, NRC staff strongly recommends consideration of the following with respect to import documentation for irradiated gemstones:

1. All imported gemstones should be accompanied by clear documentation as to whether they are irradiated or not.
2. In the United States, only an NRC or State licensee can receive, and only an NRC distribution licensee can initially distribute irradiated gemstones. Documentation provided by the supplier should state the U.S. distributor licensee name and NRC license number.
3. Irradiated gems from U.S. facilities, which may have been exported, may be imported by non-licensees if they were previously distributed in or from the U.S. under the terms of an NRC distribution license. Documentation for such re-imports should state the name of the NRC distribution licensee and NRC distribution license number. A facility operating license number is not sufficient.

4. Imported gemstones will be subject to checks by the U.S. Customs Service or NRC. Undocumented gems may be subject to import delays and returned to the foreign suppliers, pending receipt of proper documentation.

The NRC is aware that irradiated gemstones containing induced radioactivity were distributed within the U.S. without the required exempt distribution license between 2002 and 2007. NRC staff conducted radiological surveys of a sample of these gemstone inventories, which revealed that current inventories of such gemstones in the U.S. presented no health risk. In addition, NRC recognizes that significant time has transpired since these gemstones were irradiated, allowing decay of the induced radioactivity. Therefore, NRC has determined that all gemstones currently in the U.S., and irradiated prior to November 2007, can be distributed without an exempt distribution license.

The NRC advises recipients of this IN that willfully acquiring gemstones for distribution in violation of NRC regulations may result in enforcement action.

CONTACT

This IN requires neither specific action nor written response. If you have any questions about the information in this notice, please contact the technical contact listed below or the appropriate regional office.

Robert Lewis, Director
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Office of Federal and State Materials
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Enclosures:

1. List of Recently Issued FSME Generic Communications
2. Frequently Asked Questions Associated with Irradiated Gemstones

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OFC	MSSA:SMPB	MSSA:LB	MSSA:MSEA	OIP
NAME	JDeCicco: sxg6	JFoster	AMcIntosh	JOwens
DATE	05/05/09	05/11/09	04/29/09	05/19 /09
OFC	OGC (NLO)	OE	FSME:MSSA	
NAME	BJones	SMagruder, Jr	RLewis	
DATE	06/02/09	06/15/09	06/22/09	

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List of Recently Issued Office of Federal and State Material and Environmental Management Programs Generic Communications			
Date	GC No.	Subject	Addressees
01/12/09	IN-2008-22	Molybdenum-99 Breakthrough in Molybdenum-99/Technetium-99m Generators	All U.S. Nuclear Regulatory Commission medical, radiopharmacy, molybdenum-99/technetium-99m generator manufacturers, and master material licensees authorized to manufacture or use generators. All Agreement State radiation control program directors and State liaison officers.
01/22/09	IN-2009-01	National Response Framework	All holders of operating licenses or certificates for nuclear power plants, research and test reactors, independent spent fuel storage installations, fuel cycle facilities, and radioactive materials. All holders of operating licenses for uranium recovery facilities and all holders of licenses or certificates for the following types of facilities undergoing decommissioning: nuclear power plants, research and test reactors, fuel cycle facilities, and uranium recovery facilities.
02/03/09	IN-2009-05	Contamination Events Resulting from Damage to Sealed Radioactive Sources During Gauge Dismantlement and Nonroutine Maintenance Operations	All U.S. Nuclear Regulatory Commission materials licensees; all Agreement State Radiation Control Program Directors and State Liaison Officers.
03/30/09	IN-2009-07	Withholding of Proprietary Information from Public Disclosure	All current holders of and potential applicants for licenses, certificates of compliance, permits, or standard design certifications, as well as any other persons submitting a request that information be withheld from public disclosure under the provisions of Title 10 of the <i>Code of Federal Regulations</i> (10 CFR) Section 2.390, "Public inspections, exemptions, requests for withholding.
04/29/09	RIS-2009-05	Uranium Recovery Policy Regarding: (1) The Process for Scheduling Licensing Reviews of Applications for New Uranium Recovery Facilities and (2) The Restoration of Groundwater at Licensed Uranium In-Situ Recovery Facilities	All holders of operating licenses for uranium recovery facilities and all companies who have submitted applications to construct new uranium recovery facilities of all types (conventional mills, heap leach operations, and in-situ recovery facilities) or letters of intent to submit such applications.
05/07/09	RIS-2009-07	Status Update for the Implementation of NRC Regulatory Authority for Certain Naturally Occurring and Accelerator-Produced Radioactive Material	All U.S. Nuclear Regulatory Commission material and fuel cycle licensees. All Radiation Control Program Directors and State Liaison Officers.
<p>Note: This list contains the six most recently issued generic communications, issued by the Office of Federal and State Materials and Environmental Management Programs (FSME). A full listing of all generic communications may be viewed at the NRC public website at the following address: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/index.html</p>			

Frequently Asked Questions on Irradiated Gemstones

For consumers:

1. Why and how are gemstones irradiated?
2. Does irradiation make the gemstones radioactive?
3. Is it dangerous to wear blue topaz?
4. Should I stop wearing blue topaz?
5. A jeweler told me it is now illegal to sell blue topaz because it causes cancer - is this true?
6. How can I tell if my jewelry has been irradiated?
7. Will I receive a radiation "dose" from wearing blue topaz or other irradiated gemstones?

For Jewelers and Distributors:

8. Why is NRC scaring industry and disrupting the sale of irradiated gemstones?
9. Do I need an NRC license to sell blue topaz or other irradiated gemstones?
10. Why is an "exempt distribution" license required for the initial distribution of irradiated gemstones?
11. Am I selling "contraband"?
12. Should I stop selling these popular gemstones?
13. I read that there was a ban on selling irradiated gemstones. Is this true?
14. Why do some irradiated gemstones fall under NRC's authority, while others do not?

1. Why and how are gemstones irradiated?

Gemstones are irradiated in order to enhance and deepen their color. They can be irradiated in a nuclear reactor (neutron bombardment), an accelerator (electron bombardment), or by exposure to gamma rays in a cobalt-60 irradiator. The most commonly treated stone is topaz, which becomes blue as a result of the exposure to radiation.

2. Does irradiation make the gemstones radioactive?

Possibly. Generally, the longer the gemstones are exposed to radiation - and the more intense the radiation - the deeper the resulting color; also, this increases the chance that trace elements in the stone will be "activated" and become radioactive. It is important to note that activation is most likely to occur in gemstones that are treated in a nuclear reactor, though treatment in an accelerator can also make gemstones radioactive. Treatment in a cobalt-60 irradiator does not render gemstones radioactive.

3. Is it dangerous to wear blue topaz?

No. The NRC has no indication that wearing irradiated gemstones can be harmful. There have been no reported cases of anyone being harmed by wearing irradiated gemstones.

4. Should I stop wearing blue topaz?

From a safety standpoint, there is no reason to stop wearing blue topaz or any other irradiated gemstones.

5. A jeweler told me it is now illegal to sell blue topaz because it causes cancer - is this true?

No. There is no reason to believe blue topaz or any other irradiated gemstone poses any health risk. The NRC has not advised, requested, or ordered any retailers or distributors to stop selling irradiated gemstones.

6. How can I tell if my jewelry has been irradiated?

A skilled gemologist might be able to tell by examining the gemstone. However, it can be very difficult to determine whether a stone has been treated in a reactor, accelerator or irradiator. Residual radioactivity can be detected with some hand-held survey meter; however, determining whether the radiation is below NRC's regulatory limits requires a trained radiation professional to use sophisticated survey equipment.

7. Will I receive a radiation "dose" from wearing blue topaz or other irradiated gemstones?

Possibly, but it would be an extremely small dose. A study done by the NRC estimated that a person wearing a blue topaz stone at the highest level of radioactivity allowed for distribution under NRC regulations would receive an annual dose of 0.03 millirem (NUREG 1717, page 2-21). By contrast, a chest X-ray is about 10 millirem, and average annual natural background is about 360 millirem in the United States.

8. Why is NRC scaring industry and disrupting the sale of irradiated gemstones?

Early in 2007, the NRC contacted several large retailers of blue topaz seeking information about how the gemstones reached the U.S. market. The agency sought this information in order to restore the regulatory framework for the proper distribution of these gemstones under the Atomic Energy Act and NRC regulations. The NRC did not request any specific actions of industry. Industry groups and retailers have cooperated with the NRC in its efforts. The NRC continues to survey batches of gemstones for radiation. Surveys conducted to date have not given the agency any indication that current inventories are a health risk.

9. Do I need an NRC license to sell blue topaz or other irradiated gemstones?

Probably not. NRC regulations cover material made radioactive in a nuclear reactor and particle accelerators. The initial transfer of these materials must be made according to an NRC distribution license. If the radioactivity levels are below certain limits in NRC's regulations, the materials become "exempt" from further regulation, and further distribution, including to the end consumer, does not need to be licensed. This means individual jewelers do not need to be licensed provided the gemstones they sell were initially distributed by an NRC licensee.

By the end of 2007, the NRC issued three distribution licenses for blue topaz, and other license applications are under review.

10. Why is an "exempt distribution" license required for the initial distribution of irradiated gemstones?

The license provides a safeguard against the possibility that gemstones might reach the market too soon after irradiation, with radioactivity above NRC limits. The distribution licensee is required to perform sophisticated surveys to verify that the gemstones meet NRC requirements for exempt distribution.

11. Am I selling "contraband"?

No. Current inventories in retail outlets and distribution channels have not been distributed by an NRC licensee, but these should not be considered contraband. For gemstones irradiated prior to 2007, the NRC has decided that no additional actions are necessary to ensure health and safety of the public. For all gemstones irradiated after November 2007, the NRC will enforce the requirements of the exempt distribution licenses of the initial distribution.

12. Should I stop selling these popular gemstones?

That is a business decision only you can make. The NRC has sought information from industry about how irradiated gemstones reach the U.S. market, but the agency has not requested any action, including a halt in sales.

13. I read that there was a ban on selling irradiated gemstones. Is this true?

Not a ban by the NRC. When the NRC approached industry groups early in 2007 seeking information about the distribution of irradiated gemstones, several retailers pulled their gemstones from the market in response. This was a voluntary action on their part. The NRC did not request or impose any such action.

14. Why do some irradiated gemstones fall under NRC's authority, while others do not?

This is simply because of the way the law has been written. The Atomic Energy Act gave NRC regulatory authority over radioactive material produced in reactors. In the Energy Policy Act of 2005, Congress extended this authority to include accelerator-produced radioactive material that is used for a commercial, medical, or research activity. NRC regulations implementing this expanded authority took effect November 30, 2007. Information on these regulations and the agency's transition plan for implementing them is available on the NRC web site, <http://www.nrc.gov/>.

Some gemstones treated at low energy in an accelerator may not actually become radioactive, so they would not qualify as radioactive material under NRC authority. Also, gemstones irradiated in a cobalt-60 irradiator do not become radioactive.