UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, DC 20555-0001

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DRAFT NRC REGULATORY ISSUE SUMMARY 2018-XX
USE OF ELECTRONIC SIGNATURES BY MEDICAL LICENSEES
ON INTERNAL DOCUMENTS

ADDRESSEES

All U.S. Nuclear Regulatory Commission (NRC) medical licensees, NRC master materials licensees, Agreement State Radiation Control Program Directors, and State Liaison Officers. The NRC provides this regulatory issue summary (RIS) to the Agreement States for their information and for distribution to their licensees, as they deem appropriate.

INTENT

The NRC is issuing this RIS to describe one means by which medical licensees can use electronic signatures to satisfy NRC's signature requirements on internal records that the NRC requires the licensee to maintain. This RIS does not address the use of electronic signatures on official submissions to the NRC. This RIS does not impose any new requirements. No specific action or written response is required.

BACKGROUND INFORMATION

Since 2004, medical licensees that are increasingly transitioning to the use of electronic medical records have requested that the NRC accept electronic signatures on internal documents, including electronic patient care records. Many medical facilities have transitioned from paper records to electronic systems exclusively, while some are using a combination of both. These documents, such as the written directives required by Title 10 of *Code of Federal Regulations* (10 CFR) 35.40, "Written directives," and records required by 10 CFR 35 Subpart L, "Records," are not required to be submitted to the NRC, but are required to be maintained at the licensee's facilities and are subject to inspection.

On October 20, 2010, the NRC published an issues paper in the *Federal Register* (75 FR 64749) and requested public comment on specific issues related to the use of electronic signatures in medical licensee documents. The NRC received five comments. The commenters' general consensus was that the NRC should be receptive to licensees' use of electronic signatures and adopt its use for licensees' internal documents because the use of electronic medical records has become standard practice in medical facilities.

The Government Paperwork Elimination Act of 1998 (GPEA) requires agencies to allow the public or regulated entities to use electronic signatures, when practicable. Section 1704 of the GPEA provides that the Director of the Office of Management and Budget (OMB) shall ensure that Executive agencies provide:

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> (1) for the option of the electronic *maintenance* [emphasis added], submission, or disclosure of information, when practicable as a substitute for paper; and
>
> (2) for the use and acceptance of electronic signatures, when practicable.

Section 1710 of the GPEA defines an electronic signature as a method of signing an electronic message that:

> (A) identifies and authenticates a particular person as the source of the electronic message; and
>
> (B) indicates such person's approval of the information contained in the electronic message.

Neither the GPEA nor OMB guidance endorse any particular electronic signature technology to satisfy these requirements.

SUMMARY OF ISSUE

In accordance with 10 CFR 35.5, "Maintenance of records," licensees may store documents in an electronic medium capable of producing legible, accurate, and complete records for the duration of the required record retention period. These records, such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures, and the licensee must maintain adequate safeguards against tampering with and loss of records.

The NRC is aware that many medical licensees already develop and store certain documents in an electronic form and may use electronic signatures for electronic documents that require signatures by specific individuals. To satisfy the NRC's signature requirements, an electronic signature should be consistent with the definition of electronic signature in the GPEA. The electronic signature should: (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 NRC has identified seven functions of an electronic signature that would ensure that these two factors are satisfied:

> (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.

Office of Management and Budget guidance does not provide specific criteria for electronic signatures under the GPEA. Therefore, the NRC turned to other electronic transaction laws to inform its development of these seven functions. Specifically, the NRC reviewed electronic signature requirements in the Electronic Signatures in Global and National Commerce Act

(E-SIGN)[1] and the Uniform Electronic Transactions Act (1999) (UTEA). The NRC also used the guidance developed by the General Services Administration and the Federal Chief Information Officers Council (at the request of OMB), "Use of Electronic Signatures in Federal Organization Transactions."[2] This guidance provides general guidance for agencies regarding the use of electronic signatures pursuant to the GPEA, E-SIGN, and the UETA. This guidance explains that these electronic transaction laws take the "functional equivalence approach" to electronic signatures. This approach considers the requirements, purposes, and functions of a traditional non-electronic signature and specifies how these requirements, purposes, and functions could be fulfilled electronically, in accordance with the electronic transaction laws.

Electronic signatures used to satisfy NRC signature requirements should be the functional equivalent of non-electronic signatures that the NRC already recognizes as satisfying these requirements. The NRC has determined that electronic signatures that perform the seven functions listed above would be the functional equivalent of non-electronic signatures. The NRC will recognize and accept electronically signed records using software that adequately provides for these seven functions. This RIS describes one method that the NRC considers acceptable in meeting NRC signature requirements using electronic signatures. Medical licensees may use alternate methods to comply with NRC signature requirements using electronic signatures.

BACKFITTING AND ISSUE FINALITY DISCUSSION

This RIS does not apply to the entities protected by the backfit rule (10 CFR 50.109, 70.76, 72.62, or 76.76, all entitled "Backfitting") or to the issue finality provisions in 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." Therefore, the backfit rule and issue finality provisions do not apply to this RIS.

FEDERAL REGISTER NOTIFICATION

The NRC will publish a notice of opportunity for public comment on this draft RIS in the *Federal Register*.

CONGRESSIONAL REVIEW ACT

Discussion to be provided in final RIS.

PAPERWORK REDUCTION ACT STATEMENT

This RIS provides guidance for implementing mandatory information collections covered by 10 CFR Part 35 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et. seq.). These information collections were approved by the Office of Management and Budget (OMB), under control number 3150-0010. Send comments regarding this information collection to the Information Services Branch, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0010) Office of Management and Budget, Washington, DC 20503.

[1] Pub. L. 106-229, codified at 15 U.S.C. § 7001–06 (2012)
[2] Version 2.0 (Jan. 25, 2013) (Electronic Signature Guidance), *available at* https://www.idmanagement.gov/topics/

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number

CONTACT

This regulatory issue summary requires no specific action or written response. If you have any questions, please contact the technical contact listed below.

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Note: NRC generic communications may be found on the NRC public Web site, http://www.nrc.gov, under NRC Library/Document Collections.

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