

Comments from the Medical Community in Opposition to Exemption

James.Nunn@hcahealthcare.com <James.Nunn@hcahealthcare.com>
To: dwmrcpublic@utah.gov

Wed, Oct 5, 2016 at 9:01 AM

Mr. Anderson,

I saw the RFI on the Health Physics list server this morning regarding the SRT-100. As in Utah, these units are being aggressively marketed to dermatologists in Virginia. Personally, I don't think it is a good idea. I have attached some comments for your review. Of course I am not a citizen of Utah and I have no "skin in the game" so to speak, but these are the same comments I provided to Virginia. They are worth exactly what you are paying for them, and if they go straight to the trash I completely understand. But, I think there are at least a few salient points for you to consider as you work through your regulatory process. I understand the regulatory process is supposed to be dispassionate, but I would ask whether you would or would not want one of your family members being treated on one of these machines outside the setting of the clinical radiation oncology setting. Thank you in advance for your consideration of my comments.

Regards

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October 25, 2016

Scott T Anderson, Director
Division of Waste Management and Radiation Control
Multi Agency State Office Building
195 North 1950 West, 2nd Floor
Salt Lake City, Utah 8411

Re: Sensus Healthcare Variance Request for the Use of Superficial Radiation Therapy for Dermatologists

Dear Mr. Anderson:

The American Society for Radiation Oncology (ASTRO) opposes the Variance Request for the Use of Superficial Radiation Therapy for Dermatologists submitted by Sensus Healthcare, and additionally opposes any future use of electronic brachytherapy in this context primarily to protect the safety of all patients.

ASTRO is the largest radiation oncology society in the world, with more than 10,000 members who specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, biology and physics, the Society is dedicated to improving patient care through education, clinical practice, advancement of science and advocacy. ASTRO's highest priority has always been ensuring patients receive the safest, most effective treatments.

The Utah Administrative Code R313-30-3, General Administrative Requirements for Facilities Using Therapeutic Radiation Machines, correctly takes into account the complexity of superficial x-ray radiation therapy (SRT) by requiring that the registrant for a therapeutic radiation machine subject to R313-30-6 or R313-30-7 be a physician who is certified by the American Board of Radiology, the American Osteopathic Board of Radiology, a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology, the Canadian Royal College of Physicians and Surgeons, or; be in active practice of therapeutic radiology, and completed two hundred hours of instruction in basic radiation techniques applicable to the use of an external radiation therapy unit, five hundred hours of supervised work experience, and a minimum of three years of supervised clinical experience. This level of training and experience is appropriate given the complexities of the treatment modality in question.

SRT employs a small X-ray tube, rather than a radionuclide, to rapidly deliver a high dose of radiation. SRT therefore, has low energy emissions capable of delivering high dose x-ray radiation with the additional advantage that it can be turned on and off on demand. The low energy radiation (50 kVp) used in SRT requires relatively low radiation shielding, however, it should be noted that although SRT reduces the facility shielding requirements, it does not minimize the associated risk of radiation injury to the patient, or to personnel who may be in the room during treatment.

Most importantly, the characteristics of SRT do not alter the necessary physician and personnel training and experience requirements for the delivery of radiation. SRT should be supervised, delivered, and managed only by physicians who have the same level of training and experience now required for the

use of other forms of radiation therapy. Further, the complexities of dose gradient, radio-biologic equivalence and fractionation principles are best known by radiation oncologists. Lack of this expertise could lead to inappropriate patient selection, inaccurate or technically inadequate treatment delivery and poor patient outcome, both in terms of added toxicity and poorer cancer control. Appropriately trained physicians should work with medical physicists trained and experienced in SRT. SRT must be given with a full knowledge of the effects of radiation on tumor and normal tissues. While the training offered by Sensus compliments the training authorized users receive prior to board certification, it is not a replacement.

Protecting critical structures while treating with SRT, or any other form of radiation therapy, is paramount. Damage to these structures from the use of SRT might not be evident until years after treatment, sometimes decades. In the 1950s, physicians used SRT to treat fungal infections (tinea capitis) of the skin in the head and neck region, and found that many of their patients developed life-threatening secondary malignancies years or even decades after their treatments. These infections are no longer treated with SRT. As a result, many radiation oncologists prefer the use of electron beam radiation versus SRT, which is less penetrating and can protect normal tissues, such as vision/optic structures, cranial nerves, and salivary glands, to a greater extent than SRT in many situations, and may mitigate the risk of secondary radiation-induced malignancies compared to SRT.

Therefore, ASTRO has significant concerns with the proposed variance request, specifically regarding patient safety predicated upon 1) the lack of experience and training of dermatologists in administering radiation therapy, and 2) the proposed use of SRT in certain cases of skin cancers versus electron beam therapy, which can lead to increased normal tissue toxicity, and perhaps even increase the risk of secondary radiation-induced malignancies. This variance could lead to harm to the patients in the state of Utah, the very patients your agency has been charged with protecting.

ASTRO believes that the current regulations are appropriate and safeguard patients from unnecessary risk, and therefore we urge that this, and any similar requests for variance of Utah Administrative Code R313-30-3 be denied. If you have any questions or need additional information, please contact Cindy Tomlinson, ASTRO senior patient safety and regulatory affairs manager, at 703.839.7366 or cindy.tomlinson@astro.org.

Sincerely,



Laura I. Thevenot
Chief Executive Officer

James Clarke <jclarke@gammawest.com>
To: dwmrcpublic@utah.gov

Tue, Oct 25, 2016 at 4:58 PM

Scott T. Anderson, Director
Division of Waste Management and Radiation Control
Department of Environmental Quality

Dear Mr. Anderson:

I wish to submit a public comment conveying my disapproval of the pending Utah Administrative Code exemption requested by Sensus regarding the training and operation of an SRT-100 superficial radiation therapy machine. As a board certified radiation oncologist and authorized user of therapeutic radiation in the state of Utah I feel I am uniquely qualified to comment on this matter.

I have operated an SRT-100 machine in our clinic in St. George for the past 7 years. The device is an excellent tool for the treatment of superficial skin cancers and provides an affordable alternative to Mohs surgery with favorable cosmetic results.

Use of this machine in my mind clearly requires the training and expertise of a radiation oncologist and physicist, ideally in the setting of a radiation oncology clinic. Selecting treatment schedules for skin cancer requires a good understanding of equivalent dose calculations including what fraction sizes are safe on what part of the body, since there is often pressure to complete the treatment as quickly as is safe. Custom shielding at the skin surface allows for shaped fields, but requires calculations of field sizes and back scatter factors that should always be checked by a physicist before treatment. We also use in vivo dosimetry as an independent quality assurance check. A dermatologist is simply not qualified to supervise this type of treatment with nothing but the manufacturer's training.

Radiation therapists certified by the state are best qualified to administer the treatment as the opportunity for error is substantial. Many of the internal checks that are built into megavoltage units do not exist with this machine and there are greater opportunities for errors including wrong site, wrong patient, wrong dose, wrong applicator, and wrong placement of shielding, all of which could generate misadministrations.

A secondary concern that is also important is the risk of self-referral abuse that this could create. Nationally there has been a flood of reports in recent years regarding dermatology offices self-referring patients for radiation therapy on equipment that they own. I've witnessed this directly at a neighboring dermatology clinic in Mesquite, NV which had reportedly been moving a high volume of superficial skin cancer patients through treatment on a superficial electronic brachytherapy machine up until earlier this year when medicare froze payments for that particular treatment code after observing the dramatic uptick in charges.

Intentions are likely good for the Utah dermatologist seeking this exemption, but this change could open the door to a type of abuse that has no place in our state.

Please don't hesitate to contact me if you have further questions about the operation of this particular piece of equipment, to my knowledge our office is the only one in the state that is using it.

Jim Clarke

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October 26, 2016

Scott Anderson, Director
Utah Department of Environmental Quality
Utah Division of Waste Management and Radiation Control (UDWMRC)
195 North 1950 West
P.O. Box 144880
Salt Lake City UT 84114-4880

RE: Comment Against the Granting of an Exemption for the use of Sensus Healthcare SRT-100 superficial radiation therapy system by Dermatologists

Sensus Healthcare is requesting exemption from the following provisions of the Utah Administrative Code: R313-30-3(3) - Training for External Beam Radiation Therapy Authorized Users; R313-30-3(4) - Training for Radiation Therapy Physicist; R313-30-3(5) - Qualifications of Operators; and R313-30-3(6) - Written safety procedures and rules.

Dear Mr. Anderson:

The University of Utah is against the granting of an exemption request to allow the user of the Sensus Healthcare SRT-100 superficial radiation therapy (SRT) system to be considered an Authorized User without meeting the established training requirements for the following reasons:

- 1) The SRT system is a radiation therapy device designed to deliver therapeutic doses of x-ray radiation and therefore should only be allowed to be used by qualified external beam radiation therapy Authorized Users who meet the requirements of Utah Administrative Code. NOTE: The term "superficial" radiation therapy should not confuse individuals to believe that this is not a radiation therapy device. This device does not lessen the potential radiation risk to patients.
- 2) Patients treated with the SRT system require the management by a physician who has the level of training and expertise necessary for radiation therapy. Treatment of patients with therapeutic levels of radiation requires specialized knowledge in biology, dose deposition, management of side effects, and the appropriateness of patient selection for treatment. Lack of this expertise could lead to danger to the patients in inadequate or inappropriate treatment delivery and mismanaged care.

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- 3) As a therapeutic device, the SRT system must be supervised by a qualified and trained Radiation Therapy Physicist. Lack of supervision by a Qualified Medical Physicist could lead to medical events due to overdose or underdose, as well as misalignment with treatment sites. Supervision must include a regular quality assurance program of both the machine characteristics and the dose calculations performed for each patient. An appropriate quality assurance program should include daily, monthly, and annual checks of the device as well as ongoing technical reviews of cases under treatment. An annual survey of the unit by a Utah Registered Qualified Expert would be grossly inadequate in meeting these needs.
- 4) Although Sensus Healthcare representatives may arguably be considered experts in the specifics of their device, the training they may provide in the above requirements would not be sufficient. Regulated medical training programs, physics training programs, residency training programs, and board certifications, are rightly considered standard for the use of therapeutic radiation. Physicians actively administering radiation therapy treatments within the state of Utah are board certified in their specialty, in accordance with regulations. The training requirements as they currently exist in the Utah Administrative Code are appropriate and should not be considered for exemption.
- 5) It should be finally noted that Sensus Healthcare has a clear conflict of interest. They are a corporate entity aimed to maximize profit and we feel it completely inappropriate that they request a change in governmental regulatory and safety measures designed to protect patients in order to more easily sell their equipment or treatment. The UDWMRC should be aware of the motivation of Sensus Healthcare when requesting an exemption of clear safety measures.

In correlation to the above concerns, this letter is also provided as result of the need to provide additional comment due to the current makeup of the UDWMRC Board (regarding radiation). In the future, in addition to the UDWMRC asking for public comment when board actions could be controversial, we are requesting that:

- 1) board actions of concern allow for more notice than routine Board Meeting notification (i.e., more than 48 hours in advance) so that materials can be adequately reviewed and arrangements can be made to attend UDWMRC board meetings when relevant medical items are included on the Board agenda.
- 2) in addition, we feel it would be prudent for the UDWMRC to create and assign a radiation medical task force to assist the Division, as well as Jeremy Hawk (a member of the UDWMRC Board) when medical radiation issues arise which will be taken to the

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Utah Department of Environmental Quality
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UDWMRC Board. This way the medical task force could assist with the review of radiation issues before they are presented to the UDWMRC Board (which is limited in radiation expertise). By having the UDWMRC develop a specialized medical radiation task force we can feel more comfortable that all medical radiation issues will be sufficiently researched and appropriately addressed before being presented to the UDWMRC Board.

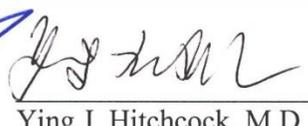
- 3) the UDWMRC provide an avenue to examine case-by-case limited scope exemptions for emergent patient issues rather than allow for exemption to Utah Administrative Code on a short timeline.

For the above reasons, our needs are not being met.

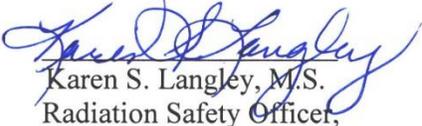
Sincerely,



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Ying J. Hitchcock, M.D.
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Karen S. Langley, M.S.
Radiation Safety Officer,
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October 27, 2016

Scott T. Anderson, Director
Division of Waste Management and Radiation Control
Multi Agency State Office Building
195 North 1950 West, 2nd Floor
Salt Lake City, Utah 84116

VIA E-Mail: dwmrcpublic@utah.gov

Re: Public Comment on Sensus Healthcare Exemption Request

Dear Mr. Anderson:

The American Association of Physicists in Medicine (AAPM)¹ is pleased to submit comments to the Utah Department of Environmental Quality Division of Waste Management and Radiation Control (Utah) regarding the request from Sensus Healthcare (Sensus), the manufacturer of the SRT-100TM, for an exemption for dermatologists providing superficial radiation therapy for the treatment of non-melanoma skin cancers from provisions of the Utah Administrative Code applicable to the use of therapeutic radiation machines. The AAPM commends Utah on its work in addressing this request for exemption and its implications for the safety of patients and healthcare personnel.

Each of the following specific comments are discussed in more detail in the attachment.

- Utah rules, which govern the use of therapeutic radiation machines, are applicable to the use of the Sensus SRT-100TM. Utah's rules appropriately define requirements for facilities using these machines and specify training and education for authorized users.
- The training requirements of Utah's current rules protect patients and personnel. Patient safety would be jeopardized by physicians using these machines without completing the detailed training pathway articulated in current Utah rules.

¹ The American Association of Physicists in Medicine (AAPM) is the premier organization in medical physics, a broadly-based scientific and professional discipline encompassing physics principles and applications in biology and medicine whose mission is to advance the science, education and professional practice of medical physics. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MR, Ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various state regulatory agencies. AAPM represents over 8,500 medical physicists.

- The regulatory supervision requirements specified in Utah's rules ensure the safe use of these machines. Dermatologists, as well as other physicians, must receive the radiation therapy specific supervision delineated in the regulations to ensure patient and healthcare personnel safety in the use of the SRT-100™ machines
- The safe use of the Sensus SRT-100™ and similar devices depends on the user's ability to deliver an accurate dose to the prescribed clinical site. Current Utah rules support development of this skill set.
- Utah's current regulatory requirements for quality management and staffing requirements are necessary for safety.

The AAPM believes AU training and experience are critical to the safe use of superficial radiation therapy (SRT) electronic brachytherapy machines such as the Sensus SRT-100™, and that current Utah regulations governing use of therapeutic radiation machines are applicable to these machines and necessary to ensure the safety of patients and healthcare personnel. An exemption to the regulations would release Sensus from these essential requirements, which is unacceptable and has the potential to do harm to patients, and would also set a very concerning precedent. Accordingly, the AAPM urges Utah to deny Sensus' request for exemption. If you have questions, please feel free to contact us or Richard Martin, AAPM's Government Relations Specialist, at Richard@aapm.org.

Sincerely,

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President, AAPM

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Alex Markovic, PhD

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Attachment to AAPM's Comments on Sensus Healthcare Exemption

1. Utah Rules Are Applicable to SRT-100™

Sensus is requesting an exemption from the following provisions of the Utah Administrative Code: R313-30-3(3)- Training for External Beam Radiation Therapy Authorized Users; R313-30-3(4)- Training for Radiation Therapy Physicist; R313-30-3(5)- Qualifications of Operators; and R313-30-3(6)- Written Safety Procedures and Rules. The exemption would allow dermatologists to become Authorized Users for this device solely by receiving two days of training from the manufacturer.

The Sensus SRT-100™ Non-Surgical Skin Cancer Treatment System is defined by the U.S Food and Drug Administration (FDA) as a “superficial radiation therapy device.” It operates between 50-100 kVp. The FDA notes that typically administered fractionated doses are 40-60 Gy, sometimes as high as 80 Gy, with applicator field sizes as large as 18 cm. The SRT-100™ is an updated version of an orthovoltage style x-ray unit, using innovative surface applicators. Similar machines (sometimes referred to as electronic brachytherapy machines) used in treating skin lesions are manufactured by Estaya, Xoft, and Elekta. These electronically-generated low-energy radiation sources (ELS) are designed to deliver low-energy radiation at a high-dose rate. Low-energy, however, does not equate to low-dose or with low risk to patients and healthcare personnel because the dose per fraction is relatively high. From an operational and physics perspective there is little difference between traditional superficial radiation therapy (SRT) units and newer electronic brachytherapy units like the SRT-100™. The newer therapy devices are capable of delivering a substantial dose to the patient and present a risk essentially at the same level as traditional SRT units. We urge Utah to maintain its focus on radiation safety, as represented by the current rules, by denying this request for exemption.

The Utah Administrative Code R313, “Environmental Quality, Waste Management and Radiation Control, Radiation,” Rule R313-30 governs use of Therapeutic Radiation Machines. Utah specifies radiation therapy machine requirements for users. These rules make no distinction between types of therapy (linac vs. Grenz, for example). The Utah Administrative Code defines requirements for facilities using therapeutic radiation machines (R313-30-3) and the specifics for training and education of authorized users (AUs) of therapeutic radiation producing equipment (R313-30-3-i (3)). The Rules require Program Director review of education and training of all physicians requesting approval for authorized use of therapeutic radiation producing equipment (R313-30-3 iii(a)). Training for AUs is codified in the rules as consistent for all devices used in therapeutic radiation treatment, and requires the AU be active in the practice of therapeutic radiology (R313-30-3 (3b)). In addition to the required training, Utah code requires supervised work experience to include a one-year formal residency and a two-year supervisory period for clinical experience training (R-131-30-3-b-iii). Rule R313-30-6 addresses special concerns/specific concerns of therapeutic radiation machines of less than 500kV, which include Sensus machines.

The AAPM believes that granting the requested exemption would set a dangerous precedent. For example, would granting this exemption lead to additional exemptions such as exempting breast surgeons requesting

use of electronic brachytherapy devices (e.g., XOFT with max 50 kVp)? We believe that such exemptions weaken the regulatory structure and put patients and healthcare personnel at risk. Due to the radiation exposure risks associated with use of these machines, the AAPM believes proper training and experience is crucial in the safe use of these devices.

2. Training Requirements of Current Regulations Protect Patients and Personnel

The Utah Code requires 200 hours of instruction to include basic radiation techniques in patient safety and radiation risk for the authorized use of therapeutic radiation machines. The vendor proposed AU training for the non-permitted authorized users (Dermatologists) requesting authorized use of this therapeutic radiation device is a 16-hour vendor-provided training course. The AAPM has grave patient safety concerns for use of the Sensus SRT-100™ therapeutic radiation device by physicians not completing the detailed training pathway articulated in current Utah administrative code.

Sensus states in the request for exemption:

“In addition to our explanations 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. [Emphasis added.] 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.”

Moreover, Sensus asserts the exemption request is based on the premise that the current Utah rules were written at a time when most radiation therapy machines in use were for treatment of tumors within the body, whereas the Sensus device is for superficial treatment of non-melanoma skin cancers.

Sensus, however, in the request for exemption omits a critical fact. While superficial (140 kVp or under) and orthovoltage (200-250 kVp) equipment has long been utilized for treatment of skin cancer, the use of radiation therapy devices in dermatology declined dramatically in the 1970’s. Dermatology residency programs eliminated radiation therapy from their curricula. As a result, a generation of dermatologists has limited exposure to radiotherapy in managing skin cancer. Many dermatologists now in practice did not receive radiation medicine and/or radiation safety training during their residencies. At present, only a few dermatology residency programs train residents in radiation medicine and/or radiation safety. Additionally, device quality assurance testing and medical physics calibration requirements are not addressed during that training.

Abandonment of radiotherapy by dermatologists may be attributed to a variety of causes including increased regulatory burden, shielding requirements, decreased reimbursement, licensure fees, and concerns over

radiation exposure. Concurrently, Mohs surgery emerged as the treatment of choice and may have contributed to the decline of radiotherapy by dermatologists for skin lesions. At present, there is a renewed interest by dermatologists to use radiotherapy to treat skin cancers. The AAPM believes, however, that dermatologists using radiation therapy devices (SRT devices) must receive the training and education specified in Utah's current regulations to ensure the safety of patients and healthcare personnel.

Sensus states in request for exemption,

“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 administering 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.”

The Sensus training curriculum is a 16-hour vendor-provided training course.

Many radiation oncologists specialize in treating cancers confined to certain organs or regions of the body. For example, some radiation oncologists limit their practice to thoracic cancers, and others limit their practice to treating cancers of the head and throat. Radiation oncologists, however, recognize the importance of training and education related to radiation medicine and safety, regardless of the body part their practice focuses on treating. As a result of this broader training, the radiation oncologist's knowledge may be critical to treating skin cancers, where the treatment site presents an interface of thin tissue and bone.

The intent of radiation safety regulations is to ensure that those using therapeutic radiation machines have been adequately trained to use those machines safely. The AAPM believes Utah's regulations for safe use of therapeutic radiation machines are written with patient safety in mind. Over-simplifying SRT-100™ technology, ignoring the high dose rates achieved with these machines, as well as the risk of harm to the patient, will not ensure safe use. The Utah rules, which are machine-specific and not body-part specific, protect the health and safety of patients and healthcare personnel. The AAPM believes the Sensus' two-day training program is not an acceptable minimum training program for use of these machines, given the great potential for patient harm.

3. Regulatory Supervision Requirements Ensure Safe Use

In addition to the required training, Utah code requires supervised work experience to include a one-year formal residency and a two-year supervisory period for clinical experience training (R313-3-3(3)(b)(iii)). Sensus is requesting an exemption from these clinical supervision requirements because, as it states in its request for exemption,

“Sensus Healthcare has a hands-on two (2) day training program with our Clinical Applications Specialist team who are supervised and certified by a Medical Physicist and Certified Medical Dosimetrist”

“...as Dermatologists will be applying SRT to only treat NMSC as their core specialty for which they are comprehensibly (sic) trained and already have societal and disciplinary oversight and mentorship programs.” [Emphasis added.]

Sensus misconstrues the regulatory supervision requirement, which applies to the machine user, not the Sensus teaching staff, and must be specific to the radiation therapy modality. Sensus’ argument that medical dermatology training establishes competency in use of therapeutic radiation machines defies logic. The AAPM believes that dermatologists must receive the radiation therapy specific supervision delineated in the regulations to ensure patient and healthcare personnel safety in the use of the SRT-100™ machines.

4. Delivering Accurate Dose to Prescribed Clinical Site

The AAPM believes the safe use of the Sensus SRT-100™ and similar devices depends on the user’s ability to deliver an accurate dose to the prescribed clinical site. Sensus in its request for exemption states,

“The Dermatologists are the ultimate experts on treating the skin cancer lesions and they are managing the disease state and tumor morphology, instead of just focusing on delivering dose to particular sites (as radiation oncologists are trained to do) [Emphasis added.]. 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 AAPM believes the Sensus’ statement above misconstrues the purpose of existing Utah rules. The rules govern use of therapeutic radiation machines, including the Sensus SRT-100™, not the practice of medicine. Accordingly, the relevant AU skill set identified by Sensus is precisely that of delivering an accurate dose to a skin tumor. The health and safety of patients protected under the Utah rule rests heavily on the physician completing specific training and experience criteria to become approved/authorized for use of therapy devices that accurately and precisely deliver radiation to a prescribed tumor site. While a physician’s ability to manage the disease state and tumor morphology is an important component in

physician practice and in the desired patient outcome, that is not governed or regulated by Utah rules for the safe use of therapeutic radiation machines.

5. Quality Management Programs Are Necessary for Safety

The AAPM urges Utah to deny any exemptions to Utah's required quality management and staffing requirements. The Utah Code for Quality Management Programs in Radiation Oncology (R313-30-5) requires a full calibration measurement and ongoing quality assurance (QA) testing of this device. These required QA measures are essential to provide accurate delivery of the radiation dose and ensure safe use of these machines. The AAPM is concerned about any exemption to current Utah quality management requirements. Moreover, the AAPM urges Utah to consider whether/how the facility using SRT-100 machines will staff for current quality management requirements. Similarly, the Utah Code requires individuals operating a therapeutic radiation device for medical use be a registered Radiation Therapy Technologist (R313-30-3-(5a)). The AAPM also urges Utah to consider whether the facility using the Sensus SRT-100™ machines will staff for this requirement, or will the AU-MD independently provide each patient treatment? Staffing concerns may be critical particularly in dermatology, a specialty in which some practices are dominated by large numbers of mid-level providers and very few supervisory physicians. It is critical to ensure that there is adequate staff with appropriate training.

6. Same Safety Concerns Addressed by Other States

The Conference of Radiation Control Program Directors (CRCPD), a professional organization of state regulators, is well-recognized for its work in developing Suggested State Regulations for Control of Radiation (SSRCR). When developing the SSRCRs, the CRCPD employs a very rigorous development and review process. This process includes state representation of the committee to develop the SSRCR, interaction from federal regulators (e.g., U.S. Food and Drug Administration), the medical community and equipment manufacturers; an extensive peer review and finally approval by the CRCPD Board of Directors. The purpose of this process is to advance greater uniformity of state regulations.

Utah is not the first state to address this issue. When presented with a similar request for exemption, Texas decided not to grant an exception to its rules under 25 TAC Section 289.229(h), which require that a user be a physician licensed in Texas, certified by a national board in radiation oncology, have completed device-specific training, as well as developed a quality assurance program.

Concerns of state regulators in Texas and elsewhere regarding unsafe use and lack of training by users of these machines prompted the CRCPD to look at the use of the electronic brachytherapy units for skin lesions. The task force has completed a survey of state regulators to determine how states are currently registering these units and other information. In addition, the task force is developing guidance for registering SRT electronic brachytherapy units and writing a "white paper" that x-ray inspectors may use as guidance during the routine inspection units. The AAPM strongly recommends that Utah make use of the CRCPD's resources when considering this request for exemption.

October 21, 2016

Scott Anderson, Director
Utah Department of Environmental Quality
Utah Division of Waste Management and Radiation Control
195 North 1950 West
PO Box 144880

I would like to express my opposition to the granting of an exemption for the use of Sensus Healthcare's SRT-100 superficial radiation therapy system by dermatologists. (Sensus Healthcare is requesting exemption from Utah Administrative Code: R313-30-3(3) -Training for external beam radiation therapy authorized users, R313-30-3(4) - Training for radiation therapy physicist, R313-30-3(5) -Qualifications of operators and R313-30-3(6) written safety procedures and rules.)

Therapeutic radiation is delivered under the direction of board certified radiation oncologists. Training to achieve board certification requires a minimum of 5 years of post medical school residency and includes extensive education in radiation physics, radiation biology, clinical oncology and perhaps most importantly radiation safety. This includes at least 500 hours of supervised work experience in addition to 200 hours of didactic instruction. Following board certification a radiation oncologist has continuing education requirements and proof of clinical quality required to maintain certification and licensure.

It is very cavalier to think that a physician with no formal training in radiation oncology can safely treat patients with superficial radiation therapy. Damage to tissues after inappropriate radiation may take many years to manifest and is irreversible. Therapeutic radiation must be administered with the utmost care and attention to quality which includes proper equipment calibration, monitoring of doses and extensive knowledge of the use of medical radiation which can only be gained via an accredited residency. Appropriately trained therapy technicians and medical physicists are also essential for safe and effective radiation administration.

The SRT-100 is a superficial radiation therapy delivery system and minimal training is provided by the vendor for its use. This does not meet any of the criteria for operating or treating patients with a radiation therapy device of any other variety. This device should not be exempted from the Utah Administrative Code qualifications.

Sincerely,



Vilija Avizonis MD
Chair Radiation Oncology
Intermountain Medical Center
Murray, UT
(801)507-3888



October 28, 2016

Scott Anderson, Director
Utah Department of Environmental Quality
Utah Division of Waste Management and Radiation Control (UDWMRC)
195 North 1950 West
P.O. Box 144880
Salt Lake City UT 84114-4880

RE: Comment Against the Granting of an Exemption for the use of Sensus Healthcare SRT-100 superficial radiation therapy system by Dermatologists

Sensus Healthcare is requesting exemption from the following provisions of the Utah Administrative Code: R313-30-3(3) - Training for External Beam Radiation Therapy Authorized Users; R313-30-3(4) - Training for Radiation Therapy Physicist; R313-30-3(5) - Qualifications of Operators; and R313-30-3(6) - Written safety procedures and rules.

Dear Mr. Anderson:

Intermountain Healthcare, Inc. is against the granting of an exemption request to allow the user of the Sensus Healthcare SRT-100 superficial radiation therapy (SRT) system to be considered an Authorized User without meeting the established training requirements for the following reasons:

- 1) The SRT system is a radiation therapy device designed to deliver therapeutic doses of x-ray radiation and therefore should only be allowed to be used by qualified external beam radiation therapy Authorized Users who meet the requirements of Utah Administrative Code. NOTE: The term "superficial" radiation therapy should not confuse individuals to believe that this is not a radiation therapy device. This device does not lessen the potential radiation risk to patients.
- 2) Patients treated with the SRT system require the management by a physician who has the level of training and expertise necessary for radiation therapy. Treatment of patients with therapeutic levels of radiation requires specialized knowledge in biology, dose deposition, management of side effects, and the appropriateness of patient selection for treatment. Lack of this expertise could lead to danger to the patients in inadequate or inappropriate treatment delivery and mismanaged care.
- 3) As a therapeutic device, the SRT system must be supervised by a qualified and trained Radiation Therapy Physicist. Lack of supervision by a physicist could lead to medical events due to overdose or underdose, as well as misalignment with treatment sites. Supervision must include a regular quality assurance

program of both the machine characteristics and the dose calculations performed for each patient. An appropriate quality assurance program should include daily, monthly, and annual checks of the device as well as ongoing technical reviews of cases under treatment. An annual survey of the unit by a Utah Registered Qualified Expert would be grossly inadequate in meeting these needs.

- 4) Although Sensus Healthcare representatives may arguably be considered experts in the specifics of their device, the training they may provide in the above requirements would not be sufficient. Regulated medical training programs, physics training programs, residency training programs, and board certifications, are rightly considered standard for the use of therapeutic radiation. Physicians actively administering radiation therapy treatments within the state of Utah are board certified in their specialty, in accordance with regulations. The training requirements as they currently exist in the Utah Administrative Code are appropriate and should not be considered for exemption.
- 5) It should be finally noted that Sensus Healthcare has a clear conflict of interest. They are a corporate entity aimed to maximize profit and we feel it completely inappropriate that they request a change in governmental regulatory and safety measures designed to protect patients in order to more easily sell their equipment or treatment. The UDWMRC should be aware of the motivation of Sensus Healthcare when requesting an exemption of clear safety measures.

In correlation to the above concerns, this letter is also provided as result of the need to provide additional comment due to the current makeup of the UDWMRC Board (regarding radiation). In the future, in addition to the UDWMRC asking for public comment when board actions could be controversial, we are requesting that:

- 1) board actions of concern allow for more notice than routine Board Meeting notification (i.e., more than 48 hours in advance) so that materials can be adequately reviewed and arrangements can be made to attend UDWMRC board meetings when relevant medical items are included on the Board agenda.
- 2) in addition, we feel it would be prudent for the UDWMRC to create and assign a radiation medical task force to assist the Division, as well as Jeremy Hawk (a member of the UDWMRC Board) when medical radiation issues arise which will be taken to the UDWMRC Board. This way the medical task force could assist with the review of radiation issues before they are presented to the UDWMRC Board (which is limited in radiation expertise). By having the UDWMRC develop a specialized medical radiation task force we can feel more comfortable that all medical radiation issues will be sufficiently researched and appropriately addressed before being presented to the UDWMRC Board.
- 3) the UDWMRC provide an avenue to examine case-by-case limited scope exemptions for emergent patient issues rather than allow for exemption to Utah Administrative Code on a short timeline.

For the above reasons, our needs are not being met.

Respectfully,



William T. Sause, M.D.
Medical Director Oncology
Intermountain Healthcare, Inc.



John Gordon, M.S., DABR
Lead Physicist, Radiation Oncology
Central Region, Intermountain Healthcare, Inc.



Julie Rupp Felice, CPM, Health Physicist
Director of Radiation Safety, Radiation Safety Officer
Central Region, Intermountain Healthcare, Inc.



UNIVERSITY OF UTAH
SCHOOL OF MEDICINE

Department of Radiation Oncology



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Jonathan D. Tward, MD, PhD
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Y. Jessica Huang, PhD
Assistant Professor

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Assistant Professor

Fan-Chi Frances Su, PhD
Assistant Professor

Martin Szegedi, PhD
Assistant Professor

Hui Zhao, PhD
Assistant Professor

Radiobiology

Srividya Bhaskara, PhD
Assistant Professor

Mahesh Chandrasekharan, PhD
Research Assistant Professor

Scott Anderson, Director
Utah Division of Waste Management and Radiation Control
195 North 1950 West
P.O. Box 144880
Salt Lake City, Utah 84114

October 21, 2016

Dear Director Anderson,

We are writing in response to the July 28, 2016 formal request by the "Sensus Healthcare" corporation requesting that the State of Utah grant an exemption to Administrative Code R313-30-3 to allow dermatologists (or other providers) to deliver orthovoltage radiation therapy for skin lesions.

We are both Huntsman Cancer Institute physicians and investigators, who specialize in the multidisciplinary management of malignant skin cancers at a National Cancer Institute designated Comprehensive Cancer Center. One of us (Dr. Jonathan Tward, MD, PhD) is a board-certified and tenured Associate Professor of Radiation Oncology at the University of Utah. The other (Dr. Glen Bowen, MD) is a board-certified Associate-Professor of Dermatology, serves on the National Comprehensive Cancer Network (NCCN) Clinical Practice for Skin Cancer guidelines committee, and is the clinical director of the Multidisciplinary Cutaneous Oncology Program at The Huntsman Cancer Institute at the University of Utah. We both frequently treat patients with malignant skin conditions, and are both respected authors of textbooks and other research papers about the management of skin cancers[1, 2], and the role of radiation therapy in its management. As such, we feel we are qualified experts to comment on this request.

We are both strongly opposed to this exemption request. It is our professional opinion that the only providers who should be authorized to perform radiation therapy services are radiation oncologists, and their skilled team (including dosimetrists, physicists, nurses and therapists). The arguments made by Sensus Healthcare, that this form of radiation therapy, or that radiation to the skin specifically is somehow unique and different in complexity to other forms of radiation therapy, demonstrate a naïve and potentially dangerous lack of understanding of radiation oncology, biology and physics. Allowing exemptions to the well-crafted rules in Administrative Code R313-30-3 will likely result in unnecessary medical complications and morbidity, overutilization of radiotherapy to the exclusion of other appropriate alternatives, and financially incentivize providers to perform a costlier procedure over other more cost-effective alternatives.

The University of Utah
Huntsman Cancer Hospital
1950 Circle of Hope, Room 1570
Salt Lake City, Utah 84112-5560
Phone 801-581-8793
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medicine.utah.edu/radiation-oncology/

It is true that in the late 19th and earliest years of the 20th century, dermatologists were practitioners of superficial radiations for virtually all types of skin lesions (both benign and malignant). In these early days of radiation therapy dermatologists would indiscriminately use superficial x-rays to treat fungal diseases, eczema, psoriasis, lichen planus, pruritus, hypertrichosis, tuberculosis, benign and congenital nevi, as well as some malignant conditions. Although many of these conditions showed some immediate and fleeting response with radiation therapy, results were often not durable, and often resulted in severe late toxicity. As radiation biology as a science unfolded in concert with appropriate medical investigation, dermatologists abandoned the use of radiation therapy for virtually all the benign skin conditions because there were less toxic and more efficacious alternatives. In addition, several decades following radiation therapy (RT), there is a greatly increased risk of skin cancer in the treatment field. This is an enormous problem in teenagers treated for acne with RT that can literally develop skin cancers on the face in the hundreds usually beginning after the age of 60. Skin cancer usually occurs later in life, therefore, RT did have, and continues to have, an important role in the multidisciplinary management of skin malignancies. As such, the practice of dermatology evolved to include consultation and inclusion of other skilled professionals, including radiation oncologists, medical oncologists, and other surgical sub-specialists when needed for the treatment of complicated skin cancers. For over half a century dermatologists have recognized that the appropriate and safe delivery of radiation therapies for skin disorders was well beyond the scope of their practices, as was the necessarily rigorous quality assurance and compliance programs which must be in place to ensure patient safety.

We believe that radiation therapy has an important role in treating skin cancers. When done in partnership with specialized teams of experts from both dermatology and radiation oncology, radiation therapy can have excellent outcomes. We would like to address the obvious and not-so obvious reasons why the exemption request should be denied:

- 1) Although superficial X-rays do deposit most of their dose within the skin, there are still varying doses to the underlying tissues. A dermatologist does not have a formal radiation biology and oncology training, and thus is not trained to consider how the effect of prior radiations, genetic or familial susceptibilities to radiation injury, interactions of radiations with current drug therapies, or normal tissue tolerances of skin and neighboring tissues to various radiation fractionation regimens would affect their patient. How would they choose the total dose and fractionation (dependent on all the above factors and more), and establish the appropriate size of the treatment field for the unique circumstance of every patient? More concerning, the submitted request implies that non-melanoma skin cancers are something akin to a benign condition akin to a mere mole, and yet, both basal and squamous cell carcinomas of the skin have the potential to invade underlying muscle and bone, the eyes, nose, and ears, and can metastasize from the skin to internal organs culminating in death. How would we ensure the dermatologist knew how to handle the complex landscape of these oncologic situations? What about using the instrument for cutaneous lymphomas, or for that matter melanomas? An exemption to the requirements would effectively authorize dermatologists to offer radiation to the skin for any condition they see fit. Even extremely low scatter doses of radiation therapy near the testicles can leave young men with fertility problems. How would the dermatologist

address the risk of secondary malignancies, especially in children and in premenopausal women? Perhaps we will see a re-emergence of irresponsibly irradiating skin for acne, psoriasis, etc? These concerns are not merely conjecture. One of us (Bowen) recently reported a case in JAMA Dermatology[3] of a Utahn who received this exact form of radiation therapy at a dermatology clinic that resulted in failure to achieve tumor control with a rapid recurrence, as well as radiation injury that required extensive reconstructive surgery to correct. Unfortunately, this same patient could have easily been treated with other forms of therapy, including various surgical approaches.

It is incredulous to believe that a company can spend a couple of days with some “training seminar” and expect that a dermatologist can possibly come away with anything more than the most cursory understanding of radiation therapy for skin lesions.

- 2) There are not any access issues to high quality radiation therapy centers within the State of Utah or neighboring states. The State of Utah has board certified radiation oncologists in Salt Lake City, Logan, Ogden, Farmington, Provo, South Jordan, and St. George. In neighboring states, there are radiation oncology centers in Pocatello, Grand Junction, and Elko. One cannot make an access to care argument. If anyone would like a truly expert opinion on the role of radiation therapy to the skin, there are no shortage of skilled radiation oncologists within a reasonable traveling distance.
- 3) This is a technically legal, but perverted form of self-referral. The Stark-Law of the United States of America specifically forbids physicians from self-referring to tests and therapies to which the physician could profit. The spirit of the law was to ensure that doctors weren't incentivized by profit motives to “do things” to people even if not medically necessary. Unfortunately, the Stark Law granted an exemption to Radiology (including diagnostic and therapeutic) services under the In-Office Ancillary Services Exemption (IOASE). The spirit of the exemption was to allow people like orthopedic surgeons to attain diagnostic X-rays within their office for clinic efficiency. It has now been proven that exploitation of the radiation therapy IOASE leads to overutilization of expensive radiation oncology services by non-radiation oncology practice owners[4]. This ethical dilemma has already been raised in the dermatology community[5]. In office RT creates a huge profit incentive to a dermatologist who will be tempted to expand treatment indications for RT to tumors where there are far less expensive and effective treatment alternatives which will consequentially substantially drive up the cost of skin cancer treatment.

Here are some slides directly from the company's prospectus listed with the Securities and Exchange Commission....

Value Proposition

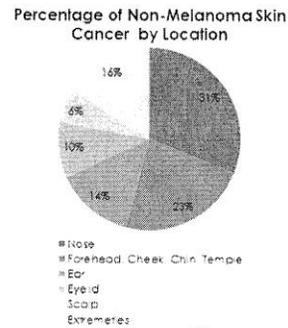
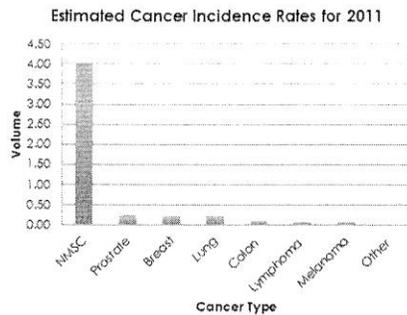
- SRT-100 and SRT-100 Vision have significant benefits for both the practitioners and patients

Practitioner	Patient
<ul style="list-style-type: none"> Cost effective Increased productivity Excellent ROI Existing CPT codes Improved cash flow Additional treatment choices 	<ul style="list-style-type: none"> No anesthesia, cutting, bleeding, stitching, or scarring Painless Comparable cure rates as Mohs Surgery (95%+) Recurrence rates < 2% Patients can continue active schedule



Skin Cancer: Large & Growing Market

- Fastest growing cancer indication with 6M+ new cases/year by 2020
- 3X greater than all other cancers combined
- 80% of skin cancers occur on head/neck regions
- 31% on tip of nose



Source: American Cancer Society, Cancer Facts and Figures 2011

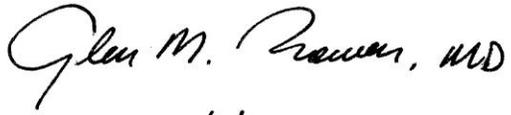


Does "improved cash flow" and "excellent ROI" in the "Fastest growing cancer indication" speak to what is best for our patients?

In summary, although we completely agree that radiation therapy is an excellent option for certain types of skin cancers in specific clinical scenarios, and agree that radiation therapy is under-utilized in

this context, we strongly object to exemptions to well-thought-out state laws designed to protect the health and welfare of Utah's citizens. We firmly believe that radiation therapy for skin cancers should be performed by multidisciplinary teams that include both radiation oncologists and dermatologists, and that the therapeutic delivery of radiation should only be performed by radiation oncologists, with their requisite trained personnel of physicists, dosimetrists, therapists and specialized nurses. We fear that allowing this exemption would lead to an overutilization of radiation therapy in this context, deprive patients of excellent and lower cost therapies, financially incentivize providers to provide this therapy over more conservative treatment options which could lead to fraud and abuse, and most importantly, result in harm (as we have already observed). We are both employees of the State of Utah and would be delighted to serve as expert resources to the State about the management of dermatologic conditions and/or radiation oncology services. Please do not hesitate to contact us for any needs.

Sincerely,

<p>Jonathan David Tward, MD, PhD Associate Professor, Radiation Oncology University of Utah, Huntsman Cancer Institute</p>  <p>October 21, 2016</p>	<p>Glen M. Bowen, MD Associate Professor, Dermatology Clinical Director of the Multidisciplinary Cutaneous Oncology Program Treatment Planning Conferences University of Utah, Huntsman Cancer Institute</p>  <p>21 October, 2016</p>
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1. Tward, J.D., et al., *Survival and recurrence in nonmycosis fungoides primary cutaneous lymphoma*. Cancer J, 2009. **15**(1): p. 87-92.
2. Jonathan D. Tward, C.J.A., David K. Gaffney and Glen M. Bowen, *Radiation Therapy and Skin Cancer*, in *Modern Practices in Radiation Therapy*, Gopishankar Natanasabapathi, Editor. 2012, In Tech: Open access Online. p. 207-246.
3. Eftekhari, K., et al., *Local Recurrence and Ocular Adnexal Complications Following Electronic Surface Brachytherapy for Basal Cell Carcinoma of the Lower Eyelid*. JAMA Dermatol, 2015. **151**(9): p. 1002-4.
4. Mitchell, J.M., *Urologists' self-referral for pathology of biopsy specimens linked to increased use and lower prostate cancer detection*. Health Aff (Millwood), 2012. **31**(4): p. 741-9.
5. Grant-Kels, J.M. and M.J. VanBeek, *The ethical implications of "more than one way to skin a cat": increasing use of radiation therapy to treat nonmelanoma skin cancers by dermatologists*. J Am Acad Dermatol, 2014. **70**(5): p. 945-7.

October 28, 2016

Scott Anderson, Director
Utah Division of Waste Management and Radiation Control
195 North 1950 West
P.O. Box 144880
Salt Lake City, UT 84114-4880

To Director Anderson,

I am writing to offer comment on the training and management exemptions proposed by Sensus Healthcare as they pertain to Superficial Radiation Therapy (SRT) for non-melanoma skin cancer (NMSC). First, I would like to concur that radiation is a viable and often superior treatment than surgery for many types of skin cancer. For many years, Radiation Oncologists have used their training and experience to provide this resource to patients, in a safe and effective way. Radiation Oncologists have proven their knowledge of radiation biology, radiation physics, and radiation safety as evidenced by board certification from The American Board of Radiology (The ABR). This distinction is unobtainable by a Dermatologist, as they have not met the requirements needed to sit for board certification by The ABR. In addition to Radiation Oncologists, Medical Physicists are also a key member of every radiation therapy center. Like Radiation Oncologists, they are board certified by The ABR in the specialty of Radiation Therapy Physics. They are integral in the quality management of radiation producing machines and radioactive materials, and their role is far more extensive than an annual check of equipment calibration. Specifically, with regard to Superficial Radiation Therapy (SRT), the customization of each treatment for a specific patient requires the determination and calculation of field sizes, back scatter factors, and dose, and is integral to providing the best patient care. Grouping treatments into baskets of template plans is inferior to the care provided when staffed with a professional team trained to deliver this therapy. The NIH agrees "Radiation physicists play important roles in both determining the dose of radiation delivered to the patient and the implementation of safety measures for the staff and patient,"² when commenting on the use of SRT for NMSC. This is clearly a financial profit driven request for both Sensus Healthcare and Dermatologists, and not as Sensus claims, a way for patients to "have access to this safe and effective modality, instead of being sent to complex surgeries." This access exists by means of direct referral to a trained professional, the Radiation Oncologist. Radiation Oncologists have had years of experience in addition to years of training that cannot be gained by means of a "two-day training session."

In researching this topic, I came across a number of articles promoting SRT, and advocating its use by dermatologists. There was almost a singular tone and theme to the articles like "Superficial radiation therapy ripe for resurgence,"¹ published April 1, 2014 in Dermatology Times. That theme was the benefit and advantage of SRT as a viable alternative to surgery. There was one other similarity noted, the disclosures. The disclosure for this article reads **Disclosures: Dr. Nestor is a consultant and advisory board member for Sensus Healthcare and has received research grants from this company.**

'Thomas' via dwmrcpublic <dwmrcpublic@utah.gov>

Fri, Oct 28, 2016 at 5:52 PM

Reply-To: Thomas <thomas.skidmore@yahoo.com>

To: dwmrcpublic@utah.gov

Too Whom it may concern,

I am against the public exemption that is being requested for sensus. Use of the machine in my mind clearly requires the training and expertise of a radiation oncologist and physicist. Selecting treatment schedules for skin requires a good understanding of equivalent dose calculations and what fraction sizes are safe on what part of the body. Custom shielding at the skin surface, which is often done, allows for shaped fields, but requires calculations of field sizes and back scatter factors that are checked by a physicist before treatment. Specific dosimetric procedures are done for QA like nanodot dosimetry which also requires more specific physics training. Radiation Oncologists must pass certification board exams in radiobiology and physics and dermatologists are not trained adequately or at all in this important subjects and have no standard for certification. A dermatologist is no more qualified to over see radiation treatments as a pediatrician is to do Moh's surgery.

Sincerely,

Thomas Skidmore, MD
Radiation Oncologist
Gammawest Cancer Services

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You received this message because you are subscribed to the Google Groups "dwmrcpublic" group.

To unsubscribe from this group and stop receiving emails from it, send an email to dwmrcpublic+unsubscribe@utah.gov.

To post to this group, send email to dwmrcpublic@utah.gov.

BJ <bjfisher7@gmail.com>
To: dwmrcpublic@utah.gov

Fri, Oct 28, 2016 at 6:58 PM

Hi Scott Anderson,

I am a radiation oncologist and am writing in opposition to allowing radiation machines to be used under the direction of anybody but a board certified radiation oncologist and physicists.

I have discussed this matter with several colleagues and physicists and have found a strong consensus in opposition to allowing non-radiation oncology trading physician manage any type of radiation machine. Radiation should only be delivered by someone who has completed their residency in radiation, which includes an in depth course of radiation physics and biology along with understanding of appropriate uses of radiation for all types of cancer. Residency training is the only appropriate training for someone who will prescribe radiation. Sensus should not be allowed to promote any training and actually makes many false claims on their website about skin cancer and radiation side effects, furthermore a drug company/manufacturer should never replace sound and approved training.

Sensus should not receive, and I am feel strongly that the should be rejected from receiving, exemption from the following provisions of the Utah Administrative Code: R313-30-3(3) - Training for External Beam Radiation Therapy Authorized Users; R313-30-3(4) - Training for Radiation Therapy Physicist; R313-30-3(5) - Qualifications of Operators; and R313-30-3(6) - Written safety procedures and rules.

The basis for these above rules are very relevant today and with all types of radiation machines. Doses to treat and cure non melanoma skin cancers are at least 60 Gy and up. This is a lot of radiation!!!! 60 Gy is 60 Gy. In the state of Utah, we have many superficial machines, electron, low energy photons and high dose rate brachytherapy. All are used by radiation oncologist in conjunction with a radiation physicist. Sensus believes that the training requirements place an undo cost burden on the dermatologist. In actuality, dermatologist have no training in radiation, no training in radiation biology and physics. They do not have to answer to the American board of radiology. Dermatologist, in order to deliver radiation should do a radiation oncology residency, that is 5 years post medical school, and should not be treated lightly. Medical physicists are now required do perform 4 years of phd work followed by a residency. Additionally, there is no need to flood the market. Sensus has approached all radiation centers selling their machine. There are adequate machines and every radiation facility in the state can adequately treat skin cancer.

- On September 9, 2016, the Waste Management and Radiation Control Board granted a 90-day exemption for use of the Sensus SRT-100 by a local dermatologist, this should never have been granted. I could not imagine getting 90 days to perform mohs surgery without performing a dermatology residency and additional fellowship training, but rather being allowed to perform surgery under a corporate manufacturers tutelage. Does the American Board of Radiology support this?

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Thanks,

Brandon Fisher
Contact me with any questions. [801-879-2594](tel:801-879-2594)