- NUREG-1535

Ingestion of Phosphorus-32 at Massachusetts Institute of Technology, Cambridge, Massachusetts, Identified on August 19, 1995

U.S. Nuclear Regulatory Commission

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NUREG–1535

Ingestion of Phosphorus-32 at Massachussetts Institute of Technology, Cambridge, Massachusetts, Identified on August 19, 1995

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Abstract

On Monday, October 16, 1995, the Massachussetts Institue of Technology (MIT, the licensee) notified the U.S. Nuclear Regulatory Commission (NRC) of an incident involving ingestion of phosphorus-32 by a researcher at the MIT Center for Cancer Research. The licensee informed the NRC that a researcher had reported the incident on August 19. The licensee initially estimated the intake as 500 microcuries (19 MBq) and the dose as 4000 millirem (40 mSv) to the individual. On October 12, the licensee informed the researcher that its final intake estimate was 579 microcuries (21 MBq), just under the 600 microcuries (22 MBq) which would represent an overexposure. On October 17, the NRC established an Incident Investigation Team to investigate the case. NRC also contracted with Lawrence Livermore National Laboratory and Oak Ridge Institute for Science and Education to do independent dose assessments of the urine sample data and the whole-body data. The Team concluded that the licensee's final intake and dose estimates were in accordance with accepted scientific references and NRC guidance. However, recognizing the uncertainties involved in the use of models to simulate human characteristics, the Team determined the intake would be better characterized as likely falling within a range of 500 to 750 microcuries (19–28 MBq). An NRC medical consultant concluded that no symptoms or acute effects should be observed from an intake of this level.

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Oak Ridge Institute of Science and Education, Oak Ridge, Tennessee, Contractor

Abbreviations

AEOD	Analysis and Evaluation of Operational Data, NRC Office for the
AIT	Augmented Inspection Team
ALI	Annual Limit on Intake
CEDE	committed effective dose equivalent
CINDY	Code for INternal DosimetrY (computer code)
cpm	counts per minute
DNA	deoxyribonucleic acid
dpm	disintegrations per minute
EDO	Executive Director for Operations, NRC
EMS	Environmental Medical Services
FR	*Federal Register*
GM	Geiger-Meuller
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
INEL	Idaho National Engineering Laboratory
LLNL	Lawrence Livermore National Laboratory
LSC	liquid scintillation counting
MIT	Massachusetts Institute of Technology
NIH	National Institutes of Health
NIST	National Institutes of Standards and Technology
NMED	Nuclear Materials Events Database
NMSS	Nuclear Materials Safety and Safeguards, NRC Office of
NRC	Nuclear Regulatory Commission, U.S.
NUDOCS	Nuclear Documents System
ORISE	Oak Ridge Institute for Science and Education
QC	quality control
RI	Region I, NRC
RP	Radiation Protection
RPC	Radiation Protection Committee
RPO	Radiation Protection Officer

SI	Systeme International
WBC	whole-body counting

Executive Summary

The Center for Cancer Research (Center) at the Massachusetts Institute of Technology (MIT) consists of several laboratories involved in various aspects of cancer research. Radionuclides including phosphorus-32 (^{32}P) are used in these laboratories for the synthesis of components of deoxyribonucleic acid (DNA). Possession limits, types of activities, and requirements for facilities and equipment in individual laboratories are reviewed and approved by the MIT Radiation Protection Committee (RPC). Each laboratory is periodically audited by the staff of the Radiation Protection Office to determine that activities were conducted in accordance with the authorization issued by the RPC as well as requirements in the NRC regulations and the NRC license issued to MIT. One particular laboratory typically receives 1 to 2 millicuries (37 to 74 MBq) of ^{32}P each week. This laboratory has a Principal Investigator and a Laboratory Manager with more than 30 postdoctoral research fellows, graduate students, and technical assistants working under their supervision. Because of the nature of the research, activities in the Principal Investigator's Laboratory frequently occur past midnight and 7 days a week.

On Saturday, August 19, 1995, at 5:10 p.m., the Campus Police at MIT received a telephone call from a senior postdoctoral fellow (Researcher A) at the Principal Investigator's Laboratory. Researcher A had noted detectable radioactivity during a routine survey of his hands about 1 hour earlier and reported that his body and urine were contaminated. Before placing the call, Researcher A determined that the contamination would not wash off his hands and appeared to be on his knees and head as well. The last time Researcher A had used ^{32}P before this date was August 14. He had surveyed himself on that date and had not found contamination.

On Tuesday, September 12, the RPC met and discussed the ^{32}P contamination incident. The Radiation Protection Officer (RPO) announced the intake as 500 microcuries (19 MBq) and the dose as 4000 millirem (40 mSv) to the individual. The RPC decided to have the Committee Chairman send a letter to Researcher A expressing regret and concern about the incident and a letter to the Campus Police urging assistance in finding how it occurred and how to prevent recurrence. On October 12, the RPO submitted to Researcher A a final intake estimate of 579 microcuries (21 MBq), just under the 600 microcuries (22 MBq) which would represent an overexposure.

On Friday, October 13, the RPO learned that the magazine *Nature* planned to publish an article about the MIT ^{32}P contamination incident. On Monday, October 16, the RPO notified the NRC Region I office of the planned article about the incident. Region I personnel began an initial onsite review of the incident that day.

On October 17, in conformance with the Incident Investigation Program, the NRC Executive Director for Operations (EDO) requested that an Incident Investigation Team (the Team) be established to investigate the ingestion of ^{32}P. Appendix A is the memorandum establishing the Team and defining the scope of the Team's charter. The Team was to find facts, determine what happened, and make appropriate findings and conclusions. The Team included members with a broad knowledge of health physics, incident analysis, radiation dosimetry, operations using radioactive materials for research, and criminal investigation. The Team included two observers

from the Commonwealth of Massachusetts and one observer from the NRC Office of the Inspector General.

On October 20, the Team charter was modified to remove references to assessing possible wrongdoing, and the member of the Team from the NRC Office of Investigations was taken off the Team (Appendix B is the memorandum modifying the Team and the attached modified charter). On the same day, the NRC Office of Investigations began an independent investigation.

The Team established a sequence of events that followed the notification by Researcher A. The following paragraphs summarize these events.

After receiving the telephone call on August 19 from Researcher A, the Campus Police dispatched an officer to the laboratory and telephoned the Environmental Medical Services and the oncall Radiation Protection Office staff. The officer arrived and, after discussions with Researcher A, walked with him to the MIT medical facility. Shortly thereafter, an Assistant Radiation Protection Officer (Assistant RPO) and the Associate Radiation Protection Officer (Associate RPO) arrived at the medical facility. They also performed surveys of Researcher A and confirmed, as Researcher A had previously concluded, that the contamination was internal and not external.

That same evening, the Associate and Assistant RPOs performed surveys of the researcher's laboratory, adjacent laboratories, offices, hallways, water coolers, and trash receptacles. They also surveyed personal belongings of Researcher A including his briefcase, coffee cup, and food. They did not find any contamination. After the laboratory surveys, Researcher A was measured using a whole-body counter. In addition, they analyzed urine and blood samples that confirmed the intake was ^{32}P.

The Associate RPO accompanied Researcher A home on August 19 and surveyed floor areas, household items, a laundry bag, the toilet, toothbrushes, towels, and washcloths. He did not find any contamination. Researcher A was requested to collect urine samples and to bring them to the Radiation Protection Office for analysis on Monday, August 21.

On Monday, August 21, staff from the Radiation Protection Office performed additional surveys in the Center including lunch rooms, coffee cups, refrigerators, food in refrigerators, empty beverage containers, and other areas. The staff also collected and analyzed urine samples from 24 other workers in the laboratory but found no additional contamination in the surveys or urine samples.

Also on Monday, Researcher A brought in clothing catalogued by day, for the past 8 days. Underwear worn beginning on August 14 had urine stains contaminated with ^{32}P. The Radiation Protection Office staff decided that day was the likely date of ^{32}P intake for purposes of investigation and dose estimation. Researcher A informed the Radiation Protection Office staff of his own calculations based on the initial ^{32}P in urine data and reference documents he had found in the MIT library. He estimated the intake to be 600 to 700 microcuries (21–26 MBq) assuming the intake had occurred on August 14. However, MIT estimated a lower intake.

On August 22, the RPO withdrew all licensed materials from the Principal Investigator's Laboratory. The RPO requested laboratory workers to perform an inventory. The workers

accounted for all ^{32}P but a volume containing nearly 500 microcuries (19 MBq). The Principal Investigator's Laboratory staff was allowed to resume use of licensed material on August 31, and control of licensed material was tightened. The controls included requirements that all licensed material be stored in a locked box for which only three individuals had keys and that all users state their need for material.

In the week after August 19, Researcher A met with Radiation Protection staff to discuss the whole-body counting and urine data. Problems with urine data ended when Researcher A received explicit instruction on how to collect a 24-hour urine sample. Researcher A also found an error in the analysis of the whole-body counting data by MIT. This error resulted in a 35-percent underestimate of intake. Researcher A consistently calculated values of ^{32}P intake closer to a range of 600 to 700 microcuries (21–26 MBq). MIT estimates increased from 300 microcuries (11 MBq) to 500 microcuries (19 MBq) in this early period as errors were found. The final intake reported to Researcher A was about 96 percent of the annual limit on intake. Exceeding the annual limit on intake would result in a dose greater than 5 rem (0.05 Sv), which is an overexposure.

The Team performed an analysis of the urine and whole-body data to evaluate the dose received by Researcher A. Independent dose assessments of the urine sample data and the whole-body data were performed under contract to the NRC by Lawrence Livermore National Laboratory (LLNL) and Oak Ridge Institute for Science and Education (ORISE). In addition, ORISE performed an independent analysis of urine samples obtained from MIT. The Team concluded that the dose calculated and recorded by MIT on the final report to Researcher A was in accordance with accepted scientific references and NRC guidance. The Team recognized uncertainty involved in determining the actual intake of ^{32}P by Researcher A, as is the case with any model based upon average human characteristics, and therefore found that the intake would be better characterized as falling within a likely range of 500 to 750 microcuries (19–28 MBq). An NRC medical consultant concluded that no symptoms or acute effects should be observed from an intake of this level.

While on site at MIT, the Team observed that MIT's policies and procedures for laboratory and building security and control of access to radioactive materials were not always being followed in all laboratories. The RPO was informed of these findings and acted to improve controls at the Center before the exit interview. The Team briefed NRC Region I managers about these findings. A Region I manager travelled to the site on October 25 to review corrective actions taken or planned by MIT.

On October 25, the Team concluded gathering information at the site and held an exit interview with MIT, which was open for public attendance and observation. After returning to the NRC headquarters facilities, the Team interviewed NRC staff in the Office of Nuclear Material Safety and Safeguards, the Office for Analysis and Evaluation of Operational Data, the Office of State Programs, and the NRC Region I Office regarding regulatory practices, procedures, and assessment of similar events.

This report documents the results of the Team's efforts.

Section 1 is a narrative of the event.

Section 2 describes the human factors considerations in the operation of the MIT radiation protection program at the Center, the response to the incident, the emergency plan, and continued operation of the research program.

Section 3 is a summary of precursors and related experiences similar to the August 1995 event.

Section 4 is a summary of the radiological dose evaluations for Researcher A.

Section 5 is a summary of the regulatory aspects of the activities associated with the event including regulatory criteria and the NRC's licensing, inspection, and assessment processes.

Section 6 contains the Team's findings and conclusions.

Section 7 contains the results of the Team's root cause analysis.

In summary, the Team concluded the following:

- Researcher A most likely ingested ^{32}P as the result of a deliberate act by a knowledgeable person.

- The amount of radioactive material ingested by Researcher A [500–750 μCi (19–28 MBq)] is not expected to result in any clinical symptoms or acute effects. Any symptoms that may have been experienced were due to factors other than radiation exposure.

- The security of radioactive materials in storage and the control of radioactive materials in use in the Center for Cancer Research were weak.

- The Radiation Protection Office exercised weak oversight with regard to storage and control of radioactive material in unrestricted and controlled areas.

- NRC regulatory standards and guidance for security and control of byproduct material were inconsistent.

- While the Team found weaknesses in the actions taken by Radiation Protection Office personnel, the licensee's overall response was good.

- Management oversight of the Radiation Protection Program was weak. MIT did not use a process of management review and self-assessment to find weaknesses in their program and to take appropriate remedial actions.

- NRC reporting requirements were not specific regarding intentional contamination. NRC reporting requirements for intake were unclear. However, sufficient data was available within the first week to indicate the event threatened to cause an overexposure.

The Team concluded that the ingestion of ^{32}P at MIT was most likely the result of a deliberate act by a knowledgeable individual. However, the Team could not determine how the ingestion

occurred. Consequently, the Team could not determine a root cause. However, the Team found sufficient information to determine the following contributing causes to the event:

- MIT's program for the control, security, and accounting of radioactive materials was not effective to deter or detect deliberate diversion of radioactive materials.

- The NRC did not have reporting requirements in place to collect information about deliberate acts in order to assess their frequency.

- The NRC did not disseminate information about known precursor events and did not inform licensees of the circumstances of a similar incident at the National Institutes of Health until 4 months after the incident was reported.

1 Narrative

This section is a description of the pertinent operations of the Massachusetts Institute of Technology (MIT) Center for Cancer Research, the events associated with the ingestion of phosphorus-32 (^{32}P) by Researcher A, and followup actions. This narrative consists of information collected from interviews with licensee and U.S. Nuclear Regulatory Commission (NRC) personnel, computer printouts, logs, and records kept by the licensee and NRC. All times are eastern daylight savings time.

MIT Center for Cancer Research Operations

The MIT Center for Cancer Research (the Center) consisted of several laboratories involved in various aspects of cancer research. The Principal Investigator's laboratory (PI Laboratory) consisted of several laboratory rooms on the third floor of the Center (Figure 1-1). More than 30 researchers worked within the PI Laboratory on numerous research projects directed by the Principal Investigator. The research activity routinely continued 7 days each week, often past midnight. However, most personnel were present between the hours of 9 a.m. and 6 p.m., Monday through Friday. Several radionuclides including ^{32}P were stored and used throughout these facilities. One storage location for ^{32}P was the freezer in room E17-347. Like most freezers and refrigerators in the Center, this freezer did not have a lock. ^{32}P was received in microliter quantities of highly concentrated frozen liquid.

Researcher A worked in room E17-347 of the PI Laboratory. He used small quantities (50 µCi (1.9 MBq) or less) of ^{32}P for labelling and column chromatography of biochemical material. On August 19, 1995, while performing a self-survey following a labelling procedure with ^{32}P, Researcher A discovered that he had been internally contaminated.

Activities Before Discovery

Thursday, August 10, 1995

Researcher A used 50 microcuries (1.9 MBq) of ^{32}P.

Friday, August 11

Researcher A used 50, 50, and 63 microcuries (1.9, 1.9, and 2.3 MBq) in three separate procedures.

Sunday, August 13

10 a.m. Researcher A arrived at the laboratory and performed a procedure and other tasks. Researcher A brought two boxes of food with him, one for lunch and the other for dinner. He placed these in the PI Laboratory refrigerator for food (Figure 1-1). Researcher A handled diluted ^{32}P solution from previous procedures.

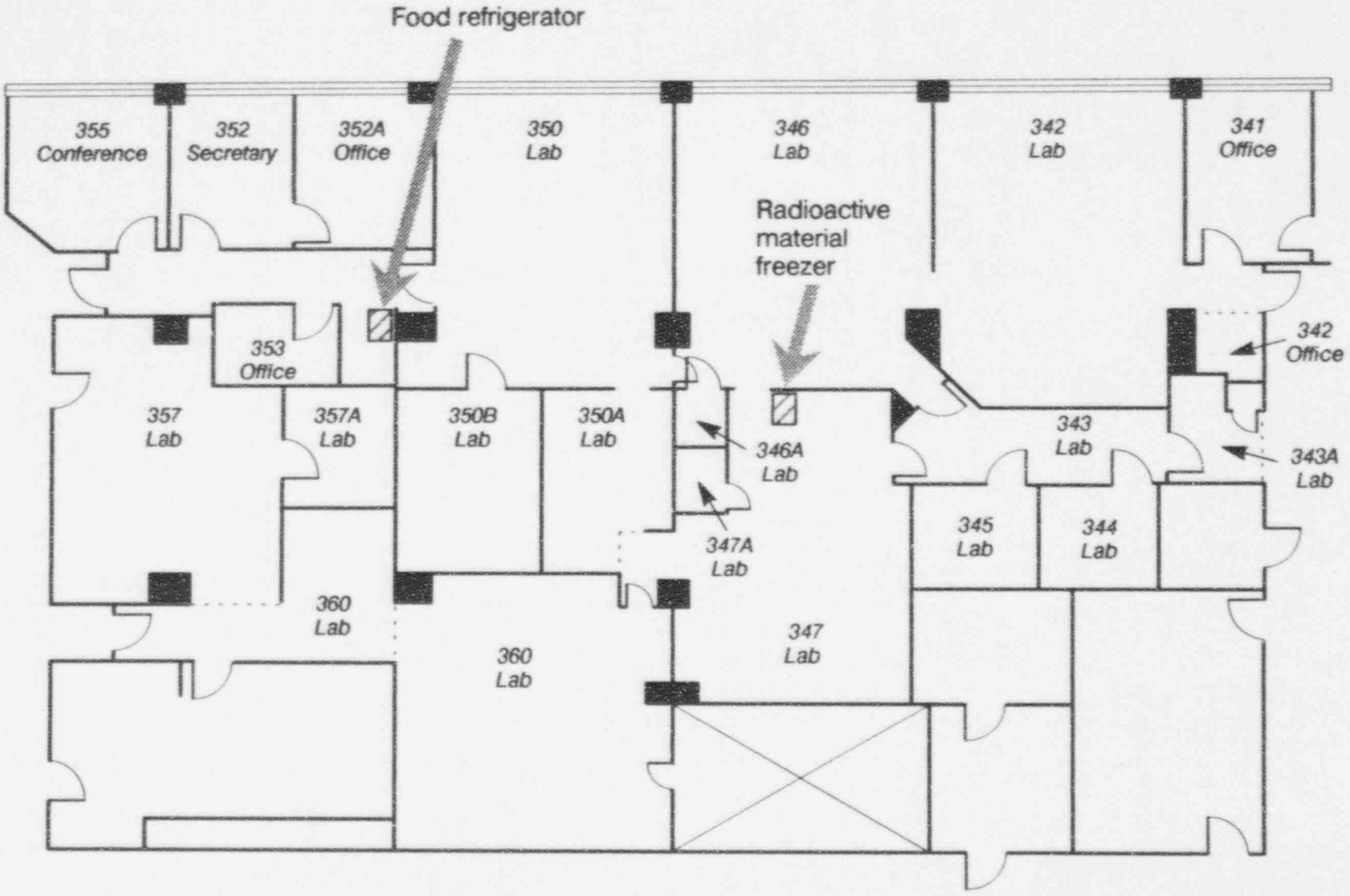

Figure 1-1 Principal Investigator's Laboratory at the MIT Center for Cancer Research (Building E17)

12 Noon — Researcher A ate lunch with his wife in the cafeteria and then left with her for personal business.

2:30 p.m. — Researcher A returned to the laboratory.

3 p.m. — Researcher A left for home. Since he did not work past dinner, he left one box of food in the food refrigerator.

Monday, August 14

8:10 a.m. — Researcher A arrived at the laboratory and used 100 microcuries (3.7 MBq) for two reactions.

A shipment of one vial of ^{32}P arrived. The results of an inventory performed by the licensee after August 21 indicated that an estimated 473 microcuries (18 MBq) from this vial could not be accounted for. During the day, Researcher A could not locate this vial.

12 Noon — Researcher A ate lunch. Researcher A stated that he ate the box of food left in the refrigerator from the previous day.

2:30 p.m. — Researcher A performed two additional procedures with 100 microcuries (3.7 MBq) of ^{32}P.

7 p.m. — Researcher A finished work. He performed a close-out survey of his work area and his hands and detected no radioactivity.

8 p.m. — Researcher A ate dinner.

8:15 p.m. — Researcher A left for home.

Tuesday, August 15 through Friday, August 18

Researcher A did not work with radioactive material.

Saturday, August 19

9:50 a.m. — Researcher A arrived at the laboratory.

10 a.m. — Researcher A used 50 microcuries (1.9 MBq) of ^{32}P.

11 a.m. — Researcher A used 50 microcuries (1.9 MBq) of ^{32}P.

TIME UNKNOWN — Researcher A went to a movie.

3:30 p.m. Researcher A returned to the laboratory and finished procedure.

4 p.m. Researcher A surveyed his hands at the completion of work and found detectable radioactivity on them. Thinking contamination was on his gloves, he washed his gloved hands. However, further survey showed that the contamination did not wash off. He then took off the gloves, surveyed his hands, and again found radioactivity. He then washed his bare hands, but surveys still detected radioactivity. While trying to determine the reason for hand contamination, he accidently moved the probe near his knee and leg and detected radioactivity. He surveyed his entire body, detected radioactivity near his head, and suspected internal contamination.

Immediate Actions

Saturday, August 19

4:15 p.m. Researcher A surveyed the work bench and desk but did not detect any contamination. He ran downstairs to get his wife before she left for home, thinking the radiation source may be at home. He surveyed his wife and determined she was not contaminated. He also surveyed a colleague and did not detect radioactive material. Researcher A reviewed the radiation protection procedures manual but later stated that he could not immediately find helpful information.

Researcher A collected and analyzed a urine sample. Results (3000 counts per minute (cpm) in 1 milliliter (ml) as counted in his laboratory) convinced him that he had ingested a radioactive substance. Researcher A consulted the radiation protection procedures manual again and determined that he should contact the Campus Police. He then called the MIT emergency telephone number.

5:10 p.m. Campus Police received a telephone call from Researcher A. Officer A was dispatched to the Center. When the Officer arrived and was informed of the survey and urine analysis results, he relayed this information to his supervisor.

5:15 p.m. Campus Police began telephoning oncall personnel at the Environmental Medical Services (EMS) office and the Radiation Protection (RP) Office.

5:30 p.m. Campus Police reached the oncall EMS representative by telephone. An oncall EMS representative then telephoned Researcher A and the Officer. The oncall EMS representative, an industrial hygienist, told the Officer that he would telephone someone from the RP Office.

Assistant Radiation Protection Officer (RPO) A received a telephone call from the EMS oncall person. When told that the entire body of Researcher A was contaminated, Assistant RPO A requested the telephone number to contact Researcher A directly.

5:45 p.m. Researcher A and the Officer interpreted radiation protection procedures to state that Researcher A must be taken to the MIT medical facility. They proceeded on foot to the medical facility.

At the medical center, Physician A took Researcher A to the Decontamination Room. Physician A surveyed Researcher A, obtained readings higher in the area of Researcher A's mouth, and concluded that he may have been contaminated by ingestion through the mouth.

5:50 p.m. The Officer responded to another dispatcher call and left the medical center.

Campus Police received a telephone call from the Associate RPO and advised him of the situation.

5:52 p.m. Campus Police received a telephone call from the medical center for assistance in contacting the RP Office. Campus Police advised them the Associate RPO was on the way.

Assistant RPO A telephoned Physician A, who informed him that the contamination could not be removed by wiping, but when asked, replied that ingestion was possible. Assistant RPO A suggested rinsing Researcher A's mouth with saline and saving the rinsings for analysis. Assistant RPO A also directed Physician A to obtain a urine sample from the researcher.

Physician A had Researcher A rinse his mouth with saline solution. A Geiger-Mueller (GM) survey of saline rinse did not detect radioactivity. Researcher A asked Physician A to take a blood sample in order to count it later for radioactivity.

6 p.m. The RPO received a page message from the Campus Police.

6:40 p.m. The RPO contacted the Campus Police to advise that RP personnel were on the way.

7 p.m. The Officer returned to the medical center. Researcher A waited for RP personnel to arrive. The Officer spoke with Physician A, then left.

The Associate RPO and Assistant RPO A arrived at the medical center and met with Researcher A and Physician A in the Decontamination Room. They surveyed Researcher A and confirmed contamination. They verified by wiping Researcher A with towels that no contamination was removable from his body. Since contamination appeared to be internal and not external, they took Researcher A back to the PI Laboratory.

The Associate RPO and Assistant RPO A surveyed the PI Laboratory, adjacent laboratories, offices, and meeting room. Surveyed areas included the laboratory benches, desks, floors, hallways, corridors, water coolers, trash and recycling

receptacles, desks, and personal belongings of Researcher A, including his briefcase, coffee cup, and snackfood items. They found no contamination.

After completing laboratory surveys, Researcher A, Associate RPO, and Assistant RPO A went to the Radiation Protection offices for a complete survey, including an analysis of a urine sample and a whole-body count. They also analyzed mouth rinses and the blood sample in a liquid scintillation counter.

The whole-body count and urine analysis confirmed the contamination was ^{32}P. RP personnel did not estimate intake or uptake from whole-body counter data because the counter was not yet calibrated for ^{32}P. Urine sample counting results were approximately 8,000 disintegrations per minute (dpm) per milliliter.

During a telephone conversation between the Associate RPO and the RPO, they established a rough dose estimate, which was based on the volume of body water. They did not know the date and time of ingestion.

RP personnel asked Researcher A to save his urine specimens. They requested a sample from every urine void, requested he submit information about the total volume voided each time, and gave him containers. Researcher A received no written instructions about urine collection.

9 p.m. The Associate RPO accompanied Researcher A back to his laboratory space to collect personal belongings. They proceeded to Researcher A's home to completely survey the apartment. Areas surveyed included all floor areas, laundry bag, toilet, toothbrushes, towels, washcloths, and bottles for sample collection. They found no contamination. The Associate RPO requested Researcher A to bring samples to the RP office on Monday and have another whole-body scan done then.

About 30 minutes after the Associate RPO left the apartment, Researcher A was called by the colleague he surveyed earlier. This individual suggested that Researcher A drink lots of fluid. Researcher A stayed awake through the night, drinking fluids. Researcher A used his home computer to log into the MIT library to get a list of information available about radioactivity.

Followup Actions

Sunday, August 20

Researcher A went to the MIT library to review the literature he found Saturday evening. He reviewed a paper from the International Commission on Radiological Protection (ICRP) that included a table depicting activity levels related to intake over time. This information led him to conclude that he must determine when he ingested the material to calculate the initial dosage. He returned home and had his wife assist in sorting and surveying his clothes because the radiation levels from his hands were too high. They found contamination in his underwear beginning with

ingested the material to calculate the initial dosage. He returned home and had his wife assist in sorting and surveying his clothes because the radiation levels from his hands were too high. They found contamination in his underwear beginning with those worn from 8 a.m. on August 14 to 8 a.m. on August 15, and found contamination in underwear worn each day following. Researcher A placed each day's clothing in a separate bag for transport to the RP Office.

Monday, August 21

The RP staff did additional surveys on the third floor of the Center, including clean areas, lunch rooms, coffee cups, refrigerators, food in the refrigerators, and empty beverage containers. They collected urine samples from 24 other workers in the PI Laboratory and found no contamination. They collected all radioactive waste from the PI Laboratory and took it the RP Office for analysis. The RPO met with other PI Laboratory personnel to discuss activities and findings.

Researcher A brought clothing catalogued by day for the past 8 days to the RP Office. The RP staff surveyed the clothing and found contamination in underwear beginning with those worn Monday, August 14. They then assumed that day to be the date of intake.

Researcher A told the RP staff that he ingested 500 to 700 microcuries (18–26 MBq) based on data he obtained from the ICRP document, his interpolation between data points from the document tables, and his assumption the day of intake was Monday August 14. The RPO agreed to consider this information, but stated that the guidance in NUREG-4884, "Interpretation of Bioassay Measurements," 1987, was better.

The RPO staff measured Researcher A for radioactive material using the whole-body counter. However, the Associate RPO informed him that the RP staff was calibrating the whole-body counter for ^{32}P and would obtain a better estimate of intake after the calibration.

Researcher A told the Associate RPO that he was drinking large amounts of fluids.

The RP Office staff calibrated the whole-body counter.

Tuesday, August 22

The RPO had the staff remove the stock vials of ^{32}P from the PI Laboratory in order for laboratory workers to do a complete inventory analysis. The RPO suspended use of all radioactive material in the PI Laboratory.

Researcher A met with Physician B and complained of physical symptoms. Physician B referred him to the Director of Environmental Medicine and told him to drink lots of fluids.

The Associate RPO and Assistant RPO A met with the PI Laboratory personnel to explain what had occurred and why the use of radioactive material was suspended, and to discuss urine samples. Results of urine analyses revealed no additional contamination.

The Associate RPO requested the Laboratory Manager to account for the entire laboratory's use of radioactive material for the period from July 31 through August 22.

Assistant RPO A spoke with other laboratory groups on the third floor of the Center, informing them of the contamination incident and recommending that all personnel perform special surveys of themselves and their work areas. He also spoke with personnel on other floors.

Researcher A was directed to collect his entire urine volume over each 24-hour period and submit it to the RP Office, but the RP personnel did not make clear how to indicate start and stop times. No written procedures were given to Researcher A.

RP Office personnel analyzed the results of the whole-body counting and urine analysis and estimated an intake of about 500 microcuries (19 MBq).

Wednesday, August 23

Researcher A met with the RPO and Associate RPO. They discussed the need to collect accurate technical data and how to properly collect a 24-hour void sample. After this day, void samples were collected each day until noon for the previous 24 hours.

The RP Office staff calibrated the whole-body counter a second time. Researcher A obtained copies of data and references from RP personnel to calculate the dose. While reviewing the data, Researcher A found they erroneously used whole-body data without accounting for the limited field of the whole-body counter (65% of entire body). Researcher A stated he wanted to know the number so that he could determine whether it was high enough to warrant expressing his concern to the police.

Thursday, August 24

Assistant RPO A searched through the PI Laboratory waste previously collected, found ^{32}P vials that had been received August 7 and 14, and set them aside for later analysis.

Researcher A contacted the Campus Police to request an investigation. The RPO also contacted the Campus Police to confirm the seriousness of the matter and urge them to work with Researcher A.

2 p.m. Researcher A met with the Campus Police and reported his suspicion that the contamination by something he ingested was a deliberate act. A detective was assigned to the case.

Researcher A met with the Director of Environmental Medicine, who was a medical doctor. The Director told Researcher A that his symptoms did not appear to be from radiation and that perhaps he was drinking too much water.

Friday, August 25

Researcher A met with the RPO, Associate RPO, and the Director of the Center. Researcher A described his concerns with regard to the ability of RP personnel. The Director suggested that Researcher A contact an independent health physics consultant for confirmation.

August 20 through 30 (specific times unknown)

The radioactive material inventory assessment for the PI Laboratory showed that seven vials of ^{32}P containing a total of 700 microliters of ^{32}P were received during the 2-week period before August 20. RP Office records of material received agreed with the assessment. The Laboratory Manager accounted for all of the 700-microliter volume except for 51.7 microliters, of which 37 microliters were traced to a vial received August 14. This vial was calibrated to contain 1 millicurie (37 MBq) of ^{32}P on August 19; therefore the missing volume of activity from this vial was estimated by RP personnel to have been 473 microcuries (17.5 MBq) on August 14.

During this period, Researcher A also compiled a list of the quantities of ^{32}P he used during the past 2 months, totalling 613 microcuries (22.7 MBq), all of which he could account for.

The RP staff collected and analyzed daily whole-body counts and urine samples.

Thursday, August 31

The RPO and the Principal Investigator met with the entire research group to discuss developments and to announce the conditions under which the laboratory could be re-opened.

The RPO again permitted the use of radioactive material in the PI Laboratory. Control of material was tightened such that all radioactive material was kept in a locked storage area for which only three individuals had keys. All users were required to justify their need for material. This change in security of material affected only this laboratory group. A fourth person was later issued a key.

Assistant RPO A began more frequent surveys of all rooms in the PI Laboratory.

Friday, September 1

Researcher A met with the RPO, who informed him of the 450-microcurie (17 MBq) intake estimate. The RPO discussed NRC guidance on the use of the urine model.

Wednesday, September 6

11:32 a.m. Researcher A transmitted a report dated September 5, 1995, by facsimile to the MIT Campus Police. The report included information regarding radioactive material usage.

Researcher A met with the Health Physics Consultant for a third-party assessment of intake. They discussed differences between urine and whole-body counting.

Tuesday, September 12

The Radiation Protection Committee (RPC) met and discussed the contamination incident. The RPC decided to have the RPC Chairman send a letter to Researcher A expressing regret and concern and send a letter to the Campus Police urging assistance in determining how this occurred and how to prevent recurrence. At the meeting, the current intake estimate was announced as 500 microcuries (19 MBq), with a dose of 4000 millirem (40 mSv) to the individual.

Tuesday, September 19

Researcher A met with the Health Physics Consultant and submitted data collected from whole-body counts and urine samples. The Health Physics Consultant used INDOS, a commercially available dose calculation computer program, to evaluate the results and estimated 754 microcuries (27.9 MBq). However, he cautioned Researcher A that future information could change this value.

Friday, September 29

Researcher A met with the Health Physics Consultant who explained that choice of urine excretion fraction F_u affected the calculated intake. If this value is 0.75 (an average of literature values of 0.6 to 0.9), the calculated intake is 754 microcuries (27.9 MBq). The Health Physics Consultant stated that 0.9 would be a more appropriate value, which would yield an intake of 584 microcuries (21.6 MBq). The Health Physics Consultant told Researcher A that 0.9 was the value recommended by NRC. Using whole-body data, the Health Physics Consultant calculated an intake of 630 microcuries (23 MBq) [the Consultant's final estimate was 571 μCi (21 MBq)].

Thursday, October 12

The RP Office issued Researcher A a report of the intake assessment, which estimated his intake to be 563 microcuries (20.8 MBq) based on urine analysis and 579 microcuries (21.4 MBq) based on whole-body data.

Friday, October 13

The RPO learned that the magazine *Nature* planned to publish an article about the MIT contamination incident in the Thursday, October 19, 1995, issue.

Monday, October 16

10:15 a.m. The RPO notified NRC of the planned magazine article about the contamination event.

3 p.m. NRC Region I personnel began onsite review of the incident.

Tuesday, October 17

3 p.m. The NRC Incident Investigation Team arrived at MIT.

2 Human Factors Considerations

This section reviews the following aspects of the organization and practices of personnel at the Massachusetts Institute of Technology (MIT) associated with this event:

1. programmatic oversight of radioactive material,
2. security and control of radioactive material in the laboratories,
3. inventory and accounting of radioactive materials,
4. response to emergencies as demonstrated by this incident, and
5. deliberate acts.

Programmatic Oversight

Three groups of personnel were responsible for overseeing individuals who used radioactive materials: the Radiation Protection Committee, the Radiation Protection Office staff including the Radiation Protection Officer, and the project supervisors authorized by the Radiation Protection Committee to use, or supervise the use of, radioactive materials.

The Radiation Protection Committee

The Radiation Protection Committee members stated that their role was to establish policies to be implemented by the Radiation Protection Office. The Radiation Protection Committee minutes from January 1992 through September 1995 revealed that the Radiation Protection Committee routinely met about 2 hours every 3 to 4 months, received an agenda and any paperwork for review approximately 1 week before the meeting, approved requests for authorizations, and received summary reports from the Radiation Protection Office staff regarding various aspects of the radiation protection program at MIT.

Committee members were not required to, and did not, perform independent audits of the Radiation Protection Office activities or of the use of radioactive materials at MIT outside of their own laboratories. Committee members stated that since most were also authorized users, they were aware of the practices and activities of the Radiation Protection Office. Neither the Committee nor any other expert group critically evaluated the Radiation Protection Office or the radiation protection practices at MIT.

In the January 4, 1995, license renewal application, the licensee proposed the duties of the Radiation Protection Committee to include conducting periodic inspections and audits of the Radiation Protection Program and observing audits performed by the Radiation Protection Office.

Radiation Protection Committee members expressed a high degree of confidence in the Radiation Protection Office staff, relying on them to find problems in laboratories where radioactive materials

were used, and bring them to the Radiation Protection Committee's attention. The members first learned of the ^{32}P contamination incident when they received the agenda for the September 12 meeting.

The Radiation Protection Committee worked to resolve safety or compliance issues brought to their attention. Committee meeting minutes recorded disciplinary actions taken by the Radiation Protection Committee in the past, including issuing written warnings to project supervisors, reducing authorization periods, and modifying procedures for particular users and uses.

In January 1994, the Committee considered whether to renew the authorization for use of radioactive materials by the Principal Investigator who supervised Researcher A. The Radiation Protection Office staff had found chronic problems regarding failure to follow the MIT procedures for radioactive waste disposal, and the Radiation Protection Committee renewed the authorization for only 3 months instead of 2 years. The Radiation Protection Committee directed the Radiation Protection Office to increase surveillance in the laboratories under the Principal Investigator's authorization.

At the next meeting, the Committee was dissatisfied with the progress reported by the Radiation Protection Office and limited the extension of the authorization to 3 months with continued special audits by the Radiation Protection Office. The Radiation Protection Committee meeting minutes recorded no discussion about this issue after the May 1994 meeting; however, the authorization was not renewed for a normal 2-year period until June 1995.

The Radiation Protection Office

The Radiation Protection Office implemented the program established by the Radiation Protection Committee. The duties of this office included activities involving radioactive material such as enforcing the conditions of the NRC licenses, evaluating protocols, approving purchases, responding to incidents, inspecting and surveying laboratories, training users, monitoring internal and external exposure, overseeing deliveries and disposals of radioactive materials, and maintaining required records.

The Radiation Protection Office had the authority to take prompt corrective actions as needed. After learning of the ^{32}P contamination incident, the Radiation Protection Office suspended the authorization to use radioactive materials and confiscated all stock vials of ^{32}P possessed under the authorization of the Principal Investigator. After the incident, the Radiation Protection Office staff increased the frequency of their audits of the activities in the Principal Investigator's laboratory from monthly to weekly.

The Radiation Protection Office was part of the Environmental Medical Service at MIT, along with the Industrial Hygiene, Biosafety, and Medical Center offices (Figure 2-1). The head of the Radiation Protection Office staff was the Radiation Protection Officer, who managed a three-part radiation protection program, each of which had its own staff: the Bates linear accelerator program, the non-power reactor program, and the campus program. The staff for the campus program, which oversaw activities at the Center for Cancer Research (Center), consisted of an Associate Radiation Protection Officer and six Assistant Radiation Protection Officers, all of whom

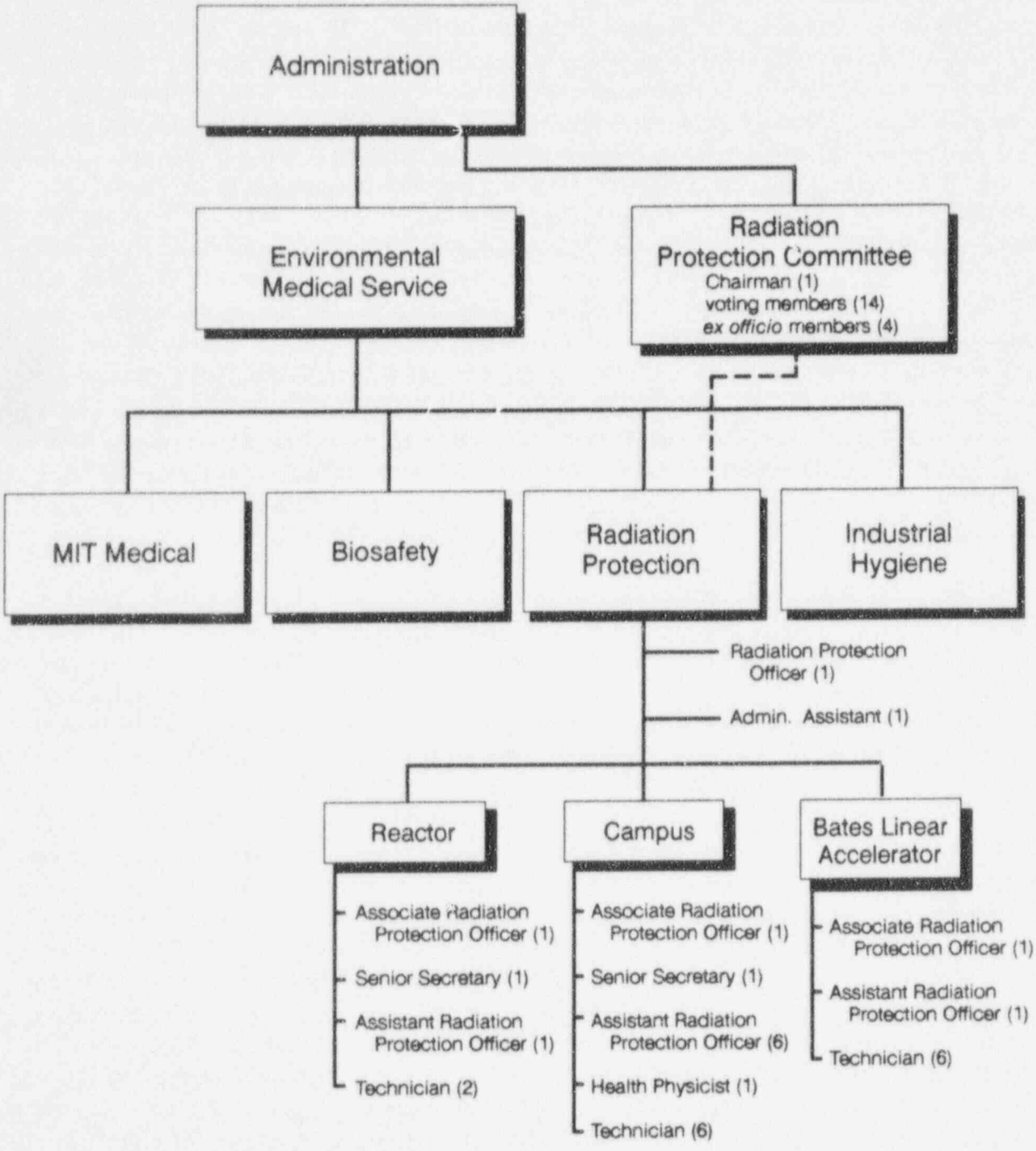

Figure 2-1 Organization and staffing of the Radiation Protection Program at MIT

were health physicists; an additional Health Physicist; six Radiation Protection Technicians; and a Secretary. The Radiation Protection Office staff members had a wide range of education and experience in health physics and participated in a variety of formal and informal professional and educational activities. The Associate Radiation Protection Officer for the campus program managed the daily activities of the Radiation Protection Office on the campus. Each Assistant Radiation Protection Officer was assigned responsibility for a set of authorizations. The Assistant Radiation Protection Officers also reviewed the records of surveys and other activities performed by the Radiation Protection Technicians for their assigned authorizations, and periodically inspected the work of the technicians. Assistant Radiation Protection Officer A was assigned approximately 40 authorizations including that of the Principal Investigator who supervised Researcher A.

Project Supervisors

The project supervisors were the individuals to whom the Radiation Protection Committee issued authorizations to use, and supervise the use of, radioactive materials. These individuals were responsible for radiological safety in the laboratories listed on their authorizations. All individuals who used radioactive material (users) under a project supervisor's authorization must have been registered and trained by the Radiation Protection Office, and must have had their names listed on the project supervisor's authorization form. According to Assistant Radiation Protection Officer A, authorizations were issued to 11 project supervisors in the Center, each authorization having from 5 to 30 users.

Researcher A used radioactive material under authorization CCR-M-6 issued to the Principal Investigator, which was renewed on June 7, 1995, with an expiration date of June 1997. Eleven laboratories, most of which were adjacent rooms in a laboratory "suite," were approved for use of radioactive materials on this authorization (Figure 1-1). The Principal Investigator's authorized possession limit for ^{32}P was 40 millicuries (1.5 GBq) , not to exceed 1 millicurie (37 MBq) per experiment. Other radionuclides were also authorized. The authorization listed 31 individuals who used radioactive material under the supervision of the Principal Investigator.

The Principal Investigator stated that he knew the storage location of materials in his laboratories and how much material was routinely ordered. He stated that he had not had any radiation safety training since he stopped doing laboratory work. The Principal Investigator also stated that his Laboratory Manager oversaw control of radioactive materials in his laboratories. The Laboratory Manager stated that he was a full-time technical staff member who also performed research. The Laboratory Manager coordinated many of the laboratory activities including ordering and taking inventory of radioactive materials. He and the users had attended the Radiation Protection Office training and received the MIT "Required Procedures for Radiation Protection" document. He and others stated that they observed most users comply with required radiation protection practices and procedures, such as wearing laboratory coats and dosimeters, and using proper equipment such as micropipetters and shielding (Figures 2-2 and 2-3). Personnel interviewed stated they rarely observed anyone eating or drinking in the laboratory, and did not recall observing anyone perform mouth-pipetting of radioactive materials.

Most of the laboratories in the Center were shared by multiple researchers and were used 7 days a week, often past midnight. Work in the laboratories could have required the use of radioactive

materials at any time. During late night and weekend work hours, the Principal Investigator, the Laboratory Manager, and the Radiation Protection Office staff were not usually on campus.

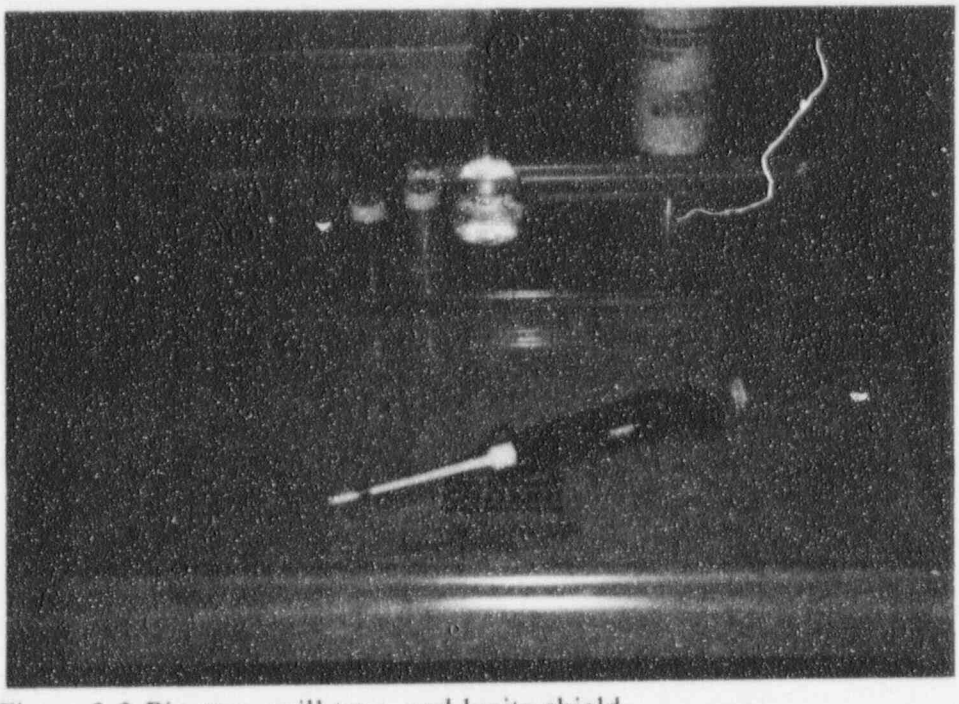

Figure 2-2 Pipetter, spill tray, and lucite shield

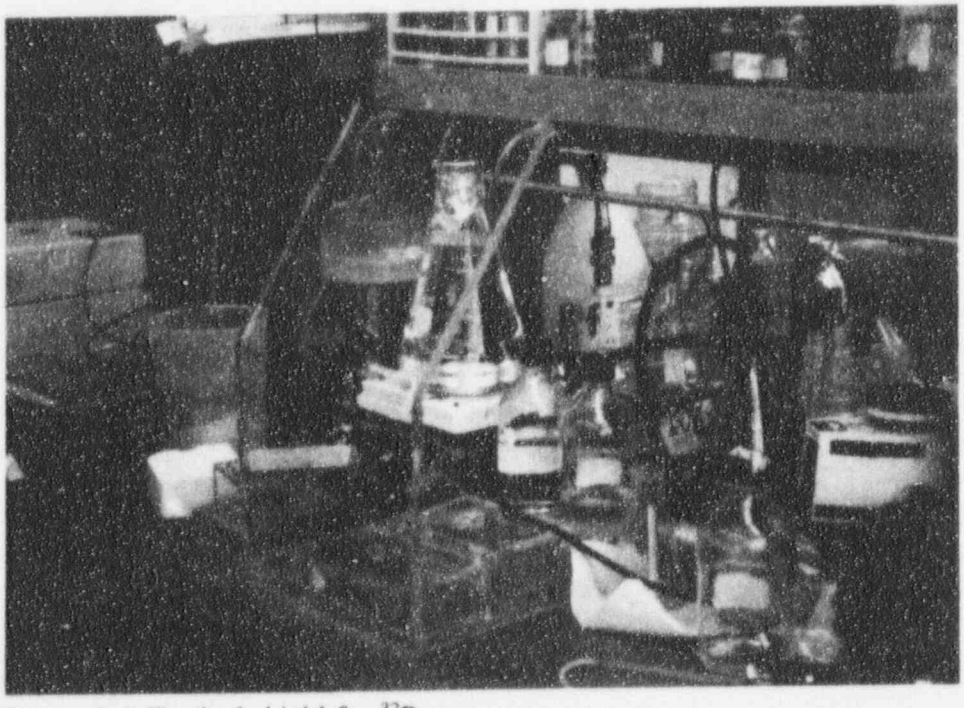

Figure 2-3 Typical shield for ^{32}P use

Security and Control of Material in Laboratories

The MIT Radiation Protection Officer stated that very few areas on the MIT campus were designated as restricted areas for the purposes of radiation protection, and that most radioactive materials laboratories in the Center for Cancer Research were considered controlled areas. A wide variety of individuals not registered as radiation workers had access to the laboratories in the Center; these individuals included delivery persons, technical staff, colleagues, friends, and family members. Most laboratory members and Radiation Protection Office staff members stated that laboratory workers would notice and challenge strangers entering the laboratories. The Radiation Protection Officer stated that MIT procedures required that all radioactive material be either under surveillance or locked, and that radioactive materials be locked at the end of the day. The Radiation Protection Officer stated that the requirement for control of radioactive materials is a key part of the MIT radiation protection training.

According to MIT personnel, the Center and other MIT buildings were locked by the MIT Campus Police in the evening and throughout the weekend. Members of the Radiation Protection Committee and the Radiation Protection Office staff stated that, outside of normal working hours, the Center could be entered only through the main door by persons knowing the keypad entry code. However, researchers working at the Center stated that entry was readily available through unlocked back doors and through doors accessible from connected buildings.

Researchers who used radioactive materials in the Principal Investigator's laboratory stated that laboratories in the Center were unlocked for normal work hours, and many were unlocked through the evening and night because individual users frequently worked during these late hours. The Laboratory Manager stated that he walked through the Principal Investigator's laboratory suite at the end of the evening before leaving for home, locking the access doors to the suite and letting individuals who remain in the laboratory know that he was locking the laboratory suite doors. The Principal Investigator stated that laboratory workers frequently had to remind each other to lock the laboratories in the evening, and that researchers considered locking the laboratories to be inconvenient since they may use equipment in various rooms during the course of their activities.

The MIT "Required Procedures for Radiation Protection," issued to users at the time of training, did not include guidance regarding maintaining surveillance of radioactive materials in use in their laboratories. Although the laboratories and the buildings were said to be locked outside of normal work hours, Team members freely entered the Center by entering the main door without needing the keypad code, by following other persons who had opened doors, by entering a door whose lock had been taped open, and by entering from adjacent unlocked buildings. Team members gained access to several laboratories where radioactive material was stored in unlocked refrigerators and which were not attended.

At the time of the event, stock vials of ^{32}P were stored in a freezer in the Principal Investigator's laboratory (Figure 2-4). The freezer did not have a lock. The freezer was located in an area that was not in the line of sight of users working in most areas of the laboratory. Most researchers stated it was unlikely that an individual from outside their laboratory would know where to look for stored radioactive material because, although storage areas were not purposely hidden, laboratories were crowded resulting in refrigerators, freezers, and other equipment being located in any

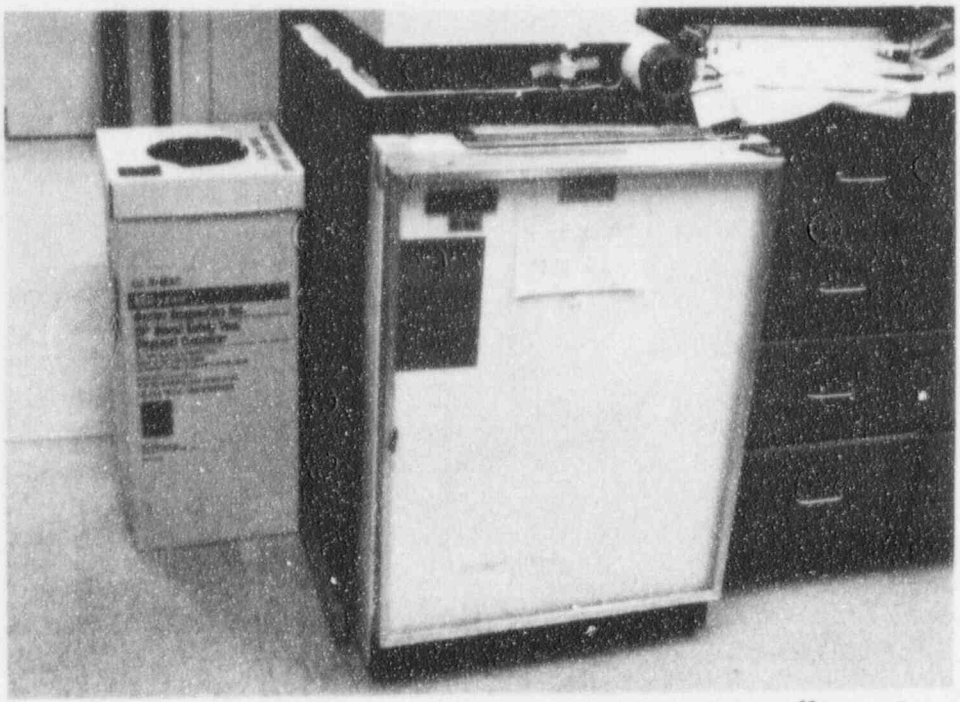

Figure 2-4 Freezer in Principal Investigator's laboratory where ^{32}P stock vials were stored

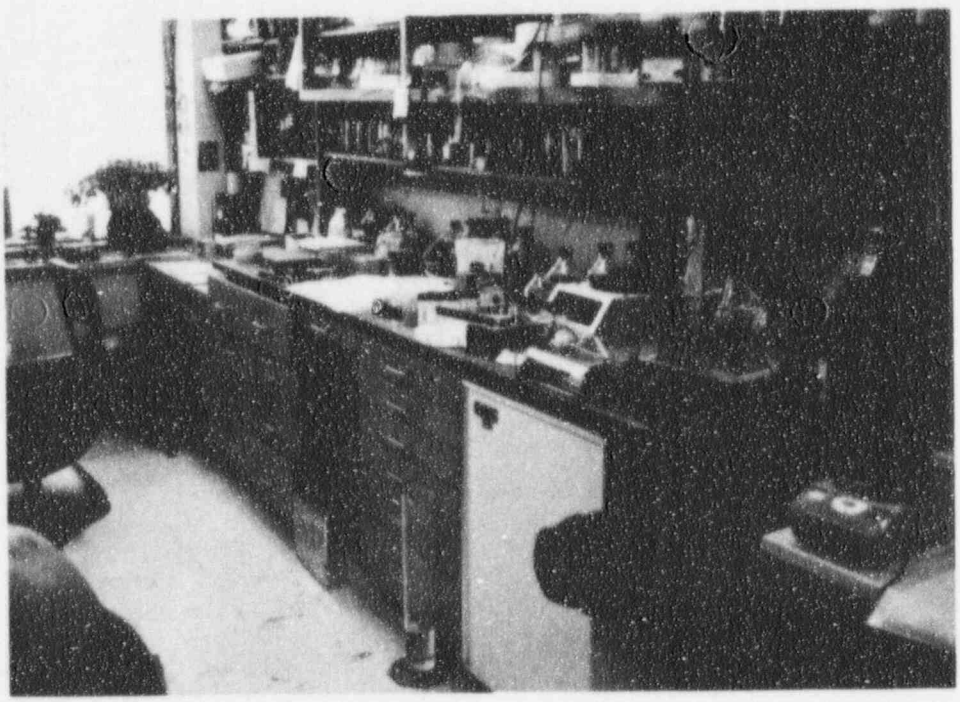

Figure 2-5 Typical laboratory

available space (Figures 2-5 and 2-6). Also, while various refrigerators and freezers had radioactive material labels on them, they may not actually have contained radioactive materials.

After the use of radioactive material in the laboratory was suspended and before its use was allowed to resume by the Radiation Protection Officer, a lockable box (Figure 2-7) was obtained

Figure 2-6 Laboratory where Researcher A worked

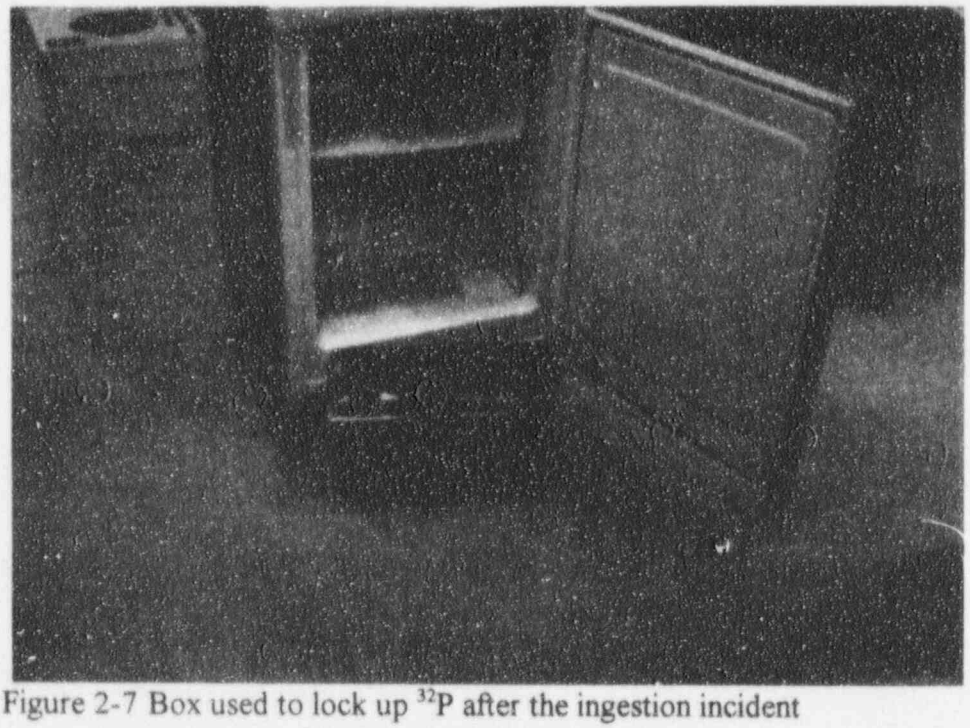

Figure 2-7 Box used to lock up ^{32}P after the ingestion incident

for the radioactive materials freezer for stock vials of ^{32}P compounds in the Principal Investigator's laboratory. Keys were initially given to only three individuals under this authorization, and these individuals removed the radioactive material for the researchers when requested. A fourth individual was later issued a key to help cover the 24-hour need for access to materials. After Team members found that the box could easily be removed from the freezer, MIT personnel secured the box to the freezer.

Radioactive material used in research activities was in a variety of forms located in a variety of containers and equipment on laboratory benches and in cold rooms. The Team did not observe any cold rooms, freezers, and refrigerators that were locked in the Center. Dry solid and liquid radioactive wastes from an individual researcher may have been stored for hours or days in small containers on laboratory benches before disposal in laboratory group containers in the laboratory (Figures 2-8 and 2-9). Radioactive waste stored in laboratory group containers was stored for several weeks or longer until the containers were full and the waste was picked up by members of the Radiation Protection Office for disposal. Radioactive waste containers in the Center did not have locks.

Although laboratories were routinely surveyed by technicians from the Radiation Protection Office, the survey results forms did not list access or security issues as items for routine review. The Assistant Radiation Protection Officers also performed laboratory audits, which were recorded on the form "Registered Laboratory Radiation Safety Audit." This form had the review item "unattended radioactive material properly labeled/shielded," but included no item to verify that unattended material was secured from unauthorized removal.

Inventory and Accounting of Material in the Laboratories

Researchers working for the Principal Investigator shared ^{32}P from common stock vials (Figure 2-10). Until the time of the contamination incident, they had access to the stock vials and took radioactive material from these vials as needed. According to members of the Radiation Protection Committee, this practice varied in other laboratories of the Center depending on the type and frequency of research using radioactive materials. Researchers stated that radioactive material was occasionally borrowed from laboratories under different authorizations, usually without informing the Radiation Protection Office.

Figure 2-8 Typical laboratory showing group radioactive waste containers

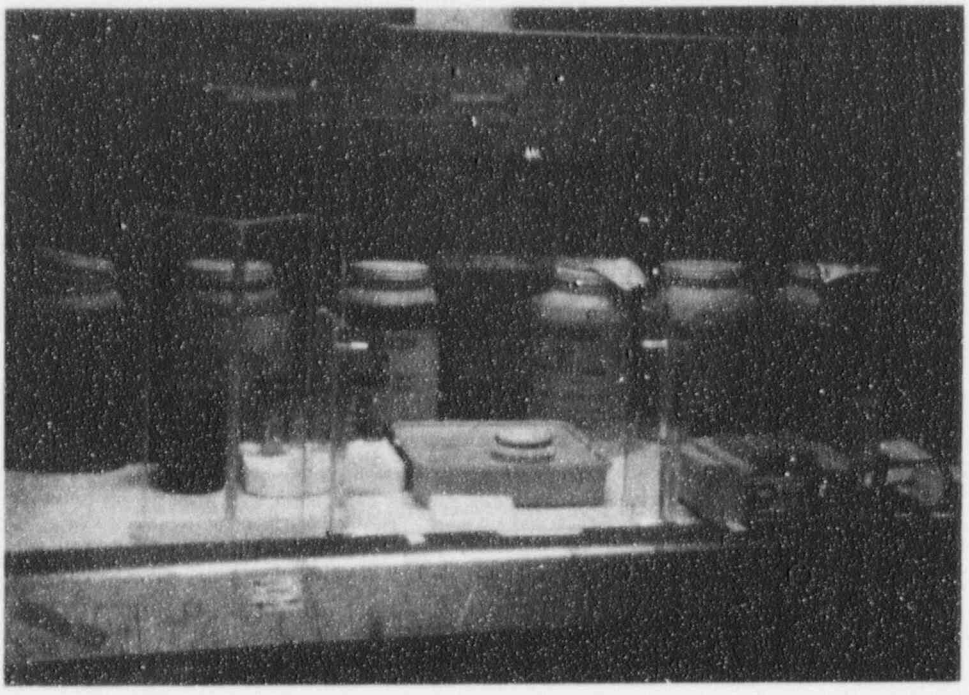

Figure 2-9 Radioactive waste containers stored in laboratory hood. Other radioactive material is also stored in this hood.

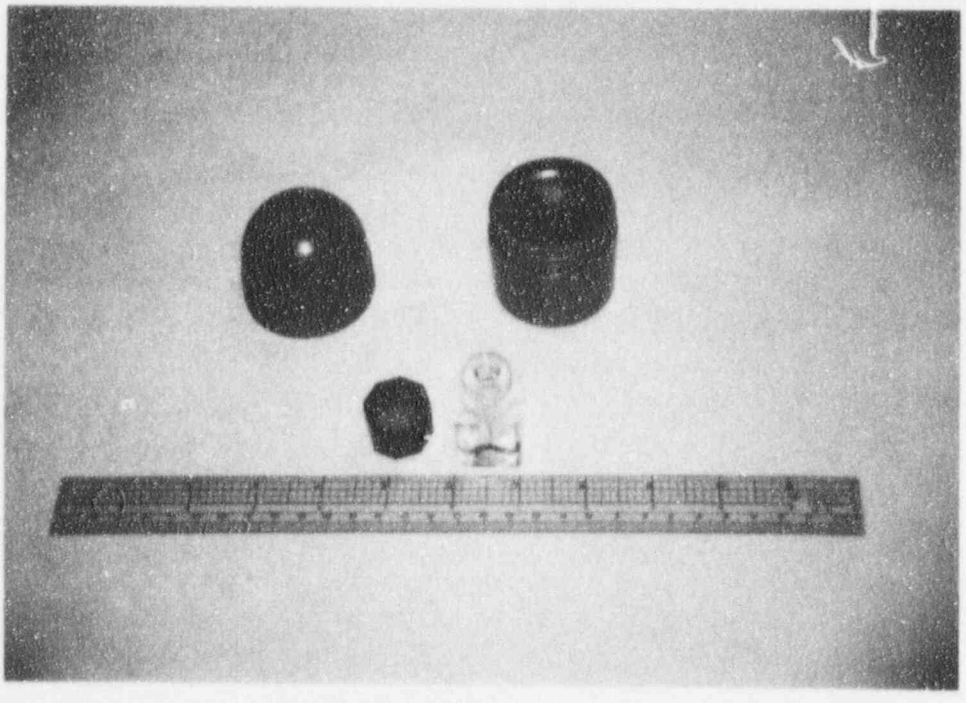

Figure 2-10 Typical stock vial in which ^{32}P compounds used in Principal Investigator's Laboratory were received and stored

In the Center, methods of recording inventory of radioactive materials varied according to the individuals' past practices at other institutions and the expectations of the project supervisor. Radiation workers accounted for the amount of radioactive material they disposed of as waste.

The researchers determined the amount of radioactive material they used by volume, not by activity. Purchased ^{32}P compounds in the Center typically had a concentration of approximately 1000 microcuries (37 MBq) in 100 microliters. Researchers usually used the material in 10-microliter aliquots, each of which contained approximately 50 microcuries (1.9 MBq) of ^{32}P.

In the Principal Investigator's laboratory, most researchers did not record the amount of material they removed from the stock vials, although the Principal Investigator stated they were supposed to record the amount taken in their laboratory notebooks. Radiation Protection Office staff members stated that most researchers recorded the amount of radioactive material they were using in their laboratory notebooks. However, although some researchers stated that they recorded the volume of ^{32}P they used, others stated that they recorded only the laboratory procedure they performed. No detailed inventory of radioactive material was maintained by anyone working under the Principal Investigator's authorization, although the Laboratory Manager stated that he assessed the amount of stock radioactive material on hand before ordering additional stock supplies.

After the contamination incident, the Radiation Protection Office required the Laboratory Manager to inventory all radioactive ^{32}P used from August 1, 1995, to the time that the contamination was found. The Laboratory Manager determined usage of ^{32}P by reviewing researchers' laboratory notebooks. He determined from receipt records that 700 microliters of ^{32}P (in 7 shipments of 100 microliters) were received during that time period. He reported he could account for all of the received volume except 51.7 microliters of material. Of this, 37 microliters came from a single vial received August 14. A volume of 37 microliters from that vial would represent an activity of 473 microcuries (17.5 MBq) of ^{32}P on August 14.

Radiation Protection Office staff members worked with the Laboratory Manager to develop criteria for managing the inventory and records of ^{32}P before allowing work with radioactive materials to resume. New procedures for inventory under this authorization required that incoming items be logged on an inventory sheet maintained by the Laboratory Manager, that radioactive material stock vials be kept in the locked storage box in the radioactive materials freezer, and that only designated individuals (initially three, later four) have keys to the box. These individuals would dispense radioactive materials to other users on request and keep a log of the dispensed material.

Licensee Emergency Response

The Associate and Assistant Radiation Protection Officers rotated, along with other members of the Environmental Medical Service staff, for a week-long assignment as the oncall responder to incidents that occurred outside normal work hours. The oncall individual was required to take the initial telephone call from Campus Police and evaluate if he or she could respond; if other safety professionals were needed, the oncall individual would contact them for assistance. This process was followed during the response to the contaminated individual.

The MIT "Required Procedures for Radiation Protection" (Required Procedures) and signs posted in laboratory rooms directed workers to contact the Radiation Protection Office during normal work hours, and to contact the MIT Campus Police at all other times, in the event of an emergency. Each listed the necessary telephone numbers.

When Researcher A found himself as contaminated, he used the MIT Required Procedures to determine that he needed to contact Campus Police. Although at first he had difficulty in finding

these instructions in the document, the Team observed that the appropriate signs were prominently posted and contained the information needed.

While waiting for the Radiation Protection Office staff to arrive at MIT, Researcher A continued to review the MIT Required Procedures document with the Campus Police Officer for additional information to determine if any other actions should be taken. They found one section of the "Emergency Procedures" that included an instruction to take contaminated individuals with minor injuries to the medical center. He showed this instruction to the responding Officer, who then accompanied him by foot to the medical center. This procedure also included instructions for contaminated individuals with no injuries, advising them to stay in the work area.

The Radiation Protection Office respondents gave Researcher A sample containers for urine collection. They requested that he collect daily urine samples for analysis. They instructed him to record the time and volume of each void, but they did not have written instructions to give him. Initially, Researcher A was asked to submit only a portion of each void. Upon finding unexpected variations in the first few days' samples, the radiation protection staff then asked him to submit the complete 24-hour volume. Again, no written instructions were given. The staff found additional problems with the collection time of the 24-hour sample. The 24-hour void samples were not collected propertly until the staff met with Researcher A a third time to set up procedures to start each sample collection container at noon. However, written instructions were still not given.

The Radiation Protection Office staff did not have written procedures for response to ingestion incidents other than those in the Required Procedures. Assistant Radiation Protection Officer A stated that on the evening that Researcher A found the contamination, he and the staff acted reasonably and appropriately based on their professional knowledge and experience. They also did not have written procedures to estimate the dose to Researcher A that evening, although most of the necessary information had been collected by the Radiation Protection Office.

Detection of Deliberate Acts

According to MIT personnel and Researcher A, in the week after the contamination incident was identified, Researcher A stated his belief that he was deliberately given radioactive material and inquired informally of colleagues about informing the police of this matter. Researcher A was told that, if he wanted the incident reported to the police as a deliberate act against him, he would probably have to do this himself. Researcher A contacted the Campus Police on Thursday, August 24, to request an investigation into the incident.

The MIT document, "Required Procedures for Radiation Protection," did not address the deliberate misuse of radioactive materials, although it did require radiation workers to notify the Radiation Protection Office of any known or suspected inhalation, injection, or ingestion of radioactive material. The MIT personnel were not aware of any incidents at MIT similar to this contamination with ^{32}P. Most of the personnel interviewed stated that about a week or so before Researcher A's incident they had heard of a similar contamination incident that occurred at the National Institutes of Health. However, most of the individuals had no prior knowledge of other incidents involving ingestion of radioactive material in general, or ^{32}P in particular. Assistant Radiation Protection Officer A stated that he had prior experience evaluating ^{32}P contamination during past employment at a facility where kilocurie quantities of ^{32}P were handled. He stated that in his experience, contamination by ingestion occurred infrequently.

3 Precursors

The following are summaries of all events the Team found involving licensees of broad scope and deliberate acts of contamination or irradiation of personnel since 1978. Examples of similar events involving medical and reactor licensees are also presented. The events were found by reviewing several databases and interviewing NRC personnel. No single database contained all instances of concern. Table 3-1 summarizes these events and includes the event at MIT.

University of California at San Francisco

On November 22, 1978, NRC State Agreements staff learned that a female graduate student in a microbiology laboratory at the University of California at San Francisco was found to have internal phosphorus-32 (^{32}P) contamination on November 15. She ingested the ^{32}P in late September, which was estimated at 3 to 5 millicuries (110–190 MBq). Additionally, external evidence of radiation exposure (skin rash and lesions) led investigators to find extensive ^{32}P contamination at the individual's home. Two friends of the student were also found to have been exposed to ^{32}P external contamination that resulted in skin rash and lesions. Subsequent investigation revealed that the contamination and ingestion events resulted from a deliberate act. The ^{32}P was believed to have been diverted from two shipments of stock material in the laboratory. The State of California, an Agreement State, requested and received investigatory assistance from NRC Region V.

Brown University, Providence, Rhode Island

On February 8, 1982, the State of Rhode Island notified the NRC's Office of State Programs of an ingestion of ^{32}P. On February 5, a female microbiologist discovered that she was contaminated when she turned on a survey meter before starting a laboratory procedure using ^{32}P. The individual had just finished eating lunch. Licensee personnel surveyed the entire floor of the laboratory building and found ^{32}P contamination only on the individual's laboratory coat, a piece of bread located on her desk in her office, and a sheet of paper in her office. The contaminated individual had eaten two pieces of bread from her lunch at approximately 2 p.m. Another researcher had also eaten two pieces of bread from the same lunch at approximately 12 p.m.; however, no uptake of ^{32}P was found in this person. On February 17, the licensee identified a second contaminated individual. On February 4, this person ate a piece of candy from the female microbiologist's desk. The licensee estimated the ingested amounts to be 157 microcuries (5.8 MBq) for the first individual and 25 microcuries (0.93 MBq) for the second. The licensee also estimated a maximum skin dose of 1100 to1500 rads (11–15 Gy) to a small skin area of the first individual as a result of the laboratory coat contamination. On February 5, the licensee notified the university police, who investigated the matter with the assistance of the State and local police. The university reported to the State that their investigation concluded that the contamination was deliberate, but did not produce a suspect.

Washington University, St. Louis, Missouri

On March 25, 1983, Washington University in St. Louis, Missouri, reported that on March 18, a hemology laboratory was vandalized. A female laboratory assistant who had reported the vandalism was found to have iodine-125 (^{125}I) contamination on her laboratory coat. Subsequent analysis also showed ^{125}I contamination in her urine. Consequently, the laboratory assistant

confessed her responsibility for the vandalism and the ingestion. Her ingestion of radioactive material resulted in a 0.360 microcurie (13 kBq) thyroid uptake of ^{125}I.

Veterans Administration Medical Center, Bronx, New York

On August 8, 1984, the Veterans Administration Medical Center, Bronx, New York, notified the NRC's Region I office of an ingestion of ^{125}I. On August 3, a foreign senior researcher was discovered to have 524 microcuries (19 MBq) of ^{125}I in his thyroid. Neither the licensee nor the NRC concluded how the ingestion occurred. Although the individual routinely worked with millicurie quantities of ^{125}I, the individual denied having mouth pipetted or having used poor handling techniques. On July 28, the researcher had handled 7 millicuries (260 MBq) of ^{125}I and had not worn a glove on his right hand. Friends and co-workers were measured and did not have contaminated thyroids. The medical center took corrective actions including restricting all iodination procedures and use of iodine stock solution to normal duty hours and normal work days. The medical center monitored and referred the researcher for evaluation and support to prevent self-destructive acts.

University of New York, Albert Einstein Medical Center

On March 1, 1988, during a routine survey, a female student at the University of New York's Albert Einstein Medical Center was found to be internally contaminated with ^{32}P. Analysis of a urine sample from the student revealed 6000 counts per minute per milliliter. The student had not worked with ^{32}P in the recent past. The licensee performed surveys of the laboratories and the student's apartment and roommates and found no contamination. Consequently, the time and date of ingestion could not be determined. The licensee estimated the uptake to be between 400 and 800 microcuries (15 and 30 MBq). The licensee stated that the cause of the ingestion was most likely a deliberate act; however, neither the university nor the student would file a complaint with the authorities. Consequently, the case was never resolved.

Duke University, Raleigh, North Carolina

On April 20, 1988, laboratory personnel at the Duke University Medical Center were scanning samples for disposal when they discovered that a female, postdoctoral researcher was radioactive. Later analysis determined that she was internally contaminated with 5.96 millicuries (220 MBq) of ^{32}P. Surveys of the laboratory and surroundings revealed only one instance of contamination, which was isolated to a food item. While the university would not support the possibility of a deliberate act, no likely accident scenario could be determined.

University of California, Irvine, California

On June 18, 1991, the State of California notified NRC Region V that the licensee had reported a thyroid burden of 78 microcuries (2.9 MBq) of ^{125}I in a foreign researcher. During a routine laboratory survey, the researcher appeared to be contaminated. When the contamination could not be removed and the most intense spot appeared at the front of the researcher's neck, the researcher was sent immediately for a thyroid bioassay which indicated approximately 78 microcuries

(2.9 MBq) of ^{125}I in the thyroid. Nose, mouth, and throat samples indicated an ingestion pathway. The university and the State investigations revealed that the isotope was most likely self-ingested.

Hospital for Sick Children Research Institute, Toronto, Canada

On November 27, 1992, a male worker at the Bayview Clinic in Toronto, Canada, was found to have ingested radioactive material. The Atomic Energy Control Board (AECB) of Canada and the Toronto Metropolitan Police jointly investigated the event and found that the worker had been deliberately contaminated with ^{32}P by his roommate who worked at the Hospital for Sick Children Research Institute in Toronto. The perpetrator had misappropriated the material from the institute and intentionally contaminated his roommate's food or drink in order to cause harm. The AECB estimated the dose to the individual to be 1.9 rem (19 mSv). In later inspections, the AECB found poor controls of radioactive material at the research institute. The perpetrator was eventually arrested and convicted.

National Institutes of Health, Bethesda, Maryland

On June 30, 1995, the National Institutes of Health (NIH) informed an onsite NRC inspector that they had responded to a reported contamination of a pregnant female researcher. NRC responded immediately by establishing an Augmented Inspection Team (AIT) from Region I. The researcher's total intake was estimated by NIH at 580 microcuries (21 MBq). Further investigation showed that the researcher's husband was also contaminated. Eventually, 26 additional personnel were found to be internally contaminated, and the source of their contamination was found to be a water cooler within the facility. These individuals did not receive as large an intake as the first researcher. At the time of this report, the final AIT report had not been issued. On October 27, NRC Region I issued a Confirmatory Action Letter to NIH because of concerns regarding security of radioactive material.

Similar Events Involving Medical and Reactor Licensees

Events involving deliberate contamination or exposure have also been reported by medical and reactor licensees. For example, on March 22, 1993, at the Veterans Administration Medical Center in Memphis, Tennessee, the licensee found that a 150-microcurie (5.6-MBq) cesium-137 dose calibrator source had been taped to the underside of the center drawer of a physician's desk. The source was found to be missing during a routine calibration check. On August 8, 1994, the licensee for the Quad Cities Nuclear Power Plant in Cordova, Illinois, notified the NRC that a small strontium-90 calibration source had been deliberately placed in the rear pants pocket of a worker's unattended street clothing while the worker was wearing plant-issued coveralls. The source was detected when the worker changed back into street clothing and set off a radiation monitor upon exiting.

On November 13, 1985, an Unusual Event was declared at the Tennessee Valley Authority's Browns Ferry Nuclear Power Plant because of the contamination of five Tennessee Valley Authority employees off site. The apparent cause of the contamination was a State of Alabama employee who, while acting as a drill controller, intentionally contaminated one of the employees by smearing technetium-99m on his laboratory coat and on an artificial wound during a drill. The other four employees became contaminated when they came in contact with the first employee.

Table 3-1 Deliberate acts at broad scope licensees

Date	Location	Agreement State (Y/N)	Source of Information	Isotope	Dose/Intake	Perpetrator	No. of People Contaminated
11/78	University of California San Francisco, CA	Y	interview/ State Programs	P-32	3–4 mCi (110–190 MBq)	suspected self	3
2/82	Brown University Providence, RI	Y	AEOD/PN	P-32	157 µCi 5.8 MBq	none found	2
3/83	Washington University St. Louis, MO	N	AEOD/ NUDOCS	I-125	0.360 µCi (0.013 MBq)	self	1
8/84	VA Medical Center Bronx, NY	n. a.*	interview	I-125	524 µCi (19 MBq)	none found	1
3/88	University of New York, New York, NY	Y	AEOD/PN	P-32	400–800 µCi (15–20 MBq)	suspected self	1
4/88	Duke University Raleigh, NC	Y	interview/ AEOD	P-32	5.96 mCi (220 MBq)	none found	1
6/91	University of California Irvine, CA	Y	NMSS briefing papers	I-125	78 µCi (2.9 Mbq)	self	1
11/92	Toronto, Canada	n. a.	interview	P-32	1.9 rem (19 mSv)	other convicted	1
6/95	NIH, Bethesda, MD	n. a.*	AEOD/RI	P-32	580 µCi (21 MBq)	none found	28
8/95	MIT, Cambridge, MA	N	IIT	P-32	579 µCi (21 MBq)	none found	1

* Federal Property

4 Dose Assessment

This section describes the methods used to assess the dose to Researcher A resulting from ingestion of phosphorus-32 (^{32}P). The dose is proportional to the magnitude of the intake, and the primary focus of bioassay procedures is to estimate that intake; therefore, much of the discussion will be devoted to the bioassay results and their interpretation, to obtain an estimate of the amount of material ingested. Dose calculations are considered in the final portion of this section.

Characteristics and Biokinetic Models

Phosphorus-32 is a pure beta radiation emitter with a half life of 14.3 days, and decays to stable sulphur-32 (^{32}S) by emitting a single beta particle with a 100-percent abundance. The maximum beta-ray energy is 1.71 MeV, and the average energy is 0.69 MeV; no photons are emitted. The *metabolic model* for phosphorus used in the present analysis was proposed by the International Commission on Radiological Protection (ICRP) in their ICRP 30 Report. The *metabolic model*, sometimes also referred to as the *biokinetic model*, describes the behavior of the element, in this case phosphorus, in the body following intake by inhalation, ingestion, or through the skin or a wound. The model permits estimation of the amounts of material deposited in the organs and tissues of the body, and the rates at which these materials are eliminated from the body through one or more excretion routes. The routes of excretion considered in this case are the urine and feces.

The biokinetic model for phosphorus predicts that about 80 percent of the ingested phosphorus is absorbed from the gastrointestinal tract and enters the bloodstream. From there, 15 percent is assumed to go directly to excretion through urine and feces, with a half-life of 0.5 day, 15 percent goes to intracellular fluids and is cleared with a biological half-life of 2 days, 40 percent is incorporated into soft tissue and is cleared with a biological half-life of 19 days, and 30 percent is incorporated into mineral bone and remains there essentially permanently. Phosphorus is one of a class of elements known as *bone seekers*, which means that a significant fraction of the amount taken into the body is eventually incorporated into the structure of the skeletal system. ^{32}P is retained on bone surfaces rather than distributed throughout the bone because of its relatively short half-life. The half-lives stated above in connection with the metabolic model refer only to biological clearance from the body, and therefore apply to any isotope of phosphorus. Superimposed on these clearance mechanisms is another elimination route, radiological decay, which in the case of ^{32}P, occurs with a half-life of 14.3 days.

The ^{32}P used by Researcher A in his research was supplied in the form of the labeled compound deoxycytidine 5'-triphosphate tetra- (triethylammonium) salt, packed in dry ice and kept frozen until just before use. The compound, which is involved in the synthesis of cytosine, a component of deoxyribonucleic acid (DNA), was used to label DNA segments. ICRP recommends that all ingested compounds of phosphorus be considered soluble, with the fraction that is absorbed from the gastrointestinal tract, f_1, taken to be 0.8 [ICRP 30]. This value was assumed in the present analysis. Inquiries with the manufacturer of the compound confirmed the validity of the assumption that the material will behave in the gastrointestinal tract as a soluble material, and therefore the f_1 value of 0.8 recommended by ICRP is appropriate.

Time of Intake

The time of intake is a critical parameter in estimating the magnitude of the intake on the basis of bioassay data. All calculations in this section are based on the assumption that an acute ingestion occurred around noon on August 14, 1995. This assumption is based on the following considerations:

- The first indication of internal contamination occurred on August 19. Therefore, contamination must have occurred on or before that date.

- August 14 was the last date Researcher A used ^{32}P before August 19. At the end of the day's work on August 14, Researcher A surveyed himself and found no unusual readings. It is therefore unlikely that the contamination occurred long before August 14, because it would have been detected during the August 14 survey.

- On August 21, Researcher A gave the licensee a set of underwear from his unwashed laundry for the previous 8 days, arranged in the order in which it was placed in the laundry bag, that is, chronologically. Surveys directly over visible urine stains on the underwear showed radioactivity for all underwear worn, starting with that worn from the morning of Monday, August 14, to the morning of Tuesday, August 15.

- Assuming that the intake was not a result of an accidental splash or spill but that the activity was ingested with food, the time of day on August 14 at which intake occurred was estimated to be noon. This estimate was based on Researcher A's recollection that he ate his lunch at that time, and also his recollection that this was the food left in the laboratory's food refrigerator on the previous day.

Bioassay Data

Bioassay describes the method of estimating the amount of radioactive material in the body by measuring radiations emitted from the body or by measuring the radioactive material content of excreta such as urine or feces. After discovering the internal contamination on the evening of August 19, Researcher A obtained a sample of his own urine and verified, by liquid scintillation counting (LSC) in his laboratory, that it contained radioactive material. The sample was later assayed by the licensee and showed a background-corrected activity of 8,000 disintegrations per minute (dpm). Later that evening at the campus medical center, a blood sample was drawn and given to the licensee to assay for radioactive content. The count revealed an estimated activity in the blood of 1.4×10^{-3} microcuries per milliliter (52 Bq/ml).

The licensee started whole-body counting (WBC) of Researcher A on August 19, and continued nearly daily WBC through August, September, and part of October. The licensee also started daily urine analysis on August 19, but did not start strictly controlled 24-hour urine collection until August 25. Before that date, the licensee had instructed Researcher A to estimate his own urine void volumes and give the licensee a sample for analysis. The licensee stated that they did not obtain reliable data, and the urine LSC results during that period showed very wide daily fluctuations that could not be attributed to normally expected biological variability. These fluctuations may have resulted in part from large variations in daily urine output, which on some

days reached up to 7 liters, in addition to misunderstandings regarding the start and end times for each 24-hour urine collection period.

Recognizing the uncertainty in the urine data obtained during the period August 19 to 25, the licensee did not use it in their intake assessments, and NRC and its contractors also did not use it. However, even though the early data was not used, the assessments were not hindered because extensive reliable data was obtained after August 25.

Whole-Body Counting

Researcher A was counted on a chair-type whole-body counter developed and built at the Massachusetts Institute of Technology (MIT) by the Radiation Protection Officer. The counter's design features and operating characteristics were described in detail in a journal article published in 1970 [Masse]. It consists of a chair lined with 0.5-inch (1.3-cm) thick lead in which the subject sits, and a 3- by 3-inch (7.6- by 7.6-cm) sodium iodide detector placed in a 2-inch (5.1-cm) thick lead shield. The detector in its shield is held in a fixed position relative to the chair. Figure 4-1 shows the counter in the licensee's counting laboratory.

As a pure beta emitter, ^{32}P does not emit photons that produce clearly defined peaks that could be seen in the detector output. The licensee therefore relied on measuring the bremsstrahlung radiation produced in the person's body as a result of interactions of the beta radiation with the body tissues. This method is used frequently in cases of pure beta emitter intakes, and has been documented in the professional literature.

The bremsstrahlung energy spectrum is a continuous spectrum that reaches maximum intensity at zero energy and declines steadily toward higher energies, reaching zero intensity at an energy equal to the maximum energy of the beta radiation, in this case 1.71 MeV. However, absorption of the low-energy photons in the body and in the detector housing produces a distinct peak at an energy level that depends on the extent of the absorption. Figure 4-2 shows an example of the bremsstrahlung spectrum obtained for Researcher A.

The licensee used a test object, called a *phantom*, made of laminated masonite layers to calibrate the whole-body counter for the bremsstrahlung spectrum. Masonite is a fiberboard made of pressed wood fibers. The phantom consisted of three separate segments that could be stacked in the chair, representing the chest, the abdominal region, and the upper thighs. Each of the sections contained holes in which plastic bottles could be placed to simulate the main internal organs. Figure 4-3 shows the three sections of the phantom. The bottles and the activities they contained during calibration were as follows:

Thighs (2 bottles)	14.8 μCi each	(0.55 MBq)
Kidneys (2 bottles)	14.8 μCi each	(0.55 MBq)
GI tract (1 bottle)	44.4 μCi	(1.6 MBq)
Liver (1 bottle)	29.6 μCi	(1.1 MBq)
Total	133.2 μCi	(4.9 MBq)

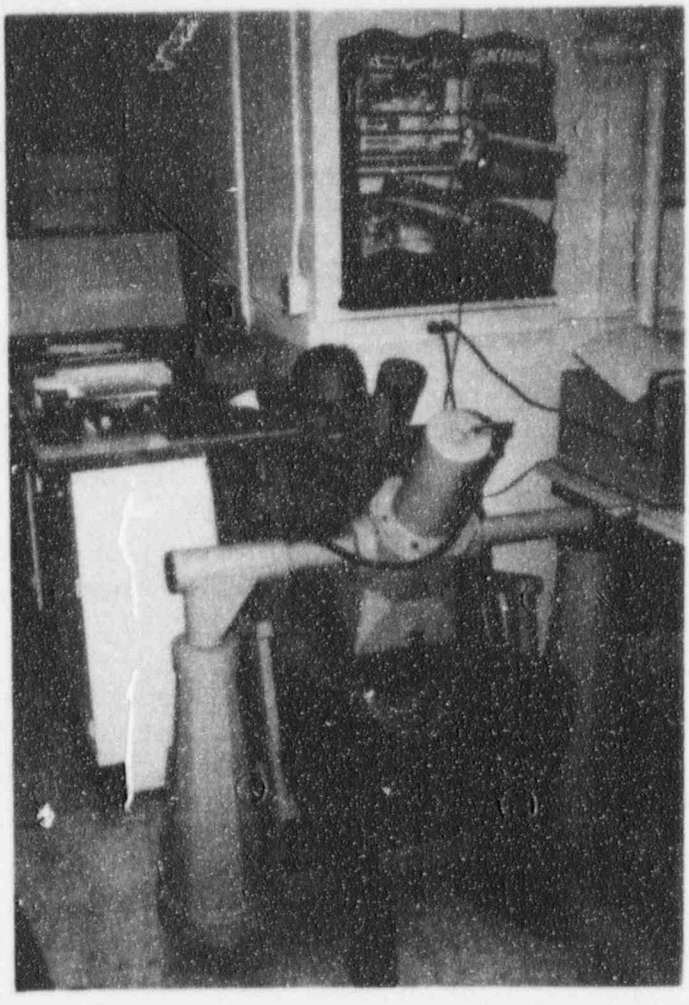

Figure 4-1 Chair-type whole-body counter used by the licensee to measure Researcher A's body content of ^{32}P

The relative activities were selected to be proportional to the sizes of the organs they represented. The bottles representing the lungs did not contain any activity because the ^{32}P was ingested, and is therefore not expected to be present in the lungs. The licensee prepared the solutions used in the calibration from a 500-microliter solution containing 1.2 millicuries (mCi) ^{32}P. The activities used in the phantom were measured on the liquid scintillation counter in the Radiation Protection Office. A 600-second calibration measurement gave an integrated count of 94,185 over the entire energy spectrum. Using this count, the licensee calculated a calibration factor of about 660 counts per 10 minutes per microcurie based on a total activity of 133.2 microcuries (4.9 MBq) in the phantom, and a background count over a 600-second interval of about 6300 counts. The background count was determined with the phantom in place in the chair, but without source inserts. Figure 4-4 shows an example of a background count with a phantom in the chair. The licensee stated that they counted several persons in the chair to compare the backgrounds obtained in this manner with that obtained using the phantom without any radioactive sources in it. The licensee found no significant differences and therefore used the phantom in background determinations. Figure 4-5 shows the phantom in the counting position in the whole-body counter.

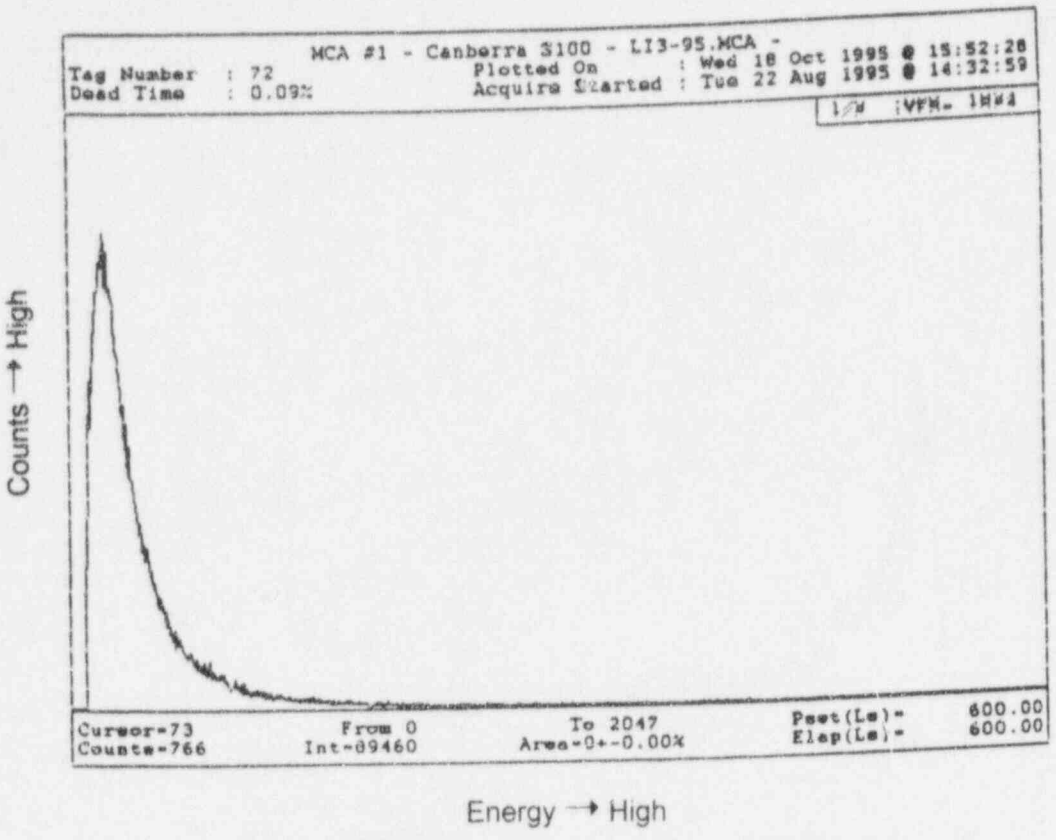

Figure 4-2 Bremsstrahlung spectrum obtained by the whole-body counter for Researcher A. The x-axis is the energy scale and extends from 0 to 2 MeV. The y-axis gives the counts per energy interval, or channel.

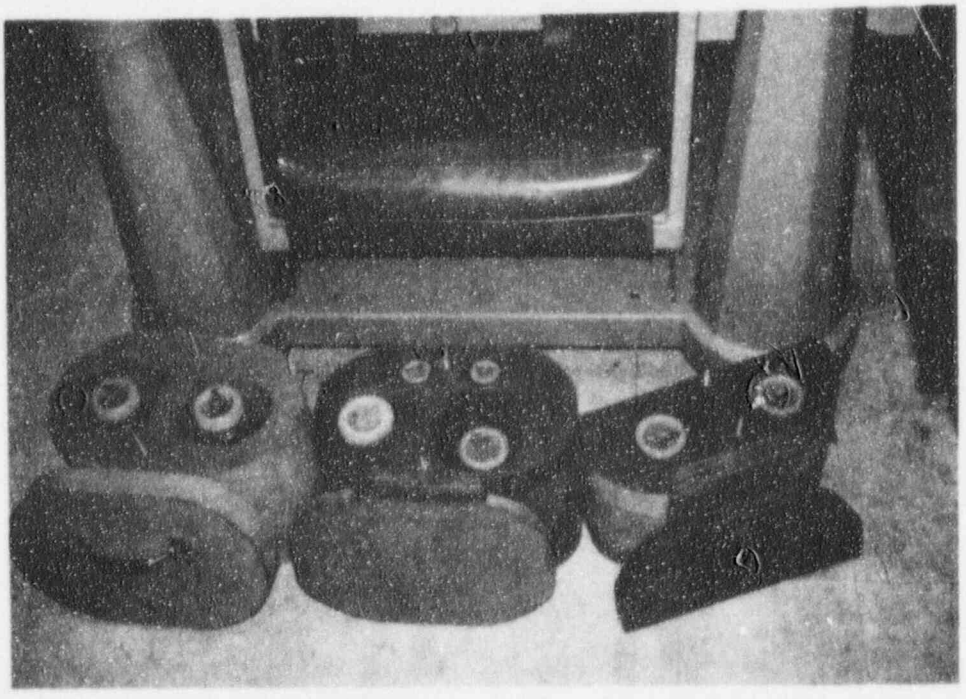

Figure 4-3 The masonite phantom used in the whole-body counter, shown with the covers removed, exposing the plastic bottles that represent the internal organs

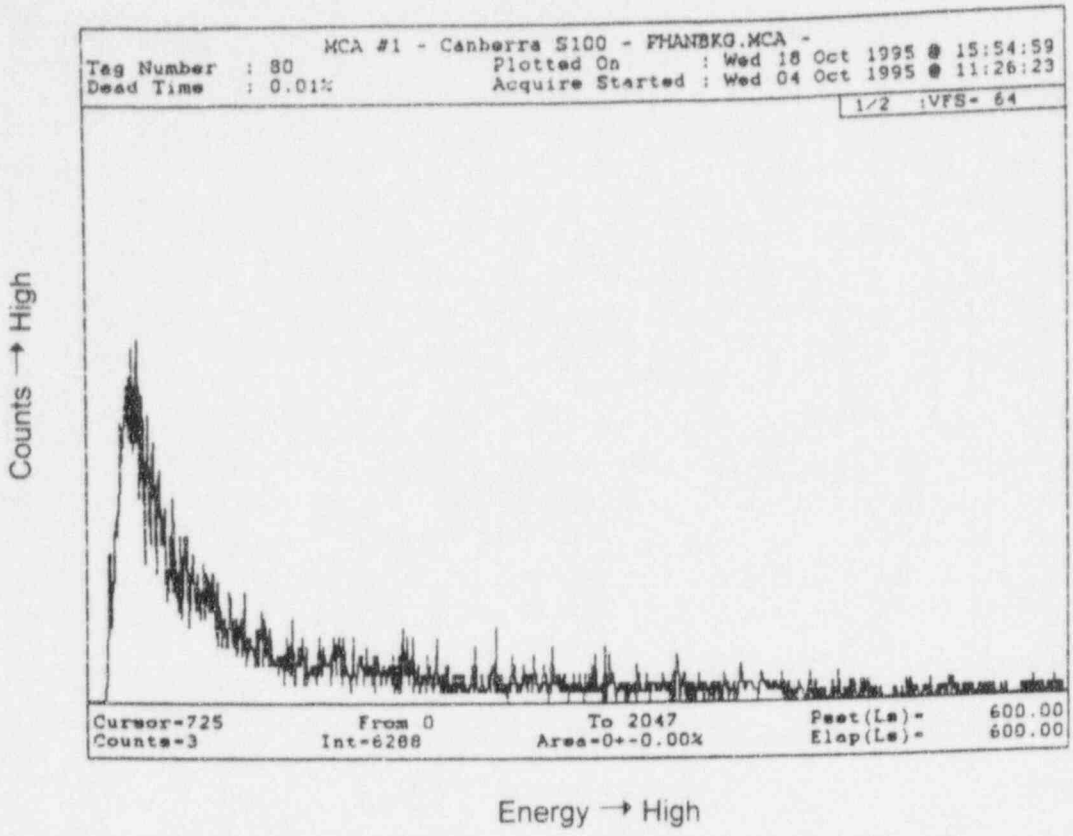

Figure 4-4 Background spectrum obtained by the whole-body counter with a phantom in the chair. The x-axis is the energy scale and extends from 0 to 2 MeV. The y-axis gives the counts per energy interval, or channel.

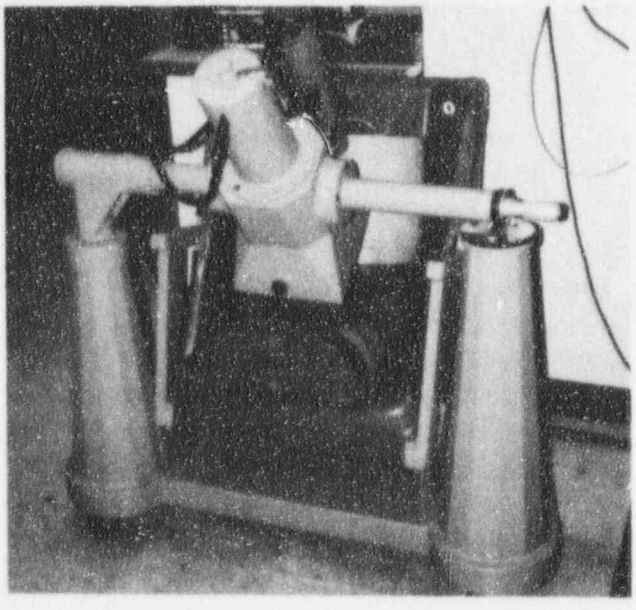

Figure 4-5 The three sections of the masonite phantom in the counting position in the whole-body counter.

The whole-body counter detector does not view the entire body of a subject sitting in the counting chair, and a geometry correction factor is therefore needed to convert the counts obtained by the detector viewing only part of the body to the equivalent counts in the whole body. Before the ingestion incident, the licensee had estimated a geometry factor of 0.65 for radionuclides uniformly distributed within the body, and used this factor in the analysis of data obtained in this case. This factor was also used by NRC and its contractors in their independent analyses of the data. Table 4-1 shows the results of the whole-body counts obtained for Researcher A up to the date on which the NRC Team obtained the data. The results shown were corrected for background, geometry factor, and counting efficiency. Figure 4-6 is a plot of the data shown in Table 4-1.

The licensee stated that the whole-body counter was not used frequently, and then only in routine screening of personnel working in the campus research reactor facility. The licensee also stated that they did not have a routine quality assurance or quality control program for the counter, and none was in place during the period in which the contaminated person was counted. The absence of a quality control program for the counter introduces some uncertainty regarding the validity of the data. However, the uncertainity is not high in this case because the analysis did not depend on isolated peaks in the spectrum but relied on the sum of the counts over the entire energy spectrum. Minor shifts in the energy scale would not have as a large an effect on such an integrated count as they would on counts under isolated peaks. Shifts in this case would only affect counts at the ends of the energy range, where the counts in this case were relatively low. The background was determined twice in August, and a value of 6288 counts per 10-minute interval was used for all subsequent counts on Researcher A. Although background counts were not verified after the initial determination, the licensee stated that the background did not change throughout the period. They based this assertion on data obtained in screening reactor personnel during August and September.

Aside from the usual uncertainties resulting from statistical variations and inaccuracies in determining the counting efficiency, the licensee's use of the whole-body counter in this case involved two additional significant sources of uncertainty: the value of the geometry factor and water phantom calibration. The geometry factor is used to adjust the counter results for the fact that the detector views only part of the body, estimated by the licensee to be 65 percent, whereas the desired result is to measure activity over the entire body. The value of 65 percent assumes that the activity is uniformly distributed throughout the body. The validity of this assumption is affected by variations in the size and position of the subject when seated in the chair as well as the distribution of ^{32}P in the body. ^{32}P may not be evenly distributed throughout the body because it is a bone seeker. According to the biokinetic model, approximately 30 percent of the activity will localize in bone, the remainder being evenly distributed in the body. The detector's field of view included the bones of the upper thighs, the spinal column and rib cage, and the pelvic bones, but not the skull, arms, lower thighs, or legs. Figure 4-1 shows the detector viewing a person sitting in the counting position. According to ICRP, the bone mass not included in the field of view of the detector is lower than 65 percent, possibly approaching 50 percent of the total [ICRP 23]. Soon after ingestion, the activity will be fairly uniformly distributed and the geometry factor of 0.65 in this case would probably be appropriate. However, this distribution changes with time, with the uniformly distributed activity decreasing because of decay and excretion, and the activity in bone contributing an increasing fraction of the counts in the detector. The effect of using a constant factor of 0.65 is to underestimate the whole-body activity by an increasing margin as time passes after intake. The upper limit for this effect, at a time when a large fraction of the activity in the body is in the bone, is an underestimation of the activity by not more than about 15 percent, and most likely by a smaller margin.

Table 4-1 Results of whole-body counting of Researcher A following discovery of the ^{32}P ingestion. All counts were decay-corrected to noon on the date shown.

Date	Activity µCi	Date	Activity µCi	Date	Activity µCi	Date	Activity µCi
8/19	263	8/31	103	9/14	44	9/27	19.8
8/21	204	9/1	99	9/15	41	9/28	18.4
8/22	194	9/5	76	9/18	34	9/29	16.5
8/23	178	9/6	69	9/19	28.3	10/2	14.5
8/24	165	9/7	65	9/20	28.5	10/3	13.5
8/25	157	9/8	66	9/21	27.8	10/4	12.3
8/28	129	9/11	50	9/22	25.8	10/5	12.3
8/29	122	9/12	49	9/25	22.3	10/6	11.1
8/30	109	9/13	45	9/26	19.8		
8/30	109	9/13	45	9/26	19.8		

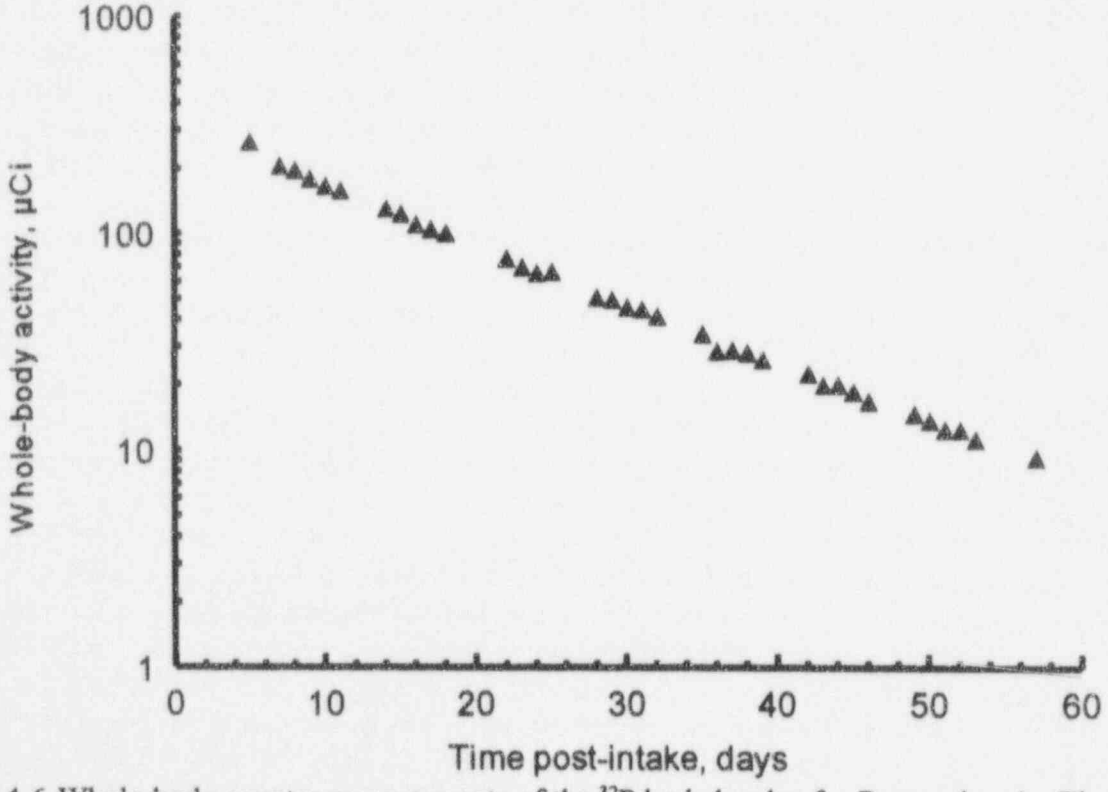

Figure 4-6 Whole-body counter measurements of the ^{32}P body burden for Researcher A. The earliest data is the count taken on August 19, 1995.

The second significant source of uncertainty is that the intensity of bremsstrahlung generation is proportional to the atomic number of the beta ray absorber. The effective atomic number of soft tissue is close to 6 and the atomic number for compact bone is close to 12. Therefore, compact bone is about twice as efficient in producing bremsstrahlung as is soft tissue. At the time of ingestion and shortly thereafter, most of the bremsstrahlung will be generated in soft tissue. However, as the ^{32}P activity in bone increases, and that in soft tissue decreases, an increasing fraction of the bremsstrahlung will be produced in bone. The intensity of the bremsstrahlung radiation per unit of activity in the body will therefore increase with time. The whole-body counter is calibrated using a phantom with the ^{32}P dissolved in water, which may be considered tissue equivalent. This factor is appropriate for times close to the time of ingestion. However, the calibration factor may become increasingly conservative as time from ingestion increases. Therefore, the activity in the body estimated by the whole-body counter may tend to be overestimated by an increasing margin with time after intake. Tests on this effect reported in the literature have shown that a factor of 1.5 to 1.7 is appropriate to account for the difference in bremsstrahlung generation between soft tissue and bone [Wenger]. These values were derived for strontium-90/yttrium-90 ($^{90}Sr/^{90}Y$), however, which has a different spectrum from ^{32}P. The appropriate factor in this case would have to be determined experimentally, but is expected to be roughly within the same range as that measured for $^{90}Sr/^{90}Y$.

The geometry effect and the bremsstrahlung effect are both time dependent, and act in opposite directions, the first causing underestimation of the body burden with increasing time, and the second leading to overestimation of the burden with increasing time. Although the effects will probably not cancel each other out, the net effect is likely to be small and will likely lead to conservative results because the effect of atomic number differences is probably dominant.

Urine Counting

All urine samples were counted in the liquid scintillation counter, a Packard Tri-Carb system, Model 2500TR, maintained in the Radiation Protection Office's laboratory. The system used an external barium-133 source for quench curve generation and contained software that permits automatic calibration, analysis of quality control data, and sample quench correction. The licensee maintained a routine quality control (QC) program for the system using hydrogen-3 and carbon-14 sources traceable to the National Institutes of Standards and Technology (NIST). Researcher A's urine was counted by adding 1 milliliter of urine to 10 milliliters of scintillation fluid in a 20-milliter counting vial. Two samples were prepared in this manner for each 24-hour urine void, and the counting results were averaged. QC tests were run each time the samples were counted, and the results, together with quench indicator data, were reviewed by the Associate Radiation Protection Officer. Each 24-hour urine sample was collected over the noon-to-noon period, and the LSC results were corrected for background and decay-corrected to the end of the respective collection period. LSC gross activity varied from a little over 1000 dpm on August 26 to a little under 200 dpm at the beginning of October. The counting time was set at 2 minutes for each sample, and background was on the order of 22 dpm. The 24-hour urine activity results are shown in Table 4-2 and plotted in Figure 4-7.

Table 4-2 Results of 24-hour urine analysis of Researcher A following discovery of the ^{32}P ingestion. Each count is decay-corrected to the end of the 24-hour collection period.

Date	Activity µCi	Date	Activity µCi	Date	Activity µCi	Date	Activity µCi
8/26	1.46	9/5	0.98	9/15	0.43	9/25	0.24
8/27	1.62	9/6	0.89	9/16	0.39	9/26	0.23
8/28	2.03	9/7	0.80	9/17	0.34	9/27	0.19
8/29	2.07	9/8	0.70	9/18	0.32	9/28	0.21
8/30	1.56	9/9	0.60	9/19	0.33	9/29	0.20
8/31	1.46	9/10	0.80	9/20	0.38	9/30	0.20
9/1	1.50	9/11	0.71	9/21	0.36	10/1	0.16
9/2	1.32	9/12	0.67	9/22	0.30	10/2	0.15
9/3	0.98	9/13	0.57	9/23	0.30	10/3	0.14
9/4	1.23	9/14	0.52	9/24	0.25	10/4	0.13

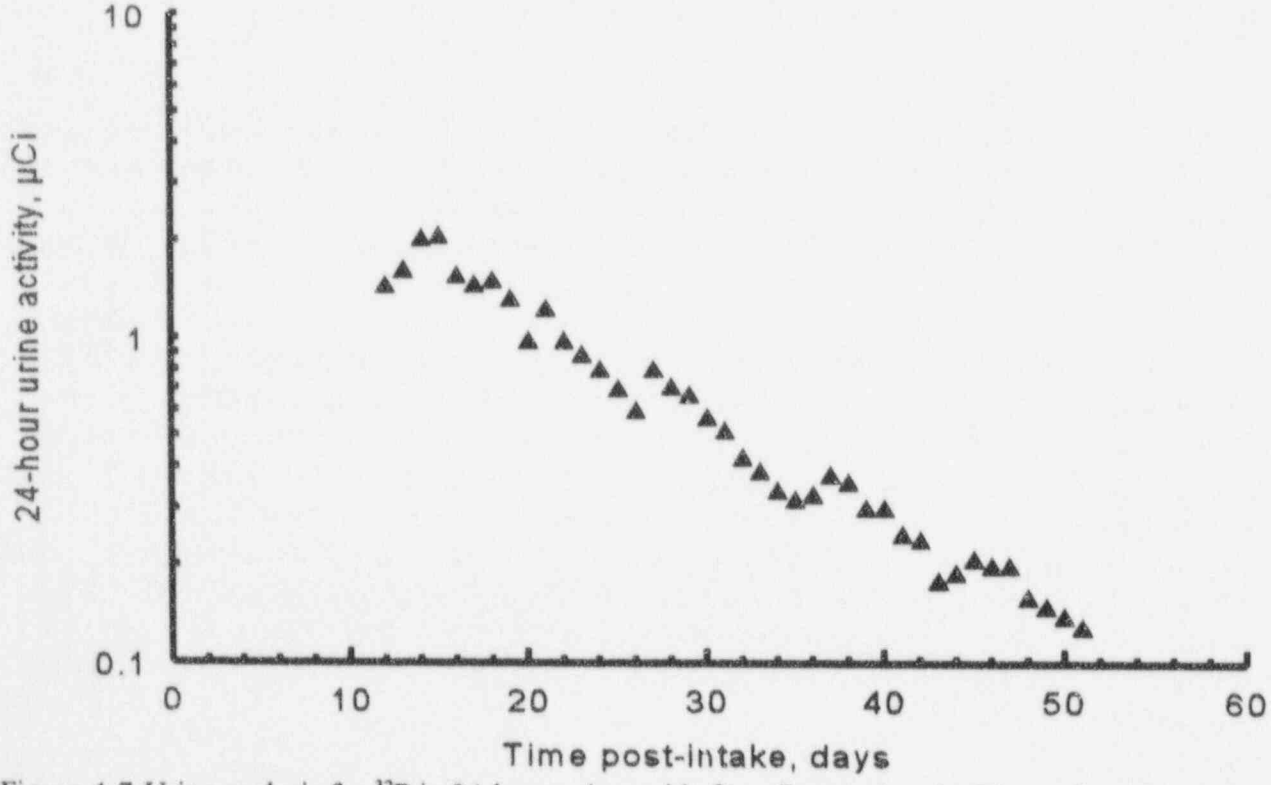

Figure 4-7 Urine analysis for ^{32}P in 24-hour urine voids from Researcher A. The earliest data point is for the 24-hour collection period ending August 26, 1995.

Researcher A's daily void volumes were substantially higher than the standard volume of 1400 milliliters per day used in ICRP 30 for Standard Man, and averaged about 2700 milliliters per day, even though he was not on any enhanced fluid intake program. Standard Man represents an average person, weighing 70 kilograms, used in internal dose calculations to derive intake limits, such as the Annual Limits on Intake tabulated in Part 20 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 20), and other quantities of dosimetric interest.

Initial Assessment of Intake

The licensee estimated the magnitude of the intake soon after discovery of the contamination on August 19. The basis of their assessment was the initial urine sample taken by Researcher A. The sample was counted on the liquid scintillation counter in the Radiation Protection Office laboratory, and gave an activity of 8,000 dpm per milliliter of urine. The radionuclide was determined to be ^{32}P because Researcher A worked only with ^{32}P, and the energy spectrum obtained from the liquid scintillation counter was characteristic of that radionuclide. The licensee assumed that the concentration of ^{32}P in body fluids was equal to that in the urine, and used a body fluid volume of 43,000 milliliters to estimate a total activity in the body of about 150 microcuries (5.6 MBq) [ICRP 23]. Concluding that the intake occurred a few days earlier, the licensee estimated that the intake was probably about twice the level in the body on August 19, or about 300 microcuries (11.1 MBq). The blood sample, which was also analyzed on August 19, gave an activity of 1.4×10^{-3} microcuries per milliliter (52 Bq/ml), but the licensee did not use this data in estimating the intake.

An alternative method to estimate the intake would have been to use urine excretion fractions, such as those tabulated in NUREG/CR-4884, "Interpretation of Bioassay Measurements," 1987. Using these tables, the expected 24-hour urine excretion fraction was about 1.4×10^{-2} of the intake on August 19. The urine volume excreted on August 19 was not known, and therefore it would have been necessary to use the standard adult volume, which is 1400 milliliter per day [ICRP 23]. Given a urine activity of 8,000 dpm per milliliter, the 24-hour excretion on August 19 is estimated to have been about 5 microcuries (0.2 MBq). As this is expected to represent 1.4×10^{-2} of the intake, the amount ingested would be about 360 microcuries (13 Mbq). Researcher A's average daily urine volume was substantially higher than 1,400 milliliters per day, and the estimated intake would have been correspondingly higher if this had been known at the time of the initial assessment. If the licensee had known and used the average daily volume of 2700 milliliters per day that was determined later, the intake estimate would have been about 700 microcuries (26 MBq). Alternatively, if the licensee had known and used the counting efficiency determined later for the whole-body counter, the body burden estimate based on whole-body counter measurements would have been 263 microcuries (9.73 MBq) on August 19. If the intake occurred on August 14, the tables in NUREG/CR-4884 for intake retention fractions would indicate a fraction of 0.417 on August 19, and the intake estimate would be about 630 microcuries (23 MBq).

After discovering the contamination on August 19, Researcher A attempted to estimate his intake using the results of the urine analysis he performed in his laboratory's liquid scintillation counter. He used information obtained from a literature search on the subject of internal dosimetry to interpret these results. He found that the expected urine excretion on August 20 was 0.252 microcuries (9.32 kBq) after an intake of 30 microcuries (1.11 MBq) of ^{32}P. Using his

measured urine excretion on August 20 of 6.21 microcuries (230 kBq), he calculated an intake of 24.61 times 30 microcuries (11.1 MBq), or about 740 microcuries (27 MBq).

In assessing Researcher A's contamination, the staff of the Radiation Protection Office performed an external survey of his body. The results of the survey are shown in Figure 4-8. The survey clearly shows that the activity had been incorporated into the bone by that time, as shown by the higher radiation readings over the head and knee areas. The higher readings over these areas were also due to the fact that the layers of tissue between the bone and the outer surfaces of the body are thinner than those in other parts of the body. Absorption in tissue layers is significant in this case because of the low energy of the bremsstrahlung radiations emitted by the ingested ^{32}P.

Licensee Intake Estimates

The licensee estimated the intake using both the whole-body count data and the urine analysis data. The calculations were performed using the commercially available computer code INDOS, marketed by Skrable Enterprises. The code implements the biokinetic models recommended by ICRP [ICRP 30 and 54]. The results of the licensee's final calculations are shown below:

From whole-body data	I = 580 μCi	(22 MBq)
From urine data	I = 560 μCi	(21 Mbq)

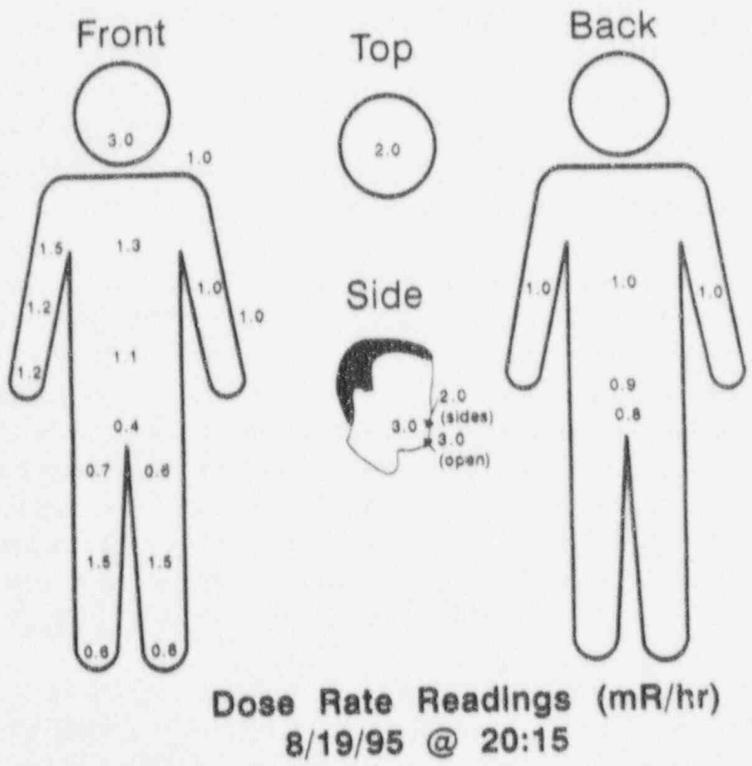

Figure 4-8 Survey map of radiation fields over Researcher A's body taken by the licensee on August 19, 1995.

Intake Estimates by the Independent Licensee Consultant

At the request of Researcher A, MIT provided the whole-body and urine analysis data to an independent health physics consultant and requested an assessment of the intake. The consultant used the INDOS program and obtained the following intake estimates:

From whole-body data	I = 570 μCi (21 MBq)
From urine data	I = 570 μCi (21 MBq)

Team Intake Estimate Using NUREG/CR-4884

The Team used NUREG/CR-4884 to analyze the whole-body and urine data and estimate the magnitude of the intake. The NUREG-series report includes tables of retention and excretion fractions for various times after inhalation or ingestion of a large number of radionuclides, including ^{32}P. The *whole-body intake retention fraction* is defined as the fraction of the intake expected to remain in the whole-body at any specified time after intake. The intake is calculated from this fraction using the equation

$$I = X_i/R_i \qquad (4\text{-}1)$$

where,

X_i = the whole-body activity obtained from whole-body count i and

R_i = the whole-body retention fraction for time t_i corresponding to the time of measurement i.

Equation 4-1 follows from the definition of the retention fraction R_i and is the equation of a straight line with slope I and zero intercept. Therefore, a plot of the whole-body count data versus the corresponding retention fractions should yield a straight line, the slope of which is an estimate of the intake. A weighted least-squares fit was used to obtain the best line that fit the data. The weighting factor was the variance of each data point. Figure 4-9 shows a plot of the whole-body count data and the best fit line. The urine data was analyzed in a similar manner, with the whole-body retention fraction replaced by the 24-hour intake urine excretion fraction. Figure 4-10 shows the corresponding plot for the urine data. The following intake estimates were obtained from measurements of the slopes:

From whole-body count data	I = 580 μCi (21 MBq)
From urine analysis data	I = 560 μCi (21 MBq)
Weighted mean	I = 570 μCi (21 MBq)

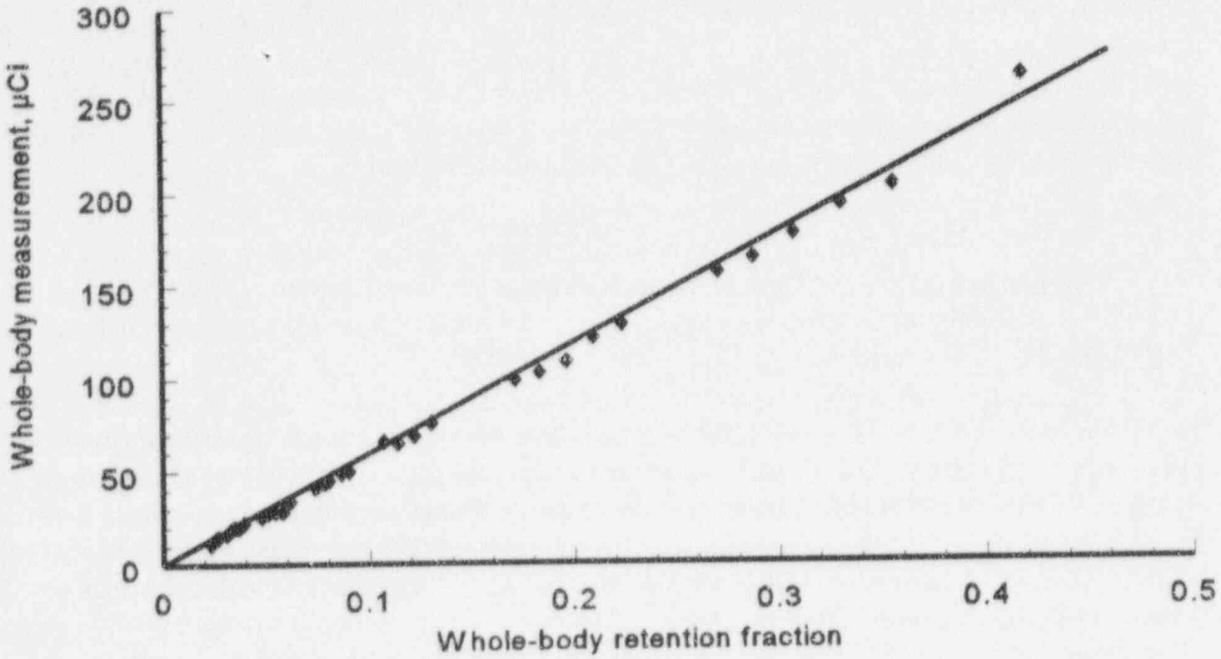

Figure 4-9 Plot of the whole-body counter data for Researcher A to estimate the intake using the tables in NUREG/CR-4884. The straight line was obtained by a weighted least-squares fit to the data.

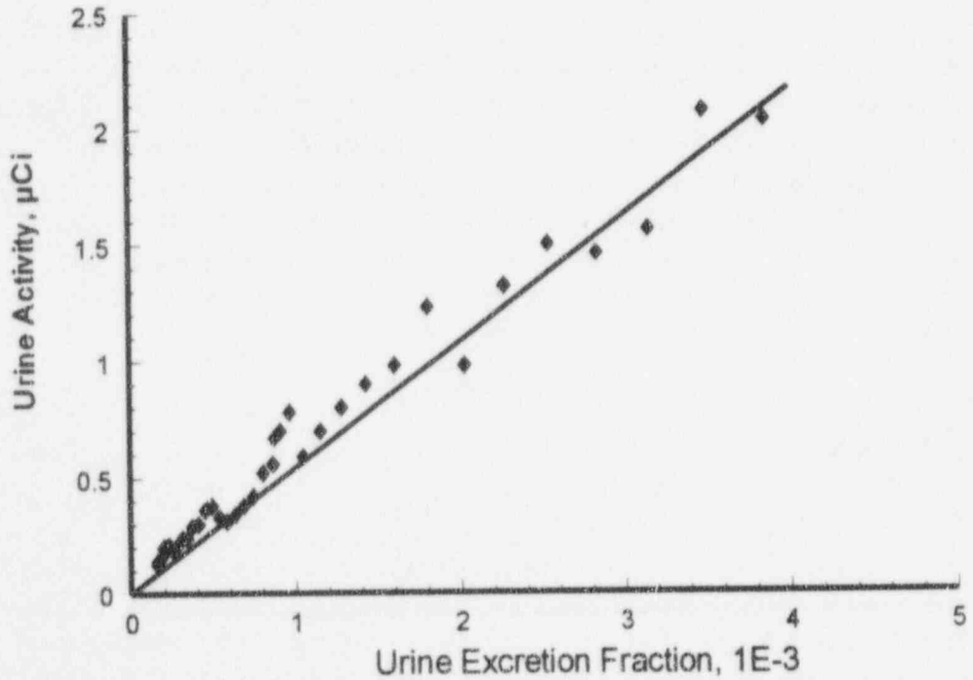

Figure 4-10 Plot of the urine analysis data for Researcher A to estimate the intake using the tables in NUREG/CR-4884. The straight line was obtained by a weighted least-squares fit to the data.

The uncertainties in both estimates arising from the statistics of least-squares fitting is of the order of a few percent, and the weighting factors used to calculate the weighted mean intake were the variances of the individual estimates from the whole-body and urine data.

The ICRP 30 model predicts that elimination during the time period shown in Figure 4-6 would include one component with an effective elimination half-life of 8.2 days, reflecting removal from soft tissues, and a second with an effective half-life of 14.3 days, reflecting removal from bone by radiological decay. A straight line drawn through the data in Figure 4-6 would have a slope that corresponds to an elimination, or effective, half-life of 11.2 days. This difference from 14.3 days may be due to the fact that the line probably represents some clearance from soft tissue in addition to clearance from bone by radioactive decay. The addition of tissue clearance has the effect of lowering the effective half-life that would be expected for bone clearance alone.

Team Intake Estimate Using Commercial Software

The computer Code for INternal DosimetrY (CINDY) was used to perform this part of the analysis. The code implements the models recommended in ICRP 30, those recommended in ICRP 54, and other specialized models. The latter are used for applications involving the alkaline earth elements, iodine, uranium, plutonium, and other radionuclides, but do not affect the ^{32}P calculations. The code was developed by Pacific Northwest Laboratories for the U.S. Department of Energy for evaluating internal exposures of workers, and has been used by many government and private organizations.

The results of using CINDY to estimate intake based on the whole-body and urine data are shown below:

From whole-body data	I = 560 μCi (21 MBq)
From urine data	I = 570 μCi (21 MBq)
Weighted mean	I = 560 μCi (21 MBq)

The estimated statistical uncertainties are of the order of a few percent, and the weighting factors used to calculate the weighted mean are the variances of the intake estimates based on the urine and whole-body data. The results of fitting the model to the data are shown in Figure 4-11 for the whole-body data and in Figure 4-12 for the urine data. The metabolic and other parameters used in the calculations were those recommended for Standard Man in ICRP 30.

Team Analysis of Data Submitted by Researcher A

Researcher A prepared his own set of urine analysis and whole-body count data and gave it to the Team for review and analysis. The whole-body data were obtained using the whole-body counter measurements obtained by the licensee. However, Researcher A chose to use a background count of 4280 rather than the 6288 used by the licensee. Researcher A obtained his background with the whole-body counter chair empty, whereas the licensee's count was obtained with a phantom in place. A background of about 6,000 counts was also obtained when the phantom was replaced by an uncontaminated person.

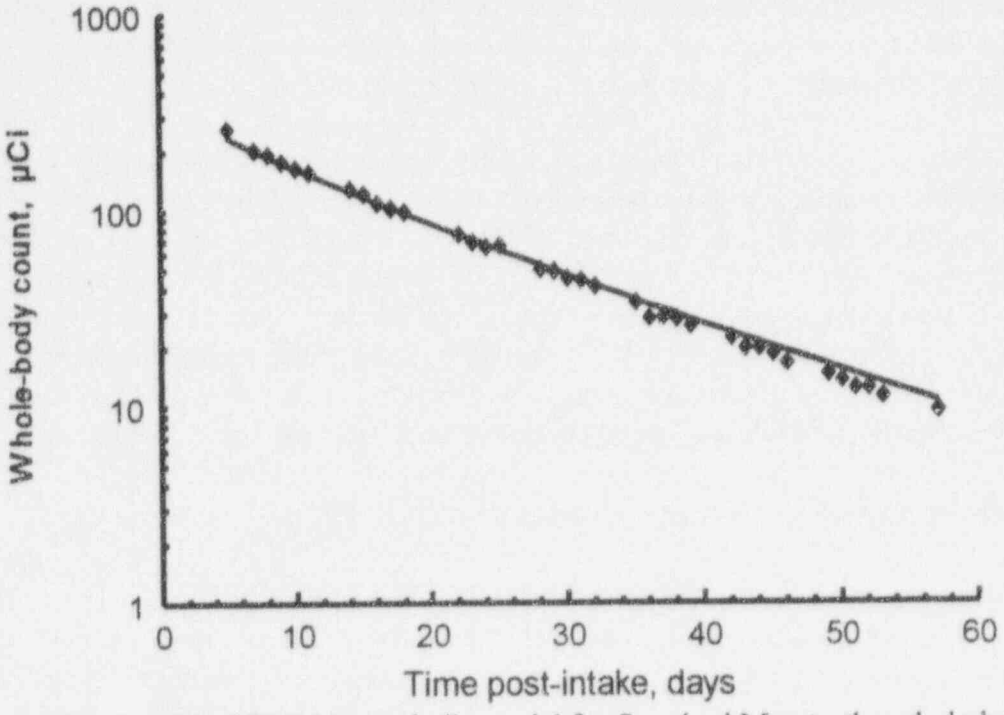

Figure 4-11 The fit of the ICRP 30 metabolic model for Standard Man to the whole-body counting data for Researcher A, obtained using the internal dosimetry computer code CINDY.

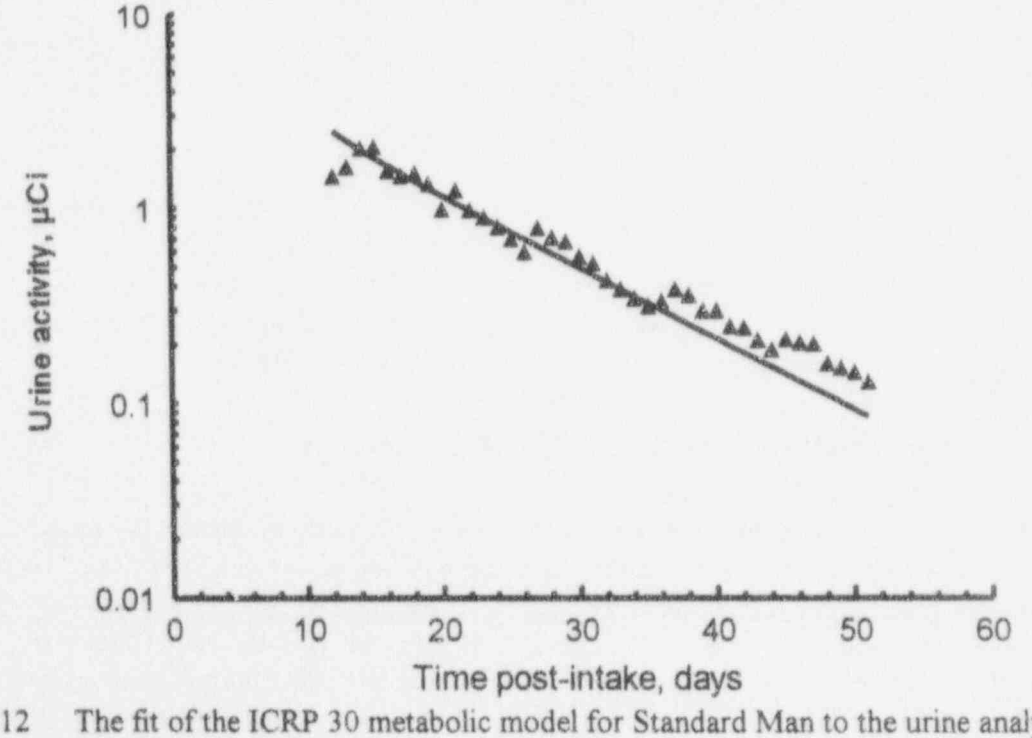

Figure 4-12 The fit of the ICRP 30 metabolic model for Standard Man to the urine analysis data for Researcher A, obtained using the internal dosimetry computer code CINDY.

Researcher A submitted a set of urine analysis data obtained by measuring a sample of the daily urine submitted to the licensee. The researcher made the measurements on the liquid scintillation counter in his research area on campus. In addition, Researcher A stated that his review of the relevant literature indicated that the appropriate value for the fraction of the activity excreted in the urine F_u should be 0.75 rather than the value of 0.9 used by the licensee, the Team, and the consultant. Using both values for F_u, as well as Researcher A's urine data and his whole-body count tabulations, in the CINDY code, the Team obtained the following intake estimates:

From whole-body data	I = 600 μCi (22 MBq)
From urine data	I = 730 μCi (27 MBq) (F_u = 0.75)
	I = 590 μCi (22 MBq) (F_u = 0.90)

The intake estimate based on Researcher A's urine data with an F_u of 0.9 is slightly higher than that based on the licensee's data because the urine analysis values have a consistent bias toward higher activities of the order of a few percent, compared with those obtained by the licensee, at least for data obtained during the first month after intake. Although the Team did not investigate the reason for this bias, the bias most probably results from slight differences between the calibrations of the two liquid scintillation counters used in obtaining the two sets of data. The difference between intake estimates is small, however, and is not significant in view of the uncertainties inherent in estimating the intake.

After considering Researcher A's reason for using a whole-body counter background of 4280, the Team concluded that it was not valid, and that the licensee's value of 6288 should be used for the following reasons. Placing a person in the whole-body counter during counting changes the scatter properties of the background radiation field and therefore changes the counter's response to that background. In addition, all persons contain naturally occurring radioactive materials, such as potassium-40, even if they have never worked with radioactive materials. This internal natural radioactivity will also contribute to the detector's output and must be considered. It is therefore important to place a phantom, or preferably a person of similar build as the subject to be counted, in the counter when measuring background. The licensee's masonite phantom contained an amount of natural radioactivity and created a scattering pattern that resulted in a detector response almost identical to that produced by an uncontaminated person. The licensee verified this similarity by counting a number of uncontaminated persons, and the Team verified it by counting an NRC representative who was present during the Team's site visit and who had never worked with radioactive materials.

The use of a urine excretion fraction F_u of 0.75 does not affect the whole-body counting results, but it does substantially increase the intake estimate based on the urine data compared with the estimate obtained using a fraction of 0.9. The literature includes values for this parameter ranging from 0.75 [ICRP 10A] to 0.9 [NCRP 54], but the more recent references, including NUREG/CR-4884, recommend a value of 0.9.

The availability of a series of whole-body and urine analysis data permits an estimate to be made of the urine fraction F_u for Researcher A. The total excretion rate, through both urine and feces, for ^{32}P may be obtained by differentiating the intake retention function R(t) with respect to time, giving Y(t), the instantaneous excretion function at time *t* after intake. At a week or more after intake, the

instantaneous excretion rate at time *t* may be considered equal to the 24-hour excretion rate at that time. Therefore, Y(t)/R(t), corrected for radioactive decay, should be equal to the ratio of the sum of the 24-hour urine and fecal activities at time *t* and the whole-body activity at that time. That is,

$$Y(t)/R(t) = [U(t) + F(t)]/W(t)$$

where U(t) and F(t) are the measured urine and fecal excretion rates, respectively, and W(t) is the measured whole-body activity, at time t after intake, and R(t) is the retention function recommended in ICRP 30. Calculating Y(t) and R(t) for the times after intake for which both whole-body and urine analysis data are available, and using the above equation, the ratio of urine to total excretion may be estimated. The result was found to be 1.0 with a 95-percent confidence interval of 0.4. Therefore, F_u is likely substantially higher than 0.8. This conclusion is based on the assumption that the standard retention function is representative in this case, and that both the urine and the whole-body data are accurate. Nevertheless, in view of these results, and the use of a value for F_u of 0.9 in the most recent technical literature, a value of 0.9 is considered justified in this case.

Team Intake Estimate Using Modified Biokinetic Parameters

The fit of the standard ICRP 30 metabolic model to the whole-body and urine data obtained for Researcher A was quite good, as shown in Figures 4-11 and 4-12. To improve the fit, especially for the urine data, the Team varied the standard model parameters and evaluated the change in fit visually. Analytical goodness-of-fit testing was not undertaken because it was deemed unwarranted, the visual evaluation being adequate in this case. The best fit was achieved by increasing the biological clearance half-life in the soft tissue compartment from 19 to 26 days. The effect of this change is shown in Figures 4-13 and 4-14. The fit to the whole-body data was not affected significantly, but the fit to the urine data was improved, particularly at the longer post-intake time end of the curve. The intake estimates using the revised parameters were

From whole-body data	520 μCi (19 MBq)
From urine data	620 μCi (23 MBq)
Weighted means	550 μCi (20 MBq)

Data Analysis by Independent Team Consultants

The whole-body and urine data obtained by the licensee and the urine data obtained by Researcher A were given to two independent NRC consultants to analyze and estimate the intake. One of the consultants, the Oak Ridge Institute for Science and Education (ORISE), used the tables in NUREG/CR-4884 to obtain the following intake estimates.

From whole-body data	I = 580 μCi (22 MBq)
From licensee's urine data	I = 560 μCi (21 MBq)
From Researcher A's urine data	I = 590 μCi (22 MBq)

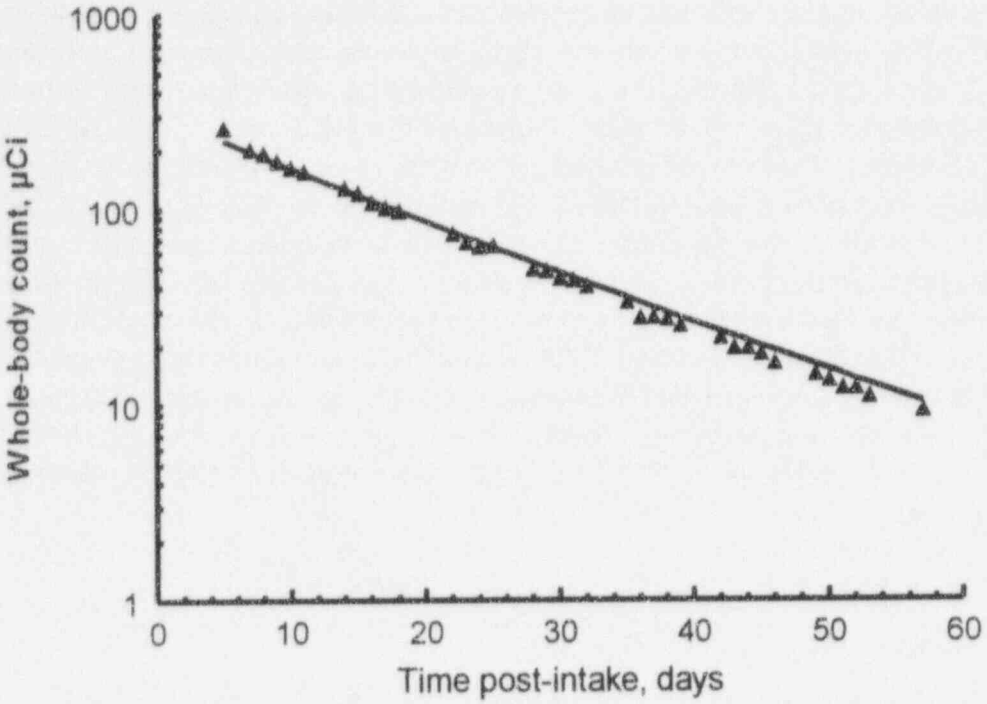

Figure 4-13 The fit of the modified ICRP 30 metabolic model to the whole-body counting data for Researcher A, obtained using the internal dosimetry computer code CINDY.

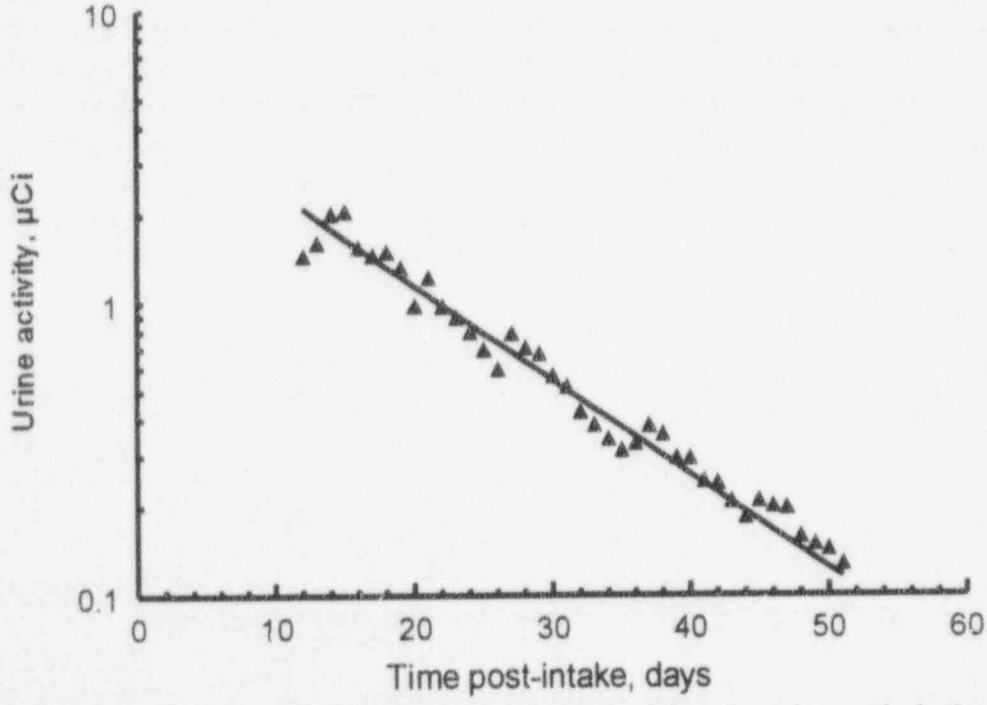

Figure 4-14 The fit of the modified ICRP 30 metabolic model to the urine analysis data for Researcher A, obtained using the internal dosimetry computer code CINDY.

The other consultant, Lawrence Livermore National Laboratory (LLNL), used the computer program CINDY to analyze the three sets of data they received from the Team: the licensee's whole-body counting data, the licensee's urine analysis data, and Researcher A's urine analysis data. The consultant made two changes to the standard ICRP 30 model to obtain an optimum fit to the data. To improve the fit to the urine excretion data, LLNL increased the biological half-life of the soft tissue compartment from 19 days in the standard model to 32 days. LLNL believed that this change provided a better fit to the data. They then made the assumption that all three sets of data were accurate and adjusted the model parameters until all three sets of data resulted in intake estimates that were as close to one another as could be achieved. In these calculations, LLNL used an F_a value of 0.8, which is the default value in the CINDY program. The changes that were necessary to achieve convergence of intake estimates included changing the fraction of the activity going to bone from 0.3 in the standard model to 0.15, and changing the fraction going to soft tissue from 0.4 in the standard model to 0.55. Using this modified model, LLNL obtained the following intake estimates.

From whole-body data	I = 540 μCi (20 MBq)
From licensee's urine data	I = 530 μCi (20 MBq)
From Researcher A's data	I = 590 μCi (22 MBq)
Mean	I = 550 μCi (20 MBq)

LLNL estimated the committed effective dose equivalent (CEDE) to be 4.6 rem (46 mSv) based on the mean intake estimate.

Researcher A's urine was also analyzed independently by ORISE. An ORISE representative travelled to the licensee's facility and obtained samples of all the urine voids that were obtained by the licensee. The urine was acidified before taking the samples to ensure that any crystallized material in the stored urine was dissolved and included in the sample. The results of the urine analyses confirmed the licensee's urine data, but the ORISE measurements were consistently higher than the licensee's by an average of 10 percent. The reason for this difference is unknown; it may have been due to differences in the calibration of the liquid scintillation counters used in the measurements, or it may have resulted from the method used to treat the samples.

Summary

Table 4-3 summarizes the results of the intake estimates completed by the various groups involved in this case.

Dose Assessment

The Team used the licensee's average of the amount of ^{32}P ingested, namely 570 microcuries (21 MBq), to estimate the doses to Researcher A resulting from that intake.

Table 4-3 Summary of intake estimates for Researcher A

Estimate source	Intake, μCi whole-body	Intake, μCi urine	Method used	Comments
Licensee	580	560	INDOS	$F_s = 0.9$
Consultant	570	570	INDOS	$F_s = 0.9$
NRC	580	560	NUREG/CR	$F_s = 0.9$
NRC	560	570	CINDY	$F_s = 0.9$
NRC [1]	600	590	CINDY	$F_s = 0.9$ backg. = 4300
NRC [1]	600	730	CINDY	$F_s = 0.75$ backg. = 4300
NRC	520	620	CINDY	modified parameters
ORISE	580	560	NUREG/CR	—
ORISE [1]	—	590	NUREG/CR	—
ORISE [2]	—	620	—	—
LLNL	540	530	CINDY	$F_s = 0.8$
LLNL [1]	—	590	CINDY	$F_s = 0.8$

1 Data from independent counting of urine by Researcher A
2 Based on the preliminary results of the independent analysis of urine samples by ORISE

Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Dose," July 1993, describes four methods acceptable to NRC to calculate the CEDE resulting from ingestion of radioactive material:

1. Federal Guidance Report No. 11 [EPA],
2. the ingestion Annual Limits on Intake (ALI) from 10 CFR Part 20,
3. ICRP 30 models and parameters, and
4. use of individual or material-specific information.

Method 2 is also described in 10 CFR 20.1202(b). Each of the four methods was used, together with the intake estimate of 570 microcuries (21 MBq) to estimate the CEDE. No adjustments for the weight of Researcher A compared with that of Standard Man were necessary because Researcher A weighed the same as Standard Man.

1. Federal Guidance Report No. 11 includes a series of tables of the committed organ and effective dose equivalents expected to result from unit intakes for a large number of radionuclides. Both inhalation and ingestion intakes are included in the tables, and the committed effective dose equivalent for ^{32}P is listed as 8.77 mrem per microcurie ingested (2.37 mSv/MBq). For an ingestion of 570 microcuries (21 MBq), the CEDE is

   CEDE = 8.77 x 570

   or 5.0 rem (50 mSv).

2. Appendix B to 10 CFR Part 20 includes tables of ingestion and inhalation ALIs for a large number of radionuclides. The Appendix lists the ALI for ingestion of ^{32}P as 600 microcuries (22 MBq). Intake of an ALI of ^{32}P is taken to result in a CEDE of 5 rem. The CEDE resulting from an intake of 570 microcuries is

   CEDE = 570/600 x 5

   or 4.8 rem (48 mSv).

3. The computer code CINDY implements the ICRP 30 models for Standard Man. Using an intake of 570 microcuries (21 MBq), the CEDE was calculated to be 5.2 rem (52 mSv).

4. The computer code CINDY was used with the adjusted biokinetic parameters discussed earlier to estimate the CEDE. The urine intake estimate of 620 microcuries (23 MBq) gave a CEDE of 5.9 rem (59 mSv), and the whole-body intake estimate of 520 microcuries (19 MBq) gave a CEDE of 4.9 rem (49 mSv).

The first three methods used to estimate CEDE are based on the same ICRP 30 models, and all use Standard Man parameters. The differences between the dose estimates arise from the differing numbers of significant figures used in the calculations. The Federal Guidance Report lists the committed effective dose equivalents per unit intake to three significant figures, whereas the ALIs are listed in 10 CFR Part 20 to one significant figure. The computer code rounds values at the end of the calculations. These differences in handling rounding result in differences among the final results. In view of the uncertainties inherent in the data and the models, only one significant figure is justified, and the best estimate of the CEDE in this case is 5 rem (50 mSv). However, it is standard practice to retain more than one significant figure to demonstrate compliance with NRC dose limits.

The committed organ dose equivalents were calculated using the computer code CINDY with both Standard Man biokinetic parameters and the adjusted parameters. The results are shown in Table 4-4.

Table 4-4 Committed organ dose equivalents calculated using the computer code CINDY with both Standard Man biokinetic parameters and the adjusted parameters

Organ	Committed Dose Equivalent, rem*		
	Standard Man	Modified Parameters	
		Urine	Whole Body
Gonads	1.4	1.7	1.4
Red marrow	18.0	20.0	17.0
Lung	1.4	1.7	1.4
Thyroid	1.4	1.7	1.4
Bone surfaces	17.0	19.0	16.0
Lower large intestine	16.0	17.0	14.0
Upper large intestine	6.3	7.0	5.9
Stomach	2.8	3.2	2.7
Small intestine	2.7	3.1	2.6
Committed effective dose equivalent	5.2	5.9	4.9

*Intake basis: Standard Man, 570 μCi; modified parameter–urine, 620 μCi; modified parameter–whole body, 520 μCi

Health Effects

NRC retained a medical consultant experienced in radiation effects to review Researcher A's case and assess the potential for any health effects that might develop as result of the ingestion of approximately 600 microcuries (22 MBq) of ^{32}P. Researcher A authorized the consultant to review his medical records and discuss his case with the physicians who examined him after discovery of the contamination. In addition, the consultant reviewed the professional literature for descriptions of similar cases involving ingestion of ^{32}P.

In arriving at his conclusion, the consultant considered the following:

- Researcher A complained of symptoms about 4 days after discovering the contamination on August 19, or 9 days after the estimated date of intake. However, the symptoms were not those associated with radiation exposures and could therefore not be related to that exposure.

- Searches of the professional literature revealed three cases in which persons were inadvertently administered high levels of ^{32}P. The intake levels involved in these cases were about 20 to

50 times greater than Researcher A's intake. The person with the highest intake reported symptoms that were consistent with low blood counts, an expected response to exposure to relatively high radiation doses. No other symptoms were reported. Similar blood count depressions, with no other symptoms, were observed in the other two cases. Researcher A did not exhibit symptoms of low blood count.

- ^{32}P is frequently injected intravenously into patients during medical treatment in doses that are 10 to 30 times greater than Researcher A's intake, but no symptoms are observed to result from these administrations.

The consultant concluded that experiences with intakes of ^{32}P, either accidental or as part of treatment, that are much larger than Researcher A's intake, has consistently demonstrated that intakes at these high levels do not lead to clinical symptoms. Wide experience with radiation exposures involving many of different radionuclides, and a wide range of doses, also supports the findings for ^{32}P. The consultant therefore concluded that any symptoms that Researcher A may have experienced must have resulted from causes other than the ingestion of ^{32}P.

Discussion and Conclusions

The Team reached several conclusions as discussed below.

- The data is well described by the standard ICRP 30 metabolic model. Somewhat improved fits to the model may be obtained by making changes to the model parameters, particularly the clearance half time for the soft tissue compartment. The half time of 32 days used by LLNL produced an improved fit of the model to the urine data at the later post-intake times, but with some degradation of fit at the earlier times. The effect on the fit to the whole-body data was small. The half time of 26 days used by the Team produced a better overall fit to the urine data compared with the standard model, and a better fit at the earlier post-intake times compared with the 32-day fit, but not as good a fit at the late post-intake times. The Team believes that making additional changes to the model to force the urine and whole-body data to predict intakes as close to one another as possible, is not justified in view of the uncertainties in the data. In any case, the modified models did not result in intake estimates that differed significantly from those produced by the standard model, and use of the standard model is therefore acceptable.

- The results of the analyses performed by all the groups supported the results obtained by the licensee, and the intake estimate reported by the licensee to Researcher A by letter of October 11, 1995 is acceptable. In that letter, the licensee reported an intake estimate of 564 μCi (21 MBq) based on the urine data, and 579 μCi (21 MBq) based on the whole-body data. The Team also accepts the corresponding total effective dose equivalents (TEDE) reported by the licensee, namely 4.702 rem (47 mSv) and 4.824 rem (48 mSv) respectively. The Team concluded that the licensee is permitted to use these doses to show compliance with regulatory requirements.

- For dosimetric purposes, Researcher A's most likely intake was about 600 μCi (22 MBq) with an uncertainty range of about 500 to 750 μCi (19–28 MBq). The resulting TEDE was about 5 rem (50 mSv). The committed organ doses were all well within the occupational nonstochastic limit of 50 rem (0.5 Sv) permitted by 10 CFR Part 20.

- The doses received, both organ and effective, were below those at which any clinical symptoms or acute effects would be expected.

- The urine data was better controlled for accuracy than the whole-body data, but both sets of data contained uncertainties in the range noted above. However, this range is an approximation, and estimation of such a range should be based on measurements on the specific equipment, with the specific procedures, used to obtain the data. Independent analysis of the urine samples by ORISE supported the accuracy of the licensee's urine results, but also showed a consistent bias at an average of 10 percent higher than the licensee's data. The cause of this difference is not known.

5 Regulatory Aspects

Responsibility for Programmatic Oversight

This section discusses the regulations, license conditions, and licensing commitments that apply to oversight of the use of radioactive materials at the Massachusetts Institute of Technology (MIT).

MIT is authorized by NRC License 20-01537-02 to possess and use byproduct material in a wide variety of forms and activities as a "Type A specific license of broad scope" issued pursuant to paragraph 33.13 of Title 10 of the *Code of Federal Regulations* (10 CFR 33.13). At the time of the investigation, the license was in timely renewal as indicated on the most recent amendment, Number 50, which lists an expiration date of "January 31, 1995 (extended)." *Timely renewal* means that the licensee filed a renewal application as required with the Region I office before the expiration of the license, and that the licensee may continue to operate under the existing license until the review of the renewal application is completed. Type A specific licenses of broad scope at academic institutions are required to be inspected by the NRC every 2 years by NRC Inspection Manual Chapter 2800, "Materials Inspection Program," April 17, 1995.

The requirements for issuance of "Specific Domestic Licenses of Broad Scope for Byproduct Materials" are found in 10 CFR Part 33. In accordance with 10 CFR 33.13, an applicant for a Type A specific license of broad scope is required to establish a radiation safety committee composed of persons such as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive materials. Paragraph 33.13 also requires the licensee to appoint a qualified radiation safety officer and to establish administrative procedures to control procurement and use of byproduct material; to evaluate proposed uses of byproduct material; and to have the radiation safety committee review, approve, and record the safety evaluations. In addition, 10 CFR 33.17(b) requires that byproduct material be used only by, or under the direct supervision of, individuals approved by the radiation safety committee.

The NRC provides each applicant for a Type A specific license of broad scope, such as MIT, with guidance regarding the information that should be submitted in their application. At the time the license application was last reviewed in 1989, the guidance was contained in Regulatory Guide 10.5, Revision 1, "Applications for Type A Licenses of Broad Scope" (RG 10.5 Rev. 1), December 1980 and FC 408-4, "Proposed Revision 2 to Regulatory Guide 10.5, 'Guide for the Preparation of Applications for Type A Licenses of Broad Scope,'" February 1985 (FC 408-4). NRC used these guides in the licensing process to evaluate the application for safety and adequacy. These guides request that the licensee submit a description of their radiation protection program, including information about the radiation safety committee, the radiation safety officer, and the radiation protection procedures. NRC reviewed MIT's renewal application dated November 29, 1989, and issued the renewal of the license in January 1990. In addition to the NRC regulations, and the license conditions, the licensee is required to comply with the statements, representations, and procedures contained in their November 29, 1989, application.

The November 29, 1989, application included the MIT document, "Required Procedures for Radiation Protection," which outlines the radiation protection program at MIT and describes the

responsibilities and requirements of the various persons using, or supervising the use of, radioactive materials at MIT. As required by 10 CFR Part 33, the licensee established a Radiation Protection Committee, which must establish a radiation protection program and grant authorizations to use radioactive materials. According to the license commitments, the duties of the Radiation Protection Committee include meeting at least once each calendar quarter and conducting an annual review of the MIT Radiation Protection Program.

As of January 1994, 10 CFR 20.1101 also required each licensee to periodically (at least annually) review the content and implementation of their radiation protection program. In October 1994, the NRC published Draft Regulatory Guide DG-0005, "Second Proposed Revision 2 to Regulatory Guide 10.5, Applications for Licenses of Broad Scope" (DG-0005). This draft regulatory guide requests that applicants for Type A specific licenses of broad scope submit more details regarding audits of the radiation protection office and staff, and the types and frequencies of communications between the committee, licensee management, and the radiation protection officer.

The MIT application for renewal received by the NRC on January 4, 1995, was based on the guidance in DG-0005 and included among the duties for the Radiation Protection Committee, requirements to conduct periodic inspections and audits of the Radiation Protection Program and observe audits performed by the Radiation Protection Office.

In accordance with 10 CFR Part 33, the licensee appointed a Radiation Protection Officer. NRC reviewed the qualifications of this individual during the licensing process, and the individual is named on the license. In the licensing process, the NRC approved the proposal that the Radiation Protection Committee delegate interim authority (between its meetings) to the Radiation Protection Officer to issue project supervisors authorizations for use of radioactive materials that meet criteria submitted in the license application. These authorizations would be ratified by the Committee in its next meeting. The Radiation Protection Officer also has the authority to suspend any authorization if radiation safety practices under that authorization are unacceptable.

The license application stated that the Radiation Protection Officer is in charge of the Radiation Protection Office, which implements the program established by the Radiation Protection Committee. The duties of the Radiation Protection Office as described in the license commitments include enforcing the conditions of the NRC licenses and managing the radiation protection program by inspecting and auditing users of radioactive materials. The Radiation Protection Office audit commitments include radiation surveys and contamination surveys, review of records and procedures as specified in a project supervisor's authorization application, checks of users' radioactive material inventory at time of purchases, and verification of training.

According to the license application, a project supervisor is the individual to whom the Radiation Protection Committee issues an authorization to use, and supervise the use of, radioactive materials. In addition, all persons working under the project supervisor's authorization must be registered and trained by the Radiation Protection Office, and their names must be listed on a project supervisor's authorization form.

The Radiation Protection Committee approved the renewal of the authorization of the Principal Investigator who was the project supervisor for Researcher A in June 1995. The authorization approved use in 11 laboratories by 31 persons listed on his authorization.

In March 1995, NRC did its most recent inspection of the MIT broad scope program. The inspection team found eight violations, two of which involved the Committee: failure to meet at the required interval (it met only three times in 1993 and three times in 1994), and failure to perform the 1993 annual review of the radiation protection program. NRC had previously inspected MIT in January 1993 (no violations), February 1991 (no violations), and April 1988 (two violations of survey requirements).

Regulations for Security and Control of Licensed Material

Paragraph 20.1801 in 10 CFR Part 20, Subpart I, "Storage and Control of Licensed Material" states, "The licensee shall secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas." Paragraph 20.1802 states, "The licensee shall control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage."

However, Question 129 of the "Questions and Answers Based on Revised Part 20" (Q/As) first published in Set 4 issued September 14, 1992, inquired if the regulations of 10 CFR 20.1801 and 1802 would be imposed (1) on all quantities of licensed material however small, to which NRC responded "no;" and (2) on quantities that are exempt from labeling in accordance with 10 CFR 20.1905, to which the NRC responded "no." The discussion of this issue continued in Question 419, published in Set 7 of the Part 20 Q/As on October 29, 1993. The commenter stated that the response to Question 129 was a very useful interpretation, but inquired about the supporting justification since it was not evident in the regulations. NRC responded by stating that the requirements of paragraphs 20.1801 and 1802 did not differ from the earlier requirements in 10 CFR 20.207(a) and (b) except for the reference to controlled areas, and that the response to Question 129 was based on the NRC staff's understanding of the intent of the requirements as reflected in NRC staff's enforcement of the requirements of 10 CFR 20.207(a) and (b).

The NRC's Statements of Consideration (56 FR 23360) for the proposed revision to 10 CFR Part 20, included a comment received about paragraph 20.1801 and 1802, that the requirement to secure small quantities of radioactive materials when they are not in use would interfere with university research. The NRC responded that locking radiotracer laboratories when they are not being used is a small nuisance compared to consequences of unauthorized access or theft, which could result in contamination of unrestricted areas or exposure of individuals.

A June 19, 1995, response from the NRC Office of Nuclear Material Safety and Safeguards to Region I concerning issues of security and of radioactive material at a research facility included guidance inconsistent with the Statements of Consideration. The proposed procedures requested, in part, that containers having quantities of radioactive materials less than those listed in Appendix C to 10 CFR Part 20 (those quantities exempt from labelling in accordance with 10 CFR 20.1905) be permitted to be stored in corridors in unlocked and unattended refrigerators or freezers. NRC approved this proposal with the note that this request "requires no exemption, since material with

activities of less than those listed in Appendix C are not regulated." Appendix C contains a list of licensed radionuclides, and quantities that are exempt only from labelling requirements. However, the same quantities are specified in 10 CFR 30.71, "Schedule B," and are exempt from the requirements for a license.

The Team interviewed two managers from the NRC Office of Nuclear Materials Safety and Safeguards regarding the application of 10 CFR 20.1801 and 1802. Both managers agreed that secured storage requires a lock or other method of preventing anyone who is not authorized to use the material, from walking away with the material. Both agreed that constant surveillance requires authorized persons to be in the line of sight of the material at all times and to be able to warn or intervene upon observing someone who could walk away with the material. They agreed that it is not sufficient to have an authorized user present in an adjacent area or room if that authorized user cannot observe the unsecured radioactive material. However, when discussing the conflicting guidance provided about these regulations, one manager stated that, if the NRC finds it is appropriate to have a threshold below which security and control of material may be relaxed, this needs to be stated on a more official basis than the guidance documents discussed above. He discussed a variety of practical problems associated with applying these regulations to all quantities and forms of unsealed materials, particularly when the quantities of material are similar to those exempt in other parts of the regulations. The second manager stated the belief that the regulations do not contain any basis for exempting Appendix C quantities from the security and control requirements, and that sufficient information is not given in the guidance documents for the basis of the staff positions expressed.

Licensing guidance in RG 10.5 Revision 1, FC 408-4, and DG-0005 stated that the licensee should describe their requirements for posting and controlling access to restricted areas, and requirements for materials storage, safeguards, labeling, and identification of use and storage areas. NRC has not issued guidance describing acceptable methods of security and control of unsealed byproduct material. The MIT license procedures required that the project supervisor establish a daily procedure adequate to ensure that each laboratory is secured at the end of the work day to prevent unauthorized access. The license procedures also required that individuals store radioactive material in a manner to protect against its unauthorized removal. The license procedures did not contain instructions for maintaining constant surveillance of radioactive materials in use.

The NRC regulations in 10 CFR 20.1801 and 1802 do not define control of licensed material to include inventory and accounting of material, and no other regulation in Part 20 explicitly requires inventory or accounting of licensed material. The regulations in 10 CFR 30.51 require that the licensee maintain records of receipt, transfer, and disposal of byproduct materials, and 10 CFR 20.2108 requires that records of disposal be maintained. Paragraph 33.13(c) also requires that the licensee holding a Type A specific license of broad scope (1) establish administrative controls and provisions for material control and accounting and (2) control procurement of licensed material.

RG 10.5 Rev.1 and FC 408-4 both stated that the radiation safety officer's duties should include determining compliance of users with the conditions specified in project approvals, and maintaining an inventory of all radioactive materials on campus. RG 10.5, Rev. 1 further stated that the inventory should include the name of the person responsible for each quantity of radioactive material, where it will be used or stored, and the date the quantity was delivered to that person.

The regulatory guides stated that items are removed from the inventory by showing how and when the radioisotope was disposed of. New guidance contained in DG-0005 stated in Item 10.3 that broad scope institutions should have a strong inventory and accountability system capable of ensuring that material is accounted for throughout the institution at any time. DG-0005 stated that the broad scope applicant must submit for review a description of the inventory, control, and accountability program for licensed material. DG-0005 further stated that the radiation safety staff audits of users should include a review of user inventory records. Although this guidance was more detailed than Regulatory Guide 10.5 Rev. 1, and suggested that individual users need to maintain inventory records, it included no suggested or model procedures to indicate the level of detail that should be maintained for unsealed materials.

In their license procedures, MIT committed that the Radiation Protection Office audits of users would include reviews of records and procedures as stated in the authorizations. According to license procedures, all purchases of radioactive materials must have prior approval from the Radiation Protection Office, and the Radiation Protection Office will check the inventory of the users at times of purchase approval requests. In the license procedures, MIT also committed that each project supervisor will maintain an adequate inventory of the amount of material possessed and will establish a system adequate to ensure that his or her project does not exceed the authorized radioactive material possession limits. The license procedures stated that transfers of radioactive material between projects are prohibited without notification of the Radiation Protection Office, and all disposal of radioactive materials must be recorded on specified forms. However, the license procedures did not require or suggest any procedures or methods for tracking radioactive materials inventory. The Radiation Protection Office did not issue procedures requiring users to record radioactive material removed from stock vials for use. The Radiation Protection Office had no audit procedures or practices to account for material that was in use or in storage, but had not been disposed of as waste.

Emergency Response

Paragraph 30.32(i) of 10 CFR Part 20 requires that the applicant for a license to possess unsealed radioactive materials exceeding specified quantities submit either an evaluation showing that the maximum offsite dose will not exceed 1 rem or submit an emergency plan for responding to releases. The quantities of byproduct materials authorized by the MIT license did not exceed these specified quantities.

However, licensing guidance contained in RG 10.5 Rev. 1 and FC 408-4 stated that an applicant for a Type A specific license of broad scope should establish written emergency procedures and instructions concerning spills, fires, release or loss of material, and accidental contamination of personnel, including decontamination procedures and the identities of persons to be notified in an emergency.

The MIT license procedures included instruction to radiation workers in the event of incidents such as spills of radioactive material. The license procedures directed radiation workers to notify the Radiation Protection Office—

- if they know of or suspect exposure to external radiation greater than values specified in the document,
- if they know of or suspect exposure by inhalation, ingestion, or injection of material, or
- if they know of or suspect if any residual contamination is found on skin, hair, or personal clothing by required surveys after use of radioactive materials.

Instructions were also listed in a separate section of the licensed procedures for emergencies that may involve

1. serious injuries with contamination of a worker,
2. minor injuries with contamination of a worker, or
3. contamination of a worker without injuries.

The instructions in the licensed procedures directed workers to contact the Radiation Protection Office during normal work hours and to contact the MIT Campus Police at all other times.

Reporting Requirements

The licensee informed the NRC of this event on Monday, October 16, several weeks after the occurrence. The stated purpose for reporting was to give the NRC advance notification of publication of a magazine news story concerning the event. The report was not made to comply with any reporting requirements in the regulations.

The regulations in 10 CFR 20.2202(b) state, in part, that

> Each licensee shall, within 24 hours of discovery of the event, report any event involving loss of control of licensed material possessed by the licensee that may have caused or threatens to cause ... (1) An individual to receive, in period of 24 hours--(i) A total effective dose equivalent exceeding 5 rems (0.05 Sv).

The regulations in 10 CFR 20.2203 similarly require reports if exposures exceed listed doses. The licensee stated that all indications throughout the evaluation of the event were that the quantity involved and the intake would not result in a dose exceeding 5 rem.

The licensee also stated that the dose would be delivered over a period of weeks instead of within 24 hours and that this had been a consideration in not reporting the event. Interviews and discussions with NRC personnel produced conflicting interpretations of the reporting requirements in 10 CFR 20.2202 with regard to the "period of 24 hours" in cases of ingestion of radioactive materials.

One interpretation was that the entire dose due to ingestion is assigned immediately, is therefore received within 24 hours, and thus may be reportable under the requirements of 10 CFR 20.2202.

Part 20 defines *total effective dose equivalent* as the sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures). Part 20 also defines *committed effective dose equivalent* as that dose from an intake that will be received during the 50-year period following the intake. The answer to Question 183 in NUREG/CR-6204, "Questions and Answers Based on Revised 10 CFR Part 20," May 1994, stated "The committed effective dose equivalent should be recorded in the year the intake was received. If the dose exceeded the limits, then it is considered an overexposure at the time when the intake occurred, and should be reported immediately."

A second interpretation would agree with the licensee that the dose due to ingestion is not all received within the first 24 hours, and therefore should not all be assigned within the first 24 hours. Consequently, if the 24-hour portion of the dose due to the intake did not cause the individual to exceed the 5 rem (0.05 Sv) limit, the event was not reportable under 10 CFR 20.2202. However, if the total committed dose due to ingestion would exceed the limits listed in 10 CFR 20.2203, the event would have been reportable as a 30-day report under those requirements.

Dosimetry Guidance

Guidance on implementing an internal dosimetry program, and on methods acceptable to the NRC for assessing intakes from bioassay measurements, was stated in NRC Regulatory Guide 8.9, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program." Guidance and biokinetics tables were also included in NRC's NUREG/CR-4884, "Interpretation of Bioassay Measurements." Both guidance documents included extensive reference material, the references most frequently cited being ICRP 30, "Limits for Intakes of Radionuclides by Workers," ICRP 54, "Individual Monitoring for Intake of Radionuclides by Workers: Design and Interpretation," and NCRP 87, "Use of Bioassay Procedures for Assessment of Internal Radionuclide Deposition."

Regulatory Guide 8.9 recommended that single intakes of less than 0.02 of an Annual Limit on Intake (ALI) need not be evaluated beyond taking a single bioassay measurement and estimating the intake from that measurement. In cases of intakes above 0.02 ALI but below 0.1 ALI, some additional bioassay measurements were recommended to enable a more reliable estimate of the intake to be made. Intakes above 0.1 ALI should be investigated thoroughly and, if feasible, daily body and excreta measurements should be made until sufficient data is available to establish the retention and excretion patterns for the contaminated person. The guide also detailed methods recommended for use in making an initial estimate of an intake based on only one or a limited number of bioassay measurements, and also methods for use when a series of bioassay measurements is available. The guide included numerical examples for a variety of intake situations, named the metabolic models that NRC finds acceptable, and listed references that detail these models and their parameters.

NUREG/CR-4884 included an extensive set of tables of intake excretion and retention fractions for a large selection of radionuclides, both for inhalation and ingestion intakes. The NUREG-series report also briefly described the models used to generate the tables, the limitations of the tables, suggested methods for using the tables, and examples of uses of the tables.

Event Assessment and Communication of Significant Findings

The Team examined information available on previous events involving the deliberate misuse of radioactive materials, and the means by which this information was disseminated inside and outside the NRC. The Team searched the databases maintained by the NRC Office for Analysis and Evaluation of Operational Data (AEOD), as well as the Nuclear Documents System (NUDOCS) and also requested information from the International Atomic Energy Agency (IAEA). The Team reviewed previous NRC documents that may have alerted licensees to such events, including information notices and bulletins. Methods in use for exchange of information between NRC and Agreement States were also examined.

AEOD oversaw two databases, the Sequence Coding and Search (SCSS) database, maintained under contract by Oak Ridge National Laboratories, and the Nuclear Materials Events Database (NMED) maintained under contract by Idaho National Engineering Laboratory (INEL). SCSS was the older system and included the reactor licensee event report (LER) database. NMED was started in 1992 and information from past materials licensee event reports had been included there. Previously, significant events such as overexposures, were entered into SCSS. NUDOCS was another database maintained by NRC that could be searched for specific types of events. An international database was maintained by IAEA.

At the Team's request, AEOD submitted the results of a search for events that may have involved deliberate misuse of radioactive materials. Although the list contained many events of interest, the Team learned during interviews of other events that did not appear on the list. The searches did not locate any reference to international events.

The contractors that maintained the SCSS and NMED databases got information on events by reviewing preliminary notifications, licensee reports, enforcement notices, monthly Office of Nuclear Materials Safety and Safeguards briefings, and inspection reports. They also received logs of events received by the regions and then forwarded by AEOD.

Agreement States voluntarily send NRC information on the occurrence and details of events in their jurisdictions. Until 1990, this information was not complete and not consistently sent. The Office of State Programs stated that the transfer of incident information from Agreement States, although still voluntary, had considerably improved.

AEOD analyzes the information received to find trends that may require the attention of the program offices and notifies the appropriate office, as needed. Contractors may also be asked to conduct some of these analyses. AEOD may also publish reports or studies concerning a trend, and may recommend that program offices issue information notices. Representatives from AEOD attend the Office of Nuclear Materials Safety and Safeguards briefings and report to the meetings any events of interest.

The Team did not find any analysis in which deliberate misuse of radioactive materials was determined to be a trend that warranted the attention of the program offices. The Team reviewed notifications sent to licensees, such as information notices, and found no discussion of deliberate misuse of radioactive materials directed against individuals until October 1995, when an information notice describing the deliberate event at NIH was issued.

6 Findings and Conclusions

Deliberate Act by a Knowledgeable Person

Conclusion

Researcher A most likely ingested ^{32}P as a result of a deliberate act by a knowledgeable person.

Findings

- Researcher A conducted experiments with ^{32}P at levels in the range of 50 microcuries (1.9 MBq), and this activity was quickly diluted when added to the experimental reagents. Accidental spills of such reagents would not involve large enough activities to account for the observed ingestion.

- The largest single quantity available in the laboratory at any time was 2 millicuries (74 MBq) or less. The observed ingestion would have required nearly half that activity to be involved in a spill without being noticed.

- The ^{32}P used in the experiments was shipped to the laboratory in frozen form and was kept frozen in freezers until just before use in an experiment. Thawing was required, either at room temperature or in a warm bath, before the material changed to liquid form. Whoever used the material in this event must have known that it was kept in freezers and that it required thawing before use.

- No traces of contamination were found in extensive surveys of the laboratory immediately after discovery of the intake and in surveys of areas adjacent to the laboratory, eating areas, refrigerators, water coolers, desktops, workbenches, and Researcher A's clothes, books, and house. An accidental spill would almost certainly have involved contamination of at least the researcher, his work areas, or both.

- An inventory of radioactive materials in Researcher A's laboratory soon after discovery of the intake could not account for about 500 microcuries (19 MBq) of ^{32}P. The missing volume activity was from a vial that had been delivered to the laboratory before the suspected time of intake and was later found in the radioactive waste container in the laboratory.

- Security of radioactive materials was weak in the building in which the laboratory was located, and any person working in any laboratory in the building would have had easy access to the freezer in which the radioactive material was stored. In fact, it was occasional practice for laboratories to borrow radioactive material from one another. Access to such material could be gained with only slightly more difficulty by anyone not working in the building and unknown to anyone working in the laboratory.

Radiological Consequences

Conclusion

The amount of radioactive material ingested by Researcher A [500–750 μCi (19–28 MBq)] is not expected to result in any clinical symptoms or acute effects. Any symptoms that may have been experienced were due to factors other than radiation exposure.

Findings

- No symptoms were reported by Researcher A before discovery of the contamination.
- The symptoms reported by Researcher A were not consistent with those expected to result from radiation exposure.
- Cases reported in the literature of intakes of ^{32}P between 20 and 50 times larger than that ingested by Researcher A reported no symptoms observed.
- Patients routinely injected with amounts of ^{32}P for medical treatment that were 10 to 30 times the intake by Researcher A reported no symptoms as a result of these intakes.

Security and Control of Radioactive Materials in Laboratories

Conclusion

The security of radioactive materials in storage and the control of radioactive materials in use in the Center for Cancer Research were weak.

Findings

- Crowded laboratory areas and benches limited the line of sight of workers to visitors, and to areas in which radioactive material was used or stored.
- Stock vials containing up to 2 millicuries (74 MBq) of ^{32}P were stored in an unattended freezer in the Principal Investigator's Laboratory. The freezer did not have a lock before the contamination incident. Other refrigerators and freezers in which radioactive materials were stored also did not have locks and were unattended.
- Licensee personnel stated that laboratories where radioactive materials were used were locked during evenings and weekends when unattended. However, on evenings and weekends, Team members found laboratories unattended and doors unlocked in the Principal Investigator's Laboratory and other laboratories.
- Team members were able to enter the Center on evenings and on a weekend through the main door without use of the keypad, and also entered through other doors.

- No required procedures, such as those for recording material removed from stock vials or recording material used during research, were used in the Principal Investigator's Laboratory to enable workers to determine whether radioactive material was missing from stock vials or not otherwise accounted for.

Radiation Protection Office Oversight of Security and Control of Radioactive Materials in Laboratories

Conclusion

The Radiation Protection Office exercised weak oversight with regard to storage and control of radioactive material in use in unrestricted and controlled areas.

Findings

- The radiation protection procedures informed users only that they must store radioactive materials to prevent unauthorized removal but did not suggest acceptable methods of doing so.

- The MIT radiation protection procedures did not include requirements for maintaining constant surveillance of radioactive materials used in unrestricted or controlled areas and not in storage.

- Surveys and audits forms prepared by Radiation Protection Office staff members did not list security of radioactive material among the items for routine review.

- Radiation Protection Office staff, including the Radiation Protection Officer, stated that the Center for Cancer Research was locked during the evenings and on weekends, and that only individuals knowing the keypad code could enter the building. In one weekend, Team members demonstrated multiple failures of the licensee to control access to buildings and radioactive material.

Regulatory Standards for Security and Control of Radioactive Material

Conclusion

NRC regulatory standards and guidance for security and control of byproduct material were inconsistent.

Findings

- The regulations in 10 CFR Part 20, Subpart I, "Storage and Control of Licensed Material" include Paragraphs 20.1801 and 20.1802. Paragraph 20.1801 states "The licensee shall secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas." Paragraph 20.1802 states "The licensee shall control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage." There is no lower limit of the quantity of licensed material to which these regulations apply.

- The NRC's "Statements of Consideration" for the proposed revision to 10 CFR Part 20 included a comment received, that the requirement to secure small quantities of radioactive materials when they are not in use would interfere with university research. The NRC response stated that locking radiotracer laboratories when they are not being used is a small nuisance compared to consequences of unauthorized access or theft, which could result in contamination of unrestricted areas or exposure of individuals.

- The commenter in Question 129 of the "Questions and Answers Based on Revised Part 20," first published in Set 4 issued September 14, 1992, inquired if the regulations of 10 CFR 20.1801 and 1802 would be imposed (a) on all quantities of licensed material, however small, and (b) on quantities that are exempt from labelling in accordance with 10 CFR 20.1905. NRC published a negative answer to each question.

- This response was followed up by Question 419, published in Set 7 of the Part 20 Questions and Answers on October 29, 1993. The commenter stated that the response to Question 129 was a very useful interpretation, but inquired about the supporting justification since it was not evident in the regulations. The answer to Question 419 reaffirmed Answer 129.

- A June 19, 1995, response from the NRC Office of Nuclear Material Safety and Safeguards concerning issues of security and radioactive material at a research facility included guidance that was inconsistent with the "Statements of Consideration." Storage in unlocked and unattended refrigerators and freezers was approved because it "requires no exemption, since material with activities of less than those listed in Appendix C are [*sic*] not regulated."

- The "small quantities" referred to above were those listed in Appendix C to 10 CFR Part 20, which did not require labelling. This list of radionuclides and quantities included many of the same items found in Appendix B to 10 CFR Part 30, quantities which, for the specified radionuclides, were exempt from the requirements of a license.

- Although NRC regulations included many requirements to report thefts, losses, and incidents involving very small quantities of licensed material, NRC regulations required only records of receipt and disposal of licensed material. NRC guidance documents for byproduct materials licensees contained little guidance as to the level of detail to which inventory and accounting of material was necessary.

Radiation Protection Office Response

Conclusion

While the Team found weaknesses in the actions taken by Radiation Protection Office personnel, the licensee's overall response was good.

Findings

Strengths

- The Associate Radiation Protection Officer and Assistant Radiation Protection Officer A arrived on site within 1 hour of notification, having previously communicated with and given advice to Physician A.

- Radiation Protection Office staff took immediate actions to confirm the lack of external contamination on Researcher A, the Principal Investigator's laboratory and surroundings, and the personal residence of Researcher A.

- Radiation Protection Office staff took followup actions to expand these surveys and confirm initial findings.

- Radiation Protection Office staff used two methods of bioassay, whole-body counting and urine analysis. Additionally, the licensee continued these bioassays for longer than 60 days.

- Radiation Protection Office staff took appropriate actions to ensure proper calibration of the whole-body counter and the liquid scintillation counter.

- The licensee took actions to suspend all use of radioactive materials in the Principal Investigator's Laboratory until an inventory could be performed. Before restoring authorization to use radioactive materials, Radiation Protection Office staff took actions to secure all stock radioactive materials in the Principal Investigator's Laboratory and reduce the likelihood of recurrence.

Weaknesses

- Radiation Protection Office staff did not give Researcher A written instructions on urine collection. This resulted in confusion and misleading initial data.

- The calculations associated with the licensee's initial intake assessment were weak and the licensee initially failed to properly account for the geometry factor of the whole-body counter.

- The licensee did not apply increased controls of radioactive materials to the entire Center for Cancer Research. However, when this weakness was found by the Team, the licensee responded by securing all radioactive materials in the Center.

Management Oversight of the Radiation Protection Program

Conclusion

Management oversight of the Radiation Protection Program was weak. The licensee did not use a process of management review and self-assessment to find weaknesses in their program and to take appropriate remedial actions.

Findings

- Violations documented in the NRC inspection report in 1995 involved weaknesses in the oversight of the Radiation Protection program at MIT, including the failure of the Radiation Protection Committee to review the program in 1993.

- Radiation Protection Committee members stated that they did not perform audits of the Radiation Protection program and did not perform random checks of performance outside their own laboratories.

- Radiation Protection Committee members stated that they depended on the Radiation Protection Office to inform them of problems and program status. The Committee was not notified of the August 14 event until the week of September 12.

NRC Reporting Requirements

Conclusion

NRC reporting requirements were not specific regarding intentional contamination. NRC reporting requirements for intake were unclear. However, sufficient data was available within the first week to indicate the event threatened to cause an overexposure.

Findings

- NRC regulations do not require licensees to report deliberate acts involving ingestion of radioactive materials.

- The licensee stated that the decision not to report the event was partially based on their finding that the dose due to ingestion of ^{32}P would be delivered over a period of weeks instead of *a 24-hour period.*

- NRC personnel gave two interpretations of the requirement to report when doses received within *a 24-hour period* exceed certain limits.

- The licensee stated that the decision not to report the event was primarily based on their finding that all data indicated that the quantity involved and the intake was less than the limits stated in the regulations. However, the data available in the first week indicated a possible dose in excess of 600 microcuries (22 MBq). Additionally, Researcher A gave the licensee an estimate in excess of 600 microcuries (22 MBq) within the first week.

7 Root Cause Analysis

The Team concluded that the ingestion of ^{32}P at MIT was most likely the result of a deliberate act by a knowledgeable individual. However, the Team could not determine how the ingestion occurred. Consequently, the Team could not determine a root cause. However, the Team found sufficient information to determine the following contributing causes to the event:

- MIT's program for control and security of radioactive materials was not effective to deter or detect diversion of radioactive materials.
- The NRC did not have reporting requirements in place to collect information about deliberate acts to assess their frequency.
- The NRC did not disseminate information about known precursor events and did not inform licensees of the circumstances of a similar incident at the National Institutes of Health until 4 months after the incident was reported.

Glossary

The following descriptions of terms are intended to aid in understanding this report and do not constitute definitions or legal interpretation of the associated terms.

Absorbed dose	the amount of ionizing radiation absorbed by an object or individual. The special name gray, symbol Gy, has been adopted for the System International (SI) unit or absorbed dose.
Activity	rate of disintegration of a radioactive source, measured in units of becquerel (Bq) [curies (Ci)]. Activity is commonly used to describe the amount of radioactive material present.
Aliquot	a small discrete volume of material, usually a liquid, removed from a larger volume.
Annual Limit on Intake (ALI)	the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year.
Attenuation	the reduction of radiation intensity as it passes through any material, for example, bone or body tissue.
Becquerel (Bq)	a unit of activity equal to one disintegration per second.
Beta particle	a charged particle emitted from the nucleus of an atom with a mass and charge equal in magnitude to that of the electron.
Bioassay or radiobioassay	the determination of kinds, quantities, or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement or by analysis and evaluation of materials excreted or removed from the human body.
Biokinetic model	a metabolic model which describes the behavior of a material in the human body following intake by ingestion or inhalation, and includes an estimation of the amounts of the material deposited in organs and tissues of the bodies, and the rates at which the material is eliminated from the body by way of one or more excretion routes.
Bone seeker	any compound or ion that migrates in the body preferentially into bone. Phosphorus is a bone seeker.
Bremsstrahlung	the secondary photon x-ray radiation produced by deceleration of charged particles passing through matter. The beta particle emitted during the decay of phosphorus-32 produces bremsstrahlung.
Byproduct materials	any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material.

Calibration — a determination of variation from a standard, or accuracy of a measuring instrument to ascertain necessary correction factors or the determination of factors to convert instrument measurements to physical quantities such as activity.

Chromatography — the separation of mixtures of material by passing the mixture through an adsorbing medium such as silica, gelatin, or starch resulting in distinct stratified layers of the constituents of the mixture.

Committed dose equivalent ($H_{T,50}$) — the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following intake.

Committed effective dose equivalent (CEDE) ($H_{E,50}$) — the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to these organs or tissues ($H_{E,50} = \Sigma w_T H_{T,50}$).

Contamination (radioactive contamination) — the presence of radioactive material in an undesired location so that residual radioactive material remains; *internal* contamination occurs by ingestion or inhalation of radioactive material.

Controlled area — an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason.

Counting efficiency — the ratio of the number of counts detected to the number of disintegrations of radioactive material in the source.

Count — the number of events registered by a radiation detector.

Curie (Ci) — a unit of activity equal to 3.7×10^{10} disintegrations per second.

Deep-dose equivalent (H_d) — the value applied to external whole-body exposure expressed at a tissue depth of 1 centimeter (1000 mg/cm^2).

Disintegration per minute (dpm) — a unit of activity commonly used in laboratory work because it is convenient for expressing the quantities typically used. One curie equals 2.22×10^{12} dpm (1 dpm = 1.67×10^{-2}Bq).

Dose equivalent (H_T) — the product of D, Q, and N at the point of interest where D is the absorbed dose, Q is the quality factor, and N is the product of all other modifying factors,

$$H_T = DQN$$

The special name *sievert*, symbol Sv, has been adopted as the SI unit of dose equivalent in the field or radiation protection. The older conventional unit of dose equivalent is rem (1 Sv = 100 rem).

Dose rate — the absorbed dose delivered per unit time.

Effective dose equivalent (H_E) — the sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighting factors (w_T) applicable to each of the body organs or tissues that are irradiated.

Exposure — being exposed to ionizing radiation or to radioactive material.

Gamma ray — short-wave length electromagnetic radiation of nuclear origin emitted from the nucleus.

Geiger-Mueller Counter — a gas-filled radiation-detection device that is highly sensitive.

Gray (Gy) — the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 Joule per kilogram (100 rads).

Internal dose — that portion of the dose equivalent received from radioactive material taken into the body.

Labelled compound (radiolabelled compound) — a compound to which one or more radioactive atoms are attached.

Labelling (radiolabelling) — a procedure in which one or more radioactive atoms are attached to a molecule or compound in order to follow the compound or its fragments through physical, chemical, or biological processes by observing the radioactivity.

Liquid scintillation counting — the detection of light emissions (scintillation) resulting from decay of radioactive material immersed in a special chemical mixture.

Metric prefixes — prefixes used with metric units to express numbers in a convenient form.

micro (μ)	$= 10^{-6}$	mega (M)	$= 10^{6}$
milli (m)	$= 10^{-3}$	giga (G)	$= 10^{9}$
kilo (k)	$= 10^{3}$		

Phantom — a device use to approximate a human body for the calibration and adjustment of radiation-measuring instruments.

Public dose — the dose received by a member of the public from exposure to radiation and to radioactive material released by a licensee, or to another source of radiation either within a licensee's controlled area or in unrestricted areas. It does not include occupational dose or dose received from background radiation, as a patient from medical practices, or from voluntary participation in medical research programs.

Quality assurance (QA)	planned and systematic actions to ensure the accuracy of measurements.
Quality control (QC)	routine inspections and tests to verify the continued accuracy of the measurements.
Radiation Protection Committee	a committee composed of such persons as a radiological safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive materials. The Committee establishes administrative policies, evaluates proposed uses, and approves users of radioactive material. Also known as Radiation Safety Committee.
Radiation Protection Officer (RPO)	the individual or the Radiation Protection Officer named on an NRC license responsible for implementing the radiation safety program. The RPO ensures that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the licensee's daily operations. Also known as Radiation Safety Officer.
Radioactive decay	the disintegration of the nucleus of an unstable nuclide by spontaneous emission of charged particles and/or photons.
Radioactive half-life	the time required for a radioactive substance to lose 50 percent of its activity by decay.
Radionuclide	a radioactive nuclide; a nuclide is characterized by the number of protons and the number of neutrons in its nucleus.
Standard Man	a person with the anatomical and physiological characteristics defined in the report of the ICRP Task Group on Reference Man (ICRP Publication 23).
Restricted area	an area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials.
Sievert	the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv = 100 rems).
Survey	an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation.
Timely renewal	the status of a licensee that has received a letter from the NRC acknowledging that the licensee has submitted an application for renewal as required by the regulations, and may continue to operate past the expiration date shown on the existing license until the review of the renewal application is completed.

Total Effective Dose Equivalent (TEDE)	the sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).
Type A specific license of broad scope	a specific license of broad scope authorizes a wide range of radionuclides in any chemical or physical form for a variety of purposes. A Type A licensee is required to establish a radiation protection committee.
Void	*verb*–to evacuate urine; *noun*–the entire volume of body waste eliminated in a particular time.
Whole-body counting	to measure directly the radiation emitted from radioactive material deposited in the organs and tissues of a body, using one or more radiation detectors to scan the entire body or a large fraction of the body. A variety of detector systems are used for whole-body counting.
Wipe test	an evaluation of removable contamination on a surface or object, wherein an absorbent material such as paper is rubbed across a surface and subsequently analyzed for radioactivity by a counting instrument.

References

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Appendix A

Incident Investigation Team Charter

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

October 17, 1995

MEMORANDUM TO: Chairman Jackson
Commissioner Rogers

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: INVESTIGATION OF A PHOSPHOROUS-32 INTERNAL CONTAMINATION AT THE CANCER RESEARCH CENTER, MASSACHUSETTS INSTITUTE OF TECHNOLOGY, BOSTON, MASSACHUSETTS

On Monday, October 16, 1995 at 10:15 a.m., the Radiation Safety Officer (RSO) for the Massachusetts Institute of Technology (MIT) informed Region I that on August 19, 1995 a male researcher at a laboratory in the MIT Cancer Research Center was found to have had an uptake of phosphorus-32 (P-32). The researcher discovered the uptake during a routine closeout survey of his work area on Saturday evening, August 19, 1995. The researcher concluded that the high background radiation in the laboratory was being caused by his internal radioactive contamination.

MIT radiation safety officials initiated surveys later in the evening on August 19, 1995 of the laboratory work areas, the individual's home and his family members with negative results. Urine samples and whole body counting of the contaminated individual and articles of clothing were also initiated. The licensee believes that the researcher was internally contaminated on August 14, 1995. Other personnel in the laboratory were evaluated for contamination on Monday, August 21, 1995 with negative results. The licensee has accounted for all P-32 material except for about 500 microcuries based on an inventory and records of its use in the laboratory.

Analysis of urine and samples over a six-week period and whole-body scans conducted by the licensee has led the licensee to conclude the individual's uptake had been a maximum of 579 microcuries. At the individual's request, an outside expert is reviewing the data and licensee assessment to determine whether appropriate samples were taken, if analyses were done correctly, and whether the assessment is reasonable. The licensee has provided NRC with a copy of the report of their assessment which was released to the contaminated individual during the week of October 9, 1995. A copy of the report from the outside expert will be provided to NRC Region I as soon as it is received by MIT.

The individual also reported the internal contamination to the MIT Campus Police and alleged that the contamination could not be explained by normal handling. The Campus police are reviewing the information. MIT will issue a press release.

Because the incident involves circumstances which are not well enough understood, and involves characteristics, the investigation of which would best serve the needs and interests of the Commission, I have requested AEOD to establish an NRC Incident Investigation Team (IIT). The IIT is to: (a) fact-find as to what happened, (b) identify the probable cause or causes as to why it happened, and (c) make appropriate findings and conclusions which would form the basis for any necessary follow-on actions. The IIT charter is attached. Based on the initial assessment by the team, it is possible that the investigation could be downgraded to an AIT.

The team will report directly to me and is comprised of: John Glenn (RES), IIT Leader; Larry Robinson (Office of Investigations, Region II); Elizabeth Ullrich (Region I); Sami Sherbini (NMSS); and Alan Madison (AEOD). Contractor support will provide additional technical expertise, as necessary. Because of the limited number of technical experts able to investigate an event of this type, some team members have had previous inspection involvement at the facility The IIT was selected on the bases of their knowledge and experience in the fields of medical physics, health physics, laboratory radiation safety procedures and investigations. All team members are relieved of all normal duties while assigned to the IIT.

The Commonwealth of Massachusetts has been notified of the event. NRC Region I and the Office of Public Affairs are prepared to respond to media interest. NRC Region I initiated an immediate inspection at MIT to follow-up on the licensee's actions in assessing this contamination event. This inspection has been subsumed by this IIT. Region I remains responsible for any enforcement or other actions resulting from this investigation.

The licensee has agreed to preserve the biological samples taken from the contaminated individual until the team has had an opportunity to evaluate the event. The licensee's actions have been confirmed by the Region in a Confirmatory Action Letter which was issued on October 17, 1995.

The IIT report will constitute the single NRC fact-finding investigation report. It is expected that the IIT report will be issued within about 45 days from the time the team exits from the site.

Attachment: As stated

cc w/encl:
SECY
OCG
ACRS
OPA
OSP
Regional Administrators

Incident Investigation Team Charter

PHOSPHOROUS-32 INTERNAL CONTAMINATION
AT THE CANCER RESEARCH CENTER,
MASSACHUSETTS INSTITUTE OF TECHNOLOGY, BOSTON, MASSACHUSETTS

The scope of the investigation should include: incident chronology; source of the P-32 and contamination characterization; analysis of actual and potential dose consequences; radiation safety program; event reporting and licensee response; an evaluation of potential wrongdoing at the center; and whether the NRC's regulatory process and activities preceding the event contributed to it. Within the framework of this overall scope the IIT should specifically:

With respect to the incident chronology; develop a probable sequence of events associated with the P-32 internal contamination including its probable source; handling and movement within the center; and ingestion circumstances.

With respect to the P-32 source and contamination characterization: determine the quantity and chemical form of the radioactive material ingested, whether any other individuals were contaminated, and any external contamination associated with the event.

With respect to analysis of the actual and potential dose consequences: evaluate the intake and the resulting internal dose received by the researcher (and any others who may have been contaminated) as a result of the ingestion or external contamination, and the potential health consequences, (if any); and assess exposures (if any) to any other individuals who were associated with the center from the time of discovery of the cancer researcher's internal contamination.

With respect to the radiation safety program: evaluate the licensee's program at the center for P-32 including material accounting; controlling access and use; evaluate the use of surveys for detecting contaminations and procedures for responding to P-32 contaminations.

With respect to event reporting and licensee response evaluate the actions taken by the licensee to: report the contamination to the NRC; assess contamination of individual(s) including medical followup and mitigation treatments; assess the extent of any other associated contaminations at the center and offsite; and prevent additional similar events. Provide input to Region I to evaluate continued operations of the center.

With respect to potential wrongdoing at the center: evaluate whether and the nature of any intentional actions by one or more individuals to cause the contamination.

With respect to the NRC's regulatory process and activities: evaluate the regulatory controls concerning this type of event.

Attachment

Appendix B

Revised Incident Investigation Team Charter

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

October 20, 1995

MEMORANDUM TO: Chairman Jackson
Commissioner Rogers

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: MODIFICATIONS TO THE ONGOING INVESTIGATION AT MIT CANCER RESEARCH CENTER

Reference: Memorandum of October 17, 1995, Subject: Investigation of A Phosphorous-32 Internal Contamination at the Cancer Research Center, Massachusetts Institute of Technology, Boston, Massachusetts

In the reference memorandum I provided you a brief description of an event at the MIT Cancer Research Center and notified you of my decision to form an IIT pursuant to Agency procedures. The team members included, among others, a representative of the Office of Investigations. The IIT Charter was attached to the October 17 memorandum. One element of the Charter included the following:

> "With respect to potential wrongdoing at the center: evaluate whether and the nature of any intentional actions by one or more individuals to cause the contamination."

I and senior staff members of HQ and Region I had an extended conference call with the IIT on Friday, October 20, 1995. On the basis of the information exchanged in this call, I now believe that a separate OI investigation should pursue the matter of potential wrongdoing. Accordingly, this memorandum directs OI to start their separate investigation, and modifies the IIT Charter to remove the task related to wrongdoing. The OI member of the IIT is removed from the IIT, and will begin the OI investigation phase in accordance with OI procedures. The principal contacts at MIT will be informed of this change.

This action is effective at noon (EDT) Friday, October 20.

Attachment: Revision 1 to IIT Charter

cc: SECY
OGC
ACRS
OPA
OSP
Regional Administrators

Incident Investigation Team Charter
Revision One
PHOSPHOROUS-32 INTERNAL CONTAMINATION
AT THE CANCER RESEARCH CENTER,
MASSACHUSETTS INSTITUTE OF TECHNOLOGY, BOSTON, MASSACHUSETTS

The scope of the investigation should include: incident chronology; source of the P-32 and contamination characterization; analysis of actual and potential dose consequences; radiation safety program; event reporting and licensee response; and whether the NRC's regulatory process and activities preceding the event contributed to it. Within the framework of this overall scope the IIT should specifically:

With respect to the incident chronology; develop a probable sequence of events associated with the P-32 internal contamination including its probable source; handling and movement within the center; and ingestion circumstances. A separate OI investigation will followup any potential wrongdoing at the centers.

With respect to the P-32 source and contamination characterization: determine the quantity and chemical form of the radioactive material ingested, whether any other individuals were contaminated, and any external contamination associated with the event.

With respect to analysis of the actual and potential dose consequences: evaluate the intake and the resulting internal dose received by the researcher (and any others who may have been contaminated) as a result of the ingestion or external contamination, and the potential health consequences, (if any); and assess exposures (if any) to any other individuals who were associated with the center from the time of discovery of the cancer researcher's internal contamination.

With respect to the radiation safety program: evaluate the licensee's program at the center for P-32 including material accounting; controlling access and use; evaluate the use of surveys for detecting contaminations and procedures for responding to P-32 contaminations.

With respect to event reporting and licensee response evaluate the actions taken by the licensee to: report the contamination to the NRC; assess contamination of individual(s) including medical followup and mitigation treatments; assess the extent of any other associated contaminations at the center and offsite; and prevent additional similar events. Provide input to Region I to evaluate continued operations of the center.

With respect to the NRC's regulatory process and activities: evaluate the regulatory controls concerning this type of event.

Attachment

Appendix C

Analysis of Urine and Whole-Body Data by Lawrence Livermore National Laboratory

Internal Dosimetry Case Narrative

Identification:

Name: MIT Researcher

ID: NA

Gender: Male

Status: Active

Incidents:

Date	Incident #	Involvement	Location	Comments
08/14/1995 at 12:00		P-32		Ingestion

Previous intake/dose assessments:

None provided.

Other information:

Whole body counting data from the Massachusetts Institute of Technology, Whole Body Counter spanning dates 19-Aug-95 through 11-Oct-95 (Masse/Bolton Chair Design, *Health Physics* Vol. 19:1, pp.27).

Urine analysis data provided by the Radiation Safety Office at MIT, spanning dates 26-Aug-95 through 4-Oct-95.

Urine analysis data provided by the MIT researcher, spanning dates 25-Aug-95 through 11-Oct-95.

Intake Assessment Summary

A) Data Summary:

Three sets of data were used for this dose evaluation; urine sample analyses performed by the Radiation Safety Office (RSO) at MIT, whole body count data from the MIT Whole Body Counter, and urine sample analyses performed by the MIT researcher who was involved in the incident. Based on the data provided by the researcher and whole body count data, the date of intake was assumed to be 14-Aug-95. The earliest measurement of ^{32}P deposition, a whole body count, was performed 5 days post the assumed intake date. Whole body count data was available until day 58 post intake. The earliest urine analysis data was 11 days post intake as obtained from the researcher's data set. The last day of available urine analysis data was 58 post intake, as obtained from the researcher generated data set. The RSO urine analyses expanded a slightly shorter period of time (26-Aug-95 through 4-Oct-95) than the whole body count data or the researcher urine analysis data. All three data sets were very precise as a function of time post intake, and were consistent with a single compartment maintaining exponential removal. None of the measurement data were provided with estimates of error.

Computations performed by the RSO, researcher, and whole body counter personnel were verified for all three data sets. Likewise, estimates of error for the RSO urine analysis data and the whole body count data were generated using information provided on the data sheets. For the RSO urine analyses, the count time used to generate error estimates was 2 minutes, as provided to LLNL by the NRC Incident Investigation Team (IIT). Summary tables of the data sets and estimates of errors used for final estimates of intakes and doses are provided in Tables 1-3.

The dose estimate assumes that all urine was collected over a 24 hour period. This assumption is supported by the data sheets provided by the MIT researcher, giving start and stop times of 12:00 hours for each sample. Likewise, the volumes of the urine samples are consistent with the expected range of 24 hour urinary excretion published in Reference Man tables provided in ICRP Publication #23.

Table 1. RSO urine analysis data used for this dose assessment, ^{32}P ingestion.

Sample Start Date	Sample Start Time	Sample End Date	Sample End Time	Measured Activity (μCi/day)	Estimated 1σ error (μCi/day)
8/25/95	12:00	8/26/95	12:00	1.32	0.058
8/26/95	12:00	8/27/95	12:00	1.56	0.075
8/27/95	12:00	8/28/95	12:00	2.02	0.081
8/28/95	12:00	8/29/95	12:00	2.07	0.075
8/29/95	12:00	8/30/95	12:00	1.55	0.063
8/30/95	12:00	8/31/95	12:00	1.46	0.055
8/31/95	12:00	9/1/95	12:00	1.49	0.056
9/1/95	12:00	9/2/95	12:00	1.13	0.057
9/2/95	12:00	9/3/95	12:00	0.88	0.057
9/3/95	12:00	9/4/95	12:00	1.16	0.060
9/4/95	12:00	9/5/95	12:00	0.970	0.048
9/5/95	12:00	9/6/95	12:00	0.890	0.049
9/6/95	12:00	9/7/95	12:00	0.760	0.040
9/7/95	12:00	9/8/95	12:00	0.685	0.043
9/8/95	12:00	9/9/95	12:00	0.490	0.393
9/9/95	12:00	9/10/95	12:00	0.680	0.041
9/10/95	12:00	9/11/95	12:00	0.644	0.040
9/11/95	12:00	9/12/95	12:00	0.647	0.040
9/12/95	12:00	9/13/95	12:00	0.540	0.040
9/13/95	12:00	9/14/95	12:00	0.520	0.033
9/14/95	12:00	9/15/95	12:00	0.348	0.035
9/15/95	12:00	9/16/95	12:00	0.330	0.029
9/16/95	12:00	9/17/95	12:00	0.312	0.034
9/17/95	12:00	9/18/95	12:00	0.302	0.027
9/18/95	12:00	9/19/95	12:00	0.318	0.031
9/19/95	12:00	9/20/95	12:00	0.367	0.031
9/20/95	12:00	9/21/95	12:00	0.341	0.034
9/21/95	12:00	9/22/95	12:00	0.296	0.026
9/22/95	12:00	9/23/95	12:00	0.252	0.029
9/23/95	12:00	9/24/95	12:00	0.222	0.030
9/24/95	12:00	9/25/95	12:00	0.231	0.030
9/25/95	12:00	9/26/95	12:00	0.206	0.026
9/26/95	12:00	9/27/95	12:00	0.174	0.022
9/27/95	12:00	9/28/95	12:00	0.211	0.029
9/28/95	12:00	9/29/95	12:00	0.170	0.023
9/29/95	12:00	9/30/95	12:00	0.177	0.025
9/30/95	12:00	10/1/95	12:00	0.149	0.021
10/1/95	12:00	10/2/95	12:00	0.149	0.024
10/2/95	12:00	10/3/95	12:00	0.142	0.022
10/3/95	12:00	10/4/95	12:00	0.122	0.016

Table 2. Researcher urine analysis data used for this dose assessment, ^{32}P ingestion.

Sample Start Date	Sample Start Time	Sample End Date	Sample End Time	Days Post Intake	Measured Activity (μCi/day)
8/24/95	12:00	8/25/95	12:00	11	2.562
8/25/95	12:00	8/26/95	12:00	12	1.517
8/26/95	12:00	8/27/95	12:00	13	1.593
8/27/95	12:00	8/28/95	12:00	14	2.064
8/28/95	12:00	8/29/95	12:00	15	2.055
8/29/95	12:00	8/30/95	12:00	16	1.664
8/30/95	12:00	8/31/95	12:00	17	1.529
8/31/95	12:00	9/1/95	12:00	18	1.573
9/1/95	12:00	9/2/95	12:00	19	1.36
9/2/95	12:00	9/3/95	12:00	20	0.985
9/3/95	12:00	9/4/95	12:00	21	1.315
9/4/95	12:00	9/5/95	12:00	22	1.044
9/5/95	12:00	9/6/95	12:00	23	1.098
9/6/95	12:00	9/7/95	12:00	24	0.885
9/7/95	12:00	9/8/95	12:00	25	0.742
9/8/95	12:00	9/9/95	12:00	26	0.706
9/9/95	12:00	9/10/95	12:00	27	0.807
9/10/95	12:00	9/11/95	12:00	28	0.773
9/11/95	12:00	9/12/95	12:00	29	0.742
9/12/95	12:00	9/13/95	12:00	30	0.572
9/13/95	12:00	9/14/95	12:00	31	0.561
9/14/95	12:00	9/15/95	12:00	32	0.439
9/15/95	12:00	9/16/95	12:00	33	0.407
9/16/95	12:00	9/17/95	12:00	34	0.354
9/17/95	12:00	9/18/95	12:00	35	0.315
9/18/95	12:00	9/19/95	12:00	36	0.344
9/19/95	12:00	9/20/95	12:00	37	0.306
9/20/95	12:00	9/21/95	12:00	38	0.341
9/21/95	12:00	9/22/95	12:00	39	0.311
9/22/95	12:00	9/23/95	12:00	40	0.268
9/23/95	12:00	9/24/95	12:00	41	0.257
9/24/95	12:00	9/25/95	12:00	42	0.263
9/25/95	12:00	9/26/95	12:00	43	0.21
9/26/95	12:00	9/27/95	12:00	44	0.219
9/27/95	12:00	9/28/95	12:00	45	0.211
9/28/95	12:00	9/29/95	12:00	46	0.216
9/29/95	12:00	9/30/95	12:00	47	0.193
9/30/95	12:00	10/1/95	12:00	48	0.169
10/1/95	12:00	10/2/95	12:00	49	0.145
10/2/95	12:00	10/3/95	12:00	50	0.154
10/3/95	12:00	10/4/95	12:00	51	0.144
10/4/95	12:00	10/5/95	12:00	52	0.131
10/5/95	12:00	10/6/95	12:00	53	0.146
10/6/95	12:00	10/7/95	12:00	54	0.101
10/7/95	12:00	10/8/95	12:00	55	0.091
10/8/95	12:00	10/9/95	12:00	56	0.109
10/9/95	12:00	10/10/95	12:00	57	0.098
10/10/95	12:00	10/11/95	12:00	58	0.092

Table 3. Whole Body Count data used for this dose assessment, ^{32}P ingestion.

Date	Days Post Intake	Measured (μCi)	Estimated 1σ error (μCi)
19-Aug-95	5	263	0.825
21-Aug-95	7	204	0.737
22-Aug-95	8	194	0.72
23-Aug-95	9	178	0.695
24-Aug-95	10	165	0.673
25-Aug-95	11	157	0.659
28-Aug-95	14	129	0.606
29-Aug-95	15	122	0.594
30-Aug-95	16	109	0.568
31-Aug-95	17	103	0.566
1-Sep-95	18	99	0.546
5-Sep-95	22	76	0.494
6-Sep-95	23	69	0.479
7-Sep-95	24	65	0.468
8-Sep-95	25	66	0.471
11-Sep-95	28	50	0.431
12-Sep-95	29	49	0.426
13-Sep-95	30	45	0.417
14-Sep-95	31	44	0.413
15-Sep-95	32	41	0.403
18-Sep-95	35	34	0.384
19-Sep-95	36	28.3	0.366
20-Sep-95	37	28.5	0.367
21-Sep-95	38	27.8	0.365
22-Sep-95	39	25.8	0.358
25-Sep-95	42	22.3	0.346
26-Sep-95	43	19.8	0.338
27-Sep-95	44	19.8	0.338
28-Sep-95	45	18.4	0.333
29-Sep-95	46	16.5	0.326
2-Oct-95	49	14.5	0.319
3-Oct-95	50	13.5	0.316
4-Oct-95	51	12.3	0.311
5-Oct-95	52	12.3	0.311
6-Oct-95	53	11.1	0.307
10-Oct-95	57	9.4	0.3
11-Oct-95	58	7.5	0.293

B) Intake estimate and dose assessment using urine data

The incident was assumed to have occurred at 12:00 on 14-Aug-95 and was deemed to be an acute intake. The parameters used in the calculation of this acute intake assume ingestion of 100% soluble material. The CINDY[1] program was used to calculate intakes of ^{32}P for the both the RSO generated and researcher generated urine bioassay results, using the standard ICRP Publication #30 models. The CINDY program was also used to make a projection of bioassay results following the intake and estimates of doses. The initial intake estimates using the standard ICRP models for ^{32}P ranged from 560 μCi to 820 μCi .

C) Intake estimate and dose assessment using whole body counts:

In vivo measurement of the ^{32}P is a direct measurement of the ^{32}P content in the body and requires fewer model assumptions when assessing intake. The CINDY program was used to calculate an intake of ^{32}P for the set of whole body counts (see Table 3). The parameters used in the calculation of this acute intake assume ingestion of 100% soluble material. The CINDY program was also used to make a projection of bioassay results following the intake. The estimated intake from the whole body measurement data ranged from 530 μCi to 570 μCi .

D) Intake estimate and dose assessment using a modified model:

There was significant discrepancy between the estimates of intake from the urine data sets and the whole body counter data set, therefore further evaluation was necessary.

The standard ICRP Publication #30 systemic biokinetic model (excluding physical decay) for ^{32}P consists of four compartments. Mathematically, the model is represented by:

$$R(t) = 0.15e^{-0.693\frac{t}{0.5}} + 0.15e^{-0.693\frac{t}{2}} + 0.4e^{-0.693\frac{t}{19}} + 0.3 \qquad \text{Eqn. 1.}$$

where: R(t) is whole body retention.

[1] CINDY is an internal dosimetry code developed by the Department of Energy in accordance with NQA-1 requirements. CINDY is commercially available through Camberra Industries, Merriden CT.

A graphical representation of the ICRP model predictions to the RSO, researcher's, and whole body count data sets are provided in Figures 1, 2, and 3 respectively. For both sets of urine sample data, the first urine sample was collected at a time long compared to the assumed intake date such that the first two compartments in the model would no longer have any significant influence on the model fit to data. Likewise, the last compartment would not be observed in the urine data since none of the ^{32}P in this compartment is excreted. Review of the model fits to each set of data (see Figures 1 & 2) indicates that the ICRP model fails to adequately explain the true retention of the ingested ^{32}P (note the lack of fit for the predicted urinary excretion curves relative to the measured data after approximately 35 days). Therefore, an alternate approach to the assessment was pursued.

Figure 1. CINDY predicted excretion rates using four analysis methods and the ICRP metabolic model for the MIT RSO data set.

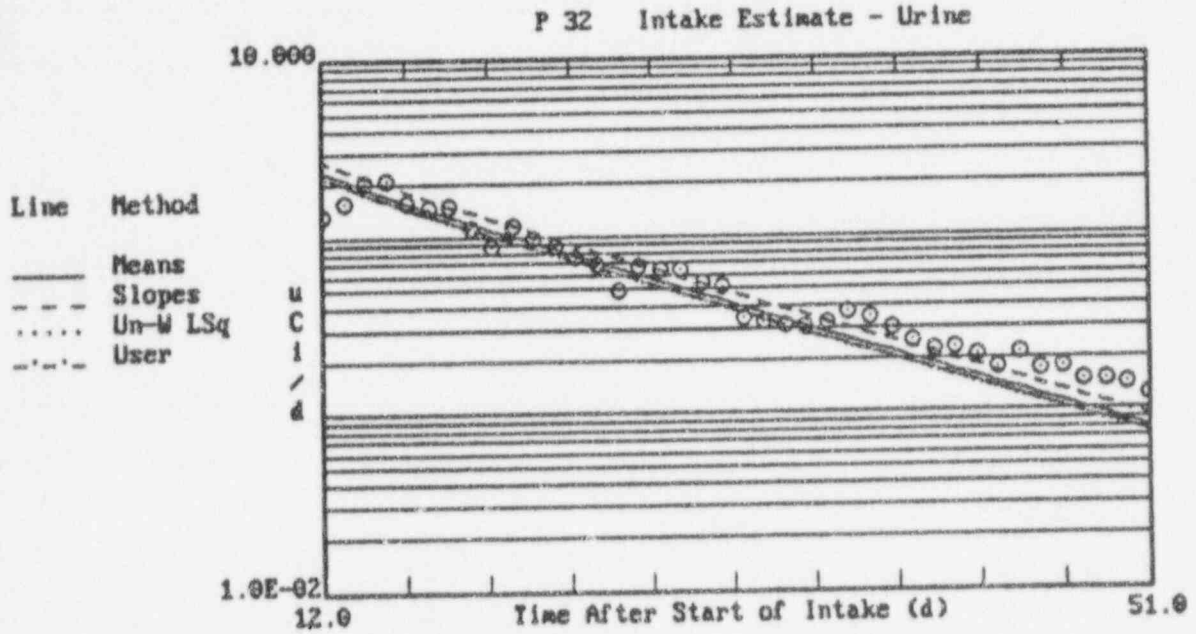


Figure 2. CINDY predicted excretion rates using four analysis methods and the ICRP Model for the MIT Researcher's data set.

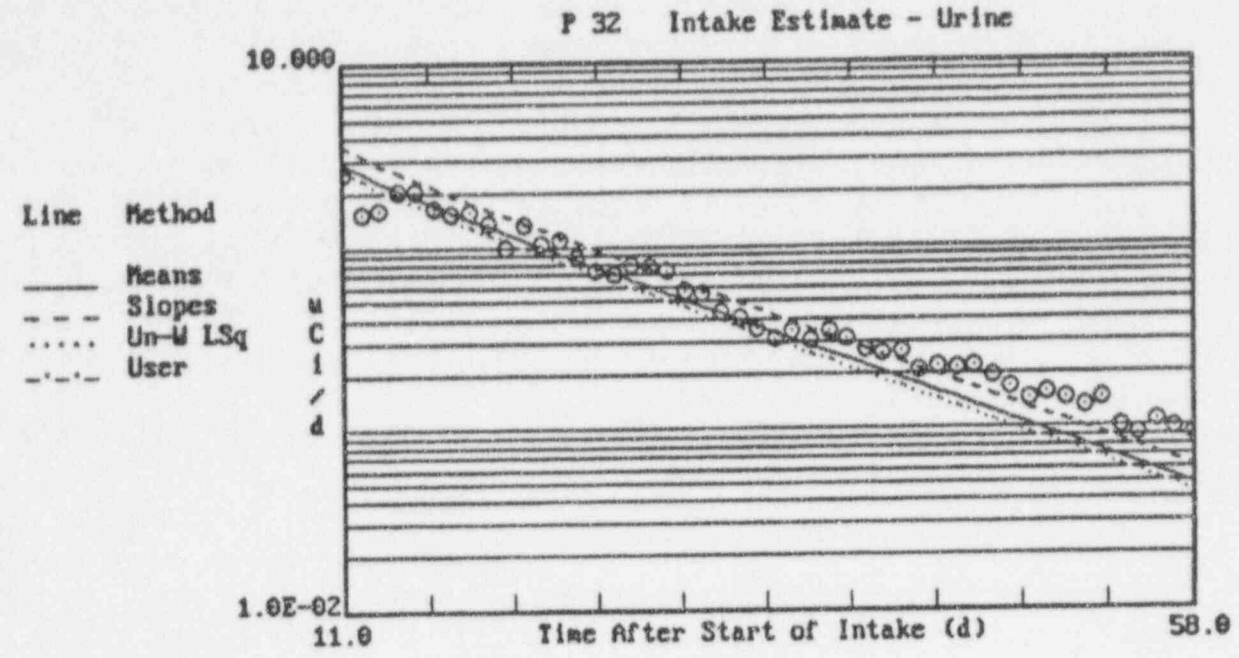
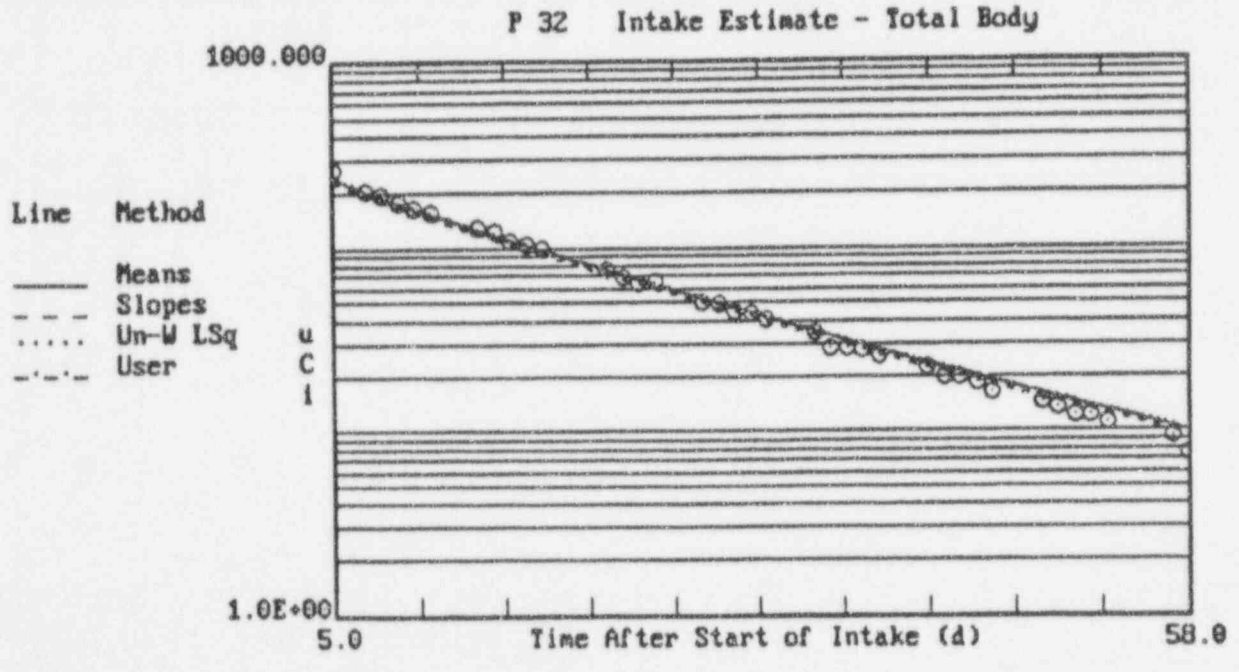


Figure 3. CINDY predicted whole body retention using four analysis methods and the ICRP model for the MIT In Vivo Measurements.



A non-linear regression analysis of each data set was performed using a statistical analysis program called SYSTAT[2]. The regression analysis performed a non-linear fit tot a single compartment exponential model. Based on these analyses, the effective half-life of ^{32}P observed in the urinary excretion data was 9.85 days and 9.90 days for the RSO and researcher data sets with $r^2 = 0.90$ and 0.95 respectively. Likewise, the effective half-life for the whole body measurement data was 10.1 days with $r^2 = 0.99$. Statistical errors associated with this statistical analysis indicate that there is non-significant difference between the effective half-lives. A single effective half-time of 9.87 days was chosen for all three data sets. Removing physical decay, an effective half-life of 9.87 days provides a biological half-time of 32 days.

Blind application of the longer biological half-time without changes to the partition fractions of the model will result in poor estimates of intake. For example, replacing the 19 day half-time with a 32 day half-time in the third component of the ^{32}P retention model results in improved model predictions for the measured excretion rates as shown in Figures 4 and 5. The predicted intakes from these assessments ranged from 720 μCi to 810 μCi, providing a much more precise estimate of intake. However, replacing the 19 day biological half-time with a 32 day half-time in the third component of the ICRP model using the whole body count data results in more variable estimates of intake (450 μCi to 520 μCi) and a poorer fit of the model to the data. In addition, replacing only the half-time results in more divergent estimates of intake between urine sample and whole body measurement data.

[2] ® Intelligent Software, Evanston, IL.

Figure 4. CINDY predicted excretion rates using four analysis methods and a 32 day half-time for the third compartment of the ICRP Model - MIT RSO data set.

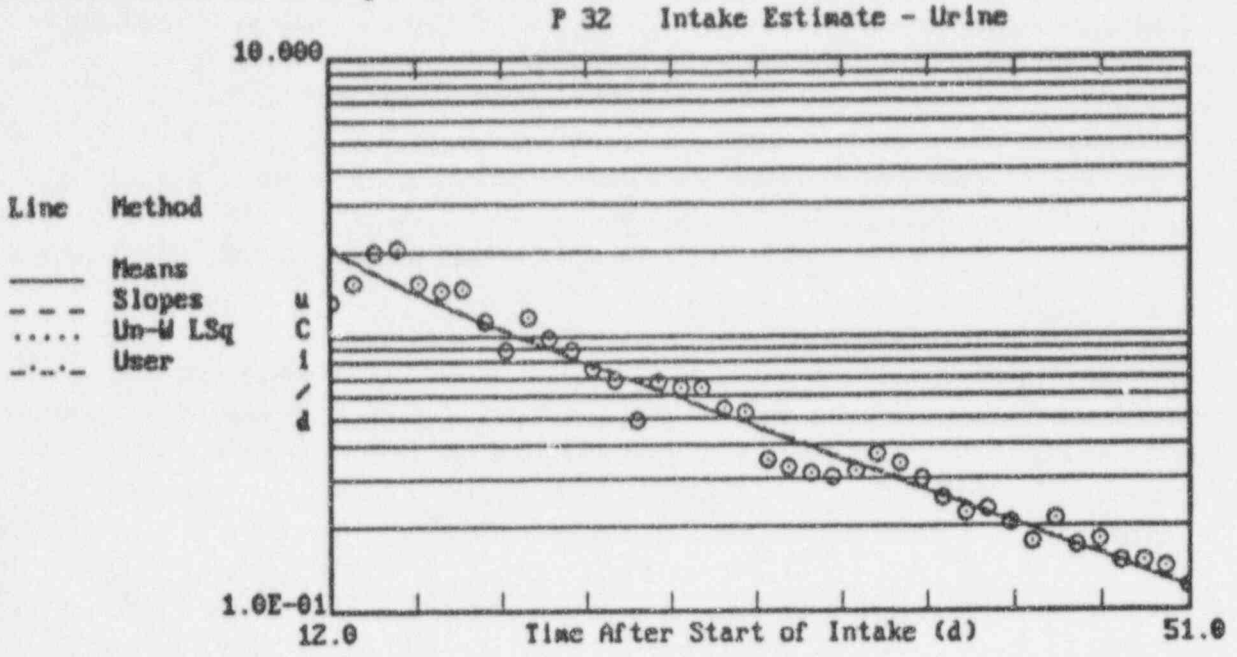
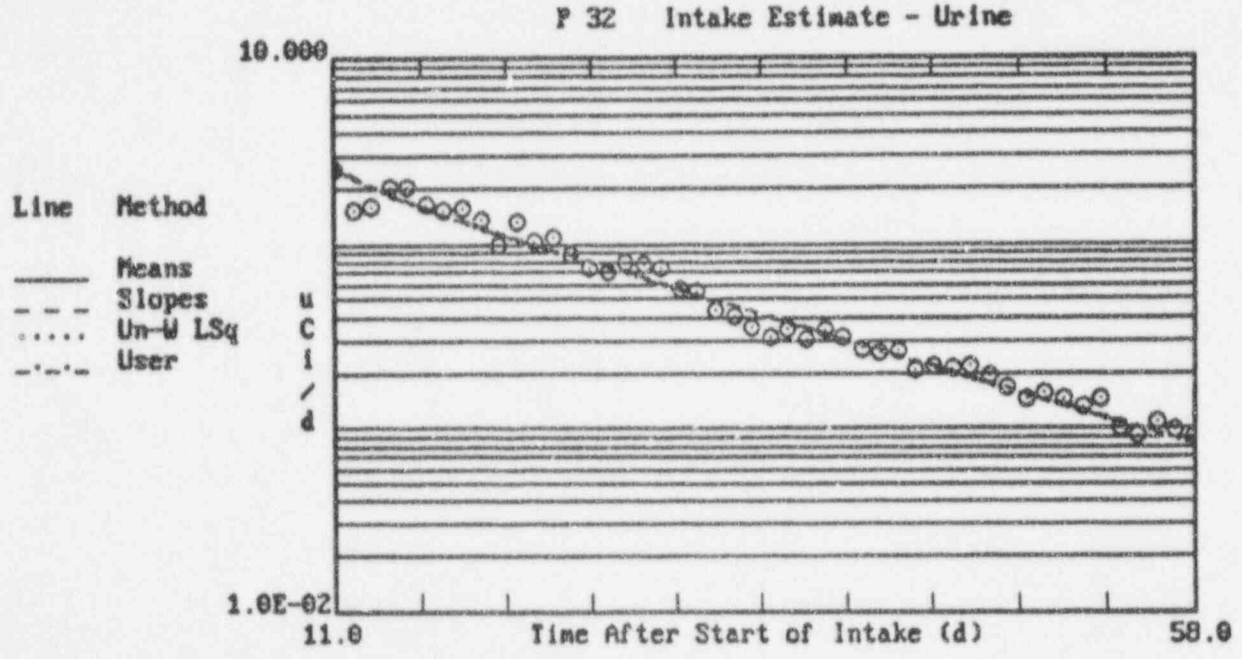


Figure 5. CINDY predicted excretion rates using four analysis methods and a 32 day half-time for the third compartment of the ICRP Model - MIT Researcher's data set.



Since the whole body measurements were not initiated until 5 days post intake, the whole body measurements are primarily a measure of the last two compartments of the biokinetic model. Thus it is a measure of the fraction of activity that is retained with a 32 day half-time and a the fraction of activity that is permanently retained in the body. In contrast, the urine data are a measure of the 32 day half-time compartment only. This allows for the adjustment of the partitioning between the last two compartments of the ^{32}P model while using the 32 day biological half-time for the third compartment. The results of the modifications to the partition fractions in the last two compartments can then be tested with respect to predictions using each data set, until the three sets of intake estimates converge.

While maintaining the biological half-time of 32 days in the third compartment of the model, the partition coefficients of the third and fourth compartments were adjusted until an optimum convergence was achieved for all three data sets. This resulting model modification is summarized as:

$$R(t) = 0.15e^{-0.693\frac{t}{0.5}} + 0.15e^{-0.693\frac{t}{2}} + 0.55e^{-0.693\frac{t}{32}} + 0.15 \qquad \text{Eqn. 2.}$$

This model was used to generate the final intake and dose estimates.

G) Final Intake and Dose Estimates:

The intake estimates and the CEDEs for each of the data sets are summarized in Table 4. These estimates were performed using the internal dosimetry code CINDY and the modified ^{32}P model which is previously described. The methods used by CINDY to calculate intake and dose are documented in Part 1, "Code for Internal Dosimetry (CINDY)", PNL-7493/UC-605. CINDY uses four analysis methods ("line methods") for evaluation of bioassay data[3]. For the purpose of this evaluation, the method which uses 'user defined weights' was evaluated using the square of the standard deviation (i.e., variance) for the measurement. Figures 6, 7, and 8 provide graphic representations of the model fits of the urine and in vivo measurement data using the modified ^{32}P biokinetic model. The four statistical evaluations of the data sets demonstrate the variability in the estimates and provides the dosimetrist with an estimate of acceptable ranges of intakes and doses that are statistically equivalent. The graphical representations of the statistical evaluations allow the dosimetrist to choose the method that best fits the data set.

[3] Note: each of the four methods represnt the 'best' statistical fit to the data for the method of statistical analysis .used.

Figure 6. CINDY predicted excretion rates using four analysis methods and the modified ICRP Model - MIT RSO data set.

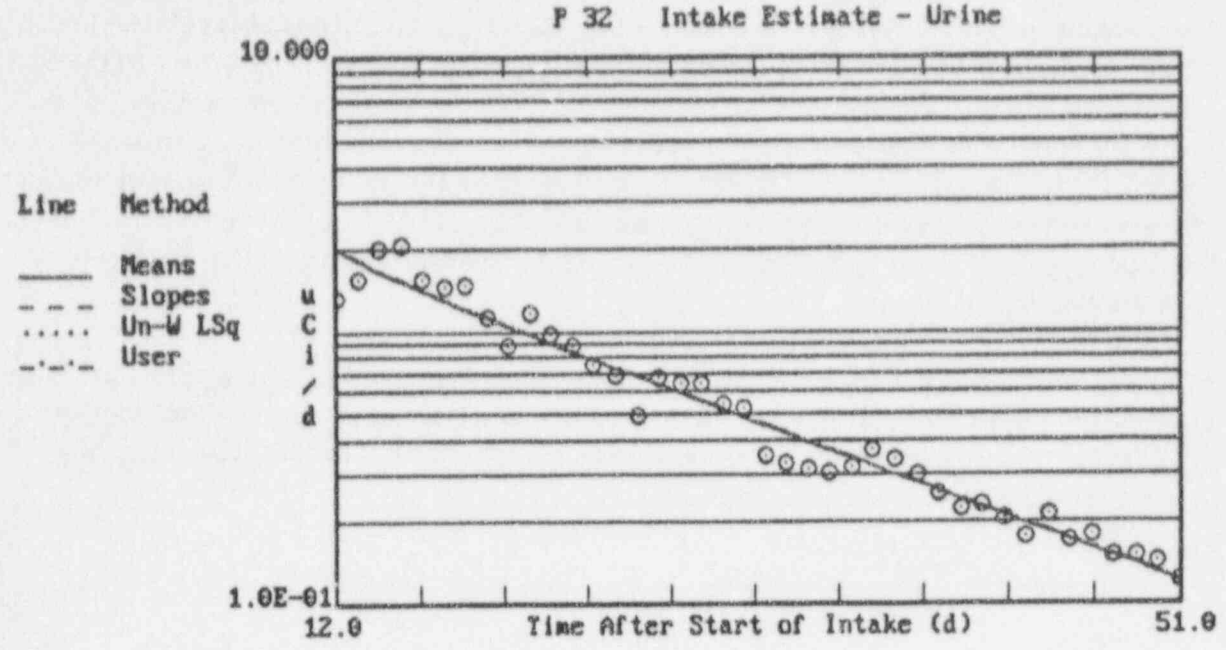


Figure 7. CINDY predicted excretion rates using four analysis methods and the modified ICRP model - MIT Researcher's data set.

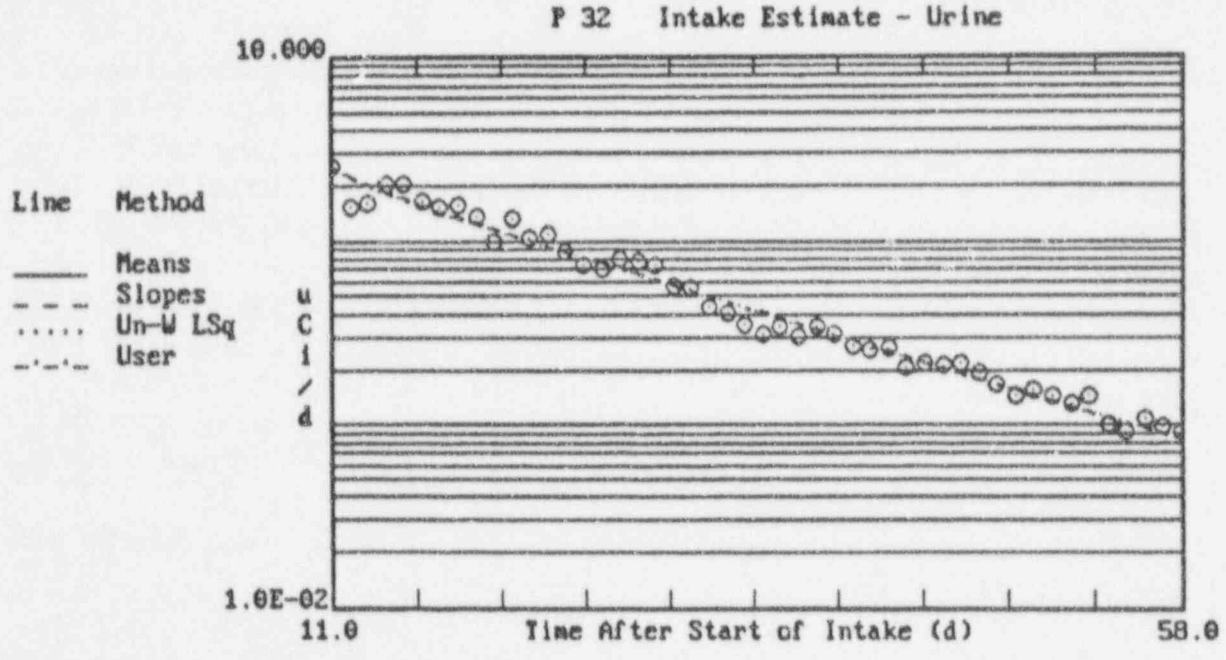


Figure 8. CINDY predicted whole body retention using four analysis methods and the modified ICRP model - MIT In Vivo Measurements.

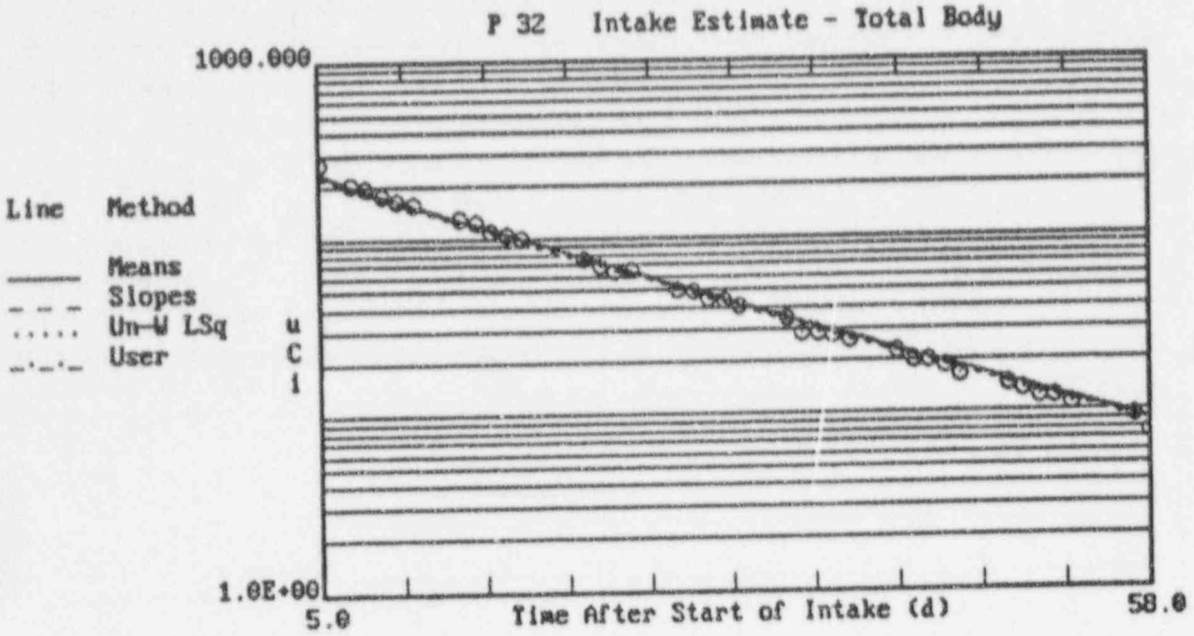


Table 4. Summary of Final Intake and Dose Estimates.[4]

Sample type	CEDE (rem)	Intake Estimate (μCi)
RSO Urine Measurements	4.4	530
Researcher's Urine Measurements	4.9	590
Whole Body Counter Measurements	4.5	540
Average	4.6	550

There are significant differences between the MIT and Researcher's measurement data. The most notable difference occurs in the volumes. The volumes for the same sample differed by as much as 130 ml. Since the volumes are a multiplicative factor for the activity concentration (dpm/ml), there were significant differences between the RSO and researcher's activity estimates. These differences are also responsible for the differences observed in the intake and dose estimates. More accurate estimates could be obtained if these differences in volume determinations could be resolved. A secondary cause for differences in the sample measurement results could be due to the inhomogeneity of the unpreserved urine samples and the aliquots collected by the researcher and RSO.

[4] Intake estimate and dose assessments using urine and whole body count data were performed using the dosimetry code CINDY version 1.4 and the modified ^{32}P biokinetic model.

The dose associated with any intake is directly proportional to the area under the excretion curve. Failure to adequately estimate the area under portions of the excretion curve will result in differing dose assessments. Usually, the largest differences will be noted when there is a failure to model the data at longer times post intake. For this reason, it is necessary to assure adequate assessment and proper modeling of data at longer times post intake. Because of the inadequacy of internationally accepted modeling methods to model for actual biokinetic responses (e.g., using a 19 day biokinetic half-time), it is sometimes necessary to modify the model, especially when adequate data is available. The best estimate of intake is one which generates expected excretion values that visually (as well as statistically) best fit the measurement data. For the MIT incident data, the best fit to the data is obtained using the model modifications provided in Eqn. 2.

Prepared by: David P. Hickman
Print or type name

David P. Hickman
Signature

11/22/95
Date

Reviewed by: Son Nguyen
Print or type name

Nguyen, Nguyen
Signature

11/22/95
Date

Appendix D

Analysis of Urine and Whole-Body Data by Oak Ridge Institute for Science and Education

ORISE
OAK RIDGE INSTITUTE FOR SCIENCE AND EDUCATION

MEDICAL SCIENCES DIVISION

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November 7, 1995

Donna-Beth Howe, Ph.D.
Division of Industrial and Medical
Nuclear Safety
Office of Nuclear Material Safety
and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Dr. Howe,

I have evaluated the whole body counting and urinary excretion data that you sent to me related to the possible intake of P-32 by the researcher at MIT. I evaluated the urinary excretion data, as performed by MIT researchers and by the contaminated individual, as indicated in the data that you provided. In all of the analyses, I assumed that the calculated values of activity (in the whole body or in a 24-hr urine sample) were correct. I did spot check a few values in each case to look for obvious errors, but found none of significance. I then used the intake retention and excretion functions (IRFs) from NUREG/CR-4884 to estimate the single value of intake that would be predicted using a least squares analysis. I used log interpolation in the NUREG tables to obtain IRFs at times intermediate between tabulated values (e.g. at 12 days post intake when values were given only for 10 days and 20 days post intake). The results I obtained were:

Type of Analysis	Intake (μCi) - Weighted Analysis	Intake (μCi) - Unweighted Analysis
Whole Body	580 μCi	590 μCi
Urine - MIT	560 μCi	500 μCi
Urine - Researcher	590 μCi	520 μCi

The weighted estimates are in excellent agreement with one another, and point to an intake of around 580 μCi. The enclosed graphs show the agreement of the data with the model, assuming these levels of intake. As is normal for this type of least squares analysis, the agreement with the early data is better than with the later data, as the least squares analysis assumes that the relative variance of data at later times is greater, and thus assigns less weight to those data. It is encouraging that all of the data in this analysis point to almost the same intake. I think we can be confident that the intake was around, or just under, 600 μCi, if the estimates of whole body and urine activity are reliable. Again, however, due to the agreement of the three results, it seems likely that the reported values are reliable.

I did not yet attempt to assign a dose for this individual, as I did not know his body weight. Using the Reference Man model (70 kg), the committed effective dose equivalent (CEDE) from an intake of 600 μCi of P-32 is approximately 4.7 rem, using the Annual Limit on Intake (ALI) for Reference Man of 640 μCi, as can be derived from ICRP 30. I realize that the ALI quoted in 10CFR20 is 600 μCi, to one significant figure, indicating that intake of 600 μCi would result in a CEDE of 5.0 rem. The more accurate value of 640 μCi, however, indicates that the dose may be slightly less. If one assumes an intake of 580 μCi, the dose assigned would be 4.5 rem, based on an ALI of 640 μCi. If the person is smaller than Reference Man, however, the dose will be higher. Please let me know if you would like any further analysis of these data.

Sincerely,

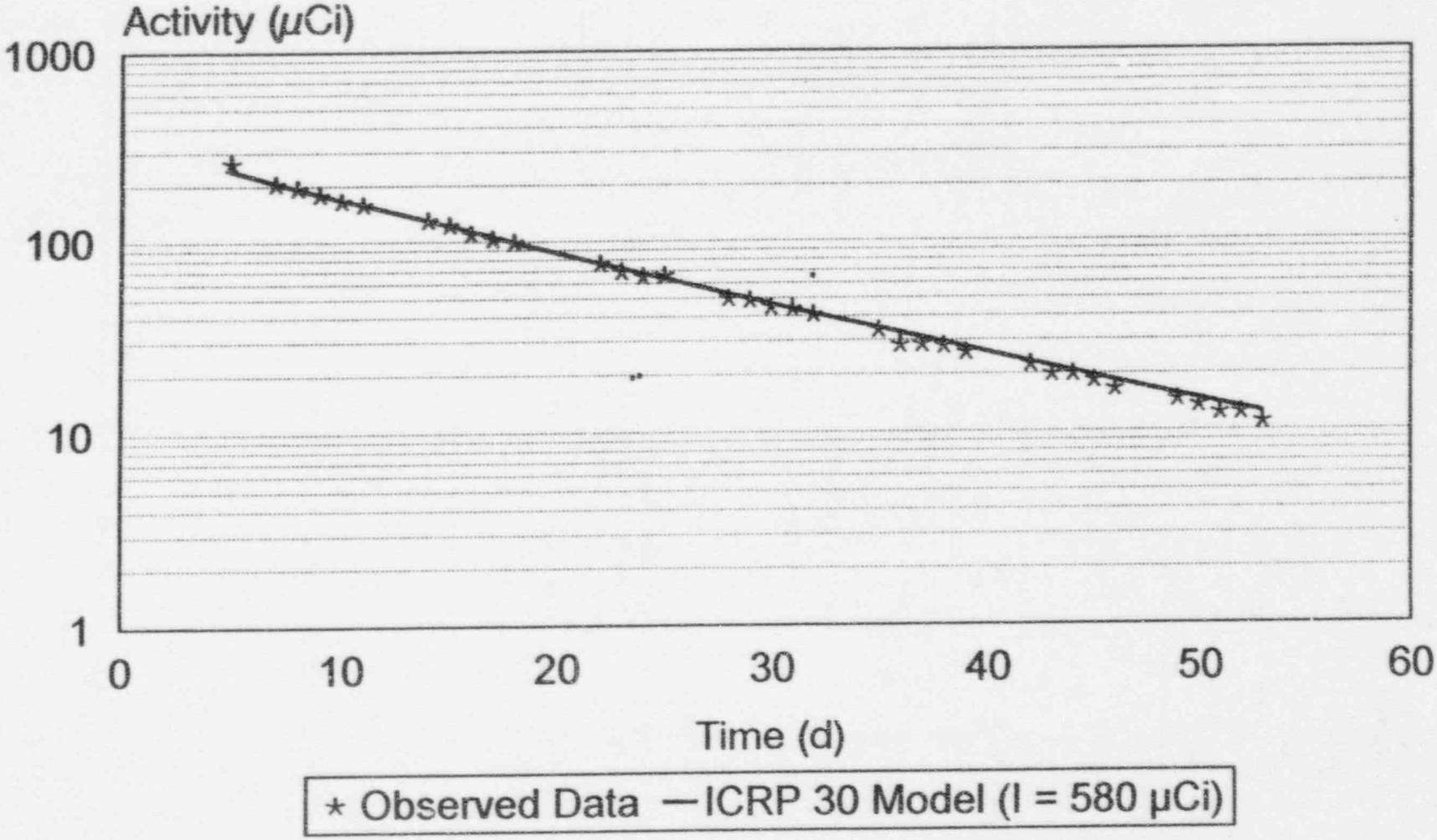
Michael Stabin, C.H.P.
Radiation Internal Dose
Information Center

enc: three graphs

cc: Toohey

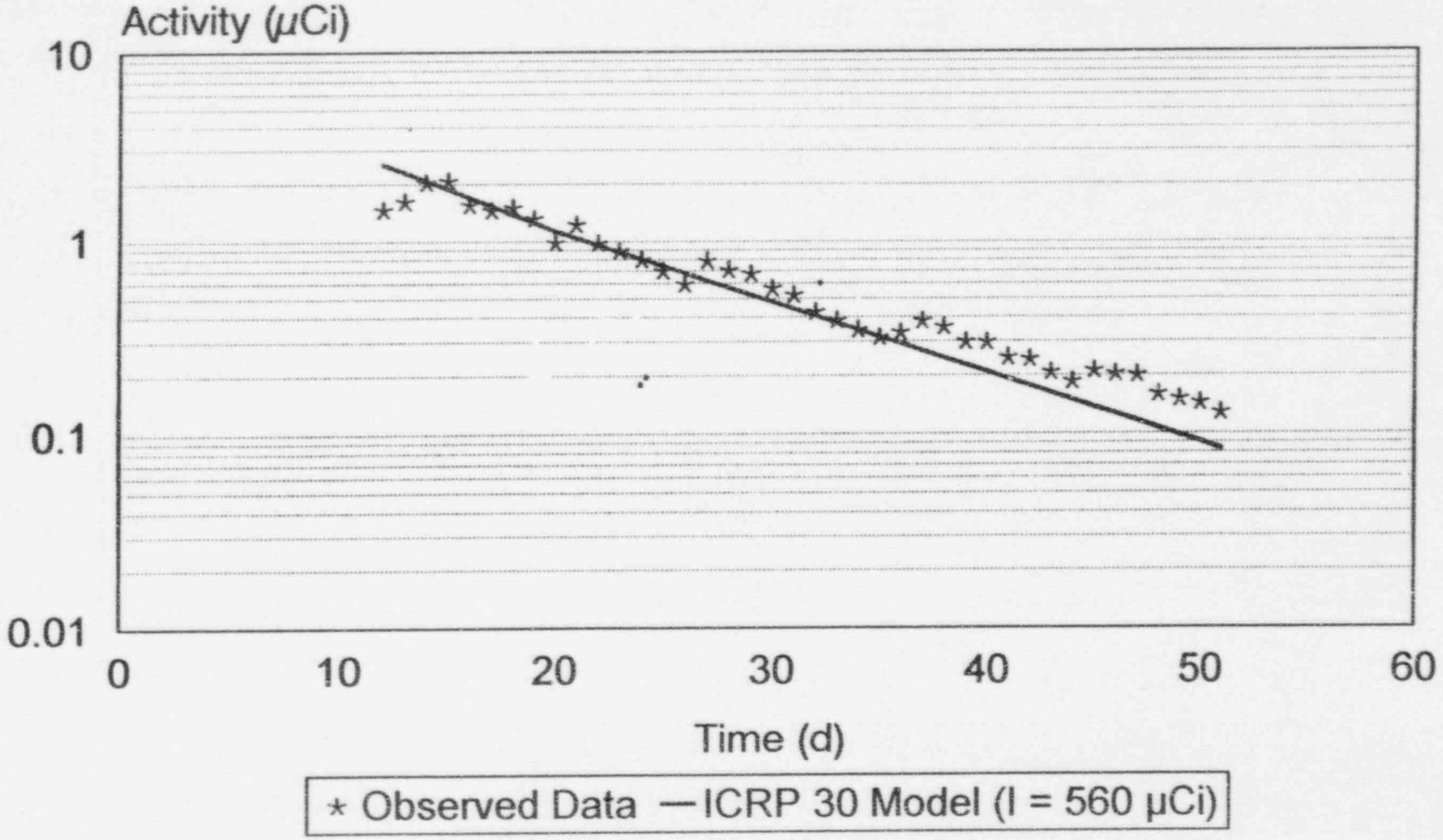
MIT P-32 Intake

Whole Body Counting Data



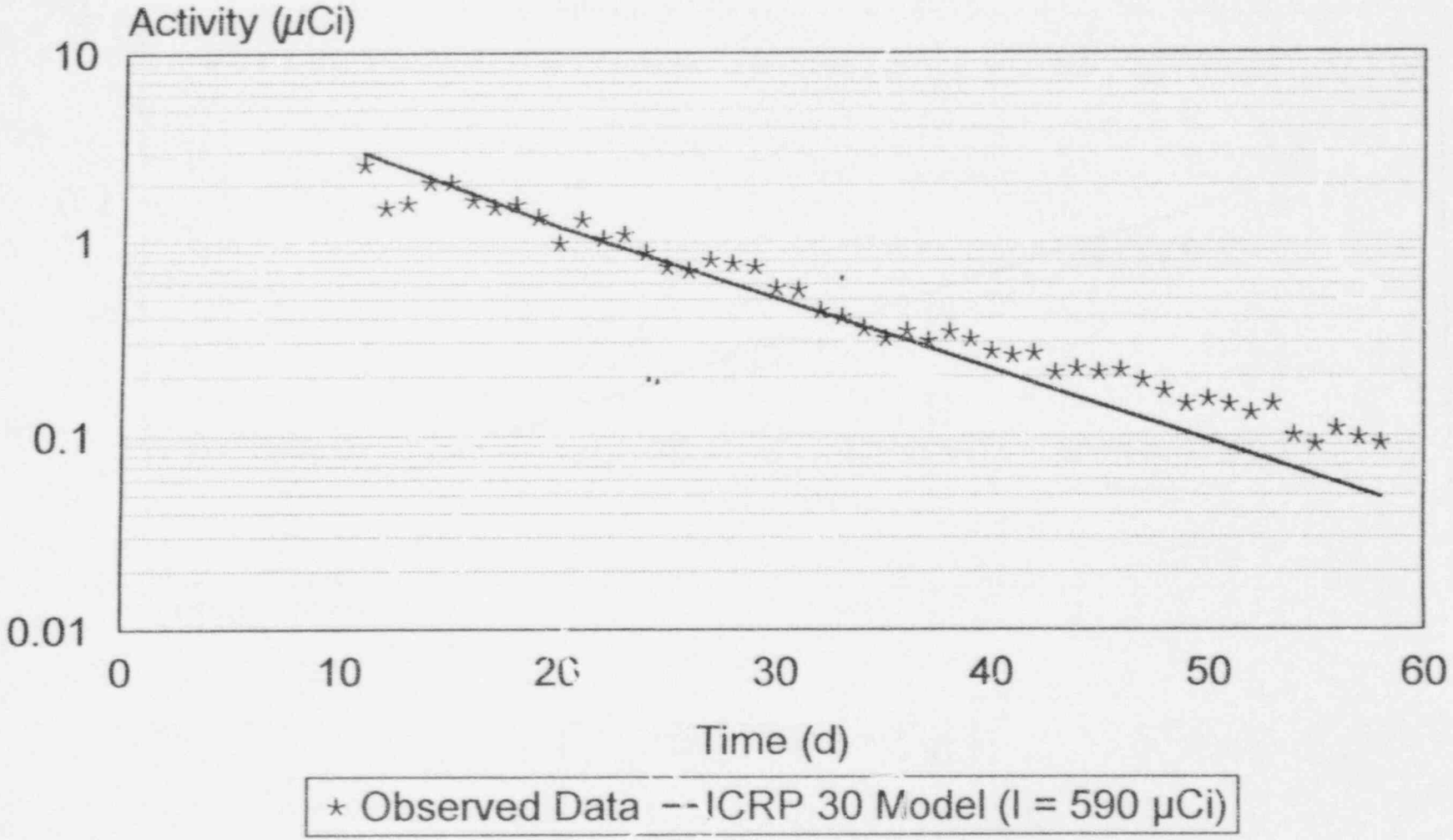
MIT P-32 Intake

Urine Data - MIT



MIT P-32 Intake

Urine Data - Contaminated Individual



ORISE
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MEDICAL SCIENCES DIVISION

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November 22, 1995

John Glenn, Ph.D.
c/o Donna-Beth Howe, Ph.D.
Division of Industrial and Medical
Nuclear Safety
Office of Nuclear Material Safety
and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Dr. Glenn,

I have completed a preliminary analysis of the urinary excretion data supplied to me from our Energy/Environment Systems Division for the MIT researcher who supposedly ingested some P-32 on August 14, 1995. From the data they provided for many urine samples, I obtained a single estimate of the intake, using both a weighted and unweighted least squares technique. Using an unweighted least squares technique, I obtained an estimated intake of 550 μCi; using a weighted least squares technique, I obtained 620 μCi. This agrees quite favorably with the estimates of 500 - 590 μCi that I reported to Dr. Donna-Beth Howe on November 7, based on the data gathered for urinary excretion and whole body retention by MIT staff or the researcher himself.

We at ORISE will need some time here to review these results and all of the input data before we make a final report of our findings. This report will include the urine concentrations measured, the model that I used to interpret these data and calculate these intake estimates, and other details. As I will be out of town during the week of November 27 - December 1, this report will not be available until sometime in the early part of December. I understood, however, that you wanted to receive some assessment of the intake this week, so I wanted to send you this preliminary estimate at this time.

Sincerely,

Michael Stabin, C.H.P.
Radiation Internal Dose
Information Center

cc: Toohey

Appendix E

Uncertainties in Dosimetry

Uncertainties in Dosimetry

The intake estimate includes uncertainties resulting from statistical variations in the data. These uncertainties are of the order of a few percent and are negligible compared with possible uncertainties resulting from systematic factors. The factors likely to cause the greatest uncertainty in estimating the intake are

1. the urine excretion fraction, F_u;

2. the geometry factor for adjusting the whole-body counter results for the limited field of view of the detector;

3. the use of a soft-tissue-equivalent phantom to calibrate the whole-body counter for bremsstrahlung, some of which was generated in Researcher A's body as a result of interactions in bone rather than soft tissue;

4. uncertainties in urine counts; and

5. the fit of the model to the data.

The estimated uncertainties that arise from these parameters are discussed below.

1. Uncertainties resulting from choice of F_u. The licensee's average estimate for the intake, namely 570 microcuries (21 MBq), was obtained using an F_u value of 0.9. Values reported in the literature vary between 0.75 and 0.9. The magnitude of the estimated intake is inversely proportional to the chosen value of F_u, and varies from about 680 microcuries (25 MBq) for an F_u of 0.75 to 570 microcuries (21 MBq) for an F_u of 0.9. Values of F_u above 0.9 have not been reported in the literature, and 570 microcuries (21 MBq) probably represents the lower limit of the range of intakes for this parameter.

2. Uncertainty resulting from choice of the geometry factor. The licensee estimated a geometry factor of 0.65 on the assumption that the activity was uniformly distributed throughout the body. However, this value may not be appropriate for the following reasons. ^{32}P localizes in bone, and the assumption of uniform distribution may not be valid; the fraction of the total activity in bone increases with time, constituting approximately 30 percent of the body burden soon after ingestion, but increasing with time as the activity in the other compartments is excreted. The distribution of bone in the body suggests that the geometry factor may be lower than 0.65, and possibly as low as 0.5 during that period. The intake estimate of 570 microcuries (21 MBq) was obtained using a factor of 0.65, and this estimate is inversely proportional to the geometry factor. Therefore, a variation in that factor between 0.65 and 0.5 would lead to a corresponding variation in the intake estimate between 570 microcuries (21 MBq) and 740 microcuries (27 MBq).

3. Uncertainty resulting from the use of a water phantom. The whole-body counter was calibrated using water-filled bottles, placed inside a masonite phantom, to which ^{32}P was added to generate a bremsstrahlung spectrum. Bremsstrahlung in the body will be

generated both in soft tissue and in bone, the latter component increasing with time. The intensity of the bremsstrahlung spectrum is directly proportional to the atomic number of the absorber with which the beta radiation interacts. Measurements suggest that use of a water phantom to calibrate for bremsstrahlung generated by $^{90}Sr/^{90}Y$ in bone will lead to overestimation of the intensity by factors of the order of 1.4 to 1.7. The ^{32}P spectrum is not identical to the $^{90}Sr/^{90}Y$ spectrum, and these factors will therefore not apply exactly to this case. However, they will probably not differ substantially, and an estimated factor of about 1.5 was used in this case. If this factor is used at a time when most of the bremsstrahlung is being generated in bone, the intake will be overestimated by a factor of approximately 1.5. The range of intakes corresponding to this effect will therefore be 380 to 570 microcuries (14–21 Mbq).

4. Uncertainties in the urine data. In an effort to verify the licensee's urine analysis, ORISE obtained samples of all the urine voidings from Researcher A. These voidings had been kept in storage by the licensee, and the urine was first acidified to dissolve any crystallized material before the samples were taken. ORISE analyzed the urine using liquid scintillation counting. The results closely matched those of the licensee, as shown in Figure E-1. However, the ORISE results were consistently higher than the licensee's results by an average of 10 percent. The reason for this difference is not known, but may have been due to differences in counter calibration or in a systematic bias in preparation and sampling the urine. The differences in urine results lead to intake estimates of 560 µCi (21 MBq) by the licensee, and 620 µCi (23 MBq) by ORISE, and this may therefore be taken as the minimum range of uncertainty for intake estimates based on urine analysis.

5. Uncertainties resulting from the model. The biokinetic parameters used in implementing the ICRP 30 model may be adjusted to improve the fit to the data in a specific case. Adjustments to the parameters for the data for Researcher A were discussed earlier. The adjustment of the model parameters in this case, which was limited to increasing the soft tissue compartment clearance half-life, led to an intake estimate ranging from 520 to 620 microcuries (19–23 MBq). Other parameter choices would have led to different intake estimates. It should be noted that the uncertainties in intake estimate in this case are of different nature from the other uncertainties mentioned above. This is because changing the model parameters affects not only the intake estimates, but also the estimated doses. The soft tissue clearance half-life is probably in the range of 19 to 26 days, resulting in an intake range of 520 to 620 µCi (19–23 MBq).

In summary, the sources of uncertainty, and the estimated range of variation each is expected to produce, are shown below.

Urine excretion fraction	570–680 µCi (21–25 MBq)
Geometry factor	570–740 µCi (21–27 MBq)
Atomic number effect	380–570 µCi (14–21 MBq)
Urine Analysis	560–620 µCi (21–23 MBq)
Model parameters	520–620 µCi (19–23 MBq)

The combination of these effects is not random, but constitutes a constant bias through all the data. The second and third factors affect the intake estimate obtained from the whole-body counting data, and the first and fourth affect the estimates obtained from the urine data. It is difficult to combine these factors to obtain a total uncertainty estimate. However, the second and third factors act in opposite directions, and the uncertainty caused by the combination of the two is almost certainly less than the outer boundaries of the two suggests. A reasonable estimate might be obtained by using values from the middle of each range as an indicator of the limit of uncertainty of the combination of the two factors. This gives an uncertainty range of about 500 to 650 microcuries (19–24 MBq). Combining this range with the range for the other factors gives a range of approximately 500 to 750 microcuries (19–24 MBq). This range of uncertainty represents a rough estimate because most of the factors that determine this range must be measured and cannot be theoretically estimated with high accuracy. It may be argued, however, that the close agreement of the estimates based on the urine analysis and the whole-body counting data suggests that the above factors were such that the estimate of 570 microcuries (21 MBq) is more accurate than is suggested by the above analysis. The validity of this conclusion is supported by the fact that the whole-body counting data and the urine analysis data were obtained using two completely different and independent methods of measurement.

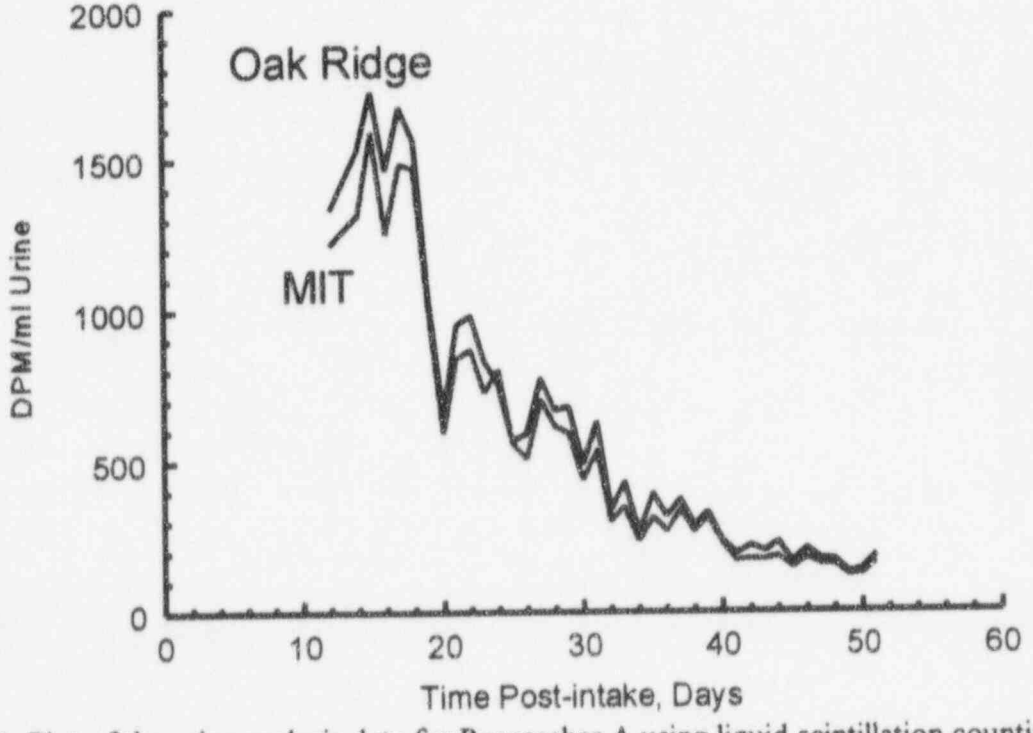

Figure E-1 Plot of the urine analysis data for Researcher A using liquid scintillation counting

Appendix F

Interviews and Meetings Conducted by the Incident Investigation Team

Interviews and Meetings Conducted by the Incident Investigation Team

Meeting/Interview	Date	Time
Initial conference call to NRC Headquarters Operations Center	10/16/95	
Meetings and Interviews on Site		
Entrance Meeting	10/17/95	4 p.m.
Interview of Principal Investigator, Center for Cancer Research (CCR), Massachusetts Institute of Technology (MIT)	10/20/95	10:33 a.m.
Interview of Laboratory Manager, CCR, MIT	10/18/95	3:08 p.m.
Interview of Researcher A, CCR, MIT	10/18/95	10:15 a.m.
Interview of Researcher A, CCR, MIT	10/19/95	9:02 a.m.
Interview of Researcher A, CCR, MIT	10/20/95	9:07 a.m.
Interview of Researcher B, CCR, MIT	10/19/95	2:06 p.m.
Interview of Researcher C, CCR, MIT	10/19/95	9:01 a.m.
Interview of Researcher D, CCR, MIT	10/19/95	4 p.m.
Interview of Researcher E, CCR, MIT	10/19/95	11:36 a.m.
Interview of Researcher F, CCR, MIT	10/23/95	3:30 p.m.
Interview of Technical Associate, CCR, MIT	10/20/95	3:35 p.m.
Interview of Radiation Protection Technician, MIT	10/23/95	2:30 p.m.
Interview of Director, Environmental Medicine, MIT	10/23/95	10 a.m.
Interview of Radiation Protection Officer (RPO), MIT	10/20/95	2:03 p.m.
Interview of Associate RPO, MIT	10/18/95	1:18 p.m.
Interview of Associate RPO, MIT	10/19/95	3:38 p.m.
Interview of Assistant RPO A, MIT	10/20/95	1:42 a.m.
Interview of Assistant RPO B, MIT	10/23/95	9:30 a.m.
Interview of Counting Room Technician, MIT	10/18/95	3:15 p.m.

Meeting/Interview	Date	Time
Interview of Radiation Protection Committee (RPC) Chairman, MIT	10/23/95	2:30 p.m.
Interview of RPC Member A, MIT	10/23/95	11:30 a.m.
Interview of RPC Member B, MIT	10/23/95	12:30 p.m.
Interview of RPC Member C, MIT	10/23/95	1:30 p.m.
Interview of RPC Member D, MIT	10/23/95	4:40 p.m.
Interview of Officer, MIT Campus Police	10/22/95	3:56 p.m.
Interview of Health Physicist Consultant	10/23/95	11:30 a.m.
Exit Meeting	10/25/95	10:05 a.m.
Meetings and Interviews with NRC Staff		
Interview of Dr. Carl J. Paperiello, Director, Office of Nuclear Materials, Safety and Safeguards, NRC	10/31/95	9:02 a.m.
Interview of Richard Bangart, Director, Office of State Programs, NRC	11/6/95	3:03 p.m.
Interview of Paul Lohaus, Deputy Director, Office of State Programs, NRC	11/6/95	3:03 p.m.
Interview of Dr. Donald A. Cool, Director, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Materials, Safety and Safeguards, NRC	11/1/95	10:02 a.m.
Interview (by speakerphone) of Susan Frant Sh. man, Deputy Director, Division of Nuclear Materials Safety, Re on I, NRC	11/2/95	12:05 p.m.
Interview of Patrick W. Baranowsky, Chief, Reliability and Risk Assessment Assessment Branch, Office for Analysis and Evaluation of Operational Data, NRC	11/6/95	1:05 p.m.
Interview (via speakerphone) of James Dwyer, Sen or Health Physicist, Medical Inspection Branch, Region I, NRC	10/31/95	1 p.m.
Interview of Joel Lubenau, Senior Health Physicist, Office of Nuclear Materials, Safety and Safeguards, NRC	11/7/95	10:34 a.m.
Interview of Donna-Beth Howe, Health Physicist, Medical, Academic, and Commercial Use Branch, Office of Nuclear Materials, Safety and Safeguards, NRC	11/1/95	3:08 p.m.

Meeting/Interview	Date	Time
Interview of Harriet Karagiannis, Senior Project Manager, Reliability and Risk Assessment Branch, Office for Analysis and Evaluation of Operational Data, NRC	11/6/95	1:05 p.m.
Interview of Samuel Pettijohn, Data Analyst Reliability and Risk Assessment Branch, Office for Analysis and Evaluation of Operational Data, NRC	11/6/95	1:05 p.m.

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(See instructions on the reverse)

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10. SUPPLEMENTARY NOTES

11. ABSTRACT *(200 words or less)*

On Monday, October 16, 1995, the Massachusetts Institute of Technology (MIT, the licensee) notified the U. S. Nuclear Regulatory Commission (NRC) of an incident involving ingestion of phosphorus-32 by a researcher at the MIT Center for Cancer Research. The licensee informed the NRC that a researcher had reported the incident on August 19. The licensee initially estimated the intake as 500 microcuries (19 MBq) and the dose as 4000 millirem (40 mSv) to the individual. On October 12, the licensee informed the researcher that its final intake estimate was 579 microcuries (21 MBq), just under the 600 microcuries (22 MBq) which would represent an overexposure. On October 17, the NRC established an Incident Investigation Team to investigate the case. NRC also contracted with Lawrence Livermore National Laboratory and Oak Ridge Institute for Science and Education to do independent dose assessments of the urine sample data and the whole-body data. The Team concluded that the licensee's final intake and dose estimates were in accordance with accepted scientific references and NRC guidance. However, recognizing the uncertainties involved in the use of models to simulate human characteristics, the Team determined the intake would be better characterized as likely falling within a range of 500 to 750 microcuries (19-28 MBq). An NRC medical consultant concluded that no symptoms or acute effects should be observed from an intake of this level.

12. KEY WORDS/DESCRIPTORS *(List words or phrases that will assist researchers in locating the report.)*

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radiation exposure
radioactivity
radioactive source
regulation of medical devices
regulation of nuclear materials
therapy misadministration
transportation of nuclear materials
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MIT Center for Cancer Research
overexposure

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