

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Report Nos. 030-01786/96-002
030-08478/96-001
030-17872/96-001

Docket Nos. 030-01786
030-08478
030-17872

License Nos. 19-00296-10
19-00296-17
19-00296-20

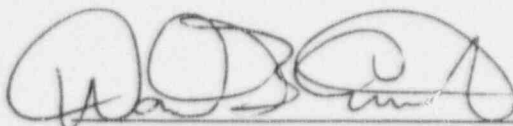
Licensee: Department of Health and Human Services
National Institutes of Health
31 Center Drive, MSC 2260
Bethesda, Maryland 20892-2260

Facility Name: National Institutes of Health

Inspection At: Bethesda, Rockville, and Baltimore, Maryland

Inspection Conducted: September 16-20, 1996

Inspectors:



David B. Everhart, Health Physicist


December 18, 1996
Date



James P. Dwyer, Sr. Health Physicist

December 10, 1996
Date

Approved By:


Mohamed M. Shanbaky, Ph.D., Chief
Nuclear Materials Safety Branch 1

12/18/96
Date

Inspection Summary:

Routine, unannounced inspection conducted on September 16-20, 1996, which focused on the licensee's program for securing and controlling licensed radioactive materials. The inspection also followed up on the licensee's actions taken in response to: Confirmatory Action Letter (CAL) 1-95-011 (Revision 1) issued July 21, 1995; CAL 1-95-018 issued October 27, 1995; Supplement 1 of CAL 1-95-018 issued November 8, 1995; Supplement 2 of CAL 1-95-018 issued December 1, 1995; and Supplement 3 of CAL 1-95-018 issued June 7, 1996.

Areas Inspected:

Oversight of the licensed program; licensee's actions in response to CAL 1-95-011 (Rev. 1); licensee's actions in response to CAL 1-95-018 and its Supplements; security and control of licensed radioactive materials; and self-shielded and panoramic irradiators

Results:

Two apparent violations were identified: failure to secure, from unauthorized removal or access, licensed materials that are stored in controlled or unrestricted areas (Section VI); and failure to follow procedures for safely opening packages containing radioactive material (Section VI).

DETAILS

I. Persons Contacted

- * Michael M. Gottesman, M.D., Deputy Director for Intramural Research
- Richard Wyatt, M.D., Assistant Director for Intramural Affairs
- * Lance Liotta, M.D., Chairman, Radiation Safety Committee
- * P. Boon Chock, M.D., Radiation Safety Committee
- * Robert Lanman, Legal Advisor
- * Robert W. McKinney, Director, Division of Safety
- * Donald M. Ralbovsky, Office of Communications, Office of the Director
- * Robert A. Zoon, Chief, Radiation Safety Branch (RSB) and
Radiation Safety Officer (RSO)
- Shawn Googins, Chief, Technical Services Section (TSS), RSB and
Deputy RSO
- * Sean Austin, Chief, Radioactive Materials Control Section (RMCS), RSB
- * Nancy Newman, Chief, Radiation Safety Operations Section (RSOS), RSB
- * Kelly Austin, Assistant Chief, RSOS, RSB
- * Roger Broseus, Ph.D., Assistant to the Chief, RSB
- * Bruce Smith, Assistant to the Chief, RSB
- * Israel Putnam, Chief, Radioactive Materials Supply Officer, RMCS, RSB
- * Michael Noska, Health Physicist, TSS, RSB
- * Ivan Wallace, Health Physicist, RSOS, RSB
- Cathy Ribaudo, Health Physicist, RSOS, RSB
- * Virginia Sheldon, Health Physicist, RSOS, RSB
- Beth Reed, Health Physicist, RSOS, RSB
- * Katharine McLellan, Health Physicist, RSOS, RSB
- * Ram Subbaratnam, Health Physicist, RMCS, RSB
- * Diane Case, Health Physicist, RSOS, RSB
- George Redmond, Health Physicist, RSOS, RSB
- * Christine Enders, Health Physicist, TSS, RSB
- * John Jacobus, Health Physicist, RSOS, RSB
- * Douglas Carter, Health Physicist, TSS, RSB
- * Anita McGill, Computer Assistant, RSB
- * Jorge Carrasquillo, M.D., Nuclear Medicine Department
- * Mark Rotman, Radiopharmacist, Nuclear Medicine Department
- * Richard Fejka, Radiopharmacist, Nuclear Medicine Department
- * Ray Johnson, Contractor
- Ken Fiester, Contractor
- Linda Fossman, Researcher
- Dr. Skolnick, Researcher
- Dr. Strako, Researcher
- Dr. Oka, Researcher

The inspectors contacted additional research and contractor staff.

- * Attended Exit Meeting on September 20, 1996

II. Scope of the Inspection

The National Institutes of Health (NIH) currently operates under three NRC licenses. License No. 19-00296-10 is a broad scope license authorizing the possession and use of byproduct material in biomedical research, diagnostic nuclear medicine, brachytherapy, and radiopharmaceutical therapy at facilities located in Bethesda, Rockville, Baltimore and Poolesville, Maryland. License No. 19-00296-17 is a limited scope license authorizing the possession and use of cesium-137 sealed sources in self-contained irradiators for the irradiation of biological specimens and blood at facilities located in Bethesda and Rockville, Maryland. License No. 19-00296-20 is a limited scope license authorizing the possession and use of cobalt-60 sealed sources in both panoramic and self-contained irradiators for the irradiation of cell cultures and small animals at the Clinical Center (Building 10), located in Bethesda, Maryland.

The September 16-20, 1996 inspection examined activities conducted under all three licenses. While several elements of the licensee's program were inspected, the inspection focus was on the security and control of radioactive materials. To this end, the inspectors: (1) conducted interviews with RSB management and staff, RSB contractors, research staff and ancillary personnel; (2) observed the conduct of, and performed an independent assessment of, licensed activities on the Bethesda Campus in Buildings 21, 10, 6, 4, 8, 8A, 36, 37, and 49, in Rockville at the Key West Center, Park 5, and Twinbrook Buildings, and in Baltimore at the Gerontology Research Center; and (3) reviewed records pertinent to the management and operation of the licensed program.

III. Oversight of the Licensed Program

The NIH Radiation Safety Committee (RSC) is responsible for oversight of the licensed program. While regulations require quarterly meetings of the RSC, NIH normally holds a RSC meeting each month. The inspector reviewed the minutes of fourteen RSC meetings conducted between July 20, 1995 and June 27, 1996. The inspector noted that the meetings were well attended and generated significant discussion. Much of the early discussion dealt with an incident, first discovered on June 29, 1995, where a pregnant researcher and 26 other researchers were internally contaminated with phosphorus-32. Later discussion supported the development of policies and actions in response to NRC findings that the licensee's program failed to provide adequate security of licensed radioactive materials.

The RSC also spent considerable time reviewing requests for the use of radiation and radioactive material in research with human subjects. The inspector noted that many of the research protocols called for the use of radiation and radioactive materials not regulated by NRC. All of the protocols reviewed by the inspector which called for the use of NRC-regulated materials involved the addition of transmission scans to previously approved protocols. The licensee stated that a transmission scan is performed to improve the quality of diagnostic images and that adding the transmission scan to a diagnostic nuclear medicine study increased the radiation exposure to the research subject by approximately 25 millirem per scan.

and 50 millirem total. The inspector noted that each protocol review performed by the RSC included consideration of the informed consent form. In one case, the RSC stipulated that the consent form be revised because of a concern that the wording was too persuasive.

The inspector reviewed reports of incidents involving radioactive materials which occurred in the licensee's facilities between January 1995 and August 1996. The inspector noted that most of the reports were written following minor personnel and facility contamination events and concluded that the licensee followed up on each event promptly and adequately, and that no hazard resulted to personnel. The inspector did not review documentation related to the licensee's response to the June/July 1995 incident involving the internal contamination of a pregnant researcher and 26 additional researchers with phosphorus-32 as the review of this incident was previously performed by a NRC Augmented Inspection Team (AIT). The findings of the AIT inspection were documented in a redacted inspection report released January 29, 1996.

The Radiation Safety Branch (RSB) staff is supplemented by contractor personnel. Contractor personnel perform several functions including radioactive material package receipt and delivery, laboratory surveys, waste pickup, and waste handling. The inspector interviewed several of the contractors who performed laboratory surveys. The contractors appeared to be very knowledgeable of regulatory requirements and the requirements of the NIH licensed program. The contractors stated that they worked with individual researchers present in a laboratory to correct problems identified during a survey and that they referred all of their survey findings to RSB managers for disposition. The inspector noted that RSB managers, in turn, provided the contractor's findings to the health physicist responsible for the particular building or area where the finding was identified and determined that area health physicists followed up on identified problems promptly.

The inspector concluded that the licensee provides adequate oversight of the licensed program.

IV. Licensee's Actions in Response to CAL 1-95-011 (Rev. 1)

CAL 1-95-011 was issued by the NRC on July 21, 1995, to confirm the licensee's actions, taken or planned, following the identification of phosphorus-32 contamination in a water cooler located on the 5th floor of Building 37 and the internal contamination, with this isotope, of several researchers who worked in this area. Revision 1 of CAL 1-95-011 was issued later that same day which refined the licensee's commitments.

CAL 1-95-011 (Rev. 1) confirmed that the licensee would:

- (1) **Complete the radiological survey of all areas of Building 37 by July 24, 1995.**

This action was monitored by the NRC Augmented Inspection Team (AIT). The licensee confirmed in a letter dated August 11, 1995, that the radiological survey was completed on July 24, 1995, and reported that no unusual or abnormal results were discovered.

The inspector determined that the licensee completed this action, as described, within the established time frame. This action is closed.

- (2) **Obtain urine samples from all available and willing individuals in Building 37 and complete the analysis of each sample by July 28, 1995.**

This action was monitored by the AIT. The licensee confirmed in a letter dated August 11, 1995, that all available and willing individuals were screened for radioactivity in urine by July 28, 1995, and reported that no additional persons were found to have internal contamination.

The inspector determined that the licensee completed these actions, as described, within the established time frame. This action is closed.

- (3) **Develop by July 21, 1995, and implement a statistically valid plan to collect and analyze urine samples from other NIH staff.**

This action was initially monitored by the AIT. The licensee stated in a letter dated August 11, 1995, that a proposed plan for random screening was in place by July 21, 1995, but that modifications of the plan were made to add some additional survey areas. The finalized plan was approved by the RSO on August 3, 1995. The licensee stated that the implementation of random screening began on July 30, 1995, in accordance with the proposed plan, and completion in accordance with the final plan was expected by August 15, 1995. The licensee reported that as of August 11, 1995, no additional personnel with internal contamination were identified.

In a letter dated August 24, 1995, NRC requested that the licensee describe the plan for collecting and analyzing urine samples from other NIH staff and provide NRC with the results of this action.

By letter dated August 30, 1995, the licensee provided a description of their plan for collecting and analyzing urine samples from other NIH staff and the results of the sampling. The plan, dated August 3, 1995, called for the random sampling of 10 percent of the staff on each floor of buildings that contained water coolers. Staff from Buildings 30, 29, 3, 7, 41, 21, and 10 were sampled. The licensee's plan required additional screening only if the initial screening identified an unexpected intake of radioactive material. The

licensee reported that none of the personnel screened were found to have detectable quantities of radioactive material in their urine.

The inspector determined that the licensee completed these actions, as described, within the established time frame. This action is closed.

- (4) **Develop and begin implementation of an augmented continuing radiological survey program (ACRSP) for the NIH campus by July 28, 1995. The program will include a survey of all publicly accessible water coolers and food storage areas in laboratory buildings. The program will also include notification of all NIH staff that any other water coolers or food storage areas will be surveyed upon request.**

By letter dated August 11, 1995, the licensee reported that the proposed plan for augmented radiological surveys of publicly accessible food storage areas and water coolers in laboratory buildings was approved by the RSO on July 27, 1995. The licensee stated that the final plan was approved on August 2 and implementation of the survey program began on August 7, 1995. The licensee reported that as of August 11, 1995, these surveys and all previous surveys of bottled water coolers had not indicated any radioactive contamination.

In a letter dated August 24, 1995, NRC requested that the licensee describe the ACRSP and provide the results of this action. NRC also requested that the licensee explain: (1) why implementation of the ACRSP was delayed until August 7, 1995, when CAL 1-95-011 stipulated that implementation would begin by July 28, 1995; and (2) why they failed to notify NRC in advance of this change and propose a revised schedule as required.

By letter dated August 30, 1995, the licensee provided a copy of their ACRSP which was approved by the RSO on July 27, 1995, and a copy of Revision 1 of the ACRSP which was approved by the RSO on August 2, 1995. The revised ACRSP required that:

- All publicly available water coolers and communal food storage areas, with the exception of those in cafeterias, snack shops, and patient care areas, in laboratory buildings on the NIH campus be identified beginning on July 28 and completed by August 4, 1995.
- After identification, each of these water coolers and food storage areas be monitored for contamination using a hand held survey meter and one or more smears.
- Initially, water coolers and food storage areas be monitored at least quarterly with a provision to adjust the monitoring frequency as appropriate, based on survey results.

- New public water coolers and food storage areas be added to the program as they are identified.
- Upon request to the RSB, additional water coolers and food storage areas, even those that are not publicly accessible, be monitored for contamination.
- Contamination above 220 disintegrations per minute/100 square centimeters (DPM/100cm²) found in food storage areas be brought to the attention of the RSO for appropriate followup.
- Contamination above 220 DPM/100cm² identified on a water cooler be brought to the attention of the RSO and required immediate follow up to obtain a water sample.

The ACRSP described publicly accessible water coolers and food storage locations as those which are typically not secured when unattended and are not located in a secure building. The licensee stated that they considered Buildings 14, 21, 28, and 49 to be secured and that Building 37 was also considered secured because it no longer had unsecured food storage areas and publicly accessible water coolers. The licensee also clarified that implementation of the ACRSP began on July 28, 1995 as committed to in CAL 1-95-011.

By letter dated September 20, 1995, NRC requested that the licensee confirm NRC's understanding that the survey program did not extend to cafeterias and snack shops because of the control exercised over food storage and water coolers in these areas by trained food service workers. NRC also requested that the licensee describe the security provisions of Buildings 14, 21, 28, and 49 that allowed them to be excluded from the program.

By letter dated September 29, 1995, the licensee confirmed that NIH cafeterias are operated with kitchens that are secured at all times and only accessible to authorized skilled food service employees of the food service contractor. The licensee stated that food in preparation by those employees is under their scrutiny throughout service time and cafeterias are locked at closing time and that these controls also applied to snack shops. The licensee stated that Buildings 14, 21, 28, and 49 were considered to be secured because access is only possible through use of card keys and that access by card key is recorded by a centralized computer. The licensee added that Building 49 is also manned by a security guard.

During an interview conducted on September 19, 1996, the RSO and Radiation Safety Operations Section (RSOS) Chief told the inspector that the quarterly surveys described in the revised ACRSP were performed through the summer but that they recently changed to semiannual surveys based on the fact that the ACRSP never identified contamination in the areas

surveyed. The RSO stated that the licensee would more than likely discontinue these surveys when CAL 1-95-011 is closed. The RSO and RSOS Chief also confirmed that, in response to a few early requests, they surveyed areas which were not included in the original program. The RSO and RSOS Chief also informed the inspector that the survey program was never expanded to include the buildings which were considered to be secured.

The inspector determined that the licensee completed these actions, as described, within the established time frame. This action is closed.

- (5) **Assist the safety committee for Building 37 to develop and implement plans for security of the food storage and preparation areas. These plans will be complete and in place by July 28, 1995.**

By letter dated August 11, 1995, the licensee reported that Building 37 food storage areas were consolidated and refrigerators in such areas were fitted with locking mechanisms by July 27, 1995.

The inspector inspected several of these areas on September 17, 1996 and determined that the licensee completed these actions, as described, within the established time frame. This action is closed.

- (6) **At a meeting of the RSC on July 20, 1995, the Enhanced Interim Security Policy (EISP) submitted on May 18, 1994, by Richard G. Wyatt, Assistant Director for Intramural Affairs, and revised on September 13, 1994, as submitted by Ted Fowler, Acting Radiation Safety Officer, was made a permanent policy effective August 1, 1995, and will include an enforcement policy that specifies that breaches of security by researchers will result in mandatory suspension of privileges to use licensed materials.**

The EISP, in part, required:

- Any radioactive material in use in a laboratory must be attended or secured by locking the room when not attended;
- Radioactive materials in storage, i.e. not being used, must be secured in accordance with the current conditions of the NRC license. These are:
 - Containers of radioactive material which exceed the activity quantities of Appendix C of 10 CFR Part 20 must be in locked storage;
 - Containers of radioactive material which are less than or equal to the Appendix C quantity may be stored without locking.

- Persons unknown to the occupants of an area where radioactive materials are used or stored shall not be permitted into the area without being requested for identification and admitted only if a legitimate reason for entry is provided.

The EISP specified, in part, the following exceptions:

- Buildings or areas within buildings which have access controlled by card key or by use of security guards are not subject to the above room locking requirements.
- Radioactive waste must be collected and stored in a properly posted restricted area until pickup. Unoccupied laboratories will not be required to be locked due to the presence of only radioactive waste.

By letter dated August 11, 1995, the licensee reported that the permanent security policy approved by the RSC and its enforcement stipulations were communicated to the NIH community by memorandum dated July 21, 1995. The licensee also reported that the enforcement provisions were implemented by the RSO effective August 1, 1995.

A review by the inspector of records of enforcement actions indicated that violations of the licensee's security policy were identified during routine contractor audits and routine health physicist visits to laboratory areas and that, between implementation of the enforcement policy on August 1 and October 27, 1995 when CAL 1-95-018 was issued (see Section 5), apparent violations of the licensee's security policy were identified on 46 occasions. Six of these apparent violations were identified by a NRC Special Inspection Team on October 23, 1995. The inspector determined that on 44 out of 46 occasions, the authorized user was suspended. On two occasions, the RSO evaluated the circumstances and concluded that a violation of the NIH security policy did not occur. Therefore, the RSO elected to only issue a warning to the researchers. The two cases involved the following:

- One suspension was not imposed because the material, 250 microcuries of phosphorus-32, was located in a room within a cold room inside of an office area. The RSO concluded that there were many barriers to secure this material. The RSO also stated that NIH policy for storage of radioactive materials in cold rooms was under development at that time and that this was recognized by NRC as late as November 8, 1995, when Supplement 1 of CAL 1-95-018 was issued confirming that the licensee would submit a plan for securing posted cold rooms and photographic dark rooms to NRC by December 6, 1995.
- A second case involved 250 microcuries of carbon-14, 800 microcuries of sulfur-35, and approximately 100 microcuries of phosphorus-32. The authorized user was not suspended on this

occasion because he was present in the adjacent laboratory for less than 5 minutes and did not see the health physicist enter his laboratory. The authorized user also returned to the laboratory before the health physicist left the laboratory. The RSO believed that these materials were adequately attended. The inspector noted that during the NRC inspection conducted in October 1995, the Special Inspection Team identified that there was a common understanding at that time among research personnel that the security policy required materials to be locked when unattended at night or during an individual's extended absence from the laboratory; however, locking was not necessarily required during absences of short duration. The inspector noted that in response to this finding, on October 25, 1995, the licensee issued a memorandum to all users of radioactive materials clarifying that doors needed to be locked when you step out of the laboratory for "even a few seconds".

The EISP required "that any radioactive material in use in a laboratory must be attended or secured by locking the room when not attended". The inspector recognizes that, at that time, a written policy for securing posted cold rooms had not been developed and that the licensee's staff had a common misunderstanding that materials need not be locked during absences of short duration. Item 6 of CAL 1-95-011 (Revision 1) specified that breaches of security by researchers would result in mandatory suspension of privileges to use licensed materials. The inspector determined that the licensee complied with their commitment to suspend privileges to use license materials for breaches of security based on the written EISP and as understood by the licensee's staff.

The inspector determined that the licensee completed these actions, as described, within the established time frame. CAL 1-95-011 (Revision 1) is closed.

V. Licensee's Actions in Response to CAL 1-95-018 and Its Supplements

CAL 1-95-018 was issued by the NRC on October 27, 1995, to confirm the licensee's actions, taken or planned, following the identification, by a NRC Special Inspection Team, of continuing problems with the licensee's program for security of radioactive materials. On October 23, 1995, the Special Inspection Team identified several laboratories containing unsecured radioactive materials.

CAL 1-95-018 confirmed the following commitments of the licensee:

- (1) On October 25, 1995, a desk-to-desk memorandum was issued under the Deputy Director for Intramural Research's (DDIR) signature to all users of radioactive material reminding them of the NIH policy for security of radioactive materials and the penalties for failure to comply with this policy. The memorandum was distributed to the Scientific Directors on October 25 and hand carried to all available radioactive material users on October 26,

1995. In addition, the DDIR personally contacted all available Scientific Directors to discuss the importance of compliance with the security policy.

The licensee provided a copy of the October 25 memorandum to NRC via facsimile transmission on October 26, 1995. The inspector confirmed that the licensee completed the actions, as described, within the established time frame. This action is closed.

- (2) On October 26 and 27, 1995, RSB staff performed a complete security sweep of radioactive material use areas on the Bethesda campus and Rockville facilities. Suspension orders for security violations identified during this sweep are in process and will be completed by October 30, 1995.

The inspector confirmed that during the October 26-27 security sweep of all radioactive material use areas on the Bethesda campus and Rockville facilities, the licensee identified 31 security violations. Six of the authorized users were suspended on October 26th and 25 authorized users were suspended on October 27, 1995. The inspector determined that the licensee completed the actions, as described, within the established time frame. This action is closed.

- (3) On October 26, the NIH RSC met and unanimously adopted a new security policy which requires the following:

- Any unattended radioactive material is required to be secured by locking;
- Any laboratory module or room posted for radionuclide use must be locked when not occupied;
- Within 60 days, radioactive material storage in corridors will no longer be permitted; and
- Liquid scintillation counters and gamma counters will be permitted in the corridors in accordance with the current NIH corridor policy.

This policy extends to all radioactive material use areas, including the buildings previously identified as being exempt because of provisions for security at the building entrances.

Supplement 1 of CAL 1-95-018, issued November 8, 1995, described the licensee's commitment to submit a plan for securing posted cold rooms and posted photographic dark rooms to NRC by December 6, 1995.

Supplement 2 of CAL 1-95-018, issued December 1, 1995, confirmed the revision of Item 3, bullet 2, of CAL 1-95-018 such that any posted room or area which contains radioactive materials in use, radioactive waste, or radioactive materials in unsecured storage shall be locked when unoccupied.

This revision recognized that rooms need not be locked when unoccupied simply because they are posted. If the posted room does not contain unsecured radioactive materials, it need not be locked or occupied. Supplement 2 of CAL 1-95-018 also documented NRC's understanding that, by January 31, 1996, the licensee would submit an amendment request to NRC to incorporate written procedures for the implementation of the security plan proposed in CAL 1-95-018.

In a letter dated December 13, 1995, the licensee requested an extension, until December 20, 1995, for submission of a plan for securing posted cold rooms and other types of rooms in which radioactivity is temporarily used, such as photographic dark rooms. This request was granted verbally by NRC Regional management on December 13, 1995.

A letter dated January 5, 1996, reiterated NRC's understanding that, by January 31, 1996, the licensee would submit an amendment request to incorporate a security policy into the license. The licensee submitted the amendment request by letter dated January 19, 1996. The proposed security policy would establish that:

- (1) Licensed materials in physical forms and quantities which could be misappropriated for purposes other than their intended use or which, if inadvertently encountered, would pose a safety concern, shall be secured from unauthorized access.
- (2) Security of the licensed materials defined by Item 1 shall be accomplished by direct oversight by a trained user, by placing the materials in a secured storage unit, by securing the room in which the materials are used when the room is unoccupied, or by securing a group of rooms by a perimeter security system.
- (3) Licensed materials which are exempt from the labeling requirements of 10 CFR 20.1905 shall be exempt from the above requirements.
- (4) The RSC may designate certain quantities of licensed materials as exempt from the requirements of Item 1 above, based on the inherent safety of the physical form into which the licensed materials are incorporated.

NRC Region I has not completed the review of this amendment request.

In a letter dated April 9, 1996, the licensee advised NRC that on November 30, 1995, the RSC revised the security policy (Item 3, bullet 3) to allow the continued storage of radioactive materials in corridor refrigerators and freezers as long as the quantities per container did not exceed those of Appendix C of 10 CFR Part 20.

During telephone discussions with the licensee's management, NRC expressed concern that the licensee had revised a commitment described in CAL 1-95-018 without first obtaining the consent of NRC.

By letter dated April 19, 1996, the licensee clarified that the November 30 revision of the security policy allowed the storage of less than Appendix C quantities of radioactive materials in corridor refrigerators and freezers only when the refrigerator or freezer was locked. The licensee stated that while the RSC approved of this policy revision on November 30, 1995, it was not implemented due to the U.S. Government furlough and the fact that a new security policy was proposed in a license amendment request dated January 19, 1996, which would make the November 30 revision moot. The licensee stated that the RSC reaffirmed the November 30, 1995, revision to the security policy on March 28, 1996, but propagation of this policy was delayed pending NRC review and approval. The licensee requested that NRC approve of this request to modify CAL 1-95-018.

In a letter dated April 25, 1996, NRC stated that the licensee's request to modify CAL 1-95-018 was tied to the review of the licensee's January 19, 1996, amendment request and that review of that amendment was not yet completed.

In a letter dated May 9, 1996, the licensee requested modification of CAL 1-95-018 to permit film exposure within locked low temperature freezers in laboratory building corridors. Film exposure is accomplished within film cassettes through the use of small quantities of licensed radioactive material. The licensee stated that the authorized users would retain control over keys or that other security measures would be used to ensure the security of the radioactive material in the film cassettes within the freezers and that the RSB would inspect for compliance during the conduct of routine surveillance programs. Following discussion with Region I staff, the licensee expanded this request to modify CAL 1-95-018 in a letter dated May 20, 1996. In that letter, the licensee requested that CAL 1-95-018 be modified to allow the locked storage of any radioactive materials approved by the RSC and RSO within corridor refrigerators and freezers.

Supplement 3 of CAL 1-95-018, dated June 7, 1996, deleted bullet 3 of Item 3 of CAL 1-95-018 and replaced bullet 3 of Item 3 with the following:

- Licensed material stored in refrigerators and freezers located in laboratory building corridors is required to be secured by locking.
- Authorized users will retain control over keys to locked refrigerators and freezers where licensed material is stored.
- The Radiation Safety Branch will inspect for compliance with these actions during its routine surveillance program.

The inspector confirmed that the licensee implemented the security policy described in CAL 1-95-018, as revised in Supplements 2 and 3. The inspector determined that the licensee did not submit a plan for securing posted cold rooms and posted photographic dark rooms as they committed to do in Supplement 1 of CAL 1-95-018; however, as described in Section 6 of this report, the inspector determined that the licensee does not permit the unsecured storage of licensed radioactive materials in posted cold rooms and posted photographic cold rooms. Furthermore, the inspector did not identify any unsecured radioactive material in posted cold rooms or photographic dark rooms. Additional follow up on this action will be performed during the next routine inspection. This action will remain open pending completion of the licensee's January 19, 1996 amendment request.

- (4) During the 10/26 RSC meeting, the RSC adopted a new enforcement/suspension policy for violations of the security policy. The enforcement/suspension policy requires:
- Suspension will result in the total loss of radioactive materials privileges, i.e., ordering, receiving, and use for the period of the suspension;
 - The mandatory suspension period for an initial security violation is 14 to 30 days, depending on the severity;
 - If a second security violation is identified within one year of the first violation, the mandatory suspension will be for a period of 60 days;
 - A third security violation will result in referral to the RSC for consideration of revocation of authorization;
 - Suspension of an authorized user's privileges extend to any individual subordinate to that authorized user who was involved in the security violation; and
 - The RSO is authorized by the RSC to secure radioactive materials found in violation of the policy, including confiscation if necessary.

RSB staff will be notified upon identification of a security violation and the violation will be immediately verified. Suspension orders will normally be signed within 24 hours of verification. The enforcement/suspension policy does not extend to the clinical uses of radioactive materials where suspension may effect patient care; however, security violations in clinical areas will be reviewed by the RSB staff and consideration of a suspension order will be discussed with the RSC Chairman and/or the RSC Executive Committee within 24 hours identification of the violation.

In their letter dated October 31, 1995, the licensee stated that Item 4 of CAL 1-95-018 needed to be clarified. Item 4 required that clinical investigators subject to enforcement would be reviewed by the RSC Chairman or RSC Executive Committee with 24 hours of the identification of the violation. The licensee requested that the 24 hour time period for review be changed to one working day. This change was approved in Supplement 1 of CAL 1-95-018 issued November 8, 1995.

By letter dated December 22, 1995, the licensee stated that the RSC had approved a revision of the enforcement policy which provided the RSO with more flexibility in determining the length of any suspensions of authorizations and placed emphasis on the achievement of permanent corrective action for radioactive materials security. The revised enforcement policy provides:

- When an apparent violation of the NIH security policy is discovered, the authorized user will be notified of the apparent violation and a written response from the authorized user which documents the circumstances of the violation and corrective actions to be taken by the authorized user will be required within two days;
- The RSO will review the authorized user's response and determine if suspension of authorization is appropriate based on the circumstances of the violation and the response of the authorized user;
- If suspension is considered appropriate, the suspension shall be for the time necessary for effective corrective action to take place and be confirmed through follow up inspections;
- The suspension will extend to any individual user that may have been responsible for the violation;
- Reinstatement shall be at the discretion of the RSO, following verification of effective corrective action.

The RSC authorized that this enforcement policy be retroactively applied to any authorized or individual users on suspension as of December 20, 1995.

NRC Region I contacted the licensee by telephone on December 26, 1995, to express concern that it appeared from their December 22 letter that they had revised the commitments made in CAL 1-95-018 and Supplement 1 of CAL 1-95-018 without the review and approval of NRC. During this telephone conversation, the Deputy Director for Intramural Research stated that the revised enforcement policy discussed in the December 22 letter should be considered a proposal and that no change to the current enforcement policy would be made until approved in writing by NRC.

By letter dated January 5, 1996, NRC approved of the licensee's proposal to institute more flexible enforcement actions, at the discretion of the RSO, in response to violations of the NIH policy for security of licensed radioactive materials.

The inspector reviewed the licensee's enforcement records and determined that between October 27, 1995, when CAL 1-95-018 was issued and January 5, 1996, when CAL 1-95-018 was revised to provide the licensee with more enforcement discretion, the licensee identified 113 violations of their security requirements. Of the 113 violations identified, 103 resulted in suspensions. In 10 cases the licensee issued a violation and a warning but did not suspend the authorized user as required by the enforcement policy adopted by the licensee's Radiation Safety Committee on October 26, 1995, and as the licensee committed to do in CAL 1-95-018.

The inspector reviewed the enforcement files for all 10 of these cases. Five of the 10 cases involved unsecured radioactive materials in cold rooms. Most of these cases involved a minimal quantity of radioactive waste. As previously discussed in Section 4 of this report, the licensee had not yet established a policy for storage of licensed materials in cold rooms. A sixth case involved the unsecured storage of liquid scintillation vials, each vial containing picocurie quantities of radioactive material. The seventh case involved a single, generally licensed, radioimmunoassay kit containing 10 microcuries of iodine-125 which the authorized user believed was exempt from the security requirements. In the eighth case the authorized user followed the health physicist into the open laboratory within 10 seconds and immediately challenged the health physicist. In the ninth case the authorized user watched the health physicist enter his laboratory but he did not stop the health physicist because he believed that his research associate was still present in the laboratory. The laboratory contained a minimal quantity of unsecured waste. In the tenth case the health physicist determined that security was adequate in the laboratory and was about to leave the laboratory when the researcher returned and told her about some minimal dry waste that was unsecured but not identified by the health physicist.

The inspector concluded that the licensee's RSO had adequate justification for deciding not to suspend the authorized users in the 10 cases described above. The inspector noted that the decisions not to suspend the authorized users in all 10 of these cases were made prior to December 20, 1995 Radiation Safety Committee meeting where the Committee proposed the more flexible enforcement policy. The inspector determined that suspensions were handed down in a timely manner and that the RSO's staff conducted follow up audits to assure that the suspended authorized users had ceased to perform licensed activities.

The inspector determined that between January 5, 1996, when CAL 1-95-018 was revised to provide the licensee with more enforcement discretion, and the time of the inspection, the licensee identified 252 violations of their

security policy. Violators were required to provide a response explaining the circumstances which led to the violation and describing the corrective actions taken to prevent recurrence. In 240 of the 252 cases, the authorized user was issued a violation and a warning. In the remaining 12 cases, the authorized users were suspended. Eleven of the twelve suspended authorized users had previously received a warning or a suspension for security violations. In several cases, the RSO required that the authorized user's staff be retrained. On other occasions the RSO required that the authorized user meet with the NIH Radiation Safety Committee.

The inspector reviewed the enforcement files of several authorized users who had received security violations. The inspector determined that the licensee's actions were prompt and focused on the development of effective corrective actions. Corrective actions included: a reduction in the number of laboratories where radioactive materials are used; increasing the number of authorized users to improve oversight of supervised users; the disposal of radioactive materials which are no longer needed; the use of alternative research techniques which do not utilize radioactive materials; and the redesign of laboratory areas so as to concentrate the use and storage of radioactive materials in specifically designated areas.

The inspector concluded that the licensee implemented the enforcement policy described in CAL 1-95-018, as revised, and that the use of this policy has resulted in significant improvement in the security of radioactive materials at NIH. However, as discussed here and elsewhere in this report, the licensee has not achieved 100 percent compliance with the security requirements described in 10 CFR 20.1801 and 20.1802.

This action will remain open pending completion of the licensee's January 19, 1996 amendment request.

- (5) The new security policy and enforcement/suspension policies described above in items 3 and 4 will be distributed by hand to all available radioactive material users on October 27 and will be discussed at an NIH "Town Meeting" for authorized users on November 2, 1995. Attendance will be taken at the meeting so that those authorized users not in attendance can be provided with the information discussed at the meeting.

The inspector determined that the new security policy and enforcement/suspension policies were distributed to the entire research population in a timely manner and that these policies are well understood by the staff. This action is closed.

- (6) The RSO will formally provide a copy of the security policy and the enforcement/suspension policy to each authorized user in attendance at the November 2 meeting with a requirement that the authorized user sign a certification attesting that the policies were read, understood, and shared with all radioactive material users under their authorization. By November 9,

the RSO will mail a copy of the security policy, the enforcement/suspension policy, and the certification form to each authorized user who was not in attendance at the November 2, 1995 meeting. The return of these certification forms will be tracked and a RSB staffmember will be dispatched if a certification form is not returned within 15 days.

Supplement 1 of the CAL added that enforcement sanctions will be exercised for authorized users who do not certify in writing their understanding of the security policy for radioactive materials.

The inspector did not review the licensee's actions to determine whether these actions were completed as described. The inspector will review this action during the next routine inspection. This action is open.

- (7) By October 31, 1995, you will develop and submit to NRC your interim surveillance program for ensuring the security of radioactive materials possessed under the NIH license. The program will require frequent, periodic, unannounced surveillances of all radioactive material use areas and will include the performance of surveillances during normal working hours, meal times, during evening and early morning hours, and during weekend periods. The surveillances will include interviews with licensed material users to determine their level of understanding of the security program requirements. In addition, this program will require the performance of weekly follow up surveillances in areas where security problems were identified to ensure that suspension orders are being properly implemented. The interim surveillance program will include guidelines for relaxation as compliance improves.

By letter dated October 31, 1995, the licensee submitted their interim surveillance program.

Supplement 1 of CAL 1-95-018, issued November 8, 1995, expanded Item 7 to include the security surveillance plan described in the licensee's October 31 letter, as modified during telephone discussions between the licensee and NRC. The plan requires:

- That inspections for compliance with the provision of the NIH radiation safety security policy, which calls for posted areas to be locked when unattended, will be: unannounced; performed in each posted area twice monthly and monthly thereafter as long as no security violations are found during two consecutive inspections; conducted at varying times throughout a 24 hour day and on varying days, including weekend periods, such that no predictable pattern is created; and conducted using several types of trained personnel.
- During routine comprehensive laboratory surveys, RSB contractor staff will question lab personnel present in posted laboratories about the security policy to ensure the personnel understand what is

required. Individuals determined to have an inadequate understanding of the security policy will be identified to the RSB and appropriate remedial action taken. A record of these determinations will be maintained for review by NRC.

By November 13, 1995, NIH will submit a sampling plan for questioning personnel present in posted laboratories about their understanding of the security policy, during conduct of "inspections for compliance"

- Each person who is conducting inspections for compliance with the security policy will be instructed that:
 - If a room is posted for use and/or storage of radioactive materials, and no one is in the room or directly observing the entrance, the door(s) must be locked.
 - If the inspector finds a room in violation, he/she is to lock the door(s), document the date, time and location of the violation, and provide this information to the RSB within one working day for appropriate action.
 - Each inspector will provide to the RSB information on what areas were inspected for compliance with the security policy.
- The RSB will conduct weekly spot checks to ensure that no authorized users who are on suspension because of security violations are using radioactive materials.
- Before reinstating authorizations of authorized users who were suspended due to security violations, RSB will verify that they understand the requirements of the radiation safety security policy.
- Communication of surveillance and enforcement results to all authorized users will be accomplished by use of the Deputy Director for Intramural Research's electronic bulletin board and the monthly report sent by the RSB to every authorized user. The authorized users are responsible for communicating this information to their subordinate individual users.
- A monthly report describing the status of the surveillance program, including: (1) the identity of the laboratory areas inspected; (2) the date and time of the inspections; (3) the number of laboratories inspected; (4) the findings of the inspection (including the number of violations identified and the results of any interviews of radioactive material users conducted to determine the level of understanding of the NIH security policy); and (5) enforcement sanctions taken by the RSO will be provided to NRC by the 10th of each month.

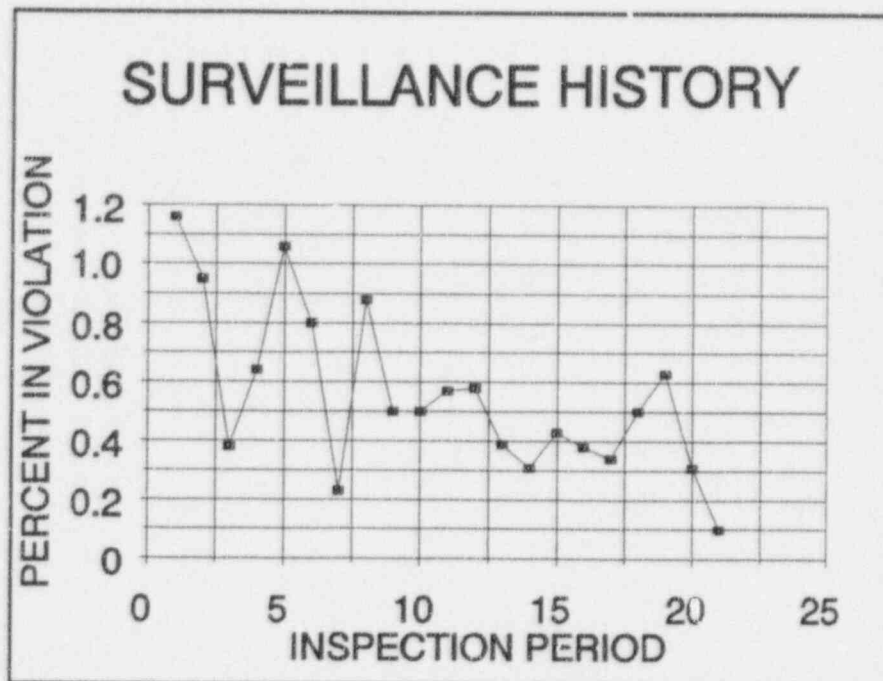
In a letter dated November 13, 1995, the licensee stated that they would question laboratory personnel during one complete security sweep and that if 95% knew the requirements, routine questioning would stop.

In a letter dated December 22, 1995, the licensee stated that they were in their third cycle of campus wide inspections for compliance and that the awareness and understanding of the security policy and its requirements were such that interviews with laboratory personnel regarding the requirements would be discontinued during the security sweeps unless a violation is identified. The licensee confirmed that RSB contractors would continue to question laboratory personnel present in posted laboratories about the security policy during routine comprehensive laboratory surveys.

As previously stated, Supplement 2 of CAL 1-95-018 amended the licensee's security policy to require that any posted room or area which contains radioactive materials in use, radioactive waste or radioactive materials in unsecured storage shall be locked when unoccupied. The licensee's instructions to persons who conduct inspections for compliance with the security policy were modified accordingly.

The inspector determined that the licensee implemented the security surveillance program, as described in Supplement 1 of CAL 1-95-018 and the licensee's letter dated November 13, 1995. While the licensee's monthly reports to NRC describing the status of the surveillance program do not include the identity of the specific laboratory areas inspected and the specific date and time of the inspections as described in Supplement 1 of CAL 1-95-018, the reports provide sufficient information for NRC to evaluate the status of the surveillance program. Furthermore, the inspector independently established that all laboratory areas were inspected and that the inspections were performed during all hours of the day and night and during weekend hours. The following table provides a synopsis of the findings identified during the surveillance program, as reported by the licensee. A graphic representation of the number of security violations identified over time for each inspection period is provided in the accompanying graph.

INSPECTION PERIOD # (DATES)	NUMBER OF LABORATORIES AUDITED	NUMBER OF SECURITY VIOLATIONS IDENTIFIED	PERCENT OF LABORATORIES IN VIOLATION
(1) 11/11-11/25	2943	34 (34 susp)	1.16%
(2) 11/26-12/9	2939	28 (28 susp)	0.95%
(3) 12/10-12/31	2931	11 (11 susp)	0.38%
(4) 1/1-1/19	2638	17 (0 susp)	0.64%
(5) 1/20-1/31	2450	26 (0 susp)	1.06%
(6) 2/1-2/15	2637	21 (0 susp)	0.80%
(7) 2/16-2/28	2211	5 (1 susp)	0.23%
(8) 3/1-3/15	2494	22 (0 susp)	0.88%
(9) 3/16-3/30	2070	10 (0 susp)	0.50%
(10) 4/1-4/15	2603	13 (1 susp)	0.50%
(11) 4/16-4/30	2093	12 (1 susp)	0.57%
(12) 5/1-5/15	2603	15 (2 susp)	0.58%
(13) 5/16-5/30	2071	8 (0 susp)	0.39%
(14) 6/1-6/15	2622	8 (2 susp)	0.31%
(15) 6/16-6/30	2099	9 (1 susp)	0.43%
(16) 7/1-7/15	2600	10 (0 susp)	0.38%
(17) 7/16-7/30	2082	7 (0 susp)	0.34%
(18) 8/1-8/15	2603	13 (1 susp)	0.50%
(19) 8/16-8/30	2067	13 (1 susp)	0.63%
(20) 9/1-9/15	2606	8 (0 susp)	0.31%
(21) 9/16-9/30	2085	2 (1 susp)	0.10%
11/11/95 to 9/30/96	51447	292 (84 susp)	0.57% average



As can be seen from the graph, the percentage of laboratories in noncompliance with the licensee's security policy has generally decreased over time. This action will remain open pending completion of the licensee's January 19, 1996 amendment request.

8. By October 31, 1995, you will develop and submit to NRC a plan for periodically communicating the status and findings of your surveillance program, including the enforcement sanctions taken by the RSO, to all users of radioactive material under the NIH license and to the NRC.

In a letter dated October 31, 1995, the licensee stated that for periodic communication of surveillance and enforcement results, they are planning to use the Deputy Director for Intramural Research's electronic bulletin board and the monthly report which is sent by the RSB to every authorized user. The licensee further stated that the authorized user will be responsible for communicating this information to their subordinate individual users. This information was incorporated into Supplement 1 of CAL 1-95-018.

The inspector reviewed several of the monthly reports which were sent by the RSB to every authorized user and determined that the licensee has communicated surveillance and enforcement results as described in Supplement 1 of CAL 1-95-018. This action will remain open pending completion of the licensee's January 19, 1996 amendment request.

9. **The new security policy and enforcement/suspension policy will be incorporated into the refresher training required for all users of radioactive material prior to the next scheduled training date.**

Supplement 1 of CAL 1-95-018 added that these policies also will be added to the user orientation training package.

The inspector determined that the security policy and enforcement/suspension policy have been incorporated into the refresher training and orientation training. This action is closed.

10. **Suspension orders for security violations identified by the NRC during a special inspection conducted on October 23 and 24, 1995 are in process and will be completed by October 27, 1995.**

The inspector determined that suspension orders for violations identified by the NRC during the special inspection conducted on October 23 and 24, 1995, were completed on October 26, 1995. This action is closed.

Items 1, 2, 5, 9, and 10 of CAL 1-95-018 are closed. Items 3, 4, 6, 7, and 8 remain open pending the completion of additional inspection effort and completion of the licensee's January 19, 1996, amendment request.

VI. Security and Control of Licensed Radioactive Materials

The inspectors accompanied licensee health physicists to observe their performance of security surveillances. These accompaniments began immediately following the entrance briefing conducted by the inspectors with licensee management on September 16 and occurred at various times of the day and in the evening hours throughout the remainder of the week. The inspectors also performed their own security surveillances with the licensee's health physicists observing. Surveillances were performed of approximately 900 of the licensee's 2600 laboratory use areas in 10 buildings located on the Bethesda campus, in Rockville, and in Baltimore, Maryland.

The inspectors determined that the licensee did not consider any building security measures to obviate the need for security at the laboratory door or the door of the refrigerator/freezer. The inspectors also determined that the licensee had no threshold for quantities of radioactive material that could be unsecured. For example, the licensee has issued numerous violations and some suspensions when health physicists find an unsecured radwaste container containing only a pair of gloves or a paper towel. The inspectors noted that the health physicist's surveillances did not normally include unposted rooms or unposted refrigerators/freezers (although some were checked) and that the health physicists did not use survey meters during their surveillances, relying on users to properly post and label radioactive material. The health physicists stated that they did not carry survey instrumentation during the performance of security surveillances.

because this equipment identified them as being from the Radiation Safety Branch and that this skewed the surveillance results. The health physicists explained that: (1) researchers would not normally challenge an individual who entered their laboratory if the individual was known to have authorized access; and (2) if they were identified as being from the Radiation Safety Branch, word would quickly spread throughout the building and, as a result, the surveillance would no longer be unannounced. The health physicists stated that this was also the reason why the surveillances in one building were normally conducted by a health physicist who was unknown to the researchers in that building.

During these surveillances, the inspectors checked numerous unposted refrigerators/freezers and rooms for the presence of radioactive material and surveyed numerous areas with survey meters equipped with pancake probes. As discussed below, the inspectors found only one example where radioactive material was stored in an unposted room or unposted refrigerator/freezer. The quantity of material found, 62 microcuries of carbon-14, did not exceed 10 times the 10 CFR Part 20 Appendix C value of 100 microcuries which, in accordance with 10 CFR 20.1902(e), would have required that the refrigerator/freezer where the carbon-14 was found be posted. The inspector noted that, in accordance with 10 CFR 20.1905, the quantity of carbon-14 found in the vial would not have required that the vial be labelled; however, the vial containing the material was labeled. All radioactive material encountered during the surveillance was properly labeled. The inspectors found very little contamination in the laboratories which were surveyed. The minor contamination found was located in controlled areas such as radwaste containers and on absorbent paper used to cover bench top work areas.

Inspectors found two examples where licensed radioactive material was unsecured:

- On September 16, a labelled vial containing 62 microcuries of carbon-14 orotic acid was found in an unposted and unlocked refrigerator/freezer located outside of Laboratory 319 in Building 8. The licensee identified the responsible authorized user through the manufacturer's lot number and is proceeding with enforcement action. The authorized user was previously cited for a security violation on March 12, 1996.
- Also on September 16, several labelled vials containing various quantities of hydrogen-3, carbon-14, and sulfur-35 were found in a posted but unlocked freezer located in an unoccupied and unlocked posted laboratory in Building 36 (36/1C11). The vials contained:

hydrogen-3	1 millicurie (1978)
	2 X 250 microcuries (1977)
	1 millicurie (undated)
	250 microcuries (undated)
	2 X 12 microcuries (1981)
	250 microcuries (undated)
	5 millicuries (undated)
	1 millicurie (undated)
	250 microcuries (1981)
	5 millicuries (undated)
	5 millicuries (undated)
carbon-14	250 microcuries
	2 microcuries
	50 microcuries
	10 microcuries
	50 microcuries
	1 millicurie
	3 X 250 microcuries
sulfur-35	97 microcuries

The authorized user responsible for the laboratory reportedly has a large number of laboratories under his authorization and has a prior enforcement history for security problems. On November 6, 1995, unsecured radioactive material was found in one of his laboratories and no one was present to prevent unauthorized removal or access. The authorized user was suspended for 14 days. This suspension was extended an additional 30 days on December 14, 1995, when follow up audits of other laboratory areas under the authorized user's authorization found additional security problems. On April 23, 1996, unsecured radioactive material was again found in one of his laboratories. The RSO brought this violation to the attention of the RSC. A violation was issued with the requirement that the authorized user's entire staff be retrained. The retraining was completed. Following identification of radioactive materials by NRC on September 16, 1996, the authorized user was suspended indefinitely and was required to meet with the RSC to determine penalty and to develop a corrective/preventive action plan.

10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are in a controlled or unrestricted area. Failure of the licensee on September 16, 1996, to secure from unauthorized removal or access, approximately 2 millicuries of carbon-14, 18 millicuries of hydrogen-3, and 97 microcuries of sulfur-35, which were stored in unrestricted areas, is an apparent violation.

The quantity of carbon-14 found in the Building 8 refrigerator/freezer did not exceed the 10 CFR Part 20 Appendix C value of 100 microcuries. The inspector noted that the NIH license currently permits the storage of less than Appendix C quantities of

radioactive material in unlocked refrigerators and freezers located in laboratory corridors. Therefore, the only apparent violation identified by the inspectors involved the security of the radioactive materials found in Laboratory 36/1C11.

The inspector noted that, as described earlier in Section V of this report, the licensee identified approximately 292 violations of their security policy between November 11, 1995 and September 30, 1996.

To evaluate the licensee's control of radioactive materials, the inspectors looked at 10 of the licensee's 13,000 radioactive material purchases and tracked these materials from the time of receipt to the time of the inspection, reviewing all aspects of the licensee's program related to these materials. The review included: (1) the authorization and training of the persons who had requested the purchase of, or used, the radioactive materials; (2) the use of dosimetry and the performance of bioassay, if required; and (3) the use and disposal of the materials. The inspector interviewed, whenever possible, the persons who ordered and used the materials, reviewed records related to the purchase, use, and disposal of the materials, and toured the laboratory areas.

Inspectors identified that on one occasion, the authorized user ordered 500 microcuries of phosphorus-33 and received two vials each containing 250 microcuries of phosphorus-33, but the Radiation Safety Branch records indicated that only 250 microcuries of phosphorus-33 were ordered and received. This error should have been caught when the material was received by the RSB but the individual who received the package did not note the presence of two vials. The researcher properly documented her receipt of 500 microcuries of phosphorus-33. The licensee determined that RSB records were inaccurate because one of the computer systems was down on the day that the material was ordered and the order had to be generated manually. The operator erred in generating the order.

Condition 29 of License No. 19-00296-10 requires that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed in Condition 29. The documents listed in Condition 29 include a letter submitted by the licensee in support of license renewal on September 6, 1988. Attachment 6 of this letter describes the licensee's "Procedures for Safely Opening Packages Containing Radioactive Material". Item 5 of this Procedure requires that the individual opening the package "verify that the stated contents agree with the order placed by the Authorized User". As stated above, the contractor who opened a package containing two vials of phosphorus-33, each vial containing 250 microcuries of phosphorus-33, failed to verify that the stated contents agreed with the order placed by the Authorized User. Specifically, the RSB records available to the contractor were inaccurate in that they only reflected the purchase of 250 microcuries of phosphorus-33 when in fact 500 microcuries were ordered and received. This is an apparent violation.

VII. Self-contained and Panoramic Irradiators

The inspector reviewed the use by individuals of a representative sample of the self-contained irradiators and all of the panoramic irradiators. A total of eight irradiators were inspected. The inspector reviewed irradiator use logs and cross-checked these logs with the training records of individual users. The inspector also determined by interviewing several of the users of the panoramic irradiator that the users exhibited an adequate understanding of good radiation safety practices and of the requirements of 10 CFR Part 36. Interviews with selected users of the self-contained irradiators indicated an adequate understanding of good health physics principles and an adequate understanding of the licensee's procedures and pertinent regulations. All the irradiators examined by the inspector appeared to be adequately secured.

The inspector determined that irradiator users were issued and wore the required dosimetry. The inspector reviewed a representative sample of the dosimetry records of active users and determined that exposures were within the expected range for this type of use.

No violations or safety concerns were identified by the inspector.

VIII. Exit Meeting

An exit meeting was held with those individuals identified in Section I of this report.