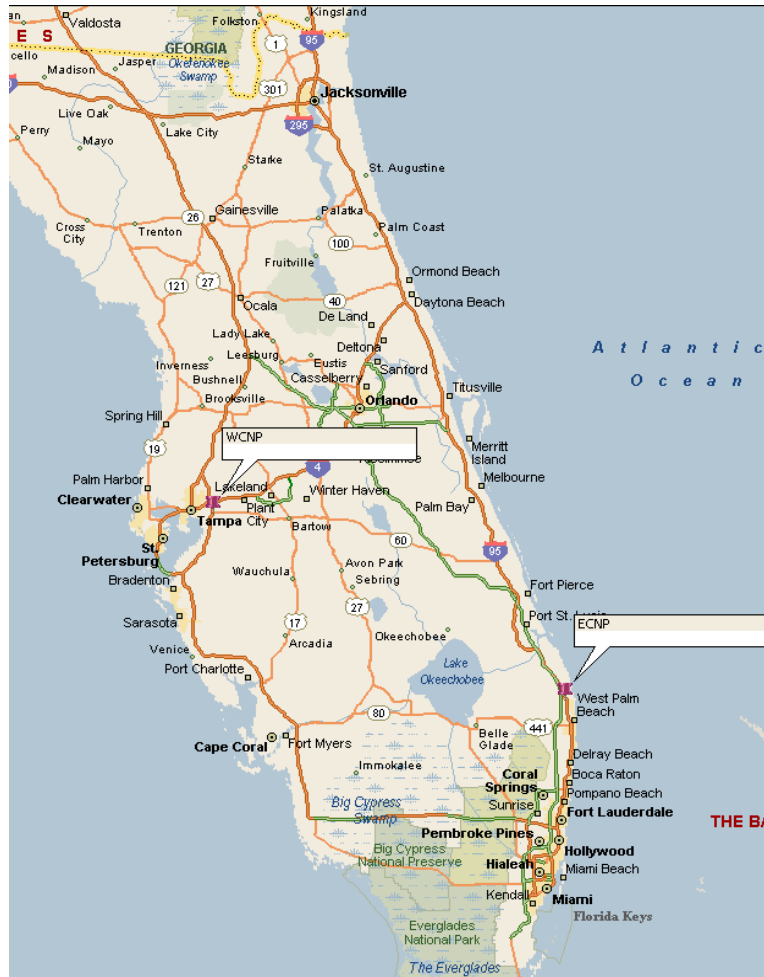




Challenges Marketing LEU (a year later)

Cal Gray Presenting
Radiopharmacies and the LEU Challenge

West Coast Nuclear Pharmacy (WCNP) East Coast Nuclear Pharmacy (ECNP)



2015 WCNP became the largest
operating radiopharmacy in Florida



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Facts Used in Marketing

On June 8, 2012, The White House announced initiatives aimed at expediting the U.S. private sector's efforts to eliminate the use of HEU Mo-99 and stimulate utilization of LEU sources by 2016

- *"The United States is committed to eliminating the use of HEU in all civilian applications, including in the production of medical radioisotopes, because of its direct significance for potential use in nuclear weapons, acts of nuclear terrorism, or other malevolent purposes"*

Source: The White House, Office of the Press Secretary, *FACT SHEET: Encouraging Reliable Supplies of Molybdenum-99 Produced without Highly Enriched Uranium*, June 7, 2012; Global Security Newswire; and CMS.



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Facts Used in Marketing

CMS released its 2013, 2014 & 2015 HOPPS Rules, which encourages through higher reimbursement the use of LEU sourced medical isotopes

- *CMS will pay medical providers an extra \$10 per unit dose for diagnostic radiopharmaceuticals that use LEU Tc-99m (a product of the decay of Mo-99) vs. Tc-99m “produced by non-HEU methods,”*

Source: The White House, Office of the Press Secretary, *FACT SHEET: Encouraging Reliable Supplies of Molybdenum-99 Produced without Highly Enriched Uranium*, June 7, 2012; Global Security Newswire; and CMS.



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Facts Used in Marketing

Additionally, the U.S. joined the western European nations in a pledge to eliminate the use of medical isotopes produced with HEU

- Goal by 2016

On January 3, 2014, VA Under Secretary release a memo for the preferred procurement of non HEU product.

- Sent to all Network Directors



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Customer Reaction Summary

Customers are reluctant to embrace.

Customers really do not believe the reimbursement.

Misinformation about LEU by non-adopters.

Seeds of Doubt

LEU requires special handling

CMS may not reimburse in 2014

CMS will demand repayment of any LEU premiums paid

LEU does not have a stable supply chain

LEU is Low Specific Activity

Too difficult to code (Qcode)

Lack of Traceability

Extensive Software Changes Required

2014

Survey Feedback

Customer Reaction Summary

No changes or improvements from the 2014 information.

New spin:

“Blended LEU” – not certified as derived from greater than 95% non-HEU Mo 99



Seeds of Doubt

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LEU is Low Specific Activity

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Extensive Software Changes Required

2015

2014 Survey Feedback

Response to Customers Reluctance

Arranged meeting with a reimbursement expert.

Created informational flyers about LEU.

Developed business case summary of benefits.

Keep Tc99m price competitive.

Show HEU/LEU Tc99m billing traceability.

2014

⇒ Built customer confidence as early adopter and made conversions.

⇒ Winning new client support through LEU customers testimonials.

⇒ LEU supply is constant and reliable and CMS reimbursement for the Qcode exists.

2015

West Coast and East Coast Nuclear Pharmacy Expectations for 2016

Marketing Effort

- HOPPS customers growing interest.
- Stand Alone Clinics continue to grow in number.
- VA Hospitals still not pursuing strongly.

Education

- Make conversion today.
- Reimbursement is not laborious.

Actions

- Deploy to more clients as the pipeline becomes more robust.
- Vigorously handle false objections and seeds of doubt

VA Specifics

▶ VISN 8

- largest VISN in the network.
- All VA's from Gainesville Fl. south have released RFP's and or in the process of releasing RFP.
- VA #1; awarded
 - Posted LEU in the RFP but makes it optional; we bided, we won the LEU products but site does not have to use.
- VA #2 (RFP is in process after multiple protests)
- VA #3; RFP is a WIP, LEU language is light.
- VA #4&5; RFP's, we a awaiting

Example of VA LEU push back, VA #2

Sect. 4.2 – “Contractor shall be able to supply 50% of the technetium radiopharmaceuticals with LEU”.

(ECNP): PLEASE CLARIFY WHETHER VA IS ASKING THE CONTRACTOR TO SUPPLY ONLY 50% OF THE TOTAL TECHNETIUM RADIOPHARMACEUTICALS DELIVERED TO VA WITH LEU -- OR WHETHER THE 50% REFERS TO THE LEU ITSELF – MEANING THAT ALL OF THE TECHNETIUM RADIOPHARMACEUTICALS DELIVERED TO VA MUST BE COMPRISED OF AT LEAST 50% LEU?

IF THE ANSWER IS THE FORMER, PLEASE CLARIFY HOW THE 50% WILL BE DETERMINED – FOR EXAMPLE ON A WEEKLY BASIS?

IF THE ANSWER IS THE LATTER, PLEASE CLARIFY WHY VA IS REQUESTING TECHNETIUM RADIOPHARMACEUTICALS WITH ONLY 50% LEU RATHER THAN TECHNETIUM RADIOPHARMACEUTICALS WITH 95% LEU --WHICH THE CENTERS FOR MEDICARE & MEDICAID SERVICES USES IN ITS SPECIFICATION AND IS THE INDUSTRY STANDARD.

PLEASE EXPLAIN WHY VA IS NOT REQUIRING THE CONTRACTORS TO PROVIDE ANY WRITTEN DOCUMENTATION TO PROVE THE PERCENTAGE OF LEU IN ITS TECHNETIUM RADIOPHARMACEUTICALS DELIVERED TO VA IF THE REQUIREMENT IS FOR TECHNETIUM RADIOPHARMACEUTICALS WITH 95% LEU.

(VA): We are referring to total number of Technetium radiopharmaceuticals doses will be at least 50% LEU. The reason for this is that we are aware that procuring LEU generators is difficult and at times impossible depending on the few suppliers in the world. In order to expand competition and ensure that the selected vendor does not run into contract compliance issues when LEU is not available we decided to give leeway for the LEU requirement. Once the supply of LEU becomes more readily available to all radio pharmacies the intent is to eventually convert to 100% LEU Technetium products. (We are not referring to 95% purity of a single dose; that would be non-compliant with industry standards.)



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Ex. of LEU RFP language, VA #3

(Currently an active bid)

▶ VA248-15-R-1322, pg. 43

“Offerors must provide evidence that they have the ability to produce and provide non-HEU (High Enriched Uranium-Derived medical isotopes, as well as HEU (High Enriched Uranium-Derived medical isotopes and provide confirmation that they can supply/provide ALL required line items specified in the price schedules in section D. “

CLIN	PRICE SCHEDULE – BASE YEAR ITEM DESCRIPTION	QTY	UNIT	UNIT PRICE FOR LEU	UNIT PRICE FOR HEU	TOTAL ESTIMATED PRICE FOR LEU	TOTAL ESTIMATED PRICE FOR HEU
0001	Tc-99m Sodium Pertechnetate Kit preparation and misc. 30 mCi DELIVERY: As Needed	2000	EA			\$ -	\$ -
0002	Tc-99m (Medronate), MDP, 25 mCi DELIVERY: As Needed	3000	EA			\$ -	\$ -
0003	Tc-99m Cardiac Agent (Cardiolite or Myoview) DELIVERY: As Needed Monday through Saturday	13,500	EA			\$ -	\$ -

Conclusion: This bid could award a supplier for LEU but the site using the LEU is uncertain. Therefore, why take the cost risk?

RFP for VA #3

► Questions submitted to CO & answer (8/25/15)

(ECNP): VA did not specify the minimum purity of LEU that the bidder must maintain to bid LEU. Today's standard for technetium radiopharmaceuticals with 95% LEU --which the Centers for Medicare & Medicaid Services (CMS) uses for its compliance specification. And this grade of LEU is commercially available on daily basis.

a. Will VA clarify whether the LEU standard for the RFP is 95% purity or better?

(VA response); “We want prices for both HEU and LEU”

Conclusion;

Without the VA mandating LEU use, with a product specification the VA Network will continue to undermine the primary goal of LEU conversion.

Ex. of LEU RFP Language, VA #1

- ▶ VA #1 was a “Line Item” award – Three pharmacies
- ▶ Oct. 15, 2015 LEU was awarded to WCNP
 - Below is ex. of award sheet prior to Oct. 15, 2015 (HEU)

DESCRIPTION, Radiopharmaceuticals Base Year Ordering Period (October 15, 2014 through October 14, 2015)	Annual Best Estimated Quantities	UNIT	UNIT COST	TOTAL COST
Tc-99m Sodium Pertechnetate Kit preparation and misc. 30 mCi DELIVERY: As Needed	Reserved	EA.	Reserved	Reserved
Tc-99m (Medronate), MDP, 25 mCi DELIVERY: As Needed	Reserved	EA.	Reserved	Reserved
Tc-99m Cardiac Agent (Cardiolite or Myoview) DELIVERY: Monday through Saturday	Reserved	EA.	Reserved	Reserved
Tc-99m Mertiatide Mag-3, 10 mCi dose DELIVERY: As Needed	Reserved	EA.	Reserved	Reserved

- Below LEU added and awarded to WCNP, Oct. 2015 – 2018

DESCRIPTION, Radiopharmaceuticals Ordering Period 1 (October 15, 2015 through October 14, 2016)	Annual Best Estimated Quantities		UNIT	UNIT COST	TOTAL COST
Non-HEU Tc-99m (Medronate), MDP, 25 mCi DELIVERY: As Needed		700	EA	WCNP	WCNP
Non-HEU Tc-99m Cardiac Agent (Sestimibi) DELIVERY: Monday through Saturday		6,690	EA	WCNP	WCNP
Non-HEU Tc-99m Mertiatide Mag-3, 10 mCi dose DELIVERY: As Needed		75	EA	WCNP	WCNP
Non-HEU Tc-99m Ceretec WBC Labeling 15-25 mCi DELIVERY: As Needed		12	EA	WCNP	WCNP



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Complication; VA #1

(Email string from WCNP with VA #1(nuclear medicine department))

From: Perry Polsinelli [<mailto:Perry@westcoastnuclear.com>]
Sent: Wednesday, August 12, 2015 4:15 PM
Subject: [EXTERNAL] Products Oct. 15, 2015

VA#1,

I have the reference sheet finished for you that will be effective October 15, 2015 per the WCNP contract award. What I would like to do is see if you have some time next week and I will come down explain the document and make sure we are all on the same page. In addition, this sheet will include new timelines for stat orders based on the new limitations from our suppliers. There are no surprises here I want to make sure everyone is on the same page. Let me know.

Next week I am free except Monday, wide open Tuesday afternoon thru Friday.

Perry

Perry, I spoke with contracting and they are not aware of any mandate to use LEU and that everything was going to remain the same unless told otherwise.

I don't want you to waste your time coming over here unless there are going to be changes.

You can contact Matt Lucas in contracting if you have any further questions.

Please keep in touch with any further updates.

Thanks.

VA Healthcare System

USING LEU IS OPTIONAL !!!!!



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What the Stakeholders Needs to Consider?

Communication

- Provide literature helps to the radiopharmacy segment.
- Recognition of radiopharmacies with LEU.

Supply

- Favorable manufacturing days (multiple).
- Mandate at the VAMC to convert to LEU to finish the task.

Successes

- Address issues to allow a domestic supply to come to market.
- End mixed messages.



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2015 Mo 99 Topical Meeting

Thank You



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