



CHARLES D. BAKER
Governor

KARYN E. POLITO
Lieutenant Governor

The Commonwealth of Massachusetts

Executive Office of Health and Human Services

Department of Public Health

Bureau of Environmental Health

Radiation Control Program

Schrafft Center, Suite 1M2A

529 Main Street, Charlestown, MA 02129

Phone: 617-242-3035 Fax: 617-242-3457

www.mass.gov/dph/rcp

MARYLOU SUDDERS
Secretary

MONICA BHAREL, MD, MPH
Commissioner

Tel: 617-624-6000
www.mass.gov/dph

October 31, 2016

RCP INFORMATION NOTICE 2016-03:

TITLE: LICENSING NEW
RADIOACTIVE
MATERIAL MEDICAL
USE MODALITIES

ADDRESSEES

All medical licensees authorized to use radioactive material in diagnostic and therapeutic administrations in Massachusetts.

INTENT

The Massachusetts Department of Public Health Radiation Control Program (RCP) is issuing this information notice (IN) to provide awareness of the requirement for authorized use of new modalities under 105 CMR 120.589 regulations. No written response is required.

BACKGROUND

Massachusetts regulation 105 CMR 120.589 covers licensee use of radioactive materials and radiation sources approved for medical use that are not specifically addressed in 105 CMR 120.500. There are several new modalities that are currently authorized by the RCP for medical use material licenses under 105 CMR 120.589. **105 CMR 120.589 requires, in part, that the applicant or licensee must submit a request to specifically include these modalities and receive written approval from the Agency in a license.**

SUMMARY OF ISSUE

Massachusetts radioactive material medical licensees have incorrectly considered new medical use modalities to be already addressed under 105 CMR 120.500 regulations rather than under the correct regulation 105 CMR 120.589.

The new modalities currently authorized by the RCP under 105 CMR 120.589 include (but not limited to):

- Best Vascular, Inc. Beta-Cath Intravascular Brachytherapy (IVB) System
- I-125 Iotrex Liquid Brachytherapy Source in Cytoc GliaSite Radiation Therapy System
- Iodine-125 and Palladium-103 Low Dose Rate Brachytherapy Seeds Used for Localization of Non-Palpable Lesions
- Leksell Gamma Knife® Perfexion™
- Leksell Gamma Knife® Icon™
- NeoVista, Inc's Epi-Rad90 (Sr-90) Ophthalmic System
- TheraSphere and SIRSphere Yttrium-90 Microspheres, and
- ViewRay System for Radiation Therapy

RECOMMENDED ACTION

Massachusetts regulation 105 CMR 120.589 corresponds to the United States Nuclear Regulatory Commission (NRC) regulation 10 CFR 35.1000. Recipients of this IN should reference the current NRC-provided listing of materials/modalities, and respective licensing guidance, to determine whether materials intended for licensee use should be considered under 105 CMR 120.589. The NRC refers to these modalities as “emerging technologies”. The listing may be reviewed at <http://www.nrc.gov/materials/miau/med-use-toolkit.html#et>

This IN requires no written response. If you have questions about the information in this notice, please contact the Technical Contact listed below.

Sincerely,

John M. Priest, Jr., Director
Massachusetts Radiation Control Program

Technical Contact:
John M. Priest, Jr., Director
(617) 242-3035 x 2001
Jack.Priest@state.ma.us