UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
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SEP 24 2015

Laura T. Smith, M.S.
Radiation Safety Officer
St. John Hospital & Medical Center
ATTN: Nuclear Medicine
22101 Moross Road
Detroit, Michigan 48236-2172

You submitted a letter dated February 21, 2009 with a request for your NRC Material License No. 21-03210-01, to have your therapy treatments written directive entirely electronic, including physician-authorized user signatures. Specifically, you were seeking guidance on whether 100 percent electronic written directives would be acceptable in accordance with NRC regulations and the inspection process.

In response to a NRC request for information dated May 5, 2009, you provided additional information in letter dated April 29, 2009 (received May 6, 2009), indicating that electronic recordings of written directives will assure documentation and delivery of therapy treatments. Additionally, you stated that the benefits of using electronic signatures include having: 1) Better security for signatures; 2) An actual electronic date of the signature; 3) An electronic written directive; 4) Printed written directives; and 5) Electronic written directives that can be inspected by the NRC.

A technical assistance request (TAR) to use electronic written directives was generated and provided to our review group for a technical review on August 25, 2009. Based on the initial review of the TAR, a request for additional information was discussed with you on June 29, 2010 and a response received dated July 26, 2010, which provided further clarification on the signature process for your software used for electronic signatures.

Based on NRC's technical review of your initial request and additional information, it was concluded that based on the regulations in 10 CFR 35.5, licensees may store any record required under Part 35, which includes written directive in electronic media with the capability for producing legible, accurate, and complete records during the required record retention period. These records may be entirely electronic, i.e., they may be produced and sorted entirely electronically. To satisfy the requirements of 10 CFR 35.40, it was determined that any medical use licensee may generate and maintain electronic written directives with electronic authorized user signatures using any software that includes the following functions:

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) Evidences the individual's intent to sign;
5) Require a new signature for changes to the record;

6) Track changes to the record including identification of the dates and times of changes and individuals who made the change; and
7) Allow an inspector to electronically review the record and all revisions, including the signature on each revision.

Therefore, you may use electronic written directives prepared using your software (as stated in your request) that provides the seven listed functions. Please note that it has been determined that it *will not* be necessary to amend your NRC Materials License to authorize the use of electronic written directives. However, note that in the future, you will need to adhere to any further guidance that the NRC, Office of Information Services (OIS) may provide on the use of electronic signatures. If you have any questions or require clarification on the information, please contact me at (630) 829-9830 or cassandra.frazier@nrc.gov.

A copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Sincerely,

Cassandra F. Frazier
Senior Health Physicist
Materials Licensing Branch

License No. 21-03210-01
Docket No. 030-02028