

October 29, 2018

May Ma
Office of Administration
Mail Stop: TWFN-7-A60M
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

RE: Request for Comment: Use of Electronic Signatures by Medical Licensees on Internal Documents (NRC-2018-0185)

Dear Ms. Ma:

The American Association of Physicists in Medicine (AAPM)¹ is pleased to submit comments to the U.S. Nuclear Regulatory Commission (NRC) regarding its draft Regulatory Issue Summary (RIS) for the Use of Electronic Signatures by Medical Licensees on Internal Documents. The AAPM commends the NRC on its work in providing a means of satisfying NRC signature requirements with electronic signatures.

The AAPM has the following specific comments:

Discussion of NRC's Seven Functions

The 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

¹ The American Association of Physicists in Medicine (AAPM) is the premier organization in medical physics, a broadly-based scientific and professional discipline encompassing physics principles and applications in biology and medicine whose mission is to advance the science, education and professional practice of medical physics. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography, CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to ensure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various state regulatory agencies. AAPM represents over 8,700 medical physicists.

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 AAPM has some concerns with these seven functions, and we address our concerns below under the specified function:

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.

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.

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.

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.

In summary, the AAPM supports NRC's adoption of the use of electronic signatures by NRC licensees. The AAPM hopes that the NRC will consider AAPM's comments and adopt the AAPM's recommendations when crafting the final RIS on the Use of Electronic Signatures by Medical Licensees on Internal Documents.

Thank you for the opportunity to comment. If you have any questions or require additional information, please contact Richard J. Martin, JD, Government Relations Project Manager, at 571-298-1227 or Richard@aapm.org

Sincerely,

A handwritten signature in black ink that reads "Bruce Thomadsen". The signature is written in a cursive, flowing style.

Bruce R. Thomadsen, PhD, FAAPM, FABS
President, AAPM