Advisory Committee on the Medical Use of Isotopes (ACMUI)

Final Comments on Proposed Revision of the NRC Policy Statement on Reporting Abnormal Occurrences to Congress

November 6, 2015

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Charge: To review the proposed revision of the Nuclear Regulatory Commission (NRC) policy statement on reporting abnormal occurrences (AO) to Congress, and to provide comments and ACMUI recommendations on the application of the proposed AO criteria on events involving patients or human research subjects.

Need for Medical Abnormal Occurrence Criteria Update:

The Nuclear Regulatory Commission (NRC) is required to annually report abnormal occurrences to Congress as defined in Section 208 of the Energy Reorganization Act of 1974.[1] This section states:

> "For the purposes of this section an abnormal occurrence is an unscheduled incident or event which the Commission determines is significant from the standpoint of public health or safety."

Establishment of the NRC Policy Statement on Abnormal Occurrence Criteria[2] provides explanation of how the Commission determines the incidents or events to be significant and included in the annual abnormal occurrence (AO) report. The NRC Staff and the Advisory Committee on the Medical Use of Isotopes (ACMUI) have discussed concerns that the medical use-related incidents and events being included in AO reports may not be significant from the standpoint of public health or safety. During an ACMUI teleconference in December 2011[3], the ACMUI endorsed their 2008 position, which is summarized by the following: AOs for medical licensees should be events which result in death or threaten life; AOs should not capture those occurrences that are accepted risks of the treatment; AOs should be of significant adverse effect; AO criteria should be qualitative and not quantitative[4].

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[1] U.S. Energy Reorganization Act of 1974, as Amended (Public Law 93-438), pages 252-253, http://pbadupws.nrc.gov/docs/ML1327/ML13274A489.pdf#page=275 (accessed September 14, 2015).
[2] Nuclear Regulatory Commission, "Revised Policy Statement on Abnormal Occurrence Criteria," 71 FR 60198, October 12, 2006, http://www.gpo.gov/fdsys/pkg/FR-2006-10-12/pdf/E6-16871.pdf (accessed March 25, 2013).
[3] Official Transcript of Proceedings, Nuclear Regulatory Commission Advisory Committee on the Medical Use of Isotopes Teleconference, December 15, 2011, http://pbadupws.nrc.gov/docs/ML1206/ML12062A278.pdf (accessed March 25, 2013).
[4] Meeting Summary, Nuclear Regulatory Commission Advisory Committee on the Medical Use of Isotopes Teleconference, December 15, 2011, http://pbadupws.nrc.gov/docs/ML1135/ML11355A253.pdf (accessed April 4, 2013).

At the September 2012 ACMUI meeting[5], the NRC Staff asked the Committee to consider their proposal to add dose-based criteria for medical licensee AO criteria to allow the NRC Staff a screening tool to decide which medical events should then be evaluated by a consultant physician to determine significant adverse effect. During discussion of this proposal, the ACMUI again voiced their concerns of using dose-based criteria to judge medical AOs. The ACMUI established a subcommittee to develop recommendations concerning the AO criteria related to medical use incidents and events.

At the request of the NRC Staff, the ACMUI subcommittee submitted recommendations[6] in 2013 for revising AO criteria related to events involving patients or human research subjects and in particular to address the use of a screening tool to decide which medical events should be evaluated by a consultant physician to determine significant adverse effect.

The ACMUI report was included in the NRC Staff proposal presented to the Commission for revision of the AO policy statement[7]. The current NRC Policy Statement on Abnormal Occurrence Criteria is being revised[8] to "clarify and restructure the criteria used by the NRC and Agreement States for determining whether to consider an incident or event as an AO" and to "ensure consistency with current NRC guidance and regulations".

ACMUI continues to have concerns with the proposed AO criteria. Future medical use-related incidents and events as defined by the proposed criteria will most likely continue to not be significant from the standpoint of public health or safety.

Comments and Recommendations

The following comments and ACMUI recommendations are submitted in response to the NRC request for comment on the proposed revisions to its policy statement on reporting abnormal occurrences (AO) to Congress[8]. The Appendix Table attached to this report provides a comparison of these current comments and ACMUI recommended new wording to those portions of the 2006 version and the 2015 proposed changes to AO Statement of Policy for which ACMUI has commented previously.

1. Statement Introduction – The Subcommittee agrees that the general descriptions of what constitutes an AO should be included in the Statement of Policy and recommends no additional changes be made to this proposed change.

[5] Official Transcript of Proceedings, Nuclear Regulatory Commission Advisory Committee on the Medical Use of Isotopes Teleconference, September 21, 2012, http://pbadupws.nrc.gov/docs/ML1232/ML12324A222.pdf (accessed April 4, 2013).
[6] ACMUI, "Report on Abnormal Occurrence Criteria for Medical Use," April 15, 2013, http://pbadupws.nrc.gov/docs/ML1311/ML13117A002.pdf (accessed September 14, 2015).
[7] NRC SECY-15-0040, "Proposed Revisions to Policy Statement on Reporting Abnormal Occurrence Criteria," March 19, 2015, http://pbadupws.nrc.gov/docs/ML1216/ML12166A091.html (accessed September 14, 2015).
[8] NRC "Abnormal Occurrence Reports – Proposed Revision to Policy Statement; Request for Comments," 80 FR 49177, August 17, 2015, http://www.gpo.gov/fdsys/pkg/FR-2015-08-17/pdf/2015-20260.pdf (accessed September 14, 2015).

2. AO Criteria I. Title and Footnote – The Subcommittee agrees with the change in title for this AO Criteria I. and the addition of footnote 2. The Subcommittee recommends the wording for footnote 2 be changed as follows with deletions noted with ~~strikeout~~ and additions noted in **bold**:

> [2] Medical patients **and human research subjects** are excluded from consideration under this criterion and these criteria do not apply to ~~medical~~ events defined in § 35.3045 **and § 35.3047** of Title 10 of the Code of Federal Regulations (10 CFR), which are considered in AO Criteria III.C, ''Events involving the Medical Use of Radioactive Materials in Patients or Human Research Subjects.''

This change addresses the Subcommittee's recommendation that medical-related events reported under § 35.3047 be screened under AO Criteria III.C. to maintain consistency with NRC regulations because the event exposure was due to the medical use of byproduct material.

3. AO Criteria III.A. Title – The Subcommittee agrees with the change in title for this AO Criteria III.A.

4. AO Criteria III.C. Title – The Subcommittee agrees with the change in title for this AO Criteria III.C., but recommends changing "Radioactive" to "Byproduct" to be consistent with 10 CFR 35 regulations.

5. AO Criteria III.C. Footnote – The Subcommittee agrees with the addition of footnote 16 clarifying that AO Criteria III.A.2, III.A.3, and III.A.4 also apply to medical licensees. The application of these criteria will allow the NRC to identify as an AO those circumstances involving the loss of management controls demonstrated by multiple medical-related events even in the absence of any one event meeting the AO Criteria III.C.

6. AO Criteria III.C.1. and 2. – The Subcommittee recommends that the proposed AO Criteria III.C.1. and 2. be replaced with the following modified wording for III.C.1.:

> A**n** ~~medical~~ event, as defined in 10 CFR 35.3045 **or 35.3047**, which results in ~~a dose that,~~ **unintended permanent functional damage to an organ or a physiological system as determined by an independent physician[FN] deemed qualified by the NRC or an Agreement State.**
>
> **[FN]Independent physician is defined as a physician not on the licensee's staff and who was not involved in the care of the patient or human research subject involved in the event**.

This wording modification removes use of a dose criterion which may have identified events which have no evidence of probable consequence while possibly missing significant events which did not exceed the dose criterion but may have resulted in damage to an organ or physiological system. The addition of the requirement for an independent physician and the associated footnote is consistent with the statement and footnote used in AO Criterion I.A.3.

7. Cost of Independent Physician Review – The Subcommittee recommends that NRC Staff evaluates whether implementation of the Subcommittee's recommended AO Criterion III.C.1. would trigger additional cost beyond the cost of providing independent medical consultation in support of the regulatory review conducted for a § 35.3045 or § 35.3047 event.

8. Appendix B. Re-Designation and New Description – The Subcommittee agrees with the change in re-designating the previous AO Criteria IV. as the proposed Appendix B with the additional description for this new appendix to clarify that it is not part of the proposed AO Criteria.

Consideration of the Meaning of Abnormal in Abnormal Occurrences

The full Section 208 of the Energy Reorganization Act of 1974[9] (Act) is provided here.

> "**Sec. 208. Abnormal Occurrence Reports**
>
> The Commission shall submit to the Congress an annual report listing for the previous fiscal year any abnormal occurrences at or associated with any facility which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954 as amended, or pursuant to this Act. For the purposes of this section an abnormal occurrence is an unscheduled incident or event which the Commission determines is significant from the standpoint of public health or safety. Nothing in the preceding sentence shall limit the authority of a court to review the determination of the Commission. Each such report shall contain–
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> (1) the date and place of each occurrence;
> (2) the nature and probable consequence of each occurrence;
> (3) the cause or causes of each; and
> (4) any action taken to prevent reoccurrence;
>
> the Commission shall also provide as wide dissemination to the public of the information specified in clauses (1) and (2) of this section as reasonably possible within fifteen days of its receiving information of each abnormal occurrence and shall provide as wide dissemination to the public as reasonably possible of the information specified in clauses (3) and (4) as soon as such information becomes available to it."

The ACMUI notes that the Act grants the Commission full discretion in defining what it determines is significant in regard to public health and safety, but a court retains the authority to review the Commission's determination. As part of the annual report, the probable consequences and actions taken to prevent reoccurrence are to be included for each AO.

The Subcommittee updated the list of medical use-related (i.e., those reported as 10 CFR 35.3045 or 35.3047 events) AOs reported to Congress since 2007, as summarized in Table 1.

[9] U.S. Energy Reorganization Act of 1974, as Amended (Public Law 93-438), pages 252-253, http://pdadupws.nrc.gov/docs/ML1327/ML13274A489.pdf#page=275 (accessed September 14, 2015).

Table 1: Abnormal Occurrences Reported to Congress

FY	All AO	AO I.A.2. ① from 10 CFR 35.3047	AO III.C. ② from 10 CFR 35.3045
2014[10]	13	1	12⑤
2013[11]	10	2	8
2012[12]	22	1	19④
2011[13]	24	2	19
2010[14]	15	3	12 ③
2009[15]	9	2	7
2008[16]	10	2	8 ③
2007[17]	11	1	10

① Each AO listed here involved one I-131 therapy patient who following her therapy was found to be in early stage pregnancy (approximately 1 to 10 weeks) at the time of her therapy.

② Each AO listed here involved one or two radiation therapy patients per medical licensee, except as noted.

③ One AO in this total involved three or more radiation therapy patients at one medical licensee.

④ Two AOs in this total involved three or more radiation therapy patients at one medical licensee.

⑤ One AO in this total (AS14-12) involved a patient who passed away. However, the cause of death and any potential association with the medical event are being evaluated.

[10] NUREG-0090, Vol. 37, "Report to Congress on Abnormal Occurrences – Fiscal Year 2014," Nuclear Regulatory Commission, http://pbadupws.nrc.gov/docs/ML1514/ML15140A285.pdf (accessed August 23, 2015).
[11] NUREG-0090, Vol. 36, "Report to Congress on Abnormal Occurrences – Fiscal Year 2013," Nuclear Regulatory Commission, http://pbadupws.nrc.gov/docs/ML1415/ML14150A073.pdf (accessed August 23, 2015).
[12] NUREG-0090, Vol. 35, Rev 1 "Report to Congress on Abnormal Occurrences – Fiscal Year 2012," Nuclear Regulatory Commission, http://pbadupws.nrc.gov/docs/ML1322/ML13225A395.pdf (accessed August 23, 2015).
[13] NUREG-0090, Vol. 34, "Report to Congress on Abnormal Occurrences – Fiscal Year 2011," Nuclear Regulatory Commission, http://pbadupws.nrc.gov/docs/ML1214/ML12142A194.pdf (accessed August 23, 2015).
[14] NUREG-0090, Vol. 33, "Report to Congress on Abnormal Occurrences – Fiscal Year 2010," Nuclear Regulatory Commission, http://pbadupws.nrc.gov/docs/ML1117/ML11172A088.pdf (accessed August 23, 2015).
[15] NUREG-0090, Vol. 32, "Report to Congress on Abnormal Occurrences – Fiscal Year 2009," Nuclear Regulatory Commission, http://pbadupws.nrc.gov/docs/ML1020/ML102080078.pdf (accessed August 23, 2015).
[16] NUREG-0090, Vol. 31, "Report to Congress on Abnormal Occurrences – Fiscal Year 2008," Nuclear Regulatory Commission, http://pbadupws.nrc.gov/docs/ML0915/ML091540747.pdf (accessed August 23, 2015).
[17] NUREG-0090, Vol. 30, "Report to Congress on Abnormal Occurrences – Fiscal Year 2007," Nuclear Regulatory Commission, http://pbadupws.nrc.gov/docs/ML0813/ML081300424.pdf (accessed August 23, 2015).

Only the 2011 and 2012 annual reports included AOs not related to Part 35 events (AS11-02, AS11-03, NRC11-02, AS12-02, and NRC12-01). Most of the medical use-related AO descriptions conclude that no adverse health effects are expected.

Since the previous revision of the AO criteria policy in 2006, 96% of the AOs reported to Congress are medical use-related, with an average of 2 per year reported under §35.3047 and 14 per year reported under §35.3045. The Subcommittee explored the NRC efforts in addressing how to reduce the number of these medical use-related abnormal events. One of these efforts is the Commission's revision of the AO criteria policy to clarify and restructure the criteria to be consistent with current NRC guidance and regulations. Another one of NRC's efforts is the current 10 CFR 35 rulemaking where changes to 10 CFR 35.3045 medical event criteria are being considered. The Subcommittee also reviewed the current NRC Strategic Plan for Fiscal Years 2014-2018[18] and the NRC Project Aim 2020 documents[19] for mention of medical use of byproduct material and indication of plans to reduce medical use-related AOs. Table 2 shows the results of searching for the term "medical" in these NRC planning documents. Based on this review, the Subcommittee concluded that while the Commission considers certain medical use-related events to be abnormal, it appears that their significance do not warrant further NRC intervention beyond the current changes being considered for AO criteria and medical event criteria.

Table 2: Use of the Term "Medical" in NRC Planning Documents

Document	Page number	Topic Using the Term "Medical"
NRC Strategic Plan Fiscal Year 2014-2018	1	What NRC regulates
	2	Number of research, medical, industrial, government, academic materials licensees
	4	Isotope production
	10	Isotope production
	30	Definition of byproduct material
	31	Definition of byproduct material
NRC AIM 2020	9	Isotope production
	10, 2 times	Isotope production
	18	Wellness program for NRC Employees
	Encl 1, 4	Example of 3D printing
	Encl 1, 8	World economy & costs of healthcare

[18] NRC "Strategic Plan, Fiscal Years 2014-2018", September 4, 2014, http://pbadupws.nrc.gov/docs/ML1424/ML14246A439.pdf (accessed September 14, 2015).
[19] NRC SECY-15-0015, "Project Aim 2020 Report and Recommendations", January 30, 2015, http://pbadupws.nrc.gov/docs/ML1502/ML15023A558.html (accessed September 14, 2015)

The National Council on Radiation Protection and Measurements (NCRP) published a report[20] in 2009 updating its estimates on the annual average U.S. exposure to radiation. As part of its analysis of exposure to man-made radiation sources, the NCRP reported the number of medical procedures shown in Table 3 which utilized byproduct materials as listed in the NCRP report Table D.3 for 2004 Medicare data.

Also included in Table 3 are estimated numbers of medical procedures utilizing radiation for medical therapy patients from the IMV Benchmark Report Radiation Therapy October 2010 report[21].

Comparison of the annual number of AOs reported to Congress (Table 1) to the number of medical procedures utilizing byproduct materials each year (Table 3) shows the low number of procedures which rise to the AO-significant reporting level (~0.1%). The Commission's establishment of AO Criteria is done to meet the Act's requirements in Section 208 to provide abnormal occurrence reports. The regulations in 10 CFR 35.3045 and 35.3047 define the criteria and review process which NRC has established to regulate the radiation safety of patients to assure the use of byproduct materials is in accordance with the physician's directions.

Table 3: Medical Procedures Utilizing Byproduct Material

Type of Medical Procedure	Number in year noted
Total diagnostic nuclear medicine procedures*	5,048,231
Thyroid diagnostic nuclear medicine procedures (2% of total)*	99,457
Total nuclear-medicine unsealed-radionuclide therapy procedures*	17,660
Nuclear-medicine unsealed-radionuclide thyroid therapy procedures (92% of total)*	16,159
Estimated external beam therapy procedures*	<900,000
Estimated total number of radiation therapy patients, excluding unsealed-radionuclide therapy**	1,092,157
Estimated total number of patients receiving radiation therapy from byproduct materials, excluding unsealed-radionuclide therapy (~8% of total number of radiation therapy patients)**	~90,000
% by gamma knife therapy**	~35%
% by other Co-60 therapy**	<1%
% by permanent implant therapy**	~23%
% by temporary implant therapy**	~5%
% by high dose rate remote after-loader therapy**	~36%

[20] NCRP Report No. 160, "Ionizing Radiation Exposure of the Population of the United States," March 3, 2009.
[21] IMV Benchmark Report Radiation Therapy October 2010, IMV Medical Information Division, Inc.

* From NCRP Report No. 160 for 2004 data

** From IMV Benchmark Report Radiation Therapy October 2010 report

Comment on Proposed Abnormal Occurrence (AO) Statement of Policy

The Subcommittee presents the following comments on the Commission's proposed changes to the AO criteria impacting events involving patients or human research subjects not to reduce the number of medical use-related (i.e., those reported as 10 CFR 35.3045 or 35.3047 events) AOs reported to Congress, but to provide ACMUI recommendations as requested for clarity and consistency with NRC guidance and regulations.

The Appendix Table attached to this report provides a comparison of portions of the AO Statement of Policy which ACMUI has commented on previously and now provides comments and recommended new wording for the 2015 proposed AO Criteria Policy change[22]. The bases for these comments and ACMUI recommended new wording are summarized here.

1. Statement Introduction

   The Subcommittee noted that the Commission has included general descriptions of what constitutes an AO into the Statement of Policy. These general descriptions had been included in the 2006 Federal Register publication of the current AO Criteria Policy. The Subcommittee agrees that the general descriptions of what constitutes an AO should be included in the Statement of Policy and recommends no additional changes be made to this proposed change.

2. AO Criteria I. Title and Footnote

   The Subcommittee agrees with the change in title for this AO Criteria I. The addition of the footnote clarifies that AO Criteria I.A. does not apply to medical patients and directs the reader to AO Criteria III.C. The Subcommittee recommends the addition of "… and human research subjects…" to be consistent with NRC regulations. The Subcommittee also recommends that events defined in 10 CFR 35.3047 "Report and notification of a dose to an embryo/fetus or a nursing child" be added to this footnote. This footnote addition of §35.3047 would take the place of the 2013 ACMUI recommendation to add AO Criterion I.A.4.

   The NRC request for comment on the 2015 proposed AO Criteria Policy specifically requests public comment on use of AO Criteria I.A.2. versus use of AO Criteria III.C. and §35.3047 criteria for screening reports on exposures to embryo/fetus or nursing child. The NRC policy statement on the medical use of byproduct material[23] includes the following statements:

   > "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."

[22] NRC "Abnormal Occurrence Reports – Proposed Revision to Policy Statement; Request for Comments," 80 FR 49177, August 17, 2015, http://www.gpo.gov/fdsys/pkg/FR-2015-08-17/pdf/2015-20260.pdf (accessed September 14, 2015).

[23] NRC "Medical Use of Byproduct Material; Policy Statement, Revision", August 3, 2000 (65 FR 47654), http://www.nrc.gov/reading-rm/doc-collections/commission/policy/65fr47654.pdf (accessed September 14, 2015).

and

"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."

The NRC has no dose limit established for patients[24]. Medical judgements on the use of byproduct materials reside with the physician and the patient, and the patient's condition of pregnancy is included in these medical judgments. NRC regulations recognize pregnancy as part of a patient's medical condition in §35.3047(a):

"A licensee shall report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of byproduct material or radiation from byproduct material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user."

To maintain consistency with NRC regulations, screening of event reports from §35.3047 criteria should be further screened using the AO Criteria III.C. established for the medical use of radioactive materials in patients or human research subjects.

3. AO Criteria III.A. Title

The Subcommittee agrees with the change in title for this AO Criteria III.A

4. AO Criteria III.C. Title

The Subcommittee agrees with the change in title for this AO Criteria III.C., but recommends changing "Radioactive" to "Byproduct" to be consistent with 10 CFR 35 regulations.

5. AO Criteria III.C. Footnote

The Subcommittee agrees with the addition of footnote 16 clarifying that AO Criteria III.A.2, III.A.3, and III.A.4 also apply to medical licensees. The application of these criteria will allow the NRC to identify as an AO in particular those circumstances involving loss of management controls demonstrated by multiple medical-related events even in the absence of any one event meeting the criteria of AO Criteria III.C.

6. AO Criteria III.C.1. and 2.

The Subcommittee acknowledges and appreciates that the Commission attempted to modify the dose criteria in AO Criteria III.C.1.b. to a value that exceeds the expected dose, but fundamental flaws remain. The Subcommittee again recommends that a dose criterion not be used in determining AOs for medical-related events.

[24] The Food and Drug Administration (FDA) has established dose limits for human research subjects in 21 CFR 361.1(b)(3).

Improved precision of radiation therapy delivery, as in external beam therapy, increases the likelihood of delivering dose to nearby tissues that exceeds the proposed dose criterion in III.C.1.b. if the beam location is off even slightly, but this slight shift in dose is most often without consequence and may not even be recognized. It also is important to be cognizant of the fact that the use of a dose criterion can exclude an event that results in unintended permanent functional damage to an organ or physiological system but does not exceed the dose criterion. Dose to other tissues or organs can be a known risk or side effect associated with the medical procedure and the physician discusses these types of risk and side effects with the patient as part of the combined medical and personal decision about whether or not to perform the procedure. The ACMUI recently provided recommendations[25] on NRC guidance regarding side effects associated with Y-90 microsphere radiotherapy.

In view of the targeted nature of external radiotherapy techniques currently in use, the inclusion of an undefined phrase, "a major portion of the bone marrow", in III.C.1.a. is too vague a dose criterion without evidence of probable consequence. The proposed dose criterion in III.C.1.b. of exceeding a given expected dose to any other organ or tissue does not have the same meaning for high dose rate precision radiotherapy techniques in use today (modern techniques) as it did when it was applied to past radiotherapy techniques (old techniques) in use at the time of the 2002 update[26] of 10 CFR 35. Using the old techniques, most patients were treated to the isocenter and any dose error was to that same point, which was in the middle of a relatively uniform field. Slight changes in beam location had little effect on dose to the target and nearby tissues and organs. Modern techniques, in contrast, specify the treatment dose at the periphery, not at the middle of the treatment volume. In addition, the penumbra for modern techniques is only a few millimeters, which is smaller than the 2 centimeter penumbra for old techniques. Consequently, moving a modern technique field, even just a few millimeters, can result in an under-dose to the target and a significantly increased dose to nearby tissues or some of a nearby organ. Invariably there is a certain amount of natural movement of the target location within a patient, and consequently, isocenter movement and field movement have always been within normal treatment uncertainties. The modern techniques of precise beam shaping have benefitted patients immensely. The medical event criteria applied to external beam therapies have not been modified to reflect this change in radiotherapy precision.

The Subcommittee recommends that the proposed AO Criteria III.C.1. and 2. be replaced with the following wording for III.C.1.:

> A**n** ~~medical~~ event, as defined in 10 CFR 35.3045 **or 35.3047**, which results in ~~a dose that,~~ **unintended permanent functional damage to an organ or a physiological system as determined by an independent physician[FN] deemed qualified by the NRC or an Agreement State.**

[25] "ACMUI Final Report on Yttrium-90 (Y-90) Microsphere Brachytherapy Medical Event Criteria", September 29, 2014, http://pbadupws.nrc.gov/docs/ML1430/ML14300A138.pdf (accessed September 19, 2015)
[26] NRC "Medical Use of Byproduct Material – Final Rule," 67 FR 20250, April 24, 2002, http://www.gpo.gov/fdsys/pkg/FR-2002-04-24/pdf/02-9663.pdf (accessed September 19, 2015)

[FN]Independent physician is defined as a physician not on the licensee's staff and who was not involved in the care of the patient or human research subject involved in the event.

This general criterion is modified to include medical-related events reported under § 35.3047. Along with the Commission's proposed modification to apply AO Criteria III.A.2., 3. and 4., the Subcommittee reviewed the AOs listed in Table 1 that were identified as medical-use events under the current AO Criteria I.A.2.[27] Most of the female patients were described in the AO annual reports as indicating they were not pregnant which the Subcommittee assumed to be part of patient's process of informed consent prior to their I-131 NaI therapy. In all but one of these events, the patient was later found to be in early stage of pregnancy (approximately 1 to 10 weeks) at the time of her therapy. The Subcommittee applied the recommended AO Criteria changes to these reported AOs and came to the following conclusions.

- The one event noted above, AS10-01, involved a patient who was 6 months pregnant at the time of her I-131 therapy. The patient indicated that she was not pregnant and the licensee decided not to perform a pregnancy test. An independent physician review is not described in this AS10-01 event report, but the full-term child was described as being born without a thyroid. This event would be identified as an AO with the recommended AO criteria changes.

- Another event, AS14-01, which did not involve a probable negative consequence to the embryo/fetus. This event should be identified as an AO based on III.A.4. because the miscommunication indicates a series of events with implications for similar facilities (generic incidents) that raise a major safety concern.

- The remaining AOs listed in Table 1 from § 35.3047 events occurred as the result of the failure of the pregnancy test to confirm pregnancy in close proximity to conception. While there may lessons to learn from these § 35.3047 events, such as changing to a more sensitive pregnancy test identified in NRC08-01 and AS09-02, or emphasizing to the patient the need to abstain from unprotected intercourse for a time prior to her I-131 therapy identified in AS08-01, NRC11-01, and AS13-01, the Subcommittee recommends that these § 35.3047 events not be identified as abnormal occurrences due the extensive review of the event already performed under the § 35.3047 regulatory requirement and due to the lack of probable negative consequences.

The Subcommittee suggests that the regulatory reviews conducted for the § 35.3045 and § 35.3047 events to identify unintended permanent functional damage to an organ or a physiological system are similar to the reviews conducted under 10 CFR 70.61 to identify high-consequence events for facilities licensed under 10 CFR part 70 and used in AO Criterion III.B.1.

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[27] "I. For All Licensees
A. Human Exposure to Radiation from Licensed Material
2. Any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual TEDE of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more."

Therefore, the Subcommittee advises the Commission to adopt the recommended wording for AO Criterion III.C.1. presented above to be consistent in applying AO criteria with NRC regulations.

7. Additional Cost of Independent Physician

The Subcommittee notes that the Commission raised concern that the requirement to consult with an independent physician was being recommended only to reduce the number of AOs reported to Congress[28]. The consultation of an independent physician is an important aspect of the regulatory reviews conducted for the § 35.3045 and § 35.3047 events to confirm the medical evaluations for the event. This independent medical evaluation is particularly important when there is a concern that the event may result in permanent functional damage. This independent medical review is also essential to evaluating the application of AO Criteria III.A. 2., 3., or 4. to the medical-related event. The Subcommittee believes that an independent physician review of a medical-related event be required as part of the NRC determination that the event is an abnormal occurrence. The NRC has established program[29] and procedures for assessing § 35.3045 and § 35.3047 events which includes when and how to consult with an independent physician[30]. The Subcommittee recommends that NRC Staff evaluates whether implementation of the Subcommittee's recommended AO Criterion III.C.1. would trigger additional cost beyond the cost of providing independent medical consultation in support of the regulatory review conducted for a § 35.3045 or § 35.3047 event.

8. Appendix B. Re-Designation and New Description

The Subcommittee agrees with the change in re-designating the previous AO Criteria IV. as the proposed Appendix B with the additional description for this new appendix to clarify it is not part of the proposed AO Criteria.

[28] Commission Voting Record on SECY-15-0040 "Proposed Revisions to Policy Statement on Reporting Abnormal Occurrences Criteria", June 30, 2015, http://pbadupws.nrc.gov/docs/ML1518/ML15181A141.pdf (accessed on September 15, 2015).
[29] NRC Medical Directive 8.10 "NRC Assessment Program for a Medical Event or an Incident Occurring at a Medical Facility", March 28, 2014, http://pbadupws.nrc.gov/docs/ML1330/ML13301A732.pdf (accessed on September 15, 2015).
[30] NRC Inspection Manual Chapter 1360 "Use of Physician and Scientific Consultants in the Medical Consultant Program", November 2, 2006, http://pbadupws.nrc.gov/docs/ML0627/ML062720195.pdf (accessed on September 15, 2015).

Conclusion:

Given the unique nature of the medical use of by-product material, where by-product material is intentionally administered to patients or research subjects it is important to include a qualitative analysis of a proposed AO. As doses measured above a set limit may or may not be accurate in measuring a meaningful effect. The proposed AO criteria will most likely continue to miss-categorize future medical use related incidents and events as not meaningful or significant. The 2015 ACMUI recommendations as listed in Appendix A have been designed to categorize future medical use related incidents and events to be meaningful and significant from the standpoint of public health or safety. ACMUI believes these appropriately categorized abnormal occurrences will fully meet the intent and spirit of the reporting requirements of the Energy Reorganization Act of 1974

Endorsement

This report was presented and discussed with the full Committee on October 09, 2015. During the meeting, the Committee approved the report with nine approvals and one dissenting vote.

The dissension opinion is included in the Enclosure.

October 26, 2015
Dissenting vote justification

Subcommittee Comments on Proposed Revision of the NRC Policy Statement on Reporting Abnormal Occurrences to Congress

The subcommittee recommends the footnote:
"Medical patients **and human research subjects** are excluded from consideration under this criterion and these criteria do not apply to ~~medical~~ events defined in § 35.3045 **and § 35.3047** of Title 10 of the Code of Federal Regulations (10 CFR), which are considered in AO Criteria III.C, ''Events involving the Medical Use of Radioactive Materials in Patients or Human Research Subjects.''

This creates two distinct Congressional reporting standards for radiation exposure to an embryo/fetus. One is the standard of exposure of TEDE of 5 rem or more, as defined in Criteria I (2), and the other is the proposed threshold of permanent functional damage or worse in the situation where the embryo/fetus is exposed as a result of a medical administration to a pregnant woman.

Creating two different thresholds for reporting an abnormal occurrence to Congress involving exposure to an embryo/fetus does not seem rational. The reasoning behind creating a less stringent threshold for reporting in the case of an unintended exposure of an embryo/fetus due to an intended medical administration should not trump the regulatory need to require reporting of exposures of 5 rem or more as outlined in the existing AO criteria. The argument that the embryo/fetus has an indirect benefit, pertaining to the health of the mother, is not compelling. There is no intended direct benefit to the embryo/fetus, and the embryo/fetus is not the intended recipient of medical administration of radioactive material.

Furthermore, there is considerable dissent among professionals as to whether or not, and the degree to which, an embryo/fetus is actually harmed by exposure to radioactive material, irrespective of gestational age. Therefore I vote against the Subcommittee recommendations, as I believe that the unintentional medical exposure of an embryo/fetus should not be held to a different standard for Abnormal Occurrence reporting than any other exposed embryo/fetus. Permanent harm or damage to the embryo/fetus due to radiation exposure is a controversial subject, and should not be an added requirement to register such an unintended medical exposure as an Abnormal Occurrence.

Respectfully submitted,
Laura Weil

Appendix Table
Comparison of Portions of the Abnormal Occurrence (AO) Criteria Policy

2006 Abnormal Occurrence (AO) Criteria Policy	**2013 ACMUI AO Criteria Recommendations on 2006 AO Policy**	**2015 Proposed AO Criteria Policy changes versus 2006 AO Criteria Policy**	**2015 ACMUI AO Criteria Recommendations on 2015 Proposed AO Criteria Policy -** deletions noted by ~~strikeout~~ and additions by **bold text**
APPENDIX A: Abnormal Occurrence Criteria	No change	No change	No change
The following criteria are used to determine whether to consider events for reporting as AOs:	No change	An accident or event is considered an abnormal occurrence (AO) if it involves a major reduction in the degree of protection of public health or safety. This type of incident or event has a moderate or severe impact on public health or safety and could include, but need not be limited to, the following:	No change
(1)		Moderate exposure to, or release of, radioactive material licensed by or otherwise regulated by the Commission or Agreement States;	No change
(2)		major degradation of essential safety related equipment;	No change
(3)		major deficiencies in design, construction, use of, or management controls for facilities or radioactive material licensed by or otherwise regulated by the Commission or Agreement States; or	No change
(4)		substantiated case of actual loss, theft, or diversion of risk-significant radioactive material licensed by or otherwise regulated by the Commission or Agreement States.	No change

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I. For All Licensees	No change	All Licensees [2]	No change
FN added		[2] Medical patients are excluded from consideration under this criterion and these criteria do not apply to medical events defined in § 35.3045 of Title 10 of the Code of Federal Regulations (10 CFR), which are considered in AO Criteria III.C, ‘‘Events involving the Medical Use of Radioactive Materials in Patients or Human Research Subjects.’’	[2] Medical patients **and human research subjects** are excluded from consideration under this criterion and these criteria do not apply to ~~medical~~ events defined in § 35.3045 **and § 35.3047** of Title 10 of the Code of Federal Regulations (10 CFR), which are considered in AO Criteria III.C, ‘‘Events involving the Medical Use of Radioactive Materials in Patients or Human Research Subjects.’’
A. Human Exposure to Radiation from Licensed Material	No change	No change	No change
2. Any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual TEDE of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more.	No change	No change	No change
4.	These criteria do not apply to events included in criteria III.C. involving medical administrations using byproduct material to patients or human research subjects.		[withdraw 2013 recommendation as it is addressed by the recommended wording of FN2]

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III. Events at Facilities Other Than Nuclear Power Plants and All Transportation Events	No change	No change	No change
A. Events Involving Design, Analysis, Construction, Testing, Operation, Transport, Use, or Disposal of Licensed Facilities or Regulated Materials	No change	Events Involving Design, Analysis, Construction, Testing, Operation, Transport, Use, or Disposal	No change
2. A major deficiency in design, construction, control, or operation having significant safety implications that require immediate remedial action.	No change	No change	No change
3. A serious safety-significant deficiency in management or procedural controls.	No change	No change	No change
4. A series of events (in which the individual events are not of major importance), recurring incidents, or incidents with implications for similar facilities (generic incidents) that raise a major safety concern.	No change	No change	No change

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C. For Medical Licensees - A medical event that:	For Events Involving Patients or Human Research Subjects	Events Involving the Medical Use of Radioactive Materials in Patients or Human Research Subjects [16]	Events Involving the Medical Use of ~~Radioactive~~**Byproduct** Materials in Patients or Human Research Subjects[16]
FN added		[16] Criteria III.A.2, III.A.3, and III.A.4 also apply to medical licensees.	[agree with addition of FN16]
1. Results in a dose that is	Medical event involving a patient or human research subject that, as determined by a consultant physician(s) deemed qualified by NRC or an Agreement State, results in one or more of the following:	A medical event, as defined in 10 CFR 35.3045, which results in a dose that:	An ~~medical~~ event, as defined in 10 CFR 35.3045 or 35.3047, which results in ~~a dose that,~~ unintended permanent functional damage to an organ or a physiological system as determined by an independent physician[FN] deemed qualified by the NRC or an Agreement State.
FN added			[FN]Independent physician is defined as a physician not on the licensee's staff and who was not involved in the care of the patient or human research subject involved in the event.
a. Equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow or to the lens of the eye; or equal or greater than 2.5 Gy (250 rad) to the gonads; or	Unintended or unexpected permanent functional damage to an organ.	Is equal to or greater than 1 Gray (Gy) (100 rad) to a major portion of the bone marrow or to the lens of the eye; or equal or greater than 2.5 Gy (250 rad) to the gonads; or	~~Is equal to or greater than 1 Gray (Gy) (100 rad) to a major portion of the bone marrow or to the lens of the eye; or equal or greater than 2.5 Gy (250 rad) to the gonads; or~~
b. Equal to or greater than 10 Gy (1,000 rad) to any other organ or tissue; and	Unintended or unexpected permanent functional damage to a physiological system.	exceeds, by 10 Gy (1,000 rad), the expected dose to any other organ or tissue from the administration defined in the written directive; and	~~exceeds, by 10 Gy (1,000 rad), the expected dose to any other organ or tissue from the administration defined in the written directive; and~~

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c.	A significant unexpected adverse health effect.		
d.	Death.		
2. Represents either	Notification under 10 CFR 35.3047 of an event involving an unintended dose to an embryo/fetus or a nursing child that results in a significant adverse health impact to the embryo/fetus or child, as determined by a consultant physician(s) deemed qualified by NRC or an Agreement State.	A medical event, as defined in 10 CFR 35.3045, which involves:	~~A medical event, as defined in 10 CFR 35.3045, which involves:~~
a. A dose or dosage that is at least 50 percent greater than that prescribed, or	[delete 2.a. with recommended change in 2.]	No change	~~A dose or dosage that is at least 50 percent greater than that prescribed, or~~
b. A prescribed dose or dosage that	[delete 2.b. with recommended change in 2.]	No change	~~A prescribed dose or dosage that~~
(i) Uses the wrong radiopharmaceutical or unsealed byproduct material; or	[delete 2.b. (i) with recommended change in 2.]	No change	~~Uses the wrong radiopharmaceutical or unsealed byproduct material; or~~
(ii) Is delivered by the wrong route of administration; or	[delete 2.b. (ii) with recommended change in 2.]	No change	~~Is delivered by the wrong route of administration; or~~
(iii) Is delivered to the wrong treatment site; or	[delete 2.b. (iii) with recommended change in 2.]	No change	~~Is delivered to the wrong treatment site; or~~
(iv) Is delivered by the wrong treatment mode; or	[delete 2.b. (iv) with recommended change in 2.]	No change	~~Is delivered by the wrong treatment mode; or~~
(v) Is from a leaking source or sources; or	[delete 2.b. (v) with recommended change in 2.]	No change	~~Is from a leaking source or sources; or~~

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(vi) Is delivered to the wrong individual or human research subject.	[delete 2.b. (vi) with recommended change in 2.]	No change	~~Is delivered to the wrong individual or human research subject.~~

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IV. Other Events of Interest	No change	Appendix B: Other Events of Interest	No change
The Commission may determine that events other than AOs may be of interest to Congress and the public and should be included in an appendix to the AO report as "Other Events of Interest." Such events may include, but are not necessarily limited to, events that do not meet the AO criteria but that have been perceived by Congress or the public to be of high health and safety significance, have received significant media coverage, or have caused the NRC to increase its attention to or oversight of a program area, or a group of similar events that have resulted in licensed materials entering the public domain in an uncontrolled manner.	No change	This appendix discusses other events of interest that do not meet the AO criteria in Appendix A. The Commission may determine that events, other than AOs, may be of interest to Congress and the public and should be included in an appendix to the AO report as ''Other Events of Interest.'' Such events may include, but are not necessarily limited to, events that do not meet the AO criteria but that have been perceived by Congress or the public to be of high health and safety significance, have received significant media coverage, or have caused the NRC to increase its attention to or oversight of a program area, or a group of similar events that have resulted in licensed materials entering the public domain in an uncontrolled manner.	No change