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

OFFICE OF THE
GENERAL COUNSEL

June 8, 1998

Charles Bechhoefer, Chairman
Administrative Judge
Atomic Safety and Licensing Board
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dr. Peter S. Lam
Administrative Judge
Atomic Safety and Licensing Board
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dr. Jerry R. Kline
Administrative Judge
Atomic Safety and Licensing Board
U.S. Nuclear Regulatory Commission
Washington, DC 20555

In the Matter of
AHARON BEN-HAIM, Ph.D.
Docket No. IA 97-068

Dear Administrative Judges:

During the administrative hearing in the above-captioned matter, on May 29, 1998, the Atomic Safety and Licensing Board directed the staff of the Nuclear Regulatory Commission to produce a document referenced during the examination of a staff witness. The document was a letter relaxing an order that was based upon a violation of 10 CFR § 30.10. Tr. 758, 759, 763-765.

Enclosed please find in response to the Board's directive a September 18, 1995, "Order Prohibiting Involvement in NRC- Licensed Activities (Effective Immediately)," issued against Dr. Hung Yu, together with a March 7, 1996, relaxation of that order.

Sincerely,

Catherine L. Marco

Catherine L. Marco
Counsel for NRC Staff

Enclosures: As stated

cc w/encl.: Service List
Aharon Ben-Haim, Ph.D.

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

September 18, 1995

IA 95-037

Dr. Hung Yu
[Home address deleted from
copies pursuant to 10 CFR 2.790]

Dear Sir:

SUBJECT: ORDER PROHIBITING INVOLVEMENT IN NRC-LICENSED ACTIVITIES (EFFECTIVE IMMEDIATELY)

The enclosed Order is being issued because of your violation of 10 CFR 30.10 of the Commission's regulations, as described in the Order.

Failure to comply with the provisions of this Order may result in civil or criminal sanctions.

Questions concerning this Order should be addressed to Mr. James Lieberman, Director, Office of Enforcement, who may be reached at (301) 415-2741.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and the enclosure will be placed in the NRC's Public Document Room.

Sincerely,

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards
and Operations Support

Enclosure: As stated

cc:
Madigan Army Medical Center
State of Washington Radiation Control Program

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UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	IA 95-037
Dr. Hung Yu	)	

ORDER PROHIBITING INVOLVEMENT
IN NRC-LICENSED ACTIVITIES
(EFFECTIVE IMMEDIATELY)

I

Dr. Hung Yu was employed by the Department of the Army at its Madigan Army Medical Center, Fort Lewis (Tacoma, Washington). Madigan Army Medical Center (Licensee) holds License No. 46-02645-03 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Parts 30 and 35 on May 12, 1960. The license authorizes possession and use of byproduct material in accordance with the conditions specified therein.

Dr. Yu was employed by the Licensee from approximately October 1993 to August 2, 1995, as a medical physicist. During his employment with the Licensee, Dr. Yu reported to the Chief, Radiation Therapy Service, and was responsible for supervising a radiation dosimetrist. Among other tasks, Dr. Yu was responsible for all dosimetry, including developing treatment plans, evaluating the adequacy and accuracy of the treatment plan for each brachytherapy treatment, and modifying treatment plans as required by authorized users. Dr. Yu was also responsible for performing the duties of a radiation therapy dosimetrist, as needed, and directing all physics aspects of intracavitary and interstitial implants. The latter responsibilities included ordering and accepting or receiving brachytherapy sources, source preparation and related quality assurance tasks, and computer calculations, including providing calibration and decay factors for brachytherapy sources. In his

role as a medical physicist who supervised a dosimetrist, Dr. Yu was additionally responsible for ensuring that the dosimetrist's activities were also in compliance with NRC regulations and the Licensee's procedures and Quality Management Program.

II

On June 2, 1995, the Licensee notified the NRC of a misadministration which occurred on May 10, 1995, but had gone unrecognized by the Licensee until June 2, 1995. This finding prompted a review by the Licensee which identified additional misadministrations. On June 8, 1995, the Licensee reported three misadministrations which occurred on February 9 and August 23, 1994, and January 11, 1995. On June 12, 1995, an additional misadministration was reported to have occurred on February 3, 1995. The misadministrations all involved brachytherapy implants using iridium-192 sealed sources, and each treatment was performed in accordance with a treatment plan developed by Dr. Yu or under his direction.

The NRC began an inspection of the events on June 6, 1995. An investigation by the NRC's Office of Investigations (OI) was initiated on June 13, 1995. Both the NRC inspection and NRC investigation are ongoing. The Licensee initiated an internal investigation of the misadministrations and related issues on June 2, 1995, and provided the NRC with a written report of its investigation on August 22, 1995. The NRC inspection and investigation demonstrate that the cause of the misadministrations was an input error of one parameter used by the computerized treatment planning system to calculate dose

rates for treatment plans. Specifically, Dr. Yu had instructed the dosimetrist to use a value, for a "calibration factor" used by the system to calculate dose rates, which was not calculated according to the computer system manufacturer's instructions.

NRC's interviews of Dr. Yu and other Licensee personnel establish that on June 2, 1995, Dr. Yu engaged in deliberate misconduct in violation of 10 CFR § 30.10(a)(2) by deliberately providing inaccurate information to the Licensee on a matter material to the NRC, specifically the dose calculation error that caused the May 10, 1995 misadministration. In response to repeated questions on June 2, 1995, by the Radiation Safety Officer (RSO), and in the presence of the authorized user (also the Chief, Radiation Therapy Service), regarding the cause of the May 10, 1995 misadministration, Dr. Yu stated that it was a "computer error," that "it was hardware error," and that it was a "software error." Dr. Yu's statements to the Licensee were deliberately inaccurate because on May 16, 1995, Dr. Yu was made aware by the computer system manufacturer that his data entry error (i.e., input error) to the treatment planning system was the cause for the dose calculation errors and, immediately after being informed of his error, Dr. Yu began to correctly enter the calibration factor. Only after the RSO stated that he had discussed the treatment plan calculations with the dosimetrist did Dr. Yu explain that the cause of the misadministration was his use of an erroneous input parameter. Dr. Yu's provision of inaccurate information to the RSO and Chief, Radiation Therapy Service, regarding the cause of the dose calculation error associated with the May 10, 1995 misadministration interfered with the Licensee's

investigation required by 10 CFR 35.21(b)(1) of potential misadministrations.

Furthermore, in violation of 10 CFR 30.10(a)(1), Dr. Yu engaged in deliberate misconduct which caused the Licensee to be in violation of NRC requirements including: (1) 10 CFR 20.1906(b), which requires, in part, that upon receipt of labelled packages containing brachytherapy sources, the packages be tested for contamination; (2) 10 CFR 20.2103(a), which requires, in part, that each licensee maintain records showing the results of surveys required by 10 CFR 20.1906(b); and (3) 10 CFR 30.9 which requires, in part, that information required to be maintained by the Commission's regulations shall be complete and accurate in all material respects. For example, Dr. Yu, when questioned about the package survey results of August 19, 1994, admitted to an NRC inspector and OI investigator that he had failed to perform NRC-required package receipt surveys for radioactive contamination and that he had deliberately completed Licensee records to falsely reflect that the contamination surveys had been performed. Dr. Yu stated that, although he was aware of the NRC requirement to perform the survey, he did not believe that the survey was important, that it was just a requirement and a formality and, therefore, he just recorded that the survey had been conducted.

III

Although the NRC investigation is continuing, based on the information developed to date, the NRC concludes that Dr. Yu engaged in deliberate misconduct: (1) in violation of 10 CFR 30.10(a)(2), by knowingly providing to the Licensee on June 2, 1995, inaccurate information relating to a matter

material to the NRC, specifically the cause of the error that resulted in the misadministration; and (2) in violation of 10 CFR 30.10(a)(1), which caused the Licensee to be in violation of NRC requirements, including 10 CFR 20.1906(b), 10 CFR 20.2103(a), and 10 CFR 30.9(a), by deliberately failing to conduct surveys of labelled packages containing brachytherapy sources and deliberately making entries to Licensee records to show that he had conducted such surveys.

The NRC must be able to rely on the Licensee and its employees to comply with NRC requirements, including the requirement to provide information and maintain records that are complete and accurate in all material respects. Dr. Yu's actions in causing the Licensee to violate NRC requirements and his misrepresentations to the Licensee have raised serious doubt as to whether he can be relied upon to comply with NRC requirements and to provide complete and accurate information to NRC licensees. Further, Dr. Yu has demonstrated an unwillingness to comply with NRC requirements necessary for the protection of the health and safety of personnel and patients affected by the areas of his responsibility. Dr. Yu's deliberate false statements to Licensee officials concerning radiological exposure to patients and his deliberate violation of NRC requirements is not acceptable conduct for a person engaged in NRC-licensed activities.

Consequently, I lack the requisite reasonable assurance that licensed activities can be conducted in compliance with the Commission's requirements and that the health and safety of the public would be protected if Dr. Yu were permitted at this time to be involved in any NRC-licensed activities.

Therefore, the public health, safety and interest require, pending completion of the investigation and further action by the NRC, that Dr. Yu be prohibited from involvement in licensed activities. Furthermore, pursuant to 10 CFR 2.202, I find that the significance of the conduct described above is such that the public health, safety and interest require that this Order be immediately effective.

IV

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, 10 CFR 30.10, and 10 CFR 150.20, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT:

> Pending further investigation and order by the NRC, Hung Yu, Ph.D. is prohibited from participation in any respect in NRC-licensed activities. For the purposes of this paragraph, NRC-licensed activities include licensed activities of: 1) an NRC licensee, 2) an Agreement State licensee conducting licensed activities in NRC jurisdiction pursuant to 10 CFR 150.20, and 3) an Agreement State licensee involved in distribution of products that are subject to NRC jurisdiction.

The Director, Office of Enforcement, may, in writing, relax or rescind any of the above conditions upon demonstration by Dr. Yu of good cause.

V

In accordance with 10 CFR 2.202, Hung Yu, Ph.D. 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. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission Washington, D.C. 20555, and include a statement of good cause for the extension. 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 shall set forth the matters of fact and law on which Hung Yu, Ph.D. or other person adversely affected relies and the reasons as to why the 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 also shall 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 IV, Suite 400, 611 Ryan Plaza, Arlington, Texas 76011, and to Hung Yu, Ph.D., if the answer or hearing request is by a person other than Hung Yu, Ph.D. If a person other than Hung Yu, Ph.D. requests a hearing, that person shall set forth with particularity the manner in which his or her 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 Hung Yu, Ph.D. 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), Hung Yu, Ph.D., 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, or written approval of an extension of time in which to request a hearing, the provisions specified in Section IV above shall be final 20 days from the date of this Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section IV shall be final when the extension expires if a hearing request has not been received. AN ANSWER OR A REQUEST FOR HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS OF THIS ORDER.

FOR THE NUCLEAR REGULATORY COMMISSION

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards,
and Operations Support

Dated at Rockville, Maryland
this 18th day of September 1995

Dr. Hung Yu

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

March 7, 1996

IA 95-037

Hung Yu, Ph.D.
[Home Address Deleted
10 CFR 2.790]

SUBJECT: RELAXATION OF ORDER PROHIBITING INVOLVEMENT IN NRC-LICENSED ACTIVITIES (EFFECTIVE IMMEDIATELY)

Dear Dr. Yu:

This refers to our Order Prohibiting Involvement in NRC-Licensed Activities (Effective Immediately) issued on to you on September 18, 1995, which prohibited you from participating in NRC-licensed activities, pending further investigation and order by the NRC.

On February 22, 1996, the NRC issued to you a letter which stated that the NRC would relax the September 18, 1995 order provided that you certify to the Commission that you will become knowledgeable of and comply with all NRC requirements, should you engage in NRC-licensed activities in the future. The NRC received your certification dated February 27, 1996. (A copy of the NRC letter and your certification are enclosed.)

Accordingly, pursuant to Section IV of the September 18, 1995 Order, and for the reasons stated in the February 22, 1996 NRC letter to you, I find that good cause is demonstrated to relax the Order and allow you to engage in NRC-licensed activities, and I hereby relax the Order.

You are now on clear notice that similar failure to comply with NRC requirements in the future may subject you to significant enforcement action.

If you have any questions, please me at (301) 415-2741.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, records or documents compiled for enforcement purposes are placed in the NRC Public Document Room (PDR). A copy of this letter will be placed in the PDR with your home address removed.

Sincerely,

James Lieberman, Director
Office of Enforcement

Enclosures: As Stated.

cc: State of Washington Radiation Control Program
Madigan Army Medical Center

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064
February 22, 1996

IA 95-037

Hung Yu, Ph.D.
[Home Address Deleted
10 CFR 2.790]

SUBJECT: NRC INSPECTION REPORT 030-03368/95-01 AND NRC INVESTIGATION REPORT 4-95-027

Dear Dr. Yu:

This refers to the NRC inspection and investigation which took place from June 6 through December 21, 1995, and to the transcribed predecisional enforcement conference conducted between the NRC and yourself on January 17, 1996. The inspection and investigation were conducted in response to the Madigan Army Medical Center (MAMC), your former employer, identification of medical misadministrations involving the use of NRC-licensed brachytherapy sources, which MAMC first reported to the NRC on June 2, 1995.

Based on preliminary findings of the inspection and investigation, the NRC concluded that you had engaged in deliberate misconduct by: (1) knowingly providing to MAMC on June 2, 1995, inaccurate information relating to a matter material to the NRC, specifically the cause of the error that resulted in a misadministration, in violation of 10 CFR 30.10(a)(2); and (2) deliberately failing to conduct surveys of packages containing brachytherapy sources and deliberately making entries to MAMC records to show that you had conducted such surveys, in violation of 10 CFR 30.10(a)(1). As a result, the NRC issued to you on September 18, 1995, an Order Prohibiting Involvement in NRC-Licensed Activities (Effective Immediately) which prohibited you from participating in NRC-licensed activities, pending further investigation and order by the NRC.

During the January 17, 1996 conference, you admitted that you provided inaccurate information to MAMC officials. However, you denied that you were trying to cover up the cause of the misadministrations. In addition, you stated that you were trying to "get rid of them [the radiation safety officer and authorized user] out of the office" because: (1) you wanted to continue practicing the multidata training you had received on June 1, 1995; (2) you were in a very bad mood; and (3) you thought that the medical consequences of the most recent misadministration was not important. You also admitted that you deliberately failed to conduct surveys of labelled packages containing brachytherapy sources.

Furthermore, you admitted that you inappropriately made the judgment that the clinical consequences of the most recent misadministration were not significant, rather than immediately informing the authorized user and RSO

about the cause of the misadministration so that appropriate actions could be taken. You also stated that, as a result of your actions, you had learned a very important lesson and would not engage in similar misconduct in the future. Moreover, you stated that should you engage in NRC-licensed activities in the future, you would study all computer manufacturer's manuals to ensure that similar errors and misadministrations do not recur.

Based on the statements you provided the NRC during the transcribed conference, we have concluded that you now: (1) understand the unacceptability of your actions; (2) realize the importance of providing the NRC complete and accurate information; (3) recognize your attitude was inappropriate; and (4) appreciate the need to comply with NRC requirements. In addition, the NRC has concluded, after conducting a predecisional enforcement conference with your former employer on January 18, 1996, that your former employer bears some of the responsibility for your actions because of its failure to provide you adequate quality management program training.

Therefore, in view of your statements, the circumstances surrounding this case, the five-month NRC prohibition, and the substantial disciplinary action, i.e., suspension from work activities, taken against you by your former employer, the NRC has determined that we should relax the September 18, 1995 order provided that you certify, as noted on Page 4 of this letter, to the Commission that you will become knowledgeable of and comply with all NRC requirements, should you engage in NRC-licensed activities[1] in the future. The NRC will relax the order, and allow you to engage in NRC-licensed activities, upon receipt of this letter with your signature and certification, under oath or affirmation. You should return the letter to Mr. James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738. You will be notified by mail when the order is relaxed.

You should note that you may be subject to significant civil or criminal action if you exhibit similar conduct in any future NRC-licensed activity.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, records or documents compiled for enforcement purposes are placed in the NRC Public Document Room (PDR). A copy of this letter will be placed in the PDR with your home address removed.

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[1] NRC-licensed activities include licensed activities of: 1) an NRC licensee, 2) an Agreement State licensee conducting licensed activities in NRC jurisdiction pursuant to 10 CFR 150.20, and 3) an Agreement State licensee involved in distribution of products that are subject to NRC jurisdiction.

If you have any questions, please contact Mr. Gary Sanborn at (817) 860-8222.

Sincerely,

L. J. Callan
Regional Administrator

cc:
State of Washington

I, Hung Yu, Ph.D., hereby certify that I have read the above letter and fully understand its contents, and that, if I engage in the future in any NRC-licensed activities, I will become knowledgeable of and comply with all applicable NRC requirements, including the requirement to provide complete and accurate information to both the licensee and NRC. I also understand that failure to meet NRC requirements may subject me to civil or criminal sanctions.

Hung Yu

Hung Yu, Ph.D.

Subscribed and sworn to (or affirmed) before me this 27th day of February, 1996

Sharon L Carnes

Notary Public

Comm. Expires 8-1-96