



*The Council on Radionuclides and Radiopharmaceuticals, Inc.*

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## **ISOTOPE SUPPLY COMMITTEE**

### **Agenda**

**Tuesday, May 3<sup>rd</sup>, 2016, 10:15 pm – 12:15 pm**

Offices of Reed Smith, 1301 K Street, NW  
Washington, DC, East Tower

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- I. Welcome**
- II. Antitrust Guidance from Counsel**
- III. Approval of the Minutes from the December 2015**
- IV. Mo-99 Secure and Reliable Supply Status.....I. Goldman/ R. Brown**
  1. DOE implementation of AMIPA and ULTB Update and Status

Alpine described recent meetings with Energy and Commerce Committee staff to discuss CORAR's 2015 letter to the Committee as well as interest in an oversight effort on AMIPA implementation. Last year Committee staff met with DOE and NRC, intended to reinforce the need for Committee action this year. At this time, the Committee has highlighted the issue for Subcommittee Chairman Murphy (R-PA) and Chairman Upton (R-MI) as an issue for this year's agenda. The staff has proposed three potential steps and requested Committee leadership approval for these proposed actions, including an off-the-record staff briefing by DOE. Subject to the feedback from that meeting, the Committee staff has recommended sending a letter to DOE and the other relevant agencies inquiring as to (1) the status of their efforts to address the Mo-99 supply and (2) their actions to ensure a reliable and adequate supply for the U.S. patients. Finally, Committee staff has recommended that the Committee should consider a public hearing if the staff believes that the Administration is putting patients at risk and that the issue warrants public action.

The Senate Appropriations Committee unanimously approved their 2017 Energy and Water Development Appropriations bill, and the bill is being considered by the full Senate today. The Senate report included language regarding DOE/NNSA's Molybdenum-99 program. The House Appropriations Committee also approved their 2017 Energy and Water Development Appropriations bill, and it is expected to be considered by the full House in upcoming weeks. The House bill's report also includes language regarding DOE/NNSA continued support for "domestic Mo-99 production without the use of HEU."

Action item: Executive Director and Alpine will follow-up with Committee staff regarding further interactions. (NOTE: A meeting was held with E&C staff on May 26<sup>th</sup> including Michael Guastell, Jim Massie, and Ira Goldman).

## 2. DOE Mo-99 Topical Meeting Update

The next topical meeting will be held in St. Louis (Clayton, MO) at the Ritz-Carlton on September 11-14, 2016. The format is anticipated to be similar to last year's meeting in Boston.

Action item: The Executive Director and ISC Co-chairs will interact with DOE prior to the meeting in regard to past recommendations to restructure the topical meeting and will participate in the meeting.

## 3. Publicly available updates from CORAR members (Nordion, Northstar, Northwest, and SHINE)

Each project provided brief updates on the status including recent and expected near-term milestones and anticipated commercialization dates.

## 4. OSTP Stakeholders Meeting

An OSTP meeting was held in January and the next meeting will be held on May 6 the day after the CORAR meeting. It was noted that efforts to convince DOE to re-evaluate the objectives and agenda of the OSTP meeting have had limited success but should continue to be pursued.

Action item: Executive Director and ISC to interact with DOE to provide recommendations to restructure the agenda and format of the quarterly meetings.

## 5. Update on Mo-99 Reviews (e.g., NSAC, NAS, OECD)

Kevin Crowley (NAS) made a brief presentation at lunch noting that the study is moving into its final, report-writing phase. The committee plans to issue the report before the Mo-99 Topical Meeting in September and will make a presentation at the meeting. He said that NAS would welcome CORAR suggestions in regard to external reviewers.

It was reported that the NSAC review is likely to take place later this year and a charge letter would be prepared soon.

Action item: The Committee requested the Executive Director to provide names of potential external reviewers with industry experience drawing from prior suggestions for panel members.

## 6. OECD/NEA High Level Group on Medical Radioisotopes Update

The February 2016 OECD HLG-MR meeting was reviewed including the most recent update of the "self-assessment" evaluation. A new version of the OECD Mo-99 global supply and demand projection has been prepared and should be officially published soon. The next HLG-MR

meeting will take place July 20-21, CORAR Executive Director Guastella and Isotope Supply Committee co-chairs Brown and Goldman will attend.

7. EU Mo-99 Observatory/AIPES Update

The EU Observatory met in late April in Luxembourg; a summary of the meeting was reviewed. The next meeting will take place in October. The AIPES Reactor and Isotope Working Group (RIWG) met in February in Paris and reviewed the reactor schedule for the first half of 2016, which did not raise any concerns (supply has been stable even without the OSIRIS and BR2 reactors). However, some vulnerable periods late in the year were identified. NOTE: NRG informed AIPES later in May that another HFR cycle was added in December. The RIWG will meet again in Fall 2016 to begin work on the 2017 schedule.

8. IAEA Activities and Projects Update (e.g., Meeting on Global Capabilities for Production of Mo-99 Targets)

It was noted that while the IAEA has generally held annual meetings related to LEU conversion, at this point there is no meeting planned for fall 2016.

9. CMS 2016 HOPPS Rule non-HEU Add-On Update

One member noted that it had recent discussions with CMS that indicated that it is considering extension of the non-HEU add-on payment beyond 2017.

10. Other Medical Isotope Update (e.g., NSACI)

It was noted that NRC is aware of a regulatory gap concerning Ga-68 generators. MORE DETAILED NEEDED

11. Overarching presentation for 2016 Industry Mo-99 session at the SNMMI Annual Meeting

The preparation of a second industry panel that will take place on Sunday afternoon at SNMMI was described.

12. Future meetings (e.g., SNMMI, Mo-99 Topical 2016)

These were covered in previous items.

**V. Additional Business**

It was noted that CORAR transmitted a letter to Senate leadership in support of the nomination of Laura Holgate to be U.S. Ambassador to the IAEA. NOTE: Mrs. Holgate was confirmed in late May.

The major outcomes of the recent Nuclear Security Summit were also reviewed.

**VI. Next Meeting – December 6, 2016**

**VII. Adjourn**