UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

In the Matter of	)	
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AHARON BEN-HAIM, Ph.D.	)	IA 97-068
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NRC STAFF'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

Catherine Marco
Counsel for NRC Staff

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I. BACKGROUND AND INTRODUCTION

1. These findings and rulings address all issues in the above-captioned proceeding concerning the August 27, 1997, "Order Superseding Order Prohibiting Involvement in NRC-Licensed Activities (Effective Immediately)," (Order) that the staff of the Nuclear Regulatory Commission (Staff) issued to Dr. Aharon Ben-Haim. 62 Fed. Reg. 47,224 (1997). The Order prohibits Dr. Ben-Haim from any involvement in NRC-licensed activities for five years from July 31, 1997. *Id.* at 47,225.

2. For the reasons described herein, we sustain the Staff's Order. The evidence supports a conclusion that Dr. Ben-Haim deliberately caused the licensee, Newark Medical Associates (NMA), to be in violation of several of the Commission's requirements, and that the five year prohibition against Dr. Ben-Haim is appropriate and justified.

3. The August 27, 1997, Order superseded in its entirely an order issued to Dr. Ben-Haim on July 31, 1997. *See* "Order Prohibiting Involvement in NRC-Licensed Activities (Effective Immediately) Pending Further Order," 62 Fed. Reg. 43,357 (1997).

4. On August 19, 1997, Dr. Ben-Haim filed an answer to the initial order in which he requested a hearing and sought rescission of the immediate effectiveness of the order. Letter from Dr. Aharon Ben-Haim to Edward Jordan, Deputy Executive Director for Regulatory Effectiveness, dated August 19, 1997. On September 8, 1997, the Staff responded to Dr. Ben-Haim's answer to the initial order, treating it as applicable to the Superseding Order. "NRC Staff's Response to Request to Set Aside Immediate Effectiveness of Order Superseding Order Prohibiting Involvement in NRC-Licensed Activities," dated September 8, 1997.

5. On August 25, 1997, this Atomic Safety and Licensing Board (Board) was established to preside in this proceeding. 62 Fed. Reg. 46,381 (1997). On September 11, 1997, the Board issued a "Memorandum and Order (Granting Request for Hearing and Scheduling Prehearing Conference)," in which it granted Dr. Ben-Haim's request for a hearing and scheduled a prehearing conference to hear oral argument on the rescission of the immediate effectiveness of the Order and to establish hearing schedules.

6. At the September 18, 1997, prehearing conference, the Board orally ruled that it would uphold the immediate effectiveness of the Order. Tr. 36. This ruling was memorialized by order dated September 25, 1997. *Aharon Ben-Haim, Ph.D.* (Upper Montclair, New Jersey), LBP-97-15, 46 NRC 60 (1997).

7. On September 30, 1997, the Staff filed "NRC Staff's Motion for Delay of Proceeding" at the request of the United States Department of Justice (DOJ). The Staff's motion

for a 120-day delay of the proceeding was based on the pendency of a criminal investigation concerning allegations of possible violations of federal criminal law by Newark Medical Associates (NMA), its owners and employees, including its consultant, Dr. Ben-Haim. The Staff's motion was supported by an affidavit from an assistant United States attorney in the United States Attorney's Office for the District of New Jersey. Dr. Ben-Haim wrote a letter on October 15, 1997, stating that he did not oppose the Staff's motion. Letter from Evert W. Van Kampen, Esq., to Catherine Marco, Esq., dated October 15, 1997. On October 22, 1997, the Board granted the Staff's motion. *Aharon Ben-Haim, Ph.D.* (Upper Montclair, New Jersey), LBP-97-18, 46 NRC 234 (1997).

8. On January 28, 1998, the Staff filed its intention not to seek a further delay of proceedings based on DOJ's determination that, while a related investigation was still continuing, it was not in the best interest of the government to extend the delay. Letter from Ann P. Hodgdon to Administrative Judges, dated January 28, 1998.[1] On March 2, 1998, after seeking a proposed schedule from the parties, the Board issued a "Memorandum and Order (Schedules for Proceeding)," in which the Board established a discovery and a hearing schedule. In accordance with the Board's schedules, litigation went forward, with the filing of interrogatories and document requests, and deposition discovery.

9. A public hearing was held in Newark, New Jersey from May 27, 1998 to May 29, 1998. Following the public hearing, on June 4, 1998, the Board issued a "Memorandum and Order (Telephone Conference, 6/3/98; Proposed Findings)" (Telephone Conference Order) in which the

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[1] On April 23, 1998, the Staff informed the Board and Dr. Ben-Haim that DOJ declined prosecution in the matter of Newark Medical Associates. Letter from Ann P. Hodgdon to Administrative Judges, dated April 23, 1998.

Board established August 14, 1998, as the date by which the Staff would file its proposed filings and August 31, 1998, as the date by which Dr. Ben-Haim's findings must be filed.[2]

II. FINDINGS OF FACT

A. Background

(1) Witness Synopsis

10. In support of its Order, the Staff presented the testimony of nine individuals. These witnesses were: Richard Gibson, the NRC Staff inspector who had conducted an inspection of NMA in January 1997 (Qualifications, ff. Tr. 72); John Kinneman, Chief of Nuclear Materials Safety Branch 2, Region I (Qualifications, ff. Tr. 73); Dr. Barry Siegel, Professor of Radiology and Medicine/ Director, Division of Nuclear Medicine, Mallinckrodt Institute of Radiology, Washington University School of Medicine (Qualifications, ff. Tr. 358); Ernest Wilson, Special Agent, Office of Investigations, Region I (Qualifications, ff. Tr. 540); William Davis, Special Agent, Office of Investigations, Region I (Qualifications, ff. Tr. 540); Dr. Gerard Moskowitz, the individual listed on NMA's license as the Radiation Safety Officer (RSO) and authorized user (Qualifications, ff. Tr. 215); Lubica Smoligova, an MRI technologist who ordered radiopharmaceuticals for NMA; Marina Geylikman, a nuclear medical technologist who performed bone scans for NMA; and Joseph DelMedico, Senior Enforcement Specialist, Office of Enforcement (Qualifications, ff. Tr. 659).

11. Dr. Ben-Haim presented himself as a witness (Qualifications, B-H Exh. 5-Exh. 11). In addition, witnesses Marina Geylikman, Lubica Smoligova, and Dr. Moskowitz had been

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[2] The Staff was given until September 11, 1998 to file reply findings.

designated as witnesses for both Dr. Ben-Haim and the Staff. *See* Memorandum and Order (Telephone Conference, May 12, 1998), dated May 13, 1998 at 3.

(2) The Licensee, Newark Medical Associates

12. NMA is the holder of an NRC byproduct materials license that was issued on September 26, 1996. *See* Tr. 77 (testimony of NRC inspector, Richard Gibson). *See also* Staff Exh. 1 (NRC Materials License No. 29-30282-01, dated September 25, 1996). The license authorizes the possession and use of byproduct material for imaging and localization procedures conducted at NMA's facilities located at 810 Broad Street, Newark, New Jersey. Staff Exh. 1.

13. NMA's president, Dr. Magdy Elamir, signed NMA's February 21, 1996 application for its NRC license. *See* Staff Exh. 2 (NRC Form 313, Application for Material License, dated February 21, 1996); Tr. 80.

14. The license lists Gerard W. Moskowitz, M.D. as the RSO and the authorized user. Staff Exh. 1 at ¶¶ 12, 13; Tr. 78.

(3) The NRC Inspection and Subsequent Licensing Actions

15. Mr. Gibson testified that he conducted an inspection of Newark Medical Associates in Newark, New Jersey in early 1997. Tr. 77. It was an initial inspection of a new licensee. Tr. 77. Mr. Gibson testified that the purpose of the inspection was to assess the licensee's compliance with the regulations and with the license conditions. Tr. 85. *See also* Staff Exh. 10 (Inspection Report No. 030-34086/97-001, dated September 5, 1997).

16. Mr. Gibson testified that, prior to the January 29, 1997, inspection, he contacted the licensee and talked to Dr. Elamir and informed Dr. Elamir that he would be conducting the inspection and that he would like to meet with him or the RSO, Dr. Moskowitz. Tr. 86. Mr. Gibson

testified that Dr. Ben-Haim met him at the facility and that neither Dr. Elamir nor Dr. Moskowitz was there. Tr. 86.

17. Mr. Gibson testified that, following the inspection, he contacted Dr. Moskowitz by telephone and informed Dr. Moskowitz about the inspection. Tr. 87-88. Mr. Gibson testified that Dr. Moskowitz informed him that he was not aware that he was listed as the RSO and authorized user for NMA; that he was never at that facility; that he had not performed any of the responsibilities of the RSO; and that he had not given his consent to be the RSO and authorized user for NMA. Tr. 88.

18. A Confirmatory Action Letter (CAL) was issued to NMA following Mr. Gibson's conversation with Dr. Moskowitz. *See* Staff Exh. 4 (Letter from Charles W. Hehl, Director, Division of Nuclear Materials Safety, to Magdy Elamir, President, Newark Medical Associates, P.A., dated February 6, 1997). The CAL documents NMA's agreement to immediately discontinue activities with byproduct material until such time as an amendment was filed and granted naming a new RSO and authorized user. Tr. 89, Staff Exh. 4. The CAL also provided that Dr. Ben-Haim, NMA's consultant, would audit all aspects of the radiation safety program to determine compliance with NRC requirements. Tr. 96, Staff Exh. 4.

19. Dr. Ben-Haim responded to the CAL by letter on February 14, 1997, stating that he performed an audit of the set-up and operations at NMA. Tr. 96, Staff Exh. 5 (Letter from Dr. Ben-Haim to Charles W. Hehl, dated February 14, 1997). Dr. Ben-Haim, in the letter, further stated that twenty-seven patients had received bone scans. Staff Exh. 5. He stated that only Tc-99m MDP single doses of 25 mCi had been ordered for bone scans, and the date of the first delivery was October 19, 1996. Staff Exh. 5.

20. On February 6, 1997, NMA submitted a license amendment application to change the RSO and authorized user on the license from Dr. Moskowitz to Dr. Maurizi. Tr. 96-97. *See* Staff Exh. 6 (Letter from Magdy Elamir, M.D. to Charles W. Hehl, Director, Division of Nuclear Materials Safety, dated February 6, 1997). The Staff issued an amended license, listing Dr. Maurizi as RSO and authorized user. Tr. 101-102. *See also* Staff Exh. 7 (Materials License Amendment No. 01, dated February 7, 1997).

(3) The OI Investigation

21. Special Agent Ernest Wilson testified that as part of his duties he conducted an investigation of Newark Medical Associates that originated from an allegation concerning the identification of the RSO and authorized user at NMA. Tr. 517. The case was initiated on February 11, 1997, and the Report of Investigation (OI Report) was issued on July 23, 1997. Tr. 517, *see* Staff Exh. 8 (OI Report, "Newark Medical Associates, P.A.: False Statement in License Application Concerning the Identification of the RSO and Authorized User," dated July 23, 1997). Special Agent William Davis assisted in the investigation. Tr. 541.

22. As part of the investigation, many documents were reviewed and individuals interviewed. Tr. 517-519. Among the individuals interviewed were: Dr. Ben-Haim, Ms. Geylikman, Dr. Moskowitz, and Ms. Smoligova. The OI Report for NMA contained thirty exhibits. Tr. 522, Staff Exh. 8.

23. In the OI Report, OI concluded that Dr. Elamir and Dr. Ben-Haim deliberately provided false information to the NRC in NMA's license application and that after the license issued, NMA operated in deliberate violation of its license. Tr. 537, Staff Exh. 8 at 23.

(4) The August 27, 1997 Order

24. The Staff in its Order asserted that from November 1996 through February 6, 1997, Dr. Ben-Haim, in his role as contractor-consultant to the licensee, Newark Medical Associates (NMA), aided and assisted the licensee in continuing to conduct NRC-licensed activities even though NMA did not employ the authorized user or the RSO named in the license application and on the NRC license, and the named individual did not serve in these capacities. 62 Fed. Reg. 47, 224 (1997). The Order stated that Dr. Ben-Haim's actions constituted violations of 10 C.F.R. § 30.10, "Deliberate misconduct." *Id.* at 47,225.

25. The Order provides that Dr. Ben-Haim violated 10 C.F.R. § 30.10 by two types of conduct: First, the Order states that Dr. Ben-Haim caused NMA to be in violation of the Commission's requirements by performing the functions of the RSO even though he knew that the RSO on the license application and the license was not Dr. Ben-Haim, but, rather, Dr. Gerard Moskowitz (RSO Violation). *Id.* Second, the Order states that Dr. Ben-Haim caused NMA to be in violation of the Commission's requirements by prescribing, in writing, the radiopharmaceuticals and dosages to be ordered and administered to patients by technologists for medical uses even though he knew that only Dr. Moskowitz could authorize or delegate the authority to authorize the ordering of byproduct material for medical uses (Authorized User Violation). *Id.* The Order also provides that Dr. Ben-Haim caused NMA to be in violation of Appendix K of the license, which sets forth requirements regarding the ordering of radiopharmaceuticals. *Id.*

26. As a result of these actions, the Staff concluded that Dr. Ben-Haim deliberately caused the licensee to be in violation of NRC requirements. *Id.* The Staff did not believe that if Dr. Ben-Haim were permitted to be involved in NRC-licensed activities reasonable assurance would

exist that licensed activities could be conducted in compliance with the Commission's requirements and that the health and safety of the public would be protected. *Id.* Therefore, the Order concluded that public health, safety and interest required that Dr. Ben-Haim be prohibited from any involvement in NRC-licensed activities for five years. *Id.*

27. The Order further provides that the prohibition is applicable to Dr. Ben-Haim as an employee, officer, contractor, consultant or other agent of a licensee and includes, but is not limited to: (1) any use of NRC-licensed materials; (2) supervising licensed activities, including (but not limited to) hiring of individuals engaged in licensed activities or directing or managing individuals engaged in licensed activities; (3) any involvement in radiation safety activities including (but not limited to) functions of an RSO; and (4) development of license applications, procedures and policies to meet license requirements, providing training to meet license requirements, and providing professional services to meet license requirements. 62 Fed. Reg. at 47,225-226.

28. The Order, among other things, requires Dr. Ben-Haim to notify the NRC within twenty days of engaging in NRC-licensed activities following his five year prohibition of the name of the NRC or agreement state licensee and location where licensed activities will be performed. This notification period runs for five years following Dr. Ben-Haim's resumption of licensed activities. *Id.* at 47,226.

B. Common Factual Findings

29. Several factual findings are common to both the RSO Violation and the Authorized User Violation. Principal among these are: (1) Dr. Ben-Haim was a Consultant to NMA; (2) Dr. Ben-Haim Prepared the License Application; (3) Dr. Moskowitz Never Performed the Role of RSO or Authorized User at NMA; and (4) Dr. Ben-Haim Knew Dr. Moskowitz Was Not

Performing the Role of RSO or Authorized User at NMA. The Board, therefore, addresses these findings first.

(1) Dr. Ben-Haim was a Consultant to Newark Medical Associates

30. Dr. Ben-Haim testified that he was an outside consultant to NMA. Tr. 787, 790. Dr. Ben-Haim testified that he had known Dr. Elamir for about a week before becoming a consultant for NMA and that he had far greater knowledge about nuclear materials than Dr. Elamir. Tr. 850-851.

31. Dr. Ben-Haim testified that he wrote a proposal to Dr. Elamir for his services on February 15, 1996 and delivered it to Dr. Elamir in person. Tr. 821. *See* Staff Exh. 8, OI Exh. 7 at 1. Dr. Ben-Haim testified that the proposal stated that "[w]e offer to obtain, on your behalf, in the shortest possible time, your state and federal materials licenses," and that the term, "we," refers to Dr. Ben-Haim. Tr. 821.

32. Dr. Ben-Haim testified that the February 15, 1996 proposal also provided that "we will install your hot laboratory and establish the necessary radiation health procedures." Tr. 821. *See* Staff Exh. 8, OI Exh. 7 at 1.

33. Dr. Ben-Haim verified that the proposal stated that "we will prepare for state and NRC inspections," and "[w]e will assure continuous monitoring of the laboratory in compliance with the regulations of the Nuclear Regulatory Commission." Tr. 822. *See* Staff Exh. 8, OI Exh. 7 at 1.

34. The proposal also provides that:

> We will train your staff, assist you in staffing requirements, perform all equipment tests such as dose calibrator constancy, accuracy, and linearity, assure that proper procedures are used in the handling of radioactive material, etc.

Staff Exh. 8, OI Exh. 7 at 1; Tr. 822.

35. On February 20, 1996, Dr. Ben-Haim and Dr. Elamir entered into a contract that provided, among other things, for Dr. Ben-Haim to supervise the NMA staff "in all aspects related to the safe use of radioisotopes" and to prepare NMA's NRC license. Staff Exh. 8, OI Exh. 7 at 2.

36. Based on the foregoing evidence, we find that Dr. Ben-Haim was NMA's consultant for the preparation of NMA's materials license and for assuring the safe use of radioactive material and compliance with the Commission's requirements. We also find that Dr. Ben-Haim held himself out to be well versed in the Commission's requirements and that he knew specifically that Dr. Elamir did not have knowledge in this area. Indeed, Dr. Ben-Haim's knowledge of the safe use of radioactive materials and understanding of the Commission's requirements were instrumental in his securing the consultant ship with NMA.

(2) Dr. Ben-Haim Prepared the License Application

37. Dr. Ben-Haim testified that he prepared the NRC license application for Newark Medical Associates. Tr. 820, 823. *See* Staff Exh. S-2.

38. Dr. Ben-Haim testified that he is familiar with Form 313, Application for Materials License. He testified that it is a one-page form and that he filled out such a form for NMA. Tr. 823. Dr. Ben-Haim testified that he prepared the supplemental pages that go to the form. Tr. 823-824.

39. Dr. Ben-Haim testified that the RSO and authorized user in the license application is Dr. Moskowitz and only Dr. Moskowitz. Tr. 826. *See* Staff Exh. 2.

40. Dr. Ben-Haim's testimony in this regard is consistent with that of Special Agent Wilson. Mr. Wilson testified that Dr. Ben-Haim told the OI investigators that he prepared the application and all the correspondence and required paperwork that needed to be submitted to the NRC. Tr. 527; *see also* Staff Exh. 8, OI Exh. 22 (interview of Dr. Ben-Haim).

41. As we previously found, the license issued to NMA to possess byproduct material provides that the RSO and authorized user is Gerard W. Moskowitz, M.D. Staff Exh. 1.

Dr. Ben-Haim Was Experienced in Preparing NRC Materials License Applications

42. Dr. Ben-Haim testified that he had experience with the NRC's regulations and considers them important in his consultant work. Tr. 822. Likewise, Dr. Ben-Haim testified that he had experience in preparing NRC license applications. Tr. 821. Dr. Ben-Haim testified that he prepared five or so license applications before preparing NMA's application and that he knows what needs to go into an NRC license application. Tr. 820.

43. Dr. Ben-Haim testified that he makes it a practice to know the regulations. Tr. 823. Dr. Ben-Haim testified that he knew a licensee must have an RSO and an authorized user. Tr. 823.

Dr. Ben-Haim Knew He Could Not Be NMA's RSO

44. Mr. Kinneman testified that in 1995, NRC Region I sent a letter to Dr. Ben-Haim, owner of Servicing Imaging Systems International, in response to an application for a byproduct materials license. Tr. 281; Staff Exh. 11 (Letter from John R. McGrath, Nuclear Materials Safety Branch, Division of Radiation Safety and Safeguards, to Dr. Ben-Haim, Owner, Servicing Imaging Systems International, dated May 5, 1995). The letter stated that the submitted qualifications of Dr. Ben-Haim did not appear to satisfy the regulatory requirements at 10 C.F.R. § 35.900 for him to be an RSO. Tr. 282, Staff Exh. 11. The letter concludes: "Please submit evidence that Dr. Ben-Haim has completed the required training and experience. If Dr. Ben-Haim has not, we recommend that you withdraw your request and reapply at a later date when a sufficient number of hours have been obtained." Tr. 282, Staff Exh. 11.

45. Mr. Kinneman testified that the Staff searched for files to assess whether Dr. Ben-Haim had provided additional information and could not find any. Tr. 284-85. Mr. Kinneman testified that as a result of the search, the Staff concluded that Dr. Ben-Haim had not submitted information which indicated that he meets the RSO requirements of 10 C.F.R. § 35.900.

46. Based on the foregoing evidence, we find that Dr. Ben-Haim was experienced in preparing license applications and prepared NMA's license application, including the supplemental information. The application provides that the RSO and authorized user is Dr. Moskowitz and the license, which was based on the application, so specifies. It is clear that Dr. Ben-Haim knew that Dr. Moskowitz was NMA's only named RSO and authorized user. Further, Dr. Ben-Haim knew that he could not be NMA's RSO because the NRC had found his 1995 application to be an RSO to be deficient.

(3) Dr. Moskowitz Never Performed the Role of RSO or Authorized User at NMA

47. Dr. Moskowitz testified that he did not know anything about NMA until February 6, 1997, when Mr. Gibson contacted him and he became aware that his name had been used in NMA's license application and subsequently on the license. Tr. 216, 223-224, 257. Dr. Moskowitz asserted that he was very concerned when contacted by Mr. Gibson and, in fact, that he was "horrified about the whole thing." Tr. 225. "It's like someone taking my medical license, putting it on their wall, practicing medicine with my name and my license . . ." Tr. 224-225.

48. Dr. Moskowitz testified that he never served as RSO and authorized user at NMA. Tr. 216. When asked whether he ever delegated to Dr. Ben-Haim the duties of RSO and authorized user of NMA, Dr. Moskowitz stated, "I never delegated that kind of responsibility to anyone." Tr. 217.

49. In response to questions posed by Dr. Ben-Haim, Dr. Moskowitz asserted:

> I was never invited to come see your facility. I was never told where your facility was. I was never shown a full-fledged application that was submitted to the NRC. I was never told that you had received a license. I was never invited to come over. Tr. 226.
>
> At no time have you ever notified me that I did not appear. You never invited me, you never sent me a letter stating that I was in any way associated with the medical facility. Tr. 259.

50. Dr. Moskowitz's testimony in this regard is supported by all the witnesses that testified on this subject. Mr. Wilson testified that he conducted two interviews with Dr. Moskowitz as part of the OI investigation. Tr. 522-523. At the first interview, which was conducted in Dr. Moskowitz's office at the University of Medicine and Dentistry of New Jersey (UMDNJ), Dr. Moskowitz told Mr. Wilson that he had absolutely no affiliation with NMA, did not know Dr. Elamir, had never been to NMA and did not have anything to do with NMA at all. Tr. 523. Dr. Moskowitz also provided a sworn statement to OI, which became part of Exhibit 15 to the OI report. Tr. 524. *See* Staff Exh. 8, OI Exh. 15 (OI interview of Dr. Moskowitz). Dr. Moskowitz's sworn statement provides, in pertinent part, as follows:

> I have absolutely no affiliation to Newark Medical Associates (NMA), Newark, NJ, and never have. I never met Dr. Magdy Elamir, M.D., any technicians that work at NMA, or any consultants to NMA. I have never visited the NMA for any purpose and, to my recollection, was never aware that NMA or Dr. Elamir had used my name as an RSO or authorized user (AU) on the NRC license application or the license itself, since the issue was made known to me by Mr. Gibson of the NRC on or about 2/6/97.

Staff Exh. 8 at OI Exh. 15, p.3.

51. Ms. Smoligova testified that she had been employed as an MRI technician for Dr. Elamir at Newark Open MRI from June of 1996 and that she ordered radiopharmaceuticals for

NMA. Tr. 125-126. Ms. Smoligova testified that she did not know who Dr. Moskowitz was, that she never heard of Dr. Moskowitz, and that she never saw him. Tr. 126. Ms. Smoligova further testified that she did not know who the RSO and authorized user for NMA were. *Id.*

52. Ms. Smoligova's testimony in this regard is consistent with what she told OI. Special Agent Wilson testified that he interviewed Ms. Smoligova and during the interview asked her if she knew who the RSO and authorized user was. Tr. 535; *see* Staff Exh. 8, OI Exh. 27 (OI interview of Ms. Smoligova). Ms. Smoligova told OI that she did not know. Tr. 535. Mr. Wilson also asked her if she knew who Dr. Moskowitz was, and she was not familiar with his name. Tr. 535, 619.

53. Ms. Geylikman worked as a nuclear medical technologist at Newark Medical Associates on Saturdays. Tr. 176; *see* Staff Exh. 8, OI Exh. 26 (OI interview of Ms. Geylikman). She testified that she never met Dr. Moskowitz and did not know who the authorized user for NMA was. Tr. 178. Ms. Geylikman testified that she heard Dr. Ben-Haim mention Dr. Moskowitz's name, but she did not remember anything that he said about Dr. Moskowitz or the purpose for which his name was mentioned. Tr. 186-187.

54. Ms. Geylikman's testimony in this regard differs somewhat from that of Special Agent Wilson. Mr. Wilson interviewed Ms. Geylikman at Harlem Hospital in the Nuclear Medicine Department. Tr. 531. Mr. Wilson testified that he asked Ms. Geylikman about Dr. Moskowitz, and she replied that she did not know who Dr. Moskowitz was and further stated that she knew the name but only because of the NRC's inspection. Tr. 532.

55. When Ms. Geylikman was asked whether she told OI that she only knew of Dr. Moskowitz as a result of NRC's inspection, she stated, "It might be, I just don't remember right now. But then I start to think and maybe I heard his name before, just once, like this." Tr. 184-185.

The Board considers that regardless of whether Ms. Geylkiman heard Dr. Moskowitz's name mentioned prior to the NRC inspection, it is clear that she did not see him at NMA or consider him to be NMA's RSO or authorized user.

56. Based on the foregoing evidence, we find that Dr. Moskowitz did not perform the role of RSO or authorized user at NMA. Further, we find that Dr. Moskowitz did not delegate the duties of the RSO or authorized user to Dr. Ben-Haim or any other person.

(4) Dr. Ben-Haim Knew Dr. Moskowitz Was Not Performing the Role of RSO or Authorized User

57. The Staff argued that Dr. Ben-Haim knew that Dr. Moskowitz was not performing the role of RSO or authorized user because at no time did Dr. Ben-Haim see Dr. Moskowitz at NMA or have any communication with Dr. Moskowitz. Further, the Staff argued that Dr. Ben-Haim was aware that an essential record at NMA had not been reviewed by Dr. Moskowitz. Dr. Ben-Haim argued in defense that he met with Dr. Moskowitz at UMDNJ prior to listing him on NMA's license application, that he was candid at the NRC inspection, and that Dr. Elamir provided assurances to him regarding his concerns about the fact that Dr. Moskowitz had not been to NMA.

58. Concerning a meeting with Dr. Moskowitz, Dr. Ben-Haim testified that he saw Dr. Moskowitz on February 16, 1996 at UMDNJ, and that Dr. Moskowitz gave him his curriculum vitae (CV) and other papers in order to be included in NMA's license application as the authorized user and RSO. (Dr. Ben-Haim's Testimony) ff. Tr. 786 at 1, Tr. 809. Dr. Ben-Haim testified that he phoned Dr. Moskowitz using the phone number provided by Dr. Elamir and spoke with Dr. Moskowitz and made an appointment for February 16, 1996, at 10:30 am in his office in the Nuclear Medicine Laboratory H141, at UMDNJ. (Dr. Ben-Haim) ff. Tr. 786 at 1, Tr. 788.

Dr. Ben-Haim testified that "there was no other purpose to my visit than to receive from Dr. Moskowitz these papers." (Dr. Ben-Haim) ff. Tr. 786 at 1, Tr. 789. Dr. Ben-Haim testified that receipt of Dr. Moskowitz's papers is "a proof of his consent" to being named as the RSO and authorized user in NMA's application for a materials license. (Dr. Ben-Haim) ff. Tr. 786 at 5. Dr. Ben-Haim admitted that no other person participated in the meeting. Tr. 828.

59. Dr. Ben-Haim admitted that Dr. Moskowitz did not specifically say that he wanted to be included in the application as the authorized user and RSO. Tr. 795, 829-830. "He didn't say, 'I will be the RSO.'. . . We were talking about scans and he said, 'I'm going to read the bone scans.'" Tr. 795. Dr. Ben-Haim testified that he equated the reader of the scans with the authorized user. Tr. 854. However, when asked, "Other than handing you the CV, did he imply in any way, by words or body language, 'Yes, I will be the RSO'?", Dr. Ben-Haim answered, "No." Tr. 854.

60. Dr. Ben-Haim testified regarding his March 7, 1997, interview with OI, in which the agents questioned him about his meeting with Dr. Moskowitz. (Dr. Ben-Haim) ff. Tr. 786 at 3. At that interview, Dr. Ben-Haim could not remember the date of his meeting with Dr. Moskowitz. (Dr. Ben-Haim) ff. Tr. 786 at 3. When asked if he had an appointment book, Dr. Ben-Haim stated that he took out his diary and came back to the two inspectors. He looked through the book in their presence and saw the entry on February 16, 1996. (Dr. Ben-Haim) ff. Tr. 786 at 3, Tr. at 800. *See* Ben-Haim Exh. 1 (excerpt from Dr. Ben-Haim's diary). Dr. Ben-Haim, however, could not recall if anybody saw him write the note. Tr. 830.

61. Dr. Ben-Haim's testimony is generally consistent with that of Special Agent Wilson. Mr. Wilson testified that he interviewed Dr. Ben-Haim at his residence in Upper Montclair, New Jersey. Tr. 527; *see* Staff Exh. 8, OI Exh. 22 (OI interview of Dr. Ben-Haim). Mr. Wilson

testified that Dr. Ben-Haim told him that Dr. Elamir said that a Dr. Moskowitz of UMDNJ had expressed interest in doing outside work and, therefore, Dr. Moskowitz would serve as the RSO and authorized user. Tr. 527. Mr. Wilson testified that Dr. Ben-Haim told him that he met with Dr. Moskowitz after calling and making an appointment with him. Tr. 528. Mr. Wilson testified that Dr. Ben-Haim retrieved a daily planner and he had an entry on February 16, 1996 that read, "H-141, Dr. Moskowitz 10:30, 982-6022." Tr. 528, 554. *See* B-H Exh. 1.

62. Dr. Moskowitz testified that he does not recall ever meeting Aharon Ben-Haim until the day of the hearing. Tr. 216-17.

63. Following his direct examination, Dr. Moskowitz was cross-examined by Dr. Ben-Haim. Tr. 217-227. When asked by Dr. Ben-Haim "And you've never seen me?" Dr. Moskowitz asserted, "[a]s far as I was concerned, the only time I've ever seen you is today." Tr. 217. Dr. Moskowitz testified that he did not recall giving his CV and papers to anyone or remember an Israeli coming and meeting with him. Tr. 220-221.

64. When asked specifically about Dr. Moskowitz's recollection of February 16, 1996, Dr. Moskowitz stated that he "would not have met somebody for an extended period of time to discuss anything on that Friday" because that was President's Day weekend, and he was going away and, therefore, Friday was a precious time to complete all the work he had to do. Tr. 217-218.

65. When asked regarding a statement Dr. Moskowitz made to OI that there was less than a one percent chance that he may have met with Dr. Ben-Haim at UMDNJ, Dr. Moskowitz clarified that his statement was made in the context that Dr. Moskowitz may have met Dr. Ben-Haim at "another conference elsewhere in the hospital," but not in the context of negotiating a position as an RSO. Tr. 220, 222. *See* Staff Exh. 8, OI Exh. 16 ("Moskowitz allowed that there was less than 1%

chance that he may have met Dr. Ben-Haim at UMDNJ"). Dr. Moskowitz testified that the only face he could conceive of meeting was different from Dr. Ben-Haim's. Tr. 231. Dr. Moskowitz stated that Dr. Ben-Haim has a "unique sort of facial appearance" and that Dr. Moskowitz would have remembered if he had seen him. Tr. 243.

66. Dr. Moskowitz did state that Dr. Baker of the UMDNJ might have given out his qualifications to a group with whom Dr. Baker, the Chairman of the Department of Radiology, was negotiating. Tr. 223. Dr. Moskowitz explained that Dr. Baker and his coordinator had his CV and they had given it out to different places for different purposes. Tr. 222. Dr. Moskowitz testified that he did not know very much about the negotiations and that he was not privy to them. Tr. 225. Dr. Moskowitz's testimony is consistent with Mr. Wilson's: Mr. Wilson testified that Dr. Moskowitz told the investigators that Dr. Baker would typically hand out his CV. Tr. 524, 599. Thus, NMA could have received Dr. Moskowitz's CV without Dr. Ben-Haim's having obtained it from Dr. Moskowitz.

67. Dr. Moskowitz, however, did state that it is possible that he gave Dr. Ben-Haim his CV, although he does not recall. Tr. 232, 238-239, 243.

68. Dr. Moskowitz's testimony is generally consistent with that of Special Agent Wilson. Mr. Wilson testified that he and Mr. Davis interviewed Dr. Moskowitz a second time after OI interviewed Dr. Ben-Haim in order to confront him regarding the meeting that Dr. Ben-Haim spoke of. Tr. 525; *see* Staff Exh. 8, OI Exh. 16 (OI interview of Dr. Moskowitz). Mr. Wilson testified that Dr. Moskowitz had no recollection that a meeting took place or of having provided his CV to Dr. Ben-Haim. Tr. 525. Dr. Moskowitz told the OI investigators that if he had been contacted by Dr. Ben-Haim he would have contacted Dr. Baker and made a note of the occurrence, because

Dr. Baker could conduct negotiations for the university and not Dr. Moskowitz. Tr. 525-526. Dr. Moskowitz looked for documents relative to such a notation and did not find any. Tr. 526. Mr. Wilson testified that Dr. Moskowitz was "very adamant" that he had not met with Dr. Ben-Haim, but he did allow that there was less than a one percent chance that he may have met Dr. Ben-Haim at UMDNJ. "[H]e highly doubted it." Tr. at 526.

69. Mr. Wilson testified that the Office of Investigations believed Dr. Moskowitz instead of Dr. Ben-Haim regarding the meeting because Dr. Moskowitz had no vested interest in the outcome. Tr. 538; *see* Staff Exh. 8 at 22. Mr. Wilson clarified that Dr. Moskowitz was not a subject or target of the investigation. Tr. 559. Mr. Wilson testified that there was no potential for Dr. Moskowitz to have gained financially regarding the resolution of whether he met with Dr. Ben-Haim and that Dr. Moskowitz was not a target of the investigation. Tr. 639. Mr. Wilson testified that he was not aware of any threat to Dr. Moskowitz that would be removed if the issue were resolved in his favor. Tr. 639.

70. Mr. Wilson testified that Dr. Moskowitz was "antagonized that someone had used his name" and that Dr. Moskowitz felt like a victim and wanted answers. Tr. 597. When asked if that showed some vested interest, Mr. Wilson said, "a little bit." Tr. 597.

71. Based on the above evidence, the Board is convinced that at no time prior to speaking with Inspector Gibson was Dr. Moskowitz aware that he was listed on either NMA's license or license application as the RSO or authorized user. Regarding Dr. Ben-Haim's defense that he met Dr. Moskowitz at UMDNJ for the purpose of having Dr. Moskowitz listed on NMA's license application, the preponderance of evidence supports a finding that such a meeting did not take place. Our finding is based chiefly on the testimony of Dr. Moskowitz, who asserted that he did not recall

ever meeting Dr. Ben-Haim until the hearing and that he would have remembered him if he had seen him.

72. We agree with the Office of Investigations' analysis that Dr. Moskowitz is more credible than Dr. Ben-Haim regarding the purported meeting. We find that Dr. Ben-Haim had a vested interest in stating that he met with Dr. Moskowitz that is evidenced by these very proceedings. That is, Dr. Ben-Haim knew that, as the preparer of NMA's license application, he might be subject to some action if the license application was prepared fraudulently. Dr. Moskowitz, on the other hand, was concerned that someone had used his name and he simply wanted the matter to be set straight.

73. Dr. Ben-Haim produced a copy of his calendar, in which he made a notation in the space for February 16, 1996, regarding a meeting with Dr. Moskowitz at UMDNJ. This diary, however, does not show that a meeting actually took place and we accord it very little weight. No other evidence exists which tends to show that a meeting took place.

74. Dr. Ben-Haim makes much of Dr. Moskowitz's statement to OI that there was a 1 percent chance he may have met Dr. Ben-Haim at UMDNJ. Otherwise stated, however, there is a 99 percent chance that Dr. Moskowitz did not meet with Dr. Ben-Haim, which was demonstrated when Dr. Moskowitz testified that the person he had in mind was not Dr. Ben-Haim.

75. Even if we were to assume that a meeting between Dr. Moskowitz and Dr. Ben-Haim did take place, we find that the most that could have taken place at the meeting would have been Dr. Moskowitz's handing his CV to Dr. Ben-Haim. Dr. Ben-Haim testified that Dr. Moskowitz did not say that he would be the RSO or authorized user on NMA's license. In fact, Dr. Ben-Haim admitted that, other than handing him the CV, Dr. Moskowitz did not imply in any way that he

would be the RSO, although he did equate Dr. Moskowitz's statement that he would read the scans with being the authorized user. We find that the receipt of the CV and Dr. Moskowitz's statement that he would interpret the scans is a feeble basis for Dr. Ben-Haim to conclude that Dr. Moskowitz would serve as authorized user for NMA and provides no support for Dr. Ben-Haim to conclude that Dr. Moskowitz would serve as RSO for NMA.

76. Regarding Dr. Ben-Haim's defense concerning his attitude during the inspection, Mr. Gibson testified that he asked Dr. Ben-Haim about Dr. Elamir and Dr. Moskowitz's absence, and Dr. Ben-Haim informed him that the licensee normally conducted work on Saturday and that Dr. Elamir had requested him to be at the inspection. Tr. 87. Mr. Gibson testified that he asked Dr. Ben-Haim if Dr. Moskowitz was ever at NMA, and Dr. Ben-Haim informed him that he did not know if Dr. Moskowitz was ever there. Tr. 87.

77. Dr. Ben-Haim testified that on the day of the inspection Dr. Elamir asked him to be present. (Dr. Ben-Haim) ff. Tr. 786 at 2. Dr. Ben-Haim testified that when Mr. Gibson asked him who the RSO was, he told him "without hesitation" that it was Dr. Moskowitz. (Dr. Ben-Haim) ff. Tr. 786 at 2. Dr. Ben-Haim testified that he was not aware that Mr. Gibson had specifically asked for the RSO to be present at the inspection. (Dr. Ben-Haim) ff. Tr. 786 at 4.

78. We do not consider Dr. Ben-Haim's statement to Mr. Gibson that Dr. Moskowitz was the RSO to be of assistance to his defense. The issue is not whether Dr. Ben-Haim knew that Dr. Moskowitz was the RSO named on the license, but, rather, whether Dr. Ben-Haim knew that Dr. Moskowitz was not performing his role at NMA. Thus, we do not accord Dr. Ben-Haim's statement to the inspector any weight.

79. Dr. Ben-Haim testified that after NMA's operations started, he was "convinced that Dr. Elamir was in contact with Dr. Moskowitz and had no way of knowing he was not." Tr. 790, *see* (Dr. Ben-Haim) ff. Tr. 786 at 1-2.

80. Dr. Ben-Haim admitted on cross-examination that he never saw Dr. Moskowitz at NMA. Tr. 838, 828-829. Dr. Ben-Haim further admitted that during the time NMA was in operation he had no communication with Dr. Moskowitz. Tr. 837.

81. Dr. Ben-Haim admitted that, as of December 1996, he knew that Dr. Moskowitz had not been to NMA. Tr. 839. Dr. Ben-Haim admitted that he was concerned that Dr. Moskowitz had not been to NMA. Tr. 790, 839, 860. Specifically, in his direct testimony, Dr. Ben-Haim stated:

> I hadn't seen any signed -- any signature of [Dr. Moskowitz's] in the log book, and I had asked [Dr. Elamir] specifically. I told him actually, 'This has to be signed. He has to review the procedures and I don't see anything.' Dr. Elamir nodded. Our encounters were very brief. So he nodded and said, 'Okay, Okay.'

Tr. 790.

Further, on cross-examination, Dr. Ben-Haim was asked, "You were concerned that Dr. Moskowitz had not been there; isn't that correct?" To which he answered, "That is correct." Tr. 839. Also, when asked by the Board whether he thought he "ought to see that there's an AU that's going to show up," Dr. Ben-Haim stated, "I was concerned about this." Tr. 860. Dr. Ben-Haim admitted that he expected to see some tangible evidence that an authorized user and RSO had been to NMA. Tr. 861.

82. As part of his defense, Dr. Ben-Haim testified that in August 1996 he prepared a form regarding dose calibrator geometry correction for the Victoreen Dose calibrator. Tr. 833. Dr. Ben-Haim testified that he signed the form as the one who performed the calibration and that he

left a place open for the RSO to sign. Tr. 834. Dr. Ben-Haim testified that the form actually shows the word "RSO" at the signature line, and Dr. Moskowitz did not sign it. Tr. 834-835. Dr. Ben-Haim admitted that he knew that Dr. Moskowitz had not signed the form. Tr. 838. *See* Ben-Haim Exh. 4.

83. Dr. Ben-Haim testified that when he told Dr. Elamir that the procedures needed to be reviewed by an RSO, Dr. Elamir told him, "I have somebody else." Tr. 861-862. When questioned by the Board as to why Dr. Ben-Haim did not advise Dr. Elamir that NMA needed a license amendment, Dr. Ben-Haim testified, "Somehow it did not click." Tr. 862. Dr. Ben-Haim's testimony contradicts what he said at his deposition. Dr. Ben-Haim admitted on cross examination that during his deposition he said he had asked Dr. Elamir why the RSO had not come in and signed. Tr. at 891. Dr. Ben-Haim admitted in his deposition that the extent of Dr. Elamir's response to this was merely to nod. Tr. 892.

84. Dr. Ben-Haim admitted that his only bases for assuming during the time NMA was in operation that Dr. Moskowitz was acting as authorized user and RSO were (1) that Dr. Elamir told Dr. Ben-Haim that Dr. Moskowitz was the RSO and (2) that Dr. Moskowitz had given Dr. Ben-Haim his CV. Tr. 867.

85. Dr. Ben-Haim admitted that he did not follow up to see to it that the RSO and AU were functioning. Tr. 862-863. Dr. Ben-Haim admitted, "I thought, 'Well, it's just the beginning. Let's see how things develop. . . . I don't want to make waves.'" Tr. 863.

86. Based on the above evidence, the Board finds that Dr. Ben-Haim knew that Dr. Moskowitz was not performing the role as RSO or authorized user for NMA. Even were the Board to conclude that a meeting with Dr. Moskowitz took place and that Dr. Ben-Haim left that

meeting believing that Dr. Moskowitz would be NMA's RSO and authorized user, the Board rejects all inferences that Dr. Ben-Haim adhered to his belief that Dr. Moskowitz was acting as the RSO and authorized user up until the NRC's inspection. We find it incredible that Dr. Ben-Haim, who saw no evidence that Dr. Moskowitz had been to NMA, who had no communication with Dr. Moskowitz, and who knew that an essential record had not been reviewed by Dr. Moskowitz, did not conclude that Dr. Moskowitz was not serving as NMA's RSO and authorized user. Further, it is clear that Dr. Ben-Haim did not view Dr. Moskowitz as the RSO because Dr. Ben-Haim did not inform Dr. Moskowitz that the license had issued, never told him that NMA was in operation, and never questioned him regarding his attendance at NMA.

87. Dr. Ben-Haim testified that he was concerned that Dr. Moskowitz had not been to NMA and he informed Dr. Elamir. Rather than serving as a defense, Dr. Ben-Haim's concern shows that he knew that something was wrong regarding Dr. Moskowitz's fulfilling any of the required duties of the RSO. Based on the statements made in Dr. Ben-Haim's deposition that Dr. Ben-Haim admitted to making on cross examination, we do not believe that Dr. Elamir told Dr. Ben-Haim he had "someone else." Thus, without regard to whether Dr. Elamir said anything to allay Dr. Ben-Haim's concerns, Dr. Ben-Haim, nevertheless, knew that Dr. Moskowitz was not acting as RSO and authorized user.

(5) Summary of Common Findings

88. In summary, we conclude the following: (1) Dr. Ben-Haim was NMA's consultant for the preparation of NMA's materials license application and for assuring the safe use of radioactive material and compliance with the Commission's requirements; (2) Dr. Ben-Haim knew that Dr. Moskowitz was named in the license application and on the license as NMA's only RSO and

authorized user; (3) Dr. Moskowitz did not perform the role of RSO or authorized user at NMA and did not delegate the duties of the RSO or authorized user to Dr. Ben-Haim, and; (4) Dr. Ben-Haim knew that Dr. Moskowitz was not performing the role of RSO and authorized user for NMA.

C. The RSO Violation

(1) NRC Requirements

89. The Order states that Dr. Ben-Haim violated 10 C.F.R. § 30.10 by causing NMA to be in violation of 10 C.F.R. §§ 35.21, 35.13 and NMA License Condition 12. These requirements were presented and explained by Mr. Kinneman, Mr. DelMedico, and Dr. Siegel. Dr. Siegel, whose CV was accepted into the record, was offered by the Staff as an expert witness. Tr. 356-357. We find that Dr. Siegel was qualified to testify as an expert regarding medical facilities that use nuclear material, such as NMA, and that he was qualified to testify as an expert regarding the NRC's regulations.

90. Mr. Kinneman testified that 10 C.F.R. § 30.10 provides that a contractor to a licensee may not knowingly cause a licensee to be in violation of any Commission requirement. Tr. 486; 10 C.F.R. § 30.10.

91. Specifically, Mr. Kinneman testified that 10 C.F.R. § 30.10 provides that any contractor, including a supplier or consultant, who knowingly provides to any licensee information or other things, may not engage in deliberate misconduct that causes or would have caused, if not detected, the licensee to be in violation of any rule, regulation, or order, or any term condition or limitation of any license issued by the Commission. Tr. 480, 481; 10 C.F.R. § 30.10(a)(1).

92. Mr. Kinneman testified that deliberate misconduct by a person means an intentional act or omission that the person knows would cause a licensee to be in violation of any term,

regulation, or order, or any term, condition or limitation of any license issued by the Commission. Tr. 480; 10 C.F.R. § 30.10(c)(1). In this regard, Mr. DelMedico testified that deliberately is the same as intentional. Tr. 750. A question was raised regarding whether a finding of careless disregard of requirements, as discussed in NUREG-1600, could also apply in this case. Tr. 701-702. Mr. DelMedico answered that a violation of 10 C.F.R. § 30.10 requires a finding of deliberate misconduct and that careless disregard is not a violation of 10 C.F.R. § 30.10. Tr. 702-703, 704, 776.

93. Mr. Kinneman testified that 10 C.F.R. § 35.21 requires that the licensee appoint an RSO and set out the specific responsibilities of the RSO. Tr. 279; 10 C.F.R. § 35.21. Mr. Kinneman testified that these duties include: investigating overexposures, accidents, spills, losses, thefts; establishing and collecting in one binder (or file) written policies and procedures for authorizing the purchase of radioactive material, receiving and opening packages, storing byproduct material, keeping an inventory, using byproduct material safely, taking emergency action if control of byproduct material is lost, performing periodic radiation surveys, performing checks of survey instrumentation, disposing of byproduct material, and training staff who work or frequent areas where byproduct material is used and stored. Tr. 280; 10 C.F.R. 35.21(b).

94. Mr. Kinneman testified that an RSO can instruct someone else to carry out the physical actions described in 10 C.F.R. §35.21, but the RSO may not delegate the responsibility for assuring that they are carried out. Tr. 279-280, *see* 10 C.F.R. § 35.21(a) ("The licensee, through the [RSO], shall ensure that radiation safety activities are being performed in accordance with . . . regulatory requirements."). Neither may the RSO delegate the performance of assessments that the RSO is expected by virtue of training and experience to perform. Tr. 280.

95. Dr. Siegel testified that, in the case of a medical facility, the individual in whom the responsibility for ordering byproduct material is embodied is the RSO. Tr. 368. The RSO has the authority to delegate that responsibility to an individual working under the RSO's direction and supervision. Tr. 368-369. Dr. Siegel testified that the delegation is usually accomplished by a memorandum of delegation. Tr. 369.

96. Mr. Kinneman testified that many of the activities of the RSO are carried out by a physicist or other consultant; however, in order for that to happen, the RSO must be active and must delegate those duties to the physicist or other person who carries them out. Tr. 290.

97. Section 35.13 (c) of the Commission's regulations provides that a licensee shall apply for and must receive a license amendment before it changes RSOs. 10 C.F.R. § 35.13(c). As previously noted, License Condition 12 of NMA's license states that the RSO for this license is Dr. Moskowitz. Staff Exh. 1.

98. The Board finds that Dr. Ben-Haim's actions would constitute a violation of 10 C.F.R. § 30.10 if he deliberately caused NMA to fail to appoint an RSO and have the RSO perform the duties delineated in 10 C.F.R. § 35.21. In addition, Dr. Ben-Haim would be in violation of 10 C.F.R. § 30.10 if he deliberately caused NMA to change RSOs without a license amendment. Finally, Dr. Ben-Haim would be in violation of 10 C.F.R. § 30.10 if he deliberately caused NMA to operate without Dr. Moskowitz as RSO. Thus, we find that NMA would be in violation of all three requirements if Dr. Ben-Haim performed the functions of the RSO without the delegation of the requisite authority by Dr. Moskowitz.

(2) Dr. Ben-Haim performed the functions of the RSO

Dr. Ben-Haim Admitted to OI that He Was the De Facto RSO

99. Special Agent Davis testified that he interviewed Dr. Ben-Haim a second time at NMA on April 22, 1997, during which interview Dr. Ben-Haim discussed the role of the RSO, among other things. Tr. 549; *see* Staff Exh. 8, OI Exh. 23 (OI interview of Dr. Ben-Haim).

100. Mr. Davis testified that the purpose of the second interview was to compare the doses of technetium-99m that were sent to NMA from Medi-Physics with the individual patient records. Tr. 542. Mr. Davis testified that Dr. Ben-Haim went over the records with him and thoroughly explained what happens from the time a physician requests a bone scan until the time the procedure is performed. Tr. 543-544.

101. Mr. Davis testified that during the conversation he mentioned the RSO and the tone of the conversation changed and Dr. Ben-Haim questioned the reasons for OI's many interviews. Tr. 545. Mr. Davis testified that Dr. Ben-Haim stated, "So I might have made some mistakes . . . I was here at NMA when I was needed, I set it all up, this was just one job, I have many other things to do." Tr. 546. Mr. Davis testified that Dr. Ben-Haim informed him about the role of the RSO. Tr. 549. Mr. Davis testified that Dr. Ben-Haim stated that he was the de facto RSO. Tr. 549, 550.

102. Mr. Davis testified that he was absolutely certain that "Dr. Ben-Haim stated that in doing his work at NMA that he was the de facto RSO." Tr. 549, 550. Mr. Davis testified that at the end of the interview, Dr. Ben-Haim repeated that one of his mistakes was "acting as the de facto RSO." Tr. 550, 580.

103. Mr. Davis testified on cross examination that this was his first assignment at NRC's Region I OI office, and that a lot of things were new to him; however, he did not believe it was

possible that he confused what was said. Tr. 564-565. Mr. Davis testified that he "remembered specifically" that Dr. Ben-Haim told him that he acted as the RSO for NMA. Tr. 578-579. Mr. Davis testified that he did not have any preconceptions regarding Dr. Ben-Haim's role at NMA before the second interview. Tr. 584.

104. Mr. Davis testified that Dr. Ben-Haim told him that Dr. Ben-Haim should have been the RSO; that he had applied to be certified for an RSO but that he was turned down. Tr. 577-578. Mr. Davis testified that he understood that to mean that Dr. Ben-Haim should have been the RSO for NMA but was not. Tr. 601. Dr. Ben-Haim testified that the agent asked why he was not the RSO, and Dr. Ben-Haim replied that he applied for another facility and was rejected. "Therefore, I knew I could not be the RSO and did not apply." Tr. 804, (Dr. Ben-Haim) ff. Tr. 786 at 4.

105. Dr. Ben-Haim testified that he never admitted acting as the de facto RSO for NMA. Tr. 798, 804, (Dr. Ben-Haim) ff. Tr. 786 at 4. Dr. Ben-Haim testified that he said he was a "Radiation Safety conscious consultant physicist." Tr. 804, (Dr. Ben-Haim) ff. Tr. 786 at 4.

106. On cross examination, Dr. Ben-Haim again denied telling Mr. Davis that he was acting as a de facto RSO. Tr. 838. Dr. Ben-Haim admitted, however, that he told Mr. Davis that "de facto [he was] doing the things that the RSO could do." Tr. 838.

107. In light of the foregoing evidence, we find that the conversation of April 22, 1997, between Special Agent Davis and Dr. Ben-Haim occurred as Mr. Davis reported it. We could not find in the record any substantial basis for attributing to Mr. Davis any bias which would discredit his testimony. Neither do we find any substantial evidence of confusion on the part of Mr. Davis as to what was said. Therefore, we conclude that Dr. Ben-Haim admitted to OI that he was the de facto RSO for NMA.

Dr. Ben-Haim Performed the Duties of the RSO

108. Dr. Ben-Haim testified that there may have been duties that he performed that may have overlapped with the duties of the RSO. Tr. 858-859. Dr. Ben-Haim stated that these duties included "radiation safety, as far as anything that has to do with instrumentation, mainly the way wipe tests are conducted." Tr. 859. In addition, these overlapping duties were "[t]o make sure that nobody has access to a lab and is not exposed unnecessarily--none of the public" and "monitoring of the facilities--of the workplace--for the personnel." Tr. 859. When asked who was filling the functions of an authorized user or RSO during the time NMA was in operation, Dr. Ben-Haim stated, "[t]he overlapping functions that the physicist has to do, I was trying, to the best of my ability, to help with." Tr. 877.

109. Dr. Ben-Haim testified that he performed several activities at NMA: he performed certain equipment tests, such as the accuracy, constancy, and geometry checks for the dose calibrator (Tr. 815, 831); he found a nuclear technician to work at NMA (Tr. 835); he gave information to Ms. Smoligova regarding where to get technetium-99m and the specific radiopharmaceuticals and millicurie amounts that she should order (Tr. 835, 840-841); he made sure the laboratory had a key and was kept locked (Tr. 836); he made sure the NRC license was posted (Tr. 836); he told NMA personnel to get personal monitoring badges in December 1996 (Tr. 837).

110. As part of his defense, Dr. Ben-Haim testified that he prepared a form, dated August 14, 1996, for NMA's dose calibrator geometry correction check. Tr. 814. *See* Ben-Haim Exh. 4 (Dose Calibrator Geometry Correction, dated August 14, 1996). The geometry correction check, which only needed to be performed one time, was prepared prior to the start of NMA's operations. Tr. 814-815, 834. Dr. Ben-Haim testified that he performed the measurements, prepared

the graphs, signed the form, and left the line blank where the RSO was to sign. Tr. 815, 834-835. Dr. Ben-Haim did not sign that place of the form. Tr. 822. Dr. Ben-Haim did admit that to do so would have been blatantly false. Tr. 835.

111. Dr. Ben-Haim admitted that Dr. Moskowitz did not delegate the authority of the authorized user or RSO to him. Tr. 826.

112. Based on the foregoing evidence, the Board finds that Dr. Ben-Haim performed the functions of the RSO, even though he knew Dr. Moskowitz did not delegate this authority to him. Dr. Ben-Haim characterizes these activities as overlapping functions that a physicist could do as well as the RSO. Dr. Ben-Haim, however, did not receive delegation from Dr. Moskowitz to perform these activities and Dr. Ben-Haim knew Dr. Moskowitz was not performing the duties of the RSO. By regulation, as explained above, the RSO is responsible for assuring that these duties are carried out. Therefore, by engaging in activities, which included some functions of the RSO, he facilitated NMA's conducting operations without the involvement of the RSO named on the license.

113. Dr. Ben-Haim called our attention to the Dose Calibrator Geometry Correction wherein he did not sign as the RSO for NMA. We do not give this evidence much weight in that it tends to prove not that Dr. Ben-Haim did or did not act as the RSO but rather that he knew he was not the RSO. The Staff need not show that Dr. Ben-Haim conducted RSO activities under a blatantly false claim that he was the RSO.

114. We find Dr. Ben-Haim caused NMA to fail to have the duties delineated in 10 C.F.R. § 35.21 performed by the RSO. In addition, by acting as the de facto RSO, he caused NMA to change RSOs without the required license amendment. Finally, Dr. Ben-Haim caused NMA to operate without Dr. Moskowitz as RSO.

115. Mr. Wilson testified that he conducted an OI interview with Marina Geylikman at Harlem Hospital in the Nuclear Medicine Department. Tr. 531. Mr. Wilson testified that Ms. Geylikman said her duties at NMA involved receiving deliveries of technetium-99m, performing surveys and wipe tests of the delivery container, and preparing the patients for injection of technetium-99m. Tr. 532.

116. Mr. Wilson testified that Ms. Geylikman told him that Dr. Ben-Haim set the procedures for those activities in place and explained them to her. Tr. 532. Mr. Wilson testified that Ms. Geylikman described Dr. Ben-Haim as "her supervisor at [NMA] for the radioisotopes of technetium-99m and how to go about using those." Tr. 532, 612.

117. Mr. Wilson testified that he asked Ms. Geylikman if she knew who the RSO at Harlem Hospital was and she clearly knew who that person was. Tr. 532-533, 612-613. Mr. Wilson testified that Ms. Geylikman likened the RSO's duties at Harlem Hospital to what Dr. Ben-Haim did for NMA. Tr. 533.

118. Mr. Wilson testified that Ms. Geylikman said that in case of an emergency she was told by Dr. Ben-Haim to page him. Tr. 538-539, 613. Mr. Wilson testified that she further said that she had to page Dr. Ben-Haim on several occasions. Tr. 539.

119. Mr. Wilson testified that the investigators understood Ms. Geylikman to mean that, if there was a problem regarding any of the procedures that Dr. Ben-Haim established, she would contact Dr. Ben-Haim. Tr. 561. Mr. Wilson testified that the focus of his questions revolved around nuclear medicine procedures -- "in context, she was discussing nuclear medicine procedures put in place by Dr. Ben-Haim, and she said when there were problems encountered, she paged him."

Tr. 613; *see also* Tr. 591. Mr. Wilson testified that Ms. Geylikman did not state that the problems for which she was to call Dr. Ben-Haim were limited to equipment problems. Tr. 640.

120. Ms. Geylikman testified that she came to NMA every Saturday when she was needed. Tr. 176. Ms. Geylikman stated that she would perform a wipe test on the package, open the package and measure the dose for the patient. Tr. 177. She testified that the material came already premeasured in a syringe but that she had to measure it before injecting the patient. Tr. 177. After injecting the patient, she would perform the scan and develop the film. Tr. 177-178.

121. During her testimony, Ms. Geylikman stated that at NMA she considered Dr. Ben-Haim to be "a supervisor, just regarding this machine." Tr. 179. She said that Dr. Ben-Haim instructed her how to operate the machine and that it was the same machine that she had in West Orange where she previously worked with Dr. Ben-Haim. Tr. 179. Ms. Geylikman testified that no one at NMA explained to her the procedures for the scans because it is a common procedure for each nuclear medicine facility. Tr. 180. When asked if anyone instructed her on the wipe test, Ms. Geylikman replied that Dr. Ben-Haim showed her these things in West Orange, but not at NMA. Tr. 180. She testified that the forms, likewise, were the same as in West Orange and that she did not need any instruction. Tr. 181.

122. Ms. Geylikman testified that most of the time she was alone at NMA when she performed her duties. Tr. 191. Ms. Geylikman testified that Dr. Ben-Haim told her to contact him in the event of an emergency -- "if I could not, for example, do the scan, if the machine stopped . . . ." Tr. 181. She stated that if there was an emergency with a patient, she would have to call a doctor. Tr. 181.

123. When asked about her statements to OI, Ms. Geylikman stated that she did not recall her response to OI--"Maybe I just misunderstood [the questions] because Dr. Ben-Haim routinely did this in the West Orange office." Tr. 184.

124. We find that the interview of Ms. Geylikman, as reported by Special Agent Wilson in his testimony and in the OI Report, occurred as Mr. Wilson stated. We could not find in the record any substantial basis for attributing to Mr. Wilson any bias which would discredit his testimony. Neither do we find any substantial evidence of confusion on the part of Mr. Wilson as to what was said. We are somewhat mystified by the inconsistency between what Ms. Geylikman told OI and what she said in her testimony. While the record is devoid of any evidence of bias on the part of Ms. Geylikman, we find that Ms. Geylikman misunderstood what OI was asking. We, therefore, accept what she testified to under oath as the truth regarding her knowledge of Dr. Ben-Haim's activities. Nevertheless, we find nothing in Ms. Geylikman's testimony that would alter our finding that Dr. Ben-Haim performed certain of the functions of the RSO at NMA without a delegation from Dr. Moskowitz, the RSO named on the license.

125. The essence of Ms. Geylikman's testimony is that Dr. Ben-Haim did not instruct her on performing wipe tests or filling out the forms because Dr. Ben-Haim had instructed her in these matters in a separate facility. We find this inconsistent with Dr. Ben-Haim's own proposal to Dr. Elamir wherein he says he will "assure continuous monitoring of the laboratory," "train your staff,"and "establish the necessary radiation health procedures." Further, we find this inconsistent with Dr. Ben-Haim's admission to OI that he was the de facto RSO and his testimony that de facto he did the things the RSO could do. He had identified one such overlapping duty as "radiation safety . . . mainly wipe tests." For these reasons, the preponderance of the evidence leads us to conclude

that Dr. Ben-Haim performed certain of the duties of the RSO at NMA without a delegation from Dr. Moskowitz, the RSO named on the license.

Staff Analysis

126. Mr. Kinneman testified that Dr. Ben-Haim's actions caused the licensee to be in violation of 10 C.F.R. § 35.21. Tr. 280. Mr. Kinneman testified that he finds it hard to conclude that Dr. Ben-Haim would not have realized in his position as a physicist that there should have been some evidence that the RSO gave Dr. Ben-Haim a delegation of authority and gave him some direction to do those RSO duties. Tr. 293-294. Mr. Kinneman testified that Dr. Ben-Haim was associated with NRC activities over a period of time, was involved with various communications with the NRC over a period of time, was apparently knowledgeable of what was going on at the facility even though not present at all times. Tr. 303. Mr. Kinneman testified that on balance it appeared that Dr. Ben-Haim and Dr. Elamir had or should have had the information they needed to conclude that NMA was not in compliance with the NRC's requirements and yet the activities continued. Tr. 303. Mr. Kinneman testified that Dr. Ben-Haim reasonably should have known that the RSO did not exist because Dr. Ben-Haim did visit on some periodic basis, he had some contact with NMA, he is not unknowledgeable about how licensees operate, and, in fact, he was to advise the licensee on such matters as compliance with the NRC's regulations. Tr. 336.

127. The Board adopts the Staff's analysis as stated above and concludes that Dr. Ben-Haim's actions in acting as NMA's RSO were intentional and, therefore, constituted a violation of 10 C.F.R. § 30.10. In so doing, we emphasize our prior finding that Dr. Ben-Haim, by virtue of his knowledge of the NRC's regulations and the fact that he personally prepared NMA's

license application, including the provisions involving the RSO, knew the requirements that he caused NMA to violate.

(3) Summary of Findings

128. In summary, we conclude: (1) Dr. Ben-Haim deliberately brought about the use of licensed material at NMA even though he knew that the RSO named on the NMA license did not perform the duties delineated in 10 C.F.R. § 35.21; (2) Dr. Ben-Haim knew that Dr. Moskowitz, the RSO named on the license, was not functioning as the RSO and that, therefore, a license amendment was required for NMA to continue to operate. Thus, Dr. Ben-Haim deliberately caused NMA to operate without an RSO and without a license amendment to change the RSO; and (3) Dr. Ben-Haim deliberately caused NMA to operate without Dr. Moskowitz as RSO. Specifically, we find that Dr. Ben-Haim deliberately performed the functions of the RSO, even though he knew Dr. Moskowitz had not delegated this authority to him. Therefore, Dr. Ben-Haim violated 10 C.F.R. § 30.10.

D. The Authorized User Violation

(1) NRC Requirements

129. The Order states that Dr. Ben-Haim violated 10 C.F.R. § 30.10 by causing NMA to be in violation of 10 C.F.R. §§ 35.53(c)(3), 35.11(a) and (b), and NMA License Condition 13. These Commission requirements were presented and explained by Mr. Kinneman, Dr. Siegel, and Mr. DelMedico.

130. Mr. Kinneman testified about the NRC requirements that were violated as a result of Dr. Ben-Haim's actions. Tr. 276-280. Mr. Kinneman testified that 10 C.F.R. § 35.53(c) requires

that the licensee retain a record of the measurement of each dosage, including prescribed dosage, of a photon-emitting radionuclide prior to medical use. Tr. 276; *see* 10 C.F.R § 35.53(a) and (c).

131. Mr. Kinneman testified that the prescribed dosage is defined in 10 C.F.R. § 35.2 and means the quantity of radiopharmaceutical activity as documented in (1) a written directive or (2) the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of an authorized user. Tr. 276-277; 10 C.F.R. § 35.2.

132. Dr. Siegel testified that Part 35 requires a written directive, or explicit prescription, for two specific circumstances: 1) any time a dose of I-131 exceeding 30 microcuries is to be administered to a patient; and 2) for any therapeutic administration of a radiopharmaceutical. Tr. 360-361, 363.

133. Mr. Kinneman testified that the diagnostic clinical procedures manual is a collection of written procedures that includes each diagnostic procedure that has been approved by the authorized user. Tr. 277. Dr. Siegel also testified that the clinical diagnostic procedures manual is a compilation of the procedures performed in a laboratory that contains information about what drug is used for the test, what the dose of the drug is, the route of administration of that drug, and then all of the other details about how the test is performed; how long to wait after injection before imaging; what kind of camera to use; what kind of collimator to use; what specific pictures to take and in what specific sequence. Tr. 361.

134. Dr. Siegel testified that the NRC regulations require that the authorized user must be the one who approves the procedures manual. Tr. 362, 363. The Commission's regulations define a diagnostic clinical procedures manual as a "collection of written procedures that describes each method . . . by which the licensee performs diagnostic clinical procedures; where each

diagnostic clinical procedure *has been approved by the authorized user* and includes the radiopharmaceutical, dosage, and route of administration." *See* 10 C.F.R. § 35.2 (emphasis added). Dr. Siegel testified that it is not permissible for a physicist who is not a physician to put into effect a diagnostic clinical procedures manual without the approval of the authorized user. Tr. 370-371.

135. Thus, Mr. Kinneman testified, that a prescribed dosage has to be in a written directive, a diagnostic clinical procedures manual, or in any other written record from the authorized user. Tr. 277. Mr. Kinneman testified that "the real key is that [it] has to be the authorized user that directs the dosage." Tr. 277. Dr. Siegel likewise testified, "the ultimate authorization to actually give [a] dose to a patient has to come from the authorized user." Tr. 430.

136. Dr. Siegel was asked whether it is permissible to administer a diagnostic radiopharmaceutical to a patient without a physician's prescription. Tr. 357. Dr. Siegel testified that there is an implicit prescription that underlies the performance of all diagnostic nuclear medicine procedures. Tr. 360. Dr. Siegel testified that for the vast majority of diagnostic administrations, an explicit written prescription is not required, and the directions can range from an oral instruction from the authorized user to the technologist to reliance on an implicit prescription contained in the clinical diagnostic procedures manual. Tr. 361, 363. Dr. Siegel testified that the procedures manual functions as the implicit prescription. Tr. 361. Dr. Siegel testified that, based on the procedures established in a given laboratory, there may be authorization for the technologists to perform the test in accordance with the procedures manual as if they had received an explicit written prescription from the authorized user. Tr. 361-362.

137. Mr. Kinneman testified that "authorized user" is defined in 10 C.F.R. § 35.2 and that it means a physician, a dentist or a podiatrist who meets the requirements that are specified in that regulation. Tr. 277.

138. Mr. Kinneman testified that the regulations in 10 C.F.R. § 35.25 require that an authorized user must provide supervision of employees or staff that carry out licensed activities. Tr. 287; 10 C.F.R. § 35.25. Mr. Kinneman testified that the authorized user may instruct other people to carry out specific tasks, such as the administration of the radioactive material to the patient; however, the authorized user must provide the supervision that is described in 10 C.F.R. § 35.25. The licensee must require that the supervised individual follow the instructions of the supervising authorized user. *See* Tr. 287; 10 C.F.R. § 35.25(a)(2).

139. Section 35.11 (b) of the Commission's regulations provides that an individual may receive, possess, use or transfer byproduct material in accordance with the regulations under the supervision of an authorized user as provided in section 35.25, unless prohibited by license condition. 10 C.F.R. 35.11(b). An individual is prohibited from these activities except in accordance with a specific license or under the supervision of an authorized user. 10 C.F.R. § 35.11(a).

140. Mr. Kinneman testified that the authorized user specifies what the dose to the patient is to be and that the authorized user must authorize the person to order the radioactive material to be sent to the facility. Tr. 308. Mr. Kinneman testified that while the RSO could order the material on behalf of the facility, the authorized user must authorize the ordering of material for use in the patients. Tr. 310. Thus, the RSO cannot direct the amount to give to each patient unless he is also the authorized user. Tr. 310. Therefore, Mr. Kinneman testified, even if Dr. Ben-Haim were the

RSO, he would be precluded from authorizing the ordering of the dosage to give to a patient. Tr. 311.

141. Dr. Siegel testified that the physician who refers a patient for a diagnostic nuclear medicine procedure is not allowed to prescribe the dosage of radioactive material if the referring physician is not the authorized user. Tr. 378, 380. Dr. Siegel testified that it would not be ordinary for a referring physician to specify the dose for a diagnostic procedure because the referring physician expects the test to be conducted properly--the dose itself is not something the referring physician is concerned about. Tr. 379.

142. Dr. Siegel testified that it is not permissible for a technologist to rely on the direction of a physicist in placing the order for a specific amount of a radiopharmaceutical. Tr. 370. Dr. Siegel further testified that while a physicist may train a technologist in the ordering of the radiopharmaceutical, the authorized user and the RSO need to validate the instruction. Tr. 430-431. "Otherwise the physicist is, in fact, acting as the RSO and the AU." Tr. 431.

143. As previously noted, NMA License Condition 13 provides that licensed material is "only authorized for use by, or under the supervision of" Authorized User, Dr. Moskowitz. Staff Exh. 1.

144. The Board finds that Dr. Ben-Haim's actions would constitute a violation of 10 C.F.R. § 30.10 if he deliberately caused NMA to fail to maintain a record of the measured amount of each prescribed dosage. That is, if he caused NMA to fail to maintain a record of the quantity of radioactive material prescribed by the authorized user as required in 10 C.F.R. § 35.53(c). Thus, we find that NMA would be in violation of 10 C.F.R. § 35.53(c)(3) if Dr. Ben-Haim determined the dosage to be ordered and administered without the approval of the authorized user.

145. The Board also finds that Dr. Ben-Haim would be in violation of 10 C.F.R. § 30.10 if he deliberately caused NMA to allow NMA personnel to receive, possess, use or transfer byproduct material without the supervision of the authorized user. Finally, Dr. Ben-Haim would be in violation of 10 C.F.R. § 30.10 if he caused NMA to operate without Dr. Moskowitz as authorized user. Thus, we find that NMA would be in violation of these two requirements if Dr. Ben-Haim performed the functions of the authorized user without the supervision of Dr. Moskowitz.

(2) Dr. Ben-Haim performed the functions of the Authorized User

146. Ms. Smoligova testified that she ordered technetium-99m for bone scans for the patients that came to NMA. Tr. 125. Ms. Smoligova testified that she ordered the radiopharmaceuticals every Thursday or Friday. Tr. 125. Ms. Smoligova testified that NMA performed bone scans only on Saturdays. Tr. 127.

147. Ms. Smoligova testified that when she met Dr. Ben-Haim, Dr. Elamir asked her if she could order some things for him, such as paper towels, injections or needles-- "whatever they're going to need." Tr. 127-128. She testified that Dr. Elamir asked her if she could help Dr. Ben-Haim with ordering what he needed for nuclear medicine. Dr. Elamir never told her that she would order nuclear materials. Tr. 133, 138.

148. Ms. Smoligova testified that Dr. Ben-Haim told her to order the nuclear materials. *See, e.g.* Tr. 139 (Q "Who told you to order the nuclear materials?" A "Dr. Ben-Haim."), Tr.168 (Q "Did I ask you to do the ordering?" A "Yes."), Tr. 140, Tr.167. Ms. Smoligova testified that Dr. Ben-Haim asked her after operations started if she was ordering the radiopharmaceuticals for the patients, and she told him yes. Tr. 147.

149. Ms. Smoligova identified Staff Exh. 8(a) as what Dr. Ben-Haim gave her regarding what she should order every Thursday or Friday for patients receiving scans. Tr. 128. She testified that Dr. Ben-Haim gave her the document with the procedures and dosages written on it. Tr. 128-129.

150. Staff Exh. 8(a) is a handwritten document that states at the top half:

RADIOPHARMACY:

MEDI-PHYSICS

1-800-242-8004

BONE SCAN -- MDP - 25 mC

HEART -- MYOVIEW
2 SINGLE DOSES
1 x 8 mCi 1 x 25 mCi

Staff Exh. 8(a). The bottom half contains telephone numbers and the name of the licensee. *Id.*

151. Ms. Smoligova testified that Dr. Ben-Haim only gave her that one note and that he gave it to her prior to starting operations. Tr. 136. She testified that the note was not wrinkled: "it was plain." Tr. 144.

152. Ms. Smoligova testified that Dr. Ben-Haim told her that she should check how many patients were scheduled and, accordingly, how many bone scans she would need to order. Tr. 129-130. Ms. Smoligova testified that the receptionist would tell her how many patients there would be. Tr. 141, 142. Ms. Smoligova testified that she was certain Dr. Ben-Haim told her to order nuclear material for bone scans at 25 millicuries. Tr. 130, 131. Ms. Smoligova testified that she ordered the nuclear medicine because she was told to order the radiopharmaceuticals. Tr. 130.

153. Ms. Smoligova testified that when she dialed the number she provided her name, Dr. Ben-Haim's name, the name and address of NMA, and the order. Tr. 145, 153. She testified that the first few times she told them that she was calling for Dr. Ben-Haim. Tr. 145, 153.

154. Ms. Smoligova testified that on subsequent calls she just told them her name, the name and address of NMA, and the amount of unit doses needed for Saturday. Tr. 153. She testified that she would say "bone scan, MDP 25 millicurie" and the amount of unit doses she needed. Tr. 154. They also asked her the time the patient was due in for the procedure. Tr. 154.

155. Ms. Smoligova's testimony is consistent with Dr. Siegel's statement that the procedure for ordering a radiopharmaceutical from a commercial nuclear pharmacy is simply to place a telephone call and request a dose. *See* Tr. 368, 410. Dr. Siegel testified that a radiopharmacy will not accept an order unless it has first been provided with a copy of a byproduct materials license. Tr. 368, 410.

156. Ms. Smoligova testified that Dr. Ben-Haim said that if there was a problem with the ordering she was to contact him. Tr. 130. When asked if Dr. Ben-Haim told her he was in charge or in control, she testified that he was in charge of the ordering. Tr. 160. When asked what she thought Dr. Ben-Haim's function was at NMA, she answered, "[a]s a supervisor of the place which was open for nuclear medicine, for patients to get bone scans." Tr. 169.

157. Ms. Smoligova testified that she ordered the radiopharmaceuticals several times a month. Tr. 162. Ms. Smoligova testified that she saw Dr. Ben-Haim "quite often, at least from the beginning every week," although she never saw him when patients were there. Tr. 169-170.

158. Dr. Siegel and Mr. Kinneman testified regarding the characterization and import of Staff Exh. 8(a), which Dr. Ben-Haim wrote and gave to Ms. Smoligova.

159. Dr. Siegel testified that Staff Exh. 8(a) would be incomplete as a diagnostic procedures manual because not only does a diagnostic procedures manual have to specify the drug that is to be used for a particular test and the dosage to be administered, but also the route of administration. Tr. 365, 367. Dr. Siegel testified that even if the route of administration had been included in the document, it would have been "the barest bones clinical diagnostic procedures manual one could conceive of." Tr. 367. In fact, Dr. Siegel testified that he never saw anything that could be properly characterized as a diagnostic procedures manual from NMA. Tr. 396.

160. Dr. Siegel testified that if that paper was posted on the wall of a nuclear medicine laboratory and there was nothing else anywhere else in the laboratory that even looked remotely like a procedures manual or instructions, one might logically conclude that it was intended to be something like a procedures manual. Tr. 403. When asked whether it would be considered less as a manual if kept in a drawer rather than being posted, Dr. Siegel testified that he did not think so, that the physical state of a manual could be variable: it could be posted on the wall; kept in a book on a shelf; kept in a drawer; or kept on a computer. Tr. 429.

161. Dr. Siegel testified that if the document was essentially the only information/instruction that had been provided to the ordering technologist and the nuclear medicine technologist who actually performed the studies, then the document operationally represented the delegation of authority to order the radioactive materials, in which case it would put Dr. Ben-Haim in the position of having acted as the RSO. Tr. 397-398. Dr. Siegel testified that it also became the apparent set of instructions on how to perform the study, which put Dr. Ben-Haim in the position of having acted as the authorized user. Tr. 398.

162. Dr. Ben-Haim testified that the piece of paper on which the information was written was "arbitrarily qualified as a prescription" by the Staff. Tr. 811, (Dr. Ben-Haim) ff. Tr. 786 at 5. Dr. Ben-Haim testified that there was no signature, no date, no name of patient, it was not meant to be presented to a pharmacy or a doctor, it was not specific to one radiopharmaceutical. Tr. 811, (Dr. Ben-Haim) ff. Tr. 786 at 5. Dr. Ben-Haim testified that it was general information, as it might appear on any pamphlet, and did not engage anybody. Tr. 811, (Dr. Ben-Haim) ff. Tr. 786 at 5. *See also* Tr. 813, (Dr. Ben-Haim) ff. Tr. 786 at 6 ("it is information only").

163. Dr. Siegel testified that he would not consider the document to represent a prescription. Tr. 387.

164. Dr. Siegel testified that if the 25 millicurie dose were administered, based on Staff Exh. 8(a), one would conclude that it was the prescribed dose and that the person who wrote the document would have prescribed it. Tr. 365-366. The person who prepared the note would need to be an authorized user. Tr. 366. Mr. Kinneman likewise testified that the document was "the closest thing that we have to a prescribed dosage" as defined in the regulations. Tr. 324.

165. Dr. Siegel testified that the physical status of the instructions regarding what doses to order and whether someone had written a telephone number on it is not relevant and does not render the instructions invalid. Tr. 380-381.

166. Regarding the characterization of Staff Exh. 8(a), we find that this document contains written instructions regarding the radiopharmaceuticals and dosages to be ordered and administered to patients for medical uses. The Board does not find that this document is an explicit prescription, as one would typically receive from a doctor to be filled by a pharmacist; nor does the Board find that it is a clinical diagnostic procedures manual, as defined in the Commission's regulations. We

find, instead, that this document is an instruction on the quantity of radioactive material to be ordered.

167. The Board also finds that the physical status of the prescribed dosage in the instant situation has no relevance to its nature and effect. That is, whether the document was wrinkled and was later annotated with extraneous information by Ms. Smoligova did not render it ineffectual in conveying instructions regarding the dose of radioactive material to be ordered and administered. Indeed, Ms. Smoligova ordered radioactive material based on that document.

168. Ms. Smoligova's testimony, as set forth above, is fully consistent with the information she provided to Special Agent Wilson. Mr. Wilson testified that he conducted an interview with Ms. Smoligova, who said that her duties were primarily magnetic resonance imaging duties and that she had one duty regarding nuclear medicine: the ordering of radioisotopes on Friday so that they could be used on Saturday. Tr. 534-535. Mr. Wilson testified that Ms. Smoligova told him that she took direction from Dr. Ben-Haim on ordering the radioisotopes. Tr. 535. Further, she told OI that Dr. Ben-Haim had given her something in writing to cause her to order the radioisotopes each and every week. Tr. 535. Mr. Wilson testified that he received a copy of the document on the day of the interview. Tr. 536. *See* Staff Exh. 8(a).

169. Mr. Wilson testified that Ms. Smoligova informed OI that Dr. Ben-Haim told her if there were any problems or emergencies regarding her ordering duties she should contact him. Tr. 536-537.

170. Special Agent Wilson testified that, during OI's first interview with Dr. Ben-Haim, the OI investigators asked him how the technetium-99m was being ordered, and Dr. Ben-Haim "really couldn't answer them. He didn't have an answer of how it was being ordered." Tr. 530.

171. Mr. Davis testified that during Dr. Ben-Haim's second interview, he showed Dr. Ben-Haim a copy of the document received from Ms. Smoligova (Staff Exh.8(a)). Tr. 547. Mr. Davis testified that Dr. Ben-Haim recognized the document and identified the top portion as his handwriting. Tr. 547.

172. Mr. Davis testified that they discussed the process of ordering the technetium-99m. Tr. 544. Mr. Davis testified that Dr. Ben-Haim said that a nurse or a secretary from one of Dr. Elamir's businesses would call the receptionist at NMA and give the name of an individual who was scheduled to have a bone scan on Saturday. That name would be placed in a log and, at a later time, the order would be called into Medi-Physics by Ms. Smoligova. Tr. 544.

173. Mr. Davis testified that "in handing this document to Smoligova, Dr. Ben-Haim admitted to me that he was giving her the authorization to order the [technetium-99m] when it was needed." Tr. 547-548.

174. Mr. Davis further testified that Dr. Ben-Haim told him "the authorized user on the license is the only individual that would be able to delegate this duty" and that the authorized user on NMA's license was Dr. Moskowitz. Tr. 548. Mr. Davis testified that Dr. Ben-Haim admitted that he had not received the authority to delegate from Dr. Moskowitz. Tr. at 548.

175. Mr. Davis testified that Dr. Ben-Haim told him, "It was impractical to always abide by the small rules." Tr. 549.

176. Mr. Davis testified that Dr. Ben-Haim stated that he "owed Dr. Elamir an apology" and that he was "aware that his actions were a mistake" and that he placed the licensee in jeopardy. Tr. 548-549. Mr. Davis testified that Dr. Ben-Haim repeated at the end of the interview that one of

his mistakes was "overseeing and delegating the authority to order the doses of [technetium-99m]." Tr. 550, 580.

177. In his direct testimony, Dr. Ben-Haim stated that he did not admit to OI giving Ms. Smoligova any authorization to order the radiopharmaceuticals. (Dr. Ben-Haim) ff. Tr. 786 at 3, 5. Dr. Ben-Haim testified that he was not aware that his actions were a mistake and placed the licensee in jeopardy and denied that he said that he owed Dr. Elamir an apology. Tr. 802, (Dr. Ben-Haim) ff. Tr. 786 at 3.

178. Dr. Ben-Haim testified that Ms. Smoligova received only one single piece of paper and not "notes" and that she did not take direction from Dr. Ben-Haim for ordering the Tc-99m. Tr. 803, (Dr. Ben-Haim) ff. Tr. 786 at 4. Dr. Ben-Haim testified that Dr. Elamir designated Ms. Smoligova as the person in charge of ordering the radiopharmaceuticals from the pharmacy and that Dr. Elamir asked Dr. Ben-Haim to write down for her the pertinent information, which he did. Tr. 808, 809, (Dr. Ben-Haim) ff. Tr. 786 at 3, 5.

179. Dr. Ben-Haim testified that he "did not know that the authorized user on the license is the only individual who, with respect to NMA, can delegate the ordering duty." Tr. 802. *See also* Tr. 802, 853, 854, (Dr. Ben-Haim) ff. Tr. 786 at 3. Dr. Ben-Haim testified that common practice, as documented in the OI report of interview of John Carr, contradicts this. Tr. 802, (Dr. Ben-Haim) ff. Tr. 786 at 3. We do not find Dr. Ben-Haim's argument credible because he was familiar with the NRC's regulations and NMA's license: he held himself out in the medical community as having knowledge in the NRC's requirements; he compiled and prepared NMA's license application; and he made it a practice to know the NRC requirements in his consultant work. Tr. 822-823. In

addition, as more fully discussed below, Mr. Carr's statement to OI did not pertain to the requirements placed on NMA and, thus, is inapposite to any discussion of them.

180. John Carr, Facility Manager, MPI Pharmacy Services, Medi-Physics, Inc., told OI that, prior to filling NMA's first order for nuclear material, Medi-Physics requested that a copy of NMA's license be faxed to Medi-Physics. *See* Staff Exh. 8, OI Exh. 25 (OI interview of John Carr). Mr. Carr told OI this was "standard operating procedure for MPI." *Id.* Mr. Carr stated that NMA called in their orders on Friday, for Saturday delivery and that the "only requirement MPI has, by law, before delivering Tc-99 to a customer, is that the customer prove it has a valid materials license." *Id.* Mr. Carr stated: "In this case, MPI was in possession of an NRC materials license for NMA that appeared to be legitimate." *Id.*

181. Dr. Ben-Haim admitted that he faxed a copy of the license on October 18, 1996, to Mr. Carr in order for NMA to be able to buy radioactive material. Tr. 863-864. Dr. Ben-Haim testified that he had no doubt in his mind at the time he sent Mr. Carr the license that there was an authorized user and an RSO. Tr. 865.

182. Upon cross-examination, Dr. Ben-Haim testified that he wrote "Radiopharmacy," "Medi-Physics," the 800 number, "bone scan," a nuclear diagnostic procedure, "MDP," and "25 millicuries" on the note he gave to Ms. Smoligova. Tr. 840-841. *See* Staff Exh. 8(a). Dr. Ben-Haim also testified that he wrote "Heart," "Myoview," and "two single doses," "8 millicuries" and "25 millicuries." Tr. 841. Dr. Ben-Haim admitted that he gave this information to Ms. Smoligova, although he objected to the characterization that they were instructions to her. Tr. 844. Dr. Ben-Haim admitted that he knew she would use the information to order the radiopharmaceuticals. *See* Tr. 844 (Q "Isn't it a fact that you knew she would use this information

to order the radiopharmaceuticals?" A "Yes."). Dr. Ben-Haim, however, maintained that he did not tell her to order the radiopharmaceuticals. Tr. 844.

183. Dr. Ben-Haim denied that he authorized Ms. Smoligova to order the radiopharmaceuticals. Tr. 844. Dr. Ben-Haim testified that, since he did not have the authority, "I could not authorize and did not authorize." Tr. 811, (Dr. Ben-Haim) ff. Tr. 786 at 5.

184. Further, Dr. Ben-Haim denied that he himself ordered the radiopharmaceuticals. Tr. 844-845 (Q. "Well, did you order the radiopharmaceuticals?" A. "No, I did not."). However, following admission of Staff Exh. 15, when asked by the Board whether he placed the first order, Dr. Ben-Haim testified: "No, I don't remember if I placed the first order. It's possible, possible, but I did not give my -- John Carr knew me from -- and I ordered from West Orange. He knew me and there was a license and I thought at that time that I could order *and I may have ordered.* I don't recollect." Tr. 886 (emphasis added).

185. During his cross-examination, Dr. Ben-Haim was confronted with a letter dated October 17, 1996. Tr. 846-849. Staff Exh. 15. Dr. Ben-Haim admitted that it was a three-paragraph letter that he wrote and faxed to Dr. Elamir on October 17, 1996. Tr. 847. Dr. Ben-Haim admitted that he sent the letter two days before the first delivery of technetium-99m to NMA. Tr. 848.

186. Paragraphs two and three of the letter state:

> 2. Please let me know asap whether we have patients on Saturday, how many and what tests, so I may notify the technician and order the radiopharmaceuticals.
>
> 3. We will have to decide who will place the orders and coordinate the logistics in the future.

Staff Exh. 15.

187. Dr. Ben-Haim testified that "we" in the letter meant NMA and did not refer to himself. Tr. 849, 870. When asked, "By 'we,' it means you and Elamir?", Dr. Ben-Haim replied, "No, not me. I meant NMA. I didn't mean a person." Tr. 870. When asked who would be speaking for the corporation, Dr. Ben-Haim replied, "Elamir would decide." Tr. 870. Dr. Ben-Haim maintained that he was not the one who authorized the ordering and did not implement the ordering. Tr. 884.

188. Dr. Ben-Haim admitted that, in paragraph 2 of the letter, it was his plan to see to it that the radiopharmaceuticals were to be ordered and that, in paragraph 3, he was one of the people who were going to help decide the ordering process. Tr. 850.

189. Dr. Ben-Haim admitted that, in writing the letter, it was either his intent to order the radiopharmaceuticals or tell the technician to order the radiopharmaceuticals. Tr. 869.

190. Dr. Ben-Haim admitted that he had only known Dr. Elamir about a week before he became the consultant for NMA. Tr. 850. Dr. Ben-Haim agreed that he had far greater knowledge about nuclear materials than Dr. Elamir had. Tr. 850. Dr. Ben-Haim admitted that Dr. Elamir had little experience with NRC requirements. Tr. 826.

191. Dr. Ben-Haim admitted that Dr. Moskowitz did not delegate the authority of the authorized user or RSO to him. Tr. 826.

Board Analysis

192. We find that the overwhelming weight of the evidence supports a finding that Dr. Ben-Haim directed Ms. Smoligova, an MRI technologist, to order a specific radiopharmaceutical in 25 millicurie unit doses for nuclear diagnostic procedures. The Board bases its finding on the testimony of Ms. Smoligova that Dr. Ben-Haim gave her written instructions on how much

radioactive material to order, the specific radiopharmaceutical, and from what source, together with her testimony that he told her to place the orders. Further, Dr. Ben-Haim admitted that he knew that Ms. Smoligova would use the information to order the radiopharmaceuticals.

193. Dr. Ben-Haim stated in his defense that he did not know the only individual who could delegate the ordering duty was the authorized user. We do not accept that Dr. Ben-Haim, who was knowledgeable of the NRC's regulations and who personally put together the license application for NMA, was not aware of this requirement. Dr. Ben-Haim further stated that OI's report of John Carr's interview contradicts the requirement. We find nothing in John Carr's interview that supports Dr. Ben-Haim's statement. Indeed, there is a difference between what a radiopharmacy must do to comply with State and federal requirements and what a nuclear diagnostic facility must do to satisfy NRC requirements. Finally, we reject as circular reasoning Dr. Ben-Haim's assertion that, since he did not have the authority to authorize the ordering, he did not authorize the ordering. Certainly, he did not need to have the authority to order the material in order to cause the material to be ordered without the knowledge of, or direction from, the authorized user, which is the essence of the 10 C.F.R. § 30.10 violation.

194. The Board was also persuaded by the testimony of Special Agent Davis regarding his interview with Dr. Ben-Haim on April 22, 1997. As we previously noted, we find nothing in the record before us to suggest that Mr. Davis either was biased or misunderstood the conversation. We therefore find, despite Dr. Ben-Haim's protests to the contrary, that he admitted to OI that he authorized Ms. Smoligova to order the radiopharmaceuticals, that he knew the authorized user on the license was the only person who could delegate that duty, and that Dr. Moskowitz had not delegated that duty to him. We also find that Dr. Ben-Haim told Mr. Davis that "[i]t was impractical

to always abide by the small rules" and that this was a true reflection of Dr. Ben-Haim's state of mind.

195. Finally, we find that Dr. Ben-Haim's October 17, 1996 letter to Dr. Elamir sufficiently demonstrates Dr. Ben-Haim's intent to bring about the ordering of radiopharmaceuticals without knowledge of, or direction from, Dr. Moskowitz. Dr. Ben-Haim wrote that he needed to know the number of patients coming in on Saturday and the tests that would be performed so that he might "notify the technician and order the radiopharmaceuticals." We find that, based on this information, he determined the 25 millicurie dosage and authorized its ordering and subsequent use. We do not accept his arguments that the letter means anything other than what it says.

196. Ms. Geylikman, the nuclear medicine technologist who performed the bone scans, testified that the radioactive material as it was ordered was always 25 millicuries and that it came in unit doses of 25 millicuries for each patient. Tr. 191-192. She stated that 25 millicuries is a standard dose for an injection. Tr. 199.

197. Ms. Geylikman stated that she would be the one who would determine how much to give the patient. Tr. 200. Ms. Geylikman testified that it makes some difference if the person is large or small and that she knew how to adjust for the difference. Tr. 188, 192.

198. Ms. Geylikman, however, also testified that she did not determine how much radioactive material to inject, but that each patient came with a doctor's order that said "what to do, what kind of scan to do, and how much is supposed to be." Tr. 191, 198-199. Ms. Geylikman clarified in response to our questioning that the doctors' orders did not specify the amount of radioactive material to inject. In this regard, the Board asked whether, when the patients came to NMA bearing doctors' orders for bone scans, it was she who determined the amount of radioactive

material to inject. Tr. 200. Ms. Geylikman replied, "Actually, yes. And the same at hospital, it's the same. We know the standard order, the standard dose between 20 and 25, maybe 22, 23. It doesn't matter." Tr. 200.

The Board then asked , "And you made some record of [dosage] for each . . . patient?"

Ms. Geylikman, replied, "Yes."

"And the amount?"

"Yes."

"But that would not be on a prescription as such?"

"No." Tr. 202.

199. Ms. Geylikman's clarification is consistent with Dr. Siegel's testimony that the referring physician would not likely specify the dose for a diagnostic procedure. *See* Tr. 378-380.

200. With respect to altering doses, Dr. Siegel testified that it is not infrequent that nuclear medicine facilities have a procedure that says something to the effect that if a dose of 25 millicuries is specified, an acceptable dose is that number plus or minus ten percent. Tr. 369. Dr. Siegel testified that a facility would create a policy on what allowable dose ranges are and that in many facilities the allowable range is not in writing. Tr. 416-417; Tr. 370.

201. Dr. Siegel testified that a technologist is not authorized to determine the range, but that the only one who is authorized to write the prescription, which includes decisions about deviations from standard doses as specified in the clinical procedures manual, is the authorized user. Tr. 370, 374. Dr. Siegel testified that the decision to use 10 millicuries, 15 millicuries, or 20 millicuries is a decision made either on a patient-by-patient basis, by the authorized user, or made on a laboratory-by-laboratory basis where they wish to be in the dose range. Tr. 373, 374.

202. Dr. Siegel testified that nuclear medicine technologists are not considered licensed practitioners and would be unable to write a prescription and, therefore, would be unable to vary the dose based on their own medical judgment. Tr. 375. Dr. Siegel testified that it is not permissible for a technologist to rely on the direction of a physicist who is not a physician in administering an amount to the patient. Tr. 370.

203. Based on the above testimony of Ms. Geylikman, we find that she injected the radioactive material into the patients using 25 millicuries as a standard dose because the material was ordered in unit doses of 25 millicuries and that is how the nuclear pharmacy provided it. And they came in unit doses of 25 millicuries because Dr. Ben-Haim determined that dosage and had them ordered as such. We find that Dr. Ben-Haim deliberately brought about the use of radioactive material at NMA without the authorization or involvement of the authorized user.

204. Mr. Kinneman testified that as part of his responsibilities he had to review the information contained in the OI report and determine what actions needed to be taken as a result. Tr. 107; *See* Staff Exh. 8. Mr. Kinneman testified that he came to conclusions based on the OI report and assisted in the preparation of the order against Dr. Ben-Haim. Tr. 107-108.

205. Mr. Kinneman stated that 10 C.F.R. § 35.53(c)(3) was violated when Dr. Ben-Haim provided the information and direction to the individuals who actually did order the doses and who administered the doses to the patients. Tr. 278-279. Therefore, since there was no authorized user, the activities had occurred in the absence of the authorized user. Tr. 279.

206. Mr. Kinneman, when asked what Dr. Ben-Haim did as an authorized user, stated that he directed the individual who ordered the dose, and the dose was waiting for the nuclear medicine technician to administer it to the patient. Tr. 327-328.

207. Mr. DelMedico testified that Dr. Ben-Haim violated 10 C.F.R. § 30.10 if he knew that the instructions that he was providing would bring about the possession of byproduct material at NMA and he knew that before NMA could possess byproduct material the approval of Dr. Moskowitz was needed. Tr. 683-684.

208. Mr. Kinneman testified that Dr. Ben-Haim should have known that there was no RSO or authorized user at NMA. Tr. 445, 446. Mr. Kinneman testified that he concluded that there was intention to continue without the RSO and AU. Tr. 448.

209. The Board adopts the Staff's analysis as stated above and concludes that Dr. Ben-Haim's actions in determining the doses to be ordered and administered to patients without the involvement of the authorized user were intentional and, therefore, constituted a violation of 10 C.F.R. § 30.10. In this regard, we emphasize our earlier finding that Dr. Ben-Haim was knowledgeable and held himself out to have expertise in the NRC's requirements and that he personally read and prepared NMA's license application. He, therefore, knew what the requirements were when he caused NMA to violate them.

(3) Summary of Findings

210. In summary, we conclude that Dr. Ben-Haim caused NMA to be in violation of 10 C.F.R. § 35.53(c)(3), by causing NMA to fail to maintain a record of the quantity of radioactive material prescribed by the authorized user through his actions of deliberately determining the dosage to be ordered and administered to patients without the authorized user having prescribed that dosage. Since no authorized user was involved in the determination of the dosage, there was no prescribed dosage as defined in 10 C.F.R. § 35.2. Thus, the records that NMA kept did not fulfill the requirements of 10 C.F.R. § 35.53(c)(3), which requires the record to include the "prescribed

dosage." 10 C.F.R. § 35.53(c)(3). We also find that Dr. Ben-Haim intentionally caused NMA to allow NMA personnel to receive, possess, use and transfer byproduct material without the supervision of the authorized user in violation of 10 C.F.R. § 35.11(a) and (b). Finally, we find that Dr. Ben-Haim intentionally caused NMA to operate without Dr. Moskowitz as authorized user, a clear violation of NMA's license. Therefore, we conclude that Dr. Ben-Haim violated 10 C.F.R. § 30.10 by deliberately causing NMA to be in violation of the above requirements.

E. The Appendix K Violation

211. We address separately that aspect of the Order which alleges that Dr. Ben-Haim caused NMA to be in violation of a provision of its license that sets forth both an RSO and an authorized user responsibility. This "Appendix K" violation touches upon both roles and, therefore, we elected to address it separately from those portions of our findings dealing specifically with the RSO and authorized user violations.

212. Under Condition 16 of NMA's license, the licensee is required to conduct its program in accordance with the "statements, representations, and procedures contained in the documents, including any enclosures, listed below." Staff Exh. 1. One such document is the license application. *Id.* Mr. Kinneman testified that License Condition 16 incorporates the application as a part of the license, "as part of the requirements that the licensee must follow and as the basis for issuing the license." Tr. 82.

213. Dr. Ben-Haim testified that he was familiar with the information in NMA's license application at supplemental Item 10, Radiation Safety Program. He read Item 10.6, which states: "Ordering and receiving. We will establish and implement a model guidance for ordering and

receiving radioactive material that was published in Appendix K to Regulatory Guide 10.8, Revision 2." Tr. 824. *See* Staff Exh. 2.

214. Dr. Ben-Haim testified that he read Appendix K, Regulatory Guide 10.2, Revision 2 and attached it to NMA's license application. Tr. 824. *See* Staff Exh. 2. Dr. Ben-Haim read paragraph number 1 under the heading, "Model Guidance." Tr. 825. That provision states:

> The radiation safety officer, RSO, or a designee must authorize each order for radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting authorized user and that possession limits are not exceeded.

See Staff Exh. 2.

215. Mr. Kinneman testified that under the NMA license, Appendix K, only the RSO or a designee must authorize each order for radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting authorized user and that possession limits are not exceeded. Tr. 285. *See* Staff Exh. 2. Mr. Kinneman testified that Dr. Ben-Haim's actions caused the licensee to be in violation of this requirement because Dr. Ben-Haim provided the direction to the individual who actually ordered the licensed material by saying how much should be ordered and where it should be ordered from. Tr. 286.

216. Dr. Ben-Haim testified that Appendix K says that the RSO or a designee can order, but that it does not specify whose designee. Tr. 808-809. "I do not know that only the RSO or a designee of the RSO. It doesn't say that. It says or a designee." Tr. 808. Dr. Ben-Haim testified on cross-examination that he "was not sure by whom" and did not know what "designee" means. Tr. 825-826. When asked whether he thought that designee meant Dr. Elamir, he stated that he "did

not know," although he admitted that Dr. Elamir had little experience with NRC requirements. Tr. 826.

217. We are unconvinced that Dr. Ben-Haim did not know that designee meant anything other than a designee of the RSO. The subject of the sentence is clear and lends itself to no other rational interpretation. We therefore find that Dr. Ben-Haim deliberately caused the licensee to be in violation of a condition of its license and thus he violated 10 C.F.R. § 30.10. In making our finding, we agree with the Staff that NMA's license incorporates, by the terms of License Condition 16, all parts of NMA's license application, such that a violation of a provision in the application constitutes a violation of the license.

F. The Sanction Imposed

218. Mr. DelMedico, a Senior NRC Enforcement Specialist in the NRC's Office of Enforcement, described in his testimony the rationale for the sanction imposed against Dr. Ben-Haim in the Staff's Order. (DelMedico) ff. Tr. 659 at 1-13.

219. Mr. DelMedico testified that the August 27, 1997 Order was issued to Dr. Ben-Haim because the NRC staff concluded that he deliberately caused NMA to be in violation of NRC requirements and therefore violated 10 C.F.R. § 30.10(a). (DelMedico) ff. Tr. 659 at 7. Mr. DelMedico testified that this conclusion was based on the inspection report and OI Report. (DelMedico) ff. Tr. 659 at 7, Tr. 668.

220. Mr. DelMedico testified that the Enforcement Policy, NUREG-1600, is the Commission's policy for exercising its authority to take actions to enforce its regulatory requirements. (DelMedico) ff. Tr. 659 at 4. *See* Staff Exh. 13. Mr. DelMedico testified that, according to the Enforcement Policy, enforcement actions may be taken against individuals in situations including deliberately causing a licensee to be in violation of NRC requirements, and

recognizing a violation of procedural requirements and deliberately not taking corrective action. (DelMedico) ff. Tr. 659 at 5.

221. Mr. DelMedico testified that, according to the Enforcement Policy, Section VIII, orders to unlicensed individuals may include provisions that would prohibit involvement in NRC licensed activities for a specified period of time and require the person to tell a prospective employer or customer engaged in licensed activities that the person has been subject to an NRC order. (DelMedico) ff. Tr. 659 at 7. Mr. DelMedico testified that the Enforcement Policy, Section VIII, states that the particular sanction to be used for enforcement actions involving individuals should be determined on a case-by-case basis. (DelMedico) ff. Tr. 659 at 8.

222. Mr. DelMedico testified that factors for deciding whether to issue an enforcement action to an unlicensed individual are set forth under Section VIII of the Enforcement Policy. (DelMedico) ff. Tr. 659 at 5.

These factors are:

1. The level of the individual within the organization.
2. The individual's training and experience as well as the knowledge of the potential consequences of the wrongdoing.
3. The safety consequences of the misconduct.
4. The benefit to the wrongdoer, e.g., personal or corporate gain.
5. The degree of supervision of the wrongdoer, e.g., how closely the individual is monitored or audited, and the likelihood of detection.
6. The employer's response, e.g., disciplinary action taken.
7. The attitude of the wrongdoer, e.g., acceptance of responsibility.

8. The degree of management responsibility or culpability.

9. Who identified the misconduct.

(DelMedico) ff. Tr. 659 at 5-6.

223. Mr. DelMedico testified that the following factors were considered in formulating the enforcement action against Dr. Ben-Haim:

> Dr. Ben-Haim is a consultant who had contracted with the licensee to prepare for State and NRC inspections, assure continuous monitoring of the laboratory in compliance with NRC regulations, and assure that proper procedures were used in the handling of radioactive material. It was apparent to the [NRC] Staff that Dr. Ben-Haim occupied a position of specialized knowledge, trust, and authority in the eyes of NMA, as well as any other licensee for whom he might consult. This gave Dr. Ben-Haim the opportunity to have broad influence over the degree of NRC compliance at such facilities.
>
> Dr. Ben-Haim had experience in NRC compliance matters. He prepared the NRC license application with commitments to follow a number of procedures that he later caused the licensee to violate.
>
> Since Dr. Ben-Haim was a consultant as opposed to an employee, his misconduct was unlikely to receive a significant response from the licensee, such as demotion, probation, or firing for cause. Presumably, if the licensee terminated Dr. Ben-Haim's consulting contract, he could still go on to consult at other facilities without the type of detailed check on previous employment that would occur for the hiring of an employee.
>
> There was tangible gain to Dr. Ben-Haim from his misconduct because the licensee's continued operation, even though it did not have a radiation safety officer or authorized user, would allow Dr. Ben-Haim to continue to earn consulting fees.
>
> The underlying licensee violations caused by Dr. Ben-Haim's conduct continued in duration from October 19, 1996 through January 25, 1997.
>
> Dr. Ben-Haim's attitude toward the noncompliances caused by his actions was that it was "impracticable to always abide by the small rules."

(DelMedico) ff. Tr. 659 at 8-10.

224. Mr. DelMedico testified that if the factors weigh against an individual, consideration is given to increasing the sanction for that individual and if they weigh in favor of an individual consideration is given to reducing the sanction based on that factor. Tr. 728-729. Mr. DelMedico testified that these factors do not necessarily carry equal weight. Tr. 729.

225. Regarding the gain Dr. Ben-Haim was expected to receive from engaging in this particular misconduct, Mr. DelMedico testified that there was tangible gain because the licensee's continued operation allowed Dr. Ben-Haim to continue to earn consulting fees. Tr. 693. In particular, Mr. DelMedico testified that Dr. Ben-Haim's agreement with NMA provided for a yearly fee of $16,000 payable quarterly at the beginning of each quarter. Tr. 693; *see* Staff Exh. 8, OI Exh. 7 at 2. When asked whether the Staff's deliberation was influenced by the fact that there were no safety consequences of Dr. Ben-Haim's deliberate misconduct, Mr. DelMedico testified that the Staff was concerned with the potential safety consequences of an individual who could influence a wide number of licensees, and that the Staff was more concerned with potential safety consequences than actual safety consequences. Tr. 722.

226. Mr. DelMedico testified on cross examination that the most important factor is the attitude of the wrongdoer. Tr. 729-730. Regarding this factor, Mr. DelMedico testified that the Commission has addressed the issue of attitude as follows:

> The Commission believes that in addressing the issue of future involvement of an individual in licensed activity, where safety is crucial, it is proper to consider the individual's attitude toward compliance with safety practices and regulations. Recognition and admission of past errors indicates a more positive attitude than continuing denial or hostility, and thus enhances the Commission's reasonable assurance that licensed activities will be conducted in a manner that protects public health and safety. However, attitude is only one factor and is not controlling in the overall determination of appropriate action.

(DelMedico) ff. Tr. 659 at 11. *See* Staff Exh. 14, at 40,676.

227. Mr. DelMedico testified that in his mind the second important factor is the severity level of the underlying violations. Tr. 730. Mr. DelMedico testified that the violations that were caused by Dr. Ben-Haim's actions would be categorized at Severity Level II under section IV of the Enforcement Policy. (DelMedico) ff. Tr. 659 at 9. The severity level of the violations, however, are one consideration of many. Tr. 755.

228. Mr. DelMedico testified that other factors would have been whether Dr. Ben-Haim engaged in deliberate misconduct at another facility or whether the deliberate misconduct was self-reported to the NRC. Tr. 731.

229. We find that the Staff considered the appropriate factors in determining the sanction to be imposed against Dr. Ben-Haim. In particular, we are guided by the importance the Commission places on the individual's attitude toward compliance with the Commission's requirements. We believe that the evidence supports a finding that Dr. Ben-Haim displayed a cavalier attitude toward compliance with the Commission's requirements and that he considered that it was "impractical to always abide by the small rules." We observed during the course of the hearing that Dr. Ben-Haim was not forthcoming in all aspects of his testimony, and we determined that his attitude falls short of what is required of a consultant to NRC licensees and applicants providing advice regarding compliance with NRC requirements. For example, we find that Dr. Ben-Haim was successfully impeached when he was confronted with his October 17, 1996 letter. He had testified that he did not authorize the ordering of radioactive material and that his involvement in this regard was minimal. Yet, the letter that he wrote to Dr. Elamir, which coveys

a sense of urgency, shows that he was an active and knowing participant in the ordering of radiopharmaceuticals and, in fact, was the initiator of this activity.

230. We also agree with the Staff that it was appropriate to consider that Dr. Ben-Haim occupied a position of authority in the eyes of NMA and other entities for whom he may have consulted. Further, Dr. Ben-Haim was not a person unfamiliar with the Commission's requirements--indeed, he prepared the application for the very license that he caused NMA to violate. The Board finds that the Staff correctly applied these factors, as well as those pertaining to the duration of the violations, the tangible gain to Dr. Ben-Haim from the violations, and the fact that as a consultant, his conduct would otherwise go unchecked. For these reasons, the Staff did not err in assessing the factors against Dr. Ben-Haim.

231. Mr. DelMedico testified that the Enforcement Policy, Section IV.C, states that willful violations, which include deliberate violations, are of particular concern to the Commission because its regulatory program is based on licensees and their consultants acting with integrity; and thus deliberate violations cannot be tolerated by the Commission. (DelMedico) ff. Tr. 659 at 9; Staff Exh. 14.

232. Mr. DelMedico testified that the Commission is relying on the licensee and its contractors and its employees to conduct their operations with integrity and in complete compliance with NRC regulations, and it is a matter of trust. Tr. 690. To this end, Mr. DelMedico testified that "*it only takes once--one time* of deliberate misconduct for the Commission to lose confidence in the ability of the individual to conduct licensed activities in compliance with the Commission's requirements." *See* Tr. 719 (emphasis added).

233. Mr. DelMedico further explained that there is a serious question raised as to how, in the absence of having an inspector there daily or some other form of continuous audit, the Commission can possibly have confidence that an individual who engaged in deliberate misconduct, even if only one time, would not do the same thing another time, either at the same facility or at another one. Tr. 715-716.

234. Mr. DelMedico testified that the Order against Dr. Ben-Haim concluded that the NRC could not have confidence that licensed activities could be conducted safely and in compliance with NRC requirements if Dr. Ben-Haim were to be permitted to be involved in licensed activities. (DelMedico) ff. Tr. 659 at 11-12.

235. We agree with the Staff's assessment and find that the Commission has made it clear that it cannot tolerate willful violations, even if committed one time.

236. Mr. DelMedico testified that the sanction in this case was established with a view to three specific goals: (1) protection of the public health and safety by prohibiting a person who has been known to engage in deliberate misconduct from involvement in NRC-licensed activities; (2) deterring other individuals from engaging in deliberate misconduct that involves licensed activities; and (3) rehabilitation of the individual. (DelMedico) ff. Tr. 659 at 11-12.

237. Mr. DelMedico testified that the duration of a sanction against an individual who has engaged in deliberate misconduct should be chosen with the intent that the sanction will restore the Commission's confidence in that individual's ability to conduct licensed activities with integrity and candor at the end of the sanction period. (DelMedico) ff. Tr. 659 at 13.

238. Mr. DelMedico testified that a five year suspension from licensed activities is a sufficient time such that, should Dr. Ben-Haim decide to become involved in licensed activities in

the future, he will appreciate the importance of strict compliance with all Commission requirements. (DelMedico) ff. Tr. 659 at 13.

239. The Board agrees with the Staff's assessment and finds that the five year prohibition from NRC-licensed activities is appropriate and justified.

III. CONCLUSIONS OF LAW

240. The Board has considered all of the evidence presented by the parties pertaining to the Staff's Order prohibiting Dr. Ben-Haim's involvement in NRC-licensed activities for five years. Based upon a review of the entire record in this proceeding and the proposed findings of fact and conclusions of law submitted by the parties, and based on the findings of fact set forth herein, which are supported by reliable, probative and substantial evidence in the record, the Board has decided all matters in controversy and reaches the following conclusions.

241. Based on the foregoing findings of fact, the Board finds that Dr. Ben-Haim caused NMA to be in violation of the following Commission regulations: 10 C.F.R. §§ 35.21, 35.13, 35.11 (a) and (b), 35.53(c)(3). The Board also finds that Dr. Ben-Haim caused NMA to be in violation of License Condition 12, 13, and 16. We find that these actions were deliberate on the part of Dr. Ben-Haim and, thus, he violated 10 C.F.R. § 30.10.

242. Based on those violations and the testimony and documentary evidence submitted in this proceeding, the Board finds that the Staff has met its burden of proof and has shown by a preponderance of the evidence that the Order should be sustained.

IV. ORDER

On the basis of the foregoing opinion, including findings of fact, conclusions of law, and the entire record, it is this ____ day of _____, 1998, ORDERED:

1. The Staff's August 27, 1997, "Order Superseding Order Prohibiting Involvement in NRC-Licensed Activities (Effective Immediately)," is SUSTAINED.

2. This Initial Decision is effective immediately and, in accordance with 10 C.F.R. § 2.760 of the Commission's Rules of Practice, shall become the final action of the Commission forty (40) days from the date of its issuance, unless any party petitions for Commission review in accordance with 10 C.F.R. § 2.786 or the Commission takes review *sua sponte*. *See* 10 C.F.R. § 2.786.

3. Within fifteen (15) days after service of this Decision, Dr. Ben-Haim may seek review of this Decision by filing a petition for review by the Commission on the grounds specified in 10 C.F.R. § 2.786(b)(4). The filing of the petition for review is mandatory for Dr. Ben-Haim to exhaust his administrative remedies before seeking judicial review. 10 C.F.R. § 2.786(b)(2).

4. The petition for review shall be no longer than ten (10) pages and shall contain the information set forth in 10 C.F.R. § 2.786(b)(2). The Staff may, within ten (10) days after service of a petition for review, file an answer supporting or opposing Commission review. Such an answer shall be no longer than ten (10) pages and, to the extent appropriate, should concisely address the matters in 10 C.F.R. § 2.786(b)(2). Dr. Ben-Haim shall have no right to reply, except as permitted by the Commission.

THE ATOMIC SAFETY AND LICENSING BOARD

Dr. Peter S. Lam
ADMINISTRATIVE JUDGE

Dr. Jerry R. Kline
ADMINISTRATIVE JUDGE

Charles Bechhoefer, Chairman
ADMINISTRATIVE JUDGE

Respectfully submitted,

Catherine L. Marco

Catherine Marco
Counsel for NRC Staff

Dated at Rockville, Maryland
this 14th day of August, 1998

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

In the Matter of	)	
	)	IA 97-068
AHARON BEN-HAIM, Ph.D.	)	

CERTIFICATE OF SERVICE

I hereby certify that copies of "NRC STAFF'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW" in the above-captioned proceeding have been served on the following through deposit in the Nuclear Regulatory Commission's internal mail system, or by deposit in the United States mail, first class, as indicated by an asterisk this 14th day of August, 1998:

Charles Bechhoefer, Chairman
Administrative Judge
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