SUMMARY MINUTES FOR THE MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
April 8, 2004

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) met on April 8, 2004, in a public teleconference session.

The ACMUI members who participated in the teleconference were:

David A. Diamond, MD	Radiation oncologist
Douglas F. Eggli, MD	Nuclear medicine physician
Nekita Hobson	Patients' rights advocate
	Medical physicist
Ruth E. McBurney	State representative
Subir Nag, MD	Radiation oncologist
Sally W. Schwarz, RPh	Nuclear pharmacist
Orhan Suleiman, PhD	Food and Drug Administration representative
Richard J. Vetter, PhD	Radiation safety officer
Jeffrey F. Williamson, PhD	Radiation therapy physicist

ACMUI members absent:

Manuel Cerqueira, MD	Nuclear cardiologist, ACMUI Chairman
Leon S. Malmud, MD	Healthcare administrator

Staff from the Office of Nuclear Material Safety and Safeguards (NMSS); Division of Industrial and Medical Nuclear Safety (IMNS); Material Safety and Inspection Branch (MSIB), participated in the teleconference.

Thomas H. Essig	NMSS/IMNS/MSIB, Designated Federal Officer[1]
Donna-Beth Howe, PhD	NMSS/IMNS/MSIB
Angela R. Williamson	NMSS/IMNS/MSIB

Members of the public participated in the teleconference. Specific participating members of the public are listed below:

Society of Nuclear Medicine
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1:05 p.m.

ed Federal Officer, made opening remarks, thanking everyone for their participation. In his remarks, Mr. Essig recused the ACMUI member, Mr. Ralph Lieto, from any decision making activities,

[1] Thomas Essig acted as Chairman for this meeting, since neither the Chair, Dr. Cerqueira, nor the Vice Chair, Dr. Malmud were presented. Mr. Essig served as Chair in accorandance with the ACMUI bylaws.

recommendations, or conclusions related to the ACMUI subcommittee's dose reconstruction effort associated with the St. Joseph Mercy Hospital case. Mr. Essig recused Mr. Lieto because Mr. Lieto currently serves as Radiation Safety Officer at St. Joseph Mercy Hospital.

HOD OF DOSE RECONSTRUCTION

so that the ACMUI's Dose Reconstruction Subcommittee (DRS) could submit, for a full committee vote, its final report on its analysis of the NRC's method of dose reconstruction. Previously, the Commission requested that the ACMUI review the NRC's dose reconstruction method in the St. Joseph Mercy Hospital overexposure case. The Commission requested this action because of criticism it received from stakeholders who assert that the NRC used an overly conservative method to reconstruct the dose to the member of the public in the St. Joseph Mercy overexposure incident. According to these stakeholders, Carol Marcus, MD, Society of Nuclear Medicine (SNM); and Jeffry Siegel, PhD, SNM; the NRC's overly conservative method lead to unnecessary alarm to members of the public and excessive enforcement action against St. Joseph Mercy Hospital.

S member, began by outlining the memorandum submitting the final report. The following is a brief summary of the six points in the memorandum, dated April 1, 2004; and signed by Leon S. Malmud, Chairman, DRS:

The DRS's calculations estimate the range of dose to the member of the public (the daughter of the patient) to be 4 to 9 rem.

Using the DRS's calculation of 4 to 9 rem as a reference point, the DRS stated that the NRC overestimated the dose to the patient's daughter by a factor 1.67 to 3.75. (Later in the discussion, the DRS retracted this statement, deeming it "redundant.")

The difference in the DRS's estimation of dose and the NRC's estimation of dose derives from differences in the assumptions of exposure time, and distance from the radiation source to the exposed individual (i.e., the distance from the patient to the patient's daughter).

The DRS stated that the NRC's dose reconstruction method was overly conservative because the method assumed extended close contact between the patient and the daughter at an unrealistically close distance; also, the NRC's calculations ignored the use of shielding. Furthermore, regarding the NRC's calculations and assumptions, the DRS noted the following:

a) The NRC's use of Monte Carlo simulation was inappropriate given the scenario of how the patient and the daughter were positioned toward each other.

b) Had the NRC used continuous decay in its calculations, this would have lowered the dose estimate by about 10 percent.

c) The licensee's post-incident interviews with the daughter led to a different scenario than the one the

NRC used in its dose reconstruction. The DRS strongly believes that these differences should have been outlined in the NRC inspection report, and should have been used to define lower and upper exposure bounds.

d) Whenever the NRC requests consultant assistance to assess medical risk, the NRC should provide the consultant an estimate of total body exposure, as well as total effective dose equivalent, since total body exposure is better correlated with any adverse medical effects associated with exposure.

e) The DRS suggests that any discrepancy between the licensee and the NRC should be described in the final presentation with data and high dose/low dose estimates.

5. The DRS believes that had the licensee promptly and contemporaneously notified the NRC when the daughter refused to follow the licensee's directions to minimize her exposure, this would have "perhaps" had the desirable effect of assisting in better documentation of the event.

6. The DRS was concerned about how any similar future events should be handled. The DRS suggested the following:

a) That the NRC develop an information notice (IN) addressing contemporaneous notification to the NRC when members of the public refuse to cooperate with licensee attempts to minimize exposure. Such an IN should summarize all available guidance on exposure limits and licensee options when the public does not cooperate with instructions to minimize exposure.

b) That the NRC develop a process to grant, based upon humanitarian reasons or medical necessity, exemptions to its 500 millirem exposure limit to members of the public.

ts, Dr. Williamson referred to some technical slides that he had prepared and submitted. He asked the DRS to peruse his slides to preclude the possibility that they contain any error or erroneous assumptions.

mpted the ACMUI to make any additional finalizing comments regarding the report, so that DRS can make a motion to the ACMUI to accept the DRS report. After incorporating any last comments, the ACMUI Chairman could then forward the report to the NRC staff.

llowing edits to the six point memorandum:

Remove Dr. Williamson's name from the report throughout and submit the report as the work of the DRS.

Delete Item #2 because it is redundant.

Re-word Item #5 (previously Item #6a) to make it more generalized. (Later in this discussion, Thomas Essig, NRC, clarified that this item (the suggestion that staff issue an an IN to address future cases of this type) was better discussed as a separate issue, since it does not address the ACMUI's assignment to analyze

the NRC's method of dose reconstruction to ascertain whether there is validity to the SNM's assertions that the NRC's method of dose reconstruction is overly conservative.

cuss the IN at length (until there was approximately 15 minutes left in the teleconference) but generally agreed that the language of the suggested IN is best addressed as an agenda item at a future ACMUI public meeting.

Marcus, MD, made three statements. In the first statement, Dr. Marcus noted that the use of the total effective dose equivalent (TEDE) in assessing the overdose was not appropriate in this case, because the TEDE applies to workers. There should be a way to establish an objective dose that has risk meaning. The second statement was that perhaps the licensee, St. Joseph Mercy Hospital, should inform the overexposed individual that her dose is likely much lower than what the NRC estimated, because she is "probably worried." The third statement was that in previous years, the issue of handling public members who disregard licensee instructions on reducing exposure was discussed with the NRC (specifically, Chairman Carr of NRC). Dr. Marcus stated that "it was agreed" that the licensee's responsibility was to inform the public that "they" (apparently, the licensee) have no legal ability to force anything on members of the public. Dr. Marcus further stated that the radiation control people in California informed her that if a member of the public is about to be exposed to a level of radiation that is truly dangerous, the licensee can call the police and have the person "bodily dragged out" of the licensee's facility. However, if the issue at hand is that the dose is likely to exceed a regulatory limit, there is nothing the licensee can do.

e a statement. Dr. Siegel stated that he was under the impression that the charge of the DRS was to assess his and Dr. Marcus's critique of the NRC's method of dose reconstruction. Currently, that charge is not included in the DRS's evaluation.

hat he was not under the impression that part of the DRS charge was to specifically address the Marcus/Siegel critique. He verified that the DRS reviewed the critique and considered it, but did not understand that a charge of the DRS was to address it specifically.

the charge of the DRS: "The Subcommittee is specifically requested to evaluate the approach to dose reconstruction taken by the NRC Region as well as the critique of the inspection report prepared by Drs. Marcus and Siegel. In preparing its report, the subcommittee should indicate for each aspect of the dose reconstruction and the Marcus/ Siegel critique whether it agrees or not with the evaluations and representations presented, and why."

understanding of the DRS's charge, Dr. Siegel then suggested that the DRS cease discussion of "minor points" and address his and Dr. Marcus's critique of the NRC's method of dose reconstruction.

r a volunteer on the DRS to carefully peruse the Marcus/Siegel critique and contrast it with the DRS's technical report to determine whether the DRS would agree with the critique. Richard Vetter, PhD, (a non DRS member) commented that the DRS report agrees, in general terms, with the

Marcus/Siegel critique. It does not agree in detail because the Marcus/Siegel team reviewed many different scenarios and concluded that the dose estimate would be lower in accordance with the particular scenarios they envisioned.

t, at this point, the DRS is not prepared to suggest a rulemaking initiative to modify 10 CFR Part 20 to rearrange all the dose quantities (TEDE, effective dose equivalent, etc.) but that this is something worth talking about. Dr. Siegel replied that his and Dr. Marcus's critique did not advocate a change in the regulatory definition of TEDE. Rather, it stated that there were regulatory criteria that had to be met, and other criteria that should be met, if risk assessment were to be involved. Dr. Williamson responded that although the DRS took a different approach to assessing the validity of the Marcus/Siegel critique, they agreed with many of the points in the critique. He then again asked for a volunteer to compare the DRS's technical report with the Marcus/Siegel critique to determine whether it would agree with the critique.

ft in the teleconference, Mr. Essig suggested that Dr. Vetter might perform this exercise. Although Dr. Vetter is not on the DRS, he is familiar with the Marcus/ Siegel critique. However, Dr. Vetter stated that he was unable to accommodate this request because he was due to travel shortly. Nevertheless, he could share his knowledge with a DRS member who could then perform the task.

o commit to performing the task. Therefore, Thomas Essig stated that staff would be in communication with the ACMUI via e-mail, and another conference call to vote on the final DRS report will have to be scheduled.

ge 7 of the meeting transcript.

9 p.m.