Commitment Time: The End of HEU in Mo-99 Production and the 2016 Nuclear Security Summit

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Overview

- Background on Current Mo-99 Market
- Recent Policy Changes
  - 2012-2013 US Policy Changes
  - 2012 NSS
  - 2014 NSS and NIS
- Recent Market changes
- The Russian factor
- An end to HEU in Mo-99 production?
  - Analysis
  - Recommendations

Global Mo-99 Overview

- Current Major Mo-99 production reactors and processors in Europe, Australia, South Africa, Canada
- All have said shifting from HEU fuels and targets at some point in next few years or shutting down
  - Russia somewhat of a question mark
- Important to lock in this contribution to global nonproliferation efforts
  - Can more be done without harming public health?

U.S. supply-side efforts: American Medical Isotope Production Act

- Signed into law January 2, 2013
- Incentivizes U.S. medical isotope production using LEU
  - Bans U.S. exports of HEU for targets, fuel to WEU and Canada over a 7-13 year period. Goal is phase out by 2020.
    - Means by those dates if major current producers aside from South Africa can't use HEU, but Russia has own supplies
  - Authorizes cost-sharing arrangements to generate domestic isotope production
    - Some moving forward
  - Establishes U.S. government responsibility for waste disposition
    - NNSA in drafting process for regulations

U.S. demand-side efforts: June 2012 commitments

- "Calling upon the Mo-99 industry to voluntarily establish a unique product code or similar identifying markers for Mo-99-based radiopharmaceutical products that are produced without the use of HEU;" (Two leading TC-99m producers have done so)

- "Preferentially procuring, through certain U.S. government entities, Mo-99-based products produced without the use of HEU, whenever they are available, and in a manner consistent with U.S. obligations under international trade agreements;" (VHA has sent out guidance, some individual offices now doing so, some implementation problems: US examining whether to have other agencies follow suit)

- "Examining potential health-insurance payment options that might promote a sustainable non-HEU supply of Mo-99;" ($10 differential for medicare/medicaid—LIMITED EFFECT,IMPLEMENTATION CHALLENGES
- "Taking steps to further reduce exports of HEU that will be used for medical isotope production when sufficient supplies of non-HEU-produced Mo-99 are available to the global marketplace;" (Nearing final shipments– how will Dutch actions affect this?)
- "Continuing to encourage domestic commercial entities in their efforts to produce Mo-99 without HEU during the transition of the Mo-99 industry to full-cost-recovery, and directing those resources to the projects with the greatest demonstrated progress;" (One project seems to be going forward in 2015-2016)
- "Continuing to provide support to international producers to assist in the conversion of Mo-99 production facilities from HEU to LEU." (Yes)

2012 Nuclear Security Summit Commitments

- Important steps toward eliminating HEU in Mo-99 production
  - Belgium, France, and the Netherlands pledged to attempt to eliminate HEU use in medical isotope production by 2015
  - Belgium, France, ROK, and U.S. promised to cooperate in development and testing of new high-density LEU fuel

- Communique:
  - Minimize use of HEU taking into account need for assured supplies of medical isotopes

2014 Nuclear Security/Industry Summits

- Communique
  - We will continue to encourage and support efforts to use non-HEU technologies for the production of radioisotopes*, including financial incentives,* taking into account the need for an assured and reliable supply of medical isotopes."
- Nuclear Industry Summit
  - Also supported financial incentives, including reimbursement for any additional costs by both private and public providers
  - Supported "full cost recovery"
  - Enco uraged new 19.75 LEU producers

2016 Nuclear Security Summit—Likely to be last one—Important to use it to make high-level political commitment

Recent market changes (1)

- One U.S producer coming online—
  - Northstar-MURR expected to begin production late 2015-2016
  - Most other having financial issues or awaiting licensing
    - i.e. SHINE has marketing deal with GE Healthcare, but needs NRC approval
- Dutch problems
  - Regulatory delays may postpone conversion until 2017.
- Number of potential foreign and U.S. producers trying to line up production

Recent changes (2)

- Russia
  - Has had problems with HEU processing
  - Indicated that if technical obstacles are overcome might be able to have non-HEU targets by 2016 if there are economic incentives
  - Problems with Ukraine, sanctions, and related congressional legislation may be barrier, but hopefully phase will pass.
  - Continued need for cooperation

Russia's Mo-99 production

- Currently, very small player in the Mo-99/TC-99m market
- Share of the world market in 2011 stood at 0.1 %
- But Russia has rushed into breach caused by looming Western shutdowns.
  - 2010: 1 billion ruble ($30 million) project to build new capacity for domestic use and export at the Research Institute for Nuclear Reactors (NIIAR) at Dmitrovgrad.
  - NIIAR wants to do so initially with HEU fuels and targets
  - Ultimately wants to produce only non-HEU based Mo-99, but no timetable.
  - Several of the production reactors needs high-density LEU fuel to convert
- Government's initial investment has yet to be borne out, significantly behind schedule
  - Makes it difficult for NIIAR to ask for additional funds for conversion

Russian & US approaches to Mo-99 market: lose/lose or win/win?

- Russia could continue with current plans to perfect HEU-based production before seriously considering conversion
  - For Russia: This could mean being effectively barred from major markets as generators companies switch to LEU and Western government restrict use and licensing to HEU-free Mo-99
  - For U.S. and international community: uncertainly about Russian production could undermine effort to win financing for non-HEU production in US, Europe, and elsewhere and undermine stability of supply when market is tight anyway
- Is there a way to make this a win-situation rather than a lose-lose one?

Food for Thought: Possible Russian commitments to U.S.

- Committing to a timetable-based road map to end HEU-based Mo-99 production.
- An agreement that in the meantime HEU-based production would be only be used for Russia and Russia's existing customers, except for any requests by the United States or other states for emergency shipments of isotopes in the event of an interruption of supply from other sources.
- U.S would pledge to make initial bulk purchases of LEU-based production to incentivize conversion of the targets and later the fuel at the irradiator reactors, where technologically feasible
- Russia would agree to price its Mo-99 on a full cost recovery basis

Food for Thought: Possible U.S. commitments to Russia

- To carry out bulk purchases of pharmaceuticals that use Russian non-HEU based Mo-99 when available, for an agreed period and to an agreed amount. A particular focus could be purchases by U.S. government agencies, such as the Veterans Health Administration and the Defense Department.
- Assistance in winning expedited licensing approval from the FDA for Tc-99m pharmaceuticals based on Russian LEU-based Mo-99.
- Cost-sharing support for converting NIFKhI and NIIAR to the use of LEU targets through co-funding of related R&D work done jointly by Russian and US scientists.
- U.S. informal assistance to Russian LEU research reactor fuel producers to spur competition in exports to third country research reactors.
- Continued joint research on high-density LEU fuels.

An end to HEU in Mo-99 production? Recommendations for Summit

- Yes, the end is coming
  - Ideally would take place before 2016 NSS
  - At 2016 NSS States should commit to end exports of HEU-based Mo-99 by end of 2016 unless the OECD Nuclear Energy Agency (NEA) says there is insufficient global non-HEU production capacity available.
  - Summit members should enact a similar pledge to ban the use of HEU-based Mo-99 if the OECD-NEA and relevant national authorities certify that a sufficient supply of non-HEU-based Mo-99 exists at that time
    - Before 2016 NSS EU medical authorities should license use of non-HEU based Mo-99 from South Africa, Australia, etc.
  - Any decisions on allowing continued HEU exports should be tied to movement on this as well as bilateral pledges

An end to HEU in Mo-99 production? Other Recommendations

- Support NIS and NSS language on financial incentives
  - Expand US purchases beyond limits today (i.e physician offices, in-patients)
  - Look for means to get private payers to follow suit
    - Outreach strategies
    - Are there legislative or regulatory incentives (tax breaks?)
  - Expand use of VA purchase ability and get new USG agencies involved (DOD)
  - Other governments, particularly in Europe, should enact similar measures
  - Other governments, particularly in Europe, should clear hurdles to licensing of non-HEU based Mo-99/Tc 99m.
- Work to encourage Russian Mo-99 to be non-HEU