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Patient Intervention Subcommittee Report

Michael Sheetz

Advisory Committee on the Medical Uses of Isotopes

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Subcommittee Members

- Gary Bloom
- Vasken Dilsizian, MD
- Ronald Ennis, MD
- Michael Sheetz (Chair)

- NRC Staff Resource: Said Daibes Figueroa, PhD

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Subcommittee Charge

- Evaluate the definition of “patient intervention” and other actions and circumstances that are exclusive of Medical Events
- Determine what types of events are intended to be captured by the term “patient intervention” and what should or should not be reported as a Medical Event

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History of Misadministration (Medical Event) Reporting Requirement

- First proposed by AEC in 1973
- NRC establishes reporting criteria in 1980
  - Wrong radionuclide
  - Wrong patient
  - Wrong route of administration
  - Diagnostic dose differing by > 50%
  - Therapeutic dose differing by >10%

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Purpose of Misadministration (Medical Event) Reporting

- Allow NRC to investigate the incident to:
  - Evaluate the corrective action taken by the licensee to minimize the chance for recurrence
  - Take generic corrective action to inform other licensees if they could make the same errors

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Exclusion to Misadministration Reporting Requirement (1980)

- Extravasation - the infiltration of injected fluid into the tissue surrounding a vein or artery
- Reason: Extravasation frequently occurs in otherwise normal intravenous or intra-arterial injections and is virtually impossible to avoid

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Revised NRC Medical Use Policy Statement (2000)

- Continue to regulate the medical use of radionuclides as necessary to provide for radiation safety of workers and general public
- Not intrude into the medical judgements affecting patients, except as necessary to provide for radiation safety of workers and general public
- When justified by risk to patients, regulate radiation safety of patients primarily to assure use of radionuclides is in accordance with the physician's direction
- In developing a specific regulatory approach, consider industry and professional standards that define acceptable approaches of achieving radiation safety

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Revised Misadministration Reporting Requirement (2002)

- Term "Misadministration" changed to "Medical Event"
- ME criteria included a dose threshold
- Purpose of reporting Medical Event
  - To evaluate if there was a breakdown in the licensee's program
  - Take corrective action If there was a generic issue that should be reported to other licensees

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Exclusions to Medical Event Reporting Requirement (2002)

- Brachytherapy sources implanted in the correct site but migrated outside the treatment site
- Patient Intervention - actions by the patient, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration
- Events involving patient intervention that result in permanent functional damage must be reported

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Previous ACMUI Recommendations Regarding Patient Intervention

- 2017 Patient Intervention Subcommittee:
  - Introduced the concept of "passive" rather than "active" patient intervention related to unintentional treatment outcomes with Y-90 microsphere therapy
- 2019 Extravasation Subcommittee:
  - Recommendation extravasation be considered a type of "passive" patient intervention, so that extravasation causing permanent functional damage be reportable as a Medical Event

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What Should or Should Not be Considered a Medical Event

- Physical action taken by patient
- Physiological changes in patient's medical condition
- Condition for licensee inability to control patient intervention event
- What benefit to reporting patient intervention events

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Specific Exemptions to Medical Event Reporting in 10 CFR 35.1000

- RSL Licensing Guidance, Revision 1
  - Patient fails to return for explant surgery
  - Determination not to explant seed due to various patient conditions
- Y-90 Microsphere Licensing Guidance, Revision 10
  - Emergent patient conditions (artery spasm or sudden change in blood pressure)
  - Stasis or dose to wrong treatment site due to shunting

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Examples of Medical Events Not Due to Patient Intervention

- NRC IN 2006-11 "Applicability of Patient Intervention in Determining Medical Events for Gamma Stereotactic Radiosurgery.."
  - Concluded licensee did not provide sufficient evidence to exclude equipment set-up error as cause of Medical Event, rather than patient intervention
- Y-90 Microsphere Licensing Guidance, Revision 10
  - Incomplete administration due to clogging or kinking of catheter not considered stasis, and therefore needs to be reported as Medical Event

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Subcommittee Position on Medical Events and Patient Intervention

- Purpose of ME reporting is to evaluate error or problem in licensee program, or generic issue that should be reported to other licensees
- Unanticipated event that occurs during properly performed clinical procedure, that results from actions taken by the patient which could not have been reasonably prevented, or from anatomical or physiological condition of the patient, should not need to be reported as a ME
- Reporting such unavoidable patient specific events will not help to prevent such events in the future, and doing so would potentially infringe on the practice of medicine

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Subcommittee Position on Medical Events and Patient Intervention

- The term “patient Intervention” should be interpreted to include:
  - Intentional or “voluntary” physical actions taken by the patient, such as removing an implanted brachytherapy source or applicator, or refusing to continue with a prescribed course of treatment
  - Unintentional or “involuntary” actions resulting from the anatomical or physiological conditions of the patient, such as extravasation, migration of implanted radioactive seeds, arterial spasm, and the onset of other underlying medical diseases and disorders which interfere with the prescribed treatment

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Subcommittee Position on Medical Events and Patient Intervention

- Expansion of the term “patient intervention” is consistent with the original objective for which it was developed in 2002
- Event resulting from patient intervention which results in unintended permanent functional damage to an organ or physiological system should be reported as a ME
- ME resulting from patient intervention (whether it causes permanent functional damage or not) should still be reported to institution’s Patient Safety Committee

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Subcommittee Position on Medical Events and Patient Intervention

- ME due to device failure or equipment malfunction, with no error on part of licensee, still need to be reported, as it may indicate a generic defect or problem that would be of benefit to other licensees

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Subcommittee Recommendations

- Current definition of "patient Intervention" should be interpreted to include both intentional (or voluntary) actions taken by the patient, and unintentional (or involuntary) actions
- Medical Events resulting from "patient intervention" should not need to be reported as it would potentially infringe on the practice of medicine, and it will not help to prevent such events in the future
- Medical Events resulting from patient intervention which result in unintended permanent functional damage to an organ or a physiological system should be reported as required by 10 CFR 35.3045(b)

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Acronyms

- ACMUI – Advisory Committee on the Medical Uses of Isotopes
- AEC – Atomic Energy Commission
- IN – Information Notice
- ME – Medical Event
- RSL – Radioactive Seed Localization

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