UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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MEETING WITH THE ADVISORY COMMITTEE ON THE

MEDICAL USES OF ISOTOPES

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PUBLIC MEETING

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FRIDAY

MAY 9, 2014

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ROCKVILLE, MARYLAND

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The Commission met at the Nuclear Regulatory Commission, Commissioners= Conference Room, 1st Floor, One White Flint North, 11555 Rockville Pike, at 9:00 a.m., Allison M. Macfarlane, Chairman, presiding.

COMMISSION MEMBERS:

ALLISON M. MACFARLANE, Chairman

KRISTINE L. SVINICKI, Commissioner

GEORGE APOSTOLAKIS, Commissioner

WILLIAM D. MAGWOOD, IV, Commissioner

WILLIAM C. OSTENDORFF, Commissioner

PRESENTERS:

BRUCE THOMADSEN, Ph.D., ACMUI Chair

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

LAURA WEIL, ACMUI Patients= Rights Advocate

ORHAN SULEIMAN, Ph.D., ACMUI FDA Representative

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

P-R-O-C-E-E-D-I-N-G-S

(9:01 a.m.)

CHAIRMAN MACFARLANE: All right. Good morning. Good morning, everybody.

The Commission meets today to hear from the Advisory Committee on the Medical Uses of Isotopes.

Today=s briefers are a subset of that Committee, which is comprised of 13 health care professionals who advise staff on policy and technical issues related to the regulation of the medical uses of radioactive materials in diagnosis and therapy.

Let me take a moment to thank the entire Committee for all of their hard work, and we do very much appreciate all of the efforts and assistance that you provide to our staff.

We are going to begin the meeting with presentations from the panel. Let me say we have 45 minutes for the presentations, so please be mindful of the time as you make your presentations. I look forward to hearing all of your thoughts on the topics that we are going to cover today, but first let me check and see if any of our fellow Commissioners have any comments?

(No response.)

Okay. Then we will go right to the presentations. We are going to begin with Dr. Bruce Thomadsen.

DR. THOMADSEN: Thomadsen.

CHAIRMAN MACFARLANE: Thomadsen, Chair of ACMUI, who will provide an overview of the Committee=s activities. That will be followed by a discussion of the Committee=s position on

patient release from Dr. Pat Zanzonico. Great. Then we are going to hear again from Dr. Thomadsen on ACMUI=s views on revisions to the NRC Medical Use Policy Statement.

After that, we are going to hear from Ms. Laura Weil, who is ACMUI=s Patient=s Rights Advocate, who is going to give us a presentation on the reliability of radiation safety instruction for patients released following iodine-131 therapy.

After hearing from Ms. Weil, we will hear from Dr. Orhan Suleiman, the U.S. Food and Drug Agency ACMUI representative, who is going to provide an overview of the FDA=s radiation regulatory responsibilities. And the final presenter is going to be Dr. Susan Langhorst, who is going to share general views on the regulation of medical uses of byproduct material, Part 35.

So I will hand it over to you, Dr. Thomadsen.

DR. THOMADSEN: Thank you very much. And the ACMUI would like to thank very much the Commissioners for this opportunity to discuss with them what we have been doing. And the first slide, please.

The ACMUI exists to provide advice to the NRC staff and, thus, to you, the Commissioners, and to talk about policy for use of medical uses of radionuclides. We also provide technical assistance to the staff and serve as consultants, as appropriate.

Next slide, please.

The Committee consists of physicians, medical physicists, pharmacists, and a patient=s rights advocate, along with the FDA representative, trying to give a broad representation of the

stakeholders involved in the use of medical radionuclides.

Next slide, please.

Some of the topics that we have addressed -- and, actually, it=s in the last year, not just the last six months -- has been a lot of the possible changes in Part 35, and we have been discussing this for a long time, and we have provided opinions to the Commission as to what should be included.

Could I have the slides back on, please? Thank you.

We also have been considering several times the assumptions that are made in release of patients having received radionuclide therapy, and you=ll be hearing more of that today.

Next slide, please.

The continuing supply of molybdenum-99 for the production of technetium-99m has been a topic that we have discussed, along with inspection guidance for permanent brachytherapy, particularly with respect to the definition of medical events.

Next slide, please.

We also have looked at medical events with yttrium-90-labeled microspheres and whether or not there has been an increase in those events and what might have been causing that. We have looked at the definition of abnormal occurrences, particularly with respect to the medical occurrences, and how to classify the newly emerging alpha emitters for medical uses.

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The classification in Part 35 of the ViewRay, which is a

combination cobalt machine and MR imager, has been a topic we have discussed, along with nuclear medicine generator breakthrough and how to deal with that.

Next slide, please.

The safety culture was a major topic of concern, not just in the safety culture at licensees but the safety culture within the NRC, and we have addressed that.

We also, on a continuing basis, evaluate our relationship with the staff and how we report to you, the Commissioners. And we want to make sure that our advice does get to you, and we try to make sure that we discuss any ways that we could improve transmitting that information.

Next slide, please.

Some of the current topics that we are dealing with include still patient release after radionuclide therapy, radionuclide availability, and medical events for -- and reliability of certain procedures. We have been -- we discussed the medical use policy, and we will be discussing that in just a couple presentations.

We also have -- are dealing with a revision of the ACMUI Bylaws to try to make sure that they are current and they are effective.

Next slide, please.

Much of the credit for the current effective operation of the ACMUI stems from the insight and the guidance of the immediate past president, Leon Malmud, who managed to bring people with quite disparate opinions together and talk together and then come to

resolutions.

Next slide, please.

Over much of the last decade, a strong cooperative relationship has developed between the ACMUI and the NRC staff, and we will be working very hard to maintain this functional, respectful spirit.

Thank you very much. And I will now turn this over to Dr. Zanzonico.

DR. ZANZONICO: Thank you, and good morning. I will be summarizing the ACMUI=s position on patient release criteria and related issues.

As you know, my name is Pat Zanzonico, and I=m a Board certified and licensed in New York State medical physicist in Memorial Sloan Kettering Cancer Center in New York City.

May I have the first slide?

It is widely recognized, of course, that the medical use of radionuclides has very widespread, longstanding benefits for patient management. And I think it is worth emphasizing that the dose ranges we are considering and debating about, and so forth and so on, are really of the order of background doses, of the order of tens of millirem. And I think it is important to bear that in mind, to maintain that perspective.

Could I have the slides back, please? Can I go back one slide, please?

And it is important for the effective, both clinically and financially, application of radionuclides to avoid burdensome regulatory control. And the ACMUI feels strongly that doses to other individuals

can be safely controlled with the current dose-based 10 CFR 35.75 criteria and combined with patient and caregiver post-release precautions.

And, further, the release criteria in the CFR is consistent with current national and international dose constraint standards.

Next slide, please.

And so the issue among them is one of dose versus activity-based release criteria. The dose-based criteria, of course, are in the current 10 CFR 35.75. Activity-based criteria were what was implemented in what everyone refers to as the 30 millicurie rule.

And, of course, absorbed dose is a more meaningful and direct metric of radiation risk and activity. And it=s well established, for example, that hyperthyroid patients treated with low activities of radioiodine actually deliver a significantly greater dose to individuals around them than do thyroid cancer patients who receive orders of magnitude higher administered activities for treatment of their disease. So it just illustrates how ineffective, actually, administered activity is as a metric of radiation risk to individuals.

May I have the slides back, please?

Patient activity, then, does not predict dose to other individuals or risk, and so the ACMUI very much endorses the current 10 CFR 35.75 dose-based criteria.

Next slide, please.

There are issues, though, as you are well aware, with current release criteria. These include the dose contribution of internalized contamination. And as it turns out, it appears very much

that the internal dose contribution from environmental contamination really is negligible.

There is the issue that has been highlighted recently in terms of patient release to non-resident locales, such as hotels and nursing homes. Another issue is the patient transportation immediately post-treatment and whether use of public transport is or is not appropriate under those circumstances.

Another practical issue is that of patient vomiting immediately post-treatment. Radioiodine treatment is administered orally, and so there is a risk of contamination, obviously, from patients vomiting. However, it is really very uncertain the frequency of patient vomiting post-treatment and the frequency of use and effectiveness of anti-emetics.

And another issue of course is the clarity and consistency of post-release precautions. And I would recommend to the Commission NCRP Report 155 which, in the interest of full disclosure, I was a co-author of, which really addresses that and many of these other issues in detail.

Next slide, please.

It is important to recognize that there is in fact a very significant and large peer reviewed literature on environmental contamination and internal dose associated with release of radionuclide therapy patients, at least 20 peer-reviewed papers in scientific journals, and these include thyroid uptake measurements, which are a very sensitive metric of contamination and intake of contamination. And all of these are consistent with a minimal internal dose contribution. And,

again, so there is -- there are established data bearing on this point.

Next slide?

Related to the issue of release to hotels, this is a calculation, one of several, from our ACMUI Subcommittee report on patient release. And it is a calculation of the absorbed dose to individuals, to hotel workers, hotel guests, and so forth, from patients released to hotels. And the model parameters are listed on this slide, 175 millicurie administered activity, the assumption, apropos of the last slide, that internal dose was negligible, and so forth.

And we have two sets of scenarios we considered -- a very conservative, conservatively unrealistic scenario and a still conservative but more realistic scenario.

Next slide, please?

And these are the doses in terms of effective dose equivalents in millirem for cumulative hospital stays ranging from one to two to three days. So these are not the doses per day, but the cumulative doses. And you can see that using these extremely conservative, really unrealistic assumptions, the maximum dose to a hotel housekeeper for a stay as long as three days would be 91 millirem.

But for realistic but still conservative assumptions, that dose would be -- only be of the order of one rem. So a single housekeeper would have to care for a room for released radionuclide therapy patients for 100 days out of the year in order to approach a 100 millirem total dose. And, in fact, on the realistic conditions, the maximum dose would be to guests in adjoining rooms, which would still

be well, well below 100 millirem limit.

Next slide, please?

And this slide deals with patient release and transportation thereafter. And this is a graph of the effective dose on a logarithmic scale on the ordinate axis versus duration of a trip. The upper two graphs are for a patient -- thyroid cancer patient receiving 175 millicuries, the lower two graphs for hyperthyroidism. And as you can see, for hyperthyroid patients receiving of the order of 10 millicuries, which is typical, their doses, even for very long trips, are of the order of 10 millirem. For thyroid cancer patients, it is of the order of several hundred millirem.

So a rule of thumb, a recommendation, would be that -- that thyroid cancer patients receiving these high hundred-plus millicurie doses avoid public transport, but that there would be no restrictions on such transport for thyroid -- hyperthyroid-treated patients.

Next slide, please?

So, to summarize, the medical use of radionuclides safely serves public interest and should not be burdened by excessive regulatory controls. There really are no compelling dosimetric considerations otherwise. And that the doses to other individuals have been and can continue to be safely controlled by the current dose-based 10 CFR 35.75.

I thank you for your time, and I now would like to introduce Ms. Laura Weil, the patient advocate representative on the Committee.

MS. WEIL: Thank you very much for the opportunity to

present a different perspective, that of the patient, on the issue of patient release.

There is general consensus in the clinical and regulatory community that patient release following treatment with iodine-131 can be safely accomplished for most patients. This consensus is based on the assumption that patients have the logistical resources to isolate themselves post-treatment and that they are given good instructions about how to limit exposure to family and the public.

A few excellent health care institutions provide some patients with the option of remaining in the institution for a period of several hours or longer after iodine-131 administration. Even where this delayed release option is not available, many fine medical facilities have elaborate and timely processes in place for educating patients about post-treatment isolation requirements.

The excellent care at these institutions provides the model and rationale for the consensus of that safe outpatient RAI. However, if you speak with patients, you hear compelling testimony about how inadequate post-treatment education process can be. Perhaps this does not represent the norm at centers of excellence, but it is happening at lesser institutions and in the non-hospital setting. The problems identified by patients include the timing of instructions and the quality of those instructions.

Many patients report that they are given instructions only at the very last minute, usually on the day of iodine-131 administration. The obvious problem with this is that it precludes adequate preparation and planning on the part of the patient and the

family for the required isolation, including maintaining distance away from family members and co-workers, particularly children and pregnant women, solitary sleeping and bathroom use, trash disposal, eating utensils, and laundry precautions.

It is important to note that patients may be severely compromised on the day of treatment due to understandable anxiety and pre-treatment hypothyroid symptoms that significant affect cognitive functioning, including the ability to understand and retain information. This is the worst possible time to deliver important instructions.

Next slide, please.

I would like to present patient testimony that has been culled from volumes of comments like this on the Thyroid Cancer Survivors Association website Inspire. Here is one such quote. "I am due to have my RAI first week in August. I have a million and one questions on it, and all I get told by my nuclear medicine doctor is I will get instructions on the day I get the RAI. I will be coming home right after receiving it. I asked to be admitted to the hospital and was told it wasn't necessary. I have four children, I'm married, and I live in an apartment."

Inconsistency in the quality and content of instructions patients are given contributes to significant anxiety and confusion and compromises patient's ability to minimize radiation exposure to the family and to the public. Another problem is that there is no mandated communicator, and patients often receive discrepant information from different sources, even within the same health care facility.

While there are recommendations regarding information to be provided, there is no consistent regulatory requirement that assures the quality of the information nor that it is provided by the appropriate clinician.

Next slide, please.

Here is more examples of patient testimony from the Inspire web forum. “I have noticed that patients are often given vague or inadequate instructions. Radiation safety is a difficult subject to boil down to a page or two of instructions. This seems to lead to more patient confusion and stress. Add some emotion, stress, fear, hypothyroid symptoms, and you are asking for problems. Luckily, I have a background in radiation safety or I would have been totally blindsided by the precautions that were expected. There has to be a better way for conveying the information”.

Next slide, please.

Here is more testimony, another patient rights. A So your doctor told you one week?@ Meaning isolation. A Mine said I=m good to go back to work on Monday, which is five days after the treatment. I teach kindergarten. I feel like the guidelines are so different from doctor to doctor. It seems as though they would be the same. I=m erring on the side of safety and staying away for one week.@

Next slide, please.

And the last patient story I=d like to tell you is from a face-to-face interview I had with the mother of a child at the Thyroid Cancer Survivors Association Conference a year ago. A 10-year old

was treated at a university hospital. Mother was given virtually no instructions for post-treatment period, other than to stay far away from the patient in the car on the long drive home.

With another young child at home, mother was given no instructions to isolate the patient from her sibling or about solitary sleeping or bathroom use, eating utensils, and laundry. She was suspicious about the lack of precautions, so the mom accessed the Thyroid Cancer Survivors Association for information, and she sent her younger child to relatives for three days.

So how does this inconsistency or incompleteness compromise safety? Well, here is one example. In 2011, Carol Greenlee surveyed a wide range of health care providers who administer iodine-131. They included endocrinologist, nuclear medicine physicians, surgeons, radiation safety officers. She found a troubling inconsistency in the kinds of instructions given to patients regarding post-treatment precautions. Particularly troubling were the variations regarding the safety of breastfeeding.

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So her survey identified that only seven percent of residents -- of respondents, excuse me, recommended avoiding breastfeeding when the therapeutic activity was greater than 30 millicuries. And half did not see a need to avoid breastfeeding beyond the first 48 hours after radioiodine treatment.

Greenlee=s findings represent a troubling potential danger, both to the nursing infant from exposure to iodine-131 as well as to the mother, whose lactating breasts are exposed to increased

iodine-131 uptake.

ATA, the American Thyroid Association, guidelines are very specific on this issue.

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The guidelines state that breastfeeding must stop six weeks prior to treatment and not be resumed, although it=s safe for the children of subsequent pregnancies, for the protection of both the mother and the child.

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In summary, while it is certainly possible to accomplish safe outpatient iodine-131 treatment, we need to assess how well this process is being realized across the board. The assumption that there is minimal radiation exposure to the public from iodine-131 patients is based on the questionable supposition that all patients are being provided with and follow adequate instruction to reduce radiation exposure at home, in hotels, in the workplace, in public transportation, and in other public venues.

The literature on the subject may be biased. Research is generally carried out in those centers of excellence where best practices are the norm. Changing paradigms of care delivery may be pushing treatment out of the hospital setting and into other venues. Given patients= recent testimony, the assumption that the very best scenario is actually playing out in all health care settings is clearly problematic.

Thank you very much. And I would like to introduce Bruce Thomadsen, who will do his next presentation.

DR. THOMADSEN: Thank you. Which is going to be about the NRC=s medical use policy.

Can I have the slides, please? Next slide. Right.

The ACMUI had been asked to consider if the NRC should look into revising the policy on the medical uses of byproduct material, and a subcommittee was formed to study that issue.

Next slide, please.

The Subcommittee consisted of Dr. Alderson, Dr. Guiberteau, Dr. Palestro, Dr. Suh, Dr. Welsh, and myself.

Next slide?

The medical policy originated in 1979 with three clauses. The first is that the NRC will continue to regulate medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.

The second clause -- next slide -- the NRC will regulate the radiation safety of patients, where justified, by the risk to patients and where voluntary standards or compliance with these standards were inadequate.

Next slide?

The third clause was the NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be parts of the practice of medicine.

In 2000, the policy statement was revised -- next slide, please -- to have four clauses. The first is that the NRC will continue to regulate the uses of radioisotopes in medicine as necessary to provide for the radiation safety of workers and the general public.

The second clause -- next slide, please -- is the NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public.

Next slide, please.

The third clause went on, the NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician=s directions.

Next slide.

And the last clause was the NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches to achieving radiation safety.

Next slide, please.

There have been some concerns of late about the medical policy and how it is being applied. Of particular concern have been involving the definition of medical events and in training and experience, and that these may have unduly affected medical practice without increasing safety.

Next slide.

With the changes in Part 35, as we would be expecting them to come about, these problems seem to have been eliminated, and mostly by making the new regulations compatible with the existing policy.

Next slide.

And the NRC -- the recommendation of the Subcommittee was that the ACMUI feels that the current statement provides for medical uses of radionuclide safety for patients, subject, staff, and the general public while avoiding intrusion into the practice of medicine, and no revision is warranted at this time. And at yesterday=s ACMUI meeting, the full Committee unanimously approved that recommendation.

Thank you. I will now turn this over to Dr. Suleiman.

DR. SULEIMAN: Thank you. I=m going to try to give you a brief and general overview of the FDA=s radiation-related responsibilities.

Next. Next slide, please.

This is my disclaimer, in case I say something I shouldn=t have.

Next slide.

Ground rules. Basically -- next -- congressional statutes really define both the NRC and FDA=s responsibility. As you well know, we are both constrained and empowered with those laws.

Next?

Standards basically educate. And as a society, that=s how we control things. I mean, we have published papers. We have guidances. You have your NUREG documents, and so on. And at some point we decided it requires some enforcement, it becomes a mandatory standard or a regulation. And this debate between education and regulation -- it=s historical within FDA, and I=m sure you have the same sort of thing at the NRC.

Many years ago one of the FDA Commissioners actually settled an internal argument where the two quarreling factions were debating educational enforcement, and he said, "We are an educational institute. We just throw slow learners into jail."

Next slide.

So when is a mandatory standard warranted?

Next.

FDA's original statute goes back to 1906, but the original Food and Drug Act has been amended many, many times over the last century, similar to the Atomic Energy Act of 1954.

Next slide.

Recently -- no, go back, go back. You got head of me.

Recently, FDA got reorganized, and now we have like four directorates. The three key centers that regulate radiation products are the Center for Drug Evaluation Research, where I have been there for over a decade -- we basically regulate radioactive drugs; the Center for Biologic Evaluation and Research, biologics are basically endogenous to the human body, and some of that authority has been passed over to the drug center; and the Center for Devices and Radiological Health, which historically has had a radiation lead, and I spent about 20-plus years of my career in that part of the center.

Next slide.

One of the major statutes that the FDA is charged with is the 1968 Radiation Control Act, and basically it establishes mandatory emission performance standards for electronic products. It includes consumer and medical products, and we actually have standards for

microwave ovens, for lasers.

We don=t have mandatory standards for the cell telephones, but we are actively involved with the community. We consider that industry and voluntary standards are probably sufficient to ensure safety, but it doesn=t mean we don=t constantly maintain surveillance on those products.

Next slide.

The Medical Device Act of 1976 gives us broad authority over medical devices. And very, very quickly, basically any product that was around before 1976, or any medical device that has been approved after 1976 and has been declared like a predicate device, can have a very simple form filed -- a 510(k) is what it=s referred to -- for approval or review or clearance -- there are different terms -- for allowing them to enter the marketplace.

There are also three categories of risk -- one, two, three. And some of the high-risk Class 3 devices may actually require clinical data prior to approval. And that is called a pre-market approval. And this is -- that=s pretty much in the Center for Devices and Radiological Health.

Next slide.

So what does it take to get a drug approved? One thing that people are not aware, or maybe there are, is that FDA wears two hats. One, we have to protect human subjects undergoing research. And so there may not be a product that=s being developed, but if it involves medical products -- and most of the time it is going to require research under investigation of new drug applications -- there

are exemptions, but generally any research, even if it=s not moving toward a product, will require FDA oversight.

And you will often hear about the phases. Phase 1 is basically in drug research, a safety part. It basically just determines toxicity. Phase 2 determines efficacy. And once these two phases are finished, there is a discussion with the agency and they either move or don=t move on to Phase 3 where it=s a much larger, broader scale, where they get all of the additional information prior to submitting for a new drug approval process.

Next slide.

There is a Phase 4 that is what=s called a post-marketing requirement where clinical trials can be required after a product is approved where we have continuing concerns. So once the vendor has gotten all of the information together, they make the decision to apply for a new drug application. Fees vary. There are different categories. There are orphan drugs that don=t have to pay a fee. There are generic drugs. But this fee structure has now come into widespread use and is being applied to medical devices, to generics, to biologics.

And the other critical thing is once they file a new drug application, we have a clock. It has to be completed within six months with a little bit of wiggle room, and that was one of the deals that FDA -- Congress established with industry, that we will accept these user fees, but we want you to get these drugs -- they want them approved, but we will review them within a certain period of time.

Next slide.

So one of the last things I want to mention that sometimes is overlooked by the general public is we inspect the manufacturing sites. In terms of drugs, not necessarily devices, we do not approve a new drug until the manufacturing site is in fact inspected. We only do our own inspections internationally as well.

We don=t delegate our authority to any other agency. And what I tell sometimes people who are -- companies who are dealing with a non-drug, I said, AYou may not be high on the inspection list, but if you have a problem you can pretty much ensure your site is going to be inspected.@ So it is important to comply with all the appropriate regulations.

Next slide.

So this is just -- I=m trying to give a quick example -- is it a drug? Is it a biological device? Well, I=ll use yttrium-90 microspheres, which the NRC also regulates, but these are tiny microspheres, physically sealed sources, that are basically trapped in the hepatic blood vessels, and, therefore, this is classified as a device and regulated by the Center for Devices and Radiological Health.

Yttrium-90 labeled monoclonal antibodies actually were approved by the Center for Biologics, because these are in fact the biologic. Later on they were transferred to the Center for Drugs in order to consolidate the -- all of the cancer drugs for approval purposes. And their mechanism of action is chemical, and it=s an attraction between the antibody and the CD20 antigen. And this is sometimes referred to as a smart probe, or it actually goes where you would like it to.

So this challenges us in terms of who within FDA has that authority. And, clearly, you regulate this product as well.

Next slide.

So my regulatory concerns, really, it=s sort of a broad thing. Technologies are getting increasingly complex, and the statutory authorities are also complex and they overlap. So we have those issues here, you have them there, and sometimes we have multiple jurisdictions.

Next?

We have an MOU with the NRC, in cases where we have overlapping authorities over a product, and we use that often to communicate and interact.

Next?

So, in the end, how do you maintain regulatory balance? Do you come up with a general simple requirement and you hope that the user is going to comply? Or do you get very prescriptive and burdensome? And so both sides always say we do not need more, but ultimately we have to protect the public. But at the same time, we can=t burden the regulated industry as well.

And, again, you get into the last question -- the last statement is, when do you educate and when do you regulate?

Next. Next.

You don=t see voluntary 50 mile an hour speed limits.

Thank you. And the next speaker, and last speaker, is Dr. Langhorst.

DR. LANGHORST: Thank you for the opportunity to

speak with you today on the topic of NRC=s medical use regulations. These are my views based on my 34 years of radiation safety experience in the production and use of radiopharmaceuticals.

I am not a physician. I am a radiation safety officer. My degrees are all in nuclear engineering, and I am a certified health physicist. I have worked for a nuclear power utility company. I have been RSO at the world=s premier university research reactor, worked with multiple federal agencies in the areas of radiation research and policy coordination, and now serve as RSO of a world-renowned university and medical center.

One reason I enjoy my job and serve on the ACMUI is that I get to see on a daily basis how medical use of radiation improves the lives of our patients. With the short time I have today, let me focus my remarks on the impact NRC regulations have on the patient-physician relationship.

Next slide, please.

NRC=s medical use policy states that NRC, when justified by the risk to the patient, regulate the radiation safety to patients primarily to assure the use of radionuclides is in accordance with the physician=s directions.

This policy is good in that it recognizes and respects the special nature of the patient-physician relationship. It is the implementation of this policy into regulations, compliance measurements, and enforcement actions that is challenging. For NRC, that challenge is having the resources and expertise to develop patient safety regulation and compliance measurements that

reasonably fit with the overall culture of health care.

Next slide, please.

Medical use of radiation is different from other uses of radiation that NRC regulates. It involves purposely exposing an individual to radiation to diagnose or treat what can be a serious or life-threatening illness. In the case of radiation therapy, the physician develops the radiation treatment he or she ideally wants to provide for their patient.

The radiation therapy team, which can include a medical physicist, dosimetrist, technologist, and others, takes the physician=s desired therapy and does its best to develop the perfect treatment plan that fits that physician=s directions for that specific patient.

The team uses various measurements to gauge that Aperfection,@ consistency, meaning, and improvements needed for the next treatment and for the next patient. There is no schematic diagram that fits all patients, and not all therapy team measurements are appropriate as a regulatory compliance measurement.

Next slide, please.

Medical use of radiation is different. Most NRC regulations focus on radiation risk, dose limits, and keeping radiation dose as low as reasonably achievable. However, NRC has a notable exception. It does not set a dose limit for patients, thus recognizing that no other use has the same level of immediate, easily recognizable personal benefits as do medical uses of radionuclides. This recognition supports the special nature of the patient-physician

relationship.

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Medical use of radiation is different. NRC needs expertise to develop regulations that support patient safety but do not adversely impact the patient-physician relationship. However, it seems that a vast majority of NRC staff has little medical use experience other than that that they have experienced personally either as a patient or during a loved one=s medical care.

In reviewing yours and past Commissioners= biographies, your medical use experience also seems limited. A regulatory mind-set can be difficult to switch from regulating nuclear reactors to regulating the different paradigm of medical use of radiation.

Next slide, please.

In my four and a half year tenure on the ACMUI, I have found the NRC=s medical team staff as knowledgeable and dedicated to fulfilling NRC=s medical use policy. But I admit to being surprised how small in number they are and how serving on the team seems not to be a permanent assignment, but, rather, a temporary tenure as part of their NRC organizational advancement.

I have also been surprised by the scarcity of active medical professionals, like physicians and medical physicists, who are on NRC staff or who might rotate through an NRC service appointment. The ACMUI provides advice to the NRC=s medical team, but our two physical meetings a year and other intermittent interactions between the team and the ACMUI members are not the same as having medical expertise readily available to provide insight into medical practice and

the regulatory and cost control challenges impacting medicine today.

And other than a periodic briefing of the Commission by the ACMUI, like today, and the Commission=s interaction with its own medical team staff, I do not know who routinely provides you with medical use advice.

Next slide, please.

Medical use of radiation is different, because it needs to be patient-centered, focusing on the medical benefits it provides. We need a unique regulatory model which recognizes and works within the environment of health care. Physicians and the rest of the patient=s medical team want to help the patient. In partnership with the patient, we use the best diagnostic tools and the best radiation therapy procedures we have available.

I know that NRC and its own medical team want to help the patient. But at times I feel that NRC=s regulatory authority over medical use is treated as a side activity with decisions being influenced by a few individuals who may not fully understand the overall medical care arena, perhaps wanting to make the regulatory control of patient safety fit within -- fit more within the rest of NRC=s regulatory control model.

Implementing NRC=s medical use policy is challenging, given the different pressures affecting a patient=s medical care. NRC needs to be aware and must consider the big picture of medical care to be a true partner in promoting patient safety.

Next slide, please.

No medical diagnosis or therapy comes with a

guarantee of success, no matter how hard we try to make it so. It is a challenge to set reasonable controls and to choose reasonable compliance measurements that fulfill NRC=s medical use policy to gauge a patient=s true risk and not intrude into the medical judgments made within the patient-physician relationship.

I think we all need to do a better job of answering the following types of questions.

Next slide, please.

How easy is it to make and document a compliance measurement? How easy is it for an inspector to judge that measurement? What does the measurement mean? Is the compliance measurement medically significant? How is patient care impacted by that measurement? What does something called a medical event do to the patient-physician relationship and the patient=s overall perception of their medical care?

How do regulatory controls impact a patient=s access to medical use of radiation? How does the compliance measurement compare to measurements from other medical procedures, some of which are not regulated by the NRC but may be by an Agreement State, and some of which involve no radiation at all? What is good enough to demonstrate regulatory compliance that reflects the NRC=s medical use policy? How do we collectively make our best effort to provide safe medical care for our patients?

Next slide, please.

Medical use of radiation is different. I believe NRC=s challenge in determining reasonable, understandable, and consistent

regulatory controls supporting patient safety needs more resources, different models of using medical expertise, and a more combined effort between the NRC, the Agreement States, and the medical community.

We owe it to our patients to find a better way to preserve their access to safe medical care that involves the use of radiation.

I thank you again for the opportunity to present my thoughts to you today.

CHAIRMAN MACFARLANE: Okay. Thank you very much. Thank you very much for staying on time. Much appreciated.

All right. Now we will have questions from the Commissioners, and we will start off with Commissioner Ostendorff.

COMMISSIONER OSTENDORFF: Thank you, Chairman. Thank you all for being here and for the people behind you that I know are part of the ACMUI community. I think we really do rely upon ACMUI for significant advice to the Commission. I=ll come back to that in the context of Dr. Langhorst=s comments in just -- in a few moments.

Let me make a couple of comments up front. I=m going to kind of go left to right here. For Dr. Zanzonico, I just want to comment that I applaud the use of two categories -- conservative and realistic. I think so many times in society when we are looking at risk people overly rely upon a single point estimate that is misleading at times. And so the use of a conservative and a realistic category resonates with me personally, so I appreciate that approach in your presentation.

Ms. Weil, I wanted to talk a little bit about, you know,

your presentation and ask you a question. I know that something we all wrestle with is, what is the proper line for this agency in Acrossing the line into the practice of medicine@? Because we are not, you know, medical practitioners, we are not physicians. And I know that Dr. Langhorst maybe has a different perspective on this and we=ll come back to that.

But I was taking -- I think your anecdotes are very helpful. I think the notion of getting advice the day of treatment is very unsettling for many people. It is further complicated by cancer patients who often have a surgeon, a general practitioner, one or more oncologists, and so the proliferation of different medical people that a patient has to talk to, who may provide at times different perspectives, makes it very confusing. And I know myself and another family member who have gone through this in the last year for cancer treatment have wrestled with the number of different experts that are -- who are trying to integrate and synthesize those comments. It=s very challenging.

I want to make a statement and ask you to react to it, though it=s kind of a question. I appreciated the anecdotes, but aren=t those messages that you are providing also applicable to the medical community? We are not physicians here, and I=m not sure we want to get into the business of telling doctors how to provide advice to their patients. And so I -- that=s one reaction I have to your anecdotes is that I believe all of those, you know, are good examples, but who should the target audience to those anecdotes be, aside from the Commission? How does your message get communicated to the

broader medical community?

MS. WEIL: Well, there are places where it=s done well, and I suppose you could -- we could all hope that those centers of excellence would be able to influence others to follow the example of good practice. However, in reality, that doesn=t seem to be happening. And I see a regulating body as having a responsibility to protect the public.

I=m not sure that it is really intruding in the practice of medicine to require that patients be given instructions in a way that can be understood and followed to protect the public after their treatment is over. It is really not a question of interfering in the medical process. It is a question of giving people the means to do well after they are discharged from the institution to be able to do the right thing. Most patients want to do the right thing, but they are not given the opportunity to do so if they are not instructed appropriately.

I don=t see -- I don=t see the rub that many of my colleagues do see. I will admit that my opinion is somewhat different from the opinion of my colleagues on the ACMUI. I think it=s a matter -- it is what Dr. Suleiman described as voluntary speed limits don=t exist. Well, voluntary instructions for protecting your family and the public from radiation exposure post-iodine-131 treatment, that shouldn=t be voluntary; that should be mandated.

Does that get to what you=re after?

COMMISSIONER OSTENDORFF: Somewhat. I=m going to ask Dr. Thomadsen to comment here, because I know that you gave -- you know, it was very helpful to go back to the 1979 policy, the

updates in 2000, and I appreciate, Laura, your mentioning that you may be a voice of -- you know, you may be in the minority view on the Committee. I=m just assuming that that=s the case. I don=t know.

But I=m curious as to how the Chairman sees this, because I think you raise a very critical point that we wrestle with. Commissioner Magwood and Chairman Macfarlane have taken initiative to recently issue a COM to address patient release issues in addition to some other actions taken two years ago, and so two colleagues have taken a very significant leadership role here. But I know that we kind of wrestle with this.

I=m curious, do you have any comments on Ms. Weil=s statement?

DR. THOMADSEN: Yes. There is already precedent for requiring instruction to patients under certain circumstances. I think what Ms. Weil is suggesting is that those -- those instructions need to be better defined, and the situations in which the patients receive those instructions need to be better defined. And I think that falls within the policy statement. I don=t think that that=s -- I don=t think that=s interfering with the practice of medicine at all.

COMMISSIONER OSTENDORFF: And I think the direction from our colleagues is to do exactly that, is to -- is consistent with that path, but I don=t know that we would necessarily go regulate in a compliance method to see whether or not a particular physician, he or she is administering those guidelines or instructions, you know, as far as a regulatory enforcement type action.

Dr. Langhorst, let me turn to you, and I=ll come back to

Dr. Thomadsen as a follow-on to this question, because you raised some provocative issues here. You=re suggesting that we do not have -- I=m making a little bit of a blunt statement. I think your statement is that we are not properly resourced to do our job. Is that what you=re saying?

DR. LANGHORST: I believe that medical use and how it=s -- the regulation of that, as reviewed, is not paid much attention and needs more.

COMMISSIONER OSTENDORFF: Okay.

DR. LANGHORST: Because it is a complicated environment.

COMMISSIONER OSTENDORFF: I agree with you that it=s complicated. I think our construct -- and this is -- you know, your brief was very interesting from this standpoint -- I think to a large extent the Commission, and I know I=m speaking for myself, we have relied upon ACMUI as having the medical practitioner from your different communities, and you have different responsibilities on your day jobs.

I think we rely upon this body here today to a tremendous extent, and we do not have, I think by intent, full-time NRC staff as federal employees who have your experience.

DR. LANGHORST: That is a challenge, because if they are a full-time employee here, they=re probably not practicing medicine.

COMMISSIONER OSTENDORFF: Exactly. So --

DR. LANGHORST: That is a challenge.

COMMISSIONER OSTENDORFF: And it=s different at one level between the use of isotopes for medical purposes and I think regulating reactor safety. I think there=s a difference there.

DR. LANGHORST: Absolutely.

COMMISSIONER OSTENDORFF: So I guess my question for you and for Dr. Thomadsen and anybody else who wants to comment -- and I think we have confidence that we=re getting the advice we need from ACMUI. Is that -- am I wrong in assuming that=s the case?

DR. LANGHORST: Can I -- okay. We are a small group of people, and the medical community is pretty large, and we don=t -- I don=t think we could function with representation of all the parties that would be out there. So I would say that, yes, we=d love being part of your advisory pipeline for medical isotopes, but I don=t think it=s enough.

COMMISSIONER OSTENDORFF: Okay. Dr. Thomadsen? Thank you.

DR. THOMADSEN: I look at the question the other way around and say if none of you had experience with reactors, and you had only a reactor advisory panel, and none of your staff had experience with reactors, would you feel that would be adequate? And that=s the situation that you have in dealing with the majority of your licensees.

COMMISSIONER OSTENDORFF: And I guess I=d respond that=s a very fair and thought-provoking response. I have to reflect upon that. I think when I came to the Commission four years

ago, I thought the reactor business, the fuel facility business, was a little bit different than the medical side of the house. I still think that=s the case today personally, because I think we really need to have the medical practitioners, the people that are out in the hospitals, and the universities and other venues providing us advice through your body.

My time is up, but this has been very helpful. Thank you.

CHAIRMAN MACFARLANE: Thank you. Okay. My turn. Let me start off by asking Dr. Zanzonico and Dr. Thomadsen, it=s my understanding that the use of radioisotopes in medicine is increasing. That=s what we heard from Dr. Suleiman; it=s getting more complex. Is that correct?

DR. THOMADSEN: The answer I think is yes. The distribution of which procedures are being done is constantly changing.

CHAIRMAN MACFARLANE: Sure.

DR. THOMADSEN: Overall, the answer is it definitely is increasing.

CHAIRMAN MACFARLANE: So does that mean we have more practitioners as well?

DR. THOMADSEN: That=s a very good question. I don=t have that answer.

CHAIRMAN MACFARLANE: Okay. Well, I=m a data person, so I appreciate having lots of data, so I=m going to ask a few more data questions.

Is it your understanding that children and fetuses are more susceptible to radiation than adult males?

DR. THOMADSEN: Definitely.

DR. ZANZONICO: Yes.

CHAIRMAN MACFARLANE: Okay. Good. That=s my understanding, too, so I=m glad we=re on the same page there.

And, Dr. Zanzonico, you gave us some nice data here, which of course I appreciate, but these are models.

DR. ZANZONICO: Correct.

CHAIRMAN MACFARLANE: Right?

DR. ZANZONICO: Correct.

CHAIRMAN MACFARLANE: I don=t know how much of this is based on actual data, and so I=m interested in the number of studies on actual patient releases and actual data collection on, you know, radioisotope contamination of other people.

DR. ZANZONICO: Certainly. Well, as I alluded to in my presentation, there is a peer reviewed scientific literature --

CHAIRMAN MACFARLANE: Yes.

DR. ZANZONICO: -- which reports such data.

CHAIRMAN MACFARLANE: And how recent is it? And how relevant is it?

DR. ZANZONICO: Well, it --

CHAIRMAN MACFARLANE: Especially in dealing with the most vulnerable, which would be children and fetuses.

DR. ZANZONICO: Understood. The data extends over the last several decades. There are papers as recent as the last several years, perhaps even as recent as the last year, and, as in any other field, there are older papers. The studies performed, the

technology required, is very mature and well established and reliable. So I think even the papers that were -- and the studies done -- that were done some 20 years ago are still reliable. It=s not that in the intervening time there has been new technology which renders these older studies less reliable.

CHAIRMAN MACFARLANE: You just told me that there is new technology that --

DR. ZANZONICO: Well, no, no, no. There=s new studies, but what I=m referring to are use of dosimeters such as thermo luminescent dosimeters and thyroid uptake measurements, and those are very mature, well-established technologies.

CHAIRMAN MACFARLANE: Right. But my concern is that there is a proliferation of radioisotope uses, which is probably a good thing, right? And I=m not interested in getting in your business, you guys, the MDs back there, and telling people how to, you know, fix people and make them well. That=s your job, not mine. What I=m -- my job is to protect public health and safety.

DR. ZANZONICO: Understood.

CHAIRMAN MACFARLANE: And I take that very seriously.

DR. ZANZONICO: Understood.

CHAIRMAN MACFARLANE: And I=m in maybe a unique position vis-à-vis my colleagues because I have both small children and I have an aging mother who we are constantly encountering the medical system. So I am very sensitive to these particular issues.

And so it seems to me I see a lack of actual data on patient release effects. And I think that there is a bit of a lacuna there that we would all benefit by filling, because we all have a better understanding of the situation.

DR. ZANZONICO: No one ever wants less data. The more data the better, but I think we=ll agree to disagree that there is not well-established credible data that bears on this point.

CHAIRMAN MACFARLANE: Well, I can go --

DR. ZANZONICO: Is there a need for more data? Certainly.

CHAIRMAN MACFARLANE: I can go and look up these 20 or so papers that you referenced and evaluate them myself.

DR. ZANZONICO: Certainly.

CHAIRMAN MACFARLANE: Which I will try to do.

Do you know what the practice is, any of you, in other countries with advanced medical systems vis-à-vis patient release?

DR. SULEIMAN: It varies.

CHAIRMAN MACFARLANE: Okay.

DR. SULEIMAN: It varies. I was on the IAEA Committee, and you heard anecdotes from some countries where they keep patients away for a year until they could keep them overnight, so they would delay therapy. I mean, you can come up with an example, so it varies. It varies.

CHAIRMAN MACFARLANE: But I=m talking about countries where the -- you know, we don=t really have the best morbidity and mortality rates in this country. I=m talking about

countries that do better than us. What are their practices? Do we know?

DR. ZANZONICO: Well, in the European countries, which I guess is the most comparable in terms of quality of medical care, in some countries they hospitalize patients who received as little as five to six millicuries of I-131. Others still adhere to what amounts to the 30 millicurie rule, and then there are a number of countries who have intermediate levels in terms of medical confinement of radionuclide therapy patients.

CHAIRMAN MACFARLANE: So I=d like to know in more detail, you know, what do they do specifically in France? What do they do specifically in Germany? What do they do specifically in Canada? I think that would be helpful, to have that -- those pieces of data as well to really understand this situation.

And then, in terms of the information that is provided to patients, I=m hoping that it=s different from the kind of information my mother receives when she gets cancer treatments. But if it isn=t, it=s not helpful, you know, especially if the patient is on their own and doesn=t have an advocate with them. That=s an extremely difficult situation.

And for some of the anecdotes that you gave, Ms. Weil, you know, a single mother going home to small kids, you know, if those kids are sick in the middle of the night, they=re going to crawl into bed with her. And she is going to -- she is going to keep them there. Are you being protective of everybody? I don=t feel that that=s protective.

So I think there are issues here. If you were queen,

Ms. Weil, how would you change things?

MS. WEIL: Well, of course, if I were queen --

(Laughter.)

-- what a lovely opportunity. You know, patient care has to be individualized, and it is often. But in this particular instance, some patients want to go home and some patients want to be separated from their families and stay in hospitals or hotels or what other venue there might be where their family members would not be exposed to the radiation.

It would be nice if patients were given more options. Most patients would go home. I believe most patients would go home if they had -- that=s my belief -- if they felt they had the tools to protect others from exposure. Some folks don=t have the logistical ability to do that. People live in small apartments with single bathrooms with little kids at home without someone else who can assist them.

CHAIRMAN MACFARLANE: And I understand the instructions are, you know, complex and lengthy. You have to wash your linens twice. You have to scrub down, you know, any --

MS. WEIL: Right.

CHAIRMAN MACFARLANE: -- anything in the bathroom, you know, flush the toilet twice, et cetera. You know, this is -- it=s a lot to remember if you=re really not feeling well.

MS. WEIL: It=s a lot to remember and it=s a lot to plan for. But the instructions have to be -- and at the best places -- minutely individualized based on the dose the patient has, based on so many different factors. Those instructions need to be made clear. It=s not

that the patient can go on the web and find out what they ought to do, because --

CHAIRMAN MACFARLANE: Right. Because it=s individualized.

MS. WEIL: -- it=s individual. So, you know, the queen would love to see every patient have enough time to talk to their clinicians about what they need to do and what they can manage and what they can=t manage and plan for a safe discharge.

CHAIRMAN MACFARLANE: Are there other areas in medicine where this is done well? I mean, it seems to me my -- just thinking of my own personal experiences with the medical system in this country -- that there have been some times when I have been given lots of information and, you know, I was thinking of when I was having children and getting tested for a variety of diseases that the kids could have, that kind of thing.

You know, there was a period -- there was a special patient advocate who would take you aside and talk to you, but, you know, of course I was also being treated in Boston at one of the best hospitals out there.

So one of my concerns here is, with the proliferation of this -- these techniques, the uses of these materials, is that they are going to places that don=t have the ability to provide this kind of information and help. And how do we make sure that that gets done? That=s the thing. So that we=re protective of everybody.

MS. WEIL: It would be nice if we could regulate it. When we=re looking at licensees to make sure they=re in compliance

with all of the other regulations, it would be nice if that -- if those regulators were able to look at the process for instructing patients and make sure that it makes sense that patients are actually being told not on the day of their administration of their radioisotope but in advance of that, so that they have time to think about these things that they are being asked to do, time to ask questions, time to come back and have those questions clarified for them, and go home with a reasonable plan that makes everybody safe.

CHAIRMAN MACFARLANE: Okay. Thank you. My time is up.

DR. ZANZONICO: If I may comment?

CHAIRMAN MACFARLANE: Yes.

DR. ZANZONICO: I think it is important to bear in mind potential unintended consequences of very well intended regulations and even guidance. In Germany, for example, where they have among the most conservative policies regarding patient release, patients have to be hospitalized down to six millicuries. They have special wards and holding tanks for excreters, so forth and so on.

In countries such as those, sometimes the only individuals who have access to such therapy are those who can travel to foreign countries where the regulations are less strict and there is greater access to this sort of therapy, because there are long waiting lists at times because there is limited rooms to hold these patients, so forth and so on.

I don=t disagree at all that there is wide disparity and inconsistency in the rules and regulations. I think there is information,

like the NCRP 155 report and so forth, which provide template documents and a systematic approach to making such regulations, and certainly those should be -- that should be more widely disseminated, so forth and so on.

But I am just concerned, among other things, with, again, potential unintended consequences of well-intended regulations that may limit access to very effective procedures.

CHAIRMAN MACFARLANE: Briefly, because I=m over my time.

MS. WEIL: Very briefly, I think, you know, you=re at both ends of the extreme. I don=t think anyone is suggesting that we should go to the German model and hospitalize patients. I think there are many interim steps that can be taken to assure that patient release can be accomplished safely and so that access to treatment is not impeded.

CHAIRMAN MACFARLANE: Okay. Thank you.

Commissioner Svinicki.

COMMISSIONER SVINICKI: Well, I will join in thanking you all for your presentations and also welcome and thank the Committee for its work. I find these direct engagements with members of the Committee very valuable, and so I want to acknowledge that there has been a point of some historic discontent over the level of the Committee=s direct engagement with the Commission. And on that point specifically, we had scheduled to have a meeting with you during the period that ended up being the government shutdown, so I regret that we went a full calendar year as a Commission and a Committee

without having this kind of direct engagement.

We also want to honor the fact that you all are very busy individuals with other jobs and responsibilities, so we wanted to connect up at a time that was convenient for you. But as a result, I just want to express my personal regret that we went a year without -- over a year without meeting with you, and I know I benefit very much.

I do read your products, the work product that comes out of the Committee. So I will assure you, at least from my standpoint, that if we=re not engaging face to face I really value the input that is provided and read -- and try to read a diversity of opinions on this -- these issues. And so it=s not surprising that we=re hearing some diversity of opinions today.

I know Chairman Macfarlane said a meeting just yesterday that very vibrant deliberation is very beneficial. I know it benefits my decision-making.

I wanted to add to what Commissioner Ostendorff said about the way we are structured as a regulator to address these important nuclear medicine issues. I agree with what we said, but I did want to add to the fact that although the ACMUI is an extremely important element of informed decision-making here, any proposed rules and changes that we have do also go out for public comment.

So I have also read the work product of the various professional medical societies that many of you are members of and patient advocates, patients= rights groups, any others who comment. So that comment record is in addition to your advice and is very, very important input to our decision-making.

But I want to conclude, having said all of that, by, Dr. Langhorst, I want to say that I really valued your challenge to us and stepping back your presentation which you had provided in advance, and I spent some time in my office with it last night. I love that you closed with the questions, because some of the point of this engagement at a high level on these issues is to make us all step back and kind of go to first principles. And I think Dr. Suleiman=s presentation had some of that as well, of saying these are the core questions that we ask ourselves about these issues.

And so although the two of you addressed different topics, I think that that=s part of what the Commission does when we engage on these issues, which I candidly acknowledge are not a dominant part of what we do here. And so I have at times talked to people about the types of individuals who are selected to serve on this Commission or nominated to serve, and there has not been I think even a health physicist for probably 10 or 15 years or someone who came with that specialty.

I have thought about that, though, and I have thought about really engaging the interest of someone who had principally a medical background. I=m not sure, you know, they would have to spend 95 percent of their time on the tedious business of power production, and I don=t know how much interest they would have in that, so it=s difficult.

So I go back to Commissioner Ostendorff said. This is the structure that at least these five individuals inherited for being informed on this, and the other thing I appreciated about your

presentation is I love key messages that repeat because it takes us so many times to hear something to remember it.

But the practice of when we regulate nuclear medicine issues it is different, and I think we come at that by weighing different factors and perhaps, you know, maybe weighing something more important than something else, depending on what individual decision is in front of us, depending on what we=re looking at.

But that=s the other benefit of a Committee structure or a Commission structure is that we are all going to weigh the factors involved in our decision-making a little differently. So I don=t know that we resolve anything today, and I don=t know the answers or response to the tough questions that you laid out. But I did want to say I spent time thinking about it last night; even hearing it again today it was raising different questions in my mind. So I appreciate -- keep challenging us in that way and on the patients= rights issues as well. I think that=s very important for us to hear.

I don=t know, you know, maybe I=d ask Dr. Suleiman since he happens to be here. How does FDA resource itself from a human capital standpoint to be kind of ahead of the issues, to be as informed as it needs to be on emergent medical technologies and things like that? Because it more dominates what you=re doing, perhaps it is appropriate for you to have federal employees who are willing to say, AI=ll step away from the practice of medicine and go work on reviewing medical devices and things like that.@

But do you have fellowships, or can you get like experts who would come in on temporary appointments? Is that -- I think as a

Commission, you know, if there were other things we could at least think about, I think we would consider it.

DR. SULEIMAN: Absolutely, yes. First off, we are very science-based, and I think a lot of times you=ll see the professional staff. We=ll default to that. And there=s clearly lots of discussions, you know, within the ranks. We have a fellowship program that the Commissioner has established -- I forget -- but all the different funding, it=s up in double, maybe triple, you know, figures. It=s a two-year program.

We interact with medical facilities. I mean, even though I=ve been a federal employee and I=ve worked for these regulatory agencies pretty much my entire career, I have worked in hospitals, I have done research in hospitals and other environments. So it=s hands -- there are some of us who have hands-on experience, so -- and there is that tension. You just can=t have people looking at the -- you assume that people are in a little office and just pushing paper, but that=s not really the case.

We are out there, and we have -- there is constant interaction with the community. I consider us pretty proactive. But we are a large agency now. We=re about -- pushing 15,000. And with the different centers, the different centers sort of focus on their products. And I think I had alluded to, but our statutory requirements are very different. I think I spent half of my time trying to communicate to other components within the agency why the other people don=t do it the way we do it and vice versa, so your statutes and your regulatory authorities. And it varies.

We regulate mammography. You talk about the mandate. One of the -- that is probably the closest thing we come to regulating medicine, where when the statute was passed in =92 it requires physicians to send back notification to women having undergone an exam.

And I think personally I -- you may not like being forced to do things, even though 90 percent of the community is doing it, if it=s good practice. And I was once advised by a very senior person, AOrhan, if it=s really a safety-related issue, if it=s good for the public health, don=t be afraid to pass a regulation.@

So sometimes you may mandate practice that is already being done by most of the people here at this table, but it will force the 10 percent or the five percent of the outliers to start doing it right. And after a while it becomes routine, but you don=t want to be burdensome, you know.

But, yes, we interact --

COMMISSIONER SVINICKI: Well, and that=s where that practitioner advice is so useful. It=s not just knowledge. It=s out there applying that knowledge in the delivery of medicine. And so -- but to keep current on all of that and to be as informed as you want to be because at the end of the day it is the individual people who are so directly impacted by what we do here.

So, you know, curious to hear more and think more about how you strike that balance. Really appreciate it and appreciated your input and your presence.

DR. SULEIMAN: But we really do interact with the

stakeholders a lot. I mean, we don=t make our decisions in a vacuum.

COMMISSIONER SVINICKI: Yes. And I know we=re trying to do that as well and want to do it with as much care and attention as we can.

I=ll just close with Dr. Thomadsen. Over again, historically, there has been a little bit of dissatisfaction that this is -- this Committee is structured to advise the staff that it has to do, as I understand it, with the fact that many of you work for licensees or are practitioners, and, therefore, we set that up to give you one degree of removal from the Commission=s direct decision-making.

But that being said, what is your assessment right now on the level of communication and engagement and cooperation with the NRC staff? I took from your presentation that it is trending in a positive direction, and you want to continue that. Do I understand that correctly?

DR. THOMADSEN: You understand that exactly right. At the moment, the communications between the staff and the ACMUI have been really stellar. We talk quite collegially. We are quite open about differences. We can discuss them. We can come up with resolutions. We have very good access and support from the staff.

This has not always been the case, as you are well aware. But the staff and the ACMUI have worked very hard to bring this about. And at the moment, I think we are all very happy with where we are.

COMMISSIONER SVINICKI: Okay. Great. Thank you.

Thank you, Chairman.

CHAIRMAN MACFARLANE: Thank you. Commissioner Apostolakis.

COMMISSIONER APOSTOLAKIS: Thank you, Chairman. Thank you all for your presentations and for being here.

Dr. Thomadsen, on Slide 8 of your first presentation, you talk about safety culture.

DR. THOMADSEN: Yes.

COMMISSIONER APOSTOLAKIS: And then you said safety culture in various applications, and the culture within the NRC. Can you elaborate a little bit on that, what you mean by that?

DR. THOMADSEN: Yes. Right. I have given a presentation at the ACMUI, because I have been concerned about some of the safety culture that the NRC exhibits, particularly with respect to its licensees.

And there was a particular presentation at the Health Physics Society last year where one person from the NRC was discussing safety culture and was talking about a chilling effect at licensed facility where people were not -- were not reporting hazardous situations.

And the person that was giving the presentation assumed that this was a cultural problem there, that the people were afraid to report what was going on because it may affect their employment, whereas some of these situations, just like he described, are not that they are, the workers, are afraid of their employment. They are afraid of getting the institution in trouble with the NRC, because of potential punitive actions the NRC would have on their

employment.

I think the concept of safety culture is very important as far as safety at the institutions. I think safety culture is also very important in how the NRC interacts with its licensees.

COMMISSIONER APOSTOLAKIS: But that would be -- that would seem to be a problem of the licensee, not ours. I mean, what does that have to do with our safety culture?

DR. THOMADSEN: The whole concept of having a safety culture is that if there are problems it=s best if there are -- if they=re unveiled, and it=s best, rather than having a blame culture, to have a culture that can work to improve the situations that are problems.

And that doesn=t come out of a blame culture, but out of a systemic viewpoint of the environment.

COMMISSIONER APOSTOLAKIS: So are you saying we have a blame culture at the NRC?

DR. THOMADSEN: I think that when the regulators go someplace and the licensees are afraid of talking openly to the regulators that that indeed does indicate that there is a blame culture, particularly if there are noted violations and that the licensees are liable for punishment.

COMMISSIONER APOSTOLAKIS: That=s a very interesting statement, and our staff is listening I hope. Dr. Langhorst, of course you know that the Commission is a decision-making body. So when you offer criticism, maybe you should accompany those with some recommendations as to what to do.

And right now I have -- I don=t know what to do. First of all, does the rest of -- the rest of the Committee agrees with you? I don=t know. I would be -- I think you said you --

DR. LANGHORST: I did not ask a vote --

COMMISSIONER APOSTOLAKIS: I=m sorry?

DR. LANGHORST: I did not ask for a vote, but I think I have support in the Committee.

COMMISSIONER APOSTOLAKIS: I have served on committees.

(Laughter.)

If you have support, that does not necessarily mean you have --

(Laughter.)

And I=m not disputing what you said, but I think they would carry more weight if they came from the Committee in a formal way. But coming back to my point about decision-making, you heard my fellow Commissioners, Ostendorff and Svinicki, raise questions about what you said, and I agree with them.

Who would advise the Commission as to what to do about your criticism? But that advice should take into account some of the issues that Commissioner Svinicki and Commissioner Ostendorff raised. Is it our staff -- in other words, is your recommendation that here are some problems and the NRC staff, which has a broader view of the agency and what the agency does, should come up with some recommendations for the Commission? Would that be a reasonable way to proceed?

DR. LANGHORST: I do not believe so.

COMMISSIONER APOSTOLAKIS: You do not believe so.

DR. LANGHORST: Because it isn=t just the staff, it=s the NRC, the NRC staff, there are Agreement States, and it is the medical community.

One recommendation I might have is that the Commission could consider something similar to what it does every year in March and have a Regulatory Information Conference. Now, that March conference, it sounds pretty open to everything, but it=s sponsored by the Office of Reactor Regulations.

And so as a medical community, we=re like, well, that=s not us, but maybe there should be something along that line. I know many of you go to various professional societies that are involved in the use of radionuclides and speak and give your thoughts and listen to their thoughts, but in a conference like that that could get many of the medical community together, not only to talk with you but to talk with each other, to talk about these tough questions and these issues.

And like Dr. Thomadsen said, the feeling of, gee, I=m not sure I can -- I can talk to that NRC inspector because they yell at me, there are -- this has happened.

COMMISSIONER APOSTOLAKIS: We shouldn=t do that?

DR. LANGHORST: This has happened. So that could be a route to get more information into the Commission and to the staff and to the Agreement States. One of the things you all -- in

regulating reactors, you are the only game in town. I mean, you=re doing that reactor regulation. But as far as the use of byproduct materials, it is also portioned out to Agreement States. And that has its own challenges of how each Agreement State regulates, how consistent the rules are, and so on.

And I=m not saying that because they are different rules they=re worse, it fits their situation. But it can be challenging as you move from state to state. So those are the topics I was bringing up, and I think you might consider something like a regulatory issue conference that focuses on medical use.

COMMISSIONER APOSTOLAKIS: That=s an interesting recommendation. I would like to note, though, that when I said that the staff may give us a recommendation, the staff when they do that they do get advice, they have public meetings, there are Agreement States, so it=s not just two or three individuals from the staff that would do that.

So I would find that very useful, but your suggestion is interesting, too.

DR. LANGHORST: One of the strengths of it is that if it could be -- I don=t know if annual is too much, but if it could be a routine conference that happens that the medical community knows this is happening, they can adjust their schedules. Sometimes the challenge that NRC staff has in doing their public outreach and engaging the medical community is that they published the meeting a month in advance and there is not opportunity for some of our medical physicians and physicists to get away at that time and to prepare, you

know, so that=s a recommendation that I think could be considered.

COMMISSIONER APOSTOLAKIS: Thank you very much. Appreciate your input.

Back to the Chairman.

CHAIRMAN MACFARLANE: Commissioner Magwood.

COMMISSIONER MAGWOOD: Thank you, Chairman. Good morning. Welcome to all of you. It=s good to see -- some of you I have met on different occasions, and a few who are in the back I=ve met as well. So it=s good to see you again.

Dr. Zanzonico and I were in Philadelphia for a while together at a common meeting, and it=s good to see you again as well.

Let me start with picking up this conversation a bit, because when I first came to the Commission and I sat with the staff and started talking about some of these -- I think we talked medical events at that time, and we talked about these issues. That was when I first realized we didn=t have any medical personnel on staff that had medical backgrounds.

And my immediate reaction is to be troubled by that, because obviously these are, you know, very complex issues. I=m less concerned about it now, and let me explain why -- a couple of reasons. One is because of something that I think several of you have mentioned, which is it=s very important that NRC not get into the business of second-guessing medical professional judgments.

And I think if we had, you know, a medical staff on -- as part of our organization, there would be a great temptation to begin to

second-guess and intrude and get into things that perhaps NRC should not try to second-guess and get into.

So I think there is a little bit of a discipline that not having staff does for us. But I do -- I am very sympathetic to what you say about the advice that we get, and I think that we, as Commissioner Svinicki mentioned, we value this Committee=s advice a great deal and respect -- because of the fact we don=t have a lot of sources of this type of advice, what we hear from this group carries a great deal of weight with us, and so we -- we rely on it a great deal.

And in that respect, I think that as we went through the exercise I guess a couple of years ago to review how the Committee reported into the organization, we looked at the possibility of having the Committee report directly to the Commission. We debated and discussed that for some time and concluded to leave it where it was.

And as Dr. Thomadsen had mentioned, it=s working pretty well, and I think everyone is satisfied with that. Even with that, I think that, you know, certainly there was an expectation for me -- and I won=t speak for my other colleagues, although I think most of them probably feel the same way -- that the Committee members would have access to us as well, and that you -- that if you had thoughts or recommendations that you should not feel restricted to come to us and give us your thinking.

And, you know, I certainly value that. I=ve had conversations with members of the Committee over time and found those conversations very enlightening. And that is part of being a Commissioner. That=s part our job -- to gather information from

different sources. So when I make decisions on things like this, it isn=t just because I=ve sat and read a staff paper. You know, I have talked to members of the ACMUI. I=ve visited hospitals. I=ve talked to patients. I=ve gone to conferences. And that is part of what we do.

You know, when I got here I knew very little about containment sumps. Apostolakis probably did, but the rest of us probably didn=t know that much about them. And so I had to learn about that. I had to go back to people. So it=s really part of that we do.

In any event, so I -- but I think that some of your comments are very thought-provoking, and I appreciate your thought about having some sort of a conference, and I=m sure we=ll chew on that a bit more.

In that respect, back to Dr. Thomadsen, just what -- you have talked about the communication with the staff being very good. How about with us? How do you feel about communication with the Commission?

DR. THOMADSEN: Right now, I think we have been doing very well. I think the briefings that we have been having with you have been effective at conveying our concerns to you. I don=t know if they have been effective at addressing the concerns you would like to be -- to have addressed. I think we do get messages as to where to direct what we bring to you.

That depends on both the makeup of this Committee and the makeup of the Commission. Right now, as I say, things are working very well.

COMMISSIONER MAGWOOD: Good.

DR. THOMADSEN: In the past, that has not always been the case.

COMMISSIONER MAGWOOD: That has not always been the case. I understand. Yes, no, I appreciate that. And, again, I encourage that -- you know, that as these issues are being discussed, you know, if you or other members wish to talk to us, I encourage you -- you know, we have open doors, talk to pretty much anybody, should certainly to you as well. So I would encourage you to do that.

Let me just go to Dr. Zanzonico for a minute because -- your data chart showing the exposure estimates was really quite interesting. It was actually a little disturbing; I didn=t expect to see the next-door neighbors getting the highest dose estimates.

I spend a lot of time in hotels, you know, so --

(Laughter.)

One thing -- delayed effect over there. One thing that occurred to me when I looked at that was you looked at those exposures over the course of three days. For hotel workers, while you -- while the dose estimate, the realistic dose was relatively low, it was over a three-day period. Isn=t it possible that there could be some hotel workers that get multiple exposures from multiple people over long periods of time? Is that something that you have given thought to?

DR. ZANZONICO: Certainly. But if you looked at the right-hand -- sort of the still conservative but more realistic conditions, the radiation doses of the hotel workers up to a three-day hospital stay

for a specific individual patient, was of the order of one millirem.

COMMISSIONER MAGWOOD: Right.

DR. ZANZONICO: And that=s why I said a specific hotel worker, a housekeeper, would have to take care of such a room for 100 days out of the year to approach 100 millirem. So I think even in the busiest hotel that might have such patients regularly as a guest, that seems unrealistic, frankly.

The other point I want to emphasize is, again, we are talking about doses to both members of the general public, hotel workers, for example, and family members, of the order of 100 millirem, more realistically under most circumstances tens of millirem. So we=re talking about doses which are comparable to the additional dose citizens of Denver get each year from additional background radiation.

So I think we need to maintain some perspective in terms of what the extent of the Ahazard@ is, even under the worst of circumstances.

COMMISSIONER MAGWOOD: Right. Now, I appreciate that, and, you know, I think that=s clearly -- the statement you just made is clearly the reason why regulations have not changed to date. If we thought that there was an imminent threat to public health and safety, we would take action. There is no evidence of that at this point, although the staff is conducting some studies that, you know, we=ll get some more information --

DR. ZANZONICO: If I may just expand on that point further. It is well-known in radiation biology that the biological effect of radiation goes down dramatically as the exposure is protracted or

highly fractionated. So one cannot conclude at all that a dose of 100 millirem over the course of the year is equivalent to an acute exposure of 100 millirem. Although that=s not -- that=s not codified in any regulation, that certainly is the reality of the science.

COMMISSIONER MAGWOOD: Yes. And the next time we review Part 20, we=ll bring you back and we can talk some more about this.

(Laughter.)

I appreciate that. And although I think that there is two questions that come to mind for me, one is that there always is a potential for an unusual acute exposure from, you know, someone becoming sick at the hotel or some such thing, and that is an issue.

But also, you know, I think there is -- and this is something I just feel personally, that it=s important that people who are doing their everyday life not receive regular exposures they=re not aware of. I think if you think that=s possibly happening in some places, that=s an issue. That=s something I think that we should be concerned about whether or not there is a health-threatening exposure. So it=s just something I think we should give some thought to.

Let me wrap up with Laura. Appreciate the special role that you serve. And as I=m someone who is very emotionally tied to our constitutional democracy, but if we had a queen I would certainly have you --

(Laughter.)

-- very high on the list of candidates. So, and I would think we would be in very, very good hands.

We have -- and I know you=re aware of the Commission=s SRM on the issue that we talked about, and you can opine on that very quickly in a few seconds. But I mostly wanted to ask you, is there anything besides this issue of instructions and patient release that you have heard from patients that just haven=t been addressed that we should be giving thought to? You mostly focus on the instructions.

MS. WEIL: I did because the instructions are the tool that patients need to manage their release. I am very struck by your statement about unintentional exposure to people who are unaware of the fact that they are being exposed, and that would be -- the public and hotel workers I suppose would be the people in that -- in that category.

And it=s that issue of consent, that ethical issue of consent, which troubles me greatly with respect to hotel workers who are usually women of child-bearing age, and I -- I guess I=ll just leave it at that, that patients are so worried about exposing people and they=re -- if they=re not given the tools to effectively deal with that problem, then they are put in an impossible situation. And these are patients with cancer who don=t need additional stress.

COMMISSIONER MAGWOOD: Appreciate that.

DR. ZANZONICO: May I offer a comment? I think we are all sensitive to the issue of uninformed, lack of consent exposures. What strikes me at times, though, is the -- is the -- and I know it=s all our jobs here -- the special attention given to radiation exposures. People with infectious diseases check into hotels all the time. Far more people die annually from flu than will ever die, if any, from low level

exposures from radiation therapy patients.

So at what point, then, should the appropriate regulatory agency regulate informed consent of workers that they will be taking care of rooms where there may be transmissible pathogens, and so forth? So I know it=s a very broad question, but I think, again, it bears -- it brings some perspective to bear that, yes, there may be non-zero exposures to hospital workers, but they are of the range where there is no demonstrable effect.

And so if there is -- if it=s deemed necessary that hotel workers exposed to these extremely low level, if any, hazardous exposures, then what about the number of other hazards to which they can be exposed that are non-radiogenic?

COMMISSIONER MAGWOOD: We are out of time, but I will just conclude by saying, first, that if I could do something about the infectious patients I probably would.

(Laughter.)

But that=s not -- we=re not the right agency for that. But, secondly, you know, I think that the point that several of you made, that it=s very important that we not go too far in regulating, I am very sensitive to what you said about the German situation where some therapies just simply aren=t available because of the extreme regulation.

We don=t want to see that happen here, so we want to move very carefully, and we don=t -- we want to approach this in a rational manner. But, again, thank you, all of you, for this very interesting conversation this morning.

Thank you, Chairman.

CHAIRMAN MACFARLANE: I think there are some additional questions. Commissioner Ostendorff?

COMMISSIONER OSTENDORFF: I just want to make two quick comments. First, it goes to Dr. Langhorst -- again, your thought-provoking slides and the discussion on the NRC staffing. And Commissioner Svinicki made a comment that I agree with that this -- your kind of comments really cause us to go back and think and reflect upon it, and I=ll do that. But I wanted to provide at least one anecdotal example that -- it was before the Chairman got here, but four of us maybe three years ago were involved in voting on a Part 35 medical event definition rule. And we were not satisfied with the rule as it came up from our staff. We disapproved that rule.

And the four colleagues here -- Commissioners Svinicki, Magwood, Apostolakis, and myself -- directed that that -- the NRC staff go back out to the medical community, because we did not believe there had been sufficient interface, dialogue, discussion to get the medical community=s views on this dose versus activity methodology.

I=m thinking out loud here, but I worry that if we had too much -- let=s say we had three physicians on our NRC staff. Would we be as inclined to go outside of our staff and ask the community those kinds of questions, if we were overly reliant or more reliant upon in-house expertise? I=m not asking you to address that, but I just wanted to share that -- we=ve gone through this issue a few years back.

The second one gets to Dr. Thomadsen=s comment on the blame culture piece. And I just wanted to highlight one example.

Again, four of us were here back in 2010 when we had an AARM meeting dealing with improper performance by the Veterans Administration in Philadelphia for prostate brachytherapy implants for administration of those doses.

Based on the events, I think Mike said that 2008 was the occurrence, and it came before the Commission in 2010. And I will also highlight -- and I don=t know how many of you know this, but I think since this is a public meeting it=s worthwhile to highlight that the Region III Administrator at that time, Mark Satorius, who is currently our Executive Director for Operations, did something that had not really been done in the aftermath of that VA incident, and he went out and offered to the VA to coach and mentor the VA hospitals= radiation safety officers and their radionuclide, you know, group on how the NRC does inspections to try to help them get better.

And so rather than it being a -- you guys are all screwed up, and we=re going to blame you, I think there is a very constructive example being offered by the Region III Administrator to help mentor, coach, and help people get better. So I think you have raised a significant issue. I wanted to highlight that I have seen at least one different example of how that has been approached in what I would view as a constructive step.

So I=ll stop there.

CHAIRMAN MACFARLANE: Anybody else?

(No response.)

So I=d just like to close by a quick comment, too, on this topic. You know, we are the regulator, and if we see violations it=s

incumbent upon us to note them and to say, "You're in violation." So if that's creating a chilling effect, I'm sorry, but that is our job. And, you know, somebody is yelling "That's improper," but that is our job.

And in terms of infectious disease killing people, I agree completely, but our job, again, is to regulate the use of nuclear material. And so it's incumbent upon us to do that, and our mission is to protect public health and safety. And so that's what we do. And that's why we're focused on this particular topic -- because it's our job.

So, but I do thank you for all your work. I thank you for your input. I look forward to continuing conversations on this topic. I don't think we are done yet. And I don't think we are done with patient release, but hopefully our SRM will move us in the direction of collection of more data. I think that will be very important in moving forward in this area.

So thank you again for all your work, thank you for the discussion, and we are now adjourned.

(Whereupon, at 10:46 a.m., the proceedings in the foregoing matter were adjourned.