U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Report No.	030-01786/98-001
Docket No.	030-01786
License No.	19-00296-10
Licensee:	Department of Health & Human Services National Institutes of Health
Location:	31 Center Drive, MSC 2260 Bethesda, Maryland 20892-2260
Inspection Dates:	March 30 thru April 3, 1998

Inspectors:

Louis Manning, III
Health Physicist — May 11, 1998 date

Neelam Bhalla — may 11, 1998 date
Neelam Bhalla
Health Physicist

Teresa Hall Darden — May 8, 1998 date
Teresa Hall Darden
Senior Health Physicist

Approved By:

M. Shanbaky — 5/19/1998 date
Mohamed M. Shanbaky, Chief
Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety

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EXECUTIVE SUMMARY

Department of Health & Human Services
NRC Inspection Report No. 030-01786/98-001

The inspection was conducted March 30 through April 3, 1998. The inspection focused on management oversight of the radiation safety program and included review of recordable and reportable incidents. The inspection also focused on nuclear medicine program activities, including radiopharmaceutical therapy; research activities, both human subject and non human research; package receipts and distribution; security of radioactive materials (RAM); effluent monitoring and waste handling operations.

On February 12, 1998, the Radiation Safety Officer (RSO) notified NRC Region I, by telephone, of the loss of a 1 millicurie (mCi) package of phosphorus-32 (^{32}P) that was discovered on February 9, 1998. In a letter dated February 23, 1998, in follow up to the February 12, 1998, telephone notification, the loss of the 1 mCi package of ^{32}P was reported. In the same letter, the licensee also reported a ^{32}P contamination incident that was discovered on January 28, 1998 during a routine survey (Discussed in Section II).

The licensee contested two violations cited in Inspection Report No. 030-01786/97-001; a 10 CFR 35.53(a) failure to assay an iodine dose prior to patient administration, and a 10 CFR 35.315(a)(8) failure to perform bioassay on the radiopharmacist within 72 hours after helping to prepare doses. However, corrective actions, to prevent recurrence, had been initiated and implemented, (discussed in Section III, B, 3).

Two violations were identified: 1) loss of control of RAM (Section II.B.1.); and 2) failure to brace packages on public highways (Section II.B.1.).

REPORT DETAILS

I. Oversight

A. Inspection Scope

The scope of this inspection included review of the licensee's management of the radiation safety program and security of radioactive materials from unauthorized access and removal.

B. Observations and Findings

The National Institutes of Health (NIH) Radiation Safety Branch (RSB) has direct responsibility for radiation safety program activities. Oversight of the byproduct materials licensed program is provided by the Radiation Safety Committee (RSC) and works in conjunction with the RSB to effectively run the radiation safety program. Although required to meet quarterly, the RSC meets monthly. Review of RSC meeting minutes indicated that they discussed several program areas including: radiation safety program administration, radiation safety aspects of research protocols, NRC violations and licensing issues, security of RAM, and incidents. The RSB, under the direction of the Branch Chief who also serves as the Radiation Safety Officer (RSO), is comprised of 35 full time equivalent (FTE) positions and a similar number of contractor positions. Areas operated with contractors include: area surveys, package receipt and distribution and waste handling. These areas, although operated with contractors, are under the direct supervision of staff area health physicists (AHP).

The inspectors observed that the licensee has launched an aggressive campaign to identify and correct deficiencies associated with security of RAM on the NIH campus which includes nuclear medicine, research laboratories and refrigerators in corridors. Doors have been installed in the Nuclear Medicine Department (NMD) that prevent entry during off hours. In many labs, RAM waste was behind locked plexiglass doors. All RAM including waste in unoccupied, and sometimes open research laboratories was observed to be secured from unauthorized removal.

C. Conclusions

The inspectors concluded that appropriate oversight is provided for the radiation safety program. Also, an aggressive campaign for security of RAM launched by the licensee has been effective in minimizing security breaches and violations.

II. INCIDENTS

A. Inspection Scope

The inspection focused on the circumstances surrounding the loss of control of 1 mCi of ^{32}P discovered on February 9, 1998; and a ^{32}P contamination incident that was discovered on January 28, 1998.

B. Observations and Findings

From records review and staff interviews, the inspector noted the following about the two incidents:

1. Lost ^{32}P package: The licensee reported that on February 5, 1998, two packages were delivered by a delivery technician to the authorized user's (AU) lab in Building 37. The packages were received and signed for by one of workers in the lab. On February 9, 1998, the AU called the RSB to request the other package that contained 1 mCi of ^{32}P, since their records indicated that only one package was received on February 5, 1998, and the lab technician did not recall that two packages were delivered on that day.

From February 9, and continuing through March 5, 1998 the licensee unsuccessfully launched an investigation to seek answers about the missing ^{32}P package. The search included staff interviews, lab checks for correct package receipt, dumpster checks, comprehensive surveys of laboratories, corridors, coffee set ups, common eating areas, water coolers, and an extensive search of Building 37 to locate the missing ^{32}P. Assistance from the NIH Police was also requested to assist in locating the ^{32}P.

In reviewing this incident, the inspector observed activities in the package receipt and distribution area (PR&DA), one of the areas covered by contractors. This included accompaniment of the delivery technician who was responsible for delivering the 1 mCi ^{32}P package on February 5, 1998, on a campus package delivery run. Delivery technicians also deliver packages off campus to NIH satellite locations. The inspector noted that when packages were delivered to the PR&DA, they were verified with the package inserts, wiped for contamination, processed, and bar code labels were assigned to each package and/or dose. Routinely, all RAM packages are delivered by a delivery technician to the AU lab. A log record sheet was prepared for each RAM package to accompany each delivery for signature by the package receiver. The PR&DA technician said that when RAM is returned, it is reconciled by the bar code identifier. Since the loss of the ^{32}P package, the log sheets were revised to include a signature for each package or dose that is delivered and received.

During the delivery accompaniment, the inspector observed that the delivery technician verified the number of packages with the number entered on the log sheet and placed packages in a huge duffle bag. A safety check was performed on the vehicles and the placard to identify that the vehicle was transporting RAM was displayed. The packages were then placed in the van. Upon arrival at the first designated building, the driver lightened the load in the duffle bag by removing the packages intended for other locations. At each designated stop, the packages were again placed in the duffle bag for delivery to that specific site. The inspector noted that the initial removal and the repacking of the duffle bag at each designated location presented opportunity

for packages to be misplaced or delivered to an incorrect location. Upon delivery of the packages to the AU lab, the inspector observed that each receiver did not actually verify the contents of packages received and signed for, but simply acknowledged the number of packages the delivery technician announced. The package contents were not announced. The delivery technician said that when they find that labs are locked and/or unattended, the packages are taken back to the PR&DA and delivered at a later time. The inspector reasoned that since an individual's signature is required to acknowledge the number of packages received, the package receiver could also verify the contents by, at a minimum, checking the label. The inspector noted that the log record sheet that was signed on February 5, 1998 for the ^{32}P package delivery and receipt indicated that at least one package was signed for. It was unclear, to the inspector, that the signature indicated that more than one package was delivered or received even though RSB staff interpreted that the signature represented that two packages had been delivered and received.

In the February 23, 1998 letter, the licensee stated that a corrective action to prevent recurrence is that the procedures for documenting the delivery of packages was revised so that "the recipient of the delivery is told the exact number of items being delivered and must sign for each and every item. The delivery technicians have been instructed to insure that each item to be delivered to a location is compared to the description on the improved delivery log prior to leaving the delivery location." Since the signature for each package was implemented as a corrective action in response to the loss of control of the one mCi ^{32}P package, the inspector noted that a weakness remained in the receipt of packages in the verification process. The licensee indicated that further evaluation would be conducted of the delivery and receipt process.

In a discussion with the licensee's contractor staff about bracing packages when delivering packages off site of the main campus, some contractor staff indicated to the inspector that they did not brace packages while traveling on public highways. They were not aware of the bracing requirement; and did not possess the necessary equipment to brace packages in vehicles while traveling on public highways. The inspector informed licensee staff that they were required by Department of Transportation (DOT) regulation to brace RAM packages when transporting on public highways.

2. ^{32}P Fixed Contamination: The licensee reported that on January 28, 1998, a contract survey technician found ^{32}P contamination in a corridor and traced its origin to an HIV lab in the same building. Response by the RSB located numerous spots of ^{32}P contamination in the corridors and on the landing and stairs leading to the next lower level. With the exception of some fixed contamination on the steps, all areas were decontaminated to levels acceptable for unrestricted use. The stairs and landing contained some fixed

contamination that exceeded limits for unrestricted areas. Various methods were used to cover or remove the fixed contamination.

The inspector interviewed staff concerning the incident and learned that surveys are conducted every six months in this area by contractor technicians. However, site surveys are performed in the lab at the user's area upon use of the isotope. Since the incident, area surveys have been expanded to include the lab and an outer room where waste is stored. The RSO advised the AHP to increase survey frequency. Both the Principle Investigator (PI) and the AU in charge of the area were interviewed. The PI was aware of the ^{32}P contamination incident and maintained project oversight by frequent staff meetings with AU and other workers.

C. Conclusions

On April 3, 1998, at the conclusion of the on site inspection, the 1 mCi ^{32}P package had not been recovered. The licensee stated that there had been no known exposures to any individual from the contents of the lost package. The inspector concluded that the ^{32}P had decayed approximately four half lives and the predicted activity was about 125 microcuries (µCi), which is greater than Part 20 Appendix C limits for labeling, but less than Appendix B (annual limit on intake) ALI quantities. The licensee questioned the cost effectiveness of expending further resource effort to locate this package and concluded that the disposition of the package is unknown. The inspector also concluded that the implemented corrective action to address loss of control of packages upon or after package receipt continues to be lacking in that receivers of RAM do not verify the actual contents delivered to them prior to signing for receipt of the package.

10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. The inspector concluded that the licensee lost control of 1 mCi of ^{32}P and has not recovered control of it. Loss of control of licensed material is an apparent violation of 10 CFR 20.1802.

49 CFR 173.448(a) requires that each shipment of Class 7 (radioactive) materials must be secured to prevent shifting during normal transportation conditions. Failure to brace packages to prevent shifting is an apparent violation of 49 CFR 173.448(a).

More frequent and enhanced surveys to identify and /or prevent contamination are being implemented by the licensee.

III. Human Use of Licensed Radioactive Materials

A. Inspection Scope

The inspection focused on training requirements for AU, Clinical Nuclear Medicine, previous violations and implementation of corrective actions, Radiopharmaceutical Therapy with sodium iodide iodine-131 (^{131}I), Brachytherapy, Therapy with Radio-labeled Monoclonal Antibodies, and Quality Management Program (QMP).

B. Observations and Findings

1. Training Requirements for Authorized Users: The RSC reviews and approves AU for human use. There are sixteen AU authorized for human use of RAM. The inspector reviewed the training and experience of three AU and determined that each of them met the requirements of 10 CFR 35, Subpart J. All AU for human clinical use are also authorized to use RAM on humans for research. However, all research protocols involving human subjects must be approved by the RSC and the Institutional Review Board (IRB). RAM use for which no approval has been given by the Food and Drug Administration (FDA), must be reviewed by the Radioactive Drug Research Committee (RDRC) before it is presented to the IRB and the RSC. Finally, all protocols involving human research subjects must be approved by the Director of the Clinical Center. The licensee indicated that there are approximately 130 active research protocols involving human subjects, and the active protocols are reviewed annually by the IRB.

2. Clinical Nuclear Medicine: The Clinical Nuclear Medicine facility is located on the first floor of Building 10, also known as the Clinical Center. The inspectors, during a security check of Building 10 noted that during "off-hours", the Nuclear Medicine facility was locked. Access was possible only through the NIH entry cards. During working hours, the inspector noted that the department is equipped with 7 imaging cameras, a "hot-lab", 2 dosing areas, and is staffed by a radiopharmacist and 8 technologists. The inspector observed the elution of a Molybdenum-99/Technetium-99m ($^{99}Mo/^{99m}Tc$) generator by the radiopharmacist and noted that the appropriate tests were performed on the eluted ^{99m}Tc. The inspector observed the radiopharmacist perform the daily constancy tests on the dose calibrators and noted that the dose calibrator response was within 5 percent of the anticipated values. The inspector observed that the radiopharmacist prepared the patient doses and logged them into the computer system. The inspector noted that appropriate radiation safety procedures were followed, in that, syringe shields were used, lab coats and gloves were worn, and whole body as well as extremity dosimeters, when required, were worn by personnel. The inspector noted that the survey meters were calibrated within the year.

3. Previous Violations and Implementation of Corrective Actions: The licensee contested two violations identified during Inspection No. 97-001 and cited in Inspection Report No. 030-01786/97-001 that occurred in the Clinical NMD. One violation was a 10 CFR 35.53(a) failure to assay an ^{131}I dose prior to patient administration that resulted in a misadministration. The second violation was a 10 CFR 35.315(a)(8) failure to perform bioassay on individuals who participate in the preparation and dose administration of ^{131}I in quantities that require patient hospitalization under 10 CFR 35.75 within 72 hours after handling the dose.

The licensee in its response letter to NRC, dated September 15, 1997, contested both violations. However, corrective actions, to prevent recurrence, had been initiated and implemented. NRC reviewed and evaluated the reasons for the licensee's objection and resolved to withdraw the violation that was cited against 10 CFR 35.53(a). The NRC alternative was to issue a violation for inadequate supervision against 10 CFR 35.25 for failure of the radiopharmacist to follow the QMP and reconcile information on the Written Directive (WD) with the information on the dose calibrator printout.

The NRC, in a letter dated March 16, 1998, withdrew one violation but issued another violation as discussed above, and the second violation remained as cited. Notwithstanding the characterization of the violations, the licensee has implemented corrective actions for both "violations". The inspector noted that several corrective actions were in place for the first "violation". These included, segregation of human use doses and non-human use doses, and discarding the dose if the patient does not show up for treatment. Most importantly, the licensee now measures the dose on the day that the procedure is scheduled, usually within an hour prior to dose administration.

To correct the second " violation", bioassays are being performed on the radiopharmacist who prepares (opens the package and measures the dose) ^{131}I doses greater than 30 mCi. The inspector noted that for ^{131}I therapies in amounts greater than 30 mCi, administered since Inspection No. 97-001, bioassays were performed on the radiopharmacist and the health physicist who administered the doses. The inspector noted that bioassays were performed within 72 hours of dose administration. Bioassay results indicated no detectable uptake of ^{131}I.

4. Radiopharmaceutical Therapy with ^{131}I: ^{131}I is used for the treatment of hyperthyroidism and thyroid cancer. The inspector noted that of the 12 treatments administered since Inspection No. 97-003, 9 treatments were for thyroid cancer. The dose varied from 65 mCi to 300 mCi. All patients were hospitalized under the provisions of 10 CFR 35.75. Although the revised (May 1997) 10 CFR 35.75 allows the release of such patients with larger quantities of ^{131}I, the licensee indicated that they have opted to keep patients hospitalized under the old release criteria. Room No. 8S263 located on the 8th floor of the Clinical Center, is dedicated for ^{131}I patient use. The room is prepared by the RSB AHP. The AHP also administers the dose to the patient under the

supervision of an AU. During the inspection, there were two ^{131}I patients hospitalized on the 8th floor of the Clinical Center. A patient that was administered 300 mCi on March 30, 1998, was located in room 8S263 and another patient that was administered 65 mCi on March 27, 1998 was located in Room 8S261, adjacent to room 8S263. The inspector observed that both rooms were properly posted, and the room floors were covered with plastic-backed absorbent paper. Both rooms were provided with receptacles for patient linen and trash. The inspector also interviewed two nurses and noted that they were trained in the radiation safety precautions, and were badged with whole body dosimeters. A member of the housekeeping staff was also interviewed, and the inspector noted that the individual had been instructed not to enter ^{131}I patient rooms until authorized by the AHP. The rooms were surveyed by the AHP, and radiation levels were posted on each room door. The inspectors performed radiological surveys in the corridors and adjacent rooms. Measurements were less than 0.1 millirem per hour (mrem/hr), within the regulatory limits of 2 mrem/hr for unrestricted areas.

5. Brachytherapy: The Radiation Oncology Department is located on the ground floor of the Clinical Center. No manual Brachytherapy procedures have been performed since the last inspection. The licensee indicated that the use of a low dose remote after loader, Nucletron Selectron has also been discontinued. There is an inventory of cesium-137 (^{137}Cs) Brachytherapy sources. stored and locked in the Radiation Oncology Department. The sources are leak tested and inventoried by the RSB.

6. Therapy with Radio-labeled Monoclonal Antibodies: Yttrium-90 (^{90}Y) labeled monoclonal antibodies are used for the treatment of certain cancers as a research protocol. The dose is prepared by the radiopharmacist in Building 21 and administered in the Clinical NMD. The inspector noted that appropriate radiological safety procedures were followed during dose preparation and dose administration.

7. Quality Management Program: The licensee performs an annual audit of all administrations of ^{131}I in quantities greater than 30 µCi and other therapeutic radiopharmaceuticals. The audit for 1997 was performed by an AU who is also the Chief of Clinical Studies Section of the NMD. The audit included a review of all 37 ^{131}I administrations for diagnostic use, 24 ^{131}I administrations for therapeutic use and 17 administrations of ^{90}Y labeled monoclonal antibody therapies. All the therapy doses were in accordance with the prescribed dose on the WD. However, there was one misadministration identified for the diagnostic dose of ^{131}I. This misadministration was reviewed during Inspection No. 97-001. As described in Section III.B.3. above, the licensee has implemented corrective actions to prevent recurrence of such an event. The inspector reviewed all diagnostic and therapeutic administrations of ^{131}I since Inspection No. 97-003 and identified no misadministrations.

C. Conclusions:

Within the scope of this inspection, for human use of NRC licensed materials, no violations were identified. The licensee has implemented corrective actions for the contested violations that were identified during Inspection No. 97-001.

IV. Radiopharmacy (Building 21)

A Inspection Scope

The inspection focused on activities in the radiopharmacy in Building 21 and its primary use for the preparation of monoclonal antibodies in support of the Anti-Tac protocol. The scope also included the labeling process which is performed with indium-111 (^{111}In) and ^{90}Y, and the monoclonal antibodies used for treatment of Leukemia and Lymphoma.

B. Observations and Findings

The inspector toured the radiopharmacy in Building 21. This radiopharmacy is used for labeling monoclonal antibodies. In particular, antibodies for the Anti-Tac protocol are prepared in this radiopharmacy. The radiopharmacy houses two fume hoods, one for high activity iodinations, and the other for low activity iodinations. The last high level iodination occurred in 1993, and was performed for antibody labeling. Activities range between 600 mCi to 1 Curie (Ci). The radiopharmacist told the inspector that a rule of thumb for labeling antibodies at this level is that whatever activity is needed for therapy, approximately twice as much ^{131}I is needed for labeling. Activities for low level iodinations are 2 mCi of sodium iodide, iodine-125 (^{125}I). These iodinations are used for either quality control (QC) purposes, or research and development (R&D). Low Level iodinations using ^{125}I are performed at least once a month, while low level iodinations using ^{131}I are performed approximately once a year. Activities used for iodinations with ^{131}I are typically 1 mCi. ^{125}I may also be used at high activities; however, it is used as a tracer, and serves no therapeutic purpose.

The inspector observed the labeling, (a two step process), of monoclonal antibodies for a patient therapy. The ^{111}In is labeled a day prior to the actual therapy, and the ^{90}Y is labeled on the day of the therapy. This is done because the high beta (-) energy of ^{90}Y can damage the protein if it is allowed to sit too long following labeling. Following labeling, the radiopharmaceutical is put into a High Pressure Liquid Chromatograph which forces the radiopharmaceutical through a dedicated pre-column and column for particle size and molecular weight separation. The pre-column prevents larger particle size and high molecular weight material from entering the column. This process yields a "purer" radiopharmaceutical. During the collection phase, a radiation peak and corresponding ultra violet peak are graphed via a plotter. The ultra violet peak is always within the radiation peak for the final product. This graph indicates the maximum tagging of the RAM to the antibody. Any material outside both peaks is disposed of as waste, and held for decay. Following this process, QC tests are performed as appropriate on the desired material. Based upon QC test results, the finished product is prepared for

the therapy. After the final products are obtained (i.e., ^{111}In labeled and ^{90}Y labeled Anti-Tac), each radiopharmaceutical is separately assayed in a dose calibrator. The inspector verified that the dose calibrator constancy test is performed prior to assaying patient dosages. The appropriate correction factors are applied to each result. The ^{111}In and ^{90}Y labeled radiopharmaceuticals are then combined into one syringe. Human Serum Albumen is then added to this syringe. The dose is then administered to the patient, usually within one to two hours following final preparation. The protocol requires 5 mCi of ^{111}In and 5 mCi of ^{90}Y. Based upon patient prognosis, the ^{90}Y dose is increased in 5 mCi increments. At the time of the inspection, the ^{90}Y dose was 20 mCi. The inspector noted that the ^{111}In labeled component serves no therapeutic purposes, and is only added for diagnostic imaging.

The inspector verified that proper radiation protection procedures were utilized during the entire labeling process. The radiopharmacist and chemist wore protective clothing and proper whole body and extremity dosimeters. In addition, personnel changed their gloves regularly throughout the labeling process. There are also adequate shields available, including polystyrene shields for the ^{90}Y. The inspector verified that this area is surveyed at the end of each day of use for radiation levels, and that weekly surveys for removable contamination are also performed. All waste that is generated is held for decay, and is segregated into solid and liquid waste. All potentially contaminated material and waste is picked up by contractors and is processed as required (See Section V.).

C. Conclusions

Based upon observations by the inspector, interviews with personnel, and examination of selected records, no safety concerns were identified in this area. Personnel interviewed were trained, and appeared knowledgeable about procedures and protocols.

V. Radioactive Waste Management and Effluents

A. Inspection Scope

The inspection focused on the licensee's generation, processing, disposal, and control of waste streams. These include: aqueous, solid, medical pathological waste (MPW), liquid scintillation vials (LSV), animal carcasses, and mixed liquid waste. Each waste stream is segregated into these classes for disposal.

B. Observations and Findings

The licensee employs a contractor who handles the collection, processing, disposal, and shipment of the waste. The inspector toured the waste facilities located in Buildings 21 and 25. Building 21 houses all aqueous, LSV, and solid waste. Building 25 houses all MPW (radioactive and non-radioactive). The radioactive MPW is short lived and is decayed in storage (DIS) in a freezer located in Building 25. Both buildings serve as processing stations for all radioactive contaminated waste and the point of shipment to the appropriate disposal companies. The waste contractors remove all waste from the

various labs throughout the campus, including the Clinical Center, when the individual waste containers are full. Users segregate the waste as it is generated and place all liquid aqueous waste into a carboy, and liquid mixed waste into a separate carboy. All solid waste is separated into either a sharps container, MPW container, or dry solid container. LSV are placed into the original container following counting and are later placed into a 55 gallon drum with the appropriate absorbing material for shipment. All animal carcasses are placed in a MPW container. All waste containers are labeled with a "Caution Radioactive Material" label, and are picked up by the waste contractor. The inspector observed several labels, and noted that each label contained the appropriate information.

Once all waste is removed to the appropriate building, the processing begins. All waste that is DIS is held for a minimum of 10 half-lives and surveyed prior to disposal. All MPW, wether or not it was previously contaminated with RAM, is passed through two sodium iodide detectors. Any waste that triggers the alarm is evaluated further. It should be noted that previously contaminated MPW is surveyed for radiation levels prior to being scanned with the sodium iodide detectors. Following these surveys, the MPW is shipped to a waste incinerator in Baltimore, Maryland. LSV are packaged into 55 gallon drums and an absorbent material is added. These drums are sent to a company in Florida for processing. All animal carcasses containing long-lived radionuclides, are packaged as MPW, and shipped to an appropriate company for incineration. Animal carcasses containing short-lived radionuclides, are also packaged as MPW and held for ten half-lives. After DIS, the carcasses are sent to the Baltimore, Maryland facility for incineration. The solid waste is either DIS or sent to South Carolina for burial. The aqueous non-mixed waste is collected into one of nine storage tanks until filled. Each storage tank receives a batch number. When the tank is filled, the waste is analyzed for total toxic organics, (as required by the sewer authority), pH, and concentration of RAM. Following the analysis, when the required criteria is met, the waste is released via the sewer.

During NRC Inspection No. 97-003, the inspector learned that the licensee would implement new procedures to treat the aqueous mixed waste. Prior to the implementation of the new procedure, the mixed waste was treated with ultra violet (UV) radiation only. This process caused the formation of an iron precipitate. To prevent the iron from precipitating out during UV processing, the licensee now adds ethylenediaminetetraacetic acid (EDTA), and adjusts the pH more carefully. The EDTA is very soluble in water, and keeps the iron in solution. The storage tank is mixed thoroughly. The treated aqueous waste is filtered via a five micron filter as it is released via the sewer. It should be noted that the final product is also analyzed for toxic organics, and concentration of RAM before release via the sanitary sewer. The inspector split samples with the licensee from two storage tanks containing non-mixed aqueous waste, and one sample from the previously mixed aqueous waste after the EDTA was added. The sample from the UV treated tank did not exhibit any significant precipitate following collection. Final results will be compared with the licensee's results, and any discrepancies will be addressed, and any potential disagreements will be resolved in an upcoming inspection. The inspector also reviewed disposal records for 1997 through February 1998. The monthly releases were within regulatory limits.

To monitor air emissions, the licensee has placed stack monitors throughout the campus. To demonstrate compliance with air emissions, the licensee uses the EPA methodology (Comply code version 1.5d). Comply is a computer software program to evaluate licensee compliance for air emissions. The inspector reviewed the licensee's 1997 data during the inspection and found the annual releases to be within the regulatory limits.

C Conclusions

Based upon interviews with personnel, and a selected examination of the licensee's records, the inspector identified no safety concerns in this area. Personnel who were interviewed were trained, and knowledgeable about the protocols and the required radiation safety procedures .

VI. Research (Non Human Use)

A. Inspection Scope

The inspection focused on the licensee's non human use research which constitutes the largest usage of RAM at NIH. The inspectors focused on the role of the AU in providing oversight for the use of RAM in the R&D labs.

B. Observations and Findings

Each AU is issued a permit through the RSC to use RAM for research. The permit contains limits, where if exceeded, would require the AU to submit a safety protocol. As long as the AU operates within the set limits, any RAM listed on the permit can be ordered according to the licensee's established procedures. The inspectors toured several research laboratories, and interviewed personnel. All AU contacted during the inspection, maintained appropriate oversight of their labs. Additionally, AU provided lab and/or procedure specific training, and scheduled the required training provided by the RSB, for new employees in their labs. All AU contacted during the inspection were aware of and implemented the RSB policy concerning security of RAM. Labs visited were either locked, or if unlocked, the material inside the lab was secured. The inspectors also followed up on enforcement findings during routine audits by the AHP or the contractor. One of the AU who was interviewed had received a written warning (WW) from the RSO. A WW is a compliance tool used by the licensee, and is issued when an AU is found to be in violation of radiation safety procedures repeatedly, dependent upon the severity of the violation. This WW concerned lab surveys that were not performed to measure radiation levels or removable contamination. The AU told the inspector that he planned to exercise greater oversight to ensure that future surveys would be performed.

C. Conclusions

The inspector concluded that activities in the research labs generally, were conducted according to the licensee's established procedures. The inspector also concluded that the RSB provides appropriate oversight for the non human use R&D radiation safety program.

VII MANAGEMENT MEETING

At the conclusion of the inspection, the inspection findings were discussed with the licensee.

PARTIAL LIST OF PERSONS CONTACTED

National Institutes of Health Personnel

Michael Gottesman, Director, Department of Intramural Research
Richard Wyatt, Management Representative (Radiation Safety Committee), OD
Anthony S. Fauci, M.D., Director, National Institute of Allergy and Infectious Diseases
Robert Zoon, Radiation Safety Officer, DS, RSB
Shawn Googins, Chief, TSS, DS, RSB
Robert W. McKinney, Director, Division of Safety
Michael Noska, Health Physicist, TSS, RSB
Richard Fejka, Radiopharmacy, Clinical Nuclear Medicine
Sean M. Austin, Chief, RMCS, RSB
Kelly H. Austin, Acting Chief, RSOS, RSB
Israel Puntnam, Chief, Materials Aquisition Unit, RSB
Bert Starbird, Health Physicist, RSOS, RSB
Diane Case, Health Physicist, RSOS, RSB
Cathy Ribaudo, Health Physicist, RSOS, RSB
Adel Baryoun, Health Physicist, RSOS, RSB
James Reynolds, M.D., Nuclear Medicine, CC
P. Boon Chock, M.D., Radiation Safety Committee

Mark H. Rotman, PharmD, M.S., F.A.S.H.P., Certified Nuclear Pharmacist
Nhat Le, Chemist, Building 21
Chang Paik, Ph.D., Authorized User, Clinical Research, Building 21
Stephen Wank, Ph.D., Authorized User, Research, Building 10
Colleen Lineham, Pre-IRTA, (Stephen Wank's, Ph.D. lab)
David Segal, Ph.D., Senior Investigator, Experimental Immunology Branch
Robert Jensen, Ph.D., Authorized User, Research, Building 10
Wei Hou, Ph.D., Individual User
Sam Mantey, Individual User
Roger Broseus, Executive Secretary, Radiation Safety Committee
Jorge A. Cararasquillo, M.D., Deputy Chief, Nuclear Medicine Department
Millie Whatley, Nuclear Medicine Technologist, Monoclonal Antibody Lab.
John Jacobus, Health Physicist, RSB
Mary Codari, Staff Nurse, 8th Floor, Clinical Center
Keiko Ozato, Authorized User, Building 6

NRC Personnel

William L. Axelson, Deputy Regional Administrator, Region I
Mohamed M. Shanbaky, Ph.D., Chief, Nuclear Materials Safety Branch 1, Region I
Teresa Hall Darden, Senior Health Physicist, Region I
Neelam Bhalla, Health Physicist, Region I
Louis Manning, III, Health Physicist, Region I

Attended Exit Meeting