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Radiation Protection and Nuclear Materials
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UNITED STATES OF AMERICA

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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON REACTOR SAFEGUARDS

(ACRS)

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SUBCOMMITTEE ON RADIATION PROTECTION AND

NUCLEAR MATERIALS

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TUESDAY,

MAY 18, 2010

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ROCKVILLE, MARYLAND

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The Advisory Committee met at the Nuclear Regulatory Commission, Two White Flint North, Room T2B3, 11545 Rockville Pike, at 8:30 a.m., Dr. Michael T. Ryan, Chairman, presiding.

COMMITTEE MEMBERS PRESENT:

MICHAEL T. RYAN Chairman

ACRS STAFF PRESENT:

DEREK WIDMAYER, Designated Federal Official

ALSO PRESENT:

JIM DANA, FSME

ANDREW CARRERA, FSME

GARY COMFORT, FSME

DUNCAN WHITE, FSME/MSSA

SOLOMON SAHLE, FSME/DILR

CANDACE J. CLEMONS, FSME/DILR

JOHN KLOS, FSME/DILR

KIM MORGAN MUTLER, FSME/DILR

MARK THAGGARD, FSME/DILR

KATHRYN BROOK, OEDO

VANESSA COX, FSME/DILR

CHARLES T. SIMMONS, ESQ.

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P R O C E E D I N G S

(8:35 a.m.)

CHAIRMAN RYAN: Okay. If I could have everybody's attention, the meeting will now come to order.

This is a meeting of the Radiation Protection and Nuclear Materials Subcommittee. I am Mike Ryan, Chairman of the Subcommittee. Other ACRS members who will be in attendance shortly are Jack Sieber and Dennis Bley.

Derek Widmayer of the ACRS is the Designated Federal Official for this meeting.

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 effect 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.

The Subcommittee will gather information, analyze relevant issues and facts, and will formulate proposed positions and actions, as appropriate, for the full Committee to deliberate.

The rules for participation in today's meeting have been announced as part of the notice of this meeting previously published in the Federal Register. Later today under stakeholder comments will hear from Mr. Charles Simmons of Thompson & Simmons, located in Washington, D.C.

We have received on additional written comments or additional requests for time to make oral statements from members of the public regarding today's meeting.

We have received no requests for people to

participate via a bridge phone line regarding today's meeting.

A transcript of the meeting is being kept and will be made available as stated in the Federal Register notice. Therefore, we request that participants in this meeting use the microphones located throughout the meeting room when addressing the Subcommittee.

The participants should first identify themselves and speak with sufficient clarity and volume so they may be readily heard.

We will now proceed with the meeting and the presentations by the staff. We will hear first from Mr. Andrew Carrera of the Office of Federal and State Materials Environmental Management Programs.

Welcome.

MR. CARRERA: Good morning ACRS Committee members and staff and Charlie Simmons and members of the audience. My name is Andrew Carrera and I work in the Office of Federal and State Materials Environmental Management Program in the Division of Intergovernmental Liaison and Rulemaking.

Today I'm here to brief you on our efforts to develop proposed rulemaking on the distribution of source materials to exempt persons and to general

licensees as well as proposed revision to the general license for small quantities of source materials and some proposed changes to certain product exemptions in 10 CFR Part 40.

Before I begin, I would like to ask for your indulgence so that I may read from my prepared script. It is going to be a long presentation.

Also, I have with me Mr. Gary Comfort, Cathy Mattsen, and Branch Chief Jim Danna. They are the experts in this particular rulemaking and are here to help me answer any questions that you may have. Additionally, I would like to correct -- make a correction to the meeting notice. The correct SECY reference number is SECY, S-E-C-Y-09-0179.

CHAIRMAN RYAN: Just say that one more time just to make sure we all have it right please.

MR. CARRERA: Yes, one more time, SECY-09-0179.

CHAIRMAN RYAN: Okay. Thank you.

MR. CARRERA: Next slide please.

And during this discussion, I plan to cover a number of topics. First I plan to briefly discuss in very general terms only background of Part 40 and current general licensing exemption conditions.

I'll follow this with a brief discussion

on the history of this particular rulemaking. Then I'll discuss why we believe the rulemaking is necessary by describing the problems we see with the current Part 40 rule and how we proposed to resolve these issues through the proposed rulemaking.

Finally, I'll introduce specific questions that we plan to solicit from the public.

Next slide please. We will move forward with the background information on 10 CFR Part 40 and current general license and exemption conditions.

Slide 4 please. As these slides indicate, the purpose of Part 40 is to establish regulations for use and possession of source material and byproduct material. However, this particular rulemaking only deals with source material.

Next slide please. The book of the regulation in Part 40 applies towards possession and use of source material. So what is source material? Source material is defined as uranium and thorium ores containing greater than .05 percent by weight of uranium or thorium. Source material does not include anything that would be considered special nuclear material. In other words, enriched uranium.

There is a significant difference between source material and most everything else that NRC

regulates in that as we all know, uranium and thorium exists throughout nature. Most other radioactive materials NRC regulates are generated by men. And, therefore, can be more easily controlled from cradle to the grave.

However, source material can be possessed with a person realizing it because it comes NRC's jurisdiction after the uranium or thorium is removed from its place in nature.

Slide six please. NRC regulates source materials under Part 40 in three basic approaches: under specific license, under general license, or through issuance of exemptions for products. I've listed a few examples of activities or products that would fall under each category.

However, this proposed rulemaking would primarily effect activities associated with general license and exemption. Although most people working with NRC understand what a specific license is, many people are more confused about how general license and exemption works.

So what are general license and exemptions? And I will start with exemption. 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 general public. And they are allowed to be disposed of without any restriction.

NRC does not generally know who possesses radioactive materials under exemptions. And in case of source material, does not know how much material is distributed for possession and use under an exemption.

General license, general license falls in a space between specific license 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 a general license.

Requirements under general license can vary from exemption like to having a number of conditions for operation. As we'll see shortly, not all general license currently have reporting requirements. And so NRC may not be directly aware of all persons who possess radioactive materials under a general license.

CHAIRMAN RYAN: Andrew, are you going to talk a little bit more about water treatment

facilities in the special place there -- radium, uranium, and other constituents?

MR. CARRERA: Water treatment facilities, sir, yes. That will be discussed later.

CHAIRMAN RYAN: Okay. You're going to get to that. All right. Great.

MR. CARRERA: And how they are not required to comply with the proposed new regulation.

CHAIRMAN RYAN: Right.

MR. CARRERA: Next I'll discuss the current general license and exemption condition, which we are proposing to revise under this proposed rule.

Next slide please. One of the areas that the staff is proposing to revise in our 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 medication institutions, and federal and 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. And this is for their operational purposes.

If a person can operate within these limits, they are exempted from the requirements in

Part 19, 20, and 21, which basically covers training and notification, health and safety, and reporting of defects and noncompliance.

These exemptions apply unless a 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 requirement, this general license operates similar to an exemption. I'll discuss why this presents problems for the staff when I get into discussion about the proposed rulemaking.

Slide number eight please. Exemptions for licensing are found in Section 40.13 and are known as unimportant quantities. Persons receiving these products are exempt from requirements to obtain license. Under NRC 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), exempt

person possessing uranium and thorium in concentration less than .05 percent of weight of source material. Section 40.13(b) exempt person possessing unprocessed source material. And Section 40.13(c) which are essentially product exemptions. The proposed rule deals solely with exemption in 40.13(c).

Next slide.

CHAIRMAN RYAN: Just a question on this .05 percent by weight. What's the basis for that. I mean I've always thought of it as simply a number below which it is difficult to recover uranium from ore economically.

So from a health and safety perspective, I don't see much difference between .049 and .051. So can you help shed some light on why this .05 percent by weight is still carried forward?

MR. COMFORT: Our understanding, I mean historically, is basically that it was a number developed when Part 40 was originally delegated in the 1946 act, I guess, or `47, I can never remember what years those are.

CHAIRMAN RYAN: `54 -- 40 was the original Atomic Energy Act.

MR. COMFORT: Yes. And basically when they set in in there, there was no regulation of

health and safety put into the act at that point. It was purely for national security to make sure there was material available for government use.

And then it came under, you know, availability when it was taken from the ground. So the .05 percent was purely, at that point, an economic, you know how easy was it to remove it from the ores at that point.

When the act was changed in `54, they did add health and safety requirements into the act. But when Part 40 was modified in 1959, they decided to keep the .05 percent. And we haven't been able, in our research, to make a real good determination if there was much of a health and safety evaluation with that number at that point.

CHAIRMAN RYAN: I think that's an important perspective on that number. You know the original McMahon Act really dealt with the strategic value of the materials that it regulated. And, you know, we're superimposing on that, of course, the health and safety structure.

So it is important to ascribe, I think, the right meaning to numerical values and based on their origin rather than based on what we currently think in terms of health and safety today.

Would you think that's a fair assessment?

MR. COMFORT: I think it's a good assessment, yes.

CHAIRMAN RYAN: Okay.

MR. CARRERA: That was Mr. Gary Comfort, ladies and gentlemen.

You have to state your name before you speak.

Slide number nine please. Now that we have a general idea of what Part 40 covers and what are the conditions for a general license and exemption, let's go back in history and follow the journey of Section 40.22 rulemaking up to this point.

Next slide please. The journey can actually be followed much further back as we had a number of starts and stops in modifying Part 40. But I'll start our discussion of this particular journey in the late 1990s.

Although NRC has already considered revision to Part 40, but in 1999 the State of Colorado and the organization of agreement states submitted a petition for rulemaking designated as PRM-40-27. In their petition, they identified concerns regarding the use of source materials under a general license granted by Section 40.22.

In particular, petitioners were concerned that general licensees are specifically exempt from meeting the requirements of Part 19 and 20, despite the fact that situation exists where the use of materials could result in exposures to workers above 100 millirems per year. And I will discuss the details of PRM-40-27 in later slides.

And in the same year, the staff proposed multiple activities associated with Part 40 to the Commission as part of a SECY paper, SECY-99-259. One of the activities that the staff recommended was to develop a rulemaking plan for the possible changes to Section 40.22, general license.

And in 2000, the Commission directed, among other things, 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 forward.

These options include 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 concern with Section 40.22. In addition, the staff offered up options for a more complete rulemaking, which would

both resolve issues in Section 40.22 and impose new distributor reporting requirements. This rulemaking plan was submitted in April 2001 to the Commission.

Next slide please. And also in 2001, the staff finalized NUREG-1717, which included an assessment of the exemptions in Part 40. These findings resulted, in part, in the development of recommendations for revising the exemption in Part 40, which were submitted the Commission as SECY paper, SECY-02-0196 in 2002.

The staff informed the Commission that it 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 the staff -- I'm sorry, the Commission returned the staff required memorandum, or SRM on Part 40 rulemaking, which directed the staff not to make changes to Section 40.13 or Section 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 operation under a general license without having a requirement for reporting.

Slide number 12 please. And 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 three years' worth of distribution reports from six specific licensees who distributed source materials to general licensees. However, in 2004, the staff had learned that five of those six specific licensees were no longer in business.

The staff contacted the remaining distributor and was able obtain distribution reports for the three previous years. In addition, the staff obtained the services of the Pacific Northwest Laboratories, also known as the PNNL, to try to identify general licensees and how source material was used.

PNNL's data indicated that the majority use of source materials was in the manufacture of thorium-coated lenses and proceeded to contacted nine manufacturers to evaluate their practices. PNNL provided a final report of their findings in 2007. And I will discuss part of that study in later slides.

Around the same time that PNNL was doing their evaluation, the staff also developed and submitted a SECY paper on tracking and providing

enhanced control for Category 3 sources to the Commission. One of the issues identified in the SECY paper was that certain isotopes of the uranium and thorium could be possessed in quantities up to Category 1 of the International Atomic Energy, or the IAEA categorization system, under the Section 40.22 general license and, therefore, without NRC's knowledge.

And in light of the 9/11 attack, 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 the SRM, the Commission approved the staff's recommendation. Among other things, directed the staff to amend the general license in Section 40.22 and its associated manufacturing 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 result of the PNNL evaluations. The information also described what the staff planned to accomplish in this proposed rulemaking. These efforts culminated in the staff's providing the proposed rule package that we are now

discussing to the Commission in late December of 2009.

Next slide please. Now that I have provided you with a basic understanding of what Part 40 encompasses, how it regulates source materials, and a history behind this rulemaking, are there any questions on what has been covered so far?

CHAIRMAN RYAN: Just a placeholder, I think, at this point, Andrew, I've got the PNNL report and I wrestled a little bit with the idea that we were going to create bounding but realistic scenarios for public exposure. Those seem mutually exclusive to me. How can it be a bounding analysis if it is a realistic scenario?

I know this is the dosimetric basis for some for the thinking you've committed. And I'd like to understand that picture a little bit better. I mean are we risk informed? Are we bounding case? Are we bounding but realistic? And I'm not sure what that means but if you could help me understand that a little at some point in the morning, that would be great.

MR. CARRERA: Yes. I remember when I went through this report, in the areas where they looked at source thorium exposures to routine use, accident, and manufacturers, they did say that it was a bounding

scenario. However, I thought it was -- in my personal experience, I thought they mislabeled that. You know, looking at the assumptions that they make, I thought it was very reasonable.

The bounding part of it comes later in the calculation where they look at a situation in a pottery shop where, you know, one person runs a small pottery shop with a low ventilation system, not as clean an environment as others. And no particular protection. Then I thought that would be, you know, just as far as a bounding.

CHAIRMAN RYAN: Again I think that's a little loose in terms of understanding exactly where we are in the risk profile. So maybe we can a little bit more about that later.

MR. COMFORT: We will get to that section.

CHAIRMAN RYAN: Okay.

MR. CARRERA: Okay.

CHAIRMAN RYAN: I mean I think it's important because the dose tables that result in this report are really the basis for you action. And so I think it's got to be crystal clear whether that basis is bounding, conservative, ultra conservative, not conservative, whatever it might be, you know, from an overall risk perspective. So that, to me, is kind of

a key point.

MR. CARRERA: Thank you.

Now let's look at what are the issues with the current requirements in Part 40 and how we propose to resolve them for the proposed Section 40.22 rulemaking. Slide number 14 please.

These issues include one, potential health and safety impacts to Section 40.22, which are not fully in alignment with health and safety standards in 10 CFR Part 40, and two, the lack of complete and timely information on the types and quantities of source material distributed for either use under exemption or by general licensees, three, changes in how some products are used under exemptions, and four, there is a lack of clarity in certain requirements in Section 40.22 such as waste disposal.

Next slide please. So in the next few slides, we'll go into the depth of each of these issues and how this rulemaking will resolve them. Let's first look at the first issue, the current health and safety impacts in Section 40.22 in greater details.

Slide number 16 please. The staff's first concern with Part 40 was to determine if the current regulatory structure in Part 40 was consistent with

the current radiation safety requirements in 10 CFR Part 20. The regulations for source materials in Part 40 have not been significantly revised since 1961.

After the health and safety regulations in Part 20 were significantly revised in 1990, the impacts of these revisions on Part 40 were never fully evaluated. In particular, as we'll discuss shortly, the staff is concerned that the general licensee for small quantities of source material in Section 40.22 may not be fully aligned with current radiation protection standards.

In addition, the IAEA has categorized radioactive sources according the potential for radiological consequences that a source poses. The IAEA categorization system is based primarily on the potential for radioactive sources to cause deterministic health effects without any regulatory control in place.

After the evaluation, for security reasons, NRC identifies a person who possesses certain isotopes of uranium and thorium. Examples are uranium-232, thorium-228 and 229. Under the 40.22 general license that could result in quantities that would fall under Category 1 of the IAEA categorization system.

Either the staff is unaware of these isotopes being used in discreet quantities, it is a concern because we have no method to identify general licensees under this section nor what the materials they are using.

CHAIRMAN RYAN: The IAEA categorization system really is a system to try and identify the risk sources falls under bad guy circumstances, people doing bad things for bad intent with the material. Yet we license on the assumption that people are going to do the right things with the materials. Do you see any disconnects there or difficulties with that strategy or comparison?

MR. COMFORT: If the material -- I mean I don't think that there is a big disconnect on it. It just means that the material that is going to cause a problem, you've got to have better oversight so the bad guys can't get it basically.

CHAIRMAN RYAN: Okay.

MR. COMFORT: You still having the licensing structure to do that. And that's part of what we're looking on this is even though we're not aware of anybody who even possesses these isotopes other than DOE might have a small -- you know a small, very, very small quantities of it, it's not used in

the commercial manufacture.

What we're trying to do is make it that, you know, without license, somebody shouldn't be manufacturing this stuff to start with so that those who do have it, we at least know who they are and where that source is going to come from. I mean this isn't going to be particularly easy material to create on their own, you know. I mean it's similar to, you know, enriched uranium, which there is difficult --

CHAIRMAN RYAN: And just to refresh you on those isotopes -- thorium --

MR. COMFORT: It's thorium-228, thorium-229, and uranium-232, they all have high specific activities.

CHAIRMAN RYAN: And they're pretty hard to come by.

MR. COMFORT: They're very hard to come by. It's just closing a loophole on that aspect of doing it. It's easier to say you can't have it under the general license. But we have no idea who has it. Rather than think that there is a real concern about it at this point.

CHAIRMAN RYAN: And that kind of covers the gap between the fact that the general license says uranium or thorium --

MR. COMFORT: Correct.

CHAIRMAN RYAN: -- and this, you're specifically talking the high specific activity isotopes out of that loop but not the others.

MR. COMFORT: Well, we're taking out any isotope other than depleted uranium. And basically saying if you want to use isotopic uranium or thorium, you've got to go through and get a specific license.

CHAIRMAN RYAN: As opposed to naturally-occurring thorium or uranium isotope mixes.

MR. COMFORT: Right.

CHAIRMAN RYAN: The language of how that's laid out has to be pretty precise to make sure it doesn't miscommunicate.

MR. SIMMONS: Totally agree.

CHAIRMAN RYAN: We have to go in order.

MR. SIMMONS: Okay.

CHAIRMAN RYAN: And please hold your comments until then.

MR. SIMMONS: Right.

CHAIRMAN RYAN: So I think that's a specific point, to me, that has to be just crystally-clear laid out in the rules to make sure that it's -- you know every understands that you are talking about specific isotopes under the question of question of a

security-kind of risk, which is a deterministic endpoint as you well pointed out, Andrew, versus the health and safety aspect of exposures in a work setting over a lifetime --

MR. COMFORT: Correct.

CHAIRMAN RYAN: -- of work. So I think some language, whether it is in the text or as notes to a table, or whatever it might be, that just nails that down so everybody clearly understands, that would be a real good way to get all of that across.

MR. CARRERA: Thank you.

MR. COMFORT: We hope that we've done that we'll get comments on it later.

CHAIRMAN RYAN: Okay, yes, okay, great. Anyway, on we go, sorry to interrupt.

MR. CARRERA: And as promised in the next two slides, I will discuss PRM-40-27 where we have a real live case and PNNL dose assessment report where we have a theoretical case of how health and safety of Section 40.22 general licensees may potentially be impacted by the current licensing condition.

Next slide please. PRM-40-27 --

CHAIRMAN RYAN: Just one more comment on the PNNL report, if I may, this is one version of a health and safety assessment for the use of these

materials. And, you know, they are really good folks that are on the report. I know most of them personally.

But is there any provision for a licensee to do an alternate assessment in the rule?

MR. COMFORT: The assumption under the general license is that that type of person who is going to normally be using the material isn't going to -- we're not -- we didn't want to put a structure in there to require them to have to. In the same case, we didn't allow them to have any out to do their own evaluation under the current proposal.

CHAIRMAN RYAN: I wonder if that's -- I'll just throw this out for discussion -- I wonder if that's worth thinking about. Because, for example, if a general licensee, for whatever purpose, for whatever endpoint wants to use material but is doing something that is not really well represented by the scenarios analyzed in the PNNL report, can they offer an alternative?

MR. COMFORT: Currently -- and one of the difficulties, again, is because we don't have a registration system or anything of that sort, you're basically relying upon after the fact that, you know, did they do their assessment correctly? You know we

come in and discover that there is a problem. I mean it's just the structure of how this general license, it doesn't make it really convenient to allow the licensee to make its own -- you know, the general licensee to make its own assessments easily.

CHAIRMAN RYAN: But a general licensee would be then constrained to whatever the general license conditions were.

MR. COMFORT: Right.

CHAIRMAN RYAN: I'm asking the question if you put in a scheme where you could get a general license or you could have a general license category prime or something where you were allowed to come in and say I want to get a general license but I want to do these things. And I've done a similar analysis to what created the general license requirements. Could I do that? I don't even know if that's possible.

MR. COMFORT: I'm not aware of any general licenses.

Cathy?

CHAIRMAN RYAN: Maybe that makes me a specific licensee all of a sudden.

MR. COMFORT: Yes, that's usually --

CHAIRMAN RYAN: So I mean I guess that's the options. I can apply for a specific license and

be in that category.

MS. MATTSEN: You don't apply for a general license. It's in the regulation.

CHAIRMAN RYAN: Right.

MS. MATTSEN: We have to set it up for -- to apply it generally to anyone. And that point is for them to be able to be exempt from a lot of the requirements of the specific license.

CHAIRMAN RYAN: Please, Kathy, just for the record, tell us who you are. You have to say your name.

MS. MATTSEN: Kathy Mattsen.

CHAIRMAN RYAN: Yes, okay. I don't think he can see your name tag.

MS. MATTSEN: So they are exempt from Part 20 where they would have to make sure evaluations. And we have to put constraints in there that protect them without them having to do all that.

CHAIRMAN RYAN: It just strikes that the PNNL report is a pretty bounding kind of analysis. So what is that -- I mean what does a bounding analysis tell us?

MS. MATTSEN: It's so that we can allow people to use small quantities and not have a lot of requirements and still know that they are perfectly

safe.

CHAIRMAN RYAN: I understand. But I'm just -- you know, because the other side of that is the amount you can use is small because -- and maybe too small for some health and safety considerations.

MR. COMFORT: And part of the other thing I'd like to also put on the general license, we look at a variety of different ways to look at this, you know that we can present it. And, you know, one of the options we've done on the original rulemaking plan was to do some sort of tiering. And it could have been based on what the uses are.

We've done a little bit of that in this current version. But you could have gotten into a variety of forms, what practices -- the problem with the current general license and the way that we have got it right now, it doesn't have any limit in how you can actually the material. So you are basically trying to get the whole realm of what types of activities.

Some people, you know, are going to be using the small quantities in very, very, you know, very, very safe -- you know they could use the full 15 pounds even though they are operating processing it and all and stuff. And, you know, you could show an

assessment on that.

But on the other hand, we've also got to limit the folks who aren't doing it. They are putting dust in the air, inhaling it. You know their operations cause a lot of dust in the air. We've got to do the same limits.

So what we're trying to do instead of requiring a general licensee to have a health physics person on staff doing these kinds of calculations, we're trying to find an easy medium as to where those levels could be cut off without them having to do those assessments where we're pretty certain that the folks aren't going to be getting a significant impact from the use of the material.

CHAIRMAN RYAN: So you kind of ended up with an all or none kind of situation rather than trying to tier it.

MR. COMFORT: Yes, that's exactly it.

CHAIRMAN RYAN: Okay.

MR. COMFORT: Now if we want to go back and limit some of the uses under the general license, we could, you know, potentially increase what those amounts are back. And actually if you go back to the history of this general license, it was originally at the limits for all uses that we're proposing to go

just for the materials that are basically dispersible on it down to the three-pound limit.

And when they modified it back up to the 15 pound, it was based mostly on, at that point, the limits were constrained to educational, research, and a couple others. But one of the things that they added at the same time but we can't find any indication that they did an analysis of was commercial use, which broadens out tremendously what you can do with it.

And that's one of the things that we're finding is a potential problem is people are using the material in ways that wasn't originally envisioned I think when they expanded the limits. And so what we're basically doing is in combination that we now have reduced health and safety limits in Part 20, we're going back to what was really originally in 40.22 general license for the limits.

CHAIRMAN RYAN: Okay.

MR. CARRERA: PRM-40-27, January of 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 exposure level on the dumpster

exterior was measured to 4.9 millirem per hour, an investigation revealed that it was a source material general licensee who was responsible for the radioactive material. And had vacated the facility.

According to the petitioner, further investigation found the licensee ensured that procurement did not exceed 150 pounds per year limit as specified in 10 CFR Part 40.22(a) and had left the building with thorium contaminated level of 734 millirem per year, which exceeded the 25 millirem per year annual limit for release for uncontrolled use.

CHAIRMAN RYAN: Tell me what -- it couldn't be contaminated to a dose level. It is contaminated and a dose level can be --

MR. COMFORT: It was calculated.

CHAIRMAN RYAN: -- calculated --

MR. CARRERA: It was calculated, yes.

CHAIRMAN RYAN: -- for what? A 365, 24-hour occupant? Or a 40-hour a week worker? Or --

MR. COMFORT: We believe based on it that it is a 40-hour a week worker because it was a work location.

CHAIRMAN RYAN: Were there external components?

MR. COMFORT: External.

CHAIRMAN RYAN: All external?

MR. COMFORT: Yes. That's what my guess is.

CHAIRMAN RYAN: You don't have --

MR. COMFORT: I don't have the detailed calculation.

CHAIRMAN RYAN: I take it from your comment you don't have the documentation, right?

MR. COMFORT: We don't have the detailed calculation from the state.

CHAIRMAN RYAN: Okay. Then it's probably not a good idea to put it out there then if you don't know what the basis is really. I mean it could be internal/external, 365 days a year. I don't know. That would be a big change. Not that it is, you know, a huge thing but the basis for that number is kind of important. Okay.

MR. CARRERA: And as a result of this finding, the petitioner requested in Petition for Rulemaking 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 note to meet the same health and safety requirements for specific licensees.

Next slide please. Now we get to Mike's favorite study. The PNNL dose assessment report. As I mentioned earlier that the staff obtained the services of Pacific Northwest Laboratory, or PNNL, to try to identify general licensees and how source materials was used.

PNNL's data indicated that the majority use of source material was in the manufacture of thorium-coated lenses and proceeded to contact nine manufacturers to evaluate their practices. PNNL provided a final report of the finding in 2007. The report is known as PNNL-16148, titled Dose Assessment for Current and Projected Uses of Source Material under NRC General License and Exemption Criteria.

The study was conducted in three phases. Phase One consists of data researches. Phase Two consists of scenario development and dose analysis. And Phase Three consists of refining dose analysis.

In the dose analysis, individual exposure scenarios were developed for each type of use or selected specific uses. Assume parameters as exposure time, exposure distance, and inhalation rate was selected on the basis of daily exposure usually in an occupational setting at a typical radionuclide concentration.

Calculations were made with appropriate computer code to standardize the data for a large number of radionuclides or variance of exposures. Radiation dose commitments from inhalation or ingestion were estimated using dose coefficient from the ICRP, Publication 68 and 72.

As summarized on this slide, the study reported that the committed effective dose to unprotected workers during routine use in the manufacture of thin-film optical coatings could approach about 800 millirems for the case of a single worker processing up to 150 pounds per year of thorium with progeny via inhalation and ingestion pathways.

This 800 millirem exposure dose became the basis for our proposed new possession limit of lowering from the current 150 pounds per year to 15 pounds per year, thus reducing the exposure dose to a worker by a factor of ten, from 800 millirem per year to 80 millirem per year.

Next slide please. The study also reporting the bounding dose assessment for an individual that uses 150 pounds of uranium or thorium powder in a small room with low ventilation and not as clean an environment as a standard industrial operation. This was considered to be an operation

such as a commercial public pottery facility in which an owner or employee works full time preparing, mixing pigments, and firing customers' creations. In such a bounding scenario, the study reported half a committed effective dose reaching close to five rems per year. However, this dose estimate is highly conservative and assuming the worker does not take an caution in protecting his or herself.

Mike?

CHAIRMAN RYAN: Yes, you know, I guess on both of these, it's hard to really judge the meaning of a number on, you know, the -- I mean the 768 for example on the previous one and, you know, 4,680 millirem. You know it is a bounding scenario yet we have several significant digits up there. I always take note of that. Around four rem would be a good number or around 40 for a half rem.

I guess you always are stuck with how do I interpret that conservative scenario based against reality. And I guess my understanding is did PNNL or have you or has anybody gone out and made actual measurements in these facilities to see what's happening?

MR. COMFORT: PNNL in regards for the -- well, PNNL did not go out and do any measurements in

the facilities themselves. As part of their survey, they did ask some of the sites to provide information of what doses they were seeing.

If I remember correctly, none of them provided that information to them. They described a little bit about the information. It was a voluntary survey and all. So they had to make assessments based upon what information they were able to get from those on how the practices were done.

CHAIRMAN RYAN: And I guess I don't mean this as any criticism of the PNNL study team, but it's real tough to interpret that as to what, you know, where are we in terms of reality versus these estimates.

MR. COMFORT: Yes. Well -- and that's part of what the proposed rulemaking process is supposed to be going through is they provide -- get comments because we don't have easy access to who is using these materials and how they are using them. And the hope is that, you know, we're going to get some of that information from people saying hey, this is totally out of place.

Now the other consideration that we haven't gotten into on this is what is the overall impact on this. And we're hoping to find out from --

when people comment on the rule.

But the fact that we are going to be doing distributor requirements that are going to require specific licensing anyways is a lot of the folks who are using the bulk of the material are likely producing products for somebody else. And they are going to come under that specific license.

So we're expecting the impact from reducing the limits to what we think are better to ensure safety with a wide spectrum of what we don't know what they can do with this material is going to be relatively limited because the folks who are using most of the material are going to have to be specifically licensed under a different condition anyways.

So it's kind of a combination of we don't know what the material is there but on the other hand, we're trying to allow people to be able to use the material without concern that they are exceeding what we'd normally have for additional requirements for a specific licensee and all.

And some folks, you know, aren't going to ever have that problem. And they are going to be limited by what they can do. Other, you know, we are helping to limit it. But --

CHAIRMAN RYAN: I guess it would be really helpful, you know, if I'm thinking about if I was on the receiving end of this request for comment, I'd want to understand or, you know, I think it is helpful if the Agency makes folks understand or gives them the information to hopefully allow them to understand that that is an upper estimate based on the technical analysis that you think is conservative but is not cuckoo, you know, it's not --

MR. COMFORT: Right.

CHAIRMAN RYAN: -- we're not having people spooning it into their sugar and their coffee --

MR. COMFORT: Right.

CHAIRMAN RYAN: -- or anything like that. But, you know, but the rulemaking will be enhanced by realistic information provided by licensees. And any dosimetric data they have, whether it is air samples or film badges or TDLs or whatever they might have might be -- would be very helpful --

MR. COMFORT: Definitely.

CHAIRMAN RYAN: -- to understanding the environment that you are creating a regulation for. I think it has got to be clear that you really don't have any solid, real, operational, health physics data from this arena that you are trying to develop a

regulation for.

MR. CARRERA: And that's because of the lack of reporting requirements.

CHAIRMAN RYAN: But we said that in the beginning, Andrew, but I think, you know, that's got to be made clear that you are really seeking the information. You need to make sure that the rule makes sense. Is that fair?

MR. COMFORT: It's fair. I mean hopefully it comes across, again, as the proposed rulemaking that we try to make it clear in that document --

CHAIRMAN RYAN: Yes, I'd make it crystal clear right up front.

MR. COMFORT: -- that we don't have that information and that's one of the reasons why we're asking for, you know, to get distributor requirements and all in making these assumptions.

And the whole idea of going out for the proposed is for people to correct, you know, our assumptions that we've made based on the data that we do have available.

CHAIRMAN RYAN: You know and this number is spectacular in the sense that that's higher than any worker gets, you know, in a year from anything that is regulated --

MR. COMFORT: Right.

CHAIRMAN RYAN: -- pretty much if that's right.

MR. COMFORT: You have the potential, yes.

CHAIRMAN RYAN: The if it's right is the big question that, you know, I don't know that was have a clear answer that that is right.

MR. COMFORT: And even though this one scenario that they're talking about for the bounding and stuff, I mean I've gotten people calling saying, you know, where can I get material for doing, you know, my pottery making. I mean they use it in their glazes and all that they want to do.

And they've run out of it and actually about the same time that I was trying to find distributors, that question came up. And I told the distributor hey, I've got somebody who is looking for this material. And their response was, you know, we consider that a frivolous use. We're not going to provide that material to them.

So the industry is a little bit self-limiting in itself as this point from letting people use it in methods that may be, you know, to the extreme that we're looking at here.

CHAIRMAN RYAN: Sure.

MR. COMFORT: You know but there is nothing limiting it in the current regulation.

CHAIRMAN RYAN: No, I understand the no limit. Thanks.

MR. CARRERA: Kathy, do you have anything to add? No? Okay.

I think, Mike, we're going to have to leave your favorite subject now.

Slide 20 please.

CHAIRMAN RYAN: One of my many favorite subjects.

MR. COMFORT: We can come back to it if he wants to.

MR. CARRERA: To resolve our concern with Section 40.22 being not in alignment with current health and safety standards, the staff's proposing to make significant revision to Section 40.22. If you remember the current general license allows for 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 the 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 radionuclides of concern to security under the general license.

Secondly, the staff found that the biggest impact from the use of source materials is resulted from the processing of dispersible source material primarily because of the inhalation and ingestion pathway.

CHAIRMAN RYAN: So this proposed change to 40.22 is really a direct result of interpreting those calculations?

MR. COMFORT: Yes.

CHAIRMAN RYAN: And you dropped -- as you said, it drops it down by a factor of ten in the dose so --

MR. COMFORT: Correct.

MR. CARRERA: Yes.

CHAIRMAN RYAN: -- that's important to understand. And, again -- I'm sorry --

MR. COMFORT: I was going to say not necessarily the bounding calculation but the more -- what we consider the more realistic with the thorium lense manufacturing. We looked at that.

MR. CARRERA: Yes.

CHAIRMAN RYAN: But they were up in the

same general range.

MR. COMFORT: Well, I mean they are almost a factor of ten apart. One is 700 millirem per year, the other one is, you know, 4,000 -- or, you know, four rem basically.

CHAIRMAN RYAN: Okay. Well how did you get to the lense manufacturer to this number?

MR. COMFORT: How did we -- they were calculated to be about 700 -- well, around 800 millirem trying to lower it below 100, you know, just doing a nice round factor of ten basically. You attribute a little bit to that you could go higher than that on the bounding but we're not trying to --

CHAIRMAN RYAN: I got you. Sorry. I misunderstood you earlier. That's fine. Thank you.

MR. CARRERA: The PNNL report indicated that it was possible for doses to persons operating under known operations to be near one rem per year. That could exceed at this level in other less likely bounding scenarios.

Although it is expected that most general licensees may implement procedures such as hot cells to maintain doses well below this level, the staff believes that the reduction of possession limit would be ensure that these materials are safety handled

without adequate training.

Currently specific licensees are required under Part 19 to provide training to a person who could potentially receive in excess of 100 millirem 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 millirem per year could be exceeded.

Rather than revoke the exemption to Part 19 and require a general licensee to obtain expertise to evaluate whether their operations may exceed 100 millirem per year, the staff is proposing to limit the possession of source material under the general license to levels where they are unlikely to exceed 100 millirem per year.

So by limiting the amount of source material a general licensee can possess, we are limiting the risk associated with having inadequate or no training.

As we saw, staff is proposing to reduce possession limits for source material to 3.3 pounds at any one time down from 15 pounds and receive up to 15.4 pounds down from 150 pounds per calendar year. However if the source material is possessed in a solid, nondispersible form or accumulated from the

treatment of drinking water to remove uranium, the licensee could continue to possess up to a total of 15 pounds at any one time and receive up to 150 pounds per calendar year.

The staff believes that these uses have been sufficiently evaluated to reduce the likelihood that excessive dose would occur to workers or the public from these later forms of uses. General licensees would continue to remain to the most part exempt from requirements in Parts 19, 20, and 21.

Although this may result in some general licensees requiring specific licenses, it is expected that the majority of larger users are likely to be distributors of exempt products which would, therefore, be required to obtain specific license under the proposed new distributor requirements. And that I will discuss shortly. Or they would be able to reduce possession limits to within the new limit.

CHAIRMAN RYAN: Again, is that based on a survey of folks? Or --

MR. COMFORT: That's based upon the information that we have to distributor -- that we've seen going to distributors or from a distributor to their clients of what type of operations that we've been able to assess from that information. You know

again, most of them are thorium lense manufacturers, which would fall under the requirement to get a -- they would be distributing an exempt product so they would have to get a license and all for that.

CHAIRMAN RYAN: Okay.

MR. CARRERA: The staff is also proposing to require the general licensee to ensure that the facility minimizes contamination during operation. This should help limit the amount of contamination remaining when operations cease.

However, when a Section 40.22 general licensee ceases operation, if they identify that there is the potential that significant levels of contamination occur, the general licensee would notify the NRC or the agreement state to determine what actions are necessary and to allow the regulator to confirm additional clean up if necessary.

Currently because of the exemption to Parts 20, a general licensee may decide that they have no obligation to clean up their facility. And instead abandoning it in place such as what I identify PRM-40-27.

Implementation of this proposed requirement would help regulators in two ways. First, it would provide a regulator with a more clear trigger

to call a former licensee back to restore an abandoned site if significant contamination is found after the site is abandoned. And second, because many general licensees may take precaution and speak with the NRC, due to this provision we would be better able to identify those general licensees that cease operation.

It is expected that the burden to the regulator from this provision would be minimal because of a number of general licensee ceasing operations that possess large enough quantities of source materials under this general license to warrant a concern will be relatively small in any one calendar year.

Next slide please.

CHAIRMAN RYAN: How about a facility that's not abandoned but changes use to say food manufacturing?

MR. COMFORT: That they no longer use the source material -- once they no longer operate under their general license, I mean if they've got operations that can result in a lot of contamination or they see contamination, the expectation would be that they would notify NRC that they have ceased operations and do we need to do anything about that.

CHAIRMAN RYAN: I'm just thinking out

loud. I've got a facility I make stuff with uranium and thorium.

MR. COMFORT: Right.

CHAIRMAN RYAN: I sell the building to Derek. He's going to make something -- open up an ice cream store.

MR. COMFORT: Right.

CHAIRMAN RYAN: How is that -- I mean abandonment I understand. There is an empty building. Somebody is going to take notice.

MR. COMFORT: Well, when we're talking about abandonment, we mean they're just ceasing operations and leaving whatever is there in place for future operations to come.

CHAIRMAN RYAN: So it could be a future sale of the property for some other use.

MR. COMFORT: Right. And that is similar to what happened under the PRM-40-27. Somebody came in -- now they happened to gut the place to be using it for other things and identified a lot of contamination. But what they didn't get, there was still a lot of contamination.

CHAIRMAN RYAN: But how would they know to look for it if I don't tell them.

MR. COMFORT: They don't. That's one of

the issues. That what we're trying to do.

CHAIRMAN RYAN: Trying to create that trigger so that a general licensee has to say something about the former use?

MR. COMFORT: Yes, I mean they should identify that they do. Now again, because we don't know who -- and even under this new rule, we won't know who everybody is under a general license so there may be difficulties identifying and getting them to follow up.

The other part, though, as was stated, what this is if we do identify it or when we do identify it, that we have a better trigger to have the person who is responsible to come back and clean up.

Under the current, they are exempt from the requirements in Part 20 so there's not a real easy trigger to say hey, you violated some regulation. You've got to come back and clean up at your own cost.

CHAIRMAN RYAN: So are you saying there's going to be some requirement to do a closure survey of some kind?

MR. COMFORT: No, I mean it is basically an identification that there is a potential that there is contamination there. And they should talk to NRC and we'll help them determine if they've got to do a

closure survey or any additional action that should be taken.

Again, the expectation is that we're not going to -- that the general licensee is not going to have the health physics knowledge, et cetera, to try to do calculations for a specific number.

CHAIRMAN RYAN: Every general licensee will have that obligation?

MR. COMFORT: They'll have -- yes, to identify contamination if there is any and notify us if they determine that there is.

CHAIRMAN RYAN: But how about if they don't -- you just said they might not know to notify you. Are they required to notify you and say I'm not going out of business as a general licensee at this location?

MR. COMFORT: No, they aren't right now. And again we may not know that they are a general licensee to start with I mean even under the new -- currently we definitely know that. We don't have either end of the spectrum covered on it.

Under the new proposal, we'll know who some of those general licensees are or a greater percentage. And then on the other end because of this requirement for them, we're hoping that most of these

general licensees will notify us when they shut down just to be on the safe side.

I mean it's not hard to make a phone call to say I've been using this material. Do you think I've got a concern that I've got to do something further on this?

CHAIRMAN RYAN: What would trigger them to do that?

MR. COMFORT: There's just the requirement in the new proposed requirements that say if you identify contamination, you know you should call NRC to find out what you need --

CHAIRMAN RYAN: But there's no requirement to even do a survey.

MR. COMFORT: Right.

CHAIRMAN RYAN: So how are they going to know they've got contamination that needs attention? The logic of it escapes me.

MR. COMFORT: If you think that you -- I mean if you've got a solid source that you're not doing anything with, you're not going to have contamination. If you're using things like, you know, an educational institution using small vials of uranyl acetate and stuff, unless there has been a spill, you're not going to really have any contamination.

It's looking at these, you know, folks who are using it in dispersible forms so they're doing some sort of dust manufacturing operation. They are going to have to have an assumption that there is contamination that was left behind, you know, that they should contact us to determine is there enough to worry about.

You know if they were again using only, you know, half a pound total, it may not be a big concern when they've said they've gotten rid of most of it. If they're, on the other hand, processing their full throughput per year in a dusty form, it's likely they've got significant contamination.

CHAIRMAN RYAN: And, again, I understand that. But I'm struggling a little bit with the logic of all of it. You've got a general licensee that's probably adept at the radiation protection question --

MR. COMFORT: Right.

CHAIRMAN RYAN: -- or contamination control questions. And I can see somebody saying well I swept up all the dust and vacuumed it, I'm done.

MR. COMFORT: Yes.

CHAIRMAN RYAN: I don't need to call anybody.

MR. COMFORT: Yes, given that, that could

be the finding.

CHAIRMAN RYAN: And that may not be right.

MR. COMFORT: They may not be sufficient, yes.

CHAIRMAN RYAN: So what do we do with that?

MR. COMFORT: Well, I mean there are two approaches. You know you could make everybody call in when they cease operations, which there is some benefit but there's burden associated with that, of course, for the staff also on it.

But versus what we currently have in place, this is just a step forward to try to reduce these problems that we've had in the past. You know we're not going to catch all of them.

Part of the problem is we're not going to catch everybody who has general license material. And in some cases, they may not even be aware of it when they have it. So if they don't know, we're certainly not going to know. That's one of the problems when we're talking about something ubiquitous.

CHAIRMAN RYAN: Okay. I understand the scope of what you're wrestling with.

MR. COMFORT: Yes, we're trying to reduce the impact but we're not going to catch all of it.

MR. CARRERA: It's a start.

CHAIRMAN RYAN: Okay.

MR. CARRERA: Slide 21 please. Issue number two is one of the biggest problems we found in the development of this rulemaking and it was the lack of verifiable information about what quantities of source materials were being distributed to persons for use under Section 40.22 general license and how the source material was actually being used under this general license.

Next slide please. Currently there are no regulatory mechanism for the Commission to ensure that products and material distributed for us general license in Section 40.22 are used and exemptions are maintained within the applicable constraints of the requirements for their uses. This is inconsistent with how we handle Part 30 byproduct material where we have requirements for distributors to be specifically licensed by the NRC.

Even the general license in Section 40.25 for source material requires manufacturers of materials to be specifically licensed and to report the transfer to and from general licensees to be reported to the NRC. Because the staff cannot readily identify who possesses source material under general

license in Section 40.22 or how and in what quantities the source material are being used, the staff cannot fully assess the resulting risk to the public health and safety from the use of source material under Section 40.22 general license.

Next slide please. To resolve the issue with the lacking of complete and timely information on the types and quantities or source materials distributed for use under exemption or by general licensees, the staff is proposing two new specific licenses for initial distribution of source material, one for the initial distributors of source materials to exempt persons under the newly proposed Section 40.52. And the second is for the initial distributors of source material to the general licensees in the newly proposed Section 40.54.

The proposed new specific license for initial distribution to exempt person would only be issued by the NRC, including for the initial distributors in agreements states. The category of the initial distributor could include manufacturers or importers of exempt products containing source materials.

Both importers and persons located in agreement state would be exempt from requirements in

Parts 19 and 20 although it is expected that the agreement state who would be responsible for the protection of public health and safety in the state would likely require such initial distributor to obtain specific licenses from agreement states.

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 control requirements like exempt products be manufactured and labeled consistent with 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 product distributed, and the source material type and content in a product.

The staff would use this information to better understand how much source material has been distributed to the public and in what form 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 Section 40.22 general license, such as thorium-coated lens manufacturers to become

specific licensees.

In addition, it is expected that the importer of exempt products containing source materials would be reduced or centralized to a smaller number of importers because of licensing fees that would apply.

Slide number 24 please.

CHAIRMAN RYAN: Just kind of a side question maybe. Where do gemstones fit into all of this that contain thorium?

MR. COMFORT: That contain thorium?

CHAIRMAN RYAN: People who import gemstones?

MR. COMFORT: I mean presuming they fall currently under exemption, you know, the change would be whoever is importing those, if they are falling under one of the 40.13(c) products, you know, because under .05 percent, you know, under that exemption it's not an issue. But if it is under one of the product limitation -- you know, exemptions, then that distributor -- or that importer would have to get a license to distribute it, you know, once it gets into the U.S.

Now they wouldn't have any health and safety requirements that they would have to meet.

They'd just have to get a pure, you know, license that would meet the requirements for distribution. They'd be exempt for Parts 19 and 20 on that.

MS. MATTSEN: The main gemstone issue is irradiated gemstones. And that is regulated under Part 32.

MR. COMFORT: Where?

MS. MATTSEN: Potential byproduct material.

CHAIRMAN RYAN: And that's irradiated to change the color of whatever it might be?

MS. MATTSEN: Yes. And that produces byproduct material. So that's under Part 32 now.

MR. COMFORT: And those importers need to be a specific license for distribution also, is that correct?

MS. MATTSEN: Yes.

CHAIRMAN RYAN: Okay. But that's under Part 32?

MS. MATTSEN: Yes.

CHAIRMAN RYAN: Yes, okay. I guess just in your background material, it might not be a bad idea to cover that difference. I think it is helpful for people to realize what is in Part 32 and what's not. I mean what's in this part versus Part 32.

MR. COMFORT: Okay.

CHAIRMAN RYAN: And that this is not effecting the requirements or obligations under Part 32.

MR. COMFORT: Right. I mean we do in our background materials state that, you know, this is currently how it is done under the byproducts in Part 32.

CHAIRMAN RYAN: Okay.

MR. COMFORT: And we're not currently requiring it. And that's what we're trying to mimic to a certain extent. The big difference in that is that if I remember correctly under the Part 32 specific licenses, the exemptions to Part 20 aren't included in there. Is that correct?

MS. MATTSEN: Pardon?

MR. COMFORT: The Part 32, you know, distributors, initial distributors still have to meet Part 20?

MS. MATTSEN: Yes.

MR. COMFORT: Whereas we're not requiring that because we're not looking at as big an external dose that if you have an accumulation of material that you would have an impact at the importer versus, you know, somebody importing a bunch of source material or

if products contain source material, the health and safety impact is not considered an external dose problem of having a large accumulation. It's more if it is going to be dispersible or anything of that sort.

CHAIRMAN RYAN: Okay.

MR. CARRERA: Slide number 24 please. Similarly, the initial distribution of source material for general licensees would also require a specific license issued either by the NRC or the agreement state. Requirements under this new license would require the initial distributor to label the materials 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 the general licensee, the distributor would be required to include information that notifies the recipient about the requirements of a general license and the appropriate safety precautions for handling, use, storage, or disposal.

The NRC staff has concern that some persons receiving these source materials may not even be aware that they are operating under a general license. So this would help alleviate those concerns.

Finally, the distributor would be required to provide annual reports not only to the Agency that is licensing them but also to any agreement state where the source material is sent. The reports would include the quantity and types of source material that was distributed by quarters and to whom it was distributed, including contact information.

This would allow the NRC and the agreement state 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 used safely and possessed safely and disposed of safely.

As stated earlier, NRC is currently aware of only one initial distributor of source material. It is expected that this requirement will only have a small impact on any distributor since they would usually already be specifically licensed.

It should be noted these new requirements would not allow NRC to identify all of general license. Neither the secondary recipient of source material or from other general licensees nor those that generate their own source material such as water treatment facilities, would be able to identify

through these new requirements.

However, the staff believes that these new requirement will have NRC to both identify and better under how most source materials is used under a general license and to better ensure public health and safety while providing minimal additional impact to general licensees themselves.

Next slide please.

MR. COMFORT: And one quick point is the differences between the distributor license from, you know, for exempt products versus the general licensees is NRC will require to specifically license all initial distributors of exempt products. So the agreement state would not be doing that portion of licensing. And that's because of 10 CFR 150.15 because it doesn't allow that afforded to the agreement state.

On the other hand, where the general distribution to general licensees could be done either through the agreement state which, you know, currently they only identify distributors located in the agreement state or from NRC. So just to make that clear that slight difference in who would be licensing on those.

CHAIRMAN RYAN: How many general licenses

are there?

MR. COMFORT: We have no clue. I mean get calls all the time, you know, just from out of the sort places. You know it could be an educational institution. How do I deal with this material that I've been holding under general license for 25 years or whatever? You know, as I said, persons doing pottery. But we just have no clue how many general licensees there really are out there that are possessing source material under this 40.22 general license. And that's been our big difficulty is both identifying how many, how much material, and how it is being used because there is no requirements.

CHAIRMAN RYAN: When you are counting the little bit of uranium that was used in a high school lab to demonstrate radioactive material that is still there in the back corner, probably nobody at the school knows they are a general licensee.

MR. COMFORT: Oh, yes, I mean that's -- I think the State of Illinois had done a thing probably about ten years ago that they realized a lot of their high schools, et cetera, had some uranyl acetate or whatever held under a general license. And they realized that and started going through to collect it.

And, you know, that's one of the problems

was how do you dispose of it, et cetera, that came up and all on it. So those are some of the issues that we're also trying to resolve in this as we'll talk about shortly.

CHAIRMAN RYAN: Yes, okay.

MR. CARRERA: Slide number 25 please.

With issue number three, after its review of NUREG-1717, the staff determined that the original use of certain products possessed under the exemption in 10 CFR 40.13(c) have changed over time. As a result, the staff is proposing to revise certain exemptions to address dose changes.

Next slide please. You remember back in the history discussion in the 1990s, the staff evaluated the uses of exempt source material. And has identified changes in the industry practice that we believe should be addressed.

These identified changes include certain source material-exempted products are no longer being manufactured or contain reduction in the concentration of source material used in the manufacturing practice or more prep and use than before of an exempted source material product.

The main exemption we determined should be considered for revision are those listed. As

indicated in this slide, some products are no longer being manufactured. Or as in the case of uranium smoke detectors, they were never manufactured in the first first place.

The staff determined that removing the exemption for future distribution of such products would be more protective of help and safety with no impact to the industry. Similarly, certain products do not contain as much source material as what was originally permitted under the exemption. As the result, the staff is proposing to reduce the allowable concentration of source materials without impacting the current manufacturers.

And finally the staff found that some products have changed over time and the exemption does not clearly fit the product any more. In this case, the staff approach to expand the exemption to fit the new product after a safety evaluation was completed indicating that the newer product provides less potential impact to health and safety than the original exempted product.

CHAIRMAN RYAN: You mean less or equal?

MR. CARRERA: Less.

MR. COMFORT: Less.

CHAIRMAN RYAN: Impact.

MR. CARRERA: Less impact.

CHAIRMAN RYAN: Well, if the other one was an exempt product and it was okay why should the new one be less?

MR. COMFORT: Well, I mean they still provide a dose. It is just a lower -- I mean the overall calculated dose is significantly lower because you're using a lot less material.

CHAIRMAN RYAN: It might be the same though.

MR. CARRERA: Well but they're using a lot less material within the individual product.

CHAIRMAN RYAN: Okay.

MR. CARRERA: Slide 27 please. To be more specific, 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 believe there is no reason to continue to allow it.

Second, the staff would prohibit further distribution of clay ceramic tableware. The staff is unaware of any product 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 for exemption of products.

Products already distributed will continue to be exempt.

CHAIRMAN RYAN: Just a question. I mean I've seen an awful lot of Fiestaware and I've seen an awful lot of the green glass. How do you get uranium out of those products into your food? I mean it's just -- unless you ingest chips of some kind off of the plate, you know, how do you get uranium out of the glaze?

MS. MATTSEN: Well, when it is just a glaze if you have like juice sitting in it or something --

CHAIRMAN RYAN: I'm sorry?

MS. MATTSEN: When it is a glaze on the surface, there is significant potential for leaching into particularly acidic foods like juice or something.

CHAIRMAN RYAN: And where is the study that shows that?

MS. MATTSEN: That's in NUREG-1717.

CHAIRMAN RYAN: I mean where you've done I mean lab studies to actually try and leach uranium out of plates?

MS. MATTSEN: Yes, well I think that type

of research had been done earlier that then used as part of the assessment. But that hasn't been done for a long time. And what's out there now is primarily a collectible.

So we're just going to assure that nobody does this in the future.

CHAIRMAN RYAN: Right. The Fiestaware is because it is -- it has uranium in it, the orange is much more expensive than any other version of it.

MS. MATTSEN: As far as ingestion goes though glassware is not a significant hazard.

CHAIRMAN RYAN: Well, I was just curious, you know, what the ingestion risk is. And if the data that you've got supports that concern. I mean we may have to go back and start --

MR. COMFORT: We'll have to go back and look --

CHAIRMAN RYAN: -- and again get it but I think it is helpful to bring in the context that if you eat off of Fiestaware and you eat some kind of acidic foods or whatever, you know your potential ingestion is -- what's the risk we're regulating here.

MR. COMFORT: I have to go back to the report.

MS. MATTSEN: Well, it is inappropriate

given our consumer product policy but you would have to be using this as your routine daily --

CHAIRMAN RYAN: I'm just trying to get a number. I'm trying to understand it if there is a leaching problem or not. I would suggest that some pottery probably doesn't leach much at all. I mean think about it.

MR. COMFORT: I'd have to go back and look at the report to see the specific --

CHAIRMAN RYAN: If you think about the glassware -- it's greenish, you know, and it's glasses and all that.

MS. MATTSEN: Well, there it is throughout the glassware. And it isn't a leaching problem.

CHAIRMAN RYAN: Right. Okay.

MS. MATTSEN: It is an external hazard only.

CHAIRMAN RYAN: Right. But, again, without the hard data to back up some of the assertions, I think your case isn't as strong as it could be with, you know, solid data to say this is the reason why we're doing it.

MR. COMFORT: Well, I mean we can go back and reference the specific numbers and studies that were done for the NUREG-1717 --

CHAIRMAN RYAN: Yes, that would be helpful.

MR. COMFORT: -- that provide us that information.

CHAIRMAN RYAN: Thanks. Okay.

MR. CARRERA: Next, the staff reduced the allowable concentration of source material in glassware from 10 percent by weight to two percent by weight of source material. This would include things such as glass figurines or other show pieces.

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

The biggest revision is proposed for the next -- for the product exemption in Section 40.13(c)(7). This exemption currently 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 lense with thorium.

This has led to numerous questions about the applicability of the exemption to the coated lenses. The staff's evaluation of coated lenses four that significantly less thorium is applied in a lens coating them incorporating homogeneously throughout

the lense. And thus resulting 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 coating are also applied to mirrors and believe that it is appropriate to allow such use under an exemption.

The staff learned that uranium may also something be used as part of the costing. And so the staff proposed to expand the exemption to include uranium.

CHAIRMAN RYAN: Andrew, did you get any insights as to how tight the bond is between the coating and the lense. I mean is it something that has to be physically scratched off? Or does it wear off over time through, you know, casual contact?

MR. COMFORT: Based on the information I've read and stuff, it's got to be actively tried to scratch it off if you want to try to remove it.

CHAIRMAN RYAN: Or grind it?

MR. COMFORT: Yes.

CHAIRMAN RYAN: You'd have to physically abrade it --

MR. COMFORT: Yes.

CHAIRMAN RYAN: -- to try and get it off.

MR. COMFORT: Yes.

CHAIRMAN RYAN: Okay.

MR. COMFORT: That's my understanding from what I've read in the reports that I've seen.

CHAIRMAN RYAN: All right. Thank you.

MR. COMFORT: Because that was our first concern is are you going to run into an issue that it is going flake off and you are going to have a higher likelihood of ingestion and all.

CHAIRMAN RYAN: Right. Yes.

MR. COMFORT: But the process basically, from my understanding on doing it, is they basically put the lenses in a hot cell and they put the thorium up in the air. And basically, you know, put an electrical charge through the lense and it attracts it.

CHAIRMAN RYAN: Yes. It's electric deposit.

MR. COMFORT: So --

CHAIRMAN RYAN: Okay.

MR. CARRERA: Finally, the staff found that current practices generally maintain concentration on lenses to less than ten 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 will provide comments during the comment period for the proposed rule if the products are still being distributed above the proposed concentration reduction.

Slide number 28 please. Finally, issue number four, over time the staff must learn that there are a few issues that aren't particularly clear in how they should be addressed in Section 40.22.

Next slide. It item, we've seen a lot of confusion on the waste disposal requirements, if any, under Section 40.22 general license. For example, because the general licensee is exempt from Parts 20, which contain NRC requirement for disposal of source material. Many general licensees have concluded that they can dispose of the waste or abandon them without further consideration.

However, the recipient of such waste unknowingly be in possession of source material such that they eventually become required to obtain specific license. This, of course, creates a problem. In real terms, the fact that 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 of provisions in 10 CFR Part 40.51 apply to all licensees, including general licensees. And would limit the transfer of materials to someone who is authorized to receive it under specific license, general license, or exemption.

As a general licensee cannot know how much materials a recipient has, they should not arbitrarily disposing of its material as the recipient may exceed its general license condition. And not be able to legally receive the additional source material without obtaining a specific license.

There are also a few other sections --

CHAIRMAN RYAN: Just a question, Andrew. Do you have any insight as to whether or not typical municipal county landfills have general licenses? Or specific licenses to receive these materials?

MR. COMFORT: Well, general, I mean general county landfills, you know, they may unknowingly have enough materials to require them to get a specific license, and the same thing with water treatment plants and stuff, too, that if people are disposing of it down that they may get quantities but they may not know it exactly themselves because, you

know, there may be no indication.

Now most landfills may have, you know, some sort of radiation alarm that will help trigger a little bit of that material as to whether they have it or not. But the idea is --

CHAIRMAN RYAN: Well, yes, that's -- I mean that's the typical, you know, medical material showing up in a dumpster load somewhere.

MR. COMFORT: Right. Or it could be something as simple as the cat litter setting it off. They look at what the material is that includes it before they let it go into the site a lot of times. But as shown in the PRM-40-27, sometimes they will go back and say where is this material from. And they can't find a good organization or good rationale that it is allowed to be in the landfill and they'll reject the material.

But some landfills don't have that sort of requirement or any type of system to detect it. So people could be disposing of this material wherever.

CHAIRMAN RYAN: Okay.

MR. CARRERA: There are also a few other sections in Part 40 that general licensees might not normally be aware of if they focused their attention solely on the tax in Section 40.22. This is because

Section 40.22 does not currently alert them about other requirements in Part 40 that may apply to them.

Slide number 30 please. We saw concerns in the area of source material waste disposal requirements. The staff is supposed to implement new requirements for disposal to ensure that contamination and the betterment 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 general licensee not abandon it's source mater, and to properly dispose of it.

The staff is allowing a general licensee to transfer up to .5 kilograms per year for permanent disposal in a solid non-disbursible 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 Parts 20. These requirements would allow small users such as educational institutions to say safely and economically dispose of source materials.

The staff is also proposing to include the recitations in Section 40.22 to other applicable

sections in Part 40 to make sure that general licensee is better aware of the additional regulations that have always been applicable to general licensee under Part 40.

Next slide please. During the rulemaking, the staff identifies certain areas the we believe public insight would be very, very helpful in directing our future course of this rulemaking or other related issues that we may consider for rulemaking in the future.

Slide number 32 please. As part of the Federal Register notice requesting comments on the proposed rule, the staff is soliciting comments on certain open issues.

First, is the concentration limit appropriate for coating on a lense when the concentration can easily be reduced by increasing the lense size? Should we instead implement something such as an activity limit? And if so, what should that limit be?

Similarly, we are asking should we limit the Section 40.22 general license by activity limit rather than total weight of source material? Taking such an approach would allow the general licensee to apply to additional isotopes over what we are

currently proposing. However, many persons using source material may not be as knowledgeable about how to calculate activity limits versus determining the total weight.

And as I discussed earlier, one of the concern 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, we are asking if we should require a survey in our situation.

The staff is also soliciting comments for potential future rulemaking topics. These would include the latter three items. For example, should Section 40.22 general license be expanded to include the 11e(2) byproduct material? And if so, how should it be implemented? Currently a lab requires a specific license just to evaluate even a small sample.

Also, should a provision be added to --

CHAIRMAN RYAN: I'm sorry. Just so I understand it a little better, 11e(2) byproduct material, say that part about a sample. I don't understand what we're trying to regulate here.

MR. COMFORT: Okay. Basically if somebody is doing an analysis of a mill tailings pile and they

want to have it evaluated, there is no minimal quantity for that lab to be able to use that material and try and sample it and all.

What we're looking at is should we be providing, you know, some minimal level that they can have material without getting a specific license to such an analysis.

CHAIRMAN RYAN: That contained in samples, you know, et cetera, and so on.

MR. COMFORT: What was that?

CHAIRMAN RYAN: Contained in samples --

MR. COMFORT: Right.

CHAIRMAN RYAN: -- for the purpose of analysis, et cetera, and so on.

MR. COMFORT: Correct.

CHAIRMAN RYAN: So you're looking to add an exemption so I can --

MR. COMFORT: Or expand the general license.

CHAIRMAN RYAN: -- expand the general license so a lab can make these analysis without a further permit --

MR. COMFORT: Correct.

CHAIRMAN RYAN: -- or licensing.

MR. COMFORT: We're asking should we

consider that for rulemaking and stuff?

CHAIRMAN RYAN: I would guess a lab is already going to have a radioactive materials license.

MR. COMFORT: Many of them probably will.

CHAIRMAN RYAN: And I'm wondering why they wouldn't have that already licensed under their radioactive materials license.

MR. COMFORT: Well, they do right now. We're just trying to offer more opportunities, you know, for folks because there could be some other small uses, you know. If you want to use it for educational uses, you know, this is what mill tailing, you know, material looks like. Technically you've got to have a specific license to be --

CHAIRMAN RYAN: Well, we're back to the classroom example which has sort of faded away from most classrooms. But the laboratory licensee, I'd probe that a little bit differently.

I'd look and see who is doing analyses of 11e(2) materials and see how they are currently licensed.

MR. COMFORT: Okay.

CHAIRMAN RYAN: And if they're licensed to receive it, possess it under their lab license, why would they need another license?

MR. COMFORT: Well, I mean a general license, again, you don't have to apply for it.

CHAIRMAN RYAN: My question still stands. Why do they need it?

MR. COMFORT: Why do they need to have that, yes.

CHAIRMAN RYAN: If their laboratory is licensed to have uranium, you know, materials, or uranium in some isotopic limit, I'm good.

MR. COMFORT: Okay. Let's say somebody wants to determine is there a better way to, you know, do some research on that material. You know, again, specific to that, they're not using any other radioactive material. That's what we're kind of looking at. It's not just for sample analysis.

CHAIRMAN RYAN: Well, again, if they are going to run a laboratory analysis of some kind, it is not something they are going to do under a general license.

MR. COMFORT: Well, I mean if they only need small quantities of it to see is a waste form going to work under this kind of thing, you know. They may not need it.

CHAIRMAN RYAN: Okay. Let me pose it this way. You are the university RSO. Are you going to

let them go hog wild under a general license? Or are you going to say no, you're going to work under the broad scope license the university has?

MR. COMFORT: On the other hand, if I'm a small company that wants to try to get into business and stuff like that, too.

CHAIRMAN RYAN: I guess.

MR. COMFORT: You know that's just a question should we. I mean we're just putting it out. We're not saying that we are necessarily. But we want to find out should we or should we not allow that.

CHAIRMAN RYAN: And I guess I'm asking, you know, you should also ask, you know, would this be an option for folks that are not otherwise licensed to have samples and do analysis on it? I mean I think you've got to recognize that a lot of people are already going to be licensed to do this.

MR. COMFORT: Okay.

CHAIRMAN RYAN: And what I'm trying to avoid is the confusion that in order to do these 11e(2) samples, I would need a new license in addition to the one I already have.

MR. COMFORT: Right, no, you wouldn't need that.

CHAIRMAN RYAN: Yes. So that's got to be explicitly clear in the request for information that you are specifically not looking to do that.

CHAIRMAN RYAN: Okay. What's next? I'm sorry, go ahead, Andrew?

MR. CARRERA: Also should provisions be added to require sources containing source material or special nuclear material be included in the source and device registry? Currently there is no such requirement.

CHAIRMAN RYAN: Are you thinking of a lower end below which you wouldn't require? I'm thinking of all the hundreds and thousands perhaps of check sources that are out there that are sealed sources, instrument check sources.

MR. COMFORT: That would be a lot.

CHAIRMAN RYAN: Those?

MR. CARRERA: The lower limit for --

MR. COMFORT: I mean that's something we'd have to consider.

CHAIRMAN RYAN: You know I mean I can understand above some quantity you might be interested in a registry. But below some quantity, you probably aren't.

MR. COMFORT: Correct. I mean that's

something we would be sourcing --

CHAIRMAN RYAN: Just think about it as a band rather than as a zero.

MR. COMFORT: Oh, yes, I agree.

MR. CARRERA: Yes.

MS. MATTSEN: Right now we have some source material in the registry but there's nothing in Part 40 that addresses it at all.

CHAIRMAN RYAN: Yes.

MS. MATTSEN: And in Part 32, it's really written up as kind of a voluntary thing right now even though in practice it's not voluntary. That's the subject of another rulemaking.

CHAIRMAN RYAN: Yes. Something is either voluntary or it's not. You can't have partially voluntarily.

MS. MATTSEN: Well, if you want to get a license and we say we're going to issue a certificate and a license --

CHAIRMAN RYAN: Again, I mean some of these questions have to do with burden. How many pieces of paper do I need to fill out and send in? You know most licensees will want to do the right thing but if they have to do the right thing three or four different ways, it can get pretty confusing. So

I'm just offering you some of these insights having been a six or seven licensee person and an RSO on, that, you know, some of things have to be crystal clear. And some of them shouldn't really duplicate what I do -- what one does in another license or in another part.

MR. COMFORT: Well, usually I mean a specific license will trump the requirements of a general license anyways. So doing anything with a general license wouldn't really impact decisions.

CHAIRMAN RYAN: It would be real nice if you said that in the guidance for a general license. I mean I would think about that. You might to say if you have a specific license that covers activities with X, you don't need a general license.

MS. MATTSEN: Well, there are circumstances where the general license is just there to provide a convenience for specific licensees to not have to add something specific like this calibration reference sources with americium. It wouldn't have to be specific. There is a general license for that that only applies to specific licensees. Then they don't have to amend to add that particular radionuclide.

CHAIRMAN RYAN: But, you know, and I'll give you just an example from my own experience as a

broad scope licensee, any check source, americium or otherwise is high on the inventory of sources that I have under the one license because I want to be able to track it specifically to that license and not have to worry about this license because that's a whole new tracking things.

And, you know, sometimes these things can get more complicated than they need to be. They create confusion rather than clarity. So that's something to thing through.

And, again, I'd ask those kinds of questions of the licensees off of the survey.

MR. COMFORT: 40.22 specifically already has -- if you've got a specific license, this doesn't apply to you, you know, kind of clause into it. So that's the -- if you have a specific license under Part 40, it doesn't apply.

MS. MATTSEN: Well, the general license does apply. They don't have to necessary tack something on to that license. But the exemption from Parts 19 and 20 do not apply.

CHAIRMAN RYAN: And that's the part I'm trying to get across. I have let's say a South Carolina broad scope license. And I want to get an americium check source. I'm going to get it under the

South Carolina license. Right?

MR. COMFORT: Correct. I mean --

CHAIRMAN RYAN: I don't need to worry about a general license.

MR. COMFORT: That's that's way I would understand it.

CHAIRMAN RYAN: I think that's going to be --

MS. MATTSEN: A general license isn't something to worry about. It's just something that extra you can do, yes.

MR. COMFORT: Yes.

CHAIRMAN RYAN: Fine.

MR. COMFORT: Okay.

CHAIRMAN RYAN: Okay, sorry. When you need to come in I think needs to be crystal clear. And when you don't need to come in, it needs to be just as clear.

MR. COMFORT: Okay.

MR. CARRERA: Finally various general license in Section 40.25, which applies to the use of products or devices to have the purpose for providing concentrated mass in a small volume such as shielding. However, the manufacturing requirements, which are found in Section 40.34 are considered overly

burdensome.

So this general license has not been utilized much. In fact, we are aware of only one specific licensee who does manufacture such product for use under the general license.

We are asking we should modify the manufacturing requirements and broaden the general license to make it easier for persons to obtain license for manufacture of such devices.

Slide 33 please.

CHAIRMAN RYAN: Are the DU uses civilian or military mainly?

MR. COMFORT: Under the general license?

CHAIRMAN RYAN: Yes.

MR. COMFORT: Again, we're not aware. You know there could be some uses under civilian that are going on that we're just not aware of.

CHAIRMAN RYAN: Again, the whole survey is aimed at gathering more information about it.

MR. COMFORT: Well, that's what we -- when we start doing the -- or getting the distributor information, we would hopefully be able to identify better how some of this material is being used by, who it goes by.

The intent is afterwards we'd collect the

data and go talk to specific general licensees to see how they're actually using that material that they are receiving, particularly once we were using larger quantities. Of it.

MR. CARRERA: All right. In conclusion, I'd like to summarize a few points. First, the staff is aware that the proposed revision related to the distribution requirement and reduction in possess limits will require a number of persons currently operating under a general license to come in as specific licensees. The staff expects most of these persons impacted will be manufacturers and initial distributors of product to an exempt person.

A second but smaller category is expected to be the persons impacted by the reduced possession limit. However, since we expect that most of the larger users likely produce exempt products, the group who can't reduce their quantities below the reduced limit we expect to be small.

The last category that would require a specific license would be any one possessing specific isotopes of uranium and thorium under Section 40.22 general license. Again, we believe this would be a very small number of persons, if any.

However, because of a lack of available

information, we hope to get a better indication of the impacts during the public comment period.

The proposed rule changes are expected to increase health and safety to workers and the general public through the reduction of the limit allowed under Section 40.22 general license for dispersible forms and for possessing of source material by providing clarification for disposal, limiting contamination, and making general licensees more aware of all the requirements that apply to them.

The new distribution license will allow NRC to better understand and react to the use of source material under exemption and general license. This new information would allow us to better refine our regulations to adapt to changing situations by both reducing allowed activities or expanding them as we better learn how source materials is being used.

And throughout development of the proposed rulemaking, we try to minimize the impact to all persons involves while at the same time ensuring that adequate protection of health and safety is provided.

We have tried to clarify the regulation to make it easier for person to operate under Part 40 of the regulation. Overall because of a lack of available information, we look forward to hear form

the industry and the general public to provide comments on the proposed rule after it is published to help us improve this proposed rule.

Slide number 34 please. And with that, I'm open to any other questions. Thank you.

MR. COMFORT: Real quickly, one of the first questions or questions I've heard from, you know, a variety of people is, you know, we don't know who these general licensees are. There's not an expectation they are going to be reading the Federal Register notices, you know, on a common basis. How are they going to know to comment?

And one of the things that we are planning to do is anybody that we've identified previously through any of these distribution reports that we have received from distributors, also from other contacts that we've gotten phone calls even off of this rule being, you know, on the NRC website, even though it is not available for public comment yet, we've gotten calls.

But anybody that we get sources through that, we're planning on trying to provide direct communication when the rule is published so that we can get the biggest expanse. We'll probably also try to identify some trade magazine where general

licensees or people who are maybe, you know, in the general license business may be reading to identify this rule is available for public comment.

So we're going to try to get it out to as many people --

CHAIRMAN RYAN: What about CRCPD and OAS?

MR. COMFORT: Yes, well they will be definitely aware of those and stuff on it. They have been involved actually -- we've had a CRCPD rep and an OAS rep on the rulemaking group also.

CHAIRMAN RYAN: Great.

MR. COMFORT: And the agreement states got an opportunity to look at the rule and provide comment on it when it was in the draft form, too, before it went to the Commission.

CHAIRMAN RYAN: Did you get many comments?

MR. COMFORT: Only got a couple of comments on it and stuff. One of them -- the more significant ones was a concern about the disposable requirements. Again, the State of Illinois had gone and done that -- looked at all their schools trying to collect, you know, loose amounts of general license material because of the concerns about disposal of it.

And they were concerned by limiting the disposal, they were collecting it all themselves to

dispose of because trying to do minimal amounts could be very expensive, particularly if you treat it as low-level waste.

Instead, you know, what we basically said is we're still allowing a minimal quantity that we're making it clear you can dispose of which would usually hit, you know, meet the requirements of most of these real small, you know, school users and stuff that they wouldn't have to do anything.

CHAIRMAN RYAN: By that disposal you're meaning --

MR. COMFORT: Minimal disposal exactly.

CHAIRMAN RYAN: Subtitle D?

MR. COMFORT: D is it? Or is it B?

CHAIRMAN RYAN: D.

MR. COMFORT: But not if you go to a low-level waste site or something like that.

CHAIRMAN RYAN: Okay. That's great. Thank you.

Derek, do you have any questions?

MR. WIDMAYER: No.

CHAIRMAN RYAN: Okay. We are a little bit ahead of schedule which is a rare thing for an ACRS Subcommittee but it's probably because I'm here by myself. So I think we're scheduled for Mr. Simmons to

give some comments at 11. We'll do that on schedule so that, you know, anybody else is dialing in or may dial in on the bridge line -- I don't think we have anybody signed up to do that -- or if anybody else wants to come here physically, we'll be here at the right time.

So I'm going to suggest we take about -- let's try to reassemble at say quarter of 11. And we'll take up any other questions or comments. And then have Mr. Simmons give his presentation and comments at 11. And go from there. Fifteen minutes satisfactory? That works for you?

MR. SIMMONS: That's fine.

CHAIRMAN RYAN: Okay. Great. Terrific. So we'll convene at quarter of 11 and pick up from there. And on we go.

MR. CARRERA: Mike?

CHAIRMAN RYAN: Yes, sir?

MR. CARRERA: You're not going to use the gavel?

CHAIRMAN RYAN: I sure can if you want. We're adjourned until 11 o'clock. Thank you.

(Whereupon, the foregoing matter went off the record at 10:22 a.m. and went back on the record at 10:51 a.m.)

CHAIRMAN RYAN: Okay. The meeting will come back in session.

We'll now have a presentation from Mr. Charles Simmons, NRC 40.22 Rulemaking, Unintended Consequences.

Mr. Simmons, welcome.

MR. SIMMONS: Thank you very much, Mr. Ryan. And thank you to the Subcommittee for inviting me to speak today.

By way of background, I'm an attorney practicing in Washington, D.C. and I've worked in the minerals industry for approximately 20 years where I have been experienced in typically the unimportant quantities of source material under 40.13(a) but often encounter the generally licensed situation, which I will speak to this morning.

The suggestion by my title of the talk is that this proposed or contemplated rulemaking may have some unintended consequences to industry in the United States and I would like to offer some thoughts for the Subcommittee to take into consideration as they proceed with the drafting of this proposed rule.

Going back to the very fundamentals, we must look at the Atomic Energy Act definition of source material where we see that source material is

either uranium or thorium or ores containing one or more of the foregoing materials, uranium or thorium, in such concentration as to be determined by the NRC.

NRC's regulations at 10 CFR 40.4 more narrowly describe the definition of source material as, again, a sort of -- in a bifurcated way as uranium or thorium or any combination, which I understand to be the elemental uranium or thorium or ores which contain, by weight, 0.05 percent or more of uranium or thorium or any combination.

An ore, of course, is not defined in NRC regulations anywhere or in the Atomic Energy Act so we must then look to the common dictionary definition as an ore as any mineral that can be used or useful for extracting the metal or mineral value therefrom.

These definitions become extremely important and they are, of course, precisely imprecise to a certain extent when it come to concluding from a user's standpoint whether they are in possession of source material requiring a general or a specific license.

Of course, Section 62 of the Atomic Energy Act makes it clear that no person can transfer, receive, or possess source material without a general or specific license except that no license is required

for unimportant quantities of source material. Within in this context, we start looking at what are unimportant quantities of source material when it come to the minerals context that I'm speaking to.

Under 10 CFR 40.13(b), we see that one form of unimportant quantity is unrefined and unprocessed ore that contains source material provided that except as authorized in a specific license, no person can refine or process that ore.

What I understand from that definition in 40.13(b) is that an ore, a material that is useful for extracting a metal value or is otherwise mined or a process of some mineral exploration containing 0.05 percent by weight or more of uranium or thorium may be possessed without refining it. The moment it is refined or processed, it becomes licensable source material.

So what then is unrefined and unprocessed ore? Turning to 10 CFR 40.4, unrefined and unprocessed ore is defined as ore in its natural form prior to any processing such as grinding, roasting, or beneficiating, or refining. There is an old health physics position paper, HPPOS paper published by NRC pertaining to unrefined and unprocessed ore. And I believe, if I recall correctly, that it had a

situation, an enforcement situation dealing with crushed ore.

So that is one of the few instances where unrefined, unprocessed has made it into an enforcement situation. And I believe that that particular determination suggests that any crushing of ore would render it processed for the purposes of becoming licensed source material.

Well, this brings us to issue number one that I see with the contemplated rulemaking. And that has to do with the minerals research and development efforts in the United States, particularly with regard to rare earth elements, rare metals, and certain transition metals such as the zirconiums and hafniums.

In the context of strategic materials, we have an issue in the United States with rare earths. This has been noted by a report to Congress that was released in April of this year. And it has been noted in a very recent --

CHAIRMAN RYAN: That's the House Bill -- I'm sorry, that's the House Bill 4866?

MR. SIMMONS: House Bill 4866 also released in April.

At 91 percent, according to the U.S. Geological Survey of our rare earth elements, they

come from China between 2005 and 2008. And it is probably higher than that in more recent years.

April, as I mentioned, as was mentioned, a House Bill 4866 was introduced to reestablish a competitive domestic rare earth mineral production industry. The rare earths, rare metals, and transition metals include neodymium, cerium, lanthanum, scandium, zirconium, titanium, hafnium, and all of which are typically associated with ore bodies that are affiliated with uranium and thorium contents. This is just a fact of nature.

And those kinds of ores include the monazites, the bastnaesites, and sometimes the zircons.

In order to develop a rare earth industry in this country, there is going to have to be a lot of sample collection. There's going to have to be mineral exploration. And there is going to have to be a lot of analysis going on.

Typically in a mineralogical situation, samples are collected in the field, they are crushed, they are packaged. They are sent to a laboratory where they are ground, pelletized, and then submitted for -- what's usually done is an x-ray fluorescence analysis to identify their elemental concentrations.

Laboratories and mineral exploration and R&D facilities will keep samples for reference. They keep samples in a library and they keep samples as standards for subsequent analysis. Many of these samples contain .05 percent uranium or thorium by the nature of the ore body.

It is okay under the current general licensing scheme to maintain 15 pounds of licensable source material or an adequate sample library, 150 pounds in a year. But we start lowering that to 3.3 pounds, I think it is going to have an effect upon the collection, the transfer for analysis, and the cataloging for future reference of mineralogical specimens by strategic industries that have been identified as very important.

So what the net effect might be is a disincentive to mineralogical laboratories and R&D folks engaged in the rare earths, especially alloys and certain advance ceramics that if it is going to be a hassle, if we have to have a specific license to engage in our sample collections, our transfers of samples to laboratories and back again, or sharing samples among mineral exploration facilities, it is going to be a lot easier to do it elsewhere rather than the United States.

There was note from the Pacific Northwest National Laboratory report. It noted correctly that the lanthanides and certain other elements such as zirconium are increasingly used as substitutes for thorium in many traditional thorium activities. That is absolutely correct. But the reality is is all of these substitute elements have to be obtained from somewhere. Right now they're coming from China.

If we want to develop a robust industry for rare earths and rare elements in this country, we're going to have to consider what the effect could be of a proposed modification to 3.3 pounds per -- 3.3 pounds or more at any given time in possession. I think it is going to be a disincentive and it is going to discourage the use or the development of the U.S. resources and industries in this area.

CHAIRMAN RYAN: Just a comment on that. And I appreciate the point that you're looking at going from 15 to 3.3 as the it kind of limits the working inventory they can have. What are the -- can you give me the details of the burden? What would the burden be? I mean is it more interaction with the regulator or is it more waste control for the disposal? Is it higher cost for these activities?

MR. SIMMONS: In the minerals industry --

in the minerals industries that I am familiar with, the zirconium and titanium and certain other elements, specific licensing is sought to be avoided, that materials standards for importation of zircon and zirconia and titanium ores coming from Australia, coming from South Africa, the materials specifications issued by U.S. importers are that this material must be less than 0.05 percent.

The minerals industries are using these minerals for other purposes rather than their radioactive properties. The uranium, the natural co-occurrence of uranium and thorium is to the minerals industries, an unfortunate and undesired thing. The only problem is being not in the radioactive materials business, a producer or a manufacturer does not want to become a licensee.

It is expensive from the standpoint of personnel, from the standpoint of recordkeeping, and maintaining compliance with all the requirements, inventory control, and so on. And moreover, it is not the primary purpose that these entities are in business.

CHAIRMAN RYAN: Okay. So if their specifications is it has to be less than .05 percent by weight, how do they even get in the game?

MR. SIMMONS: I'm sorry?

CHAIRMAN RYAN: How do they even get to licensing because theoretically if I'm less than .05 percent by weight, I'm not a licensee of any kind.

MR. SIMMONS: Well, that's correct. You are a possessor of an unimportant quantity.

CHAIRMAN RYAN: Right.

MR. SIMMONS: What is see though in -- that question responded to materials coming into the country now. What I see on the other hand is in certain elements, people would like to import and do import certain quantities but maintain the 15 pounds at any one time, 150 pounds a year and possess under a current 10 CFR 22 general license.

CHAIRMAN RYAN: All right. Okay. So we're not talking about the less than .05 percent by weight stuff. We're talking about I get a little bit higher than .05 percent by weight and I want to maintain my ability up to 15 pounds as a general licensee rather an a specific licensee.

MR. SIMMONS: I'll give you a perfect example that in the advanced refractory issue number two coming up in a moment.

CHAIRMAN RYAN: All right. Great. I'll wait. That's fine.

MR. SIMMONS: Okay. Issue number two has to do with high performance ceramics and refractories. In certain metallurgical applications involving the so-called superalloys that are used to manufacture things like airfoils that are used as blades in jet turbines, hip joint replacements, other very high performance alloys of exotic metals that perform under extreme conditions of temperature, corrosion, stress, and so on, that are being used in advanced applications, these types of alloys require a certain type of ceramic material in order to be able to melt them and cast them into the desired shapes.

In some cases, they use a natural zirconium oxide mineral baddeleyite, which is around 550 or so parts per million uranium and thorium. And that is used to make refractory articles under a specific license issued by an agreement state. I know of two such facilities that have licenses to manufacture this type of refractory, both agreement state licenses.

The manufacturer makes the ceramic shape or the casting part, the refractory under the specific license. The user, being the manufacturer of the jet engine or the exotic material, is possessing that refractory under the general license, the current

general license, 40.22.

Example, crucibles used for melting the superalloys, each one being less than 15 pounds of source material but nevertheless containing natural uranium and thorium.

CHAIRMAN RYAN: Just for scale, how big are these crucibles?

MR. SIMMONS: Oh, they're not big. I would say the smallest one is the size of a Dixie cup.

CHAIRMAN RYAN: Okay.

MR. SIMMONS: This is an example of the specialty refractories in use. On the lefthand side, there are workers that have a, as you can see, a small ladleful of superalloy and are pouring it into what is called an investment casting mold where a ceramic material has been built up over a wax model of the part to be cast. The ceramic material is then baked to make it hard. The wax melts and leaves a mold cavity which, when the mold is properly heated, the melt is poured into the mold and it fills the cavity and creates the part.

An example shown on the right is a turbo fan blade for a jet engine made using that exact process.

So you can see from the lowering the

possession limit under Part 22 is certainly going to effect the use of these advanced ceramics, advanced refractories by the users.

Query at this point what, if any, burdens are going to be added to the manufacturer who already operates under a specific license? I asked the manufacturer about recordkeeping and do they keep track -- how do they know that they are only giving 15 pounds of source material to a given person or a given user?

The answer I get back from that was that these materials are very expensive. They are specialty manufactured for a given user. And the manufacturer maintains in his inventory records who gets what and how much. So the records, at least in that particular instance, exist and I do not know what, if any, additional effect the changes or contemplated changes to 40.22 might have.

A couple of observations I'd like to make further to those two issues is that for the Part 40 general license, it seems that applications are quite different in many instances than the Part 30 general byproduct license. Under the Part 30 license, the byproduct material is being used to exploit its radioactive properties. It is being used to

illuminate a gun site or some other object. It is being used as a check source perhaps.

It is not necessarily the case with the Part 40 general license where in certain situations, an article made of a mineral is being used for purposes other than its radioactive properties.

The typical Part 40 general license product is also used in industrial situations and in industrial applications whereas many Part 30 generally-licensed devices arguably are consumer use items or can be used by the general public.

And what I'm thinking of there is a lot of tritium-illuminated objects that are sold, commonly bow and arrow sights, gun sights. There are certain illuminated watches and other luminous devices. Exit signs, I believe, is another one that is commonly found Part 30.

However, generally licensed materials under Part 40 are, at least from what I can see, can be distinguished from consumer products because they are industrial application materials.

A comment on the proposed changes to the glassware concentration of source material on 40.13(c)(2)(3), I see that the proposed language would exempt glassware containing not more than two percent

by weight source material or for glassware made prior to the effective date of the rule, it is the ten percent by weight is grandfathered. But excluded from this exemption are commercially manufactured glass, brick, pane glass, ceramic tile, or other glass or ceramic used in construction.

And by that I think it is apparent that building construction, whether it is for commercial or residential occupancy, would be excluded from this particular exemption. That is important that in that I see ceramics and glasses and bricks all being fairly well addressed in this one exemption but from the prior discussion on some of these advanced ceramics, one can see that there are a lot of ceramics and maybe specialty glass is out there, or I should say more correctly bricks, for their refractory bricks, that are not used in any kind of construction but are used in certain industrial operations.

I would suggest for the Subcommittee to consider as they are looking at that particular glassware example is that the classes of industrial ceramics could be very easily included there if a distinction is made between those items that are used in industrial situations and excluded from any type of construction whether it is residential or commercial.

Some of the problems that I think are sought to be addressed by the proposed rule could be considered to be resolved by perhaps less restrictive means. There is, from what I've discussed on the minerals applications, this is not a situation where a source material is intentionally or chemically processed to use its source material content.

These are situations where source material is possessed and used for some other purpose. It is not intentionally exploited for its radioactive or elemental properties.

The Colorado petition, as was explained, included the extraction of source material and the use of source material for its chemical or radioactive properties. And certainly limitation of possession quantities under a general license for this particular purpose I think is appropriate.

The chemical and physical processing perhaps, more so the chemical, is perhaps more likely to create environmental mobilities and lead to exposure and contamination situations, which are rightfully a regulatory concern.

As I mentioned with the case of the crucibles, the tracking of transfers from a specific licensee to a general licensee, at least in that

particular instance because of the nature of the refractory itself, that one, the industry has a standard practice of maintaining tracking of those types of things. And whether this needs to be underscored by some regulatory provision perhaps, that would be not so burdensome.

Where it becomes burdensome is when there are restrictions of the quantities that can be possessed and used.

CHAIRMAN RYAN: Just so I understand if you would back up a second please. The Colorado petition is designed to limit the extraction of source material for its chemical or radioactive properties. Can you tell me a little bit more about --

MR. SIMMONS: No, no, maybe I mis -- I didn't clearly state it. The Colorado petition is seeking to limit possession of the quantities of source material by general licensees and impose, I believe, the requirements of Part 19, 20, and 21 on general licensees.

CHAIRMAN RYAN: Oh, I see. Okay.

MR. SIMMONS: The origin, the reason for the Colorado petition was a general licensee that was using source material and processing it for its source material content to apply the thorium to a lense, I

believe. This is quite a different situation than a general licensee who is in possession of some refractory or a crucible and is not processing it.

CHAIRMAN RYAN: He was processing the ore and skipping the middle man and applying the processed material.

MR. SIMMONS: Right.

CHAIRMAN RYAN: Yes, okay. All right. I got it.

MR. SIMMONS: I have the Colorado petition here if you wish --

CHAIRMAN RYAN: Actually it would be good. If we could get a copy, that would be great.

MR. SIMMONS: Okay.

CHAIRMAN RYAN: Thank you.

MR. SIMMONS: Other considerations that I mentioned on the mineralogy, research and development, and typically in minerals exploration the uranium and thorium content is unknown prior to analysis.

And so it is a matter of grabbing the ores from the field and sending them to the lab that the actual content is found out -- 3.3 pounds certainly is a small quantity when you're limiting the amount that can be possessed under a general license.

And so technically you are transferring to

and from the laboratory. And it seems that the entire aspects of sample handling and laboratory analysis in a laboratory setting might be reconsidered as to limiting the quantities to 3.3.

CHAIRMAN RYAN: I resonate with that a little bit just from my own experience, that a lot of times, you know, you are in an unknown situation in the laboratory. And, you know, it could create a circumstance where I have to dispose of material much more frequently to make sure I don't break through that limit whereas if I bounce up, you know, pick some number between three and 15, maybe the right number is nine.

You know but three pounds of anything is an awful small amount, particularly if you are running a fairly robust laboratory program. There aren't that many labs in the country that will do uranium analysis any more.

So I just -- I think it is probably worth thinking through and maybe gathering some info on is three the right number? Or does six give them more operational flexibility without impacting any health and safety concern? You know that kind of thing. Why did we pick three?

PARTICIPANT: (Speaking from an unmiked

location.)

CHAIRMAN RYAN: Absolutely, yes. Just in a minute. But I'm just raising that question myself to think about.

Please continue.

MR. SIMMONS: Certainly one of the guiding principles of all radiation protection programs is to maintain dose as low as reasonably achievable. The ALARA definition is often only quoted for that first clause. And often times the remainder is taken for granted of ignored entirely.

And that is that what must be taken into account is the state of technology, the economics of improvements in relation to the state of technology, the economics of improvements in relation to the benefits, and the socioeconomic considerations and in relation to utilization of nuclear energy and licensed materials in the public interest.

In considering the general license, it certainly must be considered as what are these uses under a general license? Are they frivolous uses? And is there a significant societal and economic benefit from these uses that justifies the continuation of the general license?

And certainly if it is suspected that

there are doses which are an unacceptable fraction of the public dose limit, this information, I believe, ought to be confirmed with some robust field collection of data rather than some speculative modeling which certainly, as was discussed, the PNNL report is -- it's a fine document but it also is a little bit of a concern that it is both bounding and realistic.

I think that it is perhaps very conservative in some respects. And why I say that is that one of the dose situations that was mentioned is the use of a source material, airborne source material, it's .05 percent uranium or thorium, and it is assumed that the facility is maintaining a TLV, threshold limited value, for nuisance dust at ten milligrams per cubic meter.

CHAIRMAN RYAN: What page are you on please?

MR. SIMMONS: I'm on page A9.

CHAIRMAN RYAN: A9? Okay. Thank you.

MR. SIMMONS: At, you know, the standard breathing rate, 1.2 -- okay, all of this is an extreme situation, 2,000 hours per year at ten milligrams per cubic meter of nuisance dust. That's a heck of a lot of dust if there is anybody who know what ten

milligrams per cubic meter looks like in air.

And moreover, I think that what I did not see -- I think it is correct that they used the ICRP 68 methodology but what I would be interested in seeing is what was the assumed amed and particle size distribution for this material as well because I think it is going to be very dense and it is going to settle fast.

The other observation I would make on this one is that in a pottery facility, principle concern is exposure to crystal and silica, not other materials, because of the feldspars and the other materials that are used in ceramics manufacture.

The Occupational Safety and Health limitation for crystal and silica is .1 milligrams per cubic meter as an eight-hour time weighted average. And certainly if this was a pottery shop, it would be most likely in violation of the law to obtain this type of exposures.

So basic conclusions for the moment, I think the current Part 22 in industrial settings with the types of materials that I have discussed, the minerals, the refractories, if used in setting that are complying with Occupational Safety and Health Standards, in particular in respiratory protection,

that I think that a more robust study will confirm that the current Part 22 is protective and it maintains ALARA.

I believe that the current Part 22 is certainly ALARA in minerals R&D operations performed in laboratory settings. Again, more data are required to justify these conclusions. But I think such could be obtained if the right sources are sought out.

Dusty situations identified by the PNNL, we see that ALARA has not complied with OSHA. And I would point to a paper by David Bernhardt presented at the 2009 Health Physics Society meeting July 13th, 2009, that as the implications of granite countertop construction and uses, where Bernhardt did a third job on the dry grinding of granite countertops. And it was a very well documented analysis of inhalation exposures from extremely dusty conditions.

The sources of information, I think, that ought to be looked at and as the group goes forward, there are a lot of potential -- there is a lot of potential documentation coming out of Europe that could be very useful to this exercise in that the European scheme of things does not take into consideration the .05 percent being the threshold for licensing. It is a concern over exposure to natural

sources of ionizing radiation in the workplace under the directive 9629 EURATOM, which under Title 7 of that directive, said employers shall evaluate workplace exposures to natural radiation. And confirm that they are going -- exposures, worker exposures are going to be acceptable.

And each member state of the European Union has gone about this in a different way. Data have been in the process of being collected in France, I know, 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 the Directive 9629, and it is a wholesale revision of the European basic safety standards, which is involving a great deal of data analysis and collection from the so-called NORM industries, all of which could be highly relevant to this particular topic.

Among the various groups that I think ought to be apprised of -- groups including trade associations and perhaps other interests that would have no way of knowing about this exercise or being able to contribute any information, certainly the

American Ceramics Society, the Investment Casting Institute, there is a Tantalum Niobium Information Council based in Brussels, which keeps track of some of these issues.

Insofar as the European NORM issues go, there is -- the European Commission has a group of experts. I believe it's called DG6 on natural radioactivity in the workplace. There is also a European ALARA Network, which is on the internet.

The IAEA has written much about natural materials. And a good source -- well, I will backtrack on that to underscore one piece of commentary which has been seen from the earlier questions asked, the IAEA, through a fellow named Dennis Wymer, published a paper at the NORM V conference in Seville, Spain in 2008.

And in that paper, it described the evaluation of doses to natural materials in workplace settings. And it was underscored that modeling only gets you so far. You really need to have some kind of information obtained from sampling the workplace exposures because in particular with natural materials, it is very easy to overestimate doses, that occupancy times, dust loadings, particle sizes and particle size distributions are often assumed using

default values which will tend to dramatically overestimate doses.

And so that's all of the commentary I have. And I hope that this has been useful to the Subcommittee.

CHAIRMAN RYAN: Thank you, Mr. Simmons. I think your insights and the references you have pointed us to will be helpful and enrich the discussion I think we're going to have with staff as this proceeds along.

So thanks very much for taking your time and being with us today.

MR. SIMMONS: Okay. Well, thank you.

CHAIRMAN RYAN: I guess we have some time. I would suggest that we -- if you guys want to come up and sit at the table and have a dialogue and questions and understand, you know, any additional points you guys want to make. And wrap it up from here.

MR. COMFORT: Hi, I'm Gary Comfort again from NRC. And, Charlie, thank you very much. That was an insightful presentation.

I just had a couple of clarifying questions I had. With your concerns about the 15 pounds going down to three pounds, are we talking --

are they limiting themselves to the total amount of the ore material or are we talking, you know, how much uranium and thorium is there?

MR. SIMMONS: This is an interesting question, Gary, because it has to do with how does one determine, for general licensing purposes, the weight of the source material that is to be accounted for for general licensing purposes?

It is my understanding that if a material is an ore that it is licensable source material because it has been processed, then ore is source material in its entirety. So if you have 15 pounds of processed ore, you have 15 pounds of source material.

Okay. But on the other hand, if one has a say composite material, a mixture of a uranium, thorium, and some other matrix where it has not been chemically reacted to create a product, it is rather a mixture, then it would be, for accounting purposes under the general license, it would be the mass of the uranium and thorium in that matrix that is accounted for.

CHAIRMAN RYAN: But just to be very clear now, not the weight of the entire matrix --

MR. SIMMONS: Not the weight of the matrix unless the matrix is an ore.

CHAIRMAN RYAN: Right.

MR. SIMMONS: Okay. Now I have yet to see that written and expressed in any regulation or guidance document. But I do recall prior discussions with NRC over the years that is generally how things are decided.

And that's one of the things I want to point out that we probably could have highlighted is, as you stated, the current general license states 15 pounds of source material. The proposed one that we're doing is 15 pounds of uranium or thorium. So actually it is getting away from that question because we've seen that ourselves in the past of are you talking the ore is the total 15 pounds versus you can have 15 pounds --

CHAIRMAN RYAN: Sounds like you need clarification.

MR. SIMMONS: So we're clarify in the rule that it is now just we're talking uranium and thorium total content. So you may not see as much limitation as you may have been looking at before. But you have to look at that.

The other question --

CHAIRMAN RYAN: That clarification isn't going to be in the draft rule?

MR. COMFORT: Well, it is already. I mean the language is already in the rule and stuff.

CHAIRMAN RYAN: Yes.

MR. COMFORT: The other question, you, I think, stated crucibles are basically manufactured under specific license and then they are provided to the general licensee for use. Are they modified after that in any way? Or are they just used, you know, to contain a material?

MR. SIMMONS: The crucibles themselves are used to contain the molten alloy.

MR. COMFORT: Right.

MR. SIMMONS: At the end of their useful life, and this is a question that I was curious about, too, is what happens to the spent crucible?

At the end of the useful life of the crucible, it is either A, disposed of as a RCRA hazardous waste because it has picked up hazardous constituents such as chromium during its use and then will not pass the RCRA hazardous waste test.

So it goes to a RCRA C disposal facility on the one hand or it will go into the industrial solid waste, nonhazardous waste landfill where the other slags, casting sands, and other junk left over from foundry operations --

CHAIRMAN RYAN: Do these crucibles get used more than once? I would think that they get broken off the piece once it is molded.

MR. SIMMONS: They get -- a crucible, I don't know what a life of a crucible is. It is sufficient expensive so that if it is holding the molten metal and used for pouring, I would expect it to be used more than once.

CHAIRMAN RYAN: Yes.

MR. SIMMONS: For the ceramic investment casting mold substrate, that, itself, is going to be used once, broken, and then thrown away, discarded.

CHAIRMAN RYAN: Yes. There is no recycling of the crucible materials like grinding them up and reforming the crucibles?

MR. SIMMONS: Not to my knowledge.

CHAIRMAN RYAN: Okay.

MR. SIMMONS: Because of -- again, in foundry operations, often times it is unknown what metals are used for the casting. And people don't want to pick up a hazardous waste issue. So they will limit themselves in their recycling.

MR. COMFORT: Because my point on that one is also because if it is not further manufactured or processed and it stays as a solid, the 15-pound limit

would then still, you know, apply. That wouldn't be changed at all on it. So, again, that's an area not seeing an impact on.

Now I think a broader question I'd have is that it sounds to me a lot of your concern is how materials that are basically not used for the uranium and thorium content are going to be impacted and all of the stuff by this. And I can understand that.

And I think you are aware that we've got another effort that we are considering of trying to remove that from our jurisdiction. So that would resolve, at least from that side of it, those issues. It may have some other issues it brings up. But --

MR. SIMMONS: But I'd be talking to somebody else at that point.

MR. COMFORT: Right, right. So, okay, that's what I have.

CHAIRMAN RYAN: Okay. Anything else? Any other comments?

(No response.)

CHAIRMAN RYAN: Well, I want to thank all of the participants for an excellent morning. It really have been very informative. The staff briefings were terrific.

And, Charlie, thank you for being here and

sharing your views. And we've had a nice dialogue touching on some of these points. So I chalk it up as a successful meeting. And we'll look forward to the draft revision.

MR. CARRERA: Thank you, Mike.

CHAIRMAN RYAN: Thank you.

And with that, we will close the record.

(Whereupon, the above-entitled Subcommittee meeting on Radiation Protection and Nuclear Materials was concluded at 11:38 a.m.)

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

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Rulemaking Branch A
Division of Intergovernmental Liaison and Rulemaking
FSME

May 18, 2010

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Topics

- Background on Part 40 and current general license and exemption conditions
- History of rulemaking.
- Current issues and proposed resolution through rulemaking
- Requesting public input

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Background on current general license and exemptions conditions

What does 10 CFR Part 40 cover?

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

40.1 Purpose

Establish procedures and criteria for the issuance of licenses to receive title to, receive, possess, use, transfer, or deliver source material and byproduct materials, as defined in this part, and establish and provide for the terms and conditions upon which the Commission will issue such licenses.

What is Source Material?

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Source Material is defined as:

(1) Uranium or thorium, or any combination thereof, in any physical or chemical form, or

(2) Ores which contain by weight one-twentieth of one percent (0.05%) or more of: (i) uranium, (ii) thorium or (iii) any combination thereof.

Source material does not include special nuclear material.

* *Uranium and thorium are found naturally throughout the environment*

Regulation of Source Material

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

- Specific License
  - Yellow cake processors
  - Uranium conversion facilities
  - Mineral extractors
  - Uranium Mills (byproduct material)

- General License
  - Thorium-coated lens manufacturers
  - Water treatment facilities

- Exemption
  - Thorium lantern mantles
  - Thorium welding rods
  - Depleted Uranium Counterweights

“Small quantities” general license

- Section 40.22 provides a general license for “small quantities of source material”
  - Less than 15 pounds at any one time
  - Less than 150 pounds per calendar year

- Exempts licensee from Parts 19, 20, and 21
  - Exemption does not apply to Part 40 specific licensees

Exemptions

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- Section 40.13(a) exempts source material in concentrations less than 0.05 percent by weight
- Section 40.13(b) exempts “unprocessed” source material
- Section 40.13(c) provides exemptions for use of certain products

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History of section 40.22 rulemaking

What is the history of the rulemaking?

1999	NRC received PRM-40-27 petitioned by the Officers of the Organization of Agreement States and the State of Colorado
1999	Staff proposed multiple activities associated with Part 40 to the Commission in SECY-99-259
2000	Commission directed staff to move forward with developing rulemaking plan
2001	SECY-01-0072, “Draft Rulemaking Plan: Distribution of Source Material to Exempt Persons and to General Licensees and Revision of 10 CFR 40.22 General License”

What is the history of the rulemaking?

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2001	NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials" finalized and resulted in staff's recommendation to revised exemptions in conjunction with rulemaking plan
2002	SECY-02-0196, "Recommendations Stemming from the Systematic Assessment of Exemptions from Licensing in 10 CFR parts 30 and 40; and a Rulemaking Plan for Risk-informing 10 CFR Parts 30, 31, and 32"
2003	SRM to SECY-01-0072

What is the history of the rulemaking? (cont)

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2004 - 2006	Data Collection
2006	SECY-06-0094, "Tracking or Providing Enhanced Controls for Category 3 Sources"
	SRM to SECY-06-0094
2007	PNNL-16148, Rev. 1, "Dose Assessments for Current and Projected Uses of Source Material under U.S. NRC General License and Exemption Criteria"
	SECY-07-0196, "Information about Products and Quantities of Source Material Distributed to and Used by Exempt Persons and 10 CFR 40.22 General Licensees"

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What are the issues with the current Part 40 and how do we resolve them through the proposed rulemaking?

Current identified issues with 10 CFR Part 40

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1. Health and safety impacts in § 40.22 are not in alignment with current standards.

2. Lacking complete and timely information regarding distribution of source materials.

3. Changes in how some products are used under exemption.

4. Lacking clarity in certain requirements in § 40.22.

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1) Health and safety impacts in § 40.22 are not in alignment with current standards

Health and safety requirements in §40.22 are not in alignment with current standards

- Issues:
  - Part 40 not significantly revised since 1961.
  - Possession of certain isotopes could result in quantities greater than Category 1 of the IAEA categorization system.
  - PRM 40-27.
  - PNNL-16148, Rev.1 “Dose Assessment for Current and Projected Uses of Source Material Under a U.S NRC General License and Exemption Criteria”

Health and safety requirements in §40.22 are not in alignment with current standards

PRM-40-27

- In January, 1999, Colorado Radiation Control Program was notified of activated radiation alarm at a landfill by dumpster used by a source material general licensee.
- 4.9 mR/hr (1.3 uCi/kg-hr) was measured on the exterior of the dumpster and initiated an investigation.
- General licensee vacated building with contamination level of 734 mrem/year (regulatory limit is 25 mrem/year).

Health and safety requirements in § 40.22 are not in alignment with current standards

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Radiation Dose Assessment for Routine Use, Accidents, and Manufacturing Involving Thorium + Progeny Thin-Film Optical Coatings. (PNNL-16148, Rev. 1)

Scenario	Annual Scenario Dose (mrem)		
	Ingestion	Inhalation	Effective*
Routine Use (TV Camera Operator)			4.0 E-3
Accidents	8.2 E-4	6.4 E-2	6.5 E-2
Manufacturing	206	562	768

* Contribution from external dose considered negligible (except in routine use scenario where external dose predominates)

Health and safety requirements in § 40.22 are not in alignment with current standards

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Radiation Dose Assessment for Bounding Scenario Involving Thorium + Progeny in 10 CFR 40.22 (PNNL-16148, Rev. 1)

Bounding Scenario	Annual Scenario Dose (mrem)		
	Ingestion	Inhalation	Effective*
10 CFR 40.22 , Handling of 150 lb/yr of Thorium Powder	1030	3650	4680

* Contribution from external dose considered negligible (except in routine use scenario where external dose predominates)

Health and safety requirements in § 40.22 are not in alignment with current standards

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Resolution:

- Would make changes in possession limits.
  - Only in natural isotopic concentration or as depleted uranium.
  - Limited to 1.5 kg (3.3 lb) at once or 7 kg (15.4 lb) per calendar year if processed or in dispersible form.
  - No effective change in possession limit for non-dispersible materials or when removing uranium from drinking water.
- Would require contamination to be addressed when activities completed.

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2) Lacking complete and timely information regarding distribution of source materials

Lacking complete and timely information regarding distribution of source materials

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Issue:

- No method to allow understanding of amounts of source material distributed to exempt persons and general licensees.

- Difficulties in identifying general licensees.

Lacking complete and timely information regarding distribution of source materials

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Resolution:

- New specific licenses for initial distribution of source material to exempt persons (§ 40.52) .
  - ➢ Would require specific license by NRC only.
  - ➢ Certain health and safety requirements would not apply to persons in Agreement States (AS) or importers.
  - ➢ Would require annual reporting of product types, quantities of products, and source material content of products.
  - ➢ May result in certain general licensees manufacturing exempt products to become specific licensees

Lacking complete and timely information regarding distribution of source materials

Resolution:

- New specific licenses for initial distribution of source material to general licensees (§ 40.54)
  - Would require specific license for distribution (issued by either NRC or an AS)
  - Would require labeling and quality control
  - Would require recipients to be notified of § 40.22 (or equivalent AS) requirements and appropriate safety precautions for handling, use, storage, and disposal
  - Would require annual reporting to NRC or AS where source material is distributed including to whom and how much to allow identification of general licensees

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3) Changes in how some products are used under exemption

Changes in how some products are used under exemption

Issue:

- Changes in industry practices
  - Exempt products no longer being manufactured (i.e. uranium smoke detectors and glazed ceramic tablewares)
  - Reduced the concentration of source material used in the manufacturing practice (i.e. glasswares)
  - More prevalent use of thorium coated lenses

Changes in how some products are used under exemption

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Resolution:

- Revision of certain exemptions.
  - Would remove exemption for uranium smoke detectors [§ 40.13(d)].
  - Would allow no new distributions of glazed ceramic tableware [§ 40.13(c)(2)(i)].
  - Would reduce allowable concentration of source material in glassware [§ 40.13(c)(2)(iii)].
  - Would expand exemption for thorium lenses [§ 40.13(c)(7)] to include coatings, but reduce allowable concentrations.

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4) Lacking clarity in certain requirements in § 40.22

Lacking clarity in certain requirements in § 40.22

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Issue:

- Waste disposal requirements
- Lack of direct citations to other applicable sections in Part 40

Lacking clarity in certain requirements in § 40.22

Resolution:

- Would clarify disposal and transfer requirements.
  - May not abandon.
  - May dispose of up to 0.5 kg per year for permanent disposal.
  - Disposal of other material must be consistent with § 20.2001.
- Direct citations to other applicable sections of Part 40 for general licensees.

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Specific Questions to the Public

Questions to solicit public input

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- Use of concentration limit for coatings
- Use of activity limits in possession limits in § 40.22
- Should surveys be required when § 40.22 licensees cease activities?
- Should § 40.22 be expanded to cover 11e.(2) byproduct material from mills?
- Should provisions be added to include source material and special nuclear material in items in the sealed source and device registry?
- Should § 40.25 and § 40.34 be revised to make them more useful?

Conclusion

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- New specific licensees
- Providing additional health and safety
- Minimizing impacts

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Questions?

NRC 40.22 Rulemaking: Unintended Consequences

Charles T. Simmons

May 18, 2010

AEA Definition of Source Material

The term "source material" means (1) uranium, thorium, or any other material which is determined by the Commission pursuant to the provisions of section 61 to be source material; or

(2) ores containing one or more of the foregoing materials, in such concentration as the Commission may by regulation determine from time to time (42 USC 2014(z)).

NRC 10 CFR 40.4

Source Material means: (1) Uranium or thorium, or any combination thereof, in any physical or chemical form or

(2) ores which contain by weight one twentieth of one percent (0.05%) or more of: (i) Uranium, (ii) thorium or (iii) any combination thereof. **Source material does not include special nuclear material**

Section 62 of the AEA

Unless authorized by a general or specific license issued by the [Nuclear Regulatory] Commission, which the Commission is authorized to issue, no person may transfer or receive in interstate commerce, transfer, deliver, receive possession of or title to, or import into or export from the United States any source material after removal from its place of deposit in nature, except that licenses shall not be required for quantities of source material which, in the opinion of the Commission, are unimportant (42 USC 2092)

Unimportant quantities of source material 10 CFR 40.13(b)

(b) Any person is exempt from the regulations in this part and from the requirements for a license set forth in section 62 of the act to the extent that such person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided, that, except as authorized in a specific license, such person shall not refine or process such ore.

10 CFR 40.4 Unrefined Ore

Unrefined and unprocessed ore **means ore in its natural form prior to any processing, such as grinding, roasting or beneficiating, or refining.**

Issue #1 : Minerals R&D – particularly Rare Earth Elements, Rare Metals, Transition Metals

- **U.S. Geological Survey (USGS): 91 percent of U.S. consumption of rare earths came from China between 2005 and 2008.**
- **April 2010:House Bill 4866 “reestablish a competitive domestic rare earths minerals production industry”**
- **Rare Earths, Rare Metals & Transition Metals include Nd, Ce, La, Sc, Zr, Ti, Hf and ore bodies typically associated with U, Th (e.g., monazite, zircon, bastnaesite)**
- **Sample collection, preparation (grinding), laboratory analysis and cataloging reference samples permitted under current General License, but not at 3.3 lb!**

Issue #1 (continued)

- **Disincentive to U.S. mineralogical laboratories, R&D for Rare Earth Elements, specialty alloys, advanced ceramics.**
- **PNNL (2007) Report correctly notes that lanthanides, cerium, yttrium, zirconium are increasingly used as substitutes for Th in many applications… BUT YOU HAVE TO OBTAIN THESE SUBSTITUTE ELEMENTS THROUGH EXPLORATION AND LABORATORY ANALYSIS.**
- **Current General License allows sample collection, transfer, analysis, cataloging, etc.**
- **Specific licensing at 3.3 lbs would discourage development of U.S. resources and industries.**

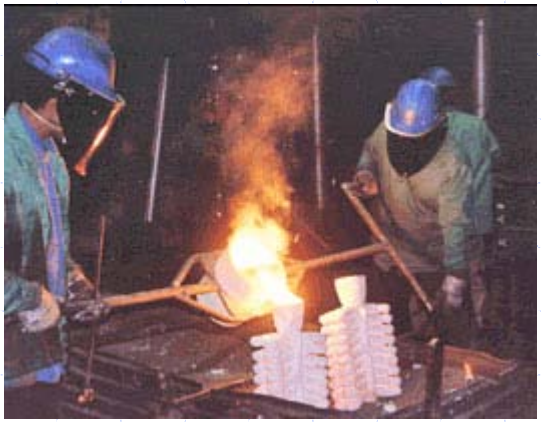
Issue # 2: High Performance Ceramics and Refractories

- Certain superalloy casting requires ultra-high performance ceramic refractories (crucibles, shapes)
- In some cases: natural ZrO2 (Baddeleyite) ~550 ppm U, Th used to make refractory articles under specific license
- User possesses refractory under current general license

Issue #2 (continued)

Issue # 2 (continued)

Specialty Refractory in use:



Part 30 vs. Part 40 General License

- **Unlike Part 30 Byproduct General License, most Part 40 general licensed materials are not intended to use source material (U, Th) for its chemical or radioactive properties.**
- **Unlike Part 30, Part 40 general licensed materials are industrial use, NOT consumer products**

Proposed 40.13(c)(2)(iii)

Glassware containing not more than 2 percent by weight source material, or for glassware manufactured before [insert effective date of rule], 10 percent by weight source material; but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction;

Suggested Alternative

Glassware and industrial ceramics containing not more than 2 percent by weight source material, or for glassware manufactured before [insert effective date of rule], 10 percent by weight source material; but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction;

Problems sought to be addressed by the proposed rule can be resolved by less restrictive means

- **Colorado petition: intentional extraction of source material for its chemical or radioactive properties.**
- **Limit quantities for this particular purpose.**
- **Tracking Transfers from S/L to G/L:**

  - refractory applications maintain records as standard industry practice

Transfer Tracking (continued)

- Mineralogy R&D – typically U, Th content unknown prior to analysis
- Technically a “transfer” to/from lab
- Samples handled in laboratory setting
- Current General License adequate

General License should maintain ALARA

ALARA **(acronym for "as low as is reasonably achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits in this part as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest.**

Conclusions

- **Current Part 22 is ALARA in industrial applications that comply with OSHA standards**
- **Current Part 22 is ALARA in minerals R&D performed in laboratory settings**
- **Dusty situation identified by PNNL is neither ALARA nor compliant with OSHA (see Bernhardt 2009 HPS paper Implications of Granite Counter Top Construction and Uses”**

Conclusions– cont'd

- **Increasing restrictions on G/L could be a significant deterrent to Rare Earths Exploration and development in the US**
- **Advanced metallurgical operations dependent on specialty refractory: easier to make in China**
- **Overall negative effect: loss of strategic materials and industries**