

Current Questions about Radiopharmaceutical Extravasations and Dosimetry

Making radiopharmaceutical administrations
safer for patients

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Question #1: Why did Lucerno petition the NRC on this issue?

- 1980 NRC reporting exemption is based on an incorrect assumption

Dr. Nag: “However, the first thing before us is, should NRC consider it as a medical event. Now if we consider this as a medical event, if we go through all the procedures and identify whatever- 3 or 4 or 5 - the patient will have to be informed; the physician have to be informed, blah blah blah [sic], and then - you have to go into all the reporting mechanisms. And therefore, I am thoroughly against this being reported as a medical event.”

Chairman Malmud: “Would you make a motion that this is not reported as a medical event at the current time?”

Dr. Nag: “Yes.”

Chairman Malmud: Second to your motion? Dr. Welch seconds the motion.”

Official Transcripts of Proceedings, Nuclear Regulatory Commission, Advisory Committee on the Medical Uses of Isotopes: OPEN SESSION, May 8, 2009

Question #1:

Why did Lucerno petition the NRC on this issue?

- Centers can take many actions to prevent extravasations
- Lucerno products can help, but are not required

Question #2:

If centers use best access practices, rarely extravasate, and there's no patient harm...what's the issue?

Medical event reporting criteria is agnostic to practices, frequency, and harm...but...

- Vascular access experts suggest nuclear medicine centers are NOT routinely using best practices to gain venous access
- Extravasations routinely happen; 1 in 5 are likely over the reporting threshold
- Patients are harmed but effects are NOT immediate
 - Adverse events *
 - Literature review *
 - Case reports *
 - Examples *

* <https://www.frontiersin.org/articles/10.3389/fmed.2021.684157/full>

* Examples provided by Vascular Wellness



Yttrium 90



Technetium 99m

Despite latent effects of ionizing radiation to tissue, significantly extravasated patients are not routinely followed. In 2021, severely extravasated patients have no dosimetry performed, are not followed, and are not told of the event.

Question #3:
**Won't addressing extravasations be a huge burden
on clinicians and regulators?**

- Licensee burden (clinical and reporting)
 - Centers already invest heavily in quality control/assurance
 - Medical and radiation protection guidelines already suggest monitoring, post extravasation characterization, and clinical follow-up
 - Petition grace period
- Regulator burden
 - Can be mitigated through the rulemaking process

Question #4:

Isn't extravasation dosimetry very complex, costly, and time consuming? Can extravasations even exceed 0.5 Sv?

- Historical dosimetry methods are either:
 - conservative and result in worst-case results, or
 - accurate, but impractical
- Recent Health Physics Journal Publication*
 - Flexible calculation of patient-specific biological clearance
 - At most one quantitative activity measurement
 - Uses pre-calculated dose data
- Free software is available
- Dosimetry can be done in minutes

* Osborne, D., J. W. Kiser, J. Knowland, D. Townsend and D. R. Fisher (2021). "Patient-specific Extravasation Dosimetry Using Uptake Probe Measurements." [Health Phys.](#)

Question #4:

Example Spreadsheet-based Workflow

AutoSave On Dosimetry Spreadsheet.xlsx Search Josh Knowland JK

File Home Insert Page Layout Formulas Data Review View Developer Help

AA22

A B C D E F G H I J K L M N O P Q R S T U V W X Y

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Basic Information

Selected Isotope Fluorine-18

Injected Radioactivity 10.22 mCi

Residual Activity Measurement 1.37 mCi

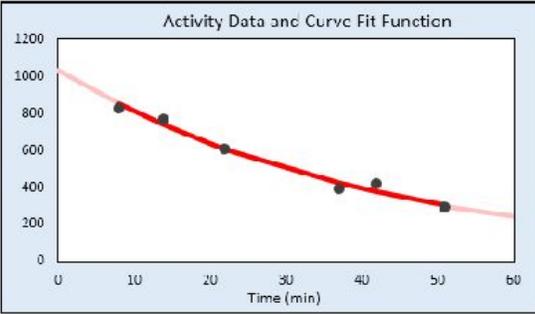
Time between injection and measurement 64 minutes

Time-Activity Data

Is the entered data already decay corrected?
 Yes No

| Time (min) | Measurement |
|------------|-------------|
| 8 | 825 |
| 14 | 765 |
| 22 | 604 |
| 37 | 393 |
| 42 | 417 |
| 51 | 291 |

Time-Activity Curve Fitting



Activity Data and Curve Fit Function

The graph shows activity (y-axis, 0 to 1200) versus time (x-axis, 0 to 60 minutes). Data points are plotted as black dots, and a red curve represents the fit function. The activity decreases over time, following an exponential decay pattern.

Absorbed Dose

| Source Volume (cm ³) | Tissue Dose (Gy) | Skin Dose (Gy) |
|-------------------------------------|---------------------|-------------------|
| 1 | 34.6 | 6.7 |
| 5 | 7.3 | 2.7 |
| 10 | 4.1 | 1.8 |
| 15 | 2.8 | 1.4 |
| 20 | 2.2 | 1.2 |

Dosimetry Worksheet Printable Report Calculations Sheet1

Ready 100%

Question #4: Example Spreadsheet-based Workflow

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Summary

- Core issue is simple
 - 1980 exemption policy is wrong and leads to irrational reporting inconsistencies
 - Laura Weil, AMCUI patient advocate and member of the Extravasation Subcommittee dissented with the ACMUI report on extravasations:

“Only rare gross discrepancies in delivered dose or tissue exposure would be reportable, and this member believes that those rare instances should be reported just as any other misadministration of such magnitude would be reported as MEs. The fact that they may result in no patient harm should have no bearing on the requirement to report. This would be consistent with the fact that all other ME’s that cause no patient harm are currently required to be reported.”

Summary

- Historically, licensees have not voluntarily addressed extravasations
- Extravasations are clearly within the NRC's responsibility
 - NRC Medical Use Policy Statement supports reporting extravasations
 - In 65 FR 47654, August 3, 2000, NRC answered the following question: Does the Commission have any useful role in assuring the accurate delivery of byproduct material to patients?

“The Commission has a role in assuring accurate delivery of radiation doses and dosages to patients and has rejected the notion that NRC should not regulate patient radiation safety (44 FR:8243, February 9, 1979). NRC will continue to regulate the radiation safety of patients when justified by the risk to patients, primarily to ensure that the authorized uses physician's directions are followed. The Commission recognizes that physicians have the primary responsibility for the protection of their patients. However, the NRC's role is also necessary to ensure radiation safety of patients.”

Thank you and Questions