



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, DC 20555 - 0001**

October 22, 2002

IA 02-018

Mr. Kenneth M. Baab  
**HOME ADDRESS DELETED  
UNDER 2.790**

**SUBJECT: ORDER PROHIBITING INVOLVEMENT IN NRC-LICENSED ACTIVITIES  
(EFFECTIVE IMMEDIATELY)  
(NRC Office of Investigations Report No. 1-2001-034)**

Dear Mr. Baab:

The enclosed Order Prohibiting Involvement in NRC-Licensed Activities is being issued to you based on the findings by the NRC Office of Investigations (OI) that you deliberately caused your employer, Advanced Medical Imaging and Nuclear Services (AMINS), to be in violation of NRC requirements. The synopsis of the investigation was sent to you on May 21, 2002. The violations, which occurred while you were in the position of Vice President at AMINS, are described in the enclosed Order to you, as well as the enclosed Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$43,200 being issued on this date to AMINS.

A predecisional enforcement conference was held with AMINS on June 17, 2002, to discuss the violations, their causes, and AMINS corrective actions. You participated in that conference as an AMINS employee. You were also provided an opportunity to attend an individual conference, since the NRC had informed you in our May 21, 2002 letter, that the NRC was considering enforcement action against you. You declined to participate in an individual conference, noting that you had the opportunity to express your views during the conference you attended with AMINS. At that conference, you acknowledged the violations, but denied your actions were deliberate.

Notwithstanding your denial, the NRC, after careful review and for the reasons set forth in the enclosed Order, has concluded that your actions were deliberate. Therefore, your actions constitute violations of 10 CFR 30.10(a)(1) which prohibits an employee of a licensee from engaging in deliberate misconduct that causes a licensee to be in violation of any rule, regulation, order, or condition of the license. Your actions caused AMINS, an NRC licensee, to be in violation of: (1) 10 CFR 35.11, which requires, in part, that a person shall not use byproduct material for medical use except in accordance with a specific license or under the supervision of an authorized user as provided in 10 CFR 35.25; (2) 10 CFR 35.21(a), which requires a licensee to appoint a Radiation Safety Officer responsible for implementing the radiation safety program; and (3) 10 CFR 30.9, which requires that information required by the license to be maintained shall be complete and accurate in all material respects.

The Order prohibits your involvement in licensed activities for one year; however, since the NRC suspended the license of your employer (AMINS) on December 14, 2001, during which time you were not involved in licensed activities, the prohibition period will begin retroactively on December 14, 2001, and end on December 14, 2002. You are also required to provide an answer to the Order within 20 days of the date of this letter. Pursuant to Section 223 of the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2273, any person who willfully violates, attempts to violate, or conspires to violate any provision of this Order shall be subject to criminal prosecution as set forth in that section.

Questions concerning this Order may be addressed to Frank Congel, Director, Office of Enforcement. Mr. Congel can be reached at telephone number (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 with your home address removed will be placed in the NRC's Public Document Room.

Sincerely,

/RA/

Carl J. Paperiello  
Deputy Executive Director  
for Materials, Research and State Programs

Enclosure: (1) Order Prohibiting Involvement in NRC-Licensed Activities (Effective Immediately)  
(2) Notice of Violation and Proposed Imposition of Civil Penalty to Advanced Medical Imaging and Nuclear Services

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Commonwealth of Pennsylvania

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Enclosure

UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION

In the Matter of )

MR. KENNETH M. BAAB )

) IA 02-018  
)  
)

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

I

Mr. Kenneth M. Baab (Mr. Baab) is Vice President of Advanced Medical Imaging and Nuclear Services (AMINS). AMINS is the holder of Byproduct Nuclear Material License No. 37-30603-01 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 30. The license authorizes AMINS to possess and use any byproduct material listed in 10 CFR 35.100 and 10 CFR 35.200. The license was issued on February 16, 2001, and is due to expire on February 28, 2011.

II

On November 30, 2001, the NRC conducted an inspection at AMINS. During the inspection, violations of NRC requirements were identified. The most significant violations involved the receipt, possession, and use of NRC licensed material between March 2001 and November 2001, without an Authorized User (AU) and Radiation Safety Officer (RSO) at the facility, contrary to 10 CFR 35.11(a) and 10 CFR 35.21. As a result of this finding, the NRC issued a Confirmatory Action Letter (CAL) on December 3, 2001, confirming AMINS commitment, in part, to: (1) immediately place all byproduct material in its possession in secured storage; and

(2) cease all licensed activities until AMINS retained an AU and RSO, and received approval (via a license amendment from the NRC) for the changes to bring the licensee's program into full compliance with 10 CFR Part 35. The NRC subsequently issued an Order Suspending the license on December 14, 2001, as well as a Demand for Information on December 21, 2001, requesting information, in part, as to why the license should not be revoked.

Between December 5, 2001 and March 27, 2002, the NRC Office of Investigations conducted an investigation of activities at the AMINS facility. During the investigation, the NRC determined that, (1) Mr. Babb, the AMINS Vice President (VP), and another individual (the Chief Operating Officer (COO)) operated the AMINS facility with the knowledge that the facility did not have an AU and RSO in deliberate violation of NRC regulations; (2) Mr. Babb and the COO knowingly caused false and misleading information to be provided to a radiopharmaceutical company to acquire the radiopharmaceuticals needed for diagnostic testing of AMINS patients; and (3) the records maintained by AMINS were inaccurate, since they named a physician as the AU, when, in fact, the individual was not acting as the AU. The evidence to support these conclusions include:

- The AMINS VP prepared the NRC license application in October 2000, with the aid of a consulting physicist, and named an individual as the AU and RSO on the application; however, the individual named on the application stated that he was never employed by AMINS and never performed the duties of the AU and RSO at AMINS.
- In March 2001, AMINS staff began performing licensed activities, including ordering and administering radiopharmaceuticals to patients on approximately 590 occasions

between June 2001 and November 2001, using the name of an individual as the requesting AU who, in fact, was not the AU and had never been hired by AMINS.

- In October 2001, a consulting physicist conducted an audit that revealed that the duties of the AU/RSO had not been performed, and he briefed Mr. Babb and the COO regarding the problem at the end of the audit, yet NRC licensed activities continued until the NRC inspection on November 30, 2001.
- Mr. Babb, when interviewed by the OI investigator, admitted that he knew the facility was required to have an AU and RSO and knew that it was a problem in June 2001, but Mr. Babb did not take action to cease all licensed activities. In addition, he admitted to the OI investigator that there were financial considerations associated with keeping the facility open.

### III

The NRC's requirements in 10 CFR 30.10(a)(1) prohibit an employee of a licensee from engaging in deliberate misconduct that causes or, but for detection, would have caused, a licensee to be in violation of any rule, regulation, or order, or any term, condition, or limitation of

any license, issued by the Commission. 10 CFR 35.11 requires, in part, that a person shall not use byproduct material for medical use except in accordance with a specific license or under the supervision of an authorized user as provided in 10 CFR 35.25. 10 CFR 35.21(a) requires that a licensee shall appoint a Radiation Safety Officer responsible for implementing the radiation safety program. Further, 10 CFR 30.9 requires, in part, that information required to be maintained by the license shall be complete and accurate in all material respects.

Based on the inspection and investigation, the NRC has concluded that Mr. Baab, as the VP of AMINS, violated 10 CFR 30.10. Specifically, Mr. Baab violated 10 CFR 30.10(a)(1) in that he engaged in deliberate misconduct that caused the Licensee to violate NRC requirements by: (1) operating the AMINS facility without an AU, contrary to 10 CFR 35.11; (2) operating the AMINS facility without an RSO, contrary to 10 CFR 35.21(a); and (3) maintaining inaccurate records, contrary to 10 CFR 30.9, in that the records (which were used to order the radioactive material from a radiopharmacy) indicated that the material was being ordered by a physician listed as the AU, when in fact, the individual had never been employed by the licensee. The violations are significant because, by allowing licensed activities to continue even though he knew that AMINS did not have an AU and RSO, Mr. Babb's actions created the potential for unnecessary radiation exposures to workers and members of the public.

#### IV

The NRC must be able to rely on the Licensee, and Licensee employees, to comply with NRC requirements, including the requirement to provide information that is complete and accurate in all material respects. Mr. Baab's deliberate violation of Commission regulations raises serious

questions as to whether he can be relied upon to comply with NRC requirements including the maintenance of complete and accurate information.

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 Kenneth M. Baab were permitted at this time to be involved in NRC-licensed activities. Therefore, the NRC has determined that the public health, safety and interest require that Kenneth M. Baab be prohibited from any involvement in NRC-licensed activities for a period of one year. Since licensed activities at AMINS ceased on December 14, 2001, with the NRC issuance of the Order Suspending License, and since Mr. Babb has not been involved in licensed activities since that time, the one-year prohibition period will retroactively begin on December 14, 2001, and end on December 14, 2002. However, if Kenneth M. Baab is currently involved in NRC-licensed activities at any NRC licensed facility, Mr. Baab must immediately cease such activities, and inform the NRC of the name, address and telephone number of the employer, and provide a copy of this Order to the employer. Additionally, Mr. Baab is required to notify the NRC of his first employment in NRC-licensed activities following the one-year prohibition period.

Pursuant to 10 CFR 2.202, I find that the significance of Mr. Baab's conduct described above is such that the public health, safety and interest require that this Order be immediately effective.

Accordingly, pursuant to Sections 81, 161b, 161i, 161o, 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:

1. Kenneth M. Baab is prohibited from engaging in NRC-licensed activities for one year effective from December 14, 2001. NRC-licensed activities are those activities that are conducted pursuant to a specific or general license issued by the NRC, including, but not limited to, those activities of Agreement State licensees conducted pursuant to the authority granted by 10 CFR 150.20.
2. If Kenneth M. Baab is currently involved in NRC-licensed activities, Mr. Baab must immediately cease such activities, and inform the NRC of the name, address and telephone number of the employer, and provide a copy of this Order to the employer.
3. For a period of one year after the one-year period of prohibition has expired, Mr. Baab shall, within 20 days of his acceptance of each employment offer involving NRC-licensed activities, as defined in Paragraph V.1 above, provide notice to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, of the name, address, and telephone number of the employer or the entity where he is, or will be, involved in the NRC-licensed activities. In the first notification, Mr. Baab shall include a statement of his commitment to compliance with regulatory requirements and the basis why the Commission should have confidence that he will now comply with applicable NRC requirements.

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

## VI

In accordance with 10 CFR 2.202, Kenneth M. Baab 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 Mr. Baab 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, Rulemakings and Adjudications Staff, Washington, D.C. 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, to the Assistant General Counsel for Materials Litigation and Enforcement at the same address, to the Regional Administrator, NRC Region I, U.S. Nuclear Regulatory, 475 Allendale Road, King of Prussia, Pennsylvania 19406, and to Mr. Baab if the answer or hearing request is by a person other than Mr. Baab. Because of continuing disruptions in delivery of mail to United States Government offices, it is requested that answers and requests for hearing be transmitted to the Secretary of the Commission

either by means of facsimile transmission to 301-415-1101 or by e-mail to [hearingdocket@nrc.gov](mailto:hearingdocket@nrc.gov) and also to the Assistant General Counsel either by means of facsimile transmission to 301-415-3725 or by e-mail to [OGCMailCenter@nrc.gov](mailto:OGCMailCenter@nrc.gov). If a person other than Mr. Baab 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 C.F.R. § 2.714(d).<sup>1</sup>

If a hearing is requested by Mr. Baab 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 C.F.R. § 2.202(c)(2)(i), the licensee 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 V above shall be final twenty (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 V shall be final

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<sup>1</sup>The most recent version of Title 10 of the Code of Federal Regulations, published January 1, 2002, inadvertently omitted the last sentence of 10 C.F.R. 2.714(d) and paragraphs (d)(1) and (2), regarding petitions to intervene and contentions. For the complete, corrected text of 10 CFR 2.714(d), please see 67 FR 20884; April 29, 2002.

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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

/RA/

Carl J. Paperiello,  
Deputy Executive Director  
for Materials, Research, and State Programs

Dated this 22<sup>nd</sup> day of October 2002