Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title: Meeting of the Advisory Committee on the Medical Uses of Isotopes

Docket Number: (n/a)

Location: Rockville, Maryland

Date: Friday, March 20, 2015

Work Order No.: NRC-1439 Pages 1-152

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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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PUBLIC MEETING

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FRIDAY,

MARCH 20, 2015

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The meeting was convened in Room T2B3 of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 8:30 a.m., Bruce R. Thomadsen, Ph.D., ACMUI Chairman, presiding.

MEMBERS PRESENT:

BRUCE R. THOMADSEN, Ph.D., Chairman

PHILIP O. ALDERSON, M.D., Vice Chairman

FRANCIS M. COSTELLO, Agreement State Representative

VASKEN DILSIZIAN, M.D., Nuclear Cardiologist

RONALD D. ENNIS, M.D., Radiation Oncologist

SUSAN M. LANGHORST, Ph.D., Radiation Safety Officer

STEVEN R. MATTMULLER, Nuclear Pharmacist

MICHAEL O'HARA, Ph.D., FDA Representative

CHRISTOPHER J. PALESTRO, M.D., Nuclear Medicine Physician

JOHN J. SUH, M.D., Radiation Oncologist

LAURA M. WEIL, Patients' Rights Advocate

PAT B. ZANZONICO, Ph.D., Nuclear Medicine Physicist

Non-Voting: FRED A. METTLER, JR., M.D.

NRC STAFF PRESENT:

PAMELA HENDERSON, Deputy Director, Division of Material Safety, State, Tribal and Rulemaking Programs

DOUGLAS BOLLOCK, Designated Federal Officer

NRC STAFF PRESENT (CONT'D):

SOPHIE HOLIDAY, Alternate Designated Federal Officer, ACMUI Coordinator

MARYANN ABOGUNDE, NMSS/MSTR/MSEB

LUIS BENEVIDES, Ph.D., RES/DSA/RPB

JENNIFER BISHOP, RIII/DNMS/MLB

MICHAEL BLAIR, OIG/AIGA/NMWSA

MARCIA CARPENTIER, OGC/GCHEA/AGCNRP

COLLEEN CASEY, RIII/DNMS/MLB

ASHLEY COCKERHAM, NMSS/MSTR/MSEB

SAID DAIBES, Ph.D., NMSS/MSTR/MSEB

SARA FORSTER, RIII/DNMS/MLB

CASSANDRA FRAZIER, RIII/DNMS/MLB

SANDRA GABRIEL, Ph.D., NMSS/MSTR/MSEB

JOSEPH GIESSNER, RIII/DRP

LATISCHA HANSON, RIV/DNMS/NMSB-A

MICHELLE HAMMOND, RIV/DNMS/NMSB-B

VINCENT HOLAHAN, Ph.D, NMSS/MSTR

DONNA-BETH HOWE, Ph.D., NMSS/MSTR/MSEB

CARDELIA MAUPIN, NMSS/MSTR/RPMB

ANGELA McINTOSH, NMSS/MSTR/MSEB

KEVIN NULL, RIII/DNMS/MLB

PATTY PELKE, RIII/DNMS/MLB

SAMI SHERBINI, Ph.D., RES/DSA

TOYE SIMMONS, RIII/DNMS/MLB

NRC STAFF PRESENT (CONT'D):

JACLYN STORCH, OIG/AIGA/NMWSA

KATIE TAPP, Ph.D, RES/DSA/RPB

FRANK TRAN, RIII/DNMS/MLB

LESTER TRIPP, RI/DNMS/MB

ALSO PRESENT:

BETTE BLANKENSHIP, American Association for Physicists in Medicine

SUE BUNNING, Society of Nuclear Medicine and Molecular Imaging

ROBERT DANSEREAU, New York State Department of Health

WILLIAM DAVIDSON, University of Pennsylvania

LYNNE FAIROBENT, American Association for Physicists in Medicine

CATHERINE GILMORE-LAWLESS, Elekta

PER KJALL, Elekta

CAITLIN KUBLER, Society of Nuclear Medicine and Molecular Imaging

RICHARD MARTIN, American Association for Physicists in medicine

MICHAEL PETERS, American College of Radiology

DHEREEN PRASAD, Roswell Park Cancer Center

CARA SANTILLO, Elekta

ALSO PRESENT (CONT'D):

MICHAEL SHEETZ, University of Pittsburgh

RUTH THOMAS, Environmentalists, Inc.

CINDY TOMLINSON, American Society for Radiation Oncology

RICHARD WAHL, Mallinckrodt Institute of Radiology

BIN WANG, Walter Reed National Military Medical Center

T A B L E O F C O N T E N T S

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P R O C E E D I N G S

(8:32 a.m.)

CHAIR THOMADSEN: Good morning and welcome to our second day. We'll start off with a talk. Dr. Zanzonico will talk to us about yttrium-90 microspheres in cadavers.

MEMBER ZANZONICO: Good morning. As Dr. Thomadsen said, I'll be speaking today about yttrium-90 microspheres and I really broadened the topic to address what I think are really pertinent radionuclides that are encountered wherever unfortunately in cadavers. First slide please. The next slide rather.

So this is outline of my talk. I'll discuss some general considerations, some pertinent critical properties of the radionuclides in question, a to-do list immediately post expiration of the patient with radioactivity; therapeutic amounts of radioactivity on board; final disposition scenarios and there is a number of those obviously; current and past guidance and some concluding marks. Next slide please.

I think something we all intuitively recognize is that fortunately the death of a patient immediately post radionuclide therapy or brachytherapy therapy is really a rare event. These sorts of therapies are rarely used and should rarely be used in

moribund patients.

And these are some data from Japan. On the left ordinate axis is plotted the number of I-125 brachytherapy cases in prostate cancer and on the right ordinate axis the number of cases among those who died within one year of their implantation. If you do the arithmetic, you'll see that only about 0.3 percent of these patients expire within one year with the treatment.

There aren't comparable data, at least that I could find, for other forms of brachytherapy radionuclide that would be. But I assume they are very similar. Again, it's a rare event.

As a result, any single mortuary or funeral home or crematorium is likely to encounter perhaps one to at most several radioactive cadavers annually. So it's not a high volume issue. Next slide please.

Just some general considerations. Not surprisingly, general radiation protection principles, time, distance, shielding, contamination controls, apply. And I think it's a fair statement that the radiation risk to personnel and to other individuals are generally going to be minimal. Next slide please.

It should be emphasized that really there's no special precautions or handling post-diagnostic

administrations just because of the levels of activity typically involved which are much lower.

I think it's also noteworthy, although it's a rare event, that consideration of the patient's families, the patient themselves and their families, and their wishes in terms of final disposition perhaps be addressed pretreatment. I mean if individuals are insisting and planning on cremation and there's something that may counter-indicate that, that sort of thing should be addressed prior rather than after the fact.

And one point I can't emphasize enough is the guidance of the institutional radiation safety officer or local radiation protection expert, both in the hospital or the funeral home or the crematorium, because the fact this is such a rare event. People may be unfamiliar with standard for caution in these scenarios such as they are. It's very important to enlist the guidance actively and early of your SO. Next slide please.

The first issue is death of a patient outside a treating facility, outside the hospital, which might be the most common occurrence. And the first or foremost thing to do is for whomever is responsible for the patient, whether it's a family

member at home, in a nursing home or other long-term care facility, that they contact the treating facility immediately for guidance.

As is typically the case for radionuclide therapy and brachytherapy patients, they should have some sort of wallet card or documentation which among other information provides contact information for the treating institutions, RSO and treating physician. And those individuals should be contacted immediately.

I think a fair general statement, though not a universal statement, is that for current outpatients -- in other words, patients who are treated but based upon either a dosimetric analysis or radioactivity burden who have deemed "safe" to be released -- the retained activities at that point likely would not warrant a radiation precautions or any excessive or dramatic radiation precautions. Next slide.

This slide has a lot of information on it. But this is pertinent physical properties of unsealed sources, sources used for radionuclide therapy. It includes I-131, yttrium-90, etc. And the point I really want to emphasize is that for yttrium-90, phosphorus-32, strontium-89, these are pure beta emitters. So there's really going to be no significant

external hazard which simplifies the radiation precautions.

And even for radium-223, which is an alpha emitter, the frequency of emissions of gammas is relatively low, particularly for the low emissive activities that are used. So there's really a minimal external hazard.

Those commonly used radionuclide therapy isotopes really are not problematic in terms of external hazard. The one caveat which I'll discuss is yttrium-90 because there are several long-lived radio-contaminants that complicate the picture to yttrium-90. And I'll discuss that.

And, of course, I-131 is both a high energy beta emitter, but of course it has abundant high energy gammas that can present a potential external hazard. So I-131, as is often indicated, might be problematic and I'll address that isotope as well. Next slide please.

Here are some brachytherapy sources. And I've divided these into temporary and permanent because in the case of temporary implants the implants should be removed postmortem. And of course there should be no subsequent hazard or special handling then required.

For the permanent implants, there is in

principal a possible postmortem hazard. But it's important to note that for the most commonly used brachytherapy sources, currently I-125 and palladium-103, these emit very low energy, non-penetrating gammas. The shielding by the patient's own body really reduces the x-ray or gamma ray flux such that any external hazard is minimal. Next slide.

What do you immediately post expiration, get, notify the RSO. Their guidance for this rare event is going to be critical. And also notify the nuclear medicine or other treating physicians in the case of unsealed source radionuclide therapy or radiation oncology in the case of brachytherapy.

For radionuclide therapy, the cadaver should be placed in body bag to contain any leaking fluids which happens post expiration. As always when working with radioactivity, the isotope, the administered activity, the date and site of administration and the treating institution's contact information should be documented on the body bag as well as on the cadaver itself, a toe tag kind of arrangement. Next slide.

And the RSO should then perform exposure rate measurements at contact at 30 centimeters and at

one meter. And based on these exposure rate measurements, the RSO can then formulate a short-term radiation precaution, admissible procedures such as embalming and the duration allowable for these procedures and so forth to maintain doses to personnel to less than maximum of admissible doses.

These data are on this table we're talking from Kelly Classic's chapter in the handbook of how you practice. And you see here for several different isotopes, palladium-103, I-125, I-131 and for different typical or likely residual activities in a caveat what the exposure rate in air in millirems per hour at 30 centimeters and one meter from the patient would be. And most importantly the chart shows the time to reach a 100 millirem dose to individual around the cadaver and a 500 millirem dose to individuals around the cadaver.

You can see that at 30 centimeters you're talking of the order of one to several hours for 100 millirem and one to tens of hours for 500 millirem. At one meter, it's tens to hundreds of hours and even longer for 500 millirem. The point is that in order to reach these doses which are the MPDs for general public and for non-occupationally-exposed individuals, you have many hours typically before these doses would be reached.

Some are performing an autopsy. Some are embalming the patients and so forth. They could do so without accruing doses exceeding or in many instances even approaching MPDs from external radiation. Next slide please.

Continuing post-expiration, for radioactive solutions or suspensions that are accessible, an intracavitary therapy, the nuclear medicine physician should withdraw that fluid to the extent it's possible with the disposal of the radioactive liquid down the drain, just like it's doing with excrement from radionuclide therapy patients.

Temporary implants should really be removed by the radiation oncologist. And I'm emphasizing who should do these procedures. It should not be the pathologist or the individual performing who administered those therapies. They would be less familiar with the site, with radiation precautions and so forth.

If the cadaver is still radioactive, again document all the pertinent information on the body bag and on the cadaver itself, if it hadn't already been done, and place the cadaver in the posted, isolated area in the mortuary.

Now people sometimes misinterpret that

kind of advice to infer that there's some hazard, some excessive hazard. But it's an indisputable error. It's a simple, easy thing to do that would further reduce dose to individuals. That's not to say that there's an excess or prohibitive hazard associated with the patient or with the cadaver. If something is simple, easy, fast, non-disruptive, there's no reason not to do it. Next slide please.

What about final disposition and these are all the scenarios. Autopsy, organ transplantation from the cadaver, embalming, a wake, burial and cremation. Next slide.

Autopsy, again as in all of these scenarios, the RSO should provide guidance. It's prudent to avoid or consider a limited autopsy unless there's some compelling reason to do otherwise. Personal protection equipment, of course, should be used. There are possible splash hazards, other contamination hazards. Double disposable gloves because doubling the gloves can reduce skin exposure from beta emitters for example. A face shield. A face mask. And apron especially for radionuclide therapy or the sources are unsealed. Many of these are used routinely in autopsy or embalming scenario. Of course, if you're removing sources or you're having

radio-contaminated items, you should shield the receptacles for those items.

And a question is removal of high-activity organs like for example the liver post yttrium-90 microsphere therapy. And I spoke to the chief of pathology at Memorial and they were not at all enthusiastic about that. It had nothing to do with the radiation.

They said a lot of these procedures are time consuming, take up to one to two hours. They're busy, so forth and so on. And they're not highly motivated to undertake such a procedure for a non-clinically-relevant reason. Generally, removal of these organs, those case-specific, is generally not recommended and not necessary frankly. Next slide.

Transplantation, some people might find this surprising that one would transplant organs from a radioactive patient. They know at the beginning that transplantation is a life-saving procedure. As we all know, donor organs are in very limited supply. And there has to be a very compelling reason for excluding otherwise useable organs for transplantation.

Of course, a targeted or diseased organ, for example, yttrium-90 microsphere therapy, you wouldn't transplant that liver in any case independent

of the radiation. So that's intuitive.

The RSO again should provide guidance in terms of the radiation dose to the transplanted organ. And for non-targeted organs, I think it's fair to say, -- for example, the heart, kidney, liver -- the doses to those organs from a radionuclide therapy would generally be sub-toxic. So those organs would remain functional, usable, transplantable.

And I think it would be prudent as well for the RSO or the dosimetry person to estimate the doses to the recipient. Again, there would be very few, if any, scenarios where those estimated doses would be prohibitive given the life-saving benefit of the transplanted organ in any case. Next slide.

Embalming, follow SO guidance. I've already identified the PPE, personal protective equipment. In NCRP Report No. 155, they recommended a target dose to embalm is less than 25 millirem. And that's sort of based on the scenario that no single embalmer would handle more than four radioactive cadavers a year. If you keep the dose per cadaver to 25 millirem, 25 times 4 is 100. You're below that limit. But that's just a very soft recommendation.

Frankly, if the dose rate at 30 centimeters is less than 50 millirem per hour, if you integrate that

over the various distances an embalmer will actually be to the cadaver you really don't need any restrictions.

Brachytherapy patients, again generally need no restrictions because these are sealed, localized sources that generally emit soft betas that are completely absorbed by the cadaver's tissue.

Radionuclide therapy patients, the embalming fluid should go down the drain, handled no differently than in the case of patient's fluids, excrement, so forth, in their homes. Next slide.

This is work from my old boss. Some of you may remember John Laughlin, Chair of the Medical Physics at Memorial. And here they estimated the radiation dose for embalming patients who have iridium-198, gold-198 and I-131. And they've estimated the mean dose to embalm is per millicurie. It's something to the order of less than about 1-2 millirem.

On the right-hand side of this slide, the activities on board that would result in a dose to an embalmer of 100 and 500 millirem. And you can see they range from hundreds to about a thousand millicuries.

And what the graph indicates, this is plotting the dose rate to embalmer versus the dose rate measured with a survey meter of about 1 meter. And you can see the dose rate measurement of 1 meter with a

Geiger counter is a very reliable metric of the mean dose rate to the embalmer.

The RSO could then provide very reliable guidance based on a simple exposure rate measurement with a Geiger counter at 1 meter in terms of allowable durations of procedures and so forth. But as the slide indicates there's really very little hazard involved. Next slide.

Wakes, one could again apply the 500 millirem limit that you would use for radionuclide therapy patients to family members. It's a comfortable, emotional situation.

Brachytherapy patients, again I-125 and palladium-123 predominantly which emit very low energy photons. It really would take tens of hours at less than 1 meter to accrue dose of 100 millirems. So there's no restriction for such patients.

For radionuclide therapy patients, again for the pure beta emitters there are no restrictions. For I-131 it's a bit more problematic because of the high activities and the penetrating parameters. And of course you have the issue of compliance. Obviously, this is a very emotional situation for many people. And there's no guarantee of compliance even if you were to recommend precautions. Next slide.

Burial, there are no restrictions at all for brachytherapy or radionuclide therapy patients. There's nothing safer than to bury radioactive sources deep in the ground and obviously there's no restriction. Next slide.

Cremation is the most problematic environmental disposition scenario because of the environmental dispersion of radioactivity. Now modern cremation is typically done at 2,000 degrees Fahrenheit with forced air flow of 2,000 cubic feet per minute for two and a half hours followed by one hour cooling period. So the total air volume released will be about 11,000 cubic meters.

There's a huge dilution factor. You have up to 10 pounds of ash which will be basically bone ash. And for other than non-bone localizing radionuclides, they should not be highly contaminated.

Now given the high temperature, you have to assume that any sealed sources would rupture and the activity contained in them would be disbursed. Again, follow the SO guidance at the crematorium with the appropriate personal protective equipment. Next slide please.

And this is a paper from Japan looking at cremation of I-125 containing cadavers where a dose

calculation was done using a Gaussian Plume Model from NCRP 123. And you could see all of the assumed parameters.

A key parameter is the dilution of the activity at the stack and all of these crematoria have by regulation stacks at fairly high elevations. There's a thousand-fold dilution typically. And if you make some conservative assumptions about inhalation added at a postulated distance of 130 meters from the stack, you're talking about an effective dose for a cadaver containing 60 millicuries of less than 1 millirem. So it's really a pretty insignificant dose.

Based on this sort of calculation, the body of I-125 prostate implant patients can really be cremated safety at any point given these dose estimates. Next slide please.

Yttrium-90 as I said is problematic, not because of the Yttrium-90 itself for cremation, but because of two long-lived radiocontaminants, europium-152 with a 13 year half-life and europium-154 with a nine year half-life. You actually get 10 times more of the 152 than the 154 because it has a larger cross section for the n-gamma reaction by which it's produced. And the best estimate I can find is about 10 microcuries combined of these two isotopes for yttrium-90

treatment.

Now Nelson published a paper where he estimated the effective dose to individuals from the crematorium effluent of up to 2200 millirems. And I'm at a loss as to how that was derived. It seems really excessive. Next slide please.

If you just use the ICRP dose conversion factor for these two isotopes and you assume that a single individual internalized, inhaled, all of that 10 microcuries from that cadaver, I come up with 1,750 millirem. But that incorporates no dilution, no dispersion into the environment and again a reasonable dispersion factor or a dilution factor would be at least 1,000. So you're talking about no more than 2 millirem in that case.

Again, I'm at a loss as to how that previous estimate was derived.

What are the options? One could take the very conservative estimate and prohibit cremation between 90 microsphere patients. You could recommend removing the liver prior to cremation which no one is enthusiastic about. Or what I would suggest is doing more realistic dose analysis, actually using the Plume model, than these ultra conservative assumptions of simple quantitative incorporation by a single

individual. Next slide.

There are standards from the National Bureau of Standards, for example, dating back to 1958. The NRC in 10 CFR 35, that's a little general recommendation. CDC says "Do not cremate a decedent whose body contains man-made radioactive material." That kind of sweeping kind of non-fact-based recommendation really seems counterproductive.

And the NCRP as I've been emphasizing recommended RSO guidance for projected dose-based precautions which to me is always the more scientific, prudent, etc., approach. Next slide please.

Now this emoticon on the right is me because I'm at a complete loss as to how the Europeans or the IAEA -- I shouldn't say the Europeans -- came up with maximum permissible activities per cadaver for different isotopes. For autopsy and embalming, they're as low as less than 1 millicurie. For cremation, likewise, less than 1 millicurie and so forth.

I'm really at a loss as to how these numbers were derived. They seem arbitrary to me. They seem ad hoc. Although they have two significant figures. Maybe they're not as ad hoc as I think. But I can't follow any rationale.

In an subsequent IAEA publication in 2014, I'd like to think they came to their senses and did not include any such MPAs and really largely adopted what the NCRP recommended, mainly SO guidance. Next slide.

These are again some European or International Standards information. For example, unless you remove the prostate, I-125 of brachytherapy patients, prostate patients, cannot be cremated for one year in Japan and up to three years in France. In various other countries, patients cannot be cremated if they had tens of millicuries of various isotopes on board.

Again, I'm always skeptical of these non-dose-based, activity-based recommendations because there's a disconnect between activity and dose. And it should be dose which is the defining metric rather than activity.

And most places where there are such recommendations require or recommend that there be ten physical half-lives allowed before scattering the ashes following cremation. Again, I'm always skeptical of that recommendation because ten half-lives following with 1 millicurie is very different from 10 half-lives with tens of millicuries. Next slide please.

The available guidance is sparse. I think

there is a need for regulatory guidance. As I tried to say, as I've editorialized, much of it is outdated and contradictory and not based on dose but what appears to be just ad hoc recommendations.

Restrictions and other precautions such as the appropriate should be based on measurement-derived projected doses. Again running throughout this whole paradigm is the critical RSO guidance.

Cremation may be problematic, but I think restrictions if appropriate should be based on realistic dose models. And the final slide is just the abbreviations and acronyms. I'd be happy to take any questions.

CHAIR THOMADSEN: Thank you very much, Mr. Zanzonico. Questions from the Committee? Yes. Mr. Costello.

MEMBER COSTELLO: Dr. Zanzonico, this is fascinating and very interesting information. You say there's not much out there. Would it be worthwhile for us to recommend to the NRC that this be put out there. I mean the people who are going to be doing this, the RSOs and so forth and so on, are here today and I'm sure you could find a way to spread this information.

MEMBER ZANZONICO: Yes, absolutely. When I was tasked with putting this presentation together,

I was there looking at the literature. And there is some literature, but as you've seen, a lot of it is very contradictory. A lot of it is outdated. And a lot of it is just based on ad hoc pronouncements.

So, yes, I think there's a pressing issue especially with yttrium-90 and the frequency with which data is done, obviously, I-125, prostate brachytherapy and so forth. Again, fortunately these are infrequent occurrences. But in the case of yttrium-90 the europium contaminant is never going away. There's an absolute need for such recommendations to be formulated and distributed.

MEMBER COSTELLO: Thank you.

CHAIR THOMADSEN: Yes, Dr. Ennis.

MEMBER ENNIS: Earlier on, were you suggesting that post expiration the SO should do a survey on every cadaver's implant within some period of time?

MEMBER ZANZONICO: Well, I think it would most commonly be done if they expired in the hospital, if they were still hospitalized. And let's put it this way. If they -- In this wallet card or this documentation, there is some period of time after which any precautions are no longer deemed necessary.

Yes, if a patient expired within that

period of time where precautions were still recommended or where police and other first responders needed to be aware of an individual radioactive that, yes, service should be done.

MEMBER ENNIS: So then you would suggest that everyone change their cards to have a line that says before this date please contact SO.

MEMBER ZANZONICO: Something to that effect, yes. We know that we give patients who have radiation therapy a wallet card – there's such a thing as that -- if they go through a radiation detector at an airport or a train station. And this would be comparable to that.

CHAIR THOMADSEN: Dr. Langhorst.

MEMBER LANGHORST: Who will pay for me to go to France to survey the cadaver that came to my institution?

MEMBER ZANZONICO: That's a very good question.

MEMBER LANGHORST: Now what you're talking about is a lot of these people have already been released under 35.75.

MEMBER ZANZONICO: Yes.

MEMBER LANGHORST: So they are no longer under NRC regulatory authority.

MEMBER ZANZONICO: Correct.

MEMBER LANGHORST: And so then what issues come up with the SO saying this is what you need to do? It really is if the crematorium, if the family, whatever entity, requests help, you can only provide them guidance.

MEMBER ZANZONICO: Yes. Understood. I was telling someone earlier, thanks to Dr. Thomadsen, I was contacted by some company which advertises themselves as the biggest funeral director company in the country like GM or Sears. And I imagine if there is a cost involved it becomes part of the cost of the final arrangements. But that's a consideration.

Again, fortunately all of this should be very rare. But it needs to be considered.

MEMBER LANGHORST: But everyone will pass away eventually.

MEMBER ZANZONICO: Yes.

MEMBER LANGHORST: So how long?

MEMBER ZANZONICO: I think the real problem, one problem to be aware of, is the yttrium-90. So I think that needs to become part of the discussion prior to treatment.

The other issue as well is we may find out that when realistic dose calculations are done these

become non-issues. So I think before trying to stipulate precautions and durations and so forth and so on we're obligated to look at things with realistic dosimetric models. And I think a lot of issues will disappear.

MEMBER LANGHORST: One more. Would that be more of an appropriate review to be done by NRCP maybe with NRC funding, but to have that kind of analysis done and recommendation?

MEMBER ZANZONICO: I would think so. Obviously, NCRP reports have a certain cachet.

CHAIR THOMADSEN: Dr. Howe.

DR. HOWE: I just wanted to reiterate that the NRC does get calls every once and a while for a patient that has passed away. We don't get the calls that they pass away in the hospital that treats them because the SO is responsible.

We get the calls when they pass away or they end up in a different hospital from where they're treated and they die. And they want to know what to do at the crematorium.

What we always tell them to do is go back and have the local SO wherever they are that's closest to them. And hopefully that SO will be a good neighbor and will assist the crematorium and will assist the

family.

A lot of times we get strange requests where people think we've got to put the body in the cold storage for six months. And we try to discourage that. We try to tell them "No, you've got to pay attention to what the family wants. If there really is a hazard, go ahead and do what you need to do."

But generally it is we're recommending people to be good neighbors and assist the crematorium -- they don't have RSOs -- and assist the hospitals that don't have radioactive material that end up with these patients.

CHAIR THOMADSEN: There goes your trip to France.

MEMBER LANGHORST: I know.

CHAIR THOMADSEN: Dr. Alderson.

VICE CHAIR ALDERSON: That was a great presentation. I hadn't really thought about this particular area. So it's more of a question than a comment as Dr. Langhorst and Dr. Ennis had comments.

As we're sitting around the table and talking about this, we all understand logically what you're saying, what the risks are. But that isn't how the general public necessarily would relate to this.

And it makes me think of the way that nurses

in the ICUs relate to the fact that there may be patients on their service who have had a nuclear cardiology study and they're absolutely panicked despite the fact that you do a large study. Two or three years when that study has been forgotten you have to do it again because of a new group. So the public is very concerned.

I wonder in academic medical center space -- I can only speak to that -- in our medical center, we have techs who work the MAR. And they're intimately involved with the bodies. And I believe that they as members of the general public knew that perhaps there was a radiation hazard they hadn't been told about there could certainly be a social/political response. It might not be as logical and well-thought out as something we would do. But it could be here.

It made me wonder in all hospitals when you dispose of your radioactive material. I mean every one of the places where your garbage goes out has those detectors. If somebody missed and something that's radioactive is headed out in general waste, the alarm goes off.

I don't know what those things cost. It made me wonder should we have them in our academic medical center MAR. When a body comes in there's at least an alarm and if there's something wrong it goes

off. And then the SO comes in.

Does that make any sense? Or is that too expensive or just not reasonable to do?

MEMBER ZANZONICO: Dr. Langhorst could give her impression. But what I would think is it's a different scenario. In the case of regulated waste, you're trying to detect something that you may not be aware of. Somehow radioactivity guys did the general waste stream.

Here all the parties involved should know based on the patient's clinical history, the chart information, so forth and so on that they had gotten radioactivity. So they should be cognizant of that. It is expensive.

VICE CHAIR ALDERSON: My fundamental assumption is that they won't have communicated with one another and they won't know. That's my fundamental assumption.

CHAIR THOMADSEN: We just had almost that similar condition where we had a patient show up who wasn't treated in our facility who was radioactive and was only found by accident much later on. And we've started putting detectors at our doors. It's not that expensive.

VICE CHAIR ALDERSON: It's not.

CHAIR THOMADSEN: Only a few hundred dollars.

MEMBER ZANZONICO: What I'm thinking I mean sort of split the difference. If you get a thin crystal survey meter, it would be less than a minute to survey every cadaver. I mean it doesn't take any more kind of training to have someone do that as an alternative to fixed detective frame. That's something to consider I think.

VICE CHAIR ALDERSON: Okay. Thank you.

CHAIR THOMADSEN: Dr. Mettler.

DR. METTLER: This effluent from the stack with the long lived stuff, does the EPA or the States regulate any of that stuff?

MEMBER ZANZONICO: That's the question. They probably do. Yes, I'm sure they do. These specifications of how high the stack should be and what the force flow rate should be, I think that's all by regulation.

DR. METTLER: So maybe there is some EPA thing that makes this prohibitive right from the get-go. I don't know.

MEMBER ZANZONICO: There may be. I haven't encountered it yet, but that's not to say it doesn't exist.

CHAIR THOMADSEN: Maybe what we should do and I don't think we need a motion for this, but make a recommendation to the NCRP that they pick up this as an extension to the question of radioactive patients which you were involved with. And that could become a basis for regulatory guidance or for just anybody. Does that seem like a reasonable approach?

MEMBER ZANZONICO: Yes, absolutely.

CHAIR THOMADSEN: And I think that would be what we might -- Yes, Ashley.

MS. COCKERHAM: I just wanted to provide a general comment since mine is on the guidance.

I'm frequently the one that gets phone calls related to Y-90. And I regularly get phone calls asking about the information. I just got one last week. They're typically from the Agreement States which makes sense as far as that's usually where the work is being done. I do get those phone calls regularly.

DR. METTLER: What do you tell them?

(Laughter)

MS. COCKERHAM: What Donna-Beth explained that we don't -- they ask if there are any other NRC regulations. And we don't do Y-90 microspheres in the regs. It's in guidance space. And we don't specifically address cremation.

A lot of the times it's more of a conversation about the long-lived isotopes and the europium and if there are other things that they need to consider along with isotopes. And it's the good neighbor principle.

CHAIR THOMADSEN: Fine. Any other questions or comments?

(No response)

Very nice report. Thank you.

And Mr. Costello, you are up talking about compatibility.

While you're coming up, I'd just say we used to have a lot of problems with radioactive bodies treating for abdominal perfusions in ovarian cases with G-32 who frequently would die in a couple of days of treatment. Those who practiced in the '60s and '70s will remember that.

MEMBER COSTELLO: Good morning. This presentation changed radically during development. I created a set of slides that I thought were okay and I talked to Dr. Langhorst. She very bluntly told me they were awful.

MEMBER LANGHORST: No, I did not.

(Laughter)

MEMBER COSTELLO: No, you were very

polite. You didn't say words like that, but your comments were so good that I concluded that my slides were awful. It was just a judgment call. In fact the whole point I was trying to make was awful.

(Laughter)

I changed the whole thrust of presentation based on your very polite, not saying that they are awful.

Before we get started, if you all could turn this book here, we have the 2013 recommendations from the ACMUI. And if you could turn to the first page of this. Okay. And just keep it open there and I'll get back to that. You won't have to flip through each page. Just hold on to that. I think I have a book. I'm pretty sure.

Okay. Just as a clue as to the value the Dr. Langhorst gave me, the whole title of this changed based on her comments. So if you ever want to have somebody provide really good comments, I suggest going to Dr. Langhorst because she's really good and really fast. I guess she just has good slides.

The original version of this, the first thing I sent it, was Compatibility for Permanent Brachytherapy Event Reporting. And that was my first slide. I sent it to Dr. Langhorst and she went through

the whole presentation. She pointed out that other than the title I never mentioned permanent brachytherapy reporting. It was nowhere to be seen.

So my presentation wasn't about that even though I thought it was about that. It was really about medical event reporting in general. Next slide.

Now about a year ago before I was on the Committee, the ACMUI comments on the proposed Part 35. And if you look at this here, it says "The ACMUI and its Rulemaking Subcommittee recommend that the draft rule redefining medical events in permanent implant brachytherapy be designated as Compatibility Category B. This recommendation was approved by the ACMUI with one dissenting vote" who I suspect is probably my predecessor. I don't know, but I'm pretty sure that is true. Next slide.

Basically, what went up to the Commission was that the staff recommended -- and by staff I really mean the standing committee of compatibility because that's the NRC's way normally for rules to determine compatibility of a particular rule. So the paper went up there, recommending Compatibility C. Next slide please.

And the Commission by a four-to-one vote adopted the ACMUI's view. But if you note in the first

check, it says a vote of four to one to change compatibility category for reportable medical events. It doesn't say reportable permanent implant events. It says reportable medical events.

And Chairman MacFarlane who is no longer the Chairman, she wrote that she was going to set the medical event definition as a trans-boundary issue where it has to be the same every year. Next slide please.

Now what will I do here? One of the things I do is I try to bring issues from the Agreement States' attention to the NRC and I was trying to guess when I was discussing patient intervention and certainly valuing compatibility of regulations. Next slide please.

Now there's another process in place and doesn't really rely on my position in the ACMUI for just compatibility and that's a Standing Committee on Compatibility. However, ACMUI also provides advice to the NRC on compatibility. And I reached out to the States and to OAS to have them given me advice on what position I should take.

Now I listened to them like the NRC listens to you. And eventually I make my own decision of what I'm going to say. But I certainly do listen to them.

Next slide.

This is probably hard to read, but these are compatibility categories. Can you all read them? At least on the paper. Basically, A is a basic standard of what's around.

B basically says that these things have to do it pretty much identically with the NRC.

C says you have essential objectives which should be adopted by the State, conflicts, duplications and gaps. And how they do it doesn't have to be exactly the same as the NRC provided the essential objectives are met.

D means the States can do what they want. It's not required for compatibility. The other two aren't relevant here. Next slide please.

This is how the current situation is. I didn't list them all, but I think this is some of the real important ones. If you notice, there are only two B's there. Lost materials aren't B. Dose of materials are not B. And at the current time, medical events are not B.

The only thing under B are things associated with national security, National Source Tracking System reporting and loss of large sources during shipment under Part 37. All other reporting

requirements that the States are required to do are C or very small sources of D. Next slide please.

This includes both medical events and notice of a dose to an embryo/fetus or a nursing child. Got that. The States have a lot of reports that they have to pass along to the NRC that require the licensees. Every single one of them is Compatibility C except for national security. I think we all can agree that medical event reporting is not a matter of national security. Next slide please.

The previous rule and the thing referred to yesterday I think that Dr. Yeager mentioned was from 1992 also specified that medical reporting at that time in the administration for C. So we almost have a quarter century of history of requiring States under Compatibility C to have those reported to C rather than B.

I'm not aware and I don't think the Committee is aware when they were thinking about this of this ever causing a single problem. It raises the question of what was broken. Next slide please.

With Compatibility C, we must meet the essential objective. It's just some flexibility sometimes and sometimes these requirements might be already state requirements for reporting any medical

event to the Department of Health or elsewhere. Next slide please.

With that said, now turn back to wherever you were before to these 2013. Save that spot. The recommendation of the Committee was that reporting of permanent brachytherapy events be Compatibility B. And I believe when the Commission discussed this and in their votes they talked about permanent brachytherapy.

And I don't know if the Committee even knows this, but this was applied to all modalities. All modalities. And I don't know whoever discussed this being a good idea.

I assume you took very seriously your discussions about permanent brachytherapy requiring to be B. You talked about training of doctors and confusion for the facilities that work cross boundaries and such. And I understand that.

Did you consider how this should be applied for HDRs? For I-130? For I-131 therapy or I-223 therapy or any other therapy now or in the future? I suspect not.

And I'm just saying from a good guy in supporting you that such a sweeping change in the compatibility designation, albeit it's been there since Ronald Reagan was President, should require at least a

little discussion and transparency before this decision was made. Next slide please.

I have a recommendation. Subcommittee at least look into this. Now my preference is to roll back everything, including permanent brachytherapy.

But I realize that some of you weren't on the Committee at the time. But a lot of consideration was given to this for permanent brachytherapy. And if you want to decide that despite my pointing out that it's not about national security. That's the only thing in Compatibility B.

For those of you who are thinking that it retained a dose-based requirement, I'm not sure that could be done in Compatibility C anyway. I mean you could talk to the NRC about that, but I don't think it could be done in Compatibility C anyway.

Now that would have to be discussed between the individual States if they were to adopt that. But to be blunt I think we were fixing a non-problem. I don't think that the States could do a dose-based role under Compatibility C.

But if you want to keep that anyway in B, at least consider whether the other modalities that were never discussed by the ACMUI and which have been Compatibility C for almost a quarter century should stay

Compatibility C because there is no compelling argument that for HDRs we should change the reporting requirement from C to B.

Is that my last slide? Okay. Who has the first question? I was giving a talk at OAS or someplace and they said people never ask questions. So if you want to get questions, ask who has the first question.

CHAIR THOMADSEN: Thank you very much for your comments. And usually I would go to the Committee for their comments before giving any of mine. But I think that for those new members on the Committee, there is some background that we should clarify.

And the first is the question of why fix something that's not broken. The Committee did feel that there was something broken dealing with the permanent brachytherapy reporting criteria which is why we proposed change which has been for the most part put into the new Part 35.

The reason that the ACMUI did recommend Compatibility B was for three reasons that I can identify. One is that many practitioners had practices across State lines. And if they were going to be practicing in States which did not adopt the new definitions and in States that were NRC that had adopted that this could cause confusion in trying to establish

what should be reported, what shouldn't be reported in given practices.

The second is that if we're looking at data in the reporting databases if different States have different criteria for what are events and what are not events it would be very difficult to establish what may be dangerous and hazardous situations if we have a mixture of incidents reported some of which are considered serious and some of which we have decided are not considered serious.

And thirdly the main reason that the whole issue came up was the great number of incidents that have been reported as events which should not have been reported in events. But because of the definitions they did qualify as events. But most experts in the field felt were perfectly fine in implants.

That's what led to the change in the definition. And that's what led to the recommendation of this body that they should be Compatibility B. I was not aware that we had been voting on making Compatibility B for all medical event definitions. That is news to me right now. I think that was an inadvertent effect of what we had done.

With that, I will open up --

MEMBER COSTELLO: Can I respond to each of

those three thoughts?

CHAIR THOMADSEN: Please do.

MEMBER COSTELLO: First of all, I don't believe that Compatibility C will allow States to retain the dose-based definition for permanent brachytherapy. And your third point about the large number of events which maybe upon further review didn't look like events, the most prominent of those, that could happen in a green room space. Right. That happened with the Philadelphia VA.

CHAIR THOMADSEN: Actually, I was thinking of Wisconsin.

MEMBER COSTELLO: And I understand that, too. Wisconsin, thank you for that. Philadelphia VA I think started a lot of interest in this unfortunately. Wisconsin was very aggressive on looking at the Y-90 and that was the be all and end all of medical events. I spoke to them there about that.

I don't believe they can continue what they were doing if the NRC changed the rule. That would be between the NRC when they did their rule review and any State including Wisconsin. I don't think Compatibility C would allow them simply to do dose-based on the rules set on activity-based.

CHAIR THOMADSEN: I have talked to several

State regulators from several States who have expressed the opinion that if it's Compatibility C they plan on maintaining the current definitions. That is between them and the NRC.

MEMBER COSTELLO: Right.

CHAIR THOMADSEN: But that is their plan. If we're done exchanging, I'll open this up to the floor.

MEMBER COSTELLO: Yes, I'm done.

CHAIR THOMADSEN: Dr. Ennis.

MEMBER ENNIS: So I was not involved in the prior discussions, but I've heard about the issue. And as someone new who practices a lot of brachytherapy, I think I should share.

I have no doubt that if I'm doing seed implants in different locations or I'm training someone who's going to another location and it is not uniform, there will be events and mistakes. Brachytherapy is not an easy procedure. It's got to be done carefully. And like most things in medicine, you need a process, you need a procedure and you need to do the same thing every time.

If I have to remember where I'm doing the case and how I have to prescribe and how I have to record, there will be events that are not events. And it will interfere with people's interest and ability to do the

seed implant procedure. It's a phenomenal procedure for prostate cancer focusing on that aspect for now.

But there are alternatives. There are alternatives for the radiation oncologists, which are frankly easier and more financially rewarding.

If we create a barrier, doctors hate regulatory barriers. And if we are going to create another level of barrier, it's just going to go -- forget it. All I need is for a city to come in and declare a medical event. And I have to tell my hospital and I have to tell the patient. I have to tell the referring. I've got to worry about getting more patients from this referring. It's not going to happen. Forget it.

The patient doesn't know any different. I'll give him the other treatment even if I think seeds are better. I won't do it because it's just too much of a hassle. We've got to make it for the patient's benefit. And for the patient's benefit, it's got to be smooth and easy and accurate and reproducible every time.

Anything we can do to make sure that's the case across the country, across state boundaries, I work in New York, New Jersey. These are two different regulatories. There are so many centers across the country right now that are transboundary. Hospitals

are amalgamating. Many of these departments are practicing in multiple States at this time for regulations.

So to me whatever it was in the past, we had a problem. We identified the problem. This is the solution to the problem that will allow the procedure to continue to be used effectively, safely, by people.

Whether this should be expanded to other medical events, I mean I can see the same argument applying to them. But frankly I don't know enough about all those other treatments to know whether the same issues apply. Although in theory, just in my thinking, it would be similar. But again, whether that was discussed before or whether it's inadvertent, those aren't really things I can weigh in on.

CHAIR THOMADSEN: Thank you. Dr. Howe.

DR. HOWE: This is just to address Frank's comment that he believes if it's Compatibility C that the Agreement States will have to adopt and record. When I do the medical event reports for you every year I scan my medical events. And I ended up this year with over 60 medical events.

I read each one of them to see if it complies with NRC's definition of a medical event. And the big one that I'm drawing a lot out on is back in 1972, not

'72, '92 or '94, we changed the definition for medical event for nuclear medicine to have to exceed 5 rem whole body, 50 rem to an organ. So that eliminates almost one biomedical that's in diagnostic.

I'm still getting 20-30 medical events a year from the Agreement States for the wrong patient, the wrong drug and they don't exceed the dose limits. So the seed does give them more flexibility. I don't know if it's not looking at things closely in IMPEP space, but I do think it is MedEX for flexibility.

MEMBER COSTELLO: Would you comment on whether or not speaking about prostate and permanent brachytherapy seed would allow them to retain the role as is as it does in this rule?

DR. HOWE: It appears as if some of the Agreement States have retained the pre '92-'94 rule.

MEMBER COSTELLO: Okay. Thank you.

CHAIR THOMADSEN: Thank you, Dr. Howe. Other comments? Dr. Zanzonico.

MEMBER ZANZONICO: I just have a question. What's the down side of making it B rather than C?

MEMBER COSTELLO: Good question. I'm tempted to say what's the positive side because remember this rule has been place for almost 25 years. And as far as I know for other modalities, no one has ever even

suggested that for HDRs or I-131 you should fix something and that it would be going from C to B.

But it's really the purpose of B and C. It's hard to say that a BCR patient, but this is a transboundary issue. And B is supposed to be for transboundary issues and it's not.

Now in fact I think C, I don't know if any State has a different definition for HDRs or I-131. You do see it for diagnostic because it's still retain both. Some of this might be caused of State law that would require that.

Medicine is probably more regulated by the States. I suspect there might be some variety in other ways from State to State. You would know that better than I would.

Some of our protection programs are under the Department of Health which regulates medicine in its own way. But basically it's to recognize that the States are the regulators here. So long as they follow the basic achievements and the goals of rule, then they can have some flexibility.

In fact, I remember yesterday we were talking about gallium and germanium. Well, if State had flexibility there, perhaps it's 35.1000 which I believe is C. Maybe the States could, some State could

try something different and not require DFPs for that.

Many of our regulations started with the States doing something different, not in this area here, but in the two person rule for the radiography and certifying radiographers. Many of these things started with States being sort of elaborate for innovation or regulation. That's some reason to do it. The purpose of the Agreement State is to allow States to vary a little bit, while still achieving the basic goals.

But the main thing I wanted by having the working group is I think something happened that went beyond our decision. And I think if you read the Commission's discussion on this, I don't think they ever talked about doing every modality. It would be a much different discussion.

And maybe if the Committee discussed that and said for the reasons you're talking about it should apply to every modality. That would be much better at least from a process point of view. Does that answer your question?

MEMBER ZANZONICO: I wouldn't agree, but it answered the question.

CHAIR THOMADSEN: Can I get a sense of the Committee? Did the Committee think when it made the

recommendations to the Commission that we were making a recommendation for all medical events or just dealing with permanent implants? Yes, Dr. Langhorst.

MEMBER LANGHORST: My recollection was we were limited to the permanent implant.

CHAIR THOMADSEN: Is there anybody who had a different opinion on what happened? Sorry for the people who weren't involved though. Maybe what we should do as a Committee is I can draft a letter to the Commission explaining that we think that the vote that they took was just misworded from the intention of both this Committee and the Commissioners and needs to be clarified.

MEMBER COSTELLO: That's even better than to the subcommittee.

CHAIR THOMADSEN: And if there's no dissension in this Committee I will do that. Yes, Dr. Ennis.

MEMBER ENNIS: Will you say that the ACMUI does not agree with what the letters are or just say that it's not what we said?

CHAIR THOMADSEN: No, I will reiterate that our intention was for permanent implants, that the new definitions would be Compatibility B and we did not discuss other forms of medical events. I was planning

on in our next open discussion bringing up the other topic and this has been a good introduction for that.

Thanks very much, Mr. Costello for alerting us to the situation. Dr. Alderson.

MEMBER COSTELLO: Thank Dr. Langhorst. I would never have found it without her.

CHAIR THOMADSEN: She reads every letter very carefully.

VICE CHAIR ALDERSON: I just need a point of clarification and there are a number of us here, among them I am, who weren't here when this happened. So on page two of the slides, a short history lesson, reading the words there, I'm going to make sure I'm interpreting this the correct way. So the Commission initially voted four to one to change the category to B. But then the next long paragraph says that the Chairman stated that she didn't agree with that.

MEMBER COSTELLO: Yes.

VICE CHAIR ALDERSON: And so it didn't change to B is what I'm understanding.

MEMBER COSTELLO: No, the Chairman didn't agree, but she was the one in the four to one vote.

VICE CHAIR ALDERSON: So she doesn't have the power to offset all the others.

MEMBER COSTELLO: No.

VICE CHAIR ALDERSON: So it is changed to B.

MEMBER COSTELLO: Right now, it's still C. It's still a proposed rule. Goes for comment until December. So as we sit here today, is Compatibility C across the country? And I would just suggest that the sun will come up again tomorrow anyway.

VICE CHAIR ALDERSON: Thank you very much.

CHAIR THOMADSEN: With that, there are no other comments. We'll move to the Status of Abnormal Occurrence Criteria from the NRC staff.

DR. TAPP: Good morning. I'm here today to give an update on the status of the proposed abnormal occurrence for the medical events. Next slide please.

First, I wanted to start with the background. Just so everyone is aware, abnormal occurrences are defined as an unscheduled incident or event that the NRC determines to be significant from a standpoint of public health and safety. I think it's good to highlight that word "significant" from the standpoint of public health and safety.

AOs are required by Section 209 of the Energy Reorganization Act of 1974 that the NRC reports these events to Congress that they deemed that are significant. The criteria was initially created in

1977, but has been updated periodically as the staff finds out new information. Next slide please.

For the current proposed abnormal events that we're going through right now, I wanted to provide a little history. The NRC established a working group back in 2011 to evaluate changes to the Abnormal Occurrence Criteria.

The NRC presented in 2012 to the ACMUI their current proposed AO criteria. You guys provided recommendations back to the staff on April 15, 2013.

In October the staff revised their AO criteria and provided that revision to the Agreement States for their comments. We received comments back from that and we did a little more revision to the Abnormal Occurrence Criteria. Now we have finalized the proposed criteria that is going to be sent out to the Commission. Next slide please.

I wanted to go over the actual criteria changes. First, the medical event criteria which is III.C. The first change was to the title. The current tile is just For Medical Licensees. The staff's proposed title change is events involving the medical use of radioactive materials in patients or human research subjects criteria. This revision was based on recommendation from the ACMUI with a slight editorial

change to fit the other criteria.

We additionally added a footnote pointing that Criteria III.A.2, A.3 and A.4 also apply to medical licensees. This criteria has always applied to medical licensees, but we're just highlighting the fact it is still applicable to them since they have their own criteria.

For the rest of the slides I do want to point the blue font highlights are the new changes to the AO criteria. Next slide please.

I point on III.A just to highlight what that footnote was showing. These are more generic trends or large nationwide impacts or a large deficiency or event that could be reported but don't actually meet the III.C criteria.

I think the fourth one really highlights it could be a generic trend which is a series of events, occurrences, incidents which have implications for similar facilities that raise a major safety concern. But they don't actually meet the III.C criteria by themselves. Next slide please.

The actual proposed new medical criteria on III.C stays similar to the old criteria where it had a dose criteria to start and then a cause, a reason why it was an event. But in addition to that, the new

proposed criteria now will require an actual side effect to occur before it is reported. That makes it a significant impact to public health and safety.

The ACMUI did not recommend to keep the dose criteria, the reason criteria. But the staff would like to keep that criteria as a screening criteria. When we generally get notification of events, we do not have enough information to know at the time if the patients are going to have an adverse effect. So this criteria knows when we do need to send out a medical consultant to look further into this information.

For the dose criteria, there are slight changes as you see on this slide. The first thing is we're highlighting a medical event as defined in regulations. The NRC is 10 CFR 35.3045. It will not be a medical event in a different term. It has to be current to that regulation.

In addition, we are changing the dose criteria to other organs or tissues that has to exceed by 10 gray the expected dose. This will change from events that had been reported in the past where there was an event but it didn't actually exceed 10 gray. It just was 10 gray even though that might have been what the wanted dose was. Next slide please.

This is cause criteria. There are no

changes to this. It's very similar to the past. Next slide please.

This is a new criteria which is the adverse effects that have to be included as an "and." So you have to have the dose, the cause and the adverse effect before it is going to be proposed as an abnormal occurrence. The criteria is very similar to what was recommended in 2013. And it states "that results in one or more of the following as determined by an independent physician deemed qualified by the NRC or an Agreement State." It has to have either an unintended or unexpected permanent functional damage to an organ or physiological system or a significant unexpected adverse health effect or death.

The slight change in wording from the recommendation is we have now changed it from consultant physician to independent physician just because some States would like the use of an independent physician maybe on their staff or not part of actual consultants.

But the independent physician has to be not directly involved in the care of the patient as well as it has to be determined to be qualified by the Agreement State or the NRC. Next slide please.

Now going back to Criteria I.A which is for all human exposures, there's been some slight changes

for this criteria as well. The new criteria, there's a new criterion as part of I.A.4 which states that these criteria in Section I.A do not apply to medical events as those were covered in III.C. Addition made is there's going to be footnote added to the title of I.A to make sure that medical patients are excluded from this criterion. We really want to highlight that I.A is for exposures not related to medical patients. Next slide please.

In addition, the staff is not recommending the removal of the embryo/fetus criterion in I.A.2 as this criterion is used for all regulated entities. There could be an overexposed, pregnant worker.

Generally it has been in the past a medical patient who had a baby at the time has been reported. But it is still possible of someone who is a radiation worker who is pregnant could have this exposure. We wanted to keep this criterion there to make sure we would capture those events.

We are also not recommending new criterion to I.C.3 regarding accidental embryo/fetus as we have it here. Next slide please.

The next steps are we are sending this up to the Commission, the staff's recommendation, the input from the Agreement States as well as the ACMUI's

recommendation. They're going to have a chance to review and vote on this.

If they approve it for a vote, we then send it through the Federal Register for a public comment period of 90 days. The staff will incorporate comments, send it back around for more comments and review.

Then the Commission will have another chance for review, final approval. And it will not go final or will not be able to use it until it's published in the Federal Register at the end. Next slide please.

That's my last slide. I'll open it up for any questions.

CHAIR THOMADSEN: Thank you very much. Any questions? Dr. Zanzonico.

MEMBER ZANZONICO: I just want to clarify things in my own mind. So these criteria III, these are all "ands."

DR. TAPP: They're all "ands."

MEMBER ZANZONICO: So all of those criteria have to be met for an abnormal occurrence. So a medical event -- an abnormal occurrence has to be a medical event, but not the other way around. A medical event is not necessarily an abnormal occurrence.

DR. TAPP: That's true.

MEMBER ZANZONICO: Thank you.

CHAIR THOMADSEN: Thank you very much. Dr. Langhorst.

MEMBER LANGHORST: I think you guys have done a wonderful job of taking our recommendations. And I really appreciate the considerations that you did because I know you look at this at a much wider space than just medical use.

I have a question concerning the embryo/fetus criterion. If kept as you have it here proposed, every patient who later finds out they're pregnant and has unintended dose no matter whether it caused no problem at all that will be an abnormal occurrence that will be reported to Congress. Correct?

DR. TAPP: As it is written and proposed, it will be reported to Congress.

MEMBER LANGHORST: Would it be possible in your -- if we could go to your slide about the new criterion in I.A. I think that's slide nine. Would it be possible to say that these criteria in I.A do not apply to medical events defined in 10 CFR 35.3045 and in the 10 CFR 35.3047 which is where we deal with an event for unintended dose to an embryo, fetus or nursing child?

I'm concerned that these types of issues

arise and they don't arise very often. But they're just automatically catapulted into a Congressional report. And I don't think that it's appropriate.

DR. TAPP: That recommendation could be made. This is actually proposed and up to the Commission. But that could be a comment or something they could see. But it's not currently in the proposed.

MEMBER LANGHORST: I'll say one thing. I totally understand that you need to keep that criterion for exactly what you're talking about like a radiation work order or other members of the public and that sort of thing. But in the medical arena, I really think that 35.3047 needs to be included in that exclusion.

DR. TAPP: Thank you.

CHAIR THOMADSEN: That was going to my comment, too, except I would disagree. I think that is something that actually happens not that uncommonly when you find out that a patient was pregnant without knowing and happened after you started radiation and haven't done any pregnancy test. You aren't going to do a pregnancy test before each fraction.

MEMBER LANGHORST: And, Dr. Thomadsen, I'm not arguing that it shouldn't be a medical event.

CHAIR THOMADSEN: Yes.

MEMBER LANGHORST: It just does it then

automatically catapult it an abnormal occurrence.

CHAIR THOMADSEN: Exactly. Mr. Mattmuller.

MEMBER MATTMULLER: Behind you.

CHAIR THOMADSEN: Oh, I'm sorry.

MS. FAIROBENT: That's okay, Dr. Thomadsen. Lynne Fairobent with AAPM. I actually really second Sue's last comment. And part of the reason is if we had a similar situation caused by machine producing radiation, say, somebody getting a CT scan or being treated on a LINAC, those events would not be reported to Congress.

They would be reported hopefully to the State in which it occurred. But they would not be triggered to an abnormal occurrence event. To me that's a disconnect. Why should it be in one case?

And if you go back and you look at the abnormal occurrences that are reported to Congress by far the majority are medical-related which is why this whole topic got initially surfaced a number of years ago. So I really do think Sue has hit a very good point. I think we ought to consider that.

CHAIR THOMADSEN: Thank you very much. Would you care to make a motion?

MEMBER LANGHORST: I would move that we

recommend the new criterion in I.A be amended to include reference to 10 CFR 35.3047. And if there is harm as noted in medical event, I think that just like your proposing in III.C that should be raised to an abnormal occurrence.

CHAIR THOMADSEN: Okay.

MEMBER LANGHORST: Does that make sense? For those of you who are new, this is all very confusing I know.

DR. METTLER: What do you mean by harm?

MEMBER LANGHORST: As defined in the medical event.

DR. METTLER: Permanent.

MEMBER LANGHORST: Right. That an independent or consultant physician would judge.

CHAIR THOMADSEN: Do we have a second.

MEMBER ZANZONICO: I'm still not clear what the motion is?

CHAIR THOMADSEN: Can you --

MEMBER LANGHORST: I wanted it added to I.A, but I'm not sure if it's included back here in the III.C. You do reference 35.3045.

DR. TAPP: Yes.

MEMBER LANGHORST: I think it should be referenced in both places. I'm sorry. Let me redo my

motion before we go any further.

CHAIR THOMADSEN: Yes.

MEMBER LANGHORST: I would move that 10 CFR 35.3047 be included in the proposed changes for III.C that was on slide six of your presentation and in the proposed criterion I.A. That's slide nine of the presentation to be part of the two reportable medical incidents of Part 35.

CHAIR THOMADSEN: Thank you very much.

VICE CHAIR ALDERSON: I'm sorry to ask for more clarification. But having said that now, what would be the functional significance of what you just said? What does that amount to?

MEMBER LANGHORST: Essentially, if it stays as is, every occurrence -- and it's not a medical event. It's reported under 35.3047 -- every one of those incidents is an abnormal occurrence. And that would probably be the only abnormal occurrence that get reported to Congress.

VICE CHAIR ALDERSON: So you're trying to exclude that by adding this as an exclusion.

MEMBER LANGHORST: That's right.

CHAIR THOMADSEN: Now can we get a second so we can discuss this?

MEMBER COSTELLO: Second.

CHAIR THOMADSEN: We have a second. Now discussion on the motion please.

MEMBER COSTELLO: I just have a question as to timing of the motion. I agree with all the content of the motion. Right now this is before the Commission.

DR. TAPP: It's in a process going to the Commission. It will be there by next week.

MEMBER COSTELLO: Okay. How would a recommendation affect a process since it's already going to the Commission? Would we be better off waiting until it came down from the Commission and we had another shot at it?

DR. TAPP: I did want to make one comment. The staff's recommendation is different from the previous ACMUI's recommendation in 2013. The previous ACMUI recommendation was to take out that criterion and move it.

This is slightly different way to do it. But as you said, the Commission will have both the staff's recommendation and ACMUI's recommendation at the time of their vote. So we do not know which way it will come back from them yet.

MEMBER COSTELLO: And I think the Commission already has this recommendation.

CHAIR THOMADSEN: Was this in the previous

ACMUI recommendation or is this both --

DR. TAPP: Not the exact wording.

CHAIR THOMADSEN: I think this has only come up because of the changes that have been made.

DR. TAPP: Yes.

CHAIR THOMADSEN: Dr. Langhorst.

MEMBER LANGHORST: We included this concept in our recommendations, not knowing how to structure your abnormal occurrence policy.

DR. TAPP: Sure.

MEMBER LANGHORST: I totally understand that your need to have that criterion still stay in there for these non-medical events. I understand that.

So I think our intent of making that recommendation in our report and that report is listed under our website in 2013 is to add that reporting section of .3047 in with .3045 in both those places. And if there's a significant adverse health impact to the embryo, fetus or child, then that gets moved forward as an abnormal occurrence. Sorry, I get confused there.

CHAIR THOMADSEN: Dr. Mettler.

DR. METTLER: If I was on the Commission, I would say tell me the rationale why you want to reports from a nuclear power reactor but not medicine if it's

an effect or an exposure to a fetus. Why are you reporting from this set but not that set?

MEMBER LANGHORST: Well, why aren't we reporting all medical events? Because we were saying some shouldn't raise to the level of abnormal occurrence. And I can't remember the definition of abnormal occurrence but it's in the Atomic Energy Act that NRC is required to report these to Congress.

DR. METTLER: Right. But the question is it's the same pregnancy here, pregnancy there. The same dose. Same whatever. Different sources. And if I was a Commissioner I would say "Tell me the rationale why this should be sent this way and this one shouldn't." All I'm saying is as you send forward your suggestion you might send forward the reason for it.

MEMBER LANGHORST: And I think we did and I'd have to look at the report again. But we did make that rationale. And if the Committee wants to change that, that's fine.

CHAIR THOMADSEN: Dr. Zanzonico.

MEMBER ZANZONICO: If I could take a stab at answering that question. The criterion is unintended which does not necessarily mean unknown. In other words, there may be some medical scenario where you're aware a patient is pregnant, you're aware the

embryo or fetus may get a dose, but it's medically justified. And I think that's the distinction.

I mean it's never justified in an occupational exposure scenario to have an excessive fetal dose. But there can be scenarios in the medical context where although it's undesirable it could be justified.

DR. METTLER: But that's intended.

MEMBER ZANZONICO: No, the dose to the fetus is not intended. It's unintended but it's incidental.

DR. METTLER: All I'm saying is if you just say we want to take this out but not this, they probably need a little bit higher --

MEMBER LANGHORST: I will point you to our report.

DR. METTLER: Okay.

MEMBER LANGHORST: And I think it's the logistics of how you do that. I think we suggested that this criteria I.A for the unintended radiation exposure to the embryo/fetus wasn't intended to totally go away. We intended it not to be applied in the case of a reporting event of 35.3047.

Now I'll say, Dr. Zanzonico, that is not a reportable event if you decide that the doctor says

"Yes, we do want to do that." That's not going to be reported under that .3047 because they involve that if the physician says "We know this and we are going to treat this patient anyway."

CHAIR THOMADSEN: Other comments?

MEMBER COSTELLO: Can we get in our recommendation to the Commission in time to have an impact since they're getting it next week?

DR. TAPP: I do not know how long the vote will take. We do not know how long that process takes once it gets up there.

MEMBER COSTELLO: I'll move in favor of the motion. I just didn't know if the timing of this would work out.

CHAIR THOMADSEN: Any other discussion?

VICE CHAIR ALDERSON: I think that the motion should be repeated before we vote just so we're all clear of what we're doing here.

CHAIR THOMADSEN: Yes. Good point. Dr. Langhorst.

MEMBER LANGHORST: I would recommend -- Can we pull it up? Yes, thank you. I would recommend that on Item 1 there when we have 10 CFR 35.3045 I would say "and 3047." I would add that.

CHAIR THOMADSEN: I think that that would

cover it, would it not?

MEMBER LANGHORST: Yes. Dr. Howe does bring up a point that it's not a medical event for the embryo/fetus/nursing child. That term is not used there. Maybe if we say -- I mean I guess you could say a medical -- I don't know what you want to call it.

MEMBER COSTELLO: It's a reportable event.

MEMBER LANGHORST: A reportable event.

CHAIR THOMADSEN: Why don't we at this moment -- Yes.

MS. COCKERHAM: Can I make a suggestion here? I think if the Committee made a recommendation to capture their intent that things reported to us under 35.3047 or that it's to things that are.

MEMBER LANGHORST: Yes.

MS. COCKERHAM: Okay. So things that are reported to the NRC under 35.3047 not be reportable to Congress in the AO criteria. That is your intent.

MEMBER LANGHORST: Right.

MS. COCKERHAM: Will unless there's harm.

MEMBER LANGHORST: Right.

MS. COCKERHAM: Then if the Committee wants to make that recommendation I wouldn't worry so much about the actual wording of the criteria because that's the message you want to send to the Commission,

right? We do not want to report things that would come to us under 35.3045 that do not result in harm to an embryo or fetus.

DR. TAPP: 07.

MS. COCKERHAM: .3047, I'm sorry. I misspoke, to Congress. That's the Committee's intention. I think that that's good enough and from a process perspective I can't promise this is what we would do, but just thinking about our processes. You're saying "How do we get this recommendation to the Commission?" You advise staff. Staff has ways to communicate with the Commission. We could send up a simple CA note that goes to them saying "We had a significant conversation that is pertaining to a paper that is coming to you."

Our CA note from the Office of NMSS could go up and coincide with a SECY paper that's coming up from Research. They will get all of the information at the same time. Or maybe they get the CA note ahead of time. We're able to brief their assistants and say "This is technical information that you're going to need to make a decision on a paper that's coming to you."

We have processes for that. Does that help?

MEMBER LANGHORST: It helps me.

MEMBER COSTELLO: Yes, a lot.

CHAIR THOMADSEN: Do we have a motion?

MEMBER LANGHORST: I will repeat that motion.

(Laughter)

I don't know that I can because we already had a motion.

CHAIR THOMADSEN: Will you withdraw your motion?

MEMBER LANGHORST: I will withdraw that first one.

CHAIR THOMADSEN: And the seconder? Who was the seconder?

MEMBER COSTELLO: I was the second.

CHAIR THOMADSEN: Will you withdraw your second?

MEMBER COSTELLO: Yes.

CHAIR THOMADSEN: Okay. Now you can make a new motion to whatever Ashley just said.

MEMBER COSTELLO: Maybe Ashley should.

MS. COCKERHAM: Would you like me to rephrase it again?

CHAIR THOMADSEN: Please.

MS. COCKERHAM: So the Committee's intent is that events reported to NRC under 35.3047 that do not

result in harm to an embryo or fetus are not included as AO capturable and reported to Congress.

MEMBER LANGHORST: Yes. And I would just add or nursing child.

MS. COCKERHAM: Okay. Or nursing child.

CHAIR THOMADSEN: Do you want to second that one?

MEMBER COSTELLO: I second that one, too.

CHAIR THOMADSEN: Excellent. Any discussion on the new motion?

(Vote)

MEMBER ENNIS: Abstain. I don't really understand.

(Laughter)

CHAIR THOMADSEN: All right. And I will have to admit that the abnormal event criteria --

MEMBER LANGHORST: Abnormal occurrence.

CHAIR THOMADSEN: I'm sorry. Thank you. Abnormal occurrence criteria is actually a lot more convoluted than it seems like it should be. So it's quite understandable. This is your first.

MEMBER ENNIS: Never heard of the concept before.

CHAIR THOMADSEN: Yes, it wouldn't be clear. But it passes anyway. Thank you very much.

DR. TAPP: Thank you.

CHAIR THOMADSEN: And with that we are up to a break until 10:30 a.m. Off the record.

(Whereupon, the above-entitled matter went off the record at 10:11 a.m. and resumed at 10:33 a.m.)

CHAIRMAN THOMADSEN: Let us resume. We now have a guest to talk with us from Elekta talking about Perfexion and Gamma Knife authorized user physical presence. And welcome to our meeting.

DR. KJALL: Thank you and thank you for inviting us to give this presentation, which as I see it is sort of a continuation or extension of the presentation given in the last meeting.

Before I start I'm here representing Elekta only. I'm not representing our users, at least not in a formal sense. However, everything I'm going to talk about today is of course based on our discussions during the years about this particular issue, which many users find some problematic.

So to be honest from the beginning, this is why I'm here. I'm here to ask for your support of a change to the licensing guidance concerning the physical presence requirements.

I'm going to use three arguments. I mention this from the beginning in order for you to sort

of detect when I gather momentum with the arguments. I'm going to talk about the design of the Perfexion system. I'm concentrating on Leksell Gamma Knife Perfexion. The design and the safety features of Perfexion. I'm going to talk about incident rates. I have data on incidents. I will define incidents later on. And I'm also going to talk about comparative safety analysis; a very simple one, but very telling. And in order to sort of assess the reasonableness of the arguments and the suggestion that we propose I'm going to show data on how patient safety is managed outside U.S.

One slide about who we are. I hope most of you already know that. Then Leksell Gamma Knife from various perspectives, how it works. Patient safety again from various perspectives. And then finally of course the recommended change.

I hope you can see the pictures there. Elekta has during many years been in the center of modern cancer care. The images show from left to right the system we're going to talk about today. Elekta Gamma Knife Perfexion system. There is a brachytherapy system, one of many. We have a range of software solutions from patient management all the way across treatment planning. And also a range of neural

accelerators. And you see a couple of numbers there representing how many patients actually deal with Elekta equipment per year and per day.

This is the primary focus of the presentation. Leksell Gamma Knife, past, present, future. The concept has always been cross-firing a large number of beams. The beams meet in a small volume and essentially this volume is thinner than the isocenter. The parameters you have at your disposal when you perform this treatment and when you plan the treatment is of course the irradiation time, the width of the beams. For Perfexion, we have three widths: 4, 8 and 16 millimeter. That is very narrow beams. And of course the number of beams. We can selectively lock beams strung from different directions. We move around the patient in order to position the isocenter in various parts of the target, of course.

During the '50s and '60s the field of stereotactic radiosurgery was established by merging the fields of open stereotactic surgery and radiation therapy. A platform was created. Prototypes on the platforms started to evolve during the years and the evolution has been in terms of patient comfort, the number of different collimators that you can use, of course patient safety. But the principle has always

remained the same, cross-firing a large number of beams in a small volume.

The latest system is, the latest released system is the Leksell Gamma Knife Perfexion system. And it's interesting to note that the Leksell Gamma Knife is still the intracranial system that all other solutions measure themselves against when it comes to accuracy and precision after all these years.

So this is what it looks like. The treatment process. Since it's a system based on stereotactic principles, the first thing you have to do is of course is to attach the stereotactic system to the patient; in this case the Leksell G Frame. On this frame you've put what we call the fiducial box. It's a box that contains markers that enables you to define the stereotactic space in the diagnostic image set, which can be based on a MR, CT, MU or PETs.

This information is then fed into the treatment planning system where you of course locate defined targets, you simulate your dose delivery, you calculate a large number of statistics in order to assess the quality of your plan, and then finally you of course treat the patient.

So what makes the Perfexion system different from the other systems? The first and the

primary difference is that when you initiate treatments you can move the patient into the treatment position without having the beams on. You stopped the treatment. Can you see them? Yes, you can see the beams. And then you can in between isocenters; that is when you move the patient -- you can turn the beams off. And you restart the treatment. And if there is an incident, something happens, you can emergency move or turn off the beams.

And this ability is designed in such a way that sources are placed on moveable mechanical structures that we call sectors. And each one of these sectors can be in a number of different positions. Two of these positions are such that the patient is shielded from the primary radiation from the sources. And the shielding thickness is between 15 and 20 half-value layers, which means that in practice the dose rates in the isocenter is almost, from a clinical point of view, zero.

And we have this system installed all over the world; around 120 here in the U.S. of which 80 to 90 is the system I'm talking about, the Perfexion system. Three hundred plus something in the world out of which two hundred are Perfexion systems. Two years ago almost 800,000 patients had been treated with this

system, with the Leksell Gamma Knife in general. Out of these 800,000 around 300,000 were treated with the Perfexion system.

Now I'm moving over to patient safety in general not related specifically or uniquely to the Perfexion system per se. And I'm sorry about sort of the linguistic proximity of medical incidents I have here with medical events. I'm not talking about medical events now. Sorry about that.

And incident can be the medical or a system failure. Medical, I'm talking about vomiting, nausea, pain, etcetera. System failure, hardware, software-related or a mix, of course.

The required actions to manage an incident is to of course first recognize it and then to respond appropriately. To recognize medical incident you of course need some medical clinical competence. To respond to a medical incident you need to know how the system works. That is, you need to have system competence. For system failure, on the other hand, you need more of a technical background for system competence. And as you see I've included knowing the risks and characteristics of a radiation in system competence.

What is a medical incident? It takes a

certain amount of time to recognize that something is happening or has happened. And these are numbers I've assumed are reasonable. To recognize a medical incident you need somewhere between 0 and 30 seconds if you are looking at the patient of course through the patient surveillance system.

To respond I've defined here as turning the beams off. And all systems on the market, regardless of manufacturer, can turn the beams off in a matter of seconds.

A system failure on the other hand may take since now the system has actually failed, may take a longer time to respond to. And during this response time there is of course a risk to be exposed to unwanted dose.

This is a graphical illustration of medical incidents. All the green bars represent dose delivered to the correct position and in the correct amount. At t equal t_1 there is a medical incident. It takes a certain amount of time to recognize it and to respond to it. At the end of the response time the beams are off and the incident is resolved. And then you restart the treatment again. No extra dose to patient, no extra dose to user.

The competencies needed here are medical;

I talked about that on the previous slide, for instance a nurse. And it has to be remembered that acute medical emergencies caused by the treatment itself during Gamma Knife treatments are extremely rare.

The same kind of graphical illustration but for a system failure. Anything up to t equal t_1 is according to plan. Dose delivered to the correct position and the correct amount. t equal t_1, something happens. And all systems on the market are designed to turn beams off if there is a system failure. However, the system has failed. So there is an uncertainty as to the state of the system.

And then of course the maximum risk is if the beams are still on. So this area of uncertainty or this dose to the patient, this uncertain dose to the patient is of course bounded from below by zero dose rate and from above by the maximum dose rate the system is able deliver. And this is sort of a fundamental principle of radiation therapy, and of course also radiosurgery. And that is that the maximum patient risk is predicated on the maximum dose rate of the system and not on the total dose planned to be delivered to the patient during the treatment. And the competencies needed here in order to manage this kind of incident, again I repeat from the previous slide, technical

radiation safety, for instance the competencies of a radiation therapist.

If we now use this principle, as I called it, that maximum patient risk is predicated on the maximum dose rates and we compare a number of different systems available on the market for the moment. LINAC is a generic LINAC. Cyber Knife you know is also a LINAC technology. ViewRay is a system based on cobalt. Gamma Knife is a system based on cobalt as well. And if we assume now a reaction time -- reaction time I define as the time it takes to recognize that there is an incident and the time to respond. If we assume that this reaction time now is the same for all these systems, I don't think that the exact number of seconds is important.

Then of course we see that the potential maximum dose delivered to the patient during this incident is of course directly proportional to the maximum dose rate. And from this point of view we see that the Leksell Gamma Knife is actually in all of the systems the safest one. And now I am talking about Leksell Gamma Knife Perfexion.

Okay. We receive reports continuously about things that have happened to our systems, and of course the Leksell Gamma Knife is not an exception.

During this nine-year period I counted 2,000 customer feedback reports about Gamma Knife. Out of these 17 reports were incidents where the users had to enter the treatment room to manually extract the patient and close the shielding doors. And this is the incident I'm going to use in the incident rate later on, and we call it manual un-docking. Out of these 17 reports 12 were for Perfexion. During the same nine-year period around 300,000 patients were treated with the Perfexion system.

So we have a situation where the incident rate is 12 incidents per 300,000 treatments, which gives an incident rate of 1 per 25,000. And I'm fully aware that there are unreported events or incidents, but we can only speculate about the number of unreported incidents. And the number given by Dr. Suh in his presentation during the last meeting had a -- there was an attempt at estimating this number of unreported incidents. And that's why he reported a lower -- or a higher incident rate. Sorry. Five to ten thousand. But these are the real numbers. Two of these twelve are from U.S. here in the NRC event reporting database. And during the same period of time in U.S. around 40 to 50,000 patients were treated with the Perfexion system. And again, so we end up with 1 in 20-25,000 treatments,

which I will say is a very, very low incident rate.

So how is patient safety managed outside U.S.? I fully understand that this is not an argument to change anything, but at least let's have a look and see to get this perspective. We asked two very simple questions: At your site who must be present at the console for the duration of the treatment, and why? And the other question was what additional personnel must be reasonably close to the console during the treatments?

The answers to the first question indicate that most sites actually want to have nurse/technologist; that is, radiation therapist at the console during the treatments. Not so many sites answered that they wanted to have a radiation oncologist at the console. But if we rephrased the question so that it reads, "Do you think that a radiation oncologist can contribute or is able to contribute the maximum amount of patient safety by staying at the console," and then the answer then clearly no. The answers to question No. 2 indicate that now there is a desire to have more clinically-proficient personnel in the vicinity of the treatment area in case something happens. And I state two examples at the bottom there of answers to question No. 1 from Canada and U.K.

So in the present licensing guidance there is a reference to this physical presence requirement, and it's very clear of course. There must be an AU and an AMP physically present, where physically present means within hearing distance of normal voice. For the other systems I've talked about there is no such thing as a physical presence requirement during LINAC treatments. There is one for ViewRay treatments, but it's much more relaxed. And the one about Gamma Knife I just mentioned.

If we now put this into perspective and summarize what I've just talked about, the design of the Perfexion system is, I would say, inherently safe because we can move the source out of the way from the collimators. Data on safety indicates that there is a very low incident rate, and a comparative safety analysis indicates that the Gamma Knife Perfexion system is actually one of the safest systems. And due to the clarity and the safeness of which the system is designed, it is the case that any one of the existing team can actually be trained to manage the system and to manage an incident appropriately.

So this is our suggestion: The first part is to have an AU and an AMP physically present during the initiation of the treatment. And now I would like

to say that physical presence should not mean within hearing distance of normal voice. It should actually be physically present in the treatment room or at the console. So maybe physically present needs to be qualified. Whereas when the treatment has started there should be an AU or an AMP physically present somewhere in the department. And this is very similar to the ViewRay requirements.

So who has the first question?

(Laughter)

CHAIRMAN THOMADSEN: Thank you very much, Dr. Kjall. Yes?

VICE CHAIR ALDERSON: Are you aware of the requirements for Cyber Knife? What are they, do you know?

DR. KJALL: There's no such thing as physical presence requirements for Cyber --

VICE CHAIR ALDERSON: Cyber Knife?

DR. KJALL: Yes.

VICE CHAIR ALDERSON: Thank you.

MEMBER COSTELLO: I apologize for asking a question you might have answered when I was out of the room, but what about the -- and I do apologize if you've already answered this question. What about Perfexion is different than other Gamma Knifes where they would

be required to have a physical presence and Perfexion wouldn't?

DR. KJALL: The other Gamma Knifes are out of sales, so we are only now talking about Perfexion systems.

MEMBER COSTELLO: Right. What I'm saying is why is a Perfexion system so different that it wouldn't require the physical presence and the other one do?

DR. KJALL: The other ones do as well. They are required to have --

(Simultaneous speaking)

MEMBER COSTELLO: So your proposal would basically to modify the physical presence requirements for the Perfexion?

DR. KJALL: Right.

MEMBER COSTELLO: But leave in place --

DR. KJALL: Yes.

MEMBER COSTELLO: -- the physical presence requirements --

DR. KJALL: For the other Gamma Knifes.

MEMBER COSTELLO: -- for the other Gamma Knifes, too.

DR. KJALL: Yes.

CHAIRMAN THOMADSEN: As a follow-up can

you answer his question as to why is the Perfexion different from the Gamma Knife in that context?

MEMBER COSTELLO: Yes. Thank you.

DR. KJALL: In this context it's different because you can turn the beams off. In a matter of seconds you can shield the patient from the primary radiation by moving the sources away from --

MEMBER COSTELLO: Thank you. You've answered my question. Thank you.

DR. KJALL: -- the collimators. Okay.

MEMBER COSTELLO: Thank you.

DR. KJALL: I'm sorry.

CHAIRMAN THOMADSEN: Thank you. Dr. Suh.

MEMBER SUH: So, thanks for a very comprehensive overview about Perfexion. So I've been a very long-time user of the Gamma, actually for over 18 years now. I've used the Perfexion since 2007. There is no question that from the design standpoint and the safety feature standpoint there is definitely an improvement over the model B, the model C, the model 4C, which I have used.

Because of the changes that have occurred with the machine, I think because of the current requirements that have been required as a result of having an authorized user present during treatment the

safety record for the Gamma Knife Perfexion is incredibly good. No one around this table would argue that the safety record isn't very good.

So one of my contentions is because it is so good and we make a change and all of a sudden things are not as good, have we -- is that the right -- because right now you're saying this incidence is between one to 5,000 and one to 25,000, which I would argue that's a very high bar. And right now in terms of, in my view, having an authorized user present in the console area to do a treatment, especially when you're treating benign conditions like arteriovenous malformations, acoustic neuromas, tremors, or if you miss -- and as we heard yesterday we had situations where the wrong patient was treated, the wrong site got treated, and ultimately the physician, who I believe is the authorized user, has to take responsibility.

So in terms of the treatment and I think in terms of the integrity you set up, any medical issues that occur during treatment, any issues that may occur with the machine, I think ultimately the authorized user is responsible. Now, you're arguing in terms of what happens in Canada, outside of the United States. As you know, it's practiced very differently outside the United States. And I would say that one is better than

the other, but it practices very differently and it's very much -- you're a surgery-driven versus here in the United States we really have equal balance between what medical physics does, what radiation oncologists do, what neurosurgeons do as well.

DR. KJALL: Yes, I understand your concern. One response is of course that the -- as I shared, the incident rate outside U.S. and in U.S. are almost identical based on the statistics here. So by relaxing the rules here moving towards the situation outside U.S. apparently the incident rate doesn't change.

When you mention the wrong site being treated, even wrong patient being treated and so on, I think that is something that happens much earlier in the work flow and there is an error being made during planning. And that will not be captured unless the authorized user and the AMP are there during the initiation of the treatment. And that is what we suggest. So I think the errors being made upstreams can be captured. I'm not saying they are captured, because if it's the same person selecting the trigeminal on the wrong side, then of course nothing would change even though you will sit and look at the patients for hours.

So, but at least set up errors, obvious

errors and maybe having another pair of eyes looking at the patients during set up and initiation will prevent some of these incidents.

CHAIRMAN THOMADSEN: We have a member of the public. Please?

DR. PRASAD: Yes, I'm Dr. Prasad. I'm the Medical Director of Radiation Medicine at Roswell Park, and I must say I'm a poster child for the NRC because when the rules changed from neurosurgeons to radiation oncologists being the prime driver of this technology at the console, I actually went back and trained as a radiation oncologist to keep up with the rules. So I've been doing it just like John from 1992, nearly 9,000 patients, all models except the very first one. And there has been a distinct change in the Perfexion technology from the user point of view. There is a very high level of record and a very high level of ongoing supervision during delivery from an engineering standpoint, which is what this discussion --

I support what Per is saying. Up to the point of planning and setting a patient up there is no disagreement that the parties involved in neurosurgery, radiation oncology, medical physics, everyone has to be involved in the writing and prescribing of the written directive and positioning of the patient. And

hopefully at that point existing rules and double-checks and cross-checks have prevented the errors you discussed yesterday.

But at that point Per is right, if you have committed to treating the wrong side and none of the three in the group have picked it up, then that error will occur. And the system can't catch that. So that leaves us with the actual delivery piece, which I agree with John there's a wide variety of indications. It's one of the few technologies that crosses over from functional, like epilepsy, trigeminal, to benign conditions like benign tumors which are traditionally not radiated to actual cancer. The mix, however, has changed as you saw in the utilization curve. The number of patients with malignant tumors, especially multiple tumors, being treated has gone up.

And what it's done is that for that subset of patients its continued utilization and the clinical benefit which it unquestionably brings to our patients is going to ultimately get time-limited by the physical presence of a person. And the question is who has the competence to look at the console, be patient-focused and really pick up an early event like a seizure or vomiting or anything of those? And I personally feel, despite being a physician, I'm not necessarily the most

competent in picking that up. I think a trained nurse has a much more directed portfolio.

I am, despite being physically present at the console, under much more pressure in a system. And I'm being very honest. I can get paged, I can get called. That is not necessarily the case with a technician and a nurse. In my opinion if we're moving towards safety, fragmentation of responsibility is an organizational strategy that medicine doesn't adopt very quickly. And I totally support every rule coming out of this office and we've followed them to the letter.

I think the rules need to re-look at where the technology is at, how it's being deployed, and I think we can provide exceptional patient safety going forward in the American context with a qualified nurse and a therapist or two, if the States require it, be at the console.

Just to give you a clear idea, currently in my institution we have a physicist, a nurse, a radiation oncologist and a neurosurgeon, all four, at the console for every treatment we do. So we have not taken any -- we can't give you statistics on how it would change if one of us wasn't there. And I think John's point is valid that it's a great safety record. Do we want to mess with it? But I feel that the kind of patient that

we treat today, especially being a cancer hospital -- I think it would help. The technology would remain much more palatable.

To speak to Dr. Ennis' point, sometimes regulation can take choices away. And I feel that we are getting to that point where the physical presence barrier does take certain clinics out of using the Gamma Knife for what it is really designed to do, and more and more data is coming out to show that it has become a very, very -- a big step away from whole brain radiation, which is not a discussion here, but I feel we can do this safely with the right people. And my nurse has a call button right next to her for additional support and code. So if an event occurs, like anywhere else in a radiation therapy department during any procedure, she could call for help.

CHAIRMAN THOMADSEN: Thank you very much, Dr. Prasad. Yes, Dr. Ennis?

MEMBER ENNIS: Actually, I would like to be able to ask the question to the prior speaker.

CHAIRMAN THOMADSEN: Oh, sure. Sorry.

MEMBER ENNIS: So, I don't know a whole lot about the regulations for this because I'm new to the Committee, but is a neurosurgeon required to be at the console? And if not, why does he choose to stay?

MEMBER PRASAD: So, we are an Agreement State. And we were one of the first Gamma Knifes in the State and our medical physics group was advising the State in writing those regulations. And so, it was stipulated and so it has been. I think there is some flexibility. The absolute mandate is AU and AMP. The neurosurgeon is only at our institution more of our guideline. And I think the State of New York does not require at all the other centers. So that's changed back. But I was just giving you context as to how many full-time man hours we invest in keeping the procedure the way we do it.

Just to echo what John said, that I think center of excellence models are a great base to look at things, but sometimes when you're deploying a technology and technology evolves, maybe a readdressing of what should be the bare minimum mandated is well worth consideration primarily to maintain acceptance and deployment of a technology that has great social value. That's my point.

MEMBER ENNIS: And that's just what I was trying to get at. Doesn't the fact that the neurosurgeon chooses, even though not required, to be there belie the notion that you don't need a physician/authorized user present? I would think the

neurosurgeon would say, oh, no, I'm not needed here. Once the treatment is going I'm going to go do my next case.

PARTICIPANT: They have to be there to bill.

PARTICIPANT: That's true.

DR. PRASAD: And we absolutely do feel that none of this should ever allow an escape hatch for somebody to sort of abdicate their responsibility. That is not the intent of this discussion. All I'm saying is that the intent of the ruling is to get the patient safety front and center. So I'm being more of a patient advocate from a safety point of view, how I do my job, and be -- deployment and utilization of technology is a patient advocacy issue, too. Because if we kind of end up not using it as often because it's onerous to fulfill the requirements, we are actually seeing a negative in social terms. I mean, these are expensive technologies. They take a lot of stuff to get together and put in a building. if you don't use them enough -- we don't have to over-use them, right? And using enough might be an issue, just like the brachy considerations you were raising earlier.

CHAIRMAN THOMADSEN: Thank you again. Dr. Mettler?

DR. METTLER: Two questions: The first one is how long do these treatments take?

DR. KJALL: For a newly loaded Gamma Knife it takes maybe -- depends on the treatment itself, but between 15 minutes and up to maybe 2 hours. If the plan contains many metastases, of course you have to assign the treatment for each one of those. Dr. Suh, I think you mentioned up to two hours. Fifteen minutes up to two hours.

MEMBER SUH: It varies on the source strength, how big the lesion is, what you're trying to target, what you're trying to shield, but a -- I'd say a functional case like trigeminal neuralgia, depending on how hot the source is, you're probably looking at about 38 minutes, 50 minutes, something like that.

DR. METTLER: The second question. So if you would like to have the regulations relaxed because you can turn the beam off and the other guys can't, how does the radiation therapist being there or not being there have any -- what is the reason? I don't get that the radiation therapist is going to be able to do something different --

CHAIRMAN THOMADSEN: Do you mean --

DR. METTLER: -- because the beam is not --

CHAIRMAN THOMADSEN: -- radiation oncologist?

DR. METTLER: Sorry. Radiation oncologist.

CHAIRMAN THOMADSEN: Yes.

DR. METTLER: Yes. But I don't see that whether you can turn the beam off or not, that that makes the difference about whether the radiation oncologist needs to be there.

DR. KJALL: No, not that single fact, but what I wanted to share was that the system is safe from that point of view. And I also added the incident rates and the comparative safety analysis. And from these three points, or these three arguments I think they clearly show that the competence is needed at the console or well-filled by a nurse and the radiation therapist.

DR. METTLER: Well, I guess you're advocating that the other manufacturers don't get relaxed requirements. Just your company. And I don't see the reason for that.

DR. KJALL: Do you mean for instance the LINAC manufacturers? They don't have this requirement, so they don't need to be there.

DR. METTLER: The other people who make

similar machines to yours?

DR. KJALL: Yes. Yes, they don't have these.

DR. METTLER: I thought they did.

MEMBER COSTELLO: I think he means the other Gamma Knifes.

DR. METTLER: Yes.

DR. KJALL: Oh, you mean the Gamma Knifes that is now out of sales, the old -- what we call the old Gamma Knifes?

DR. METTLER: Well, there are other manufacturers besides your company?

DR. KJALL: No. No.

DR. METTLER: Yours is the only one?

MEMBER ENNIS: You're talking about previous generations of the equipment versus the current generation.

DR. METTLER: But the question is still a good one, I think. Why not from your perspective relax regulations for all Gamma Knifes? Why just for Perfexion? Because maybe the -- I don't really kind of get why it matters.

DR. KJALL: I think the safety record and the fact that you have -- as we talked about earlier, the fact that you have the ability to turn the beams off

very quickly and the design of the system makes it safer than the other systems. So in case -- older Gamma Knife is -- if there is an incident occurring on an older Gamma Knife, we have to enter the treatment room. The beams are still on.

DR. METTLER: But how does that reflect on whether radiation oncologists are at the console or not? It's a riskier thing to deal with, but again it has nothing to do with whether a radiation oncologist is there or not. So I don't get the connection.

DR. KJALL: Yes, we just have rather few old systems out, so they would be gradually replaced. So we are aiming at changing the licensing guidance for Perfexion only. There is no other sort of reason why. They will be replaced, thank God.

CHAIRMAN THOMADSEN: Dr. Langhorst?

MEMBER LANGHORST: I am hesitant to speak because I do have a license amendment in with our region to change our AU physical presence requirement for Perfexion, but I do want to clarify why talking about Perfexion and not the older units. Perfexion is licensed under 35.1000. And so the requirements of that use are in licensing guidance which is relatively easy to change. The old units are under 35.600. That would require rulemaking, and plan on about 15 to 20

years.

CHAIRMAN THOMADSEN: Thank you, Dr. Langhorst. Dr. Zanzonico?

MEMBER ZANZONICO: I have a question. You mentioned that outside the U.S. where the physical presence requirement is not as extreme, for lack of a better term, the error rate, as far as you can tell, is comparable to what is in the U.S.

DR. KJALL: Right.

MEMBER ZANZONICO: I don't know if these data are available or not, but is the response rate in the event of an error comparable. I've heard that the times you were referring to were basically assumed. In other words, they weren't based on measurements.

DR. KJALL: The 45 seconds that I --

MEMBER ZANZONICO: Yes. Right.

DR. KJALL: No, I said that doesn't really matter because it's proportional to the maximum dose rate. So it could be 15 seconds or 50 seconds. Response rate? Do you mean the --

(Simultaneous speaking)

MEMBER ZANZONICO: Well, it seems to me that the physical presence of physician/radiation oncologists as opposed to a tech plus a nurse -- I think as most people are suggesting, wouldn't improve things

in terms of a recognition of an event, that the radiation technologist can be adequately trained to recognize and respond to a technical event, and a nurse, as has been suggested, would perhaps even be better in recognizing a medical event. The question is it seems then is the timed response. In other words, would those individuals respond as quickly and therefore limit the potential damage from an event? And my question is are there any data on that?

DR. KJALL: No.

MEMBER ZANZONICO: Okay.

CHAIRMAN THOMADSEN: Okay. Thank you very much. Dr. Ennis?

MEMBER ENNIS: It just seems worth noting that although it may not be required in Europe -- well, I guess this is kind of similar to my previous comment. A high proportion of European patients who are being treated with a neurosurgeon or radiation oncologist present, so that high-level kind of observation is occurring in Europe, at least in the majority of cases as well. So it's not as though in Europe and U.K. it's just always a nurse and therapist treating the patient. That's not the reality there.

DR. KJALL: In U.K. it actually is.

MEMBER ENNIS: Oh, it could be in U.K., but

certainly it wasn't for the rest.

DR. KJALL: No. The most common answer was actually a radiation therapist alone, followed by a neurosurgeon alone, followed by radiation therapist and a nurse and the neurosurgeon, in that order. So a lot of sites they only have a radiation therapist and a nurse at the console.

MEMBER ENNIS: I mean, it was over 50 percent where there was a neurosurgeon present.

DR. KJALL: Yes.

MEMBER ENNIS: So that's not most.

DR. KJALL: There is a wide variety of sort or constellations. And I think that it's interesting to note that the incident rate doesn't really vary that much even though the data is of course maybe not that sensitive to this. But the incident rate doesn't vary with the constellations you have at the console. So it's more important to talk about the competencies there than actually job descriptions and types. And one country even reported that when they had got rid of the radiation oncologist, patient satisfaction went through the roof.

MEMBER ENNIS: So, I'm going to -- so let me -- Dr. Suh, in response to that?

MEMBER SUH: So, I can just tell you I have

been involved with several thousand cases now. I think the patients and their family members are very reassured when they know that I'm at the console. So I think the last statement that you made is probably not an appropriate statement.

CHAIRMAN THOMADSEN: Ms. Weil?

MEMBER WEIL: How many of the older Gamma Knifes are out there in proportion to the Perfexions?

DR. KJALL: Globally or here? About two-thirds are Perfexion globally.

MEMBER WEIL: Yes.

DR. KJALL: Eighty, ninety out of hundred and twenty something here are Perfexion.

MEMBER WEIL: And what's the life span of those existing older units? Are they nearing the need the need to be replaced by Perfexion units, or will they be functional for a long period of time if they facility chose to keep them?

DR. KJALL: Oh, I really don't know. I think they are -- my own interpretation, are being replaced continuously right now.

MEMBER WEIL: What is - does a Perfexion cost?

DR. KJALL: That is --

(Laughter)

MEMBER WEIL: It just seems to me that it would be very advantageous to an institution who wants to use the unit more without having -- it would be an incentive to replace the unit if the requirements for people at the console were changed.

DR. KJALL: Yes, that would be a driving force, of course.

CHAIRMAN THOMADSEN: Any other comments? Hearing none, I will thank you for the presentation.

DR. KJALL: Thank you.

CHAIRMAN THOMADSEN: And that bring us to a discussion of 10 CFR Part 35 rulemaking. Mr. Danna, are you alone or is Neelam --

MR. DANNA: I'm alone. Well, actually no, someone's on the phone, hopefully.

CHAIRMAN THOMADSEN: Okay.

MR. DANNA: Okay. Good morning. My name is Jim Danna. I'm the Branch Chief for Rulemaking in the Office of Nuclear Material Safety and Safeguards, and this morning I will provide you an update of the status of the Part 35 medical rulemaking.

Giving today's presentation will be Neelam Bhalla, who should be on the phone.

Neelam, are you there?

MEMBER COSTELLO: Someone is there.

MS. HOLIDAY: Neelam, are you on the line?

MS. BHALLA: Yes, Jim, I am.

MR. DANNA: Because this might be confusing, I'll go through the presentation. And, Neelam, if you can hear me, if you have anything to add, you can do so at the end. And there are several others in the room that can answer questions.

Neelam is the project manager. She knows the ins and outs of the rulemaking. So I'll do my best.

Okay. As you're aware, the Part 35 rulemaking amends the regulations related to the medical use of byproduct material. The NRC published a proposed rule for comment on July 21st. It was available for public comment for four months and the comment period closed on November 18th, 2014.

The NRC received approximately 47 comment letters. Those comment letters were parsed into several hundred individual comments. The Rulemaking Working Group is currently getting those comments into topical areas and summarizing those comments and developing responses. Now once they finish evaluating those comments, they'll them make modifications to the proposed rule, prepare the final rule package. And that will be delivered to the Commission in December of this year.

What we wanted to do is just summarize who we've received comments from and the nature of those comments, and this is just a summary. The staff is still in the process of evaluating the comments.

We did include comments from professional societies, the Organization of Agreement States, the CRCPD States, individual States, practicing physicians, medical physicists, radiation safety officers, nuclear pharmacists, as well as individual members of the public. Recently we also had an inquiry from Congressman Heck from Nevada. We arranged a call with the Congressman. He has a medical background. He had some interest in this rule on training requirements. He followed it up with a letter to the NRC, which we also included in the docket as an additional comment. We received that, I think it was last week.

And to summarize the comment, just key areas -- and actually maybe I'll turn to Donna-Beth or Sandy Gabriel. Could you summarize the commentaries? You could probably do a better job than I could.

DR. HOWE: Because we've got a new individual identified as the associate radiation safety officer we got a lot of comments on how we added them into the regulation and our requirements on them. So we got a lot of comments on the associate radiation

safety officer.

The medical event definition in permanent implant brachytherapy, that certainly is a major part of the rule, so we had a lot of comments on what we had proposed for specific requirements and also for written directives and the program to assure that administrations are in accordance with the intended written directive.

Agreement State compatibility from B to C was certainly a major topic, and we got comments from the Agreement States and individual States on that. And also got comments from individuals, members of the public on that.

We had a number of comments on the alpha and beta emitters, and we'll be working those.

We had comments on reporting of failed generators. And that would be the molybdenum-99m, technetium-99m and the strontium-rubidium generators. So we got comments on reporting and other issues with that.

And we got a lot of positive comments on the attestation requirements for board-certified individuals, both the new people coming in as board-certified and the grandfathered board-certified individuals.

MR. DANNA: Okay. Thanks, Donna-Beth. As I said earlier, the working group is in the process of evaluating those comments, summarizing them and developing responses. The working group will then make any modifications as appropriate from the proposed rule. I believe Neelam scheduled calls for having a revised rule package sometime in the May or June time frame, and I believe at that time the Committee will receive a copy of the proposed [final] rule for comment as they did the -- a copy of the final rule for comment as you did the proposed rule. And it's due to the Commission with a summary of those comments in December.

Any questions?

CHAIRMAN THOMADSEN: Thank you very much. Dr. Zanzonico?

MEMBER ZANZONICO: I'd just like to point out the ACMUI had submitted a detailed report on the proposed rulemaking. The ACMUI isn't listed among the commenters.

MR. DANNA: Yes, you're right. That's a good point.

MEMBER ZANZONICO: I presume --

(Simultaneous speaking)

MR. DANNA: Yes, you're right. Yes, we need to include those in the comments. But, yes, those

are being included along with the other comments. Thank you.

CHAIRMAN THOMADSEN: Thank you. Any other comments or questions?

(No response)

CHAIRMAN THOMADSEN: In that case thank you very much.

MR. DANNA: Okay. Great. Thank you.

CHAIRMAN THOMADSEN: Ms. Holiday? Our next topic is our reporting structure.

MS. HOLIDAY: I didn't bring my tent. I hope you guys know who I am by now.

(Laughter)

MS. HOLIDAY: So today I'm here to talk to you about our annual reporting structure. So of course I'm going to talk about what the current reporting structure is, talk about the annual review that the Committee requested that I make, discuss our meetings in terms of how often the Committee meets, and then open it up for discussion. Thank you.

So this is a chart that should look very familiar to the Committee, or not so familiar to our new individuals, but the way that the hierarchy works is that ACMUI does not report to Sophie, although it may seem like that sometimes.

(Laughter)

MS. HOLIDAY: But ACMUI does not report to Douglas. In fact, the ACMUI reports to the division director of the Division of Material Safety, State, Tribal and Rulemaking Programs. I know last time we met we had a different division name, and the names never get any better.

(Laughter)

MS. HOLIDAY: And of course we are now under the director of the Officer of Nuclear Material Safety and Safeguards, NMSS. I believe you all met Catherine Haney last time and Scott Moore. They are our director and deputy officer director. And then of course NMSS reports to the EDO, Mark Satorius. And then the EDO goes up to the channel for the Commission.

So our branch -- oh, yes. I'm sorry.

MEMBER ENNIS: I'm sorry, but EDO stands for?

MS. HOLIDAY: Executive Director for Operations. Yes. So he is like the voice of all the offices in NRC.

And so our branch, MSEB, Medical Safety and Events Assessment Branch, we are in charge of overseeing the day-to-day operations for the ACMUI. So again, that's why you probably think I am in charge of you,

because I'm the one that is in charge of overseeing the Committee.

Okay. So now we're at the current reporting structure. This all came about because in January of 2011 the ACMUI held a public teleconference where they discussed the current reporting structure, which was what I just described in the previous slide, and the Committee made the recommendation unanimously to continue reporting to our division director. This was then captured in what we call a SECY paper, a paper that's sent up to the Commission where the Commission approves the Committee's recommendation to retain their current reporting structure.

Okay. So in the subsequent teleconference that happened a week later, January 12th of 2011, the Committee requested that we continue to review this reporting structure on an annual basis to make sure that you're still happy with my interactions with you, your interactions with our branch, with our division through the office versus going straight to the Commission because there's been a comparison between the ACMUI and ACRS, which is our Advisory Committee on Reactor Safeguards. They report to the Commission versus the ACMUI, which reports to staff.

So since then we have had an annual review

in September of 2012, September 2013, and in May of 2014. And so I brought this up here so I could quote something. At the May 2014 ACMUI meeting Dr. Zanzonico presented the ACMUI Bylaw Subcommittee report. And one of the tasks that the ACMUI was charged with was reviewing your reporting structure and informing staff if they preferred continuing this reporting structure and if they wanted to change the frequency of meetings, so on and so forth.

So I thought that it was befitting for me to quote something directly out of that report, in which it says, "The working relationship between the NRC and the ACMUI remains excellent. The reporting structure through NRC staff continues to function effectively and the associated logistical overhead associated with direct reporting to the Commission; e.g., the need for more frequent meetings, did not and does not now justify any change in the ACMUI's reporting structure. This recommendation is predicated on the annual Commission briefing by the ACMUI and the annual review of its reporting structure remaining in place." And that report of course was endorsed by the Full Committee.

So then that brings me to the frequency of our meetings. As you all know, we meet here at NRC headquarters in this room twice a year, once for the

spring and once in the fall. Previously our spring meetings were April-May, but we've moved them to March-April. And our fall meetings are between September and October. Then we have public teleconferences on an as-needed basis, which I will cover at our administrative closing because it looks like we have quite a busy summer this year.

Okay. So now that brings me to our discussion portion. This is my time to ask you are you still satisfied with our current reporting structure or do you want to report directly to the Commission? Do you agree with the frequency of these meetings? Is two in-person meetings enough or should there be three or should there be four? What other changes do you want? Thank you.

CHAIRMAN THOMADSEN: Comments from the Committee? Dr. Zanzonico?

MEMBER ZANZONICO: Having been involved with the Bylaws Committee and --

CHAIRMAN THOMADSEN: I'm sorry.

MEMBER ZANZONICO: I said having been involved with the Bylaws Committee and generating the verbiage that Sophie just quoted, I don't feel that there's been any change, at least personally, in my perception of how the Committee, the ACMUI is

functioning and so forth. So I don't see any compelling or really any need to change or reporting structure or frequency of meetings. I don't have the impression that there are unaddressed issues that would be better addressed or addressed at all in there were more frequent meetings. I mean, I think the teleconference mechanism is fine in addressing issues that may arise or require attention between meetings. But my point is I think the current reporting structure is perfectly adequate.

CHAIRMAN THOMADSEN: Dr. Alderson?

VICE CHAIR ALDERSON: Yes, I would agree with that comment. What I wanted to know about was where the other people that we see a lot around the tables like Sophie, you, Dr. Howe, Ashley, where do all those people belong on this chart? Are you under Material Safety?

MS. HOLIDAY: Under the block that says MSEB.

VICE CHAIR ALDERSON: MSEB?

MS. HOLIDAY: MSEB is the acronym for our branch. And so, Ms. Cockerham, Dr. Daibes, Ms. Abogunde, Dr. Gabriel, Dr. Howe. There are other individuals in our branch. We're all a part of that branch. And Douglas Bollock is our branch chief, who

is the new branch chief as Laura Dudes mentioned earlier. So he is actually now your new designated federal officer as well.

VICE CHAIR ALDERSON: Okay.

CHAIRMAN THOMADSEN: Thank you for the clarification.

MS. HOLIDAY: You're welcome.

CHAIRMAN THOMADSEN: Mr. Costello?

MEMBER COSTELLO: And I agree I don't think there's any change. I just do have a question based on something we discussed over lunch. Is there a provision if the ACMUI did want to communicate directly to the Commission for something that they felt was so important that they'd want to do that? Can that be done?

MS. HOLIDAY: Absolutely. I know you weren't here before when we discussed this, but our Commission has an open-door policy. They've always had the door open for the ACMUI Chairman or any other individuals on this Committee to come up and have a discussion with them. But since you report to staff, we just want to be made aware that you're coming. Not that you have to tell us what you're talking about. It would just be nice to know that you're in town.

MEMBER COSTELLO: Good neighbor policy?

MS. HOLIDAY: That's right.

(Laughter)

CHAIRMAN THOMADSEN: Ms. Cockerham, were you going to say something?

MS. COCKERHAM: I was just going to point out to Dr. Alderson that we're on the bottom right. I had the chart brought up. All of staff falls --

VICE CHAIR ALDERSON: Under MSEB?

MS. COCKERHAM: Yes.

VICE CHAIR ALDERSON: Okay. Great. Thank you.

CHAIRMAN THOMADSEN: Dr. Zanzonico?

MEMBER ZANZONICO: Just a technical suggestion.

MS. HOLIDAY: Sure.

MEMBER ZANZONICO: I think it would be helpful if there could be a secure server established, something analogous to Google Docs or some such thing as that where Committee members could deposit and access documents, working documents and so forth, rather than having to go constantly through email. It seems like we're a step behind the times in terms of remote access networks. And I know there are all kinds of security issues. We can't get Internet service here, so forth and so on, but I imagine that could be done.

CHAIRMAN THOMADSEN: There is also some open record issues with that. Just as we can't on email have a discussion with the whole Committee, we would have to have particular rules with --

(Simultaneous speaking)

MS. HOLIDAY: To respond to your request, do you know how every fall we have required annual trainings, and you know how onerous and burdensome those trainings can be? If we were to give you access to some internal stuff, that would open up a whole other can of worms. More training. NRC would monitor your computers, things like that, things that happen for us.

MEMBER ZANZONICO: So let's take that off the table.

(Laughter)

MEMBER ZANZONICO: But what about the possibility still of a server specifically for the ACMUI? In other words, a mechanism other than email for reviewing documents and so forth?

MS. HOLIDAY: I think the only response that I could probably make is I'll look into it and get back to you, but I wouldn't be surprised if my answer changes much differently.

MEMBER ZANZONICO: Okay.

CHAIRMAN THOMADSEN: Oh, Ms. Cockerham?

MS. COCKERHAM: This is Ashley, and Sophie's right, it opens up another can of worms specifically with regard to training. There would be multiple courses that would be required and also the computer monitoring. Anything that we provide would have to be on the NRC servers and therefore you would be subject to all of the requirements that we deal with internally with documents.

MEMBER ZANZONICO: But we all come from institutions where there are HIPAA and other laws and all sorts of firewalls and so forth. I don't understand the fundamental difference why a server couldn't be firewalled from the rest of NRC's computer --

(Simultaneous speaking)

MS. COCKERHAM: We would have to look back at all of the exemption memos that we initially wrote, because we provided very specific justifications for exempting you from training. And our whole premise is that you do not have access to the NRC network. Opening up your computers to the NRC network, it presents difficulties.

CHAIRMAN THOMADSEN: Mr. Costello?

MEMBER COSTELLO: Currently I notice on the Web site we have subcommittee reports there, we have agendas there, many ACMUI documents there. I assume

those are all on NRC servers. Right?

MS. HOLIDAY: Those are publically available and captured into our Agency-wide Document -- ADAMS. It's captured in our publically-available ADAMS system.

MEMBER COSTELLO: Understood. But would it be possible for us to give to the NRC to put on their server something that could be password protected or something that we won't be placing there, right, but we could have access to it?

MS. HOLIDAY: Anything on our public Web site must be publically --

MEMBER COSTELLO: I'm not saying that. It doesn't have to be identical to the way that we currently do ACMUI documents. I think the ACMUI documents are on the NRC server and we have access to them. The public has access to them. Could there be other documents on the NRC server that we give to them to place on the server which could potentially then give access to and which would not be publically available?

MS. COCKERHAM: In that case we would be giving you access to internal NRC servers, and therefore you would be subject to --

MEMBER COSTELLO: Okay.

MS. COCKERHAM: -- all of the security

requirements.

MEMBER COSTELLO: In other words, no?

MS. COCKERHAM: This is something I've looked into extensively. I think for those of you that have been around, you know I'm a make-it-happen-type person. And I wrote numerous memos to sort of make these things happen. And this was one of those where -- like Dr. Zanzonico said, okay, never mind I take it back, to just get back into that space. It doesn't mean Sophie can't look into it again.

MEMBER COSTELLO: Our sister committee has access, don't they?

MS. COCKERHAM: It's different.

MEMBER COSTELLO: But they have access, the other --

(Simultaneous speaking)

MS. COCKERHAM: But they come here.

MEMBER COSTELLO: Okay.

MR. BOLLOCK: That's something we can look into like an information exchange. I mean, I know there are restrictions for what we as the NRC staff have -- we have our internal SharePoint sites and things like that. But we can look into something that would maybe be accessible to you and us for that information exchange. So that's something we can look into.

CHAIRMAN THOMADSEN: Thank you very much. Dr. Alderson?

VICE CHAIR ALDERSON: Just a comment about the structure as it sits up there on the screen. And now from the questions I understand that all of the people who support us and with whom we work here are in MSEB. The diagram itself, I would submit, doesn't imply to anyone else that we communicate with one another. I mean, ACMUI is over there and MSEB is over there. It would seem like on a lot of TOs you have a little dotted line or you have other ways that show that these two groups actually work together. It's just a minor comment.

MS. HOLIDAY: Understood.

CHAIRMAN THOMADSEN: Dr. Mettler?

DR. METTLER: Yes, I'm not sure this is exactly in relation to what you're asking, but when I was looking into this Committee to begin with, I went on the Web pages and looked all around back for about three years. And a curious thing that I ran into was it said support for this Committee is 1.3 FTE and $300,000. And I thought to myself that can't be. I don't know, do you guys have any input into saying, excuse me, they actually need more money than that or something? I mean --

(Laughter)

DR. METTLER: I don't know, maybe you guys could talk about it, but it just was strange.

CHAIRMAN THOMADSEN: There have been occasions when we've discussed things such as the additional topical meetings, and the expenses that may be incurred in order to have those occur. For the most part I think we've found that when we want to have something happen it does. I don't think we've been starved for resources.

DR. METTLER: No, and apparently you get the resources.

CHAIRMAN THOMADSEN: Yes.

DR. METTLER: I just don't know why it was on the site like that and --

CHAIRMAN THOMADSEN: No, I have not --

DR. METTLER: -- whether that -- if somebody decides to cut a budget somewhere, that this is an issue.

CHAIRMAN THOMADSEN: Yes.

MR. BOLLOCK: I think it's just the transparency. This is how much effort and money we put towards this committee on a yearly basis.

MS. COCKERHAM: Yes, FACA requires that to be a part of the information provided.

MR. BOLLOCK: Right. We have to report that information annually.

DR. METTLER: If that's what you're doing it with, this is the best deal the taxpayers have.

(Laughter)

MS. HOLIDAY: I will say that what you bring up is something that has been brought up by this Committee before where they felt that just Sophie in this position -- because ACMUI is not my only duties, although it course seems like it, isn't enough.

(Laughter)

MS. HOLIDAY: It's just a matter of how our budget is formulated from year to year. And the numbers that you see on the Web site, as Mr. Bollock indicated, every year we are required to submit a publically available report to GSA every year because this is a federal advisory committee. And so the numbers, the dollar signs that you see there are calculated based on what we pay for your hours of work and for your travel here and for when staff does work that's related to this Committee.

So some years it's higher. Like for example, when we had the rulemaking year, that was a very, very busy year. 2013 was pretty high for those reasons. But then there are other years where there

aren't as many pressing matters and the money for that year is just not as high because there aren't as many hours or efforts put towards certain topics. So that's where the money dollar signs come from.

CHAIRMAN THOMADSEN: Mr. Costello?

MEMBER COSTELLO: On the previous question about can we go to the Commission if we really need to, and you said yes. Anybody can go to the Commission.

MS. HOLIDAY: Absolutely.

MEMBER COSTELLO: I was thinking a little more than that. But would there be a value -- can the chart have a dotted line to the Commission to indicate that if a situation requires it, particularly a chairman could talk to them?

MS. HOLIDAY: So I'll be honest with you guys, this is just a chart that Sophie put together. So if there are no dotted lines or solid lines, that's because Sophie didn't --

(Laughter)

MS. HOLIDAY: So if it would please you, I can add the dotted lines.

(Laughter)

MEMBER COSTELLO: Well, it says something. It says something.

MS. HOLIDAY: Understood.

MEMBER COSTELLO: In a lot of places you go you'll see an RSO will be reporting -- the RSO will have access to the highest levels of the institution.

MS. HOLIDAY: Sure.

MEMBER COSTELLO: And I think that to say that we do is not a trivial matter.

MS. HOLIDAY: Sure.

MEMBER COSTELLO: Okay? Depending what the issue is.

CHAIRMAN THOMADSEN: Ms. Weil?

MEMBER WEIL: In response to that comment, I think we tried to address that in the Bylaws Subcommittee by changing some of the wording in our reporting relationship. It originally said we report to staff, and we changed it to say we report to the Commission through staff --

MS. HOLIDAY: Through staff.

MEMBER WEIL: -- or something similar.

MS. HOLIDAY: Yes.

MEMBER WEIL: So it's there.

CHAIRMAN THOMADSEN: Mr. Mattmuller?

MEMBER MATTMULLER: A question, a comment, and a question. Can we turn off the public record for a while?

(Laughter)

MEMBER MATTMULLER: Sophie, it's okay if you're in charge. We're happy with that.

(Laughter)

MEMBER MATTMULLER: But my real question is this is my sixth-and-a-half year on the Committee and we're now on our fourth director of MSTR. And is that typical for NRC positions, or are we that challenging for a director?

(Laughter)

MS. HOLIDAY: Oh, no.

MS. HENDERSON: No, no, it has nothing to do with ACMUI.

(Laughter)

MS. HENDERSON: And it has been a little unusual. Hopefully it will settle down.

MEMBER MATTMULLER: Settle down. Because my concern would be with that rapid turnover that that might dilute or interfere with the continuity of our message to the Commissioners. So I wish you a long tenure, Doug.

MS. HENDERSON: Thank you. So do I.

MS. HOLIDAY: I would like to add that -- I know we said this at the last meeting when we changed from FSME to NMSS that our new office director; not so new anymore, and deputy office director originally came

from Materials. So they know medical. And your new, soon-to-be division director was a medical physicist. So I would think that that's major progress in what this Committee would like to see happen.

CHAIRMAN THOMADSEN: Any other comments of questions from the Committee?

(No response)

CHAIRMAN THOMADSEN: I think we're set. Which brings us to the open forum again. Just as we opened, we'll close with that. And I'll ask the Committee do you have comments, items you would like to consider? Mr. Costello?

MEMBER COSTELLO: Can I raise a logistical issue rather than medical topic of interest?

CHAIRMAN THOMADSEN: Yes.

MEMBER COSTELLO: This is purely logistical. I think it may still be snowing out there and I have a long drive back. Could we shorten our lunch a little bit?

CHAIRMAN THOMADSEN: Yes, that would be fine. If we can get through -- why don't we set the time once we're done with everything and -- I see no problem with doing that. Yes, I think we'd all like to do that.

Other issues that are coming up? Mr. Mattmuller?

MEMBER MATTMULLER: Well, I suppose I need clarification as to what our pathway is for germanium-68 and the DFP issue.

CHAIRMAN THOMADSEN: That's a very good question. Sophie, can you answer that?

MS. HOLIDAY: You want to know what options you have or what the charge is or the task for the Subcommittee going forward? Or maybe I should say that's something we can talk about outside of this piece since I'm the staff resource person for that.

MEMBER MATTMULLER: Okay.

MS. HOLIDAY: So I will be working very closely with the Subcommittee to discuss different avenues for pursuing that.

MEMBER COSTELLO: Can I venture a possible answer to that?

CHAIRMAN THOMADSEN: Yes, please.

MEMBER COSTELLO: It is to come up with the most expeditious how.

MS. HOLIDAY: Yes.

MEMBER COSTELLO: And I don't think the Subcommittee has to discuss anymore why this is a good idea because I don't think there are any dissenters, and the "what" and the "why" I think are clear. I think it should just simply be a logistical question using the

NRC processes, whatever they may be, to get this done as quickly as possible.

CHAIRMAN THOMADSEN: Thank you. Ah, a member of the public.

MS. FAIROBENT: Dr. Thomadsen, we've been having some --

CHAIRMAN THOMADSEN: This is Lynne --

MS. FAIROBENT: Lynne Fairobent with AAPM. Sorry. We've been having some difficulty hearing in the back and I just wondered if I may have missed what action the Committee is thinking of taking based on the Elekta presentation. I didn't hear if there was any follow-up, if there's a Subcommittee or just sort of -- from what I could hear it seemed to be hanging. So that's my question.

CHAIRMAN THOMADSEN: And I think that that's exactly the case. There was no motion that was raised following that presentation. We may pick up the topic in the future if somebody on the Committee decides to raise that.

MS. FAIROBENT: Thank you.

CHAIRMAN THOMADSEN: You're welcome. Did somebody else have their hand up? No. Yes.

MEMBER LANGHORST: Go ahead.

CHAIRMAN THOMADSEN: Anyways, in response

to your question, Mr. Mattmuller, I think your subommittee's charged -- not to belittle exactly that we've -- we have been very convinced that there is a problem that needs to be addressed. I think in the addressing of it, it probably will be useful to have a document that very clearly and concisely describes the problem and probably its origin. But, right, your subcommittee will work --

MEMBER MATTMULLER: Okay.

CHAIRMAN THOMADSEN: -- off-line would the --

MEMBER MATTMULLER: Okay.

CHAIRMAN THOMADSEN: -- NRC staff to come up with what documentation is necessary and the most expedient remedial action.

Yes, Dr. Langhorst. Sorry.

MEMBER LANGHORST: I think a question that came up that we may want to explore; this was during Mr. Costello's talk, is the compatibility B, and maybe exploring what this means, program elements with significant direct trans-boundary implications, what that means in medical practice across different states and so on. That seemed to be a question that Dr. Ennis raised.

CHAIRMAN THOMADSEN: Yes.

MEMBER LANGHORST: And I don't know if that would be worth a look at from the Committee's point of view on that.

CHAIRMAN THOMADSEN: Thank you. Probably so. If there are no others, I would raise an issue that became clear to me when I was involved with a discussion at the University of Wisconsin dealing with a medical event on a linear accelerator, which turned out not being a medical event, but it was clear that the definition of "medical event" contained some ambiguities that we had tended to clarify in the permanent implant cases. And I think an issue for us to consider in the future is the definition of a medical event outside of permanent implants to clarify some ambiguities that exist in there.

DR. METTLER: What were the ambiguities specifically?

CHAIRMAN THOMADSEN: The question surrounded exactly the issues that we dealt with in permanent implants; that is, was the dose in excess to a point exactly what should be the issue under judgment? And the definitions for the medical event in Wisconsin statutes which governed the linear accelerator were I think exactly the same as in Part 35 for medical events other than permanent implants in dealing with

radioactive materials.

Which leads us to the question -- I now have an incredibly long list of items that have been raised here which all are very good and what to do with this all? I would propose that I will try to come up with some priority for addressing these issues, send it to the Committee. I don't think that this is something that we have to worry about open records since this is just our scheduling issues.

MEMBER MATTMULLER: There's one item I'd like to add to your list, if possible.

CHAIRMAN THOMADSEN: Sure.

MEMBER MATTMULLER: And that is with the new NorthStar technetium-99m generator system that's undergoing FDA review right now that it might be beneficial to contact the NorthStar people for them to give a presentation on how it works, because it is significantly different from a standard technetium-99m generator.

CHAIRMAN THOMADSEN: Thank you for alerting us to that fact.

MEMBER ZANZONICO: Pat Zanzonico. That actually raises an issue that since we have had industry representatives here, relative to my presentation on the cadaver issue, it's been very difficult to try and

get from the manufacturers of -- the producers of yttrium-90 what their -- the actual radionuclide composition is. I mean, they're not anxious to publicize the radio-contaminants that may create logistical and other problems. Perhaps in terms of inviting an industry rep you might want to invite the manufacturer --

MS. HOLIDAY: Dr. Thomadsen?

CHAIRMAN THOMADSEN: Yes, Ms. Cockerham?

MS. HOLIDAY: That's information that staff will be able to provide to you.

CHAIRMAN THOMADSEN: I'm sorry.

MS. COCKERHAM: This is Ashley Cockerham. I can get in touch with you, Dr. Zanzonico --

MEMBER ZANZONICO: Okay.

MS. COCKERHAM: -- if we want to talk, because I have additional questions for you following your presentation.

MEMBER ZANZONICO: Okay.

CHAIRMAN THOMADSEN: Okay. Thank you. Dr. Alderson?

VICE CHAIR ALDERSON: I have a comment on that issue, and it's just a general concern. When we invite, and when any federal committee, but when this Committee invites industrial representatives to come to

speak before us, we have to think about the entire industry because we are in fact potentially giving a benefit to one particular seller of a product over the others. So the more that you open up the door to industry people coming here and talking to us, you're going to have to keep opening it wider and wider and wider or you're be accused of favoritism. So I just throw that out there as the Committee thinks about industrial reps.

CHAIRMAN THOMADSEN: Thank you for keeping that foremost in our minds. Oh, yes, Dr. Howe.

DR. HOWE: As I was giving my presentation on medical events I was realizing that in the past we've had two presentations to the ACMUI. One was the medical events and the other was the reportable events coming from medical use licensees. And that kind of dropped off the table. And I don't know whether the ACMUI would like to consider adding that back in.

CHAIRMAN THOMADSEN: I'm sorry, I wasn't hearing you very well at all. What have we lost?

DR. HOWE: You've lost the presentation that Ralph Lieto used to present, which was the reportable events from medical use licensees that were not medical events. They were more the radiation safety issues. And I don't know whether the ACMUI wants

to go back and add those or not.

CHAIRMAN THOMADSEN: I think when we added Dr. Langhorst to the Medical Event Subcommittee that she would probably be assigned to pick up on those types of issues that Mr. Lieto did.

MEMBER LANGHORST: And sorry, I've never been told that.

CHAIRMAN THOMADSEN: Well, we'll talk about that.

(Laughter)

MEMBER LANGHORST: Sounds great.

CHAIRMAN THOMADSEN: But thank you for bringing that up. And since discussion has terminated on this -- oh, do you have something else to say, Dr. Langhorst?

MEMBER LANGHORST: Well, I just wondered if you might share with us your list.

CHAIRMAN THOMADSEN: Oh, yes, I'll be happy to. Source security assessment, potential Part 20, Part 35 comments, the mirrored alpha dose tracking through the National Academy's report, regulatory dose limits, radioactive cadavers, continued nanotechnologies, licensing guidances, older, and reviewing those. That's from you. Security of sources, further on the germanium/gallium situation,

and NorthStar's technetium-99m generator, compatibility implications that we've discussed so far. And I apologize for those being just shorthand parts of my list, but they will be filled of course in what I send out.

MEMBER LANGHORST: Thank you.

CHAIRMAN THOMADSEN: All right. In that case it's time for summaries. And now we're [going to] find out if we actually did something this meeting.

(Laughter)

MS. HOLIDAY: And I will provide a hard copy to the Committee after this.

So the first recommendation -- or for those of you in the audience or our new members, at the end of every meeting we go over the current recommendation action chart which captures all of the items that either the Committee said that they would do, or a Subcommittee, or that they requested staff do.

So yesterday Dr. Langhorst committed for herself and Mr. Costello to distribute questions to the Committee regarding the proper platform, their expected and necessary participants, and the feasibility in conducting this additional medical meeting. So that's an ACMUI action. Are there any questions on that one?

(No response)

MS. HOLIDAY: Okay. Moving on to the second item, Dr. Thomadsen formed a subcommittee to review and evaluate the phrase "patient intervention." Members include Dr. Dilsizian as the chair, Dr. Alderson, Mr. Costello, Dr. Ennis, Dr. Suh and Ms. Laura Weil. The staff resource person is Dr. Gabriel.

Okay. The third item is that Dr. Thomadsen formed another subcommittee to review the existing 10 CFR 35.1000 guidance for the radioactive seed localization. That was the guidance that Mr. Sheetz presented yesterday. The subcommittee was tasked with making their recommendations to revisions to that guidance. Members of that subcommittee include Dr. Ennis as the chair, Dr. Alderson, Mr. Costello, Dr. Zanzonico and Dr. Mettler pending security clearance. A public teleconference will be held with the next several months. We'll do that planning after I get through this list. And your staff resource person will be myself as I am the co-chair for the NRC Agreement State Working Group that's been put together for this.

The next item is that because we've had members that rotate off the Committee and we have new members now this is simply to state that we have added Dr. Ennis, Dr. O'Hara and Dr. Zanzonico to the Standing Medical Events Subcommittee. So for the full

membership -- and I wasn't sure if we wanted to make Dr. Ennis the chair of that subcommittee. I was just thinking that Dr. Welsh was the chair last time, so that's a call for you, Dr. Thomadsen.

CHAIRMAN THOMADSEN: Are you comfortable with that, Dr. Ennis?

MEMBER ENNIS: I don't really know what's involved, so it would be hard to speak to that.

(Laughter)

CHAIRMAN THOMADSEN: It sounds like you don't have an objection then.

(Laughter)

MEMBER ENNIS: I learned a lot of lessons today.

(Laughter)

MS. HOLIDAY: And so the other members of that subcommittee are Dr. Langhorst, Mr. Mattmuller, Dr. O'Hara, Dr. Palestro, Dr. Suh, Dr. Thomadsen and Dr. Zanzonico. While this is 8 members out of 13, this is a subcommittee that simply reports on the previous year's fiscal year's medical events, so this doesn't violate any of the rules because there are no recommendations or actions that come out of this report.

Next item is that Dr. Thomadsen has tasked the existing Germanium/Gallium-68 Subcommittee with:

(1) estimating the number of potential gallium-68 generator licensees; and (2) making a recommendation to the Full Committee on which route of action it believes NRC should pursue to address the decommissioning funding plan issue. The subcommittee should plan to hold a public teleconference again within the next several months. Just to recap, members of that subcommittee include Mr. Mattmuller as the chair, Mr. Costello, Dr. Langhorst, Dr. Palestro and Dr. Zanzonico. And again that staff resource person is myself.

Are there any comments or issues on that one?

MEMBER LANGHORST: I'm not sure that the subcommittee was going to have a public --

MS. HOLIDAY: I think --

MEMBER LANGHORST: I think it's the Committee.

CHAIRMAN THOMADSEN: No, the ACMUI will have --

MEMBER LANGHORST: Right.

MS. HOLIDAY: Yes. I'm sorry.

MEMBER LANGHORST: I thought you said the subcommittee would. And so I just wanted to clarify that.

CHAIRMAN THOMADSEN: Right.

MS. HOLIDAY: Oh, yes. I'm sorry. That's the ACMUI will hold a public teleconference to discuss what the --

MEMBER LANGHORST: The subcommittee's --

MS. HOLIDAY: -- subcommittee will have that --

MEMBER LANGHORST: Yes.

MS. HOLIDAY: -- report. Thank you.

The next is an item that Dr. Thomadsen said he would do. He will draft a letter to the Commission addressing the miswording of the intention of ACMUI's recommendation that they made for rulemaking where the intent was a compatibility category B for permanent implant brachytherapy only and not across all modalities.

Are there any issues or comments on that?

(No response)

MS. HOLIDAY: Thank you. I think this is the last item, is that the ACMUI recommended -- and this was during Dr. Tapp's presentation on the AO criteria -- recommended that events reportable under 10 CFR 35.347, which is the embryo/fetus/nursing child category, that do not result in harm to the embryo, fetus or nursing child not be captured as AOs reported to

Congress.

Are there any comments, questions or issues on that?

(No response)

MS. HOLIDAY: Thank you. Okay. Said, if you would switch to the Word document?

Okay. This is the part where we have to plan for our fall meeting. I think we should do this one before we tackle the teleconferences.

As always, I sent out the meeting wizard to pulse the Committee on their availability. There are a couple of people that didn't respond. I'm afraid I didn't include you, Dr. Mettler. Based on this -- Said, if we could go to the October calendar? I have here October 8th and 9th highlighted in green because that was a day that all 10 persons that responded had no issues. So does still remain as the ideal date for the Committee to hold its fall meeting? October 8th and 9th.

Dr. Mettler, Dr. Ennis, Dr. O'Hara, is this an issue with either three of you?

DR. METTLER: I don't think so. I don't have my schedule.

MS. HOLIDAY: Okay.

MEMBER ENNIS: I don't think so.

MS. HOLIDAY: Okay. No? Okay. I take it from no objections perhaps this should be our first choice for the fall meeting, October 8th and 9th. All the days marked after that are not available because this will be our Chairman's last meeting, and we need him to be here. So we would not want to schedule a meeting after that date.

Okay. So then of course we like to pick up an alternative date just in case October 8th and 9th does not work.

So if you would scroll back up to September for me, Said?

There were two sets of dates where only one person out of the 10 who responded said they weren't available for the 3rd and 4th, and then for the 10th and 11th. So I guess are there any other persons who are unavailable for September 3rd and 4th? Dr. Palestro?

MS. COCKERHAM: This is Ashley. I would just note that that's Labor Day weekend.

MS. HOLIDAY: Is it?

MS. COCKERHAM: The 7th is Labor Day, so you're coming up on --

MS. HOLIDAY: Okay.

MS. COCKERHAM: If you're going to leave on Friday to go to something Labor Day weekend.

MS. HOLIDAY: Thank you. Okay. Then let's look at September 10th and 11th. Are there any persons outside of Mr. Mattmuller who have issues with those two dates?

MEMBER ZANZONICO: Well, we have our institutional Committee on Radiation meetings the second Thursday of every month, so I can miss one, not two, since I chair the meetings.

MS. HOLIDAY: Understood. So hearing that, the only person other than Mr. Mattmuller is Dr. Zanzonico. It looks like we have two people who have issues with both sets of dates, so it's really a toss of do you want your backup date to be the two days before Labor Day weekend or would you prefer that they be September 10th and 11th? And 9 times out of 10 we never even go to our backup date, just to throw that out there.

CHAIRMAN THOMADSEN: I would suggest the 10 and 11.

MS. HOLIDAY: Ten and eleven? So I have our first choice for the fall 2015 meeting to occur here in 2 White Flint North, Room 2B3 to be October 8th and 9th with a backup date of September 10th and 11th. Is that amenable to the Committee?

(No response)

MS. HOLIDAY: Thank you. Okay. So we

have quite a bit of topics for discussion during the time frame before the next fall meeting, so I pulled up between June and August.

Said, if you would scroll down to June?

I would like to note that we have several topics to discuss, one being the Germanium/Gallium-68 Subcommittee report. The Working Group for the Radioactive seed Localization. And also there was a request made Spectrum Pharmaceuticals to make a presentation to the Committee on the training and experience for alpha and beta emitters.

I was thinking that, for our new members, our public teleconferences are usually between two and three hours apiece, so we like to conduct those using GoToMeeting or GoToWebinar so you're able to see the slides in real time on the screen. But you do not have to physically leave your office, so it makes it a little bit more convenient for members to participate.

So I was looking at the month of June, and these are the only days that I have marked off. So I guess my question is which month is easier? And I want the Radioactive Seed Localization subcommittee and the Spectrum Pharmaceuticals teleconference together, to have both topics together, and that would be our long teleconference for three hours. So is there a month

that is not good for anyone and we can just start with that?

MEMBER COSTELLO: July is terrible for me.

MS. HOLIDAY: July is terrible? I believe July is terrible for quite a lot of people.

MEMBER COSTELLO: Actually July is wonderful for me, but it's not good for meetings.

(Laughter)

CHAIRMAN THOMADSEN: How about between the 15th or the 26th?

MS. HOLIDAY: Fifteenth or twenty-sixth?

MEMBER ZANZONICO: Also the Society of Nuclear Medicine and Molecular Imaging meeting is --

CHAIRMAN THOMADSEN: Is what?

MEMBER ZANZONICO: Is in June.

PARTICIPANT: It's the 5th through the 10th.

MS. HOLIDAY: Fifth through the tenth?

MEMBER ZANZONICO: Yes. And, Dr. Suh, you are on travel when?

MEMBER SUH: Fifteenth to the twenty-sixth.

MS. HOLIDAY: Okay.

MEMBER SUH: I mean, I could try to calling from the other side of the world, but --

MS. HOLIDAY: Okay.

CHAIRMAN THOMADSEN: Actually, we have GoToMeeting. It doesn't make any difference other than when you're awake.

MEMBER WEIL: Yes, that's the trick.

MS. HOLIDAY: I would also like to note as part of our bylaws discussion that we had and when we finalized the bylaws in November the Committee was very adamant on the amount of membership that should be present. Of course you know in order to have a meeting, you must meet a quorum, which means in a case by then we will have 13 members. So we would have to have at least seven members. But I believe we also need to have a quorum in order to pass a major recommendation by the Committee. So I think that means we need at least maybe nine members to make a recommendation. And to be honest, it may be that we want to discuss dates for a public teleconference off-line because these are three months that we're polling from. So what I could do is I could send out another MeetingWizard and that would be the most efficient way to go about picking dates for teleconferences, if that would be acceptable to the Chair.

CHAIRMAN THOMADSEN: That's very acceptable.

MS. HOLIDAY: Thank you. Okay. So I will just go on the record and say that the ACMUI will plan to hold two public teleconferences this summer, one for three hours to discuss the Radioactive Seed Working Group's report, as well as the presentation from Spectrum Pharmaceuticals. And the second public teleconference should be about an hour-and-a-half, two hours to discuss the Germanium/Gallium-68 Subcommittee report and its recommendations.

MEMBER LANGHORST: I would strongly recommend you schedule two hours --

MS. HOLIDAY: Sure.

MEMBER LANGHORST: -- and if you're done early, that's great.

CHAIRMAN THOMADSEN: Right.

MS. HOLIDAY: Absolutely.

CHAIRMAN THOMADSEN: Yes.

MS. HOLIDAY: Absolutely. Okay?

CHAIRMAN THOMADSEN: Sounds good.

MS. HOLIDAY: Thank you. I think that's all that we have on our side for administrative closing. As always, take your name tags off because I don't want to have to make them over. And I'm finished with my portion of the meeting.

CHAIRMAN THOMADSEN: We will be adjourning

for lunch shortly and returning for a closed working session. The question was raised before whether we can shorten lunch and get back to work more quickly. Right now we're scheduled to come back at 1:45. It's 12:15 right now. I would think we should be able to get back by 1:15. Is that good by everybody?

VICE CHAIR ALDERSON: I have to go to my hotel down in Bethesda and check out and get back, so I don't know. I mean, it was supposed to be an hour-and-a-half and that's how I planned it.

CHAIRMAN THOMADSEN: That's correct. You are correct.

VICE CHAIR ALDERSON: Yes.

CHAIRMAN THOMADSEN: Why don't we try for 1:30?

VICE CHAIR ALDERSON: That's fine. Thank you.

CHAIRMAN THOMADSEN: And we'll see who's here at that point. With that we will close the open meeting. Thank you all for attending.

(Whereupon, the above-entitled matter was adjourned at 12:15 p.m.)