U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Report Nos. 030-31621/95-003
030-31622/95-003

Docket Nos. 030-31621
030-31622

License Nos. 20-27938-03G
20-27938-02

Licensee: HNU Systems, Inc.
160 Charlemont Street
Newton Highlands, Massachusetts 02161-9987

Facility Name: HNU Systems, Inc.

Inspection At: 160 Charlemont Street
Newton Highlands, Massachusetts

Inspection Conducted: December 8, 1995 through April 23, 1996

Inspector: for Francis M. Costello 5/24/96
Anthony Kirkwood, Health Physicist date

Approved By: Francis M. Costello 5/20/96
Francis M. Costello, Chief date
Nuclear Materials Safety Branch 3

Inspection Summary: Special safety inspection conducted December 8, 1995 through April 23, 1996 (Report Nos. 030-31621/95-003 and 030-31622/95-003)

Areas Inspected: Confirmatory Action Letter follow-up; response to Notice of Violation, and status of compliance with the Order Suspending License.

Results: Six apparent violations are identified, five were repeat violations identified during NRC Inspection Nos. 030-31621/95-001 and 030-31622/95-001. The licensee's actions taken in response to CAL No. 1-95-010, remain incomplete in regards to a physical inventory and training. In addition, the level of effort by the Radiation Safety Officer (RSO) to reestablish and implement an effective radiation safety program appears inadequate. Lastly, the licensee had resumed operations on April 3, 1996, until the inspection on April 23, 1996, despite the fact that the Order Suspending License issued on March 1, 1996, for failure to pay all fees associated with licensed activities, was still in effect.

DETAILS

1. Persons Contacted

   * John Marshall, Vice President
   * Abraham Berger, Radiation Safety Officer
     Lydia Mathis, Glass Lab Technician
     Rich Cohen, Technical Service
     Phil LaPolla, Director Service
     Peter McGondel, Product Engineer
     Ted Atwood, Senior Research Chemist

   * present at exit interview

2. Background

   As a result of an NRC inspection conducted on June 7 and 8, 1995 (NRC Inspection Report Nos. 030-31621/95-001 and 030-31622/95-001), Region I issued a Confirmatory Action Letter (CAL) No. 1-95-010, dated June 15, 1995, to HNU Systems Inc. (HNU). This CAL required: (1) a copy of the procedures used to document the Radiation Safety Officer (RSO) responsibilities, duties and level of effort required to re-establish and implement an effective radiation safety program, (2) submittal of a comprehensive inventory of all radioactive materials received and/or in the licensee's possession, (3) performance of a comprehensive audit of the radiation safety program consisting of a thorough examination of the duties of the RSO, the training of personnel, the Radiological Safety policies and procedures, the purchase, receipt, use, storage and disposal of radioactive materials, inventory, personnel, dosimetry and radiological surveys, (4) submittal of training program procedures to Region I which provide training to all personnel who use or supervise the use of radioactive materials to include the safe receipt, handling, use, storage, security and disposal of radioactive materials. The training program must include initial and refresher training as well as customized training for special or new operations and (5) the evaluation and determination of the potential radiation doses received by personnel involved in radioactive material operations or those who frequent radioactive material use areas for the period from January 1, 1993 to the present. The licensee responded to this CAL in letters dated June 23, July 10 and 26, and August 14, 1995, and January 30, March 12 and 19, 1996.

3. Confirmatory Action Letter Follow-Up

   3.1 Dr. Abraham Berger has continued as the Radiation Safety Officer (RSO), but currently only spends the equivalent of one day per week at HNU. A copy of the procedures used to document the RSO responsibilities, duties and level of effort required to re-establish and implement an effective radiation safety program was included with the licensee's letters dated June 23 and July 10, 1995. From approximately March to September 1995, Dr. Berger performed RSO duties the equivalent of three days per week. After September 1995, Dr. Berger's RSO duties were limited to the equivalent of one day per week.

The duties of the RSO were discussed in the licensee's letter of June 23, 1995, in response to the CAL of June 15, 1995. This discussion included level of effort to implement an effective Radiation Safety Program. In that letter, the licensee stated that HNU would be bound by the level of effort recommended by the RSO. In an interview with the RSO, he stated that he has recommended an increased level of effort, above the one day per week, to the Vice President to implement an effective radiation safety program. As of April 23 , 1996, the RSO was still working about one day per week.

3.2 A comprehensive audit of the radiation safety program was performed by the Radiation Safety Officer (RSO), submitted to the NRC in the licensee's letter dated July 10, 1995. An examination of the duties of the RSO, the training of personnel, the Radiological Safety policies and procedures, the purchase, receipt, use, storage and disposal of radioactive materials, inventory, personnel, dosimetry and radiological surveys were included in the procedures. In addition, the licensee stated in a letter dated August 21, 1995, in response to a Notice of Violation dated July 27, 1995, that when the radiation protection program was brought into full compliance no later than October 10, 1995, they would request an external audit by a certified health physicist. No external audit had been performed as of April 23, 1996.

3.3 The inspector examined documents indicating that radiation safety training had taken place on July 13 and 26, 1995. One of the glass lab technicians noted as attending the training was interviewed. She remembered the training session slides and had copies of handouts. The technician appeared familiar with the radiation safety requirements associated with her job responsibilities. The inspector reviewed the outline of the training and determined that its contents appeared to meet regulatory requirements in 10 CFR 19.12. The licensee submitted a copy of training program procedures to the NRC which provided for training to all personnel who use or supervise the use of radioactive materials to include the safe receipt, handling, use, storage, security and disposal of radioactive materials. The training program included initial and refresher training.

The licensee committed to a radiation safety training of personnel in a letter dated July 10, 1995, in response to the NRC CAL No. 1-95-010. The licensee's letter stated that written examinations would be given at the conclusion of the training. Three separate training sessions were conducted in 1995, but no written exam was given, contrary to the licensee's commitment made in their July 10, 1995 letter.

3.4 An evaluation of dosimetry doses received by individuals using radioactive material for badge periods in which dosimetry was not consistently distributed or exchanged was complete to the extent reviewed by the inspector. Specifically, dose assignment methodology was found adequate. Individual dose assignments were not reviewed.

4.0 Response to Notice of Violation

A Notice of Violation enclosed with a letter dated July 27, 1995, was issued to the licensee as a result of the NRC inspection on June 7 and 8, 1995. Ten violations were identified at that inspection. As a result of this inspection, five apparent repeat violations were identified during this inspection.

4.1 Condition No. 20 of License No. 20-27938-02 requires, in part, that licensed material be possessed and used in accordance with statements, representations and procedures contained in a letter dated July 3, 1990. Item 6 of Page 3 of the letter dated July 3, 1990, states, in part, that all survey results will be entered in a bound notebook. It further states that this notebook will also be used to record the arrival and shipment of all sources and the survey results that accompany the arrival or shipment.

The inspector learned from the RSO that for the period from October 13, 1995 to January 29, 1996, a notebook could not be located. In addition, only two monthly survey results were entered on existing notebooks examined from August 1995 to April 1996. Specifically, the RSO stated that one of his notebooks was missing covering the period from October 13, 1995 to January 29, 1996 and although he had done monthly surveys, he had not had time to enter all surveys in the notebooks that were available for review by the inspector.

Failure to maintain the Radiation Safety Records Notebook is an apparent repeat violation of Condition 20 of License No. 20-27938-02.

4.2 Condition No. 12.A. of License No. 20-27938-02 requires, in part, that sealed sources and detector cells be tested for leakage and/or contamination at intervals not to exceed 6 months. The inspector determined that as of April 23, 1996, three electron capture detector (ECD) sources containing about 10 millicuries of nickel 63 each, were in drawers in the Applications Lab and had not been leak tested.

Failure to perform leak tests of sealed sources every six months is an apparent repeat violation of Condition 12.A. of License No. 20-27938-02.

4.3 Condition No. 20 of License No. 20-27938-02 requires, in part, that licensed material be possessed and used in accordance with statements, representations and procedures contained in a letter dated July 3, 1990. Item 4 of Page 2 of the July 3, 1990, letter states, in part, that the licensee's survey instrument will be calibrated at six month intervals. The inspector determined that from June 7, 1995 through April 17, 1996, the licensee's Victoreen Model 471 (Serial No. 1399) survey meter was calibrated on a ten month cycle instead of a six month cycle.

Failure to calibrate survey instruments every six months is an apparent repeat violation of Condition 20 of License No. 20-27938-02.

4.4 10 CFR 32.52(a) requires, in part, that each person licensed under 10 CFR 32.51 report to the NRC, all transfers of such devices to persons for use under the general license in 10 CFR 31.5 of this chapter. The RSO stated that from June 8, 1995 to April 23, 1996, the licensee, licensed under 10 CFR 32.51, did not report to the NRC all transfers of such devices to persons for use under the general license in 10 CFR 31.5 of this chapter. Specifically, the RSO had concentrated his efforts on reporting previously missed reports from 1993.

Failure to file quarterly reports of generally licensed device transfers from June 8, 1995 to April 23, 1996, is an apparent repeat violation of 10 CFR 32.52.

4.5 A comprehensive inventory of all radioactive materials was conducted on March 30, 1995, by the RSO. No missing material was noted. The next scheduled six-month physical inventory was due on September 30, 1995. The RSO stated that this inventory was not conducted during a February 22, 1996, telephone conversation. Subsequently, the RSO has completed an inventory dated April 17, 1996, accounting for all but one source. The RSO is continuing in his efforts to account for the source.

Failure to conduct a complete physical inventory every 6 months is an apparent repeat violation of Condition 14 of License No. 20-27938-02.

5.0 **Status of Compliance With Order Suspending License**

On March 1, 1996, NRC issued an Order Suspending License, effective immediately, to the licensee for failure to pay fees to the NRC associated with licensed activities. At the time of the inspection on April 23, 1996, the licensee had not requested a hearing nor paid the delinquent fees in full, but resumed licensed activities despite the Order still in effect. The RSO stated that he understood that a letter received on April 3, 1996 from NRC permitted the resumption of licensed activities. When the inspector read the letter he noted that the letter stated that an extension of license will be issued when a promissory note was signed by the licensee and then the NRC would issue an Order extending the license. The inspector contacted the Region I office and confirmed that the Order was still in effect until the promissory note was signed and returned and an Order was issued to extend the license. The inspector directed the licensee to return all licensed material to the storage location, padlock the storage container, and have the only key be held by the Vice President until the Order was extended by letter from NRC. The inspector confirmed that all licensed material was returned to the storage location, padlocked, and gave the only key to the Vice President prior to the conclusion of the inspection.

The use of licensed materials from April 3 to April 23, 1996 is an apparent violation of Paragraph II of the Order Suspending License, effective immediately, dated March 1, 1996.

6.0 Exit Interview

The inspector spoke with the licensee representatives denoted in Section 1.0 of this report on April 23, 1996. The inspector summarized the purpose, scope and findings of the inspection. The inspector indicated that further escalated enforcement action was possible because of the lack of progress in reestablishing an effective radiation safety program.