

**Official Transcript of Proceedings**  
**NUCLEAR REGULATORY COMMISSION**

Title: Independent External Review Panel Meeting

Docket Number: (n/a)

Location: Rockville, Maryland

Date: Wednesday, November 28, 2007

Work Order No.: NRC-1886

Pages 1-242

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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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INDEPENDENT EXTERNAL REVIEW PANEL MEETING

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WEDNESDAY

NOVEMBER 28, 2007

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VOLUME II

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ROCKVILLE, MARYLAND

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The Review Panel met at the headquarters of the Nuclear Regulatory Commission, Two White Flint North, Room T2B3, 11545 Rockville Pike, at 9:00 a.m., Mr. Thomas E. Hill, Chairman, presiding.

PANEL MEMBERS PRESENT:

THOMAS E. HILL, Chair

MICHAEL T. RYAN, Member

BENJAMIN NERUD, Member

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NRC STAFF PRESENT:

AARON McCRAW

JOHN HICKEY

DUNCAN WHITE

JAMES MONTGOMERY

MICHELLE BEARDSLEY

KEVIN HSUEH

## C-O-N-T-E-N-T-S

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P R O C E E D I N G S

(9:01 a.m.)

OPENING REMARKS AND INTRODUCTIONS

CHAIR HILL: Good morning.

MEMBER RYAN: Good morning.

CHAIR HILL: I want to welcome everyone here, and ask that the meeting now come to order.

This is the second day of our second meeting of the Independent External Review Panel. We are charged to identify vulnerabilities in the U.S. Nuclear Regulatory Commission's materials licensing program.

This meeting is being conducted in accordance with the provisions of the Federal Advisory Committee Act. And Aaron McCraw is the Designated Federal Official for today's session.

In accordance with the Federal Advisory Committee Act, this meeting is being transcribed. To ensure an accurate account of today's discussion please use one of the microphones at the table in making your statements. Identify yourself please, when speaking, and speak with sufficient clarity and volume to be picked up by the microphone.

Please conduct any necessary side

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1 conversations outside the room, and if you have a  
2 cell phone or pager, please put them in silent  
3 mode or turn them off. The Panel appreciates your  
4 cooperation with this request.

5 This is a public meeting. If you  
6 haven't already, I ask that you sign in on the  
7 sheet provided here. Remember, members of the  
8 public will be afforded an opportunity to provide  
9 oral comments at the time designated on the  
10 agenda.

11 And on the back table we have provided  
12 a list of reference materials, documents that have  
13 been or will be discussed by the Review Panel.

14 And there are also feedback forms for  
15 anyone who wishes to provide his or her comments  
16 on today's session.

17 At this time, I'll ask the Review  
18 Panel participants here at the table to introduce  
19 themselves, starting at my right.

20 MEMBER RYAN: Mike Ryan, member of the  
21 Panel.

22 MEMBER NERUD: Ben Nerud, member of the  
23 Panel.

24 MR. McCRAW: Aaron McCraw, Office of  
25 Federal and State Materials and Environmental

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1 Management Programs. I am the staff liaison to  
2 the Review Panel.

3 MR. WHITE: Duncan White, FSME.

4 MS. BEARDSLEY: Michelle Beardsley from  
5 NRC Region I.

6 MR. MONTGOMERY: Jim Montgomery, NRC  
7 Region IV.

8 CHAIR HILL: And I'm Tom Hill, formerly  
9 of the Georgia Department of National Resources,  
10 Radioactive Materials Program.

11 CHAIR HILL: Aaron, would you give us  
12 quick overview of today's agenda, where we're  
13 going?

14 MR. McCRAW: Sure, but before I get to  
15 that, I think Mike has a special announcement  
16 regarding the microphones.

17 MEMBER RYAN: Yes, I just want to let  
18 everybody know, this room is fully microphoned, so  
19 there is no such thing as a side conversation in  
20 this room, because it is all picked up.

21 MR. McCRAW: For our agenda this  
22 morning, we are very grateful to have our guests  
23 from the Region IV and Region I offices, Jim and  
24 Michelle. They will be discussing industrial and  
25 medical specific licensing.

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1           The format of the meeting today is,  
2 they will provide their presentations, and then  
3 there'll be a timeframe for an open discussion for  
4 the Review Panel to ask questions, and further  
5 probe their particular topics.

6           This afternoon we are going to be  
7 graced with Duncan White and Kevin Hsueh to  
8 discuss distribution licenses, general licenses,  
9 and the Agency's general license rulemaking  
10 efforts.

11           Again, same format in the afternoon.  
12 They will provide their presentations, and then  
13 there'll be a time period for open discussion.

14           We'll have an opportunity for public  
15 participation in the afternoon, and then the  
16 review panel has some open time for writing and  
17 discussing their work product.

18           CHAIR HILL: Thank you.

19           Before we get into the presentations,  
20 Mike, Ben, do any of you have any thoughts,  
21 comments before we start today?

22           MEMBER RYAN: Fire away.

23           CHAIR HILL: Fire away? Nothing then.  
24 Okay, with that I guess, James, you're up for  
25 specific licensing.

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## 1 SPECIFIC LICENSING - INDUSTRIAL

2 MR. MONTGOMERY: Thank you very much.

3 It's a pleasure to be here. My name is Jim  
4 Montgomery. I'm a senior license reviewer with  
5 the Nuclear Regulatory Commission's Regional  
6 Office, Region IV, out of Arlington, Texas.

7 And formerly, I was with NRC's Region  
8 V out of Walnut Creek, California. I still work  
9 out of my home in California for NRC through a  
10 special work-at-home arrangement when they closed  
11 Region V several years ago.

12 And I've been doing materials  
13 licensing and inspection for most of my career,  
14 which actually goes back over 30 years when I  
15 started originally in the Agreement State of  
16 Colorado.

17 I appreciate the opportunity to be  
18 here today to provide you with some information  
19 concerning the licensing of radioactive material  
20 used in industrial applications.

21 My discussion will focus on the use of  
22 sealed radioactive sources used in a wide variety  
23 of industrial applications worldwide.

24 Before delving into some of these  
25 applications I would first like to define or

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1 describe what we mean by a sealed source.

2           There are many types of radioactive  
3 material that could be used in a sealed source.  
4 Radioactive atoms are produced in a nuclear  
5 reactor or accelerator, and are chemically  
6 combined with other non-radioactive compounds to  
7 create the desired chemical form to be used in the  
8 sealed source.

9           Physically, the radioactive material  
10 is usually in the form of something like a powder  
11 or pellets or microspheres, but it may also be a  
12 liquid or a gas.

13           This material must be handled very  
14 carefully. Not only is it radioactive, but the  
15 chemical substance may be easily dispersed in air  
16 and cause contamination problems.

17           Therefore, to safely contain it,  
18 technicians place the material in small metal  
19 capsules which are then sealed using special  
20 welding or other techniques to safely contain the  
21 material.

22           The chemical and physical makeup of  
23 these sealed sources varies considerably,  
24 depending on what type of device they will be used  
25 in, and under what type of environmental

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1 conditions the source will be exposed to.

2 The makeup of the capsule and how it  
3 is sealed or welded also varies depending on  
4 environmental conditions. For example, a source  
5 that is to be used deep within a well where  
6 temperatures and pressures can be extreme will  
7 have to be manufactured with much higher integrity  
8 than a source used at normal temperatures and  
9 pressures above ground.

10 Occasionally, due to age, accidents,  
11 or misuse, these sources can begin to leak their  
12 radioactive material. Periodic tests are required  
13 to ensure that any leakage is detected at an early  
14 stage before much of the material can escape or  
15 pose a hazard.

16 All sealed sources have to be  
17 evaluated and approved before they can be sold to  
18 customers. The manufacturer of the source must  
19 submit to NRC or an Agreement State the technical  
20 specifications regarding source design and  
21 construction. Various national standards, for  
22 example, the American National Standards  
23 Institute, or ANSI, have been developed to help  
24 ensure proper design and construction principles  
25 will be used to minimize source failure during

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1 normal use.

2 The source design and use are reviewed  
3 by either NRC or Agreement State personnel whose  
4 job it is to ensure the manufacturer commits to  
5 following accepted construction and radiation  
6 safety specifications.

7 For example, the manufacturer would  
8 have to submit procedures that are compatible with  
9 NRC standards and NRC regulations.

10 If all of the applicable standards and  
11 requirements are met, the NRC or Agreement State  
12 reviewer, prepares a sealed source or device  
13 document which describes the technical  
14 specifications for the source or device  
15 construction, including all of the applicable  
16 radiation safety precautions.

17 The reviewer then signs the document,  
18 and it is entered into a registry, which contains  
19 all of the other sealed source device documents  
20 previously approved.

21 The registry is available to all  
22 license reviewers and other NRC personnel who can  
23 access it online for the purpose of confirming if  
24 the source has been approved, and also to obtain  
25 technical information about the source fabrication

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1 and radiation safety precautions.

2 The registry is also available to  
3 Agreement State personnel performing licensing and  
4 regulatory functions.

5 Industrial licensing, for the most  
6 part, covers the use of these sealed sources. And  
7 the sources are typically used in machines or  
8 other devices which both safely shield the  
9 ionizing radiation, for example, gamma radiation,  
10 produced by the source. But the device will also  
11 allow the radiation to escape and expose the  
12 desired object in a controlled manner.

13 Commonly used radioactive isotopes  
14 emitting primarily gamma radiation are cesium-137,  
15 iridium-192, and cobalt-60.

16 Other gauges are designed to emit  
17 beta, alpha or neutron radiation, and typically  
18 contain sources such as americium-241, polonium-  
19 210, strontium-90.

20 These are just a few of the more  
21 common examples. Literally, hundreds of different  
22 isotopes and uses exist.

23 In general the purpose for allowing  
24 the radiation to expose something is to conduct  
25 qualitative or quantitative measurements on an

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1 object of interest. These industrial sources and  
2 machines are often used in a manner similar to the  
3 way a physician would use an X-ray, X-ray machine  
4 to study something inside a patient's body.

5 In industry, the object of interest  
6 might be a steel vessel, a valve, a pipe, or a  
7 geological material. Whenever someone needs to  
8 know about the internal structure of something  
9 they cannot easily physically access or see,  
10 ionizing radiation can be used to penetrate the  
11 object and see inside.

12 The term nondestructive testing is  
13 also used for a lot of these examinations, because  
14 it allows - it allows the evaluation of the object  
15 without destroying it or damaging it.

16 The scene is done either in real time,  
17 such as a fluoroscope, or with film or electronic  
18 imaging, similar to a doctor's x-ray.

19 In many cases, instead of film, the  
20 radiation can be made to expose a detector, which  
21 produces quantitative information that shows how  
22 much radiation is passed through the object of  
23 interest.

24 This type of information can actually  
25 determine - can accurately determine the fill

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1 level or density of material in a vessel for  
2 example.

3 Also, radiation gauges are used to  
4 measure the density of material filling a  
5 container. This ensures consistency of thickness  
6 of the product.

7 Or volume measurements can be made to  
8 determine fill level of liquids in containers.  
9 Fixed gauges are attached to manufacturing process  
10 equipment. The radiation from the sealed source  
11 inside a fixed gauge is used to measure many items  
12 passing along assembly lines for example.

13 Portable gauges are typically used in  
14 the field where the operator, such as an engineer  
15 or geologist, needs to travel across outdoor  
16 areas, sometimes remote, to take measurements of  
17 geological or construction materials. For example  
18 portable soil gauges are in wide use to measure  
19 construction materials such as soil, rock,  
20 asphalt, concrete. Other portable gauges can  
21 determine the chemical content of objects. Some  
22 gauges are capable of detecting hazardous  
23 chemicals and explosives.

24 Some radiation sources are used to  
25 kill or retard the growth of unwanted biological

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1 material, such as bacteria, or mold or insects.

2           These highly radioactive sources are  
3 contained in large machines called irradiators.  
4 The sources within these devices typically contain  
5 either cobalt-60 or cesium-137.

6           Well logging is another specialized  
7 use of sealed sources found in the oil and gas  
8 well drilling industry. To study the material  
9 being drilled, geologists lower radioactive sealed  
10 sources down a borehole. As the radiation  
11 interacts with the geological formation, it is  
12 detected by instruments which can perform  
13 quantitative and qualitative measurements,  
14 providing vital information about the possibility  
15 of reaching oil and gas deposits.

16           Industrial radiography is a technology  
17 that uses high energy radiation emitted from  
18 sealed sources, such as iridium-92 and cobalt-60  
19 for the purpose of taking quote x-rays of dense  
20 objects to determine the structural integrity of  
21 safety-critical materials, such as welded parts,  
22 crusher vessels, pipelines, aircraft parts, et  
23 cetera.

24           The idea is to use photographic or  
25 digital images to see inside dense metallic

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1 objects to detect defects which could indicate  
2 weakened structures. These defects might take the  
3 form of cracks or voids which could indicate  
4 impending failure of a critical safety component.

5 These radiographic images can be  
6 viewed by a trained radiographer or other  
7 specialists in a manner similar to the way a  
8 radiologist might study the x-ray of a broken  
9 bone.

10 Now I've very quickly gone over what  
11 a sealed source is, and just very generally some  
12 of the more common uses. There are, as I said,  
13 literally hundreds, probably over - maybe  
14 thousands of uses of sealed sources that go on  
15 worldwide, and I've just touched the highlights  
16 here.

17 What I'd like to do for the rest of my  
18 talk is describe how NRC, and specifically how I,  
19 perform license reviews when we receive an  
20 application from someone who wants a license to  
21 use this material in some of the ways that I just  
22 described.

23 What I'd like to do is use industrial  
24 radiography as an example of the process to get a  
25 license. There are some specific differences with

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1 radiography compared to other uses, but  
2 radiography will serve as a good example. And a  
3 lot of these processes that I will describe are  
4 generic across any type of source that you might  
5 want to get a license for.

6 As a guide through the various types  
7 of licensing that we use in the NRC, reviewers use  
8 several NRC publications known as NUREG-1556, 1-5-  
9 5-6. There is a series of 21 volumes covering all  
10 forms of licensing conducted by the NRC, and the  
11 Agreement States.

12 The Agreement States often also use  
13 their own publications, guides, and procedures  
14 which are generally compatible with the NRC's.

15 Each of these NUREG-1556 volumes, and  
16 I'm holding up Volume I - we used to call these  
17 the orange books; most of them are orange, but now  
18 they are coming out in other colors - but Volume  
19 I is on the portable soil gauges that I briefly  
20 described earlier.

21 And these volumes contain virtually  
22 all the information needed to obtain a license.  
23 They also contain detailed checklists which both  
24 the applicant and license reviewers can use to  
25 migrate through the entire application process.

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1                   These checklists refer to applicable  
2 NRC regulations, and direct the applicant to  
3 comment - or to commit to model procedures which  
4 the NRC has determined will satisfy the  
5 requirements of a particular regulation.

6                   However, an alternate procedure can be  
7 submitted by the applicant, and will be accepted  
8 if it is at least as complete - as stringent as  
9 the model procedure in the NUREG.

10                   All of the NUREG-1556 volumes are  
11 available on the NRC's website.

12                   Now, the following is a summary of the  
13 checklist for the industrial radiography  
14 application. I could talk for hours on just this  
15 one process, so I'm going to quickly go over  
16 these, and then allow time for questions if anyone  
17 wants to delve more thoroughly into this.

18                   Of course the first thing - and again  
19 this is pretty much a generic type of application  
20 for any sealed source - the first thing you would  
21 obviously put in your application would be the  
22 name of the applicant, name, address, telephone  
23 number, so we can contact the individual. And we  
24 usually have a lot of contact, both electronic, by  
25 email, telephone, and regular mail with the

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1 applicant, depending on the questions that we ask  
2 during the process of the application review.

3 The address where the licensed  
4 material will be used and possessed is listed;  
5 description of the sealed sources and devices to  
6 be used - this is a major area with the sealed  
7 sources, because a lot of information has to be  
8 provided - sealed source, manufacturer, model  
9 number, how much of the material is requested.

10 And then the reviewer goes in and  
11 looks through this registry of sealed sources that  
12 I mentioned and looks up each source and model  
13 number to verify that they are currently approved  
14 and to review all of the specifications on  
15 radiation safety and source manufacturing use that  
16 are contained in there.

17 The types of use: what are the sealed source  
18 going to be used for? This is a very - can be a  
19 very specific, very lengthy description, depending  
20 on the size of the applicant's business and how  
21 many different applications of the sources they  
22 intend.

23 Then we get into personnel. The NRC  
24 and Agreement States spend a lot of time reviewing  
25 the individuals who want to possess and use this

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1 material. This is critical and takes up a great  
2 deal of our time. We need to make sure,  
3 obviously, that the applicant and his or her staff  
4 are properly trained and experienced to use the  
5 material safely and in accordance with the  
6 regulations.

7 The radiation safety officer is the  
8 key individual at all licensed facilities who is  
9 responsible for radiation safety. That  
10 individual's training and experience are carefully  
11 spelled out in these NUREG volumes.

12 The training and experience  
13 requirements vary considerably depending on the  
14 type of material to be used. An industrial  
15 radiographer, since they handle potentially very  
16 high - highly radioactive sources, their training  
17 and experience has to be very extensive. And  
18 it's reviewed very carefully.

19 The RSO's authority in the licensee's  
20 organization is also reviewed. We want to make  
21 sure that the radiation safety officer has the  
22 authority, that the management of the company  
23 gives that individual authority to conduct  
24 radiation protection properly, that he has the  
25 authority for example to shut down an operation if

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1 they deem it to be unsafe, and that they don't  
2 have to go and get somebody's permission to do it.  
3 If they see a critical hazard or danger, they take  
4 action immediately, and that is what we look at in  
5 the authority, and this is pretty much across the  
6 board with all radiation safety officers in all  
7 different uses of material.

8 Then we get into the actual, who are  
9 the actual people in radiography that use the  
10 sources. These are called radiographers and  
11 assistant radiographers. Their training has to  
12 be, again, very extensive, very specific. They  
13 are required to be certified by a national  
14 organization for radiographers, and we review this  
15 very carefully.

16 Some radiography is conducted at what  
17 we call permanent installations, permanent  
18 facilities, where a source is used, and the  
19 material to be radiographed is brought into the  
20 facility. These are called permanent  
21 installations. They have their own separate  
22 requirements for many different radiation safety  
23 parameters.

24 Field locations: radiography is  
25 typically conducted using portable units in field

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1 applications, such as where a pipeline is being  
2 constructed across an area where weld - pipes are  
3 welded together, valves are welded and this kind  
4 of thing, is where radiography using portable  
5 devices is done, and this kind of use is carefully  
6 reviewed during the whole process.

7 Obviously, to accurately measure  
8 radiation that is being produced by these devices,  
9 survey instruments need to be used. We look at  
10 these very carefully. There are all kinds of  
11 survey instrument requirements, calibration  
12 requirements.

13 The sealed sources in radiography  
14 frequently come and go. By that I mean, iridium-  
15 192, which is the most commonly used source, has  
16 a relatively short half-life, and it - so as the  
17 strength of the source decreases, they have to  
18 replace with a new source.

19 So radiographers are continually  
20 having sources coming in and going out. Source  
21 exchanges are very common. All of this requires  
22 written procedures and training on how to do this  
23 safely. They have to account for all of these  
24 sources, and they have to keep detailed records so  
25 they know where everything is, where it's going,

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1 where it's coming, what's going out. Inventories  
2 are kept.

3 The sources have to be leak tested,  
4 and I mentioned the potential hazard if any of  
5 this material ever gets out of the sealed sources.  
6 So leak tests are very important, and have to be  
7 done for radiography in all of the different  
8 sealed source uses.

9 Occupational dosimetry: instruments  
10 that measure the individual worker's radiation  
11 exposure. Radiography has probably more of these  
12 than anyone else, so that we review those devices.  
13 They have to describe how they are used, and what  
14 type they are, and action to be taken if the  
15 dosimetry shows high exposure.

16 Quarterly maintenance of the equipment  
17 is vital in radiography. The radiographer's  
18 equipment gets an extreme amount of physical abuse  
19 and use. Just by the nature of the job and the  
20 environment they work in, the devices have to be  
21 maintained properly so that they work safely. So  
22 we have all kinds of requirements for how they  
23 maintain these devices, and how often they check  
24 them.

25 Last but not least in radiography is

1 what we call the operating and emergency  
2 procedures. These are - this is, usually  
3 comprises the thickest part of the application,  
4 because it requires a lot of written description  
5 of basically how they're going to operate, and  
6 what are they going to do if they have an  
7 emergency with the radioactive material.

8 So for example they have to provide  
9 step-by-step handling procedures for the devices  
10 they're using. How do they use them? How does  
11 the radiographer receive the device? How do they  
12 use them? How do they set it up? How do they  
13 take the exposures? How do they secure everything  
14 when they are done? How do they exchange sources?

15 This is a fairly involved process  
16 where you take one source that is no longer  
17 needed, you exchange it with a new source, a fresh  
18 source that has the higher activity you need to do  
19 your job. That has to be done very carefully,  
20 using very specific equipment, which must be  
21 compatible with each, so that you're exchanging  
22 one source for another, you have to make sure that  
23 everything hooks up and is compatible. You are  
24 using a lot of physical devices to make that  
25 transfer safely.

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1                   Performing radiation surveys: how are  
2 surveys done? How are they to be done? Where are  
3 they to be done? When? All of that has to be  
4 described in the operating emergency procedures.

5                   Controlling access is critical. These  
6 radiographers typically work in areas where there  
7 may be other non-radiation workers present;  
8 members of the public may be nearby. So  
9 controlling access to the radiation areas, to the  
10 hazardous areas, is extremely important, and very  
11 detailed procedures have to be spelled out for  
12 this.

13                   Locking and securing the radiographic  
14 equipment, because it is portable. It can easily  
15 be picked up and carried off. There are all kinds  
16 of procedures on how do you lock it and secure it  
17 so that isn't going to happen, so unauthorized  
18 people cannot just come and pick it up or take it.

19                   How they use personnel monitoring  
20 devices is a part of that procedure.

21 Radiographers transport these gauges all the time  
22 in vehicles; transport them in land vehicles.  
23 There's a lot of radiography that is done at sea,  
24 so there are a lot of boats ingoing and carrying  
25 materials.

1                   So all the transportation procedures  
2                   and requirements have to be spelled out.

3                   The equipment, because it does get  
4                   such heavy use, has to be inspected daily, and  
5                   maintained, so that the parts are not going to  
6                   fail, or if they do fail they have to be repaired  
7                   and replaced.

8                   Instrument    alarms    and offscale  
9                   dosimeters have to be described.  What are they  
10                  going to do if one of their instruments has a high  
11                  reading?  What is a radiographer supposed to do?  
12                  All of that has to be spelled out.

13                  Defective equipment: what if they do  
14                  find - what if they find a particular device that  
15                  has something that breaks, and maybe it's starting  
16                  to happen to several of them, they are noticing  
17                  some type of defect.  That has to be described,  
18                  and is spelled out, how they're going to report  
19                  that.  That is something we would want to know  
20                  about, because it might affect many of our  
21                  licensees who are using that same model.

22                  Notification of radiation incidents  
23                  and emergencies.  If they have an accident,  
24                  something goes wrong, who do they call?  What do  
25                  they do?  Who does what?  What is the procedure?

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1 All of that has to be spelled out.

2           Radiation safety precautions in the  
3 event of an emergency. If a source gets out of  
4 its shield, and it cannot be returned to its  
5 shield, which sometimes happens, how do they  
6 retrieve the sources safely? What is the  
7 procedure for doing it so you don't get yourself  
8 or someone else overexposed to radiation?

9           And finally maintaining records. When  
10 we inspect these facilities we are not there all  
11 the time; we don't watch them all the time. The  
12 records they keep help to tell us what they've  
13 been doing, and whether they have been performing  
14 these functions properly.

15           We try to when we do inspections of  
16 radiographers - it's critical that we do the  
17 inspections as often as possible in the field,  
18 where we can actually observe the men or the women  
19 working with the sources and see firsthand what  
20 they're doing, and not just looking at records.  
21 But that covers the inspection.

22           So that in a nutshell is industrial  
23 licensing. And I've covered a tremendous amount  
24 of material in a very short period of time, so I  
25 think I'll stop here, and I'm sure there will be

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1 questions later, and I'd be glad to try to answer  
2 them.

3 CHAIR HILL: Well, I've got two - three  
4 questions, and I don't know if Ben and Mike have  
5 any or not. I'll start with one, and see where  
6 everyone wants to go.

7 The registry for sealed sources and  
8 devices, SS&D registry, you mentioned that was  
9 available for licensed reviewers, et cetera. Is  
10 that online available for the public?

11 MR. MONTGOMERY: No. It used to be,  
12 but now it is - it is restricted because the  
13 registry does contain a lot of drawings and very  
14 detailed information about how the source is  
15 constructed, and it isn't the kind of information  
16 that you'd want just anyone to be able to look at.  
17 It's really specifically designed for the people  
18 who are regulating the material.

19 It's also - it is also available to  
20 the licensees if they have a need to know. They  
21 can obtain copies of the sealed source and device  
22 registry from us.

23 CHAIR HILL: That's hard copy?

24 MR. MONTGOMERY: Yes.

25 MR. WHITE: This is Duncan. I'd like

1 to add something to that. The SS&D registry is  
2 password protected, is changed periodically, and  
3 also Agreement State people have access to it. So  
4 it is truly used by all license reviewers  
5 nationally to review information.

6 And again, I'd point out most sheets  
7 on there are done by Agreement States, since they  
8 have the bulk of the manufacturing licensees in  
9 the country.

10 CHAIR HILL: I assume most of the  
11 Agreement States, as well as NRC, have two or  
12 three or four volumes of hard copies of this in  
13 their office, of all SS&D registry sheets?

14 MR. MONTGOMERY: Yes, I know our Region  
15 maintains the old hard copies, but I think we go  
16 to the online registry now for - because a lot of  
17 times the hard copies are out of date.

18 MR. WHITE: Again, point out about  
19 Agreement States, a lot of Agreement States are  
20 going away from the hard copies, because it's time  
21 consuming, as Jim pointed out, they are  
22 voluminous. They take up usually a whole cabinet,  
23 a number of them. A lot of States consequently  
24 just depend on the electronic version. And I  
25 recall several years ago STP, Office of State and

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1 Tribal Programs, made a concerted effort to go  
2 through the online registry, make sure it was up  
3 to date and as complete as possible.

4 Again, that information is sent into  
5 Headquarters, and floated up from Headquarters.

6 CHAIR HILL: How many - you mentioned  
7 the model procedures in NUREG-1556 were available  
8 - and that's available online as well?

9 MR. MONTGOMERY: They are.

10 CHAIR HILL: For license reviewers,  
11 NRC/Agreement States, as well as the public?  
12 Okay.

13 How many - this is going to be a  
14 judgment question, and I don't know that you are  
15 going to have statistics on this by any means -  
16 how many licensees use the model procedures in  
17 their application versus those who develop their  
18 own equivalent procedures?

19 MR. MONTGOMERY: It's been my  
20 experience that the vast majority of the licensees  
21 adopt most of the model procedures. Sometimes  
22 they will make slight modifications to it to fit  
23 their own program. But they generally - it's been  
24 my experience they - it's just easier and the  
25 procedures are generally accepted. These are

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1 generally accepted Health Physics practices, I  
2 think, within the industry.

3 So it's been my experience to rarely  
4 see someone completely try to reinvent the wheel  
5 so to speak and come out with a whole new  
6 procedure.

7 There will be some modifications,  
8 slight modifications, to it. But I'd say, I don't  
9 know, I'd say probably 90 percent of the  
10 applications that I look at go with our  
11 procedures.

12 CHAIR HILL: I would think that that is  
13 probably consistent with what I remember seeing in  
14 the Agreement States, not being that much  
15 different.

16 One other question, then I'll let Mike  
17 and Ben ask questions if they want to.

18 You mentioned the checklist was  
19 available for the reviewer and the applicant?

20 MR. MONTGOMERY: Yes.

21 CHAIR HILL: And so that is online?

22 MR. MONTGOMERY: Yes. The checklists  
23 are an appendix in all these volumes, and they -  
24 and the checklist, it's just exactly what it says.  
25 It just walks the applicant through the whole

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1 process, step by step. And then they can refer to  
2 the NUREG for detailed information if they need  
3 help in providing whatever is asked for in the  
4 checklist.

5 For example the checklist might say,  
6 it might actually say, submit procedures for - and  
7 then they can use the model procedure if they want  
8 to, or they can, as I said, they can modify it if  
9 they need to.

10 And so the procedure, the checklist  
11 really contains a lot more than just what you see  
12 here. Some of it requires a lot more description.  
13 Others, they can just commit to or say we will  
14 follow such and such, or we will do this, and they  
15 just check it off.

16 And then when they are inspected, the  
17 inspector is going to go in, and this checklist of  
18 course is part of their application, and it's  
19 actually referenced in their license, so they are  
20 bound to follow it, what they say they're going to  
21 do here.

22 Then the inspector goes in and checks  
23 and verifies that if they said they are going to  
24 do such and such, then that's what they got to do.  
25 And that's how the system works.

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1 CHAIR HILL: All right, Ben, questions?

2 MEMBER NERUD: In the beginning, when  
3 you talked about manufacturers, and creating the  
4 sealed sources, you said that Agreement States or  
5 the NRC can give them a license to operate. When  
6 they're given this license, does that allow them  
7 to ship to any state in the country? Do you see  
8 the point of my question?

9 MR. MONTGOMERY: Okay, if - you are  
10 talking about the manufacturer?

11 MEMBER NERUD: The manufacturer, yes.

12 MR. MONTGOMERY: Yes, if the  
13 manufacturer of the source gets approval to - for  
14 the source - in other words the sealed source and  
15 device registry sheet as we call it, or document,  
16 is signed off and approved, goes into the  
17 registry, then that manufacturer can sell that  
18 source, distribute that source, to anyone who has  
19 a license to receive it. And the license would  
20 have to specify that source specifically by  
21 manufacturer and model number.

22 And then the manufacturer is required,  
23 when he gets - the manufacturer gets an  
24 application from someone for that source, the  
25 manufacturer is required to verify that that

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1 customer has a valid license specifically for that  
2 source. And basically they ask for a copy or  
3 other evidence that that license exists and is  
4 current, by date and signature everything is - and  
5 then once they see that and verify, then they can  
6 ship that source to that customer.

7 MR. McCRAW: I would like to point out  
8 to the review panel that we will be having a  
9 discussion this afternoon specifically on  
10 distribution licenses as well.

11 MEMBER NERUD: You had mentioned, or  
12 you had talked about licensing for radiographers.  
13 And you said that the process is very similar for  
14 everyone, and then went into the requirements for  
15 that particular - that particular type of  
16 radioactive material.

17 Are there - while the processes may be  
18 the same, is the level of scrutiny on every one of  
19 those different areas that you identified, is that  
20 all - is that the same? Is it assumed that that  
21 is the same level of scrutiny that is going to be  
22 provided regardless of the type or quantity of  
23 radioactive material or type of device that is  
24 going to be used? Is it all the same degree of  
25 scrutiny?

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1 MR. MONTGOMERY: Yes, I think depending  
2 on what you mean by degree of scrutiny. For  
3 example, we might get an application from someone  
4 who wants to use a fairly small amount of material  
5 in a sealed source, in a manner that even if they  
6 didn't use - didn't use the device properly, or  
7 they made a mistake, the consequences - because of  
8 the low level of radioactivity the consequences  
9 would be fairly minor.

10 As opposed to a radiographer who is  
11 using a source that you know could potentially be  
12 extremely dangerous or even lethal if it's  
13 misused.

14 So when you talk about scrutiny, the  
15 regulations, when you look at a radiographer, and  
16 what he's required, his training and all these  
17 things I went through, those are all based on NRC  
18 and Agreement State regulations.

19 Those regulations are far more  
20 stringent and far more detailed than it would be  
21 for someone using a very small source.

22 So we - so the terms of scrutiny, it's  
23 easier to review the requirements for a small  
24 source. It takes much longer to go through the  
25 radiographer part, just because it's much more

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1 stringent and more detail that we require.

2 But no matter what you review, you've  
3 got to be diligent and thoroughly look at - make  
4 sure that they are complying with all the  
5 requirements.

6 MEMBER NERUD: Okay. You discussed  
7 personnel and reviewing the backgrounds and  
8 qualifications of personnel.

9 Radiation Safety Officer, I know there  
10 are a couple of different ways you can become a  
11 Radiation Safety Officer. One of them is a course  
12 you can take, I don't know, it's 5 or 6 weeks  
13 long, and they provide the certificate.

14 How do you validate that they are  
15 actually a Radiation Safety Officer?

16 MR. MONTGOMERY: A Radiation Safety  
17 Officer's requirement, training, again, varies  
18 considerably depending on the type of source and  
19 the type of use.

20 But we - generally the process is to  
21 obtain a written confirmation of the training.  
22 This can take several forms. If they have taken  
23 a course - well, first of all, let me start over.  
24 The application that comes in has to be signed by  
25 someone in the company, someone in the licensee's

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1 organization that is authorized to sign for them,  
2 so this is typically the president of the company  
3 or some manager, some management representative,  
4 signs that application and by signing that that  
5 person is verifying that the informatoin provided  
6 is correct, and NRC has a regulation actually that  
7 that information has to be submitted, has to be  
8 correct and truthful and so forth.

9 So that individual signs that, and  
10 then everything that is submitted is submitted  
11 under that manager's authority, that manager's  
12 auspices.

13 And in that submittal would be  
14 something - a typical example would be RSO has  
15 taken some training class as you just said, and  
16 there would be a certificate signed by the  
17 instructor of that class.

18 It might be - the class might be given  
19 by the manufacturers themselves of the source.  
20 It's very common that - that if you are going to  
21 order a source from them, they will provide you  
22 training for your people. And they conduct the  
23 training, and there is a certificate issued.  
24 Usually some kind of outline of the training,  
25 what's covered, an instructor's qualifications to

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1 conduct the training; all of that is submitted and  
2 signed off on, and it can be verified. If need be  
3 the reviewer - it depends on how it's submitted.  
4 If the reviewer looks at it and says, this doesn't  
5 look quite right to me, the reviewer certainly has  
6 the option to call the trainer, talk to the  
7 instructor directly, look at more details about -  
8 a lot of these courses are known to us from past  
9 experience. They are companies that do this all  
10 the time, and we are familiar with them. They may  
11 even have a license from us themselves, so we know  
12 who they are.

13 If we don't know who they are, we have  
14 questions. You know we can always look into it  
15 further to verify the validity of the training.

16 Does that answer your question?

17 MEMBER NERUD: Sure does. We're here  
18 because of the GAO report, so here's the loaded  
19 question: At what point do you validate that the  
20 company is actually a bonafide company, that they  
21 are who they say they are, and how do you do that?

22 MR. MONTGOMERY: Okay, and I think that  
23 - I'll be glad to answer this, your question, but  
24 I also think there is going to be a separate  
25 session on the whole - on how we do that in which

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1 I'll go into more detail.

2 We have a procedure now that we follow  
3 that's been developed to review - if the applicant  
4 - there's two kinds of scenarios here.

5 First is a scenario where we deal a  
6 lot with people in this industry, and any of these  
7 industries that we license, not just industrial  
8 but medical and academic and everything else,  
9 research. But in a - we are familiar with a lot  
10 of these people because they've been around.  
11 They're in the profession. We know them; we've  
12 seen them before, especially an experienced  
13 reviewer. A lot of these people have been known  
14 to the NRC for many, many years. And if you see  
15 somebody come in with an application, you know the  
16 person, you know the company, you know the name,  
17 and you know them from personal experience, or  
18 maybe you've licensed them before. They've been  
19 on another license. You may have inspected them,  
20 or if I haven't inspected them, I may be able to  
21 go down the hall and talk to one of my inspectors  
22 and say, do you know this guy? Oh yes, that guy  
23 worked for that radiography company for 15 years,  
24 and now it looks like he's gone off on his own to  
25 form his own company. Yes.

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1                   So you know the guy's legitimate; I  
2 mean there is no question. In that case we know  
3 who it is, and there are several different ways to  
4 determine, do we know this person or not. If we  
5 do, then we're not worried about - we assume it's  
6 going to be a legitimate use. We know that  
7 individual. We trust that individual. And so we  
8 go ahead and license them.

9                   On the other hand, the other scenario  
10 is, we get an application, we don't know the  
11 person, never heard of them before. In fact I  
12 just worked on a case up in Alaska. There was an  
13 engineer up there who wanted to get a license. We  
14 had never heard of him before, and he had never  
15 shown up on any other application as a user or  
16 name or anything, just out of the blue he applies  
17 for a portable gauge license to use americium and  
18 cesium in one of these soil gauges.

19                   So the first thing I did, and this is  
20 in our guidance, we check off, okay, we don't know  
21 this guy so we have to go to the next step. And  
22 the next step is - there is a whole list of  
23 criteria to apply to this unknown individual.

24                   And you start - you go as far through  
25 this as you feel you need to until you get

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1 comfortable that this guy is legitimate.

2           So you start off, for example, is he  
3 known - this guy was up in Juneau, Alaska. So the  
4 first thing is, is this guy known up there by  
5 anybody? And I noticed on his application he put  
6 down that he had - that he had a company up there,  
7 an engineering company that he - was his company.  
8 So I thought well, has anybody ever heard of this  
9 company. So I went online, I googled this  
10 company, and right away all these hits came up,  
11 you know, with his name, the company's name, it  
12 happened to be his name as well. All these hits  
13 came up. He's involved in building this highway  
14 project over in Anchorage. And he's doing this  
15 over here. So right away I thought, well this  
16 guy, it looks like he's been in business for a  
17 long time, and some of those hits went back years  
18 ago, so I thought, okay, this guy is known up  
19 there as an engineer, as a construction engineer.

20           And then I went, I went on the  
21 Secretary of State's website to see if this guy's  
22 company is registered. And it was, it was on the  
23 Secretary of State of Alaska's website; he's  
24 there. He's a legitimate - he's registered with  
25 them.

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1           And then I went on and I looked at -  
2 ended up finally finding an individual, another  
3 engineer in town, and I called this guy up. And  
4 I just said, you ever heard - this other guy is  
5 one of our licensees, and I said, have you ever  
6 heard of this guy?

7           And he said, oh yes, he actually used  
8 to work for us. And he said, I guess he's -  
9 what's he doing now? And he - so the guy has been  
10 an engineer up there. He's an old timer. He's  
11 been around awhile.

12           And anyway, then you can go on  
13 through, there are several other criteria. And  
14 you can keep going deeper and deeper into this.  
15 But at that point I thought, this guy is  
16 legitimate.

17           But then since he's a new licensee we  
18 actually had an inspector going up there, so we  
19 asked our inspector to stop in and meet with this  
20 guy at his facility. And again the inspector saw  
21 his setup; it looked like a legitimate engineering  
22 facility. She talked to him, and again - so there  
23 was no question in my mind the guy was legitimate  
24 getting the license. He met all the requirements.

25           That's kind of how we proceed in

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1 these.

2 MEMBER NERUD: And one last question,  
3 for a new licensee, somebody you haven't issued a  
4 previous license to, at what point do you do the  
5 initial inspection? Is it before you give them  
6 the license? Is it within a year of granting them  
7 the license? What is the customary -

8 MR. MONTGOMERY: It's customary to  
9 inspect them and do the official inspection within  
10 the first year of - after he gets the license.

11 Now that's different than this visit,  
12 what I call the pre-licensing visit that we do  
13 now. The visit is not an inspection, it's not an  
14 official inspection because the guy doesn't have  
15 a license yet. So we are going to visit them for  
16 the purpose of just making that final kind of yes,  
17 for sure he's legitimate.

18 But the official inspection by an NRC  
19 inspector is done in the first year.

20 MEMBER NERUD: So the pre-license  
21 visit, do that every time? Do that half the time?

22 MR. MONTGOMERY: If we do not know the  
23 individual, the individual is unknown to the NRC,  
24 it's a policy in my Region - I think it's NRC  
25 policy right now, and this has just changed

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1 because of all the events - but it is NRC policy  
2 now to physically visit the applicant before the  
3 license is issued if he is an unknown to the NRC

4 MEMBER NERUD: Thank you, Jim.

5 CHAIR HILL: Mike, have any questions?

6 MEMBER RYAN: Yes, a couple from the  
7 earlier part.

8 Could you give us an overview of how  
9 many sealed sources by category are out there in  
10 terms of the line up of the IAEA categories? I  
11 mean over the years there have been sealed sources  
12 that have been absolutely immense, for things like  
13 remote lights. Hundreds of thousands of carriers  
14 and trucks. And there are programs  
15 internationally, for example, that will go and  
16 pick up those very large sources that are out.  
17 That's very different world from what you are  
18 licensing everyday. Can you kind of give us a  
19 range we deal with between one and - I don't mean  
20 for irradiators with fixed facilities. Sealed  
21 sources that are out and about in commerce.

22 MR. MONTGOMERY: Okay, are you asking  
23 how many different ones?

24 MEMBER RYAN: How big?

25 MR. MONTGOMERY: Or how large is the

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1 activity?

2 MEMBER RYAN: Yes, both.

3 MR. MONTGOMERY: Okay, well there are -  
4 there are - the number of sources - and again  
5 you've got to think worldwide. I mean it's not  
6 just in the United States. But there's got to be  
7 tens of thousands, maybe, I don't know, tens of  
8 thousands of sources out there. If you went  
9 through all of the possible uses of sealed  
10 sources, and of course, even - a lot of sealed  
11 sources are used in medicine. I didn't cover  
12 medical use; Michelle is going to talk to that.  
13 But a lot of sealed sources are used in the  
14 medical arena as well.

15 But yes, there's got to be - if you  
16 look at everything from a tiny little source that  
17 might be used in a chemical detector, or a gas  
18 chromatograph in a laboratory, and then you add up  
19 - then you go all the way up to the millions of  
20 curies that might be used in one of these  
21 irradiators used to kill or sterilize, the range  
22 is going to be from a few millicuries to  
23 megacuries in terms of activity, and if you added  
24 all the sources, over all these years they've been  
25 used, there is probably no industry - I would dare

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1 say there is probably very few industries, major  
2 industries, that don't use some kind of radiation  
3 to gauge or control their manufacturing or  
4 production process.

5 Now when I say radiation, in some  
6 cases it may be an X-ray device and not a sealed  
7 source; not a radioactive material. But there are  
8 very few industries in the world that don't use  
9 some kind of radiation just to help them produce  
10 their product. It's an incredibly useful tool.

11 MEMBER RYAN: What I'm reaching for, my  
12 recollection, and I'm thinking about a recent  
13 article that Bob Emory from the University of  
14 Texas published. It shows that at least in the  
15 well logging industry there is a real correlation  
16 between exposures and overexposures to training.  
17 So what I'm trying to get a handle on, there is a  
18 big universe of sources out there, and I'm trying  
19 to focus in on where the risks are.

20 If we talk about risk-informed  
21 regulation, which we touched upon yesterday, it's  
22 what can go wrong, how likely is it, and what are  
23 the consequences? And from the consequence  
24 perspective, it seems like there are a couple of  
25 segments where the headaches really are.

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1           Is it fair to say that's well logging  
2           and down hole camera work and things of that sort?  
3           Or do you have another segment that are problem  
4           areas or sources that are lost, or sources that  
5           are stolen?

6           MR. MONTGOMERY: From a health physics  
7           standpoint, radiation safety standpoint, you know,  
8           the well logging and radiography sources and the  
9           devices and the way they're used, probably have  
10          the greatest potential for some problem.

11          MEMBER RYAN: I'm not looking for  
12          potential. I'm looking for facts.

13          MR. MONTGOMERY: Statistically, some of  
14          the more serious accidents have occurred in those  
15          industries, as far as you know a source, leaking  
16          source, overexposure, some kind of incident  
17          occurring, and exposing people, those two  
18          industries probably - and I'm going to leave - I'm  
19          going to set the irradiator industry aside for a  
20          moment; I'll address that separately.

21          Well logging and radiography is a  
22          unique situation, because sources are not fixed,  
23          usually they are not fixed in one place. They  
24          move around all the time, and they are used,  
25          typically used, in very harsh environments, and

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1 physically they get a lot of use, a lot of  
2 mechanical use.

3 So - and they are typically used in  
4 very harsh - can be used in very harsh conditions  
5 and climates and so for a multitude of reasons,  
6 those industries probably historically had the  
7 most incidents, problems, and the - and  
8 overexposures and injuries and that kind of thing  
9 from radiation.

10 The irradiator industry, however,  
11 those have had some of the most serious  
12 fatalities, especially in other countries.  
13 Because in those cases, you know, if you get  
14 exposed to a radiography source for say a few  
15 seconds or a few minutes, it's probably not going  
16 to be fatal. It's not going to be a good thing,  
17 but the person is not going to die from it.

18 But an irradiator accident, those  
19 sources, if somebody happened to get exposed to  
20 those megacurie sources, there's no such thing as  
21 an injury. It's a fatality. It's just automatic.  
22 If you happen to walk into one of these and see  
23 the source in the exposed position, that would be  
24 it.

25 So - and there have been accidents,

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1 mostly in foreign countries, with those sources,  
2 through some really poor practices and accidents.

3 MEMBER RYAN: How about lost sources?  
4 I know down hole logging wells, it's in the well,  
5 and it gets cut off and collapses.

6 MR. MONTGOMERY: But they're known,  
7 those are -

8 MEMBER RYAN: You sign it off and that  
9 is the end of that.

10 MR. MONTGOMERY: Those are known, and  
11 those are marked and identified.

12 MEMBER RYAN: How many unaccounted for  
13 stolen sources are there?

14 MR. MONTGOMERY: The most common, as  
15 far as lost or stolen sources, the most common -  
16 one of the most common problems we have are with  
17 these portable gauges, these soil gauges. There  
18 are so many of them out in use, and there again,  
19 most of those incidents occur because of lack of  
20 security. And we actually increased our  
21 regulations in that regard, because of some of the  
22 problems we had with those getting stolen, in  
23 particular.

24 A typical situation, the guy's got one  
25 in the back of his pickup truck, and he goes to

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1 lunch, and just leaves the key in the truck. It's  
2 at the construction site. Somebody gets in there,  
3 some kid gets in there and drives off with the  
4 truck. The gauge is in the back. The kid might be  
5 interested in stealing the truck rather than the  
6 gauge. Might not even know what hte thing is.

7 But that is a problem. And again it's  
8 just carelessness on the part of users. And  
9 again, the consequences from those gauges are far  
10 less, because the radiation is just much lower  
11 than say in an industrial radiography camera. If  
12 somebody gets into a radiographer's truck and  
13 drives off with radiography cameras, that is going  
14 to be far more potentially serious.

15 MEMBER RYAN: How many of those two are  
16 missing, unknown where they are?

17 MR. MONTGOMERY: Oh, gosh.

18 MR. WHITE: Mike, I probably could  
19 answer that. The NRC maintains a database called  
20 NMED, the Nuclear Materials Event Database. It's  
21 been in existence probably 15, 16 years now.

22 And we acquire - events are reported  
23 of course by NRC licensees and of course by the  
24 Agreement States for their licensees, and we do -  
25 they do have statistical ways of looking at it.

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1 MEMBER RYAN: Just by number.

2 MR. WHITE: I don't know. I would have  
3 to check that.

4 MEMBER RYAN: I think it would be  
5 helpful to us to know. Are we talking about one  
6 or 100 or 10,000. You know the scope of what is  
7 actually missing and unaccounted for.

8 MR. WHITE: Unaccounted for. That's  
9 something NMED would probably tell you. And Jim  
10 is absolutely right, by far the biggest lost  
11 sources are from portable gauges. Probably have  
12 over 100 - you know 100 - I don't know if it's 100  
13 stolen gauges, but there are hundreds of events  
14 involving portable gauges every year. Not only  
15 may they be stolen, but they may be damaged in  
16 accidents.

17 MEMBER RYAN: Sure, and there's, you  
18 know, the kid steals the truck, and he throws the  
19 thing by the side of the road and it's found  
20 later, those have occurred.

21 I guess it would just be helpful --for  
22 us to get some scope on it from a national  
23 perspective. What - of well logging and  
24 industrial radiography sources, how many of them  
25 were licensed and are now missing. I think that

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1 would be helpful.

2 MR. WHITE: That's something we can  
3 probably get from them and provide to you.

4 MR. MONTGOMERY: I think that would be  
5 good to know.

6 MR. WHITE: I'd also like to comment on  
7 a couple of other things you were talking about  
8 earlier, Mike.

9 You asked about number of sources in  
10 general. We do - NRC does - has taken a couple  
11 years, we've polled the States and of course our  
12 own licensees on the inventory of Category 1 and  
13 2 sources that are in country. It's probably a  
14 good topic for Friday's discussion. We'll have  
15 detailed information on that.

16 Again this information will be fed  
17 into the National Source Tracking System; that  
18 goes online.

19 Another point Jim touched on about  
20 radiographers, and it's a question you asked about  
21 the linkage between training and risk and safety,  
22 one of the - I think one of the things that was  
23 done with the radiography regulations by Texas in  
24 the mid-80's was they were having a lot of events  
25 involving overexposure and stuff. And they

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1 revised the regulation, one, to require two people  
2 be present; and secondly, to greatly increase the  
3 level of training. And they have seen a drop in  
4 that - drop in that. And there was a direct  
5 interest in that.

6 And I think, you mentioned Mr. Emory.  
7 He has done work with Texas, and a lot of their  
8 data. I'm sure he's written an article about  
9 that.

10 MEMBER RYAN: Yes, actually it was  
11 published in *Health Physics*. And basically he  
12 showed it was two things: one was the training  
13 question; and two it really correlated with new  
14 entrants and pulses in oil exploration. Oh, let's  
15 get some oil; the price is right. So there are  
16 hundreds of new people in the oilfields. And  
17 guess what? The accidents are correlated with the  
18 rise in new people. Isn't that a surprise?

19 So it's those kind of tracking and  
20 trending kinds of things that would help us advise  
21 management at the NRC on where do you want to put  
22 your resources. And I'm not looking to say well,  
23 what we should criticize. But to say very large  
24 irradiators - this is just my gut feeling, with  
25 the exception of cesium irradiators, which Tom

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1 knows all too well about because of their leaking  
2 sources - but you know, even with that, that was  
3 a problem that was handled. I mean it was not  
4 something that was out of control at any point.  
5 It was just something that needed to be handled,  
6 and it was a hard one to solve.

7           So I don't think you want to talk  
8 about sources based just on the quality. That's  
9 not right. It's also not right to just dismiss  
10 certain ones because they are common devices.

11           So what I'm trying to reach in this  
12 is, where have there been issues and problems?  
13 And maybe that's the area to focus in terms of  
14 where materials are.

15           And to my mind, particularly things  
16 that are unaccounted for at this point. They have  
17 been lost and they haven't been retrieved. And if  
18 there is some subset of things, that's really  
19 where there is a risk. And maybe that's a point  
20 of attention that needs to be thought through.

21           Now what we would think through on  
22 that I don't know, haven't come to a conclusion of  
23 course. But the information that helps us  
24 identify that, or those categories of materials  
25 might really be helpful, things like radium

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1 needles for medicine, for example, I'm sure we'll  
2 hear a bit about them, even though that's not  
3 really an NRC issue.

4 CHAIR HILL: I hope you're not - it is  
5 now, I think.

6 MR. MCCRAW: November 30, it will be.  
7 (Simultaneous voices)

8 MR. MONTGOMERY: In fact, I mentioned  
9 there were 21 volumes of this book [holding up  
10 NUREG-1556], and Volume 21 is on NARM issues of  
11 licensing.

12 MEMBER RYAN: So again the question I  
13 think I'm reaching for is what about the place  
14 where the risks are real and not - and more often  
15 than other areas, so we can better shape the  
16 advice we may offer.

17 MR. MONTGOMERY: I think - I do think -  
18 I'm on a working group second time around now to  
19 develop even better guidance. I thought the  
20 guidance we had originally on this, the whole pre-  
21 licensing screening that we briefly talked about  
22 to make sure that the applicant is legitimate, and  
23 going to use material as intended.

24 We are on the second go-around to try  
25 to come up with guidance that - and you can't, you

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1 can't use the word, fail safe. And I know my  
2 colleagues and I have talked at length, and I've  
3 talked to Agreement State people all about what -  
4 where are there weaknesses still in this process?

5 And I know you guys are looking at  
6 this and are going to hear more about this this  
7 week. But it still really is a concern that just  
8 how far would somebody go to try to deceive us,  
9 and I've always said you know, just get some  
10 license - get a room - get a committee of license  
11 - experienced license reviewers from the NRC and  
12 Agreement States, and some inspectors together,  
13 and say okay, you guys are the bad guys. What  
14 would you do, and how would you do it, to pull the  
15 wool over the regulators' eyes to get a license  
16 for illegitimate purposes? How would you do it?

17 In my opinion those are the people  
18 that should be asked. Those are the people that  
19 should be working on this. Because no one knows  
20 better than those people. Because they're out -  
21 they're inspectors, and they are out there,  
22 they're seeing how, this incredible variety of  
23 stuff is used. They know the internal workings of  
24 all these companies from these little mom and pop  
25 operations to these giant manufacturing plants.

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1 And they know the ins and outs, the inside and out  
2 of this whole process.

3 So you know, and there is no fail-safe  
4 system. But I certainly think if the guidance is  
5 applied that I described, and just doing online -  
6 you know, we have such incredible power now to go  
7 online and search for so much information on these  
8 people. Just that alone can - if that's done you  
9 can find out so much information, and I think  
10 we've come a long way.

11 We used to take the position that,  
12 well, no one would ever try to do anything with  
13 these big sources, because it would be suicide to  
14 try to handle them and move them around. But of  
15 course that has completely gone out the window  
16 now, because you know, you can envision many  
17 people -

18 MEMBER RYAN: Let me go back to the  
19 beginning part of your comment if I may just for  
20 a second. What other agencies do you think might  
21 also aid to that discussion? And I fully  
22 appreciate that experienced license reviewers and  
23 inspectors have a lot of experience that's not  
24 written in any book and know when to figure out  
25 when things are going right and things aren't.

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1                   And you get that by walking around.  
2                   And you get that by talking to folks and asking  
3                   the same question of seven technicians and seeing  
4                   if you get the same answer every time, things like  
5                   that.

6                   So it's those sorts of insights that  
7                   give - feel is not exactly the right word, but a  
8                   pattern of information that can give you a feeling  
9                   that things are going right, or things are not  
10                  going so right.

11                  But when you get to the security  
12                  aspects, beyond the assumption of trust, which is  
13                  what you're talking about, I wonder if involving  
14                  others in that dialogue or conversation might be  
15                  useful.

16                  MS. BEARDSLEY: I know when Ben was up  
17                  in the Region we were discussing this, because our  
18                  whole mindset is on a totally different level;  
19                  it's with safety and not security.

20                  And he was mentioning that there are  
21                  indicators where if I saw that, he's looking just  
22                  for that, he would have pointed out many  
23                  indicators -

24                  MEMBER RYAN: Ben shared some of those  
25                  insights with us too. And I think that is a

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1 dimension that is not so well explored from the  
2 NRC's perspective. If you've got an applicant,  
3 just inherent in the fact that he's asking for  
4 something means he's trying to be open and honest  
5 because he wants you to give him something.

6 But the idea that they would lie and  
7 cheat and steal and misdirect and mislead through  
8 the entire process, including hiring legitimate  
9 people who have degrees to be their RSO. I'm sure  
10 they could come up with a Ph.D. in health physics  
11 that wanted to be an RSO. And he would say, wow,  
12 look at this, this is great. But he might be a  
13 bad guy.

14 MS. BEARDSLEY: He pointed out a lot of  
15 them will form legitimate businesses. So how  
16 would we know that?

17 MEMBER RYAN: So I applaud the idea  
18 that you can certainly look for the routine NRC  
19 side of the house things that would give you  
20 indicators or hints. But there is a dimension  
21 beyond that that I think we are wrestling with  
22 probably as well as you are.

23 Again, if you can think about that and  
24 give us any insights that would be really helpful  
25 in the rest of our discussions over these few days

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1 and weeks ahead.

2 With that, Mr. Chairman, I'll turn it  
3 back to you. Thank you.

4 CHAIR HILL: I've got a follow-up that  
5 goes back earlier. Two things that I don't  
6 remember being mentioned that maybe we ought to  
7 get on the record: reciprocity and the sealed  
8 source and device registry, which is it fair to  
9 say that an SS&D review is a licensing action, a  
10 type of license? When you do an SS&D review?

11 MS. BEARDSLEY: Well, we don't do the  
12 SS&D review.

13 MR. WHITE: I have a suggestion. This  
14 afternoon we are going to talk about distribution  
15 licenses. And I can certainly cover sealed  
16 sources and devices, which is kind of married to  
17 that. And as they point out, it is done - SS&D  
18 reviews are done at Headquarters.

19 CHAIR HILL: And in the Agreement  
20 States.

21 MR. WHITE: Agreement States do their  
22 own SS&D reviews, yes.

23 CHAIR HILL: But when that review sheet  
24 is approved then it's available for all license  
25 reviewers, NRC and Agreement States to use?

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1 MR. WHITE: Yes, as I said earlier what  
2 the Agreement States do, they provide a copy of  
3 the finished registry sheet to our division, and  
4 we load it up on the website and talk about the  
5 database of all the registry sheets that's  
6 available to Agreement State and NRC personnel.

7 CHAIR HILL: So each regulatory agency  
8 doesn't have to reinvent the wheel on each device?

9 MR. WHITE: Right. As I said, this is  
10 very widely used for -

11 MR. MONTGOMERY: Yes, I might point  
12 out, I didn't go into this, but there is a - the  
13 Health Physics Society and the American National  
14 Standards Institute collaborated and wrote up -  
15 this is a great document, and there may be a more  
16 up-to-date version of this, but this is an ANSI  
17 standard on how - if you wanted to know all the  
18 nuts and bolts of how is a sealed source - how are  
19 these reviews done? I mean what does a reviewer  
20 look for when they are doing this? What are the  
21 standards for these things? What does a source  
22 have to meet? What standards do they have to  
23 meet? This is really an interesting document.

24 MEMBER RYAN: Excuse me, Jim, could you  
25 give the title and number of that for the record?

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1 MR. MONTGOMERY: Yes, it's an ANSI  
2 slash Health Physics Society, N as in Nancy 43.6  
3 and it's 1997, the one I have. N43.6. And it may  
4 have been updated. This is just a version I've  
5 had around for some time.

6 But it goes through all the tests and  
7 criteria that are applied to these sealed sources.  
8 It's a national - it's a national standard. So  
9 when these reviews are done, you know, whether  
10 it's an Agreement State or the NRC, this is the  
11 kind of thing we look for, and the manufacturers  
12 all need to follow this and know about it too.

13 CHAIR HILL: One other thing, and  
14 Duncan, you touched on this a while ago in your  
15 comments, radiographer training, radiography  
16 certification testing. Would you please give us  
17 just a thumbnail?

18 MR. WHITE: When we revised the  
19 radiography regulations in 1997 when the  
20 requirements we put in there was - referred to as  
21 third-party certification. And what this requires  
22 is that someone who wants to become a radiographer  
23 has to take a - basically take a test and after a  
24 certain level of experience with basically a third  
25 party outside the licensee. Prior to that the

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1 licensee developed a training certification.

2           And again the idea, this was taken  
3 from Texas, this is what Texas did back in the  
4 1980s was that they - someone independently  
5 evaluates the radiographer. Again, the test  
6 really focuses on is on radiation safety. The  
7 equipment, training, and those specific things are  
8 still left to the licensee, the training of  
9 radiographers. But the radiation safety part as  
10 it pertains to radiography was what was tested by  
11 a third party.

12           What - in fact if you look at Part 34  
13 which covers radiography in our regulations, there  
14 is an appendix about what a certifying agency has  
15 to meet to become a third party certifier.

16           NRC has recognized one outside agency,  
17 that's ASNT, American Society of Non-Destructive  
18 Testing. They are out of Ohio. They recognize -  
19 they administer these tests.

20           State of Texas also administers their  
21 own tests. Again, there are certain  
22 requirements, and I'll just name a few of them.  
23 The bank of questions. Proctoring the test. A  
24 limited period of time that - they get a card, and  
25 they refer to it - having a card, vows for 3-5

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1 years, and things such as that.

2 So what you have is that you have ASNT  
3 certify people. State of Texas also does a  
4 similar process. And there are like seven or  
5 eight other Agreement States that also certify  
6 their own radiographers in their own State.

7 But as I recall, all of them use -  
8 work through Texas. Texas helps them with the  
9 question banks. They will modify the questions  
10 for example to tailor it to the particular State's  
11 requirements and regulations. But generally they  
12 use their data and information, and Texas has  
13 quite a lot of experience in that area. So that's  
14 been in place for NRC since 1997, and for the  
15 State of Texas since I guess the mid-80s they've  
16 been doing that.

17 CHAIR HILL: Thank you.

18 MR. McCRAW: If I may interject here,  
19 Mr. Chairman, we are straying horribly from our  
20 agenda. I recommend we take a break, and then if  
21 we can move on to Michelle's presentation, we may  
22 have some extra time for additional questions.

23 CHAIR HILL: You are reading my mind,  
24 to give Michelle justice. I think that is  
25 appropriate.

1 So shall we come back at 20 till?

2 (Whereupon at 10:22 a.m.  
3 the proceeding in the  
4 above-entitled matter went  
5 off the record to return on  
6 the record at 10:40 a.m.)

7 CHAIR HILL: Well, it's 20 till. So we  
8 will continue with briefings.

9 And Michelle, the floor is yours.

10 SPECIFIC LICENSING - MEDICAL

11 MS. BEARDSLEY: Thank you.

12 Good morning, Mr. Chairman and panel  
13 members. My name is Michelle Beardsley. I'm a  
14 senior health physicist in the NRC's Region I  
15 office.

16 I am currently in the decommissioning  
17 branch, but I've been with the NRC for 17 years,  
18 and 14 of those I spent in the medical branch  
19 doing both licensing and inspections.

20 In our Region, all of our inspectors  
21 are licensed reviewers, and vice versa. We just  
22 find that keeps us up on the issues, not only to  
23 do the licensing, but also to follow up on it in  
24 the inspection arena. So we find that we learn  
25 from both ways.

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1           Before I joined the NRC, I was a  
2 nuclear medicine technologist for 13 years, and I  
3 went through many NRC inspections, so I was quite  
4 familiar with both the inspection and licensing  
5 processes.

6           I'm going to speak to you today on  
7 specific licensing for the medical area, and I  
8 have to note that 10 CFR Part 35 is where you can  
9 find all the regulations specifically regarding  
10 medical uses of byproduct material.

11           It went through major revisions in  
12 2002 and part of that was to keep with the NRC's  
13 strategic plan of making all of our regulations  
14 risk-informed and our inspections performance-  
15 based.

16           So in medicine you can have licenses  
17 anywhere from small practice facilities, which do  
18 only diagnostic studies, very low-risk activities.  
19 Most of those doses are what we call unit doses,  
20 in that they are already pre-calibrated and pre-  
21 loaded into a syringe.

22           So we tried to take a lot of the  
23 prescriptiveness out of the regulations for those  
24 types of facilities, and we shifted our focus to  
25 the high end for therapeutic purposes. And

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1 that's both - there are unsealed materials and  
2 sealed sources used for therapeutic activities.

3 The unsealed is mostly for nuclear  
4 medicine studies. When you get into sealed  
5 sources that's in brachytherapy for radiation  
6 oncology.

7 Also the sealed sources used in  
8 oncology come in devices. One of those is known  
9 as a high dose-rate remote afterloading device,  
10 and another one is the gamma knife. I'm not sure  
11 if you're familiar with those technologies, but  
12 those are some of the higher-risk activities for  
13 medical use.

14 MEMBER RYAN: I'm sorry, did you  
15 mention blood irradiators too?

16 MS. BEARDSLEY: Blood irradiators I  
17 didn't mention, and those are sealed sources also  
18 of smaller amounts, and they are in shielded  
19 devices. So they pose a small risk of activity.  
20 They are not considered in our high risk. However  
21 when we go into the security arena, they are one  
22 of the higher risk probability for the security  
23 area in that they can - we've been shown how you  
24 can remove those sealed sources if you were  
25 trained, and wanted to, within a matter of

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1 minutes.

2 So while on the medical, they don't  
3 treat any public; it's not for patient exposure.  
4 It's in a device that usually is just used to  
5 irradiate blood.

6 MEMBER RYAN: That I think is a good  
7 example, the kind of shift in thinking we touched  
8 on before the break, is that we think about it  
9 from a licensing standpoint of detecting workers  
10 or detecting members of the public. And the  
11 patients in the case of medical. And there may be  
12 a different tact when you think about it from a  
13 security standpoint. And actually some of those  
14 things could be reversed.

15 So that's just another helpful example  
16 where there might be a shift in thinking.

17 MS. BEARDSLEY: Absolutely. And as far  
18 as the gamma knife goes, you have 206 sources of  
19 cobalt in there. And we think of somebody going  
20 in, it's a huge device, I don't know if you are  
21 familiar with it, but it's a huge shielding  
22 device. And we always thought, well, nobody can  
23 pick up this device and leave.

24 However they've shown us videos in  
25 which if you know where the sources are located in

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1 the device, the sources can be removed in a matter  
2 of minutes.

3 So it is a whole different mind shift  
4 from what we as license reviewers are looking at  
5 as to someone who has malevolent ideas to use the  
6 sources for is thinking.

7 As far as licensing goes, we issue  
8 licenses that we call limited scope and broad  
9 scope. And they are both found in NUREG-1556.  
10 Volume 9 is the guidance that we use for  
11 conducting licensing reviews of medical licensees.

12 In the limited scope, the difference  
13 here is we actually specify possession limits in  
14 here, and we also specify the authorized users.  
15 And like I said, these can run from small private  
16 practice cardiology practices which we have many  
17 of, and that's probably where we get the most new  
18 license applications from is for these private  
19 practice cardiologists, because they are all going  
20 through the training to become authorized users,  
21 and they are all opening up their private practice  
22 facilities to do the stress cardiac studies, and  
23 all the related cardiac studies; there are many  
24 different imaging studies.

25 And those types of practices they only

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1 use short-lived materials, so for those we allow  
2 them to have as-needed quantities, because most of  
3 it is technetium-99m, which is a half-life of six  
4 hours, so very short lived, not much of a risk  
5 there.

6 So when Part 35 was revised we took  
7 out a lot of those requirements on those, and  
8 placed them on the unsealed and sealed materials  
9 for therapeutic use.

10 Under a university medical broad scope  
11 license they can have multi-curie quantities of  
12 materials, but they also need to have a committee  
13 in place for research review. And they do a lot  
14 of research studies there.

15 So we try not to impede them from  
16 doing research studies, but we only give these out  
17 to large facilities that have trained authorized  
18 users in all the different fields who can review  
19 applications for research, human use, and then we  
20 allow them to have multiple quantities of both  
21 sealed - multicurie quantities of both sealed and  
22 unsealed materials. So that's the range of our  
23 licenses, and there are many in between just from  
24 regular nuclear medicine, imaging departments  
25 within hospitals or in private practices. And

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1 many combinations for both of those.

2 What we tried to do with Part 35 when  
3 we revised it to - instead of us prescribing what  
4 medical procedures can be used for what use, we  
5 put the onus on the authorized user and they have  
6 to provide a written directive, which is basically  
7 a prescription. Any time they get into certain  
8 activities for unsealed iodine above 30  
9 microcuries, that requires a written directive.  
10 Also, unsealed amounts for therapy; any type of  
11 therapeutic procedure. So we have like thyroid,  
12 where they'd oblate the thyroid or get rid of it,  
13 or treat for hyperthyroidism, things like that,  
14 any type of therapy study and any use of sodium  
15 iodide, I-131, we require them to have a written  
16 directive. We put it in the regulation because we  
17 think it's important that if the physician  
18 prescribes it then we're not really going to  
19 question the medical decision or the related  
20 prescription details.

21 So the written directive is very  
22 important to us, and these are the standards that  
23 we mostly have a lot of review; they undergo a lot  
24 of review during the licensing process.

25 As a license reviewer, as Jim said, we

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1 address items of safety, radiation safety, to  
2 prevent overexposure for the worker, the patient,  
3 and members of the public. So that's basically  
4 our guidance.

5 We use Volume 9, and as he said, there  
6 is a sample checklist in here that we would accept  
7 from the licensees.

8 When you were asking about, you know,  
9 do they use the checklist, well, when we have  
10 applications coming in, and they appear that they  
11 have not used this guidance for their review, most  
12 of the time we'll go back to the licensees and  
13 recommend that they use this, because this is how  
14 their application is going to be reviewed.

15 So we kind of force the issue, and  
16 make them resubmit, hopefully they'll come back  
17 with something like this.

18 And a lot of, like I said, the smaller  
19 private practice cardiology places are using this  
20 because they know it's probably the fastest and  
21 easiest way to get a license if they go with our  
22 model procedures in the back of the guide, and  
23 they just check off on the checklist that they'll  
24 use those.

25 We try to issue new licenses within 90

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1 days, so we do have a timeliness limit on there,  
2 where we try to get them through the process. We  
3 use deficiency letters, deficiency phone calls,  
4 depending on the type and amount of questions that  
5 we come up with in the licensing process to help  
6 it along, help them understand what they need.

7 And I have to say a lot of them use  
8 consultants, health physics consultants, to help  
9 them with these applications. And a lot of those  
10 consultants are known to us. So during the  
11 screening process that Jim was describing in the  
12 pre-licensing screening process, that's one good  
13 source that we use are these health physics  
14 consultants, and a lot of times that's the contact  
15 person for the application.

16 Because as far as cardiologists go,  
17 they know cardiac medicine, but as far as  
18 radiation safety, they did go through the  
19 authorized user training, so they are somewhat  
20 familiar with it. But when it comes to  
21 regulations they are very uncomfortable with the  
22 regulations and knowing how to be in compliance.

23 So I would say probably about 90  
24 percent of them hire these health physics  
25 consultants to help them with the regulatory

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1 process.

2 On these checklists, most of the items  
3 that we go into depth on are for radiation safety  
4 to prevent overexposures which would in shielding  
5 of the facility, of the different types of  
6 accessories you use. When you are using unsealed  
7 materials a lot of the exposures go to the  
8 extremities, because the technologists are  
9 handling liquid technetium or liquid iodine, so a  
10 lot of the questions we have are about radiation  
11 safety procedures, as far as unsealed materials  
12 go. And those require a written directive.

13 I should mention also that when we do  
14 high-risk activities that also include the use of  
15 generators and some of the clinics, though not a  
16 lot, some of them will order generators which you  
17 can elute to get the radioactive materials that  
18 you use for everyday imaging.

19 So that's where a high risk also is,  
20 so we will ask questions about shielding for the  
21 generator use if they are going to have a  
22 generator.

23 But most of the time when you start  
24 getting into the sealed sources with the devices  
25 with the larger curie amounts of materials, these

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1 are self-shielded. However, they have to be  
2 secured, and they have to do surveys of the  
3 adjacent areas, and give us those calculations.  
4 So that's one area where we really delve into a  
5 lot of detail about exposure amounts in the  
6 contiguous adjacent areas to these devices, how  
7 you are going to control the doses in those areas  
8 to occupationally exposed people and members of  
9 the public. So that's where a fair amount of the  
10 time is spent in the licensing process.

11 The other items are, as Jim said, they  
12 have to have operating and emergency procedures  
13 for these devices in case - a lot of times we get  
14 reports of, the source gets stuck either outside  
15 of the device, or we've had - had them stuck in  
16 patients. And there was one time in Indiana,  
17 Pennsylvania, where there was a fatal overexposure  
18 of a patient, because the source - the wire was  
19 cut, and the source was allowed to remain in the  
20 patient, and she went back to the nursing home,  
21 and they didn't discover that for awhile. I think  
22 that was one of the latest fatalities from  
23 overexposures in the brachytherapy field.

24 However, like I said, these are all  
25 self-shielded devices. So if used properly we

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1 don't see too many overexposures in those fields.

2 Also for the therapy uses, the sealed  
3 and unsealed therapy uses, we have in 10 CFR it  
4 contains requirements for patient release. What  
5 we found was that a lot of the patients who were  
6 given large amounts, we used to make them all be  
7 hospitalized, and a lot of times, and I think  
8 probably the pressure from the insurance  
9 companies, they wanted them released. They didn't  
10 want them to be in the hospital for 5 days after  
11 a certain amount was given to them for either a  
12 thyroid ablation treatment or a temporary implant  
13 or something like that.

14 So we'd have patient release  
15 requirements that hold the exposure to the members  
16 of the family while it's above our general limits,  
17 they can still go home and be exposed to that  
18 overage amount. So we hold them within that  
19 dosage.

20 MEMBER RYAN: That's the 500 millirem?

21 MS. BEARDSLEY: That's the 500  
22 millirem, exactly.

23 So we have, I'd say, probably most  
24 hospitals now are releasing the patients that can  
25 be released under that requirement. Not too many

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1 are admitting them.

2           However, if they are admitting them we  
3 do get into training for the nurses and ancillary  
4 personnel for those patients who are going to  
5 remain in the hospital. And that's usually a big  
6 inspection focus, if they have somebody in there,  
7 we go up there, check it out, make sure the nurses  
8 are trained. We take our surveys in the adjacent  
9 areas because they have to do that just to make  
10 sure that all the adjacent rooms -

11           MEMBER RYAN: That's a little shift in  
12 definition. Because the workers in that case, the  
13 nurses and aides and all, are workers; they're not  
14 members of the public or caregiving family  
15 members.

16           MS. BEARDSLEY: Right, right.

17           MEMBER RYAN: So you're actually  
18 reviewing them on the worker standards and not  
19 this 500?

20           MS. BEARDSLEY: Exactly right.

21           MEMBER RYAN: I just wanted to be clear  
22 for everybody's benefit.

23           MS. BEARDSLEY: Right, and in the areas  
24 adjacent to that there are unrestricted areas they  
25 have to follow - there are limits in Part 20 which

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1 has to below the 2 mR per hour. So we usually  
2 check those areas around there, just for  
3 verification that they are doing that.

4 When 2000 - when Part 35 was revised  
5 in 2002, a large part of the effort was on the  
6 requirements for the training experience for the  
7 authorized users. And that went through a whole  
8 shift where we used to prescribe hours in each  
9 field. In academic, they had to have so many; in  
10 clinical, they had to have so many. And it went  
11 through many changes, to the point now where it's  
12 pretty complicated, and we have it up on our  
13 website.

14 A lot of these were changed where now  
15 we put the onus on a preceptor statement, and it's  
16 an attestation statement saying from one physician  
17 who is supervising the use of this person, or the  
18 experience of that person, attesting to the  
19 competence of the authorized user applicant.

20 So this is up on the website. We  
21 refer to this a lot when we do these license  
22 applications for the training criteria for the  
23 authorized users of the different materials.

24 MEMBER RYAN: And again that's separate  
25 from the licensed physician or, say, the medical

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1 physicist or health physicist.

2 MS. BEARDSLEY: They are all included  
3 in here.

4 MEMBER RYAN: They're all included?

5 MS. BEARDSLEY: For authorized nuclear  
6 pharmacist, authorized medical physicist,  
7 diagnostic users and therapeutic users. So -

8 MEMBER RYAN: Isn't that wrapping up  
9 again, yet again, for medical physicists and  
10 others.

11 MS. BEARDSLEY: Right, and there's a  
12 whole thing about grandfathering, too, I know with  
13 the NARM rule coming in, there are some questions  
14 about that. So that's why they keep it on the  
15 website, because we want to keep people current on  
16 the latest regulations for it.

17 So I think this is probably the area  
18 in the licensing process that probably is where  
19 most of our resources are spent, just the  
20 authorized user training and experience  
21 requirements, for medical anyway.

22 I also mentioned radiopharmacy, and  
23 Aaron had just asked me to touch on that a little  
24 bit. These are mostly in distribution licenses,  
25 and they're covered under our Part 32, where they

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1 have to have a Part 32 license to be able to  
2 distribute to specifically licensed users.

3 In the radiopharmacy, they're using  
4 very large amounts, because they handle all the  
5 generators that I spoke of previously. Also they  
6 handle a lot of unsealed quantities of material.

7 So we found through operating  
8 experience that the overexposures are usually  
9 going to occur to the extremities, the hands of  
10 these workers. So a lot of the licensing and  
11 inspection focus is centered on the extremity  
12 exposures.

13 Also the facility has to provide  
14 certain shielding requirements, glove boxes, fume  
15 hoods, and the like when you are handling unsealed  
16 volatile materials.

17 And also just, they go into a lot of  
18 creative efforts on how to cut down on just the  
19 normal standard - drawing up the dose, sticking it  
20 in a dose calibrator. So they've devised a lot.  
21 And I saw recently an automated piece of equipment  
22 that now they're going to start probably using in  
23 a lot of these pharmacies just to cut down on a  
24 lot of the hand exposures. Because they do push  
25 the limits sometimes with those. So a lot of the

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1 licensing effort is expended just on the exposures  
2 of personnel.

3 As far as release to members of the  
4 public through any type of air effluence, we have  
5 very specific limits on how much can be released  
6 through a glove box or through any type of stack  
7 that's going to be going to the outside of the  
8 facility.

9 So they have to come in, you know, and  
10 basically tell us if there was a total release of  
11 this much of xenon-133, which is a noble gas, how  
12 would we make sure that the air effluent  
13 constraint limits weren't exceeded.

14 Like I said on these licenses we do  
15 review and authorize nuclear pharmacists. So they  
16 are specifically required. They could either go  
17 through - be board certified, or go through an  
18 alternative route, just like the authorized users.  
19 There is always a board certification they can go  
20 through, or the alternate route. And it's usually  
21 on the alternate route where we start getting into  
22 very complicated details about what type of  
23 experience and hours they have to have; classroom;  
24 laboratories; supervised clinical; their  
25 experience with patient treatment; things like

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1 that. So probably most of the effort would be  
2 with that field.

3 So that's basically the licensing  
4 process, and I don't know how much more detail you  
5 want me to go into. But like I said, we mostly  
6 use the NUREG guidance, and we try to have a  
7 licensee follow that route as far as the  
8 application process.

9 We also do the pre-licensing that Jim  
10 spoke about, the checklist to make sure that the  
11 material is going to be used as intended. With  
12 medical, I mean I'm sure it can be done, but you  
13 know, a lot of these we could just check the  
14 medical websites to make sure that these are  
15 licensed physicians, if there was ever a question  
16 with this. So it's a somewhat perhaps easier area  
17 that we cover in medical is that there aren't too  
18 many medical users that we don't know of or can't  
19 ask about or look on websites for their  
20 certificates and licenses. So not too much of a  
21 deal there. Most of it is in the facility, the  
22 security components of the facility as far as -  
23 like you said, with the irradiators, the blood  
24 irradiators, a lot of that has to do with  
25 prescriptive requirements for how they have to be

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1 secured. So we will check that on inspection  
2 also.

3 So that's it in a nutshell. If there  
4 is anything else I could explain for you I'd be  
5 happy to.

6 CHAIR HILL: I think the questions that  
7 I had regarding NUREG-1556, information online,  
8 checklist, ditto for medical; so I don't have to  
9 ask those questions all over again and go that  
10 route.

11 In the medical area, the largest  
12 activity of unsealed radioactive material is  
13 probably with the radiopharmacies; is that a fair  
14 statement?

15 MS. BEARDSLEY: As far as bulk amounts?

16 CHAIR HILL: Bulk amounts.

17 MS. BEARDSLEY: Yes, that would be a  
18 fair statement since they are taking a bulk amount  
19 and then distributing it. Some of that could be  
20 brought in in unit doses. The pharmacies can  
21 split up dosages, and send them to different  
22 hospitals.

23 CHAIR HILL: And the largest sealed  
24 sources are used in the hospitals such as gamma  
25 knives, et cetera?

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1 MS. BEARDSLEY: Yes.

2 CHAIR HILL: Okay, questions?

3 MEMBER RYAN: I guess I'm trying to ask  
4 the same question in my head: where are the  
5 headaches in medicine? I mean iodine seeds fall  
6 on the floor.

7 MS. BEARDSLEY: Well, are you talking  
8 about as a security risk or as a patient risk?

9 MEMBER RYAN: First off, where are the  
10 headaches? And are there overlaps with sources  
11 that have security? I mean most medical stuff is  
12 relatively - very short half-life.

13 MS. BEARDSLEY: That's right. Even  
14 iodine, which is an exposure risk with unsealed  
15 iodine does have an 8-hour half-life.

16 MEMBER RYAN: So you know 8 days later  
17 -

18 MS. BEARDSLEY: Eight days, I'm sorry,  
19 not 8 hours; eight day half-life. So that's  
20 relatively short. But you know you can get a lot  
21 of occupational exposures from it, especially if  
22 there is contamination to it, and in the risk  
23 studies that was one of the areas of high risk  
24 besides the generator elution that they found was  
25 with the unsealed iodine activities of just

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1 preparation and handling of the dosages was one of  
2 the areas where workers can receive the highest  
3 dosages, and also any family members that were  
4 near the patient at that time.

5 And that's under normal operations.  
6 Accident operations, there is not a lot of data on  
7 it; however, but studies show that most of the  
8 risk could be attributed to the normal operations  
9 of just handling those dosages.

10 MR. MONTGOMERY: I might point out that  
11 with the NARM rule coming into effect, however,  
12 there is a potential for extremity exposure from  
13 people who handle accelerator targets in nuclear  
14 medicine or in pharmacies.

15 And that's going to be something that  
16 the NRC is going to have to pay a lot of attention  
17 to; it historically has been a problem.

18 MS. BEARDSLEY: And I was a part of the  
19 guidance writing team for Volume 21, so that was  
20 where we put a lot of the shift too was. The same  
21 thing with the exposure calculations, and the  
22 different areas, this patient waiting room or  
23 resting area, after they are injected, where they  
24 sit, that gives off a lot of external exposures.

25 And with the device itself we still

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1 will regulate the dose that the workers get from  
2 working on the device. However, we won't regulate  
3 the device.

4 But still like Jim said, a lot of  
5 exposures can come up for people who handle the  
6 targets and work in the accelerator area.

7 MEMBER RYAN: That's all health  
8 physics, though; almost all of that is health  
9 physics. It's not security and safeguards kinds  
10 of things.

11 MS. BEARDSLEY: Right.

12 MEMBER RYAN: To me the security and  
13 safeguards are always in a sealed - the  
14 irradiators, whether it's a blood irradiator or a  
15 gamma knife or some other sealed source. And I  
16 would guess - tell me if I'm wrong - but I don't  
17 know how many cobalt units are still out there in  
18 the U.S.

19 MS. BEARDSLEY: Teletherapy?

20 MEMBER RYAN: Yes.

21 MS. BEARDSLEY: There are some;  
22 not a lot, but there are some out there.

23 MEMBER RYAN: Under 50, under 20, a  
24 100?

25 MS. BEARDSLEY: I would probably say

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1 less than 100, maybe.

2 MEMBER RYAN: Those are probably of  
3 concern from a safeguard and security standpoint.  
4 They are a big - I guess Atomic Energy of Canada  
5 made most of them. They have six sizeable cobalt  
6 sources in them, as I understand it that are  
7 fairly easy to get out.

8 MS. BEARDSLEY: Right, and that's why  
9 I said, when they showed us the videos of how fast  
10 gamma knife sources can be removed, HDR sources  
11 probably one of the easier types of -

12 MEMBER RYAN: HDR? I'm sorry.

13 MS. BEARDSLEY: That's the high dose-  
14 rate remote afterloader. And in that case, the  
15 source actually comes out of the machine on a  
16 wire. Well, if you clip the wire you could have  
17 that source out of there in seconds.

18 For me that was shocking to see that.  
19 I'm picturing these huge things. Nobody could get  
20 in the shielding and all that. And surprisingly  
21 they can. Less than 10 minutes I think to remove  
22 like an irradiator source from the blood  
23 irradiator and from the gamma knife.

24 So that's probably, I would say, as  
25 far as risk goes, it would be in the large sealed

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1 source devices.

2           However you can create a panic with  
3 unsealed material. It wouldn't create much of a  
4 risk, but you take some unsealed material, and  
5 blow it up and contaminate a lot - a few blocks.  
6 That wouldn't be much of a radiation exposure  
7 risk. But you are going to create quite a panic  
8 if you have a dispersal device.

9           MEMBER RYAN: Or a patient that throws  
10 up on the sidewalk. That happens all the time,  
11 with a whole bunch of iodine in it.

12           MS. BEARDSLEY: Right. Urine, after  
13 body scanning agents are given. The urine is very  
14 "hot." So there are areas -

15           MEMBER RYAN: And they are not  
16 restricted to which bathroom they use or restroom.  
17 So I guess some of those things I guess I would  
18 tend to discount even in a dispersed  
19 circumstances.

20           Because there things are working in  
21 your favor. One is any dispersal is going to  
22 spread it very thin, and decay is always in front.

23           MS. BEARDSLEY: Right, exactly.

24           MEMBER RYAN: So you just don't see the  
25 integrated dose as even being a part of the radar

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1 screen. I'm just guessing.

2 MS. BEARDSLEY: Exactly. And that's  
3 why I think it's going to be a very hard job for  
4 us to determine, are we serious about this? Do we  
5 want to preclude anything happening from a small  
6 amount of an unsealed material being exploded -

7 MEMBER RYAN: Well, in fact you've  
8 already made that cut by saying 500 millirem is a  
9 perfectly acceptable number for a member of the  
10 public who happens to see an occasional caregiver.

11 MS. BEARDSLEY: For the family member,  
12 right, caregiver.

13 MEMBER RYAN: So there's a prescription  
14 on how to assess that. So I guess I don't see why  
15 that's much different from some of these other  
16 circumstances, waiting rooms, all that kind of  
17 thing.

18 MS. BEARDSLEY: Exactly. But I think  
19 most of the risks from these materials is probably  
20 just mostly perception of the risk, you know, they  
21 got something liquid on them, members of the  
22 public, it would create a panic.

23 You can restrict unit dosages of  
24 technetium, and we do - that's one of our areas  
25 when we license the facility is, we look, is the

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1 key padlocked, how is the hot lab secured. So  
2 just physical access is also a big item.

3 MEMBER RYAN: Do hospitals - and I  
4 don't know this answer at all - do hospitals and  
5 medical facilities have security and safety and  
6 safeguards plans? I mean do they have formal  
7 lock-and-key procedures that you look at, and  
8 authorized access and all that?

9 MS. BEARDSLEY: Well, they have it for  
10 us as far as the material is secured. As far as  
11 building security, I mean most hospitals do, but  
12 these private practice cardiology offices, it's  
13 usually, you know, it's a locked door to an  
14 office, and then the hot lab restricted area needs  
15 to be locked off to only trained individuals.

16 So if you have a secretary that you  
17 are not training, then you have to make sure that  
18 anyone that's not trained can't get access to the  
19 hot lab where the materials are stored.

20 MEMBER RYAN: And that's an inspection  
21 point?

22 MS. BEARDSLEY: That's an inspection  
23 focus.

24 MEMBER RYAN: Out of all the material,  
25 how much is used in a hospital versus a clinic or

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1 a one-stop shopping practice?

2 MS. BEARDSLEY: Well, it depends on the  
3 size of the program. In a private practice most  
4 of the time they might be getting 8 to 10 unit  
5 doses, and each unit dose may be approximately 20  
6 millicuries of technetium a day. They use  
7 thallium too for these cardiac scans.

8 So they may be using a few hundred  
9 millicuries where in a hospital you may be getting  
10 into a curie of technetium, and then they use  
11 xenon for lung imaging, and iodine for thyroid  
12 treatment. And different isotopes for imaging.

13 MEMBER RYAN: So let's step to therapy.  
14 I mentioned iodine seeds have been a headache here  
15 and there, and they certainly are not sealed. I  
16 know they say they are sealed.

17 MS. BEARDSLEY: Right, there have been  
18 ruptured seeds.

19 MEMBER RYAN: Iodine is never a solid.  
20 That's a rule I've always had, never a solid. It  
21 is always going to go somewhere.

22 MS. BEARDSLEY: There is like less than  
23 a millicurie usually, and you know for the most  
24 part -

25 MEMBER RYAN: Perceived.

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1 MS. BEARDSLEY: Yes, perceived.

2 MEMBER RYAN: Which are -

3 MS. BEARDSLEY: Teeny tiny sources.

4 They are hard to track, because they have a weak  
5 energy. So we have, you know, they are supposed  
6 to count them before they go in, after they come  
7 out. A lot of time they are lost in the operating  
8 room, and they may be thrown out in the trash.

9 But basically once after they are  
10 implanted in the patient, and the patient leaves  
11 the hospital, they are released. So they can be  
12 lost at home; they can be flushed down the toilet  
13 in a public sewer. Things like that. Once the  
14 patient leaves the hospital the accounting of them  
15 is, you know -

16 MEMBER RYAN: But again the idea of the  
17 half life is working with you.

18 MS. BEARDSLEY: Right, that's right,  
19 short half life, low energy.

20 MEMBER RYAN: And I'm just curious, do  
21 you guys respond to waste identifications at  
22 landfills or things of that sort?

23 MS. BEARDSLEY: We usually get  
24 notifications from the States where that happens,  
25 or within our States -

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1 MEMBER RYAN: Patient trash and so  
2 forth that tends up setting off a monitor?

3 MS. BEARDSLEY: Monitor, right. Now we  
4 don't go out and do the actual "dumpster diving"  
5 as we call it, but you know, we will oversee the  
6 efforts. Usually they get consultants or someone  
7 else out there to retrieve the materials.

8 MEMBER RYAN: So again, even with all  
9 that discussion, we're kind of back to the idea  
10 that the sealed sources, the gamma knives and the  
11 blood irradiators are where the security and  
12 safeguards questions are of primary significance?

13 MS. BEARDSLEY: That's right.

14 MEMBER RYAN: Okay, thanks.

15 CHAIR HILL: One question, though. You  
16 mentioned HDR, high dose-rate afterloaders. Is  
17 the low dose-rate afterloaders - are those sources  
18 being used very much anymore, the afterloaders?

19 MS. BEARDSLEY: The low dose-rate? In  
20 my experience, I don't see too many of them at  
21 all.

22 CHAIR HILL: Have most of those sources  
23 been collected up, or are they still sitting in -

24 MS. BEARDSLEY: Well, most of the time  
25 they hold on to the device with the source in it  
in case they're going to use it again. And if

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1 they don't, they are supposed to ship it back;  
2 they can't hold anything for decay and storage if  
3 it's not a short half life.

4 CHAIR HILL: I'm thinking of the cesium  
5 sources that were radium - milligram radium  
6 equivalents that were used in the Mick  
7 afterloaders, et cetera. Are there very many of  
8 those still out there?

9 MS. BEARDSLEY: There are some. And  
10 they keep them in the safe.

11 CHAIR HILL: And they keep them in the  
12 safe?

13 MS. BEARDSLEY: Right, and a lot of  
14 them tell us, well, we are going to get rid of it.  
15 But they still have to inventory them; so they  
16 have to account for them every 6 months until they  
17 get rid of it. And most of the time it's a cost  
18 thing to get a waste disposal processor for it.  
19 But a lot of them hold on to them in case they  
20 ever need them. So we can't really force them to  
21 get rid of them if they say they are going to  
22 possibly use them again.

23 CHAIR HILL: But they are - from a  
24 security standpoint, where I'm coming from on this  
25 - they are secured?

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1 MS. BEARDSLEY: Same thing; has to be  
2 in a secured area; only authorized personnel that  
3 are trained, you know are allowed to have access.

4 CHAIR HILL: So they don't grow legs  
5 very easily and walk away.

6 MS. BEARDSLEY: Not so far.

7 MEMBER NERUD: You said earlier, an  
8 application comes in, you have 90 days to process  
9 that license. Any flexibility built into that?

10 MS. BEARDSLEY: Yes, of course. If  
11 there is an issue that sometimes we can't resolve  
12 in a timely manner, we will grant an extension.  
13 But for the most part, it's to keep us actively  
14 working on the license, because like I said, we go  
15 out on inspections too, so sometimes, you know,  
16 something may get pushed off for awhile, and you  
17 know, one of our main concerns is, we don't want  
18 to hold up any type of patient treatment. So  
19 that's another reason why we have to issue a lot  
20 of these in a timely manner. Because if they want  
21 to open up a clinic in an area where there is no  
22 other treatment source or imaging place, the  
23 physicians are very outspoken and will say that,  
24 "wow, there are patients there that need treatment  
25 or need to have imaging." So we get pressured

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1 from that end too.

2 MEMBER NERUD: Fairly common timeline  
3 for all license reviewers?

4 MS. BEARDSLEY: That's our procedure.  
5 That's our policy, is that amendments -

6 MEMBER NERUD: Ninety days, any  
7 license? Okay. What are the ramifications to the  
8 license reviewer if they don't meet that license  
9 or that 90-day thing? Does it show up on their  
10 performance evaluations?

11 MS. BEARDSLEY: If it's a consistent  
12 problem where they are not working on them and are  
13 not issuing them in a timely manner for no reason  
14 - I mean usually they tell you, if you see you are  
15 going to run into problems speak to your branch  
16 chief, because then they can reassign them, or we  
17 can avoid it or do something, or someone else can  
18 work on it.

19 If you let it go to the point where  
20 you are not keeping your supervisor in touch with  
21 the fact that you have a lot of these actions that  
22 are always going overdue, and these come up on the  
23 list, and then usually it gets higher management  
24 attention if they are always running over time.

25 Then it would be a reviewer problem,

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1 because you should speak to your branch chief if  
2 that's going to be happening, and they are not  
3 following procedure that way.

4 MEMBER NERUD: You had mentioned for  
5 some of these smaller places that are individual  
6 doctors, cardiologists I believe you mentioned,  
7 they use a contractor to help them fill out their  
8 license application.

9 Are these contractors, are they  
10 registered? What are their qualifications? Or do  
11 they just read the NUREGs, advertise, and start  
12 making money?

13 MS. BEARDSLEY: Well, most of them are  
14 health physicists, and a lot of them are certified  
15 health physicists. But we don't require them to  
16 be - you know they're basically a contractor of  
17 the licensee, and we don't get involved with that.

18 But a lot of them advertise, we have  
19 certified health physicists. Their reputation  
20 usually precedes them, so everyone knows who the  
21 good health physics consultants are in the area.

22 MEMBER NERUD: All right. And one last  
23 question, again for these smaller doctors using  
24 this - correct me if I'm wrong, please - you have  
25 to have a radiation safety officer for these

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1 things?

2 MS. BEARDSLEY: Right.

3 MEMBER NERUD: How do they comply with  
4 that radiation safety officer requirement? If  
5 it's a doctor, he doesn't have to go out and hire  
6 somebody to do it. Does he have to send someone  
7 to that 5-week course?

8 MS. BEARDSLEY: No, they basically -  
9 radiation safety officer for medical practice, we  
10 have a separate requirement in Part 35, and that  
11 was on the website that I was showing you. It's  
12 part of the training and experience requirements.

13 So while they don't have to be an  
14 M.D., they do have to go meet the clinical and  
15 classroom hours that are prescribed in Part 35,  
16 and they have to have a preceptor attestation  
17 statement if they aren't a board certified  
18 physician.

19 MEMBER RYAN: So a board-certified  
20 physician would satisfy the radiation safety  
21 officer requirements?

22 MS. BEARDSLEY: If they are board  
23 certified, and they get the attestation statement,  
24 that would satisfy the requirements.

25 MEMBER RYAN: Board certified for what?

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1 MS. BEARDSLEY: There are boards that  
2 we have accepted their certificates from, and they  
3 are also on the website. So like the American  
4 Board of Radiology; American Board of Nuclear  
5 Medicine; and they are all on our website, because  
6 we are adding them continually, whoever applies  
7 for that process.

8 MEMBER RYAN: APM, AHP, all those?

9 MS. BEARDSLEY: Right, right.

10 So we, you know, RSOs, radiation  
11 safety officers, can be anyone from a nuclear  
12 medicine technologist who meets the requirements  
13 in there to a physician.

14 We've had health physicists, we've had  
15 authorized medical physicists.

16 MEMBER RYAN: Attestation statement,  
17 does that carry any liability with it? I'm just  
18 curious?

19 MS. BEARDSLEY: As far as?

20 MEMBER RYAN: I say you are going to do  
21 good work, and then you don't?

22 MS. BEARDSLEY: Well, that was a point  
23 of contention, and I think they are still working  
24 with that, because a lot of the physicians don't  
25 feel comfortable saying that, yes, you are

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1 competent to perform as an authorized user. So I  
2 think they had some change in the language to that  
3 recently, and I would have to check on the  
4 statement.

5 MEMBER RYAN: That was just a curiosity  
6 point.

7 MS. BEARDSLEY: That was their point  
8 too; they did not like it when we made that - when  
9 we put that in the regulation, that they had to  
10 have an attestation statement. So we did get a  
11 lot of problems with the cardiologists and the  
12 other physicians, nuclear medicine physicians  
13 about that.

14 MEMBER RYAN: Interesting. Okay.

15 CHAIR HILL: Question I guess for both  
16 of you.

17 Got a list of questions that I put up.  
18 This is it, I'll just read it, and we'll go back  
19 to a couple of issues with the NUREG being online,  
20 et cetera.

21 How have these weaknesses or  
22 vulnerabilities been informed or institutionalized  
23 by the "good faith presumption?"

24 Now I wasn't here yesterday for that  
25 bit of our discussion - on good faith; I missed

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1 that, so my question might not be quite  
2 appropriate there.

3 But the SS&Ds are restricted now. And  
4 NUREG-1556 is not. How has that being on there,  
5 if we say - if we say that that is a weakness, how  
6 has that been informed by that "good faith  
7 presumption?"

8 MS. BEARDSLEY: If we say that what is  
9 a weakness?

10 CHAIR HILL: If we say that is a  
11 weakness, NUREGs being online. That's just if we  
12 say that. Not saying that it is.

13 MS. BEARDSLEY: If we say it's a  
14 weakness to have it available to the public - what  
15 was the rest of your question?

16 CHAIR HILL: Then how has making it  
17 available to the public and everyone, very readily  
18 and very easily available, been basically informed  
19 by that "good faith presumption?"

20 MS. BEARDSLEY: Well, I think if you  
21 put the application process out there and make it  
22 easy I mean anyone can follow it and check off the  
23 boxes and come in and get a license.

24 So but that was the whole point. We  
25 had a streamlining process that was set up years

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1 ago. And back when I first started at the NRC,  
2 and I'm sure Jim will remember, that the licensing  
3 process used to be onerous. We had them submit  
4 every procedure step by step. We reviewed  
5 everything. It took months. I mean it took a  
6 long time.

7 Then we went - they did this whole I  
8 guess Phase 2 effort they called it, and came out  
9 with this licensing streamlining. And we were  
10 told as part of that they are going to make these  
11 documents, everything in one place for applicants  
12 to follow, to make it easier, to make it faster  
13 for both them and us.

14 And now basically we've made it pretty  
15 easy to get a license.

16 MR. MONTGOMERY: We also used to have  
17 all these different reference documents that they  
18 had to use, or were expected to use. And they  
19 were spread over - it was really complicated. Now  
20 everything is condensed, solid data.

21 MS. BEARDSLEY: They were per topic,  
22 they were regulatory guides per topic, like as far  
23 as you know patient release, and then there was  
24 one if you were handling unsealed iodine. So  
25 there were many, many different ones that people

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1 would follow. And they'd put their procedures  
2 together with a bunch of different reg guides.

3 MEMBER RYAN: All kinds of formats.

4 MS. BEARDSLEY: All kinds of formats.

5 It was very complicated.

6 MR. MONTGOMERY: I don't see a weakness  
7 with the NUREGs that we use. The focus has got to  
8 be on the individuals, the persons. And we've got  
9 to look at the individual and their integrity and  
10 their veracity.

11 And I think the NUREGs help the  
12 licensees streamline the process, make it more  
13 efficient, and provide a valuable tool for  
14 everybody. That's my opinion of it.

15 I think the personnel issue, looking  
16 at the individuals in the company itself, the  
17 applicant, that's really a separate scrutiny that  
18 the reviewer has to do aside from this.

19 This really doesn't have anything to  
20 do with looking at the security end of it. It's -  
21 these were written long before we thought we had  
22 to do anything like that. So the guidance for  
23 security is separate from this.

24 And I don't see this being on line as  
25 a problem personally.

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1 MR. McCRAW: Tom, your question really  
2 kind of hits right to the heart of a struggle the  
3 Agency has had, especially in the post-9/11  
4 environment.

5 We want to be an open, transparent  
6 agency, but we also have to restrict access to  
7 some information. And where we draw that line is  
8 becoming more and more difficult. We are a  
9 regulatory agency, but we're also a customer  
10 service agency. We're trying to make it easier  
11 for someone to attain a license when they intend  
12 to use that legitimately. However, the guidance  
13 may actually serve an unintended purpose. It may  
14 make it easier for a terrorist to apply for a  
15 license with a legit application. At the same  
16 time, it may also act as a deterrent. I may flip  
17 through that guidance, and see all these things I  
18 have to meet, all this training I have to do, all  
19 these additional supplies I have to purchase, and  
20 I'm going to be like, I'm just going to go steal  
21 a gauge out of the back of a truck. There is a  
22 portable gauge there; I'll just take that rather  
23 than trying to go through this legit route.

24 So we are continually analyzing how  
25 much information is too much information.

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1 CHAIR HILL: Any other questions on  
2 licensing before we move on to our discussion and  
3 deliberation?

4 MEMBER RYAN: Just a thought on what's  
5 on the web and all that. I appreciate Aaron's  
6 comment.

7 I hope that in that deliberation, and  
8 you hit on customer service, that there is such a  
9 huge value for the regulated community of having  
10 regularity of guidance, not only for NRC license  
11 applicants, but also Agreement State applicants,  
12 which is where the majority of the action is just  
13 in sheer numbers of applicants. That really is a  
14 huge benefit.

15 Having been an applicant, I can tell  
16 you that clear guidance is welcome every day of  
17 the week.

18 So that's a positive thing. I think  
19 if you were going to ask what would the negative  
20 be, then I think you get back into, what would the  
21 negative be if we took certain steps to increase  
22 the evaluation of the potential for bad guys or  
23 people who don't know as first applicants.

24 It's pretty easy when you get a 10-  
25 year licensee who is extending. That's very

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1 straightforward in my opinion. Because this is  
2 the same person and the same people; and you've  
3 visited them eight times, and it becomes a pretty  
4 routine matter.

5 But if there is a vulnerability, it's  
6 new applicants we don't know. Or even just from  
7 a health physics standpoint, new applicants that  
8 may not have all the hands-on experience that you  
9 know they are representing exactly in their  
10 application. And they took a training class, and  
11 it was a good class, but they didn't do a good  
12 job, they are not well schooled about hands-on  
13 training.

14 So I think the question too has to be  
15 - is a two-parter. It's not only do you have to  
16 say what's right on the web, but for what purpose?  
17 And how can you, if there is a risk of a downside,  
18 what can you do to mitigate that? Getting out of  
19 your chair and going to a facility and looking  
20 somebody in the eye are two really good ways to  
21 overcome that.

22 And look at the GAO case. What was  
23 Maryland's first answer? Well, we'll come visit  
24 your facility. What is your address? That's  
25 easier in Baltimore because it's a smaller place

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1 to get around. But we'll get back to you; that  
2 was it. It was over.

3 I know in South Carolina, I'm not for  
4 sure but I can almost guarantee, they'll get the  
5 same answer. If you're going to set up shop,  
6 we're going to come see you.

7 MR. MONTGOMERY: I know when we  
8 developed the guidance originally for the pre-  
9 licensing screening as we called it, I felt real  
10 strongly about the power of using the Internet to  
11 search for these people.

12 If somebody - like I said in my  
13 presentation, if somebody is in business, and they  
14 are legitimate, they are probably going to show  
15 up, not always. But if you do a search of them  
16 and their business, their name is probably going  
17 to come up somewhere. And that's got to be one of  
18 the first things I think you do to verify -

19 MS. BEARDSLEY: But then it was pointed  
20 out to us that anyone can set up a website and  
21 make it look legitimate.

22 MR. MONTGOMERY: Sure. Yes. But I  
23 mean as a starting point at least you know -

24 MEMBER RYAN: Yes, I don't think though  
25 that's a substitute for what I'm suggesting. I

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1 agree with you 100 percent. Do all the homework  
2 from every resource you can to prepare for your  
3 site visit. But put your eye on somebody and  
4 seeing the facilities they plan to use is going to  
5 tell, in my view, at least to a seasoned license  
6 writer, this is going to work or there are  
7 problems here. I just can't imagine that's not  
8 the case.

9 MS. BEARDSLEY: We do have a procedure  
10 now for doing the licensing visit, the pre-  
11 licensing visit. However I can look at someone's  
12 driver's license. I wouldn't know whether it was  
13 legit or not. So as a license reviewer, I don't  
14 feel comfortable with the onus being on me to  
15 determine that this licensee is legitimate. And  
16 a lot of us have told our management that, because  
17 we just don't - we're not trained adequately.  
18 It's not our background.

19 So I would feel horrible if I issued  
20 a license and it was used in a terrorist activity.  
21 That would just be terrible. But -

22 MEMBER RYAN: Let me shift gears a  
23 little bit to a different side of this if I may,  
24 Mr. Chairman, because we haven't touched on it  
25 much this morning, while we've got these folks

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1 here. What happens once you issue a license, and  
2 let's say the licensing process works fine, and  
3 it's kind of the case where the GAO said, well,  
4 now I'm going to buy some material. I've got a  
5 license. What are the issues there in terms of  
6 the agency's control of - you issue a license to  
7 an authorized licensee who now goes and buys  
8 stuff. In the case of the sting, they falsified  
9 the quantity they were allowed to possess. I  
10 don't know, used white out and typed over it, or  
11 whatever they did.

12 And what are your thoughts? Have you  
13 thought about this problem of how do you make sure  
14 that the license that's faxed or somehow  
15 transmitted to a provider, material, vendor, is a  
16 legitimate transaction?

17 MR. MONTGOMERY: You've asked the  
18 \$64,000 question.

19 MEMBER RYAN: All right.

20 MR. MONTGOMERY: You know the whole  
21 issue of counterfeiting a license is - I know NRC  
22 is looking at this, and I think I don't know if  
23 Pam is going to address this when she is here  
24 tomorrow.

25 But there is - this is a big concern

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1 for the Agency. We certainly know anybody that  
2 has ever worked with a computer knows what you can  
3 do with a computer, anybody can do with a  
4 computer, and simple graphics software, you can  
5 pretty much reproduce anything, even money. It's  
6 being done, and it's a big problem.

7 And I don't know what the answer is.  
8 The manufacturers have also weighed in on this.  
9 In fact some of the - one of the big manufacturers  
10 of these portable gauges that I mentioned is very  
11 concerned about this. They don't want to get  
12 caught in the middle of sending material to a  
13 malevolent individual either. So they are looking  
14 at trying to work with NRC and the States to  
15 prevent this from happening.

16 And I don't know, all the answers  
17 haven't come in yet. But I think you certainly  
18 hit the nail on the head with that question.

19 MEMBER RYAN: Well, and again, in the  
20 medical area there are a lot of transactions  
21 everyday with nuclear pharmacies, because just the  
22 nature of short half life material, there is  
23 transaction after transaction; even though it's  
24 low risk, there is a lot of transaction traffic.  
25 Gauges is probably a little bit more than, say,

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1 irradiators of some sort.

2 And the bigger the device and the  
3 source, the more likely it is, it's a little more  
4 that there's a little catch in my license and you  
5 can ship me one. You know there is going to be a  
6 purchase order, and there are going to be more  
7 elaborate arrangements made, which slow down the  
8 process for somebody getting some stuff and then  
9 disappearing with it somehow or doing something  
10 bad with it.

11 MR. MONTGOMERY: But ionizing radiation  
12 is a real enigma, because it can take lives;  
13 destroy lives; but it also saves lives both  
14 industrial and medical uses save a lot of lives.  
15 And so -

16 MR. McCRAW: As Jim does point out, you  
17 really did ask the \$64,000 question. Because it  
18 can also go back to the good faith presumption  
19 again. We assume that our licensees are only  
20 going to ask for the amount that they are  
21 authorized. If they need more they are going to  
22 come in for an amendment; they are not going to  
23 try to illegally obtain this material.

24 MEMBER RYAN: Oh, yes, for an honest  
25 licensee. The inspection headache, oh we've got

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1 10 times more than they are authorized to have is  
2 a real show stopper.

3 MR. MONTGOMERY: But we also rely on  
4 the good faith of the vendor to look at that  
5 request and say, "this is a reasonable request."  
6 We have the good faith that they will call us and  
7 say, "hey, this guy is trying to obtain a hundred  
8 and some portable gauges." Nobody on earth would  
9 try to do that in one sitting.

10 But you know it's not a fail-safe  
11 method. There are plenty of opportunities there  
12 for error.

13 MEMBER RYAN: The one thing about the  
14 GAO report, and again I'm not trying to diminish  
15 in anyway their findings or observations, but they  
16 never physically got the material. They didn't  
17 take it to the end of the road. And that's - I  
18 guess we are not exactly clear on it, I've heard  
19 comment that there was somebody who called and  
20 said, who are these people ordering 10 of these  
21 when most people only get one.

22 MR. McCRAW: In our future meetings  
23 I'd like to have some individuals come in and  
24 discuss the Web-based Licensing and the National  
25 Source Tracking System and the agency's future

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1 plans to integrate those, because that will serve  
2 if it's - if it operates as intended, it will  
3 serve as basically a license verification tool,  
4 electronically, so there is not as much burden on  
5 the regulatory body.

6 Right now all we can do is manual  
7 verification. And Pam Henderson will talk about  
8 that tomorrow.

9 MEMBER RYAN: Okay, so that is being  
10 addressed. And that's an important aspect of  
11 trust but verify as an alternative to trust.

12 MEMBER NERUD: Now in our discussions  
13 with Doug Broaddus, who is with the Web-based  
14 Licensing project manager, that process has  
15 languished for years. And to get it off the  
16 ground they've cut significant portions from it,  
17 like license verification; like material tracking,  
18 integration; a lot of these things that would make  
19 the web-based licensing process a very effective  
20 tool in preventing an adversary from getting a  
21 quantity of this are being dropped in order to get  
22 the program up and running.

23 And what is happening is they're  
24 getting a web-based licensing lite that does  
25 nothing more than what the current License

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1 Tracking System does right now.

2 It's not out there for vendors to look  
3 at. It's not out there for Agreement States to  
4 look at. It's an NRC tool that's used internally  
5 to NRC.

6 In order for this to accomplish what  
7 needs to be accomplished, you've got to have a  
8 full program, as designed from the beginning.

9 MEMBER RYAN: Then how do we tap into  
10 some of that information? You know banks do  
11 millions of transactions a day that are secure.  
12 Driver's licenses can be renewed online, things of  
13 that sort. How do we tap into some basic  
14 understanding of that expertise?

15 MEMBER NERUD: Well, first of all, I'm  
16 not the expert there. But that being said I have  
17 talked to some people who do produce secure  
18 websites. And registration technologies are out  
19 there. They discussed having a token in which, in  
20 order to get access to this application process,  
21 you apply for the license online and all the rest  
22 of it, what you have to do is actually register  
23 with the NRC, or an Agreement State if they want  
24 to use this. NRC will do a background check on  
25 you, generally just a national criminal check, or

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1 you know an FBI check. They'll send you a token.  
2 When you get that token, well, that's your key  
3 plus your pin number to access the system. So you  
4 have one layer of security right there. You apply  
5 for all this online.

6 Now the great part of having this  
7 online is the ability to have predesignated  
8 indicators if addresses don't match; if people  
9 with executive positions in a company are also  
10 serving in positions where executives normally  
11 don't serve, it would highlight those things. It  
12 would say we've tagged some items in this  
13 application that you need to resolve before you go  
14 any further to validate the organization.

15 So you can build some of those things  
16 in there. After that, it's just like regular  
17 license tracking system in which you do your  
18 reviews, follow the procedures, NUREG-1556, follow  
19 it through, get your license.

20 Once it's done, currently the licenses  
21 are all stored on ADAMS. Well, what would  
22 actually happen on this is there's a field set  
23 aside for, here's the license; here's where it's  
24 being stored; here's how much material, what  
25 quantity of material; what the material state is;

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1 if it's a portable gauge, how many portable gauges  
2 they're allowed, et cetera, et cetera.

3 And you actually have that data right  
4 there. Individual goes to the company to purchase  
5 this, not only does he have to give him his  
6 license, but the vendor is now required to check  
7 this web-based licensing process in which he gets  
8 to see, okay, yes, here's the license. The big  
9 issue with the GAO report is, they had modified  
10 the license. They had a real license; they  
11 modified it. You get a real license and it's  
12 modified, it doesn't show up what's on the web-  
13 based licensing thing, sorry we can't sell this to  
14 you, and notification to the authorities at that  
15 point.

16 The other part that is real nice about  
17 it -

18 MEMBER RYAN: I guess theoretically all  
19 the vendors that sell this stuff would be given  
20 authority to look at licenses by category or  
21 whatever it might be.

22 MEMBER NERUD: Exactly. The other part  
23 of it is that it also fits into the material  
24 tracking system. So what would end up happening  
25 is a licensee goes to a vendor, gets six portable

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1 gauges; that's the maximum he is allowed to use.  
2 Well, he can go to another vendor and buy six  
3 more, because there is no, how much material do  
4 you actually have.

5 With a web-based licensing system  
6 integrated into the material tracking system, when  
7 they get on - when the vendor gets on it, says, no  
8 you've already bought six gauges. You don't get  
9 six more.

10 So there are a lot of advantages on  
11 this.

12 MEMBER RYAN: So you are not relying on  
13 the licensee then -

14 MEMBER NERUD: You are not relying on  
15 the licensee. You are not relying on a phone call  
16 to an Agreement State license reviewer, or an NRC  
17 license reviewer. You are relying on this  
18 database manufacturer to validate the application,  
19 everything else.

20 And as I mentioned before, this web-  
21 based licensing system as identified in the  
22 original statement of work years ago, with all the  
23 caveats attached to it, is really a major step in  
24 the solution of this entire process.

25 Because I don't see this as just a

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1 licensing process. There is a whole bunch of  
2 stuff that goes with this to make this process  
3 exploitable. Yes, licensing is part of it.  
4 Vendors are a part of it. Material tracking is a  
5 part of it. Policy, antiquated policy, old  
6 policy, by a variety of people, not just NRC, not  
7 just the Agreement States, but by the doctors, by  
8 the contractors, by the vendors, all these other  
9 things.

10 It all combines into this critical  
11 mass that allowed GAO to do what they did.  
12 Problem with GAO was not just NRC. And in trying  
13 to put all that blame in this one process, it  
14 doesn't float the boat.

15 You said it yourself; they didn't get  
16 the material. That's a way to get a big part of  
17 that process.

18 MR. MONTGOMERY: Are you familiar, have  
19 you been briefed on - there is a difference  
20 between - there are these higher, more highly  
21 radioactive and potentially detrimental sources  
22 are - come under an NRC program that was  
23 instituted after 9/11 for either increased control  
24 security orders, or Increased Controls,  
25 radioactive materials, quantities of concern, and

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1 all of that, there is a whole separate security  
2 requirement that's been placed on these larger  
3 licensees in which they have to meet all kinds of  
4 security requirements. They are asked to do  
5 criminal background checks, for example, on the  
6 people authorized to handle these sources and  
7 enter these areas of these large sources.

8 But there is a whole other group of  
9 sealed sources used, many of which I talked about,  
10 and these are the smaller sources, gauges for  
11 example, all these gauges and stuff that we talked  
12 about.

13 A lot of those aren't currently under  
14 this security - this increased security things.  
15 But there is this whole area of security  
16 heightened security awareness that is a big deal  
17 now, and a lot of them - all these big irradiators  
18 for example have to come under this. And that's  
19 really, hopefully that's going to catch any  
20 situation.

21 And Michelle touched on something that  
22 I could really identify with, and that is you know  
23 license reviewers historically are health  
24 physicists with radiation safety backgrounds. And  
25 their training and all their experience is based

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1 on that. This whole security dealing with a  
2 malevolent individual or a criminal element is  
3 pretty foreign to people who have had this kind of  
4 background.

5 And yet we certainly feel a  
6 responsibility not to allow anything to slip  
7 through us like this. But I think - it's been my  
8 belief, my philosophy, if I have even the  
9 slightest doubt about who I'm dealing with, if I  
10 have any concern at all that this person is not  
11 100 percent legitimate, I'm going to stop right  
12 there. And our guidance, we tried to emphasize  
13 this in our guidance to the reviewers, don't go  
14 any further. If you are uncomfortable for any  
15 reason turn it over - there are people in NRC who  
16 are experts at dealing with this kind of  
17 individual. And turn it over to them. They have  
18 criminal investigative background experience, and  
19 those are the people that should be taking over at  
20 that point, and the reviewer should back away,  
21 that's it, and let the people that really deal  
22 with this kind of thing take over.

23 And I think that is in our guidance.  
24 We emphasize it strongly. And I can't say any  
25 more than that.

1                   MEMBER NERUD: And I'm sorry, but I  
2                   kind of have to disagree with that. The guidance  
3                   that is out there, and I am not a license  
4                   reviewer, I don't have that breadth of experience,  
5                   when I read the guidance, and I read a lot of it,  
6                   I read it for health, for safety, for  
7                   administrative procedure. I didn't see it for  
8                   security. That whole paradigm, that's what I said  
9                   when I mentioned that the guidance is antiquated.

10                   Nowhere in the guidance does it really  
11                   come out and say you need to check this to make  
12                   sure a terrorist isn't trying to get a license.  
13                   It doesn't go to that level, and rightly so. This  
14                   is a new paradigm for us.

15                   What we've tried to do though is,  
16                   we've tried to adapt current guidance to fit that  
17                   model, and in order to fit that model you end up  
18                   with ease of access to information, reviewing  
19                   guidance with, here's our model, use our model and  
20                   you'll get a license.

21                   And the good faith presumption, all  
22                   fits in line with that. All these factors allow  
23                   someone to get a license; that's our business, get  
24                   somebody a license. Not identify who is the bad  
25                   guy trying to get a license; that isn't what's

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1 included in the guidance.

2 MS. BEARDSLEY: I think he's referring  
3 to that (c) (6) checklist that we showed you.

4 MEMBER NERUD: And I understand that  
5 checklist, but again, that checklist focuses on  
6 what currently is in the guidance, and some  
7 additional steps, but they don't really go to the  
8 extent that a terrorist organization would go to  
9 to prevent that activity.

10 And I'll give one really good example  
11 of this. In Mumbasa, Kenya, the Nairobi embassy  
12 bombings, the guy who set that program up  
13 established five legitimate businesses, and a  
14 charity. The charity was called, Help Africa  
15 People. And that charity was recognized not only  
16 in Kenya, but in Saudi Arabia, Germany, England,  
17 France, and Spain, as a legitimate charity.

18 Do a website search on that; they're  
19 legit, because they have branches in all these  
20 other places.

21 So while I'm a huge fan of open source  
22 information, I love the Internet, I think it's  
23 great, I don't think that the Internet is the  
24 appropriate venue for validating a company when we  
25 have all the resources available to the Federal

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1 government to do that. We have Federal tax IDs  
2 that we could get. We have State tax IDs that we  
3 could validate. We have employment records. We  
4 could check contracts. There are a lot of other  
5 ways to really establish a legitimate business  
6 that has a cash flow. That would have been a key  
7 indicator with the Kenyan bombings. Those  
8 businesses didn't generate any cash. They were  
9 legitimately set up, but there was no cash being  
10 generated from them with the exception of the gem  
11 business.

12           So there are things that we can do.  
13 But again, and I'm going to go back to something  
14 I mentioned in Region I - I'm sorry for  
15 interrupting, Jim - but this is not something a  
16 license reviewer is trained or for that matter,  
17 and I'm not denigrating their abilities, qualified  
18 to do. Okay? You're health physicists. You are  
19 there for health safety, administrative clients.  
20 There has to be a mechanism by which a suspect  
21 license, any of those things that you said doesn't  
22 feel right, goes to someone and they check it out.

23           MR. MONTGOMERY: And we have that. We  
24 do that. We have an Office of Investigations in  
25 the NRC, and the Regions have it. And in fact, I

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1 encourage you to - what you said is so germane to  
2 what Pam Henderson is going to talk about  
3 tomorrow. And I encourage you to broach that  
4 subject with her.

5           Because our group, which she chairs,  
6 has been talking about this very thing. And the  
7 NRC Office of Investigations has a lot of these  
8 investigative techniques that you alluded to. And  
9 they know how to use this software, stuff that we  
10 don't have access to at all, and they have access  
11 to the FBI techniques and all kinds of other  
12 Agencies including your own Agency, and what your  
13 own Agency does.

14           So they are tied into all of this,  
15 it's my understanding. And that's why I said,  
16 what we can do as reviewers is only - it may only  
17 be the beginning, and it certainly isn't the end  
18 all to this whole process.

19           And I don't know where you draw the  
20 line, and where you say, okay, we've done what we  
21 can as reviewers. If we're uncomfortable with  
22 anything, like I said, the only thing we can do is  
23 tell our people, hey if you are uncomfortable at  
24 all, or have any kind of doubt, you turn it over  
25 to other people like you've talked about and we

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1 get away from it, hands off.

2 We could even compromise a whole  
3 investigation if we continued to try to probe and  
4 got suspicious and all that stuff.

5 So I have pushed to have our guidance  
6 clearly spelled out. And that's the hard part,  
7 though. Where do you decide? How do you decide  
8 when to - when you are at that point? And I guess  
9 each reviewer has just got to make that decision.

10 MEMBER NERUD: I don't think it's each  
11 - I'm sorry - I don't think it's each reviewer.  
12 I think it goes back to the guidance. The  
13 guidance needs to reflect the current environment,  
14 and it should identify indicators in there that  
15 would lead someone to say, something is not right  
16 with this license, and as I learned when I was up  
17 in Region I, things that I thought were fairly  
18 significant indicators were very commonplace, but  
19 they still should be considered as indicators.

20 MS. BEARDSLEY: And that's why I should  
21 point out that our license reviewer follows the  
22 (c)(6) checklist and still issued the license, so  
23 he did do the checks that were on there, and it  
24 still turned out to be illegitimate.

25 MEMBER RYAN: Ultimately, if there is

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1 an item in the GAO audit, that's one. You  
2 followed the process.

3 MS. BEARDSLEY: We followed the  
4 procedure, right, and it didn't work.

5 MEMBER RYAN: So I think the next step  
6 is, well, what would make it work. And that's  
7 probably the aspect that Ben is hitting on. And  
8 maybe I think the idea that you have specialist  
9 resources available to address those security and  
10 safeguards kind of questions which is a field unto  
11 itself beyond radioactive materials, security and  
12 safeguards of gold or money or anything, banks,  
13 computer systems, or whatever it might.

14 But I think, how do we get the NRC  
15 licensing staff in the Regions and everywhere, and  
16 the Agreement States for that matter,  
17 knowledgeable and trained? I mean there is an  
18 element of, if you are going to do something  
19 different, then the roll out of it has to be part  
20 of what we think through to.

21 And again I think about all the folks  
22 in the Agreement States are going to have to  
23 understand this a little better as well.

24 MR. MONTGOMERY: You know there is  
25 going to be another test. There is going to be

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1 another sting. It's got to be coming. I mean you  
2 know the powers that be are sitting there  
3 thinking, okay, NRC they made some adjustments,  
4 based on our last attempt.

5 Now what are we going to do? Let's  
6 see. I mean you know this is coming. There is  
7 going to be another attempt to try to get in, and  
8 go around, and these Increased Controls now that  
9 we have, I mean we all -

10 MEMBER RYAN: We don't know; we can  
11 suppose.

12 MR. MONTGOMERY: We all know - I'll bet  
13 my next paycheck; I know it's coming. And all the  
14 reviewers are on pins and needles. We're all on  
15 pins and needles, because we don't want to be the  
16 next victim, you know what I mean?

17 But at the same time, we don't - I  
18 mean there is the real world out there too. We  
19 are not just playing games here with GAO. And  
20 we've got to be - we can't forget that either.

21 So it's really putting the reviewers  
22 in a tough situation. There is a lot of stress  
23 right now, every time you look at one of these  
24 applications.

25 CHAIR HILL: One of the comments I'll

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1 have, and it looks like it's getting time for  
2 lunch, talked about Office of Investigations at  
3 NRC, whatever that means, 34 Agreement State  
4 regulatory programs do not have that Office of  
5 Investigations. They may have their bureaus of  
6 investigation you know at the State level. And so  
7 what changes may be done here are going to be  
8 considered adequacy issues for the Agreement  
9 States or compatibility.

10 MR. MONTGOMERY: I believe a number of  
11 the States don't even have the authority or at  
12 least there is some problem with doing these  
13 criminal background checks, investigating employee  
14 history, background, all of that.

15 Fingerprinting is another issue with  
16 a lot of the states. They don't have - they may  
17 not have the statute authority. This is all in  
18 the mix.

19 CHAIR HILL: Well, any other comments?  
20 Or is everybody ready for lunch?

21 MEMBER NERUD: I could eat.

22 CHAIR HILL: Lunch is always in order,  
23 isn't it?

24 Well, let's adjourn til 1:00 o'clock  
25 for lunch. And Michelle and Jim, we appreciate

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1 your being here. We appreciate your efforts and  
2 preparation. Thank you much.

3 (Whereupon at 12:00 p.m.  
4 the proceeding in the  
5 above-entitled matter went  
6 off the record to return on  
7 the record at 1:02 p.m.)

8 CHAIR HILL: Well, good afternoon and  
9 welcome to the afternoon session of the second day  
10 of our second meeting.

11 And I think we are in the agenda to  
12 distribution licenses, specific, general and  
13 exempt.

14 Duncan.

15 DISTRIBUTION LICENSES - SPECIFIC, GENERAL AND  
16 EXEMPT

17 MR. WHITE: The NRC and the Agreement  
18 States will both issue distribution licenses for  
19 devices that have been reviewed and meet certain  
20 safety requirements.

21 We heard a little bit about that this  
22 morning with regard to how we evaluate devices.  
23 Devices are either reviewed by the NRC  
24 Headquarters or by our Agreement States. And they  
25 will look at the device, and make sure it meets

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1 certain performance requirements, that it will not  
2 result in undue risks to the user, and it will  
3 operate in a manner consistent with - lost the  
4 words there - with standard industry practices.

5 And we touched a little bit on that  
6 with regard to use of industry standards, the A -

7 MR. HSUEH: ANSI?

8 MR. WHITE: ANSI, thank you.

9 And those are industry standards that  
10 are used for the construction and evaluation of  
11 particular classes of products, and they are  
12 written for different classes of products like for  
13 gauges, for radiography equipment, for  
14 irradiators, different clinical devices. There is  
15 a whole series of these standards.

16 So these are evaluated as part of  
17 that. They're looked at from the health and  
18 safety, the construction, compatibility of the  
19 materials, radiation levels, a whole series of  
20 things they look at.

21 And we talked this morning about  
22 issuing registry sheets, sealed source and device  
23 registry sheets. And when they issue those sheets,  
24 those are used to incorporate on the various  
25 licenses.

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1           Now in the NRC regulations, and  
2           accompanying Agreement State regulations, there  
3           are certain performance criteria that they have to  
4           be able to secure a device, a generally licensed  
5           device, or a specifically licensed device, or  
6           again, an exempt device.

7           Generally, the licensed device is  
8           designed for use by someone with little or no  
9           radiation training. It's supposed to be  
10          inherently safe. And when it's given to someone  
11          to use as that - and an example - a couple of  
12          examples of that would be some fixed gauges; exit  
13          signs. And what they will use these - and these  
14          sources are used - devices are used, they have to  
15          go through a distribution license. They are  
16          manufactured in accordance with the registry sheet  
17          by a manufacturer under a specific license, and  
18          then they are distributed, or given to a - the end  
19          user.

20          For a generally licensed devices, and  
21          for exempt licenses, there is a separate specific  
22          license issued to the manufacturer to distribute  
23          these products.

24          These separate licenses do not  
25          authorize possession. They only really authorize

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1 the transfer of these devices, and manufacture  
2 according to the sheets, according to regulations,  
3 to these individuals.

4 Specific devices that don't meet the  
5 criteria for exempt distribution or general  
6 license are considered specifically licensed  
7 products. Those are the things we were talking  
8 about here earlier, portable gauges, radiography  
9 devices, things such as that.

10 We do not issue a separate  
11 distribution license for devices requiring a  
12 specific license. They are usually transferred  
13 under the possession license as part of the  
14 overall license.

15 So for example a nuclear pharmacy for  
16 example, it's a form of distribution. It manages  
17 doctors' medical products for often diagnostic  
18 type of uses. These products are - they have one  
19 license. They have a license to manufacture and  
20 make the isotope, that radioisotope, and it's  
21 transferred under the same license to another  
22 specific user. So it's a specific user to  
23 specific user transfer.

24 And because the other - for general  
25 and exempt licenses, they don't have another

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1 license. They are not required to come into the  
2 NRC or to an Agreement State to get a license,  
3 apply for a license and have a specific radiation  
4 program in place to use these devices, because  
5 they are supposed to be inherently safe; that's  
6 why you have a distribution license. It's a way  
7 that for the NRC and Agreement States to keep  
8 track of what is - where stuff is going. And  
9 particularly with general license distribution,  
10 there is a requirement for the manufacturer who  
11 has that license to report on a quarterly basis  
12 who and what he sells to.

13           So we get these quarterly reports,  
14 Agreement States get these quarterly reports  
15 saying that company X - manufacturing company XYZ  
16 distributed 100 exit signs, and here's who they  
17 distributed it to. This is how we keep track of  
18 the stuff.

19           Items that are distributed under a  
20 general license are still - there is a minimum  
21 amount requirement for the end user to use them,  
22 and we'll talk about those later, what a general  
23 license has to do. But they are still under  
24 regulatory control, and they still have to be  
25 disposed of properly. So for example an exit sign

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1 which is distributed under a general license must  
2 be returned to a manufacturer or to another  
3 specific licensee authorized to possess that  
4 material. It can't just be thrown out.

5 Under an exempt distribution item,  
6 exempt distribution license, a classic example of  
7 that is a smoke detector, once a smoke detector is  
8 distributed to an end user, it can be - it's no  
9 longer under any regulatory control whatsoever and  
10 can basically be thrown out in the trash.

11 Again, exempt distribution, items that  
12 have very low quantities of material, or may have  
13 just above exempt qualities of materials again.  
14 Again, Part 30 law regulation there's a table for  
15 each isotope for what the exempt concentrations or  
16 quantities of materials.

17 And often the exempt quantity  
18 materials have very low - very small amounts of  
19 material are designed and built for someone who  
20 doesn't have any radiation training whatsoever,  
21 usually consumer-type products, like smoke  
22 detectors I think are far and away the biggest  
23 group of those.

24 Another interesting group that fall  
25 under exempt distributions is irradiated

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1 gemstones. Irradiated gemstones are used to color  
2 topaz which is white in color when it comes out of  
3 the ground. They irradiate them to make them nice  
4 colors so people will buy them and wear them. But  
5 in the process of - since they irradiate them in  
6 accelerators and reactors, there are impurities in  
7 them. The impurities are activated, and you get  
8 very low concentrations of certain items,  
9 typically five or six different isotopes typically  
10 show up, and these are usually above exempt  
11 concentration, and therefore you need a license to  
12 distribute, at least initial distribution of them.

13           Once the existing distribution items  
14 are distributed, they are no longer under  
15 regulatory control, and you don't care about  
16 intermediaries or anything like that after that.

17           So for example a company builds a  
18 smoke detector, you would go buy it at Home Depot  
19 or something like that, or the local hardware  
20 store, you go buy the thing. It may go to a  
21 middle distributor; it may go to several  
22 intermediate points before the end user has it.  
23 That's very typical, and we don't track that at  
24 all. All we do with exempt distribution is track  
25 quantities of material, how much is going out.

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1           And again, the idea is, they are a  
2 consumable that can be thrown out. There is no  
3 regulatory hazard associated with them.

4           A general license on the other hand  
5 can have significant quantities of radioactive  
6 materials involved with them. Tritium exit signs  
7 typically have curie amounts of materials in them.  
8 The typical exit sign has five curies in it; it  
9 can have an even larger amount of tritium in it.

10           Again, once after their useful life is  
11 used, they are to be - the intention is to return  
12 them to either the manufacturer, or again,  
13 disposal in a commercial waste disposal site,  
14 whatever that - an appropriate manner to get rid  
15 of it. They can't - they can't just be thrown  
16 out, although we do find them in the waste stream,  
17 and they do get reported.

18           MEMBER RYAN: How often? What's the  
19 material balance on those distributed and those  
20 returned?

21           MR. WHITE: I don't know the answer on  
22 that. Exit signs typically have a 10-year  
23 lifespan before they - that they can be used.

24           In terms of - again, get back to - the  
25 distribution licenses themselves, generally NRC

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1 renews licenses on a 10-year frequency, and that's  
2 generally how we do it. If someone gets a new  
3 sheet, we will have to amend that distribution  
4 license to update the - make sure that they are  
5 authorized to distribute what they have the  
6 registry sheet for.

7 MEMBER RYAN: Could you talk a little  
8 more about specific distribution?

9 MR. WHITE: Okay, sure.

10 Specific distribution licenses are -  
11 again devices that require specific license also  
12 have to be reviewed, and have a sealed source and  
13 devices registry sheet.

14 Again, someone who is in specific  
15 distribution will have it listed on their license  
16 for specific distribution; it will actually say  
17 that's a condition of use on the license.

18 MEMBER RYAN: Give us some examples.  
19 What is in that category?

20 MR. WHITE: Well, I mentioned the  
21 pharmacy before; I mentioned a nuclear pharmacy  
22 falls in that. Radiography cameras; there are  
23 three manufacturers of radiography cameras in this  
24 country. They specifically distribute the cameras  
25 to people who have appropriate licenses.

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1           Some fixed gauges, like portable  
2 gauges, portable gauges - the question you asked  
3 yesterday was about what types of licenses and how  
4 many we have. The biggest category of any  
5 licensee we have is portable gauges. They require  
6 specific licenses. Manufacturers will distribute  
7 those gauges under a specific license. It will go  
8 to specific license, specific license.

9           MEMBER RYAN: Got you.

10          MR. WHITE: There is no separate  
11 distribution - there is no separate distribution  
12 license for -

13          MEMBER RYAN: That's the part I was  
14 kind of getting at. Basically you get a  
15 specifically licensed manufacturer transferring  
16 material to a specific authorized licensee.

17          MR. WHITE: And what the regulations  
18 require the specific licensees to do, in our  
19 regulations they have to track who they sent to,  
20 so we can go in and inspect, and say, who did you  
21 sell the stuff to, they can show that.

22                 Under a general license you don't have  
23 - the end user doesn't have a license. You need  
24 to keep track of where they are. That's why it  
25 goes to a distribution license. Records are made.

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1 Records are turned over to the regulatory  
2 authority, and we can track it that way.

3 So that's I guess in a nutshell what a  
4 distribution license is.

5 Oh, one more thing about distribution  
6 licenses. Exempt distribution licenses are only  
7 issued by the NRC; no one else does that. It's  
8 about 100 - we have about 100 exempt distribution  
9 licenses for those products.

10 General licensing material, a specific  
11 license can be issued by NRC and Agreement States.

12 MR. McCRAW: Are we ready to move on to  
13 general licenses?

14 CHAIR HILL: Sure.

15 MR. McCRAW: We have a period set aside  
16 for questions and answers later. We could roll  
17 through these presentations

18 CHAIR HILL: Probably a good idea.

19 MR. WHITE: Okay, general licenses.  
20 General license is basically - doesn't require -  
21 it allows the use of radioactive material without  
22 getting specific - going with a specific  
23 application to the NRC or Agreement State. You  
24 basically get the license by virtue of getting new  
25 material.

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1           For generally licensed material, that  
2 quite often involves a lot of involvement with the  
3 manufacturer. The manufacturer will send to an  
4 end user, and the manufacturer often assists -  
5 depending on the type of device - will assist the  
6 end user with some basic training and  
7 understanding what their requirements under the  
8 regulations are to do.

9           Again, generally licensed devices, and  
10 general licenses require minimum radiation they're  
11 expected to use. There are very few regulatory  
12 requirements. Regulatory requirements usually  
13 require, depending on the device they have, leak  
14 testing, reporting if the thing is lost or stolen;  
15 and proper disposal. Those clearly are the basic  
16 things they have to do.

17           There are certain materials and  
18 certain isotopes and certain types of devices that  
19 have to be - NRC has a registration program. The  
20 NRC does have a registration program for general  
21 license devices. It's rather limited. We have  
22 about 6,000 devices in our registration program.  
23 Again it's very specific isotopes and it's very  
24 limited. For example, it does not include tritium  
25 exit signs. It includes mostly cesium, americium,

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1 isotopes like that. It does not include tritium.

2 Tritium exit signs are by far away the  
3 largest group of general licensees out there are  
4 our tritium exit signs.

5 MEMBER RYAN: From a hazard perspective  
6 they're all tritium gas.

7 MR. WHITE: Correct.

8 MEMBER RYAN: So if they break it's  
9 over.

10 MR. WHITE: Correct.

11 MEMBER RYAN: The tritium gas is  
12 diluted in the atmosphere.

13 MR. WHITE: Yes.

14 MEMBER RYAN: There is a little bit of  
15 residual in the phosphor and the paint and stuff.

16 MR. WHITE: Right, that's pretty much  
17 it.

18 One of these incidents that have  
19 happened in the past have resulted in - all the  
20 people who were exposed got over 100 millirem,  
21 talking direct physical contact. Very low doses.

22 MEMBER RYAN: Yes, that sounds like  
23 really an odd circumstance. It's hard to get  
24 excited about tritium, other than a contamination  
25 hazard and clean up mess and that sort of a

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1 problem.

2 And I don't see it having any value,  
3 because it's H<sub>2</sub>, it's just going to disperse at a  
4 diffusion coefficient of hydrogen gas, which is  
5 pretty quick.

6 MR. WHITE: There are a number of -  
7 again, the NRC's registration program for GIs  
8 focus on the higher risk items. And there are  
9 some devices out there that have relatively large  
10 quantities of cobalt and cesium, particularly  
11 cobalt, used in the steel industry, are generally  
12 licensed.

13 Again, they have large quantities of  
14 materials, and they are generally licensed,  
15 because again, as mentioned earlier, when the  
16 manufacturer constructs these things, they are  
17 constructed in a manner to ensure that someone  
18 with little or no radiation training can safely  
19 use them. And they are constructed in a manner  
20 that they can't be tampered with or manipulated at  
21 all.

22 And these devices could contain curies  
23 of amounts of materials, potentially, typically  
24 the larger ones. There are very few of them out  
25 there, but there are a few large ones out there.

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1 MEMBER RYAN: Large ones being what?

2 MR. WHITE: Curie amounts of cobalt.

3 MEMBER RYAN: One curie, 100 curies?

4 MR. WHITE: Anywhere from one to 30

5 curies.

6 MEMBER RYAN: One to 30 curies, okay.

7 MR. WHITE: And there are a number of  
8 americium-241s also often used for - in industry  
9 for - as a backscatter gauge, and when they use  
10 like paper manufacturing. Jim has probably seen a  
11 large number of these things. Thin mylar, very  
12 thin material; again, you have a large gamma and a  
13 large beta for backscanner purposes. Those gauges  
14 can be anywhere from 100 to 1 curie - 100  
15 millicuries to 1 curie americium.

16 Again, the - again, there have been  
17 occasions when these things have been lost or  
18 misplaced. There have been occasions when  
19 generally licensed devices have ended up in the  
20 waste stream and have caused significant  
21 contamination at the facilities.

22 Americium is obviously a particular  
23 problem, because you know it's a transuranic and  
24 has a very low ALI involved with it, so it doesn't  
25 take much to get a very high dose. So again those

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1 are of particular concern, when those get out  
2 there and get lost.

3 Again these are given to people who  
4 are not used to radiation control, and the reason  
5 for the registration program, part of that is on  
6 an annual basis, we charge them a fee, but also  
7 more importantly, we have some contact with them,  
8 hey you got these things, keep us up to date.  
9 Keep track of them; don't need to lose them.

10 In comparison, just give you, in terms  
11 of all generally licensed devices, our database  
12 has about 600,000 generally licensed devices. And  
13 again, like I said, only about 6,000 of them are  
14 registered. Because general license, these  
15 600,000 exit signs, lot of smaller -

16 MEMBER RYAN: 600,000 individual items?

17 MR. WHITE: Individual items, yes.

18 Another very common item that is often  
19 used, and a lot of them are out there, not as many  
20 as exit signs, is X-ray fluorescence analyzers.  
21 They are also quite prevalent out there and widely  
22 used for lead paint analysis and evaluation of  
23 metals and things like that. They are pretty  
24 widely used. Again, the quantities in those  
25 devices are very low, tens of millicuries for

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1 cobalt-57, americium and such. Those would not be  
2 registered. No, they would be registered in the  
3 system.

4 General license is also a term used,  
5 beside those type of devices, general license is  
6 also a term used in regulatory space for other  
7 things. When an Agreement State licensee wants to  
8 file for reciprocity to work in an NRC  
9 jurisdiction, those - we issue them, we recognize  
10 their Agreement State license basically under a  
11 general license. They have to fill out a form and  
12 register with us, and by accepting that form and  
13 approving that form we essentially issue a general  
14 license to that Agreement State licensee to  
15 operate under certain parameters in our  
16 jurisdiction. So again it's a little interesting  
17 twist on the use of the words general license, but  
18 that's something -

19 MEMBER RYAN: That's really just a  
20 mechanism for authorization rather than a risk -

21 MR. WHITE: And for enforcement.

22 MEMBER RYAN: Oh, okay.

23 MR. WHITE: Enforcement. Also a  
24 general license is also a mechanism that is used  
25 to license - to allow the possession of a couple

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1 of isotopes that do not have exempt quantities  
2 involved, americium, plutonium, fuel specific - if  
3 you have a specific license you are allowed to  
4 possess small quantities of americium and  
5 plutonium, check sources and calibration sources,  
6 under a general license, provided you already have  
7 a specific license. You can't have a general  
8 license of these two items by themselves; it has  
9 to stand with another license.

10 So quite often when people possess  
11 material, they will possess a material maybe under  
12 a specific license and a general license at the  
13 exact same time. And again it's not unusual to go  
14 up, particularly to an industrial facility, where  
15 you'll have one gauge sitting there being  
16 specifically licensed, and maybe the gauge right  
17 next to it be generally licensed.

18 From a practical and health and  
19 safety, there's not a lot of difference. But  
20 there is a regulatory difference. Because when  
21 they dispose of the generally license items,  
22 there's a lot of less - they just return it to the  
23 manufacturer. When they get rid of the  
24 specifically licensed device, they like want to  
25 terminate their license, they have to actually

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1 come back and say we got rid of this device to the  
2 licensing authority. They're all handled a little  
3 bit differently. Again, this is where we get into  
4 a problem about losing stuff. Because people  
5 forget under a general license forget that there  
6 is a requirement at the back end when you are done  
7 with this thing. Return it to someone who is  
8 authorized to take it, and you let the licensing  
9 authority know that. If you get one out of two,  
10 that's pretty good, because they'll be sent to the  
11 right person, but often they forget to notify the  
12 licensing agency. So it's one of the challenges  
13 with setting up a registration system. We may  
14 have a lot of information about who was sold  
15 stuff. Then we go and ask them, say, well, do you  
16 have - we have this list of 10 things that you  
17 have. And they say, well, we only have four of  
18 them. What happened to the other ones? Well, we  
19 sold it back - gave it back to the manufacturer  
20 and he never recorded that with the licensing  
21 authority. So it requires extra tracking.

22 And again, general licensing, the  
23 practice of general licensing came about in the  
24 late '50s because there was just a large volume of  
25 applications the Agency was getting, and the

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1 relative safety of a number of the devices being  
2 used, so they created this new category to deal  
3 with that.

4 MEMBER RYAN: That back-end hole seems  
5 to be something to pay attention to.

6 MR. WHITE: I agree.

7 MEMBER RYAN: I mean if you don't have  
8 positive - it's supposed to be a positive control  
9 step, and there is confusion about it being a  
10 requirement or not. That's something that -  
11 without numerical values on how many and how often  
12 it's hard to judge that; but that's a gap.

13 MR. WHITE: That's true. A large part  
14 of the problem, what the registration system was  
15 set up to do, it's one thing to remind people.  
16 Because often they will install these generally  
17 licensed devices in a plant or a facility, and the  
18 people who are there during the installation of it  
19 may be gone, and that institutional knowledge has  
20 now passed. This is why things sometimes get  
21 lost, are not properly disposed of.

22 MEMBER RYAN: That doesn't get at my  
23 question, though.

24 MR. WHITE: I know it doesn't.

25 MEMBER RYAN: The question is, what do

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1 you want to do about it? What should be done  
2 about it?

3 (Simultaneous voices)

4 MR. WHITE: An excellent example is,  
5 what do the Agreement States do. Agreement States  
6 have NRC - recently registered devices, the last 6  
7 or 7 years I think, it's relatively recent - some  
8 Agreement States have registration programs that  
9 go back 20 years or more. A couple of Agreement  
10 States don't even recognize - they treat  
11 everything as specifically licensed. That way  
12 they control everything. Everything is put on a  
13 specific license, if it's generally licensed it's  
14 put on a license like that; that way they can keep  
15 track of it.

16 Some States have registration programs  
17 that are very broad; they include everything under  
18 a general license, the quantity, and isotope  
19 involved; they just register everything, and some  
20 have some stuff in the middle.

21 As you can see for the NRC to do all  
22 GLs something on the order of hundreds of  
23 thousands of devices, that's quite a challenge,  
24 quite a resource to train and follow up.

25 MEMBER RYAN: Well, something simple

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1 like a postcard.

2 MR. WHITE: Well, that's what we do now  
3 with the our current registration program  
4 basically is that method.

5 CHAIR HILL: Why a postcard? Why  
6 quarterly? With electronic communication why not  
7 change it so that the distributors, let them  
8 notify the regulator of the distribution of a GL  
9 device.

10 MR. WHITE: Some of them do do that.  
11 It's the people at the back who are receiving the  
12 stuff; how do we keep track of those people.

13 MEMBER RYAN: Well, they've got an  
14 obligation under their license, and they simply  
15 have to put in a quarterly e-mail to some address  
16 that says, I still have the source and it's in  
17 use.

18 MR. WHITE: Yes, they can do that.

19 MEMBER RYAN: That's something they can  
20 do in 10 seconds. That's not a burden.

21 MR. WHITE: But the back end is, we  
22 have to track all that stuff. Someone has to sit  
23 and track all that stuff. And what do you do -  
24 again, I'm not disagreeing with you. I'm just  
25 saying, the challenge, the resource challenge

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1 behind this. What do you do when someone doesn't  
2 respond by e-mail? How long do you wait for them  
3 to do that, you send people out to go track stuff  
4 down.

5 MEMBER RYAN: Yes, there's going to be  
6 a graded approach. You give people a reminder e-  
7 mail; say this is a licensing requirement subject  
8 to penalties and fines, and we need an answer.  
9 And if you get the e-mail bounced back, you pick  
10 up the telephone.

11 But at least - again, my caveat is  
12 without knowing whether there are six or 6,000 of  
13 these that are in this we-don't-know-where-they-  
14 are category, we-don't-have-confirmation category,  
15 it's hard to know how to judge it. But you can do  
16 a lot with electronic feedback.

17 MEMBER NERUD: As a matter of fact the  
18 electronics can generate those overdue notices  
19 automatically.

20 MEMBER RYAN: Yes, exactly. They can  
21 create a database on one button and say that any  
22 license that was issued on this date is due an e-  
23 mail; boom, send them.

24 MEMBER NERUD: Integrate that right  
25 into the material tracking system.

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1 MEMBER RYAN: Sure.

2 CHAIR HILL: Would that be one tracking  
3 system for a nationwide program, or would it be  
4 35? Each of the Agreement States having to do the  
5 same thing?

6 MEMBER RYAN: Well, again, there are  
7 other examples of things that the NRC and the  
8 Agreement States share, and that could certainly  
9 be an easy way to do it.

10 MR. WHITE: That is shared right now.

11 MEMBER NERUD: I think that should be  
12 an NRC program. States can either use it or  
13 develop their own identical program for  
14 compliance. They are all going to use it because  
15 it's there.

16 MEMBER RYAN: Indeed. But it just  
17 seems to me there is a little category of sources  
18 here where it's not really clear that there is  
19 positive information of control over long periods  
20 of time.

21 MR. WHITE: Yes, I mean the higher risk  
22 stuff is done on an annual basis right now, and we  
23 do follow up with that. But the broader picture,  
24 if you look at all the generally licensed devices,  
25 most of them are not tracked on a routine basis;

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1 that's true.

2 MEMBER RYAN: But generally licensed -

3 MR. WHITE: In NRC jurisdiction.

4 (Simultaneous voices)

5 MR. WHITE: Some of them do things

6 differently than we do.

7 CHAIR HILL: I've got a couple of  
8 questions to go back and clarify.

9 You used the term, "alley" awhile ago.  
10 From my memory, A-L-I, annual limit on intake?

11 MR. WHITE: Yes.

12 CHAIR HILL: Okay, just seeing if I  
13 could remember. And did you say about 600,000  
14 possibly GL devices out there of which 6,000 were  
15 registered, approximately?

16 MR. WHITE: If you look at the world -  
17 anything that is distributed under a general  
18 license, we have about 600,000 of them in our  
19 space. Our registration program looks only at  
20 certain isotopes, the higher risk ones. You  
21 specifically have to have a registration, be  
22 registered. They pay an annual fee. There are  
23 about 6,000 of those.

24 CHAIR HILL: Okay. And of the cobalt-60  
25 you said, this is my note, make sure I got it

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1 right, the range of activity for the larger ones,  
2 cobalt-60, cesium-137, is 1 to 30 curies?

3 MR. WHITE: The larger ones, yes.

4 CHAIR HILL: Any idea how many of those  
5 are out there?

6 MR. WHITE: There are not many. No, I  
7 don't know the exact number on a quantity basis.  
8 But I mean there are very few out there. I  
9 believe they are all used in the steel industry.

10 CHAIR HILL: Mostly the steel industry?

11 MR. WHITE: Yes.

12 CHAIR HILL: Are there any that's not  
13 accounted for?

14 MR. WHITE: I think those are all  
15 accounted for.

16 CHAIR HILL: All accounted for?

17 MR. WHITE: I believe that's true.

18 One of the things you may hear, I  
19 guess Kevin may touch on this, is one of the  
20 things we're maybe moving towards, there used to  
21 be no limit on what could be generally licensed,  
22 no real practical limit. We're moving towards  
23 putting a ceiling on that I think, to ensure that  
24 large devices that are generally licensed are not  
25 - are made specifically licensed, controlled

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1 better, again, larger higher risk ones.

2 CHAIR HILL: I understand, you made the  
3 comment that some States include generally  
4 licensed devices on specific licenses as a method  
5 of tracking and keeping up so when they go to do  
6 inspections, we did that on some. I understand  
7 that some States, the legal authorities are  
8 saying, you can't do that. That's something that  
9 I read in a comment at the Agreement States  
10 meeting, have you heard anything on that?

11 MR. WHITE: This issue is very  
12 contentious with the Agreement States and the NRC.  
13 When NRC passed this registration program and  
14 adopted it as part of rulemaking, the Commission  
15 decided that it had to be a high level of  
16 compatibility. Basically the Agreement States had  
17 to have something virtually identical to the NRC.

18 Staff interestingly recommended that  
19 the States could be, if they choose to be more  
20 restrictive if they want to be. The Commission  
21 has decided against that. They decided to make it  
22 more - they were looking for uniformity.

23 There have been a couple of I believe  
24 OAS, I know the State of Florida, there might have  
25 been a second petition that has come in asking to

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1 change that, to allow States to become more - be  
2 more restrictive in their registration program for  
3 GL.

4 They're working to a resolution of  
5 that.

6 MR. HSUEH: Actually, the OAS petition  
7 on GL, the State of Florida has sent a request.  
8 OAS petition to - on the GL rulemaking, that's  
9 one. We received this petition in 2005. About  
10 the same time, the State of Florida also sent a  
11 request to change the compatibility of the GL rule  
12 that Duncan mentioned. Our Commission made a  
13 determination that compatibility be by the State  
14 of Florida, sent a request, want to change the  
15 compatibility from B to C.

16 And these two OAS petition, and in the  
17 State of Florida request, they are all put in the  
18 data as one petition, and it was docketed in 2005,  
19 and recently we evaluated the petition, and the  
20 NRC made a decision that we grant the petition, to  
21 the extent that all the issues are raised in the  
22 OAS petition, and then the issues raised by the  
23 State of Florida will be incorporated in this  
24 common GL rulemaking, and that's something I will  
25 touch on later.

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1 MR. McCRAW: It actually sounds like a  
2 perfect segue for you to touch on it now if you  
3 want to start your presentation.

4 MR. HSUEH: Okay, thank you.

5 (Comments off the record)

6 GENERAL LICENSE RULEMAKING EFFORTS

7 MR. HSUEH: Good afternoon. My name is  
8 Kevin Hsueh, and I'm the Branch Chief over  
9 Rulemaking Branch A, and the thing I'd like to  
10 talk about is the general license rulemaking  
11 effort.

12 First of all I'd like to give you some  
13 background how this rulemaking effort got started.  
14 In 2005, the States sent the Commission a proposed  
15 rule on the national source tracking of sealed  
16 sources for Category 1 and Category 2, and we  
17 found that the proposed rule review of the  
18 proposed rule, as the Commission directed staff to  
19 provide a paper to the Commission regarding the  
20 tracking and providing enhanced control of those  
21 Category 2's.

22 The staff submitted a second paper,  
23 SECY-06-0094 in April, 2006, and in that SECY  
24 paper the staff presented actions to provide the  
25 enhanced controls of Category 3 sources. And the

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1 staff also recommended initiating rulemaking to  
2 amend general licenses in 10 CFR 31.5. This is  
3 something that Duncan touched on earlier, this  
4 registration requirement

5 And then 40.22, these are the source  
6 material general licenses, to limit the activity  
7 levels. And because these two categories of  
8 general licensees who possessed associates they  
9 are above Category 2 threshold.

10 In the paper, the staff also  
11 recognized that NRC does not have sufficient data  
12 to support tracking of sources that are for those  
13 with Category 2 threshold. So the staff  
14 recommended performing one-time data collection of  
15 Category 3.

16 The primary objective of collecting  
17 the Category 3 - the data collection, the primary  
18 objective of data collection will be to quantify  
19 the number of licensees, and the number of  
20 sources, and then also the number of conditions.  
21 And the data can also be used to determine the  
22 appropriate regulatory actions regarding extending  
23 the NSTS to below the Category 2 threshold.

24 And then also changing the GL  
25 regulations, the 40.22, and the 31.5 that I

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1 mentioned earlier.

2 In response to the SECY paper, the  
3 Commission approved performing a one-time data  
4 collection, and analysis of Category 3.5 sources.  
5 And this design was issued in June, 2006.

6 The Commission also approved amending  
7 the GL regulations, and associated manufacturing  
8 requirements.

9 So those are the directions from the  
10 Commission. And as I mentioned earlier, another  
11 part of this is the OAS petition. We received a  
12 petition from the Organization of Agreement States  
13 in 2005, for GL rulemaking, and on the 31.5, and  
14 then also mentioned 31.6. And then at the same  
15 time the State of Florida also sent in their  
16 request, wanting to change the compatibility. NRC  
17 evaluated the petition and make a decision this  
18 year, to the extent the NRC will address this  
19 issue and consider the petition by incorporating  
20 into the GL rulemaking.

21 So right now we have basically, as a  
22 result of the SI, we have two GL rulemaking  
23 efforts. One is under CFR 31.5. Generally it's -  
24 the general schedule is the - about - it takes  
25 about a year to complete a proposed rule. And

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1 after that it would take about one year after the  
2 proposed rule is published in the Federal Register  
3 notice, it would take about a year to finalize the  
4 rule.

5 And for the GL restriction rulemaking  
6 on the current schedule is, the proposed rule go  
7 to the Commission next September, and the final  
8 rule is September, 2009.

9 And for another rulemaking source  
10 material, GL rulemaking, that's what we call the  
11 proposed rule, is due to the Commission next  
12 December, December of 2008, and then the final  
13 rule will be December of 2009.

14 I'd like to briefly talk to you about  
15 the rulemaking steps. These are very general  
16 steps. Before we start a rulemaking, basically  
17 the staff would prepare the technical basis. But  
18 nowadays we kind of want to use another term, the  
19 rulemaking bases. The rulemaking bases basically  
20 are what address the - not only the technical  
21 issues, but the policy issue, the legal issues  
22 surrounding this rulemaking, what's the rationale,  
23 the policy rationale, the legal rationale, or the  
24 technical rationale for the rulemaking.

25 And that part will be documented

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1 before the initiation of rulemaking.

2 And then after we will form a working  
3 group, and then the working group will review the  
4 technical basis, and then will work on the draft  
5 proposed rule, and normally would include in our  
6 regulatory analysis, considering the cost and the  
7 benefit.

8 And then there is also 30 days, when  
9 the working group prepare a draft proposed rule,  
10 there is a 30-day Agreement State review of that  
11 draft proposed rule, in parallel with the NRC  
12 office concurring.

13 And after that the working group would  
14 work on the comment resolutions of any comments we  
15 see, and then the staff would prepare the proposed  
16 rule to the Commission.

17 And then after that we will publish  
18 the proposed rule for public comment.

19 And then there is a 75-day public  
20 comment period, and then after that the working  
21 group will work on the comment resolution on the  
22 comments we received from the public, and then  
23 also work on the draft final rule. And then the  
24 draft final rule again we share with Agreement  
25 States for 30-day review and comments. And then

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1 the working group will again work on the comment  
2 resolutions, and then the final rule to the  
3 Commission, and then publish the final rule.

4 So the whole process is from the  
5 proposed rule, and then finally the whole process  
6 normally takes about 2 years.

7 We currently already initiated the GL  
8 Revision Working Group. It was initiated about  
9 two months ago in September, so the working group  
10 started to work on this, and it's in a very early  
11 stage.

12 The working group consists of NRC  
13 Headquarters and the Regional staff, and we also  
14 have two OAS representatives in this working  
15 group.

16 And then we are going to form the  
17 other GL working group. We call it Source  
18 Material GL Working Group, and it's going to be  
19 formed December 2007, next month. And hopefully  
20 we can have a kick off meeting early next year.

21 That's the third thing that I'd like  
22 to talk about, just very briefly touch on the two  
23 GL rulemaking efforts that we are currently  
24 working on.

25 CHAIR HILL: Questions?

1 DISCUSSION AND DELIBERATION OF DISTRIBUTION AND  
2 GENERAL LICENSES

3 MEMBER RYAN: Yes, Kevin, could you go  
4 back to the slide that had the Category 3.5 on it?  
5 Maybe you can help me understand why 3.5? Why do  
6 we define a new category?

7 MR. HSUEH: Oh, I think that is defined  
8 by the Commission. I know that we do not have the  
9 basis on the Code of Conduct. We have basically  
10 one, two, three, four, five, and this is something  
11 that is based on the SRM, we have this 3.5, and  
12 that's one-tenth of Category 3.

13 MEMBER RYAN: What is the basis for  
14 that?

15 MR. HSUEH: I don't have the answer for  
16 you, but I can find out for you.

17 MR. HICKEY: John Hickey from the NRC  
18 staff. Category 4 is a factor of 100 lower than  
19 3, so the concern was aggregation. And Category 4  
20 was considered so small that it probably was  
21 better to create another tier between Category 3  
22 and 4, so there is some arbitrariness. But the  
23 basic issue is aggregation, that if you don't look  
24 at anything below Category 3, you are going to  
25 miss some aggregation potential of having several

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1 sources that could be combined to form a Category  
2 3 quantity.

3 MEMBER RYAN: I'm going to pick on this  
4 a little bit. Based on what evidence that there  
5 is aggregation? I mean this is all supposition.

6 MR. HICKEY: Well, in terms of somebody  
7 deliberately aggregating material for a terrorist  
8 purpose, it's based on supposition. But licensees  
9 have individual sources that are below Category 3  
10 which are kept in the same room which together  
11 form a Category 3 quantity, like they might have  
12 an americium source next to a cesium source.

13 So in terms of how the material is  
14 stored, it's factual; it's not suppositional.

15 MEMBER RYAN: I see. So it's based on  
16 the actual practice of storage?

17 MR. HICKEY: Yes.

18 MEMBER RYAN: Doesn't that put aside a  
19 step with the whole IAEA category system?

20 Yes, is the answer, but is that a  
21 problem?

22 (Laughter)

23 MR. HICKEY: I'll take it as a  
24 rhetorical question.

25 (Laughter)

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1           MEMBER RYAN: It's a little out of  
2 whack now. So you know we always get an answer  
3 about why we're out of whack. What benefit do we  
4 gain by having a Category 3.5?

5           MR. HICKEY: Well, the Commission  
6 stated that they recognized that, and some of the  
7 drawbacks to that. But the sources that raised  
8 the GAO concerns are Category 4 sources, and  
9 nevertheless, the concerns were raised.

10          MEMBER RYAN: Okay, thanks.

11          MR. HSUEH: Thank you, John.

12          MEMBER RYAN: Just as - I'm sorry, one  
13 more follow up. Do the Agreement States have the  
14 ability to not use Category 3.5? Can they just  
15 stick with the IAEA categorization?

16          MR. HICKEY: Well, the final decisions  
17 haven't been made on what role 3.5 is going to  
18 play, and part of the process will be to listen to  
19 comments from the States and the general public.

20          MEMBER RYAN: Okay, so that's still  
21 kind of an open question. Great, thank you.

22          CHAIR HILL: Any other questions?

23                   (No audible response)

24           I don't have any other questions  
25 either, Kevin, thank you.

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1 MEMBER RYAN: Thank you, Kevin.

2 MR. HSUEH: Thank you.

3 CHAIR HILL: Well, at this point we are  
4 a little ahead of our opportunity for a break.  
5 And immediately following what was the break was  
6 the opportunity for public participation.

7 So why don't we open the floor up for  
8 comments for public participation at this point.

9 Do we have any?

10 OPPORTUNITY FOR PUBLIC PARTICIPATION

11 MR. McCRAW: We lost one member of the  
12 public. He had to go away to another meeting.  
13 And I believe the other individual has stepped out  
14 for a telephone call.

15 Perhaps if we did go to break, and  
16 then come back and have an opportunity for public  
17 comment.

18 CHAIR HILL: Let's do that.

19 (Whereupon at 1:56 p.m. the  
20 proceedings in the above-  
21 entitled matter went off the  
22 record to return on the  
23 record at 2:15 p.m.)

24 CHAIR HILL: Well, it's quarter after.  
25 That was the appointed time for reconvening. And

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1 on the agenda is the opportunity for public  
2 participation, and it's my understanding that a  
3 member of the public participating today wishes  
4 just to observe.

5 So we appreciate his attendance and  
6 his observation.

7 OPEN TIME FOR WRITING AND DISCUSSING WORKPRODUCT

8 CHAIR HILL: I want to go back for  
9 just a minute and revisit, maybe flesh out just a  
10 little bit more, GL quarterly reporting.

11 I know from past experience that was -  
12 the paper reports came in quarterly, and it was a  
13 resource problem of keeping the information and  
14 the GL licensees current. Sometimes those reports  
15 just got filed after a cursory review, and that  
16 was it. And I know that a lot of the  
17 distributors, also included in those reports,  
18 gauges that had been returned to them just like  
19 it's supposed to occur.

20 But if you weren't keeping track by  
21 serial number or model number, then you didn't  
22 necessarily know how many gauges were out there in  
23 your jurisdiction. But with larger gauges, larger  
24 sources, I think Duncan said one to 30 or some  
25 curies, on some of those, why not at some point

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1 have real-time reporting, electronic reporting?

2 It may not be reporting of all the  
3 exit signs, but maybe larger GL sources, just have  
4 reporting as distributed. Yes, it's still  
5 resource - it could be resource intensive.  
6 Somebody has got to take those reports, look at  
7 them. But you could also end up with a quarterly  
8 paper if that's what's desired; I don't know.

9 So I wanted to get some thoughts or  
10 comments on that. Whether Duncan wants to or Aaron  
11 or Jim.

12 MR. McCRAW: I know to some degree what  
13 Kevin was talking about earlier with the  
14 rulemaking efforts, they are going to try to put a  
15 cap on - get some of these larger sources so they  
16 will be specifically licensed.

17 And I'm not sure what that threshold  
18 is. So that may take down a number of your  
19 concerns. There still may be a significant number  
20 of sources out there that still have significant  
21 quantities that would fall under this umbrella of  
22 what you're looking at.

23 MEMBER RYAN: Well, you know, specific  
24 and general licenses 40 years ago probably were so  
25 there wouldn't be so much paper floating back and

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1       forth. It's just hard to keep track of all the  
2       paper.

3                       So again I go to the fact that a bank  
4       makes a million transactions a second or an hour,  
5       or something outrageous. Why can't this be an  
6       automatic system that is really independent of  
7       quantity?

8                       I'm just throwing out a wild idea  
9       here. What makes us any different than a point of  
10      sale collection at McDonald's? I don't know if  
11      you know that, but when you swipe your card, or  
12      they swipe you in as a customer, how much you buy  
13      and what you buy goes to McDonald's Central and  
14      they know how many burgers they've sold every  
15      second. And they can do it by State or Region.

16                      So I'm not saying we need that level  
17      of complexity or power. But boy oh boy, keeping  
18      track of a few thousand items when they go to a  
19      certain place or are returned to the originator  
20      shouldn't be so tough electronically.

21                      MR. McCRAW: I am not sure if there is  
22      any plans in place to try to integrate Web-based  
23      Licensing, National Source Tracking System, and  
24      the GL Tracking System all in one so you would  
25      have this all-inclusive panorama -

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1           MEMBER RYAN: Yes, and if I've got a  
2 license for something at the NRC, why can't I just  
3 go and deal with my license independent of its  
4 category?

5           You're categorizing it for management  
6 purposes of people who are specialists in this  
7 area will deal with reactors, and people who deal  
8 with gauges are in this area and so forth. And  
9 that's all fine.

10           But for the user point of view, I've  
11 got a license and I have obligations under my  
12 license. I can go in electronically and read  
13 those obligations, and I want to hear from you  
14 electronically if you've got any questions.

15           And I don't know, I just think that -  
16 break the egg and make eggs. Go for it.

17           That may be a long way - a big reach,  
18 or that may take resources and time and a plan,  
19 but ultimately that's the way to do it.

20           MEMBER NERUD: You are exactly right,  
21 because that - that addresses several issues that  
22 are buried in the GAO reports and other documents  
23 of that type, in that you have a license, you're  
24 authorized to have this much material of this  
25 quantity; you need to report that you have that.

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1           And that way when you go to a new  
2 vendor to pick up more material, he can check.  
3 Have you exceeded what's on your license? If you  
4 have he can't make that sale.

5           MEMBER RYAN: That's what I'm thinking.  
6 I'll give you an example from my home state of  
7 South Carolina. We had just a ball-and-chain  
8 system for renewing your driver's license. And  
9 the Governor came in 6 years ago and said this is  
10 going to stop period. It's too cumbersome.

11           Well, now you can go online and you  
12 can renew your driver's license online three  
13 times; fourth time you have to go get an eye test.

14           They just decided - and if you are  
15 above a certain age you've got to do it, I think  
16 it's first 10 and then five, so they make sure  
17 you're still healthy and capable of physically to  
18 drive.

19           Piece of cake. You know? Zip, bing,  
20 boom, put in your credit card; your license is in  
21 the mail.

22           And it's got the picture on it, and  
23 it's got the IDs, and it's got all the security  
24 seals and everything else under the sun. And I  
25 can log in with my unique license number.

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1           And so far I've not heard anything, in  
2 terms of fraud or abuse or any real forgery or  
3 that kind of counterfeiting sort of issues that  
4 have come up. But boy it's a whole lot better  
5 than standing in line for 3 hours at a DMV office.

6           So I'm not saying that we've got some  
7 magic bullet answer, some panacea that would solve  
8 all problems. But the idea that agency - it's  
9 now ripe to explore a global licensing system that  
10 will deal with health and safety related  
11 categorization of sources, but treat all  
12 information gathering and information  
13 dissemination issues electronically, that's not a  
14 bad principle or at least example, I don't think.

15           Any of you guys think I'm nuts by  
16 saying that?

17           MR. WHITE: No, a couple of comments,  
18 to build on what Aaron said.

19           The goal with NSTS and Web-based  
20 Licensing is so that when a manufacturer can query  
21 us when someone wants to buy specifically licensed  
22 substance, get a license to authorize it, and the  
23 data would be in there and he could automatically  
24 check that.

25           One of the challenges, this may

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1 require us to change the way we do business with  
2 general licensees. There is no limit of what you  
3 can buy with GLs. You can buy as much as you  
4 want. If you want to spend the money you can buy  
5 it. There is no upper limit. You don't have a  
6 license.

7 MEMBER RYAN: So I can buy 4,000  
8 tritium light sources?

9 MR. WHITE: Absolutely.

10 MEMBER RYAN: And maybe that's one  
11 extra little safeguard to put in on those items.

12 MR. WHITE: The advantage of doing some  
13 sort of electronic system like that, you could see  
14 that someone is starting to accumulate all these  
15 exit signs.

16 MEMBER RYAN: Yes, right off the bat  
17 you could have a little tickler file that says,  
18 query the system every Monday. If somebody goes  
19 over X in this category, put it in bold red  
20 letters on my report.

21 Quite frankly you are going to get it  
22 a lot faster that way than if you have the scribes  
23 and the quills and pens method, and paper.

24 So that's a good thing actually. And  
25 by the way it does away with GL 3.5; we don't need

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1 it anymore, because you'll have direct reading  
2 information on all sources at the same speed.

3 Okay?

4 MR. McCRAW: I think one of the other  
5 unique challenges of that is going to be the fact  
6 that NRC does relinquish its authority in the  
7 States. And having that one-stop shop where  
8 everybody... You probably will have those States  
9 that have their "philosophical differences" that  
10 don't want to report to anything NRC; but for the  
11 most part I'm sure that it would actually benefit  
12 all the regulatory bodies to have that one system.

13 MEMBER RYAN: And in fact my view is  
14 the Agreement States would probably get on board  
15 with it, particularly if they didn't have to pay  
16 for it. That's the way to - you know anytime  
17 you're saving a Governor some budget money, you're  
18 his friend I think. I mean, maybe I'm  
19 oversimplifying. But you know access to an  
20 existing system that gives you the same quality  
21 and control for no extra cost is a real plus.

22 Okay?

23 CHAIR HILL: Good comments.

24 MEMBER RYAN: Do you need a little  
25 coffee in you?

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1 CHAIR HILL: You're getting enough  
2 caffeine in you to wake up.

3 We'll move to the next thing I had  
4 was, I understand that yesterday there was a  
5 question about specific licenses, specific license  
6 distribution, and Duncan has the answer for us.

7 MR. WHITE: The way NRC tracks the type  
8 of licenses that we have is, we have a program  
9 code, and that program code, there's about 100 of  
10 them, and they reflect the primary activity that  
11 the licensee does basically.

12 And we have approximately 4,400  
13 specific licenses in our jurisdiction. And as you  
14 know, overall you can add the 19,000 Agreement  
15 State licenses, whatever the number is. I don't  
16 have information on the Agreement States, but if  
17 you look at the information from our database,  
18 I'll give you all the information so you get the  
19 breakdown here, but just to give you a little  
20 flavor at the top five - I pulled the top five  
21 categories. And they interestingly represent 62  
22 percent of all our licenses, which is quite  
23 surprising. The largest group is portable gauges.  
24 We have almost 1,000 of those licenses.

25 We have 670 licenses involving medical

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1 private practice. Those would be people who do -  
2 doctors' offices or clinics that do small - use  
3 small quantities of diagnostic isotopes.

4 MR. MONTGOMERY: Say that again. So  
5 you have 1,000 gauges?

6 MR. WHITE: Close to 1,000 gauges.

7 MR. MONTGOMERY: Licensees.

8 MR. WHITE: Licensees.

9 MR. MONTGOMERY: Some licensees have  
10 numerous gauges.

11 MR. WHITE: They could have one, two,  
12 whatever.

13 The third largest category, over 410,  
14 is medical institutions that do some level of  
15 therapy. These would be classic hospitals.

16 And they would - again, they do  
17 therapy. And again this would generally be  
18 perceived as doing iodine therapy or something  
19 along those lines, the type of thing they would  
20 typically do.

21 The next category is fixed gauges,  
22 about 350. And there is about 300 small R&D  
23 facilities. That represents, those five  
24 categories represent 62 percent of all specific  
25 licensees in NRC's jurisdiction.

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1 CHAIR HILL: Sixty-two percent?

2 MR. WHITE: Sixty-two percent.

3 MEMBER RYAN: So I'm sorry, it's gauge  
4 licensees, and what was the second one?

5 MR. WHITE: Portable gauges, second one  
6 is medical private practice. The third one would  
7 be the hospitals. Fourth one would be fixed  
8 gauges. And then the fifth one would be small  
9 R&Ds.

10 And I'll leave with you a printout  
11 from our licensee tracking system. They queried  
12 it today.

13 And I also will leave with you a copy  
14 of Appendix G from NUREG-1556, Volume 20, and it  
15 has the detailed descriptions of each one of the  
16 program codes so you know what you are looking at.  
17 Otherwise you're just looking at a number here,  
18 and it's not very helpful.

19 CHAIR HILL: A clarification. I was  
20 making my notes, medical private practice, was  
21 that 650 or 750?

22 MR. WHITE: Six seventy.

23 CHAIR HILL: Six seventy?

24 MR. WHITE: 6-7-0.

25 MR. MONTGOMERY: Could I ask a

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1 question? Duncan, do you know how many general  
2 licensees are exclusively general? In other words  
3 they have no specific material. Has that ever  
4 been separated out?

5 MR. WHITE: I don't know the answer to  
6 that.

7 MR. MONTGOMERY: I was just wondering  
8 how difficult it would be to just put general -  
9 especially if you've got a mix, you've got a  
10 specific license, and they've got some general -  
11 put all the general, make sure all the generals  
12 get on the specific. Because you are going to  
13 inspect that facility anyway; you are going to be  
14 there. It's like resource wise it would not be a  
15 big deal to do that.

16 If you've got a huge number though of  
17 exclusively general, then trying to - that would  
18 be a different story. But I would - I was just  
19 curious about how many exclusively general we've  
20 got.

21 MR. WHITE: I don't know that. One of  
22 the interesting ideas I've heard being bandied  
23 around, if someone already has a specific license,  
24 and they get general license devices, they don't  
25 have a separate license now; they have a specific

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1 license. I mean that's one way to deal with the  
2 accountability issues. You have a specific  
3 license, then everything you get is specifically  
4 licensed, regardless of how it's distributed.  
5 It's one way of dealing with accountability.

6 MEMBER RYAN: You know that's not a bad  
7 thought, actually. I mean if you have a specific  
8 license what difference does it make? If I have  
9 100 curies of tritium gas in a cannister for an  
10 R&D activity, and I have 100 curies of tritium in  
11 exit signs, I have 200 curies of tritium and a  
12 license.

13 CHAIR HILL: It probably doesn't make  
14 any difference provided that you have that  
15 capability in your enabling legislation or your  
16 rules and regulations. And if you don't, then you  
17 probably are going to have an attorney somewhere  
18 that says, you can't do that.

19 But I like the idea too.

20 MEMBER RYAN: There is a big hurdle in  
21 all the regulations.

22 MR. WHITE: You would have to amend the  
23 regulations I would think to do that.

24 MEMBER RYAN: Because all the Agreement  
25 States would have to do it with compatibility over

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1 some period of time.

2 MR. WHITE: Some States would be very  
3 happy with that, because they already do it;  
4 they'd think it was a great idea.

5 And the other thing is, absent some  
6 sort of computerized system to track who has what  
7 general licenses, the other thing you can do is,  
8 again it would require regulatory changes, cap the  
9 number of general license devices you could have.  
10 If you go over that then you'd have to get a  
11 specific license. It's another - that's another  
12 option. There are different variations of that.  
13 You can do that, but again, people have to start -  
14 again, one of the concerns is, this came up in the  
15 GAO sting, was accumulation. Why we set the  
16 Category 3.5, you worry about accumulation.

17 Well, in general license space, you  
18 should deal with it there too, because there is no  
19 cap on what you can buy in the general license  
20 devices, where you could just accumulate as much  
21 as you want.

22 MEMBER RYAN: Well, here's a question  
23 for you. I don't think it's fair to say  
24 accumulation is the worry. That's not really the  
25 worry. There are lots of people who accumulate

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1 lots of material under general licenses.

2 What I think the worry is,  
3 accumulation of stuff where the accumulation stays  
4 below the radar screen. That's the problem. At  
5 least to me. Let me tell you why.

6 If I'm an irradiator, and I want to  
7 buy a million curies of cobalt-60, right off the  
8 bat I'm in all the spotlights of all the  
9 regulators, whether it's an Agreement State or the  
10 NRC. I'm going to put in a license application  
11 for a million curies of cobalt-60, and I'm an  
12 irradiator.

13 Guess what? I'm going to be invited  
14 up to Bethesda or the Regional office to come and  
15 give a presentation to staff on what your facility  
16 is going to look like. It's going to be a long  
17 process, where everybody is going to know  
18 everybody by the time you stop. And that's one  
19 you said is a two-step, there is instruction,  
20 authorization, very formal and thorough inspection  
21 process on it, after it's built, and I'm sure even  
22 testing with dummy sources, and all kinds of  
23 stuff. So all that gets done.

24 So accumulation in that world is not  
25 an issue. It's only accumulation where you don't

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1 have as much information about the accumulator or  
2 the accumulated quantity.

3 So if I solve the problem of knowing  
4 more about them, and having ready access to  
5 updated information on what they are accumulating,  
6 not only from the licensee but from those  
7 supplying the licensee so I can do a check and  
8 make sure the checkbook balances, haven't I solved  
9 the real issue which is knowledge of anybody that  
10 is accumulating?

11 MEMBER NERUD: That's a great point.

12 MEMBER RYAN: So this isn't a problem  
13 of how much; this is a problem of how much.

14 MR. WHITE: That's what it's all about.  
15 Because the person who is using it for legitimate  
16 purposes, fine. No problem. They have nothing to  
17 hide.

18 MEMBER RYAN: Yes, legitimate person  
19 and a legitimate purpose, it's over. So it's the  
20 veracity of the information you can gather about  
21 that activity.

22 So make it electronic, and make it  
23 happen concurrent with the sale. It's what  
24 McDonald's does. Every night at 5:00 o'clock they  
25 can tell you how many hamburgers they've sold in

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1 the last 24 hours worldwide.

2 Think about it.

3 CHAIR HILL: Point made.

4 MR. WHITE: Very good point.

5 CHAIR HILL: Well, that addresses our -

6 MR. WHITE: I will leave this data with  
7 you all.

8 MEMBER RYAN: Thank you, that's very  
9 helpful.

10 MR. WHITE: And as I recall from  
11 earlier discussions, I just wanted to make sure I  
12 got my list complete with that.

13 You are also interested in breakdowns  
14 of admin data in terms of events, in terms of lost  
15 and stolen materials over some period of time.

16 And you are also interested in data on  
17 the - database we have on Category 1 and 2  
18 sources.

19 MEMBER RYAN: And if there is anyway we  
20 could actually see it demonstrated? Because I  
21 think it's good to hear a briefing about it, but  
22 if we can actually see it work, and ask questions  
23 while it's being exercised, that's also very  
24 helpful.

25 MR. WHITE: As I said before, right now

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1 they are doing like an annual update from the  
2 States and to get - to keep it updated. But  
3 that's when we'll basically go live with NSTS, and  
4 that will be fed more real time.

5 MEMBER RYAN: Sure.

6 MR. WHITE: But I think just a few  
7 people who work in this building who do do that,  
8 and keep the - update the database already so they  
9 can demonstrate it for you.

10 CHAIR HILL: Well, at this point, Ben  
11 did some field trips since our last meeting, and  
12 this may be a good time, Ben, for you to update  
13 us.

14 MEMBER NERUD: All right.

15 CHAIR HILL: Give us information on  
16 what you learned.

17 MEMBER NERUD: First thing, we  
18 discussed this on our very first meeting. We had  
19 mentioned we needed to have a definition of  
20 vulnerability. And I think that's a very good  
21 point that needs to get brought out.

22 So when I went up and I started  
23 looking at this, my definition, the definition  
24 that I used in this, is vulnerability was a  
25 condition that if it existed would allow an

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1 adversary to acquire a quantity of radioactive  
2 material.

3           The caveat to that is, he's only  
4 exploiting this condition. There is nothing else  
5 associated with that that would allow him to do  
6 it. I can - here's the example. GAO got a  
7 license. Right. That did not get them a quantity  
8 of material. They exploited some procedural  
9 aspects of the licensing process to obtain a  
10 fraudulent license. They then went forward to a  
11 vendor to try to acquire that material. The  
12 vendor agreed, but they didn't actually get the  
13 material.

14           What I discovered is, using that  
15 definition for vulnerability, is that there really  
16 aren't any vulnerabilities in the licensing  
17 process. There are a lot of conditions that there  
18 are issues with. And what really became prominent  
19 in the whole 3 days that I worked with this is  
20 it's not just a licensing issue. It's a vendor  
21 issue; it's a materials accountability issue; it's  
22 a format issue; the simplicity and lack of  
23 controls on the actual printed license makes them  
24 easy to counterfeit.

25           So there is a lot of conditions that

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1 have to fall exactly into place in order for an  
2 adversary to obtain radioactive material. So that  
3 said, when I looked at the exploitable conditions,  
4 as I had mentioned before, I came up with  
5 basically seven conditions that I found up there,  
6 throughout the whole process: ease of access to  
7 the material; to the guidance and the processes  
8 that were in place. This is a very important  
9 consideration, considering that this was the  
10 primary reason GAO was able to obtain a license;  
11 they could get the information online. Not only  
12 did they get the information to complete a license  
13 application, they knew the requirements, they  
14 could develop their subsequent guidance for  
15 safety, for management, for the administration of  
16 the material; everything was available to them.

17 In addition to that they knew what  
18 actions the license reviewer was going to take,  
19 should any issues arise. And because they knew  
20 what those actions were, they could counter them.

21 They had the playbook. They knew what  
22 we were going to do before we even started.

23 So that said, and this does play into  
24 the good faith policy, and some other issues on  
25 there.

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1           My initial thoughts concerning the  
2 ease of access to this material is, it has to be  
3 available to the licensed applicants. We can't  
4 get away from that.

5           We don't need to make it quite so easy  
6 for the applicant to get. What I envision was a  
7 portal on the NRC license or the NRC website that  
8 you would have to log into. You would have to  
9 register to have access to that. And that would  
10 give you access to the guidance and the processes.  
11 This is not going to stop a determined adversary.  
12 What it is is a speed bump in the road. It is  
13 going to give them pause before they start  
14 registering on a government system to get access  
15 to this information.

16           The other part of it is, and I'm still  
17 trying to work my way through this portion, is the  
18 NRC operations security process. License  
19 applicants need to know what to submit. They  
20 need example guidance. They need example formats.  
21 They need that information so they submit a  
22 reasonably complete license application for  
23 examiners to review.

24           They don't need to know the steps that  
25 the reviewer is going to take when we submit

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1 discrepancy notices, I forget what they were -

2 MR. McCRAW: Deficiency letters.

3 MEMBER NERUD: Deficiency letters, the  
4 process to resolve those deficiencies that can be  
5 identified, if it can be done over the phone, if  
6 it can be done by agreeing to accomplish what it  
7 is, all very handy information for an adversary if  
8 he realizes, all I have to do is agree to  
9 accomplish this. I don't actually have to produce  
10 anything.

11 Now that policy can still exist, but  
12 it doesn't have to be out there for the adversary.

13 In an operational security program,  
14 they're called essential elements of friendly  
15 information. And that is information that you  
16 need to know but you don't necessarily want your  
17 adversary to have access to.

18 And what it does is, it provides a  
19 layer of confusion to him. He doesn't understand  
20 where the process is going completely. He's got  
21 his part; you've got your part; and it's going to  
22 even out at the end. If he doesn't understand  
23 that middle section, there is a discrepancy or a  
24 deficiency letter goes out, again it gives him  
25 pause to his whole process, and may cause them to,

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1 like GAO did with Maryland, pull out.

2 So I think that it's fairly important  
3 that we think about integrating operational  
4 security, website security, validating what really  
5 needs to be out there on the website for the  
6 applicants to obtain.

7 MEMBER RYAN: You know it's  
8 interesting, the Maryland example, because they  
9 were, as I understand reading the document if I  
10 read it right, they were shut down just right out  
11 of the box. What is your address? We are going  
12 to come see you.

13 So that was step one.

14 MR. WHITE: Not exactly.

15 MEMBER RYAN: No?

16 MR. WHITE: They started into the  
17 process, and it became pretty quickly apparent  
18 that they reviewed the steps to get the license,  
19 and the reviewer indicated one part of the process  
20 is we come out and visit you. So that's when they  
21 turned it off.

22 MEMBER RYAN: So the minute they heard  
23 the word, we want to put an eyeball on you, it was  
24 over.

25 MR. WHITE: That's when they pulled,

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1 yes.

2 MEMBER RYAN: We're not ready yet; see  
3 you later, whatever they said, and that was the  
4 end of it.

5 So how does that fact - and the reason  
6 I'm bringing that up is, how does that fact enter  
7 your security thinking? I mean to me if that -  
8 that sort of gets you on track with who are these  
9 people and where are they located and are they  
10 legitimate?

11 MEMBER NERUD: Exactly, and that is  
12 another issue that I am going to bring up.

13 We can do it now.

14 MEMBER RYAN: No, no, I don't want to  
15 get you out of order. If you are going to cover  
16 it, that's fine.

17 MEMBER NERUD: Well, there is no  
18 particular order here other than my notes.

19 (Laughter)

20 But that's just to keep me on track.

21 The inspection process: I think that  
22 the inspection process is vital, a vital component  
23 to the entire licensing process. We should within  
24 reason, and this is where the risk decision models  
25 that we use come into play, visit all new license

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1 applicants before we actually grant a license.

2 When I saw new, we need to quantify  
3 new. And new means, they don't have a license,  
4 with NRC, with an Agreement State, with anybody  
5 else. We don't do this for amendments; they're a  
6 known, trusted, vetted, organization. If it's a  
7 new license, but they have, they already have -  
8 the Army, for example, all right. The Army has a  
9 license; if they go get a new license, we don't  
10 need to go visit the Army again. They are a known  
11 trusted entity.

12 With this inspection process, before  
13 we go out, those people we've never heard of  
14 before; we don't know who they are. Maybe they're  
15 a new organization broken off from another group;  
16 fine, you're new. We'll come out and visit you.

17 I don't think, and just from the data  
18 that I got from Region I, I don't think we're  
19 talking about thousands of applicants in that  
20 regard. We are talking about a few hundred maybe,  
21 if that. And that is for NRC total.

22 MR. WHITE: that's correct.

23 MEMBER NERUD: So I think we've  
24 achieved a reasonable level of risk reduction at a  
25 reasonable cost to accomplish that. We don't need

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1 a lot of extra resources to do that. We go out,  
2 we visit, we do what we need to do.

3 And like I say, I think the inspection  
4 process needs to be integrated completely into the  
5 licensing realm.

6 MEMBER RYAN: And you also said the  
7 risk element. We talked a lot about, you know,  
8 where should a cut be? I mean obviously you are  
9 not going to go down for a trivial small source to  
10 every new applicant.

11 MEMBER NERUD: No.

12 MEMBER RYAN: And we haven't really  
13 tried to put a mark in the map where that is yet.  
14 But we think there ought to be some consideration  
15 of it.

16 MEMBER NERUD: There has to be a risk  
17 threshold. And that was another part of the GAO  
18 report where they said, we could obtain, we could  
19 stockpile over a course of months, years, decades,  
20 enough material to build a dirty bomb.

21 Again, going back to my definition of  
22 vulnerability, you are assuming that a lot of  
23 things are going to fall into place for you to  
24 accomplish that. So - well, there is that aspect,  
25 and then if we recommended something like this

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1 other licensing scheme that is online and up to  
2 date, it sort of takes a little wind out of the  
3 sails of surreptitious accumulation.

4 Takes a lot of wind out of it, which  
5 is a great segue for the other report, which is  
6 this Web-based Licensing program. And I talked a  
7 little bit about that this morning. Absolutely  
8 must do that. In the full scope of work that was  
9 originally identified, it's going to force a  
10 national tracking system, or the material tracking  
11 system; it's going to force the licensing; it's  
12 going to force the vendors; it's going to force  
13 everybody who has a role in the security of  
14 nuclear or radioactive material to play a role in  
15 making sure that an adversary doesn't get hold of  
16 it. Putting the onus on protecting the Nation  
17 just on the license reviewer, you are only  
18 achieving a tenth of it.

19 And you know they have control of 10  
20 percent of this whole process; 90 percent is a lot  
21 of other people. You need to bring all those  
22 other people in together and have a consolidated  
23 system. And the way to do that, the way that the  
24 Web-based Licensing program was described, with  
25 the ability for vendors to check, for it to

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1 interact with tracking sources to ensure that  
2 individuals didn't get more than what they were  
3 authorized, it just makes way too much sense.

4 It is the system that would resolve  
5 many of the issues that we are struggling with  
6 right now. Falsification of licenses, illegal or  
7 illicit falsification of license quantities of  
8 material, type of thing, all eliminated going to  
9 this system.

10 Going to be expensive, but the benefit  
11 of having that system online and in use, for  
12 everybody, and this includes the Agreement States,  
13 all right. Now maybe the Agreement States don't  
14 process licenses using this, but there is an end  
15 result to their licensing process that needs to  
16 get integrated into this national system.

17 MR. WHITE: Just to comment on that, I  
18 think Agreement State participation is vital  
19 because of, manufacturers are located in the  
20 Agreement States, and it's just the - commerce is  
21 done in this country. It's done widely across  
22 State lines, it's done internationally. You need  
23 everyone to buy in. It's the only way this will  
24 ever work.

25 MEMBER RYAN: And then it's a national

1 database; it's not the NRC's; it's not the  
2 Agreement States; it's the national database;  
3 that's the whole point.

4 MEMBER NERUD: That's the whole point.  
5 And the Constitution of the United States says the  
6 Federal Government is responsible for interstate  
7 commerce.

8 MR. WHITE: And national security and  
9 defense.

10 MEMBER NERUD: That's what this falls  
11 into. And it's - when I saw the system, and they  
12 described what it was to me, I realized that it  
13 was coming up real close to this is the answer,  
14 and a good system, a good process, good faith  
15 policy.

16 My background, I am obviously very  
17 averse to it; sorry.

18 MEMBER RYAN: If I point a gun at you  
19 it's hard to -

20 MEMBER NERUD: Exactly. Exactly. I  
21 see it's place. I see it's role within NRC. The  
22 issue that I have with it, and this was a comment  
23 that was made several times in the - during my  
24 visits, was, we have to review licenses within the  
25 guidance.

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1           And what that lends itself to is, the  
2 guidance says this. Good faith says that if you  
3 are adhering to the guidance you get a license.

4           Problem comes in, just like with GAO  
5 and these other things is, there are bad people  
6 out there who can read and who can submit what  
7 we've got. As Michelle had stated earlier and Jim  
8 had confirmed, there is a 90-day policy for  
9 completing the licenses. Well, that compounds  
10 this problem, because now rather than going in and  
11 really doing an in depth search when you have  
12 something that is suspicious, well, I've got 90  
13 days. It's a hunch. They still adhere to the  
14 guidance. It's still what's in the book. It's  
15 exactly right. I just don't feel right about it.  
16 But I've only got 90 days; I'm going to let it go  
17 through. And there is nothing wrong with that.  
18 They adhered to the guidance.

19           But the good faith policy can  
20 exacerbate some of the deficiencies in the license  
21 review.

22           Now what I would like to recommend is  
23 as some mentioned earlier, indicators of potential  
24 discrepancies within the licensing process.

25           I reviewed the GAO report. It

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1 provided a real good example of what I'm talking  
2 about with indicators. I reviewed their license  
3 application, I'm sorry. What it said in the  
4 application, there were about three or four points  
5 in there that in and of themselves don't seem to  
6 be anything, but indicated to me that there was  
7 something off about this process.

8 The first one was, the mailing address  
9 was a P.O. box. The corporate office was a  
10 physical location, and the - in West Virginia -  
11 and the device was being used in Delaware. All  
12 right?

13 Three different locations. Well,  
14 shouldn't the mailing address really be the  
15 corporate office, and not a P.O. box?

16 MEMBER RYAN: Is the P.O. box in a  
17 different state?

18 MR. WHITE: It's a suite. It's a  
19 suite. The actual location of it, they went and  
20 checked, was a P.O. box. They listed it on the  
21 application as suite -

22 MEMBER NERUD: The suite was, the  
23 mailing address had a P.O. box. So that was the  
24 first thing, why aren't these the same? Why  
25 aren't you sending something to them?

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1           Now as I found out that's fairly  
2 common. Hospitals have a P.O. box or some of  
3 these other things. So it was fairly common.

4           But it was an indicator. It was  
5 something that struck me as odd in the process.

6           The next one was the radiation safety  
7 officer was also the vice president for field  
8 operations I believe was his official title.

9           What struck me there was, normally  
10 vice presidents of operations are salesmen, they  
11 are trying to get more business. Why would you  
12 take someone in that capacity as a ranking member  
13 of a company and make him your radiation safety  
14 officer?

15           MEMBER RYAN: It also has an inherent  
16 problem in the operations and how physics are  
17 typically reported, separately in the  
18 organization. You know you have an executive  
19 branch to which compliance functions are brought,  
20 like industrial safety, health physics, or  
21 whatever, and operations which is, you know,  
22 interested in making money is always kind of an  
23 organizational structure, where there is a check  
24 and a balance on those two.

25           That would have risen a flag for me.

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1 MEMBER NERUD: The next one-

2 MR. WHITE: Can I comment on that,  
3 having reviewed a number of licenses. I'm sure  
4 Jim's been down the same road too. It's  
5 particularly in small companies of only a few  
6 people you might have a radiation safety officer  
7 be even the president of a company; be also an  
8 officer of a company.

9 MEMBER RYAN: President I can  
10 understand. But having the operations guy and the  
11 health physics guy reporting, that's common in  
12 small companies?

13 MR. MONTGOMERY: It is. And sometimes  
14 the company consists of one person. The guy-the  
15 example I gave up in Alaska. One man, had his own  
16 business, a civil engineer. He was the president,  
17 owner, RSO.

18 MEMBER NERUD: And I understand those  
19 things. And what I'm doing here is obviously  
20 Monday morning quarterbacking. But these were  
21 things that struck me as odd in this application.

22 Nothing I've mentioned so far is  
23 counter to the guidance in the process, or in the  
24 1556. But like I say these were indicators.

25 The other indicator that I saw was

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1 approximately 2 months before they applied for the  
2 license to get these portable gauges, they went  
3 through the 5-6 week radiation safety officer  
4 course.

5 MR. WHITE: That was a 1-week course.

6 MEMBER NERUD: One-week course?

7 MR. WHITE: It was 40 hours, I think,  
8 or -

9 MEMBER NERUD: Okay, I didn't pay that  
10 much attention to the certificate other than the  
11 date of completion.

12 Here is my thought process on that:  
13 This is a new direction for a company. They are  
14 now getting into radioactive material; they are  
15 using portable gauges, et cetera. A lot of new  
16 requirements come with that.

17 Why would a new company hire someone,  
18 send them to a 1-week course, and hope they  
19 achieve all the requirements of that NUREG,  
20 considering there are so many people out there, as  
21 I've learned over the last month, that have this  
22 expertise, that have this experience? Why  
23 wouldn't you go out and hire somebody to be able  
24 to accomplish that?

25 Again, it was just an indicator.

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1                   MR.    WHITE:    In   portable   gauge  
2   licensing, it is extremely common to take one of  
3   your employees who has been using the gauge just  
4   as a user, sending him to a 1 day -    1 day -  
5   radiation safety officer training given by the  
6   manufacturer, and designate him as the RSO on the  
7   license. That is - that is so common you won't  
8   believe it.

9                   MEMBER NERUD: And I understand that we  
10   are talking common. Again what my point is, these  
11   things were indicators to me that something needed  
12   to be reviewed a little bit further on this.

13                   The last one, which goes back to the  
14   security and safety and health requirements that  
15   are in the guidance, and the good faith policy.  
16   We have created models in the guidance that say,  
17   adhere to this model and you are good. Here's  
18   your contingency plan, here is your response plan;  
19   conform to these things.

20                   When I looked at this application and  
21   I read their contingency plans, word for word out  
22   of the NUREG-1556; word for word. Cut, paste.

23                   Even in instances where there should  
24   be some localization, some degree of specificity  
25   on how they are going to accomplish it.

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1           When you put all those things together  
2           it gave me that gut feeling that something just  
3           isn't right. And it should be looked at a little  
4           bit more in depth, rather than accepting it on  
5           that good faith principle. You adhere to the  
6           guidance, but there's a bunch of these other  
7           indicators that are in that process.

8           It goes back to some of the comments  
9           we had - you had made earlier, and Michelle and  
10          those things, when these types of things come up,  
11          it needs to get validated. And it can't be  
12          validated by the license reviewer. They're  
13          focused on health and safety.

14          It needs to go to someone who has the  
15          capability to check, not to do a website search,  
16          to do an IRS search, to do a Dtate tax search, to  
17          look into and call business contacts, check  
18          references, who are your customers, I'm going to  
19          talk to your customers, did they provide this  
20          service.

21          Yes, it's a little bit more in depth.  
22          But again that would virtually ensure that we're  
23          not giving a license to someone who doesn't need  
24          the license.

25          Developing the list of indicators is

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1 what's key in that regard. These are things to  
2 look for, and then give the license reviewer the  
3 benefit of the doubt when they see it.

4 I don't like this. I want to turn it  
5 over. Great; it gets turned over. That 90-day  
6 process stops at that point. That check is not  
7 part of the - if it gets turned over there, the  
8 license reviewer sends the applicant a letter  
9 saying your application has been turned over to  
10 Office of Investigations for further  
11 investigation, processing, whatever, they will be  
12 in touch. And until such time your license  
13 activity is being delayed.

14 A legitimate applicant is going to  
15 come down to your office and say, what do you  
16 need? What do you want me to do? The other type  
17 of applicant, the adversarial applicant, they're  
18 not. They're going to call you up and say, we  
19 don't want the license. We don't need the license  
20 anymore, whatever, we stopped.

21 Well, at that point we now have an  
22 idea that this guy may not be a good idea. And  
23 his name should go out to Agreement States, those  
24 types of things, so they can be on the lookout for  
25 it. It's a push-pull system of sharing of

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1 information on this, so that you know I didn't get  
2 it in Maryland, I'm going to try for the NRC. If  
3 I didn't get it from the NRC, I'm going to try  
4 from Wisconsin. I'm going to try from Puerto  
5 Rico. I'm going to try somewhere else until I get  
6 what I want.

7 Well, a nice list of indicators, and  
8 you do have an intelligence organization in here  
9 that would be suited to tracking that type of  
10 data.

11 The - going back to the good faith  
12 portion of this, as the process goes through its  
13 machinations to completion, accepting an  
14 organization's word on how something would be  
15 done. Yes, we'll comply. Great, we'll check it  
16 when we do the inspection.

17 It goes hand in hand with the health  
18 and safety requirements that are in the NUREG. We  
19 have models in there for a reason. We want people  
20 to do certain things when something bad happens.

21 Localizing - adding that degree of  
22 specificity. This is what we're going to do; this  
23 is who we're going to call; this is how quickly  
24 we're going to call them. This is how we're going  
25 to set up our hot zone, warm zone, cold zones.

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1 This is how we're going to do this I think is  
2 critical not only for security but for health and  
3 safety.

4 And by requiring an organization to  
5 actually produce valid documents like that, not  
6 word for word cut and pasted out of the NUREG,  
7 would go a long way in determining just how valid  
8 is this RSO. How valid is the company? It would  
9 require a terrorist organization to specifically  
10 hire a guy from Pakistan to come in and write  
11 that. Whereas a legitimate company would hire a  
12 contractor. They're already paying them for the  
13 application in most cases, from what I hear, to  
14 actually write bonafide regs that they are going  
15 to follow.

16 It would give the inspector something  
17 to assess when they go and do their inspections.  
18 Can you do this rather than you agreed to do this.  
19 I think it would go a long way to even improving  
20 the health and safety aspect of it.

21 The license itself I saw that, I  
22 understand that they are looking into security  
23 papers and those types of things. It is very  
24 simple. It is easy to modify. You can find it on  
25 the web. You can do a lot of things with that.

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1           Faxed copies of this - I understand we  
2           need to do business. People need to do business.  
3           And if the web-based licensing doesn't happen or  
4           isn't going to happen for a period of time, the  
5           license application, or the license itself should  
6           change. And if that means that the applicant says  
7           I want four portable gauges, I'm going to purchase  
8           them all from this guy, fine. We will give you  
9           two copies of their license, two originals. You  
10          get to send that one original to this other guy to  
11          get your license. And tell all vendors you will  
12          only accept original licenses.

13                 MEMBER RYAN: Well, that's the pencil  
14                 and paper method. But you could actually do it  
15                 electronically.

16                 MEMBER NERUD: You could do it  
17                 electronically. There's a lot of things that you  
18                 can do. The web-based licensing really  
19                 accomplishes a lot of that.

20                 The last thing that I wanted to  
21                 mention was on the actual inspection of the sites,  
22                 we went and saw a licensee. They had portable  
23                 gauges, which was great; I actually got to see  
24                 one. I touched the rod; I was worried that my  
25                 skin would melt. Apparently they are not that

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1 bad.

2 But I saw their security requirements  
3 and what there was protecting these gauges. I've  
4 read the new requirements that NRC has published,  
5 you know, double locks, doors, secure the  
6 containers, those types of things.

7 I was not impressed with the security  
8 at all. That's my business; that's my profession.  
9 There was a crowbar right there. Grab the crowbar  
10 and in five seconds, I'm through the first door.  
11 Because it's wood with a wood jamb. There is  
12 nothing there.

13 The next door, which was a steel door  
14 on a steel jamb with a handle lock, again, the  
15 same crowbar that I've picked up and in 10  
16 seconds, I've moved the jam far enough to enter  
17 inside.

18 The total time to access that  
19 illegally would probably be less than two minutes  
20 with material that I found right there.

21 Adding a security specialist - and I  
22 know there are many security specialists out in  
23 the Region, somebody who actually does security -  
24 to the inspection process, can take a look at just  
25 how much security is really provided there.

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1                   At this licensee that we saw, all that  
2 needed to be done was an additional dead bolt with  
3 an extended throw on that steel door. It's  
4 secure. You're not getting into it. Total cost:  
5 \$40.

6                   I don't expect the license reviewer  
7 and inspector who's out there for health and  
8 safety to know these things. It's not their job.

9                   Adding the security element to it is I  
10 think important when you're looking at an  
11 adversary getting these materials. Because not  
12 only could they exploit our licensing process,  
13 they could steal it from delivery vehicles. They  
14 could do these other things.

15                   They could also go to a licensee, find  
16 out who they are, break in, and steal the  
17 material.

18                   Adequate security does not have to be  
19 expensive. Like I said, in this one place it was  
20 a \$40 dead bolt, and they're good. They're gold.  
21 No alarms; nothing else.

22                   A security specialist would be able to  
23 identify that.

24                   So I think that that should be  
25 something that we consider not as part of the

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1 initial inspection process, the initial visit  
2 where you are validating the applicant. But on  
3 the followup, especially with those organizations  
4 that have a quantity of material that we would be  
5 concerned with.

6 And it all boils down to my last point  
7 which is, a risk management model for safety and  
8 security of basically the country against the  
9 illegal use of radioactive material.

10 We have a risk management - or a risk  
11 model for the licensing process in determining  
12 safety and health and those types of things. And  
13 this quantity requires this type of license  
14 requires this type of review requires these steps  
15 be gone through. We have that; we have 20 NUREGs  
16 for different categories of material.

17 We can take that same process, modify  
18 it so it becomes applicable to not only the  
19 licensing process but the inspection process, the  
20 pre-visit process, the monitoring, the reporting  
21 of materials. You can have that type of model go  
22 in there so we can achieve an acceptable level of  
23 risk at an acceptable cost.

24 And that's the key point: we are not  
25 going to eliminate RDDs from the terrorist

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1 repertoire of weapons. They can go to Mexico,  
2 they can go to Brazil, they can go to Canada, they  
3 can go to Germany, Russia, get any type, quantity  
4 of material they want to and smuggle it into the  
5 United States. It's possible, plausible. How  
6 feasible is it? Don't know.

7 But we're not going to eliminate the  
8 RDD from their repertoire. What we can do is we  
9 can eliminate us from being part of that supply  
10 process. Acceptable level of risk at an  
11 acceptable cost.

12 None of the things that I've really  
13 discussed here with the discussion of the web-  
14 based licensing really costs any money. It's an  
15 investment of time by the risk skillset of people.  
16 Indicators need to come from the intelligence  
17 folks. Security needs to come from security  
18 folks. Reviewing the guides for operational  
19 security issues and central elements of  
20 information, that's got to come from the license  
21 reviewers, that panel that you had discussed, Jim,  
22 of who are the experts. This is information I  
23 need. The applicant does not need this.

24 Keep them together. Redact what you  
25 need to so that you aren't operating as you were

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1 years ago from two different sets of manuals that  
2 may not coincide with each other.

3 I think this is all feasible. I think  
4 this can be done fairly quickly. I don't think it  
5 requires a lot of rulemaking and that process. I  
6 made the comment, in DOD we just give an order.  
7 It seems to be - work fine there.

8 So putting these things in place, I  
9 don't know as they require a rule as much as they  
10 require a paradigm shift of understanding the  
11 world and the world situation in this regard has  
12 changed for NRC. Not only because of 9/11, but  
13 primarily because of the GAO report. And adapting  
14 our processes to reflect that would go a long way  
15 into preventing the next GAO sting operation.

16 Not talking about millions of dollars,  
17 thousands of hours of effort, radical changes.  
18 Shift the paradigm. Make people review the  
19 criteria from a slightly different perspective.  
20 Indicators, and give - this is an important point  
21 - I spoke with at least three license reviewers in  
22 Region I. Every single one of them wanted to do  
23 the right thing. All right?

24 When I do vulnerability assessments,  
25 you can generally count on there being one person

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1 who really doesn't care, and doesn't want to do  
2 it. Didn't find that at Region I. They genuinely  
3 cared. They wanted to do what's right. They  
4 needed to do what's right. They didn't know - and  
5 I'm saying this very simplistically - they didn't  
6 know how to do what's right, because they were  
7 restricted by the guidance.

8           And like I said, that's a very simple  
9 way of putting it. It's not to say they don't  
10 understand they can go to their supervisors and  
11 those kinds of things. They wanted to make  
12 changes. They wanted to do what's right to keep  
13 the Nation safe and stop this.

14           How that gets accomplished, they  
15 didn't have that clear path, that paradigm shift  
16 to allow them to do it.

17           And I think that's one of the big  
18 things that this panel can bring is, as I said, I  
19 didn't find vulnerabilities. I didn't find that  
20 single thing that allowed them to get and use  
21 radioactive material against a target.

22           So I think that the GAO report was a  
23 little enthusiastic in that regard in labeling  
24 them vulnerabilities. What I did find was things  
25 that concerned me. I think they are fairly easily

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1 correctable. And I think the license reviewers,  
2 at least the ones I talked to, are ready to make  
3 that change. They just need to get pointed in the  
4 direction, and they are off and running.

5 That's what I found. Did I miss  
6 anything here?

7 MR. McCRAW: No, I think that was a  
8 very accurate account.

9 CHAIR HILL: So you found no  
10 vulnerabilities in the licensing process, but  
11 problems in the business process; is that a -

12 MEMBER NERUD: Problems in the business  
13 practices?

14 CHAIR HILL: Or concerns, maybe.

15 MEMBER NERUD: Concerns.

16 CHAIR HILL: Concerns.

17 MEMBER NERUD: Concerns in the business  
18 practices, how we conduct business is what I  
19 really saw. I think that the NUREG guidance suits  
20 exactly what it was intended for, which is health,  
21 safety, and administrative requirements to obtain  
22 radioactive material. There isn't a single guide  
23 that I've read that discusses identifying a  
24 terrorist and preventing them from getting  
25 radioactive material.

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1                   MEMBER RYAN: One thing to think about,  
2                   though, is we're talking about basically source  
3                   applications, because that's what GAO applied for,  
4                   sealed sources.

5                   And I fully appreciate, Ben, what you  
6                   are talking about. It's not just health, safety  
7                   and environment which you have to add too. But  
8                   health, safety, and environment, and now you are  
9                   adding this dimension of security and safeguards.

10                  And I guess my thought is that in  
11                  certain licenses those are all on the plate:  
12                  reactors, health, safety, environment, security  
13                  and safeguards. It's all one line. And I guess  
14                  it's a rhetorical question at this point. But  
15                  reactors address this duplicate, triplicate and  
16                  quadruplicate, both in terms of the operations  
17                  staff, and their qualifications, training, and  
18                  pedigree in terms of drug testing, and all kinds  
19                  of stuff that goes on at a power plant to address  
20                  the quality of the people as well as everything  
21                  else that's involved in very substantial security  
22                  staff, trained and armed, and all sorts of stuff,  
23                  probably, I don't even have a clue about half of  
24                  what it's about.

25                  So that's a very robust system in this

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1 whole area of safety and security.

2           You know there are smaller facilities  
3 that I know a little bit about, a waste site that  
4 has 24-hour security guards because of the nature  
5 of its operation. So there were elements of  
6 health, safety, environment, security, and  
7 safeguards. Very large quantities of irradiated  
8 hardware, for examples, tens of thousands of  
9 curies of cobalt and everything else to irradiate  
10 hardware.

11           So I think as you come from the  
12 reactor facility down the chain a ways, it seems  
13 as if we've gotten to the point were at the  
14 smaller sources or the discrete sources, or the  
15 gauges and instruments and articles and items, the  
16 security and safeguards point is not as forcibly  
17 made as it is.

18           So there is to my way of thinking  
19 there is some infrastructure within the agency  
20 that deals with these issues that you've heard a  
21 little bit about. And I just wonder if we're kind  
22 of getting toward a recommendation. Maybe a  
23 second one should be taken on what level of  
24 security and safeguards needs to be plugged in as  
25 a complement to the licensing process.

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1                   It already exists.

2                   MEMBER NERUD: I agree, but it needs to  
3           be done from a risk management standpoint,  
4           acceptable risk at an acceptable cost.

5                   MEMBER RYAN: Absolutely.

6                   MEMBER NERUD: We don't want a guy with  
7           portable gauges running around with 24-hour  
8           security.

9                   MEMBER RYAN: No, no, absolutely.  
10           That's exactly the point to make, the risk and the  
11           response to that risk ought to be matched in an  
12           appropriate way based on appropriate measures, and  
13           maybe that's what we ought to talk about.

14                   I agree with your comment, coming from  
15           your observations, that if you take care of the up  
16           front licensing process in a more automatic and  
17           controlled way, so that access is controlled and  
18           all those things, a lot of that stuff kind of gets  
19           looked at right off the bat.

20                   MR. MONTGOMERY: Well, you're also  
21           talking about, and I think it's really important  
22           to distinguish here between overt attempts to  
23           obtain material and covert attempts. Overt  
24           attempts, I mean you know, if you have a  
25           determined force of individuals willing to

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1 sacrifice their lives, and particularly if you  
2 have an insider involved as well, there is  
3 probably nothing that they can't get hold of  
4 certainly in the materials license world.

5 I mean they've worried about this for  
6 decades in nuclear power plants and fuel  
7 facilities and weapons facilities, is that kind of  
8 scenario.

9 But the covert attempt is I guess  
10 where so much focus has been applied recently  
11 because of the GAO thing. And I feel like, and I  
12 keep hearing people use the term, referring to new  
13 licenses that we don't know, that we've got to  
14 watch for.

15 And I've got a real concern about even  
16 license amendments that could be fraudulently  
17 submitted on a licensee's letterhead, with ESO  
18 signature forged, with requesting a change of  
19 address.

20 MEMBER RYAN: Real simple.

21 MR. MONTGOMERY: Yes real simple.  
22 Change my address; I'm moving. These are routine  
23 amendments we get all the time.

24 And I'm thinking, what is to prevent a  
25 change of address on a license, gets approved,

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1 gets mailed out. We don't - this is something  
2 we're not - we know this guy. We know this  
3 licensee.

4 MEMBER NERUD: Well, the comment that I  
5 would make to that is, that's exactly the paradigm  
6 shift that I'm talking about, is, I don't know how  
7 you looked at that particular process before  
8 today. But I hope your opinion of it changed just  
9 a little bit after today. You know, hey, maybe  
10 that is something that is suspicious there.

11 And that's the paradigm shift that I'm  
12 talking about. That is where the license reviewer  
13 comes into play. A guy gets an amendment. He's  
14 changing his address. Wait a minute; he hasn't  
15 changed his address in 20 years. What makes him  
16 do it now? Let me give him a call. Why are you  
17 moving? I'm not. What happened to this  
18 amendment?

19 And again those are those indicators  
20 that I'm talking about. And it's a paradigm shift  
21 for the license reviewer, when he's looking at his  
22 licenses. No longer, does this comply to the  
23 guidance, but is there something funny about it.  
24 You're still reviewing it in accordance with the  
25 guidance, but you are shifting your look a little

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1 bit less from good faith to a little bit more of  
2 verify, then I'll make sure - then I'll provide  
3 good faith.

4 MEMBER RYAN: And if that request came  
5 in on an electronic system that was secure and  
6 password protected, you'd probably automatically  
7 have a little higher confidence than if it showed  
8 up on letterhead -

9 MEMBER NERUD: Exactly; that's the  
10 point.

11 MEMBER RYAN: So I keep coming back to  
12 between, well, let's think of this going wrong,  
13 well, if it was an electronic database that was  
14 secure and password protected, you know, a lot of  
15 stuff goes off the radar screen when you think  
16 about that.

17 MEMBER NERUD: Falls away.

18 MEMBER RYAN: And I know that could be  
19 a challenging effort to put into place over some  
20 period of time. But boy, that makes it 21<sup>st</sup>  
21 century, too, instead of paper and faxes and  
22 stamps and envelopes and stuff.

23 MEMBER NERUD: And it brings all the  
24 players into it, the suppliers, the transport  
25 people, the tracking people, everybody is now

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1 involved in this in a concerted effort to keep  
2 this material out of the hands of an adversary.

3 MR. MONTGOMERY: Your comment about the  
4 90-day process, deadline, possibly being a problem  
5 if a reviewer feels pressured to move through and  
6 get it done, this has been very sensitive, and Pam  
7 will probably talk about this tomorrow. This is  
8 one of the areas that we've addressed on our  
9 working group on this guidance is that very thing,  
10 that we don't want management to put pressure on  
11 the reviewer in those circumstances, and the  
12 reviewers, we'll recommend the reviewers be  
13 trained that if you have any problems or  
14 suspicions, don't worry about that 90 days; you  
15 take care of business as you need to and forget  
16 that deadline.

17 MEMBER RYAN: I think Michelle had a  
18 thought that was very much on point, the  
19 difficulty for a reviewer is not in raising issues  
20 and having concerns; it's in not reporting them to  
21 management within 90 days. That's where the focus  
22 ought to be. If they just kind of sit on it,  
23 that's a slip. But if they're reporting it to  
24 management, and it's on the plate, on the agenda,  
25 they've met their obligation.

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1 MR. MONTGOMERY: Exactly. And that is  
2 already I think well - that word has already gone  
3 out. I know my management in my Region has made  
4 that extremely clear to all of us.

5 MEMBER RYAN: Let me second, Jim,  
6 something that Ben said that I agree with  
7 completely. And that's that I think reviewers,  
8 having been an applicant in a number of  
9 circumstances both here and in Agreement States,  
10 they all want to do a good job. They want to be  
11 thorough; they all want to be mindful of health,  
12 safety, and environmental issues, yet help the  
13 licensee get the activity underway and do it  
14 safely and effectively. And I think the NRC staff  
15 should be commended for their constant balancing  
16 of all those issues. It's a hard job, and they  
17 take it seriously. And it was refreshing to hear  
18 Michelle you know affirm the fact, they don't want  
19 to do anything that would be dangerous to anybody;  
20 in fact just the opposite, they want to make sure  
21 to the best of their ability to avoid that.  
22 That's fully commendable.

23 MEMBER NERUD: And you need to look at  
24 the track record. We've been issuing licenses for  
25 30 years.

1 MR. WHITE: Closer to -

2 MEMBER RYAN: Since 1954.

3 (Simultaneous voices)

4 MR. MONTGOMERY: I think your first  
5 licenses started going out in the late `40s.

6 MEMBER NERUD: And you've issued, what,  
7 one bad one to GAO? That's a pretty good track  
8 record.

9 MR. MONTGOMERY: I don't know of any  
10 malevolent individual who has ever gotten a  
11 license.

12 MEMBER NERUD: I did a search. I found  
13 nothing.

14 MR. MONTGOMERY: I know some pretty  
15 incompetent ones, and some ones that commit  
16 violations, but not -

17 MEMBER RYAN: And we should, there is a  
18 book called "The Medical Basis for Radiation  
19 Accident Preparedness" by Shirley Fry and Karl  
20 Hubner, and there was a case where a guy used  
21 cobalt sources to actually irradiate his son.

22 MR. MONTGOMERY: Oh, that's true.

23 MEMBER RYAN: Crazy people.

24 MR. MONTGOMERY: You're right. They're  
25 relatively rare.

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1 MEMBER RYAN: They are very rare; no  
2 question. But it's not zero.

3 CHAIR HILL: Having been a license  
4 reviewer, and spent a lot of time on one  
5 particular license, but whenever it got down to  
6 the bottom line, all the I's had been dotted, and  
7 the T's crossed, there still wasn't a good feeling  
8 in the gut. The license was issued, but  
9 everything had been met. All the requirements had  
10 been met.

11 MEMBER RYAN: And what happened?

12 CHAIR HILL: Everything worked as  
13 designed except the source.

14 MEMBER RYAN: Sources?

15 CHAIR HILL: Well, one source.

16 MR. MONTGOMERY: You made - if I may,  
17 you made another comment, something to the effect  
18 that if a reviewer is suspicious don't worry about  
19 the 90 days; turn the whole thing over to, in our  
20 case, our Office of Investigations, and let people  
21 who are trained to look at this malevolence get  
22 involved.

23 And I think you added something about  
24 notifying the applicant this is going to be done.

25 We addressed this in our group, and

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1 you may want to mention this or discuss this with  
2 Pam tomorrow. We talked about this at length, and  
3 came to the conclusion that the reviewer should  
4 not - the Region should not communicate to the  
5 applicant in anyway that there may be some  
6 suspicion. And that if the applicant - just go  
7 ahead and quietly turn it over to our Office of  
8 Investigations.

9 And if the applicant inquires about,  
10 hey, what's taking so long? Just tell them it's  
11 under review, and we are backlogged; make up some  
12 little excuse, but don't reveal that you are  
13 suspicious, because that could compromise the  
14 investigation

15 MEMBER NERUD: That's true. And I  
16 don't disagree with that. My inclination is most  
17 of these that we do that we would turn over to an  
18 independent reviewer like that are benign. They  
19 are going to be nothing. And the sole purpose -  
20 I'm trying to recognize the good faith aspect of  
21 it, the business aspect of it, the  
22 commerce/economic ramifications of it is to let  
23 the applicant know.

24 A legitimate applicant is going to,  
25 like I said, they're going to be down in your

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1 office with anything and everything that you need  
2 to prove it right. An illegitimate applicant is  
3 going to say, I don't want it anymore.

4 Well, at the point they say, I don't  
5 want it anymore, that application leaves NRC and  
6 goes to FBI. And the intel shop here sits on the  
7 JTTF. No problem. I mean that transfer would  
8 happen immediately.

9 So that was in recognition of business  
10 - of the business aspect of it; again a decision  
11 NRC would have to make. If you don't want to do  
12 that, that is a perfectly valid and reasonable  
13 means of dealing with that situation. For that  
14 matter call the police, have them send a SWAT team  
15 over there. That's reasonable also... at least  
16 from a DOD perspective.

17 MR. MONTGOMERY: Duncan, in that GAO  
18 report, correct me if I'm wrong, but didn't GAO  
19 make a comment that if a search had been done on  
20 the Internet, and I know, maybe I'm  
21 overemphasizing how great Internet searches are,  
22 but I believe they said something to the effect,  
23 if a search had been done on this applicant and  
24 the address that was given, that it would have - I  
25 believe they even - they were very specific - they

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1 said it would immediately have revealed that this  
2 was a bogus operation. I think those are almost  
3 their exact words, at the conclusion of their  
4 report.

5 MEMBER NERUD: I don't recall anything  
6 on the Internet. There are a lot of companies out  
7 there that don't have an Internet website.

8 MR. WHITE: That's exactly true.

9 MEMBER NERUD: Especially some of these  
10 small companies that don't - I wouldn't expect a  
11 guy who has your - your guy with one portable  
12 gauge, the one-man operation, and he's got a - did  
13 he have an actual website for his company?

14 MR. MONTGOMERY: He didn't have a  
15 website, but his name showed up on a number of  
16 hits, because he's very active in the civil  
17 engineering field. Non-radioactive - I mean he's  
18 been around. Just decided to get himself a gauge.

19 MEMBER NERUD: So having that - the  
20 Internet quantify that aspect, I think there are a  
21 lot better ways of doing it: tax numbers,  
22 State/Federal customers, references.

23 MR. MONTGOMERY: Sure, nevertheless, I  
24 would start there.

25 MEMBER NERUD: It would be a great

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1 place to start.

2 MEMBER RYAN: There are services where  
3 you can hire somebody for \$50 to do exactly what  
4 you're saying, and what you are saying, all in one  
5 report. They have a tax number; they don't have a  
6 tax number. They have an address; there is a  
7 building. That go out and do that for people that  
8 are seeking loans. You know, they do loan  
9 reviews, and they do the exact same kind of  
10 veracity checks we're talking about if you apply  
11 for a business loan. Banks do it all the time.

12 You know the Internet is a good tool,  
13 and I'm sure all these services that search do  
14 that. But somewhere along the line you've got to  
15 get up and go out into the fresh air, and see if  
16 there really is a building there.

17 MR. MONTGOMERY: You know speaking of  
18 that, another tool I use is Google Earth. You can  
19 type in the address on Google Earth.

20 MEMBER RYAN: Yes, you can go see if  
21 there is a place.

22 MR. MONTGOMERY: And if you see a  
23 swimming pool, a country club there, or nothing,  
24 you know, you get suspicious.

25 MEMBER RYAN: The point is that all the

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1 Internet searches in the world don't replace  
2 personal information and direct contact.

3 A guy comes to your office, an  
4 applicant walks in, says, here's my application.  
5 Already there is a step up, because they've shown  
6 up. Who do I talk to? And what is your name and  
7 phone number, because I am going to be working  
8 with you on my license application. Here's our  
9 brochures. Come out and see us. All of a sudden  
10 there's a rapport, and there is some stuff going  
11 on there.

12 MR. MONTGOMERY: It could still be a  
13 malevolent individual, but it's hard to imagine,  
14 not impossible, but let's say you have a meeting  
15 here, and you have the applicant come in here and  
16 sit in those chairs and talk to all of us; come  
17 into NRC Headquarters or one of the Regional  
18 offices. You got to have some - you got to really  
19 have some nerve to pull that kind of thing off.

20 MEMBER RYAN: So the odds of a bad guy  
21 go way down.

22 MR. MONTGOMERY: I would think so.

23 MEMBER RYAN: Way, way down.

24 But the point is that a physical visit  
25 to where the material is going to be, and where

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1 it's going to be used, tell you a lot more than  
2 what's in the application sometimes.

3 So first hand visits and hand shakes,  
4 and I think more robust electronic skills  
5 including all these searches, and all these kind  
6 of veracity checks on all the information really  
7 gets you way down the road in terms of making sure  
8 you're not going to be stung again.

9 MR. WHITE: There's one thing I wanted  
10 to comment on, Ben, one of your things about the  
11 inspection process being a vital part, actually  
12 going there and seeing the place. I tend to agree  
13 with that, it's very important.

14 Could you shed any light on when would  
15 be a good time to do that? Early on in the  
16 process, or like some states do, some Agreement  
17 States actually deliver the license, because they  
18 want to make sure that they're ready to receive  
19 material.

20 MEMBER RYAN: Yes, I couldn't agree  
21 with you more. I think that's the right way to do  
22 it.

23 MR. WHITE: The basis of the whole  
24 thing is to make sure that they are capable of  
25 acquiring stuff. NRC doesn't normally do that.

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1 Is it more important to go visit them earlier on  
2 in the process?

3 MEMBER RYAN: Let me give you a simple  
4 example. I am applying for a license on January  
5 1. RSO will be Tom Hill, capable, here's his  
6 resume, CV.

7 Well, on February 15<sup>th</sup>, Tom got a  
8 better offer; he's no longer there. So come about  
9 June 1 you show, can you issue me my license, and  
10 I had forgotten to tell you, sorry, that Tom is no  
11 longer our SRO, and I'll deal with that later  
12 because I'm busy with other stuff.

13 Well, you know, you can kind of at  
14 least go down a check list of things that were in  
15 the application, things that were - and you just  
16 show up and say, here, we're going to go do a  
17 quick check of these 20 items or 10 items, and  
18 verify that everything is in place ready to go,  
19 and we'll give you your license, and have a cup of  
20 coffee, and head home.

21 MR. MONTGOMERY: In that scenario that  
22 you just described has happened many times.

23 MEMBER RYAN: I can imagine. And  
24 that's the point. During the application process,  
25 so it gives you kind of a quality check. And you

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1 know if you have somebody along that has some  
2 insight or training in safeguards and security  
3 matters, they can begin to look at the basic  
4 things like a \$40 dead bolt versus a lock you can  
5 pry open with a crowbar, and a few basic odds and  
6 ends, and you can make those points of compliance  
7 down the line.

8 MEMBER NERUD: It goes even further  
9 than that I think, where you use this good faith  
10 presumption, and they say, we're going to use this  
11 principle or this policy. We're going to use  
12 this model. We're going to use this guidance.

13 All right, great. You didn't have it  
14 in your application. You said you were going to  
15 use it. When you show up, well, all those things  
16 that he agreed to do, which is a check on that,  
17 let's see it. I don't have it. Well, when you  
18 get it give me a call and I'll come back with your  
19 license.

20 MEMBER RYAN: No, I got involved with a  
21 facility that had a lot of problems, and had a lot  
22 of self reports that they had to make, and they  
23 did make them to both a RCRA permit and an  
24 Agreement State license.

25 And you know what is the corrective

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1 action plan? Well, here's the corrective action  
2 plan in the first TAD. We're on the plan for the  
3 second TAD.

4 In the first three due dates, the  
5 members of the first three, guess what happened?  
6 There was an inspection on the due date. All  
7 three were done. All three were done  
8 satisfactorily. All of a sudden there is a  
9 confidence building with those corrective actions  
10 being implemented.

11 And again that wouldn't have happened  
12 any other way than a physical visit. So I know  
13 that's a challenge. And again, I'm very  
14 appreciative, in a bigger Region, or in a Region-  
15 wide geographic distribution, that can be  
16 challenging. But I just don't see how you get  
17 around it.

18 MR. MONTGOMERY: That's true. If we  
19 have to go to Guam to deliver a license, that's  
20 about a 7,000-mile trip. But great, that's the  
21 real world now.

22 MEMBER NERUD: And Hawaii is just going  
23 to be horrible.

24 MR. MONTGOMERY: It's a dirty job, but  
25 somebody has to do it.

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1                   MEMBER RYAN: I was going to say, I'll  
2 be happy to volunteer for the Guam trip.

3                   CHAIR HILL: I want to go back, now  
4 that you have made something that I read that I  
5 cannot remember the acronym for real well, and see  
6 if I can kind of get a handle on this.

7                   The point that, okay, we've hit the  
8 indicators, and it needs to go to the  
9 investigative group. It's a new license, a new  
10 licensee that we have no knowledge of being one of  
11 the first ones. And the comment was, then maybe  
12 we need to have the investigative background check  
13 done.

14                   So this is kind of a process comment.  
15 There is as I recall a system record of - OR-  
16 something or another - where licenses are entered  
17 into the system, and up front, if I remember what  
18 I was reading, and maybe I misinterpreted the  
19 document I was reading, official record -

20                   MR. WHITE: Copy?

21                   CHAIR HILL: Is that in ADAMS?

22                   MEMBER NERUD: ADAMS has a copy of all  
23 licenses in them.

24                   CHAIR HILL: Is the process of the - is  
25 the process of the review and actions that are

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1 taken documented in that?

2 MEMBER NERUD: No, it's documented in  
3 the license tracking system.

4 MR. WHITE: No, the license tracking  
5 system is just a statistical information, data  
6 information on a licensee; very basic information,  
7 contact names, authorized material, location, and  
8 some additional information.

9 Official record copies, as NRC is a  
10 public agency we have to have documents available  
11 for public review. And we have to make, during  
12 the course of a licensing action or any sort of  
13 action, we have to make, you know, make our final  
14 decision public. And that's usually, in this case  
15 it's usually a license. And the license has to  
16 be backed up by documentation that went back and  
17 forth.

18 And we do have a SUNSI way to evaluate  
19 that policy through evaluating incoming -  
20 correspondence that is incoming or going out for  
21 extensive information that has to be withheld from  
22 public view. We go through that process.

23 Also during licensing action,  
24 sometimes, and particularly with sealed source and  
25 device applications and stuff, you see this stuff

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1 is proprietary information. They don't want their  
2 trade secrets given out. We have a process for  
3 that. That stuff can be withheld from public  
4 view.

5 Otherwise it doesn't meet those  
6 standards, it can be made publicly available. And  
7 that's what ADAMS is. ADAMS is the official -  
8 what the NRC makes our actions available to the  
9 public.

10 CHAIR HILL: So official -

11 MR. WHITE: Record copies.

12 CHAIR HILL: - record copies that are,  
13 have non-proprietary -

14 MR. WHITE: Or nonsensitive information  
15 go into ADAMS.

16 CHAIR HILL: Does it go in immediate -  
17 let's say a license application comes in.

18 MR. MONTGOMERY: Yes, it's scanned, it  
19 is scanned and it is put into ADAMS.

20 CHAIR HILL: Made an official record  
21 copy?

22 MR. WHITE: But it may not be available  
23 for public use.

24 MR. MONTGOMERY: Exactly. If it  
25 contained sensitive information it will be

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1 designated nonpublic. It still goes into ADAMS.  
2 And it can be looked at by NRC staff. But it is  
3 nonpublic.

4 MR. WHITE: Now there are interesting  
5 things that we are dealing with right now at the  
6 agency from a policy standpoint.

7 There is a requirement in the Act in  
8 the Department regulations for - we particularly  
9 see this on the reactor side - when a reactor  
10 comes in to do an action, it is noticed, and the  
11 public is allowed to have hearing rights for that.  
12 Very commonly done. People have an opportunity to  
13 comment on it. The States can comment. Anyone  
14 can comment.

15 Those also apply to material  
16 licensees. The problem with material licensees  
17 is, one, the sheer volume of stuff that we do; and  
18 secondly, we don't - we handle - we have no good  
19 avenue of announcing where those actions go. We  
20 can't afford to put everything in the public  
21 record every time we get a licensing action coming  
22 in. We can't put it in the *Federal Register*.  
23 It's too voluminous.

24 So one thing we'll be implementing  
25 very shortly is a way to post the receipt of

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1 licensing actions, the receipt by the agency on  
2 the public website, so people if they are  
3 interested in looking at them can go in and say,  
4 yes, I'm interested in - I work down the street  
5 from that hospital. I want to see what the  
6 licensee action is, and they have the opportunity  
7 to look at that action if they choose to do so.

8 CHAIR HILL: My point really does -  
9 what I was getting at - doesn't have any thing -  
10 doesn't have to be a public document. At the  
11 point that the official record copy goes in, if  
12 one of the indicators is that it's brand new,  
13 there is no one that - this is an entity that we  
14 know nothing about, could that not be indicated,  
15 and then basically simultaneous with the license  
16 reviewer's work, the investigations folk pick it  
17 up and go do the - that's kind of what I'm  
18 thinking.

19 MEMBER NERUD: I spoke with the people  
20 that develop our databases, and I asked not that  
21 particular question but very similar questions  
22 about, when an application goes in, can the system  
23 check data, compare data, to each other, those  
24 types of - each other, and other specific  
25 information, and generate - tag those things so

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1 that when the license reviewer gets it, the first  
2 thing that happens is, it pops up and it says, you  
3 need to check off everyone of these things before  
4 you can issue a license. So everyone of these  
5 things, at a minimum, must be investigated because  
6 they are indicators.

7 The same thing could happen in that  
8 regard is that new application, it gets compared  
9 to everything else in the rest of the database;  
10 says, nope, never saw this guy, never heard of  
11 this guy, don't know who he is, and the first tag  
12 that comes up there, says, brand new application,  
13 consider sending for investigative review.

14 MR. MONTGOMERY: The reviewers use a  
15 form, every case that comes in, reviewer has  
16 several pages of form they go and check off, and  
17 it contains all these criteria, the kind of thing  
18 you are talking about. It's not electronic. It's  
19 not automatic. The reviewer physically goes  
20 through the form, and it asks you questions, and  
21 you proceed from step one to step two and all the  
22 way to step three if you go - in 99.9 percent -  
23 well, in a high percentage of the cases you never  
24 get out of step one, because you know who it is.  
25 It's a known entity. And - but it's all there.

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1 And those forms are completed, signed off by a  
2 reviewer, and management, and they go - they are  
3 entered into ADAMS as sensitive material,  
4 nonpublic.

5 CHAIR HILL: That's what I was reading  
6 where I came up with that -

7 MR. WHITE: But what you can do with  
8 our system though, as Jim has indicated, you put  
9 the information that goes into the system, the  
10 application goes into the system; it's available  
11 for viewing by other NRC people. And that would  
12 allow - this doesn't have the capability of these  
13 things that you - searching and stuff like that.  
14 That has to be done manually, or someone has to  
15 program the thing to go through and look for the  
16 stuff.

17 But what you could do is, it does  
18 allow, as the reviewer looks at it, they can  
19 immediately have someone get someone else involved  
20 with it very rapidly. Because things staying  
21 there electronically. All they have to do, they  
22 just need the information, types it in, boom, the  
23 thing pops up.

24 CHAIR HILL: Send an email to the  
25 investigator, say, look at it.

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1                   MEMBER NERUD: And that would be the  
2                   advantage of that web-based licensing is that a  
3                   lot of those things that you are doing right now  
4                   we are not getting out of step one because they  
5                   are a known entity. Well, under the web-based  
6                   licensing, you are not even doing step one because  
7                   you already know who he is. And you don't have to  
8                   do all that. You don't have to waste your time.  
9                   You know who his radiation safety officer, and you  
10                  know what the program they've got is. Okay.

11                  MR. WHITE: LTS may have some, again,  
12                  use of this, but again, the limitation of the  
13                  current system is, NRC looks at their licensees.  
14                  And that's what, that goes back to what with this  
15                  licensing and you want the Agreement States  
16                  involved with this licensing because then you can  
17                  search - truly search through, do a national  
18                  search that way.

19                  MEMBER NERUD: But that's going to be  
20                  an important part when NRC goes through with this  
21                  web-based licensing is, understand, this is not a  
22                  process by which a guy can apply for his driver's  
23                  license online and get a radioactive materials  
24                  license.

25                  This is a process by which you can go

1 in and there are safeguards, security issues,  
2 health, safety, environment, everything is all in  
3 this system that allows - it'll help the license  
4 reviewer go through the process, but it's going to  
5 also require increased scrutiny where necessary.

6 CHAIR HILL: All right, very  
7 interesting, and a lot of food for thought. And  
8 digesting as to what this panel's recommendation  
9 in this area can and will be.

10 One thing I wanted to mention, since  
11 I've just about headed up - I'm not sure we can  
12 absorb much more today. This panel has a work  
13 product due, probably by the end of this meeting.  
14 The timeline, the deadline may not be as critical  
15 as the final report, but we are supposed to have a  
16 work plan for the director of FSME, probably about  
17 the end of the meeting, shortly thereafter. So we  
18 need to be thinking about that, and probably spend  
19 some time tomorrow afternoon looking at that  
20 document and maybe doing some final edits tomorrow  
21 or Friday morning as appropriate.

22 MR. MONTGOMERY: Please make those  
23 comments if you would to Pam Henderson tomorrow.  
24 She's the chair of the committee that's currently  
25 working on the revised guidance. And I know she

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1 would be very interested in your - particularly  
2 your comments, but of course all three of you.

3 CHAIR HILL: Anything else for the good  
4 of the group?

5 MEMBER RYAN: Nope.

6 CLOSING REMARKS AND ADJOURNMENT

7 CHAIR HILL: Well, if nothing else,  
8 then let's adjourn.

9 MR. McCRAW: One more administrative  
10 announcement. We will be back in this room again  
11 tomorrow, although the agenda indicates that we  
12 will be next door; we will be in this room again.  
13 We'll put up some kind of notification so  
14 individuals will be directed this way.

15 CHAIR HILL: Aaron, thank you.

16 Well, if that is it.

17 MEMBER RYAN: Gentlemen, thank you for  
18 all your time today. We know it's a busy schedule  
19 for you, and we appreciate your coming.

20 CHAIR HILL: We will consider ourselves  
21 adjourned.

22 (Whereupon at 3:59 p.m. the proceeding  
23 in the above-entitled matter was adjourned.)

24