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

OFFICE OF THE
SECRETARY

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February 5, 1993

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OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

MEMORANDUM FOR: B. Paul Cotter, Jr.
Chief Administrative Judge
Atomic Safety and Licensing Board Panel

FROM: Samuel J. Chilk, Secretary

SUBJECT: REQUEST FOR HEARING SUBMITTED BY
ONCOLOGY SERVICES CORPORATION

Attached is a request for a hearing dated February 2, 1993, submitted by the Oncology Services Corporation (Docket No. 30-31765) in response to an "Order Suspending License (Effective Immediately)" issued by the NRC Staff on January 20, 1993. The Order was published in the Federal Register at 58 Fed. Reg. 6825 (February 2, 1993). (Copy Attached)

The request for hearing and a letter from the Region I Administrator to Oncology dated January 22, 1993, amending the suspension order are being referred to you for appropriate action in accordance with 10 C.F.R. Sec. 2.772(j).

Attachments: as stated

cc: Commission Legal Assistants
OGC
CAA
EDO
NMSS
Dr. Douglas R. Colkitt
Marcy L. Colkitt, Esquire
General Counsel
Oncology Services Corp.

D502

ONCOLOGY SERVICES CORPORATION

110 Regent Court • Suite 100 • State College, PA • 16801 814-238-0375 • 800-628-9076 • 814-238-8069

(412) 463-3570 February 2, 1993

VIA OVERNIGHT UPS

Office of Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
Attn: Chief of Docketing and Services Branch

James Lieberman, Esquire
Director, Office of Enforcement
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Lawrence J. Chandler, Esquire
Assistant General Counsel for
Hearings and Enforcement
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Thomas T. Martin, Regional Administrator
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

Re: Order Suspending License of Oncology Services Corporation License No. 37-28540-01 issued January 20, 1993

Gentlemen:

Please be advised that Licensee, Oncology Services Corporation, respectfully requests a Hearing on the January 20, 1993 Order issued by the Nuclear Regulatory Commission suspending License No. 37-28540-01. Notification regarding the Hearing should be sent to Douglas R. Colkitt, M.D., Oncology Services Corporation, 110 Regent Court, Suite 100, State College, PA 16801.

Oncology Services Corporation's Answer to said Order will be filed via telecopy on Monday, February 8, 1993 at fax number 301-504-1672 and a hard copy of the Answer will be filed with the Office of Secretary on Tuesday, February 9, 1993. If the telecopying of the Answer on Monday, February 8, 1993 presents a

problem or is impermissible, please notify me of such immediately at telephone number 412-463-3570 or telecopier number 412-463-3569.

Thank you for your attention in this matter.

Very truly yours,

Marcy L. Colkitt

General Counsel

cc: Douglas R. Colkitt, M.D. (via telecopy)
Kerry A. Kearney, Esquire (via telecopy)
David Cunningham, Ph.D. (via telecopy)

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

January 22, 1993

93 FEB -4 P4:34

Oncology Services Corporation
ATTN: Douglas R. Colkitt, M.D.
775 South Arlington Avenue
110 Regent Court, Suite 100
Harrisburg, Pennsylvania 16801

License No. 37-28540-01
Docket No. 030-31765
EA No. 93-006

SUBJECT: MODIFICATION TO ORDER SUSPENDING LICENSE

Dear Dr. Colkitt:

This refers to our Order Suspending the Above Named License (Order) issued January 20, 1993, to Oncology Services Corporation and to your request to Mr. Richard Cooper of this office on January 20, 1993, requesting a modification to the Order. This also refers to telephone conversations between Susan Shankman of this office and Dr. David Cunningham on January 22, 1993, during which Dr. Cunningham requested that authorization be given to allow resumption of treatment of one patient at your licensed facility in Pittsburgh, Pennsylvania.

You informed us in writing that the reason for requesting authorization to resume treatment was the immediate distress of the patient. You also provided information about the qualifications of the persons implementing the treatment. Subsequently, our inspector Ihor Czerwinskyj, spoke by telephone with the physicist, Mr. Mitch Jarosz at the Pittsburgh Center to verify the information provided by you.

We have evaluated the information you have provided and find good cause is demonstrated for the resumption of treatment for this patient.

Therefore, in accordance with your January 22, 1993 request, and pursuant to Section VI of the Order, Section VI, paragraph 2 of the Order is amended to read as follows:

> The licensee may treat the patient at the Pittsburgh Center for which relief was requested on January 22, 1993.

All other provisions of the January 20, 1993 Order remain in effect.

If you have any questions regarding this matter, please contact Dr. Richard Cooper of my staff at (215) 337-5281.

Sincerely,

Thomas T. Martin
Regional Administrator

cc:
State of New Jersey
State of Pennsylvania
State of Ohio

Distribution
PDR
SECY
CA
JMTaylor
HThompson
JLieberman
RCooper, RI
JGoldberg, OGC
RBernero, NMSS
RECunningham, NMSS
Enforcement Coordinators
RI, RII, RIII, RIV, RV
FIngram, GPA/PA
BHayes,OI
DWilliams, OIG
VMiller, GPA/SP
EJordan, AEOD
JDelMedico, OE
Day File
EA File
DCS

for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1) (i)–(v) and 2.714(d).

The Commission hereby provides notice that this is a proceeding on an application for a license amendment falling within the scope of section 134 of the Nuclear Waste Policy Act of 1982 (NWPA), 42 U.S.C. 10154. Under section 134 of the NWPA, the Commission, at the request of any party to the proceeding, is authorized to use hybrid hearing procedures with respect to "any matter which the Commission determines to be in controversy among the parties." The hybrid procedures in section 134 provide for oral argument on matters in controversy, preceded by discovery under the Commission's rules, and the designation, following argument, of only those factual issues that involve a genuine and substantial dispute, together with any remaining questions of law, to be resolved in an adjudicatory hearing. Actual adjudicatory hearings are to be held on only those issues found to meet the criteria of section 134 and set for hearing after oral argument.

The Commission's rules implementing section 134 of the NWPA are found in 10 CFR part 2, subpart K, "Hybrid Hearing Procedures for Expansion of Spent Nuclear Fuel Storage Capacity at Civilian Nuclear Power Reactors" (published at 50 FR 41662 (October 15, 1985). Under those rules, any party to the proceeding may invoke the hybrid hearing procedures by filing with the presiding officer a written request for oral argument under 10 CFR 2.1109. To be timely, the request must be filed within ten (10) days of an order granting a request for hearing or petition to intervene. (As outlined above, the Commission's rules in 10 CFR part 2, subpart G continue to govern the filing of requests for a hearing or petitions to intervene, as well as the admission of contentions.) The presiding officer shall grant a timely request for oral argument. The presiding officer may grant an untimely request for oral to respond to the untimely request. If the presiding officer grants a request for oral argument, any hearing held on the application shall be conducted in accordance with the hybrid hearing procedures. In essence, those procedures limit the time available for discovery and require that an oral argument be held to determine whether any contentions must be resolved in an adjudicatory hearing. If no part to the proceeding requests oral argument, or if all untimely requests for oral argument are denied, then the usual procedures in 10 CFR part 2, subpart G apply.

For further details with respect to this action, see the application for amendment dated December 7, 1992, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555 and at the local public document room located at W. Dale Clark Library, 215 South 15th Street, Omaha, Nebraska 68102.

Dated at Rockville, Maryland, this 27th day of January 1993.

For the Nuclear Regulatory Commission.

George T. Hubbard,

Acting Director, Project Directorate IV–1, Division of Reactor Projects—III/IV/V, Office of Nuclear Reactor Regulation.

[FR Doc. 93–2377 Filed 2–1–93; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 030–31765; License No. 37–28540–01; EA 93–006]

Order Suspending License (Effective Immediately)

In the Matter of Oncology Services Corporation, Harrisburg, Pennsylvania

I.

Oncology Services Corporation (Licensee) is the holder of Byproduct Material License No. 37–28540–01 (Licensee) issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR parts 30 and 35. The License authorizes possession and use of over 500 curies of iridium-192 as sealed sources for use in brachytherapy remote afterloaders for the treatment of humans at several specified facilities located within the State of Pennsylvania. The License was originally issued on August 3, 1990, and is due to expire on August 31, 1995. The License names Dr. David E. Cunningham as the Radiation Safety Officer (RSO). The duties and responsibilities of the RSO are set forth in the License and in 10 CFR 35.21(b).

II.

On December 1, 1992, the NRC Region I Office was notified of an incident involving the loss of a 3.7 curie iridium-192 source from the Licensee's Indiana, Pa. facility (Indiana Regional Cancer Center) on November 16, 1992. It was subsequently determined that the source, which was connected to the metal drive wire on an Omnitron 2000 High Dose Rate (HDR) remote afterloader machine, had broken off during a patient treatment. The machine directs the source into catheters placed in a patient and retrieves the source at the conclusion of the treatment via the drive wire. When the source became disconnected, it remained in one of the catheters in the patient for approximately 91 hours. During that time period, the patient incurred a radiation dose estimated at greater than one million rads to the wall of the bowel.

When the radiation therapy technologists at the Indiana Regional Cancer Center operated the machine to insert the radioactive source into the last of five patient catheters involved in the treatment, the machine gave numerous "error" messages. The technologists next operated the machine to insert a nonradioactive source wire into the catheter in an attempt to clear any potential constriction. At some time during the time the machine was indicating error messages, the area radiation monitor alarmed with a flashing red light although the source was not then thought to be in use. A technologist informed the attending physician of the difficulties with the treatment and that the alarm had flashed. The physician, who is an authorized user named on the NRC license, went into the room to examine the patient. The physician directed the technologists to terminate the treatment and disconnect the patient from the HDR machine.

License Condition 17 requires that a radiation monitor be mounted on the wall and remain in place as a means of verifying the source location. Further, failure of the radiation monitor requires termination of treatment until the monitor is repaired and no personnel will be permitted to enter the room without a portable survey meter or audible dosimeter. In addition, 10 CFR 20.20(b) requires that the Licensee make such surveys as (1) may be necessary to comply with the regulations in 10 CFR part 20 and (2) are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. In direct violation of these requirements, and even though a calibrated, operational survey meter has available in the immediate vicinity, neither the physician nor the technologists utilized an audible dosimeter or survey meter upon entering the room, when they apparently believed that the area radiation monitor had malfunctioned and signaled a false alarm. In spite of the obvious difficulty encountered with the treatment, these individuals also did not survey the patient following discontinuation of the treatment to

assure that all sources had been removed from the patient.

In violation of 10 CFR 19.12, the radiation therapy technologists had not been trained in the use of a survey meter and did not know when to use a survey meter or how to interpret the readings of a survey meter to determine the presence of a radioactive source in the patient or in the area.

The patient, whose body still contained the catheter with the radioactive source lodged inside it, was returned to a nearby nursing home. At the nursing home, the catheter containing the source became loose and dislodged itself from the patient's body on November 20, 1992. The catheter, with the source still in it, unknowingly was initially placed in a biological waste bag which was stored with other biomedical waste in a room at the nursing home and was subsequently placed in a storage shed behind the nursing home. On November 25, 1992, the biomedical waste containing the radioactive source was collected by a waste carrier and transported to a disposal facility where the source was detected when a radiation alarm sounded.

The patient expired on November 21, 1992. Regardless of the specific cause of death in this case, the amount of radiation received by the patient was significant. Numerous other individuals including health care workers, visitors, sanitation workers, and other members of the general public, were exposed to unnecessary radiation as a result of this event.

III.

On December 1, 1992, NRC initiated an inspection to review the Licensee's actions. On December 2, 1992 a Confirmatory Action Letter (CAL 1–92–016) was issued to the Licensee to, among other things, confirm its commitment to suspend use of the HDR at the Indiana Regional Cancer Center for patient treatment until specifically authorized by NRC to resume use of the HDR. The CAL stated that its issuance did not preclude issuance of further actions. On December 3, 1992, NRC established an Incident Investigation Team to review this event.

On December 8, 1992, NRC conducted unannounced inspections at two of the Licensee's facilities, the Licensee's Exton Cancer Center, Exton, Pa. (Exton), and the Mahoning Valley Cancer Center, Lehighton, Pa. (Lehighton). These inspections included reviews of the organization and scope of licensed activities, training of personnel, posting, instrumentation, personnel monitoring, HDR afterloader operations, and the Licensee's Quality Management (QM) program. The findings of this inspection included:

A. Dr. Cunningham, who is the RSO named on the License, had not visited the Lehighton facility in the past 6–9 months.

B. Dr. David J. Moylan, Medical Director of the Lehighton facility and an authorized user named on the License, indicated that he had not read the terms and conditions of the License and was not aware that Dr. Cunningham was the RSO named on the License.

C. At the Exton and Lehighton facilities, the Licensee failed to provide training to the radiation therapy technologists in the requirements of the License conditions and of the NRC regulations as required by 10 CFR 19.12. Copies of the documents incorporated into the License by reference were not available to the individuals at the Lehighton facility as required by Condition 17 of the License.

D. Emergency training provided to the radiation therapy technologists at the Exton and Lehighton facilities did not include a "Simulation Emergency" (i.e., "dry run") of the source not retracting at the end of a treatment as required by Condition 17 of the License.

E. At the Exton facility, emergency procedures were not posted at the console of the HDR afterloader as required by the License.

F. At both the Exton and Lehighton facilities, the key to activate the Linear accelerator and the key to activate the HDR unit were not on the same key ring so as to prohibit the simultaneous activation of both units within the same room as required by Condition 17 of the License. Instead, the key to each unit was left in the respective console of that unit.

G. The staff of the Exton facility was not aware of the specifics of the Licensee's Quality Management program.

Additionally, although the physicists at the Exton and Lehighton facilities are key personnel who bear responsibility for avoiding or preventing the recurrence of an event such as the November 16 event described in Section II above, the inspectors determined that these individuals did not learn of the event via an appropriate corporate radiation safety communication, but instead learned about the event through the coverage in the news media.

On December 14, 1992, NRC Region I issued a Confirmatory Action Letter (CAL 1–192–020) to the Licensee's president wherein the Licensee committed to: (1) Have independent audits of the radiation safety program, (2) provide a corrective action plan, (3) clarify the reporting and oversight responsibilities of the corporate RSO, (4) conduct training on radiation safety and routine and emergency operations of the HDR machines, and (5) communicate to its staff management expectations for operating the HDR machines and the specifics and significance of recent failures of these machines. The CAL stated that its issuance did not preclude issuance of further actions.

On December 11, 1992, the Licensee requested that it be allowed to resume patient treatment with the HDR at the Indiana facility. This request was made because patients, whose palliative treatment had been discontinued as a result of the December 2, 1992 CAL, were in need of relief from pain and suffering through treatment with this modality. By letter dated, December 15, 1992, the NRC approved resumption of treatment with a HDR afterloader provided that the Licensee had taken the actions specified in NRC Bulletin 92–03, December 8, 1992.

IV.

Following the NRC inspection at the Exton and Lehighton facilities and the issuance of the December 14, 1992 CAL, the NRC learned that the Licensee's RSO communicated with the medical directors of the Licensee's five satellite facilities by letter dated December 18, 1992. The letter stated, "It is not possible for Corporate Administration to supervise your radiation safety program on a routine basis." In the letter, Dr. Cunningham sought to delegate to the Medical Director/Authorized User at each of the satellite facilities the radiation safety officer responsibilities that are assigned to Dr. Cunningham under the terms and conditions of the License. Dr. Cunningham also stated in the letter that it is appropriate for the Medical Director/Authorized User to further delegate the radiation safety responsibilities of the Medical Director/Authorized User to "the technical support including the physicists and chief technologist."

V.

The facts described above demonstrate a significant corporate management breakdown in the control of licensed activities wherein key Licensee employees at several satellite facilities do not know the requirements of the NRC License, do not have access to the pertinent License documents, and have not been adequately trained in either the pertinent regulatory requirements or the procedures and instrumentation to be employed to protect themselves and others from radiation exposure. This problem is of

the utmost regulatory concern because it contributed to a situation in which a patient was unknowingly exposed to a significant level of radiation, and in which numerous members of the general public received unnecessary radiation exposure.

In addition, the corporate RSO contributed in large part to this problem by not maintaining an adequate physical presence at the satellite facilities; failing to implement appropriate training programs for Licensee employees, which the RSO is required to do under 10 CFR 35.21; and failing to establish and implement a periodic corporate audit program to identify and promptly correct violations to ensure compliance with NRC regulatory requirements. The corporate RSO now seeks to delegate these functions in violation of the License to the managers of the individual facilities where the problems are occurring and suggests that those managers, in turn, delegate the functions further down the chain of command. Therefore, it has been concluded that the Licensee's RSO is not willing to be responsible for its radiation safety program so as to ensure that the radiation safety activities are being performed in accordance with Commission requirements in the daily operation of licensed activities as required by 10 CFR 35.21.

Consequently, while NRC is continuing to investigate the activities of this Licensee, as a result of the information available to date and the incident in which an iridium-192 source was unknowingly left within a patient, I lack the requisite reasonable assurance that the Licensee's current operations can be conducted under License No. 37-28540-01 in compliance with the Commission's requirements and that the health and safety of the public, including the Licensee's employees and patients, will be protected. Therefore, the public health, safety, and interest require that License No. 37-28540-01 be suspended pending the results of the NRC investigations and the institution of appropriate corrective actions on the part of the licensee. Furthermore, pursuant to 10 CFR 2.202, I find that the significance of the circumstances described above is such that the public health, safety, and interest require that this Order be immediately effective. This Order supersedes the relief provided in the December 15, 1992 letter.

VI.

Accordingly, pursuant to sections 81, 161b, 161i, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR parts 30 and 35, *it is hereby ordered, effective immediately, that:*

License No. 37-28540-01 is suspended pending further Order. This suspension precludes the performance of any licensed activity at any of the Licensee's facilities authorized by the License. The Licensee is required to place all licensed material in a locked, stored, and shielded condition. All other requirements of the License continue in force.

The Regional Administrator, Region I, may, in writing, relax or rescind this order upon demonstration by the Licensee of good cause.

VII.

In accordance with 10 CFR 2.202, the Licensee must, and any other person adversely affected by this Order may, submit an answer to this Order, and may request a hearing on this Order, within 20 days of the date of this Order. The answer may consent to this Order. Unless the answer consents to this Order, the answer shall, in writing and under oath or affirmation, specifically admit or deny each allegation or charge made in this Order and set forth the matters of fact and law on which the Licensee or other person adversely affected relies and the reasons as to why this Order should not have been issued. Any answer or request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Docketing and Service Section, Washington, DC 20555. Copies of the hearing request also should be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406, and to the Licensee, if the hearing request is by a person other than the Licensee. If a person other than the Licensee requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by the Licensee or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

Pursuant to 10 CFR 2.202(c)(2)(i), 57 FR 20194 (May 12, 1992), the Licensee, or any other person adversely affected by this Order, may, in addition to demanding a hearing, at the time the answer is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the Order on the ground that the Order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error.

In the absence of any request for hearing, the provisions specified in section VI above shall be final 20 days from the date of this Order without further order or proceedings. An answer or a request for hearing shall not stay the immediate effectiveness of this order.

Dated at Rockville, Maryland this 20th day of January 1993.

For the Nuclear Regulatory Commission.

Hugh L. Thompson, Jr.,

Deputy Executive Director for Nuclear Materials Safety, Safeguards, and Operations Support.

[FR Doc. 93-2322 Filed 2-1-93; 8:45 am]

BILLING CODE 7590-01-M

Atomic Safety and Licensing Board

[Docket Nos. 50-275-OLA-2 and 50-323-OLA-2; ASLBP No. 92-668-03-OLA-2]

Pacific Gas and Electric Company (Diablo Canyon Nuclear Power Plant, Units 1 and 2); Notice of Hearing; Facility Operating Licenses No. DPR-80 and DPR-82

January 27, 1993.

Before Administrative Judges: Charles Bechhoefer, Chairman, Dr. Jerry R. Kline, Frederick J. Shon.

On July 22, 1992, the Nuclear Regulatory Commission published in the **Federal Register** a notice of opportunity for hearing with respect to proposed operating-license amendments that would extend the operating licenses for the Diablo Canyon Nuclear Power Plant, Units 1 and 2, located in San Luis Obispo County, California, to recover or recapture into the licenses the period of construction of the reactors (57 FR 32571, 32575). The amendments would extend the expiration date of the Unit 1 license from April 23, 2008 to September 21, 2021, and the expiration date of the Unit 2 license from December 9, 2010 to April 26, 2025.

One request for a hearing and petition for leave to intervene, filed by San Luis Obispo Mothers for Peace, was received. On September 10, 1992, an Atomic Safety and Licensing Board was established to rule on this request/petition and to preside over the proceeding in the event that a hearing were ordered. 57 FR 43035 (September