



February 16, 2023

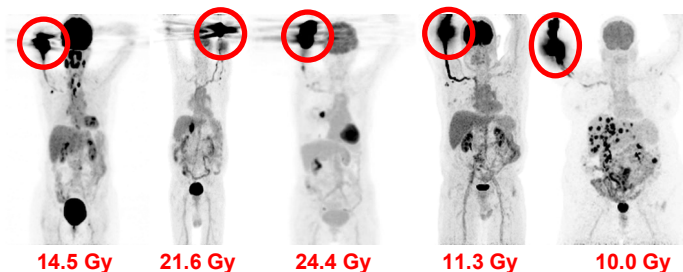
Christopher Hanson, Chairman
Jeff Baran, Commissioner
David Wright, Commissioner
Annie Caputo, Commissioner
Bradley Crowell, Commissioner
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Chairman Hanson and Commissioners,

We believe the U.S. Nuclear Regulatory Commission (NRC) is not meeting its statutory requirements to Congress and is violating its own policies. When provided an opportunity to correct these matters and protect patients, the NRC medical staff produced Commissioner Paper SECY-22-0043¹ for the Commissioners. SECY-22-0043 does not meet NRC Information Quality Guidelines.

The NRC is required by law² to report Abnormal Occurrences (AOs) to Congress and make certain information about AOs publicly available. Extravasations that result in tissue doses >10.0 Gy or that have significant safety implications or that represent recurring incidents with implications for similar facilities that raise a major safety concern meet AO reporting criteria³. It is also NRC policy to establish procedures⁴ to ensure that an abnormal occurrence (AO) is identified and reported to Congress in compliance with Section 208 of the Energy Reorganization Act of 1974 and the Federal Reports Elimination and Sunset Act of 1995. NRC's procedures do not result in AO reporting of extravasations to Congress.

Since 2008, NRC has been aware that extravasations should be reported as medical events. Since 2018, NRC has learned through publications^{5,6} and received case reports that extravasations can exceed Abnormal Occurrence reporting criteria.



Dosimetry for these extravasated patients, all potential Abnormal Occurrences, is included below.

Lucerno petitioned NRC to ensure a transparent evaluation of extravasation medical event reporting. In response, NRC staff developed SECY-22-0043 but it was withheld from the public until January 2023, after the Commission finalized its PRM-35-22 decision. As evidenced in your Commissioners' Notation Vote comments, SECY-22-0043 influenced each of your responses to the petition. Based on the information you were provided, the Commission adopted the recommendation of SECY-22-0043 rather than use the existing medical event criterion to report extravasations and to identify and report Abnormal Occurrences.



During a thorough review of SECY-22-0043, we found serious information quality deficiencies. Additionally, SECY-22-0043 appears to justify past medical staff actions and continues to keep extravasations that meet medical event reporting criteria from being reported to patients, their doctors, NRC, and Congress. As a result, Lucerno submitted an Information Correction Request (accompanying this letter) identifying the many deficiencies of SECY-22-0043. Given the number of patients affected by large extravasations, some of which are egregious enough to meet AO reporting criteria (examples on previous page with further documentation below), we suggest that the Commission immediately issue Interim Staff Guidance to ensure radiation protection of patients. Guidance could include:

- initiating rulemaking to ensure extravasations are reported using the existing dose-based threshold,
- standardizing an extravasation dosimetry model for tissue using the latest published method, and
- requiring licensees begin immediate efforts to monitor for and reduce extravasations.

We believe that with the information provided in the Information Correction Request, the Commission will establish procedures to ensure that AOs are identified and reported to Congress.

If you need any clarification, please contact me directly.

Sincerely,

Ronald K. Lattanze
Chief Executive Officer
Lucerno Dynamics, LLC

Cc:

- Chair Cathy McMorris Rodgers (R-WA), House Energy & Commerce Committee
- Ranking Member Frank Pallone (D-NJ), House Committee on Energy & Commerce
- Chairman Tom Carper (D-DE), Senate Committee on Environment & Public Works
- Ranking Member Shelley Moore Capito (R-WV), Senate Committee on Environment & Public Works
- Chairman Jeff Duncan (R-SC), House Energy & Commerce Subcommittee on Energy, Climate & Grid Security
- Ranking Member Diana DeGette (D-CO), House Energy & Commerce Subcommittee on Energy, Climate & Grid Security
- Chairman Ed Markey (D-MA), Senate Environment & Public Works Subcommittee on Clean Air, Climate, and Nuclear Safety
- Ranking Member Pete Ricketts (R-NE), Senate Environment & Public Works Subcommittee on Clean Air, Climate, and Nuclear Safety
- Chairman Morgan Griffith, House Energy & Commerce Subcommittee on Oversight & Investigations
- Ranking Member Kathy Castor (D-FL), House Energy & Commerce Subcommittee on Oversight & Investigations
- Chairman Chuck Fleischmann (R-TN), House Appropriations Subcommittee on Energy & Water Development
- Ranking Member Marcy Kaptur (D-OH), House Appropriations Subcommittee on Energy & Water Development



- Chair Dianne Feinstein (D-CA), Senate Appropriations Subcommittee on Energy & Water Development
- Ranking Member John Kennedy (R-LA), Senate Appropriations Subcommittee on Energy & Water Development
- White House Office of Management & Budget
- White House Office of Science & Technology Policy
- Patients for Safer Nuclear Medicine
- Organization of Agreement States Executive Board
- NRC General Counsel

Endnotes:

¹ Commission Paper, SECY-22-0043. May 9, 2022. <https://www.nrc.gov/docs/ML2126/ML21268A006.pdf>

² Energy Reorganization Act of 1974, as Amended (Public Law 93-438), pages 252-253.

<https://www.nrc.gov/docs/ML1327/ML13274A489.pdf#page=275>

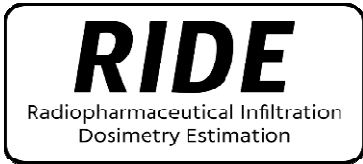
³ Abnormal Occurrence Reports Policy Revision, 82 FR 45907 pages 45907-45912, October 2, 2017.

<https://www.federalregister.gov/documents/2017/10/02/2017-21043/abnormal-occurrence-reports>

⁴ Abnormal Occurrence Reporting Procedure, U.S. Nuclear Regulatory Commission Management Directive 8.1, May 24, 2018. <https://www.nrc.gov/docs/ML1812/ML18127B179.pdf>

⁵ Osborne D, Kiser JW, Knowland J, Townsend D, Fisher DR. Patient-specific extravasation dosimetry using uptake probe measurements. Health Phys 120: 339-343; 2021.

⁶ Tsorxe IY, Hayes RB. Dose estimation for extravasation of ¹⁷⁷Lu, ^{99m}Tc, and ¹⁸F. Health Phys 124: 217-220; 2023.



Record Number	Scan 20954
Analysis Performed By	JK
Analysis Date	2/12/2023



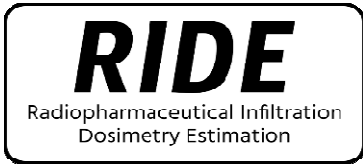
Isotope	F-18
Injected Activity	14.2 mCi
Measured Activity	3.872 mCi
Measurement Time Post-Injection	65 min

Injection Site Tissue Absorbed Dose Scenarios

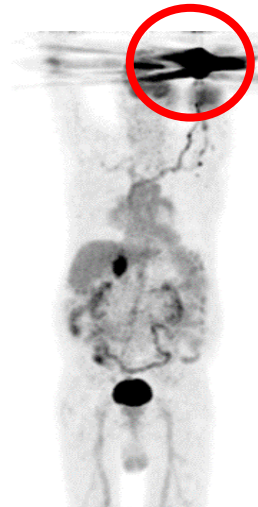
Scenario	Initial Activity (mCi)	Effective Half-life (min)	Absorbed Dose to 5g of Tissue (Gy)
Physical Decay	5.84	109.8	18.91
Count-Rate	14.20	34.7	14.53
Complete	14.20	34.7	14.53

Notes:

The IV was placed by a Registered Nurse while using ultrasound guidance. The nurse reported that the venous access was difficult, but that good blood return was obtained. The patient complained of a burning sensation during the radiopharmaceutical injection.



Record Number	Scan 21842
Analysis Performed By	JK
Analysis Date	2/12/2023



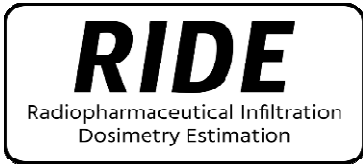
Isotope	F-18
Injected Activity	13.01 mCi
Measured Activity	6.218 mCi
Measurement Time Post-Injection	60 min

Injection Site Tissue Absorbed Dose Scenarios

Scenario	Initial Activity (mCi)	Effective Half-life (min)	Absorbed Dose to 5g of Tissue (Gy)
Physical Decay	9.08	109.8	29.43
Count-Rate	13.01	56.3	21.63
Complete	13.01	56.3	21.63

Notes:

The technologist stated that the "patients iv blew at the end of the injection."
 The patient was scheduled to be re-scanned.



Record Number	Scan 24105
Analysis Performed By	JK
Analysis Date	2/12/2023



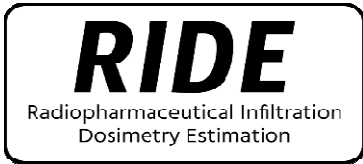
Isotope	F-18
Injected Activity	12.26 mCi
Measured Activity	6.29 mCi
Measurement Time Post-Injection	65 min

Injection Site Tissue Absorbed Dose Scenarios

Scenario	Initial Activity (mCi)	Effective Half-life (min)	Absorbed Dose to 5g of Tissue (Gy)
Physical Decay	9.48	109.8	30.72
Count-Rate	12.26	67.5	24.43
Complete	12.26	67.5	24.43

Notes:

The IV was placed by the nursing manager with ultrasound guidance who indicated that the IV flushed well, but that it seemed to have extravasated.



Record Number Scan 26948
Analysis Performed By JK
Analysis Date 2/12/2023



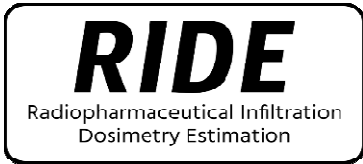
Isotope F-18
Injected Activity 11.77 mCi
Measured Activity 2.93 mCi
Measurement Time Post-Injection 65 min

Injection Site Tissue Absorbed Dose Scenarios

Scenario	Initial Activity (mCi)	Effective Half-life (min)	Absorbed Dose to 5g of Tissue (Gy)
Physical Decay	4.42	109.8	14.31
Count-Rate	11.77	32.4	11.26
Complete	11.77	32.4	11.26

Notes:

The nuclear medicine physician deemed this scan to be non-diagnostic and the patient was rescanned three days later.



Record Number	Scan 27124
Analysis Performed By	JK
Analysis Date	2/12/2023



Isotope	F-18
Injected Activity	10.41 mCi
Measured Activity	2.746 mCi
Measurement Time Post-Injection	65 min

Injection Site Tissue Absorbed Dose Scenarios

Scenario	Initial Activity (mCi)	Effective Half-life (min)	Absorbed Dose to 5g of Tissue (Gy)
Physical Decay	4.14	109.8	13.41
Count-Rate	7.98	42.2	9.95
Complete	10.41	33.8	10.39

Notes:

This scan was for staging of lymphoma. No further notes were recorded.