



Taking New Aim At Skin Cancer™

Div of Waste Management
and Radiation Control

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Scott Anderson, Director
Utah Division of Waste Management and Radiation Control
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To Director Anderson,

This letter is a formal request by Sensus Healthcare (Sensus) to the Utah Department of Environmental Quality (UDEQ) to receive an exemption to Utah Administrative Code R313-30-3, which are the general administrative requirements for facilities using therapeutic radiation machines. Sensus has a formal training program in place, specifically for its Superficial Radiation Therapy (SRT) products, which we believe should satisfy these requirements based on our SRT device. Sensus would like to offer UDEQ the following explanation, using references to the three (3) Sensus training handbooks: SRT Cutaneous Lesion Clinical Handbook, SRT Keloid Clinical Handbook, and RSO Physician Training Handbook, to demonstrate its claim that Sensus training for its products is proper in lieu of Utah Administrative Code R313-30-3 requirements in order to ensure patient and user safety. In addition to our explanations of below, Sensus wishes to point out that Dermatologists, whom Sensus primarily sells its SRT device to, have been using superficial radiation therapy to treat malignant skin lesions since the early 1900's. It is a time-honored art and Dermatologists, who essentially see and treat the vast majority of skin cancer patients, have perfected and optimized the science and protocols utilized to safely and effectively cure hundreds of thousands of non-melanoma

skin cancer (NMSC) patients on our SRT-100™ systems. We passionately believe that Dermatologists and their patients should have access to this safe and effective modality, instead of being sent to complex surgeries, which is the alternative to SRT.

Sensus Training Introduction

Sensus Healthcare takes responsibility for training physicians who purchase a Sensus product in all facets of radiation therapy, in a very focused and honed fashion as it pertains to treating NMSC lesions. Since the nature of this training is pertinent to only two-dimensional NMSC lesions, and not the much broader entire science of radiation oncology, Sensus fully covers all the required aspects of delivering radiation therapy to treat and cure NMSC lesions. When a physician purchases a Sensus product, Sensus, at no cost to the physician, conducts a two-day training session at the physician's facility, which covers all the subject matter and topics provided in the three handbooks. That includes the vocational delivery of the material and OJT-style training with the authorized user. At the conclusion of this training, Sensus, if satisfied with the physician's knowledge, will certify that physician as a Radiation Safety Officer (RSO), using the Authorized User form, which can be found in the "SRT-100 Cutaneous Lesion Clinical Handbook; Appendix T: Authorized User Form". Upon certifying this physician, Sensus submits this form to the State in which the physician is practicing for their records, tracking, and acknowledgement.

R313-30-3(3)(b)

The requirement for 200 hours of training in R313-30(3)(b) is not relevant to Dermatologists, as it is written with the art of Radiation Oncology in mind, which is much

broader and pertains to so many more disease types and sites (location of tumors) that are three-dimensional in nature, as it is pertaining to the tumor itself and its location in the body, which requires so many more considerations when planning, prescribing, and administrating the radiation therapy. The Radiation Oncologists utilize EBRT/LINAC as their primary radiation treatment modality, which also requires very special considerations and more complex treatment planning and dosimetry calculations. The Dermatologists, as the specialists for NMSC, will never treat those diseases and tumors, therefore will not need to apply the rather more complex methodologies and therapy philosophies as the Radiation Oncologists are required, but will narrowly focus on solely treating superficial planar tumors of the skin. Due to this fact, the Dermatologists will be sufficiently trained on the core foundation of radiation biology, radiation physics, and radiation safety, together with the clinical application and dosimetry for treating NMSC lesions through the Sensus training curriculum, which properly satisfies the fundamental education for Dermatologists in the arts of radiation therapy for their specialty and very specific focus. Combining the Dermatologists' very comprehensive education on NMSC lesions, tumor morphology, disease management, dermatopathology, tumor biology, treatment modalities and approaches, biochemistry, and patient staging and Sensus' radiation therapy clinical training makes the Dermatologists optimal authorized users to utilize and provide SRT to their patients as an excellent and safe treatment modality for NMSC, which makes a significant difference in their patients' lives and overall outcomes (clinically and aesthetically).

Sensus Healthcare addresses all training topics required by this section, as pertained to treating NMSC lesions. The primary and only focus is on treating cutaneous lesions,

which the Dermatologists are the utmost experts on and are trained for many hours to diagnose, manage, and treat. The Dermatologists are the ultimate experts on treating the skin cancer lesions and they are managing the disease state and the tumor morphology, instead of just focusing on delivering dose to particular sites (as radiation oncologists are trained to do). Since the tumor topology of skin lesions is relatively simple and planar and thanks to the intrinsic nature of Bremsstrahlung x-rays, the need to focus and manage the tumor and disease progression is of importance and, therefore, Dermatologists are the ideal specialists to utilize the SRT modality in their art of practice. The Dermatologists also have all the sufficient training, knowledge, and experience to effectively treat and manage all malignant skin lesions from all aspects, including and beyond radiotherapy in itself. Sensus provides the supplemental aspects of training to safely and effectively administer the SRT modality in the Dermatologists' arsenal of fighting skin cancer. Please see below for references to Sensus training material:

a. R313-30-3(3)(b)(i)(A) – Radiation physics and instrumentation – See SRT-100 Cutaneous Lesion Clinical Handbook, Chapter 1: Radiation Physics.

b. R313-30-3(3)(b)(i)(B) – Radiation Protection – See SRT-100 Cutaneous Lesion Clinical Handbook, Chapter 3: Principles of Radiation Safety; Chapter 4: Principles of X-Ray Production; Chapter 6: Controlling Factors for X-Ray. Also, see the RSO Physician Training Handbook, especially page 24 which discusses “Shielding” for x-ray.

c. R313-30-3(3)(b)(i)(C) – Mathematics pertaining to the use and measurement of radioactivity – See SRT-100 Cutaneous Lesion Clinical Handbook, Chapter 9: Medical Dosimetry.

d. R313-30-3(3)(b)(i)(D) – Radiation biology – See SRT-100 Cutaneous Lesion Clinical Handbook, Chapter 2: Radiobiology. Also, see RSO Physician Training Handbook page 18 (“Biological Effects of Radiation”), page 20 (“Biological Effects” and “Effects of Radiation by Biological Organization”), and page 21 (“Mechanisms of Biological Damage”).

e. R313-30-3(3)(b)(ii)(A) – Review of the full calibration measurements and periodic quality assurance checks – See SRT-100 Cutaneous Lesion Clinical Handbook, Chapter 19: Cutaneous Lesion Clinical Applications Procedures – P4: Quality Assurance Procedures, P5: Emergency Procedures, P6: Morning QA Procedure, and P7: Quality Management Program. In regards to “calibration measurements” please also see SRT-100 Cutaneous Lesion Clinical Handbook, Appendix N: Commissioning Report, Appendix O: Final Survey Report, and Appendix P: Commissioning Output Sheet. All calibration measurements will be done by a Medical Physicist that is certified to State standards and is approved and licensed within the State of Utah.

f. R313-30-3(3)(b)(ii)(B) – Preparing treatment plans and calculating treatment times – See SRT-100 Cutaneous Lesion Clinical Handbook, Chapter 8: Fractionation, Chapter 10: TDF Tables: Time, Dose, & Fractionation for BCC and SCC, Chapter 11: Therapeutic Index for BCC and SCC, Chapter 12: Cutaneous Lesions: Energy Margins & Fractionation Guidelines, Chapter 13: Indications for Cutaneous Lesion SRT-100™ Treatment, Chapter 15: Patient Selection for Cutaneous Lesion Treatment, Chapter 16: Cutaneous Lesion Clinical Treatment Planning, Chapter 17: Cutaneous Lesion Clinical Treatment Documentation, Chapter 19: Cutaneous Lesion Clinical Applications Procedures, P1-P9.

g. R313-30-3(3)(b)(ii)(C) – Using administrative controls to prevent misadministrations – See SRT-100 Cutaneous Lesion Clinical Handbook, Chapter 17: Cutaneous Lesion Clinical Treatment Documentation, Chapter 19: Cutaneous Lesion Clinical Applications Procedures: P1-P9, Appendix F: Declaration of Pregnancy, Appendix G: Cutaneous Lesion SRT-100™ Documentation for Clinical Treatment, Appendix H: Morning QA Form, Appendix I: Annual ALARA Review of Radiation Safety Program, Appendix J: Radiation Safety Training Sign-In, Appendix L: X-ray Sign, Appendix M: Badge Reports, and Appendix R: Notice to Employees.

h. R313-30-3(3)(b)(ii)(D) – Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console – See SRT-100 Cutaneous Lesion Clinical Handbook, Chapter 19: Cutaneous Lesion Clinical Applications Procedures – P5: Emergency Procedures. (Please also note that the Sensus SRT-100 is not External Beam like a Linear Accelerator would be categorized. The SRT-100 is “contact therapy”.)

i. R313-30-3(3)(b)(ii)(E) – Checking and using radiation survey meters – This will be performed by a Certified Medical Physicist in the State of Utah. All sites that use a Sensus device have a Medical Physicist that is hired as a contractor by them, in collaboration with Sensus. This Medical Physicist will perform an initial commissioning calibration and shielding survey for the site and create a Shielding Plan prior to system delivery on site, Shielding Survey Report and a Commissioning Report upon completion of system installation and commissioning. The site will have recurring annual calibrations scheduled thereafter to ensure safety and proper system functionality.

R313-30-3(3)(b)(iii)

Sensus Healthcare has a hands-on two (2) day training program with our Clinical Applications Specialists team who are supervised and certified by a Medical Physicist and a Certified Medical Dosimetrist. In addition to the initial physician training, Sensus provides ongoing full on-call clinical and physics support during normal business hours for physicians using our devices to answer any questions they have. Sensus also provides follow-up on-site training for practices who either undergo personnel changes, or just request additional training. Sensus also provides three annual clinical training workshops that cover all the facets of radiation physics, radiation biology, clinical protocols, quality, and best practices through the American Academy of Dermatology (AAD), American Cutaneous Oncology Society (ACOS), and the South Beach Symposium (SBS) societal annual meetings. Sensus Healthcare is therefore requesting a waiver for the three (3) year supervisory period, as Dermatologists will be applying SRT to only treat NMSC as their core specialty for which they are comprehensively trained and already have societal and disciplinary oversight and mentorship programs. Furthermore, the supervisory requirement will be addressed through the current and future SRT best practices and oversight initiatives that Sensus, its Medical Advisory Board, AAD, and ACOS shall be deploying throughout the nation.

a. R313-30-3(3)(iii)(A) – Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and limitations and/or contraindications – See SRT-100 Cutaneous Lesion Clinical Handbook, Chapter 13: Indications for Cutaneous Lesion SRT-100 Treatment, Chapter 14: Clinical Radiation Oncology, and Chapter 15: Patient Selection for Cutaneous Lesion Treatment.

Furthermore, Sensus is in the process of deploying the SRT University ELM system, through which physicians will be submitting monthly case studies, will be examined on ongoing clinical education topics, and evaluated on their proficiency of the subject matter by an ACOS-appointed medical committee.

b. R313-30-3(3)(b)(iii)(B) – Selecting proper dose and how it is to be administered

– See SRT-100 Cutaneous Lesion Clinical Handbook, Chapter 8: Fractionation, Chapter 9: Medical Dosimetry, Chapter 10: TDF Tables: Time, Dose, & Fractionation for BCC and SCC, Chapter 16: Cutaneous Lesion Clinical Treatment Planning, Appendix A: TDF Tables for Patient Treatment Planning for BCC and SCC, and Appendix Q: Cutaneous Lesion FX Time Tables: 50kV, 70kV, & 100kV. Also, please see RSO Physician Training Handbook, page 23 (“Radiation dose from natural and man-made sources”).

c. R313-30-3(3)(b)(iii)(C) – Calculating the external beam radiation therapy doses and collaborating with the authorized user in the review of patients’ progress and consideration of the need to modify originally prescribed doses as warranted by patients’ reactions to radiation – During the two-day training that Sensus performs, our Clinical Applications Specialist will teach and demonstrate with pre-treatment simulations and prior to treating the first patients for the authorized user. In addition, the Clinical Applications Specialist will be available for the authorized user to discuss/review patients’ progress and considerations of the need to modify originally prescribed doses and/or treatment plans as warranted by patient’s reactions to treatment.

d. R313-30-3(3)(b)(iii)(D) – Post-administration follow-up and review of case histories – As stated in R313-30-3(3)(b)(iii)(C) above, Sensus’ Clinical Applications team will be available for authorized users to review case histories. Furthermore, Sensus

provides access to its Certified Medical Dosimetrist and Medical Physicist network for additional and higher level review of case studies and particular clinical, radio-biology, and physics questions. In addition, there are 500+ users of Sensus systems in the U.S., some of which have been safely and successfully treating with SRT for over ten (10) years, and whom Sensus maintains close contact as high level advisors to authorized users nationwide. The most experienced SRT users serve on the Sensus Medical Advisory Board, the ACOS advisory and executive boards, and on our global KOL Speakers' Panel, to which Sensus provides access for any authorized user in need of assistance in reviewing case histories, or for any other pertinent clinical and scientific consultation.

R313-30-3(4)

The Dermatologist will hire a Radiation Therapy Physicist that is registered and approved by the State of Utah as a third-party provider of services. (For example, Seth W. Streitmatter is a licensed Medical Physicist in the State of Utah who was used for Dr. Parkinson's office.)

R313-30-3(5)

Sensus Healthcare is asking for an exemption to this qualification for Dermatologists based on the training that will be provided by Sensus to them in conjunction with their usage of the SRT-100™.

R313-30-3(6) – R313-30-3(11)

Sensus Healthcare and its operators will comply fully with these requirements as they are a standard procedure of Sensus Healthcare throughout the country in all facilities which use the SRT-100™.

Sincerely,



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Taking new aim at skin cancer therapy

