



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

November 4, 2003

Docket No. 03036239

License No. 37-30804-02

James Wood
President
CFC Logistics, Inc.
4000 AM Drive
Quakertown, PA 18951

SUBJECT: INSPECTION 03036239/2003001, CFC LOGISTICS, INC., QUAKERTOWN,
PENNSYLVANIA

Dear Mr. Wood:

On October 1 through October 20, Judith A. Joustra and Sattar Lodhi of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection included reviews of implementation of your security procedures during the receipt of licensed material, and your procedures during the installation of licensed material in the irradiator. The inspectors also reviewed operations of the irradiator and its components, and the security of licensed material within the facility, measured radiation dose rates in the irradiator room, and interviewed personnel.

The findings of the inspection were discussed with you and Ms. Marie Turner of your organization on October 20, 2003, at the conclusion of the inspection. During these discussions, I explained to you the NRC's observations concerning following required procedures during the inspection. These observations are described in detail in the enclosed inspection report. While these observations did not represent violations of NRC requirements, we are concerned about your implementation of required procedures and the meticulous attention to detail expected of all NRC licensees. It is our understanding that you plan to take steps to strengthen your adherence to approved procedures. You should describe the steps you have taken or plan to take in this area in writing in response to this letter, within 30 days.

Within the scope of this inspection, no violations were identified.

In accordance with 10 CFR 2.790, a copy of this letter will be placed in the NRC Public Document Room and will be accessible from the NRC Web site at <http://www.nrc.gov/reading-rm.html>.

J. Wood
CFC Logistics, Inc.

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Your cooperation with us is appreciated.

Sincerely,

Original signed by John R. McGrath

John D. Kinneman, Chief
Nuclear Materials Safety Branch 2
Division of Nuclear Materials Safety

Enclosure:
Inspection Report No. 03036239/2003001

cc:
Marie Turner, Radiation Safety Officer
Commonwealth of Pennsylvania

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| OFFICE | DNMS/RI | N | DNMS/RI | N | DNMS/RI | N | | |
| NAME | Jjoustra/jrm for: | | SLodhi/sl | | Jkinneman/jrm for: | | | |
| DATE | 11/04/03 | | 11/04/03 | | 11/04/03 | | | |

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U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No. 03036239/2003001
Docket No. 03036239
License No. 37-30804-02
Licensee: CFC Logistics, Inc.
Location: 4000 AM Drive
Quakertown, PA 18951
Inspection Dates: October 1, 2003 through October 20, 2003

Inspectors: **Original signed by**
John R. McGrath for: **11/04/03**

Judith A. Joustra date
Senior Health Physicist

Original signed by: **11/04/03**

Sattar Lodhi, Ph.D. Date
Health Physicist

Approved By: **Original signed by**
John R. McGrath **November 4, 2003**

John D. Kinneman, Chief date
Nuclear Materials Safety Branch 2
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

CFC Logistics, Inc.
NRC Inspection Report No. 03036239/2003001

CFC Logistics, Inc., submitted its application dated February 19, 2003, for an underwater pool irradiator. Construction of the irradiator facility had started in early February 2003, and Region I staff monitored the construction and installation activities by visiting the site several times since February 13, 2003. The licensee completed installation of the irradiator and its associated equipment before the license was issued on August 27, 2003. The license authorizes the licensee to use as much as one million curies of sealed cobalt 60 in the irradiator.

On September 25, 2003, the licensee notified the NRC Region I that it expected to receive licensed material on October 2, 2003. The NRC staff conducted an inspection of the licensee's facilities following the notification. The inspection included a review of the facility and licensee's implementation of procedures for the receipt, storage and installation of licensed material in the irradiator.

The irradiator facility is constructed and equipped in accordance with the description provided in the application dated February 19, 2003. The licensee tested the equipment by performing several dry runs to verify that the equipment performed as planned. NRC Region I staff observed a few of these dry runs and confirmed that the equipment performed as the licensee had planned. The licensee conducted these dry runs prior to receiving the licensed material.

The licensee received the licensed material on October 2, 2003. The NRC staff observed the licensee's activities during the receipt, and transfer of licensed material to the irradiator room. Storage of transport casks in the irradiator pool, and transfer of licensed material from the casks to the source holders was performed by the personnel from the supplier of licensed material because the licensee is not authorized to perform these operations.

The licensee performed radiological surveys of the facility after installation of licensed material in the irradiator to demonstrate that the radiation dose rates within and around the facility are within the respective regulatory limits.

The inspection identified the following: the licensee modified the source plenum without obtaining authorization from the NRC; the licensee did not notify the NRC prior to authorizing irradiations; the RSO did not ensure that all non-routine operations (the modification of the plenum) are consistent with conditions of the license, and the RSO did not maintain records of non-routine operations of the irradiator. However, no violations occurred because the modifications were removed before licensed material was received and the NRC was notified before irradiations actually occurred.

REPORT DETAILS

I. Organization and Scope of the Program

a. Inspection Scope

Inspection consisted of a review of the licensee's organization and scope of activities.

b. Observations and Findings

CFC Logistics, Inc., owns and operates a large cold storage warehouse facility, and has installed an underwater pool irradiator within the facility. Activities at the warehouse facility are divided into three separate departments, namely, Warehouse Operations, Irradiator Operations, and Administrative Operations. The Manager of each of these departments reports to the President.

The staff in the Irradiator Operations department includes the Radiation Safety Officer (RSO), irradiator operators and material handlers. The license authorizes the licensee to receive up to one million curies of sealed cobalt 60 for use in the irradiator. The irradiator is to be used for commercial irradiation of food items, cosmetic and pharmaceutical products, and similar other products excluding explosives and flammable material. The license does not authorize use of the irradiator for research activities.

c. Conclusions

The inspection did not identify any violation of NRC requirements or safety concerns.

II. Management Oversight of the Program

a. Inspection Scope

The inspection consisted of a review of conduct of licensed activities and the oversight of the licensed activities provided by the licensee's management.

b. Observations and Findings

The licensee has established a Radiation Safety Committee (RSC) that provides oversight of licensed activities. The RSC membership includes the RSO, a member of management, and an irradiator operator. The RSO is the Chairman and Secretary of the RSC. Responsibilities of the RSC are specified in the licensee's application dated February 19, 2003 (ML030630036), which is incorporated into the license via Condition No. 21. of the license. These responsibilities include implementation of the

radiation safety program, and review and approval of changes in irradiator operating procedures, including all license amendment requests before submission to the NRC.

During a telephone conversation with the inspector on September 25, 2003, the RSO informed the inspector that the check valve at the bottom of the plenum had been removed and the opening had been plugged to allow the removal of water from the plenum via an alternate route. The valve is shown in Drawing No. 36783-017-000 (ML031610287) which is included in the licensee's application dated February 19, 2003. The inspector discussed with the RSO Condition No. 18. of the license that requires that the licensee request and receive authorization from the NRC before making any modifications to the source plenum described in the application.

Modification of the plenum without specific authorization from the NRC once the license was issued would be a violation of Condition 18 of the license.

Following the discussions with the inspector the RSO stated that the check valve would be reinstalled, and subsequently Region I received a letter from the licensee via facsimile on September 25, 2003, notifying the NRC of its intention to replace the valve. The letter was dated September 24, 2003.

On October 1, 2003, the inspector reviewed the circumstances surrounding the removal of the check valve, and noted that the licensee had reinstalled the check valve in the plenum. The RSO stated that the check valve was removed because the supplier of cobalt 60 sealed sources (Revis Services) had expressed a concern that purging of the plenum through the check valve may not remove the water completely from the plenum and this could result in deposits on the sealed sources as the residual water evaporated. The licensee stated that the accumulation of such deposits is not likely to be significant because the pool water quality will be maintained between 5 and 10 microsiemens per centimeter which is well below the regulatory requirements. Neither the RSO nor the contractor who removed the valve knew the date on which the valve was removed. Both of them stated that it was removed few weeks ago. The RSO did not have documentation that indicated the date on which the valve was removed or that the change was reviewed and approved by the RSC.

The inspector discussed with the licensee the RSO's responsibilities specified in Item 7 of the licensee's application dated February 19, 2003. The application is incorporated into the license via Condition 21 of the license. The responsibilities of the RSO include ensuring that non-routine operations of the irradiator are consistent with the limitations in the license, and ensuring that appropriate records associated with the irradiator operations are maintained.

If sealed sources had been present, removal of the valve without prior authorization by the NRC would not have been consistent with Condition 18 of the license; in addition, the RSO must maintain records of such changes, and documentation that the RSC reviewed and approved the changes.

These actions are not violations of NRC requirements because the plenum was returned to the approved configuration before licensed material was received.

On October 3, 2003, upon completion of installation of sources into the plenum, and upon completion of radiological surveys of the facility, the RSO approved irradiation of certain items. The inspector reminded the RSO of the requirements in Condition No. 13.C., of the license and explained to her that Condition 13.C., requires that prior to irradiations, the licensee notify the NRC, in writing that assurance and the required tests and surveys have been satisfactorily completed. Authorization to commence irradiations prior to notification to the NRC would have been a potential violation of Condition 13.C., of the license because, had the inspector not brought Condition 13.C., of the license to licensee's attention, the irradiations would have been performed. Subsequently, the RSO rescinded her approval and assured the inspector that irradiations will not be performed until the NRC has been notified as required by the conditions of the license.

c. Conclusions

The licensee needs to strengthen adherence to required procedures. The RSO was not fully familiar with all of the regulatory requirements and the conditions of the license. This resulted in the four potential violations of license conditions described above; modification of the plenum without specific authorization by the NRC; failure of the RSO to ensure that all non-routine operations are consistent with limitations of the license; authorizing irradiations before notifying the NRC, and that records of irradiation operations are maintained.

III. Facilities and Equipment

a. Inspection Scope

The inspection consisted of a review of the completed irradiator facility and adequacy of the associated facilities and equipment at the site.

b. Observations and Findings

The licensee completed the construction and installation of irradiator components as described in the application dated February 19, 2003. The irradiator is located in the middle of an enclosed area within a large hall. The large hall is part of a larger cold storage warehouse that is owned by the licensee. Overhead cranes are used to move the product bells around, into and out of the irradiator pool. The entire product movement equipment and its control console are located within the enclosed area. In one corner of the enclosed area is a small room that houses the dosimetry equipment, and in another corner is another small room that is designed for use by the operators and for maintenance of daily records. Access to the enclosure is restricted to authorized

personnel only and the security system installed at the facility, including the irradiator room is as described in the licensee's application dated February 19, 2003.

The inspector had reviewed dry runs of the equipment prior to receipt of licensed material, and had noted that the equipment functioned as planned. These dry runs included loading of product bells, movement of the product bells around, into and out of the pool. The licensee also demonstrated the response of product carriers in case of power failure during their movement around the pool, into the pool and out of the pool. The inspector observed that the product bells remained stationary at their respective positions when power was disconnected, and the system had to be reset to resume the movements of the bells from their stationary positions when the power was restored.

The irradiator is equipped with required radiation monitors and water circulation system as stated in the application. The inspector noted that the licensee had installed a bypass valve in the water circulation system to facilitate purging of the plenum. This additional valve is located outside of pool and is not part of the plenum. The valve is not indicated in the drawings submitted by the licensee with its application. The licensee possesses appropriate portable survey meters to measure the dose rates around the irradiator. Water quality in the pool, and the pool water temperature are continuously monitored. On October 2, 2003, before the licensed material was placed in the pool, the inspector noted that the conductivity of the pool water was approximately 8 microsiemens per centimeter, and the pool water temperature was 59°F.

On October 15, 2003, after the licensed material had been in the pool for over 12 days, the temperature of the pool water had reached 86°F, and the conductivity of the pool water had dropped down to 4.5 microsiemens per centimeter, which is below the regulatory limit. NRC regulations require that the conductivity of the pool water be maintained below 20 microsiemens per centimeter. The licensee's procedures require that the pool water temperature be maintained below 105°F. The inspector discussed the increase in pool water temperature with the licensee and the procedures to maintain water temperature below 105°F. The licensee stated that if deemed necessary, a water chiller will be installed in the pool water circulation system to ensure that the pool water temperature remains below 105°F.

c. Conclusions

The irradiator facility is constructed as described in the licensee's application except that a bypass valve is installed in the air circulation system to facilitate purging of the water from the plenum. The inspector concluded that this modification does not affect the operation of irradiator.

IV. Material Receipt, Use, Transfer, and Control

a. Inspection Scope

The inspection included a review of the implementation of licensee's procedures for the security of licensed material against the requirements of 10 CFR Part 20.

b. Observations and Findings

The inspector discussed with the licensee the system of security alarms installed at the facility to control access to the irradiator facility and to prevent unauthorized access to licensed material stored at the facility.

Prior to the arrival of licensed material at its facilities, the inspectors reviewed licensee's procedures for receipt of licensed material, its transfer to the irradiator room, and security and surveillance of the material during these activities. The inspectors observed the arrival of licensed material at the licensee's facility, and its subsequent transfer to the irradiator room. The material was contained in two transport casks. The licensee's procedures assured that the casks remained attended by authorized personnel and that constant surveillance of the material is maintained at all times during these activities.

The inspectors also observed transfer of licensed material from transfer casks to the irradiator pool and its subsequent installation into the plenum. The removal of licensed material from the transport casks, loading of the material in the source holders and installation of source holders in the plenum were performed in the irradiator pool under water at a depth of approximately 14 feet from the surface of the pool. The license does not authorize the licensee to perform these activities. The supplier of the licensed material is authorized by an Agreement State to perform these activities. The reciprocity provisions in 10 CFR 150.20 allow an Agreement State licensee to perform the authorized activities in areas where the NRC has jurisdiction of regulating the use of licensed material. Two individuals, who are listed as authorized users on the supplier's Agreement State license performed and/or supervised these activities at the licensee's facility.

The licensee inventoried the material, verified the identity of each sealed source, and its location within the plenum as required by the licensee's procedures.

c. Conclusions

The security system installed in the completed facility appears to be as described in the licensee's application. The licensee has developed adequate procedures for the receipt, transfer, security, and use of licensed material, and implemented these procedures during its activities. All of procedures in the application appear to be in place. The licensee maintained security and control of licensed material as required by regulations in Subpart I of 10 CFR Part 20.

The inspection did not identify any violation of NRC requirements or safety concerns.

V. Training of Workers

a. Inspection Scope

The inspection consisted of review of the licensee's training program and its implementation.

b. Observations and Findings

The licensee's training program is described in detail in its application dated February 19, 2003, and includes training of personnel who are authorized unescorted access to the irradiator facility as well as those who may have escorted access to the irradiator room. The training program also includes training of emergency response personnel prior to receipt of licensed material. Inspector discussed the implementation of the training program with the licensee. The licensee stated that appropriate training has been provided to all personnel, including the appropriate emergency response personnel, and two individuals have completed the training program for irradiator operators. The licensee has also provided training to personnel who work in the vicinity of the irradiator but do not have unescorted access to the irradiator facility. Inspector discussed the operation of the irradiator, radiation safety procedures, etc., with one of the qualified irradiator operators and found the individual to be familiar with these procedures.

c. Conclusions

The licensee's training program is adequate and the individuals appeared to be familiar with the irradiator operation and radiation safety procedures.

The inspection did not identify any violation of NRC regulations or safety concerns.

VI. Radiation Surveys

a. Inspection Scope

The inspection consisted of a review of the licensee's procedures for radiological surveys and its implementation.

b. Observations and Findings

The facility is equipped to continuously monitor radiation dose rates within the irradiator room. The monitoring also triggers an alarm to alert personnel when the radiation dose

rates exceed a preset limit. The inspectors observed the licensee personnel performing radiological surveys upon the arrival of the licensed material at its site. The personnel used appropriate survey instruments to perform these surveys. The licensee also performed radiological surveys of the areas where the casks containing licensed material were stored in the irradiator room. The licensee maintained continuous monitoring of radiation dose rates during the process of removing the material from the transport casks, loading of the material in the source holders and installing the source holders into the plenum. The inspectors observed that the dose rates at the surface of the pool during these operations remained below 1 millirem/hour (1 mR/hr). The inspector also performed surveys of area around the pool and along the air circulation lines and noted that the radiation levels at these locations remained below 1 mR/hr.

c. Conclusions

The licensee has developed and implemented appropriate procedures for radiological surveys of the facility during routine and non-routine operations.

The inspection did not identify any violation of NRC requirements or safety concerns.

VII. Posting and Labeling

a. Inspection Scope

The inspection reviewed the required postings at the facility

b. Observations and Findings

The inspectors noted that the facility is appropriately posted. Warnings and NRC Form 3 are posted at appropriate locations. A copy of the license is also posted in the irradiator room.

c. Conclusions

The facility is posted appropriately.

The inspection did not identify any violation of NRC requirements or safety concerns.

VIII. Exit Meeting

a. Inspection Scope

The inspection consisted of summarizing the results of the inspection.

b. Observations and Findings

The inspector and the Chief, Nuclear Materials Safety Branch, met with the licensee's management on October 20, 2003, and discussed the preliminary findings of the inspection. The inspector summarized NRC's inspection and enforcement procedures and policies, and explained to the licensee's management the findings of the inspection, including the concerns about adherence to required procedures. The inspector stated that a written report of the inspection will be sent to the licensee and the licensee will be required to respond in writing, to the report.

c. Conclusions

The management representative assured the inspectors that immediate actions will be taken to ensure that all procedures are strictly adhered to and all activities are conducted in accordance with approved procedures and conditions of the license. The licensee also stated that the planned actions will be included in their written response to the findings of the inspection.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

Marie Turner, Radiation Safety Officer
James Wood, President
Thomas Clemens, Facility and Property Planner
Leon Dieter, Irradiator Operator
David Blattner, Irradiator Operator
Rick Kiper, Contract Engineer
Tony Parsons, Senior Operations Engineer (Reviss Services)
Dave Gilbert, Operations Engineer (Reviss Services)
Russell Stein, Vice President, Gray*Star, Inc.