UNITED STATED NUCLEAR REGULATORY COMMISSION

In the matter of:	]	Docket No. 03-31765
	]	
ONCOLOGY SERVICES CORPORATION, Harrisburg, Pennsylvania	]	License No. 37-28540-01
	]	EA 93-006
	]	

RESPONSE OF ONCOLOGY SERVICES CORPORATION ("OSC")
TO ORDER OF NRC DATED JANUARY 20, 1993
SUSPENDING BY-PRODUCT MATERIAL
LICENSE NUMBER 37-28540-01

Oncology Services Corporation makes the following response under oath to the NRC's Suspension Order of January 20, 1993.

I.

OSC requests a hearing at which it will present evidence on its behalf to support the statements and defenses set forth under oath in this response.[1]

Brachytherapy has been available for at least [illegible] years to treat advanced forms of cancer. Radioactive materials are inserted into a tumor mass for the purpose of shrinking the mass and providing relief and/or cure to the treated patient. More recently, high-dose radiation (HDR) units have been offered by

[1] OSC's response was made based on interviews and document searches. It did not have the benefit of NRC transcripts which had not been released before preparation of this response.

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manufacturers to deliver, in a sealed container, a radioactive material directly into the tumor mass. HDR reduces the risk found in typical Brachytherapy procedures by encapsulating the radioactive source and reducing the danger to the patient and treating personnel.

Oncology Services Corporation's mission under the License is to provide HDR to patients located in smaller communities who otherwise are unable to get such advanced, state-of-the-art cancer therapy. HDR is typically provided to patients who are the sickest and most in need of immediate and often palliative treatment. OSC was granted a license to provide HDR in September of 1990 using a Sauerwein GammaMed III unit with a 10-curie IR-192 source. In 1991 and 1992, OSC sought and was granted amendment of its license to purchase additional HDR units from Omnitron. Because of improvements in the alloy source wire, the Omnitron unit was considered superior to earlier HDR units. The Omnitron unit had been reviewed by the FDA and the Omnitron operation manual and training materials were NRC approved.

The NRC, Region 1, performed a safety inspection on September 4, 1991 and reviewed the entire Oncology Services Corporation HDR/Radiation safety program and found no deficiencies with regard to HDR operation or treatment procedures. Two minor regulatory infractions were noted.[2]

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[2] Badge from wrong center and transport form incompletely filled out.

II. REVIEW OF FACTS AND REGULATORY SECTIONS CITED WITH REGARD TO INDIANA, PENNSYLVANIA FACILITY

Oncology Services Corporation believes that the facts recited in the License Suspension Order with regard to the Indiana, Pennsylvania incident of November 16, 1992 are incorrect.

The staff at the Indiana Regional Cancer Center include James E. Bauer, M.D., a board certified radiation oncologist and an authorized user named in the NRC license; Gregory A. Hay, M.S., a highly-qualified and experienced physicist; Sharon A. Rickett, the chief radiation therapy technician; Rudy A. Balko, a radiat. . therapy technician; and an x-ray technician, Robby E. Ackerman.

Prior to becoming Medical Director at Indiana Regional Cancer Center, Dr. Bauer was a radiation oncologist with more than 30 years' experience in Brachytherapy . More importantly, he served with distinction as RSO for an entire hospital complex for more than 20 years until 1988. Dr. Bauer taught radiation safety, including the use of survey meters, at the University of Missouri Medical School. Radiation therapy technicians Rickett and Balko graduated from accredited schools and are Board-certified by ASRT. They learned all aspects of radiation safety including the use of the survey meter. Rickett and Balko had used portable survey meters at the Indiana Center in 1991 when the wall-mounted survey meter was undergoing part replacement and in 1992 when a source was delivered to the Indiana Center.

All treating personnel including both technologists at the Indiana Center had received NRC approved-training from Omnitron using the NRC approved Omnitron emergency procedures and NRC-approved operating manual. (See attached Statement of Balko. Certain NRC findings suggests incorrectly that he did not attend

training). Only after the personnel had been properly trained was the Indiana Center allowed to treat patients without direct supervision starting in about February 1992. In addition, OSC provided corporate training for all personnel including those from the Indiana Center in a special session in Atlantic City, in August of 1992. An in-service was provided by Dr. Cunningham on HDR including basic radiation safety, training requirements, HDR emergency response, film badge use, distances, shielding and time and survey meter use.

Medical Directors/authorized users had refresher training by Dr. Cunningham at semi-annual meetings which covered regulatory compliance and the importance of reading the license and its conditions. At these training sessions the responsibility of being an authorized user was also reviewed. The license had been sent to all centers including Indiana by Dr. Cunningham, the RSO.

Greg Hay, the physicist at the Center has prepared an affidavit, a copy of which is attached, indicating that he was instructed by Dr. David Cunningham, the RSO, to survey patients having HDR treatments, as required in the regulations and that personnel at the Indiana Center were informed of this regulation.

The NRC Brachytherapy regulations are ambiguous with regard to surveys after HDR treatments. A radiation survey of the patient with a "radiation survey detection instrument" is required under Section 35.404 of the regulations after removing "the last temporary implant source." During treatment of the affected patient at the Indiana Center on November 16, 1992, the patient was surveyed before and after the HDR procedure using the PrimeAlert, a wall-mounted survey meter. There is nothing in the regulations in effect in November of 1992 requiring an additional

survey with a portable survey meter. Because of this ambiguity in the regulations, a bulletin was issued by the NRC on December 8, 1992 requiring HDR patients to be surveyed with a portable survey meter. This was the first indication from the NRC that a wall-mounted survey was insufficient.

The use of and reliance on the wall-mounted survey meter was an "evaluation of the radiation hazards incident to the use or presence of sources of radiation" in compliance with the regulations in 10 C.F.R. Part 20 and was "reasonable under the circumstances to evaluate the extent of the radiation hazards that may have be present" in accordance with 10 C.F.R. 20.201(b).

The treating personnel at the Indiana Center followed NRC regulations by using the NRC-approved emergency procedures in the Omnitron manual. A thorough analysis and extensive interviews with those involved in the Indiana incident appear to indicate this sequence of events.

The subject patient was scheduled for HDR at Indiana on November 16, 1992. Dr. Bauer was informed of a HDR treatment delivery problem as indicated by the operations console of the Omnitron 2000. Additionally, he was informed that the wall-mounted survey meter had flashed red verifying that a treatment related problem with regard to the retraction of the Omnitron source potentially existed. Dr. Bauer assumed complete control of the situation. Dr. Bauer indicates that he did not personally see the wall-mounted survey flashing red thereby indicating a potential problem. As per his NRC-approved Omnitron training, Dr. Bauer systematically reviewed the redundant Omnitron internal safety check alerts, which had been reviewed by the NRC and FDA.

Dr. Bauer know that the HDR console green alert light indicated that the source was in the "safe" position and that the green alert light on the afterloader unit indicated that the source was in the "safe" position. Further, another Omnitron monitor on the floor flashed "green" indicating no radiation danger. According to the Omnitron 2000 Training Session Course Materials, the green "SAFE" alert "indicates that the active wire is parked and a manual retract is not required." Further, the "active wire parking" interlock failed to sound an alarm alerting the operators that the source was not parked in the "Safe" position. The Omnitron Manual states that: "Successful parking is determined by a mechanical switch located at the end of the wire travel path. When the switch is tripped, the active portion of the wire at the other end is in the lead safe. If the parked condition is not detected after a preset step limit, an emergency retract is initiated. SHOULD THIS EVER FAIL, A MANUAL RETRACT ALARM WILL SOUND". No alarm sounded on November 16, 1992. It has subsequently been learned that the interlock failed due to a design defect which disengages the wire length check under an emergency retract condition. This design flaw was unknown to Dr. Bauer.

Dr. Bauer also relied on the "wire length check" safety feature which at all times indicated that the wire length was unchanged. According to the Omnitron Manual

> the length of the wires is checked just before parking to make sure that no length errors have occurred during treatment. This is done by comparing the wire position when the home sensor is activated during extension to the position when the home sensor is deactivated during retraction. Any length errors are reported to the operator at the main console AND WILL CAUSE A MANUAL RETRACT ALARM TO SOUND.

The Omnitron Manual further indicates that "applicator wire lengths are checked each time the wires are retracted into the machine to ensure the entire wire had been retrieved with no breaks."

The source length check interlock failed under emergency retraction conditions. This appears to be a design problem in that the system may be designed to operate in this manner. In OSC's view, this is a serious concern for two reasons. When a system has a safety interlock that is stressed as a feature that makes the unit "extra safe", it may be excessively relied upon by operators. It is particularly bad in this case in that no person who completed the Omnitron training course was aware of this limitation. It is OSC's opinion that it is better not to have the interlock than to have an interlock that is not active during emergency conditions when the interlock is needed.

Additionally, Dr. Bauer as well as all Omnitron-authorized users, were trained that the wire could not break. Indeed, at the time of discovery of the potential source break, Greg Hay the Indiana physicist contacted Omnitron and was informed that such an event was "impossible". This is reinforced in the two Omnitron Manuals and in the Omnitron sales literature. The fact that the source is an integral part of the wire and not welded onto the wire as in competitor's units is the major selling feature of the Omnitron 2000.

The technologists at Indiana were aware of the significance of the radiation trigger on the wall-mounted survey meter. Although the NRC has reported that they claim the wall-mounted survey meter had malfunctioned in the past, it had not malfunctioned for over a year. When the last malfunction was reported to supervisory personnel, the monitor was immediately

repaired. The technologists test the wall-mounted survey meter every morning and if it had been malfunctioning they should have reported it to Dr. Bauer and/or Greg Hay. Greg Hay checks the wall-mounted survey meter as part of his routine quality assurance and confirms that the monitor was operating correctly. During the NRC investigation, there were reports of occurrences of flashing after the linear accelerator was turned off; however these reports are not consistent among the technologists and they all confirmed it was never a continuous flashing indicating a potentially serious radiation exposure situation. Further it was not made known to the RSO.

Additional statements made by the NRC in its Suspension Order with regard to the Indiana incident are also incorrect. License condition 17 requires that a radiation monitor be mounted on the wall. No violation occurred with regard to this condition. A radiation monitor in working order was available and mounted in the required place in the Indiana facility. Further, the Suspension Order incorrectly states that there was some form of "failure of the radiation monitor". It is unclear whether the wall-mounted survey did or did not fail on November 16, 1992. But if it did fail, the failure had not been reported to OSC or its RSO. The Suspension Order states that failure of the radiation monitor "requires termination of treatment". Even though no monitor had failed, treatment of the affected patient was terminated by Dr. Bauer as soon as he learned of problems.

Although a working portable survey meter was available and although all personnel present had been trained in the use of portable survey meter, the portable survey meter was not used with regard to this patient. The personnel relied on the internal safety devices in the Omnitron 2000. Since the NRC-approved Omnitron manual approved this handling of an emergency, the

failure to use a portable survey meter, although very regrettable in light of what later happened, is not a violation of any Regulation or License Condition. The failure of Dr. Bauer to do a hand survey of the patient is the result of his reliance on the NRC-approved procedures of Omnitron. Those procedures proved to be insufficient because of multiple machine failure. There was no regulation which was willfully or negligently violated by Dr. Bauer or other personnel at the Indiana Center.

Page three of the Suspension Order incorrectly states that a direct violation of the regulations occurred when personnel entered the treatment room without using a dosimeter or survey meter. Item 6 of the letter of August 2, 1990, incorporated by reference into Condition 17 of the License provides that "In the event of failure of the room monitor, no personnel will enter the room without a portable survey meter or audible dosimeter." The room monitor did not fail to anyone's knowledge and this License requirement was not triggered. Further, 10 C.F.R. 20.201(b) does not prohibit personnel from entering the room without using a dosimeter or survey meter. Rather, Dr. Bauer's reliance on the wall-mounted survey and the machine console which indicated successful source retraction complied with the 10 C.F.R. 20.201(b) survey requirement. Neither the physician nor the technologists were required to utilize an audible dosimeter or survey meter upon entering the room because under the circumstances an evaluation of the radiation hazards "incident to the use or presence of a source of radiation" was made which complied with 10 C.F.R. Part 20 and which was "reasonable under the circumstances to evaluate the extent of the radiation hazards" that may have been present.

Despite the statement on page three that a violation of 10 CFR 19.12 occurred, no violation for lack of training by the corporate RSO occurred. All personnel including the two radiation

therapy technologists, Dr. Bauer and the physicist Gregory Hay had been trained extensively by Omnitron and also in the use of a survey meter. If any personnel denied such knowledge, it was in spite of extensive training. All had used a portable survey meter on prior occasions. Rickett and Balko had used a portable survey at the Indiana facility on prior occasions when the wall-mounted survey meter was temporarily removed for part replacement in 1991. As explained above, corporate oversight of training with regard to personnel at the Indiana facility was extensive.

OSC regrets the unfortunate incident in which a radiation source was left in the body this patient. As indicated above, this incident occurred because of a totally unanticipated failure of the Omnitron retraction mechanism and a reliance by Dr. Bauer on NRC-approved Omnitron procedures which did not anticipate or cover this emergency. Dr. Bauer was properly trained, had more than 20 years Brachytherapy experience, had himself worked as an RSO under an NRC license and knew how to use the hand-held survey device which was available. In this case, the doctor relied on the high-tech state-of-the-art Omnitron 2000 and the NRC approved training manual. The machine malfunctioned and the training did not cover this emergency. These malfunctions were the result of something Omnitron did in its design of the machine, not something OSC or its medical director did.

III FACTS AND REGULATORY ISSUES RELATING TO DECEMBER 8, 1992 INSPECTION AT EXTON CANCER CENTER, EXTON, PA AND MAHONING VALLEY CANCER CENTER, LEHIGHTON, PA

A. Personnel at the Mahoning Valley Cancer Center -- Lehighton

David J. Moylan, III, M.D. is the Medical Director/ Authorized User at the Lehighton facility and a Board-certified radiation oncologist with 14 years' experience in radiation therapy including Brachytherapy. Dr. Moylan has served as Associate Professor of Radiation Oncology at Thomas Jefferson University Medical School and is a Board member of the American Society of Therapeutic Radiation Oncologists. Karen E. Wagner, M.S. is the physicist at the Lehighton Center. She has been a Board-certified physicist since 1990 and has five years' experience as a physicist at the Mahoning Valley Cancer Center. Two certified technologists work at the Mahoning Valley Cancer Center.

B. Personnel at Exton Cancer Center

Richard Yelovich, M.D. is the Medical Director of the Exton facility and is a Board-certified radiation oncologist with 10 years' experience in radiation therapy including Brachytherapy. He is a former Associate Professor of Radiation Oncology at Thomas Jefferson University Medical School. Paula Salinitro, M.S., the Exton physicist, has been Board-certified for 6 years and has 15 years' experience as a physicist. She has taught radiation physics at Thomas Jefferson University Hospital. There are three licensed technologists at Exton

C. Review of Inspection Results

Oncology Services Corporation has reviewed and undertaken an extensive investigation with regard to the factual findings set forth in the NRC Suspension Order with regard to the Exton and Lehighton inspections on December 8, 1992. Not one of the asserted facts set forth in subparagraphs A through G is correct. The correct and verified facts are set forth:

A. There is no regulation which would have required Dr. Cunningham to visit the Lehighton facility during the six to nine-month period prior to the December 8, 1992 inspection. The regulations, in particular ¶ 35.20(3), require meetings with management on a once-a-year basis. Furthermore, Dr. Cunningham had expended considerable time and attention to the Lehighton facility. In the License Application which is incorporated into the License as part of Condition 17, Dr. William Ying, Ph.D. is permitted, with Dr. Cunningham, to do HDR training. Dr. Ying, who specializes in HDR physics and who is Dr. Cunningham's direct assistant as permitted in the License, travelled to the Mahoning Center in Lehighton on ten occasions between November of 1991 and March of 1992 to train center personnel including Karen Wagner, the Center physicist. During the training period which extended over for many months, no HDR procedures were performed in Lehighton without direct supervision from the Harrisburg HDR team. The technologists at the Mahoning (Lehighton) Center were trained in the correct use and operation of portable survey meters, wall-mounted radiation monitors, door interlocks and patient audio-visual communications systems by OSC. Training covered a review of emergency procedures. In addition to the specific visits to the facility, Dr. Cunningham was in continuous contact by FAX and phone with the Lehighton Center during the six to nine months prior to the December inspection.

B. Dr. David Moylan has prepared a statement attached to this Response setting forth that he did not state to any NRC inspector the words quoted to him in subparagraph B. Dr. Moylan was an authorized user under the License and had read the terms and conditions of the License and was familiar with them and with Dr. Cunningham's status as the RSO. Dr. Cunningham sent to each of the Centers a copy of the complete

NRC License. That License was updated thereafter. Dr. Moylan had the License and was familiar with it.

C. There is nothing in the regulations or license which requires the Exton and Lehighton technologists to be trained on License conditions in light of the fact that they do not do HDR procedures. There is nothing "within these workers' control". HDR procedures are performed under the direction of trained personnel, who at Exton and Lehighton, were fully familiar with the License conditions and the NRC regulations. Technologists were trained as required in 10 C.F.R. ¶ 19.12 "commensurate with the radiation risk". For technologists, this training included such relevant topics as operation of the equipment and emergency procedures but did not include License conditions or NRC regulations. At no time at Exton or Lehighton would a technologist be in charge of a HDR procedure. Furthermore, those who "receive, possess, use or transfer byproduct material" within the meaning of Section 35.25 are required to comply with the regulations and license conditions but not to know the terms of the regulations or conditions themselves, if they were otherwise trained and are supervised by an "authorized user" who is familiar with the terms of the regulations and license at Exton and Lehighton Centers. The physicist or Medical Director/authorized users were at the console during HDR procedures.

Exton employees including Paula Salinitro, the Exton physicist, were trained at Exton by Dr. Ying on six days between November 1991 and February 1992. In addition, Paula Salinitro received additional calibration training on the HDR Omnitron in Harrisburg. This was in addition to NRC-approved Omnitron training for all personnel at both the Exton and Lehighton facilities. The Atlantic City training session described above covered personnel from the Exton and Lehighton Centers.

The statement in paragraph C that a copy of the License was not available at the Lehighton facility is incorrect. As indicated earlier, the License had been sent by Dr. Cunningham to all Centers and was available to all personnel at the facility. A copy of the License with all documents incorporated is at each of the Centers covered by the License.

D. Condition 17 of the License incorporates the License Application which states that users will demonstrate "emergency routine competence during a 'dry run' emergency". The NRC states that its inspections were unsatisfactory

because neither Exton nor Lehighton had done a simulation emergency or dry run including "the source not retracting at the end of the treatment as required by Condition 17 of the License." There is nothing in License Condition 17 which required that a "simulation emergency" or "dry run" cover the source not retracting at the end of the treatment. The "dry run" language in Condition 17 sets forth no description of any dry run emergency that should be covered. The Omnitron HDR units were purchased because of a special alloy source wire without a weld on the proximal end. This newly-designed source wire was considered by the manufacturer to be safer. The kind of emergency that happened in November of 1992 at the Indiana Center was not anticipated by the manufacturer or OSC or its RSO because it had never occurred previously. Dry runs emergency simulations cover events that have occurred or are anticipated. They did not cover the totally unexpected events like the simultaneous machine failure and internal safety monitoring system failure at Indiana. There is nothing in the regulations or the License conditions which required Oncology Services Corporation to anticipate the totally unexpected Omnitron machine failure.

E. The NRC License Suspension Order is incorrect in stating that emergency procedures were not at the console of the HDR afterloader at Exton. The emergency procedures were located right at the console but were not attached to the wall because prior attempts to attach them had resulted in the document not staying in place. The Exton facility complied with the License in this regard.

F. The keys to activate the linear accelerator and the key to activate the HDR afterloader were not kept on the same key ring at Lehighton and Exton. It is not good practice to have personnel authorized to use the linear accelerator having access to the HDR key. The linear accelerator key can be used by employees with less experience than those who have access to the HDR key. The linear accelerator key was stored in the console cabinet during the time the HDR unit was assembled for operation, in use for calibration-quality assurance checks or in use for patient treatments. With that linear accelerator key stored in the console cabinet during HDR operation, it was not possible simultaneously to activate the linear accelerator and the HDR unit. To the extent required otherwise by the NRC, an unsafe condition would have occurred.

G. The NRC's statement in the License Suspension Order that the staff of the Exton facility was not aware of the specifics of the Licensee's Quality Management Program is

incorrect. Oncology Services Corporation does not know what person at the Exton facility was queried about quality management since no name was given in the Order. Further, the NRC term "quality management" was only added by regulation effective for OSC in January of 1992. OSC had a quality management program in effect well before December of 1992 which had been submitted to the NRC. All personnel involved in the delivery of treatment had been trained in "quality management". The term "quality assurance" is more commonly used in the medical field, has been used by the NRC for many years, is virtually identical to the new term quality management and would have been understood even by staff at Exton.

The NRC License Suspension Order makes one additional allegation with regard to Exton and Lehighton which is not included in an alphabet-lettered paragraph. The NRC charges that physicists at the Exton and Lehighton Centers had not been informed of the November 16, 1992 event at Indiana. At the outset, there is no requirement anywhere in the regulations regarding such notification. The only notification requirements in the regulations is from the Licensee to the NRC. OSC gave prompt notification as required by the regulations to the NRC. Furthermore, HDR operations were suspended at Exton and Lehighton which was appropriate corporate action to prevent the recurrence of any event such as the November 1992 incident at Indiana. Until OSC and Dr. Cunningham had an understanding of what had occurred on November 16, 1992, it would have been inappropriate to issue a "corporate radiation safety communication" designed to prevent "the recurrence of an event such as the November 16, [1992] event." The NRC inspections occurred within days of OSC learning of the incident and before it understood how the machine had malfunctioned or how Center personnel had reacted to the malfunction. Further, Bernard Rogers, M.D., the OSC Director of Brachytherapy, notified each Medical Director/Authorized User under the License of the incident on or about December 2, 1992.

(See attached statement of Dr. Rogers). No misconduct occurred in this regard.

IV. RSO DAVID CUNNINGHAM, PH.D. LETTER TO MEDICAL DIRECTORS OF HDR FACILITIES DATED DECEMBER 18, 1992

OSC believes that the Nuclear Regulatory Commission has misinterpreted Dr. Cunningham's December 18, 1992 letter. This letter came on the heels of OSC's decision, with advice from the individual and independently-owned cancer centers where HDR is performed, to suggest that each individual cancer center seek its own license for HDR treatment.

Each center was staffed from the outset with personnel who, if licensed, could operate independently of a corporate RSO, and, if licensed, were qualified to act as direct RSOs for a particular center. Each center is staffed by a Medical Director who is a radiation oncologist, certified by the American Board of Radiology. Each physician has certified experience in Brachytherapy. The Medical Director at each center was supported by a senior physicist with years of experience. Most of these physicists were either board certified or board eligible. No junior physicists had HDR treatment related responsibility. In addition, each center was staffed by registered technologists, a nurse, and ancillary office staff. Clearly, each center had a staff qualified to support its own HDR license.

Furthermore, the December 18, 1992 letter delegated "tasks", which is permitted, rather than "responsibility" which is not permitted by the NRC regulations. The NRC has previously published a comment on a new regulation to the byproduct material section on the differences between "tasks" and "responsibility" in

the Federal Register. The RSO's performance of the tasks in 10 C.F.R. 35.21 in relation to the implementation of OSC's radiation safety program can be delegated. The NRC stated: "[t]he assigned responsibilities are essential elements of a radiation safety program...., the NRC repeats that tasks, but not responsibility can be delegated". 51 FR 36939 October 16, 1986. Clearly, the RSO for OSC delegated tasks but not responsibility.

Dr. Cunningham's December 18, 1992 letter was written at a time when HDR procedures were voluntarily, temporarily suspended at all but the Harrisburg and Pittsburgh Centers. Dr. Cunningham was performing his RSO duties for Harrisburg and Pittsburgh when the December 18, 1992 letter was written.

In accordance with the intention of the December 18, 1992 letter, Oncology Services Corporation notified the NRC, Region I at a January 27, 1993 meeting of its intent to go forward with transferring license responsibility from one corporate license to several licenses. At no time did Dr. Cunningham delegate radiation safety responsibility in violation of 10 C.F.R. 35.21 to individual centers. Individual centers were properly supervised by Dr. Cunningham both before and after the December 18, 1992 letter.

V. CONCLUSIONS BY NRC ARE INCORRECT

Oncology Services Corporation submits that it has properly refuted any issue regarding a breakdown in corporate management in the control of licensed activities. As set forth above, each center had a complete copy of the license and conditions. Key personnel at all centers had been instructed in the requirements of the license and had been trained in the

regulatory requirements and procedures and instrumentation for emergencies using approved NRC training manuals supplied by Omnitron. In addition, training was supplemented by Dr. Cunningham and Dr. Ying, both of whom were authorized to train under Condition 17 of the NRC license.

To the extent an individual patient was not surveyed with a portable meter, the regulations in effect in November of 1992 did not require a portable survey. The affected patient was surveyed using the wall-mounted survey meter. Only after this event in December of 1992 did the NRC amend its guidelines with a bulletin to set forth a specific requirement that HDR patients be surveyed using a portable survey meter, not using a wall-mounted survey meter.

It is regrettable that an individual patient was exposed to radiation, and it is regrettable that 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 and the Omnitron console. Clearly that physician relied on Omnitron training. Even if good practice would have required Dr. Bauer to use a portable survey device in light of the inconsistent signals, which OSC does not concede, that failure does not rise to the level of a regulatory or license violation. More importantly, that failure does not result from any lack of RSO oversight, since Dr. Bauer had many years' training and experience as a Radiation Safety Officer, as a Brachytherapy specialist, as a medical school teacher of radiation safety and as a radiation oncologist. Even with that training, Dr. Bauer relied on the NRC-approved Omnitron material and believed the Omnitron internal safety check system.

Oncology Services Corporation believes that it has properly refuted any charges with regard to corporate or RSO oversight. Dr. Cunningham or Dr. Ying maintained adequate presence at HDR centers. Center personnel were trained. Furthermore, there is no specific regulation that the NRC alleges was violated with regard to the number of visits which allegedly should have been made by Dr. Cunningham to any HDR facility.

As set forth above, Dr. Cunningham implemented an NRC approved training program using Omnitron materials and supplemented that training program with detailed training as each center came on board, with in-services, with special meetings and with semi-annual meetings for medical directors.

No violation of any NRC regulation has been shown with regard to a corporate audit program as no then current regulation required such an audit program to exist. More importantly, Oncology Service Corporation and Dr. Cunningham clearly had in place adequate training and supervision for all centers that provided HDR treatment under the license and conducted annual reviews as required by the amended regulations.

There has been no improper delegation by the corporate RSO. The December 18, 1992 letter referenced by the NRC has been misinterpreted. Furthermore, even if the December 18, 1992 letter had some significance, which Oncology Services Corporation disputes, that letter was written at a time when only two centers were in operation. Each of those two centers has now been permitted by the NRC Region 1, with good cause shown, to treat specific identified patients on an emergency basis. Eight patients have now been authorized for one or more HDR treatments without incident. NRC personnel observed an HDR procedure under the direction of Dr. Unal and Dr. Cunningham at the Harrisburg

Center on February 2, 1993 and reported to Dr. Cunningham that the procedure was well done, carefully monitored and in all ways complied with the requirements of the regulations and the license.

OSC submits further that the License Suspension Order creates an extreme hardship on patients at the two centers where OSC proposes to continue treatment. These patients have no alternative effective therapy available. All have cancer. Many have advanced and life threatening cancers. No other HDR treatment is available in Harrisburg or Pittsburgh. No incident has occurred, or been suggested, at the Pittsburgh or Harrisburg Centers. Although OSC disputes the general allegations made by the NRC with regard to other centers, it will currently not seek to operate HDR units at those other centers. These centers, which are all separate entities, have informed OSC that they will seek their own by-product licenses from the NRC.

VI. CONCLUSION

Oncology Services Corporation submits that there has been no showing by the NRC of any regulatory or license violation by it or the Radiation Safety Officer. Oncology Services Corporation submits further that its procedure for handling HDR complied with the requirements of the license and with NRC regulations. The public health or safety will not be jeopardized by overturning the Suspension Order. The regrettable incident at Indiana cannot be imputed to Dr. Cunningham or OSC.

For the reasons set forth above, Oncology Services Corporation requests that it be granted a hearing at which it can seek to have the Suspension Order lifted.

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DATED: February 8, 1993

VERIFICATION

My name is MARCY L. COLKITT, Esquire, and I am General Counsel of Oncology Services Corporation. I verify that I have made an investigation of the facts set forth in the License Suspension Order of the Nuclear Regulatory Commission and can attest upon personal knowledge and based on investigation that the facts set forth in this Response are true and correct.

I make this statement under penalty of perjury set forth in the Pennsylvania Crimes Code, 18 Pa. C.S. 4904.

Marcy L. Colkitt, Esquire

DATE: February 5, 1993

VERIFICATION

My name is Bernard R. Rogers, M.D. and I am Clinical Director of Brachytherapy for Oncology Service# Corporation. On December 1 or 2, 1992, I personally contacted all Medical Directors at each facility utilizing an Omnitron 2000 unit for the purpose of notifying the relevant staff at each facility about the preliminary nature of the occurrence at Indiana, Pennsylvania.

I understand that false statements made herein are subject to the penalties of 18 Pa. C.S. Section 4904, relating to unsworn falsification to authorities.

Bernard R. Rogers

Bernard R. Rogers, M.D.

Date: February 5, 1993

VERIFIED STATEMENT

My name is David J. Moylan, III, M.D. and I am Medical Director of the Mahoning Valley Cancer Center referred to as the Lehighton Facility in the NRC Order Suspending License of Oncology Services Corporation.

In that Order at page 5, paragraph B it states that I "had not read the terms and conditions of the License and was not aware that Dr. Cunningham was the RSO named on the License." This statement is false. Indeed, I never discussed with anyone from the NRC my knowledge regarding the terms and conditions of the License or anything to do with the issue of Dr. Cunningham being the RSO. To the contrary, I am familiar with the terms and conditions of the License and am fully aware that Dr. Cunningham is the named Radiation Safety Officer.

Further, by memo dated July 10, 1992, David E. Cunningham, Ph.D. forwarded to the Mahoning Valley Cancer Center the complete binder containing the NRC License. That entire License has always been maintained at the Mahoning Valley Cancer Center.

I make this statement under penalty of perjury set forth in Pennsylvania Crimes Code, 18 Pa.C.S. Section 4904.

David J. Moylan, III, M.D.

Date: February 4, 1993

AFFIDAVIT OF GREGORY A. HAY

STATE OF PENNSYLVANIA)
) SS
COUNTY OF INDIANA)

1. My name is Gregory A. Hay, M.S. and I am physicist for the Laurel Highlands Cancer Program and the Indiana Regional Cancer Center (the "Indiana Center").

2. As a physicist to the Indiana Center, I report directly to James E. Bauer, M.D. and David Cunningham, Ph.D.

3. In February, 1992 Omnitron personnel were present at the Indiana Center for purposes of training the Center personnel on the use of the Omnitron 2000. During that training time I specifically informed the Center personnel that each brachytherapy patient must be scanned with a survey meter upon the completion of each treatment.

4. I am personally aware that radiation therapy technicians Rudy A. Balko and Sharon A. Rickett have used the survey meter and the Prime Alert at the Indiana Center.

Gregory A. Hay, M.S.

SWORN TO AND SUBSCRIBED
before me this 4th
day of February, 1993.

Notary Public

My Commission Expires:

NOTARIAL SEAL
BETTYJEAN LESNAK STEELE, Notary Public
Indiana County, Indiana, PA
My Commission Expires Oct. 1, 1994

SWORN VERIFICATION

My name is Rudy Balko, and I am employed as a radiation therapy technician at the Indiana Regional Cancer Center. I participated in and completed training on the use of the Omnitron 2000 unit in or about February of 1992. This training was given by Omnitron personnel on-site at the Indiana Regional Cancer Center.

I understand that false statements made herein are subject to penalties of 18 Pa. C.S. Section 4904, relating to unsworn falsification to authorities.

Rudy Balko

Rudy Balko, R.T.

DATE: February 6, 1993