14076

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

June 18, 1993

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Docket No. 030-31765 - EA

Board Notification 93-17

MEMORANDUM FOR: Atomic Safety and Licensing Board
and All Interested Parties

FROM: John E. Glenn, Chief
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: NEW INFORMATION POTENTIALLY RELEVANT TO LICENSING BOARD PROCEEDING IN THE MATTER OF ONCOLOGY SERVICES CORPORATION

In conformance with the Commission's policy on Board notifications, this memorandum calls attention to the staff's actions with respect to Incident Investigation Team (IIT) report (NUREG-1480) on the Oncology Services Corporation (OSC) incident at Indiana, Pennsylvania.

Following the publication of NUREG-1480 in February 1993, NRC received the response of OSC to this report on March 5, 1993 (Enclosure 1). Receipt of this response was acknowledged in a letter (Enclosure 2) dated March 23, 1993 from Edward L. Jordan of the NRC Office for Analysis and Evaluation of Operational Data (AEOD). These two documents were printed together and distributed by NRC using the same distribution as was used for NUREG-1480 in April 1993.

NRC received a letter on May 5, 1993, from the law firm of Patton, Boggs, & Blow, representing Omnitron International, Inc., commenting on prior correspondence to the NRC from OSC (Enclosure 3). Receipt of this letter was similarly acknowledged by a letter from Edward L. Jordan, AEOD, dated May 27, 1993 (Enclosure 4). These two letters are presently being combined and printed for eventual distribution to the recipients of the original distribution of NUREG-1480.

John E. Glenn

John E. Glenn, Chief
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

Enclosures:
1. Ltr fm Reed Smith Shaw & McClay dtd 03/05/93
2. Ltr fm Edward L. Jordan dtd 03/23/93
3. Ltr fm Patton, Boggs & Blow dtd 05/05/93
4. Ltr fm Edward L. Jordan dtd 05/27/93

cc: Service Lists

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9/21/94

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Board Notification 93- 17 dated June 18, 1993

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March 5, 1993

VIA FAX: 301/504-2162
AND BY MAIL

James M. Taylor
Executive Director for
Operation United States
Nuclear Regulatory Commission
Washington, DC 20555

Re: Oncology Services Corporation - Response to IIT Report on Indiana, PA Incident - Nureg-1480

Dear Mr. Taylor:

By letter dated February 4, 1993, you sent to Dr. Douglas R. Colkitt, the president of my client Oncology Services Corporation a copy of the NRC Incident Investigation Team Report relating to an incident at the Indiana Regional Cancer Center, Indiana Pennsylvania on November 16, 1992. In that letter you stated that Oncology Services Corporation had an opportunity to respond by March 5, 1993.

Enclosed are Oncology Services Corporation's responses to the NRC's Incident Investigation Team Report.

Note that Dr. Paperiello, who was head of the IIT, told Dr. Colkitt and Oncology Services Corporation that transcripts of his interviews would be available to Oncology Services Corporation on February 8, 1993. To date, despite requests to several departments of the NRC, Oncology Services Corporation has been denied access to those transcripts.

As a result of the fact that we have not received transcripts to which we are entitled under the NRC regulations, we asked for additional time to respond. Your office indicated that we could make a partial response. We reserve the right to add additional comments on this NRC IIT Report after those transcripts have been received and we have had an opportunity to review them.

Please contact me if you need any additional information regarding this report.

Very truly yours,

REED SMITH SHAW & McCLAY

By
Kerry A. Kearney

KAK:clc

Enclosure

cc: Douglas Colkitt, M.D.
Marcy Colkitt, Esquire

RESPONSE OF ONCOLOGY SERVICES CORPORATION TO NUREG-1480 REPORT OF U.S. NUCLEAR REGULATORY COMMISSION, IIT: REGARDING INDIANA REGIONAL CANCER CENTER INDIANA, PENNSYLVANIA - NOVEMBER 16, 1992 INCIDENT

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March 4, 1993

INTRODUCTION

The Response of Oncology Services Corporation ("OSC"), the holder of NRC Byproduct Material License No. 37-28540-01 to the NRC's IIT Report NUREG-1480 follows. Despite the fact that OSC is entitled under NRC Regulations to a copy of all of the transcripts made by the NRC as part of its IIT investigation, and despite repeated requests by OSC for those transcripts, OSC has been denied access to the transcripts. As a result of OSC's inability to review important evidence upon which the NRC based its IIT Report, OSC reserves the right to amend its response at a later time when IIT transcripts are received from the NRC.

ABSTRACT

On November 16, 1992 a patient was treated at the Indiana Regional Cancer Center, a facility licensed under the OSC Byproduct Material License to provide HDR treatments. Treatment was provided with an Omnitron 2000 high dose remote Brachytherapy afterloader using an Iridium-192 source. The machine malfunctioned during treatment of the subject patient causing the source wire to become dislodged in the patient's body. The back-up safety devices built into the Omnitron 2000 failed simultaneously, thereby misleading personnel at the cancer center into believing that the radioactive source was in a "safe" position. A wall mounted radiation monitor had flashed indicating the presence of a radioactive source. The physician in charge at the center believed that the source was in a safe position after he followed the NRC approved emergency procedures in the Omnitron Manual. The radiation source left in the body of the patient. Several people in the community were exposed to small doses of

radiation. OSC physicists calculated the amount of radiation for exposed individuals and found the exposures significantly less than those reported by the NRC in its IIT Report. Those figures were previously submitted to the NRC.

OSC very much regrets the unfortunate incident at the Indiana Center but believes that, at best, it resulted from a mistake in judgment by an individual physician with 30 years experience in radiation safety who had been properly trained. The NRC regulations were ambiguous. Although it may have been prudent to survey the patient a second time with a hand held survey, this was not done. The regulations in effect in November 1992 did not require a hand held survey. Only after the incident, in December of 1992, did the NRC clarify its regulation to require survey with a hand held survey meter after Brachytherapy.

RESPONSE TO EXECUTIVE SUMMARY

As indicated above, an Omnitron 2000 afterloader failed on November 16, 1992. The patient left the facility with a radioactive source in her body and others in the community were exposed to small amounts of radiation. OSC has demonstrated under oath to the NRC that its Radiation Safety Officer ("RSO") had in place a training program for all facilities under the license, including the Indiana facility, which complied in all regards with the NRC regulations.

OSC and its RSO had in place procedures for checking equipment that were in compliance with the NRC regulations. The wall mounted radiation survey device at the Indiana Center failed approximately one year before this incident and had been replaced. OSC and its RSO had no information regarding any failures of this survey device at or near the time of the incident despite daily

checks. A working hand held survey device was available at the Indiana center and all technicians and physicians at the center knew how to use it and had used it in the past.

When a problem occurred during the November 16, 1992 procedure, the Medical Director at the facility, a radiation oncologist with 30 years experience who had been a RSO for 20 years at a major hospital, took complete charge from the technologists. He, rather than any technologist or technician, handled this emergency. Even Dr. Paperiello, the head of the NRC's IIT team conceded during the February 8, 1993 hearing before the Nuclear Regulatory Commission that for the people at the Indiana Cancer Center "there was probably only a period of 30 seconds for these people to make the right decisions and they made the wrong one." (Transcript of February 8, 1993 proceedings at 61). The regulatory violations cited were a failure to use the hand held survey unit and a lack of training for people at the Indiana Center. As indicated above, the IIT team admitted that the NRC survey regulation was ambiguous. OSC has demonstrated that all personnel at the center were properly trained. This incident happened not because of any regulatory violation or lack of training. The incident happened because a properly trained, highly experienced physician, who had himself been licensed as a RSO by the NRC, made an unfortunate judgment call in a period of "30 seconds."

RESPONSE OF OSC TO NRC TABLE OF EXPOSED INDIVIDUALS

OSC does not have the benefit of materials collected by the NRC regarding exposures of persons in the community. As a result, it does not know who the individuals are that were identified by the NRC as the 94 exposed to radiation or how the NRC calculated exposures. OSC's physicists are highly experienced

in making such calculations and do not agree with the calculations they know about. The NRC totally ignores the effect of tissue attenuation on dose evaluation. Tissue attenuation will reduce the dose substantially. OSC's determinations regarding exposures of individuals in the communities show that the number of persons exposed and the exposure levels were very small. Even without calculating tissue attenuation, all but one exposed individual received exposure to a radiation dose less than one CAT Scan. Only one individual from the community was found with a calculated linear exposure of 10.2 rads. With attenuation, this exposure would be much less as well. In any case, this is a very small dose and should result in no injury to the individual. No individuals were found with a linear exposure greater than 10.2 rads other than the subject patient whose exposure was calculated at no more than 160 to 400 rads.

OSC does not believe that the subject patient died as a result of acute radiation exposure. Her radiation exposure was well below the amount that would be needed to kill an exposed person in a short interval. If the radiation exposure were 10,000 or more rads, death could occur in 48 hours. At a radiation exposure of 500 rads, 50% of exposed individuals will die within 25 to 35 days after exposure. In this case, the patient died within 91.5 to 92.5 hours of exposure. The small exposure (160 to 400 rads) combined with the short time to death, conclusively demonstrates that her death was not caused by acute radiation exposure. The 82 year old patient suffered numerous debilitative illnesses including advanced metastatic cancer and a non-functioning immune system. She had suffered several "codes" in the recent past. The patient's personal physician believes that death was related to her underlying illnesses.

OMNITRON 2000 SYSTEM

OSC has requested but not received information regarding the FDA and NRC investigations of Omnitron.

OSC had been conclusively told by Omnitron that the source wire could not break. If OSC had been told in September of 1992 that the source wire could break, its emergency response to this incident may have been different. OSC did not learn about corrosion in the Omnitron source wire resulting from teflon packaging until the IIT Report was published on February 4, 1993.

OSC personnel were trained using the NRC approved Omnitron training procedures. Those procedures proved inadequate in this incident.

OSC-IRCC PERSONNEL

OSC had in place a training program at all of its licensed centers which fully complied with the NRC Regulations in place for Brachytherapy. The individuals working at the Indiana Regional Cancer Center had been properly trained. There is no relationship between any lack of training and the incident in issue.

The Quality Management program at Oncology Services Corporation complied with applicable NRC Regulations. Personnel at the IRCC complied with the QM program. To the extent the IIT report identified additional points which might of been covered in an OSC QM Program, the NRC has conceded that these additional points were not required under the regulations in place in November of 1992. The NRC regulations were clarified in December of 1992 to require a survey using a hand held survey meter after Brachytherapy. Under the regulations in effect in November of

1992, a hand held survey was not required. Dr. Paperiello, during the February 8, 1993 NRC Commission Hearing, admitted that staff in his own Region (Region III) and in Region I both interpreted the existing NRC regulations to permit survey with a wall mounted survey device, such as the PrimAlert, rather than with a hand held survey. A Geiger counter is not used by OSC which had other portable survey equipment.

RADIOLOGICAL DOSE EVALUATION

OSC does not have sufficient information to refute the NRC's dose evaluations but incorporates its earlier discussion of dose evaluations and reserves the right to supplement. OSC does not believe that the NRC dose evaluations have value because they do not take into account tissue attenuation. The fact that the NRC IIT assumes linear exposure demonstrates that its investigative personnel are not familiar with Brachytherapy.

RESPONSE TO INCIDENT

OSC takes the position that it fully complied with NRC regulations in promptly reporting this incident to the NRC and in cooperating in all regards with the NRC and IIT investigations of the incident. All reports were promptly filed with the NRC as required under the regulations.

As indicated above, OSC disagrees with many of the factual statements contained in this section of the IIT report.

As an example, there is no indication to support the conclusion that the subject patient experienced a severe acute radiation reaction after the November 16, 1992 incident.

Dr. Bernard Rodgers, the Director of Brachytherapy of OSC immediately notified all HDR centers licensed under the OSC license of the incident after OSC learned of the incident so that precautions could be taken in other HDR procedures.

REGULATORY OVERSIGHT

This section of the IIT report underscores OSC's belief that it properly interpreted and applied the NRC's Brachytherapy regulations to HDR. The NRC, in the ITT report, concedes that its regulatory oversight was confused and insufficient because the regulations were ambiguous and misleading to licensees such OSC and because its own experienced employees and inspectors did not understand the application of Brachytherapy regulations to HDR.

The ambiguity of the NRC regulations is admitted in the IIT report and underscored by the regulatory activities taken by the NRC at the September 1991 inspection of OSC and since this November 1992 incident, including the adoption of 92-03 and 92-84 in December of 1992.

OSC disagrees with any assertion made by the NRC that there are deficiencies at any other centers of OSC for HDR which justify the license suspension issued by the NRC on January 20, 1993. That license suspension has been appealed and is under consideration before an NRC licensing board.

PRECURSORS

OSC has no information sufficient to respond to this section of the report since its request for information from the NRC has not been granted.

FINDINGS AND CONCLUSION

Overall Comments.

It is the belief of OSC and its experienced consultant-auditors that the NRC's IIT would have benefited by the addition of professional members of the team with specific experience in high dose Brachytherapy. The emphasis on items stressed in the report is influenced by the lack of experience of the investigators regarding HDR procedures. An example includes the failure of the IIT to take into account tissue attenuation in dose calculations.

OSC Radiation Protection Program.

In its findings, the ITT report states that "OSC's Radiation Protection Program was ineffective and incomplete" and then proceeds to put the blame for this "perceived" problem on the corporate RSO. As a result of independent investigations done as part of an independent medical/health physics and regulatory audit, most if not all of the statements made by the NRC relative to the RSO are the result of inaccurate, incomplete or not-well-understood statements made by various individuals interviewed by the NRC's IIT during its investigations.

With regard to training, the RSO complied with regulations to ensure that all personnel associated with operation of the HDR equipment were properly trained in its use. This included OSC provided training to the staff, including at IRCC, in accordance with the requirements of the license. The license required the initial training to be performed by the manufacturer with an annual in-service provided by the corporation. A corporate radiation in-service training was given by the RSO on

August 15, 1992. Provisions were in place for providing the annual in-service at each cancer center prior to completion of one year of HDR treatments which for IRCC would have been February, 1993. OSC did not rely on the staff's previous formal education for any aspect of HDR training. Despite the knowledge by OSC corporate that the Medical Director at IRCC was a senior physician with more than 30 years of radiation oncology experience, including extensive experience with low dose rate Brachytherapy and that he had served on a license as a radiation safety officer for 20 years prior to accepting his position at IRCC, the RSO had provided training for all of the oncologists both by the manufacturer and by OSC at the physicians' meetings every six months.

OSC provided the following systematic radiation therapy training for HDR staff.

1. Annual in-service was provided for all radiation therapy technologists. Technologists from the various centers were to attend. This was conducted in August of 1992. It covered the use of HDR equipment, and general radiation safety principles including the use of survey meters.

2. Semiannual radiation safety in-services were conducted as part of the OSC physicians meetings by the RSO with a review of HDR teletherapy including radiation safety.

3. OSC HDR centers were given on-site training by Omnitron, the manufacturer as required by the license. The training is described in detail below.

4. Training at cancer centers was provided by the senior physicist.

The Omnitron training was approved by the NRC. As per the NRC license, the RSO assured that all appropriate personnel received training from the equipment manufacturer Omnitron. This included all personnel at the IRCC. One technologist initially stated that he had not completed the Omnitron training course. He now has signed an affidavit that he did complete the course. Lack of any training for an emergency in which the source wire breaks contributed greatly to the IRCC incident. Obviously, Omnitron did not think this was a possibility. There is a direct reference made by the NRC investigator in the IIT report to training by Omnitron on December 9 and 10, 1991 with additional training on February 27, 1992 by trainer A. This training included the "emergency and safety procedures" of the Omnitron afterloader unit. Radiation incidents are a significant part of the emergency procedures. This is formal radiation safety training. The document entitled Omnitron International Corporation - Guide to Afterloading Licensing states on Page 3 that "Omnitron will provide on-site training for operators from each site as selected by the customer." Further, it states that "training shall include treatment planning, afterloader operator, applicator operation, and safety and emergency procedures." As a condition of the NRC license, the only authorized trainers in the use of the Omnitron Unit are employees of the manufacturer. There were no OSC employees that were approved as initial trainers in the use of the Omnitron 2000 afterloader. Complete instructions including orientation on safety and emergency procedures were accepted by OSC as a regulatory requirement by the NRC to be provided by Omnitron. This license requirement is stated in OSC's August 16,

1991 response to the NRC in relation to a license amendment request.

Specifically in relation to the training of the staff at the IRCC, the independent OSC auditor reports that in his interview of the IRCC staff, he was informed by the physicist that he had personally provided training to the technical staff in radiation safety including the use of the survey meter. Furthermore, the Omnitron trainers have included emergency procedures as an important and integral part of their presentations. At other centers similar training was given.

It is difficult to evaluate the effectiveness of any training. An effort has been made by OSC since February 6, 1993 to test with a written examination all technologists attending radiation safety review sessions.

The RSO was aware of the alleged wall mounted monitor (PrimAlert-10) spurious alarms at the IRCC, but spurious alarms were reported to have occurred over one year before the IRCC incident. At that time, the device was replaced. This was borne out by the audit which showed that the technologist who had worked at the IRCC for more than a year had never seen the device alarm spuriously.

If the IRCC personnel did not respond adequately during recovery of the source, this resulted from a mistake by experienced and well-trained professionals from the IRCC and not from "lack of management oversight, guidance and training" as the IIT report states.

The proper response and actions by the physicist at the Greater Pittsburgh Cancer Center (GPCC) were due to the same RSO oversight which the NRC concludes was ineffective at IRCC.

Machine Design

In addition to the concerns stated by the NRC in its IIT report about the Omnitron 2000, the licensee's independent auditor-consultants have identified additional concerns which cannot fully be addressed without NRC documents relating to Omnitron. The auditors believe that it is equally probable that the source wire failures were caused by poor design, in addition to failures caused by mechanical trauma and environmentally induced embrittlement. The auditors were concerned about the weakening of the source wire due to stress concentrations produced by the boring of the hole in this very fine metal wire, plus the possibility of an uneven or off center boring producing a wall thickness that is even less than the 0.15 millimeter design thickness. The auditors report that similar design and/or manufacturing defects of other encapsulated radioactive sources have resulted in extensive, highly dangerous dissemination of radicactive materials as described by the NRC in its Precursor Section of the IIT report.

Additional concerns about the Omnitron Safety and lock out Systems which could have contributed to this incident were discussed in detail in the OSC response to license suspension.

Safety at IRCC

The independent auditors opined that Dr. Bauer, heading the IRCC staff, did not respond to the incident as an emergency because staff members were overconfident in the Omnitron safety

system and did not recognize the occurrence as a radiation emergency. They believed the automatic indicators on the control panel which indicated the source was safely parked in the Omnitron afterloader unit. This belief was based in large measure on NRC approved training that they had received from Omnitron which stressed the safety features of this unit. These safety features include the three green "safe lights" located on the treatment room door, on the treatment console, and on the afterloading unit. All three of these safety alerts indicated that the source was safely parked within the shielded container. Dr. Bauer also put significant reliance on the computer console, having been trained by Omnitron that the computer console will always indicate the position of the source. Training also included the source length check, which is an additional safety measure built into the unit which would notify by an alarm and console message of any change in the source length.

Since there was no alarm, Dr. Bauer did not believe that there could be any change in the source length. However, Dr. Bauer was not aware, nor had he or any other OSC personnel been informed by Omnitron trainers, that this safety feature was inoperative during an "emergency retract procedure." This "safety" feature of the Omnitron 2000 should be removed, since the machine poses a greater hazard with it than without it. The auditors concluded that this lack of proper functioning of this very important safety device on the Omnitron 2000 during emergency retraction procedures is not a "weakness" in design but is a "significant design flaw."

The OSC staff put such trust in the reliability of the Omnitron 2000 safety features that they ignored the PrimAlert wall mounted survey device believing it to be malfunctioning and neglecting to double check with the available survey meter. In

the past, when a wall mount survey device malfunctioned during linear accelerator use, the technologists had used a portable survey meter to confirm the presence or absence of radiation.

The NRC approved Omnitron emergency procedures only addressed the possibility of a wire that did not retract. At the time of the IRCC incident, the emergency instructions from Omnitron gave absolutely no guidance for a broken source wire or defective encapsulation of the Iridium-192 source. The NRC approved Omnitron training, as presented to OSC, did not address the possibility of a broken wire or Iridium-192 encapsulation.

Based upon independent interviews with the technical and professional staff at IRCC, it is certain that the PrimAlert wall mounted survey was functioning properly at the time of the November 16, 1992 incident. The PrimAlert wall mounted survey is checked daily as part of the morning quality assurance program. Two of the technologists were unsure how long it had been since the last alleged malfunction of the PrimAlert wall mounted survey. One of the three technologists stated that the PrimAlert wall mounted survey had not malfunctioned since she started work in May of 1991. The physicist and the physician at IRCC stated that they had not been informed of any problem with the PrimAlert wall mounted survey. Each morning the PrimAlert wall mounted survey is checked as part of the start-up procedures. There is no indication of malfunction at or near the time of the incident. The medical physicist checks the PrimAlert wall mounted survey regularly by three separate tests: a check source, the linear accelerator and the HDR unit.

Patients at IRCC were surveyed using the wall mounted monitor. The fact that the NRC survey regulation was modified in December of 1992 to require a hand held survey and the fact that

NRC regulators in Regions I and III did not read the November, 1992 regulations to require a hand held survey shows that the NRC's position about regulatory violations is incorrect.

Although this unfortunate incident should not have happened, the incident did not result from a lack of safety culture or training at the IRCC or at OSC.

NRC Regulatory Oversight

The NRC concedes in this report that the relevant sections of 10 CFR Part 35 do not specifically recognize HDR brachytherapy or provide any requirements specifically for HDR Brachytherapy. Regulatory guide 10.8 referenced as a guide for medical users also has no guidance for high dose rate users. OSC's independent auditors have concluded that overall regulatory oversight is weak and very confusing when applied to HDR afterloaders. The fact that the NRC insisted in the license that only Omnitron provide training compounds, the problem in that the Omnitron training may have undercut basic common sense radiation safety by stressing that the computer console should be relied on. This problem with NRC oversight exists despite the fact that the NRC has been licensing users for high dose rate units for over ten years. The NRC is presently trying to stretch the meaning of ambiguous regulations which its own regulators feel did not apply to HDR Brachytherapy to cover the fact that there was little regulatory guidance for the event at IRCC and what existed was confused and misleading.

CONCLUSION

OSC hired independent consultant-auditors both with extensive experience in medical radiation, NRC licensing and HDR

Brachytherapy to review the issues raised in the IIT report. In addition, its own investigations supplied information used to formulate this Response. The response is incomplete because OSC was refused access to the IIT's materials and interviews collected during the IIT investigation.

OSC greatly regrets the unfortunate incident in Indiana, the death of the subject patient and the exposure of others in the community to radiation. It does not believe any regulatory violations occurred or contributed to the event.

OSC reserves the right to supplement this response when the IIT materials are released.

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

March 23, 1993

Ms. Kerry A. Kearney
Reed Smith Shaw & McClay
435 Sixth Avenue
Pittsburgh, PA 15219-1886

Dear Ms. Kearney:

We have received your letter of March 5, 1993, to James M. Taylor, Nuclear Regulatory Commission (NRC), transmitting Oncology Services Corporation's response to the NRC Incident Investigation Team (IIT) Report on the November 16, 1992 incident at the Indiana Regional Cancer Center, Indiana Pennsylvania (NUREG-1480). We understand that you may provide additional comments at some later date. The response has been evaluated by the NRC, and it was concluded that no new or additional information was provided to form the basis for revising the IIT report. In accordance with the NRC's rules of practice, a copy of your March 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

cc: Douglas Colkitt, M.D.
Marcy Colkitt, Esquire

ENCLOSURE 2