



COMMONWEALTH of VIRGINIA

M. Norman Oliver, MD, MA
State Health Commissioner

Department of Health
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October 22, 2019

Effective October 22, 2019, 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 Sensus SRT-100. The exemption is granted with the following conditions:

1. The Sensus SRT-100 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 medical physicist. Each individual must complete the training as specified below:
 - a. Prior to each individual's first use of the Sensus SRT-100 device on a patient, the individual must complete the device training program presented by authorized Sensus personnel. The training shall be conducted for the duration specified in the exemption request using the training materials described in the Sensus exemption request to ORH's X-ray Program Director dated October 15, 2019. Sensus shall provide an annual refresher training for all applicable personnel.
 - b. Sensus 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, 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 shall be reported as a misadministration to the ORH X-ray Program Director.
3. Sensus shall notify the ORH X-ray Program Director whenever a SRT-100 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 Sensus to market the SRT-100 to dermatologists in Virginia. As noted above, the user(s) of the SRT-100 must receive the required training conducted by Sensus staff, or contractors certified by Sensus 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 SRT-100 to dermatologists, use of the SRT-100 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,

Lea Perlas
Director, X-ray Program

Cc:
Steve Harrison
Director, Office of Radiological Health