



UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
WASHINGTON, DC 20555 - 0001

June 24, 2010

MEMORANDUM TO: ACRS Members

FROM: Neil Coleman, Senior Staff Scientist *NMC*
Reactor Safety Branch B, ACRS

SUBJECT: CERTIFICATION OF THE MINUTES OF THE ACRS SUBCOMMITTEE
ON RADIATION PROTECTION AND NUCLEAR MATERIALS, MAY 18,
2010

The minutes for the subject meeting were certified on June 24, 2010. Along with the transcripts and presentation materials, this is the official record of the proceedings of that meeting. A copy of the certified minutes is attached.

Attachment: As stated

cc w/o Attachment: E. Hackett
C. Santos
D. White

cc w/ Attachment: ACRS Members

ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
MAY 18, 2010
ROCKVILLE, MD

Introduction

The ACRS Subcommittee on Radiation Protection and Nuclear Materials met on May 18, 2010 at NRC headquarters in Rockville, MD. Michael Ryan, Chairman, was presiding. The Subcommittee met with NRC staff members and members of the public. The purpose of this meeting was for the Subcommittee members to hear a staff briefing titled "Proposed Rulemaking on Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions." In addition, a brief presentation was given to the subcommittee by Mr. Charles Simmons. That talk was titled "NRC 40.22 Rulemaking: Unintended Consequences."

Attendees (5/18/2010)

ACRS Members/Staff

Michael Ryan (Chairman)

Derek Widmayer (DFO)

**Law Office of Charles T.
Simmons, LLC**

Charles Simmons

NRC Staff

Jim Dana

Kim Morgan Butler

Gary Comfort

Mark Thaggard

Andrew Carrera

Kathryn Brock

Candace Clemons

Vanessa Cox

John Klos

The presentation slides used during the open portions of the meeting are attached to the transcript of this meeting at the following website: <http://www.nrc.gov/reading-rm/doc-collections/acrs/tr/subcommittee/>. The presentations to the Subcommittee are summarized below. Apart from the presentation by Mr. Simmons, there were no additional requests by members of the public to make written or oral statements.

MAY 18, 2010 - OPENING REMARKS BY CHAIRMAN RYAN

Chairman Michael Ryan brought the meeting to order and announced that it is a meeting of the Subcommittee on Radiation Protection and Nuclear Materials. Derek Widmayer of the ACRS is

the Designated Federal Official for this meeting. Chairman Ryan indicated that the purpose of this meeting is to inform the Subcommittee about the staff's plan to amend 10 CFR Part 40, Domestic Licensing for Source Material, to require specific licenses for the initial distribution of source material to exempt persons and to persons operating the general license for small quantities of source material, 10 CFR 40.22. The proposed amendment would modify the existing possession and use requirements for a Part 40.22, general license, to better align the requirements with current health and safety and security standards. Finally, the proposed amendment would revise, clarify, or delete certain product exemptions in 10 CFR 40.13, unimportant quantities, to make the exemptions more risk informed. This rule would affect manufacturers and distributors of certain products and materials containing source material and certain persons using source material under general license and under exemptions from licensing. The proposed rule has not undergone public comment.

Chairman Ryan stated that the Subcommittee will gather information, analyze relevant issues and facts, and will formulate proposed positions and actions for the full Committee to deliberate. The rules for participation in the meeting were announced as part of the notice of this meeting previously published in the Federal Register. Chairman Ryan noted that, later in the day under stakeholder comments, the subcommittee would hear from Mr. Charles Simmons. The subcommittee has received no additional written comments or requests for time to make oral statements from members of the public, and there were no requests for people to participate via a bridge phone line. Chairman Ryan then introduced Mr. Andrew Carrere of the Office of Federal and State Materials and Environmental Programs (FSME), who was making the first presentation.

STAFF PRESENTATION - Proposed Rulemaking on Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions

Mr. Andrew Carrera summarized the topics to be discussed during the presentation. He first planned to do a general discussion on 10 CFR Part 40 and current general license and exemption conditions. He planned to follow this with a brief discussion on the history of this particular rulemaking, and then would discuss why the rulemaking is necessary by describing problems with the current Part 40 rule and how those can be resolved through the proposed rulemaking. He also will introduce specific questions that will be posed to the public.

Source material is ore containing greater than 0.05 percent by weight of uranium or thorium. Source material does not include anything that would be considered special nuclear material. There is a significant difference between source material and most everything else NRC regulates in that uranium and thorium exist throughout nature. Most other radioactive materials NRC regulates are generated by humans and therefore can be more easily controlled from cradle to grave. However, source material can be generated without a person realizing it because it comes under NRC's jurisdiction after the uranium or thorium is removed from its place in nature.

NRC regulates source material under 10 CFR Part 40 in 3 ways: Under specific license, under general license or through issuance of exemptions for products. Most materials and products that are provided an exemption are determined to present an insignificant impact to public health and safety without further regulation. Normally, they have no additional requirements for safe use when possessed by the general public and they are allowed to be disposed of without restriction. The NRC does not generally know who possesses radioactive materials under the

exemption, and in the case of source material, does not know how much material is distributed for possession and use under an exemption.

General licenses fall in a space between specific licensing and exemptions. Whereas, a specific license requires an application to the NRC to become a licensee, a general license is granted to any person without an application to the NRC as long as they meet the underlying conditions of the general license. Requirements under a general license can vary from exemption-like to having a number of conditions for operation. As we'll see shortly, not all general licenses currently have reporting requirements and so NRC may not be directly aware of all persons who possess radioactive material under a general license.

One of the areas that the staff is proposing to revise in the rulemaking is the general license from small quantities of source material in Section 40.22. Section 40.22 currently provides a general license to commercial and industrial firms, research, educational and medical institutions, and Federal, State and local government agencies to use and transfer not more than 15 pounds of source material at any one time and no more than 150 pounds total in any one calendar year for their operational purposes. If a person can operate within these limits, they are exempted from the requirements in Parts 19, 20, and 21 which basically cover training and notification, health and safety, and reporting of defects and non-compliance. These exemptions apply unless the general licensee already has a specific license issued under Part 40. This general license includes no reporting or registration requirements and so NRC has no easy way to identify persons operating under this general license. Because of the minimal operating requirements and lack of reporting and registration requirements, this general license operates similar to an exemption.

Exemptions for licensing are found in Section 40.13 and are known as "unimportant quantities". Persons are exempt from the requirements to obtain a license. Under NRC's consumer protection policy, product exemptions should only be able to impose a small fraction of NRC's public dose limit to persons possessing the products. There are three major categories of exemptions in Part 40. Section 40.13(a) exempts persons possessing uranium and thorium in concentrations less than 0.05 percent by weight of the source material. Section 40.13(b) exempts persons possessing unprocessed source material. And section 40.13(c) which are essentially product exemptions. The proposed rule deals solely with the exemptions in section 40.13 (c).

Although the NRC staff was already considering revisions to Part 40, in 1999, the State of Colorado and the Organization of Agreement States submitted a petition for rulemaking, and designated as PRM-40-27. In their petition, they identified concerns regarding the use of source material under the general license granted under §40.22. In particular, the petitioners were concerned that general licensees are exempted from meeting the requirements of Parts 19 and 20, despite the fact that situations exist where use of the material could result in exposures to workers above 100 mrem per year. In the same year, the staff proposed multiple activities associated with Part 40 to the Commission as part of SECY-99-259. One of the activities that the staff recommended was to develop a rulemaking plan for possible changes to the section 40.22 general license. In 2000, the Commission directed, among other directions, for the staff to move forward on developing the rulemaking plan. The rulemaking plan that the staff developed discussed issues with the current general license in section 40.22 and introduced numerous options in how to proceed. These options included just addressing PRM-40-27

(which I mentioned earlier), or just implementing distribution reporting to gather information before we did a bigger rulemaking to address concerns with section 40.22. In addition, the staff offered options for a more complete rulemaking which would both resolve issues with section 40.22 and impose new distributor reporting requirements. The rulemaking plan was submitted in April of 2001.

Also in 2001, the staff finalized NUREG-1717 which included an assessment of the exemptions in Part 40. These findings resulted in development of recommendations for revising the exemptions in Part 40 which were submitted to the Commission as SECY-02-0196 in 2002. The staff informed the Commission that they would make any revisions to exemptions in Part 40 in conjunction with the rulemaking described in the 2001 rulemaking plan.

It was not until June of 2003 that the Commission returned a staff's requirement memorandum (or SRM) on the Part 40 rulemaking plan which directed the staff to not make changes to sections 40.13 or 40.22 at this time, but to instead try to collect more data to support a rulemaking. This was despite the fact that the staff had informed the Commission about the difficulties of collecting data about the operations under a general license without having a requirement for reporting.

As a result of the Commission's direction, the staff began to try to collect data about general licensees. Through a search of NRC records, the staff had identified that in 1986; the staff had requested and received 3 years of distribution reports from 6 specific licensees who distributed source material to general licensees. However in 2004, the staff learned that 5 of those 6 specific licensees were no longer in business. The staff contacted the remaining distributor and was obtained distribution reports for the 3 previous years. In addition, the staff obtained the services of Pacific Northwest Laboratories (PNNL) to identify general licensees and how source material was used. PNNL's data indicated that the major use of source material was in the manufacture of thorium coated lenses and proceeded to contact 9 manufacturers to evaluate their practices. PNNL provided a final report of their findings in 2007.

Around the same time that PNNL was doing their evaluations, the staff developed and submitted SECY-06-0094 on tracking or providing enhanced controls for category 3 sources to the Commission. One of the issues identified in SECY-06-0094, as mentioned earlier, was that certain isotopes of uranium and thorium could be possessed in quantities that exceeded category 1 of the IAEA Categorization system under the section 40.22 general license, and therefore without the NRC's knowledge. In light of 9/11, that immediately represented a security and safety issue. As a result, the staff recommended that the rulemaking envisioned in the 2001 Rulemaking plan be restarted to address this concern. In their SRM, the Commission approved the recommendation and directed the staff to amend the general licensees in 40.22 and associated manufacturer requirements. In 2007, the staff provided the Commission with an information paper that included the data that had been collected on source material general licensees to date and the results of PNNL's evaluations. The information also described what the staff planned to accomplish in the proposed rulemaking. These efforts culminated in the staff providing the proposed rule package to the Commission in late December, 2009.

Mr. Carrera then listed some issues with the current requirements in Part 40 and how NRC plans to resolve them through the section 40.22 rulemaking. These issues include potential health and safety impacts in section 40.22 are not fully in alignment with health and safety

standards in 10 CFR Part 20. There is a lack of complete and timely information on the types and quantities of source material distributed for use either under exemption or by general licensees, changes in how some products are used under exemption, and finally there is a lack of clarity in certain requirements in Section 40.22 such as waste disposal.

The staff's first concern with Part 40 was to determine if the current regulatory structure was consistent with the current radiation safety requirements in 10 CFR 20. The regulations for source material in Part 40 have not been significantly revised since 1961. Although the health and safety regulations in Part 20 were revised in 1990, the impact of these revisions on Part 40 were never fully evaluated.

In addition, the International Atomic Energy Agency (IAEA) has categorized radioactive sealed sources according to the potential for radiological consequences. The IAEA categorization system is based on the potential for radioactive sources to cause deterministic health effects, without any regulatory controls in place. After evaluations for security reasons, NRC identified that persons could possess certain isotopes of Uranium and thorium (U-232, Th-228, and Th-229) under the 40.22 general license that could result in quantities what would fall under Category 1 of the IAEA Categorization system. Although the staff is unaware of these isotopes being used in discrete quantities, it is a concern because we have no method to identify general licensees under this section, nor what materials they are using.

In January 1999, the Colorado Radiation Control Program was notified that a dumpster had activated a radiation alarm at a landfill. The dumpster had been used for construction debris resulting from a remodeling project after a source material general licensee had vacated the facility. After exposure levels on the dumpster exterior was measured 4.9 mR/hr, an investigation revealed that it was a source material general licensee who was responsible for the radioactive material. According to the petitioners, further investigation found the licensee ensured that its procurement did not exceed the 150-pound (68kg) per year limit specified in 10 CFR 40.22(a), had vacated the building with contamination [calculated at 734 mrem/year] that exceeded the 25 mrem annual limit for release for uncontrolled use, and had significant levels of exposure to thorium and its daughters at its current facility. As a result of these findings, the petitioners requested in PRM 40-27, that Section 40.22 be modified to remove the exemption in 10 CFR 40.22(b) to Parts 19, 20, and 21, so that this and all other general licensees who use similar quantities of source material would have to meet the same health and safety requirements for specific licensees.

To resolve concerns with the current section 40.22 being not aligned with current health and safety standards, the staff proposes to make significant revisions to section 40.22. The current general license allows the possession and use of up to 15 pounds of source material at any one time and receipt of up to 150 pounds per year, independent of form or use. The first significant revision the staff is proposing is to limit source material covered under this general license to uranium and thorium in its natural isotopic concentration or in the form of depleted uranium. This would remove the possibility that a person could possess category 1 or 2 quantities of source material under the general license.

Secondly, the staff found that the biggest impacts from the use of source material resulted from the processing of dispersible source material primarily because of the ingestion and inhalation pathways. The PNNL report indicated that it was possible for doses to persons operating under

known operations to approach 1 rem per year and could exceed this level in other less likely bounding scenarios. Although it is expected that most general licensees may implement procedures to maintain doses well below this level, the staff believes that the reduction of possession limits would best ensure that these materials are safely handled without adequate training. Currently, specific licensees are required under Part 19 to provide training to persons who could potentially receive in excess of 100 mrem per year. Because of the exemption to Part 19, general licensees do not have this requirement, despite the fact that there are potential scenarios where 100 mrem per year could be exceeded. Rather than revoke the exemption to Part 19 and require a general licensee to obtain the expertise to evaluate whether their operations may exceed 100 mrem/yr, the staff is proposing to limit possession of source material under the general license to levels where they are unlikely to exceed 100 mrem per year. By limiting the amount of source material a general licensee can possess, it is possible to limit the risk associated with inadequate training.

The staff is proposing to reduce the possession limits for source material to 1.5 kg (or 3.3 pounds at one time down from 15 pounds) and receive up to 7 kg (or 15.4 lbs down from 150 pounds) per calendar year. However, if the source material is possessed in a solid non-dispersible form or accumulated from the treatment of drinking water to remove uranium, the licensee could continue to possess up to a total of 7 kg (15 pounds at one time) and receive up to 70 kg (170 pounds) per year. The staff believes that these uses have been sufficiently evaluated to reduce the likelihood that excessive doses would occur to workers or the public from these latter forms or uses. General licensees would continue to remain, to the most part, exempt from the requirements in Parts 19, 20, and 21. Although this may result in some general licensees requiring specific licenses, it is expected the majority of larger users are likely distributors of exempt products which would be required to obtain a specific license under proposed new distributor requirements.

The staff is also proposing to require the general licensee to ensure that their facility minimizes contamination during operations. This should help limit the amount of contamination remaining when operations cease. However, when a section 40.22 general licensee ceases operations, if they identify that there is the potential that significant levels of contamination occurred, the general licensee would notify NRC (or the Agreement State) to determine what actions are necessary and to allow the regulator to confirm additional cleanup if necessary. Currently, because of the exemption to Part 20, a general licensee may decide that they have no obligation to clean up their facility and instead abandon it in place (such as that identified in PRM-40-27).

Implementation of this proposed requirement would help regulators in two ways: (1) it would provide the regulator with a clear trigger to call a former licensee back to restore an abandoned site if significant contamination is found after the site is abandoned and (2) because many general licensees may take precautions and speak with NRC because of this provision, we would be better able to identify those general licensees that cease operations. It is expected that the regulatory burden from this provision would be minimal because the number of general licensees ceasing operations that possessed large enough quantities of source material under this general license to warrant a concern about contamination will be small in any one year.

The staff found Issue number 2 to be one of the biggest problems in developing this rulemaking, i.e., the lack of available information about what quantities of source material were being

distributed to persons for use under the 10 CFR 40.22 general license and how the source material was actually being used under exemption. Currently, there are no regulatory mechanisms for the Commission to ensure that products and materials distributed for use under the general license in § 40.22 or use under exemption are maintained within the applicable constraints of the requirements for these uses. This is inconsistent with how NRC handles Part 30 byproduct material where there are requirements for distributors to be specifically licensed by NRC (for all byproduct material being used under exemption) or by NRC or an Agreement State for distributions of byproduct material for use and possession under general license. Even the general license in 40.25 for source material requires manufacturers of materials to be possessed by under 40.25 to be specifically licensed and for reports of transfers to and from 40.25 general licensees to be reported to NRC.

Because the staff cannot readily identify who possesses source material under a general license or how and in what quantities the source materials are being used, the staff cannot fully assess the resultant risks to public health and safety from the use of source material. To resolve the issue with lacking of complete and timely information on the types and quantities of source material distributed for use either under exemption or by general licensees, the staff proposes two new specific licenses for initial distribution of source material: one for initial distributors of source material to exempt persons under a newly proposed section 40.52 and the second is for initial distributors of source material to general licensees in a newly proposed section 40.54.

The proposed new specific license for initial distribution to exempt persons would only be issued by the NRC for initial distributors in Agreement States (although those persons located in Agreement States would still be licensed by the Agreement State for possession and use). The category of initial distributors could include manufacturers or importers of exempt products containing source material. Both importers and persons in Agreement States would be exempt from requirements in Parts 19 and 20, although it is expected that the Agreement States, who would be responsible for protecting public health and safety in their States, would likely require such initial distributors to obtain specific licenses from the Agreement State. Manufacturers of exempt products located in non-Agreement States would also be required to be specifically licensed by NRC for possession and use with all the associated requirements.

The distribution license would implement quality assurance requirements that exempt products be manufactured and labeled consistent with the requirements of any exemption that applies. In addition, initial distributors would be required to report annually about the types of products distributed, the quantities of products distributed, and the source material type and content in the products. The staff would use this information to better understand how much source material is being distributed to the public and in what forms to better ensure that the evaluations supporting the exemptions are reasonable.

It should be noted that these new requirements may force some persons manufacturing exempt products under the 40.22 general license (such as thorium coated lens manufacturers) to become specific licensees. In addition, it is expected that the import of exempt products containing source material would be reduced or centralized through a smaller number of importers because of the licensing fees that would apply. Similarly, the initial distribution of source material to general licensees would also require a specific license, issued either by NRC or an Agreement State. This new license would require the initial distributor to label the material

and provide quality control so that the recipient knows what they are receiving. In addition, prior to or with the first shipment of source material to a general licensee, the distributor would be required to include information that notifies the recipient about the requirements of the general license and appropriate safety precautions for handling, use, storage, and disposal. The staff has concerns that some persons receiving source material may not even be aware that they are operating under a general license.

Finally, the distributor would be required to provide annual reports not only to the Agency that is licensing them (either NRC or an Agreement State), but also to any Agreement State (and the NRC if the distributor is located in an Agreement State) where the source material is sent. The reports would include the quantity and types of source material that was distributed by quarter and to whom it was distributed, including contact information. This would allow the NRC and the Agreement States to better identify what persons are operating under a general license for source material and these persons could be contacted to better understand how it is being used and to ensure that it is being safely possessed and disposed of.

These new requirements would not allow NRC to identify all general licensees. Neither secondary recipients of source material from other general licensees, nor those that generate their own source material (such as water treatment facilities), would be able to be identified through these new requirements; however, the staff believes that these new requirements will help NRC to identify and better understand how most source material is used under the general license to better ensure public health and safety while providing minimal additional impact to general licensees themselves.

With issue number 3, after its review of NUREG-1717, the staff determined that the original use of certain products possessed under the exemptions in 10 CFR 40.13(c) have changed over time. As a result, the staff is proposing to revise certain exemptions to address those changes. Some products are no longer being manufactured or as in the case of uranium smoke detectors never were manufactured. The staff determined that removing the exemption for future distribution of such products would be more protective of health and safety with no impact to industry. Similarly, certain products do not contain as much source material as was originally permitted under the exemption. As a result, the staff is proposing to reduce the allowed concentrations of source material without impacting current manufacturers.

Finally, the staff found that some products have changed over time and the exemption doesn't fit the product anymore. In this case, the staff proposed to expand the exemption to fit the new products after a safety evaluation was completed indicating that the newer products provided less potential impact to health and safety than the originally exempted product. First, the staff is proposing to remove the exemption for uranium smoke detectors. The staff is unaware of any product that has ever been distributed under this exemption and believes there is no reason to continue to allow it. Second, the staff would prohibit further distribution of glazed ceramic tableware. The staff is unaware of any products currently being newly distributed. The staff's evaluation indicated that the possibility of ingestion could result in doses in excess of a small fraction of the public dose limit which is NRC's policy or exemption of products. Products already distributed would continue to be exempt. Next, the staff would reduce the allowable concentration of source material in glassware from 10 percent by weight to 2 percent by weight of source material. These would include things such as glass figurines or other show pieces (mostly containing uranium for its greenish tint and the novelty of displaying it under ultraviolet

lighting). The staff is unaware of products currently being distributed above this new limit. Previously distributed products would continue to be exempt.

The biggest revision is proposed for the product exemption in section 40.13(c)(7). This exemption applies to thorium contained in lenses up to 30 percent by weight. Industry practice has changed from homogeneously incorporating the thorium in the lens to instead coating the lens with thorium. This has led to numerous questions about the applicability of the exemption to coated lenses. The staff's evaluation found that significantly less thorium is applied in a lens coating than when incorporated homogeneously throughout the lens, and thus results in an even lower potential dose. Therefore, the staff is proposing to expand the exemption to specifically apply to thorium coated lenses. The staff also has found that such coatings are also applied to mirrors and believes it is appropriate to allow such use under the exemption. The staff learned that uranium may also sometimes be used as part of the coating and so the staff proposes to expand the exemption to include uranium. Finally, the staff found that current practices generally maintain concentration on lenses to less than 10 percent by weight and so the staff is proposing to reduce the concentration limit for lenses to this lower limit. Again, previously distributed products would remain exempt. The staff hopes that the public would provide comments during the comment period during for the proposed rule if products are still being distributed above the proposed concentration reductions.

Finally, issue number 4, the staff over time has learned that there are a few issues that aren't particularly clear in how they should be addressed in section 10 CFR 40.22. The first item is what are the waste disposal requirements, if any under the Section 40.22 general licensees? For example, because a general licensee is exempt from Part 20 which contains NRC's requirements for disposal of source material, many general licensees have concluded that they can dispose of their wastes (or abandon them) without further consideration. However, this leads to the recipient of such wastes unknowingly being in possession of the source material such that they eventually could become required to obtain a specific license. In real terms, although a general licensee is exempt from Parts 19, 20, and 21, they are not exempt from the remaining requirements in Part 40. For example, the transfer provisions in 10 CFR 40.51 apply to all licensees (including general licensees) and would limit the transfer of material to someone who is authorized to receive it under specific license, general license, or exemption. As a general licensee cannot know how much material a recipient has, they should not arbitrarily dispose of materials as the recipient may exceed general license quantities and not be able to legally receive the additional source material without obtaining a specific license.

To resolve concerns in the area of source material waste disposal requirement, the staff propose to implement new requirements for disposal to ensure that contamination and abandonment of source material possessed by general licensees become less of a concern. The staff is proposing revision in section 40.22 to clarify certain activities, including specific requirements that a general licensee not abandon source material and to properly dispose of the material. The staff is allowing a general licensee to transfer up to 0.5 kg per year for permanent disposal (for example to a landfill that is willing to take it) in a solid, non-dispersible form and would exempt the recipient from requiring a license. Disposal of source material above this level would be required to be consistent with the requirements for disposal in Part 20. These requirements would allow small users (such as educational institutions) to safely and economically dispose of source material. The staff also proposes to include direct citations in 40.22 to other sections in Part 40 to make sure the general licensee is better aware of the additional regulations that have always been applicable to a general licensee under Part 40.

During the rulemaking, the staff identified certain areas where public insight would be helpful in directing our future course of this rulemaking or other related issues that may be considered for rulemaking in the future. As part of the Federal Register Notice requesting comment on the proposed rule, the staff is soliciting comments on certain open issues. First, is a concentration limit appropriate for coatings on a lens, when the concentration can easily be reduced by increasing the lens size? Should NRC instead implement something such as an activity limit, and if so what should that limit be? Similarly, should NRC limit the section 40.22 general license by activity limit rather than total weight of source material?

One of the concerns about the section 40.22 general license was source material contamination being abandoned at a site. Although the staff is proposing to require that contamination be examined when ceasing activities at a site, NRC is asking if surveys should always be required. The staff is also soliciting comments for potential future rulemaking topics. For example, should the section 40.22 general license be expanded to include 11.e (2) byproduct material and if so how should it be implemented? Currently, a lab requires a specific license just to evaluate even small samples. Also, should provisions be added to require sealed sources containing source material or special nuclear material be included in the sealed source and device registry. Currently there is no such requirement.

Finally, there is a general license in Section 40.25 which applies to the use of products or devices that have the purpose of providing a concentrated mass in a small volume (such as shielding). However, the manufacturing requirements in Section 40.34 are considered overly burdensome, so this general license has not been used much. NRC is aware of only one specific licensee who does manufacture such products for use under the general license. NRC is asking if we should modify the manufacturing requirements and broaden the general license to make it easier for persons to obtain licenses for manufacturer of such devices?

The proposed rule changes are expected to increase health and safety to the workers and the general public through the reduction of the limits allowed under the section 40.22 general license for dispersible forms and processing of source material and by providing clarification for disposal, limiting contamination, and making general licensees more aware of other requirements that apply to them. The new distribution licenses will allow NRC to better understand and react to the use of source material under exemption and general license. This new information would allow NRC to better refine the regulations to adapt to changing situations, by both reducing allowed activities or expanding them as the staff better learns how source material is being used.

Questions Raised by the Subcommittee

The following is a list of questions raised during the staff briefing that may be examined in more detail in a future briefing:

- There are three major categories of exemptions in Part 40. Section 40.13(a), exempt person possessing uranium and thorium in concentrations less than .05% of weight of source material. What is the basis for the value 0.05%?
- The PNNL report has been described as analyzing bounding but realistic scenarios for public exposure. These concepts seem mutually exclusive - how can an analysis be bounding if it represents a realistic scenario? What can usefully be learned from a "bounding" analysis?

- Are there provisions for a licensee to do an alternate assessment of dose calculations in the proposed rule? This situation could arise for future licensees doing work with source material that is different from historic uses.
- Under what conditions would a licensee need to do a “closure” survey after their commercial operation ceases?
- Where would imported gemstones fit into this regulatory framework?
- Are there any dose consequences from leaching of uranium from certain ceramic glazes or glassware?
- For lens coatings made with source material, how resistant is the coating to abrasion?
- If a laboratory is already licensed to receive source material, why would they need a general license? They don’t have to apply for it, so why would such a lab need this license?

Public Comments

Presentation by Charles Simmons – NRC 40.22 Rulemaking: Unintended Consequences

Mr. Simmons identified himself as an attorney practicing in Washington, D.C., who has worked in the minerals industry for approximately 20 years. The theme of his presentation was that the proposed rulemaking may have unintended consequences for industry in the U.S. The first part of his talk included background discussion of NORM and TENORM regulation in the U.S., along with a review of many definitions (e.g., source material, unimportant quantities, unprocessed ore, byproduct material, TENORM, etc.). Mr. Simmons then presented information about regulatory issues that arose in the State of Oregon and in several court cases in various states.

Mr. Simmons identified recommended several key sources of information that the staff could look at for technical information relevant to the rulemaking. There is a lot of potential documentation coming out of Europe that could be very useful. Each member state of the European Union has gone about this in a different way. Data have been collected in France since about 2005 when the French Ministry of Labor issued a directive to ten identified NORM industries to start collecting data. Currently the European basic safety standards and several different directives are being recast or rolled into one, including Directive 9629, and it is a wholesale revision of the European basic safety standards, which involves a great deal of data analysis and collection from the so-called NORM industries. Mr. Simmons suggested that various groups be apprised of the rulemaking, including the American Ceramics Society, the Investment Casting Institute, and the Tantalum Niobium Information Council, based in Brussels, which keeps track of some of these issues. The IAEA has written much about natural materials.

Mr. Simmons noted another good source of information. Dennis Wymer published a paper at the NORM V conference in Seville, Spain in 2008 that evaluates doses from natural materials in workplace settings. The paper points out that modeling only goes so far. One needs to obtain information from sampling workplace exposures because, in particular with natural materials, it is easy to overestimate doses, that occupancy times, dust loadings, particle sizes and particle size distributions are often assumed using default values that tend to dramatically overestimate doses.

After Mr. Simmons presentation, there being no additional public comments, Chairman Ryan closed the record. (Whereupon, the above-entitled Subcommittee meeting on Radiation Protection and Nuclear Materials was concluded at 11:38 a.m.)