AMERICAN ASSOCIATION *of* PHYSICISTS IN MEDICINE

Advancing the Science, Education & Professional Practice of Medical Physics

REGULATORY UPDATE: ADVANCING SAFETY

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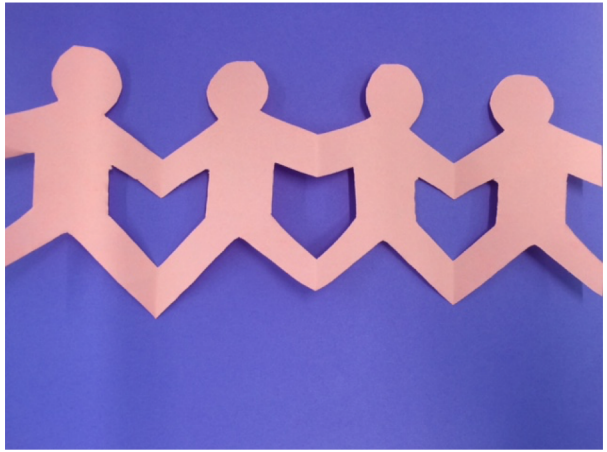
OBJECTIVES

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"

NRC-OCTOBER 2015 OFFICE OF INSPECTOR GENERAL'S AUDIT OF NRC'S OVERSIGHT OF MEDICAL USES OF NUCLEAR MATERIAL

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

NUCLEAR REGULATORY COMMISSION (NRC) MEDICAL EVENT REPORTING (10 CFR 35.3045)

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.

ACMUI REPORT "MEDICAL EVENT REPORTING AND IMPACT ON MEDICAL LICENSEE PATIENT SAFETY CULTURE"

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

ACMUI RECOMMENDS PILOT

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

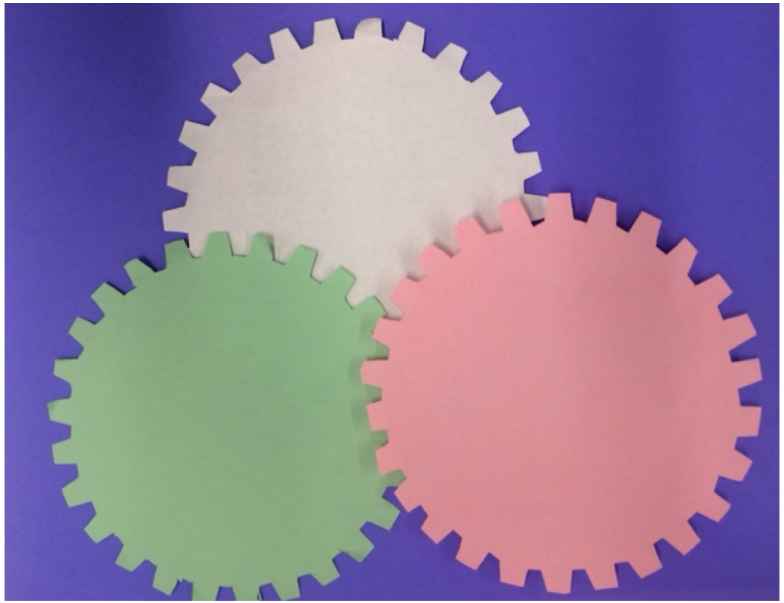
ACMUI ME REPORTING AND IMPACT ON MEDICAL LICENSEE PATIENT SAFETY CULTURE (SEPT. 2017)

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



PATIENT SAFETY AND QUALITY IMPROVEMENT ACT (2005)(PSA)

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)

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RADIATION ONCOLOGY INCIDENT LEARNING SYSTEM (RO-ILS)

AAPM/ASTRO collaboration

Clarity Patient Safety Organization

Initiated June 2014

AHRQ GUIDANCE PATIENT SAFETY WORK PRODUCT (MAY 2016)

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

TIBBS V BUNNELL
US SUPREME COURT

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.

US S CT REFUSES TO HEAR TIBBS

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

BAPTIST HEALTH RICHMOND V CLOUSE (KY S CT 2016)

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

FL AMENDEMENT 7

Malpractice amendment to state constitution enacted 2004

Provides citizens access to records of medical incidents involving physicians, hospitals, other providers

CHARLES V SOUTHERN BAPTIST HOSPITAL OF FLORIDA (FL S CT -JAN 2017)

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

PATIENT SAFETY WORK PRODUCT (PSWP): BOTTOM LINE

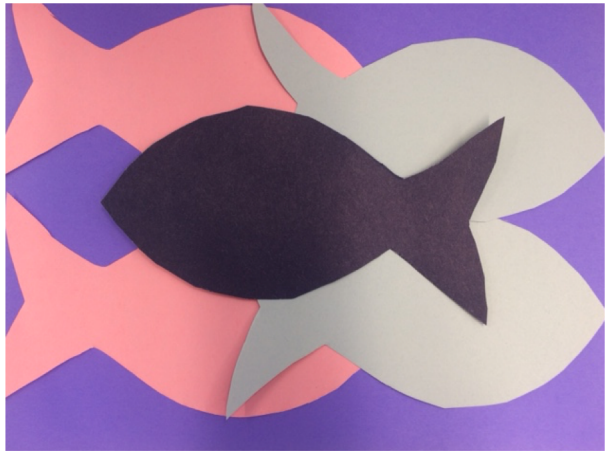
The cases from Kentucky and Florida analyze statutory provisions under PSA and harmonize with the AHRQ advisory opinion of May 24, 2016

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

ACMUI SUBCOMMITTEE ON T & E

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

YTTRIUM-90 MICROSPHERE BRACHYTHERAPY SOURCES AND DEVICES NRC DRAFT GUIDANCE

Arises under10 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 hat 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

VENDOR REQUEST FOR EXEMPTION FROM OREGON T & E REGULATIONS (2018)

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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