



COMMONWEALTH of VIRGINIA

Department of Health
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RICHMOND, VA 23218

M. Norman Oliver, MD, MA
State Health Commissioner

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October 8, 2021

Effective October 6, 2021, The Virginia Department of Health, Office of Radiological Health and Safety Regulations (ORH) approved your request for an exemption from regulation 12 VAC 5-481-3380 and regulation 12 VAC 5-481-3390 of the Code of Virginia for the Xstahl RADiant. The exemption is granted with the following conditions:

1. The Xstahl RADiant device shall be used by only a licensed dermatologist, a radiation therapy technologist certified by the American Registry of Radiologic Technologists (ARRT) in radiation therapy, or a qualified medical physicist. Each individual must complete the training as specified below:
 - a. Prior to each individual's first use of the Xstahl RADiant device on a patient, the individual must complete the device training program presented by authorized Xstahl personnel. The training shall be conducted for the duration specified in the exemption request using the training materials described in the Xstahl exemption request to ORH's X-ray Program Director dated September 28, 2021. Xstahl shall provide an annual refresher training for all applicable personnel.
 - b. Xstahl shall document each individual's successful completion of the training by forwarding a Certificate of Training to ORH's X-ray Program Director for each person trained. Additionally, a copy of the individual's ARRT Certification, Qualified Medical Physicist Certification and/or Physician's license must be maintained at the facility for inspection.
2. In addition to the requirements of 12 VAC 5-481-3380 and in accordance with 12 VAC-481-3390. Quality Management Program, use of the wrong treatment applicator (if applicable) or modality shall be reported as a misadministration to the ORH X-ray Program Director.
3. Xstahl shall notify the ORH X-ray Program Director whenever a RADiant unit is sold in Virginia (Form 2579).

4. The exemption shall expire upon the regulatory adoption of rules for superficial radiation therapy.

This exemption will allow Xstahl to market the RADiant to dermatologists in Virginia. As noted above, the user(s) of the RADiant must receive the required training conducted by Xstahl staff, or contractors certified by Xstahl to conduct the training using the training documents provided in the exemption request.

Please note that any change in the training material must be submitted to the ORH X-ray Program Director for approval. Also, please note the exemption covers only the sale of the RADiant to dermatologists, use of the RADiant by any other person or group must meet all of the applicable regulations in 12 VAC 5-481-3380 and 12 VAC 5-481-3390.

As noted in the condition approved by the Virginia Department of Health, Office of Radiological Health and Safety Regulations, the exemption will be withdrawn when rules for superficial radiation therapy are adopted.

If you have any questions, please feel free to contact me by telephone at (804) 864-8170 or by email at Lea.perlas@vdh.virginia.gov

Sincerely,

A handwritten signature in cursive script that reads "Lea Perlas". The signature is written in black ink on a white background.

Lea Perlas
Director, Office of Radiological Health