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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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September 13, 2016

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Disclosures

- 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

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Learning Objectives

1. 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

- A nuclear physician or technologist will call the pharmacy and they will order a prescription for a Tc-99m compounded preparation for a patient scan.
  - 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
    - Cost for the dose may be more than the extra $10 reimbursement.

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What's In It For Me?

- 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

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Increase Costs of Production

- 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.

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Increased Cost to Manufacturing

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

Increased Cost to Nuclear Pharmacies

- If manufacturers of Mo99/Tc99m generators pass along some or all of their costs, the nuclear pharmacies will then incur them when purchasing 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?
  - Does the nuclear pharmacy defer all of the additional cost?
    - How?

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 Mo-99 generators

- 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.

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Non-HEU Mo-99 generators

- 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.
    - Pharmacy incurs the cost.
- 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.

Nuclear Pharmacy Risks

- 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.

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Increased costs to nuclear medicine

- 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.
  - 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

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Increased cost to insurance/patient

- The insurance will reimburse what they will.
- The patient will possibly need to pay out of pocket or the hospital will dismiss the extra and eat the costs.

Hidden Increase Costs

- 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.

So What?

- 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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Questions?

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