November 17, 2014

Attn: Rulemakings and Adjudications Staff
Secretary, U.S. Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, Maryland 20852

Subject: Medical Use of Byproduct Material-Medical Event Definitions, Training and Experience, and Clarifying Amendments; Comments of the American College of Radiology (Docket ID: NRC-2008-0175; 79 FR 42409)

The American College of Radiology (ACR)—a professional organization representing more than 35,000 radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists—appreciates the opportunity to comment on the U.S. Nuclear Regulatory Commission's (NRC) Notice of Proposed Rulemaking (NPRM), "Medical Use of Byproduct Material-Medical Event Definitions, Training and Experience, and Clarifying Amendments," published in the *Federal Register* on July 21, 2014 (79 FR 42409).

As a general comment, the ACR supports the formal recommendations and feedback of the NRC Advisory Committee on the Medical Uses of Isotopes (ACMUI) pertaining to this rulemaking, including the committee's recommendations over the years on the various subtopics. The ACMUI is comprised of recognized experts in their field who are committed to the safe use of nuclear material in medicine and who also understand the clinical and operational issues associated with daily medical practice. Furthermore, the ACMUI has been receptive to divergent view points, has attempted to achieve consensus when possible, and has recognized minority viewpoints in an open and transparent process. We strongly recommend that NRC implement the ACMUI's recommendations in the final rule wherever there is disagreement between the NPRM content and the committee's input.

10 CFR 35.3045 - Report and Notification of a Medical Event

The ACR supports the proposed modifications to §35.3045 to use activity instead of absorbed dose for determining medical events (MEs) during permanent implant brachytherapy procedures. Likewise, we agree that reportable MEs should be of sufficient significance to outweigh the administrative burden of reporting, and more importantly, any stress or confusion for patients, their families, and the extended care team. Additionally, we agree with the guiding principle that ME thresholds for permanent implant

brachytherapy should enable physician discretion and intended variance.

The ACR strongly supports the proposed designation of Compatibility Category B for §35.3045, thereby requiring Agreement States to adopt ME reporting and notification program elements essentially identical to NRC's. While we appreciate the challenges of revising state regulations, it would be counterproductive for Agreement States to maintain alternative ME criteria not listed in the revised §35.3045. If dose-based ME reporting and notification criteria were interpreted by the States as more "restrictive," and thus states continued to have some manner of ill-fitting ME methodology, this would significantly confuse the regulated community and continue to weaken confidence in the significance of reported permanent brachytherapy MEs.

Thus, if NRC were to revert to a lower-than-proposed Compatibility Category, we would then recommend as a last resort that NRC explicitly state in the preamble of the final rule that activity-based ME metrics are an essential program element, and that dose-based metrics are unacceptable for use. Absorbed dose-based ME metrics are not "more restrictive" per se, but instead unsuitable and confusing when misapplied to the specific procedures in question.

10 CFR 35.40 - Written Directives

The ACR supports NRC's proposal to allow modification of the Written Directive documentation based on the medical situation encountered by the physician during the permanent implant brachytherapy procedure. This proposal aligns with the dynamic intraoperative decision-making and technique characteristic of these procedures.

10 CFR 35.41(b)(6) - Procedures for Administrations Requiring a Written Directive

ACR believes the post-procedure dosimetric evaluation of each permanent implant brachytherapy patient within 60 calendar days of when the procedure was performed is generally appropriate. However, we are concerned that there may be other obstacles to meeting this requirement beyond patient unavailability that should be permitted with an appropriate written justification. We recommend that the language be modified to "unless accompanied by a written justification related to patient unavailability or other factor reasonably outside the control of the licensee."

10 CFR 35 [Multiple] - T&E Requirements for AUs, AMPs, RSO, and ANPs

The ACR supports the proposal, supported by years of discussion and recommendations from the NRC ACMUI, to eliminate the preceptor attestation requirement for individuals seeking authorized status via the board certification pathway. We agree that the preceptor attestation requirement has proven to be redundant for approved board certified professionals.

For a non-board certified professional seeking an authorized status via the alternate pathway, we support the NRC's proposal to require the written attestation to "verify that the individual can independently fulfill the radiation safety-related duties," rather than has "achieved a level of competency to function independently." The term competency has certain implications and liabilities in

the medical domain which should not factor into an attestation statement meant to assure regulators that the individual received an adequate amount of radiation safety-specific T&E.

PRM-35-20 - "Ritenour Petition" - Proposed Implementation

As an original supporter of the Ritenour Petition for Rulemaking (PRM-35-20), the ACR also agrees with NRC's proposal to "grandfather" all professionals who met the requirements of the previous Subpart J for an AU, RSO, AMP, or ANP before that subpart was eliminated on October 24, 2005. We agree that preceptor attestations should not be required for these "grandfathered" individuals.

Moreover, instead of using the verbiage "for the modalities that they practiced October 24, 2005," the ACR recommends that the NRC implement the ACMUI-recommended verbiage "for the uses [or procedures] covered by their board certification on October 24, 2005." This would help eliminate any potential uncertainty or subjectivity around what the term "practiced" means, as well as avoid introducing a new administrative problem of requiring individuals to find documentation proving which procedures they actively practiced nearly a decade ago.

10 CFR 35.3204 - Report and Notification for an Eluate Exceeding Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations

The ACR recommends that NRC implement the ACMUI recommendation to only require licensees to report generator elution results with parent breakthrough beyond the §35.204 limits to the manufacturer/distributor, and not to both the manufacturer/distributor and the NRC. The manufacturer/distributor alone should be responsible for reporting the out-of-tolerance parent breakthroughs to the NRC. Requiring the licensee to report to both the company and the NRC, while the company also reports to NRC, is unnecessarily duplicative. If the NRC seeks redundancy, the duplicative licensee report to the NRC should be encouraged but not required.

Thank you in advance for your consideration of these comments. As always, the American College of Radiology welcomes the opportunity for continued dialogue with the NRC on all medical use issues. Should you have any questions on the points addressed herein, or if we can otherwise be of assistance, please do not hesitate to contact Gloria Romanelli, ACR Senior Director of Government Relations, at 703-716-7550, or Michael Peters, ACR Director of Legislative and Regulatory Affairs, at 703-716-7546.

Sincerely,

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Chair, Board of Chancellors
American College of Radiology