



State of Utah

GARY R. HERBERT
Governor

SPENCER J. COX
Lieutenant Governor

Department of
Environmental Quality

Alan Matheson
Executive Director

DIVISION OF WASTE MANAGEMENT
AND RADIATION CONTROL
Scott T. Anderson
Director

A regular meeting of the Waste Management and Radiation Control Board has been scheduled for November 10, 2016 at 1:30 p.m. at the Utah Department of Environmental Quality, Multi-Agency State Office Building, Conference Room #1015, 195 North 1950 West, SLC.

(One or more Board members may participate telephonically.)

AGENDA

- I. Call to Order.
- II. **Approval of Meeting Minutes for the October 13, 2016 Board meeting (Board Action Item)..... Tab 1**
- III. **Underground Storage Tanks Update..... Tab 2**
- IV. **Underground Storage Tank Rules..... Tab 3**
 - A. Final adoption of changes to Underground Storage Tank Rules R311-200, R311-201, R311-202, R311-206, and R311-212 (**Board Action Item**).
 - B. Approval of a Change in Proposed Rule for R311-203 to incorporate comments made by the Environmental Protection Agency (**Board Action Item**).
- V. **Low Level Radioactive Waste Section..... Tab 4**
 - A. EnergySolutions LLC request for a site-specific treatment variance from the Hazardous Waste Management Rules. EnergySolutions seeks authorization to receive Cemented Uranium Extraction Process Residues for disposal (Information Item Only).
- VI. **Administrative Rules Tab 5**
 - A. EnergySolutions' Petition to Initiate Rulemaking to repeal and reenact R313-25 and adopt 10 CFR Part 61 by reference (Information Item Only).
- VII. **X-Ray Program Tab 6**
 - A. Exemption request for the Sensus SRT-100 machine from the requirements of R313-30-3(3), R313-30-3(4), R313-30-3(5) and R313-30-3(6) (**Board Action Item**).

(Over)

VIII. Other Business.

- A. Misc. Information Items.
- B. Scheduling of next Board meeting.

IX. Adjourn.

In compliance with the Americans with Disabilities Act, individuals with special needs (including auxiliary communicative aids and services) should contact Dana Powers, Office of Human Resources at (801) 499-2117 TDD (801) 903-3978 or by email at dpowers@utah.gov.

Waste Management and Radiation Control Board Meeting
Utah Department of Environmental Quality
195 North 1950 West (Conference Room #1015) SLC, Utah
October 13, 2016
1:30 p.m.

Board Members Present: Brett Mickelson (Chair), Danielle Endres, Jeremy Hawk, Alan Matheson, Steve McIff and Vern Rogers

Board Members Participating Telephonically: Richard Codell and Mark Franc

Board Members Absent: Dennis Riding (Vice Chair), Shawn Milne and Shane Whitney

Staff Members Present: Scott Anderson, Brent Everett, Ralph Bohn, Doug Hansen, Arlene Lovato, Rusty Lundberg, Deborah Ng, Rick Page, Jerry Rogers, Elisa Smith, Don Verbica and Otis Willoughby

Others Present: Sawyer Hill, Tim Orton, Dan Shrum, Brent Snelgrove and Ashley Soltysiak

Others Participating Telephonically: Dr. Erik Natkin

I. Call to Order.

Brett Mickelson (Chair) welcomed all in attendance and called the meeting to order at 1:30 p.m. Shawn Milne and Shane Whitney were excused from the meeting. Richard Codell, Mark Franc and Dr. Erik Natkin participated telephonically.

II. Introduction of Nathan Rich – New Board Member

Mr. Rich is the Executive Director of Wasatch Integrated Waste Management District which operates a Solid Waste Landfill and Waste to Energy Facility in Davis County. Mr. Rich fills the vacancy left by Dwayne Woolley and serves as one of two non-federal government representatives on the Board.

III. Approval of the Meeting Minutes for the September 8, 2016 Board Meeting.

It was moved by Danielle Endres and seconded by Vern Rogers and UNANIMOUSLY CARRIED to approve the September 8, 2016 Board meeting minutes.

IV. Underground Storage Tanks Update.

Brent Everett, Director of the Division of Environmental Response and Remediation (DERR), informed the Board that the cash balance of the Petroleum Storage Tank (PST) Trust Fund at the end of August 2016 was \$17,974,397.00. The preliminary estimate for the cash balance of the PST Trust Fund for the end of September 2016 is \$16,972,968.00. The cash balance of the PST Trust Fund is watched closely to ensure sufficient funds are available in the PST Trust Fund. There were no questions on the PST Trust Fund balance.

V. Administrative Rules.

- A. Final adoption of repeal of Rule R313-27, “Medical Use Advisory Committee” (Board Action Item).

Ralph Bohn, Section Manager, Planning and Technical Support Section, reviewed the request to approve the repeal of Rule R313-27 “Medical Use Advisory Committee” and set an effective date.

R313-27 was adopted by the Radiation Control Board in its final meeting in June 2015. This rule requires the Board to appoint a Medical Use Advisory Committee to review any rule or other policy that affects the medical use of radiation and to make a recommendation to the Board on the proposed rule. The rule establishes the makeup of the committee and requires the committee to report to the Board prior to any Board action on a rule related to the medical use of radiation.

The Attorney General’s Office has determined that the Radiation Control Board did not have the authority to promulgate R313-27. (See memorandum from Craig Anderson, Assistant Attorney General, that was provided in the July 14, 2016 Board packet).

The proposed repeal of R313-27 was published in the September 1, 2016 Utah Bulletin. Comments received along with the letter sent to the Board prior to the July 14, 2016 meeting were included in the October 13, 2016 Board packet. The Director’s response to the comments on the proposed repeal of R313-27 was provided to the Board in a separate e-mail document, dated October 12, 2016.

Alan Matheson, Executive Director, Department of Environmental Quality explained that the proposal to repeal R313-27 arises from a technical legal concern about the Board’s authority to create the Medical Use Advisory Committee, not from any failure to recognize its value.

Mr. Matheson stated that, because the Board and Division staff do not have expertise in every issue that comes before the Board, the goal is to establish a workable and legal mechanism to ensure the Board and staff have sound information on medical radiation before making decisions in that area. However, because the Attorney General’s Office has determined that the Board did not have the legal authority to promulgate a rule to create a Medical Advisory Committee, the UDEQ now has to be compliant with the law and act within its authorities. The UDEQ has every intention of identifying appropriate ways to gather input on the medical use of radiation. At this time, the matter at hand has to address the legal authority of the Board and the request to approve the repeal of Rule R313-27.

It was moved by Steve McIff and seconded by Nathan Rich and carried for the Board to approve the repeal of R313-27. Brett Mickelson, Danielle Endres, Mark Franc, Jeremy Hawk, Alan Matheson and Vern Rogers voted in favor of the motion. Richard Codell voted against the motion.

Richard Codell noted that all comments received were against the repeal of R313-27 and felt that an alternative should be in place to ensure matters are handled adequately in the future.

Vern Rogers stated that, as he read the information/comments from last year, it was determined that the Board had the authority to create R313-27. Mr. Rogers asked if it is common to have opposing opinions from the Attorney General’s Office.

Mr. Bohn stated that the legal opinion at the time the rule was promulgated was based on a similar provision enacted by the Water Quality Board. The Attorney General’s Office has researched that rule

and also determined that the Water Quality Board will have to withdraw its rule. The Division of Water Quality has been notified that their rule did not have a legal basis and will have to be repealed.

Danielle Endres asked if the Division has any plans to make a more formalized committee as Board members would like participation by experts when they desire it. Mr. Matheson stated that the Department can establish committees and he is open to that idea. However, there are some complications with that concept, such as deciding which issues need what outside expertise, if any, or creating committees with lots of people but without having any issues for months or years. There are a number of other ways to gather input and the exact form it takes may vary, but the fundamental principle is finding the best way to get the most relevant information for the Board before a decision is made. Mr. Matheson asked for ideas other than just a formalized committee.

Richard Codell suggested a medical use advisory group could be formed to be available when needed; but not place an undue burden on the State of Utah. Mr. Matheson reiterated his openness to recommendations from the Board for his consideration.

Scott Baird, Director of Legislative and Government Affairs, Utah Department of Environmental Quality, informed that Board that he has been involved in discussions with Mr. Peter Jenkins on this matter and committed to sit down with Mr. Jenkins and others to see what solutions could be considered.

VI. Used Oil Program.

- A. Approval to proceed with formal rulemaking and 30-day public comment period for Used Oil Rule, R315-15-13 (Board Action Item).

Deborah Ng, Hazardous Waste Section Manager, reviewed the request for the Board to approve for publication in the Utah Bulletin and commencement of a 30-day public comment period, the proposed changes to the Used Oil Rule, R315-15-13.

R315-15-13 is the section of the Used Oil Program Rules that covers the registration and permitting of used oil handlers.

Subsection R315-15-13.4(f) allows generators of used oil to transport quantities exceeding 55 gallons under a permit by rule. The permit by rule exemption is limited to facilities that fall within certain North American Industry Classification System codes.

The Division has been approached by Rocky Mountain Power asking if the utilities sector code could be added to the list in the rule. Rocky Mountain Power generates large amounts of used oil, some of which is located in remote locations where it is difficult or impossible to get a used oil transporter to pick up the oil.

This change would allow the utility to transport its own oil under permit by rule. The change also updates the reference to the current version of the North American Industry Classification System.

It was moved by Nathan Rich and seconded by Danielle Endres and UNANIMOUSLY CARRIED to approval to proceed with formal rulemaking and 30-day public comment period for Used Oil Rule, R315-15-13.

Danielle Endres asked if the utilities transporting their used oil themselves will be held to the same standards as others transporters. Ms. Ng explained that they would need to meet the same standards.

Ms. Endres also asked if there is any higher risk in allowing them to transport it on their own. Ms. Ng said no.

Richard Codell asked if the oil contained PCBs. Ms. Ng explained that the oil does contain PCBs but the concentration is less than 50 ppm. Transporting oil with PCBs over 50 ppm would subject the transporter to other TSCA requirements.

VII. X-Ray Program.

A. Request for Exclusion from certain requirements of R313-28-31(5) (Board Action Item).

Ralph Bohn informed the Board that Dr. Erik Natkin has requested an exemption from Rule R313-28-31(5). This rule governs the use of x-rays in the healing arts and reads: "Portable or mobile equipment shall be used only for examinations where it is impractical to transfer the patient to a stationary radiographic installation."

The basis for the exemption request was provided in a letter to the Director received September 2, 2016. The letter was included in the October 13, 2016 Board packet. The Division requested comments on the exemption request from several radiation safety officers and other health care professionals in the state. No comments were received.

Mr. Bohn recommended that the Board grant the exemption with the following language in the motion for approval: "The request of Dr. Erik Natkin for an exemption from R313-28-31(5) is granted. The exemption has no expiration date. The exemption granted by the Board is from the requirements of R313-28-31(5) only and not from any other applicable part of R313-28, including the plan review requirements of R313-28-32, the operator protection requirements of R313-28-52(8)(b) and the source-to-skin distance limit of R313-28-53."

Mr. Bohn noted that two other machines in the State of Utah like this have been grandfathered into the rules.

Dr. Erik Natkin explained his reasons for the exemption request and his intent to position and use this device in a designated shielded room, practically making it a stationary device and thus compliant with potential radiation exposure management dictated by Utah Code.

It was moved by Steve McIff and seconded by Jeremy Hawk and UNANIMOUSLY CARRIED to approve Dr. Natkin's request for exclusion from certain requirements of R313-28-31 (5). Specifically, this approval is only for using a portable machine in a permanent location. Dr. Natkin is subject to all other requirements of R313-28-31(5).

VIII. Other Business.

- A. Misc. Information Items. – None to Report.
- B. Scheduling of next Board meeting.

The next Board meeting is scheduled for November 10, 2016 at 1:30 p.m. at the Utah Department of Environmental Quality, 195 North 1950 West, Salt Lake City, Utah.

IX. Adjourn.

The meeting adjourned at 2:04 p.m.

UST STATISTICAL SUMMARY
October 1, 2015 -- September 30, 2016

PROGRAM													
	October	November	December	January	February	March	April	May	June	July	August	September	(+/-) OR Total
Regulated Tanks	4,000	3,989	3,991	4,003	4,007	4,006	4,015	4,017	4,019	4,015	4,035	4,052	52
Tanks with Certificate of Compliance	3,889	3,887	3,887	3,916	3,919	3,917	3,911	3,916	3,919	3,916	3,935	3,919	30
Tanks without COC	111	102	104	87	88	89	104	101	100	99	100	133	22
Cumulative Facilities with Registered A Operators	1,334	1,333	1,332	1,333	1,333	1,332	1,332	1,324	1,327	1,325	1,320	1,315	97.05%
Cumulative Facilities with Registered B Operators	1,335	1,334	1,333	1,334	1,334	1,333	1,333	1,325	1,328	1,326	1,320	1,316	97.12%
New LUST Sites	5	4	6	3	4	10	13	4	8	7	5	7	76
Closed LUST Sites	9	7	10	9	3	10	2	14	4	11	12	11	102
Cumulative Closed LUST Sites	4857	4859	4867	4878	4886	4889	4892	4905	4913	4921	4932	4942	85
FINANCIAL													
	October	November	December	January	February	March	April	May	June	July	August	September	(+/-)
Tanks on PST Fund	2,844	2,840	2,840	2,763	2,766	2,764	2,758	2,752	2,751	2,753	2,757	2,741	(103)
PST Claims (Cumulative)	648	649	647	647	649	649	649	651	651	655	655	655	7
Equity Balance	-\$7,663,788	-\$7,186,058	-\$7,441,692	-\$7,435,326	-\$7,180,546	-\$7,535,427	-\$7,425,420	-\$8,031,463	-\$6,636,622	-\$7,375,813	-\$7,326,360	-\$8,286,855	(\$623,067)
Cash Balance	\$16,357,660	\$16,835,389	\$16,406,467	\$16,412,833	\$16,667,613	\$16,375,040	\$16,422,739	\$17,142,184	\$17,376,517	\$17,213,545	\$17,974,397	\$16,972,968	\$615,308
Loans	0	0	2	0	1	0	0	0	2	1	0	0	0
Cumulative Loans	105	105	107	107	108	108	108	108	110	111	111	111	6
Cumulative Amount	\$3,727,980	\$3,727,980	\$3,889,300	\$3,889,300	\$3,911,924	\$3,911,924	\$3,911,924	\$3,911,924	\$4,039,774	\$4,069,774	\$4,069,774	\$4,069,774	\$341,794
Defaults/Amount	0	0	0	0	0	0	0	0	0	0	0	0	0
	October	November	December	January	February	March	April	May	June	July	August	September	TOTAL
Speed Memos	52	38	20	18	10	49	49	61	32	53	52	47	481
Compliance Letters	14	3	6	13	1	5	0	8	7	8	3	9	77
Notice of Intent to Revoke	0	0	0	0	0	0	0	0	1	0	0	0	1
Orders	1	0	0	1	0	0	5	1	0	0	0	1	9

**Utah Waste Management and Radiation Control Board Action Item
Proposed changes to R311, Utah Underground Storage Tank Rules
Final Adoption and Change in Proposed Rule**

The Division of Environmental Response and Remediation (DERR) requests that the Utah Waste Management and Radiation Control Board approve proposed changes to the Utah Underground Storage Tank (UST) rules for final adoption and, for R311-203, a Change in Proposed Rule.

Background:

On September 8, 2016, the Board approved proposed changes to the Utah Underground Storage Tank rules for publication and public comment. The proposed changes incorporate by reference new Federal UST regulations that became effective on October 13, 2015, make changes to the Utah rules to administer the Federal regulations, simplify the Utah rules, and remove rule wording that is redundant or no longer applies.

The rules to be amended are:

R311-200, Underground Storage Tanks: Definitions.

R311-201, Underground Storage Tanks: Certification Programs and UST Operator Training.

R311-202, Underground Storage Tank Technical Standards.

R311-203, Underground Storage Tanks: Technical Standards.

R311-206, Underground Storage Tanks: Certificate of Compliance and Financial Assurance Mechanisms.

R311-212, Administration of the Petroleum Storage Tank Loan Program.

Notice of the proposed changes and the public comment period was sent to UST owner/operators, certified individuals, and other persons interested in UST rulemaking, and was published in major newspapers throughout the state.

The proposed changes were published in the *Utah State Bulletin* on October 1, 2016. The public comment period was held October 1, 2016 to October 31, 2016, and a public hearing to receive comments on the proposed changes was held on October 17, 2016.

One comment was received during the public comment period. US EPA Region 8 commented on R311-203-7, the operator inspection rule, stating that subsection R311-203-7(c) may result in Utah's operator inspection rule being less stringent than the Federal regulations, thereby endangering Utah's State Program Approval. R311-203-7(c) provides for approval by the Division Director for a facility to have operator inspections conducted less frequently in situations where it is impractical to conduct the inspections every 30 days. Because the new Federal regulations require inspections every 30 days, keeping subsection (c) could result in Utah's rule being considered less stringent than the Federal regulations.

The Division requests that the Board approve a Change in Proposed Rule for R311-203, with Subsection R311-203-7(c) to be removed. If the Change in Proposed Rule is approved by the

Board, the change would be published in the Utah State Bulletin on December 1, 2016, and the rule could be effective 30 days later.

The text of the proposed change to R311-203 is attached, with the Change in Proposed Rule form that will be submitted to the Division of Administrative Rules. The previous proposed changes to R311-203 are shown as if they had become effective, and the new changes are shown in the rule text. Wording to be removed is struck out, and wording to be added is underlined.

Please note: Because the end of the public comment period is only a few days before the date the Board packet information is sent to the Board members, it is possible that a comment postmarked by October 31, 2016 could be received by the DERR after the Board packet is sent. If this occurs, the comment and a DERR staff response will be forwarded to Board members electronically before the November Board meeting.

Action Items:

1) The Division of Environmental Response and Remediation requests that the Utah Waste Management and Radiation Control Board adopt the proposed changes to R311-200, R311-201, R311-202, R311-206, and R311-212. It is requested that the effective date of the new rules be January 1, 2017.

2) The Division requests that the Board approve a Change in Proposed Rule for R311-203, with publication date to be December 1, 2016 and the effective date of the changed rule to be January 1, 2017.

NOTICE OF CHANGE IN PROPOSED RULE

- The agency identified below in box 1 provides notice of proposed rule change pursuant to Utah Code Section 63G-3-301.
- Please address questions regarding information on this notice to the agency.
- The full text of all rule filings is published in the Utah State Bulletin unless excluded because of space constraints.
- The full text of all rule filings may also be inspected at the Office of Administrative Rules.

Rule Information

DAR file no: 40755 Date filed:
 State Admin Rule Filing Key: 158069
 Utah Admin. Code ref. (R no.): R311-203

Agency Information

1. Agency: ENVIRONMENTAL QUALITY - Environmental Response and Remediation

Room no.: First Floor

Building:

Street address 1: 195 N 1950 W

Street address 2:

City, state, zip: SALT LAKE CITY UT 84116-3085

Mailing address 1: PO BOX 144840

Mailing address 2:

City, state, zip: SALT LAKE CITY UT 84114-4840

Contact person(s):

Name:	Phone:	Fax:	E-mail:	Remove:
Gary Astin	801-536-4103	801-359-8853	gastin@utah.gov	<input type="checkbox"/>

(Interested persons may inspect this filing at the above address or at DAR during business hours)

Rule Title

2. Title of rule or section (catchline):
 Underground Storage Tanks: Technical Standards.

Notice Type

3. Type of notice: Change in Proposed Rule
Changes DAR No.: 40755
(If you do not know the DAR no., call 801-538-3218.)

Rule Purpose

4. Purpose of the rule or reason for the change:
During public comment for proposed changes to R311-203, a comment was received that indicated that subsection R311-203-7(c) contains language that may conflict with requirements for Utah to maintain state program approval of its underground storage tank (UST) regulatory program. The conflicting language provides for underground storage tank operator inspections to be performed less frequently than every 30 days in situations where it is impractical to conduct the inspections every 30 days. The conflicting language is now removed from the rule to eliminate the possibility that it could cause Utah to lose state program approval.

Response Information

5. This change is a response to comments by the Administrative Rules Review Committee.
 No Yes

Rule Summary

6. Summary of the rule or change:
Subsection R311-203-7(c) is removed from the rule.

Aggregate Cost Information

7. Aggregate anticipated cost or savings to:

A) State budget:

Affected: No Yes

No cost or savings. The state, as an owner of USTs, has not been approved for a reduced inspection schedule for any of its UST facilities, so there will be no change in the state's inspections costs.

B) Local government:

Affected: No Yes

No cost or savings. No local governments that own USTs have been approved for a reduced inspection schedule for any of their UST facilities, so there will be no change in their inspections costs.

C) Small businesses:

Affected: No Yes

("small business" means a business employing fewer than 50 persons)

No cost or savings. No small businesses that own USTs have been approved for a reduced inspection schedule for any of their UST facilities, so there will be no change in their inspections costs.

D) Persons other than small businesses, businesses, or local government entities:

Affected: No Yes

("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an agency)

No cost or savings. No UST owners have been approved for a reduced inspection schedule for any of their UST facilities, so there will be no change in their inspections costs.

Compliance Cost Information

8. Compliance costs for affected persons:

No compliance costs. No UST owners have to date been approved for a reduced schedule of operator inspections, so there will be no cost for them to continue to perform inspections as they are already doing them. If an UST owner had received approval for a reduced inspection schedule, the cost required to begin performing the inspections every 30 days would depend on the number of additional inspections required. The most likely scenario would be a UST facility in a mountainous area, that is not easily accessed during the winter. If four additional inspections were required for the winter months, the increased cost would be approximately \$500 to \$700 per year, depending on the individual characteristics of the UST site and the available resources of the UST owner to provide access to the UST facility.

Department Head Comments

9. A) Comments by the department head on the fiscal impact the rule may have on businesses:

The fiscal impact of this rule change will be minor. There are a handful of UST sites in the state that are likely to be inaccessible or have another situation where a monthly inspection would be impractical. No tank owners have been granted an exemption from doing the inspections each month. Removing the ability to grant the exemption will only mean that UST owners and operators will continue to do the inspections monthly, so fiscal impacts to tank owners will be minimal.

B) Name and title of department head commenting on the fiscal impacts:

Alan Matheson, Executive Director

Citation Information

10. This rule change is authorized or mandated by state law, and implements or interprets the following state and federal laws.

State code or constitution citations (required) (e.g., Section 63G-3-402; Subsection 63G-3-601(3); Article IV) :

19-6-403, 19-6-105, 19-6-408

Incorporated Materials

11. This rule adds, updates, or removes the following title of materials incorporated by reference (a copy of materials incorporated by reference must be submitted to DAR; if none, leave blank) :

Official Title of Materials Incorporated (from title page)
Publisher
Date Issued (mm/dd/yyyy)
Issue, or version (including partial dates)
ISBN Number
ISSN Number
Cost of Incorporated Reference
Adds, updates, removes-- SELECT ONE --

Comments

12. The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the Utah State Bulletin. See Section 63G-3-302 and Rule R15-1 for more information.)

A) Comments will be accepted until 5:00 p.m. on (mm/dd/yyyy) : 12/30/2016

B) A public hearing (optional) will be held:

On (mm/dd/yyyy): At (hh:mm AM/PM): At (place):

Proposed Effective Date

13. This rule change may become effective on (mm/dd/yyyy): 01/01/2017

NOTE: The date above is the date on which this rule MAY become effective. It is NOT the effective date. After a minimum of seven days following the date designated in Box 12(A) above, the agency must submit a Notice of Effective Date to the Office of Administrative Rules to make this rule effective. Failure to submit a Notice of Effective Date will result in this rule lapsing and will require the agency to start the rulemaking process over.

Indexing Information

14. Indexing information - keywords (maximum of four, one term per field, in lower case, except for acronyms (e.g., "GRAMA") or proper nouns (e.g., "Medicaid")):
fees, petroleum, hazardous substances, underground storage tanks

File Information

15. Attach an RTF document containing the text of this rule change (filename):
No document is associated with this filing.

To the Agency

Information requested on this form is required by Sections 63G-3-301, 302, 303, and 402. Incomplete forms will be returned to the agency for completion, possibly delaying publication in the Utah State Bulletin, and delaying the first possible effective date.

Agency Authorization

Agency head or designee, and Brent Everett
title: Director

Date (mm/dd/yyyy): 11/01/2016

R311. Environmental Quality, Environmental Response and Remediation.

R311-203. Underground Storage Tanks: Technical Standards.

R311-203-1. Definitions.

Definitions are found in Rule R311-200.

R311-203-2. Notification.

- (a) The owner or operator of an underground storage tank shall notify the Director whenever:
 - (1) new USTs are brought into use;
 - (2) the owner or operator changes;
 - (3) changes are made to the tank or piping system; and
 - (4) release detection, corrosion protection, or spill or overfill prevention systems are installed, changed or upgraded.
- (b) All notifications shall be submitted on the current approved notification form.
- (c) Notifications submitted to meet the requirements of R311-203-2(a)(1) through (4) shall be submitted within 30 days of the completion of the work or the change of ownership.
- (d) To satisfy the requirement of Subsection 19-6-407(1)(c) the certified installer shall:
 - (1) complete the appropriate section of the notification form to be submitted by the owner or operator, and ensure that the notification form is submitted by the owner or operator within 30 days of completion of the installation; or
 - (2) provide separate notification to the Director within 60 days of the completion of the installation.

R311-203-3. New Installations, Permits.

- (a) Certified UST installers shall notify the Director at least 10 days, or another time period approved by the Director, before commencing any of the following activities:
 - (1) the installation of a full UST system or tank only;
 - (2) the installation of underground product piping for one or more tanks at a facility, separate from the installation of one or more tanks at a facility;
 - (3) the internal lining of a previously-existing tank;
 - (4) the installation of a cathodic protection system on one or more previously-existing tanks at a facility;
 - (5) the installation of a bladder in a tank;
 - (6) any retro-fit, replacement, or installation that requires the cutting of a manway into the tank;
 - (7) the installation of a spill prevention or overfill prevention device;
 - (8) the installation of a leak detection monitoring system; and
 - (9) the installation of a containment sump or under-dispenser containment.
- (b) The UST installation company shall submit to the Director an UST installation permit fee of \$200 when any of the activities listed in R311-203-3(a)(1) through (6) is performed on an UST system that has not qualified for a certificate of compliance before the commencement of the work.
- (c) The fees assessed under 19-6-411(2)(a)(i) shall be determined based on the number of full UST installations performed by the installation company in the 12 months previous to the fee due date. Installations for which the fee assessed under 19-6-411(2)(a)(ii) and R311-203-3(c) is charged shall count toward the total installations for the 12-month period.
- (d) For the purposes of Subsections 19-6-411(2)(a)(ii), 19-6-407(1)(c), and R311-203-2(d), an installation shall be considered complete when:
 - (1) in the case of installation of a new UST system, tank only, or product piping only, the new installation first holds a regulated substance; or
 - (2) in the case of installation of the components listed in Subsections R311-203-3(a)(3) through (a)(6), the new installation is functional and the UST holds a regulated substance and is operational.
- (e) If, before completion of an installation for which an UST installation permit fee is required, the owner or operator decides to install additional UST system components, the installer shall notify the Director of the change. When additions are made, the UST installation permit fee shall not be increased unless the

original UST installation permit fee would have been higher had the addition been considered at the time the original fee was determined.

(f) The number of UST installation companies performing work on a particular installation shall not be a factor in determining the UST installation permit fee for that installation. However, each installation company shall identify itself at the time the UST installation permit fee is paid.

(g) When a new UST system, tank only, product piping only, or new cathodic protection system is installed, the owner or operator shall submit to the Director an as-built drawing, to scale, that meets the requirements of R311-200-1(b)(2).

R311-203-4. Underground Storage Tank Registration Fee.

(a) Registration fees shall be assessed by the Department against all tanks which are not permanently closed for the entire fiscal year, and shall be billed per facility.

(b) Registration fees shall be due on July 1 of the fiscal year for which the assessment is made, or, for underground storage tanks brought into use after the beginning of the fiscal year, underground storage tank registration fees shall be due when the tanks are brought into use, as a requirement for receiving a certificate of compliance.

(c) The Director may waive all or part of the penalty assessed under Subsection 19-6-408(5) if no fuel has been dispensed from the tank on or after July 1, 1991 and if the tank has been properly closed according to Rules R311-204 and R311-205, or in other circumstances as approved by the Director.

(d) The Director shall issue a certificate of registration to owners or operators for individual underground storage tanks at a facility if:

- (1) the tanks are in use or are temporarily closed according to 40 CFR Part 280 Subpart G; and,
- (2) the underground storage tank registration fee has been paid.

(e) Pursuant to 19-6-408(5)(c), all past due registration fees, late payment penalties and interest must be paid before the Director may issue or re-issue a certificate of compliance regardless of whether there is a new owner or operator at the facility. However, the Director may decline active collection of past due registration fees, late payment penalties and interest if a certificate of compliance is not issued and the new owner or new operator properly closes the underground storage tanks within one year of becoming the new owner or operator of the facility.

(f) An underground storage tank will be assessed the higher registration fee established under Section 63J-1-504 if it is found to be out of significant operational compliance with leak prevention or leak detection requirements during an inspection, and remains out of compliance for six months or greater following the initial inspection. The higher registration fee shall be due July 1 following the documented six-month period of non-compliance. A tank will be out of significant operational compliance if it fails to meet any of the significant operational compliance measures stated in the EPA compliance measures matrices incorporated by Subsection R311-206-10(b)(1).

(g) When the Director is notified of the existence of a previously un-registered regulated UST, the Director shall assess the registration fee for the current fiscal year. If the UST is properly permanently closed within 90 days of the notification of the existence of the UST, the Director may decline active collection of past-due registration fees, late payment penalties, and interest for previous fiscal years.

R311-203-5. UST Testing Requirements.

(a) Tank tightness testing. The testing method must be able to test the UST system at the maximum level that could contain regulated substances. Tanks with overfill prevention devices that prevent product from entering the upper portion of the tank may be tested at the maximum level allowed by the overfill device.

(b) Spill prevention equipment. An individual who conducts a test of spill prevention equipment to meet the requirements of 40 CFR 280.35(a)(1)(ii) shall report the test results using:

- (1) the form "Utah Spill Prevention Test", or
- (2) the form "Appendix C-3 Spill Bucket Integrity Testing Hydrostatic Test Method Single and Double-Walled Vacuum Test Method", found in PEI RP1200, "Recommended Practices for the Testing and Verification of Spill, Overfill, Leak Detection and Secondary Containment Equipment at UST Facilities", or

(3) another form approved by the Director.

(c) Containment sump testing. An individual who conducts a test of a containment sump used for interstitial monitoring to meet the requirements of 40 CFR 280.35(a)(1)(ii) or a test of a piping containment sump or under-dispenser containment to meet the requirements of R311-206-11 shall report the test results using:

(1) the form "Utah Containment Sump Test", or

(2) the form "Appendix C-4 Containment Sump Integrity Testing Hydrostatic Testing Method", found in PEI RP1200, or

(3) another form approved by the Director.

(d) When a sump sensor is used as an automatic line leak detector, the secondary containment sump shall be tested for tightness annually according to the manufacturer's guidelines or standards, or by another method approved by the Director. The sensor shall be located as close as is practicable to the lowest portion of the sump.

(e) Cathodic protection testing. Cathodic protection tests shall meet the inspection criteria outlined in 40 CFR 280.31(b), or other criteria approved by the Director. The tester who performs the test shall provide the following information: location of at least three test points per tank, location of one remote test point for galvanic systems, test results in volts or millivolts, pass/fail determination for each tank, line, flex connector, or other UST system component tested, the criteria by which the pass/fail determination is made, and a site plat showing locations of test points. A re-test of any cathodic protection system is required within six months of any below-grade work that may harm the integrity of the system.

(f) UST testers performing tank and line tightness testing shall include the following as part of the test report: pass/fail determination for each tank or line tested, the measured leak rate, the test duration, the product level for tank tests, the pressure used for pressure tests, the type of test, and the test equipment used.

R311-203-6. Secondary Containment and Under-dispenser Containment.

(a) Secondary containment for tanks and piping.

(1) To meet the requirements of Section 42 USC 6991b(i) of the Solid Waste Disposal Act, all tanks and product piping that are installed as part of an underground storage tank system after October 1, 2008 and before January 1, 2017 shall have secondary containment if the installation is located 1000 feet or less from an existing community water system or an existing potable drinking water well.

(2) The secondary containment installed under Subsection (a) shall meet the requirements of 40 CFR 280.42(b), and shall be monitored monthly for releases from the tank and piping. Monthly monitoring shall meet the requirements of 40 CFR 280.43(g).

(3) Containment sumps for piping that is installed under Subsection (a) shall be required:

(A) at the submersible pump or other location where the piping connects to the tank;

(B) where the piping connects to a dispenser, or otherwise goes above-ground; and

(C) where double-walled piping that is required under Subsection (a) connects with existing piping.

(4) Containment sumps for piping that is installed under Subsection (a) shall:

(A) contain submersible pumps, check valves, unburied risers, flexible connectors, and other transitional components that connect the piping to the tank, dispenser, or existing piping; and

(B) meet the requirements of Subsections (b)(2)(A) through (C).

(5) In the case of a replacement of tank or piping, only the portion of the UST system being replaced shall be subject to the requirements of Subsection (a). If less than 100 percent of the piping from a tank to a dispenser is replaced, the requirements of Subsection (a) shall apply to all new product piping that is installed. The closure requirements of R311-205 shall apply to all product piping that is taken out of service. When new piping is connected to existing piping that is not taken out of service, the connection between the new and existing piping shall be secondarily contained, and shall be monitored for releases according to 40 CFR 280.43(g).

(6) The requirements of Subsection (a) shall not apply to:

(A) piping that meets the requirements for "safe suction" piping in 40 CFR 280.41(b)(2)(i) through (v), or

(B) piping that connects two or more tanks to create a siphon system.

(7) The requirements of Subsection (a) shall apply to emergency generator USTs installed after October 1, 2008.

(b) Under-dispenser containment.

(1) To meet the requirements of Section 42 USC 6991b(i) of the Solid Waste Disposal Act, all new motor fuel dispenser systems installed after October 1, 2008 and before January 1, 2017, and connected to an underground storage tank, shall have under-dispenser containment if the installation is located 1000 feet or less from an existing community water system or an existing potable drinking water well.

(2) The under-dispenser containment shall:

(A) be liquid-tight on its sides, bottom, and at all penetrations;

(B) be compatible with the substance conveyed by the piping; and

(C) allow for visual inspection and access to the components in the containment system, or shall be continuously monitored for the presence of liquids.

(3) If an existing dispenser is replaced, the requirements of Subsection (b) shall apply to the new dispenser if any equipment used to connect the dispenser to the underground storage tank system is replaced. This equipment includes unburied flexible connectors, risers, and other transitional components that are beneath the dispenser and connect the dispenser to the product piping.

(c) The requirements of Subsections (a) and (b) shall not apply if the installation is located more than 1000 feet from an existing community water system or an existing potable drinking water well.

(1) The UST owner or operator shall provide to the Director documentation to show that the requirements of Subsections (a) and (b) do not apply to the installation. The documentation shall be provided at least 60 days before the beginning of the installation, and shall include:

(A) a detailed to-scale map of the proposed installation that demonstrates that no part of the installation is within 1000 feet of any community water system, potable drinking water well, or any well the owner or operator plans to install at the facility, and

(B) a certified statement by the owner or operator explaining who researched the existence of a community water system or potable drinking water well, how the research was conducted, and how the proposed installation qualifies for an exemption from the requirements of Subsections (a) and (b).

(d) To determine whether the requirements of Subsections (a) and (b) apply, the distance from the UST installation to an existing community water system or existing potable drinking water well shall be measured from the closest part of the new underground tank, piping, or motor fuel dispenser system to:

(1) the closest part of the nearest community water system, including:

(A) the location of the wellheads for groundwater and/or the location of the intake points for surface water;

(B) water lines, processing tanks, and water storage tanks; and

(C) water distribution/service lines under the control of the community water system operator, or

(2) the wellhead of the nearest existing potable drinking water well.

(e) If a new underground storage tank facility is installed, and is not within 1000 feet of an existing community water system or an existing potable drinking water well, the requirements of Subsections (a) and (b) apply if the owner or operator installs a potable drinking water well at the facility that is within 1000 feet of the underground tanks, piping, or motor fuel dispenser system, regardless of the sequence of installation of the UST system, dispenser system, and well.

(f) To meet the requirements of 40 CFR 280.20, all tanks and product piping that are installed or replaced as part of an underground storage tank system on or after January 1, 2017 shall be secondarily contained and use interstitial monitoring in accordance with 40 CFR 280.43(g).

R311-203-7. Operator Inspections.

(a) Owners and operators shall perform periodic inspections in accordance with 40 CFR 280.36. Inspections shall be conducted by or under the direction of the designated Class B operator. The Class B operator shall ensure that documentation of each inspection is kept and made available for review by the Director.

(b) The individual who conducts inspections to meet the requirements of 40 CFR 280.36(a)(1) or (a)(3) shall use the form "UST Operator Inspection- Utah" or another form approved by the Director.

~~(c) [The Director may allow operator inspections to be performed less frequently in situations where it is impractical to conduct an inspection every 30 days. The owner or operator shall request the exemption, justify the reason for the exemption, and submit a plan for conducting operator inspections at the facility.~~

~~(d)~~ An UST facility whose tanks are properly temporarily closed according to 40 CFR 280.70 and R311-204-4 shall have an annual operator inspection.

~~(e)~~ An owner or operator who conducts visual checks of tank top containment sumps and under dispenser containment sumps for compliance with piping leak detection in accordance with 40 CFR 280.43(g) shall conduct the visual checks monthly and report the results on the operator inspection form.

R311-203-8. Unattended facilities.

(a) A facility that normally has no employee or other responsible person on site, or is open to dispense fuel at times when no employee or responsible person is on site, shall have:

(1) a sign posted in a conspicuous place, giving the name and telephone number of the facility owner, operator, or local emergency responders, and

(2) an emergency shutoff device in a readily accessible location, if the facility dispenses fuel.

KEY: fees, hazardous substances, petroleum, underground storage tanks

Date of Enactment or Last Substantive Amendment: February 14, 2011

Notice of Continuation: April 10, 2012

Authorizing, and Implemented or Interpreted Law: 19-6-105; 19-6-403; 19-6-408

WASTE MANAGEMENT AND RADIATION CONTROL BOARD

Executive Summary

REQUEST FOR A SITE-SPECIFIC TREATMENT VARIANCE

EnergySolutions LLC

November 10, 2016

What is the issue before the Board?	<p>This is a request from EnergySolutions LLC for a one-time site-specific treatment variance from the Utah Hazardous Waste Management Rules to receive and treat cemented uranium extraction process residues for disposal.</p>
What is the historical background or context for this issue?	<p>The Mixed Waste Facility proposes to receive up to 600 cubic feet of cemented monoliths. This waste retains hazardous waste codes for barium, cadmium, chromium, lead and spent solvents. The generator has encapsulated the waste in concrete for security reasons.</p> <p>EnergySolutions proposes to treat this waste by macroencapsulation in the Mixed Waste Landfill Cell rather than perform chemical stabilization, as required. This request is based on the fact that the waste has already been encapsulated in concrete at the generator's site. Treating this waste by the required method would mean grinding the waste and potentially exposing workers to unnecessary contamination.</p> <p>The proposed treatment will further encapsulate the waste and protect it from contact with precipitation, thereby decreasing the potential of leaching.</p> <p>A notice for public comment was published in <i>The Salt Lake Tribune</i>, <i>The Deseret News</i> and <i>The Tooele County Transcript Bulletin</i>.</p> <p>The comment period began November 8, 2016 and will end December 7, 2016.</p>
What is the governing statutory or regulatory citation?	<p>Variations are provided for in 19-6-111 of the Utah Solid and Hazardous Waste Act. This is a one-time site-specific variance from an applicable treatment standard as allowed by R315-268.44 of the Utah Administrative Code.</p>
Is Board action required?	<p>No, this is an information item before the Board.</p>
What is the Division/Director's recommendation?	<p>The Director will provide a recommendation at the next Board meeting.</p>
Where can more information be obtained?	<p>For technical questions, please contact Otis Willoughby (801) 536-0220. For legal questions, please contact Raymond Wixom at (801) 536-0290.</p>

DSHW-2016-014062

Attachment: DSHW-2016-013913



OCT 27, 2016

DSHW-2016-013913

October 27, 2016

CD16-0216

Mr. Scott T. Anderson
Director
Division of Waste Management and Radiation Control
195 North 1950 West
Salt Lake City, UT 84114-4880

RECEIVED

OCT 27 2016

DEPARTMENT OF
ENVIRONMENTAL QUALITY

2:56 pm dq

Subject: EPA ID Number UTD982598898 ✓
Request for a Site-Specific Treatment Variance for Cemented Uranium
Extraction Process Residues

Dear Mr. Anderson:

EnergySolutions hereby requests an exemption from the treatment standards described in Utah Administrative Code (UAC) R315-40(a)(2) for uranium extraction process residuals that retain the hazardous waste codes D005 (barium); D006 (cadmium); D007 (chromium); D008 (lead); D030 (2,4-dinitrotoluene); D032 (hexachlorobenzene) and F001, F002, and F005 (spent solvents) and are encased in cement. This exemption is requested for the purposes of safety, security, and transportation of the radioactive waste.

This request is submitted in accordance with the requirements of UAC R315-260-19.

The regulatory requirement for this request is found in UAC R315-268-44 which allows a site-specific variance from an applicable treatment standard provided the following condition is met:

UAC R315-268-44(h)(2) It is inappropriate to require the waste to be treated to the level specified in the treatment standard, or by the method specified as the treatment standard, even though such treatment is technically possible.

This variance is being requested for approximately 600 cubic feet of cemented uranium extraction process residuals from EnergySolutions generator 9061-06. The waste is generated as part of a uranium recovery process that involves creating an enriched uranium contaminated ash through a thermal process and then recovering the enriched uranium through an organic solvent extraction process. The residual waste from this extraction system is collected in small cans (~ 2 ½ gallons each) and stored at the generator's facility. The process residuals within these cans are in the form of an ash generated through this process. The process residuals within the cans have been characterized through a random sampling and analysis process. At the beginning of this

campaign, approximately 2,000 cans of process residues were collected and stored by the generator. The process is ongoing and additional cans are being generated every year. Further, due to safety concerns, some of the cans are being split prior to the repackaging process described below; thereby generating more total material for disposal than originally anticipated.

F-listed solvent codes within this waste are derived from rags that are burned in a furnace in order to recover the uranium present within them. None of the F-listed constituents were present above Universal Treatment Standard (UTS) concentrations within the random characterization samples of the process residues. The random characterization samples were also analyzed for metals using the Toxicity Characteristic Leaching Procedure (TCLP). These samples detected elevated concentrations of barium (up to 6,740 mg/L TCLP), cadmium (up to 16.4 mg/L TCLP), chromium (up to 15.2 mg/L TCLP), and lead (up to 10.5 mg/L TCLP). Based on these elevated metal concentrations, the characteristic waste codes D005, D006, D007, and D008 were applied to the process residue. Slightly elevated concentrations of 2,4-dinitrotoluene (D030) and hexachlorobutadiene (D032) were also detected in separate analyses. The residue may potentially contain these codes also.

The uranium content within the process residues is enriched. From a health and safety standpoint, the enrichment makes the waste more hazardous to employees managing the waste. Further, enriched material has increased security concerns and must be managed appropriately. To ensure the enriched uranium concentration limits required for worker safety, security, and transportation of this waste are met, appropriate packaging procedures were created and are currently being utilized at the generator's facility. These packaging procedures include repackaging the cans into 16-gallon drums and filling the void spaces with cement; formal treatment for the elevated metals concentrations is not performed during this process. The generator has assessed other options, including treatment for the hazardous constituents; however, additional processing introduced unacceptable hazards from a health and safety, and security viewpoint. Additionally, the waste within the cans is inherently safe from a criticality aspect and the generator concluded that it is unwise to perform extra processing that could potentially change this aspect. Furthermore, encasing enriched uranium within concrete is the preferred method of stabilization as recommended by the Nuclear Regulatory Commission (NRC). The waste material packaged in these 16-gallon monolithic forms is inherently safe and is the form that will be shipped and received at the EnergySolutions Clive facility.

The characteristic hazardous waste codes associated with the process residues has numerical concentration-based treatment standards based upon the leachability of the contaminants. Treatment of the monolithic form for these concentration-based treatment standards would entail a process that includes shredding of the monolith followed by mixing with a stabilizing reagent in a permitted mixer. Both of these steps could mobilize the enriched uranium and possibly cause airborne contamination, increasing the potential for releases to the environment as well as the potential for personnel exposure; thereby violating radiation protection (ALARA) principles. Also, the shredding of the solidified uranium ash results in a more accessible form of enriched uranium with potential security ramifications.

EnergySolutions proposes to macroencapsulate the waste, thereby isolating the waste from potential leaching media. Macroencapsulation is a permitted process utilized at the Clive facility that significantly reduces the potential for migration (leaching) of waste. Macroencapsulation requires less handling of the waste and creates a waste form for disposal that is protective of human health and the environment. Macroencapsulation also adds a further level of security to access of the enriched uranium.

In summary, a variance should be granted based upon three considerations:

1. for both health and security reasons, enriched uranium concentration within the waste precludes actual treatment of the waste;
2. processing this waste in preparation for stabilization treatment would increase worker exposures and the potential for releases to the environment; and
3. the leachability of the waste would be significantly reduced through macroencapsulation, thereby protecting human health and the environment.

EnergySolutions requested this same variance for this generator in letters dated July 20, 2007, July 28, 2008, July 15, 2009, July 15, 2010, July 28, 2011, August 13, 2012, July 15, 2013, July 25, 2015, and November 4, 2015. These previous requests were approved on September 13, 2007, September 13, 2008, September 10, 2009, September 9, 2010, September 8, 2011, September 13, 2012, September 12, 2013, August 14, 2014, and December 10, 2015.

Shipments began in April, 2008 and have been relatively continuous since that time. Since the last variance was approved, EnergySolutions has received approximately 500 cubic feet of this waste (the 16-gallon monoliths). EnergySolutions has received approximately 7,600 cubic feet of this waste since the first variance approval in 2008. This variance request is for the ongoing processing and disposal of additional uranium extraction process residues created by the generator.

EnergySolutions requests that a variance be granted to allow the receipt, macroencapsulation treatment and disposal of approximately 600 cubic feet of cemented uranium extraction process residuals that retain hazardous waste codes.

Upon approval of this variance, the monolithic waste will be managed as debris.

The name, phone number, and address of the person who should be contacted to notify EnergySolutions of decisions by the Director is:

Mr. Vern C. Rogers
Manager, Compliance and Permitting
EnergySolutions LLC
299 South Main Street, Suite 1700
Salt Lake City, UT 84111
(801) 649-2000

Should there be any questions to this request, please contact me at 801-649-2144.

Sincerely,



Timothy L. Orton, P.E.
Environmental Engineer

cc: Don Verbica, DWMRC

I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.

WASTE MANAGEMENT AND RADIATION CONTROL BOARD

Executive Summary

EnergySolutions Petition for Rulemaking

November 10, 2016

<p>What is the issue before the Board?</p>	<p>On October 12, 2016, EnergySolutions submitted a petition to initiate rulemaking to repeal Utah Administrative Code (UAC) R313-25 and reenact UAC R313-25 by incorporating 10 CFR 61 by reference. (A copy of the Petition is included in the November 10, 2016 Board Packet).</p>
<p>What is the historical background or context for this issue?</p>	<p>The Utah Administrative Rulemaking Act (Utah Code Ann. 63G-3-101, <i>et seq.</i>) provides that an interested person/party may petition a rulemaking agency to make, amend, or repeal a rule. (Utah Code Ann. 63G-3-601(2)) The Utah Administrative Code (UAC) establishes additional requirements for rulemaking petitions. (<i>See R15-2.</i>)</p> <p><u>REQUIRED BOARD ACTIONS</u> (Utah Code Ann. 63G-3-601(6), R15-2-3 & R15-2-5)</p> <p>As the “agency” that has been granted rulemaking authority by the Legislature, the Board is required to:</p> <ul style="list-style-type: none"> • Record the date the petition is received; • Review and consider the petition; • Within 45 days of the submission of the petition, place the petition on its agenda for review; • Within 80 days of the submission of the petition, write a response to the petitioner stating either: <ul style="list-style-type: none"> ○ the petition is denied and the reasons for denial; or ○ the date when the Board is initiating rulemaking proceedings consistent with the intent of the petition. • Retain the petition and a copy of the Board's response as part of the administrative record; and • Mail copies of its decision to all persons who petitioned for a rule change. <p>Additionally, the Board may (R15-2-5(2)):</p> <ul style="list-style-type: none"> • Interview the petitioner; • Hold a public hearing on the petition; or • Take any action the Board, in its judgment, deems necessary to provide the petition due consideration.
<p>What is the governing statutory or regulatory citation?</p>	<p>Utah Code Ann. 63G-3-601 and Utah Administrative Code R15-2.</p>
<p>Is Board action required?</p>	<p>No. This is an informational item only. The Board is only being notified of the petition as required by statute.</p>
<p>What is the Division Director’s recommendation?</p>	<p>The petition raises significant issues that require detailed analysis and discussion. The Director will make a recommendation in the December Board Meeting.</p>

Where can more information be obtained?

Questions may be directed to Ralph Bohn at (801) 536-0212 or Rusty Lundberg at (801) 536-4257.

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DEPARTMENT OF
ENVIRONMENTAL QUALITY

October 12, 2016

Mr. Scott T. Anderson
Executive Secretary
Utah Board of Waste Management and Radiation Control
195 North 1950 West
Salt Lake City, Utah 84114-4880

DRC-2016-010559

Subject: Utah Administrative Code R313-25; **Petition to Initiate Rulemaking**

Mr. Anderson:

Pursuant to Utah Code Ann. § 63G-3-601, EnergySolutions hereby submits a Petition to Initiate Rulemaking to the Waste Management and Radiation Control Board (Board) to repeal and reenact Utah Administrative Code (UAC) R313-25 and adopt by reference 10 CFR Part 61. As promulgated in § 63G-3-601, the Board is required to place this Petition on its agenda for review and either initiate rulemaking proceedings or deny the petition in writing within 60 days of submittal of the petition. As such, this letter sets forth the statement of the jurisdiction of the Board to consider this Petition to repeal and reenact UAC R313-25, as required by Utah Code Ann. § 63G-3-601(4) and explains the basis for the Petition.

The Petition to repeal and reenact UAC R313-25 is within the jurisdiction of the Board under Utah Code Annotated § 19-3-104(4) which authorizes the Board to make rules “*to meet the requirements of federal law relating to radiation control to ensure the radiation control program under this part is qualified to maintain primacy from the federal government.*” The proposed Petition brings UAC R313-25 into alignment with corresponding U.S. Nuclear Regulatory Commission (NRC) rules. Specifically, the Petition proposes replacement of UAC R313-25 and adoption of Chapter 61 of Title 10 from the Code of Federal Regulations by reference. This action will assure that as 10 CFR Part 61 is amended (amendments are currently under consideration), the Utah rules will automatically be in compliance with federal rules, without further Board action. Additionally, this proposed Petition will bring the Division into compliance with Senate Bill 173.

The primary purpose and reasoning for EnergySolutions Petition is as follows:

1. Senate Bill 173 was signed into law on March 31, 2015. Utah Code Ann. § 63G-3-301(13)(b) requires the Division to “*initiate rulemaking proceedings no later*

than 180 days after the effective date of the statutory provision that specifically requires the rulemaking". The Petition's proposed revisions address the requirements of Senate Bill 173 and bring the Board into compliance with these statutory requirements.

2. The current UAC R313-25 rules, adopted by the legacy Board of Radiation Control (dissolved and replaced in 2015 with the Board of Waste Management and Radiation Control), are "more stringent" than corresponding federal regulations. These rules, therefore, are not in compliance with Utah Code Ann. § 19-3-104(7)(a), as the adoption of these rules did not following the requirements found in Utah Code Ann. § 19-3-104(8)(a). This creates undo and illegal regulatory burden on EnergySolutions and should be remedied by the current Board. The proposed repeal and reenactment of UACR313-25 and adoption by reference of 10 CFR Part 61 will assure that state rules are consistent with, but not more stringent than the corresponding federal rules.

Below is the statutory language that governs rulemaking, followed by specific examples of how the requirements of UAC R313-25 are more stringent than corresponding federal regulations.

Utah Code Annotated § 19-3-104(7)(a) states:

"Except as provided in Subsection (8), and in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, the board may not adopt rules, for the purpose of the state assuming responsibilities from the United States Nuclear Regulatory Commission with respect to regulation of sources of ionizing radiation, that are more stringent than the corresponding federal regulations which address the same circumstances." [emphasis added]

Similarly, Utah Code Annotated § 19-5-105(5) states:

"Except as provided in Subsections (2) and (3), no rule that the board makes for the purpose of the state administering a program under the federal Clean Water Act or the federal Safe Drinking Water Act may be more stringent than the corresponding federal regulations which address the same circumstances. In making rules, the board may incorporate by reference corresponding federal regulations." [emphasis added]

Specific examples of where the regulations in UAC R313-25 are more stringent than the corresponding federal regulations include:

1. UAC R313-25-2: Federal regulatory definition of an *Inadvertent intruder* in 10 CFR 61.2 is considered a person “*who might occupy the disposal site after closure and engage in normal activities....*” By comparison, UAC R313-25-2 considers an *Inadvertent Intruder* as “*a person who may enter the disposal site after closure and engage in activities unrelated to post closure management....*” Design and performance requirements to protect individuals from inadvertently “*entering*” and “*engaging in activities unrelated to post closure management*” at the disposal site are significantly more stringent than those required to protect inadvertent occupation of the disposal site “*and engage in normal activity*”.
2. UAC R313-25-9: Federal regulations promulgated in 10 CFR 61.13 *Technical Analyses* require licensees to provide specific technical information demonstrating (a) protection of the general population, (b) protection of individuals from inadvertent intrusion, (c) protection of individuals during operations, and (d) long-term stability of the disposal site without ongoing active maintenance. UAC R313-25-9 includes additional requirements. In UAC R313-25-9(1) through UAC R313-25-9(3) and UAC R313-25-9(5) there are requirements to perform site-specific analysis for waste not included in the Draft Environmental Impact Statement for Class A waste, or additional analyses if the waste is likely to result in greater than 10% of the dose limits in UAC R313-25-19 in the time period when peak dose would occur. This additional analysis is more stringent than required by corresponding federal regulations. In promulgating UAC R313-25-9, the board did not make a finding as per UAC 19-3-1048(a) and (b) allowing more stringent rules.
3. UAC R313-25-20: Federal regulations require a licensee’s demonstration of the protection of the general population to an “*annual dose exceeding an equivalent of 25 millirems to the whole body, 75 millirems to the thyroid, and 25 millirems to any other organ of any member of the public.*” 10 CFR 61.41. By comparison, UAC R313-25-20 more stringently requires demonstration that “*[n]o greater than 0.04 mSv (0.004 rem) committed effective dose equivalent or total effective dose equivalent to any member of the public shall come from groundwater.*”
4. UAC R313-25-27(4): In addition to several requirements associated with environmental monitoring, UAC R313-25-27(4) requires licensees to demonstrate that they have additional plans not required by NRC.

5. UAC R313-25: By not incorporating NRC requirement 10 CFR 61.58 into UACR313-25, Utah licensees are held to more stringent standards because NRC's alternative requirements for waste classification and characteristics are not available.
6. UAC R313-25-33: requires licensees to maintain original, reproduced copies, or microfilm records, while 10 CFR 61.80 acknowledges and incorporates technological advances in record archival by amending 10 CFR 61.80(c) with

“The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.”

As part of its current 10 CFR Part 61 rulemaking, NRC has deemed the current Part 61 rules as protective to human health and the environment. This has been stated by the NRC in various stages of the rulemaking, and was specifically stated by the NRC in letters to the Utah Division of Radiation Control, dated January 21, 2010¹ and August 6, 2010². The State of Utah has not met the requirements found in Utah Code Annotated § 19-3-104(8), specifically § 19-3-104(8)(b) which requires the State to publish the evaluation of the public health and environmental information and studies that form the basis for rules that are more stringent than the Federal counterpart.

A secondary and more pragmatic reason for the repeal of the rules are the significant changes to 10 CFR Part 61 currently being promulgated by the NRC. While not final, the Board will be required to make significant changes to UAC R313-25 in order to conform to the new revision of Part 61. It would be prudent to adopt 10 CFR Part 61 in total so that the more extensive Part 61 changes can be incorporated by reference.

¹ Reis, Terence. “NRC Review of Proposed Changes to the Utah Regulations R313-25-8” Letter from Terrence Reis, Deputy Director of the Division of Material Safety and State Agreements, U.S. Nuclear Regulatory Commission to Dane L. Finerfrock, Director of the Utah Division of Radiation Control, January 21, 2010.

² Reis, Terence. “NRC Review of the Final Changes to the Utah Regulations R313-25-8” Letter from Terrence Reis, Deputy Director of the Division of Material Safety and State Agreements, U.S. Nuclear Regulatory Commission to Rusty Lundberg, Executive Secretary of the Utah Division of Radiation Control, August 6, 2010.

Rule repeal and reenactment with reference to comparable federal requirement has been a long-standing common practice by the Board. For example, in March 2016, the Board approved commencement of a Notice of Continuation (five-year review) of Utah Administrative Code R315. At the conclusion of its review, the Board fully repealed Hazardous Waste Rules R315-1, R315-2, R315-3, R315-4, R315-5, R315-6, R315-7, R315-8, R315-9, R315-12, R315-13, R315-14, R315-16, and R315-50 and then replaced them with reference to corresponding U.S. Environmental Protection Agency requirements.

This Petition to repeal UAC R313-25 and reenact it with reference to 10 CFR 61 also addresses changes made in the 2013 Utah Legislature to UAC R313-25-6 via House Bill 124. That language has been retained in the replacement text proposed in the attached pages. Revisions to the statutory and regulatory requirements of House Bill 124 have been amended to be consistent with the approval process promulgated for State-issued Part B Permit modification requests in Utah Administrative Code R315-270-42(b)(6)(iii) (which is equivalent to U.S. EPA regulations in 40 CFR 270.42(b)(6)(iii)). This hazardous waste permit modification provision allows that “[i]f the Director fails to make one of the decisions...by the 120th day after receipt of the modification request, the permittee is automatically authorized to conduct the activities described....” Without an equivalent provision in UAC R313-25, there is no controlling provision enforcing the licensing action time requirements currently promulgated in UAC R313-25-6 (rendering the statutory provisions revised by House Bill 124 in 2013 ineffectual). Similarly, changes created by the 2015 Utah Legislature to UAC R313-25-31 via Senate Bill 173 have been retained in the reenactment text hereto attached.

Should the Board deny this Petition to repeal and reenact UAC R313-25 as currently promulgated, EnergySolutions requests that the Board prepare “a reasoned justification for continuation of the rule, including reasons why the [Board] disagrees with comments in opposition to the rule,” as required by Utah Code Annotated § 63G-3-305. I look forward to working with the Board on this Petition.

Please contact me at 801-649-2000 if there are any comments or questions.

Sincerely,



Dan Shrum

Oct 12 2016 2:26 PM



Daniel B. Shrum
Senior Vice President
Regulatory Affairs

cc: Ralph Bohn, DWMRC
Rusty Lundberg, DWMRC

Enclosure

Request to Initiate Rulemaking to R313-25

Utah Code Ann. § 63G-3-601(4) requires: *“A statement shall accompany the proposed rule, or proposed amendment or repeal of a rule, demonstrating that the proposed action is within the jurisdiction of the agency and appropriate to the powers of the agency.”*

The petitioned repeal and reenactment of Utah Administrative Code (UAC) R313-25 is within the jurisdiction of the Board under Utah Code Annotated §§ 19-1-106 and 19-3-104(4). Under those provisions of the Radiation Control Act, the Board may make rules *“that are necessary to implement the provisions of the Radiation Control Act”* (§19-6-104(1)(a)), to control exposure to sources of radiation (§19-3-104(4)(a)), and to meet federal legal requirements to ensure that the Utah radiation control program is qualified to maintain primacy from the federal government (§ 19-3-104(4)(b)).

The petitioned repeal and reenactment brings R313-25 into alignment with the requirements of Senate Bill 173, signed into law on March 31, 2015. Utah Code Annotated §63G-3-301(13)(b) requires the Division to *“initiate rulemaking proceedings not later than 180 days after the effective date of the statutory provisions that specifically requires the rulemaking”*. The proposed reenactment addresses Senate Bill 173 and brings the Board into compliance with these statutory requirements and corresponding Nuclear Regulatory Commission (“NRC”) requirement.

Finally, the petitioned repeal and reenactment brings UAC R313-25 into compliance with Utah Code Annotated §§ 19-3-104(7) and (8), which prohibits the adoption by the Board of any *“rules, for the purpose of the state assuming responsibilities from the United States Nuclear Regulatory Commission with respect to sources of ionizing radiation, that are more stringent than the corresponding federal regulations which address the same circumstances”* unless the Board *“makes a written finding after public comment and hearing and based on evidence in the record that corresponding federal regulations are not adequate to protect public health and the environment of the state.”* The petitioned repeal and reenactment will reduce the circumstances under which a licensee will be required to comply with requirements that are more stringent than those found in the corresponding NRC regulations or policies.

Replacement of UAC R313-25 with Reference to 10 CFR 61

R313. Environmental Quality, Waste Management and Radiation Control, Radiation. R313-25. License Requirements for Land Disposal of Radioactive Waste - General Provisions.

For the purposes of Rule R313-25, 10 CFR 61.1(a) through 60.54 and 61.56(a) through 61.84 are incorporated by reference with the following clarifications or exceptions:

(1) The substitution of the following:

- (a) "Director" for reference to "Commission"
- (b) "Rule R313-24-4" for reference to "§ 40.4 (a-1)" in 10 CFR 61.1(b)(2)
- (c) "Rule R313-15" for references to "part 20"
- (d) "Division enforcement action" for references to "NRC enforcement action"
- (e) "Division enforcement action" for references to "NRC enforcement action"
- (f) "Division of Waste Management and Radiation Control" for references to "Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission."
- (g) "State of Utah" for references to "United States of America"
- (h) "Director, Division of Waste Management and Radiation Control, 195 North 1950 West, Salt Lake City, Utah 84114-4880 " for references to " Document Control Desk; Director, Office of Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; by hand delivery to the NRC's Offices at 11555 Rockville Pike, Rockville, Maryland"
- (i) "Attorney General" for references to "General Counsel"
- (j) "Rule R313-37" for references to "Part 73"
- (k) "Rule R313-15-1009" for references to "10 CFR 61.55"

(l) "§ 61.6(a)" for references to "§ 61.6"

(m) "Disposal site means that portion of a land disposal facility which is licensed for disposal of waste. It consists of disposal units and a buffer zone." for reference in § 61.2 to "Disposal site means that portion of a land disposal facility which is used for disposal of waste. It consists of disposal units and a buffer zone."

(2) Delete the following:

(a) "as provided for in part 60 or 63 of this chapter" from 10 CFR 61.1(b)(1)

(b) "Commission means the Nuclear Regulatory Commission or its duly authorized representatives" from 10 CFR 61.2

(c) 10 CFR 61.8(a)

(3) Insert the following as § 61.6(b). *Director Review of Application:*

"(1) Unless the Director determines that there is sufficient technical or regulatory justification for a denial, the Director shall review and approve each approval application within the time allotted to determine that it complies with applicable statutory and regulatory requirements. Approval applications will be categorized as Category 1, 2, 3 and 4 applications, as provided in § 61.6(b)(2) through (5). Absent denial by the Director, the approval application shall be judged as having been approved at the expiration of the applicable allotted review time.

(2) Category 1 applications.

(a) A Category 1 application is an application that:

- (i) is administrative in nature;
- (ii) requires limited scrutiny by the Director; and
- (iii) does not require public comment.

(b) Examples of a Category 1 application include an application to:

- (i) correct typographical errors;

(ii) Change the name, address, or phone number of persons or agencies identified in the license or permit;

(iii) change the procedures or location for maintaining records;

(iv) Director's financial assurance determinations of financial assurance cost estimates prepared in accordance with R313-25-32(1)(d)(ii)(B); or

(v) extend the date for compliance with a permit or license requirement by no more than 120 days.

(c) (i) The Director shall complete review of a Category 1 application within a Category 1 application's allotted review time of 30 days after the day on which the Director Receives the application.

(ii) The period described in § 61.6(b)(2)(c)(i) shall not be tolled.

(3) Category 2 applications:

(a) A Category 2 application is one that is not a Category 1, 3 or 4 application.

(b) Examples of a Category 2 application include:

(i) Increase in process, storage, or disposal capacity

(ii) Change engineering design, construction, or process controls;

(iii) Approve a proposed corrective action plan;

(iv) Director's financial assurance determinations of financial assurance cost estimates prepared in accordance with R313-25-32(1)(d)(i) or R313-25-32-(1)(d)(ii)(A); or

(iv) Transfer direct control of a license or groundwater permit.

(c) (i) The Director shall complete review of a Category 2 application within a Category 2 application's allotted review time of 180 days after the day on which the Director receives the application.

(ii) The period described in § 61.6(b)(3)(c)(i) shall be tolled as provided in § 61.6(b)(7).

(4) Category 3 applications.

(a) Category 3 application is an application for:

(i) a radioactive waste license renewal;

(ii) a groundwater permit renewal;

(iii) an amendment to an existing radioactive waste license or groundwater permit to allow a new disposal cell;

(iv) an amendment to an existing radioactive waste license or groundwater permit that would allow the facility to eliminate groundwater monitoring; or

(v) approval of a radioactive waste disposal facility closure plan.

(b) (i) The Director shall complete review of a Category 3 application within a Category 3 application's allotted review time of 365 days after the day on which the Director receives the application.

(ii) The period described in § 61.6(b)(4)(b)(i) shall be tolled as provided in § 61.6(b)(7).

(5) Category 4 applications.

(a) A Category 4 application is an application for:

(i) a new radioactive waste license; or

(ii) a new groundwater permit.

(b) (i) The Director shall complete review of a Category 4 application within a Category 4 application's allotted review time of 540 days after the day on which the Director receives the application.

(ii) The period described in § 61.6(b)(5)(b)(i) shall be tolled as provided in § 61.6(b)(7).

(6) (a) Within 60 days after the day on which the Director receives a Category 2, 3 or 4 approval application, the Director shall determine whether the application is complete and contains all the information necessary to process it for approval and make a finding by issuance of a written:

(i) notice of completeness to the applicant; or

(ii) notice of deficiency to the applicant, including a list of the additional information necessary to complete the application.

(b) The Director shall review written information submitted in response to a notice of deficiency within 30 days after the day on which the Director receives the supplemental information and shall again follow the procedures specified in § 61.6(b)(1)(a).

(c) If a document that is submitted as an application is substantially deficient, the Director may determine that it does not qualify as an application. Any such determination shall be made within 45 days of the document's submission and will include the Director's written findings.

(7) Tolling Periods. The periods specified for the Director's review and approval or denial under § 61.6(b)(3)(c)(i), (4)(b)(i), and (5)(b)(i) shall be tolled:

(a) while an owner or operator of a facility responds to the Director's request for information;

(b) during a public comment period not to exceed 60 calendar days; and

(c) while the federal government reviews the application.

(8) Before expiration of the allotted review time, the Director shall prepare a detailed written explanation of the technical and regulatory basis for the Director's approval or denial of an approval application. If absent such written explanation at the expiration of the allotted review time, an approval application will be deemed as having been approved without finding."

(4) Insert the following as § 61.62. *Funding for Disposal Site Closure and Stabilization:*

(1) The applicant shall provide assurances prior to the commencement of operations that sufficient funds will be available to carry out disposal site closure and stabilization, including:

- (a) decontamination or dismantlement of land disposal facility structures and disturbed lands in all areas subject to the licensed or permitted portions of the facility, and
- (b) closure and stabilization of the licensed disposal embankment(s) so that following transfer of the disposal site to the site owner, the need for ongoing active maintenance is eliminated to the extent practicable and only minor custodial care, surveillance, and monitoring are required. The Director shall annually make a financial assurance determination that the approved cost estimates reflect the Director approved plan for the licensed disposal unit(s) closure and stabilization and decontamination or dismantlement of land disposal facility structures in all areas subject to the licensed or permitted portions of the facility. The applicant's cost estimates shall take into account total costs that would be incurred if an independent contractor were hired to perform the closure and stabilization work.
- (c) dismantlement and final license approved radiation survey of above-ground facility structures not subject to the licensed or permitted portions of the facility, as determined by mutual agreement between the Director and the applicant, that may present an attractant nuisance for potential inadvertent intruders.
- (d) At the option of the applicant, the cost estimates shall be based on:
 - (i) an annual calculation using the most recent edition of RS Means Heavy Construction Cost Data and an indirect cost multiplier agreed upon between the applicant, licensee or permittee and the Director; or
 - (ii) (A) for an initial financial assurance cost estimation determination and for each financial assurance cost estimation at the time of license renewal thereafter, a certified competitive site-specific estimate to address the requirements of R313-25-31(1)(a) through R313-25-31(c), where the preparer has certified that the financial assurance cost estimation has been prepared in conformance with all applicable federal, state, and local requirements; and

(B) for each year between the initial financial assurance cost estimate determination and license renewal financial assurance cost estimate determination found in Section R313-25-31(1)(d)(ii)(A), an annual inflation adjustment to the previous year's financial assurance cost estimation using the Gross Domestic Product Implicit Price Deflator of the Bureau of Economic Analysis, United States Department of Commerce, calculated by dividing the latest annual deflator by the deflator for the previous year and an Professional Engineering Analysis of significant changes in the licensed disposal unit(s) and other areas subject to the licensed or permitted portions of the facility.

(2) The Director will accept financial sureties that have been consolidated with earmarked financial or surety arrangements established to meet requirements of Federal or other State agencies or local governmental bodies for decontamination, closure, and stabilization. The Director will accept these arrangements only if they are considered adequate to satisfy the requirements of Section R313-25-31 and if they clearly identify that the portion of the surety which covers the closure of the licensed disposal unit(s) is clearly identified and committed for use in accomplishing these activities.

(3) The licensee's financial or surety mechanism shall be annually reviewed by the Director to assure that sufficient funds will be available for completion of the closure plan.

(4) The amount of the licensee's surety liability shall change in accordance with the predicted costs of future closure and stabilization. Factors affecting closure and stabilization cost estimates include inflation, increases in the amount of disturbed land, changes in engineering plans, closure and stabilization that have already been accomplished, and other conditions affecting costs. The financial or surety arrangement shall be sufficient at all times to cover the costs of closure and stabilization of the disposal unit(s) that are expected to be used before the next license renewal.

(5) The financial or surety arrangement shall be written for a specified period of time and shall be automatically renewed unless the person who issues the surety notifies the Director; the beneficiary, the site owner; and the principal, the licensee, not less than 90 days prior to the renewal date of its intention not to renew. In such a situation, the licensee shall submit a replacement surety within 30 days after notification of cancellation. If the licensee fails to provide a replacement surety acceptable to the Director, the beneficiary may collect on the original surety.

(6) Proof of forfeiture shall not be necessary to collect the surety so that, in the event that the licensee could not provide an acceptable replacement surety within the required time, the surety shall be automatically collected prior to its expiration. The conditions described above shall be clearly stated on surety instruments.

(7) Financial or surety arrangements generally acceptable to the Director include surety bonds, cash deposits, certificates of deposit, deposits of government securities, escrow accounts, irrevocable letters or lines of credit, trust funds, and combinations of the above or other types of arrangements as may be approved by the Director. Self-insurance, or an arrangement which essentially constitutes self-insurance, will not satisfy the surety requirement for private sector applicants.

(8) The licensee's financial or surety arrangement shall remain in effect until the closure and stabilization program has been completed and approved by the Director, and the license has been transferred to the site owner.

(9) If the Director and applicant do not agree on a financial assurance determination made by the Director, the licensee or permittee may appeal the determination in:

(a) an arbitration proceeding subject to Title 78B, Chapter 11, Utah Uniform Arbitration Act, with the costs of the arbitration split equally between the licensee or permittee and the Division, if both the licensee or permittee and the Director agree in writing to arbitration; or

(b) a special adjudicative proceeding under Title 19, Chapter 1, Section 301.5."

(5) Insert the following in § 61.2. Definitions:

"Disturbed lands" means the portions of the licensed disposal site other than disposal unit(s) that are not in native or natural form due to licensed or permitted operations.

"Financial assurance determination" means a decision on whether a facility, site, plan, party, broker, owner, operator, generator, or permittee has met financial assurance or financial responsibility requirements as determined by the Director of the Division of Waste Management and Radiation Control under the authority of Title 19, Chapter 3.

WASTE MANAGEMENT AND RADIATION CONTROL BOARD

Executive Summary Sensus SRT-100 Exemption November 10, 2016

What is the issue before the Board?	This is a request for an exemption for the Sensus SRT-100 machine from the requirements of R313-30-3(3), R313-30-3(4), R313-30-3(5), and R313-30-3(6) of the Utah Administrative Code.
What is the historical background or context for this issue?	<p>The Sensus SRT-100 is a superficial radiation therapy machine for treatment of skin cancers and keloids. It is a low radiation output unit that is used to treat two dimensional skin lesions. The therapy rules, from which the exemption is being requested, are for the high radiation output machines used to treat three dimensional tumors within the body. The training requirements, physics of positioning and dosing are quite different for the two types of treatment. The Sensus exemption request, received July 28, 2016, is to enable dermatologists to own and operate this unit in their offices as an alternative to surgical removal of the skin lesions.</p> <p>A public comment period was held from September 28, 2016 to October 28, 2016.</p> <p>Several comments were received and are attached to this summary.</p>
What is the governing statutory or regulatory citation?	In accordance with R313-12-55(1) of the Utah Administrative Code, the Board may, upon application or upon its own initiative, grant exemptions from the requirements of Rules R313-12 through 70 as it determines are authorized by law and will not result in undue hazard to public health and safety or the environment.
Is Board action required?	Yes.
What is the Division Director's recommendation?	<p>The Director recommends the Board grant an exemption for the Sensus SRT-100 machine from the requirements of R313-30-3(3), R313-30-3(4), R313-30-3(5), and R313-30-3(6) under the following conditions:</p> <ul style="list-style-type: none">• Sensus shall conduct training of dermatologists to allow them to be the Authorized User of the SRT-100;• Training shall be conducted using the training materials and duration described in the Sensus July 28, 2016 exemption request to the Director (DRC-2016-008950);• Sensus shall document the training by forwarding a Certificate of Training to the Director for each person trained;• Sensus shall notify the Director whenever a SRT-100 unit is sold in Utah (F2579).• The exemption shall expire upon Board adoption of rules for superficial radiation therapy requirements. <p>Note: the SRT-100 falls under the radiation therapy facility inspection schedule which requires annual inspections.</p>

Where can more information be obtained?

Please contact Lisa Mechem, DVM, at (801) 536-4286 for further information.

DSHW-2016-013861

Links has been created to assist you in navigating through this document:

LETTER FROM SENSUS REQUESTING THE EXEMPTION

COMMENTS FROM PATIENTS OR RELATIVES OF PATIENTS IN SUPPORT OF THE EXEMPTION

COMMENTS FROM THE MEDICAL COMMUNITY IN SUPPORT OF THE EXEMPTION

COMMENTS FROM THE MEDICAL COMMUNITY IN OPPOSITION TO EXEMPTION



Taking New Aim At Skin Cancer™

Div of Waste Management
and Radiation Control

July 28, 2016

AUG - 1 2016

DRC-2016-008950

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,

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,

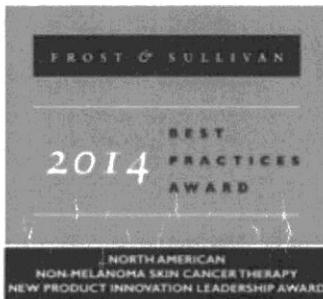


Joseph C. Sardano

President / CEO
Sensus Healthcare
851 Broken Sound Pkwy NW #215
Boca Raton, FL 33487
Main: (561) 922-5808
Toll free: (800) 324-9890
Mobile: (865) 310-3888
Fax: (561) 948-2071



Taking new aim at skin cancer therapy



Comments from Patients or Relatives of Patients in Support of the Exemption

Aaron Brown <ABrown@rooseveltcity.com>
To: "dwmrcpublic@utah.gov" <dwmrcpublic@utah.gov>

Tue, Oct 18, 2016 at 8:37 AM

Hello,

My grandma has been receiving Superficial Radiation Therapy from Dr. Parkinsons office and it has been extremely helpful with her current cancer. Just recently she has been told that she can no long receive these very helpful treatments because the state is regulating it. Please let them continue to use SRT and help our loved one and many others.

Regards,

Aaron Brown

Head Golf Professional

Roosevelt Golf Course

1155 Clubhouse Dr.

Roosevelt, UT 84066

P:435-722-9644

F:435-722-3213

From: Jackie Bradford <jackieut@hotmail.com>
Sent: Saturday, October 15, 2016 11:56 AM
To: dwmrepublic@utah.gov
Subject: Superficial Radiation Therapy

I hope this email is read with an open mind, and caring person.. I just wanted the DWM to be aware of all good the Superficial Radiation Therapy does.. I know it first hand, as my 88 year old mother has suffered from squamous cell cancer for the last five years.. We put her through a horrific head surgery 4 years ago, and it didn't stop the cancer growth at all. The only thing that has helped is the SRT.. While the procedure does prevent the cancer from occurring in new areas, its will kill the cancer that makes large open sores. The cancer if allowed to break the skin is extremely painful..She has new cancer behind her left ear, SRT ill prevent the event of an open sore.

My family are so very grateful to Dr Richard Parkinson, and his staff.. they are very professional ,well educated and caring when administering the SRT.. I personally have seen many people benefit from the procedure.. You know, cancer is evil, and if there is a chance to help someone deal with it on a better level, then I believe a procedure as easy and inexpensive should be available. Please will the State of Utah help these cancer victims receive this life saving treatments.
Thank you Jacqueline Bradford



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brent.crosland via dwmrcpublic <dwmrcpublic@utah.gov>
Reply-To: brent.crosland@yahoo.com
To: "dwmrcpublic@utah.gov" <dwmrcpublic@utah.gov>

Sat, Oct 15, 2016 at 12:01 PM

Utah State Board of Radiation Control

I have been a patient of Dr. Richard Parkinson for about 20 years. The past 10 years I have had to have several skin caners surgically removed mostly from my face and top of my head, always leaving scars one up to 2" long on my forehead. One surgery was a MOH's and I was sent to SLC for that. I recently completed a SRT treatment in Dr. Parkinson's office for two different cancers, one on my cheek and one on my forehead. During these treatments in his office I was never in his office more than 15 minutes usually 10 minutes. If treatment was done in a hospital setting I am sure the cost would be much greater (200 % plus) and the time for the treatment would be several times longer than that done in Dr. Parkinson office. This treatment was worked well for me and my family. I would hope that this SRT remains an option for myself, as well his other patients

Deanna Johnson <jlggsnd1@gmail.com>
To: dwmrcpublic@utah.gov

Mon, Oct 17, 2016 at 3:35 PM

To Whom it May Concern:

Mary Jean Brown is in desperate need of her continued radiation therapy. To stop Superficial Radiation therapy would be unconscionable. It improves her quality of life as well as lessening her pain. In her case, it is a lifesaving therapy. Please do not discontinue this option for her. I plead with you to allow her to continue to receive this care.

Sincerely,

Deanna Johnson

Martha Clayson <martha.clayson@icloud.com>
To: dwmrcpublic@utah.gov

Mon, Oct 17, 2016 at 11:06 PM

"If it ain't broke, don't fix it!"

If a person has had over fifty treatments, mostly successful, and these treatments have saved a life; given a more quality, pain free life, why would treatments not be continued in an office a person is familiar and comfortable with?

I have known Mary Jean Brown my whole life! She is one of Payson's elite women! She deserves treatment that works for her, and for any other person like her! She is comfortable in this situation, so why stress her out with more, new unnecessary change! She deserves the dignity of continuing what works for her in her confused, elderly state!

Thanks to Dr. Parkinson who has probably helped many more like her live a comforting routine situation that is cost efficient and working!

Logan Hamling <logan.hamling@gmail.com>
To: dwmrcpublic@utah.gov

Sun, Oct 16, 2016 at 6:26 PM

Please don't eliminate the SRT treatments they are doing so much good for older patients without causing a lot of pain or expense.

JERRY HAMLING <jerryhamling@gmail.com>
To: dwmrcpublic@utah.gov

Sun, Oct 16, 2016 at 5:54 PM

SRT stands for Superficial Radiation Therapy.. This is a low cost benefit afforded to cancer patients. why in the world would this procedure be stopped. Cancer should always be treated.. Some people have horrific sores and pain without the srt.. Don't take this out of Utah please

fghill@cut.net <fghill@cut.net>
To: dwmrcpublic@utah.gov

Sun, Oct 16, 2016 at 3:30 PM

To Whom it may concern:

I am a patient of Dr. Richard W. Parkinson and went through the Superficial Radiation Therapy treatments. When I was diagnosed with squamous cell skin cancer the options for treatment were explained to me. I either had to have extension surgery which required a long recovery time to heal or the in office SRT treatment. Due to my age of 77, at the time, I elected the SRT treatment. This was more convenient for me. I did not want to have surgery on my arm to remove the cancer and then possible skin grafts, pain, possibility of infection, reduced strength in my arm and a longer recovery time. Going to the Dr. Parkinson's office twice a week, once the determined amount of treatments needed, was more beneficial to me than one time in surgery. If I am ever diagnosed with squamous or basal cell cancers that can be treated without surgery I will opt for SRT. I hope that you will change the wording and continue to allow this treatment option available.

On a personal note, the older you become the less likely you want to be cut open. The healing time, pain, recovery time, mental stress, and negative feelings linger longer. My quality of life relies on a positive environment.

Thank you Francis Hill Mt. Pleasant, Utah

KELLY BEVERLY LLOYD <bevtumbles@msn.com>
To: "dwmrcpublic@utah.gov" <dwmrcpublic@utah.gov>

Sun, Oct 16, 2016 at 2:03 PM

To whom it may concern,

I am a daughter to a patient (Mary Jean Brown) who has had 50 treatments from Dr. Parkinson. These treatments have saved not only my mothers life but countless hours of pain and suffering. I can't believe that the state would take away a life saving practice from patients like my mother and countless others. We don't have a cure for cancer but when we find something that works why would you take it away? Is it because big corporations can make more money? My mom is 88 years old and she doesn't need any more pain in her life. Please let this practice continue to help her.

Beverly Lloyd

From: Jackie Bradford <jackieut@hotmail.com>
Sent: Saturday, October 15, 2016 11:56 AM
To: dwmrcpublic@utah.gov
Subject: Superficial Radiation Therapy

I hope this email is read with an open mind, and caring person.. I just wanted the DWM to be aware of all good the Superficial Radiation Therapy does.. I know it first hand, as my 88 year old mother has suffered from squamous cell cancer for the last five years.. We put her through a horrific head surgery 4 years ago, and it didn't stop the cancer growth at all. The only thing that has helped is the SRT.. While the procedure does prevent the cancer from occurring in new areas, its will kill the cancer that makes large open sores. The cancer if allowed to break the skin is extremely painful..She has new cancer behind her left ear, SRT ill prevent the event of an open sore.

My family are so very grateful to Dr Richard Parkinson, and his staff.. they are very professional ,well educated and caring when administering the SRT.. I personally have seen many people benefit from the procedure.. You know, cancer is evil, and if there is a chance to help someone deal with it on a better level, then I believe a procedure as easy and inexpensive should be available. Please will the State of Utah help these cancer victims receive this life saving treatments.
Thank you Jacqueline Bradford



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Speedy7491 <speedy7491@gmail.com>
To: dwmrcpublic@utah.gov

Wed, Oct 19, 2016 at 3:39 PM

As a patient previously treated with SRT I would request your continuing allowance of the exemption for physician's offices.

With damaged DNA from my teenage years I have spent a significant amount of time at the dermatologist's office. At a maximum I was treated as often as weekly. I've been doing this for the last 25 years. It is no fun when the last treatment scars are still healing upon arrival for the next set.

When offered SRT I jumped at the chance to minimize the 25-30 liquid nitrogen treatments per visit.

Since my treatment started I have been pleased to endorse the procedure to others but especially at my particular doctor's office.

One particular reason I feel an exemption is in order is the continuing care and concern of the office staff. Turnover at local hospitals is rampant, a patient usually does not see the same technician again. In contrast, the physician's office has the same staff year after year, they know me and my particular history far more intimately than a hospital ever could hope for.

Finally, I have a susceptibility to staph infection. Infections are significantly higher at hospitals no matter what they do. Hence I avoid trips to hospitals when an alternative is available. SRT at an office minimizes this risk for me.

John Lockwood
[801-222-0222](tel:801-222-0222)

Kathleen Muhlestein <kmul13109@q.com>
To: dwmrcpublic@utah.gov

Mon, Oct 17, 2016 at 3:09 PM

Concerning Grandma Jean- please do not refuse her treatments at Dr. Parkinsons office. It is imperative for her continuing care.

Sincerely Kathleen Muhlestein- kmul13109@q.com

Lafe Parrish <ljparrish10@gmail.com>
To: dwmrcpublic@utah.gov

Mon, Oct 17, 2016 at 8:27 AM

This method of treatment was chosen for the desired result. Prognosis as good as surgery with less chance of scarring, drooling, infection and pain. It took longer than a surgery but it is my face, my lip. I felt time invested was worth it for the result desired.

My experience in Dr. Parkinsons' office was very good and professional. I practiced thirty years as a veterinarian, we had X-ray units in our hospital, so i was aware of safe procedures. I was very impressed with the protection they gave me as a patient and the safe procedures they used to protect office personal.

I would make the same choose again. If it wasn't my face i probably would select surgical procedure.

I appreciate being able to be in their office twice a week for the period of the treatment.

Sincerely, Lafe A. Parrish

Peter Crawley <pc@rockcanyonamericana.com>
To: dwmrcpublic@utah.gov

Sun, Oct 16, 2016 at 7:51 AM

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

Dear Sir:

Late last year, I had Superficial Radiation Therapy (SRT) to treat a squamous cell carcinoma in the middle of my forehead above my right eye, at the office of Dr. Richard W. Parkinson in Provo, Utah. When the cancer was diagnosed, the treatment choices available to me were either surgical removal or SRT. I elected to have SRT because it would be much less invasive, be considerably less painful, and not leave an obvious scar in a prominent part of my face. Further, since I am eighty years old, the possible long term side effects would not apply to me.

As it turned out, my expectations were more than met. Each of the treatments took only a few minutes. Throughout, there was no pain and no discomfort. The only obvious consequence of the treatments was a slightly red 2-inch disk on my forehead that quickly disappeared once the treatments were concluded. And all indications are that the cancer was successfully treated. I would certainly elect SRT again for a cancer that posed the same problems as my earlier one, and I would not hesitate to recommend it, particularly to my older friends.

Sincerely,

Peter Crawley
1133 N Temple Dr
Provo, UT 84604

Bernice Prigmore <bernicp2013@gmail.com>
To: dwmrcpublic@utah.gov

Wed, Oct 19, 2016 at 9:37 AM

To Whom it May Concern,

I received Superficial Radiation Therapy (SRT) to treat basal cell carcinoma this year at the office of Dr Richard Parkinson, my dermatologist. I cannot express how grateful I am that I could receive the treatment that Dr Parkinson was able to give. The carcinoma was on the left side of my nose. The option other than SRT would have been to have slices of the side of my nose removed. That would have been painful, and it would have been disfiguring. I had 17 treatments of radiation, and yes, I had a red "target" from the radiation for the length of the treatments, but after a few weeks the redness had disappeared.

My quality of life was certainly affected for the good, by the treatment Dr Parkinson was able to offer. Even a slow growing carcinoma like basil cell has a bit of personal trauma, and now it appears that my chance of having other basil cell carcinomas is higher. I feel quite a bit of peace knowing that I can receive the SRT for other incidents if and when they occur. I would ask you to approve a variance to the existing law in order to allow Dr Parkinson to continue to offer this care. It means a lot to me, and I am sure to others in the same category as I am. I absolutely would recommend this treatment to anyone who might find themselves in need of treatment for basil cell carcinoma. As I said before, this procedure has improved my quality of life.

Thank you,
Bernice Prigmore

Joe Swenson <joe.swenson@imaginelearning.com>
To: "dwmrcpublic@utah.gov" <dwmrcpublic@utah.gov>

Wed, Oct 19, 2016 at 2:33 PM

I understand the State of Utah is considering whether or not to offer a variance for office-based Superficial Radiation Therapy through Dr. Parkinson's office in Provo, Utah. I hope my experience may be helpful in making an informed decision.

My name is Joe Swenson and I live in Midway, UT. Over the past couple of years I have had several diagnoses of skin cancer on my face. Two in particular were surgically removed and both have left scars on my face not to mention the trauma associated with that type of surgery.

My latest bout of skin cancer appeared on my neck just below the chin. It would have required surgery cutting out a chunk about the size of a quarter – another scar, another traumatic event. I was told about and chose to use Superficial Radiation Therapy offered at Dr. Parkinson's office. I went in for 17 visits that lasted just minutes each. I completed my last visit about a month ago and the skin looks fabulous without more scarring. The staff at Dr. Parkinson's office is outstanding and I felt completely comfortable in their hands.

While I am no expert in SRT, I do recognize that more and more procedures are moving out of the extremely costly hospital environment and into more patient and wallet-friendly facilities – and I had to pay for the treatments myself.

This seems like a no-brainer decision. Please listen to the patients and grant the waiver allowing Dr. Parkinson's office to continue to offer this valuable treatment. I have no doubt I'll be back with more skin cancer issues in the years to come and I would much prefer the convenience and professionalism of Parkinson's office to take care of me. I do not want to go to the hospital for the treatment and I do not want to have more surgery. I would recommend the same to anyone else with a similar diagnosis. Please grant the waiver!

If you have any questions, I would be glad to respond.

Joe Swenson

[801-500-0465](tel:801-500-0465)

Joe.swenson@imaginelearning.com

Joan Watkins <wasapick@gmail.com>
To: dwmrcpublic@utah.gov

Mon, Oct 17, 2016 at 7:49 PM

Please consider extending treatments for a good friend Mary Jean Brown!

Kimberly Wynne <kimberlywynne@me.com>
To: dwmrcpublic@utah.gov
Cc: info@parkinsonderm.com

Thu, Oct 20, 2016 at 10:47 AM

I would like to give some feedback on receiving superficial radiation therapy over the last year. I was seen and diagnosed at the office of Dr. Richard Parkinson in Orem/Provo Utah with 2 different spots on my face that were squamous cancer skin cells. Knowing that my options were limited to surgical removal and each spot would leave a 2" scar was pretty devastating. I was thrilled to hear that there was a new option that was non invasive, less expensive, pain free and would eliminate the cancer with the same probability of the other traditional surgeries called SRT. I did the 8 week treatment program and was very impressed with the professionalism and attention given to me throughout the process. it was very convenient to be in office and took a very minimal amount of time (generally 10 minutes or less).

I would without hesitation recommend this treatment as a great option for anyone dealing with skin cancer. It is the best option because of price, ease of treatment and the fact that your face is left without major scarring. The only thing, which is mild, is that the treatment area becomes faded and "whiter" than the surrounding skin...but for me it was totally worth it and makeup covers it up just fine.

if I can be of further assistance, please feel free to contact me at [435-671-7653](tel:435-671-7653) or at my email [@kimberlywynne@me.com](mailto:kimberlywynne@me.com)

thank you!

Kimberly Wynne

OLINATOR <olinator@comcast.net>
To: dwmrcpublic@utah.gov

Tue, Oct 18, 2016 at 12:17 PM

I am writing on behalf of a senior citizen suffering from skin cancer, who is currently receiving the subject therapy to combat this disease, at Dr. Parkinson's office in Utah County. This is the only doctor who offers this treatment in his office in the entire state and it is vital to the patients in this area. I am requesting that the radiation procedure remain in his office to accommodate patients who are dealing with these dreaded diseases. Thank you for your consideration in this matter.

Vicky Yearby

Carly Christiansen <carlycaroline@gmail.com>
To: dwmrcpublic@utah.gov

Sat, Oct 22, 2016 at 1:58 AM

To whom it may concern:

I had the treatment SRT or also known as Superficial Radiation Therapy. My results turned out phenomenally. I had the treatment done on my nose and show no sign of scarring or reoccurring symptoms. It looks smooth and natural, with no indication of any previous treatment.

I chose this type of treatment over any other, knowing I'd be completely and overly satisfied with my results. I didn't have a huge cut out of my nose and I don't have any scarring. Which if I had chose or didn't have SRT, I would have one or both.

I would recommend this procedure to anyone, over any other type of treatment available. Due to how wonderfully my results were. The scheduling was easy and convenient, being able to get the treatment directly at my doctors's office. Plus, the fact of it being at my own doctor's office. I know it saved me way more than if I had to travel to the hospital or another facility.

I was totally pleased with the whole operation. I had good results and am so glad it was available to me.

Thank you,
Carol Bonnett
[801-375-2323](tel:801-375-2323)

fghill@cut.net <fghill@cut.net>
To: dwmrcpublic@utah.gov

Fri, Oct 21, 2016 at 8:04 PM

As the wife of a patient who had the Superficial Radiation Therapy treatment, I was so grateful that my husband Francis Hill was able to have the treatments in Dr. Parkinson's office. We live in Mt Pleasant and getting appointments which worked for us was very important. Sitting in a hospital waiting your turn to have a treatment and not knowing how long you were going to have to wait was not a consideration for my husband. Patience is not his best quality. The alternative to the SRT was surgery which would have been a struggle for him. The down time for recovery, the deepness of the cancer and the chances of infection, loss of muscle and mental stress what not something we were looking forward to.

Having the opportunity to do the prescribed treatments, convenience of treatment, time involved was a God sent to us. We were so relieved when Dr. Parkinson was able to perform the treatment opposed to surgery that it lifted a heavy weight from our shoulders.

Having this type of treatment creates such a positive attitude that I wonder WHY the hospital is the ONLY place to have it done. Who really benefits from this. Insurance is a major factor in selecting the type of treatment one can afford. I wonder just how much it would have cost us if we would have been forced to have the treatment in a hospital.

Both my husband and myself hope that you will reconsider changing the wording of the law as long as ALL the requirements are met by the physician who wishes to provide the SRT treatment.

If you have any questions please feel free to contact me. Thanks you
Mary Hill [435-462-3960](tel:435-462-3960)

From: Max Curtis [mailto:maxcurtis2@gmail.com]

Sent: Friday, October 21, 2016 4:48 PM

To: ismith@fiber.net

Subject: Subject SRT

Dear Ilene,

I have been very satisfied with my SRT treatments.

I chose this treatment because it does not leave a scar. I would recommend this treatment to others.

Everyone was helpful and very kind.

Sincerely

Marilyn Curtis

'patricia dalton' via dwmrcpublic <dwmrcpublic@utah.gov>
Reply-To: patricia dalton <patriciadalton84606@yahoo.com>
To: "dwmrcpublic@utah.gov" <dwmrcpublic@utah.gov>

Sat, Oct 22, 2016 at 9:31 AM

My name is Patricia Dalton. I am one of the very luck people to be able to get SRT at my Dr.'s Office. I had a squamous cell skin cancer on my forehead, and other treatments had not been able to kill it. I had the choice of having my forehead cut wide open or have SRT for several weeks. I chose SRT. It was pain free. and the cost was affordable. Also I have had other cancers and surgeries. This was truly a great relief for me to know I could get this done at my Dr.'s office.

Please allow this SRT treatment to continue, for all of us.

knhinclegg <knhinclegg@comcast.net>
To: "dwmrcpublic@utah.gov" <dwmrcpublic@utah.gov>

Sun, Oct 23, 2016 at 4:38 PM

“Public comment on Sensus Exemption.”

I have received Two (2) SRT treatments at Dr. Richard W. Parkinson's office and was totally pleased with not only their service, but with the outcome.

I chose the SRT treatments because of the appearance of scarring in the face area and with the “No surgery” involved. I am on a blood thinner for a heart condition and concerned about the bleeding that would have been involved.

I am retired, on a tight budget, so cost was a factor for my considering the “in office visits”.

In a few weeks, I will require additional SRT treatments in the facial area. Please consider in their favor a variance to the law that will allow Dr. Richard Parkinson to continue this valuable treatment to myself and other patients.

Thank you;

Ken A. Clegg

Wanda H York <teywhyork@gmail.com>
To: dwmrcpublic@utah.gov

Sun, Oct 23, 2016 at 10:26 PM

To whom it may concern, please add my request with the many other family and friends. Please allow Grandma Jean to have the continued treatments that she needs to fight her cancer.
Wanda York

BJ Wright <bwright@aplusbenefits.com>
To: "dwmrcpublic@utah.gov" <dwmrcpublic@utah.gov>

Mon, Oct 24, 2016 at 10:47 AM

Greetings:

Dr. Richard W. Parkinson's office started with State approval over one year ago a procedure called Superficial Radiation Therapy (SRT) to treat basal cell and squamous cell skin cancers. It has been very effective for Jean Brown and safe. It also is reasonably priced for anyone on Medicare to be able to afford. This procedure eliminates the non-melanoma skin cancers without cutting, scarring, risking infection and resulting in little or no pain.

This form of treatment has been very effective and not so evasive as regular visits to Hospitals or Cancer Treatment Centers. I would recommend this procedure to others as an option.

I am asking that you grant the variance to Dr. Richard W. Parkinson for this procedure in order for Grandma Jean to continue her treatments. Changing things for her now would be absolutely devastating.

With Warmest Regards,

Brenda J. Wright
131 West 970 South
Midway, Ut 84049

Linda Renzello <linda.renzello@gmail.com>
To: dwmrcpublic@utah.gov

Mon, Oct 24, 2016 at 1:57 PM

Dr. Parkinson has been offering superficial radiation treatments for his patients in his office. These treatments have been a life saving procedure for my friend's skin cancer. She has been informed that these treatments will no longer be available at his office. Please reconsider taking this SRT treatment away. It has been very effective. Her pain has been diminished and it is something that she has been able to afford to have done. At present time, she has developed another area that is in need of this treatment. Why would you take away something that is working for not only her but other away?

Linda Renzello

From: Karl Farnsworth [mailto:karl@famsworth.us]
Sent: Monday, October 24, 2016 10:43 AM

In December, 2015, I was diagnosed with basal cell carcinoma on the left side of my face. I previously had two melanoma surgeries in the same area. This basal cell was directly on the scar of the first melanoma surgery. Rather than have more cutting in the same spot of my face, I chose to receive SRT (Superficial Radiation Therapy), which I did from January to March 2016. I was very please with the treatment. It was fast, easy, pain free and the results were great - no more scaring. It was the perfect treatment for me. I wouldn't have to think twice to do it again if necessary. I have shared my experience with many friends and family members and highly recommend it for any one who has non-melanoma skin cancer.

It is my desire that you will approve a variance to the law to allow treatments to continue in the office of Dr. Richard W. Parkinson.
Sincerely, Joyce J. Farnsworth

laurie clegg <llclegg07@gmail.com>
To: dwmrcpublic@utah.gov

Fri, Oct 21, 2016 at 9:18 AM

To Whom It May Concern:

I am a medical assistant in the office of Richard W. Parkinson Dermatology, and have worked closely with our Superficial Radiation Therapy patients. SRT has become a important treatment option our patients have come to rely on.

SRT has been a successful treatment for our patients who are frail and would not do well with MOHS or an excision that would put them at risk of infection or excessive bleeding. Patients have chosen SRT so they would not have to have disfiguring excisions or complicated grafts. Some of our patients are exhausted from many skin cancer surgeries and have chosen radiation treatment to avoid more cutting. I know some of our patients like SRT because it is an affordable option compared with MOHS or grafts.

We have an elderly patient that had several large and fast growing squamous cell cancers on her scalp, that were extremely painful and too large to excise. SRT was an effective treatment that reduced the size of the lesion, eliminated the pain, and treated the cancer.

Our office has complied with all safety regulations, and I view it as a safe and necessary treatment option for the patients in our office. I hope you will consider the variance so we can continue to provide the people of Utah this affordable and effective treatment.

Sincerely,

Laurie Clegg
Medical Assistant
Dr. Richard W. Parkinson's Office

From: Heidi Taylor [mailto:heiditay1@gmail.com]
Sent: Monday, October 24, 2016 3:30 PM
To: ismith@fiber.net
Subject: dick taylor letter about radiation treatment

Public comment on Sensus Exemption

I chose this form of treatment over surgical removal because:

1. This treatment is completely painless.
2. There is absolutely no scarring.
3. There were not side effects at all.
4. Because there was no invasion of the skin there was no danger of infection.
5. Going to Dr, Parkinson's office was much more convenient than going to a hospital.
6. Even though I recieved 17 treaments, I was never in the office more than ten minutes or less.

I would highly recommend this form of treatment to anyone who is eligible. This

treatment eliminates the fear that anyone may have of needles, surgery or hospitals. The cost of the treatment is significantly less money than having it done in a hospital.

Sincerely,
Dick Taylor

Oct 23, 2016

To whom it may concern.

My name I Robert E. Hahne. I am a retired Professional Engineer. I am writing to **strongly recommend** with no reservations that the office of Dr. Richard Parkinson in Provo , Utah be given permission continue giving radiation treatments for skin cancers .

I have been a patient of this office for many years and have always been given care in a kind and professional manner. Over the years I have given recommendation for this clinic to many friends and associates

I am a down winder having grown up in southern Utah during the time of above ground atomic bomb testing. I have many friends and relatives who have died due to cancer. I am on chemotherapy for a blood condition known as myleofibrosus.

Accordingly, when biopsies revealed that I had two different kinds of skin cancerous growths on my upper lip I wanted the best treatment I could get.

I was originally told that my half of my upper lip up to my nose would have to be surgically removed leaving me disfigured as well as at great risk for eventually losing my teeth because of having no lip. This was a very disheartening diagnosis. When I returned to Dr.Parkinson's for consultation I was told of the option of radiation. I knew that this procedure was new and not performed widely.

Given the possibility of major disfigurement for the rest of my life I went with full confidence for the radiation treatment. I am thrilled with the results. My lip is fully recovered (I won't be able to grow a mustache but since I don't wear one anyway, it's a very small sacrifice for a wonderful cure) .

I again recommend that this office be given permission to continue with radiation treatment procedures for skin cancers. I'm sure that many folks will benefit. Please consider contacting me if needed.

Respectfully,

Robert E Hahne P.E.



633 West 80 North, Orem UT, 84057

801-225-0100

bobhahne@netzero.net

From: Charles Tate [mailto:cdtatejr54@gmail.com]
Sent: Friday, October 21, 2016 11:44 AM
To: ismith@fiber.net
Subject: reply to SRT treatment

Dear Ilene,

Here are a few comments on the SRT treatment I received in your office.

I chose this treatment, because it was the least invasive and very easy to do. Even though it required many visits to the office, they were very short, and the staff was very accommodating. I felt like the results were very good. My skin looked better than it ever had and I felt confident that the cancer had been eliminated.

I would be glad to recommend it to others.

The cost was very reasonable.

All in all I was very pleased with the treatment and the result of the SRT.

Thank you,

Dianne Tate

Steve Howarth <sbhowarth@gmail.com>
To: dwmrcpublic@utah.gov

Fri, Oct 21, 2016 at 12:45 PM

Dr. Parkinson, Provo Utah office.

One year ago Dr. Parkinson found a cancer area beneath my right eye. He told me that this particular cancer would best be taken care with a new machine that he was in process of procuring (SRT). Dr. Parkinson had removed several cancer spots from my body over the years. He has my trust, and when he told me about this new method of treatment, it was great news for me.

I visited his office 17 separate times, although the travel time to and from the office was somewhat tiresome. The procedure in and of itself was successful. If there had been a surgery involved, the risk to hit a nerve was too much for me to have. Also the time table for me at my age to heal would have been difficult.

I hope that Dr. Parkinson will continue to have access to this SRT treatment to help people that need this non-invasive treatment.

Thank You
William Boyd Howarth

Ned Warner <nedmaasai@hotmail.com>
To: "dwmrcpublic@utah.gov" <dwmrcpublic@utah.gov>

Fri, Oct 21, 2016 at 1:05 PM

I recently received SRT for two cancer lesions on my left shoulder at Dr. Parkinson's office in Provo.

I chose SRT because I wanted to avoid the experience of excision and recovery of excision. Although it was a longer period of time; each treatment visit at Dr. Parkinson's was fast, painless and well organized.

I experienced some minor localized pain and itching but this was much better than my cancer excision experiences.

I am recommending this option to friends and family.

Sincerely,

Ned Warner

From: Barbara Barron [mailto:bbarron@byu.net]
Sent: Monday, October 24, 2016 10:34 PM

Re: Superficial Radiation Therapy

I am writing relative to my experience with Superficial Radiation Therapy. About a year ago, I had several areas that proved to be cancerous and two of them were such that they could be removed by cutting. However, one of the two on the bridge of my nose had difficulty healing and even came open after the stitches had been removed. The third covered a much larger area and would have left real scarring. I was hesitant, at first, to use the radiation therapy. However, Dr. Parkinson assured me that is was only superficial, not deep radiation. After much deliberation, I elected to proceed with the SRT.

I could not be more pleased. The treatment involved a number of brief treatments which produced a red-colored area on my temple. This I treated with a cream that I was given and there was no further discomfort or problem. The procedure was completed several months ago and I am very pleased. The area of red is completely gone and there is no scarring or any indication of anything having been done. I would recommend this procedure to anyone with a problem similar to mine.

'S Clement' via dwmrcpublic <dwmrcpublic@utah.gov>
Reply-To: S Clement <sclcm60@yahoo.com>
To: "dwmrcpublic@utah.gov" <dwmrcpublic@utah.gov>

Fri, Oct 21, 2016 at 4:06 PM

To Whom it may concern:

I had SRT 7 months ago. I go to Dr. Richard W. Parkinson's office every 6 months for routine check ups due to Melanoma. Obviously all of my appointments do not end in a diagnosis of Melanoma, but rather pre-cancerous things like Basal cell carcinoma, or Squamous cell carcinoma's.

When I did the SRT, my doctor felt it would be a great alternative based on the fact that whenever I get chopped on, which is usually every six months, that perhaps it would be less invasive if I tried out this new procedure in his office. I was pleased that I could do it there in the office as well as have it done with much less expense. This was a great alternative for me due to the fact that I tend to end up having multiple surgeries in the exact same spot to get it gone. This procedure may have been more lengthy, but certainly better than having the scarring, swelling, pain, and all that goes along with going under the knife/scalpel, stitches, and the ugliness that goes along with it.

I know that I am more than likely not the only patient that has to have multiple surgeries. I have been seeing Dr. Parkinson for over 30 yrs. now. And, I appreciate that he does all he can to make things easier on his patients. Having the machine there was so much more convenient, and made me feel comfortable being able to go there since I already have to travel a distance for treatments as it is.

The only people that know that this procedure was ever done are the people that I know and love. But you certainly can't see any sign of it by just looking at me. This was done on an area on my face that would certainly be noticeable if it had had a different result. ie. my other surgical procedures up to this point. I also feel good knowing that I will not have to worry about a re-occurrence of cancer etc. in the area that was treated. This certainly gives me a lot of comfort.

I truly hope that you will continue to allow this procedure and machine to remain within the doctor's office rather than my having to go to a hospital etc. to receive treatment and have the added expense of doing so. This is a procedure that I would do again, verses getting chopped on. It's a much more pleasant experience and outcome.

Thanks so much,

S. Clement

Marcine Brown <mmojo57@gmail.com>
To: dwmrcpublic@utah.gov

Mon, Oct 24, 2016 at 8:47 PM

To Whom it May Concern,

My mother- in- law, Mary Jean Brown Nielsen, has been being treated at Dr. Parkinson's office for skin cancer on her head. I believe my sister in law, Jackie Bradford has sent you some graphic pictures of Mary Jean's before and after treatment. The pictures tell a huge story. This SRT treatment has literally saved my mother-in-laws life. It is a painless treatment and has some remarkable results for her. It has almost completely cured her cancer sores on her head. She is now experiencing more of these hideous cancers coming on her head and without this treatment she will be in some excruciating pain and terrible disfigurement on her scalp. Please, please, please allow this doctor's office to retain this machine so that Mary Jean can have the quality of life that she deserves. Without this treatment we are really afraid of what she will be subjected to. We know this for sure that it won't be a good outcome without this treatment.

Thank you for your consideration and time concerning this matter.

Sincerely,
Marcine H Brown

dhubbard@xmission.com <dhubbard@xmission.com>
To: dwmrcpublic@utah.gov

Tue, Oct 25, 2016 at 11:57 AM

Utah State Board of Radiation Control,

The purpose of this email is to provide a little feedback on my recent Superficial Radiation Therapy (SRT). My treatment occurred at Dr. Richard W. Parkinson's office in Provo, UT.

I chose SRT because it was less invasive than the cutting treatment I had received several times before. I have several scars (one by my eye, one on my back, and one on my arm; to name a few) from having either basal cell or squamous cell skin cancers removed. I did not want another butterfly type scar (this time on my forehead) so I opted for SRT.

It has been several months since I finished SRT and thus far I have been happy with it and I would recommend it to others, especially for older patients and for treating highly visible areas on the body like the face.

Thank you for your time and consideration.

Daniel H

Jeanne Clawson <jeanne.clawson@gmail.com>
To: dwmrcpublic@utah.gov, Jeanne Clawson <jeanne.clawson@gmail.com>

Tue, Oct 25, 2016 at 10:14 AM

It is not very often that a patient can evaluate a medical program.

The decision for superficial radiation on my scalp and right ear in Dr. Richard W. Parkinson 's office was the right decision. It was easy and painless as was the price.

I was treated very well and I would advise anyone needing this treatment to participate.

Thank you,

Robert G. Clawson

Don Rasmussen <DONRAS11@msn.com>
To: "dwmrcpublic@utah.gov" <dwmrcpublic@utah.gov>

Tue, Oct 25, 2016 at 10:32 AM

To whom this may concern,

I chose this procedure so I didn't have to go in for any type of surgery, it didn't scar my face and it was really easy. If I had it do all over again I would still chose the route. It's fast, simple, and pain free.

I hope that my doctor can still use this procedure option in his office, it would be a shame to see it go.

Best of Wishes,

Don A. Rasmussen

njofuller@comcast.net <njofuller@comcast.net>
To: dwmrcpublic@utah.gov

Tue, Oct 25, 2016 at 12:45 PM

Dear Friends,

PLEASE do not stop physicians in Utah from performing the vital, life-saving procedure of Superficial Radiation Therapy to treat cancer! It has been so very beneficial to so many people - it is less painful, less expensive, and less damaging. I have a friend who has benefited greatly from this procedure, and it has saved her life, as well as saving her family thousands of dollars. Please do not take this away from her and the many others it is saving.

Respectfully,

Nancy Fuller
2131 W 360 S
Provo, UT 84601
[801-836-5329](tel:801-836-5329)

Sunny Elton <cscmielton5@gmail.com>
To: dwmrcpublic@utah.gov

Wed, Oct 26, 2016 at 9:42 AM

To whom it may concern

We beg of you to not get rid of the superficial radiation program as it has been proven to stop squamous cancer cells in its tracks. My grandma has been sick for quite some time and has taken this route and it has cleared her cancer with no pain or sickness. She probably would not be around without it. Once again she is getting a new lump and will be needing these treatments and we no longer know weather they will be available to her. PLEASE I beg of you to not shut this program down it is the only one in the state of Utah. I can only imagine what she will have to go through if she can not use this method. It is very effective and LIFE SAVING not to mention painless and very inexpensive!! PLEASE re consider!

Thank you for your time
Sunny Elton

Sunny Elton <cscmielton5@gmail.com>

Wed, Oct 26, 2016 at 9:42 AM

To: dwmrcpublic@utah.gov

To whom it may concern

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Thank you for your time

Sunny Elton

betty birrell <jbbd52@gmail.com>

Wed, Oct 26, 2016 at 9:55 AM

To: dwmrcpublic@utah.gov

I had radiation therapy to treat basal cell cancer on back of my right leg. It was a good experience and I felt comfortable being there. They were very professional and was explained the treatment that was to be done. I was given a chose and I wanted the radiation treatment. I felt like they knew me and cared about me. If I have to have radiation therapy again I would hope it could be in the same office.

I have gone to Dr. Richard W. Parkinson for many years. I trust him and the staff that is there.

I have had many surgeries on my body and was glad to have the option of radiation.

I would recommend to family and friends the option of radiation therapy.

Joe R. Birrell

Highland, Utah

MARK L BROWN <EmilyCheryl@msn.com>

Wed, Oct 26, 2016 at 4:03 PM

To: "dwmrcpublic@utah.gov" <dwmrcpublic@utah.gov>

Please do not remove the radiation machine at Doc Parkinson office . this machine has lessened the horrific pain that Mary Jean Brown has been in with the Cancer on her skull. We as a family have to take work off to take her to her appointments. What a blessing to not have to make her ride an other hour each way to North SLC. Not to mention the extra cost just in travel and time off from work. Instead of 3 hour it will be at least 5-6 hours. Doc Parkinson staff are capable professionals,with kind hearts working hard to help Mary Jean.

Cheryl Brown

C. Wilfred <cwgriggs@hotmail.com>
To: "rbohn@utah.gov" <rbohn@utah.gov>

Wed, Oct 26, 2016 at 9:38 AM

I am sending my comments on the Superficial Radiation Therapy I received in the year 2016 in the offices of Dr. Richard W. Parkinson. Would you please acknowledge receipt of this e-mail.

I have been treated for skin cancers for a number of years, and have undergone surgery, freeze-burning, and an extensive ointment treatment one summer some years ago. All treatments have been successful. I have had two surgeries on my ears for removal of skin cancers, but in 2016 the diagnosis was a significant basal cell cancer spreading in my right ear. After consultation with two dermatologists, I was given the option of having surgery or Superficial Radiation Therapy. The success rate was considered similar for both treatments, but the surgery would have resulted in the removal of most of my ear. That would have necessitated in plastic surgery and the creation of a prosthetic ear (unless I decided to remain earless, preventing me from wearing glasses).

I chose the radiation therapy, receiving some 17 or 18 treatments (I don't recall which number is correct). The staff took all necessary precautions to ensure that I was protected from scattered radiation, and the treatments resulted in the eradication of the cancer in the ear.

During some 30 years of archaeological excavation in Egypt, I had the opportunity to take x-rays of hundreds of mummies which my team and I had discovered. A portable x-ray unit and developer had been donated to my project, and I received training on its use by the directors of 2 hospital radiation departments. I am therefore aware of the potential dangers involved in such work, and I made certain that my colleagues and I took every precaution to avoid stray radiation (I confess that we did not worry too much about overdoses of radiation on our 2000-plus year-old specimens).

I mentioned the above to indicate my awareness of the delicacy of allowing out-of-hospital usage of this type of therapy. I believe that Dr. Parkinson and his staff are fully qualified to carry on with this radiation therapy, and I certainly would not have been pleased with having to go to a hospital for my treatments. I would be willing to undergo similar treatment in the future (though I do not anticipate the need to do so), and I would highly recommend the same kind of treatment (certainly over surgery) to anyone else who needed to undergo cancer therapy by a dermatologist.

I hope the above comments are helpful. I will be happy to give further details if requested to do so.

Emeritus

Sincerely, Dr. C. Wilfred Griggs (PhD), Professor

*"Public Comment on Seniors Exemption"

Div of Waste Management
and Radiation Control

OCT 25 2016

10/21/16

Dear Scott J. Anderson,

I desire to write you and explain why it was an amazing opportunity for my dad to have radiation therapy for the Basal Cell CA under his chin in Dr. Parkinson's office. He is 91 years old and also has dementia. I felt that a surgery that deep would've been quite traumatic for him and so I was delighted to be able to bring him to the office for radiation treatment. The staff and technician were delightful and professional. It was so great to be able to bring him to the same office where he was already accustomed to the staff and surroundings. It helped him be at peace. My dad is prone to Basal Cell CA. I am in hopes that I will be able to bring him again to Dr. Parkinson's office for future radiation treatments when the need arises. Please consider granting Dr. Parkinson's the needed variance to the law, so I can continue to have him treated with SRT in the future. Thanks for your consideration.

Lisa Brothers
for my father
William S. Brothers

'Jeffrey Jones' via dwmrcpublic <dwmrcpublic@utah.gov>
Reply-To: Jeffrey Jones <bertozzi0323@yahoo.com>
To: "dwmrcpublic@utah.gov" <dwmrcpublic@utah.gov>

Wed, Oct 26, 2016 at 3:10 PM

The opportunity for patients with skin cancer to have an alternative like SRT-100 to traditional methods of treatment (surgery) is a benefit for patients. I imagine that patients are most likely offered in house methods of treatment first for there skin cancer. So owning your own machine can be a good thing for patient options. In a perfect world a patient wanting treatment with x-rays, electrons, or gamma rays, etc. would be referred by a dermatologist to a radiation oncologist.

The dermatologist is not the expert in this field and has not the training and experience with these treatments. Perhaps the training and education conducted by the Sensus team would satisfy this requirement.

Still, I imagine the radiation oncologist would feel like the dermatologist is starting a turf war in a way. Traditionally rad oncologist have treated cancer with x-rays. What has changed? Now the dermatologist feels they can carry this role as well. It is difficult to say if Utah should stick to traditional historical ways or begin to change. It is also interesting to think about what is the motivation for the dermatologist? Is it for dermatologist benefit, is it for patient benefit?

Based solely on safety and quality and forgetting moral factors would I feel comfortable being treated as a patient? If the facility has appropriate staff, necessary education and training, followed radiation safety rules, proper policy and procedures, then maybe I would feel comfortable being patient.

Being treated with Sensus machine at dermatology clinic could be more convenient. Such as not having to go to extra doctor and in some cases closer to home since dermatology clinics seem to be more common than rad onc clinics.

All this said I would want the best care possible whether it is from a dermatologist or radiation oncologist.

Tracie Bradford <tracie.doterra@gmail.com>
To: dwmrcpublic@utah.gov

Wed, Oct 26, 2016 at 9:17 PM

To whom it may concert,

I'm writing this on behalf of Mary Jean Brown, one of Dr. Parkinson's patients. Mary Jean is my husbands grandma and I've been amazed at how well the therapy has worked for her on the cancer on her head. It would be an absolute mistake to take away this procedure that is working for so many people. Why anyone would think it was ok to discontinue this procedure has not seen someone who has benefited from these procedures. Please reconsider this decision and listen to us that have seen how well this procedure works and is helping our grandma and many others to have a better quality of life because of her treatments.

Thank You
Tracie Bradford

Kaye Budge <kayebudge@gmail.com>
To: dwmrcpublic@utah.gov

Wed, Oct 26, 2016 at 10:33 PM

I had Superficial Radiation Therapy about 6 months ago in the office of Dr. Richard W. Parkinson. I had both a Basal cell and a Squamous cancer removed successfully leaving no scars. His radiation therapist was very competent and careful in my opinion, and he was very kind and helpful to me.

I am somewhat physically challenged and use a walker to get around. It was much easier for me to park and get into Dr. Parkinson's office for this treatment than to get into a hospital for this same treatment.

I would definitely recommend Dr. Parkinson and his staff to anyone else who needs this Superficial Radiation Therapy. I hope if I need this service again, I will be able to have it done by Dr. Parkinson's radiation staff in his office.

W. Don Budge

cebrown@rburst.com <cebrown@rburst.com>
To: dwmrcpublic@utah.gov

Wed, Oct 26, 2016 at 11:06 PM

To whom this may concern I am writing to let you know that my mother used to receive a treatment through the Superficial Radiation Therapy that worked wonders for her and the cancer she has, it was convenient, painless, effective and inexpensive for her and our family. I believe this has extended her life and has given her and us some hope for the future. I understand they don't allow this anymore from a Dr. office, I would ask you to reconsider letting this treatment be done in a Dr.'s office.

Thank You
Chad Brown

Cody Bradford <cb@rburst.com>
To: dwmrcpublic@utah.gov

Thu, Oct 27, 2016 at 6:50 AM

I'm writing this on behalf of Mary Jean Brown one of Dr. Parkinson patients this is my grandmother I have seen the cancer on her head before she went to Dr. Parkinson's and after she's been in the treatments this would be a crying shame if you guys took this away whatever this is doing is been helping please reconsider keeping this in the state of Utah for though those who need this help this could really benefit each and everyone of them please read these emails reconsider for my grandmother needs to live longer I ask you please please please reconsider this we love her very much.

Cody Wayne Bradford

Wayne Carlile <wcarlile@professionalcopy.net>
To: "dwmrcpublic@utah.gov" <dwmrcpublic@utah.gov>

Wed, Oct 26, 2016 at 7:48 PM

I would like to express my desire to have an exemption for Dr. Richard Parkinson granted allowing the continued use of the cancer radiation unit to be used in his facility to treat skin cancer. My elderly father has been treated by Dr. Parkinson for several years with numerous malignant skin cancers on his body which were removed surgically. These procedures were done in Dr. Parkinson's office but some treatments were very painful and resulted in infections which required numerous trips back to the office to treat. My father has multiple health issues, one being a stroke which requires him to be on blood thinners which complicates any surgical procedure.

The last two skin cancers were both very deep into the skin on the back of the neck making surgery even more risky. We were presented by Dr. Parkinson the option of surgery or the use of the spot treated radiation therapy. We were informed that the radiation is very low level and very effective to remove the cancer. The surgery would have been the most severe than any of the other surgeries in that it would be extremely invasive, cause severe pain, may get infected and ran the risk of maybe not getting all the tissue. Weighing all the options we decided to treat the cancer with radiation due to the fact it was painless and eliminated risk of infection. Being able to do the treatment in the office was also a deciding factor. Taking at the most 10 minutes each treatment was extremely convenient and the result was very successful. My father was never in pain and never showed any signs of side effects. This radiation was definitely the most humane way to treat the cancer.

If more treatments are needed, I will use the treatment for sure. Having this treatment available in the Dr. Parkinson's office first of all makes the cost so much less expensive than going to a hospital, the time is shorter than a hospital due to closer parking and their awesome friendly staff is more personable than a hospital. The benefit of having this treatment available in the office far outweighs using a hospital facility. I will recommend this procedure to anyone I know who is going through skin cancer treatments.

Please allow the continued use of this equipment in Dr. Parkinson's office for the benefit of hundreds if not thousands of patients who need it making their lives better with less pain, great results for the cure and for the convenience it provides being in this facility.

Thank You for your Consideration,

Wayne K. Carlile

DAVID C JOHNSON
2271 NO 1200 EAST
LEHI UTAH, 84043.

SUBJECT.

PUBLIC COMMENT ON SENSUS EXEMPTION.

DURING NOV. & DEC. 2015 AND JAN. 2016
I RECEIVED SRT TREATMENTS ON
MY NOSE AND FOREHEAD AT DR RICHARD
W. PARKINSONS OFFICE IN OREM, UT.
I WAS VERY PLEASED WITH THIS
PROCEDURE AND THE RESULTS WERE
EXCELLENT WITH NO SCARING AS WITH
SURGICAL REMOVAL. IF NEEDED I
WOULD HAVE THIS PROCEDURE AGAIN
AND RECOMMEND IT TO OTHERS.
BECAUSE OF COST AND CONVIENECE
OF AN OFFICE SETTING.

DAVID C. JOHNSON

 page 1

NOTES: 10-24-2016

Because I have no computer to inform you of my experience with radiation, I am writing to you instead.

I was diagnosed with Basal Cell on the right top of my head in April, 2016.

I have ^{been} going to Dr. Parkinson once a year for twenty years so when I went in for my yearly checkup, a piece was cut out ~~out~~ resulting in the diagnosis.

Dr. Parkinson called me on the telephone to inform me that it was cancer. He said I could choose between surgery that would be performed by someone else at the hospital or radiation performed by him at his office.

I had previously had surgery for cancer at my right nose nostril where they cut out the cancer and grafted skin from

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Close to Home

my neck. That graft has slowly ⁽²⁾
sloughed off, making my nostril
come to a point rather than
round. So I did not think much
of surgery. I had heard radiation
was painless with no incisions,
stitches or blood, so I immediately
said radiation.

Over the years I have had complete
trust in Dr. Parkinson and wanted
him. We then scheduled a meeting
with Dr. Parkinson. At the meeting
I was informed of the process for
surgery and for radiation. I still
choose radiation and available
appointment times were given to me.
I had 18 radiation treatments
and two meetings without
radiation where I was checked
to determine how I was tolerating
the procedure.

It was an extremely pleasant
experience. Lots of handicapped
parking was available, unlike hard
to find parking at the hospital. I
had no wait time at the office -
I was immediately escorted to the
radiation room. The procedure
was a minute. The whole
experience from arrival to driving
away took maybe ten minutes.
I was sad when I was
told I had my last procedure.

 page 3

NOTES:

Twice a week for ten weeks was an experience I looked forward to.

Since I have had both surgery and radiation, I will recommend radiation over surgery any time. It was easy for me, fast and painless.

Contact me any time if you need more information.

Glenda Ferguson
430 South Main
Orem, Ut 84058-6202
801-225-6085

OUR HOUSE ASSISTED LIVING

Close to Home

October 25, 2016

Dear Mr. Anderson,

I had a cancer on my left cheek.

If the doctor had cut it out I would have had a large 5 inch scar on my face. The cancer was growing both wide and deep. My face after having the SRT-100 treatment has no blemish and is very normal looking. It was checked today in the Doctors office by Carrie Jackman and she said it was perfectly fine! I would highly recommend this treatment to anyone with a similar problem.

Sincerely
Jon Ostler
1711 N. 240 W.
Orem, Utah
84057
801-224-0376

Emily Finch <ejbfinch@msn.com>
To: "DWMrcpublic@Utah.gov" <DWMrcpublic@utah.gov>

Thu, Oct 27, 2016 at 4:52 PM

To whom it may concern,

My grandmother chose to receive superficial radiation therapy to treat her skin cancer. She had been experiencing a lot of pain prior to treatment. She has benefited greatly from this treatment being available. We live in south Utah county. Having to drive to Huntsman's for treatment would have taken a toll physically, financially and time wise.

Please consider allowing others to benefit from this therapy as my grandmother and our family has.

Thank you

Emily Finch

Sent from my iPhone

'Debra Fercik' via dwmrcpublic <dwmrcpublic@utah.gov>

Thu, Oct 27, 2016 at 8:30 PM

Reply-To: Debra Fercik <debra.fercik@yahoo.com>

To: "dwmrcpublic@utah.gov" <dwmrcpublic@utah.gov>

I choose this way to go because i didn't want to lose my nose. i have had alot of cancer cells on my body most being on my nose, they have cut and frozen them and in 2004 i even had MOH,'s surgery done. that surgery left me with a little chunk out of it enough to notice and it came back. I like it in the office there because its convinient and you don't have to wait a long time. I have been seeing dr. parkinson since he first started, i have a good relationship with him and his staff. I would highly recommend him and the SRT treatment to everyone

'Diann Brown' via dwmrcpublic <dwmrcpublic@utah.gov>

Thu, Oct 27, 2016 at 11:07 PM

Reply-To: Diann Brown <dab7a@yahoo.com>

To: dwmrcpublic@utah.gov

To Whom it May Concern,

Please know that we have appreciated finally having available the SRT (Superficial Radiation Therapy) program for my mother-in-law. She suffered with pain with some severe cancer sores on her head until this treatment program was available. This procedure stopped squamous cancer cells in their tracks. Her huge sores have healed, but another cancer spot has appeared. We were so disappointed to find this treatment is now not available. We were excited to stop it early before it became so painful after having success on the other spots.

This treatment was a lifesaving proccedure for Grandma Jean. At 87 years old It was painless, effective, and inexpensive. I believe cancer should be treated whenever possible. Thank you for reconsidering and making this treatment again available in doctor offices.

Let's help Grandma Jean and many others who benefit from this treatment.

Thank you,

Diann Brown

Marva Johnson <mjohnson@nuskin.com>
To: "dwmrcpublic@utah.gov" <dwmrcpublic@utah.gov>
Cc: "pennyspresser@yahoo.com" <pennyspresser@yahoo.com>

Thu, Oct 27, 2016 at 11:26 PM

Utah State Board of Radiation Control

My name is Gloria Spresser. Earlier this year, I had a sore on my nose that would not heal. After trying everything I could I finally went to see Dr. Richard W. Parkinson and his staff. I was diagnosed with Basal Cell Carcinoma (skin cancer) at that time. I was given a choice between surgery or radiation. I looked at the pros and cons of both and decided on doing radiation in an attempt to avoid facial scarring and any issues healing caused by me being a diabetic. Plus the convenience of being able to go to my own doctor (who I felt comfortable with) to have my treatment. The ability that they had to personalize my appointment and explain the procedure to me and my family helped relieve the anxiety and stress brought on by being diagnosed with a cancer. They accommodated my busy lifestyle as much as possible which included the fact that they were normally on schedule. I never had to wait long for my appointment. I believe that the longest wait time was at the most 10 minutes but normally less. The added benefit of having the ability pay only one insurance copay for my treatment instead of the higher amounts otherwise required for this treatment when done other places. This is extremely helpful for someone on a fixed income and helped make the choice of a less invasive treatment easier.

I just recently was diagnosed with another skin cancer. I have hopes that the option to once again seek treatment with this great doctor and his amazing staff will remain in place so that this time around can go as smoothly as the last time did. Please take into consideration the great experience that is offered because of the opportunity for this treatment to be done in this office and grant the ability for this great service to continue being offered at my doctors office.

Thank you for your time and consideration,

Gloria Dell Spresser

Gloria Dell Spresser

[\(801\)368-0460](tel:(801)368-0460)

Regarding: "Public Comment on Sensus Exemption"

To Whom It May Concern:

I am writing about the **Superficial Radiation Therapy** treatment my mother, **Mildred Jean Herron**, received at **Dr. Richard W. Parkinson's** office, starting last November, 2015 and completed in March, 2016. We chose this form of therapy because of the serious skin cancer that afflicts my mother's lower legs and feet. She has had this condition for many years (she is now 92). She has repeatedly had her cancer eruptions surgically removed--a painful and at her age, an increasingly slow-healing process. As her daughter, primary source of transportation, and fiduciary, I have attended each session with her. During our visits I have carefully watched and monitored the procedures that were performed, my mother's responses to them, and the results.

We have been very pleased with the result of her SRT treatments. Both her legs and feet were treated and have vastly improved as a direct result of this treatment. Her skin is cleaner and healthier in appearance and her level of anxiety and irritation has been reduced. Where she had the radiation therapy, the cancer has not returned. She still has occasional outbreaks on previously untreated areas, but generally speaking the number of cancer eruptions has been minimized. And, most significantly, my mother is pleased with the outcome.

The treatments my mother received were impressive. They took place in a very clean and professional atmosphere, and were administered by a skilled, kindly and board certified radiation therapist. While this treatment could have taken place in a hospital setting, the convenience of having easy access to such high level care in Dr. Parkinson's office, has proven a God-send. This is because my mother is essentially immobile and has great difficulty walking any distance, even with assistance. Easy access to parking and to his offices made the many treatments she received less tiring and more convenient than would have been possible within a hospital environment.

Given the effectiveness, convenience, and user-friendly atmosphere in which the treatments were delivered and the professional and very human way the treatment was administered, *I would enthusiastically recommend this treatment (as delivered by Dr. Parkinson's office) to anyone suffering from this very irritating and potentially life-threatening condition.* We also appreciate the significant *cost savings* to her insurance and the *reduction in out of pocket expenses* associated with this treatment, given my mother's limited and fixed income.

I would encourage you to continue to license Dr. Parkinson's office. My mother's scaring has been significantly reduced. The pain usually associated with the removal has been minimized. And, the results have been very positive.

Thank you for allowing me to contact you and submit my observations and recommendation. Please feel free to contact me if you have any questions.

From: Lafe Parrish [mailto:ljparrish10@gmail.com]
Sent: Friday, October 28, 2016 7:17 AM

This method of treatment was chosen for the desired result. Prognosis as good as surgery with less chance of scarring, drooling, infection and pain. It took longer than a surgery but it is my face, my lip. I felt time invested was worth it for the result desired.

My experience in Dr. Parkinsons' office was very good and professional. I practiced thirty years as a veterinarian, we had X-ray units in our hospital, so i was aware of safe procedures. I was very impressed with the protection they gave me as a patient and the safe procedures they used to protect office personal.

I would make the same choose again. If it wasn't my face i probably would select surgical procedure.

I appreciate being able to be in their office twice a week for the period of the treatment.

Comments from the Medical Community in Support of Exemption

From: doc Parkinson [mailto:docparkinson@gmail.com]
Sent: Monday, October 10, 2016 11:36 AM

Here is the letter explaining my training in the field of radiation therapy for skin cancer.

TO WHOM IT MAY CONCERN

My name is Richard Parkinson, and I'm a board certified dermatologist and pathologist. I've been in practice in Provo, Utah since 1978, and I've never had a complaint of malpractice suit filed against me. I graduated from Tulane Medical School 1974 and completed an internship and residencies in dermatology and pathology at Charity Hospital of New Orleans, Louisiana, as well as a one year fellowship in plastic surgery at UCLA. I have special expertise in the treatment of skin cancers of all types. I have held many positions in the medical world, and for ten years was an editor for PostGraduate Medicine, a major medical journal.

During my dermatology training I spent an entire year working under Dr Henry Jolley, a pioneer and renowned expert in the use of radiation for treatment of skin cancer. Dr Jolley was Chairman of the Department of Dermatology at LSU Medical School, and was the director of the school's radiation oncology section. During the year I spent with Dr Jolley I learned about all aspects of radiation oncology including the physics of radiation, the design and upkeep of all the equipment we used, the proper use of radiation for treatment of the various types of skin cancer, and most importantly how to care for our patients. While in training I was involved in the treatment of over a thousand patients using radiation. The comprehensive exams that took in order to become certified by the American Board of Dermatology dealt extensively with radiation technology.

It is fair to say that radiation was a widely used method for treating skin cancers in the 70s and 80s, but that for a variety of reasons it fell out of favor by most dermatologists and was replaced by surgery. Nonetheless, I've kept up to date on the recent advances in the field, and when the technology became affordable, safer, and very easy to use, I jumped at the chance to once again offer this wonderful modality to my patients.

Fortunately, superficial radiation therapy (SRT) of skin cancer is making a comeback around the world, and for good reason. SRT is safe, effective, painless, has fewer side effects than any other treatment, and is very cost effective. The new equipment that I use in my office is to the equipment I once used as the smart phone is to telegraph.

May I end by reminding everyone that dermatologists were the first doctors to use radiation to treat disease, and I'm very proud that things have come full circle and we're getting back in the game, so to speak.

Should the board decide to reject Sensus' request for variance I respectfully request that the board consider granting me an individual exception based on my extensive training, sizeable investment of \$250,000 and the past year's history of patient satisfaction with treatment as verified by patient response to the public comment page and significant cost savings (around \$1,500 for in office SRT compared to 2-4 times more for Moh's surgery and up to \$20,000 at hospital based treatment centers).

To Whom It May Concern,

I've been asked to contact you regarding the utilization of superficial radiation therapy (SRT) for the treatment of skin cancers by dermatologists in the state of Utah. By way of background, I am a Clinical Professor of Dermatology and Pathology at the University of Texas Southwestern Medical Center and Director of the Division of Dermatopathology. I am also the President and Owner of Cockerell Dermatopathology and the past Medical Director of Cockerell and Associates Dermatopathology as well as a diplomat of the American Academy of Dermatology and American Board of Dermatopathology. I also had the honor of being a past president of the American Academy of Dermatology. For many years, I oversaw an educational program designed to train the next generation of dermatopathologists. I also served as Associate Editor of the Journal of the American Academy of Dermatology and I am on the editorial boards of a number of medical journals including the American Journal of Dermatopathology. I am also a founding member of the American Society of Cutaneous Oncology.

As you can discern from the synopsis of my biography, I am very passionate about clinical dermatology, dermatopathology, and the well-being and outcomes of our patients. I have diagnosed many thousands of skin cancers and I believe strongly that superficial radiation therapy is an extremely beneficial device for dermatology patients for a number of reasons. As was practiced for many decades in the past, dermatologists always utilized superficial radiotherapy as a safe and effective modality to treat their patients' skin cancers.

In most dermatology practices, we see a great number of patients who are elderly and have a variety of complicating and debilitating medical conditions. This is coupled with the fact that a significant proportion of the patients are also taking one or more blood thinners. While dermatologists are extremely proficient at a variety of surgical techniques to treat skin cancers, not all of our patients are ideal candidates for our surgical intervention. In the past, we have referred patients to hospital centers for radiation therapy, but there have been problems and limitations with this approach. Most if not all radiation therapy treatment centers whether in the hospital or at outpatient facilities use equipment that is not specifically designed to treat skin cancers but is primarily used to treat other types of cancers. The use of these high-powered devices for the treatment of most skin cancers is not only extremely expensive (both for the patient and for the health care system), but it can cause nonspecific damage to surrounding tissue and organs. Furthermore, patients often have significant issues with outpatient facilities and hospital facilities because of having to wait to receive each treatment. Because of these and other issues, the number of patients who were either willing to have radiation therapy or had optimal outcomes declined significantly over the years.

The advent of equipment such as the Sensus SRT-100, which is specifically designed to treat skin cancers in the dermatologists' office, has dramatically benefited our patients in a number of ways. First off, we are able to treat patients using a type of radiation therapy that is specifically designed to treat skin cancers while leaving most normal tissue unaffected. This dramatically reduces both short-term and long-term side effects associated with treatment and is a much less expensive modality both for the patient and the health care system. Additionally, because the treatments are performed in a simple outpatient manner in the dermatologists' office, they can be performed in a very user-friendly, patient friendly, and time efficient way to optimize the experience for our patients.

In short, receiving surface radiation therapy in the dermatologist office provides a very beneficial treatment modality to skin cancer patients that is clinically effective, has very low relative side effect profiles, is extremely cost-effective both for the patient and the health care system/state, and as a whole call is certainly beneficial for the needs of the patients. For these reasons I would passionately recommend that for the citizens of the state of Utah the use of the SRT-100 by dermatologists is an important addition for their healthcare needs, quality of life, and overall clinical outcomes.

Please call me if you have any further questions.

Sincerely,

Clay J. Cockerell, MD

Clay J. Cockerell, MD | President

2110 Research Row, Suite 100

Dallas, Texas 75235

[214.530.5200](tel:214.530.5200) |

cckerell@dermpath.com

*We treat every specimen as if it
came from one of our own family
members.*

Cutting Edge Technology Without the Cutting

uvhw | HEALTH

We are in the middle of an epidemic of skin cancers. During the past two decades dermatologists have reported dramatic increases in skin cancer rates among their patients in all 50 states. Why Utah is at the top of the list isn't well understood, but it's undeniable. We have more skin cancers than nearly all other states, including states that are more populated than we are. Fortunately, most of the skin cancers we are seeing are the "good kind," which means that they are usually treatable and rarely fatal. Melanoma, the "bad kind," is also on the rise, but in terms of numbers, the "good kind" outnumber melanomas and other very rare skin cancers by better than a thousand to one.

Regarding the "good kind," mostly basal cell and squamous cell cancers, there is good news. For the past 40 years most skin cancers have been treated by surgery in the doctor's office. Since the majority of skin cancers are small, the surgeries, which are done under local anesthesia, often don't even require sutures. Larger skin cancers and skin cancers in difficult spots, like the eyelid or nose, sometimes required more complicated procedures with potential complications such as bleeding, infection, scarring, and pain. That was then. SRT is now.

SRT (superficial radiation therapy – see photo on previous page) is an exciting new technology that can now treat many skin cancers. It is interesting to note that dermatologists were the first doctors in the world to use radiation to treat cancer. However, while radiation fell out of favor among skin specialists for a variety of reasons, it gained in popularity with doctors who treat cancers inside the body such as breast and prostate cancers. With the advent of new technology, radiation for skin cancers is now back and much better than ever.

The most important things you should know about SRT are 1) It is very effective, on par with Mohs surgery; 2) It is comparable in cost to traditional surgery; 3) It is painless, requires no shots, and leaves no (or very faint) scars; 4) It has almost none of the side effects of surgery, such as infection or bleeding; 5) The treatments are done in a dermatology office and take just a few minutes; and 6) The radiation does not get into your body the way other types of radiation do.

Can treating skin cancers, and even larger cancers in hard to get places, be this easy and this effective? The answer is an enthusiastic "YES!" SRT is the most exciting thing to come along in my medical lifetime. While it is not effective for melanoma, and while there is still an important role for surgery, we have entered a new era in cancer care, one that promises to address the epidemic of skin cancers that has targeted our state, and do so in a cost saving, painless, and very effective way.



About the Author

Dr. Parkinson is board-certified in both dermatology and pathology. He earned his medical degree at Tulane University and received his specialty training there, as well as UCLA. He began his dermatology practice in Utah in 1978. His special interests are skin cancer and rare skin diseases.

This is an article written by Dr. Parkinson for the March/April 2016 "Utah Valley Health and Wellness" magazine



BROOKS BAHR, M.D.
General Dermatology

KATHERINA BASIC, M.D.
General Dermatology

JOHN L. BEZZANI, M.D.
General Dermatology

ANNFEL R. BOWEN, M.D.
Dermatopathology

GLEN M. BOWEN M.D.
Melanoma and Mohs Surgery

KRISTINA CALLIS DUFFIN, M.D.
General Dermatology, Psoriasis

JENNIE CLARKE, M.D.
General Dermatology

KETHIL DUFFY, M.D.
Mohs Surgery, Dermatopathology

MARK J. ELIASON, M.D.
Uricaria and Skin Cancer

SCOTT R. FLORELL, M.D.
Dermatopathology

GERALD J. GILKICH, M.D.
Allergy

DOUGLAS GROSSMAN, M.D., Ph.D.
Mohs, Melanoma, Skin Cancer

CHRISTOPHER B. HANSEN, M.D.
General Dermatology, Rheumatic Skin Diseases

C. DAVID HANSEN, M.D.
General Dermatology

CHRISTOPHER M. HULL, M.D.
General Dermatology, Bullous Diseases

STEPHANE Z. KLEIN, M.D.
General Dermatology

GERALD G. KRUEGLER, M.D.
Psoriasis

KRISTIN M. LIEBERMAN, M.D.
Immunodermatology

BETHANY K. H. LEWIS, M.D.
General Dermatology

GARRETT LOWE, M.D.
Mohs Surgery

LAURENCE J. MEYER, M.D., Ph.D.
Genetics, Melanoma

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Mohs Surgery / General Dermatology

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Vice-Chairman
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General Dermatology

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Aesthetics / General Dermatology

RICHARD D. SUNDBLUMER, M.D.
Rheumatologic Skin Diseases

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Aesthetics, General Dermatology

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Mohs, Cutaneous and Laser Surgery

HILKA M. SUMMERS, M.D.
Aesthetics / General Dermatology

PAYAM TRISTANI-FIROUZ, M.D.
Mohs, Lasers and Aesthetics

SHERYLL L. VANDERHOEFT, M.D.
Parkinson Dermatology

DAVID A. WADA, M.D.
Cutaneous Lymphoma,
Dermatopathology

JAMIE WOODCOCK, M.D.
General Dermatology

JOHN J. ZOMI, M.D.
Chairman
Immunodermatology

JAMIE ZUSSMAN, M.D.
General Dermatology

June 17, 2016

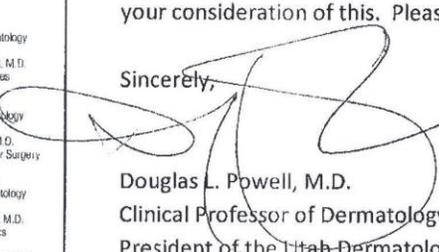
Re: Superficial Radiation Therapy (SRT)

To Whom It May Concern:

This letter is requesting approval of the use of superficial radiation therapy (SRT) in selected patients with skin cancer in Dermatology Clinics that have the appropriate device and are trained appropriately. SRT has been used for nonmelanoma skin cancer for well over 100 years. The technology used with SRT has advanced in recent years and is highly safe, effective, and is relatively inexpensive. It is a procedure that is well accepted by the patients and physicians alike. Although this treatment would not be the appropriate choice for the majority of skin cancers, there are select situations in which it is not only the best treatment, but is a reasonably priced and appropriate for patients who are elderly or infirm and cannot tolerate surgery. Also, it could be used for those in which tumors may be a risk for excessive bleeding, and for those who cannot safely be taken off blood thinners. Likewise, it is appropriate for those who are prone to infection, or simply in patients whom surgical treatments have been exhausted and other alternatives are necessary. It is an outstanding treatment. SRT is not brachytherapy, which is very expensive and in our view not appropriate for dermatology. As I mentioned, there are only a handful of clinics that have this available and are appropriately trained. I believe that these clinics should be able to use this procedure and that this should be a covered procedure by insurance.

On a very personal note, my grandmother received SRT at age 96. Tumor was eroding to her skull and she was not able to undergo surgery at that time. She was, however, able to undergo radiation therapy. Obviously, this is very personal issue to me. I feel strongly that we need to maintain those therapies, which are needed to take the best care of our patients. Therefore, in summary, I strongly request the coverage of SRT by the few select clinics that are set up for it and that are trained for it in the handful of patients that would best be suited for this therapy. We appreciate your consideration of this. Please call me if you have any questions.

Sincerely,


Douglas L. Powell, M.D.
Clinical Professor of Dermatology, University of Utah
President of the Utah Dermatology Society.

The University of Utah
Department of Dermatology
Midvalley Health Center
243 East 6100 South
Murray, UT 84107
Telephone 801-581-2955

May 26, 2016

To whom it may concern,

This is a letter in support of the utilization of superficial radiation therapy for non-melanoma skin cancers. Superficial radiation therapy has been used to treat both squamous cell carcinomas and basal cell carcinomas of the skin for decades with local control rates greater than 90%. It is also a cost-effective option. If you have questions or need additional information, please feel free to contact me at (801) 357-7575.

Sincerely,

Jay Clark, MD
Radiation Oncology
Utah Valley Regional Medical Center

Darrell S. Rigel, MD MS
New York University Medical Center
35 E 35th Street Suite 208
New York, NY 10016
(212) 684 4542 rigeld01@nyumc.org

Scott Anderson, Director
Utah Division of Waste Management & Radiation Control
P.O. Box 144880
Salt Lake City, UT 84114
T: (801) 536-0200

Re: Sensus Healthcare Exemption Request – Utah

Dear Mr. Anderson,

I am reaching out to you regarding the utilization of superficial radiation therapy for the treatment of skin cancers by dermatologists in the State of Utah. I am a Clinical Professor of Dermatology at New York University and a board-certified dermatologist by the American Board of Dermatology. I am a Fellow and an Honorary Member in the American Academy of Dermatology where I served as President in 1999. I have also served as President of the American Society for Dermatologic Surgery and American Dermatological Association.

I received my MD degree from George Washington University. I attended Cornell University Medical Center for my Internship in Internal Medicine and completed my training at NYU where I was a Resident, Chief Resident, NIH Training Fellow and Dermatology Surgery Fellow. I have authored numerous articles and abstracts in professional journals as well as being lead editor of Cancer of the Skin, the major textbook in this field. I have testified before Congress regarding skin cancer and have made over 600 presentations at medical and governmental policy conferences worldwide and have chaired numerous national and international conferences and symposiums. I have also been a visiting Professor at the Huntsman Cancer Center in Salt Lake City.

In regards to Superficial Radiation Therapy (SRT), dermatologists were at the forefront of developing and utilizing this modality long before there was ever a subspecialty of radiation oncology. This body of knowledge has been carried down over the last 50 years in multiple textbooks and articles. The efficacy rate of superficial x-ray therapy has never been in dispute and is felt to be as good as or superior to electron beam therapy for the majority of skin cancers. Its usage is far less complex than electron beam therapy, that must be delivered by linear accelerators and used by radiation oncologists. Electron beam therapy is more powerful radiation and was originally designed and heralded as skin sparing (i.e. able to pass through the skin to treat deeper organs). In order to utilize electron beam on the skin, one needs to employ very complex physics, complex shielding and boluses (i.e. tissue like layers over the skin of varying thickness) to deposit an optimal dose at the skin surface.

SRT has been proven very safe and effective, especially for elderly patients who are not good candidates for surgery (i.e. diabetes, thin/frail skin, and other co-morbidities). SRT allows dermatologists to treat skin cancers on the face, scalp, neck, ears, and lower limbs with no deformity or scar. With surgical excision, poor healing and infections are not unusual. SRT will improve the quality of care that any dermatologist provides and will help elderly patients tremendously. SRT allows patients to continue their normal activities such as exercise and bathing and patients do not need to worry about anticoagulant therapy. SRT improves the experience of having a skin cancer treated and patients will seek out this therapy.

SRT has also been proven cost-effective, especially when one is dealing with elderly and frail individuals, where travel and cost are a factor. The typical course of SRT is under \$2,000 whereas a typical course of electron beam therapy is estimated to range from \$6,000 - \$10,000. SRT is typically delivered in a physician's office in 8-12 fractions as compared to electron beam therapy which must be delivered in a specialized vault and typically utilizes 15-30 fractions.

In addition to SRT, dermatologists use multiple modalities on a daily basis where the physics of radiation come into effect (i.e. ultraviolet therapy, ultraviolet A, ultraviolet B, PUVA therapy, and various laser platforms). The latter modalities have very complex physics which dermatologists have pioneered and mastered. Dermatologists are more than capable of using SRT in a safe and effective manner when properly trained on the SRT device they are using.

The State of Utah should allow dermatologists to utilize SRT technology in their offices. The United States has a rapidly aging population who are dealing with medical comorbidities and coagulation and SRT is a logical and cost-effective alternative for treating skin cancer in appropriate patients.

Please do not hesitate to contact me if you have any questions regarding this. Thank you.

Sincerely,

A handwritten signature in black ink that reads "Darrell Rigel". The signature is written in a cursive, flowing style.

Darrell S. Rigel, MD MS
Clinical Professor of Dermatology
New York University Medical Center

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Darrell S. Rigel, MD
New York, NY

William Roth, MD
Boynton beach, FL

Scott Anderson, Director

Utah Division of Waste Management & Radiation Control
195 North 1950 West
P.O. Box 144880
Salt Lake City, Utah 84114-4880
T: (801) 536-0200
F: (801) 536-0222

Re: Sensus Healthcare Exemption Request - Utah

Dear Mr. Anderson,

I've been asked to contact you regarding the utilization of superficial radiation therapy for the treatment of skin cancers by dermatologists in the state of Utah. By way of background, I am a board-certified dermatologist who has been practicing in South Florida for over 20 years. I am a President of the American Cutaneous Oncology Society (ACOS) as well as the past president of the Florida Society of Dermatology and Dermatologic Surgery.

My clinical practice involves treating patients with a variety of dermatologic conditions, and my practice includes a large number of patients with skin cancers. I also conduct a significant number of clinical studies including a recently published study on the incidence of non-melanoma skin cancers. I utilize multiple modalities to treat skin cancers in order to assure that my patients receive the best care and have been using superficial radiation therapy (Sensus SRT-100™) in my practice for some time. I received my initial training in the use of superficial radiation therapy in my residency and had additional further training prior to my beginning to use this device on our patients. I have treated hundreds of skin cancers with the SRT-100™ and I believe strongly that superficial radiation therapy is an extremely beneficial device for dermatology patients for a number of important reasons.

As with most dermatology practices, we see a large number of patients who are elderly and have a variety of complicating and debilitating medical conditions. This is coupled with the fact that a significant portion of the patients are also taking one or more blood thinners. While dermatologists are extremely proficient at a variety of surgical techniques to treat skin cancers, not all of our patients are ideal candidates for our surgical intervention. In the past, we have referred patients to

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Scott Dinehart, MD
Cabot, AR

Jose Lutzky, MD
Miami, FL

William Mendenhall, MD
Jacksonville, FL

Darrell S. Rigel, MD
New York, NY

William Roth, MD
Boynton beach, FL

hospital centers for radiation therapy, but there have been problems and limitations with this approach. Most, if not all radiation therapy treatment centers whether in the hospital or at outpatient facilities use equipment not specifically designed to treat skin cancers but instead primarily used to treat other types of cancers. The use of these high-powered devices for the treatment of most skin cancers is not only extremely expensive (both for the patient and for the health care system), but it can cause nonspecific damage to surrounding tissue. Additionally, patients often have significant problems with outpatient facilities and hospital facilities because of having to wait a significant amount of time to receive each treatment. Because of these and other issues, the number of patients willing to have radiation therapy and who had optimal outcomes declined significantly over the past number of years.

The advent of equipment such as the Sensus SRT-100™, which is specifically designed to treat skin cancers in the dermatologist office, has dramatically benefited our patients in a number of ways. We are now able to treat patients using a type of radiation therapy that is specifically designed to treat skin cancers while leaving most normal tissue unaffected. This dramatically reduces both short-term and long-term side effects associated with treatment and is a much less expensive modality both for the patient and the health care system. Additionally, because the treatments are performed in a simple outpatient manner in the dermatologist's office, they can be performed in a very user-friendly, patient friendly, and time efficient way to optimize the experience and life quality for patients.

In short, receiving surface radiation therapy in the dermatologist's office provides a very beneficial modality to skin cancer patients that is clinically effective, safe, has a very low relative side effect profiles, is extremely cost-effective both for the patient and health care as a whole, and is certainly beneficial for the needs of the patients. For these reasons, I recommend the use of the SRT-100™ by dermatologists for of the citizens of the state of Utah. I believe that it is an important addition for their healthcare needs.

Please call me if you have any questions.

Sincerely,



Mark S. Nestor, M.D., Ph.D.

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

James P. Nunn, MS, CHP, DABR
Senior Medical Physicist
Radiation Safety Officer

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LewisGale Regional Center at Pulaski
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[\(540\) 994-8545](tel:5409948545) Clinic
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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,

A handwritten signature in cursive script that reads "Laura Thevenot".

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

--

James W. Clarke M.D.
Radiation Oncologist
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Prema Rassiah-Szegedi, PhD
Associate Professor

Vikren Sarkar, PhD
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

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.

Scott Anderson, Director
Utah Department of Environmental Quality
Utah Division of Waste Management and Radiation Control (UDWMRC)
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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

Scott Anderson, Director
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.

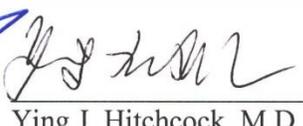
- 3) the UDWMRC provide an avenue to examine case-by-case limited scope exemptions for emergent patient issues rather than allow for exemption to Utah Administrative Code on a short timeline.

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

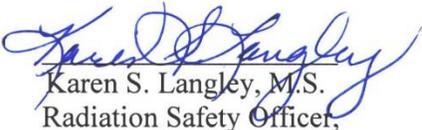
Sincerely,



Bill Salter, Ph.D.
Director – Radiation Oncology
Professor and Chief – Division
of Medical Physics
Department of Radiation Oncology
Huntsman Cancer Institute
University of Utah School of
Medicine



Ying J. Hitchcock, M.D.
Professor
Department of Radiation Oncology
Huntsman Cancer Hospital
University of Utah



Karen S. Langley, M.S.
Radiation Safety Officer,
Director
University of Utah



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,

Bruce H. Curran, MEng, MS, FAAPM, FACMP, FACR

President, AAPM

Email: Bruce.Curran@vcuhealth.org

Phone: 804-675-5000 Ext: 3109

Alex Markovic, PhD

President AAPM Rocky Mountain Chapter

Email: alex_medphys@yahoo.com

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 SSRs, the CRCPD employs a very rigorous development and review process. This process includes state representation of the committee to develop the SSR, 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

Adam B. Paxton, PhD
Assistant Professor

Prema Rassiah-Szegedi, PhD
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Assistant Professor

Fan-Chi Frances Su, PhD
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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

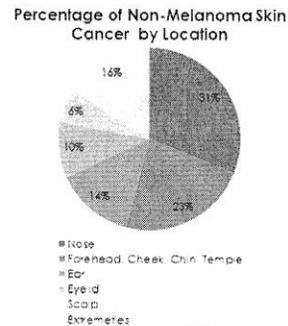
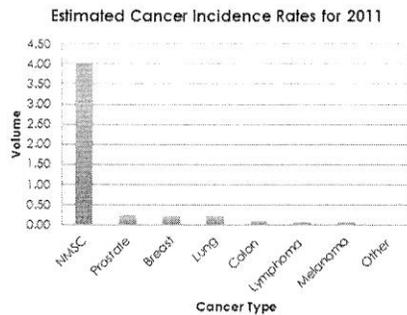
- SRT-100 and SRT-100 Vision have significant benefits for both the practitioners and patients

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

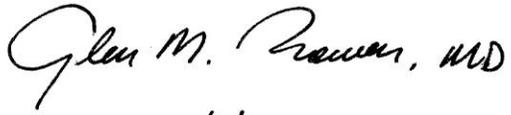


Does "improved cash flow" and "excellent ROI" in the "Fastest growing cancer indication" speak to what is best for our patients?

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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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/manufacture 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?

•

Thanks,

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