Analysis of Public Comments on
DRAFT NRC REGULATORY ISSUE SUMMARY 2020-XX, "USE OF ELECTRONIC SIGNATURES BY MEDICAL LICENSEES ON INTERNAL DOCUMENTS" (ADAMS Accession No. ML20279A425)

Comments on the subject draft regulatory issue summary (RIS) are available electronically at the U.S. Nuclear Regulatory Commission's (NRC's) electronic reading room at https://www.nrc.gov/reading-rm/adams.html. From this page, the public can gain entry into the Agencywide Documents Access and Management System (ADAMS), which provides text and image files of the NRC's public documents. The NRC received comments from the following individuals or groups:

Letter No.	ADAMS Accession No.	Commenter Affiliation	Commenter Name
1	ML21105A813	University of Mississippi Medical Center	Chunli Yang
2	ML21105A812	American Association of Physicists in Medicine	Bruce R. Thomadsen

This document lists each public comment by letter number. For each comment, the NRC has repeated the comment as written by the commenter, followed by the NRC's response. In some instances, the staff has broken the comment down into segments for clarity. Each comment is referred to by the letter number listed above and the number of each individual comment from the corresponding letter.

Please note that RISs are used to (1) communicate and clarify NRC technical or policy positions on regulatory matters that have not been communicated to or are not broadly understood by the nuclear industry, (2) inform the nuclear industry of opportunities for regulatory relief, (3) communicate previous NRC endorsement of industry guidance on technical or regulatory matters, (4) provide guidance to applicants and licensees on the scope and detail of information that should be provided in licensing applications to facilitate NRC review, and (5) request the voluntary participation of the nuclear industry in NRC-sponsored pilot programs or the voluntary submittal of information that will assist the NRC in the performance of its functions. The purpose of this RIS is to clarify the regulatory requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, "Medical Use of Byproduct Material."

A draft RIS was developed summarizing the findings and published in the *Federal Register* (83 FR 44247) on August 30, 2018, seeking public comment. The NRC received **two comments** supporting the adoption of the use of electronic signatures by NRC medical licenses.

Comment 1:

Electronic signature should be implemented cross the board from radiation therapy external beam therapy either LINAC based or radioactive materials based (e.g. using Cobalt-60 radioactive source), and Brachytherapy using radioactive seeds in the format of manual implant (e.g. using I-125 seeds, Ir-192 or Pd-103) or using radioactive source in the format of an afterloader (e.g. Ir-192). As electronic medical records in health care is almost a standard, one should accept electronic signature everywhere. Certainly, rules and measures must be in place to ensure e-signature meeting the seven requirements proposed in the draft. To implement

electronic signature will reduce physical paper work and increase efficiency, and could be a more reliable way of storing medical documents.

As a health care worker and a person in charge of radiation therapy and safety, I see clearly the benefit of implementing the electronic signatures. Currently, we do both in paper and electronic format, which is a duplicate of work and waste of resource.

NRC Response:

Thank you for submitting your comment to the NRC. The NRC agrees with your comment and believes that encouraging the use of electronic signatures will modernize processes and decrease the use of paper.

Comment 2:

The [draft] RIS states that the purpose of the electronic signature is to: "(1) identify and authenticate the person who is the source of the information in the record, and (2) indicate that person's approval of the information in the record." The RIS lists seven functions of an electronic signature designed to meet these goals, as follows:

(1) uniquely identify the individual who affixed the signature
(2) ensure that the individual completing the signature process is the individual who started the process
(3) affix the date and time of the signature
(4) evidence the individual's intent to sign
(5) require a new signature for changes to the record
(6) track subsequent changes to the record, including identification of the dates and times of changes and individuals who made the changes, and
(7) allow an inspector to electronically review the record and all revisions, including the signature on each revision.

The American Association of Physicists in Medicine (AAPM) has some concerns with these seven functions, and we address our concerns below under the specified function:

Comment 2-1

Function (2)
The AAPM believes the individual completing the signature process does not necessarily need to be the person starting or entering information on the document. These documents are often created, edited by a person or persons, then finally signed—indicating final approval—by another person authorized to approve the document. The AAPM recommends that this function be clarified to allow editability with final authority of the approval indicated by the authorized individual's signature.

NRC Response: The NRC staff agrees with the comment that the individual completing the signature process is not necessarily need to be the person starting the process or entering the information on the document. The NRC has removed that function.

Comment 2-2

Function (3)
The AAPM questions the purpose of requiring the time of the signature on the document. The time of the signature is not recorded currently for paper records. We believe the information is extraneous to identifying and authenticating the person who is the source of the information or indicating that person's approval of the information in the record. The RIS should not require time of the signing to be noted on the document.

NRC Response: The NRC staff agrees that time of the signing should not be required to be noted on the document and has made corresponding changes.

Comment 2-3

Function (4)
The AAPM questions what is meant by evidence of the individual's intent to sign. We believe the intent is self-evident by virtue of the electronic signature unless the signature has been fraudulently affixed. Other enumerated functions, however, guard against fraudulent use of electronic signatures. We recommend that Function (4) be eliminated.

NRC Response: The NRC staff disagrees with the suggested change but has modified the function, which is now function 3 in the RIS, to read "demonstrates the individual's intent to sign." The NRC staff agrees that other functions guard against fraudulent use of electronic signatures. However, the staff disagrees that the function should be removed. As articulated in the recently issued "Electronic Signature Implementation Assessment Guide" (September 29, 2017) (ML17053A536), the intent to sign is a critical component and that the mere application of a sound, symbol, or process that is commonly used as a form of signature does not make it a legally binding signature.

Comment 2-4

Function (6)
Tracking changes with times and individuals who made the change is not done now with paper records. The AAPM questions the purpose and value of requiring this information.

NRC Response: The NRC disagrees with the comment as this function will allow changes to be recorded and tracking of individuals that implemented the changes.