



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

February 28, 2019

ALL AGREEMENT STATES, VERMONT

U.S. NUCLEAR REGULATORY COMMISSION NOTIFICATION OF PUBLIC MEETING ON
THE FINAL 10 CFR PARTS 30, 32, AND 35 RULE (STC-19-015)

Purpose: To inform the Agreement States that the U.S. Nuclear Regulatory Commission (NRC) staff plans to have public meetings on the final Title 10 of the *Code of Federal Regulations* (CFR) Parts 30, 32, and 35 rule, “Medical Use of Byproduct Material-Medical Event Definitions, Training and Experience, and Clarifying Amendments,” which was effective January 14, 2019. The Agreement States are encouraged to forward this public meeting information to their licensees. These public meetings are scheduled for March 26 and April 24, 2019.

Background: The NRC published revisions to the regulations in 10 CFR Parts 30, 32, and 35 for drug manufacturers, commercial nuclear pharmacies, and medical use licensees on July 16, 2018, in the *Federal Register* (83 FR 33046). The final rule can be found in the NRC Medical Uses Licensee Toolkit (Toolkit) (<https://www.nrc.gov/materials/miau/med-use-toolkit.html>) under “Regulations” or in the Federal Register (<https://www.gpo.gov/fdsys/pkg/FR-2018-07-16/pdf/2018-14852.pdf>). The accompanying final guidance is also available in the Toolkit under “Guidance.”

Discussion: The NRC is conducting these public meetings to provide information on the changes to the regulations. The final rule includes changes in the following eleven broad categories:

Generators	Diagnostic medical uses
Associate Radiation Safety Officer and Ophthalmic Physicist	10 CFR 35.300 Radiopharmaceuticals
Emerging Technologies	Sealed Source and Device Registry
Notification	Vendor Training
Manual Brachytherapy	Gamma Knife Source Exchange
Training and Experience	

The public meetings will be conducted via webinar and are scheduled for March 26 and April 24, 2019, from 10:00 a.m. – 3:00 p.m. (Eastern Time). The presentation slides from the meetings will be available on the Toolkit under “Guidance.” Participants must register in advance of the webinar at the following link: <https://attendee.gotowebinar.com/rt/5204863042699910403>.

If you have any questions regarding this correspondence, please contact me at 301-415-2368 or the individuals named below:

POINT OF CONTACT:

E-MAIL:

TELEPHONE:

Donna-Beth Howe

Donna-Beth.Howe@nrc.gov

(301) 415-5441 or

Maryann Ayoade

Maryann.Ayoade@nrc.gov

(301) 415-0862

/RA/

Andrea L. Kock, Director
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety
and Safeguard

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION NOTIFICATION OF PUBLIC MEETING ON THE FINAL 10 CFR PARTS 30, 32, AND 35 RULE.
DATE: FEBRUARY 28, 2019. (STC-19-015)

ML19043A902

OFFICE	NMSS/MSEB	NMSS/MSEB	NMSS/MSEB	NMSS/MSST
NAME	MAyoade	LDimmick	PMachalak	AKock
DATE	02/21/19	02/21/19	02/24/19	02/28/19

OFFICIAL RECORD COPY