



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA ST., N.W., SUITE 3100
ATLANTA, GEORGIA 30303

INVESTIGATION REPORT NO. 30-1246/81-02

SUBJECT: Okeon Associates, Inc.
P. O. Box A
Parkersburg, WVA 26101

Possible Willful Unauthorized Use of Licensed Material

PERIOD OF INVESTIGATION: March 11-April 1, 1981

INVESTIGATORS:

J. C. Howell, Regional Investigator
Enforcement and Investigation Staff

6-5-81

Date

R. A. Brown, Radiation Specialist
Technical Insection Branch

6/2/81

Date

REVIEWED BY:

Carl E. Alderson, Director
Enforcement and Investigation Staff

6-5-81

Date

TABLE OF CONTENTS

Section I. SUMMARY OF INVESTIGATION

- A. BACKGROUND
- B. SCOPE
- C. CONCLUSIONS

Section II. DETAILS OF INVESTIGATION

- A. PERSONS CONTACTED
- B. INVESTIGATIVE EFFORT AND FINDINGS

SECTION I

SUMMARY OF INVESTIGATION

OKEON ASSOCIATES, INC.

MARCH 11 - APRIL 1, 1981

A. BACKGROUND

A routine inspection of Okeon Associates, Inc., a nuclear medicine service located in Parkersburg, West Virginia was conducted by a radiation specialist from the Materials and Radiation Protection Section, Region II, on January 28, 1981. The inspector identified an apparent violation of Materials License No. 47-16563-01 which requires the licensee to use material in accordance with statements, representations, and procedures contained in the January 29, 1975 license application. That application indicates the licensee's generator and other byproduct material will be "based at main lab, St. Joseph's Hospital", Parkersburg, West Virginia, while a mobile scan unit is to be "used at Calhoun County General Hospital, Grantsville, West Virginia". The inspector noted that, in fact, the licensee had relocated the generator and entire nuclear medicine operation to the Calhoun County General Hospital in direct conflict with the license requirements. This matter was referred to the Region II Enforcement and Investigation Staff to determine the circumstances leading to the unauthorized use of licensed materials.

B. SCOPE OF INVESTIGATION

An investigation was initiated on March 11, 1981 under the authority provided by Section 161.c of the Atomic Energy Act of 1954, as amended, to ascertain if the licensee had willfully used licensed material at an unauthorized location. The scope of this investigation included the following:

1. Review of NRC Materials License No. 47-16563-01;
2. Interview of licensee management;
3. Review of licensee's patient dose records;
4. Interviews of pertinent hospital management and employee personnel;
5. Review of Calhoun General Hospital X-Ray Request and Reports and;
6. Interview of the Radiological Technologist previously associated with licensed operations.

C. CONCLUSIONS

Three violations of NRC Materials License No. 47-16563-01 issued to Okeon Associates, Inc., were noted during this investigation; however, no evidence of willfulness was established.

Based on information obtained through records reviews, interviews, and written statements, the investigators confirmed that licensed material was prepared at an unauthorized location. Additionally, it was determined that the licensee permitted medical procedures to be performed at Calhoun County Hospital without the presence of a physician trained in nuclear medicine and that licensed material was used by individuals other than those authorized by the license.

Although the licensee emphatically denied willfully violating NRC requirements, a written statement acknowledging violations of the materials license was provided.

SECTION II

DETAILS OF INVESTIGATION

OKEON ASSOCIATES, INC.

MARCH 11-APRIL 1, 1981

A. PERSONS CONTACTED

Okeon Associates, Inc.

Melvin M. Okeon, M.D.

St. Joseph Hospital

Wolfgang Strobl, M.D.

Carolyn I. Hoselton, Chief Radiological Technologist

Calhoun County General Hospital

Kay Wriston, Hospital Administrator

Rebecca Nichols, Chief Radiological Technologist

James A. Kolovich, Senior Staff Radiological Technologist

John D. Stump, (Former) Radiological Technologist

Fairmont General Hospital

John C. Turner, M.D.

D'Orazio, Marshall and O'Rourke, Attorneys of Law

Philip E. D'Orazio, Attorney

B. INVESTIGATIVE EFFORT AND FINDINGS1. Conduct of Investigation

A review of NRC Material License No. 47-16563-01, issued to Okeon Associates, Inc. for the period March 5, 1976 - February 28, 1981, was conducted to clarify license requirements. An investigation was then conducted by a Regional Investigator and a Radiation Specialist at St. Joseph Hospital (SJH), Parkersburg, West Virginia and Calhoun County General Hospital (CCGH), Grantsville, West Virginia to determine the facts and circumstances surrounding the licensee's apparent unauthorized use of licensed material.

2. Interview of Chief Radiological Technologist, SJH

On March 11, 1981, Miss Carolyn I. Hoselton, Chief Radiological Technologist, was interviewed regarding licensed activities at SJH. Also present was Miss Shirley Bartley, Senior Radiological Technician.

Miss Hoselton stated that she had been professionally associated with the licensee, Dr. M. M. Okeon, in his position as Director of Radiology at SJH. She related that Dr. Okeon's association with SJH was terminated in March 1979 at the expiration of his contract.

She related that he formed a medical corporation, Okeon Associates, Inc., in Parkersburg and contracted with SJH and with CCGH in Grantsville, West Virginia to provide radiological services. Dr. Wolfgang Strobl, M.D., a current member of the SJH medical staff assisted Dr. Okeon in this service and is identified as an authorized materials user in that corporation's NRC material license. Miss Hoselton stated that as she understood the agreement, all materials were to be prepared at SJH and transported to CCGH for patient injection. She added that this arrangement terminated in March 1979 when Dr. Okeon left the SJH staff. When questioned concerning personal knowledge of specific license violations, Miss Hoselton could not recall any such information.

3. Interview of Dr. Wolfgang Strobl, M.D.

Dr. Wolfgang Strobl, M.D., an SJH staff radiologist, was interviewed on March 11, and again on March 12, 1981, regarding his knowledge of activities conducted under the materials license in question.

Dr. Strobl stated that he was professionally associated with Dr. Okeon from early 1976 until March 1979 at both the St. Joseph and Calhoun County Hospitals. Dr. Strobl stated that he is identified as an authorized materials user in the NRC license issued to Okeon

Associates, Inc., but that he has not participated in activities related to that license since March 1979. In response to questions regarding use of licensed material, he stated that he was unaware of any specific violations, but indicated that he was not familiar with all of the license requirements. He recalled that when Dr. Okeon left his position at SJH, the preparation of isotopes for this license was conducted at CCGH and that he understood the license had been "transferred" to that hospital. He added that Dr. Okeon had a long standing professional relationship with the CCGH Chief Radiological Technologist, Mr. John D. Stump, and any actions necessary to transfer the license would probably have been accomplished by Stump. Dr. Strobl believed that it was normal for Dr. Okeon to depend on others for matters not directly medically associated; often to the extent that routine administrative matters were not adequately accomplished. He related that in his opinion, neither Dr. Okeon nor Mr. Stump would knowingly violate any license requirement and that both were medically dependable, capable, and responsible. Concerning his personal knowledge of the operations conducted at CCGH, Dr. Strobl stated that to his knowledge a physician trained in nuclear medicine was always present during licensed activities and that scan results were always interpreted by that physician.

4. Interview of Dr. Melvin M. Okeon, M.D.

On March 11, 1981 Dr. Melvin M. Okeon, Okeon Associates, Inc., was interviewed regarding NRC licensed activities.

Dr. Okeon stated that in March 1979 he was notified by SJH that his contract with that hospital would not be renewed. He added that to maintain his service to his patients, he decided to move his entire radiological service to CCGH. He related that he requested Mr. John D. Stump, the Chief Radiological Technologist at CCGH, to check into the possibility of preparing isotopes at that hospital and that he was subsequently informed by Mr. Stump that it would be permissible for them to conduct his radiology service at CCGH. Mr. Stump then contacted medical suppliers and arranged for delivery of appropriate materials, and isotopes were then prepared at CCGH. He added that "in retrospect, his operation at CCGH was apparently not in accordance with his license."

In response to questions regarding other aspects of his license requirements, Dr. Okeon related that after his move to CCGH, the scan results were read and interpreted only by him. Scans had been interpreted by both he and Dr. Strobl prior to the move, but Dr. Strobl ceased to participate in licensed activities during early 1979. Dr. Okeon continued by saying that at times it was not possible for him to travel to CCGH and that scans would be transported to him in Parkersburg for interpretation. He stated that once the scans were reviewed, the results were recorded and sent to

the CCGH medical records section where they were transcribed onto an "X-Ray Request and Report" form. He further stated that the transcribed reports were then reviewed and signed by the doctor if he was available; however, at times the typed reports were reviewed for accuracy by the technologist, John Stump. In these instances, the doctor's name would also be signed by Mr. Stump.

The investigators requested and received from Dr. Okeon copies of patient dose records for the period December 1979 - October 1980.

When given the opportunity to provide a written statement further explaining the operational aspects of his medical service, Dr. Okeon declined, pending consultation with his attorney.

5. Interview of Hospital Administrator, CCGH

Miss Kay Wriston, Hospital Administrator, CCGH, was interviewed on March 11, 1981. She related that upon assuming her duties in May 1980, she noted questionable (non-medically related) practices within the Nuclear Medicine Department and a thorough review of that department revealed that Dr. Okeon was operating in violation of his NRC license. The license indicated that all isotope preparation was to be accomplished at SH; however, she observed that the entire operation was being conducted at CCGH. Miss Wriston stated that she brought this and other practices to the attention of both Dr. Okeon and John Stump. She stated that as a result of a direct confrontation, Mr. Stump terminated his position as Chief Technologist in October 1980 and Dr. Okeon submitted his resignation in November 1980 with termination effective on January 10, 1981. She stated that neither individual currently has any professional dealings with CCGH and that the hospital now has its own NRC materials license.

In response to questions relating to specific license requirements, Miss Wriston did not know who interpreted scan results or if the scans were actually transported to Dr. Okeon in Parkersburg for his evaluation. She was aware of x-ray reports contained in CCGH files that reflect scan results bearing signatures other than that of Dr. Okeon.

5. Interview of the Chief Radiological Technologist, CCGH

Miss Rebecca Nichols, Chief Radiological Technologist, CCGH, was interviewed on March 11, 1981. She related that she had been employed at CCGH since December 15, 1980 and worked with Dr. Okeon for approximately 3 weeks until his departure on January 9, 1981. She related seven (7) occasions in December 1980 on which elutions were prepared at CCGH. She stated that the proper procedure for scan interpretation was for Dr. Okeon to view the scans at CCGH or to have them transported to Parkersburg for his evaluation. She was not personally aware of deviations from this procedure.

7. Interview of the Senior Staff Radiological Technologist, CCGH

Mr. James A. Kolovich, Senior Staff Radiological Technologist, CCGH, was interviewed on March 11, 1981. He related that he had been employed at CCGH since December 1974 and had known Dr. Okeon professionally since that time.

In response to questions regarding licensed activities, Mr. Kolovich stated that on a regular basis he observed Mr. Stump, the previous Chief Technologist, preparing elutions and conducting scans without the presence of a nuclear medicine physician. He continued that to the best of his knowledge, the scans were all interpreted by a radiologist and results were dictated to the records department where they were transcribed onto "X-Ray Request and Report" forms. He added that occasionally, in the absence of Dr. Okeon, other physicians substituted for him to perform the required scan procedures and interpretations.

Mr. Kolovich expressed his opinion that Mr. Stump was extremely conscientious and quite capable of performing the radiological procedures. He added that he did not know nor had he ever heard it mentioned that NRC requirements were possibly being violated.

8. Record Reviews

On March 11, 1981 a review was conducted of X-Ray Request and Reports on file in the CCGH records department. The forms reflected pertinent patient information, type of examination conducted, attending physician, medical findings, and identified the "roentgenologist" or radiologist conducting licensed activities.

It was noted that the patient dose records previously received from Dr. Okeon established that licensed material was used as reflected in the X-Ray Request and Reports. However, in several instances the radiologist identified was either Dr. John C. Turner, M.D. or Dr. John Coyner, M.D., neither of whom is identified by Materials License No. 47-16563-01 for authorized materials use.

9. Telephone Interview of Dr. John C. Turner, M.D.

Dr. John C. Turner, M.D. was telephonically interviewed on March 31, 1981, regarding his activities relative to Okeon Associates, Inc.

Dr. Turner related that he is currently a radiologist at Fairmont General Hospital, Fairmont, West Virginia. He stated that he has performed radiology functions at CCGH on several occasions during Dr. Okeon's absence. He did not recall the specific dates he substituted for

Dr. Okeon, but remembered signing the x-ray reports and agreed that the dates reflected thereon are "probably correct." He stated that when working at CCGH, he supervised licensed procedures, interpreted and dictated the results of scans.

Dr. Turner stated that he had not reviewed Dr. Okeon's material license for specific authorization, but assumed that since he is a qualified radiologist it was permissible for him to perform under any license.

10. Interview of John D. Stump

Mr. John D. Stump, former Chief Radiological Technologist, CCGH, was interviewed on March 31, 1981 and executed a written statement regarding his knowledge of activities relating to this investigation. He explained that he received his radiological training at St. Joseph Hospital in Parkersburg, West Virginia during 1967-1969 and was employed at CCGH from July 1969 until his resignation in October 1980.

He stated that he had known Dr. Okeon professionally since 1972 when Okeon Associates, Inc. contracted with CCGH to provide a radiology service to that hospital. He continued by saying that Dr. Okeon left SJH in 1979 and began to devote his full attention to CCGH. During that transition period, Dr. Okeon presented him with a copy of NRC Materials License No. 47-16563-01 and requested that he see about obtaining isotopes for the CCGH.

Mr. Stump stated that he was given only two (2) pages of the license and did not see the license application or other supporting documents which he now knows are a part of the license. He quoted License Condition No. 10 which states in part "Licensed material shall be used only at St. Joseph's Hospital...and Calhoun County General Hospital...". He emphasized that both he and Dr. Okeon interpreted License Condition No. 10 to mean that it would be permissible to commence full operations at CCGH. He related that he then contacted two material suppliers, furnished them with copies of the license and began receiving generators at CCGH on a continuing basis.

The investigator informed Mr. Stump that the license application and accompanying documentation submitted January 29, 1975, by Okeon Associates, Inc., reflected that the "generator and other byproduct material (is) based at main lab, St. Joseph's Hospital...Mobile Scan Unit (is) used at Calhoun County General Hospital...". Although this information is not included in the basic two page NRC license, License Condition No. 15 contained within those two pages does require the use of licensed material "in accordance with statements, representations, and procedures contained in application dated January 29, 1975...". Mr. Stump stated that he was not aware of this requirement at that time nor did he ever see the referenced application.

In response to additional questions concerning licensed activities, Mr. Stump related that elutions were prepared and injected by him at CCGH from January 1979 until October 1980 and at times these procedures were performed without the supervision of a physician trained in nuclear medicine. Occasionally, in Dr. Okeon's absence, radiologists from other hospitals would substitute for him by supervising procedures, injecting isotopes, and interpreting scans. He identified Drs. Coyner, Turner and Strobl as physicians that had substituted for Dr. Okeon. He added that all scan interpretations were accomplished by a qualified radiologist.

Upon termination of the interview, Mr. Stump volunteered his opinion that he did not believe Dr. Okeon ever intended to violate any NRC requirements, but simply neglected the administrative details that such matters require.

11. Reinterview of Dr. Melvin M. Okeon, M.D.

On April 1, 1981 Dr. Okeon was reinterviewed in the presence of his attorney, Philip E. D'Orazio, Parkersburg, West Virginia. A signed statement regarding licensed activities was completed by Dr. Okeon, reviewed by his attorney, and provided to the investigators.

In response to specific questions regarding licensed activities, Dr. Okeon readily acknowledged the preparation of elutions at CCGH, but denied willfully violating license requirements. He stated that he thought John Stump, the Chief Technologist at CCGH, had received the appropriate permission to commence operations. He felt this was further evidenced when the materials supplier received a copy of his NRC license and began providing isotope service to CCGH. He verbally stated that he was informed by the CCGH Hospital Administrator "sometime during 1980" that he was in violation of his license by receiving material at CCGH and that he then "discontinued the service."

Dr. Okeon also acknowledged that the Chief Technologist had performed licensed activities in the absence of a physician trained in nuclear medicine and that other radiologists had occasionally substituted for him in the performance of licensed activities. Dr. Okeon stated that at the time of occurrence he was unaware that these activities might be violations of his NRC material license.