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TRANSCRIPT OF PROCEEDINGS

Public Meeting

Before the U.S. Nuclear Regulatory Commission:

Gregory B. Jaczko, Chairman

Kristine L. Svinicki, Commissioner

George Apostolakis, Commissioner

William D. Magwood, IV, Commissioner

William C. Ostendorff, Commissioner

APPEARANCES

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Vice-Chair

Debbie Gilley
Agreement State Representative

Susan Langhorst, Ph.D.
Radiation Safety Officer

Steven Mattmuller
Nuclear Pharmacist

James Welsh, M.D.
Radiation Oncologist

Stakeholder Panel:

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Chair, Organization of Agreement States

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Committee on Radiation Medical Events
Conference on Radiation Control Program Directors and Environmental Scientists
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P R O C E E D I N G S

CHAIRMAN JACZKO: Well, good morning everyone. Today we have a briefing on a variety of different issues related to the medical uses of sources. We will be hearing from the staff, the Advisory Committee on the Medical Use of Isotopes, and other stakeholders. This is a very long and comprehensive meeting, so I won't make very extensive comments other than to say that I hope everyone does their best to stick to their allotted times as we go forward because there is a lot of people we have to hear from today, and I think that will make for a very productive meeting. So with that if my colleagues wanted to make any opening remarks. Okay, well, we'll begin. Dr. Thomadsen if you want to start.

DR. THOMADSEN: Thank you, Mr. Chairman and Commissioners. Thank you for having us here today. My name is Bruce Thomadsen. I am a medical physicist and associate professor at the University of Wisconsin, Madison, Wisconsin. I serve as a therapy physicist and vice chair for the ACMUI. Unfortunately, the ACMUI chairman, Dr. Leon Malmud, is ill today. He became sick yesterday and is unable to attend today's briefing, so I will be acting as the chair in his stead. Dr. Malmud sends his regrets to the Commission, and we send our best wishes to Dr. Malmud for a speedy recovery.

I would like to introduce the other ACMUI members seated at the table here today. Steve Mattmuller is the chief nuclear pharmacist at Kettering Medical Center in Dayton, Ohio. Mr. Mattmuller serves as a Nuclear Pharmacist on the ACMUI.

Susan Langhorst is the radiation safety officer and director of the Radiation Safety Division in the Department of Environmental Health and Safety at Washington University in St. Louis, Missouri. Dr. Langhorst serves as a Radiation Safety Officer for the ACMUI.

Debbie Gilley is the environmental manager and director of Training and Quality Assurance at the Florida Department of Health's Bureau of Radiation Control. Ms. Gilley serves as the Agreement State representative for the ACMUI.

Dr. James Welsh is a professor of radiology, neurosurgery, and radiation oncology at Louisiana State University School of Medicine in Shreveport. Dr. Welsh serves as one of the two Radiation Oncologists on the ACMUI.

Today we will cover a range of topics of significant interest to the ACMUI. We have been working closely with staff on key issues and look forward to sharing our thoughts with you. Although we may provide different opinions, we believe that the staff understands our views and is very responsive. We hope to continue to work well together to achieve a favorable outcome for the issues that face us today.

I now turn it over to Mr. Mattmuller to provide an update on the impact of Medical Isotope Shortage.

MR. MATTMULLER: Good morning. First slide please. Good morning, I am Steve Mattmuller, nuclear pharmacist on the committee. Today I will give you a brief update on the Medical Isotope Shortage. Next slide, please.

Over 16 million nuclear medicine procedures are performed in the U.S. each year that depend on a robust supply of moly-99 or molybdenum-99. It is needed as it is the parent medical isotope for technetium 99m, which is the

actual medical isotope used in our procedures. This image shows a diagnostic metastatic -- it is a bone imaging study done to diagnose metastatic bone disease. Unfortunately for this patient the dark areas represent numerous areas of metastatic disease throughout their skeleton. It is a good example of how nuclear medicine images are based on cellular function and physiology. They don't have the sharpness of an anatomical study such as CT or MRI, but they do have a greater sensitivity. These images are based on functional differences not anatomical differences. Bone imaging studies account for about one in five of all nuclear medicine procedures that use technetium 99m, and even though they are not the most common, they require special attention because during a shortage, there is no alternative radio-pharmaceutical we can use in their place. There is no alternative study that can provide this type of information. Next slide, please.

This slide shows the world's major reactors that produce moly-99. The NRU in Canada, now 52 years old, has been down for repairs for over 14 months restarting in July of this year. Current plans are for it to end operations in 2016 with no replacement reactor. The HFR in the Netherlands, now 48 years old, has been down for seven months restarting in September of this year. The Dutch are planning to replace it and plans are being developed but have yet to break ground on the new reactor. Together these two reactors produce about two-thirds of the world's supply of moly-99. It also shows a very large disconnect exists in that the U.S. uses over one-half, one-half of moly-99, but it does not have a single reactor producing it, and is completely dependent on foreign reactors. Next slide, please.

This was our latest disruption, 16 months from Covidien's perspective describing their moly-99 supply which of course translates to the

availability of their technetium generators during the shortage. Green is normal, good; blue, some shortages; yellow, more shortages; orange, extensive shortages. If you have good eye sight you can see some Xs up on the oranges, which means zero, nothing; no moly-99 at all; no technetium 99 at all for any of our patients. But this was just for half of our patients, half of our community in the U.S. The other half, supplied by Lantheus, suffered the shortage much more severely than Covidien.

So this image serves in a way as sort of a snapshot of the recent shortage. It shows the disruption in the supply or rather the disruption in the health of the nuclear medicine community, and its inability to provide care for its patients during these 16 months. Or think of it this way; a robust supply is to the health of our patients as a strong safety culture is to the health of a nuclear power plant. With a robust supply patients get the best tests they need which leads to the best treatments, and, hence, they have the best health. A nuclear power plant with a robust safety culture has a strong safety culture work environment and operates efficiently and safely.

Now, a poor supply is like a weak safety culture in a nuclear power plant; one that has a cost conscious work environment. On the healthcare side due to the poor supply patients won't die tomorrow, but they may endure alternate procedures not as accurate, not as safe, resulting in the wrong diagnosis or a delay in reaching the correct diagnosis which leads to the wrong treatment or delay in getting the correct treatment which all leads to poorer health of our patients. Likewise a nuclear power plant with a cost conscious work environment won't have a major safety incident tomorrow, but as minimal

regulatory compliance attitudes set in over time as issues are put off or ignored, major safety issues will develop under a poor safety culture. Next slide, please.

From January 2007 through September of this year we have endured five periods of supply disruptions in our moly supply. The last one has been by far the longest and most severe disruption we have ever experienced. So despite the fact that right now we have a good supply in no way can we relax. Hence the efforts by Babcock and Wilcox with Covidien's help and General Electric Hitachi's efforts to produce moly-99 in the U.S. are critical. Both are pursuing unconventional methods to produce moly-99, B&W with their Aqueous Homogeneous Reactor where the liquid low enriched uranium target and fuel are one in the same, GE Hitachi producing moly-99 from the neutron bombardment of moly-98, which has been done before, but this time using a non-conventional neutron source, a nuclear power plant. Both face challenges and need the continued support of the NRC to help them to be successful, to be successful before the nuclear medicine community and our patients have yet to endure another shortage. Last slide, please.

So this is our goal. A robust source of moly-99 made in U.S. During the last three months we have endured five periods of supply disruptions. This has made it very difficult and challenging for the nuclear medicine community to provide the best care for our patients. To do this we need a robust source of moly-99 in the U.S. and every month needs to be a green month. Thank you.

DR. THOMADSEN: Thank you. We will now have Dr. Langhorst discussing patient release issues.

DR. LANGHORST: Good morning and thank you very much for this opportunity to speak with you on behalf of the ACMUI Patient Release Subcommittee. Next slide, please.

Our subcommittee was formed in May 2010 to review and analyze issues associated with patient release, including review of the current international recommendations. We were also asked to provide statements on patient release to locations other than private residences, per release limit versus annual limit for other individuals exposed to the released patient and to recommend needed changes or improvements. Next slide, please.

The subcommittee concluded that dose to other individuals is safely and cost effectively controlled by the current Patient Release Criteria supported by scientifically developed dose-based release calculation methods and physician assessment of patient release suitability, and with patients and their care givers understanding and adherence to release instructions on maintaining dose to others as low as reasonably achievable. Next slide, please.

Use of radioactive materials in medicine is the example I often use when giving public talks explaining the three fundamental principles of the use of radioactive materials. First there must be justification for that use and overall benefit from that use. Medical diagnosis and treatment are benefits that are readily recognized. Second, the principal of maintaining doses low as reasonably achievable is applied, taking into account economic, societal, and medical factors. The third is the application of appropriate dose limits. In the case of patients there is no dose limit. Instead we rely on the physician’s medical judgment of benefit versus risk for the patient and the application of ALARA precautions. Next slide, please.

Based on these three fundamental principles, the subcommittee considers the current NRC Patient Release Criteria appropriately balances public safety, patient's access to treatment, and cost. We believe the criteria are consistent with NCRP, ICRP and IAEA recommendations, both in principal and in practice. That is the limit of five milliseverts per release for family and care givers and addition of written ALARA instructions if dose to others is likely to exceed one millisevert. These instructions are needed most often with therapy doses involving I-131 pharmaceuticals. These are typically administered once a year, but in some cases may involve two or more treatments within a year. The subcommittee considers the ALARA precautions provided to patients give reasonable assurance that doses to children, pregnant women, and the general public are well below one millisevert even in the cases of multiple therapies. So we recommend to keep the current release limit rather than an annual limit, and recommend that focus should be on the reasonable development and effective communication of these precautions. Next slide, please.

The NRC has been petitioned to return to the old Release Criteria known as the 30 millicurie rule where release is based on 30 millicuries of activity remaining in the patient or dose rate less than five millirem per hour at one meter. The subcommittee rejects this suggestion. There is no scientific basis for returning to this old criteria which is not based on risk or patient actions. The ICRP and the IAEA specifically state that they do not recommend this type of release criterion. We therefore believe return to the 30 millicurie rule is inappropriate for today's NRC regulations. Next slide, please.

Instead the subcommittee advises the NRC to update and improve guidance for release dose calculations using current knowledge of bio-kinetic

models in patient dose-rate data. We recommend that NRC support the development of computer-based calculation tools with realistic assumptions for use by licensees. While the subcommittee believes patient release to a private residence is preferred, we also recognize that circumstances may warrant different living or release situations. We recommend NRC guidance be developed to address these various release situations. Next slide.

The IAEA states that the success of a patient release program is critically dependent on the quality and the specificity of the information provided to the patient, the skill with which it is communicated, and whether or not the patient believes the information provided. Again, the subcommittee believes NRC should enhance its support of this aspect of Patient Release such as development of scientifically based communication tools that are readily available to physicians and patients and support the research efforts to gather scientific data to better understand patient behavior and effectiveness of communication for patient comprehension, those circumstances that impact release decisions, instructions and perceptions. The Patient Release Subcommittee will be presenting our draft report to the ACMUI and NRC staff at our committee meeting tomorrow. We will be discussing in more detail our review and recommendations.

To summarize today's presentation, medical use of radioactive materials benefits millions of patients and their families each year. The subcommittee advises that the current Patient Release Criteria not be changed. We recommend that NRC focus on providing appropriate and realistic guidance for licensee's and patients, and focus on providing research support for

understanding and communication of the real world issues impacting patient care and public safety. Next slide, please.

Finally, I would like to recognize my fellow subcommittee members and thank them for their efforts on drafting this report. Thank you.

DR. THOMADSEN: Thank you. I think we have Ms. Gilley on the next presentation on the discussion of the proposed rule change for Part 37.

MS. GILLEY: Good morning, Commissioners, NRC staff, and members of the public. Thank you for the opportunity to come and give you a preliminary review of potential concerns the ACMUI may have with Part 37. ACMUI will be meeting as a group this afternoon to further discuss these security rule concerns. Next slide, please.

The potential concerns are impact to access to healthcare, justification of additional regulatory requirements beyond the IC orders, additional costs to licensees, and implementation obstacles that may impact regulatory compliance. Next slide. The three areas that I would like to discuss today include background checks, security plans, and the coordination with the local law enforcement. Next slide.

Background investigations in the proposed rules expand to including background checks for the reviewing official and also allowing the reviewing official unauthorized access to radioactive material, even if they are not an authorized user of the material. The collection evaluation of background information has expanded from a fingerprinting record and sending it into NRC for verification to include additional items such as a credit and local criminal law enforcement history. These collections may be a drain on human resources and may limit authorized users having access to radioactive material. It may be

difficult also for some of our medical institutions to actually get that information from some individuals. Next slide, please.

In 2008, Dr. Vetter from the ACMUI came before the Commission and discussed the cost of the fingerprinting issue only. At his institution the cost was about $76,000, and that was just for processing and doing the fingerprinting that was required. The additional cost in the review include Credit Bureau checks, which could be anywhere from $30 to $100; local background checks, which vary in price, and if you look at the last 10 years with some students that may be moving around, maybe multiple local background checks, and that cost could exceed $150 per employee. For this same institution with the direct cost, loss of hours worked, and the administrative cost you could be as much as $100,000. Next slide, please.

Security Program Justification, the way that I have interpreted the proposed regulations are it will be based on the security plan, will have to be in place if you have possession limits whether or not you possess that amount of radioactive material at all. So it appears that there is some security creep into category three sources even if the licensee never exceeds category two level sources. It has also expanded to include sealed and unsealed sources. The program looks at physical accumulation of sources and for many medical institutions there are no waste disposal options for them. It is based on co-location and aggregation which are some terminology that is not clearly understood or defined on implementation. Next slide, please.

The next one is coordination with local law enforcement and regulatory compliance. It is very difficult for some authorized users and licenses to assure compliance with local law enforcement when they don’t have a direct

regulatory relationship with them. They do have security plans in place. They do go forth and meet with local law enforcement and discuss those to be compliance, but mandating local law enforcement do what they are supposed to do, would be very difficult for licensee to be held responsible for. Next slide, please.

Some of the things that the ACMUI would be interested in discussing is: should the regulations be codified, the orders? Should the proposed expanded regulatory requirements, are they reasonable? Are the regulations understandable and flexible and continue to use the material both efficiently and effectively? And do the regulations impede access to medical care or research? Next slide, please.

I would like to acknowledge the assistance of Dr. Langhorst in preparing these slides. Thank you.

DR. THOMADSEN: Thank you. Now, we will have Dr. Welsh talking about the Byproduct Material Events Subcommittee report.

DR. WELSH: Thank you. Good morning Commissioners, NRC staff, and members of the public. Thank you for the opportunity to present to you the subcommittee report on material events and our analysis. First slide.

The subcommittee has reviewed the NMED database and tabulated the medical events as per our custom. The subcommittee has goals which include identifying trends and causes and coming up with solutions. Next slide.

However, our goals may not be possible with the raw data alone that is available in the NMED database as it is today. An obvious limitation with the database is the absence of denominators. As an extreme example, if we say

that there are 10 medical events per year from procedure X but five from procedure Y, one might conclude that procedure X is a little bit riskier than Y. But if there are a million X procedures and 10 Y procedures obviously your conclusion would differ. Next slide.

So unless these denominators are available, trends can't be accurately identified. We can make educated guesses and estimates based on data from 2006 and other sources, but these would be nothing more than guesses or estimates and could be far off. On the other hand there are accurate figures available and these can be obtained through agencies including CORR, IMV, Arlington and others. Next slide.

One question is obviously where do they get their data, and how can the NRC and Agreement States also obtain such data? I naively assumed that we could just ask the licensees to provide these numbers, but in the subcommittee discussions I was educated and informed that licensee's would most likely not provide these numbers unless it is required. If it is required, the question becomes is regulatory requirement a wise use of resources. One then has to ask themselves, is it worth it? What if the cost is $1,000 per year? If one less medical event per year can be obtained through such information, I would argue that it is worth it. Additionally if we can accurately identify trends we can perhaps allow better allocation of funds for training and education. Next slide.

The subcommittee identified a possible trend in medical events involving radio-pharmaceuticals that had as a common denominator failure to verify the amount that was about to be administered. A suggested solution is that the written directive could include a check box or inclusion of check lists to prevent such errors in the future. Next slide.

In the nuclear medicine category -- and this is from the period of October 1, 2008 to September 30, 2009, there were two diagnostic medical events and five therapeutic medical events which is down from 15 in the prior year. There were 13 shipment reports in this period. Next slide.

In the 35-600 category, there were seven high dose-rate brachytherapy medical events compared to eight in the year prior. There were six gamma knife medical events compared to one in the year prior and no teletherapy, intravascular or other medical events. Two of these involved gynecological cylinders, confirming that this supposedly simple procedure is not truly simple; nothing involving by product material is. Next slide.

In the 35-400 category, there were 26 events involving 27 patients, and this contrasts sharply with the 10 events involving 114 patients in the period prior to this. Nine were involving Y-90 microspheres and 17 involved prostate brachytherapy. Several of these prostate brachytherapy procedures were medical events based on estimated dose, for example D-90, and one wonders if these would still be medical events if the definition were activity based. With the Y-90 microspheres most were under dosings, and they were due to technical errors such as three-way stopcock malfunctions, catheter occlusions, or adherence of microspheres to the septum vile. The manufacturers have offered some solutions for these problems. Next slide.

So the subcommittee recommends further improvements to the NMED database. The subcommittee feels that denominators are necessary for the exercise to be valuable, and without this the value of the exercise is highly questionable. We understand that there may be some good news that will be

discussed at the ACMUI meeting this afternoon in regard to this particular issue. Thank you.

DR. THOMADSEN: Thank you, Dr. Welsh. Now, I would like to continue a discussion about the Patient Event Database. Essential to trying to improve patient safety and eliminate or reduce at least the number of events is having good information about what has happened in the past. This requires a very useful patient safety database. Next slide, please.

Essential to having a radiotherapy database that's useful is consolidating all the databases that are out there. Right now, several government agencies have patient safety databases and several organizations do, too. Obviously it would be good to have all this data together. One is to reduce the redundant effort that goes into that. Two is to increase information on events. Three is to facilitate research on prevention of events. And four is to get a better estimate of how many events are happening. In order to do that we also need a unified taxonomy. Next slide, please.

A unified taxonomy is going to require cooperation among the groups involved. This would have to include experts who have been working on database technology, taxonomies rather. A poor taxonomy, such as that that exists in all the existing databases, greatly reduces the utility of any of the databases. There is right now a multi institutional group working on this but it is unofficial. Next slide, please.

Also required is a carefully crafted and smart database entry method designed by experts and users. Nothing kills a reporting system faster than a bad interface. Also, the data that is kept has to be very carefully chosen. There are many types of information that are useful for various types of analyses.

All of these have to be included into the database. This shouldn't be haphazard, but be guided both by the users and by people who are experienced and experts in creating databases. Next slide, please.

The existing database that is used by the Nuclear Regulatory Commission looks at things that are useful for the regulators. It is entered by either the NRC investigators or those from the Agreement States. These people often do not really understand the clinical or physical aspects of the case very well. The licensees also may not be entirely forthcoming with data involving the events. Next slide, please.

If we look where NMED is lacking, NMED being the NRC's database, all of the procedural information is in free text which means it is not readily searchable, and it is not very useful as far as trying to assess what happened in an event. It is often incomplete and sometimes inaccurate. There is little information on the cases, and the confounding circumstances that may have led to an event. There is a general description of the types of treatments, the devises used such as a high dose rate unit or the activity in that unit, which is not terribly useful information as far as the patient's safety goes. Next slide, please.

In order to make a database useful, you need to get a lot of information on the events. Right now, most states have laws that prohibit release of information on events to a database. If the event's going to undergo root cause analysis, and this is to try to alleviate the concerns of the people who may be testifying to the committee about what happened, that what they say might be released. Exceptions are made for required reporting to organizations such as the NRC. Legislation would be required to require release of patient events to a

database that would be created. Next slide, please. But very importantly there needs to be an incentive to get information into the database. The airlines crafted a method to exempt from discipline those who were involved in incidents and hazardous activities if they report to the database immediately. This has worked very well and has raised the safety level in the airline industry tremendously. Next slide, please.

The incentive in this case is the absence of punishment. In order to apply a similar type of incentive in patient safety would require change in culture amongst the regulatory bodies, preferring patients' safety to punishment. Next slide, please.

In conclusion, radiotherapy needs a discipline-wide consolidated reporting system. Right now several government agencies and professional organizations have been meeting to try to put together a unified database system, and the Nuclear Regulatory Commission's participation will be essential in the success of that endeavor. The system needs to be drafted very carefully with a taxonomy and data entry methodology that are put together by those people who have to use the system and those people who are experts in the field. And, finally, regulatory culture needs to shift its focus from punishment of errors to making radiotherapy safety a high priority. Thank you.

CHAIRMAN JACZKO: Well, thank you very much for those presentations. We'll start with Commissioner Svinicki. for questions?

COMMISSIONER SVINICKI: Thank you all for those presentations and on both Part 35 rulemaking and Part 37 as well. I sometimes think to myself in an area as complex as this our rulemaking activities can only be as informed as the willingness of various experts and external stakeholders to participate in

the process. So I thank you all for your involvement, not only in ACMUI, but I know such as Ms. Gilley, you have other capacities that you are involved in these issues. So I appreciate that very much.

I might ask specifically on the Part 35 rulemaking, I had a little cheat sheet that I neglected to bring down here with me, but it is -- I believe there's 28 separate component parts that the NRC staff is looking at provisions in 28 separate areas of Part 35 are related to it, for this rulemaking development that they have underway right now, and I've been told that the history is that NRC will try to group changes in the area of Part 35 and do kind of what I'll term one massive rulemaking, as opposed to doing individual rulemaking activities and perhaps breaking the activities down into less involved rulemakings. And I really can see both sides in judging as to whether it's better to kind of collect a whole series of changes, and in some cases we have petitions, for changes in petitions for rulemaking that go back to, you know, almost 10-years old now that we're trying to address in this rulemaking. Do any of you as constituents who are very involved in these rulemaking activities over the years, do any of you have any view about whether it really is more efficient for us to wait to collect a kind of critical mass of changes and move forward, or do you have an opinion that some of these issues are severable and could be disposed of and maybe more of a concise rulemaking package? I don't know if it's anything any of you have formed a view on over time as you've observed these rulemakings.

DR. THOMADSEN: I would say that having learned about how the rulemaking proceeds from my time on the ACMUI, it's a lot more involved and cumbersome than I had ever expected as a user. In order to have a lot of small changes in the rule, as the procedures are right now would all take a lot of time,

which is sort of why things pile up into large changes. If there were a different methodology for getting smaller changes out there, that probably would be beneficial to the community.

COMMISSIONER SVINICKI: Anyone else?

DR. LANGHORST: I would add to that. I would be very helpful that certain changes, once new regulation is put in place that have unexpected consequences that may be not doing what they had been intended to do, that it would be very helpful to get those addressed more quickly. For instance, training and experience requirements and so on, that there were a few little glitches in that, that it'd be nice that we could have addressed those more quickly.

COMMISSIONER SVINICKI: Yeah, and I'm perhaps not suggesting we are bound by the Administrative Procedure Act, so there's not a lot we can do there. What I'm thinking of is as cumbersome as the process may be, and we're confined to that process, complexity then adds additional -- makes it move a bit more slowly sometimes, if you bundle a lot of issues together. And maybe the simplest analogy I could think of is legislating is a very complex process as well, but occasionally the Congress will move what they call technical corrections bills, and there's the general acknowledgement, meaning that, you know, we promulgated, it got signed into law, and yet we realize now that certain adjustments need to be made there really. It's the same process, but it's just kind of an acknowledgement on the part of lawmakers that they need to move something perhaps in a more expedited way, and I don't know. I think sometimes that, you know, you can become resigned to something being ponderous and complex, and so maybe I'm pushing back against the system a little bit to say rulemaking does require time and care, but is there a way to kind

of not just reconcile or content yourself that it has to be that way, but is there any way to move things forward. And where we do find that a rule promulgated and then put into practice had an unintended consequence, it does seem like it's a very long process then to make adjustments, even if there's general agreement that they're needed.

So I'm just -- maybe I'm being a malcontent today and I'm just saying, you know, we need to keep looking at if there's ways to move things forward a bit more quickly. And I would ask on the taxonomy, that intrigues me, and it strikes me as a very difficult thing to do; you acknowledge that in your presentation. But you mentioned this group that is tackling this but unofficially. Could you tell me a little bit more about that? Is that just an ad hoc group that came together to try to do some good in this area?

DR. THOMADSEN: Pretty much so. It's mostly representatives from the American Association of Physicists in Medicine from the American Society for Radiation Oncology and from some of our Canadian colleagues, along with people who have been working on the databases through the International Atomic Energy Agency. And right, it's really just a bunch of people who have gotten frustrated with the lack of progress and are trying to put together something that could be useful if we could get a database together.

COMMISSIONER SVINICKI: Great, another group of malcontents, I'm in good company, alright, thank you all.

CHAIRMAN JACZKO: Commissioner Apostolakis.

COMMISSIONER APOSTOLAKIS: Thank you, Mr. Chairman. Your presentation, Dr. Welsh, was very interesting to me because a lot of the things you said I heard many years ago, when we started quantifying the risk

from nuclear reactors, where we had lots of licensee event reports, LERs, that had the same problems that you mentioned in your area; we didn't have denominators. But another thing that Dr. Thomadsen also addressed is the quality of the description of the event. There was a reluctance to say in the description that something was due to a human error. It was always pull pump's fault or the valves' fault, never the operators. On your slide eight, for example, you have, there were three events, wrong location in brachytherapy, wrong side, three events, low dose, one event. Are these seven human errors, would someone do that after an evaluation or are they really separate?

DR. WELSH: There's no doubt that those were human errors. For example, in some of the Gamma knife procedures, during this procedure, wrong location or wrong side was the error, and there's no way you can attribute that to a machine problem or technical error in the equipment. That's human error and due to improper oversight as the common denominator in those events.

COMMISSIONER APOSTOLAKIS: So, there is a fair evaluation then, and as you mentioned, Dr. Thomadsen, root cause analysis, so somebody will know why these occur, then maybe take action. Is that the idea here?

DR. WELSH: It does not explicitly state that in the NMED database, but one can only conclude that if you confuse the left side and the right side that that is human error and there is no mention of technical malfunction in these events compared to the Y-90 microsphere events, for example, where the microspheres adhere to the top of the vile and nobody noticed that. One could say that that's a combination of human error and technical difficulties with that particular device.

COMMISSIONER APOSTOLAKIS: Okay, now you complained or expressed frustration that you didn't have the denominators then somebody may give them to you. So, you're going to get the rate. What will you do with those rates? Instead of three events, you would say it's point zero something per year.

DR. WELSH: One example would be if we identified that the rate or incidents of a specific medical event is higher than we might have anticipated, and we have data to support that now. States could allocate funds more appropriately for training and education in that particular area. Whereas if you just have X number of procedures, you have no idea if this is a high risk procedure or a low risk procedure and doing very well. So, that information could be used in that fashion.

COMMISSIONER APOSTOLAKIS: And it seems to me you would have the same problem that, again, we have in the reactor area. The question is always if I see a number of events, are these random occurrences, in which case I really can't do much about them, or is there an underlying systemic or systematic cause, in which case I have to take action. So, I mean, I'm sure you would have that same problem. Is that an issue with you? I mean because, you know, as you say, there may be thousands or tens of thousands of operations of certain thing every year. If you have two incidents, maybe you say, "Well, that's life" -- I mean, things happen. But if you had several and then you realize that there is a fundamental misunderstanding or something which is wrong, then action is required. I mean is that an issue that you're facing?

DR. WELSH: It is and it is why if we could identify genuine trends and have true incidents rates, we might be in a better position to identify the root cause of these problems, and identify if it's a systemic -- a systematic error that's

going on, rather than a random fluke that happens to happen every so often and cannot be accounted for or prepared for. If a trend can be identified that can perhaps be prevented and addressed.

COMMISSIONER APOSTOLAKIS: Dr. Thomadsen, I think your statement and your conclusion -- I find it a little perplexing. The regulatory culture needs to shift focus from punishing errors to making radiotherapy safer. Why can't we do both? We do that in reactors. We do punish people, but we also make sure their plants are safe.

DR. THOMADSEN: They found in the airline industry that fear of reporting events reduced the information that they got about events, and when they eliminated that fear by changing what happened when you reported events and preventing punishment of that, they found they got much more useful information about hazardous situations that they can -- that they did address to make flying safer. There is an inhibitory effect of punishment. Yes, you can force people to do certain things by the fear of punishment, but what you can't do is force them to be terribly cooperative in giving you the information that you need.

COMMISSIONER APOSTOLAKIS: So, if a licensee violates our regulations, we can say, "Well, it doesn't really matter, because we're learning from it, and they're making the process safer." I mean, can we really say that?

DR. THOMADSEN: Well, if the goal is to correct what the violation was so that the violation is gone and to get information about what happened, why did that happen, so that you could prevent such violations in the future, yes, it would make things safer by doing away with that punishment. The goal is to --

COMMISSIONER APOSTOLAKIS: I'll have to think more about it, I mean --

DR. THOMADSEN: Yes, right. Yeah.

COMMISSIONER APOSTOLAKIS: Thank you, Mr. Chairman.

CHAIRMAN JACZKO: Commissioner Magwood.

COMMISSIONER MAGWOOD: Thank you, Mr. Chairman. Let me echo Commissioner Svinicki's thanks to you personally and to the committee. I think that obviously, you know, the Nuclear Regulatory Commission is not populated with a lot of medical doctors and physicians, so your advice is extremely valuable and I appreciate what you've done for us and take your advice quite seriously. Let me -- I'm not sure I have a question for Dr. Mattmuller, but I just want a chance to pontificate a little bit on the moly-99 crisis. The fact is this is a crisis that's been on the way for 10 or 15 years, and many people have spoken up about it over the years, and, you know, unfortunately, the pleas have fallen on deaf ears, and here we are. And it's a bit frustrating now to see the calendar you put up with people who are not able to obtain the therapy or the diagnosis that they need.

I visited facilities in Pittsburgh a few weeks ago, and I was talking to the personnel up there, and they were telling me, you know, that they had to turn, literally turn people away, that people were not able to get these treatments or these diagnosis and that's just really a very embarrassing, unfortunate turn of events. That said, I recognize that there are industry initiatives, and you've listed a few that are underway to try to develop, I think you used the word unconventional approaches to producing moly-99. And, I just want to sort of put the cautionary note out that this is not a crisis that certainly NRC has created.

And, these technologies are going to require significant analysis. There's a lot of questions that have to be asked and answered. So I just wanted to caution -- don't think -- I think the agency's going to move as quickly as it can to deal with this, but we're not going to take any shortcuts either. So just recognize it, despite the crisis, despite the fact this has happened, we're not in a position to short circuit what we do in ensuring public health and safety to make this crisis go away, so I just wanted to make sure that that's clearly understood. So, again, look, I appreciate what your comments to them, I'm happy that you -- please continue to bring it up and please continue to tell others about this, because this is a very important issue.

The -- I have a -- I wanted to ask a couple of questions to Dr. Welsh. First, welcome back. You've appeared before us earlier this year and this issue of medical events is something that's, we've -- I guess we've talked about for quite some time since I've been here. It seems like -- I've only been here for six and a half months, but this issue seems like it's been with me a lot longer, somehow. And, you know, I appreciate the conversation you had with my colleague, Commissioner Apostolakis, although I have to admit, I was a little afraid, Commissioner, that you were going to suggest we create HRA analyses for medical events and create PRAs for medical procedures, but you fell short of that, but --

COMMISSIONER APOSTOLAKIS: It's too soon, Commissioner.

[laughter]

COMMISSIONER MAGWOOD: But, and I appreciate, you know, the interest in getting the denominators, but the nature of this information, I would think, is such that it would not be difficult for agencies outside of NRC to obtain

the information on an anonymous basis, because you're just looking for the denominator. You're not looking for a lot of specifics. Is there no way that the societies couldn't collect this information and make it available?

DR. WELSH: We've discussed this at an ASCMUI meeting recently, and we've learned that there are organizations that do collect this information. The question comes about how do they get the information, how accurate is the information, and are there ways that it can be easily obtained by the NRC itself. We discussed various solutions, and I believe that a solution has been obtained that will be announced today, and that one of the organizations that collects the data may sell the data for $1,000 to the NRC. I don't know if that's the exact solution, but I look forward to hearing about that this afternoon, and I believe that this problem may be solved in part.

COMMISSIONER MAGWOOD: Well, that's good news, although I'm not sure we have $1,000 to spend on that, but --

[laughter]

COMMISSIONER MAGWOOD: We'll have to look at the budget, Mr. Chairman, and see what's possible there. Let's see -- well, my time is up. I did want to just very quickly, to Dr. Thomadsen, this issue of medical events, and I'd appreciate your comments about collecting this error information, but I mean, to some degree I feel like we're rearranging deck chairs on the Titanic with this, because you're collecting -- you want to collect this information, but there seems to me there's a major debate out there about what actually is an error. And I think that that's something that clearly has been discussed before this Commission, and I consider it to be something of an open issue that we still have to work through. So -- but before -- I think before I give a lot of thought to what

your comments about creating this database, I'd like to understand whether we can reach some resolution on understanding what is a medical event. You know, what should be called a medical event? Whether we should we even be using that term? And then once we decide on that I think it'll be a lot easier to collect the information you're talking about. Thank you, Mr. Chairman.

CHAIRMAN JACZKO: Commissioner Ostendorff.

COMMISSIONER OSTENDORFF: Thanks, Mr. Chairman. I want to start off by saying I really appreciate how clear each of you have been in your presentations, so that we understand your positions. In some cases we may agree, some cases we may not agree, but it's very helpful as a Commissioner to clearly understand where you are, so I just want to thank the group for that.

I wanted to turn, Dr. Langhorst, to your area first if we could and discuss the patient release criteria. I had a good friend who had thyroid cancer, and she had gone through treatment about a year ago, and I've talked in detail to her. She had shared with me her patient release instructions, as she was coming out of the hospital, to some length and had a chance similar to Commissioner Magwood, to go to the University of Pittsburgh Medical Center and Cindy Carpenter is back there. We went there in July, and we spent some time in the various clinics, looking at the Gamma knives and the various radioisotope treatment protocols, and read the instructions that were given to patients who had had iodine 131 treatment, and those two data points from my friend and from the instructions that we read personally, that one, in just one hospital, the instructions were very clear. I thought unambiguous and clearly talked about the issues, and I know in your slides you talked about patient release instructions. Is there a benefit or should there be further standardization

of at least maybe putting out the best practices of instructions for the community? And if so is that best done by the medical practitioners or what might the NRC's role be in such effort?

DR. LANGHORST: Well, we believe that the NRC can help support that effort. Now, whether it is NRC exact guidance or support of groups trained to put out those best practices, that gets more consistent information out to both our patients who may not remember everything that they have been told. They have the written instructions, but if they have other avenues to go to confirm that, that helps them in their understanding and belief of what they're being asked to do and how that helps their family members to minimize their dose to their family.

COMMISSIONER OSTENDORFF: I think I clearly have your message on the health impacts to the non-patient in these situations and I just want to make sure I'm not putting words in your mouth, but as I'm understanding from your presentation, your slides, you're not seeing that there's any untoward negative health impact on family members or others in association -- who are associated with the patient by physical location or a proximity upon release. Is that a fair interpretation of your slides?

DR. LANGHORST: We think that there is more data that can be gathered to see exactly how these precautions are exercised and what effect they have, and so that can help us identify those areas where maybe there is better guidance needed, better, more consistent precautions given for the case of a patient being released to a non-private residence. One of our former colleagues, Dr. Richard Vetter, has worked with a group and is gathering information from patients to determine their behavior and their understanding and

comprehension of these. And, for instance, in a report that he gave this summer at the Health Physics Society, their initial results showed that 94 percent of the patients go to private residences and maybe four may go -- four percent may go to hotels. I think there's more scientifically-based data that could be gathered on this type of patient precautions, so that we understand better how best to help in those endeavors for them to get this medical treatment and to keep their families safe and minimize their dose to as low as reasonably achievable.

COMMISSIONER OSTENDORFF: Thank you. Thank you, Chairman.

DR. LANGHORST: Thank you.

CHAIRMAN JACZKO: Well, I appreciate Commissioner Ostendorff's questions, and I think I certainly would be supportive of efforts to try and gain some more data here, and I think, I've never had a medical procedure like this. I've had other medical procedures, and whether it's a broken bone or whatever, you get lots of instructions, and it's never easy to follow those instructions. You know, I always find I forget when I'm supposed to do certain things, and then you go back and refer to things that didn't seem as clear. You never remember exactly what the doctor told you, and here we have a very different situation, because in this case a lot of the instructions really effect the health and safety of family members, not really the individual patient him or herself. So I certainly think it's an area where we should at a minimum take a look at some better data and see if, in fact, patients are following the instructions to the extent that we can. I think that would be very valuable for us and provide good insight into whether the approach we've taken, which to some extent I think has always put a bit of responsibility on the patient to maintain the ALARA and

given that they may be experiencing lots of challenges because of the procedure, physically, emotionally, or whatever they may be, that may be a difficult burden for the patient. So I certainly think this is an area where we can continue to look. I know in the past the Commission has taken a look at this and I think had a discussion, and even voted on this I think several years ago, about 10 years ago, about whether or not there should be reporting requirements on some cases in particular where high doses may have been received by family members generally exceeding I think five rem was the standard they were looking at at the time. I don't know if you have thoughts on that reporting requirement, what you think that would be.

DR. LANGHORST: Well, I think another use of this type of data can help physicians to assess whether this patient is understanding, whether this patient's caregivers, family members can support this and whether release of that patient is reasonable or maybe not. So I think that that would help physicians in getting that message across and assessing where a patient is in regard to being able to understand and follow those precautions.

CHAIRMAN JACZKO: Well, I appreciate that, and I certainly would be very supportive of efforts to collect that data. We can always -- I think we can never have enough data to make good decisions. One of the issues that's tied up in this patient release issue as well as perhaps the confusion right now about what the dose limits in our regulations mean. I think we generally have a 500 MR limit. It's perhaps not clear whether that's a per treatment or per -- and per year dose on it. I don't know if you or anyone else on the committee has a thought on what you think that is or what you think it should be.

DR. LANGHORST: We believe that it is a per-release does limit and should remain that way.

CHAIRMAN JACZKO: Okay, thanks. Turning to this issue of reporting a little bit, I perhaps have a slightly stronger reaction to the statement, and perhaps it's not geared or directed towards the NRC about that the regulatory culture needs to shift from punishing errors to making radiation -- radio therapy safer. I think that was your comment. I would say that certainly I would hope that this Agency's not in the business of punishing errors. I think -- I would take some strong opposition to that statement that that's what we do as an Agency. Again, that may not have been necessarily directed at the NRC. But I think we're in the business of holding people accountable, and we do that because we think that's the best way to achieve safety. And our focus in our statutory requirement is ultimately on public health and safety. That's really all it is. It's not a -- it's not about trying to find people and punish them or -- when they make mistakes.

One of the challenges, and I think as Commissioner Apostolakis raised, in the medical events area is that most of the incidents are human performance errors. That seems to be the trend that I've seen from the time that I've been on this Commission. So, it is an area in which the accountability often does rest with practitioners and so it does present unique challenges in terms of how we go about our approaches for dealing with those and holding people accountable ultimately to ensure safety.

So, I don't think you necessarily meant it in that way. I think I understand the point of what you were saying was that we -- we want to try and find ways to get people to bring information to light so that ultimately we can get -

- we can make the kind of safety enhancements we need. I think you pointed to the airline industry as one model. Again, I would say, in this Agency, throughout all the industries that we regulate, I think we have a different model, and I think it's a model that's worked perhaps as well, or perhaps even better than what's been done in the aviation area. So, I think it's one that -- I think there are ways to achieve the same thing but again that -- you know, they require some kind of reporting, but I think we can do that in a way that's not punishing but that does get the information we need to do the things we do.

Again, I appreciate everybody's comments, and I think this committee, as several have said, is extremely valuable to us because this is an area of practice for which few of us have any personal expertise, and so your insight is extremely valuable as we carry on in trying to put in place the right kind of regulations to ensure public health and safety. So, thank you very much for your presentations.

CHAIRMAN JACZKO: Well, if you all will please come up, we'll get started with our second panel. You've got to go with wherever your name tag is.

[laughter]

Well, thanks. Well, now we'll start our second panel. We have David Walter who is the incoming chair of the Organization of Agreement States. He'll talk about NRC's Part 35 efforts. Then we'll hear from Jennifer Elee who's on the Committee on Radiation Medical Events at the CRCPD and Environmental Scientists, with Louisiana Emergency and Radiological Services Division. She'll talk about her efforts to develop a national database for medical event reporting. Then we'll hear from Gary Bloom, who's the executive director of the Thyroid Cancer Survivors' Association, followed by Dr. Richard Wahl, who

is a member of the Society of Nuclear Medicine and with the Johns Hopkins University Hospital and he'll talk about the medical isotope shortages and releases of patients with Iodine 131 treatments. And then finally we'll hear from Dr. Tony Seibert who is the president-elect of the American Association of Physicists in Medicine and with the Radiology Department at the UC Davis Medical Center. So we begin Mr. Walter.

MR. WALTER: Thank you, Mr. Chairman, and I'd like to also express my appreciation to all of the Commission for allowing us to come in and speak to you on Part 35. I don't believe any of the topics that I'm going to discuss today are going to take anybody by surprise. This rule has been a quite open rule for a number of years, and people know pretty much exactly where we've been looking and what we've been trying to fix.

But the OAS would like to offer some comments on three specific topics and areas of the rule. The first is training and experience. What we would like to see is to simplify the rule and by simplifying it we might -- you might consider a set of national standardized radiation safety examinations; in particular, for the authorized users and for radiation safety officers. These can be set up similarly to what we already have in place for industrial radiography, in that there are three exams. And that all depends on what the candidate wishes to be able to do when they successfully complete the exam -- use radioactive materials only, use X-ray only, or use both. So, for example, the authorized user exam questions could be designed for the current 35, 100, 200, and 300, 400 and 600 uses. Now, it may take a bit longer to develop and implement such a program, but this keeps us in the radiation safety area and gives us, as

regulators, verification that an individual has adequate radiation safety knowledge.

The second is medical events. Authorized users have and will continue to provide a written directive that specifies a radiation dose to a target in volume and may not even consider the activity needed to perform that procedure. It's quite possible to have a less than 20 percent error in the activity but a greater than 20 percent error in the dose. Activity and dose do not directly relate in the majority of these brachytherapy procedures. Time and distance or the placement of the source must also be included in any calculations to determine the target volume dose. And we feel that the placement of the sources relative to the target volume is at least as crucial as how many sources or how much activity is use -- excuse me -- used.

And the third area I wanted to touch on was patient release, and we would say that you should start with the current rule. We don't believe that the old rule, as simplistic as it was, and a go/no-go situation as it was, is proper for our current medical situations and uses that we have these days. But we would ask that you would consider including sections that allow some amount of responsibility for radiation safety issues after the patient is released to remain with the licensee. Now, some examples might include holding the licensee responsible for the proper disposable of radioactive waste that gets into the solid waste stream and can be traced back to the licensee. And that is quite easy to do. For those of who have been doing this for a number of years, we can attest to the fact that it's not that hard to find out. Another one would be notifying the NRC if a licensee discovers that a released patient has died, and that it is possible that an individual could receive exposures in excess of 5 millisieverts as

a result of being exposed to the deceased body. A third might be notifying the NRC if a patient departs prior to an authorized release. The patient is not in prison and if they choose to step out, the licensee would have to have some way of keeping them in. Well, the rules don't talk about that so they might have to pass that on to the regulator for some help in that. Many of us in our states, for instance, are parts of health departments and we have the ability to do something about that. And then last you might also want to consider notifying or being -- putting some kind of requirement into the licensees to document the housing arrangements for those patients who are released so that you'll have that data that was being discussed earlier.

Now, I realize that these are only three issues and these are just the three that I chose to cover in this short time frame, and I do want to thank the Commission again for the chance to talk to you, and I want you to understand and hope that you understand the OAS stands ready and willing and always to stand as partners in helping you and working with you in putting together any regulations. Thank you.

CHAIRMAN JACZKO: Ms. Elee?

MS. ELEE: I also would like to thank you for the opportunity to speak with you today. I can go to my first slide. And the next slide.

Why are -- why is the conference CRCPD interested in medical advance? We represent state and local radiation programs and we do feel we could host a database for these medical events. We know that state programs already receive and evaluate reports of medical events, not only from radioactive material but also from diagnostic x ray and therapeutic x ray. We do -- many

states license and approve physicists, therapists and physicians and we do track compliance as part of the regulatory inspection.

What have we done? The next slide please. The committee, we conducted an initial survey of states. We've had a special interest meeting and a follow-up survey based on some of the information that came out of the special interest meeting and additional information that we've discussed at several committee meetings and conference calls that we've had.

Next slide, please. Our initial survey results, we had responses from 29 states. This was a very short overview survey and what we found was that 79 percent of those 29 states had adopted regulations similar to the suggested state regulations for linear accelerators and 70 had adopted regulations similar to our medical therapy suggested state regulations. At the time we were looking at the medical therapies since that was the focus of the issue then. And since then, you know, things have moved forward in different directions.

At our special interest meeting, at which we held in Rhode Island, at our annual meeting and many of your staff were there, we discussed what would the states and/or facilities be willing to report into a database, what current databases are out there, and how could they coincide? Could we take data-- you know, data from what we already have and somehow incorporate it all together so we have a single repository for this data. And would we be collecting for regulatory or best practice purposes? And with that, we did a follow up survey. We had 37 responses from the states, LA County and New York City. And we actually have two states that do not have radiation programs so we can account for 39 responses. And what we found when we asked the generic question was

about do you have reporting requirements for medical events material or machine based, that 97 percent had something in place for one or the other or both. Ninety-two had reporting for RAM based therapy radiation medical events, and 81 percent for diagnostic medical events involving radioactive material. Next slide.

We found when we got into the machine area, though, things were a little different. Eighty-three percent had reporting for machine based therapy radiation events, and approximately 130 events had been reported since January of 2009. And we did find that the regulations are fairly consistent with the suggested state regulations for therapy for radiation machines. Next slide, please.

For diagnostic, we had a significant drop off. And about 43 percent of the states that responded had something in place for reporting for diagnostic x-ray radiation event reporting. This would be something similar to the CT brain profusion events that have been in the press lately. And we've actually had only 53 events documented by the states since January of 2009. And there are significantly more diagnostic x-ray units than there are therapy units. So, there's a big -- big gap there. And the regulations from state to state are not as consistent for what they require to be reported. We also found that of the states and local entities responding, 30 percent make them easily available to the general public. Some states, you can actually go to the state website and you can see the events that occurred in that state and read about them. Some do an annual summary report that is posted on their website. And a lot of the other states do have methods in place for you to get the information although it is

somewhat more cumbersome through a FOIA request of something of that nature. Next slide.

So where are we now? We have developed a draft definition for machine based radiation which includes therapy and diagnostic. We've held several conference calls and participated in many outreach meetings, and I believe you did receive a copy of that definition as part of your written material. So, next slide.

Where we plan to go from here is we are looking at a reporting form -- developing a reporting form that we could use for our database. And we would like -- we are looking at the NMED information, we are looking at the FDA Maude database reporting form, trying to find something that there is some commonality between the forms so that even if we don't have a single -- we would like to have a single repository at least where we could draw from these other databases to include that information as well as the information that's not being collected. So, we are also looking at expanding our definition to include radioactive materials. We started with machines because we knew there wasn't a definition for machines whereas NMED and the Nuclear Regulatory Commission does have information available for radioactive materials. So, we would like to incorporate that into our definition. So that's kind of where we would like to move next and we're also looking at, you know, what would it take to develop, house and man this database at CRCPD.

And, in summary, we do want to provide a single point for states and facilities to enter events, and we are willing to work with the states and our federal partners and other experts to analyze the data when it comes in and provide timely notices and additional information to the community on the events.

CHAIRMAN JACZKO: Thank you. Mr. Bloom?

MR. BLOOM: Good morning. I'd like to also thank you all for allowing me to present here this morning. I've come here on behalf of thyroid cancer survivors, everywhere. I'm the executive director of ThyCa: Thyroid Cancer Survivors' Association. We're a nonprofit organization, representing more than 22,000 people dealing with a thyroid cancer diagnosis, and we are advised by the leading medical experts in thyroid cancer management in the United States. I also come to you as a thyroid cancer survivor, someone who has had five treatment doses of radioactive iodine within a three year period beginning in 1996.

As I begin, I would like to thank James Leuhman, one of this morning's speakers, who participated at this year's 13th International Thyroid Cancer Survivors' Conference, on behalf of the NRC. Thank you. Next slide.

Why am I here? Based on discussions -- excuse me, next slide -- based on discussions at the just completed Thyroid Cancer Survivors' Conference, we would like you to consider some of the following questions. What instructions are patients given before receiving radioactive iodine? Are the instructions given both orally and in writing? Do the instructions account for potential language barriers? Do they account for someone reading at or below a sixth grade reading level? Do they account for the fact that the patient may be significantly hypothyroid, making processing of instructions difficult or impossible? Who is released after radioactive iodine? How quickly and after what dose? How does the dosing hospital determine who is safe to discharge after what dosing or do they simply discharge everyone shortly after the dosing has been given? Does a dosing facility thoroughly examine the patient's home

set up? Is there a spare bedroom to go to? Is there an extra bathroom, one that no one else will use for a period of days? Does the patient drive herself home or does she take public transportation thereby exposing others to the radiation she will emit? Does she go home and risk exposing family members or does she go to a hotel and expose unwitting staff and guests, including the room's next occupant? Next slide please.

What resolution would ThyCa like? ThyCa does not advocate that everyone treated with radioactive iodine need be isolated for one to three nights after a dosing. However, dosing facilities need to adhere to standard instructions in evaluating who can and can't be released from the dosing facility, including taking into account where the patient will reside post-treatment as well as how this person will get to those sleep quarters, thereby addressing the issues of private housing and transportation versus commercial. Each dosing facility can't impose its own standard above the minimum which we as part of ThyCa hear about all too often, now. Next slide please.

With regard to the issue of taking radioactive iodine and vomiting, ThyCa recently developed an online survey. This survey was presented to approximately 15,000 thyroid cancer survivors. Approximately 2,420 thyroid cancer survivors participated. Of the survey participants, 1,551 had at least one out patient radioactive iodine treatment. Of those treated, 147 of the 1,483 who answered the question regarding vomiting had experienced vomiting. That's about 10 percent. And 67 of those participants who had vomiting did so within the first four hours. That's almost five percent. Next slide please.

Presently, many facilities are releasing all of their patients shortly after they receive radioactive iodine. A compromise between this near

immediate release and isolating overnight or longer is holding patients for a period of hours before releasing to ensure no nausea and/or vomiting. For most patients, holding the patient for three to four hours will ensure that the radioactive iodine has been absorbed. Use of antiemetics should also be considered. NCRP155 addresses this very option. Slide 10 please.

Oh, excuse me, next slide. It is time for action. It's time to update the standard written instructions regarding patient release and public safety to be at or below a sixth grade reading level, to make it easier for the patient to read and understand. Additionally, develop a script for oral instructions regarding patient release and public safety because this redundant effort is absolutely necessary. Make the oral and written instructions available in a number of languages. Consider the level of understanding, keeping in mind that the patient may be extremely hypothyroid. Require all dosing facilities to use the same baseline standards. Next slide please.

In closing, I invite all of you present as well as all interested parties to join us at next year's 14th International Thyroid Cancer Survivors Conference in Los Angeles, California, the weekend of the 14th through 16th of October. This would be a great opportunity for you all to hear about the concerns and experiences of hundreds of people regarding their radioactive iodine journeys and rather than us presenting anecdotal information here today. And finally, I'd like to thank you all for the opportunity to present this morning as well as for your attention to this matter. Thank you.

CHAIRMAN JACZKO: Thank you. I will now turn to Dr. Wahl.

DR. WAHL: Thank you, Mr. Chairman, Commissioners, staff, the public. I appreciate the opportunity to address you on -- as a representative of the Society of Nuclear Medicine. Next slide, please.

As background, the Society of Nuclear Medicine was founded in 1954. It's the largest international scientific organization dedicated to radiopharmaceutical imaging and therapy. It's a multidisciplinary organization with physicians, scientists, pharmacists and technologists, and again, dealing with both diagnostic and therapeutic issues. Next, please.

A slide briefly describing my background. I'm a radiologist and nuclear medicine physician. I'm director of nuclear medicine at Johns Hopkins Hospital, and in that capacity, I see patients on a regular basis who need diagnostic scans with technetium, who need radiopharmaceutical therapy, both inpatient and outpatient, and to counsel those patients before and after the therapies, and also supervise a staff of around 100 -- over100 people who are radiation workers who are subject to the radiation rules which will be discussed today. And so I have some exposure, so to speak, to all of these areas. Next slide, please.

So, it was well covered in Dr. Mattmuller's comments that the medical isotope shortage has seriously disrupted patient care in the U.S. and other parts of the world, and I think that it's important to know from a physician and patient perspective, that if you can't get your scan, you may have an invasive procedure, you may have the wrong procedure, the health outcomes can be unexpected, you may have surgery unnecessarily, cardiac caths can occur -- these are major issues. And giving -- if there's a limited supply but not enough supply, you may end up giving too low a dose of radiation to patients for imaging

and the scans may be compromised in their quality. Or alternatively we may have to substitute radiopharmaceuticals with longer half lives which will give the patient more radiation but perhaps a less good diagnostic study. So, clearly we need to have the radiopharmaceuticals, the technetium available, and I think you know that the reactors that we depend on are non-domestic and they are quite ancient, they could quit working at anytime and we realize this is not the NRC's fault, but we are hopeful that, as back up plans become available that with the appropriate balance between safety and efficacy, that the regulatory process can move forward. Because many patients have already suffered and I'm sure will continue to suffer from this deficit in technetium.

As far as patient release criteria, the -- I have treated many -- I mean, hundreds of patients as inpatients, and actually, hundreds as outpatients and the current regulations allow patients to be released after we determine that it's appropriate -- that with appropriate safety instructions and restrictions given by medical professionals that it is feasible -- certainly not always the case -- that patients are discharged in centers that carefully assess these data. And there's a lot of peer-reviewed data that we can calculate half lives and disappearance rates of radioactivity and with appropriate education and evidence from family member studies, control the radiation risk to bystanders and that this risk is really not an excessive risk at all.

So, the consequences of changing the release criteria to make patient access less good for the therapies and require more in patient therapies, potentially would be some radioactive therapies couldn't be available because facilities don't exist. Certainly, health care costs could be driven up, a potential for multiple low does therapies in thyroid cancer where somebody might get four

or five doses when, in fact, one larger dose could have been given which could have been driven by an artificial 30 millicurie rule could potentially compromise care. And this is an important set of issues. One other risk is of course, being in a hospital isn't the safest place and there are antibody resistant bacteria and people are at risk in the hospital, and you expose healthcare workers unnecessarily. So, we believe, even data presented last week at the European Association Nuclear Medicine Support the fact that outpatient therapy is quite safe if patients are properly educated and all data are taken into consideration.

Radiation worker exposure. The current rules allow radiation workers in medicine to safely and cost effectively deliver medical procedures including with radiopharmaceuticals to patients with cancer, heart disease and so on. The ALARA concept is in place and universally applied in the U.S. Sometimes -- and data keep coming out on this -- people who are really sick and need our scans most are the ones where we have to spend the most time with them and as radiation workers, we may have the greatest exposure. So the sickest patients who need our scans most may result in high exposure. Just last week I had a patient who had a very severe respiratory problem which necessitated additional care and time with the patient. In this particular instance, we were fortunate, we had not yet given the radioactive drug but had the patient been radioactive, the dose rate to the staff would have been driven up, and this can happen in hospitals. Not everybody can be done in a routine way. So, we have to be able to have workers on occasion have little higher exposure than the proposed reduction to 20 millisieverts. So, we believe -- the SNM believes that the current safe exposure limit of 50 millisieverts per year is appropriate.

So, I'd like to summarize by saying a reliable domestic supply of Tc-99m is essential for the 16 million scans that are hopefully going to be done in the U.S. a year, and we ask the NRC to help facilitate the regulatory process for this, yet do it safely; that patients must have access to radiopharmaceutical therapies. The alternatives include surgery and are not sometimes as appropriate. The current guidelines of practice are appropriately safe. And the current guidelines are appropriate and radiation exposure is an essential part for radiation workers and the current guidelines are also, in our estimation, appropriate. Thank you.

CHAIRMAN JACZKO: Thank you. Dr. -- is it --

DR. SEIBERT: Seibert.

CHAIRMAN JACZKO: Seibert.

DR. SEIBERT: Dr. Seibert. Thank you, Mr. Chairman, Commissioners, NRC staff, and attendees this morning. I represent the AAPM which is the premiere organization in medical physics whose mission is to advance the science, education and professional practice of medical physics. We represent over 7,300 medical physicists. There are medical physicists outside of the AAPM, but we represent the majority.

I'd like to comment on four items that are really important the AAPM. First, is event reporting. We've already heard a lot about the event reporting issues earlier this morning. It's a really important thing that we have a national system. We believe it's very essential. It must be modality independent; it must be easy to use, universal, anonymous and non-punitive. It must be able to collect potential and actual event data, completely and efficiently. Data on medical errors is essential to conduct a trend analysis -- we've already heard

about some of those issues -- make assessments, inform the community and make improvements. Reflective of the testimony provided to Congress by our president Mike Herman in February, we continue to reach out to other societies and regulatory agencies such as the NRC as well as Congressional staff regarding the design and concept of a national reporting system. For example, yesterday, October 19, an all day meeting that was sponsored by the foundation for the National Institutes of Health and co-organized by the AAPM, brought these stakeholders together to discuss these important issues.

And thinking about important issues one of the things is that the Nuclear Materials Event Database -- next slide please -- is one of those areas where we think improvements could be made and we've already heard about a lot of those improvements. First of all, it's not really, truly, publicly accessible. It requires a Freedom of Information Act to request information that exists on the current database. It only includes radioactive materials; we think it should be -- well, at least for the overall, overarching, thing -- totally expanded. And it doesn't currently allow for trend analysis. We've already talked about the normalization issues and the lack of a denominator. We think that that's a really important issue that needs to be taken care of. Also, the taxonomy issue. Dr. Thomadsen, earlier, talked about taxonomy and there has been an official effort that has been implemented within the AAPM as a working group on the prevention of errors task group. So, we are moving forward on developing some taxonomy issues that are important we believe.

The next issue that we'd like to cover is the Ritenour Petition PRM-3520. This was filed on September 10 2006, by the AAPM. And in this situation it was initially published in a Federal Register in 2006, November. The decision

was published on May 2008 and what it entails is the request for the certifying boards for information before regulatory basis, which was closed in January, 2009. The whole purpose of this particular petition is to revise the grandfather provision of Part 35 to recognize individual diplomats of certifying boards that were previously named in Part 35 prior to October 25, 2005. Next slide, please.

The NRC prepared a Regulatory Basis document and it was reviewed by rule-making staff and found to be sound. The issue is that without a regulatory change, which continues to be in limbo, this continues to be a problem for listing authorized medical physicists for radiation and radiation safety officers, authorized users and authorized nuclear pharmacists. We believe it affects negatively on approximately 2,000 authorized medical physicists and, four years later, we still do not have final regulatory solution. And we urge the NRC to take action in finalizing this regulatory change as the impact is significant on many individuals and sites. Obviously there were some other mitigating circumstances; VA issues and things that have stopped some of that progress. We recognize that.

The final issue that I would like to talk about is the isotope shortage that we've already heard a lot about. There needs to be a continuous and reliable supply of medical radioisotopes. The AAPM supports the American Medical Isotope Production Act of 2010 and, as we've heard from my colleagues on this panel and on the previous panel, that without a reliable supply of technetium-99 use of alternate radioisotopes can result in increased occupational doses to technologists and may not result in the gold standard of care being available for all patients. There's been changes in practices and an inability to really deliver appropriate medical care. Next slide.

The AAPM would like to acknowledge the NRC's efforts in this area and urges the NRC to expedite licensing actions for new facilities to produce a U.S. medical supply of isotopes.

So, in summary, I'd like to thank you all for the opportunity to brief you on these important issues and also for extending the comment period on both the 10 CFR Part 37 proposed rule and its draft guidance document. We really appreciate that. And thank you for listening to our information and desires. Thanks.

CHAIRMAN JACZKO: Thank you. We'll start with Commissioner Svinicki.

COMMSSIONER SVINICKI: Thank you all for your presentations. I know that you were asked here today and given a limited time and directed specific topics to talk about, but on my time I would like to ask, as you sat and listened to the previous panel are there anything you heard in the presentations or the Q and A that you'd like to offer an additional or different perspective on? I would just offer that if there was anything noteworthy. Yes, Mr. Walter?

MR. WALTER: Yes. One of the items that was discussed earlier had to do with whether or not there should be a single rulemaking process or should we break out some of the areas and try and expedite those. I agree that expedition is really good, however, it might -- in my mind I see it as being a little bit better if we can put them together so that you can make sure that they all meld together properly. I know that there's always communication, but there's always, always communication problems as well. And I believe that if you put one rulemaking together it will be a more coherent rule than if you were to try and break it up.

COMMSSIONER SVINICKI: And I think as a general principle I wouldn't offer any argument with that. I will confess though that it was actually the Ritenour Petition that was the motivation behind that question when we have -- that seems to me to be an area that has not necessarily got a tremendous -- you know, doesn't implicate other parts of that rulemaking. And so, that really, although I didn't identify it to the previous panel, that was, in looking at that history where it seemed like there was general agreement, perhaps, on a path forward on that that now is paced along with 27 other issues to be resolved.

DR. SEIBERT: Sure. Sure. And it is an issue and, of course, once it gets into the process it continues to take a significant period of time after the fact that it already has been initiated. And when there is general agreement it just seems to us that things need to move forward. And we understand that there are other mitigating circumstances and other things that are going on, but it would be really nice to be able to smooth that process.

COMMSSIONER SVINICKI: Yeah, and as I've said, I don't know the perfect answer and the answer is probably different depending on the issue. I know that the NRC staff certainly struggles in making these recommendations as to whether to join these issues or to do separate rulemakings. And I'm guided in cases by their expert judgment on that point.

I did want to ask Mr. Walter about on the patient release topic. You had mentioned the experience of the states and how often the radiation expertise is part of a health department and you said in patients leaving prior to authorized release at the state level there are sometimes -- I think your exact term was, "Something we can do about this." But you did mention that these patients, of course, are not confined against their will. What does the state do or what is the

experience there? Is it just that you intervene to try to talk somebody out of it or what do you do?

MR. WALTER: Well, ultimately the health department has quarantine capabilities if necessary. If we feel that there is a public health and safety risk as a result of this patient being released then we can quarantine them to their own home and make sure that they stay there.

COMMSSIONER SVINICKI: Have you done -- I mean, is that done?

MR. WALKER: We have not had to do that as of yet. We have not have to do that it's just a power that we do have in the health department. That may or may not be something that could be done with the NRC, although you would have to work with health departments of whatever states would be involved, I would assume, if that were the case. My biggest point that we have had in the past and we have been successful in doing is tracing where did this waste in the solid waste stream come from? Where, ultimately, was the patient dosed? It's not that hard to find in a bag of waste, as unpleasant as it is, to find the location from where that bag originated. And when you show up on their doorstep and you ask if there was anyone in the home that had a medical treatment in the last couple of weeks, the look on their face could be very interesting. But the problem that you find is that the medical waste -- well, it's not medical waste. The waste that is contaminated is going to a landfill that is expressly prohibited from receiving any radioactive materials.

Now, we have gotten together with our environmental management agency and have gotten approval to state that if we see no health and safety issues, no environmental issues, we can ask the landfill operator if they would be

willing to go ahead and bury that waste. They usually do. We've had only one time that they haven't. But they don't have to. It is not a public -- it's a privately owned landfill and so they don't have to do that. We as an agency don't have much space to put iodine waste, for instance, and decay it. So we would take it back to the licensee and ask for them to decay it in their regular waste stream. That's what I was talking about.

COMMSSIONER SVINICKI: Okay. Thank you. Thank you all for your presentations. Thanks, Mr. Chairman.

CHAIRMAN JACZKO: Mr. Apostolakis?

COMMISSIONER APOSTOLAKIS: I don't have any questions, Mr. Chairman. But I do want to thank the panel for a very interesting presentations. I mean I'm in a learning mode and I learned a lot from you. Thank you.

CHAIRMAN JACZKO: Commissioner Magwood?

COMMISSIONER MAGWOOD: Thanks, Mr. Chairman. Well, again, let me echo my colleagues in thanking all of you for coming here today. Your testimony is very, very important to us. I appreciate the time and effort to come here. Welcome back, Mr. Walter. Good to see you again. I think I'd like to chat with you offline about this at some length because you're actually moving in a direction I guess I wasn't quite prepared for. As you pointed out, patients are not prisoners. But I think the tenor of some of your comments with regard to tracking movements – I think that you are hinting that we should require licensees to even collect all waste products. I mean it's a very tight noose I think we're putting on the patients. And I guess I have to wonder if we're going to basically create a bubble around people as they are released to force them to do certain things and not do other things. And there's more of a strong-arm fashion

than what we currently have in place. The question I have to ask is why are we releasing them? I mean that's the first question that would come to my mind, personally. I'd like to sort of give you a chance to expand on some of those comments especially about tracking the movements. I'd like to understand exactly what you think we should do and what you think the states should do.

MR. WALTER: Okay. In the last -- well, I don't know if it's the last rewrite, but in the 2004 rewrite of Part G of the CRCPD suggested state regulations there were some additional sections that were suggested as possibilities, but were not required in the rule. And some of those -- well all of those addressed these issues that we're talking about. We didn't actually state that the licensee is responsible for tracking the individual at all times, we were only stating that if they became aware of something occurring. In the case of the waste, all the correct information was given to the patient. They were requested to keep the waste stream, the solid waste stream, of that patient separate from the rest of the household and to not dispose of it for 90 days. In August in Alabama, that's not going to happen [laughs]. They fully understood what was being said. They got home and they realized that that just wasn't going to work after a little less than a week. And so they didn't realize, not understanding radiation, really, not knowing that it was trackable, not knowing that there was going to be a landfill that was going to have a monitoring system that it was going to go to. They did what they felt was best for everyone involved and particularly for their noses and they got rid of it. And that's how it was tracked back.

We get calls on a fairly regular basis from landfills that have alarms that go off. And we do go and respond to them and try to identify what the isotope is. If it's iodine and it's a small amount in most cases we don't even try

and track where it came from because we can talk to the landfill operator and they will go ahead and dispose of it and bury it, and that's the end of it because we know that it's just going to decay away. Other isotopes we have found on rare occasions we don't feel quite as good about it. We have been able to do the -- run the numbers and say, "Okay, it's going to be a long time before this is going to get into the water table and there should not be any problem whatsoever. This'll be well-decayed out by that time." We've only had one or two times -- one particular instance an individual was also incontinent when they were released and also that same individual was undergoing -- what is it with the liver, the blood, when you're -- dialysis, thank you -- was undergoing dialysis at the same time. And so we traced back the dialysis center and found that they had some problems and we were able to get them to just segregate those filters and the filtrate so that they didn't go through the disposal company and be returned to them as well, because we knew they would in those cases. So there is a little bit of information out there that we've had to deal with and we all, in the states, are the ones that are dealing with this. And we're doing, I think, a very good job on it. It's just that if we don't have it in the rule that we can take this waste back to them we really haven't got a leg to stand on.

COMMISSIONER MAGWOOD: I appreciate that. Thank you for that. Again, I'd like to discuss this with you further at some point. Mr. Bloom, I wanted to ask you principally just more from a -- as you interact with patients who have been through these experiences, I wonder if you give us just a view as to whether, as you talk to people, it's clear that they give instructions, that they understand and what attitude they bring to those instructions. And then I'd like to give you a chance to sort of react to what you heard from Mr. Walter as well.

MR. BLOOM: They're given instructions. I'm not sure I can entirely agree. Not all do understand what the instructions are and that's why I brought up the idea of lowering the understanding bar down to a sixth grade level. Too often we find that people don't understand the instructions. Mr. Ostendorff -- excuse me, did I get that right? -- mentioned the example at the University of Pittsburgh, and a lot of what I hear about institutions of a larger size, absolutely great instructions. Problem is they're not all University of Pittsburgh or Sloan-Kettering and so on. The dosing facilities seem to have the ability to have an impact on what the instructions are. And, again, the language barrier is becoming more and more critical. We've probably had people who spoke 40 or 50 language with us this past weekend. And just in communicating with them it's very clear that they don't have an understanding of really what experience they were going through. And that's our concern. With regards to—are you saying with regards to waste, et cetera?

COMMISSIONER MAGWOOD: In patient movement particularly.

MR. BLOOM: I'm sorry?

COMMISSIONER MAGWOOD: In patient movement.

MR. BLOOM: Patient movement? Is that what you're saying? Do you mean as far as leaving the facility and going --

COMMISSIONER MAGWOOD: Well, we're sort of a little bit over our time. But I think the thrust is that we as regulators and the federal government and the states should do more to have licensees take a more proactive action to track patient movement to make sure we know where people are going and to also deal with the waste issue. Just curious to your reaction to all that.

MR. BLOOM: Again, when people leave the institution where they've been dosed, the theory is that they would have had a conversation as to where they are going. But many times, apparently, they are not asked how they are going to get there. We've had incidences of people leaving on a bus and actually vomiting on the bus. I would assert that's a problem after 150 millicurie dose of radioactive iodine. But they do leave and take public transportation because no one has informed them to be in a closed environment with re-circulating air could put others at risk.

COMMISSIONER MAGWOOD: I appreciate that. My time is up but I just wanted to welcome Dr. Wahl. We haven't met, but I've had a lot of interaction with the Society of Nuclear Medicine over the years and found their advice and counsel very important and they were always a good part of us at DOE. So, welcome. Thank you, Mr. Chairman.

CHAIRMAN JACZKO: Commissioner Ostendorff?

COMMISSIONER OSTENDORF: Thank you, Mr. Chairman. I want to kind of pick up real quick where Commissioner Magwood left off with Mr. Bloom. My wife's a public school special education teacher in the elementary schools in Fairfax County, Virginia. A very diverse area and because of the special education needs of her students she has to have a lot of interface with parents and the number of parents she interfaces with for whom English is not their native language is significant. So I really resonated with your comment on the languages as well as the oral and the grade level of the instructions. So thank you for providing that experience. And also thank you for coming today with your own personal experience and health issues. I think that really is significant for us.

MR. BLOOM: Thank you.

COMMISSIONER OSTENDORFF: Jennifer, is it Ehle?

MS. ELEE: Elee.

COMMISSIONER OSTENDORFF: Elee. I'm sorry. I had a chance to hear, soon after I got to the Commission in April at the Newport, Rhode Island at the CRCPD Conference about the efforts that you're undertaking for the medical event tracking in the database, and I want to applaud you and your team for what you've done there and I'm very encouraged by the level of effort and the progress that's being made. Just one question, is there any additional support that you need from the NRC in order to continue forward?

MS. ELEE: We do have a resource person on the committee and that's been very helpful. As we spoke yesterday with the FDA and FNIH group. CRCPD -- we want to move forward. We feel like there are certain things we can do and we're going to get to a point where we're going to need additional resources to do all that we would like to do.

COMMISSIONER OSTENDORFF: I want to turn to the medical isotope reactor question and I want to ask this question to both Doctor's Wahl and Seibert. And I know that prior panels had discussed the moly/technetium shortage and that was very helpful to have a concrete perspective on the shortages and the impacts it's having on medical practice. My colleagues have also noted that certainly as far as our regulatory responsibilities our staff is not going to cut any corners. We're going to complete a safe licensing process. That's our obligation to the American public.

I'm going to ask the question in that area from a little different perspective, though. You're both associated with major United States medical

centers in California and Maryland. You have a broad perspective, not just in your localities, but also across the country. We've had briefings, colleagues and I have as well, on proposed or potential applications that might come in for medical isotope reactor facilities. So my question is -- but we haven't seen an application yet. We can't act upon it and staff can't do anything until it arrives. Given the stark statements we've heard from both panels so far about the impact of these shortages of isotopes for medical and health care in the United States, from where you sit, is there adequate incentive to have a licensee come in and submit an application? And recognizing that we deal with the supply and demand as an economic factor here that no one's going to come in and submit an application if there's not an economic incentive to do so; that there's sufficient demand equation to drive that kind of action. Can you comment on that aspect from the medical community?

DR. WAHL: Well, I think that the cost of producing technetium -- if you want to talk about the economic and cost benefit, I haven't done the calculations, but just sort of the back of the envelope. You have 50 plus year old reactors that are fully depreciated and paid for that are generating molybdenum at a relatively low -- pretty much the cost of labor without the cost of the new investment. The new investment plus the regulatory costs, plus the operational costs would allow us to have the radiotracer, but the reimbursement for this drug, for these technetium agents, are pretty much based on the assumption that you have a reactor that was built 50 years ago and has fully depreciated and you're not paying for the reactor. So I worry that reimbursement rates for technetium as currently available probably are a deterrent to seeing a superb business model for this going forward because these are mainly -- many of these are generic

radiopharmaceuticals. So if you look at -- I haven't done numbers, but my expectation is that this isn't such a compelling business model with the big lead time to getting it going. I think it's a national issue, a societal issue that needs to be resolved where I don't know that the private sector is going to be able to step up and do it that easily. I know that efforts are ongoing, but there would have to be strong incentives to do so.

COMMISSIONER OSTENDORFF: Let me just make one point more clearly. I guess I'm trying to understand to what extent is there a clear demand signal to a B&W or a GE Hitachi from the medical community to move forward? I wouldn't expect you to have an economic analysis of building a reactor --

DR. WAHL: I mean if you have 16 million doses a year, that's a lot of doses. And then $16 million times what do you get per dose obviously would be the revenue stream. Unfortunately -- well, fortunately for healthcare delivery right now the costs have been quite low per dose of technetium because we have an infrastructure that was built many years ago, but to replace it it's a tough model based on the reimbursement.

DR. SEIBERT: There has been some technological advances, though, that will reduce the cost of being able to generate these molybdenum sources that will ultimately result in technetium 99m. I really can't speak to the number of doses. I really don't know. The business model's another question, but certainly there are hurdles in being able to cite these devices and to be able to take advantage of the licensing capabilities -- being able to smooth it through to be able to make it economically viable for these companies to undertake these issues. The fact is that there are two companies right now that are developing

some of these possibilities. So I know they've been looking at it from a business model and the likelihood of them moving forward is going to be dependent upon whether or not there will be a valid business model, and also looking at the costs of licensing, of citing, and all the hurdles they have to jump through. The technological advances are going to be really important for -- and the future supply of technetium is going to be really critically dependant, I think, on being able to establish these capabilities.

COMMISSIONER OSTENDORFF: Thank you. Thank you, Mr. Chairman.

CHAIRMAN JACZKO: I appreciate a lot of the discussion we've had about the patient release. It seems like, certainly from what I'm hearing from commissioners, there are certainly questions about the current system and if it's working I think the way that everything is intended. I would note, I think, Mr. Bloom, your slides made several statements about things that need to be done. Facilities need to adhere to standard instructions and questionnaires; facilities need to address the issues of private housing and transportation versus commercial. To some extent it just surprises me a little bit that maybe we haven't done that and that maybe we're in a place that we don't have clear answers to those questions. I think that's certainly something we would need to take a good solid look at, and make sure we do have the right system in place here.

MR BLOOM: Thank you.

CHAIRMAN JACZKO: I don't know, Dr. Wahl, you have experience with this. I don't know if you want to comment.

DR. WAHL: Well, I would say you just said that we hadn't done this and I would say that at least the practice of institutions and trainees that I've had

is that if you make an assessment on a patient for radiopharmaceutical therapy, the questions about can they comply with the instructions are key discussions that take place before a decisions is made as to whether they are suitable for radiopharmaceutical therapy. There may be patients who just can't follow instructions worth a darn who need to have surgery. And that's a decision you have to make medically. You have to weigh the different kinds of therapies. There may be individuals who are unable -- incontinent, who may need to be hospitalized because they can't comply with the rules as outlined right now. So our typical evaluation includes an assessment of whether they are suitable for radiopharmaceutical therapy, what kind of therapy, what's their living arrangement, can they follow these instructions, they receive written instructions and a certain fraction are not treated as outpatients. I think it is an individualized process and there are guidelines that have been put in place by professional organizations, written instructions. But I think there's always room for improvement and there's always room for tracking the process. The issue of vomiting, one we handle, is we keep our patients around for at least an hour after administration of radiopharmaceuticals orally, and for that very issue liquids are absorbed quite rapidly. The rate he described was only in patients who happened to respond. He said, "Just as an example," you didn't say, "All patients responded to that question."

So I think it's not peer reviewed and it wasn't the entire database and it's based on memory, but our experience is much less than the percentage you described. But I agree that proper instruction and asking the patients these questions is essential. And, of course, in Baltimore we care for patients from all over the world and if you can't understand the patient and the patient can't

understand you the fundamental issue is how can you deliver medical care let alone do a therapy? So you need translators and you need to be sure there's understanding and if there's not these patients just may not be suitable for outpatient therapy. But that is a medical decision has to be made as to whether it's appropriate and whether they're an appropriate patient to follow those instructions. And then, again, we've done some of this published on some of it, tracking the family members and making sure that your predictions are in fact accurate for family exposure is important. The issue of travel. I mean, I have had patients, just anecdotally, who have wanted to come in and be treated and the first question I say is, "Well, you're coming in from California. How are you -- what do you plan to do?" "I plan to get in a plane and fly out tomorrow." "No, you're not." That's not appropriate to the public. But these are the questions that have to get asked and I think that our societal guidelines are quite clear that they should be asked. Like any aspect in medical practice, could we do better? I think the answer is yes. Could we be more standard? Probably, yes. But I think these are key questions that have to be asked in a competent practice of medicine. Following those regulations, I think we do very well with the current rules and there are quantitative data to support that.

I also wanted to comment on the issue of receiving back of radioactive wastes from patients several weeks after we've treated them. This isn't obviously something -- my office doesn't actually have a space for that material either. So it's important to define the amount of radioactivity. You can have extremely sensitive radiation detectors that are put in place and if you have an extremely sensitive radiation detector you may detect microcuries or less of radioactivity and still get a signal. There's no public health issue with that, yet

sometimes these waste disposal facilities have very sensitive detectors. And I think -- I just want to make it clear that that may be overstated in some instances -- like we've had a radioactive diaper come back from someone who in the past who's been detected with just the smallest amount of radioactivity has been detected. And if they're very sensitive detectors then what you're doing is you're hauling around radioactive materials all around bringing it back so you can keep it away from people. If you think about the logic of that it's not so good.

So the other thing is 16 million or 20 million nuclear studies done a year you have the risk, in some instances with very sensitive detectors, of finding diagnostic doses of tracers that disappear in less than two hours. So, you know, one of the things about using nuclear techniques for producing energy and for taking care of patients is there is a risk benefit and we cannot absolutely do nuclear procedures of any type without having some measureable radiation and we have to think about the amount. And I do caution the issue of tracking. I think that's not a good place to go. It would have to be documented that there are large amounts escaping due to bad instructions or poor patient behavior for me to be convinced this is an issue because almost every instance I've heard of have been tremendously miniscule doses. Those are comments I thought I should make.

CHAIRMAN JACZKO: Well, I appreciate that. And I think it's certainly -- it seems clear that there's perhaps -- if nothing else this agency has a dearth of data really to, I think, at this point to accurately assess whether our regulations are accomplishing what we're intending to accomplish. And I think, Dr. Wahl, you certainly make a good case for the practice at Johns Hopkins. I don't know today that we can say that's a uniform practice. And that may be part

of the challenge that we're facing is the inconsistency in different facilities and the inconsistency in different individual cases. So I think at the minimum it seems like data here will only help. If I could just follow up one quick question with Ms Elee. I think you've touched on a little bit with Commissioner Ostendorff about the issue of resources. If I could maybe just clarify that a little bit. You were saying that you would be requesting financial resources from the NRC in order to develop this database? Is that --

MS. ELEE: Well, as we progress and we have had input from a lot of different agencies and organizations and states. CRCPD can do what we can do and if we want to do all that everyone would like for this to do then, yeah, it's going to require some financial resources, not just from NRC, but from other groups as well. And in addition to financial, expertise. If we want to analyze the data and give good information back then we all have to work together to come to what we feel the best conclusions are to -- so there's several different areas of resources we would need help with to progress in the way that it appears from yesterday's meeting, and what I've heard today, a lot of people would like us to move in that direction of being able to have everything in one place and look at things aggregately.

CHAIRMAN JACZKO: Well, I appreciate you clarifying that.

MS. ELEE: Yeah.

CHAIRMAN JACZKO: Again, I don't know if any comments or remarks. Well, again, I want to thank everybody for getting here and providing your information. We'll take a very short break and then hear from the staff.

[break]

CHAIRMAN JACZKO: We'll start with the staff presentations. You

want to begin?

MR. BORCHADT: All right, good morning. Dr. Josie Piccone and Jim Luehman will be doing the staff presentations this morning, but we also have two additional staff members at the table that I wanted to introduce.

To my far right is Ms. Neelam Bhalla. Neelam is the senior project manager and the lead staff member for the current effort to revise Part 35. And then to my left is Dr. Ron Zelac. Ron is the senior health physicist on our medical team. So Josie will begin the brief.

DR. PICCONE: Thanks, Bill. Good morning, Chairman and Commissioners. In my portion of the presentation, I'm going to start with a bit of a discussion on the more recent Part 35 revisions on the current rulemaking that's in process right now, on some of the high visibility issues in that rulemaking, and potential impacts on the current schedule.

Regarding Part 35 revisions, the regulations were revised in its entirety in 2002, and this revision was to focus on those medical procedures that pose the highest risk to workers, patients, and the public, and to make the rule more performance-based. In the 2002 Final Rule, Subpart (J), which was the existing training and experience requirements, were reinserted in the rule because staff determined that at that time only one of the certifying boards met the revised criteria for training and experience, which is why the training and experience regulations were then revised later in 2005.

Since the 2002 revision and the minor edits to that revision, there were eight additional Part 35 amendments. The most significant being the NARM Rule, which expanded the definition of byproduct material, to include naturally occurring and accelerator-produced material. Of these eight

amendments, however, three were direct final rules, which is our streamline process when there are issues that just involve clarifications to the rule, or very minor amendments to notifications, recognition of specialty boards, or other clarifications like that, or a simple administrative amendment to correct addresses or ensure Subpart (J) references were taken away. So there is a process to handle some of those simpler things in a more direct way. Agreement States have three years to adopt any revisions that we make to our regulations.

Turning to the current rulemaking, the items in the current rulemaking have been identified through implementation of Part 35 through ACMUI recommendations and through petition for rulemaking, some of which are heard from the previous panels. There are a total of 28 specific items or issues in the expanded Part 35 rulemaking, and it does not include the implant therapy medical event rulemaking.

There are a number of higher visibility issues in this proposed rulemaking. I've chosen four to do a bit of an expanded brief on this morning and based on whether or not there will be diverse views in these areas in the course of the rulemaking, both a diversity of views amongst our stakeholders, our co-regulators, and within NRC staff as well.

So I will talk about the request to amend the preceptor attestations. The Ritenour Petition regarding training and experience requirements, the frequency of testing for Molybdenum-99 contamination, and the naming of assistant or associate RSOs on a medical license.

The preceptor attestation revision involves a requirement in the regulations that there be a statement from a preceptor that an individual has satisfactorily completed the necessary training and experience requirements and

achieved a level of competency sufficient to function independently in the position for which authorization is sought. Amendment to this requirement has been proposed by the ACMUI in April 2008, and they cited that there may be some unintended consequences from this regulation from the reluctance of some preceptors to sign this attestation statement, and that it is being interpreted by some to mean “clinical competency,” even though that is not the intent of the NRC, but it is still being interpreted this way, and some preceptors feel that there is a liability if they sign these attestation statements. ACMUI indicated that this may result in a shortage of authorized users.

Prior to the 2005 training and experience revision, attestation, or this preceptor statement, was not required for board certified individuals. The staff provided the Commission recommendations in 2008, which were approved by the Commission, and these recommendations were to eliminate the requirement for all board certified individuals, to revise the wording on achievement of competency, and to allow residency program directors to provide these attestations.

Turning now to the Ritenour Petition. Dr. Ritenour, on behalf of the American Association of Physicists and Medicine, submitted a petition for rulemaking in September 2006, and I -- you’ve heard from the previous panel what that was. It’s primarily to request a change to the grandfather provision in the T&E requirements that were revised in 2005. Those requirements recognized certification before a certain a date -- October 2005, and also required that the individual be listed on a license, on an existing license.

So the issue is that there may be individuals who have had this certification prior to 2005 but were not listed as an authorized medical physicist

and RSO and authorized user prior to those revised regulations going into place, and in which case, they would then need to pursue the alternate pathway to become an authorized user. NRC resolved the petition in May 2008 and concluded that the revision in 2005 may have adversely affected some board certified individuals. And staff, in fact, expanded that to include some authorized users.

So in the resolution of the petition, what staff indicated was that this would be considered in the rulemaking process, and in that consideration it meant there needed to be the development of a technical basis. And if a technical basis could be developed, then this would be addressed in the future rulemaking.

In developing the technical basis, NRC staff asked all certifying boards to survey their diplomats who are or may be affected by the 2005 training and experience revision. Responses back from the certifying boards indicated that about 10,000 individuals, most of these physicians, may be potentially affected in a negative way by the current training and experience requirements.

The next issue I'll highlight is the frequency of molybdenum-99, or moly-99 testing. The current requirement is that this testing is performed on the first elution of a molybdenum-99, technitium-99m generator. And the regulations require a record of this measurement be kept, but it does not require reporting to the NRC if the threshold is exceeded. Prior to the 2002 revision, there was a requirement for this testing on every elution of a moly tech generator, not just the first elution.

But since the 2002 revision, and more specifically, in October 2006, in February 2007, and again in 2008, staff received reports of failed moly

breakthrough testing. And, in fact, one manufacturer reported 106 test failures in 2008. So with this information in hand, staff proposed and briefed ACMUI on this issue and is proposing that this testing be again done on each elution of a generator and that there be a reporting requirement established if the regulatory limit is exceeded. Now, staff issued in January 2009 an Information Notice to make licensees aware of this issue and to alert them that we have been receiving some increased reports of the failure of this test.

The last issue I'll highlight is one of naming assistant RSOs on a medical license. Current requirements in Part 35 did not allow for more than one permanent RSO on the license. In fact, our regulations require licensees to appoint an RSO who agrees in writing to implement the radiation safety program.

This issue was highlighted by ACMUI in their June 2007 meeting, and they expressed some concern about naming only one person on a license as the RSO. They believe that this was creating a situation in which individuals who are qualified and, in fact, performing some of the duties of an RSO, cannot be recognized or listed as an RSO. They also believe that this may contribute to an overall shortage of RSOs and, more importantly, to radiation safety officers who could precept or sign as preceptors for other individuals who were looking to become RSOs on a medical use license.

Both ACMUI and staff believe that naming more than one individual would increase the RSO pool, would recognize the qualified individuals, and would allow the licensee to quickly appoint an RSO if the named RSO leaves the facility for some reason.

Last month, staff issued a regulatory issue summary to address one of the issues connected with the assistant RSO problem, and that is in the

pool of preceptors. So this RIS clarified that all individuals who met the definition of an RSO may serve as a preceptor, even if that individual is not listed on a license as an RSO. And this significantly increased the pool of potential preceptors.

I'd like to conclude with some potential impacts on the schedule of the current expanded 35 rulemaking. The current proposed rule is due to the Commission March 2012, with the final rule in September 2013. The schedule will be impacted by the incorporation of the new procedure that we are developing to incorporate ACMUI comments and staff's reaction to those comments. That procedure is under development right now and, in fact, is with ACMUI for review and will be discussed at the meeting tomorrow.

The other thing that will impact the current rule schedule is because the rule does encompass a number of issues, staff is proposing to expand the time that the Agreement States have for review, and also to expand the time after the proposed rule is published, in order to allow for increased time for public comments and for public meetings.

The last thing that may impact on the schedule as well is the development of the integrated plan as directed by the Commission. This is due back to you in early March. And this integrated plan will take into consideration, not only this current expanded Part 35 rulemaking, but also a number of other high-priority medical-related tasks that are ongoing right now with staff and the permanent implant medical event rulemaking. With that, Jim will continue with the presentation.

MR. LUEHMAN: Thanks, Josie. I'm going to cover two topics -- patient release, and then talk about our NMED database. Some brief

background on patient release. In May 1997, as has been discussed, I think, in previous panels, the NRC changed from an inpatient only above certain dose threat -- I mean, dosage thresholds to a release based on dose. A little bit more background on that. In September 2005, we received a petition for rulemaking to return to the previous model. And then in 2008, the NRC denied that petition, concluding that there was current -- the current rule was protective of public health and safety. The one thing that's not on my slide is the NRC was subsequently taken to court on this issue, and there was a successful outcome for the NRC in that the present rule is in place.

In October 2009 and 2010, specifically on the issue of patient release, we received some extensive questions from Congressman Markey, and I think that in the background books for this meeting, that we provided both the letters and our responses to those letters.

Real quickly, on Slide 19, the patient release criteria as they are now, that patients can be released if any other individual will not likely get more than 5 millisieverts (500 millirem), that the patient or patient's guardian is provided written instructions, including instructions for keeping doses ALARA if the dose is likely to exceed 1 millisievert.

The key phrase that I would like the Commission to pay attention there is "written instructions," that right now, we are required to provide -- the licensees are required to provide written instructions. You've heard a lot of discussion from the previous panels about oral instructions that are given. I think that at the vast majority of our licensees, that one briefing by the doctor and maybe another one by the nuclear medicine department, are probably the standard of care at most of our facilities. But I think that I've heard, in fact, I

know I've heard from a lot of patients, that at a small minority of our facilities, unfortunately, the only thing that is given is the written instructions, and the only time -- and the time that those written instructions are given is after the patient has been -- has received the dosage. In fact, in some cases, those written instructions are given with the, you know, their discharge paperwork, you know, along with their bill and their other prescriptions, they'll have the written instructions stuck in there. In fact, that was told to me by a woman who was a discharge nurse at a small hospital.

So I think that the key phrase here, if the Commission going forward wants to look at this regulation, is whether simply providing written instructions is sufficient and when those instructions are provided.

In the next page, patients can be released. The licensees need to maintain records of the basis for authorizing the release. On page 21, there's a very specific set of guidelines for a patient who's nursing an infant or child. I won't spend a lot of time on that.

There are three national and international sets of guidance that are out there. The titles of those reports appear on pages 22 and 23. The one thing I will note before I get to the next page, which is a chart, is NRC regulations do not presently provide distinction between exposure limits for family members, general public, and children as separate groups, as you will see in the guidance from some of those bodies.

Also, right now, our regulation -- I think as was discussed in the previous panel -- our regulations are silent on whether the issue is one of per episode or per treatment versus per annum. Turing to my table. The table lays out what the recommendations from the IAEA, NCRP, and ICRP are. I would

make a couple of comments on this first.

In the first column on pregnant women and children, they both recommend 1 millisievert a year, and our limit is 5 millisieverts a year. But I would point out that -- two things, that above 1 millisievert as the note says, they have to provide ALARA instructions. And, in addition, we have issued guidance to our licensees specifically to have them use added precautions when dealing with pregnant women and children. So while our limit is higher than those, we do have additional measures that we have in place.

As far as the differences, you can see for immediate family that IAEA and ICRP recommended on a per-episode basis and NCRP has it on a per-year basis, and our regulations are silent. Now, the staff takes a position, based on guidance we've gotten from OGC, that we think the best interpretation is on a per annum basis but the regulations are silent.

The one thing I would note about the public receiving -- that we have a 5 millisievert limit, again, for everybody, but the other groups have a 1 millisievert limit for the public. The reality is that the likely most exposed member that we're talking about is going to be a family member in most cases or somebody who's in the immediate family or a roommate or something like that. And so really, the operative column, if you will, besides the special exception at the top, is the immediate family column because that's going to be the most likely, in most cases, the most likely exposed individual, and we're pretty -- where our regulations are very consistent with that.

The present NRC guidance. We have two Regulatory Information Summaries out there. We have one, which is -- the first one is the one where we discuss the per-limit or per-episode issue. The second one is the guidance that I

alluded to for precautions for children who may come in contact with patients after release. Our general guidance is contained in NUREG-1556, Volume 9, Appendix U.

The path forward on Slide 27, this is a summary of the ACMUI's views. I would note that in her presentation, Dr. Langhorst emphasized that patient understanding and compliance are key, and, therefore, I go back to the issue of the written instructions, whether they're sufficient and the timing of the written instructions.

At the meeting of the Thyroid Cancer Survivors Association this year, I learned something different than I learned last year, and that is, that the language barrier. At that meeting, which was in Texas, I met with an individual who was an advocate for the Hispanic community -- actually, not in Texas, but in Florida -- and she said this is a real issue. That if they only get -- if the patients only get the written instructions at the end, then there's been nobody that's really made any kind of determination that this patient can really do anything with these instructions, or that there's somebody in the household, such as an older child, who could interpret those instructions for the patient. So, again, I go back to the issue of whether written instructions alone are sufficient, and when those instructions are delivered. Next page.

The staff will evaluate all the ACMUI recommendations. I think that it was discussed that that will be a subject of the ACMUI meeting that's going to go on this afternoon and tomorrow.

The one issue we are developing a RIS on, and we have shared that with both the Agreement States and the ACMUI, is the issue of patients being released to locations other than private residences. We think the staff has

concluded that there is mounting anecdotal evidence that patients are -- more patients than we believed -- are being released to hotels or other such facilities. Four states, in fact, have guidance in place that restricts that from happening. We think that it may be time for the staff to take a position on that. It was not envisioned in the original rule. And the underlying concern that we have is the assumption in the original rule was that patients would be released to individual residents, and then basically, the exposure of members of the public would be randomized in that only their direct relatives would be subject to that radiation exposure.

The concern we have is for hotels that may be close to large hospitals or hotels in small communities that have large hospitals. If you have a large number of these patients being continually released, that you may invalidate the assumptions on whether the original rule was promulgated, which was that the members of the public that would be exposed would be on a random basis. So we really haven't done the analysis of that, but that's really one of the underlying concerns. So that's the presentation on patient release.

I next want to get to the nuclear materials event database. And I want to go through that really quickly, but I want to say I think that in the previous presentations, our database, which we are very happy with, was unduly maligned.

[laughter]

It's a good database for what it's designed to do. And what it's designed to do is capture all nuclear materials events, not just medical events. It's a general database. It does not have all the fields that you would have for a specific database, but, overall, we think it's a pretty good product, and we use it.

What do we use it for? We use it to identify situations where there's been deficient use, precursor of higher risk problems and potentially generic issues. It also is the data we use to determine whether we have abnormal occurrences that may be reported to Congress. It helps us respond to the Government Performance Act, and a GAO report recommendation, which means we have to have quantifiable goals and track those goals, and it helps us do that.

Right now, the database only responds to AEA material, and I need to keep that clear because a lot of the discussion today was about databases to collect all radiation data. There's a number of efforts going on in that. In fact, earlier this year, I met with the Congressional staff. They're looking at a comprehensive database, they're looking at what it should have in it, and where it should be housed, whether it should be in the Joint Commission for Accreditation, whether it should be at the FDA, and they have a number of other options. So ours is separate and distinct from that, in that it only collects AEA material and it's all of our -- the materials licensees that have to report, not just medical.

The last slide just has a sample NMED sheet. And really that's the conclusion of my presentation. I just wanted to make two other comments on other subjects that were covered.

One is that in the medical isotope area, I think, as the Commission has said a number of times, our responsibility in this is a regulatory one, that when a license application is brought, that we will review it. And that's -- I agree with that. I think that the Commission should be aware that we have in place an agency-wide team that's ready to respond to any of those licenses and any

permutation that may come in, depending upon the technology, depending upon the location, and depending upon, you know, how much of the work is going to be done at one site versus the separation being done somewhere else, and the production of the moly may be at a separate site or in an Agreement State. So we've got a team that's ready, standing by to work those issues expeditiously, should they come forward and NRR has the lead for that effort.

The one thing that we have done in FSME at the beginning of this crisis was we did at the beginning when the Chalk River Reactor went down, we did issue a blanket exemption that lessened the amount of testing that had to be done because there was certain testing that was done for calibration that actually used up certain quantities of moly. And over a long term, while on each test, it was a small amount of moly over a long term that would be using up potentially a lot of doses, and so, that exemption is still in place. So from a regulatory standpoint, we've done the things that we can do to assist in that area. And that's it.

CHAIRMAN JACZKO: Commissioner Svinicki.

COMMISSIONER SVINICKI: Thank you, Josie and Jim for those presentations. And, Josie, particularly, I'm glad that you covered some of the history and the scope of the rulemaking and our ability to do direct finals, you know, for very minor changes to rules, and so I appreciate you covering those topics.

You did have a slide that talked about the date for the proposed rule was March 2012, but then the second half of the slide talked about the schedule being impacted by some things that you listed there. So do I understand correctly that the date of March 2012 for a proposed rule is

potentially impacted by the things that you described on the second half of the slide and that the staff is evaluating what the extent of that impact might be? Okay. Do you have any preliminary sense, or is it too early; you're still working through the estimate of schedule adjustment there?

DR. PICCONE: If we just look at the impacts of the new ACMUI coordination procedure and staff's recommendation to increase comment period times with public meetings, that would increase by about six months.

COMMISSIONER SVINICKI: Okay. And so you're saying that alone adds six months?

DR. PICCONE: That alone.

COMMISSIONER SVINICKI: Okay.

DR. PICCONE: That alone would increase about -- the proposed rule by about six months. And then probably a final rule by 18 months after the proposed rule is published --

COMMISSIONER SVINICKI: Okay.

DR. PICCONE: -- because there's some time there. It's a little too soon to give you anything more definitive on the impact of the integrated plan because staff has still -- we're still working on that and evaluating what recommendations that we will send up to the Commission.

COMMISSIONER SVINICKI: Okay. And I don't want to hold you. That wasn't my purpose was to hold you to that. I know you're still evaluating it, and I look forward to whenever the staff is ready to let the Commission know what the proposed impact is there and get the Commission's feedback on that. Sometimes it just helps to know whether, you know, it's the six weeks or 16 months, you know, it's just to have kind of range of estimates here.

I had a couple of other questions about the areas that you discussed in the Part 35 rulemaking that may possibly generate more comment than other areas.

On the frequency of the moly-99 testing, now, Jim was just mentioning something, and I was -- it helped refresh my memory. I visited one of the largest radiopharmacies in the Northeast, outside of Boston. And they had mentioned something about a suspension of some of the testing requirements because it essentially would use up extra dosages during the shortage period. And they were complimenting the NRC staff on exhibiting that flexibility in light of a national shortage situation. Does the frequency of moly-99 testing, Josie, that you were describing have an effect on -- during a shortage period? Would that be a similar kind of effect of kind of using doses up for calibration and testing?

DR. PICCONE: No, Commissioner.

COMMISSIONER SVINICKI: Okay. So that's not related to that one.

And then on the listing of assistant RSOs or associate RSOs, what is the flip side of what would be continuing to just list one? Is there any advantage to that? Was the staff's thinking, you know, singular accountability or something, or was it really just that that's the way it's always been structured and we really didn't give any thought to the potential benefits that others have outlined?

DR. PICCONE: No. The thinking was that there would be one individual who was known to be responsible for the program and that there wouldn't be issues at the facility itself on who had the responsibility for this. Staff -- I think there will always be a primary radiation safety officer. But what staff is

looking at right now is the potential for adding assistant RSOs or associate RSOs. But there would still need to be one individual who has the ultimate responsibility for the license.

COMMISSIONER SVINICKI: Okay. So maybe looking at an alternate structure there but still retaining that benefit of having --

DR. PICCONE: Yes.

COMMISSIONER SVINICKI: -- some ultimate accountability for one individual. Okay, thank you for that. And Jim, on the database, something we heard from -- I can't recall if it was the panelist on the first or second panel today -- but they talked about key elements of the way NMED is structured right now is the text field. And you provided an example that I think makes it just visually obvious that in an entry, there is a lot of this kind of freeform text entry and that that may make it difficult. I don't know if it's an issue of sorting. I'm sure you could do a keyword search in terms of this large text field. But is that -- it seems to me it would be very hard, though, to structure a database where you could capture all these event particulars and not have this large text field. Large text fields can also be helpful too because it again allows a freeform description of things. Do you have any thoughts about how staff is kind of structured -- struggled with the database as being structured this way?

MR. LUEHMAN: Well I -- Commissioner, I think that, as I said, one of the things that we have always had to balance is the fact that this has got to be a generic database, and therefore, we can't have, you know, too many specific fields because a lot of them are not going to be -- either we're going to have to have a huge number to capture every possible, or we're going to have a lot of them that are not going to be applicable, and then we're going to have a lot that

aren't applicable.

We are looking at the database again, especially in light of the security requirements, because right now we do think that some tweaks and some additional fields may be necessary because with the added security requirements, sometimes when we have an event, for instance, a lost device, sometimes the thing that's reported is the serial number of the source, sometimes that what's reported is the serial number of the device, which are not necessarily the same. So we do think that we are looking at some added, you know, enhancements to the database. But I don't think that unless we do a full rework, which we don't have in the works, that we're going to necessarily be able to get away from a text field, especially when we're using this as a generic database for all the reporting, whether it's radiography, whether it's well-longing, or whether it's medical.

COMMISSIONER SVINICKI: Okay, thank you. Thank you, Mr. Chairman.

CHAIRMAN JACZKO: Commission Aposlotakis.

COMMISSIONER APOSTOLAKIS: Thank you, Mr. Chairman. I -- going back to Slide 25, I look at the NRC limits on dose, and you pointed out that the regulations don't make it clear whether they're on a per-episode basis or per annum. I just don't understand that. How can that be? I mean, how did this happen? Am I the only one?

MR. LUEHMAN: No, I can't --

COMMISSIONER APOSTOLAKIS: Does it make sense?

MR. LUEHMAN: It doesn't make sense.

COMMISSIONER APOSTOLAKIS: Oh, okay.

MR. LUEHMAN: And I think that if I -- while I haven't done a real look at it, Commissioner, I think that probability the history would tell you that everybody on this staff was probably thinking it's per year, of course it is, and so nobody bothered to -- and then when it got written down, nobody wrote it down because they all -- because the people who were working on it, all understood it to be per year. I think that that's the case. Because I think that, as I said in my statement, I think that if you look at the history available, as well as the documentation that we have internal to the staff, not in the regulation itself; it's pretty clear that we meant that. Unfortunately, we didn't say that.

COMMISSIONER APOSTOLAKIS: Okay. You didn't say it in writing or orally, right? So this is something that you are revisiting and also the other differences between, you know, episode, per annum -- or family members versus public?

MR. LUEHMAN: Well, right now, we have no rulemaking in -- we have no plan for rulemaking --

COMMISSIONER APOSTOLAKIS: Oh.

MR. LUEHMAN: -- for 3575. This would be in addition to the list if it got added to this rulemaking, and it is not in the plan. But we do think that it's something that at some point does need to be resolved.

COMMISSIONER APOSTOLAKIS: Now, you mentioned that you have a team that's ready to review potential applications for facilities to produce molybdenum. How long would that review take? Are there any estimates?

MR. LUEHMAN: I think it's going to depend upon -- it's going to depend upon a number of factors. As I said, I think one of the things it's going to make a difference is, right now there are some of the potential applicants that are

talking about using fairly conventional reactors to be the source, and I think that the review of that reactor will be, you know, fairly pro forma, something that the staff has done before and would take a less time frame, for instance, a research reactor, than some of the more exotic technologies or advanced technologies that I think that were discussed on one of the earlier panels.

The other things that come into it, as I alluded to in my remarks, are where is the actual production and distribution of the molybdenum going to be done? Is it going to be done at that site? Is the material going to be transferred? And is that going to be done somewhere else? And what technology is going to be used to do that separation? Because one of the things that we don't control -- they also -- when they do these separation of these isotopes, if they're using a methodology that's not been previously used, that has to get approved by the FDA. So we're not -- we're not the only players in this.

And, obviously, the third part of that answer -- I hate to make it complicated is that the distribution or production could actually be done in an Agreement State where we would not -- we would have responsibility for the reactor but then the state would have the responsibility on the material side. So I think that there's a lot of variables. I think that the team has looked at -- the team that's looked at the various options probably does have some time frames, but I really have to defer to NRR to give you any more exact answers than that.

COMMISSIONER APOSTOLAKIS: And a final question. You've heard earlier from Dr. Thomadsen that we need to change our culture. You think we should change our culture?

MR. LUEHMAN: No, I don't.

COMMISSIONER APOSTOLAKIS: Not the safety culture. I mean,

the, you know, regulatory culture.

MR. LUEHMAN: I think that I -- what I would say in response to what Dr. Thomadsen said is that reporting of medical events, okay, is not a violation. I mean, you report a medical event, a medical event may -- there may or may not be an underlying violation there. It just may be an error. So the key is that the failure to report it is the violation. If there's something that meets the criteria that's not reported, that's the violation.

So I don't think that our present system is a punitive one. I think that we do have a different philosophy than the FAA, but I don't think it's a punitive philosophy. In fact, our enforcement policy recognizes when licensees identify and correct their own errors that they will get discretion.

COMMISSIONER APOSTOLAKIS: Thank you, very much. Mr. Chairman?

CHAIRMAN JACZKO: Commissioner Magwood?

COMMISSIONER MAGWOOD: Thank you, Chairman. First, let me thank the staff for today's presentation and really for doing such good work on this particular rulemaking. It's rare that we have an opportunity to work on something that's not just administratively complex and technically complex, but something that actually affects people who have not chosen to become involved in nuclear matters but, through matters of their own health, were forced to take part in all this. So I know you appreciate that, and I appreciate your work on this.

Let me just -- actually I'm going to sort of piggyback on something that Commissioner Svinicki had asked and a couple of others today. Start with you, Josie, and that is there do seem to be some pieces of the Part 35 rulemaking that do seem to lend themselves towards being broken out and dealt

with separately. I'd just like to give you a chance to sort of speak to that since this was brought up earlier today.

DR. PICCONE: The problem with doing that is, even when we do a direct final rule, it needs to be on an issue that we believe will not have public comments. So when we do a direct final rule, we also prepare a proposed rule. I don't believe that the issues that we presented this morning, at least, will be issues that will have no comments as we go forward.

COMMISSIONER MAGWOOD: Okay, great. Thank you, thank you, Josie. Jim, let me pick on you for a little while -- well, not pick on you, but, you know, ask you a few questions here. Well, no, let me pick on you. [laughter]

One of the things about this conversation about patient release that I'm still trying to come to grips with is that we give people instructions or people are given instructions on how to behave after they get a dose. But the more I learn about this, the more it sounds like that we're putting people in very difficult positions, and positions that, perhaps, they aren't well equipped to deal with.

For example, Dr. Wahl, I think, mentioned that the scenario of a patient who says, "I'm about to fly back to California." And he says, "Oh, no, you're not." And, you know, so this person is going to have to go find a hotel somewhere, obviously, which is not the intent that the staff had when this was first written. But what do we expect this person to do? I mean, where are they -- they have to go somewhere.

Then when you think about the issue of waste, and you know, the idea that someone has to collect these wastes, and we heard the example well in the summer in Alabama, you know, it's kind of a difficult situation. We don't equip people to deal with these scenarios. And I wonder, as the staff has gone

through these discussions, have you thought about whether part of this needs to come back to requiring the licensees, not simply to inform people, but to give them facilities and equipment and whatever else is necessary to make this -- to make these instructions practical to actually carry you?

MR. LUEHMAN: Commissioner, on the first issue of the placing people in difficult situations, I think that the staff is looking very carefully at the issue of release to places other than residences. I don't think that we would support -- the regulation doesn't allow us to ban because it says people can be released, ban people from going to other locations. And I don't think that the guidance that we would put out would attempt to do that because we do think that there are going to be unique situations.

The situation you talked about, there could be people that decide that they are going to leave the hospital against medical advice and they've just had this treatment, and, you know, isn't it going to be better to get them some place, rather than have their wife take them home on a six hour journey back to the middle of Kansas sitting next to them the whole time? So I think that we are trying to be sensitive to that in our guidance.

As I stated in my presentation, what we're concerned about, though, we're concerned about the systemic release of patients to hotels, because I think it's no secret that there's hotels near hospitals for reasons because people are going to stay there. In communities that have large medical centers around universities and small towns, there's only a few hotels that those patients can go to. We haven't evaluated the risk to the other members of the public if you have those systemic releases.

But to get to your point about the individual special case release,

we think that's a valid concern. We've heard that from the states as well. The states have told us that if -- but if you're going to allow that, then you need to give us some guidance as to what kind of guidance should our licensees then give the hotel or give the patient that's going to the hotel? And that's an issue that we're going to have to deal with in that regard.

With regard to the waste, I have to agree with Dr. Wahl. Let's remember that the waste we're talking about is the clothing and the bed sheets that the patient had for the first few days in isolation. Because after typically two to four days, okay, the patient, the activity in their body, by radioactive decay and by biological processes, is going to be down to the level that it's very -- there's very little risk, either through contamination or direct radiation, to other members of the household or the public. So we're really talking about the bed sheets and clothing that they were wearing for the first few days, not for the whole 90 day period or so that it's going to take all the iodine to decay away.

For most people, I don't think, and I think we don't have any experience to suggest otherwise, that storing a bag of linens and a couple of pairs of shorts and T-shirts, or something like that, that they are probably going to dispose of at the end of the period anyways, is a big burden on most people. They can put it in a garage; they can put it somewhere for a period of time, and then dispose of it or wash it after that.

COMMISSIONER MAGWOOD: Okay, thank you, Jim. I do have the sense that some of the earlier panel members had an expanded view of what they thought the waste was, but we'll have to pursue that some other time. Thank you, Mr. Chairman.

CHAIRMAN JACZKO: I think just before we go on, I think Virginia,

did you want to comment on the medical isotope issue?

MS. ROSS-LEE: Mary Jane Ross-Lee from NRR. I'm currently leading the moly working group that is looking at the potential licensing of moly production facilities. And on your question about the licensing of those facilities, what Mr. Luehman said is true, that there's going to be a variance based on technologies of those actual production facilities, a variance on the separation facilities, and the distribution of those. But the team itself has been working at and looking at being able to support licensing of those facilities for what the cooperative agreements of DOE and NNSA have, which is to have domestic production in place by 2014. So our scheduling for those -- admittedly, there are some still unknowns, is going to be to attempt to support that scheduling.

CHAIRMAN JACZKO: Commissioner Ostendorff?

COMMISSIONER OSTENDORFF: Thank you, Mr. Chairman. Jim, I want to kind of pick up maybe a little bit where Commissioner Magwood left off? And I was -- in the previous panel, the Chairman had made a comment that I agreed with, and a lot of cases, who don't always have the data we want in order to make informed policy decisions. And I wanted to maybe get just more down just a bit into the patient release data, looking at what actual -- what actual data or studies exist to show the actual exposure of family members or other members of the public, i.e., it could be housekeeping staff at a hotel near a hospital? Do you have any actual data that talks about the actual exposure, the doses received, as a result of the patient release events?

MR. LUEHMAN: In support of the rulemaking, there was one, albeit fairly limited study, that was done where a number of patients and their families or the family members of patients were actually given monitoring

devices. And in that study, I think that the results were that typically, the typical badged individual, or most highly-exposed badged individual, received on the order to 100 to 125 millirem. So about a quarter of what the limit is.

Now, the two things that I would point out about that study is that one is that the -- I think that the dosages used in that study were I think were on the order of 120 to 150 millicuries. That was the dose delivered to those patients. There are frequently dosages delivered that are higher than that, so that would probably proportionately bump up the exposure to the maximally exposed individual.

And the other thing is, I mean, obviously, there's an artificiality in this study that the people in those families know that their badged and probably know that they need to pay attention because they're part of this study. But I guess my sense is that from my radiation experience in, you know, both in power plants and now working in the materials area, that, you know, those estimates from that study, though, it's limited, is probably pretty good. Is it a little higher? Is it a little lower? Yeah, maybe it is based on dose. But you know, I don't know that any expanded studies are going to show that it's going to be radically different. That's just my personal opinion.

COMMISSIONER OSTENDORFF: Okay, thank you. Josie, I want to go back to a point that Commissioner Svinicki was discussing on your Slide 15. And looking at the schedule and getting a rule out is kind of the focus here. The final rule is currently projected to be September 2013. And correct me if I'm wrong here, but I understand that at least part of the petition for rulemaking occurred back in 2006? Is that correct, I'm not sure?

DR. PICCONE: Yes.

COMMISSIONER OSTENDORFF: Okay. Recognizing that your organization deals with a lot of very important stakeholders externally and that perhaps compared to other areas of NRC, that the medical rulemaking does require and warrant more extensive public interface, medical community practitioner interface, and perhaps some other areas might, in that we always benefit from having significant public comment and feedback.

I am concerned just individually that -- about the time periods, about going, you know, perhaps six or seven years to get to that stage. Has your organization looked at all with respect to the rulemaking process on manners in which, or ways in which, the process could be streamlined to speed it up a bit while not lessening the amount of public comment? Is there some kind of way that more things could be done in parallel or through other modalities to maybe tighten the time period up a bit?

DR. PICCONE: Commissioner, this was looked at years ago when rulemaking was actually split between NRR and then NMSS. Rulemaking, at one time, was done exclusively in the Office of Research. And one of the reasons it was split into the program offices was to see what could be done and to be closer to the folks who would implement the rule as well. So there was a lot of tightening, I will say, of the process at that time when that was done. And this is something that is continually looked at in the rulemaking process. We do look at issues of how can we minimize the time for internal reviews, parallel reviews internally, which are already done, but there is a public comment period, there is, and we're finding that --

COMMISSIONER OSTENDORFF: And I'm just looking -- excuse me just a -- and I think we all value, need, and want the public comment. I'm just

looking if there may be other ways of achieving that because it seems like the public comment period is -- was discussed in a prior response to a question, was, perhaps, resulting in some extension of the time periods. I'm looking at that subset of issues on public comments as to whether there's any streamlining for that part.

DR. PICCONE: We do in terms of the medical rulemaking, and I'll start it off and turn to Neelam to supplement the response to you. But in terms of medical rulemaking, which we're talking about this morning, there are a number of efforts to get the information out to the parties so that they can look at the potential rules or draft rules as soon as possible. So there are alternate mechanisms used to get this public comments rather than just publishing in the Federal Register for the public comment period. Neelam, do you want to add to that?

MS. BHALLA: I just wanted to say that in terms of streamlining the rulemaking process, we have done it as in the -- for the spent fuel storage, the cask system. I think we have streamlined to a point that in a matter of six to eight months, we are able to have a COC out. And, again, we use the direct final rule, along with that goes the proposed rule. So it's still meeting the APA requirements, and yet, we have streamlined that process.

When it comes to medical rulemakings, it's a little bit different because also we have most of our licensees are now in the Agreement States. So our coordination has to be with Agreement States as well. And then with the ACMUIs, we need their interaction because, as you know, it's the practice of medicine, and we don't want to step into that or intrude on that practice.

Added to that are just so many different modalities in medical use in

itself. We have the sealed sources, we have the unsealed products, we have diagnostics issues, we have therapeutics issue, we have the gamma knifes, we have the eye applicator. So it's like a whole gambit of things which are going on, and, therefore, I think medical rulemaking just becomes -- we want to give it a fair shake whenever we are changing the rulemaking, and in the process, it just takes longer time.

COMMISSIONER OSTENDORFF: Thank you. Thank you, Mr. Chairman.

CHAIRMAN JACZKO: In the interest of time, I won't necessarily ask any questions here. Well, maybe just one quick one. Medical events definition, that is an issue right now that's just prostate brachytherapy, as far as I'm aware. Is that -- we don't have any other areas in which those concerned --

MR. LUEHMAN: No, I think that --

CHAIRMAN JACZKO: -- about the medical events definition?

MR. LUEHMAN: -- prostate brachytherapy is the one area where the present rule is viewed by the community to not be a good fit, but for gamma knife, HDR, and other modalities, they would tell you that if they were out, 20 percent outside, where they should be, they've got real problems.

CHAIRMAN JACZKO: Okay, thanks. Again, I would just close this thing. I certainly would concur with Commissioner Svinicki and Commissioner Ostendorff about the importance of moving these things along expeditiously. Obviously, sometimes it's perhaps a definitional issue that -- I mean, in general, we do rules in about two years, and that's fairly rigorous, sometimes it's the technical basis development that may take time. And for many of these rules, that's really where it seems to be the complicated aspect is getting all the

comments, understanding what our regulations, how they're going to impact clinical practice, and those kinds of things that may take more time. So but certainly, if there are ways to keep that one to the March 2012, I'd certainly be supportive of looking at that. But, again, there may be unintended consequences. Perhaps when the Commission suggested improving the process of working with ACMUI, we might have been better served knowing that that was going to have an impact on the actual rules that we want to get done. So at this point, I'll just certainly leave that thought in your mind.

Again, this has been a very long meeting with a lot of different issues. I appreciate very much all the people who have come forward there. I suspect there'll be several things to look at in the SRM. Commissioner Ostendorff, did you have something you wanted to --

COMMISSIONER OSTENDORFF: I appreciate your comments. I'd be interested in asking my colleagues to support a request on this notion strictly in the context of the Part 35. As you come back with, I think, the March 2011 integrated plan for moving forward, I'd find it helpful if there's just maybe a short section in that that would bring back to the Commission any suggestions or thoughts or recommendations you may have recognizing that Neelam has articulated that the complexity of this area, I think, nevertheless, it will be helpful for us to hear any recommendations the staff may have on how might we maybe look at our process in the context of the Part 35 to perhaps shorten it time-wise.

CHAIRMAN JACZKO: Any others that would agree? Okay. That's fine. Any other items people would like to raise at this point? Okay. Well, good.

Well, I want to thank everyone for everyone who was on the previous panels. This is obviously a very important issue. And as Commissioner

Magwood indicated, this is an area in which people are receiving doses, and obviously for beneficial purposes for them, but it is, nonetheless, very different from so many of the other things we regulate, and, perhaps, that's one of the complexities and challenges with it. But I think it was a very interesting briefing, and I appreciate everybody's participation. Thank you. We're adjourned.

[Whereupon, the proceedings were concluded]