

TELECONFERENCE MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

JANUARY 22, 2009

MEETING SUMMARY

PURPOSE: To brief the Advisory Committee on the Medical Uses of Isotopes (ACMUI) on the outcome of a recent meeting with international regulators on the issue of medical isotopes shortages and to discuss the ACMUI subcommittee recommendation for potential Authorized Users (AUs) who will experience a delay between their completion of Training & Experience (T&E) and receipt of their board certificate from the American Board of Radiology (ABR).

OUTCOME: The ACMUI gained a better understanding of the current status of the medical isotopes shortage issue from an international perspective, and the Nuclear Regulatory Commission (NRC) staff gained a better understanding of the views and opinions of the ACMUI subcommittee, as well as other stakeholders' views and opinions, on the T&E issue discussed. The ACMUI subcommittee is working to create a final draft report for approval by the full Committee at the May 2009 ACMUI meeting.

NRC STAFF BRIEFING ON RECENT MEETING WITH INTERNATIONAL REGULATORS ON THE ISSUE OF MEDICAL ISOTOPES SHORTAGE

The French Nuclear Safety Authority (ASN) held a meeting in Paris on January 7-9, 2009, for international regulators to discuss the medical isotopes shortage issue, coordinate the supply of radiopharmaceuticals, and manage the transition period between the shut down of old reactors and the commissioning of new ones. Mr. Chris Einberg, NRC, provided a brief overview of this meeting he attended on behalf of NRC with Dr. Charles Miller, Director of NRC's Office of Federal and State Materials and Environmental Management Programs. Representation included international regulators from Australia, Belgium, Canada, France, the Netherlands, South Africa, and the United Kingdom. Mr. Einberg described each country's current production capabilities. Of most interest to the ACMUI was news that the reactor in the Netherlands, which is currently shut down, may be decommissioned. The Netherlands' reactor currently supplies approximately 30 percent of the world's supply. The United States (US) is not currently producing any medical isotopes; however, the University of Missouri and Babcock & Wilcox are exploring the possibility of producing molybdenum-99 (Mo-99). Production in the US is expected to be at least four or five years in the future. Mr. Einberg explained that the information provided at the ASN meeting would be passed along to the Nuclear Energy Agency (NEA). The NEA scheduled another meeting on the same issue for later in January.

Mr. Steve Mattmuller, ACMUI, stated that the news about the possibility of the Netherlands' reactor not restarting was devastating. Dr. Darrell Fisher, ACMUI, asked if the Maple 1 and Maple 2 reactors in Canada were expected to go online soon. Mr. Einberg stated that Canada did not expect either reactor to become operational. Dr. Douglas Egli, ACMUI, described the impact of the medical isotopes shortage at his facility. He stated that they are not currently receiving any generators; however, they are receiving technetium-99m (Tc-99m) in bulk and unit doses during the day. His facility does not receive Tc-99m for emergency after hours studies. Dr. Mickey Guiberteau, ABR, stated his hospital was having the exact same issue and added

that when they do receive bulk Tc-99m, they do not receive it in the amounts needed for compounding. This is resulting in interruption of good patient care, and often it is necessary to perform more expensive procedures as an alternative. Dr. James Welsh, ACMUI, suggested that the US seriously consider medical isotope production within the US; however, the ACMUI understood that the NRC cannot promote isotope production. Mr. Mattmuller added that the NRC should not embrace the recent report issued by the National Academies. The report suggested replacing Highly Enriched Uranium (HEU) targets with Low Enriched Uranium (LEU) targets. Mr. Mattmuller stated that there are some significant issues, especially with regard to technical feasibility and barriers for implementation, that were not addressed accurately in the report. The ACMUI also discussed general economic factors that impact medical isotope production.

ACMUI SUBCOMMITTEE RECOMMENDATION FOR AU STATUS DELAY FOR ABR CANDIDATES

Dr. Douglas Eggli, ACMUI, described the change in ABR's board certification process that will include a 15-month gap between completion of T&E and issuance of a board certificate. The ACMUI subcommittee's goal was to develop a way of maintaining the relevance of the Board and the board certification pathway but allowing these diplomates to become AUs after completion of T&E. The subcommittee recommended that the ABR train residents as they currently do, maintaining the same kind of record keeping requirements, but the ABR would provide a separate certification indicating that the resident has met the T&E requirements and is AU eligible. This certification would be issued prior to actual board certification. Dr. Eggli added that the solution for ABR could be applied by any certification board with the problem of a time gap between completion of T&E and when the individual actually achieves board certification; however, no board would be required to implement a solution that they did not need.

Mr. Chris Einberg, NRC, indicated staff was still evaluating the subcommittee's proposal and was not in a position to provide comments at the time.

Dr. Mickey Guiberteau, ABR, stated that the ABR had reviewed the subcommittee's proposal and was moving in the direction of supporting this proposal by actively changing some of their policies as to when then ABR will provide certification; the ABR's willingness to provide a certificate stating assurance that the candidate has completed their T&E; and that the candidate has finished an exam related to radiation safety.

Dr. Eggli, ACMUI, stated that the primary difference between the board certification pathway and the alternate pathway is the burden of recordkeeping. Dr. Eggli also added that it was the intent of the subcommittee that the "decoupled" certificate would serve permanently as having met all the T&E requirements to be an AU, and, in fact, the final board certificate, which serves as a clinical statement, would not be necessarily relevant. The AU eligible certification would stand on its own as a document that fulfills the requirements of the board certification pathway. Mr. Ralph Lieto, ACMUI, supported the subcommittee's proposal and added that the certification should not be rescinded in the event the candidate did not go on to receive their actual board certificate.

Ms. Colleen Casey, NRC Region III, asked the subcommittee if it would be possible for the "first level" certification for T&E to be a time-limited, provisional, certification that would expire, if the final board exam was not completed. Dr. Eggli, ACMUI, clarified that the initial board certificate would relate only to T&E and radiation safety, and the second certification would relate only to clinical competence. Dr. Eggli added that since clinical competence is not required for AU

status, the second certificate would be completely separate. Dr. Eggli also described how a candidate who failed to achieve the AU status eligible certification from a recognized board would need to achieve a higher quality of documentation to meet the alternate pathway requirements.

Ms. Casey, NRC Region III, inquired as to whether or not the proposal would require rulemaking. Dr. Donna-Beth Howe, NRC, stated that if the proposal fit into the current regulations, no rulemaking would be required; however, NRC staff would need to review the final subcommittee report carefully.

The subcommittee was expanded to include Ms. Debbie Gilley, Mr. Ralph Lieto, Mr. Steve Mattmuller, and Dr. Richard Vetter. The subcommittee expected to revise the draft report based on the current discussion and provide a final draft for vote at the May, 2009 ACMUI meeting.