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Bureau of Radiation Protection

I-131 MIBG Medical Event

Niki Noll

Pennsylvania Department of Environmental Protection
Southeast Regional Office

Tom Wolf, Governor

Patrick McDonnell, Secretary

Outline

- What is MIBG?
- What happened?
- Cause of the event
- Corrective actions
- Things to consider

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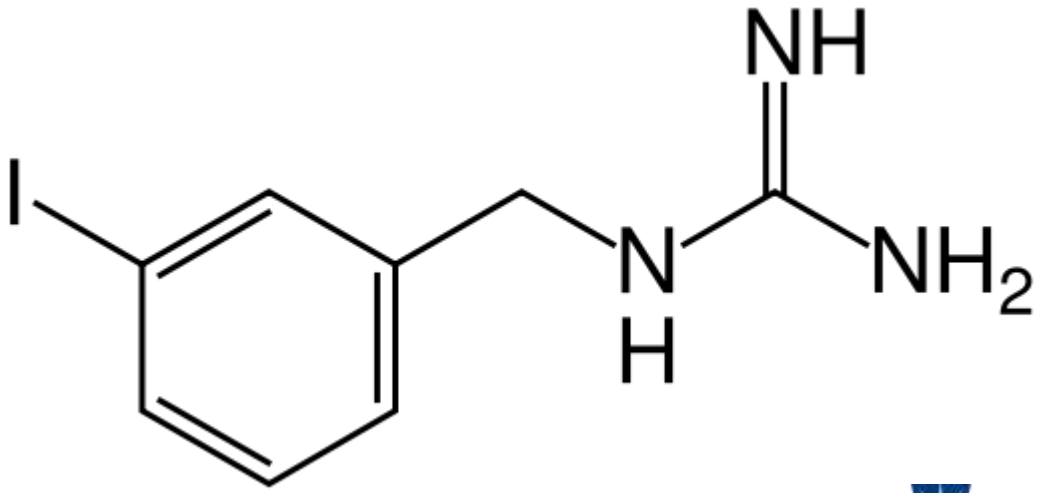
What is MIBG Therapy?

- I-131 Metaiodobenzylguanidine
- IV therapy
- Used for relapsed or refractory neuroblastoma



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Administration

Standard Treatment:

- 18 mCi/kg I-131 MIBG
- 30 ml of MIBG is infused over 90 minutes
- Pump is stopped at 45 minutes and reset
- Infusion is followed by 30 ml saline flush for 20 minutes

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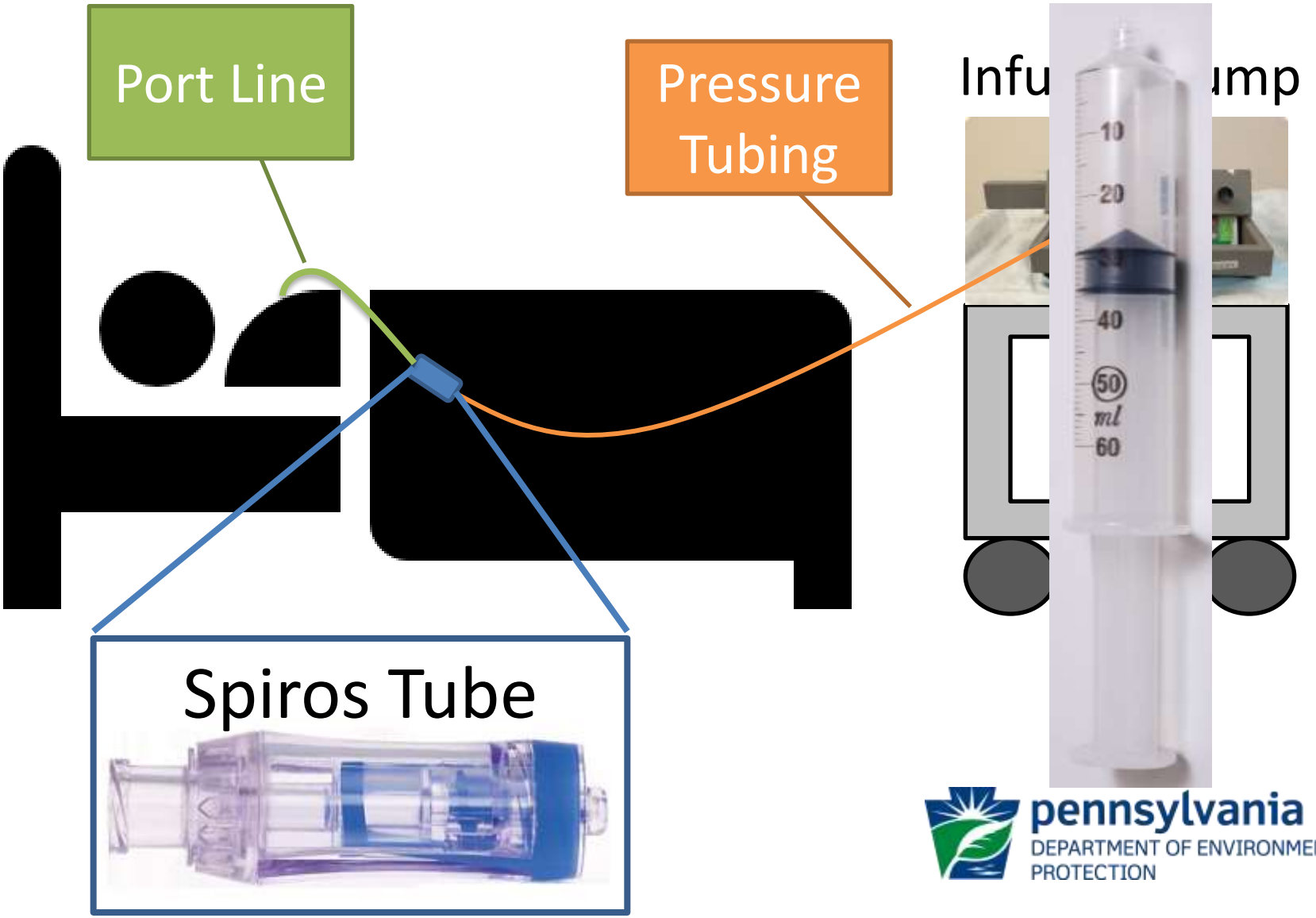
Infusion Setup



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Be Careful What You Wish For

Goodman, Jenny <Jenny.Goodman@dep.nj.gov> | Derstine, Terry; + 1 | 5/24/2018

RE: OAS Meeting

You replied to this message on 5/24/2018 3:31 PM.

From: Derstine, Terry [mailto:tderstine@pa.gov]
Sent: Thursday, May 24, 2018 2:02 PM
To: Goodman, Jenny <Jenny.Goodman@dep.nj.gov>
Cc: Noll, Jennifer <jenoll@pa.gov>
Subject: RE: OAS Meeting

Hi Jenny:

Niki and I have been racking our brains out trying to think of anything interesting on which we've been working that would make a good OAS presentation. We've not come up with anything fun and/or sexy enough to present. Sorry! But I should also add that I hope nothing comes up real soon.

Have a great Memorial Day weekend!

Thanks,

Terry W. Derstine | Radiation Protection Program Manager
Department of Environmental Protection | Southeast

Initial Report

May 25th, 2018 (Friday)

- The Department was notified at 4:15 pm that a medical event had occurred.
- Children's Hospital of Philadelphia (CHOP)
- 17 year old male with neuroblastoma
- Prescribed 817 mCi; administered 834 mCi I-131 MIBG
- 7th and final treatment
- ~50% administered

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Reactive Inspection

June 7 and 13, 2018

- Investigated both the under-dose and skin contamination

- Interviewed referring physician, Radiation Safety staff, Nuclear Medicine team leader, nuclear medicine technologist, nurse who cared for the patient immediately post-infusion, lead nurse for I-131-MIBG therapies

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Timeline of Event

Friday May 25th, 2018

- **12:30** – MIBG infusion was started
- **13:00**
  - Patient expressed the need to urinate
  - Nuclear Medicine consulted with Radiation Safety and agreed that the toilet was the best option
- **13:15**
  - First half of infusion was completed
  - Patient was disconnected at Spiros tube to use the toilet
  - Patient was reconnected, pump was reset and infusion was resumed

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Timeline

- **14:00** - Infusion completed and began saline flush
- **14:30**
  - After the flush, nuclear medicine technologist noted blood in the port line and a pinkish fluid on the bed sheets.
  - Nuclear medicine technologist stripped bedding and asked patient if he felt wetness anywhere. Patient indicated his pants were wet at the hip; pants were not removed at this time.

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Timeline

- **14:45 – 16:00**
  - Health physics tech arrived and nuclear medicine tech left area
  - Readings of the patient were taken
    - 48 mR/hour at 1 meter
    - Expected 75 mR/hour

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Timeline

- **16:00**
  - Patient's pants were removed and all waste and contaminated items were removed from the room
  - Another reading of patient was taken
    - 38 mR/hour at 1 meter
  - 50% of the dose was received by patient
- **16:15**
  - Notification of medical event
  - Friday after normal business hours before Memorial day weekend
  - Notification went through Department stand-by duty officer

Timeline

Friday after notification:

- Readings of waste, contaminated linens, and clothing indicated 210 mCi (26%) I-131 in waste
- Determined 74% of prescribed dose was administered
- Contamination surveys:
  - Inside room
  - Hallway

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What about patient decontamination?

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Decontamination?

- The patient was given standard hygiene care over the weekend
  - Chlorohexidine wipes
- **The patient was never purposefully decontaminated**

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Timeline

May 27, 2018 (Sunday)

- Patient reported reddening and discomfort on right hip
- Patient showered twice, but they were unable to remove the contamination
- Readings were taken using a Ludlum 44-9 probe to determine activity
  - 6.5mCi over 2x3cm area
- Estimated skin dose: 500-1,200Gy

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Timeline

Following week:

- Calculations were verified by REAC/TS and Michael Stabin, Ph.D. CHP
- Four days later patient developed moist desquamation, diagnosed with Grade 3 radiation burn
- Patient was referred to Plastics and was monitored by Authorized User

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Effect on Patient

- Final report to the Department indicated an estimated skin dose of at least 550 Gy
- The patient developed moist desquamation, but no further ulceration. This is consistent with a Grade 3 radiation burn.
- Patient fully recovered from his injury

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Causes

- Leak in the system
  - After extensive testing and inspection, no defects in the Spiros tube or line were found
- Policies and procedures are lacking coordination between departments
- Lack of patient decontamination procedures

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Corrective Actions

- Absorbent chux under line
- Patient will wear a fluid impermeable gown and gloves
- Infusion is not to be stopped unless medically necessary
- Continuous monitoring of patient during infusion
- Development of fluid management procedure
- Review of infusion system and additional training on the use of the Spiros tube

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Corrective Actions

- Two nuclear medicine techs inspect the setup
  - Prior to infusion, during reset, and after flush.
- Nuclear medicine tech checks on patient every 15 minutes
- Proactively looking for contamination on linens, gowns, chux, cart wheels, and floor
- A multidisciplinary MIBG committee has been established to review and update policies

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Corrective Actions

- Patient specific decontamination procedures for each case will be developed
- Looking into beta measurement devices to have better ability to detect skin contamination
  - Patients are reading ~1R/hour at 1cm
- Development of a “time-out” procedure when an event occurs
- Conducting drills on responding to a patient contamination incident

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Things to Consider

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Similar Incidents

- Stage 4A thyroid carcinoma patient undergoing liquid I-131 therapy was contaminated after feeding tube leaked during administration
- I-131 MIBG pediatric patient had minor skin injury to inner thighs and buttocks after urinary catheter leaks
- Y-90 TheraSphere® treatment – catheter leaked causing contamination to the thigh and groin of the patient

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Similar Incidents

- Sm-153 – IV tubing damaged and leaked
- Tc-99m – leakage at connection
- I-124 – leakage at connection
- Sm-153 – leakage at connection
- I-131 – IV leaked
- F-18 – IV infiltrated
- And these are just a few…

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Final Thoughts

- Increase in liquid therapeutic modalities
  - MIBG
  - IOMAB
  - Lutathera
  - And many more…
- How do we detect and manage contamination in these treatments?
- Is there a complacency in the industry for unsealed medical isotopes?
- Are we aiding in this complacency?

Niki Noll
(484) 250-5846
jenoll@pa.gov

Elaine Crescenzi
(484) 250-5835
ecrescenzi@pa.gov

Katie Scott
(484) 250-5833
katscott@pa.gov

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