Advisory Committee on the Medical Use of Isotopes (ACMUI)

Medical Event Reporting and Impact on Medical Licensee Patient Safety Culture Interim Report

Interim Report Date: April 27, 2017

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Charge: To 1) explore the impact of medical event reporting and its impact on self-reporting (safety culture); 2) identify potential ways to improve effectiveness of self-reporting in support of a culture of safety; and 3) suggest ways to share medical event reports and lessons-learned with the medical community to promote safety.

Recommendations:

- Radiological protection is greatly different for control of patient exposures as opposed to radiological protection for control of occupational exposures and public exposures. To give everyone a common perspective of these differences, the Subcommittee has provided in this report background information on radiological protection differences and on the U.S. regulatory history of medical use of byproduct materials[1].

- The establishment of safety culture standards has grown in recent years with efforts by the Nuclear Regulatory Commission (NRC) and with efforts by other regulators and organizations involved in U.S. healthcare. To give everyone a common perspective of different safety culture standards, the Subcommittee has provided background information on the development of different areas of patient safety standards and self-reporting in support of a culture of patient safety.

- Given the background information provided in this report, the Subcommittee recommends that the ACMUI discuss at its April 2017 meeting the pros and cons of the NRC medical event reporting regulations in support of patient safety culture and as compared with other patient event reporting programs used by U.S. healthcare.

- Based on the April 2017 ACMUI discussion, the Subcommittee asks the ACMUI to decide whether to continue exploration of establishing a new way for the NRC to support patient safety culture and the Subcommittee will work on a report for the Fall 2017 ACMUI meeting to identify specific options the NRC may take to encourage a licensee's patient safety

[1]The Atomic Energy Commission (AEC) and the NRC are described in this report as the regulatory authorities for medical use of byproduct material, but that regulatory authority may have been transferred to States approved as Agreement States - https://www.nrc.gov/about-nrc/state-tribal/agreement-states.html (last accessed 3/27/2017).

culture, while maintaining its regulatory authority to protect patients treated with byproduct materials.

I. Background on Radiological Protection and U.S. Regulatory History for Medical Use

Medical use of ionizing radiation is different from every other use of ionizing radiation in that it involves purposely exposing an individual to ionizing radiation to diagnose or treat a medical condition some of which can be a serious or life-threatening illness. This medical exposure is to patients who have been informed by their physicians why the medical procedure is needed along with the potential medical risks, and who have consented to undergo the medical procedure.

For most health physicists, and others who regulate non-medical uses of radioactive materials, purposely exposing an individual to radiation can be a foreign concept. This is why the purposeful exposure of human beings to radiation in the arena of medical care needs to be approached in a special regulatory context. This is particularly true with respect to reporting of medical events and promoting patient safety.

A. Fundamental Principles of Radiological Protection

The International Commission on Radiological Protection (ICRP) published its latest revised recommendations for a system of radiological protection in 2007[2]. The ICRP stated that the primary aim of the recommendations was "to contribute to an appropriate level of protection for people and the environment against the detrimental effects of radiation exposure without unduly limiting the desirable human actions that may be associated with such exposure." The ICRP considers three types of exposure situations – planned exposures, emergency exposures, and existing exposure situations. Medical exposure is a planned exposure. For planned exposures, the ICRP recommends three fundamental principles of radiological protection which were retained from the 1990 ICRP update[3] and remained largely the same as established in the 1977 ICRP update[4] of the radiological protection recommendations. These fundamental principles are:

- The Principle of Justification: Any decision that alters the radiation exposure situation should do more good than harm.
- The Principle of Optimization of Protection: The likelihood of incurring exposure, the number of people exposed, and the magnitude of their individual doses should all be kept as low as reasonably achievable, taking into account economic and societal factors.

[2] ICRP Publication 103, "The 2007 Recommendations of the International Commission on Radiological Protection" – http://www.icrp.org/publication.asp?id=ICRP%20Publication%20103 (last accessed 3/27/2017).
[3] ICRP Publication 60, "1990 Recommendations of the International Commission on Radiological Protection" – http://www.icrp.org/publication.asp?id=ICRP%20Publication%2060 (last accessed 3/27/2017).
[4] ICRP Publication 26, "Recommendations of the ICRP" (1977) – http://www.icrp.org/publication.asp?id=ICRP%20Publication%2026 (last accessed 3/27/2017).

- The Principle of Application of Dose Limits: The total dose to any individual from regulated sources in planned exposure situations other than medical exposure of patients should not exceed the appropriate limits specified by the Commission.

The ICRP distinguishes these exposures between three categories: occupational exposures; public exposures; and medical exposures of patients, comforters, carers, and volunteers in research.

Each of the fundamental principles is meant to be applied differently to each exposure category. The Principle of Justification is easily applied in the case of medical exposure because the patient is the individual who receives the measurable benefit of the exposure and the one who accepts the theoretical risk of that exposure. The Principle of Optimization has been applied to medical exposures in recent years in continuing efforts in improving imaging techniques with reduced ionizing radiation exposures, or more precisely targeting radiation exposure to diseased tissues and protecting healthy tissues. In the case of the Principle of Dose Limits, medical exposure of patients is explicitly excluded from requiring dose limits.

B. NRC Regulatory History - Recognizing Medical Exposures as Different from Other Exposure Categories

From the start of regulatory controls for the use of radioactive materials, the primary exposures categories considered for regulatory controls were occupational exposures and public exposures. Medical exposures were recognized as being different and were taken into consideration. As time has gone by to present day, NRC's recognition that patient exposures are different from occupational or public exposures has become less clear.

1. 1950s – Early 1970s AEC Establish Medical Use Regulations

The Atomic Energy Commission's (AEC) first rule establishing the standards for protection against radiation[5] was published in 1957. Medical use of radiation was addressed in the following sections:

> § 20.104 – "*Medical diagnosis, therapy, and research*. Nothing in the regulations in this part shall be interpreted as limiting the intentional exposure of patients to radiation for the purpose of medical diagnosis or medical therapy."
>
> § 20.204 "*Exceptions from posting requirements...* (b) Rooms or other areas in hospitals 'are not required to be posted with caution signs because of the presence of patients containing byproduct material provided that there are personnel in attendance who shall take the precautions necessary to prevent the exposure-of any individual to radiation or radioactive material in excess of the limits established in the regulations in this part."

[5] Atomic Energy Commission, 10 CFR Part 20, 22 FR 548, January 29, 1957 – http://loc.heinonline.org/loc/Page?handle=hein.fedreg/022019&id=1&collection=journals&index=fedreg/022#18 go to page 548 (last accessed 3/27/2017).

§ 20.303 "*Disposal by release into sanitary sewerage systems*. Excreta from individuals undergoing medical diagnosis or therapy with radioactive material shall be exempt from any limitations contained in this section."

The exemption of last section still remains in place today in § 20.2003(b).

The AEC's first rule establishing a specific set of regulations related to medical use of byproduct material[6] was published in 1965. This set of regulations was established to better clarify licensing of individual physicians, medical use of sealed sources, and licensing of medical use in institutions, and to grant general license for medical use of certain byproduct material quantities.

2. 1970s to 1980s - Development of NRC Medical Use Regulations

In 1974, the NRC was established to provide regulatory oversight of the civilian use of nuclear material, including byproduct material[7], and took on rulemaking begun by the AEC to establish additional requirements for medical use of byproduct material. In 1979, the NRC published its first medical use policy statement[8] to inform of the Commission's general intent on regulating medical uses of radioisotopes:

1. "The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.
2. The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.
3. The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine."

A major update of the NRC's medical use regulations was published in 1980 which established the concept of reporting medical misadministrations[9]. The NRC has previously stated[10] that one purpose of the misadministration reporting requirements was to allow NRC to

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[6] Atomic Energy Commission, "Licensing Byproduct Material", includes initial 10 CFR Part 35, 30 FR 8185, June 26, 1965 – http://loc.heinonline.org/loc/Page?handle=hein.fedreg/030123&id=1&collection=journals&index=fedreg/030#5 go to page 8185 (last accessed 3/27/2017).

[7] Energy Reorganization Act of 1974 – https://www.nrc.gov/docs/ML1327/ML13274A489.pdf#page=241 (last accessed 3/27/2017).

[8] Nuclear Regulatory Commission, "Regulation of the Medical Uses of Radioisotopes; Statement of General Policy", 44 FR 8242, February 9, 1979 – http://loc.heinonline.org/loc/Page?handle=hein.fedreg/044029&id=1&collection=journals&index=fedreg/044#16 go to page 8242 (last accessed 3/27/2017).

[9] Nuclear Regulatory Commission, "Misadministration Reporting Requirements", 45 FR 31701, May 14, 1980 – http://loc.heinonline.org/loc/Page?handle=hein.fedreg/045095&id=1&collection=journals&index=fedreg/045#15 go to page 31701 (last accessed 3/27/2017).

[10] Nuclear Regulatory Commission, "Misadministration Reporting Requirements; Proposed Rule", 43 FR 29297, July 7, 1978 –

investigate the incident, to determine if there was a violation, to evaluate the licensee's corrective action, and to allow NRC to inform other licensees of the potential problem and to take generic corrective action if there is a possibility of other licensees making the same error. The NRC stated[10] another purpose was to inform the patient or the patient's responsible surrogate so that corrective action could be taken, although the Commission was concerned this could represent undue intrusion into the physician-patient relationship[10]. Following a public comment period on the proposed rule, the Commission ultimately decided[9] it believed the misadministration recordkeeping and reporting requirement was necessary to protect patients. The Commission did recognize in the final misadministration rule[9] one medical limitation by excluding extravasation as a misadministration, which was subsequently reviewed and reconfirmed by the ACMUI as appropriate in both diagnostic[11] and therapeutic[12] procedures.

The NRC published another major update of the medical use regulations in 1986 to clarify and consolidate all the requirements in use at that time into the Part 35 regulations[13]. This regulatory change established the different types of medical uses, the required training and experience for individuals involved with medical administration of byproduct materials, and the authority and responsibility for medical use radiation safety programs. The NRC described this Part 35 change as retaining the "current balance between adequate controls and undue interference in medical judgments." The NRC further stated that "too much regulation could result in poorer health care delivery to patients", and that "insufficient regulation could result in the unwarranted or unsafe use of radiation[13]."

3. Early 1990s – Quality Assurance Requirements Added to NRC Medical Use Regulations

In 1991, the NRC amended the Part 35 to require a quality management program for therapeutic administrations and certain uses of radioactive sodium iodide[14]. This change was made to provide high confidence that the byproduct material or radiation from byproduct material will be administered as directed by an authorized user physician. The Commission stated it believed "this performance-based amendment will result in enhanced patient safety in a cost-effective manner while allowing the flexibility necessary to minimize intrusion into medical judgments[14]." Under the discussion of the medical use policy, the NRC stated:

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http://loc.heinonline.org/loc/Page?handle=hein.fedreg/043131&id=1&collection=journals&index=fedreg/043#49 go to page 29297 (last accessed 3/27/2017).

[11] Advisory Committee on the Medical Uses of Isotopes, "Infiltration of Therapeutic Radiopharmaceuticals", Cindy Flannery slide presentation, May 8, 2009 – https://www.nrc.gov/docs/ML0914/ML091400100.pdf go to page 79 (last accessed 3/27/2017).

[12] Advisory Committee on the Medical Uses of Isotopes, May 7-8, 2009 Meeting Summary – https://www.nrc.gov/docs/ML0917/ML091730001.pdf (last accessed 3/27/2017).

[13] Nuclear Regulatory Commission, "Medical Use of Byproduct Material; Final Rule", 51 FR 36932, October 16, 1986 – http://loc.heinonline.org/loc/Page?handle=hein.fedreg/051200&id=1&collection=journals&index=fedreg/051#144 go to page 36932 (last accessed 3/27/2017).

[14] Nuclear Regulatory Commission, "Quality Management Program and Misadministrations; Final Rule", 56 FR 34104, July 25, 1991 – http://loc.heinonline.org/loc/Page?handle=hein.fedreg/056143&id=1&collection=journals&index=fedreg/056#110 go to page 34104 (last accessed 3/27/2017).

> "The NRC has the authority to regulate the medical use of byproduct material or radiation from byproduct material to protect the health and safety of patients, but also recognizes that physicians have the primary responsibility for the protection of their patients. NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions that are in the best interest of their patients."

And in describing their responsibilities, the NRC stated:

> "The NRC distinguishes between the unavoidable risks attendant in purposefully prescribed and properly performed clinical procedures and the unacceptable risks of improper or careless use. The NRC is responsible, as part of its public health and safety charge, to establish and enforce regulations that protect the public from risks of improper procedures or careless use."

In this 1991 final rule, the NRC added dose criteria to the misadministration reporting requirements based on NCRP[15] dose levels described as having a total detriment from stochastic effects as less than one percent. These dose criteria were added to better clarify the definition of a misadministration to rule out diagnostic radiopharmaceutical administrations that were considered to be low-risk. The Commission noted that these dose levels also corresponded to the annual dose limits for occupational workers which are thresholds for reporting overexposures to the NRC, and thus felt it was reasonable to apply these dose criteria to patient exposures[14].

In a separate rulemaking updating Part 20[16] in 1991, the NRC clarified in the definitions that occupational dose and public dose does not include the intentional dose received as a patient from medical practices or from voluntary participation in medical research programs.

4. Late 1990s to present - NRC Strategic Planning for Current Medical Use Regulations

In the 1995, the NRC began a Strategic Assessment and Rebaselining Project to develop an agency-wide strategic plan which included a Direction-Setting Issue Paper[17] to define NRC's future role and scope of NRC's regulations of the medical use of nuclear materials. A key consideration in this direction-setting issue paper was described as "the interpretation that the Commission has adopted and implemented that medical patients are include in the 'public.'" Also discussed were the regulatory options set forth in the Institute of Medicine (IOM) of the

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[15] National Council on Radiation Protection and Measurements, Commentary No. 7, "Misadministration of Radioactive Material in Medicine – Scientific Background" (1991) – https://www.ncrppublications.org/Commentaries/07 (last accessed 3/27/2017).

[16] Nuclear Regulatory Commission, "Standards for Protection Against Radiation; Final Rule", 56 FR 23360, May 21, 1991 – http://loc.heinonline.org/loc/Page?handle=hein.fedreg/056098&id=1&collection=journals&index=fedreg/056#180 go to page 23360 (last accessed 3/27/2017).

[17] Nuclear Regulatory Commission, SECY-01-0057- Enclosure 7; "Strategic Assessment Issue Paper , DSI 7: Materials/Medical Oversight," September 16, 1996, ML010780349 – https://www.nrc.gov/docs/ML0107/ML010780349.pdf (last accessed 3/27/2017).

National Academy of Sciences (NAS) independent review and evaluation of the NRC's Medical Use Program[18]. While the IOM recommended that regulatory authority over medical use of byproduct materials be given to the States, the Commission ultimately decided to continue to regulate medical use of byproduct materials and to utilize a risk-informed performance-based approach to determine which activities in the medical area are low-risk activities for decreased NRC oversight. These Commission directions have shaped the subsequent changes to the Commission's Medical Use Policy and Part 35 regulations.

In 1997, the NRC changed § 35.75[19] to allow patients administered radiopharmaceuticals or permanent implants containing radioactive materials to be released from the licensee's control if dose to any other individual did not exceed 5 mSv (0.5 rem). In the same rulemaking, the Part 20 occupational dose and public dose definitions were again modified to note that dose from patients released under the § 35.75 release criteria is not considered occupational dose or public dose.

The NRC updated the Medical Use Policy Statement[20] in 2000 to guide the NRC's future regulation based on:

1. "NRC will continue to regulate the uses of radionuclides in medicine as necessary to provide for the radiation safety of workers and the general public.
2. NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public.
3. NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's directions.
4. NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety."

The Commission explained in a report to Congress[21] that a key assumption in the Commission's medical use policy item 3 "…is that a patient, like everyone else who is not exposed as part of their employment functions, is a member of the public to be protected by NRC. The focus of NRC regulation—to protect the patient's health and safety—is primarily to ensure that the authorized user physician's directions are followed as they pertain to the administration of the radionuclide."

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[18] Institute of Medicine, "Radiation in Medicine: A Need for Regulatory Reform," National Academy Press (1996) – https://www.nap.edu/catalog/5154/radiation-in-medicine-a-need-for-regulatory-reform (last accessed 3/27/2017).
[19] Nuclear Regulatory Commission, "Criteria for the Release of Individuals Administered Radioactive Material; Final Rule", 62 FR 4120, January 29, 1997 – https://www.gpo.gov/fdsys/pkg/FR-1997-01-29/pdf/97-2166.pdf (last accessed 3/27/2017).
[20] Nuclear Regulatory Commission, "Medical Use of Byproduct Material; Policy Statement, Revision", 65 FR 47654, August 3, 2000 – https://www.gpo.gov/fdsys/pkg/FR-2000-08-03/pdf/00-19573.pdf (last accessed 3/27/2017).
[21] Nuclear Regulatory Commission, "Report to Congress on Part 35", February 11, 2002 – https://www.nrc.gov/docs/ML0135/ML013550321.pdf (last accessed 3/27/2017).

The most recent major update of Part 35 was implemented beginning 2002[22] with completion of its full implementation in 2005[23]. The NRC described[21] the underlying premise of these regulations was that authorized user physicians will understand radiation safety principles and practices and will make decisions that are in the best interests of their patients. The regulations for a quality management program to be submitted to the NRC were removed, but the requirement to provide high confidence that byproduct material will be administered as directed by the authorized user through written procedures for medical administrations requiring a written directive was retained. Reporting of medical events, previously called misadministrations, was retained with the same dose reporting criteria for patient exposures.

Since the current major revision of 10 CFR Part 35 was fully implemented in 2005, the NRC has been working to do additional major updates of the Part 35 regulations, but as of the date of this ACMUI Subcommittee report, the final rule has not been approved. One cause for this delay has been the continuing discussions and disagreements regarding what should be the medical event reporting criteria for permanent brachytherapy implants.

II. Development of Safety Culture and Standards

A. NRC Nuclear Safety Culture Policy

The NRC has encouraged development of what is now known as safety culture in its regulatory framework and encouragement of workers to report to their licensee or to the NRC safety concerns and items of non-compliance. In 1996, the Commission issued a policy statement[24] on "its expectation that licensees and other employers subject to NRC authority will establish and maintain safety-conscious environments in which employees feel free to raise safety concerns, both to their management and to the NRC, without fear of retaliation." And in 2002, NRC staff presented the Commission with policy options and recommendations for revising the NRC's process for handling discrimination issues[25]. The staff recommended that the Commission pursue rulemaking for oversight of a safety conscious work environment, including provisions for handling discrimination complaints. The Commission did not approve the NRC staff recommendation[26] principally because of the subjectivity associated with direct regulation of safety culture and instead directed the staff to develop guidance, in consultation with stakeholders, that would identify best practices to encourage a safety conscious work

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[22] Nuclear Regulatory Commission, "Medical Use of Byproduct Material; Final Rule", 67 FR 20250, April 24, 2002 – https://www.gpo.gov/fdsys/pkg/FR-2002-04-24/pdf/02-9663.pdf (last accessed 3/27/2017).
[23] Nuclear Regulatory Commission, "Medical Use of Byproduct Material – Recognition of Specialty Boards; Final Rule", 60 FR 16336, March 30, 2005 – https://www.gpo.gov/fdsys/pkg/FR-2005-03-30/pdf/05-6103.pdf (last accessed 3/27/2017).
[24] Nuclear Regulatory Commission, "Freedom of Employees in the Nuclear Industry to Raise Concerns without Fear of Retaliation; Statement of Policy", 61 FR 24336, May 14, 1996 – https://www.gpo.gov/fdsys/pkg/FR-1996-05-14/pdf/96-12028.pdf go to page 24336 (last accessed 3/27/2017).
[25] Nuclear Regulatory Commission SECY-02-0166, "Policy Options and Recommendations for Revising the NRC's Process for Handling Discrimination Issues", September 12, 2002 – https://www.nrc.gov/docs/ML0221/ML022120479.pdf (last accessed 3/27/2017).
[26] Nuclear Regulatory Commission SRM-SECY-02-0166, "Policy Options and Recommendations for Revising the NRC's Process for Handling Discrimination Issues", March 26, 2003 – https://www.nrc.gov/docs/ML0308/ML030850783.pdf (last accessed 3/27/2017).

environment. As a result, the NRC issued a regulatory issue summary[27] providing guidance on establishing and maintaining a safety conscious work environment.

In 2008, the Commission issued another SRM[28] directing the NRC staff to expand the Commission's policy on safety culture to address the unique aspects of security, considering safety and security interfaces, and to ensure the resulting policy is applicable to all licensees and certificate holders. And with consultation of the NRC's various stakeholders, the Commission issued its final statement of policy[29] in 2011 setting forth its expectation that "individuals and organizations performing or overseeing regulated activities establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions." The NRC policy statement defined "Nuclear Safety Culture" as "the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment." NRC noted that safety and security activities are closely intertwined, and their respective activities may complement each other, or there may be instances in which safety and security interests create competing goals. Organizations under the NRC regulatory authority were cautioned to ensure that personnel in the safety and security sectors have an appreciation for the importance of each, emphasizing the need for integration and balance to achieve both safety and security in their activities so as not to diminish or adversely affect either, but to establish mechanisms to identify and resolve these differences.

The NRC safety culture policy[29] also set out certain personal and organizational traits that should be part of a positive safety culture:

(1) Leadership Safety Values and Actions—Leaders demonstrate a commitment to safety in their decisions and behaviors;
(2) Problem Identification and Resolution—Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance;
(3) Personal Accountability—All individuals take personal responsibility for safety;
(4) Work Processes—The process of planning and controlling work activities is implemented so that safety is maintained;
(5) Continuous Learning—Opportunities to learn about ways to ensure safety are sought out and implemented;
(6) Environment for Raising Concerns—A safety conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination;
(7) Effective Safety Communication— Communications maintain a focus on safety;
(8) Respectful Work Environment— Trust and respect permeate the organization; and

[27] Nuclear Regulatory Commission "Regulatory Issues Summary 2005-18, Guidance for Establishing and Maintaining a Safety Conscious Work Environment", August 5, 2005 – https://www.nrc.gov/docs/ML0522/ML052220239.pdf (last accessed 3/27/2017).
[28] Nuclear Regulatory Commission SRM–COMGBJ–08–0001, "A Commission Policy Statement on Safety Culture", February 25, 2008 – https://www.nrc.gov/docs/ML1025/ML102500672.pdf (last accessed 3/27/2017).
[29] Nuclear Regulatory Commission, "Final Safety Culture Safety Policy", 76 FR 34773, June 14, 2011 – https://www.gpo.gov/fdsys/pkg/FR-2011-06-14/pdf/2011-14656.pdf (last accessed 3/27/2017).

(9) Questioning Attitude—Individuals avoid complacency and continuously challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action.

The NRC safety culture policy[29] ends with the following statements:

> "It is the Commission's expectation that all individuals and organizations, performing or overseeing regulated activities involving nuclear materials, should take the necessary steps to promote a positive safety culture by fostering these traits as they apply to their organizational environments. The Commission recognizes the diversity of these organizations and acknowledges that some organizations have already spent significant time and resources in the development of a positive safety culture. The Commission will take this into consideration as the regulated community addresses the Statement of Policy."

In order to support licensees in their development and maintenance of a positive nuclear safety culture, the NRC has developed a website[30] devoted to safety culture and provided outreach materials. Unfortunately, the site provides no specific links related to safety culture and medical use of byproduct materials. Safety culture trait educational tools are provided in the NRC's Trait Talk[31] issues, but only one example in the Questioning Attitude Trait Talk mentions a Medical Physicist evaluating equipment and computer software issues for a high dose rate afterloader therapy. The NRC does not address patient safety culture and given the emphasis on the use of the word "nuclear," it is clear that NRC would restrict any discussion on patient safety culture to that small portion of patient safety issues that are under NRC's regulatory authority.

B. Development of Patient Safety Culture in U.S. Healthcare

The development of patient safety culture and patient safety programs has greatly advanced since 2000 with the advent of some key reports published by the National Academies of Science. In addition to NRC regulatory authority, healthcare providers are regulated or otherwise influenced by other organizations which have impacted the providers' fostering a patient safety culture and developing patient safety reporting and review programs.

1. Medicare Program for Oversight of Accrediting Organizations

To be eligible to receive Medicare reimbursement, certain types of health care facilities must demonstrate compliance with the Medicare conditions of participation (CoPs), conditions for coverage (CfCs), or conditions for certification[32]. The health care facilities are allowed to

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[30] NRC Safety Culture website – https://www.nrc.gov/about-nrc/safety-culture.html (last accessed 3/27/2017).
[31] NRC Trait Talks – https://www.nrc.gov/about-nrc/safety-culture/sc-outreach-edu-materials.html#sctt (last accessed 3/27/2017).
[32] Centers for Medicare and Medicaid Services, "FY 2015 Report to Congress (RTC): Review of Medicare's Program Oversight of Accrediting Organizations (AOs) and the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Validation Program", January 29, 2016 – https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-07.pdf (last accessed 3/27/2017).

demonstrate this compliance through accreditation by a Centers for Medicare & Medicaid Services (CMS)-approved accreditation program of a private, national Accrediting Organization (AO). Beginning in the 1990s, AOs initiated compliance demonstration requirements which have become more focused on issues associated with patient safety[33].

2. NAS IOM Reports on Patient Safety

As the NRC was completing their most recent update of 10 CFR Part 35, the NAS IOM began releasing a series of reports under the Quality of Health Care in America project[34]. The committee working on this project was directed to:

- "review and synthesize findings in the literature pertaining to the quality of care provided in the health care system;
- develop a communications strategy for raising the awareness of the general public and key stakeholders of quality of care concerns and opportunities for improvement;
- articulate a policy framework that will provide positive incentives to improve quality and foster accountability;
- identify characteristics and factors that enable or encourage providers, health care organizations, health plans and communities to continuously improve the quality of care; and
- develop a research agenda in areas of continued uncertainty."

The purpose of the first report[34] was to focus the Committee's initial attention on quality concerns that fall into the category of medical errors. They stated:

> "In health care, building a safer system means designing processes of care to ensure that patients are safe from accidental injury. When agreement has been reached to pursue a course of medical treatment, patients should have the assurance that it will proceed correctly and safely so they have the best chance possible of achieving the desired outcome."

The second report in the series[35] focused more broadly on how the health system could be reinvented to foster innovation and improve the delivery of care with a comprehensive strategy and action plan for the next decade. The Committee presented six aims for improvement which need to be accepted by health professionals, federal and state policy makers, public and private purchasers of care, regulators, organization managers and governing boards, and consumers for their explicit purpose to continually reduce the burden of illness, injury, and disability, and to

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[33] The Joint Commission website history – https://www.jointcommission.org/assets/1/6/TJC-history-timeline_through_20161.PDF (last accessed 3/27/2017).
[34] Institute of Medicine, "To Err is Human: Building a Safer Health System", National Academy Press (2000) – https://www.nap.edu/catalog/9728/to-err-is-human-building-a-safer-health-system (last accessed 3/27/2017).
[35] Institute of Medicine, "Crossing the Quality Chasm: A New Health System for the 21st Century," National Academy Press (2001) – https://www.nap.edu/catalog/10027/crossing-the-quality-chasm-a-new-health-system-for-the (last accessed 3/27/2017).

improve the health and functioning of the people of the United States. The six aims were built around the core need for health care to be:

- Safe: avoiding injuries to patients from the care that is intended to help them.
- Effective: providing services based on scientific knowledge to all who could benefit, and refraining from providing services to those not likely to benefit.
- Patient-centered: providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions.
- Timely: reducing waits and sometimes harmful delays for both those who receive and those who give care.
- Efficient: avoiding waste, including waste of equipment, supplies, ideas, and energy.
- Equitable: providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.

The Committee felt that achieving these aims would ensure patients would experience care that is safer, more reliable, more responsive to their needs, more integrated, and more available, and they could count on receiving the full array of preventive, acute, and chronic services that are likely to prove beneficial. To redesign of the health care system, the Committee formulated ten rules:

1. Care is based on continuous healing relationships. Patients should receive care whenever they need it and in many forms, not just face-to-face visits. This implies that the health care system must be responsive at all times, and access to care should be provided over the Internet, by telephone, and by other means in addition to in-person visits.
2. Care is customized according to patient needs and values. The system should be designed to meet the most common types of needs, but should have the capability to respond to individual patient choices and preferences.
3. The patient is the source of control. Patients should be given the necessary information and opportunity to exercise the degree of control they choose over health care decisions that affect them. The system should be able to accommodate differences in patient preferences and encourage shared decision making.
4. Knowledge is shared and information flows freely. Patients should have unfettered access to their own medical information and to clinical knowledge. Clinicians and patients should communicate effectively and share information.
5. Decision making is evidence-based. Patients should receive care based on the best available scientific knowledge. Care should not vary illogically from clinician to clinician or from place to place.
6. Safety is a system property. Patients should be safe from injury caused by the care system. Reducing risk and ensuring safety require greater attention to systems that help prevent and mitigate errors.
7. Transparency is necessary. The system should make available to patients and their families information that enables them to make informed decisions when selecting a health plan, hospital, or clinical practice, or when choosing among alternative

treatments. This should include information describing the system's performance on safety, evidence-based practice, and patient satisfaction.

8. Needs are anticipated. The system should anticipate patient needs, rather than simply react to events.
9. Waste is continuously decreased. The system should not waste re-sources or patient time.
10. Cooperation among clinicians is a priority. Clinicians and institutions should actively collaborate and communicate to ensure an appropriate exchange of information and coordination of care.

A third report[36] on patient safety was issued in response to a request from the Department of Health and Human Services (HHS) for the IOM to produce a detailed plan to facilitate the development of data standards applicable to the collection, coding, and classification of patient safety information. To achieve an acceptable standard of patient safety, the committee conducting this work recommended that all health care settings establish comprehensive patient safety programs operated by trained personnel within a culture of safety and involving adverse event and near-miss detection and analysis. In addition, the committee recommended that the federal government pursue a robust applied research agenda on patient safety, focused on enhancing knowledge, developing tools, and disseminating results to maximize the impact of patient safety systems. And finally, the committee recommended that a standardized format and terminology be developed for the capture and reporting of data related to medical errors to achieving patient safety as a standard of care.

To date, many more NAS reports have been written to address various aspects of these early key reports.

3. Legislation and Regulatory Development Supporting Patient Safety Culture

In July 2005, Congress passed the Patient Safety Act[37] amending title IX of the Public Health Service Act to provide for the "improvement of patient safety and to reduce the incidence of events that adversely affect patient safety." Elements of the act were similar to the NAS patient safety report recommendations[36]. The HHS adopted rules[38] in November 2008 to implement certain aspects of the Patient Safety Act. Specifically, the HHS final rule established a "framework by which hospitals, doctors, and other health care providers may voluntarily report information to Patient Safety Organizations (PSOs), on a privileged and confidential basis, for the aggregation and analysis of patient safety events." But the Act and the final rule recognize that the privileged and confidential protection afforded by reporting to a PSO does not relieve an entity from its obligation to comply with other Federal, State, or local laws pertaining to information that is not privileged and confidential.

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[36] Institute of Medicine, "Patient Safety: Achieving a New Standard of Care," National Academy Press (2004) – https://www.nap.edu/catalog/10863/patient-safety-achieving-a-new-standard-for-care (last accessed 3/27/2017).
[37] PUBLIC LAW 109–41—JULY 29, 2005 "Patient Safety and Quality Improvement Act of 2005" – https://www.gpo.gov/fdsys/pkg/PLAW-109publ41/pdf/PLAW-109publ41.pdf (last accessed 3/27/2017).
[38] Department of Health and Human Services, "Patient Safety and Quality Improvement; Final Rule" established 42 CFR 3, 73 FR 70732, November 21, 2008 – https://www.gpo.gov/fdsys/pkg/FR-2008-11-21/pdf/E8-27475.pdf (last accessed 3/27/2017).

As defined in 42 CFR 3.20, patient safety activities carried by or on behalf of a PSO or provider include the following activities:

(1) Efforts to improve patient safety and the quality of health care delivery;
(2) The collection and analysis of patient safety work product;
(3) The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices;
(4) The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk;
(5) The maintenance of procedures to preserve confidentiality with respect to patient safety work product;
(6) The provision of appropriate security measures with respect to patient safety work product;
(7) The utilization of qualified staff; and
(8) Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.

III. Current Patient Safety Groups Influencing Medical Use of Byproduct Materials

A. Centers for Medicare & Medicaid Services (CMS)

As noted above, the CMS administers the program to approve and review Accrediting Organizations (AO). The AOs are private, national organizations which have accreditation programs by which health care facilities may demonstrate compliance with the Medicare conditions of participation (CoPs), conditions for coverage (CfCs), or conditions for certification in order to be granted "deemed status" and receive Medicare reimbursement. Health care facilities are not required to seek AO accreditation, but are then subject to assessment of compliance by the applicable State Survey Agency (SA) if the facility seeks Medicare reimbursement.

An AO can provide different types of accreditation for different types of health care facilities. In FY 2014, CMS reported[39] the following types of Medicare-participating accreditation program facilities:

- Hospitals
- Psychiatric hospitals
- Critical access hospitals
- Home health agencies
- Hospices
- Ambulatory surgery centers

[39] Centers for Medicare and Medicaid Services, "FY 2015 Report to Congress (RTC): Review of Medicare's Program Oversight of Accrediting Organizations (AOs) and the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Validation Program", January 29, 2016 – https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-07.pdf (last accessed 3/27/2017).

- Outpatient physical therapy and speech-language pathology services
- Rural health clinics

For purpose of this report, the Subcommittee decided to focus discussion on hospitals because these facilities would conduct the majority of medical use of byproduct materials. In FY 2014, the CMS noted[39] that 80% of all Medicare-participating hospitals had deemed status through an AO.

1. The Joint Commission (TJC)

The Joint Commission (TJC) is considered the market leader[40] and was the AO for 88% of the hospitals granted deemed status in FY 2014[39]. TJC first established its Sentinel Event policy in 1996[41] to help their accredited hospitals that experience serious adverse events improve safety and learn from those sentinel events. Sentinel event is defined as a patient safety event that reaches a patient and results in any of the following:

- Death
- Permanent harm
- Severe temporary harm and intervention required to sustain life
- Other event that signals the need for immediate investigation and response[42].

The accredited hospital "is strongly encouraged, but not required, to report sentinel events to" TJC and can benefit from self-reporting in the following ways[41]:

- "The Joint Commission can provide support and expertise during the review of a sentinel event."
- "The opportunity to collaborate with a patient safety expert in The Joint Commission's Sentinel Event Unit of the Office of Quality and Patient Safety."
- "Reporting raises the level of transparency in the organization and promotes a culture of safety."
- "Reporting conveys the health care organization's message to the public that it is doing everything possible, proactively, to prevent similar patient safety events in the future."
- "Further, reporting the event enables "lessons learned" from the event to be added to The Joint Commission's Sentinel Event Database, thereby contributing to the general knowledge about sentinel events and to the reduction of risk for such events."

In 2002, TJC established its first National Patient Safety Goals[43] to help their accredited hospitals address specific areas of concern regarding patient safety. Each year TJC publishes an

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[40] V.M. Fennel, "Accreditation options, Selecting an accrediting source ", Becker Hospital Review, September 24, 2014 – http://www.beckershospitalreview.com/quality/accreditation-options-selecting-an-accrediting-source.html (last accessed 3/27/2017).
[41] The Joint Commission, "Sentinel Event policy" – https://www.jointcommission.org/sentinel_event_policy_and_procedures/ (last accessed 3/27/2017).
[42] The Joint Commission, "Sentinel Event policy for hospitals" – https://www.jointcommission.org/assets/1/6/SE_2017_CAMH.pdf (last accessed 3/27/2017).

updated set of safety goals[44]. Another resources developed by TJC is the Patient Safety Systems chapter which describes the relationship between TJC accreditation and patient safety[45]. And, TJC provides access to the National Patient Safety Foundation (NPSF) report[46] on "RCA2: Improving Root Cause Analyses and Actions to Prevent Harm."

2. DNV GL Healthcare[47]

DNV GL-accredited hospitals are described as pioneers in that they commit to annual surveys with the ultimate goal of achieving ISO9001 certification[40]. DNV GL offers the National Integrated Accreditation for Healthcare Organizations (NIAHO®) program which is described as the first integrated accreditation program for hospitals in the United Sates[48]. The CMS reported that DNV GL was the AO for 7.5% of the accredited hospitals in FY 2014[39].

3. Healthcare Facilities Accreditation Program (HFAP)

The Healthcare Facilities Accreditation Program (HFAP) has been described as predictable and may be an AO option preferred by community hospitals[40]. The CMS reported that HFAP was the AO for 4.3% of the accredited hospitals in FY 2014[39]. The HFAP describes itself as meeting or exceeding the standards required by CMS/Medicare to provide accreditation for all hospitals[49] to advance high quality patient care and safety. The HFAP has adopted the 34 Safe Practices[50] established in 2009 by the National Quality Forum (NQF). The NQF is a consensus-based healthcare organization defined by the Office of Management and Budget (OMB) to allow the federal government to rely on NQF-defined measures or healthcare practices as the best, evidence-based approaches to improving care[51].

The HFAP encourage facilities to provide documentation of self-reported patient safety incidents[52]. Once reported, the HFAP requests a copy of the hospital's policy on Root Cause Analysis (RCA) and the actual RCA conducted as a result of the incident be forwarded to HFAP

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[43] The Joint Commission, website history – https://www.jointcommission.org/assets/1/6/TJC-history-timeline_through_20161.PDF (last accessed 3/27/2017).
[44] The Joint Commission, "National Patient Safety Goals Effective January 2017 - Hospital Accreditation Program" – https://www.jointcommission.org/assets/1/6/NPSG_Chapter_HAP_Jan2017.pdf (last accessed 3/27/2017).
[45] The Joint Commission, "Patient Safety Systems", March 3, 2017 – https://www.jointcommission.org/assets/1/18/CAMH_04a_PS.pdf (last accessed 3/27/2017).
[46] National Patient Safety Foundation, "RCA2: Improving Root Cause Analyses and Actions to Prevent Harm" Version 2, January 2016 – https://npsf.site-ym.com/?RCA2 (last accessed 3/27/2017).
[47] DNV GL website – http://dnvglhealthcare.com/ (last accessed 3/27/2017).
[48] DNV GL website, "What We Do" – http://www2.dnvgl.us/l/127291/2016-11-18/21d8t9 (last accessed 3/27/2017).
[49] Healthcare Facilities Accreditation Program, Overview website – http://www.hfap.org/about/overview.aspx (last accessed 3/27/2017).
[50] Healthcare Facilities Accreditation Program, "National Quality Forum (NQF) Endorsed Set of 34 Safe Practices", February 2013 update – http://www.hfap.org/pdf/patient_safety.pdf (last accessed 3/27/2017).
[51] National Quality Forum, history website – http://www.qualityforum.org/about_nqf/history/ (last accessed 3/27/2017).
[52] Healthcare Facilities Accreditation Program, Patient Safety website – http://www.hfap.org/resources/patientsafety.aspx (last accessed 3/27/2017).

for review within 60 days so that the HFAP staff can assess the plan of correction to verify implementation of an effective process and provide guidance if necessary.

4. Center for Improvement in Healthcare Quality (CIHQ)

The Center for Improvement in Healthcare Quality (CIHQ) is described as pragmatic and practical with an approach to accreditation that is straightforward[40]. The CIHQ is the newest AO[53] which accredited 0.2% of the accredited hospitals in FY 2014[39].

B. Patient Safety Organizations Supporting Medical Use of Byproduct Materials

At the October 6, 2016 meeting[54] of the NRC Advisory Committee on the Medical Uses of Isotopes (ACMUI), four groups were invited to brief the ACMUI on development of their event reporting databases in support of patient safety for medical procedures involving ionizing radiation. Two of these groups are registered as PSOs.

1. Radiation Oncology Incident Learning System (RO-ILS)

The American Society for Radiation Oncology (ASTRO) and the American Association of Physicists in Medicine (AAPM) sponsor the Radiation Oncology Incident Learning System® (RO-ILS)[55]. Clarity PSO (DHHS PSO P0015), a division of Clarity Group, Inc., provides PSO services to the radiation oncology practices enrolled in RO-ILS. ASTRO report that more than 250 facilities have joined RO-ILS and receive benefits like:

- Contribute to a national database and collectively improve the field of radiation oncology.
- Track and review internal incidents, near misses, and unsafe conditions.
- Track and analyze internal incidents while contributing to the national database.
- Receive institution-specific summary reports, including aggregate data on events entered throughout the country.
- Receive educational materials such as PSO-sponsored instructional webinars or Tips of the Month about features/tools, best practices to prevent errors, and general patient safety initiatives to improve safety culture.

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[53] Center for Improvement in Healthcare Quality, "Welcome to the CIHQ Hospital Accreditation Division" – http://cihq.org/hospital_accreditation_division.asp (last accessed 3/27/2017).

[54] Advisory Committee on the Medical Uses of Isotopes, "October 6-7, 2016 Meeting Agenda" – https://www.nrc.gov/docs/ML1620/ML16209A233.pdf (last accessed 3/27/2017).

[55] "RO-ILS: Radiation Oncology Incident Learning System®," sponsored by American Society for Radiation Oncology and by American Association of Physicists in Medicine – https://www.astro.org/RO-ILS.aspx (last accessed 3/27/2017).

2. Center for the Assessment of Radiological Sciences (CARS)

An organization called the Center for the Assessment of Radiological Sciences (CARS) is a PSO (DHHS PSO P0149) and maintains a radiotherapy incident reporting and analysis system[56]. The CARS provides its clients professional support in completely filing out the reporting database information and in doing root cause analysis for radiotherapy incidents. As with all PSOs, confidentially is maintained of the reported incident, good catch (sometimes called a near miss), or unsafe condition, and of the associated patient safety work product developed in accordance with 42 CFR Part 3 rule. CARS-PSO has been in existence since 2014.

IV. How Should NRC Support of a Positive Patient Safety Culture?

The use of nuclear medicine and radiation therapy began growing into more universal use in the 1970s as the NRC came into existence, and it could be said that the NRC was the "only game in town" in addressing patient safety in its limited regulatory authority over health care. The NRC established its misadministration reporting and quality management program regulations in part due to patient diagnostic and therapeutic procedures which were not correctly administered. The NRC recognized[57] that the misadministration rate for radiopharmaceuticals was much lower than for other drugs, that there was no reporting requirement for misadministrations of cyclotron-produced radiopharmaceuticals[58], x-rays, and nonradioactive drugs, and that the risk to patients, workers, and the public was small. But, their view was that therapy clinical procedures presented greater risk to the public and patients than diagnostic clinical procedures. The NRC concluded that misadministrations which resulted in a dose to the patient greater than a dose to a member of the public permitted under Part 20 should require a report to the NRC and the referring physician[57]. In maintaining the reporting of medical events[59], the NRC believed that the reporting and notification requirements were necessary so that the NRC was aware of the events to determine what actions, if any, needed to be taken to prevent recurrence; so that other licensees could be made aware of generic problems that result in medical events; and so that patients would make timely decisions regarding remedial and prospective health care.

In developing the Nuclear Safety Culture Policy, the NRC cautioned organizations under its regulatory authority to ensure that personnel in safety and security sectors have an appreciation for the importance of each. The NRC emphasized the need for integration and balance to achieve both safety and security in their activities so as not to diminish or adversely affect either, but to establish mechanisms to identify and resolve these differences. The Subcommittee asks the ACMUI and the NRC to consider that there is a similar relationship

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[56] "RIRAS: Radiotherapy Incident Reporting & Analysis System" – www.cars-pso.org (last accessed 3/27/2017).
[57] Nuclear Regulatory Commission, "Medical Use of Byproduct Material; Final Rule", 51 FR 36932, October 16, 1986 – http://loc.heinonline.org/loc/Page?handle=hein.fedreg/051200&id=1&collection=journals&index=fedreg/051#144 go to page 36932 (last accessed 3/27/2017).
[58] The NRC later was given regulatory authority of cyclotron-produced radiopharmaceuticals as the result of the Energy Policy Act (EPAct)of 2005 – https://www.nrc.gov/materials/byproduct-mat.html
[59] Nuclear Regulatory Commission, "Medical Use of Byproduct Material; Final Rule", 67 FR 20250, April 24, 2002 – https://www.gpo.gov/fdsys/pkg/FR-2002-04-24/pdf/02-9663.pdf (last accessed 3/27/2017).

between Nuclear Safety Culture and Patient Safety Culture with need to find balance by identifying and resolving the differences between the two safety cultures. We have provided a review of differences between occupational and public exposures as compared to patient exposures, the history of NRC regulatory authority over medical use of byproduct material, recent legislative and regulatory development regarding patient safety, and the establishment various patient safety groups and organizations to further discussions of how the NRC may consider alternatives to medical event reporting that support both their regulatory authority and a medical licensee's safety conscious work environment in regard to patient safety.

The Subcommittee requests that the ACMUI discuss at its April 2017 meeting the pros and cons of the NRC medical event reporting regulations in support of patient safety culture and as compared with other patient event reporting programs used by U.S. healthcare. The Subcommittee suggests example topics here for this discussion.

Example Topic	NRC	AOs or PSOs
Safety Culture	NRC/AS Safety Culture is narrowly focused on "nuclear safety" and primarily focused on occupational safety and public safety; NRC has challenge dealing with patient safety issues versus interfering with the practice of medicine.	Legislative and regulatory changes have encouraged the development of hospital patient safety culture and formal patient safety programs.
Initial patient event review	Licensee required to review event with emphasis on regulatory compliance, but it is unclear if the licensee has more time than by the next calendar day to make this review.	Personnel required to review event and report to hospital patient safety program to determine extent of review and process improvement needed for the event.
Timing of initial patient event review	It is unclear if the licensee has more time than by the next calendar day to make this review.	Personnel encouraged to report a patient event or near-miss at the time of the incident to evaluate need for process improvement.
Patient event reporting	Medical event reporting is required for NRC regulatory compliance.	Event reporting to AO or PSO is voluntary, but encouraged.
Reason to report event	Review NRC regulatory compliance.	Reporting viewed as non-punitive and part of process improvement in support of patient safety.

Example Topic	NRC	AOs or PSOs
Identity	Reporting information, including licensee identity, is posted on the NRC website and remains even if the event is later determined by the NRC not to be a medical event.	Reporting is anonymous to those outside the hospital, the patient or patient advocate, and the AO or PSO.
Extent of patient event review	Only covers NRC regulatory compliance.	Review covers overall patient safety and possible needs for process improvement.
Type of review	Review primarily driven by regulatory inspector focused on identifying areas of NRC non-compliance.	Hospital patient safety program includes staff qualified in patient safety, performance improvement, and root cause analysis who assist the medical staff in making and documenting their review.
Corrective actions	Focused on NRC regulatory compliance and kept minimal to avoid having additional regulatory compliance requirements imposed in the future.	Review used to encourage a culture of safety and to provide feedback and assistance to effectively minimize patient risk
Oversight expertise	Regulatory inspector trained in identifying NRC regulatory non-compliance.	AO or PSO have staff qualified in medical care, patient safety, performance improvement, and root cause analysis able to assist the hospital patient safety program.
Information sharing	Besides posting the event report on the NRC website, the NRC posts the inspection reports and notices of violations and licensee responses. If similar events occur, the NRC may issue a regulatory summary document alerting licensees or may initiate rulemaking to prevent future events.	AO or PSO provides database to track events, and provide education or tips on tools, best practices to prevent errors, and general patient safety initiatives to improve safety culture.

The Committee recommended at the April 27, 2017 ACMUI public meeting to continue future discussions on this topic. The Subcommittee will continue working on a report for the Fall 2017 ACMUI meeting to identify specific options the NRC may take to encourage a licensee's patient safety culture, while maintaining its regulatory authority to protect patients during medical use of byproduct materials.