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Re: Omnitron International, Inc. -- Reply to Oncology Services Corporation's

(1) Response to the Nuclear Regulatory Commission Report on the November 6, 1992 Indiana Regional Cancer Center Incident (NUREG-1480).

(2) Response to the January 20, 1993 Order Suspending By-Product Material License Number 37-28540-01 (Docket No. 03-31765).

On behalf of Omnitron International, Inc. (hereinafter "Omnitron"), manufacturer of the Omnitron 2000™ high dose rate remote afterloader brachytherapy device, I am writing to respond to a number of incorrect statements made in two of Oncology Services Corporation's (OSC) submissions to the Nuclear Regulatory Commission (NRC): (1) the February 8, 1993 response to the NRC's suspension of OSC's license; and (2) the March 5, 1993 response to the NRC's Incident Investigation Team (IIT) Report on the incident at Indiana Regional Cancer Center (IRCC), Indiana, Pennsylvania, on November 16, 1992. In both responses, OSC inappropriately attempts to shift responsibility for the therapy misadministration incident from themselves to Omnitron.

Before addressing specific inaccuracies in the OSC responses, we note the NRC's conclusion as stated in their December 17, 1992 Information Notice No. 92-84 --

> Based on what is presently known about this incident, it is clear that if proper radiation surveys of the patient had been made, before releasing the patient from the facility, the consequences of this incident would have been largely avoided.

ENCLOSURE 3

No amount of obfuscation by OSC can obscure the basic cause of the IRCC misadministration as identified by the NRC -- OSC simply failed to adhere to basic principles of radiation safety.

Background

A high dose rate remote afterloader is used to move a radioactive source attached to the end of a wire to the site of a malignant tumor in order to destroy the tumor with radiation. The device moves the radioactive source to the prescribed position(s) for a prescribed period of time(s) and then returns the source to a protective safe after the treatment. The Omnitron 2000™ safety features and the operator emergency procedures are therefore directed toward two classes of emergency events:

1. the source wire fails to retract after the treatment;

or

2. the source detaches from the source wire.

Since it is universally recognized that any component or system can (and will eventually) fail, overall system reliability and safety is achieved by redundancy in safety features. The Omnitron system relies on this type of redundancy to address these two classes of emergency situations.

The redundancy in the wire retraction mechanisms may be described as follows--

1. Normal retraction using the primary stepper motor drive system.

2. Retraction using the primary stepper motor drive system following an error detection.

3. Emergency retraction using the secondary d-c motor override system if the primary stepper motor drive system fails to retract the wire.

4. Manual wire retraction if both the primary stepper motor drive system and the emergency d-c motor override system fail to retract the wire.

When the incident occurred at IRCC, the wire retraction redundancy was effective since the secondary emergency d-c motor override system effectively retracted the wire when the primary system was unable to retract it because of the obstruction.

The redundancy in the detection of detached sources may be described as follows:

1. Under normal circumstances the measured length of the wire going out is compared to the length coming in and an error condition is generated if it is determined that the source is detached from the end of the wire.

2. If the normal length measurement should fail to detect a source detachment, a Prime Alert area radiation monitor is provided to alert medical personnel to the presence of a radioactive source outside the storage safe.

3. Omnitron instructions (and NRC regulations) require the operator to use a survey meter to check for residual radiation after each use of the system.

Under the exceptional circumstance when the emergency secondary d-c motor override system retracts the wire, the system is designed to release the length measuring device from the wire (because it may theoretically be part of the problem preventing normal wire retraction), and therefore a source detachment would not be automatically detected by the length measuring system. In all other circumstances, the system is designed to measure the length of the returning wire and alarm if a detached source is detected.

Given the nature of any medical device with a radioactive source, it is widely recognized that redundancies must exist to ensure safe therapy administration. These include competent personnel and appropriate radiation monitoring and surveys. Unfortunately, in the IRCC misadministration both of these safeguards -- which were the sole responsibility of OSC -- were ineffective.

When the IRCC incident occurred, the source detection redundancy was also effective since the Prime Alert area radiation monitor alarmed when the source detached even though the length measuring function was released (as designed) when an emergency d-c monitor override was required to retract the wire. Unfortunately, the medical personnel in attendance chose to disregard the Prime Alert alarm even though they stated that they observed it flashing. The OSC personnel also failed to implement the safety redundancy check of a survey meter to ensure patient safety, as required by law and by Omnitron instructions. As the NRC states in their December 8, 1992 Bulletin No. NRCB 93-02:

> Although a wall-mounted area monitor alarmed when the treatment was completed, the licensee's staff believed the device was emitting a false signal and chose to ignore it. Also, no survey of the patient was conducted, using a hand-held survey instrument, to determine if a source remained in the patient, as required by 10 CFR 35.404(a).

Despite this clear finding, in its responses to the NRC, OSC repeatedly attempts to disclaim responsibility for its careless actions by making erroneous claims regarding Omnitron and the Omnitron device. Each of these erroneous allegations is addressed below --

Specific Responses

1. **OSC's Allegation that Omnitron Represented that the Source Wire Could Not Break.**

OSC claims in its response to the license suspension order that "Dr. [James E.] Bauer as well as all Omnitron-authorized users were trained that the wire could not break." (February 8, 1993 OSC Response at page 7.) In fact, Omnitron does not "authorize" anyone to use its equipment. The user is issued a license by the NRC, and OSC authorizes its employees to perform their assigned duties. Moreover, no one at Omnitron has ever trained anyone to believe that a wire cannot break, and no Omnitron instructional materials suggest a source wire cannot break.

Any component can fail for unanticipated reasons, and backup safety systems and emergency procedures are designed to deal with such possibilities. In fact, Omnitron's Directions for Safe Use of the Source Wire specifically state:

> 4) With each use of the IR-192 seed in titanium nickel, a G-M survey meter should be used to survey the area for the possibility of a lost source.

and

> 5) Any accident or loss of the radioactive source should be reported at once to the State Nuclear Regulatory Division.

These Directions for Safe Use are provided to the user each time a source wire is installed in the machine, along with the source calibration information. OSC's failure to cite these instructions is reflective of its selective quotation of Omnitron's labeling.

Moreover, it is also inconsistent for OSC to claim on the one hand that they are thoroughly familiar with the fact that the wire length check safety feature could detect a detached source while on the other hand stating that they believed that Omnitron claimed that there was no possibility of a source detachment.

Finally, if Dr. Bauer and his associates are as experienced in brachytherapy as they claim, they should know that incidents such as this have occurred before with other high dose rate afterloader systems, and source detachment is, in fact, a frequent occurrence with low dose rate brachytherapy. As the NRC states in their December 17, 1992 Information Notice #92-84:

> Failure to perform proper radiation surveys, after treatment of patients with low-dose manual brachytherapy procedures, has led to loss of control of one or more sources. NRC has received several recent reports of such incidents, where the sources were eventually discovered in normal trash, at a disposal facility. (emphasis added)

2. OSC's Contention that An Area Monitor Substitutes For A Survey Meter.

Throughout their responses to the NRC, OSC refers to the Prime Alert area monitor as a "wall mounted survey meter" (emphasis added). This is an attempt to argue that OSC was in compliance with NRC regulations and Omnitron Instructions for Safe Use, which require the use of a survey meter after each treatment to assure that no radioactive material is left in the patient or in the room. In fact, anyone with rudimentary knowledge of the field understands that an "area monitor" and a "survey meter" are not equivalent devices. The NRC states in its December 17, 1992 Information Notice #92-84 that:

> All licensees are reminded that, in accordance with 10 CFR 35.404(a), the licensee shall perform a radiation survey of all patients being treated with brachytherapy sources, with an appropriate radiation detection or measurement survey instrument, as specified in 10 CFR 35.420, to confirm that all sources have been removed. ...An area monitor provides an immediate indication of a possible problem and thus serves a useful function as an early warning device. However, it has neither the accuracy or sensitivity required to comply with the survey requirements of 10 CFR 35.404(a). The surveys shall be performed immediately after completion of the therapy procedure before removal of the

> patient from the treatment room, and appropriately documented in accordance with 10 CFR 35.404(b).

Moreover, Omnitron requires in its Instructions for Safe Use of the Source Wire that:

> with each use of the Ir-192 seed in titanium nickel, a G-M survey meter should be used to survey the area for the possibility of a lost source.

Furthermore, the United States Atomic Energy Commission in its December 1967 publication from the Division of Technical Information provides the following definition of a "survey meter" (emphasis added):

> Survey Meter: Any portable radiation detection instrument especially adapted for surveying or inspecting an area to establish the existence and amount of radioactive material present. (page 58)

Clearly, the use of an area monitor does not substitute for the use of a survey meter and failure to use a survey meter after the treatment removes one of the most important redundant safety checks.

Even though OSC personnel failed to survey the patient as required by both law and Omnitron Instructions for Safe Use, it is difficult to comprehend how they could have chosen to ignore the area radiation monitor. In OSC's February 8, 1993 response, it states that:

> Additionally, [Dr. Bauer] was informed that the wall mounted survey meter (sic) had flashed red verifying that a treatment related problem with regard to the retraction of the Omnitron source potentially existed. (page 5)
>
> The technologists at Indiana were aware of the significance of the radiation trigger on the wall mounted survey meter (sic). (page 7)
>
> The room monitor did not fail to anyone's knowledge. (page 9)

If OSC personnel had followed instructions and acted reasonably under the circumstances of an alarming area radiation monitor, the misadministration incident could have been avoided. However,

having ignored the area monitor alarm, OSC nonetheless could have avoided the misadministration by following the NRC's regulations and Omnitron's instructions by conducting a patient survey to discover the detached sou . Under no set of circumstances is it reasonable for OSC to a e that collapsing two levels of safety checks into one constitutes compliance with the law, when it ignored the safety check upon which it now purportedly relies to satisfy the NRC's survey meter requirement.

3. **OSC Personnel "Relied" on Omnitron Training**

On page 18 of OSC's February 8, 1993 response it states that:

> It is regrettable that an individual patient was exposed to radiation, and it is regrettable the individual physician with years of experience and training in the use of portable survey meters, did not use a portable survey meter. The physician was charged with failing to resolve any inconsistency between the wall mounted survey meter (sic) and the Omnitron console. Clearly the physician relied on Omnitron training.

In fact, the physician clearly did not rely on Omnitron training. Had the physician relied on Omnitron training, this unfortunate incident would have been prevented. Whatever reasons led him to ignore the warning device were independent from any Omnitron training. Omnitron has never recommended that an area radiation monitor be ignored. Omnitron has always both insisted upon an area monitor (a Prime Alert area monitor is installed by Omnitron at no charge if one is not already in place at a facility) and has insisted that each patient be surveyed using a survey meter after each treatment.

4. **OSC's Allegations of a "Design Defect" in the Omnitron Device**

In a number of places in OSC's responses to the NRC the allegation is made that a "design flaw" or "design defect" led to a failure by the Omnitron 2000™ system to detect a length check error when an emergency retraction occurred. What OSC refers to is neither a flaw or a defect, but rather an important safety feature.

When the system is having difficulty retracting an active wire using the primary stepper motor drive system, there is no way of knowing why this difficulty is being experienced. It may

be that the primary stepper motor has failed and is not moving, or that the encoder tracking the wire position may have locked up, or that some external force is preventing wire movement. Whatever the cause may be, the most prudent and logical course of action is to remove as many potential causes of the difficulty as possible and attempt to retract the wire using a completely independent drive system. The Omnitron 2000™ therefore releases both the primary drive system and the encoder which tracks wire position before attempting to retract the wire using the emergency d-c motor wire drive system. Because the wire position tracking encoder is released from the wire during this circumstance, no length error check is possible. The emergency being addressed in this situation is a wire not retracted, not a detached source, and there are, as noted, redundant mechanisms for detecting a detached source (the Prime Alert area monitor and the survey of the patient using a survey meter).

Omnitron's labeling correctly states that the green "SAFE" light on the control console, afterloader, and door panel indicate that the wire has been retracted and manual retraction is not required. It does not indicate "no radiation danger" as alleged by OSC, and nowhere in Omnitron's labeling or training is there any statement which says that this signal indicates that there is no radiation danger.

In conclusion, after the source separated from the wire in the IRCC incident, the Omnitron system functioned appropriately and in accordance with its design and labeling. The redundant backup drive system retracted the wire, and the redundant backup source separation detection system alarmed to notify the medical personnel that radiation was still present. It was the human error and neither failure of the device nor the area monitor that resulted in the misadministration to the 82 year old patient.

We will appreciate your consideration of Omnitron's response when considering the OSC submissions, and request that this letter be made a part of the NRC's public file.

Respectfully submitted,

Mark A. Heller
Daniel A. Kracov
Counsel for
Omnitron International, Inc.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

MAY 27 1993

Mr. Mark A. Heller
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Dear Mr. Heller:

We have received your letter of May 5, 1993, to Messrs. James M. Taylor and Hugh L. Thompson, Nuclear Regulatory Commission (NRC), on behalf of Omnitron International, Inc., commenting on prior correspondence to the NRC from Oncology Services Corporation (OSC). This correspondence involved OSC's February 8 and March 5, 1993 submittals to the NRC responding, respectively, to the January 20, 1993 NRC Order suspending Byproduct Material License Number 37-28540-01 (Docket No. 03-31765) and the NRC Incident Investigation Team (IIT) Report on the November 16, 1992 incident at the Indiana Regional Cancer Center, Indiana Pennsylvania (NUREG-1480).

Your letter has been evaluated by the NRC staff, and based on the information provided there is no need to revise the IIT report. In accordance with the NRC's rules of practice, a copy of your May 5, 1993 letter has been placed in the NRC's Public Document Room. Please feel free to contact me, if you have any questions regarding this letter.

Sincerely,

Edward L. Jordan, Director
Office for Analysis and Evaluation
of Operational Data

ENCLOSURE 4

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