



Triad Isotopes, Inc. perspectives and efforts of a nuclear pharmacy to support the use of non-HEU Mo-99 for Tc-99m compounded patient preparations.

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- I have no conflicts of interest that I am aware of.
- I do speak on behalf of myself, with the full awareness and approval of Triad Isotopes, Inc.
- Due to proprietary and sensitivities of pricing and costs, this presentation information is for general use only and not specific to any one entity.
  - This is a follow up to the 2015 Abstract and Presentation: "Triad Isotopes, Inc. perspectives on nuclear pharmacy's role in the use of non-HEU Mo-99 for Tc-99m compounded patient preparations."

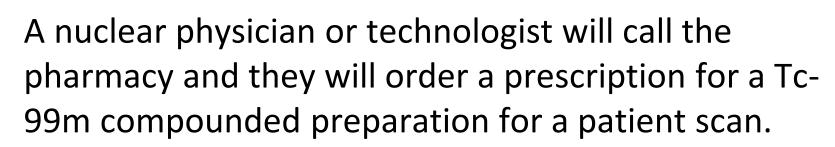
http://mo99.ne.anl.gov/2015/pdfs/presentations/S5P2\_Gattas\_Presentation.pdf



 Understand what drives a nuclear medicine department to prescribe a dose compounded from Tc-99m sourced from Non-HEU Mo-99

2. Understand the possible cost increases of using Non-HEU Mo-99

3. Understand the possible payers for the cost increases of using Non-HEU Mo-99



In the Beginning and WIFM

- Do they order one where the Mo-99 came from HEU?
- Do they order one where the Mo-99 came from Non-HEU?
  - Medicare Hospital Outpatient doses currently receive an extra \$10
  - Hospital policy may dictate the decision

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• Cost for the dose may be more than the extra \$10 reimbursement.



- There is no known *clinical difference* between a dose compounded with Tc-99m from a HEU Mo-99 generator and a Non-HEU Mo-99 generator.
- Will administration logistics and other considerations make a case for:
  - All conversion to Non-HEU Mo-99 derived Tc-99m compounded doses
  - A split amongst Medicare Hospital Outpatient Patient doses for Non-HEU Mo-99 derived Tc-99m compounded doses and "regular" Tc-99m for all other patients



- Reactor costs to produce Mo-99 from Low Enriched Uranium is greater than using High Enriched Uranium.
- Low Enriched Uranium produced Mo-99 will probably cost more to the Mo99/Tc99m Generator manufacturer unless the Mo99 producer is willing to absorb the cost.
- Non-reactor costs for producing Non-HEU Mo-99 or Tc-99m is proprietary, but will probably be market priced similar to LEU produced Mo99.

If manufacturers are receiving higher cost Mo-99, there are three options.

Increased Cost to Manufacturing

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- Purchase the higher priced Mo-99 and absorb all of the cost.
- Purchase the higher priced Mo-99 and defer some of the costs downstream.
- Purchase the higher priced Mo-99 and pass along all of the costs downstream.
- Only purchase some higher priced Mo-99 and continue purchasing "regular" lower priced Mo-99

If manufacturers of Mo99/Tc99m generators pass along some or all of their costs, the nuclear pharmacies will then incur them when purchasing

Increased Cost to Nuclear Pharmacies

the generators for their use. Then the decision must be made:

- Does the nuclear pharmacy absorb this additional cost?
- Does the nuclear pharmacy defer some of this cost?
  - How?

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- Does the nuclear pharmacy defer all of the additional cost?
  - How?

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Nuclear Pharmacy Process

- At the current time, it is unlikely a nuclear pharmacy will only have Non-HEU Mo-99 generators available, due to the following: greater expense, limited supply, limited availability on certain days of the week, and limited demand from end users.
- Therefore, the process to compound the dose is complicated by logistics challenges that arise when a mix of HEU/Non-HEU Mo-99/Tc- 99m generators are inventoried by the pharmacy. That incurs increase costs.



## Non-HEU generator is eluted.

- This generator can be used for any patient, however the cost of this generator is more than the cost of a "normal" generator.
  - Pharmacy may incur extra cost.
- Non-HEU Tc-99m pertechnetate elution is processed and entered into inventory.
  - This elution can be used for any doses, but most likely at a higher cost.
    - Pharmacy incurs the higher cost if dispensed as a "normal" Tc-99m compounded dose.

- Tc-99m kit is compounded from elution and placed into inventory.
  - This kit can be used for any doses that are not Non-HEU, but probably at a higher cost.

Non-HEU Mo-99 generators

• Pharmacy incurs the cost.

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- Doses are drawn from the compounded kit
  - This dose is labeled with reference to Non-HEU Mo-99 wording for extra reimbursement i.e. Mo-99 is 95% or more from Non-HEU production.
  - Cost may be higher to end user and may exceed extra \$10 reimbursement addition.



- There is not a direct line of Cost of Goods (COG) as with the previous entities.
- Passing along the increased costs is much more difficult for the Nuclear Pharmacy.
- The Nuclear Pharmacy may still lose money based on demand of the unit doses compounded with Tc-99m derived from Non-HEU Mo-99.

Nuclear Medicine departments may then receive higher priced unit doses to compensate for the increase cost of the Non-HEU Mo-99 generated Tc-99m and the inherent inefficiencies of the elution by the nuclear pharmacy.

Increased costs to nuclear medicine

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- The Nuclear Medicine Department will possibly need to increase their charge to the patient/insurance and also submit for the extra \$10 as long as it is available.
  - IF administered to an individual who is a hospital outpatient covered by Medicare

The insurance will reimburse what they will.

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The patient will possibly need to pay out of pocket or the hospital will dismiss the extra and eat the costs.

Increased cost to insurance/patient



- It is also possible that the increase cost of Non-HEU may allow an entity to have their "foot in the door" to increase costs above and beyond what their cost increase is.
- That cost will then have the opportunity to roll downhill.



- Potential options of who is "holding the bag"
  - Reactor operators, generator manufacturers, nuclear pharmacies, nuclear medicine departments, patients, and/or insurance providers.
- Sourcing higher priced Non-HEU generators adds considerable costs to a nuclear pharmacy, especially if demand isn't available to efficiently use the elution and compounded kits.
- Currently we see little demand from end users for Non-HEU Mo-99 derived generators, due to possible increased net costs and no known clinical advantages.





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