UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-4005

October 12, 2005

Mr. Jack L. Coffey, Senior Vice President
Cardinal Health
Nuclear Pharmacy Services
7000 Cardinal Place
Dublin, Ohio 43017

SUBJECT: NRC INSPECTION REPORT 030-36973/05-001

Dear Mr. Coffey:

This letter and the enclosed inspection report refers to the inspection conducted on September 13-15, 2005, at the Cardinal Health Nuclear Pharmacy Services corporate office in Dublin, Ohio. At the conclusion of the onsite inspection, the inspection findings were discussed with you, Mr. Paul Gotti, corporate Radiation Safety Officer, and other members of the Cardinal Health Quality & Regulatory staff.

The inspection included a review of activities conducted at your Nuclear Pharmacy Services corporate office, interviews with Cardinal Health Nuclear Pharmacy Services personnel, demonstrations of nuclear pharmacy related software, and reviews of internal audit findings, the external and internal dosimetry program, public dose evaluations, incident and event reporting program, the Authorized Nuclear Pharmacist training program, and other records as they relate to radiation safety and to compliance with the NRC's rules and regulations and with the conditions of your license.

Within the scope of this inspection, no violations were identified; therefore, no response to this letter or the enclosed inspection report is required.

Please note that due to the recent relocation of the Cardinal Health Nuclear Pharmacy Services Quality & Regulatory department from Woodland Hills, California, to Dublin, Ohio, the NRC is transferring oversight of your licensed activities from Region IV to Region III. With this correspondence, Region IV finalizes its longstanding oversight of your license and transfers responsibility to Region III. As noted during the onsite inspection, your points of contact in Region III are Patricia J. Pelke, Chief, Materials Licensing Branch (630-829-9868) and John R. Madera, Chief, Materials Inspection Branch (630-829-9834).

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Should you have any questions concerning this inspection or the enclosed report, please contact either Dr. Janine F. Katanic at (817) 860-8151 or the undersigned at (817) 860-8287.

Sincerely,

/RA/ Robert A. Brown for

Mark R. Shaffer, Chief
Nuclear Materials Inspection Branch, Region IV

Docket No.: 030-36973
License No.: 34-29200-01MD
Enclosure: NRC Inspection Report 030-36973/05-001

cc w/enclosure:
Ohio Radiation Control Program Director

bcc w/enclosure (via ADAMS distrib):
LDWert
CLCain
MRShaffer
JEWhitten
JLMontgomery
JFKatanic
KEGardin
PJPelke, RIII
JRMadera, RIII
CFFrazier, RIII
KJLambert, RIII
JPDwyer, RI
NMIB File
RIV Nuclear Materials File - 5th Floor

ADAMS: : Yes 9 No Initials: JFK
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ENCLOSURE

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Report No.	030-36973/05-001
Docket No.	030-36973
License No.	34-29200-01MD
Licensee:	Cardinal Health
Location:	Dublin, Ohio
Inspection Dates:	September 13-15, 2005
Inspectors:	Janine F. Katanic, Ph.D., Health Physicist Nuclear Materials Inspection Branch, Region IV
	James L. Montgomery, Health Physicist Nuclear Materials Licensing Branch, Region IV
	Cassandra F. Frazier, Senior Health Physicist Materials Licensing Branch, Region III
	Kenneth J. Lambert, Senior Health Physicist Materials Inspection Branch, Region III
Approved By:	Mark R. Shaffer, Chief Nuclear Materials Inspection Branch, Region IV
Attachment:	Supplemental Inspection Information

EXECUTIVE SUMMARY

Cardinal Health (Cardinal)
Dublin, Ohio
NRC Inspection Report 030-36973/05-001

This was a routine, announced inspection conducted on September 13-15, 2005, of Cardinal's radiation safety program. The inspection included a review of activities conducted at the licensee's corporate office, interviews with licensee personnel, demonstrations of nuclear pharmacy related software, and a review of other records as they relate to radiation safety. Also discussed during the inspection were the findings from NRC inspections conducted at the licensee's radiopharmacies and of the licensee's transportation related activities.

Program Scope

Cardinal's NRC byproduct materials license 34-29200-01MD authorized the preparation and distribution of radioactive drugs and radiochemicals, the compounding of iodine-131, the redistribution of used and unused molybdenum-99/technetium-99m generators, and the redistribution of sealed sources to authorized recipients. At the time of the inspection, the licensee operated 32 radiopharmacies in NRC jurisdiction under the aforementioned license. In June 2005, Cardinal's Nuclear Pharmacy Services Quality & Regulatory (Q&R) department relocated to Ohio. The Q&R department experienced several staff changes, including the corporate radiation safety officer (RSO) and several health physics support staff. (Section 1)

Radiation Safety Program Oversight

The radiation safety committee (RSC) was found to function as described and appeared to be effective in its oversight of the radiation safety program. The RSC meetings observed by the inspectors included a comprehensive list of agenda items, with attendees encouraged to actively participate. The corporate RSO was found to have the necessary authority and resources to effectively implement the radiation safety program. Oversight of individual radiopharmacy RSOs was accomplished mainly through internal audits. (Section 2)

Radiation Dosimetry Program

The licensee's personnel dosimetry program was found to be implemented effectively and was appropriate for the licensee's scope of operations. The licensee's use of conservative investigational levels and timely reviews of radiation dosimetry results appeared to be effective in identifying areas of improvement. The licensee's research to characterize and reduce extremity exposures was evident by their activities to complete the ongoing extremity exposure glove study. Though the licensee had established a program to evaluate public dose at each of its radiopharmacies, there did not appear to be an effective method to document that the annual dose to members of the public did not exceed NRC's regulatory limit. Though this was identified as a weakness in the licensee's public dose evaluation program, for those records reviewed by the inspectors, there did not appear to be any instances of individual radiopharmacies exceeding NRC's regulatory limit for members of the public. (Section 3)

Licensee Audits

The licensee's trimester points-based audit program was found to be both comprehensive and effective, providing a high degree of confidence that each radiopharmacy was in compliance with NRC requirements and the conditions of Cardinal's license. The RSC's review of audit findings was thorough and effective in identifying areas where additional resources were necessary. All radiopharmacies were required to provide a written response to audit-identified findings. The licensee's graded approach to oversight of newly acquired radiopharmacies appeared to be effective in helping the facilities implement the licensee's radiation safety program. The licensee's corporate audit functioned as a periodic review of their radiation protection program content and implementation, but did not appear to be an effective mechanism to identify program strengths or weaknesses and implement corrective actions. The licensee indicated that future radiation safety program audits would be performed differently to better capture licensee-identified audit findings. (Section 4)

Authorized Nuclear Pharmacist (ANP) Training and Approvals

The inspectors found that the licensee's training program for ANPs was being implemented in an effective manner. Training for licensed pharmacists to become ANPs consisted of a series of on-line radiation safety training modules, timed and graded examinations, hands-on training using radiopharmacy and radiation safety equipment, and practical on-the-job training under the supervision of a preceptor. Each student must receive the recommendation of his or her preceptor, who then forwards it for RSC review and approval. (Section 5)

Miscellaneous Records Review

Decommissioning files of several radiopharmacies that were removed from the NRC license were reviewed by the inspectors and were noted to contain detailed information on the surveys performed, including confirmation that no residual radioactivity was present and that the site was suitable for release in accordance with NRC requirements. Incident and event reports reviewed by the inspectors were found to contain sufficient details regarding the incident or event for the Q&R department to adequately assess radiation dose, if necessary, and to determine the root cause of the event and appropriate corrective actions. The licensee performed several demonstrations of the computer program they use to verify that customer orders are in agreement with the radioactive material possession limits on their customers' NRC or Agreement State license. Each demonstration correctly confirmed that the customer, based on their possession limit, ordered and received the correct isotope and activity of licensed material. (Section 6)

NRC Inspection Findings

Between October 1, 2004, and September 30, 2005, NRC conducted 16 routine inspections of Cardinal radiopharmacies as well as two inspections of the licensee's activities regarding the transportation of radioactive material. There were no violations associated with any of the inspections, providing evidence that Cardinal's radiation safety program was well-implemented at its individual radiopharmacies. (Section 7)

REPORT DETAILS

1 Program Scope (87127)

Cardinal Health (Cardinal) is a large corporation that provides products and services in support of the pharmacutical and health care industry. Cardinal's Nuclear Pharmacy Services (NPS) is a business division within the Cardinal organization. Within Cardinal NPS, the Q&R department possesses and maintains NRC byproduct materials license 34-29200-01MD, which authorizes the preparation and distribution of radioactive drugs and radiochemicals, the compounding of iodine-131, the redistribution of used and unused molybdenum-99/technetium-99m generators, and the redistribution of sealed sources to authorized recipients. At the time of the inspection, Cardinal's NPS division operated 32 radiopharmacies in NRC jurisdiction under its NRC byproduct materials license. At Cardinal radiopharmacies, ANPs prepare and compound radioactive drugs. These radiopharmaceutical preparations are packaged and distributed to client facilities, such as hospitals and clinics, primarily for administration to patients for diagnostic and therapeutic nuclear medicine applications.

In November 2004, Cardinal announced that the NPS Q&R department would be relocated from Woodland Hills, California, to Dublin, Ohio, the home of Cardinal's corporate headquarters. The business decision to relocate was due, in part, to a Cardinal-wide initiative to improve efficiency. In March 2005, Cardinal NPS Q&R department notified NRC of its relocation timetable and indicated that relocation would be completed by June 30, 2005. Accordingly, this inspection was conducted at the licensee's new location in Dublin, Ohio.

Concurrent with its change in location, the Q&R department experienced several staff changes. In January 2005, Cardinal's corporate RSO left the organization and was replaced by an interim corporate RSO. In July 2005, a permanent corporate RSO was named on Cardinal's NRC byproduct materials license. The new corporate RSO was a former Cardinal employee that possessed numerous years of experience in the radiopharmaceutical industry with commensurate training qualifications. Changes also took place among the health physics support staff when several individuals opted to not relocate to Ohio. The licensee hired several new health physicists and several additional program support staff. Though a few support positions remained unfilled at the time of the inspection, the licensee is expected to fill the positions in the near future.

2 Radiation Safety Program Oversight (87127)

2.1 Inspection Scope

The inspectors conducted a review of the oversight of Cardinal's radiation safety program. During October 1, 2004, through September 30, 2005, the inspectors observed three RSC meetings. In addition, the inspectors reviewed the RSC meeting minutes and evaluated the effectiveness of the RSC in providing oversight of NRC-licensed activities. The inspectors interviewed Cardinal's corporate RSO concerning his authorities and responsibilities regarding Cardinal's NRC byproduct materials license. The activities and oversight of a sample of RSOs of individual

Cardinal radiopharmacies were reviewed to the extent that their activities were described in inspection records prepared by NRC region-based inspectors and documented in Cardinal's internal audits.

2.2 Observations

Within Cardinal's NPS division, both the Q&R department and Operations department played roles regarding the implementation of Cardinal's radiation safety program. The Q&R department had oversight of radiation safety issues at Cardinal's nuclear pharmacies, was responsible for training, and performed audits of individual pharmacies to determine regulatory compliance. The Operations department oversaw the activities of the regional pharmacy managers, the individual pharmacy managers, and the individual pharmacy RSOs. Though the Cardinal corporate RSO reported to the Q&R department, he had authority to directly interact with and direct individual radiopharmacy RSOs as appropriate.

At the time of the inspection, the vice president of Cardinal's NPS Operations department served as chairman of the RSC. The chairman, along with other Cardinal NPS corporate managers, composed the voting members of the RSC. Other Cardinal NPS personnel as well as regional managers, radiopharmacy managers, and radiopharmacy RSOs of Cardinal's nuclear pharmacies also participated in RSC meetings though they were not voting members of the RSC. The RSC meetings observed by the inspectors were noted to be well organized, with attendees actively participating in discussions pertaining to each agenda item. Agenda items typically discussed during RSC meetings included: approvals of ANPs, internal audit findings, radiopharmacy performance issues, personnel dosimetry, Cardinal's As Low As Reasonably Achievable (ALARA) program, incident and event reports, NRC and Agreement State inspection findings, recent licensing actions, and other regulatory issues as appropriate. The RSC meeting minutes were found to be concise, well-written and reflected issues discussed by the RSC members including the results of voting. The RSC was found to be effective in its oversight of NRC-licensed activities.

The senior director of the Q&R department of Cardinal's NPS division also served as Cardinal's corporate RSO. The corporate RSO was responsible for the oversight of nuclear pharmacy practices and radiation safety issues at Cardinal's radiopharmacies. The corporate RSO was found to have the necessary authority and resources to effectively implement the radiation safety program. The corporate RSO played a role in the oversight of the RSOs of individual radiopharmacies. In turn, each individual RSO of a radiopharmacy was responsible for the local implementation of Cardinal's radiation safety program. The Q&R department's regulatory compliance, or audit, group conducts trimester internal audits of each radiopharmacy. Through the results of the audits, the corporate RSO reviewed and evaluated the performance of individual radiopharmacy RSOs. Inspections of Cardinal radiopharmacies performed by NRC region-based inspectors also provided information about the performance of individual radiopharmacy RSOs.

2.3 Conclusions

Within Cardinal's NPS division, both the Q&R department and Operations department played roles regarding the implementation of Cardinal's radiation safety program. The RSC functioned as described in Cardinal's license application and appeared to be effective in its oversight of Cardinal's radiation safety program and NRC-licensed activities. The RSC meetings observed by the inspectors included a comprehensive list of items for discussion and attendees were encouraged to actively participate.

The corporate RSO and the supporting Q&R department staff appeared to effectively implement and maintain Cardinal's radiation safety program. The corporate RSO was found to have the necessary authority and resources to effectively implement the radiation safety program. Oversight of the individual radiopharmacy RSOs through internal audits and NRC inspections contributed to the effective implementation Cardinal's radiation safety program.

3 Radiation Dosimetry Program (87127)

3.1 Inspection Scope

The inspectors interviewed Q&R department personnel responsible for the implementation of Cardinal's personnel dosimetry program and reviewed a selective sample of the licensee's internal and external personnel dosimetry records. The inspectors also reviewed the results of dosimetry evaluations performed as a result of an incident or when Cardinal's ALARA investigative levels were exceeded. In addition, licensee staff gave the inspectors a brief overview of Cardinal's ongoing extremity exposure glove study. Lastly, inspectors reviewed the licensee's procedures and results for determinations of radiation dose to members of the public for individual radiopharmacies.

3.2 Observation and Findings

The licensee's routine personnel radiation dosimetry program consisted of both whole-body and extremity monitoring devices. Cardinal employees whom the licensee determined to be occupationally exposed (i.e. working in the radiologically restricted areas of the radiopharmacy) were issued monthly whole-body dosimeters. Individuals whom either compounded or dispensed radiopharmaceuticals were also issued weekly extremity dosimeters; one dosimeter was issued for each hand. Individuals handling doses for packaging purposes (not compounding or dispensing) were issued monthly right and left extremity dosimeters. Contracted delivery personnel who were not Cardinal employees were not provided dosimetry by the licensee but instead were provided dosimetry by their individual contractors.

Cardinal's dosimetry provider electronically alerted the Q&R department whenever a dosimeter exceeded Cardinal's established ALARA investigational levels for either whole-body or extremity exposures. The Level I ALARA investigational levels were 800 millirem per week for extremity dosimeters and 125 millirem per month for whole body dosimeters. If these levels are exceeded, Q&R department staff contact the individual

to begin an investigation into the possible causes of the elevated reading and to obtain information from the individual regarding actions taken to correct any identified causes, such as technique, equipment, or staffing problems.

The licensee's dosimetry program also included bioassay for those employees working with iodine-131. The bioassay is performed within 6-24 hours after working with unsealed quantities of iodine-131 and uses a single channel analyzer coupled to a sodium iodide detector. A barium-133 rod or an iodine-131 capsule is used in a neck phantom as a standard. Individual radiopharmacy RSOs entered the bioassay data for their staff into a computer database which was then able to be accessed by the Q&R department staff for analysis and trending purposes. The licensee has established the Level I ALARA investigational level to be 0.04 microCuries of iodine-131. A review of the licensee's records indicated that over the prior year, no individuals at pharmacies listed on the NRC license exceeded the licensee's bioassay investigational levels.

The annual occupation dose (external and internal) to each employee is compiled by the Q&R department staff and provided to employees in accordance with NRC regulations. The licensee's personnel dosimetry program was found to be implemented effectively and appropriate for the licensee's scope of operations.

Licensee staff gave the inspectors a brief overview of Cardinal's ongoing extremity exposure glove study. This study is being conducted in response to incidents and events concerning extremity exposures in excess of NRC's regulatory limits. The radiopharmaceutical industry has traditionally relied upon finger-ring type extremity monitors to determine shallow-dose equivalent. However, previous NRC inspection findings have questioned whether an extremity monitor, such as a finger-ring type dosimeter, is an accurate measure of dose to the region of highest potential extremity exposure. Accordingly, a study was developed to attempt to determine whether the traditional finger-ring type extremity dosimeters worn by individuals is representative of the dose to the other portions of the extremity that may have the potential to receive higher doses. Cardinal has worked with its dosimetry provider to develop a glove that allows an individual to wear multiple extremity dosimeters on each hand. The so-called "glove study" tracks the extremity exposures of two groups of employees with eight subgroups consisting of four employees each. The first group of employees includes those employees who typically received the highest extremity doses among all radiopharmacists and the second group of employees includes those who typically received the lowest extremity doses among all radiopharmacists. The gloves are worn on each hand with a traditional extremity dosimeter on the individual's index fingers underneath each glove. The gloves are exchanged each week and are worn for a total of four weeks. The licensee is currently analyzing data from those employees who have completed the study and results from the full study are expected in the near future.

The licensee has developed a formal mechanism for the evaluation of radiation doses to members of the public. Within the past year, three memos have been issued to the individual radiopharmacies regarding detailed guidance on the placement of monthly dosimeters to monitor public dose and guidance on the application of occupancy factors to the dosimeter results. The licensee had established an action level of 8 millirem per month for dosimeters used to determine public dose. If the action level were to be

exceeded, the radiopharmacy was directed to take mitigating actions, such as adding shielding or relocating the potential sources of exposure. The radiopharmacy staff then applied occupancy factors as appropriate using the guidance provided by the Q&R department. The licensee's audit staff was tasked to verify that the results of the individual radiopharmacy monthly public dose evaluations were being recorded, were less than the licensee's action level, and that appropriate occupancy factors had been applied. The inspectors reviewed the monthly public dose evaluation data from several pharmacies and verified that the licensee had established a program to monitor and evaluate public dose. The inspectors noted, however, that there did not appear to be a method for the Q&R department and/or the individual radiopharmacies to total the monthly results and verify that the annual dose to members of the public from the individual radiopharmacies did not exceed NRC's regulatory limit of 100 millirem per year. This was identified by the inspectors as a weakness in the licensee's public dose evaluation program. However, for those records reviewed by the inspectors, there did not appear to be any instances of individual radiopharmacies exceeding NRC's regulatory limit for members of the public.

3.3 Conclusions

The licensee's personnel dosimetry program was found to be implemented effectively and was appropriate for the licensee's scope of operations. The licensee's ALARA program, use of conservative investigational levels, and timely reviews of radiation dosimetry records, appeared to be effective in identifying areas of improvement. Dosimetry evaluations performed by the licensee as a result of an incident or when investigative levels were exceeded appeared to be thorough and well-documented. The licensee's research and significant efforts to characterize and reduce extremity exposures were evident by their activities to complete the extremity exposure glove study.

Though the licensee had established a program to monitor and evaluate public dose at each of its radiopharmacies, there did not appear to be an effective method for the Q&R department and/or the individual radiopharmacies to total the monthly results and verify that the annual dose to members of the public not exceed NRC's regulatory limit. This was identified as a weakness in the licensee's public dose evaluation program. However, for those records reviewed by the inspectors, there did not appear to be any instances of individual radiopharmacies exceeding NRC's regulatory limit for members of the public.

4 Licensee Audits (87127)

4.1 Inspection Scope

The inspectors interviewed members of the Q&R department, including the licensee's chief auditor, and reviewed Cardinal's internal radiopharmacy audit program, including audit findings and corrective actions associated with the findings. The inspectors also reviewed the licensee's corporate radiation safety and ALARA review audit.

4.2 Observations and Findings

The licensee's internal radiopharmacy audit program specified that three audits be performed per year for each radiopharmacy listed on the NRC byproduct materials license that is the subject of this inspection. The licensee's regionally located audit staff continue to work out of their private residences and thus remained unchanged following the licensee's relocation to Dublin, Ohio. The licensee's audit, or regulatory compliance, staff consisted of five auditors that reported to a manager who also functioned as the chief auditor.

The audit form used to determine regulatory compliance contained approximately 190 line items to be reviewed during each audit. The line items related to NRC regulations, as well as other regulations that apply to radiopharmacies. The audit form was routinely revised to remain current with applicable regulatory requirements. So that audit findings may be acted on efficiently and in a timely manner, audit results are electronically transmitted to all appropriate managers and staff immediately following the on-site audit. The audit items total to 361 points. Points per line item were based on the severity of the finding, with severe findings being 5 points each. Pharmacies that receive between 1 and 11 points were classified as either "Outstanding", "Excellent", or "Acceptable." These radiopharmacies must respond to the audit findings and their responses must include the corrective actions already taken and results achieved, actions planned to prevent future occurrence, and the date when full compliance will be achieved. Radiopharmacies whose audit results are greater than 12 points, receive a "Below Standard" rating and must develop a detailed program improvement action plan. This action plan is reviewed by the corporate RSO for appropriateness and to determine what actions the Q&R or Operations department might need to take to bring the radiopharmacy into compliance. Radiopharmacies that receive more than 17 points on an audit also receive a visit from a Cardinal regional manager within 2 days. Individual radiopharmacies can appeal audit findings by first going through their local management chain for approval and then presenting their case at the next planned RSC meeting. All audit findings were summarized and presented at RSC meetings, with particular emphasis placed on those locations determined to be "Below Standard." Depending on the underlying cause of the rating, the RSC was able to discuss and allocate additional resources as necessary to bring the facility into compliance and to improve performance.

The inspectors reviewed audit results from selected radiopharmacies and noted that appropriate corrective actions were documented in response to the identified deficiencies and that improvement plans were developed and reviewed for those radiopharmacies with more than 12 audit points.

Radiopharmacies that are newly acquired by Cardinal were considered to be under "Program Development" and were audited with increased management oversight for a time period not to exceed one year. This method of increased oversight allows newly acquired pharmacies the time necessary to effectively implement the licensee's radiation safety program and procedures.

The inspectors also reviewed the licensee's corporate radiation safety program and ALARA review audit. Though the audit was found to provide a comprehensive overview of many pertinent radiation safety and ALARA issues, there did not appear to be recommendations for improvement or identification of findings. The licensee's corporate audit functioned as a periodic review of the licensee's radiation protection program content and implementation but did not appear to be an effective mechanism that would identify program strengths or weaknesses and result in corrective actions as appropriate. This matter was discussed with the corporate RSO, who indicated that the manner in which future audits would be performed would be evaluated and changed as necessary to better capture licensee-identified audit findings.

4.3 Conclusions

The licensee's trimester points-based audit program was found to be both comprehensive and effective. The audit program provided a high degree of confidence that each NRC-regulated radiopharmacy was in compliance with NRC requirements and the conditions of Cardinal's NRC byproduct materials license. Radiopharmacies that were "Below Standard" were required to submit an action plan for correcting identified deficiencies. The RSC's review of audit findings was thorough and appeared to be effective in identifying areas where assistance and additional resources were necessary. The licensee's graded approach to oversight of newly acquired radiopharmacies appeared to be effective in helping the facility implement the licensee's radiation safety program and procedures.

The licensee's corporate audit functioned as a periodic review of their radiation protection program content and implementation but did not appear to be an effective mechanism that would identify program strengths or weaknesses and result in corrective actions. The licensee indicated that future radiation safety program audits would be performed differently in a manner that would better capture licensee-identified audit findings.

5 Authorized Nuclear Pharmacist Training and Approvals (87127)

5.1 Inspection Scope

The inspectors interviewed Q&R department personnel regarding the licensee's implementation of their ANP training program, reviewed a sample of the ANP training materials, and reviewed a selective sample of ANP training records and RSC approvals.

5.2 Observations and Findings

Notwithstanding the requirements of 10 CFR 32.72(b)(2)(ii), Cardinal is authorized by its NRC byproduct materials license to self-approve ANPs following the criteria specified in 10 CFR 35.55, 10 CFR 35.57, and 10 CFR 35.59. The inspectors reviewed the licensee's ANP training program and found that the Nuclear Education On-Line (NEO) program was extensively used by the licensee for training purposes. This program involves computer on-line training modules on basic radiation safety training and was developed and administered by the University of New Mexico and the University of

Arkansas Pharmacy Departments. All individuals must be a licensed pharmacist to be eligible to take the training program. The program consists of 8 weeks of on-line training with weekly conference calls involving university faculty and Q&R department staff. Timed and graded exams are given on-line following each module. The student's preceptor, usually a Cardinal pharmacy manager and a local radiopharmacy RSO are also involved in the training. After successful completion of the on-line segment, the student spends 3 weeks at the licensee's facility in Dublin, Ohio, to receive hands-on training in the licensee's on-site radiopharmacy training facility. Following successful completion of the 3 week in-house training, including passing two practical and two written exams, the students return to their respective pharmacies and receive approximately 4-6 weeks of supervised practical on-the-job training and experience under the supervision of their preceptor.

Upon successful completion of the practical training, the pharmacy manager/preceptor makes a written recommendation to the RSC that the student be certified as an ANP. The seven RSC members, using specific approval criteria, review the training and experience of the student pharmacist. A majority (4) vote by the RSC must be obtained to approve an applicant as an ANP. The corporate RSO has the authority to veto any applicant approved by the RSC. Following approval, the name of the ANP is added to the licensee's list of authorized ANPs.

The inspectors reviewed the documentation of several ANPs who had been approved by the RSC and determined that the RSC adequately applied the current NRC regulations and guidance in their approval process as required by their license. However, there was one isolated case for a request to approve a student applicant whose documented training and experience did not appear to include one of the areas required under work or practical experience with radiation. However, after further discussion with the licensee, it was determined by the inspectors that the individual had extensive practical, as well as, supervised clinical case experience and was sufficiently qualified. The licensee noted the documentation deficiency after it was pointed out by the inspectors.

5.3 Conclusions

The inspectors found that the licensee's training program for ANPs was being implemented in an effective manner. Training for licensed pharmacists to become ANPs consisted of a series of on-line radiation safety training modules, timed and graded examinations, hands-on training using radiopharmacy and radiation safety equipment, and practical on-the-job training under the supervision of a preceptor. The student must receive the recommendation of his or her preceptor, who then forwards it for RSC approval. The RSC was found to be reviewing the training and experience of the candidates as appropriate. Though a majority of RSC members can approve an individual, the corporate RSO has the authority to veto any applicant approved by the RSC. Following approval, the name of the ANP is added to the licensee's list of authorized ANPs.

6 Miscellaneous Records Review (87127)

6.1 Inspection Scope

The inspectors interviewed Q&R department personnel and reviewed records regarding the licensee's decommissioning files and incident and event reporting system. Licensee staff also demonstrated their electronic customer license verification system.

6.2 Observations and Findings

The inspectors reviewed decommissioning files for several Cardinal radiopharmacies that had been removed from the NRC byproduct materials license. Each decommissioning file was noted to contain specific and detailed information on the surveys performed, including confirmation that no residual radioactivity was present and that the site was suitable for release in accordance with NRC requirements. The decommissioning information submitted to the NRC for facilities to be decommissioned was adequate to make an assessment to remove the location from the license.

The inspectors reviewed several incident and event reports, which included vehicle accidents, needle stick injuries, skin contamination, and major radioactive material spills and found the reports to be detailed and thorough. When an incident or event involving radioactive material occurs, local radiopharmacy personnel must submit a questionnaire to the Q&R department. Questionnaires reviewed were found to contained sufficient details of the incident or event for the Q&R department to adequately assess radiation dose, if necessary, and to determine the root cause of the event and appropriate corrective actions. For each incident, the Q&R department develops a report that contains a description of the incident, corrective actions, and plan to prevent recurrence. A summary of all incident reports is discussed during RSC meetings to ensure that the corrective actions and preventative plan are adequately addressed and that lessons learned are shared.

The licensee demonstrated "InPharm," the computer program they use to verify that customer orders are in agreement with the radioactive material possession limits on their customers' NRC or Agreement State license. The licensee performed several demonstrations of the InPharm system and each demonstration correctly confirmed that the customer, based on their possession limit, ordered and received the correct isotope and activity of licensed material. The InPharm system is used routinely by the licensee to track customer licenses but also has a lesser-used function to track the information contained in the Cardinal NPS license. When the licensee is issued an amendment to their NRC license, the radiopharmacies are provided with the current information and maintain a hard copy of the current license. The licensee's audit staff reviews the hard copies at each location to make sure they are current. However, though not an audit item, the radiopharmacy staff is also supposed to update their InPharm system with the current NRC license information. The inspectors reviewed the InPharm system and found that several locations had not entered the current NRC license information into their InPharm system. Many of the locations had license information that dated back to the year 2003. Note that the current NRC license was recently amended in June 2005 to reflect the change in the mailing address of the corporate office, which also involved

the issuance of a new NRC license number. After being noted by the inspectors, the licensee issued a memo to all radiopharmacies instructing them to update the InPharm system with the current NRC license amendment information. The licensee cautioned their staff to be extra diligent in insuring licenses are current in the InPharm system and agreed to follow-up with the radiopharmacies to ensure that the updates to the system had been performed.

6.3 Conclusions

Decommissioning files reviewed by the inspectors were noted to contain detailed information on the surveys performed, including confirmation that no residual radioactivity was present and that the site was suitable for release in accordance with NRC requirements. Incident and event reports reviewed by the inspectors were found to contain sufficient details regarding the incident or event for the Q&R department to adequately assess radiation dose, if necessary, and to determine the root cause of the event and appropriate corrective actions. The licensee performed several demonstrations of the computer program they use to verify that customer orders are in agreement with the radioactive material possession limits on their customers' NRC or Agreement State license. Each demonstration correctly confirmed that the customer, based on their possession limit, ordered and received the correct isotope and activity of licensed material. The inspectors identified that several radiopharmacies needed to update their system to reflect the current NRC license information. The licensee took immediate corrective action and agreed to perform follow-up on their corrective actions.

7 NRC Inspection Findings (87127)

7.1 Inspection Scope

Oversight of the Cardinal radiation safety program by NRC Region IV was conducted through both licensing and inspection activities. Between October 1, 2004 and September 30, 2005, NRC conducted routine inspections of the licensee's radiopharmacies including inspections of activities regarding the transportation of radioactive material to client facilities. The results of inspections conducted by NRC region-based inspectors were transmitted to Region IV for review and communication with the licensee.

7.2 Observations and Findings

Between October 1, 2004, and September 30, 2005, NRC conducted 16 routine inspections of Cardinal radiopharmacies. A summary of the locations inspected and inspection dates is presented in Table 1 below. No violations were identified as a result of these routine inspections.

Table 1

Summary of Routine Inspection Data	
Location Inspected	**Inspection Date**
Jenison, Michigan	11/16/2004
Swartz Creek, Michigan	11/17/2004
Virginia Beach, Virginia	11/18/2004
Richmond, Virginia	12/01/2004
Duncansville, Pennsylvania	12/01/2004
Springfield, Missouri	12/15/2004
St. Paul, Minnesota	1/14/2005
Moorhead, Minnesota	3/15/2005
Glastonbury, Connecticut	3/22/2005
Bristol, Pennsylvania	3/31/2005
Bradford, Pennsylvania	3/31/2005
Seaford, Delaware	4/26/2005
Fort Wayne, Indiana	5/10/2005
Indianapolis (Georgetown Road)	5/12/2005
Princeton, West Virginia	6/28/2005
Duluth, Minnesota	7/11/2005

Between October 1, 2004, and September 30, 2005, NRC conducted two inspections of the licensee's activities related to the transportation of radioactive material. A summary of the inspection information is presented in Table 2 below. In these cases, NRC inspectors were conducting inspections of NRC-regulated medical facilities when Cardinal delivery drivers were observed to be making deliveries to the medical facilities. Both transportation inspections resulted in the identification of no violations.

Table 2

Summary of Transportation Inspection Data		
Location of Inspection	**Originating Cardinal Radiopharmacy**	**Inspection Date**
William Beaumont Army Medical Center El Paso, Texas (location is exclusive Federal Jurisdiction)	El Paso, Texas	10/27/2004
Du Bois Regional Medical Center Du Bois, Pennsylvania	Duncansville, Pennsylvania	12/14/2004

7.3 Conclusions

Between October 1, 2004, and September 30, 2005, NRC conducted 16 routine inspections of Cardinal radiopharmacies as well as two inspections of the licensee's activities regarding the transportation of radioactive material. There were no violations associated with any of the inspections, providing evidence that Cardinal's radiation safety program was well-implemented at its individual radiopharmacies.

8 Exit Meeting Summary

No violations were identified during this inspection. The inspectors presented the inspection findings to members of Cardinal management on September 15, 2005. Cardinal management acknowledged the inspection findings.

ATTACHMENT

PARTIAL LIST OF PERSONS CONTACTED

Licensee
J. Coffey, Senior Vice President, Quality & Regulatory
P. Gotti, corporate Radiation Safety Officer
T. Simonian, Manager, Regulatory Compliance
E. Malconian, Senior Manager, Training and Health & Safety
W. Regits, Manager, Compliance
R. Green, Senior Manager, Pharmacy Practice
D. Breuning, Associate Health Physicist

INSPECTION PROCEDURES USED

87127 Materials Inspection Program: Radiopharmacy Programs

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened
None

Closed
None

Discussed
None

LIST OF ACRONYMS USED

ALARA	As Low As Reasonably Achievable
ANP	authorized nuclear pharmacist
Cardinal	Cardinal Health
CFR	Code of Federal Regulations
NEO	Nuclear Education Online
NPS	Nuclear Pharmacy Services
Q&R	Quality & Regulatory
RSC	radiation safety committee
RSO	radiation safety officer