U. S. NUCLEAR REGULATORY COMMISSION
REGION I

Report Nos. 030-00582/89-001
030-06886/89-001
070-00053/89-001

Docket Nos. 030-00582
030-06886
070-00053

License Nos. 06-00183-03 Priority II Category F1A Program Code 01100
06-00183-06 III E 03510
SNM-52 VI E2 22120

Licensee: Yale University
314 Wright Nuclear Structure Laboratory, West
260 Whitney Avenue
New Haven, Connecticut 06520

Facility Name: Yale University

Inspection At: New Haven, Connecticut

Inspection Conducted: May 30 - June 2, 1989

Inspectors: Laurence F Friedman 6/27/89
Laurence F. Friedman, Ph.D., C.H.P. date
Senior Health Physicist

John T. Jensen 6/27/89
John T. Jensen, Health Physicist date

Approved by: John D. Kinneman 6/27/89
John D. Kinneman, Chief date
Nuclear Materials Safety Section B

Inspection Summary: Routine Safety Inspection Conducted May 30 - June 2, 1989 (Combined Report Nos. 030-00582/89-001, 030-06886/89-001, and 070-00053/89-001)

Areas Inspected: Licensee action on previous violations, licensee event reports, and NRC Notices; organization and scope of program; chronology of exposure event; review of applications for use of licensed material; licensee internal audits; use of materials; training.

8907180086 XA
05-00183-03 PNU

Results: Twelve apparent violations were identified: Extremity exposure above regulatory limits - 178 rems to extremities (Section 4); failure to wear gloves while using radioactive material (Section 4); appropriate instrumentation not available in laboratory (Section 4); failure to perform thyroid monitoring at required frequency (Section 4); eating and drinking in laboratories where radioactive materials were used (Section 7); failure to properly train an individual who used radioactive material (Section 8); authorization to use radioactive material issued without adequate review (Section 5); failure to survey laboratories at required frequencies (Section 6); unauthorized disposal of radioactive material (Section 4); failure to hold radioactive waste for decay in storage for a minimum of 10 half-lives (Section 7); failure to maintain records of waste held for decay in storage (Section 7); failure to maintain records of contamination surveys performed by laboratory personnel (Section 7). One apparent violation of an OSHA requirement was also identified (Section 7).

DETAILS

1. Persons Contacted

*George R. Holeman, M.A., C.H.P., Radiation Safety Officer, (RSO) Director, Radiation Safety Department
*Kenneth W. Price, M.P.H., C.H.P., Deputy Director, Radiation Safety Department
Frederick W. Greenhalgh, Health Physicist, Radiation Safety Department
George Andrews, Chief Technician, Radiation Safety Department
June Tamkin, Health Physicist, Radiation Safety Department
Paul Dinnean, Health Physics Technician, Radiation Safety Department
Len Grabowski, Health Physics Technician, Radiation Safety Department
Laurence A. Cole, Ph.D., Assistant Professor, OB/GYN, Principal Investigator (PI)
*Frank M. Turner, Ph.D., Provost
*Edward A. Adelberg, Ph.D., Deputy Provost for the Biomedical Sciences
*Lawrence Gibbs, Director of University Safety
*Franklin Hutchinson, Ph.D., Director of Undergraduate Studies, Molecular Biophysics & Biochemistry, Chairman, Radiation Safety Comm (RSC)
*William D. Stempel, Esq., Deputy General Counsel, Management Representative on the RSC
*Halvor G. Aaslestad, Assistant Dean for Research and Administration, Medical School
**Individual A

*indicates those present at exit interview
**identity withheld in accordance with 10 CFR 2.790(a)

2. Licensee Action on Previous Violations, Licensee Event Reports, and NRC Notices

(Closed) MLER-RI-89-007, exposure to worker above regulatory limits. The event was investigated in detail during this inspection. See below.

(Closed) Inspection No. 88-001, radioactive waste discarded to normal trash by custodian. Corrective actions reviewed during Inspection No. 88-001. The inspector discussed a memorandum reprimanding the custodian involved in the incident with licensee representatives and observed the training intended for the custodial staff by a Radiation Safety Department staff member. (In addition, see comments in the following paragraph regarding the licensee's audit in this area.)

(Closed) Inspection No. 88-001, incoming package containing radioactive material discarded to normal trash. All Principal Investigators (PI's) were required to submit procedures for maintaining custody of incoming packages to Radiation Safety Office for review and to train personnel in procedures. Procedures submitted by PI's were reviewed by inspectors in Radiation Safety Office files. The licensee also committed to performing an audit of the flow of licensed material through the University. The audit has been performed in small parts, is not yet complete, and the results to date have been reported to the RSC at various meetings.

(Closed) Inspection No. 88-001, failure to post Form NRC-3 in a sufficient number of places. Inspectors observed forms posted so that they could be seen by all persons going to and from licensed activities.

(Open) Inspection No. 87-001, package containing radioactive waste transported between campuses as a Limited Quantity with excessive surface radiation levels. Corrective action not reviewed during this inspection.

(Open) Inspection No. 87-001, item omitted on radioactive waste shipment manifest. Corrective action not reviewed during this inspection.

(Open) Inspection No. 87-001, two instances of observed eating and drinking and three instances of food or drink stored in laboratories where radioactive materials are used. This item was identified during Inspection Nos. 86-001 and 87-001 and has recurred. The licensee stated in a letter dated December 21, 1987, in response to our letter dated November 9, 1987, that an educational program, concerning eating and drinking in laboratories where radioactive materials are used, aimed at the Principal Investigator, would be instituted in January 1988. This educational program, which was intended to introduce new procedures regarding food in laboratories, was not implemented. The new procedures were incorporated in the license effective with its renewal on May 23, 1989.

3. Organization and Scope of Program

The use of radiation and radioactive material at Yale University occurs under an NRC license of broad scope. The Radiation Safety Committee (RSC) reports to the Provost of the University who, in turn, reports to the President. In practice, the Deputy Provost has acted as the contact with the RSC for the Provost. The University's Deputy General Counsel has served as the management representative on the RSC.

The Radiation Safety Department has been reorganized within the past year. The former chain of command was from the Provost to the University Board of Health to the Director, University Health Services to the Director, Division of Occupational and Environmental Health and Safety to the Director, Radiation Safety Department. The Deputy Provost stated that, since the Director, Division of Occupational and Environmental Health and Safety had left the University approximately one year ago, the Directors of the various safety departments had been reporting directly to him.

The present organization is the Radiation Safety Department reports to the Director of University Safety, who reports to the Provost. The Departments of Biosafety and Chemical Safety also report to the Director of University Safety. The present Director of University Safety assumed his duties June 1, 1989. The Director of the Radiation Safety Department is also the Radiation Safety Officer (RSO) for the University, and serves as a member of the Radiation Safety Committee. Since the Radiation Safety Department

obtains its funds and direction from the Director of University Safety, implementation of Radiation Safety Committee recommendations requires his approval and cooperation. The inspectors reviewed a memorandum from the Deputy Provost to the Director of Radiation Safety, dated May 23, 1989, directing him to route all communications through the Director of University Safety, and not to communicate directly with the Deputy Provost without the Director of University Safety's approval.

There are approximately 265 Principal Investigators (PI's) authorized by the RSC to use radioactive materials under the NRC licenses. They have approximately 1000 authorizations (one radionuclide per authorization) and operate in approximately 530 laboratories at the main campus and the Medical School. There is no human use of radioactive material under this license.

4. Chronology of Exposure Event

The licensee reported to Region I by telephone, and subsequently by letter dated May 17, 1989, that Individual A had received an extremity exposure to iodine-125 above regulatory limits, and an internal exposure that might exceed regulatory limits. The licensee discovered that Individual A had a thyroid burden and hand contamination during a routine thyroid count on April 19, 1989. Radiation Safety personnel and the PI involved began an immediate investigation.

From a review of written reports prepared by Dr. Lawrence A. Cole, the PI for whom Individual A works, and members of the Radiation Safety Department, and interviews with these individuals, the inspectors determined that Individual A was working in a cold room on the third floor of the Laboratory for Surgery, Obstetrics and Gynecology (LSOG) building, with a Sephacryl S200 column which separates proteins by molecular weight. To determine the behavior of the protein of interest on the column (i.e., to calibrate the column), Individual A introduced trace quantities of the protein labeled with iodine-125 (0.4-2.0 uCi for each calibration) into the column and assayed the elution fractions with a gamma counter to determine the fraction in which the protein was eluted. Individual A assumed that when no more iodine-125 was detected in the eluate, the column was free of iodine-125. Dr. Cole stated that he later learned that Individual A considered 1000 cpm to indicate "background."

On February 23 and February 28, Individual A calibrated a Sephacryl S200 column with two, different iodine-125-labelled proteins. After the second calibration, the column was washed until the eluate read "background." Appropriate radioactive precautions were used, and all radioactive waste was properly discarded. It appears, in retrospect, that the conclusion that the absence of iodine-125 in the eluate indicated that no iodine-125 remained on the column was erroneous. Dr. Cole stated that he had chided Individual A in a memorandum dated May 30, 1989, and several times during

the preceding six months, for not keeping better records, particularly of how much iodine-125 had been placed on the column, so that a material balance could be done. Individual A attempted to verify that the column was free of iodine-125 by a direct radiation measurement, but recognized that the instrument available in the laboratory was not sufficiently sensitive to iodine-125 radiation. He made no attempt to obtain a more suitable instrument from a neighboring laboratory.

On March 6, Individual A eluted the column with a stronger eluant in order to improve recovery of a particularly "sticky" protein. It appears, in retrospect, that this action caused the radioiodinated protein, which had been used in the calibration of the column and which had been partially retained in the column, to be released. Dr. Cole later determined that a total of 2.6 uCi of iodine-125 had been eluted from the column in this operation. Individual A assumed, however, that the material was "cold," and took none of the usual precautions required when working with radioactive material. Part of the processing of the eluate involved placing 3.5 ml of material in a 4.5 ml test tube, and then vortexing the tube. During vortexing, the top of the test-tube is held between the thumb and forefinger. Vortexing causes splatter, and probably accounts for the skin contamination. Samples of protein from this preparation in a freezer were found to be contaminated with iodine-125, and led to the conclusion that this, and subsequent work with this column, were the source of the hand contamination. Dr. Cole estimated that as much as 0.1 uCi of iodine-125 was discarded in the normal trash. A sample of the protein containing 0.0023 uCi of iodine-125 was sent to a researcher at Columbia University on April 1. The RSO at Columbia University was notified as soon as the presence of the contamination became known.

On March 14 and 15, and again on April 2 and 3, Individual A calibrated the column with iodine-125-labeled proteins, using proper radioactive precautions. In each case, the column was assumed to be free of iodine-125 when no further iodine-125 could be washed off the column.

On April 4, Individual A added a chaotropic agent to improve elution of protein from the presumed "cold" column. No radioactive precautions were used. It was later shown that 1.8 uCi of iodine-125 was eluted from the column in this operation, and the eluate was vortexed in the same manner described above, which probably caused additional hand contamination.

Licensee records show that, during this period, Individual A performed iodinations using 1 mCi of iodine-125 on February 16, March 7, and March 14, and three iodinations using 1 mCi each on March 31. Licensee records also show that Individual A had thyroid counts (bioassays) performed on March 1, March 15, and April 19. The March 1 count showed a thyroid burden of 1.4 nCi. The March 15 assay was invalid because the equipment had been set for the wrong iodine isotope, and no attempt was made to recall Individual A and repeat the assay. The assay on April 19 showed a thyroid burden of 225 nCi, which precipitated the investigation.

The finding that an individual used radioactive material without using disposable gloves is an apparent violation of License Condition 21.

The finding that licensed material was used and an appropriate radiation survey instrument was not available in the laboratory and an inoperable survey instrument was used in a laboratory (see Section 7) are apparent violations of License Condition 21.

The finding that an individual performed iodinations and did not have a thyroid burden measurement 1-2 days after iodinating is an apparent violation of License Condition 21.

The finding that radioactive material was discarded in the normal trash is an apparent violation of 10 CFR 20.301.

In evaluating the dose, internal and extremity, to Individual A, the licensee assumed that all contamination occurred on March 7, and that the release of material from both the skin and thyroid was exponential. Licensee surveys showed that the tips and bearing surfaces of all ten fingers and the ring areas of both ring fingers were contaminated, and that the greatest amount of contamination was on the thumb and middle finger of the left hand. A licensee representative stated that Individual A is right handed, but had stated that he used both hands in holding test tubes while vortexing. The licensee's estimation of the extremity dose is for the middle finger of Individual A's left hand, which has been determined to have received the highest dose.

The licensee followed the decay of the contamination of Individual A's fingers from April 19 for a period of more than 30 days. The effective half life was determined to be 5 days. The integrated dose to the hand, using dose factors that assume considerable penetration of iodine into the basal layer (which is consistent with the presence of iodine-125 in the thyroid) was 178 rems. The inspectors have reviewed the methodology used by the licensee and concur in the licensee's determination. The inspectors made an independent assay of the contamination on Individual A's fingers and thyroid gland with an Eberline LEG-1 probe connected to an Eberline ESP-2 smart portable meter, operated in the scaler mode with pulse height analyzer (one minute count) and agree with the licensee's assay.

The finding that the licensee used licensed material in such a way as to cause an individual to receive a dose to the hands in excess of 18.75 rems in a calendar quarter is an apparent violation of 10 CFR 20.101.

Similar measurements of Individual A's thyroid burden showed an effective half-life of 23 days. While this appears shorter than expected, the literature shows a wide variation in reported effective half-lives for radioiodines. Based on this half-life, the licensee has estimated Individual A's initial thyroid burden on March 7 to be approximately 0.7 uCi. By contrast, inhaling the maximum permissible concentration of iodine-125 for a calendar quarter (the regulatory limit) would produce a thyroid burden of about 0.95 uCi.

The inspectors reviewed the licensee's bioassay methods, including the instrumentation, calibration, and calculations. No problems were identified.

5. Review of Applications for Use of Licensed Material

Under the Type A License of Broad Scope, the Radiation Safety Committee is charged with the responsibility for determining who at the University may use licensed material, which material and how much, in which facilities, under what circumstances, and with what precautions. This function is accomplished by a subcommittee, which reviews applications filed on a form designed for that purpose, determines whether the appropriate criteria are met, negotiates any changes deemed necessary, imposes any requirements needed for safe operation, and then reports its findings to the RSC, which approves the application, and reports the findings in the minutes of the committee. A separate application is submitted for each radionuclide. A Principal Investigator, therefore, may have several authorizations. An authorized user who joined the P approximately one year ago has been performing evaluations of appli ions for new uses of materials as chairman of the subcommittee. e inspectors reviewed approximately 10 of these reviews, and found that the proposed uses of material were described in detail, the reviewer contacted and sometimes visited the applicant to clarify the proposed use of material, and frequently made suggestions as to improved procedures or alternative radionuclides that would provide better safety. The approval process also included a visit to the applicants laboratory by a member of the health physics staff, who wrote a brief memorandum on his findings. Authorizations are approved for a period of three years.

By contrast, renewals of the approximately 1000 current authorizations are based on descriptions of proposed uses that are one to four lines in length, and name rather than describe the proposed use. The form provides only one inch of space for this information. This applies to the original applications for existing authorizations, as well as renewals. The inspectors reviewed approximately 65 authorizations, originals and renewals, from approximately 21 PI's. Of these, the inspectors found no more than five that had more than a cursory description of the proposed use of material. Licensee personnel stated that review of the initial applications for these approvals had included a visit to the laboratory, but no records were made of these visits, and the inspectors could find no records that indicated that the reviewer had actually made a critical assessment of the proposed use. Licensee representatives stated that they had no plans to subject applications for renewal of existing authorizations to the same scrutiny being accorded new applications. The application by Dr. Cole, the PI involved in the event described above, to use iodine-125, was originally filed in September 1986 and renewed in January 1989. The application made no mention of the methods that would be used to handle the radionuclide, only that it would be used for "iodinations" and "immunoassays."

The finding that the licensee's Radiation Safety Committee performed inadequate evaluations of applications for uses of licensed material is an apparent violation of License Condition 21.

6. Licensee Internal Audits

Licensee procedures require that each laboratory authorized to use radioactive material under the University license be surveyed by a member of the Radiation Safety staff at three-month intervals. The results of the surveys are reported to the Radiation Safety Committee during its quarterly meetings. The minutes of the meetings also show a tabulation of the number of laboratories and the number of PI's who were visited during the quarter. Licensee representatives estimated that there were approximately 530 laboratories to be surveyed, and 265 PI's. The inspectors observed the following in the minutes of the RSC:

Period	No. of Labs Surveyed	No. of PI's Surveyed
Apr-Jun 88	484	213
Jul-Sep 88	311	139
Oct-Dec 88	452	199

It is clear from these data that the required number of surveys was not being performed in each quarter. Licensee representatives estimated that the survey frequency was approximately every four months. The inspectors could find no evidence in the minutes of the RSC meetings that the RSC had taken note of the deficiency in the survey program, or made any attempt to correct the situation.

The finding that surveys were being performed by the Health Physics Staff at intervals greater than three months is an apparent violation of License Condition 21.

Three individuals from the Health Physics staff are assigned to perform laboratory surveys. One devotes 1.0 Full Time Equivalent (FTE) to surveys (1990 person-hours per year per FTE), one devotes 0.5 FTE to surveys, and one devotes 0.25 FTE, for a total of 1.75 FTE's allocated to laboratory radiation safety surveys. The inspectors accompanied each of the surveyors, and observed them performing surveys, in order to evaluate the quality of the surveillance of the licensed program by the Radiation Safety Department.

The individual who devoted 0.25 FTE to surveys appeared knowledgeable in health physics, and was well prepared for the surveys. The individual selected appropriate instrumentation (a "pancake" G-M and a thin-crystal scintillation probe) and spent a significant amount of time interviewing the laboratory workers and the PI. The contamination survey was thorough, and the surveyor dealt effectively with problems encountered, such as contamination on laboratory equipment. The surveyor reviewed records of contamination surveys by the laboratory staff.

During the survey, the inspector noted a hole in the floor which had been overlooked by the surveyor. The inspector observed that the hole provided a path for radioactive material to run into the spaces beneath the floor in the event of a spill and should have been identified as part of the survey. The PI stated that the hole was also a physical hazard, since it was large enough for the caster of a stool to drop into. The PI stated that he had notified maintenance several times with no result.

The individual who spent full time doing surveys (1.0 FTE) stated that he had no previous training in health physics or any of the physical sciences (B.A. in History, M.S. in Education, M.A.'s in economics, etc.) When interviewed by the inspector, this individual appeared to have little or no understanding of the properties of the radionuclides or radiation for which he was surveying, nor the function and capabilities of the instrument he was using. He stated that he did not select instrumentation for his surveys, but used the instrument he was instructed to use, a "pancake" G-M tube. He was observed using this probe to survey for iodine-125 contamination, and stated he was not aware that the probe was not sufficiently sensitive to detect iodine-125 contamination.

The individual was observed to do a very thorough contamination survey, both with the instrument and wipes. He did not, however, interview any of the personnel in the laboratory, was not aware of whether there were any new workers in the area who might not have been through the required health physics training, observed but did not comment on or address an empty cigarette pack in the waste can in one of the laboratories, and did not discuss his findings with the PI. He also was unaware of whether the laboratory workers did their own contamination surveys, and did not review records of contamination surveys done by laboratory workers, if any were performed and documented.

The individual who devoted 0.5 FTE to surveys performed a thorough laboratory contamination survey and dealt effectively with problems encountered, such as equipment contamination and evidence of food consumption. He did, however, also use a "pancake" G-M tube instead of a scintillation detector in laboratories where low-levels of iodine-125 were used. The Deputy Director of the Radiation Safety Department agreed that the G-M tube has an minimum detectable activity of approximately 1.5E5 dpm for iodine-125 and stated that the G-M tube was chosen for laboratory surveys because its ability to detect more types of radiation would expedite the survey.

The inspectors reviewed the reports of laboratory surveys performed by the Radiation Safety Department staff. The reports include a diagram of the laboratory on which the staff indicates areas of contamination. The reports also contain a check list of items of compliance with University safety regulations (i.e., posting, labelling of equipment, etc.). The inspectors noted that on nine survey reports radioactive material was identified in

the normal waste. The RSO meets weekly with the radiation survey technicians and discusses the results of the laboratory surveys. At this meeting, they submit summary reports of their findings which indicate the laboratories where radioactive contamination was identified. The summary reports do not include the unauthorized disposal findings. The RSO indicated that, while the disposal is immediately rectified in the laboratory, the non-compliance is not documented in an easily retrievable form.

7. Use of Materials

The inspectors toured approximately 10 laboratories, including three iodination facilities located within Principal Investigators' laboratories as well as the iodination facility operated by the Radiation Safety Department. There are 10 dedicated iodination facilities for use by the University staff; the majority are glove box units (with gloves) which are exhausted to a nearby fume hood. All iodination hoods are exhausted through charcoal filters. Records of air sampling in the effluent and in the breathing zone indicated that concentrations of iodine-125 are well below permissible limits. Personnel who perform iodinations are required to have their thyroids monitored at the Radiation Safety Department laboratory on the Wednesday morning following the iodination. The responsibility for reporting for the bioassay is left to the individual, and the Radiation Safety staff does not verify compliance.

The inspectors observed an individual eat a piece of cake in Room 409 of Lauder Hall where 10 millicuries of hydrogen-3 were used per month and an individual drink from a paper cup in Room 515 of the J. W. Gibbs (JWG) building where 200 microcuries of hydrogen-3 were used per week. In addition, the inspectors observed partially filled containers of beverages, potato chips on a plate, an apple, and chicken remains in a waste container in four laboratories where millicurie amounts of iodine-125 and millicurie amounts of phosphorus-32 were present. Some laboratory personnel indicated that they were not familiar with the University's policy on the prohibition of eating and drinking in laboratories where radioactive materials are used. Others indicated that the lack of designated areas for eating and drinking forced them to use their laboratories.

The finding that laboratory personnel consumed food and beverages in laboratories where radioactive materials were present is an apparent violation of License Condition 21.

Laboratory personnel indicated that they perform radioactive contamination surveys frequently when they work with radioactive material. The inspectors surveyed the area around a sink in Room 510 of the Tompkins East building and measured approximately 200,000 disintegrations per minute of phosphorus-32 contamination on a lead vial shield. A laboratory technician indicated that she had surveyed the area after she had made radioactive waste disposals in the sink and that she did not maintain

records of these surveys. She also indicated that personnel from nearby laboratories used the sink for radioactive waste disposals. In nine out of the ten laboratories visited by the inspectors, laboratory personnel indicated that they do not maintain records of contamination surveys.

The finding that records of radioactive contamination surveys were not maintained by laboratory personnel is an apparent violation of License Condition 21.

The inspectors observed, in Room 412 of the Brady Memorial Laboratory building, where millicurie amounts of phosphorus-32 were used, that the response of a G-M survey instrument used by laboratory personnel was intermittent and the efficiency was much lower than the "pancake" G-M tube used by the Radiation Safety Department staff. An individual in the laboratory indicated that he had thought there was a "problem" with the instrument but continued to use it. This is an additional example of an apparent violation (see Section 4) of not having an appropriate instrument available for laboratory surveys.

A laboratory technician, who used radioactive materials in Room 505 of the Laboratory of Clinical Investigation building, stated that he treated a few mice each month with approximately one millicurie of phosphorus-32 and stored their carcasses to allow for decay of the phosphorus-32 prior to disposing them as non-radioactive waste. He surveyed the carcasses, after storing them for about seven phosphorus-32 half-lives, to assure that their radiation levels were not distinguishable from background. He stated that he did not maintain records of these disposals.

The finding that radioactive waste, with a half-life of less than 65 days, was not held for decay for a minimum of 10 half-lives and that records of these disposals were not maintained are apparent violations of License Conditions 19 and 21, respectively.

In Room 210 of the Sterling Hall of Medicine and Room 300 of the LSOG building, compressed gas cylinders were observed in areas where they might have been knocked over, and which were unsupported.

The observation that compressed gas cylinders were stored or in use and not secured from being knocked over is not in conformance with 29 CFR 1910.101(b). Licensee management was informed of this matter.

8. Training

Most of the laboratory personnel interviewed indicated they had attended the Radiation Safety Seminar presented by the Radiation Safety Department and received additional training through the Principal Investigator under whom they work. An individual who used 200 microcuries of hydrogen-3 per week in animal studies in Room 515 of the JWG building since March 23, 1989, stated that she had not attended the Radiation Safety Seminar. She

also stated that she had not been trained, and did not know how, to perform radioactive contamination surveys. The inspectors observed the individual drink from a paper cup and observed two bottles of soda stored on a laboratory bench. She stated that she often drank in the laboratory and was not aware of the University's prohibition of eating and drinking in laboratories where radioactive materials are present.

The finding that an individual who used radioactive material was not trained in radioactive contamination survey techniques or in the prohibition of eating and drinking in laboratories where radioactive materials are used is an apparent violation of License Condition 21.

9. Exit Interview

The inspectors discussed the results of the inspection with the individuals indicated in Section 1. The inspector stated that there appear to be weaknesses in the management control of the University's licensed program which had contributed to the reported exposure to radiation of an individual above regulatory limits. He stressed that the license was issued to the University, which had a corporate responsibility for the safe operation of the licensed program. He stated that the root causes of the exposure event appeared to be the failure of the University to perform an adequate review of the proposed use of licensed material before that use was authorized, the failure of the University to detect the violation of and enforce its own requirement that an appropriate survey instrument be present in the laboratory where the event occurred, and the use by the University of surveyors who were not qualified to judge the appropriateness of the instrumentation in use in the laboratories.

ENFORCEMENT CONFERENCE WITH YALE UNIVERSITY

PROPOSED AGENDA

I. Welcome

II. Purpose of Enforcement Conference

III. Opening Remarks by Licensee (if desired)

IV. Problems/Violations associated with exposure event

A. Extremity exposure beyond regulatory limits (Section 4)***
B. Inadequate review of applications for authorization (Section 5)*
C. Appropriate instrumentation not available (Section 4)
D. Thyroid monitoring not performed at required frequency (Section 4)
E. Laboratory surveyor not qualified (Section 6)**
F. Gloves not worn while working with licensed material (Section 4)
G. Unauthorized disposal of licensed material (Section 4)

V. Problems/Violations which indicate programmatic weaknesses

A. Inadequate review of applications for authorization (Section 5)*
B. Laboratory surveyor not properly trained (Section 6)* **
C. Laboratory surveys not performed at required frequency (Section 6)
D. Survey frequency reported to RSC, no action (Section 6)**
E. Weaknesses in tracking system and follow-up for bioassays, training, etc. (Section 4)**
F. Content of surveys, training of surveyors inadequate (Section 6)**
G. Food and drink in areas of licensed material use (Section 7) (third occurrence in last four inspections)

VI. Other violations

A. Licensed waste not held 10 half lives for decay (Section 7)
B. Records of disposal of decayed waste not maintained (Section 7)

*listed twice on purpose
**not a violation
***report section where item is described

VII. Response/Discussion by License

VIII. NRC Summary

IX. Enforcement Options, Policies and Procedures

X. Close