



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

August 9, 2007

MEMORANDUM TO: A. Duncan White, Chief
State Agreements and Industrial Safety Branch
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

FROM: Joseph E. DeCicco */RA/*
State Agreements and Industrial Safety Branch
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

SUBJECT: MEETING BETWEEN THE NUCLEAR REGULATORY
COMMISSION STAFF AND STAKEHOLDERS CONCERNING
LICENSING FOR DISTRIBUTION OF IRRADIATED
GEMSTONES

On July 26, 2007, the U.S. Nuclear Regulatory Commission (NRC) staff met with jewelers' industry representatives, and other stakeholders at NRC headquarters to discuss the issue of regulatory requirements for distribution of irradiated gemstones. Attachment 1 lists the meeting attendees.

A public meeting notice was issued on July 12, 2007 and was posted on the NRC's external website on July 13, 2007 (ADAMS Accession No. ML071930452). This notice included the meeting agenda, which was also available as a handout at the meeting. A revised meeting notice was posted on July 23, 2007 because of a need to change the meeting room (ADAMS Accession No. ML072040146).

In the opening remarks, Mr. Scott Moore, Deputy Director of the Materials Safety and State Agreements Division, which has regulatory oversight responsibility for radioactive material safety at NRC, introduced the issues to be discussed during the meeting. He thanked Cecelia Gardener of the Jeweler's Vigilance Committee (JVC), and JVC for stepping forward, to seek information on a solution on the issue of irradiated gemstones.

Mr. Moore indicated that the purpose of the meeting was to exchange information, between JVC, the American Gem Trade Association, the Jewelers of America, other stakeholders, and NRC staff, on the issue of irradiated gemstones. In particular NRC hoped to discuss the long-standing requirements for distribution of exempt concentrations of byproduct material, the requirements for possession of material, practices within the gem industry, the new rule on accelerator produced byproduct material, and possible paths forward, given the present concern about distribution of irradiated gemstones without licenses.

Mr. Moore emphasized that NRC wants to work with industry to find a solution to this issue, while assuring that the public is adequately protected. NRC and industry worked together to address this in the early 1990s, and NRC issued guidance on it at that time. History has shown that it is generally not an imminent health and safety threat, depending on several variables, such as how fast the gemstones get to market from the time that they are irradiated, how they are irradiated, and the activity that they are at that time. Individual gemstones may potentially be a problem. The meeting was called to address how to mitigate that risk.

Before the dialogue began, Joseph DeCicco, staff member of the Materials Safety and State Agreements Division, indicated that the meeting was a category 1 public meeting, which meant that the public is invited to observe the meeting and would have the opportunity to communicate with the NRC after the business portion of the meeting, but before the meeting is adjourned. This did not preclude the interested parties from responding to questions if they chose to do so. Then each individual at the meeting was asked to state their name and their affiliation.

Ms. Cecilia Gardner, Jeweler Vigilance Committee, gave an overview of the issues of irradiated gemstones. She indicated that the gemstone jewelry industry is a billion dollar per annum industry that involves a wide variety of entities, including importers, exporters, wholesalers, distributors, retailers, and end users of the product. The current issues involving this regulatory aspect of the industry has severely interrupted the trade, with some dealers having taken the product off their shelves, and some having returned the product to their providers. An immediate issue is the current time of year with conventions going on, current inventories, and inventories changing for the upcoming holidays.

Ms. Gardner expressed that the industry has had a long tradition of legal compliance, and gave as an example the regulatory processes involved with the diamond trade industry. Health and safety has always been part of that compliance, that the industry would have no tolerance for products that would cause a health and safety concern; it would be detrimental to the industry.

Ms. Gardner completed her presentation with the indication that industry was standing ready to work with NRC to co-operate with requirements. She emphasized the time sensitivity issue with holiday trade starting soon, and the need for guidance from NRC as soon as possible. A representative of the Gemological Institute of America (GIA) indicated they would provide history and test information. Scott Moore accepted the offers. He then wanted to discuss and address two issues: 1) what was needed to bring industry into compliance, and 2) how to address the issue of what to do with current inventories.

A Code of Ethics was read by a member of Jewelers of America.

Duncan White, NRC, summarized the licensing of irradiated gemstones. The exempt distribution license requirements are found in 10 CFR Part 32. The distribution of irradiated gemstones are based on health and safety, which in turn are based on allowable concentrations of radioactive material found in tables in 10 CFR 30.70. A specific license is required to initially distribute in the U.S., and another specific license is required to possess the material. Possession licenses are issued by Agreement States or NRC. The exempt distribution license is issued by NRC Headquarters only. Importation of small quantities of radioactive material can be done under a general license provided that the consignee is authorized to receive and possess the material under a specific possession license.

Licensing guidance for exempt distribution is found in NRC publication NUREG-1556, Volume 8, "Consolidated Guidance About Material Licenses, Program-specific Guidance About Exempt Distribution" (<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v8/>). Appendix G pertains to importers and Appendix H pertains to domestic reactors. NRC issued a number of exempt distribution licenses for irradiated gemstones in the late 1980s and early 1990s, but none exist today.

As a result of the Energy Policy Act of 2005, naturally occurring and accelerator-produced material (NARM) will come under NRC's jurisdiction. NRC regulations for NARM have been approved by the Commission, and are intended to be published later this year. These will be effective shortly after publication. Many States already regulate NARM. The transition of authority from States to NRC is summarized in attachment 3.

Several issues were raised by members of the public. An individual raised the issue that it was not clear, in the statements of consideration for the upcoming NRC regulations, that accelerator-irradiated gemstones would come under the NRC jurisdiction. Another issue raised was that currently there is no known way of distinguishing accelerator-irradiated gemstones from neutron (reactor) irradiated gemstones, in light of the fact that the NRC regulations governing accelerator-irradiated gemstones is not final at this time. A question was raised that if the gemstones are irradiated outside the U.S. and meet standards of that country, might they be considered non-radioactive and not under NRC jurisdiction. It was emphasized that currently NRC has jurisdiction over reactor-irradiated gemstones, that the final rule for accelerator-irradiated gemstones has not been published and is not final, but that the comment period for the final rule has closed.

The following is a list of points raised by the stakeholders and members of the public during discussions that ensued.

- There was no one way that industry does business or that the process flows in bringing gemstones into the U.S.; this is a large industry with many small dealers;
- Not many of the irradiations of gemstones occur in the U.S.;
- Most gemstones come from overseas; gemstones are primarily cut overseas;
- The time interval between irradiation and introducing the gemstone into the public is not as short as one might think, and gemstones are not sold immediately after irradiation; some gemstones take a year from irradiation to final sale;
- There is some monitoring performed in the industry after release from the irradiator facility, but there is no standard operating procedure;
- The jewelry industry takes public safety seriously; it must maintain good will with its customers;
- The storage time after irradiation of gemstones depends on many factors, including how long they have been irradiated;
- Foreign standards for release of irradiated gemstones are different than the U.S.; for example, there is a release criterion in Thailand of 74 becquerels/gram; decay-in-storage times to meet 10 CFR 30.70 concentration levels would substantially increase.

A suggested path forward was to look at what other countries are doing to regulate irradiated gemstones. Pursuing reliable information about the process was also suggested.

Robert Lewis, NRC, mentioned that members of the public also included persons remote from the final sale, such as the gemstone handlers, shippers, transporters, and custom agents, that also needed to be considered in the process. The question of how did we get to where we are now was raised. Some of the reasons given were that it is difficult to keep abreast of the

regulations by reading the Federal Register, enforcement action was minimal, gemstones come across our border virtually unimpeded, and the industry got into a pattern and practice of accepting irradiated stones as a non-NRC-regulated issue.

Suggestions for a path forward and follow-on actions were discussed. The GIA had an exempt distribution license in the 1980s and 1990s. The GIA is a non-profit, educational and certification institute that has been testing diamonds; its representative indicated it would be interested in again obtaining an NRC exempt distribution license. There was a suggestion that a few licensed entities step forward to provide an avenue to test/sample gemstones, near the location where they enter the U.S., in order to be more efficient than having every dealer pursuing an exempt distribution license. NRC addressed the issue of current inventories by indicating that it would be open to ideas if it could be assured that the material is safe, as indicated by independent verification. If major retailers would provide gemstones for inspection, NRC would welcome the opportunity to gather and evaluate the information. NRC would then evaluate next steps based on the results and additional records submitted by industry representatives. Industry reiterated that it was willing to work with NRC to move forward, and emphasized the need to proceed as quickly as possible.

Enclosures:

1. Meeting attendees
2. Agenda presented at the meeting
3. Implementation of NRC Regulatory Authority
For Certain Naturally-Occurring and Accelerator-
Produced Radioactive Material

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NAME	JDeCicco	D White	R Lewis
DATE	08/08/07	08/09/07	08/09/07

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List of Attendees
 Meeting Between the Nuclear Regulatory Commission Staff and Stakeholders
 Concerning Licensing for Distribution of Irradiated Gemstones
 July 26, 2007

<u>Name</u>	<u>Organization</u>
S. Moore	NRC, FSME
A. D. White	NRC, FSME
A. Kirkwood	NRC, FSME
R. Struckmeyer	NRC, FSME
M. Burgess	NRC, FSME
T. Taylor	NRC, FSME
R. O'Connell	NRC, FSME
D. White	NRC, FSME
A. Mauer	NRC, FSME
S. Wastler	NRC, FSME
C. Mattsen	NRC, FSME
J. DeCicco	NRC, FSME
R. Lewis	NRC, NMSS
B. Jones	NRC, OGC
S. Chidakel	NRC, OGC
S. Magruder	NRC, OE
M. Schwartz	NRC, OE
S. Woods	NRC, OE
D. Vito	NRC, OE
L. Jarriel	NRC, OE
L. Rakovan	NRC, OEDO
S. Dembeck	NRC, OIP
S. Baker	NRC, OIP
S. Zuberi	NRC, OIS
D. McIntyre	NRC, OPA
A. Carson	RSCS, Inc
A. Schildcrout	Hannah Rose Co., Inc
K. Guray	Leo Wollern, Inc
W. Wang	Gemological Institute of America
T. Haake	Jewelers of America
C. Gardiner	Jewelers Vigilance Committee
P. Donahue	Jewelers of America
M. Grayski	Venable LLP
E. Getterman	Jewelers of America
J. Miller	International Isotopes Inc
D. Nelson	Consultant
D. Nelson	Trade/Jeweler Appraiser
R. Setareh	R.S. Importing Co. Ltd
S. Pradeep	STS Jewelers Inc.

<u>Name</u>	<u>Organization</u>
B. Lipatapanlop	International Colored Gemstone Association
T. Smith	Winston & Strawn
D. Federman	Colored Stone Magazine
R. Kempler	Aaron group
O. Azrielant	Andin International, Inc
J. Johnson	Collector Universe GCAL Gemprint
D. Alger	Quali-Tech, Inc.
R. Berlion	Instrumentation Association
R. Kremenz	American Gem Trade Association
S. Walker	Manatt, Phelps, Phillips (via phone)
Anine Grumbles	Dept. of Health, Washington State (via phone)
E. Braunwart	Columbia Gem House Inc. / Trigem Designs (via phone)
R. Jensen	Columbia Gem House Inc. / Trigem Designs (via phone)

FSME = Office of Federal and State Materials and Environmental Management Programs

NMSS = Office of Nuclear Material Safety and Safeguards

OGC = Office of the General Counsel

OE = Office of Enforcement

OEDO = Office of the Executive Director for Operations

OIP = Office of International Programs

OIS = Office of Information Services

OPA = Office of Public Affairs

AGENDA FOR PUBLIC MEETING TO DISCUSS
REGULATORY REQUIREMENTS FOR DISTRIBUTION OF IRRADIATED GEMSTONES,
AND NRC'S PROPOSED RULE ON THE EXPANDED DEFINITION OF BYPRODUCT
MATERIAL

Thursday, July 26, 2007

10:00 am

Room T-8A1

1. Welcome and Purpose of Meeting (5 minutes) (NRC - D White/S Moore)
2. Introductions and Ground Rules (5 Minutes) (NRC- J DeCicco)
3. Discussion: (50 Minutes)
 - a. Current state of the industry regarding licensing for importation and exempt distribution of nuclear irradiated gemstones (JVC)
 - b. NRC requirements for neutron irradiated gemstones, and future regulations of accelerator irradiated gemstones (NRC-D White, A. Mauer)
 - c. Current inventories of irradiated gemstones (JVC)
 - d. What is industry doing currently with irradiated gemstones (JVC)
 - e. Path forward (NRC/JVC)

External stakeholder attendees:

Cecilia Gardner, Jewelers Vigilance Committee;
Rick Krementz, Chairman of the Board of Director, American Gem Trade Association;
Tim Haake, Jewelers of America

NRC Invitees:

Office of Federal and State Materials and Environmental Management
Office of International Programs
Office of the General Counsel
Office of Enforcement
Office of Public Affairs

IMPLEMENTATION OF NRC REGULATORY AUTHORITY FOR CERTAIN NATURALLY-OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIAL

BACKGROUND

On August 8, 2005, the President signed the Energy Policy Act of 2005 (EPAct) into law. Section 651(e) of the EPAct expanded the definition of byproduct material as defined in Section 11e of the Atomic Energy Act of 1954 (AEA), as amended. This change placed certain naturally-occurring and accelerator-produced radioactive materials (NARM) under the NRC's jurisdiction, as defined in sections 11e(3) and 11e(4) of the AEA.

FINAL REGULATIONS

The NRC plans to publish its final regulations in the Fall of 2007. These final regulations will become effective 60 days after publication. Further information can be accessed on the NRC's Public Involvement Rulemaking Web site, which is located at the following link:

<http://ruleforum.llnl.gov/cgi-bin/rulemake?source=narm&st=prule>

WAIVER ISSUED ON AUGUST 31, 2005 (70 FR 51581)

As authorized by Section 651(e) of the EPAct, the Commission issued a waiver on August 31, 2005, to allow continued use and possession NARM while the Commission developed a regulatory framework for regulation of the new byproduct material. The Commission plans to terminate the waiver in phases, beginning on the effective date of the final regulations and ending on August 7, 2009. On the effective date of the final rule, the Commission will terminate the waiver for Federal Government agencies, Federally Recognized Indian Tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana.

Upon waiver termination, all persons who possess the new byproduct materials in these States, U.S. Territories, or areas of exclusive Federal jurisdiction must be in compliance with NRC regulations. Being in compliance with the NRC regulations means that such persons are responsible for the proper handling, transfer, and disposal of these new byproduct materials as specified in the NRC's regulations. In addition, such persons will either be required to: (1) apply for license amendments for the new byproduct material within 6 months from the date the waiver is terminated, if they hold an NRC specific byproduct materials license, or (2) submit a license application for the new byproduct material within 12 months from the date the waiver is terminated.

In addition, the Commission also intends to terminate the waiver for all 34 Agreement States that provided a certification from their Governor to the Commission, in conjunction with the effective date of the final rule. These certifications document that the respective States have a program for licensing byproduct material, as defined in paragraph (3) or (4) of Section 11e. of the Atomic Energy Act of 1954, as amended, which is adequate to protect public health and safety, and that the State intends to continue to implement its authority with respect to the new byproduct material. Upon acceptance of the certification by the Commission and termination of the waiver, as described in Section 651(e) of the EPAct, the State's Agreement will be considered to include AEA 11e(3) and 11e(4) byproduct material. Users of the new byproduct materials in Agreement States should contact their respective Agreement State regulatory agency with any questions related to the regulation of these materials.

The approach used for the selection of the States and U.S. Territories for the initial phase of waiver terminations considered (1) the scope of the State's current regulatory program, (2) the estimated total number of licensees impacted, and (3) the State's level of interest in becoming an Agreement State. At this time, the NRC has not established the timing and schedule for waiver terminations for the remainder of the non-Agreement States and U.S. Territories. However, the NRC intends to use the same selection approach for the remaining States and U.S. Territories. The NRC also plans to terminate the waiver for non-Agreement States that enter into an agreement with the NRC under Section 274b of the AEA, coincident with the effective date of such an agreement. A notice in the *Federal Register* will be published approximately 6 months before the effective date of the waiver termination to notify users of their waiver terminations and implementation dates of the rule.

TRANSITION PLAN

The EPA Act requires the NRC to prepare and publish a transition plan that addresses both Agreement and non-Agreement States to facilitate an orderly transition of regulatory authority with respect to the newly added byproduct material. The draft transition plan is available for review via the NRC's Agency-wide Documents Access and Management System (ADAMS) at <http://www.nrc.gov/reading-rm/adams.html>; click on the Web-based access link. The document is available in ADAMS under Accession No. ML062990137. The NRC anticipates that publication of the final transition plan, which will not be substantively changed from the draft transition plan, will occur shortly before the effective date of the final regulations.

The Commission, pursuant to 10 CFR 150.15, retains the authority to license the distribution of byproduct material to persons who are exempt from regulatory requirements. Since the Commission did not have jurisdiction over section 11e.(3) and 11e.(4) byproduct material previously, the States had the authority to issue licenses for the distribution of NARM to persons who were exempt from licensing and regulatory requirements. With the expansion of the definition of byproduct material, NRC authority pre-empts the States' authority to issue such licenses.

NRC understands that there are a limited number of State issued exempt distribution licenses for the new byproduct material, which will transfer to NRC on termination of the waiver for the State. The specifics of the transfer will be addressed directly with the involved States and distributors, on a case-by-case basis. On expiration or earlier termination of the waiver, NRC will issue licenses for the distribution of products containing AEA section 11e.(3) and 11e.(4) byproduct material to persons who are exempt from licensing and regulatory requirements.

ADDITIONAL INFORMATION

Information on NARM-related activities is also available in the "NARM Toolbox" at the NRC's Office of Federal and State Materials and Environmental Management Programs (FSME) Web site at <http://nrc-stp.ornl.gov/narmtoolbox.html>.