REGULATORY UPDATE: ADVANCING SAFETY
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OBJECTIVES

Update of some current radiation safety issues impacting medical physicist practices
Provide discussion of Patient Safety Quality Improvement Act (2005) (PSA), which spurred growth of incident learning systems including the Radiation Oncology Incident Learning System (RO-ILS), and provide update on evolving law relating to the patient safety work product (PSWP) privilege
RELATIONSHIPS EVERYWHERE
ACMUI ADDRESSING ME REPORTING AT NRC

“Medical Event Reporting and Impact on Medical Licensee Patient Safety Culture”
Medical event reporting requirements inconsistently understood by licensees and NRC staff because there is no clarity surrounding NRC’s requirements and purpose for reporting medical events.

NRC provides insufficient medical event data to medical licensees and therefore is not achieving all benefits of reporting.

NRC has not conducted a periodic self-assessment of its medical events reporting requirements to determine if they are effectively meeting their intended purpose.
Dose administered differs from what was prescribed, and the difference meets the NRC’s reporting requirements

AND

One or more of the following occur:
Dose administered differs by at least 20 percent from the prescribed dose,
Wrong radioactive drug is used,
Radioactive drug is administered by the wrong route,
Wrong individual receives the dose,
Dose is administered to wrong part of body and exceeds by 50 percent or more dose that area should have received, or
Sealed source used in the treatment leaks.
Focus of ME reporting should be on learning and how to avoid/reduce likelihood of future event rather than punitive

Identify potential ways to improve effectiveness of ME reporting

Explore sharing of ME reports/lessons learned with medical community to promote safety
ACMUI ME REPORTING AND IMPACT ON MEDICAL LICENSEE PATIENT SAFETY CULTURE

Report to NRC Commissioners March 2018

ME reporting has not changed significantly for years

Annual number of reports is low, but are reports reflective of true number of cases?

Perception of ME is punitive/negative: Are licensees reluctant to report MEs?
ACMUI RECOMMENDATIONS FOR NRC POLICY AND REGULATORY CHANGES FOR ME REPORTING

Define high vs low impact MEs

Low impact events would undergo self-evaluation and corrective action reporting through NRC or NRC-approved PSOs or institutional patient safety program

Only high impact events would require timely notification to NRC, NRC reactive inspection, and timely written report to NRC

Low impact events would not require notification to NRC
NRC develops pilot to allow medical use licensees to evaluate MEs
Licensee would report MEs per current requirement
NRC will not post event report on its website or it will make posting anonymous
NRC will not conduct reactive inspection except in high impact MEs
After test period, NRC would consider opening program to all NRC medical use licensees
At March 7 ACMUI meeting NRC staff responded to the ACMUI’s recommendation for pilot expressing concerns about:

- Meeting regulatory purpose of medical event reporting
- Limitations to conducting a pilot program using PSOs
- Changing criteria for an NRC reactive inspection

ACMUI continues to evaluate ME reporting and its impact on patient safety culture
A LOT OF MOVING PARTS
Agency for Healthcare Research and Quality (AHRQ) rule effective 2009

Creates Patient Safety Organizations (PSOs) and Network of Patient Safety Databases

Provides confidentiality /privilege protections for Patient Safety Work Product (PSWP)
RADIATION ONCOLOGY INCIDENT LEARNING SYSTEM (RO-ILS)

AAPM/ASTRO collaboration
Clarity Patient Safety Organization
Initiated June 2014
Clarify what information can become PSWP
Address questions raised by the Tibbs case
AHRQ Approach to PSA Interpretation
How Information Becomes PSWP
Information that is not PSWP
Purpose for which information was assembled or developed
The PSA does not relieve a provider from its external obligations
AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ) GUIDANCE (MAY 24, 2016)

PSA does not relieve a provider from complying with its external obligations.

PSA works in concert with external obligations to reduce medical errors through creation of a culture of safety.

Information is PSWP if it has potential to increase patient safety is not an original provider record, was created with purpose of being reported to PSO, and was reported to a PSO.

Original provider records cannot be considered to be PSWP even if they are maintained inside a Patient Safety Evaluation System (PSES).

Confidentiality protections afforded by PSA are distinct from and in addition to other potential protections and privileges including but not limited to peer review.

Availability and application of peer review, confidentiality and/or privilege is governed by state law and must be analyzed through that lens.
KY S Ct held incident reports may be discoverable if they are prepared pursuant to state laws requiring their preparation

Hospital asked US S Ct to grant certiorari

US S Ct asked Sol Gen to submit brief

US S Ct denied cert.
Release of AHRQ guidance may have contributed to US Supreme Court’s denial to hear Tibbs v Bunnell (KY S Ct 2014)

US S Ct hearing of Tibbs would have provided nationwide interpretation of privilege and confidentiality protections under PSA for reports submitted to PSO as well as whether PSA preempted state laws

Leaves KY S Ct’s ruling (investigative report not PSWP) in place

Because US S Ct denied petition in Tibbs disputes to be decided on state-by-state basis

Other cases in state courts looking at privilege and confidentiality creating dynamic environment
KY S Ct citing its prior opinion in *Tibbs v Bunnell* (KY 2014) held federal act does not protect information collected, maintained, or developed separately from patient safety evaluation system (PSES) even if it is collected by PSES and reported to PSO.

Clouse shows movement in favor of privilege by creating more practical analysis: Facility must show documents requested are PSWP and proof that documents are maintained in PSES. Once shown, privilege remains intact unless requesting party can show information was essential for compliance with state statutory and regulatory requirements.
Malpractice amendment to state constitution enacted 2004
Provides citizens access to records of medical incidents involving physicians, hospitals, other providers
FL S Ct held that documents that hospital claimed as privileged as PSWP were discoverable under the Florida constitutional provisions giving patients access to these records.

Hospitals are required to create and maintain records of adverse medical incidents under the licensing provisions of FL law.

Adverse medical incident reports do not become patient safety work product merely by reporting documents to PSO because FL statutes and administrative rules require providers to create and maintain these records and FL constitution provides patients with a constitutional right to access these records such records are discoverable.

FL constitutional right to access these records (Amendment 7) was not preempted by PSA: PSA preserves and incorporates rather than preempts a provider’s reporting and recordkeeping obligations under state law.
EDWARDS V THOMAS (FL S CT - OCT 2017)

FL S Ct held physician peer reviews not protected from public disclosure

External peer review report was “fact work product” and subject to disclosure under Article X, Section 25 of the Florida Constitution (the “Patient’s Right to Know”) Amendment, aka Amendment 7

Critical point: Peer review is subject to disclosure even if it is created by outside entity at express direction of attorney solely for purposes of anticipated litigation
The cases from Kentucky and Florida analyze statutory provisions under PSA and harmonize with the AHRQ advisory opinion of May 24, 2016.

Two state Supreme Court cases and AHRQ Guidance Advisory show imitations on patient safety work product and provide guidance as to what is to be considered patient safety work product under PSA.

Critical to know specific legal obligations that providers have for creating and maintaining documents concerning adverse medical incidents under state law to determine whether such documentation will be considered PSWP.

Other cases in state courts looking at privilege and confidentiality creating dynamic environment.
WHERE ARE WE GOING?
TRAINING AND EXPERIENCE

NRC Advisory Committee on the Medical Uses of Isotopes (ACMUI) Subcommittee Report To Commission March 2018

Use of Unsealed Byproduct material for which a written directive is required (10 CFR 35.390) and FDA approval of 177 Lu-dotatate

Y-90 NRC Draft Guidance

Dermatology Request for Exemption
Established in 2016

Recognizes changing healthcare environment requires periodic review T & E requirements currently in effect for all modalities

Developed comprehensive review template, standardized review process, meaningful comparisons, and decisions based on data
CONCERNS EXPRESSED IN MARCH 2018

Waning number of nuclear medicine physicians/Number of nuclear radiologists trending downward

T & E /possible development of alternate pathway must consider future needs

Could decrease in number of AUs and increase in procedures impact patient access?
FDA APPROVAL OF 177 LU-DOTATATE

Patient access concerns prioritize ACMUI review of T & E requirements for Use of Unsealed Byproduct Material for which a Written Directive is Required (10 CFR 35.390)

Jan 2018 FDA approved 177 Lu-dotatate (Lutathera) for treatment of gastroenteropancreatic neuroendocrine tumors (GEP-NETs).

High demand for 177 Lu-dotatate anticipated

Previous T & E discussions focused on whether insufficient number of AU's at present time for administration of infrequently used therapeutic radiopharmaceutical (Zevalin)

Approval of 177 Lu-dotatate with potential for high volume supports reevaluation

ACMUI will consider developing an alternative AU pathway for 10 CFR 35.390
Arises under 10 CFR 35.1000

Alternate pathway put in place 10 years ago over concerns of interventional radiology community about availability of Y-90 AUs to supervise trainees' cases. NRC proposing to remove alternative pathway after 2 years grace period.

Three cases for each type: TheraSphere or SIR-Spheres

AAPM submitted comments February 2018: AAPM supports maintaining alternate pathway that allows applicants to gain clinical experience and achieve AU status under the supervision of a manufacturers' representative who is an AU.

Awaiting NRC review of comments and decision.
Sensus Healthcare requested exemption from state regulations that require radiation therapy physician and qualified medical physicist for use of radiation therapy x-ray unit. Exemption sought to allow dermatologists to provide superficial radiation therapy for non-melanoma skin cancers with only two days of training by manufacturer. Safe use of Sensus SRT-100 and similar devices depends on user’s ability to deliver accurate dose to prescribed clinical site. Oregon’s current regulatory requirements for quality management and staffing are necessary for safety. Oregon denied request for exemption.
THANK YOU!
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