

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.

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